

US EPA ARCHIVE DOCUMENT



# Biopesticides Registration Improvement Course



## **Ecological Risk Assessment**

**Mike Rexrode, Ph. D., Senior Biologist**

**Gina Casciano, M.S., Biologist**

U.S. Environmental Protection Agency

Office of Pesticide Programs

Biopesticide and Pollution Prevention Division



## Objectives of Presentation

- Ecological Risk Assessment
  - Problem Formulation
  - Analysis
  - Risk Characterization
- Flexibility in Biological Pesticide data needs
  - Tiered Data requirements
  - Data waiver justification
  - Non-guideline data acceptability



## What is Ecological Risk ?

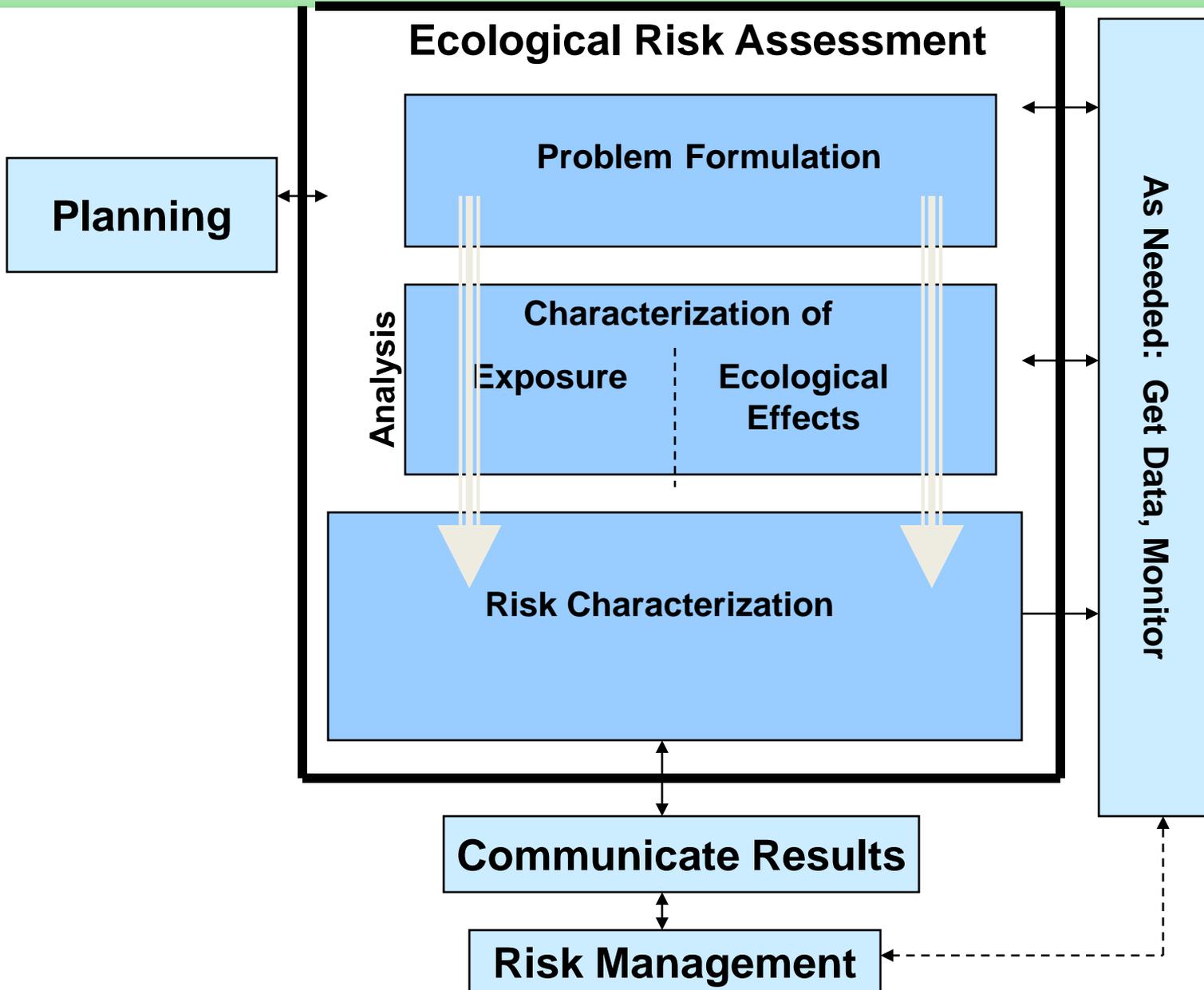
- **Assessment and Risk Characterization**
  - A process that evaluates the likelihood that ecological effects may occur as a result of exposure to a stressor.





## **Basic Components of a Risk Assessment**

- **Problem Formulation:**
  - Identify the problem.
- **Analysis:**
  - Identify exposure and effects endpoints.
- **Risk Characterization:**
  - Deterministic Risk Quotient (RQ)





## **Problem Formulation**

- Establish the direction and scope of the risk assessment.
- Identify the environmental values to be protected and how this is to be evaluated.



## **Exposure Assessment or Exposure Characterization**

- The process of modeling residue levels and estimating exposure or dose...considering:
  - Fate of the chemical
  - Environmental or use site conditions
  - Likelihood of organism exposure in proposed sites (TREX, GENECC, PRZMS/EXAMS)





## Ecological Effects

- Tier I acute testing on aquatic and terrestrial species.
- Tier II and III testing on aquatic and terrestrial species (more relevant for conventional pesticides).
- Field studies.



## Endangered Species Concerns

- Conclude that exposure may affect endangered species
  - Level of Concern for aquatic species is  $EEC/LC50 \geq 0.05$
  - Level of Concern for Terrestrial (avian and mammalian)  $EEC/LC50 \geq 0.1$
  - Level of Concern for plants is  $EEC/LC05 \geq 1.0$
  - Chronic Level of Concern if maximum exposure  $\geq$  the chronic NOEC





## Environmental Data Requirements/Resources

- US Data Requirements:
  - Found at 40 CFR 158.2060 <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=cd8f1e147413b4eb189cf9b0286129ae&rgn=div8&view=text&node=40:23.0.1.1.9.15.1.6&idno=40>
  - Data is required according to use pattern, with test notes describing the exceptions
- Test Guidelines:
  - Found at EPA's website: <http://www.epa.gov/ocspp/pubs/frs/home/draftguidelines.htm>
  - Guidelines are available for all data requirements





# US Data Requirements in 40 CFR 158.2060 ( Tier I )

Guideline Number	Data Requirement	Use Patterns					Test Substance	Test Notes
		Terrestrial	Aquatic	Greenhouse	Forestry, Residential Outdoor	Indoor		
		Food/Feed/ Nonfood	Food/ Nonfood	Food/ Nonfood		Food/ Nonfood		
<b>Tier I</b>								
<b>Avian Testing</b>								
850.2100	Avian acute oral toxicity	R	R	CR	R	CR	TGAI, EP	1, 2, 3, 4
850.2200	Avian dietary toxicity	R	R	CR	R	CR	TGAI, EP	1, 2, 3, 4
<b>Aquatic Organism Testing</b>								
850.1075	Fish acute toxicity, freshwater	R	R	CR	R	CR	TGAI, EP	2, 3, 4, 5
850.1010	Aquatic invertebrate acute toxicity, freshwater	R	R	CR	R	CR	TGAI, EP	2, 3, 5
<b>Nontarget Plant Testing</b>								
850.4100	Terrestrial Plant Toxicity, Seedling emergence	R	R	NR	R	NR	TGAI, EP	5
850.4150	Terrestrial Plant Toxicity, Vegetative vigor	R	R	NR	R	NR	TGAI, EP	5
<b>Insect Testing</b>								
880.4350	Nontarget Insect Testing	R	R	R	R	NR	TGAI	14



## Environmental Assessment Test Note Examples

“Required for the EP when any end-use formulation may contain other ingredients that may be toxic to nontarget organisms or to support arthropod pheromones that would be available to avian wildlife, (e.g., a granular product).”

“Tests for pesticides intended solely for indoor application would be required on a case-by-case basis, depending on use pattern, physical/chemical properties, production volume, and other pertinent factors.”



“Not required for any use groups if the pesticide is highly volatile (estimated volatility  $>5 \times 10^{-5} \text{ atm m}^3 / \text{mol}$ ).”



## Tier II and Tier III Testing

- Tier II Environmental Fate Testing is required when results from Tier I studies indicate adverse effects
- Tier II Nontarget Plant Studies are required for known phytotoxicants, *i.e.* , herbicides, desiccants, defoliants, and plant growth regulators.
- Tier III Testing includes Aquatic Fauna Chronic, Life Cycle, and Field Studies, Freshwater fish/invertebrate testing, Marine/Estuarine fish/invertebrate animal testing, Aquatic field fish/invertebrate testing, Avian Reproduction, Wild mammal acute toxicity and Beneficial Insects testing.



## Data Waivers

- 40 CFR 158.45 - Applicant must provide explanation/rationale why a specific data requirement should be waived
- Waivers are sought..
  - because it would not be possible to generate the required data
  - because the data would not be useful in the Agency's evaluation of the risks or benefits of the product.
- Present your case clearly with references (Don't do a "data dump")
- Submit copies of your references



## Non-guideline Data Acceptability

- Cite peer reviewed studies from the scientific literature
- Study must clearly address the data requirement
- Explanation (in writing) must be submitted along with copy of referenced study





## Endangered Species Concerns

- Nontoxic does not mean “no effect”
  - Plant growth regulators
- Use rate is important
  - Coyote urine
- Use pattern is important
  - Spraying crops vs. use around structures
- Fate data is extremely important





**Thank you!**