Weight-of-evidence:
An evolving approach to pesticide consultations
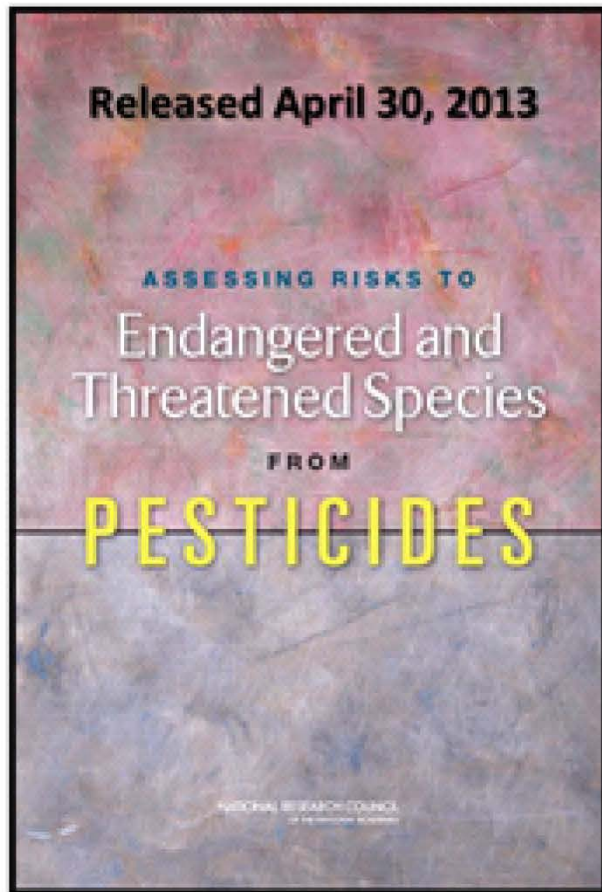
NMFS/ EPA / FWS

4/15/2015

Scott Hecht NMFS
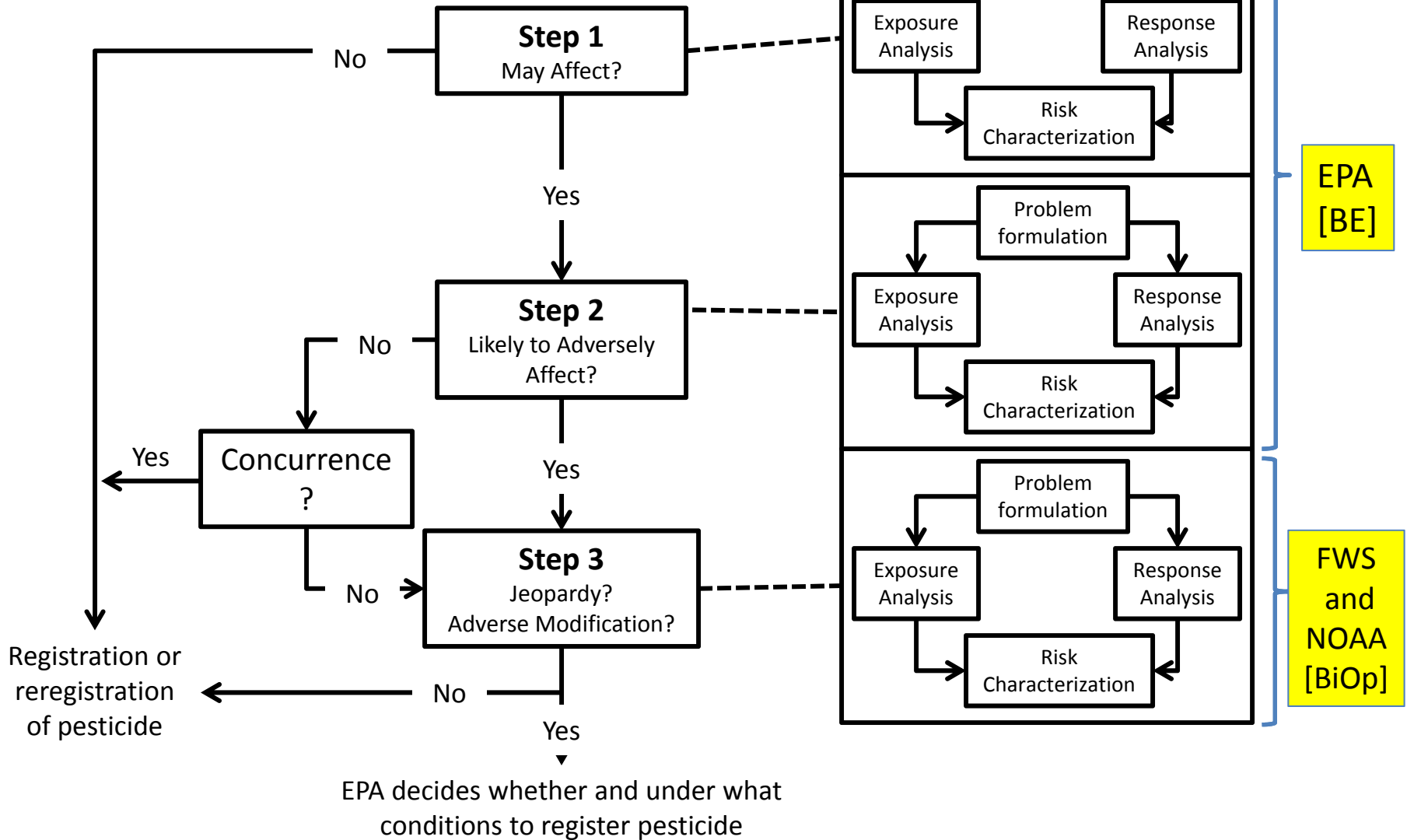
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Recent Review

Released April 30, 2013

ASSESSING RISKS TO
**Endangered and
Threatened Species**
FROM
PESTICIDES

NATIONAL RESEARCH COUNCIL

- National Academy of Sciences Committee Report

- Developed in response to a request by EPA, NOAA, USFWS, and USDA

- Recommended three step process that integrates ecological risk assessment methods with ESA section 7 consultations

Leatherback sea turtle

Island marble butterfly

Three Step Approach: ESA Consultation and Ecological Risk Assessment

Step 1
May Affect?

No →

Yes ↓

Step 2
Likely to Adversely Affect?

No → Concurrence?

Yes →

Concurrence? → Yes

Concurrence? → No → Step 3

Step 3
Jeopardy? Adverse Modification?

No → Registration or reregistration of pesticide

Yes ↓

EPA decides whether and under what conditions to register pesticide

Problem formulation
Exposure Analysis
Response Analysis
Risk Characterization

EPA [BE]

FWS and NOAA [BiOp]

Agenda

- Status Update and Background

- Weight of Evidence Approach in Step 2: What We're Currently Considering

- Summary

Status Update: Where We Are

- Collected, reviewed, and discussed weight-of-evidence approaches (January – November 2014)

- Presented weight-of-evidence concepts at Stakeholder meeting and SETAC conference (November 2014)

- Inter-agency meetings to develop process for Step 2 (November 2014 – present)

- Currently working through examples with two species

Key Questions of Step 2: Effect Determinations

ESA Step	Key questions addressed	Findings/ determinations	ESA Product
1	Any effects from the action?	No effect or May Affect	Request for consultation
2	Is an individual's fitness reduced? Are species' essential habitat features affected?	Not likely to Adversely affect (NLAA) or Likely to Adversely affect (LAA)	Concurrence letter Biological Evaluation
3	Species response? Is Designated Critical Habitat's conservation value reduced?	Jeopardy (yes/no) Adverse modification (yes/no)	Biological Opinion

Weight-of-Evidence Approach for Step 2: Arriving at Effect Determinations

- Following an ecological risk assessment paradigm
  - Risk hypotheses
  - Lines-of-evidence
- Produce pesticide exposure estimates
- Review and assign toxicity data to lines of evidence
- Weighing lines of evidence

Protection Goals for Step 2

- Species (DPSs and ESUs):

    Individual fitness

- Designated Critical Habitat:

    Primary constituent elements/ Primary biological features

Species Risk Hypotheses

1. Use of pesticide X according to registered labels results in exposure that reduces the fitness of an individual from a listed species based on direct effects.

2. Use of pesticide X according to registered labels results in exposure that reduces the fitness of an individual from a listed species based on indirect effects.

Designated Critical Habitat Risk Hypothesis

Use of pesticide X according to registered labels results in effects to designated critical habitat by adversely impacting the essential physical and biological features (PBFs), such as primary constituent elements (PCEs) or other important physical and biological features.

15 Species Groupings

AQUATIC

- freshwater fish
- marine fish
- amphibians
- aquatic-dependent birds
- marine invertebrates
- mammals
- plants
- freshwater invertebrates
- reptiles

TERRESTRIAL

- plants
- amphibians
- invertebrates
- mammals
- reptiles
- birds

Exposure Information

Two components to exposure to the stressors of the action:

- Pesticide Information

- Species and/or habitat information

Exposure: Pesticide Information

Two primary attributes:

- Relevance of environmental models for generating EECs for receiving habitats (terrestrial and aquatic)

- Robustness of EECs derived from environmental models

Relevance of Environmental Exposure Models

- Models that were developed to predict concentrations in species' habitats receive more certainty which strengthens confidence in the EECs.

- Models that were not developed specifically to address species' habitats (but adapted to achieve this purpose) may still provide useful EECs but with less certainty.

- Models that were not developed specifically to address species' habitats and are not good surrogates can still be used because they are the best available tools. Uncertainty is expected to be large in these cases.

Robustness of EECs: Values Used as Input Parameters for Environmental Fate Models

- High certainty (or low uncertainty) when a robust fate data set is available.

- Medium to low certainty (or high to medium uncertainty) when an incomplete fate data set is available. Describe how fate parameters were adjusted to address the lack of data.

Effects (Toxicity) Information

- Collect, review, and assign toxicity information/data to lines of evidence. Sources include:

    -ECOTOX

    -Registrant-submitted data

    -Other peer-reviewed information from open literature

- Place toxicity effect levels in data array
- Calculate effects thresholds
- Discuss toxicity information within each line of evidence

Lines of Evidence: Effects to Species

- Mortality from direct, acute exposure
- Reduced growth of an individual
- Reduced or impaired reproduction of an individual
- Impaired behavior that could result in increased mortality or decreased growth/reproduction
- Impaired sensory function

Lines of Evidence: Effects to Species

- Indirect effects to listed species
- Differences in toxicity observed when exposed to mixtures
- Factors such as bacteria/viral prevalence, temperature, or pH in the environmental baseline enhances the susceptibility of listed species to pesticide X

Considerations for Weighing Effects Information for a Line of Evidence

Biological Relevance

Surrogate Relevance

Robustness of information

Biological Relevance of Effects Data for a Line of Evidence

An AOP is used as scientific support for drawing logical connections between indirect measures and an assessment endpoint.

An established relationship is one that is documented in the available literature e.g., AChE inhibition from OP insecticides.

Biological Relevance of Effects Data for a Line of Evidence

- If there is a well-established link, the information is weighted high.

- If a logical link can be made, the information is weighted medium.

- If a logical link cannot be made, the information is weighted low.

Surrogate Species Relevance of Effects Data for a Line of Evidence

Are the effect endpoints measured with the listed species or an appropriate surrogate?

Greater confidence should be assigned when the surrogate species is more taxonomically related to the listed species or shares similar life history or physiology.

Robustness of Effects Data for a Line of Evidence

- Higher confidence - Multiple, independent studies showing consistent results

    There may be cases when a single, highly relevant and well-conducted study directly addresses a line-of-evidence for a species or a species grouping that alone would result in a high weight.

- Moderate confidence–a small number of scientifically valid studies indicate effect from exposure.

- Lower confidence– There are few studies/data (of lower quality) and/or there are inconsistencies among the results.

Combining Exposure with Effect Levels to Arrive at a Risk Level for a Line of Evidence

- Compare effect thresholds within each line of evidence to EECs and describe level of overlap.

- The more exceedances of values the higher the risk.

Weighing Lines of Evidence

Lines of Evidence	Weight of evidence (confidence in exposure and effects data)					Risk Estimate (Overlap of exposure and effect)	Overall confidence high, medium, low
	Factors to consider for confidence in data						
	EXPOSURE		EFFECTS				
	Relevance	Robustness	Biological Relevance	Species Surrogacy	Robustness		
Mortality							
Growth							
Reproduction							
Behavioral							
Sensory effects							
Indirect effects							
Mixtures							
Abiotic/Biotic factors (bacterial/viral. pH, temperature)							

Matrix for Lines of Evidence: Hypothetical Example
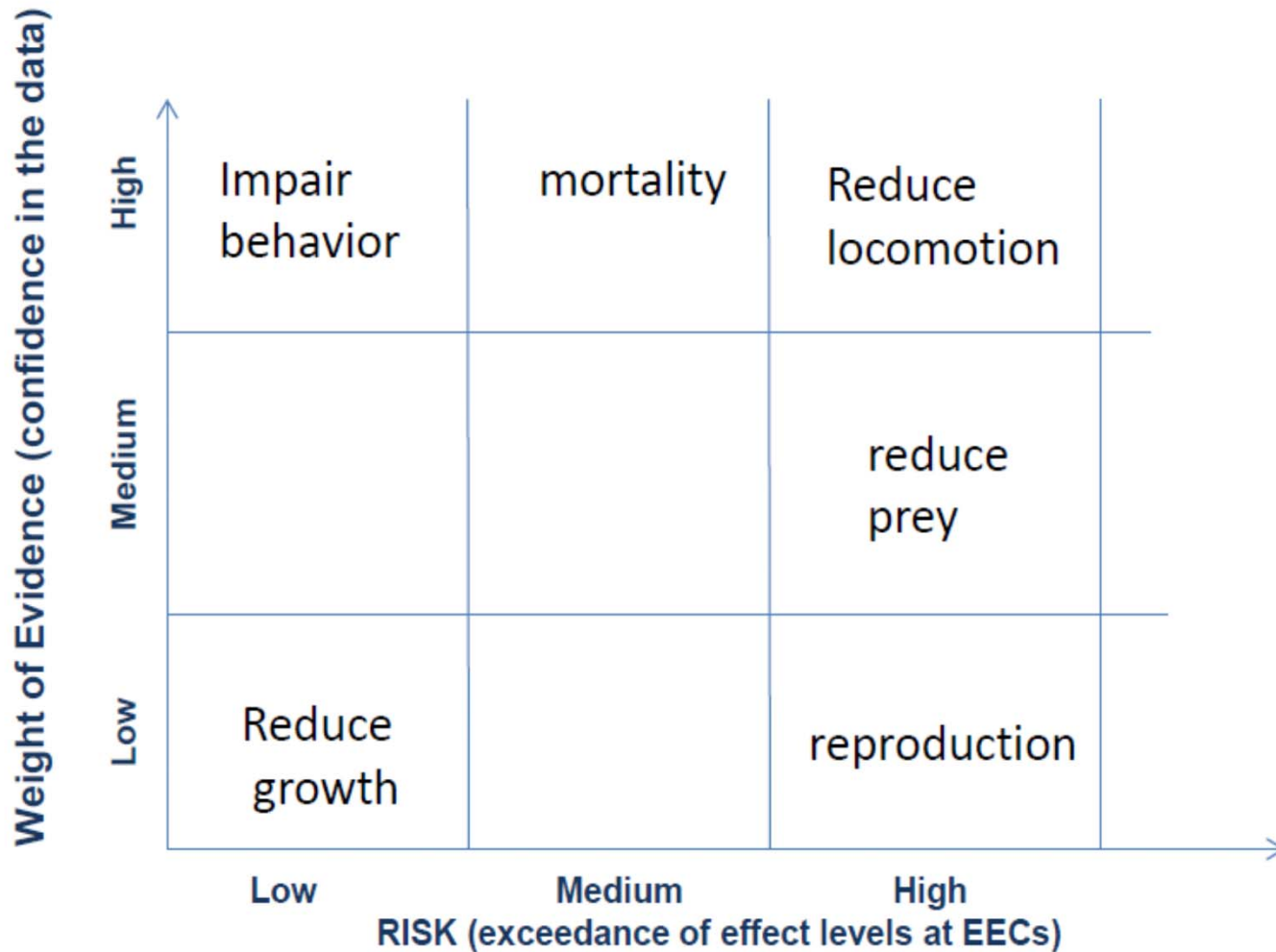
Summary

- Weight of evidence is a work in progress

- A systematic approach is being developed

- The approach will be applied and revised based on lessons learned from the pilot pesticides

Questions welcome…