Pesticide Regulations and the Endangered Species Act

https://www.epa.gov/endangered-species

Disclaimer: Author's perspectives are not necessarily those of EPA or USFWS

EPA Office of Pesticide Programs

- Regulatory gateway to pesticide market
- Regulatory decisions on statutory schedules for new pesticides, new uses, new end use products; experimental use permits; emergency exemptions; and reevaluation of existing pesticides
- Approximately 1,200 active ingredients and 17,000 products in commerce
- EPA's Office of Pesticide Programs has a multi-disciplinary staff of risk assessors and risk managers.

Pesticide Regulation -- Overview

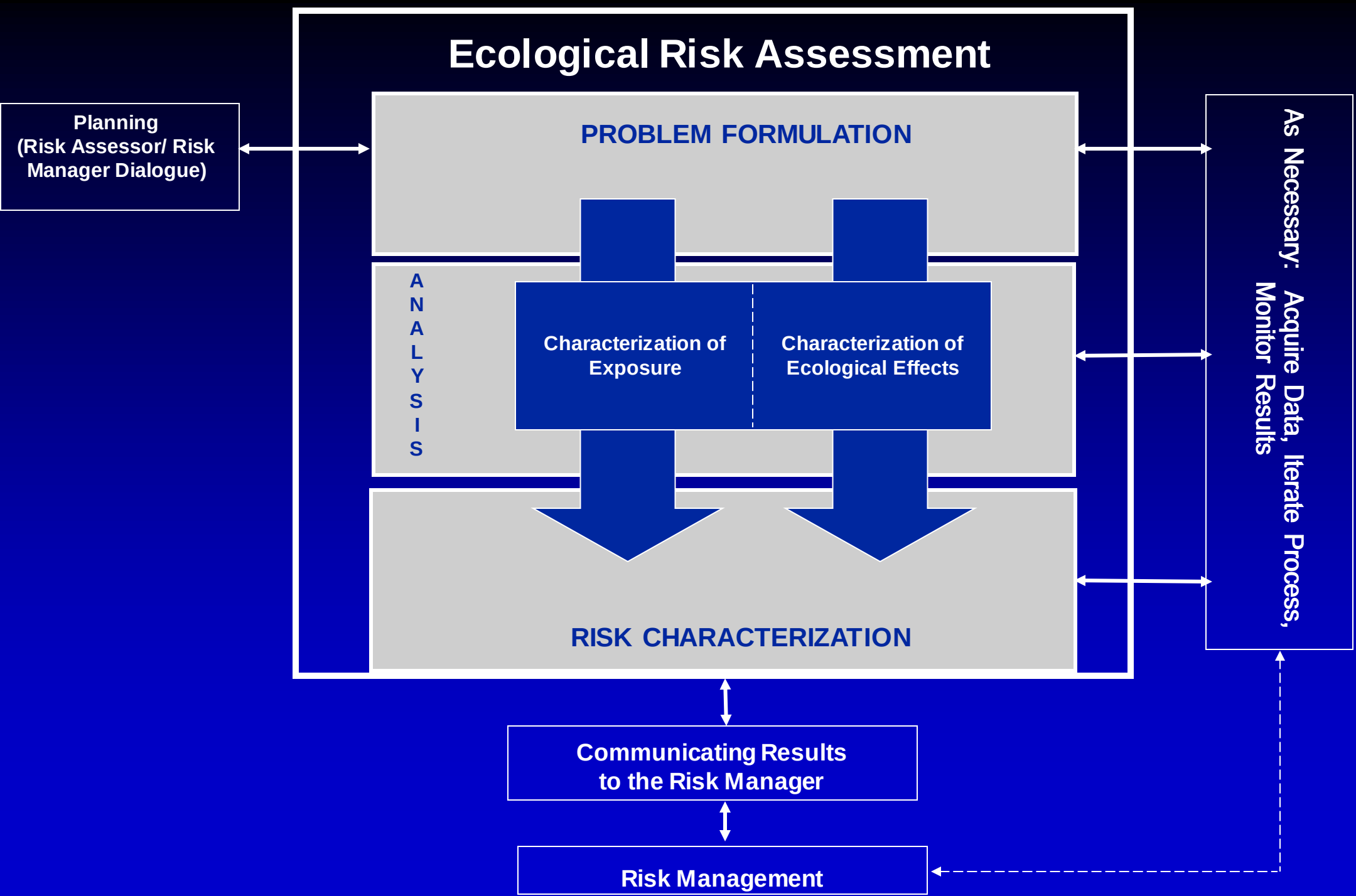
Under the Federal Food Drug and Cosmetic Act (FFDCA), EPA ensures pesticide residues in the human food supply and drinking water are safe

Risk only standard: Reasonable certainty of no harm

EPA registers pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

EPA may register a pesticide if use is protective of human health and the environment by not "cause[ing] unreasonable adverse effects on the environment"

Unreasonable adverse effect – "any unreasonable risk […] taking into account economic, social and environmental costs and benefits of the use of any pesticide"


Ecological Risk Assessment
Planning
(Risk Assessor/ Risk Manager Dialogue)
PROBLEM FORMULATION
ANALYSIS
Characterization of Exposure
Characterization of Ecological Effects
RISK CHARACTERIZATION
As Necessary: Acquire Data, Iterate Process, Monitor Results
Communicating Results to the Risk Manager
Risk Management

Risk Characterization

Screening Level Risks to Individuals of a Species

Risk Quotients

RQ: Estimated Environmental Concentration/Individual Toxicity Threshold

High end acute and chronic exposure estimates

Corresponding acute and chronic effects endpoints (e.g., LC_{50}, LD_{50}, EC_{50}, MATC) for most sensitive tested species for different taxa

Risk Management

- If the RQs for a proposed or existing use does not exceed a level of concern, no additional **FIFRA-based** regulatory action is required (i.e.; the product can be used consistent with the registrant's proposed or existing label requirements).

Levels of Concern: Aquatic Organisms

Acute Unlisted Species: RQ > 0.5

Acute Risk Listed Species: RQ > 0.05

Chronic Risks (Unlisted/Listed): RQ > 1

Levels of Concern: Terrestrial Organisms

Acute Unlisted Species: RQ > 0.5

Acute Risk (pollinators): RQ > 0.4

Acute Risk Listed Verts: RQ > 0.1

Acute Risk Listed Inverts: RQ > 0.05

Chronic Risks (Unlisted/Listed): RQ > 1

Risk Management

- If the screening-level risk estimate does exceed a level of concern, the assessment is refined; e.g., increased spatial/temporal resolution, probabilistic analyses, etc.
- If level of concern still exceeded, EPA determines if pesticide use(s) can be registered with additional risk mitigation.
- If registration approved, the 'label is the law' – the pesticide's use is 'safe' only if used according to the label instructions.
  - Can have spatially/temporally-explicit risk analyses and associated labeling, including dynamic web-based maps

ESA Section 7 and EPA Pesticide Registrations

EPA's pesticide registration decisions are agency actions as defined under the ESA.

Consultations with the Services for pesticide-specific registrations can require additional, enforceable risk mitigation measures to ensure compliance with the ESA.

Applicators following pesticide label requirements based on consultation findings have regulatory protection under ESA for incidental take.

ESA Section 7 and EPA Pesticide Registrations

EPA's lack of compliance with the ESA is an on-going, 40+ year challenge

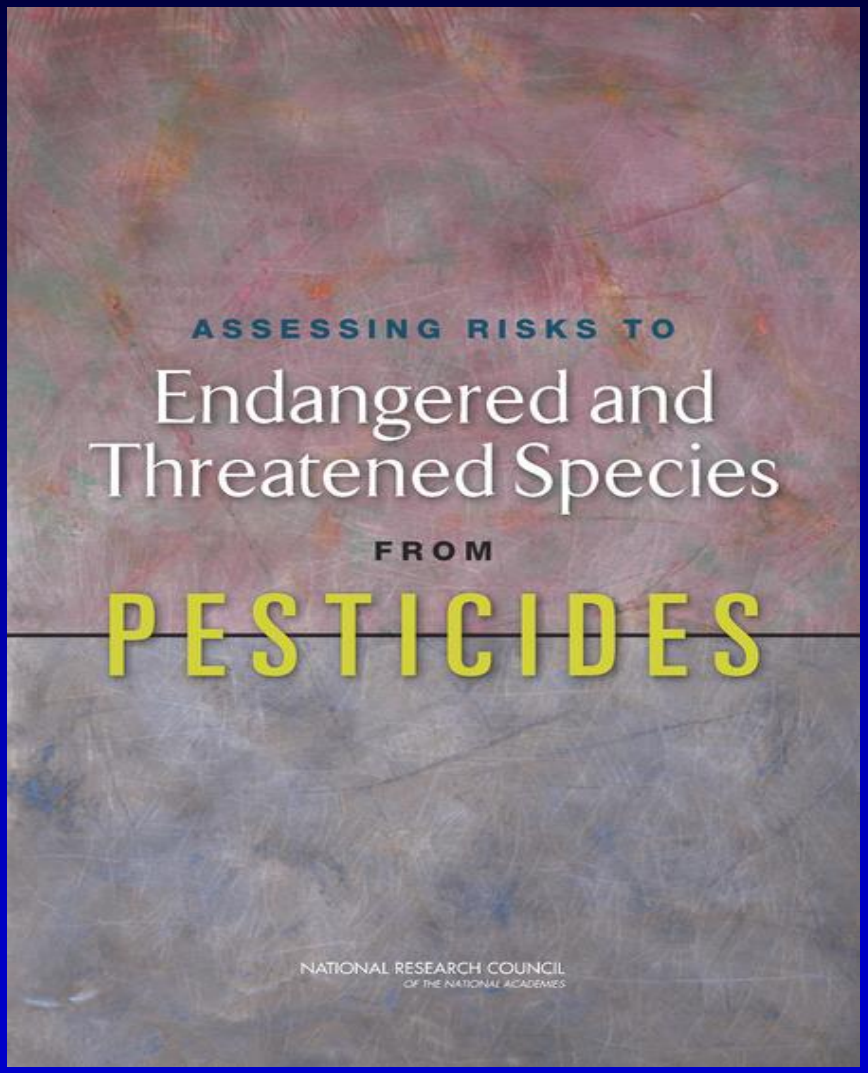
Endangered species analyses for pesticides are complex and resource intensive

Taking years to complete pesticide-specific consultations

Increasing number of EPA requests for formal consultations

Court ordered/supervised deadlines for consultations is driving EPA's and FWS's work flow

NAS Report (2013): A Common Approach



NAS Three Step Process

Step 1 (EPA)
NE or MA?

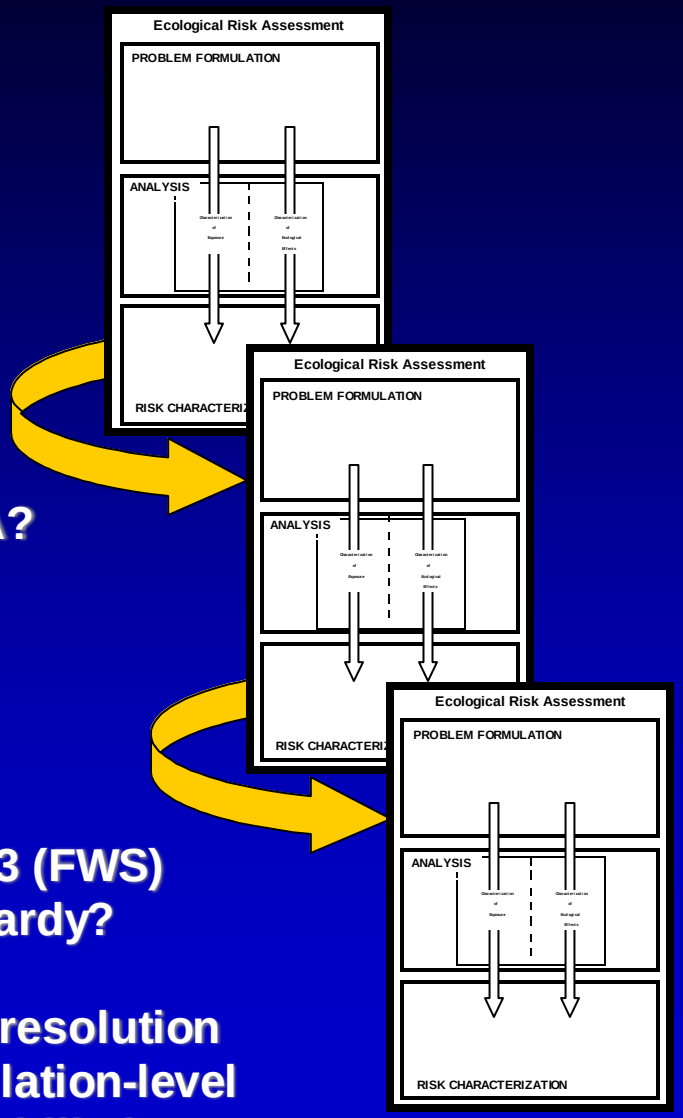
High Resolution
Spatial Analyses

Step 2 (EPA/FWS)
If MA, NLAA or LAA?

High Spatial
Resolution
Individual-level
Deterministic

Step 3 (FWS)
Jeopardy?

High resolution
Population-level
Probabilistic



Step 1. Increased Spatial Resolution Significantly Increase NEs? No

Step 2. Increased Spatial Resolution Significantly Increase NLAAs? No

Step 2. Individual-level Assessments; one or more harmed individuals results in LAA determination.

Step 3. FWS Still Overwhelmed with Formal Consultation Requests

EPA's Endangered Species Act Workplan (2022)
EPA's Insecticide Strategy (2025)

Strategy identifies pre-consultation mitigation measures under FIFRA to address potential **population-level impacts** for conventional agricultural insecticides used in the lower 48 states

EPA believes the Strategy provides a proactive and more efficient means to meet Section 7(a)(2) obligations.

Strategy identifies mitigations to protect populations of listed invertebrates, populations of listed animals that depend on invertebrates for prey, and listed plants that depend on insect pollination

'Paper' and web-based labels to support implementation of mitigations

EPA estimates the strategy will reduce population-level impacts to more than 900 listed species in the lower 48 states.

Insecticide Strategy: Assessing Population Effects

For listed invertebrates and listed obligate insectivores

- Species Sensitivity Distribution 5th percentile value when sufficient multi-species toxicity data available; if not, then
- Most sensitive tested species (e.g., honey bee) LD_{10} or LC_{10}
- Chronic direct effect thresholds are the MATC from most sensitive tested species

(For a monarch butterfly assessment there is existing species-specific toxicity data)

- For listed invertebrate generalists SSD (25th percentile value), if available, or best estimate (e.g., LD_{50} or LC_{50} value for most sensitive tested species) to protect invertebrate communities

Expected environmental concentrations based on central tendency values, not high-end values used in individual-based, screening risk assessments

Magnitude of Difference

MoD = Estimated Environmental Concentration/Population Toxicity Threshold

MoD: < 1, Adverse population impact not likely

MoD: 1 to < 10, Low potential of adverse population impact

MoD: 10 to < 100, Medium potential of adverse population impact

MoD: ≥ 100, High potential of adverse population impact

If MoD value greater than 1, label provides a suite of vetted mitigation options available ('pick list') for users to reduce MoDs

As needed EPA will establish Pesticide Use Limitation Areas that require specific, mandatory mitigations.

Revised Three Step Process

Step 1 (EPA)
NE or MA?

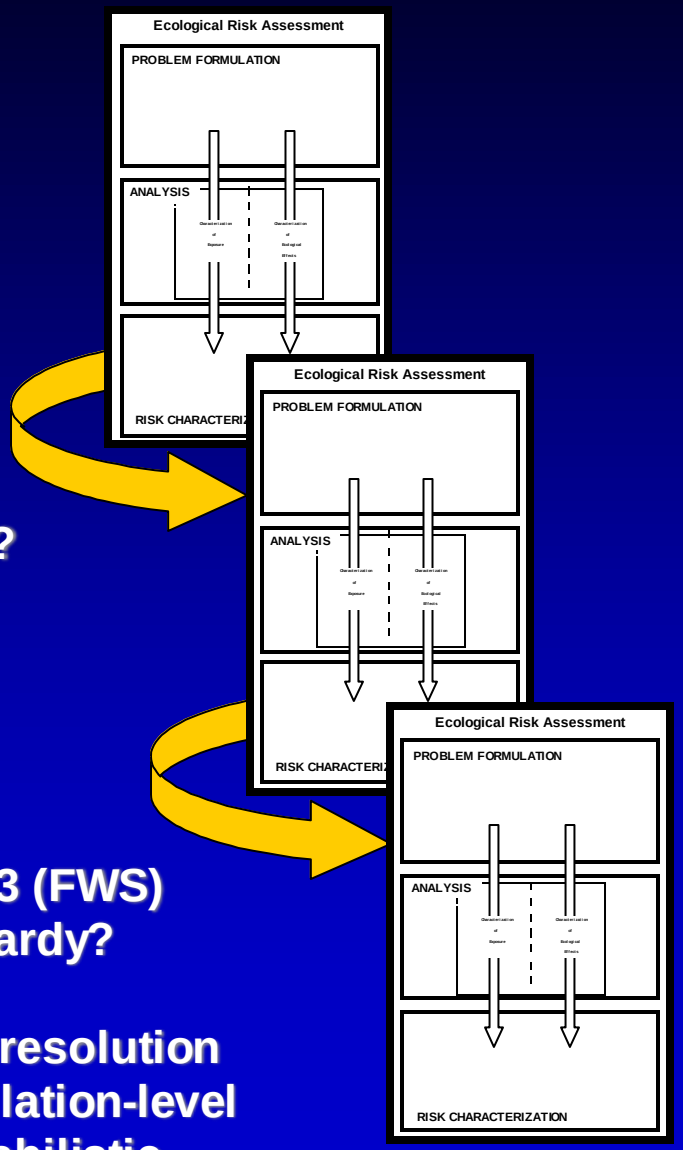
Low resolution
Individual-level
Deterministic

Step 2 (EPA/FWS)
If MA, NLAA or LAA?

Higher resolution
Population-level
Deterministic/
Probabilistic

Step 3 (FWS)
Jeopardy?

High resolution
Population-level
Probabilistic

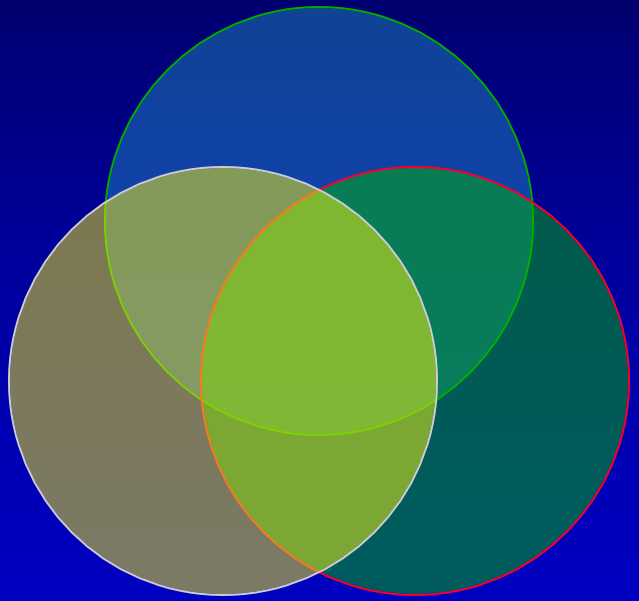


Step 2. Will population-level assessments increase NLAA determinations? Probably.

Step 3. Will fewer formal consultations increase efficiencies for EPA and FWS? Probably

Integration of Laws, Science and Policy

Laws & Regulations



Science

Policy

Pesticides & Monarch Conservation

Emily May
Agricultural Conservation Lead, Pesticide Program
The Xerces Society for Invertebrate Conservation

XERCES SOCIETY
for Invertebrate Conservation

Photo: Stephanie McKnight/XS

Pesticides are a primary threat to monarchs

- A growing body of research connect pesticides with monarch decline
- Pesticide mixtures are everywhere we look
- Regulatory models fail to reflect this complexity

Photo: NCTC Creative Imagery-USFWS/Flickr CC

EPA's regulatory framework underestimates risk – significant gaps include:

- Pesticide toxicity to butterflies & their larvae
- Combined and cumulative exposure to pesticides
- Sublethal harms
- Seed treatments

What this means for conservation

- Pesticide exposure threatens conservation success
- Labels are not protective
- To recover monarchs, we have to reduce contamination in breeding, migratory, and overwintering areas

Photo: K. Morgan

- Technology considerations to evaluate complex ecosystems.
  - Ag Tech is built for monocultures
  - Multi-purpose and Multi-task
  - Introduce SMEs into the process
  - Identify Results of Human Activity Simultaneously

- Precision supports pollinator habitat by:
  - Producing Multiple Data Products
  - Boosting biodiversity through targeted action
  - Improving Management Practices
  - Levels the playing field

- Focus on double bottom line value:
  - Financial and Environmental Benefits
  - Focused on the root cause of invasive distribution

POLLi

Greg Emerick
Founder, POLLi

What could an "Offset" process look like for pesticide registrations?

Current project is a collaboration between US FWS, CSI, Bayer, and Syngenta

- What?
  - Mitigation option (avoid/minimize)
  - Examples from other industries
- Who would be involved?
  - US EPA, US FWS, NGO, Registrant
- How could it be implemented?
- Why?
  - Meet ESA obligations (US FWS/US EPA)
  - Provide flexibility and options
  - Benefit ESA species conservation

Potential Pesticide 4(d) Rule Scenarios

Scenario 1

4(d) rule: Users follow existing EPA labels with voluntary stewardship practices (e.g., IPM when available)

Users have ESA Section 9 and FIFRA protection

EPA sued under ESA for failure to consult?

FWS sued for not providing sufficient ESA protections?

Potential Pesticide 4(d) Rule Scenarios

Scenario 2

4(d) rule: Users follow existing EPA labels with additional **FWS** mitigations consistent with EPA's Insecticide Strategy

Users have ESA Section 9 (and FIFRA) protection, but significant burden to implement for pesticide users and FWS?

EPA sued under ESA for failure to consult?

FWS sued under ESA for not providing sufficient mitigation?

FWS challenged for de facto implementation of FIFRA?

Potential Pesticide 4(d) Rule Scenarios

Scenario 3

4(d) rule: Users follow existing EPA labels with mandatory stewardship practices (e.g., IPM) when available

Users have ESA Section 9 protection, burden to implement for users and FWS?

EPA sued under ESA for failure to consult?

FWS sued for not providing sufficient mitigations?

Potential Pesticide 4(d) Rule Scenarios

Scenario 4

No 4(d) rule

Pesticide users may have no Section 9 protection if/when listing finalized

If listed, EPA sued under ESA for failure to consult?

If EPA requests a conference opinion prior to the listing decision, users provided regulatory assurance on pesticide use through a final Biological Opinion (assuming monarch listed)?

Hip Pocket Slide Follows

Endangered Species Act

- Sec. 7(a)(1) – Federal agencies have programs to conserve listed species (EPA/FWS Joint Statement; January 2025)

- Sec. 7(a)(2) – Federal agencies must ensure actions will not jeopardize the continued existence of a listed species or adversely impact critical habitat
  - If Federal agency determines 'no effect' - done*
  - If Federal agency determines action 'may affect', then must consult with Service
    - Informal Consult: If Service concurs 'not likely to adversely affect' - done*
    - Formal Consult: If Service determines the action 'likely to adversely affect' then prepares jeopardy analysis
    - Jeopardy determination – risk based
    - Biological Opinion includes Incidental Take Statement

- Sec. 9 - Illegal to 'take' a listed species or harm critical habitat, unless actions protected under a Biological Opinion
  - Citizens and Federal agencies can be liable*

*ESA Sec. 11 allows citizen lawsuits against Federal agencies and the Services