

Environmental Fate and Effects Division: Who We Are and What We Do!

Ingrid M. Sunzenauer
Environmental Fate and
Effects Division,
Office of Pesticide
Programs

Purpose Of Presentation

- Mission of the Environmental Fate and Effects Division (EFED)
- Processes to ensure sound science
- How we evaluate ecological risk from pesticides

EFED's Mission: Assessing Environmental Risks

- Assess and characterize the potential ecological risk to non-target organisms
- Provide critical information to Agency regulators for registration and reregistration decisions

Ensuring Sound Science

Therefore, it is essential to conduct high quality risk assessments that are:

- Scientifically credible
- Follow the Agency's science and policy guidance
- Consistent within OPP and with other Agency offices

Accomplished by implementation of processes to support sound science.

Sound Scientific Processes

1. Follow Agency guidance
2. Follow internal guidance
3. Subject to internal and external peer review mechanisms
4. Evolve and improve by the development of new risk assessment tools and methods
5. Implemented through training programs

1. Agency Guidance

- US EPA “Ecological Guidelines”
<http://www.epa.gov/ncea/ecorsk.htm>
- US EPA “Risk Characterization Handbook”
<http://epa.gov/osp/spc/rchandbk.pdf>

2. Internal Guidance

- Pesticide Assessment Guidelines
 - Guidance and standards on how to conduct acceptable studies and report the results
- Standard Evaluation Procedures
 - Internal guidance on how to evaluate studies and conduct a risk assessment
- Miscellaneous policies, procedures, guidance memoranda, and references

2. Internal Guidance (cont'd)

- Generic Format and Guidance Document
 - Provides the basic format for EFED's screening ecological risk assessments
- Overview Document
 - Provides an overview of the assessment process for potential risk to listed species

3. Internal and External Peer Review Mechanisms

- Internal peer review mechanisms
- External peer review: Scientific Advisory Panel
 - Multi-disciplinary, independent, peer review body
 - National and international scientific experts
 - Formal setting and opportunity for public comment

4. New Risk Assessment Tools/Methods

- Evolving process. As science progresses, the assessment process will continue to develop
- Examples include
 - Refined (Probabilistic) Risk Assessments
 - Developing a new statistical package for analyzing plant data
 - Developing shells PE4 and Express for PRZM/EXAMS

5. Training

EFED staff and other OPP Divisions

- EPA's Ecological Risk Assessment Guidelines
- EPA's Risk Characterization Guidelines

EFED staff

- Generic Format Document
- Various statistical models and use of GIS

Extensive training currently in progress for new EFED employees and others

Ecological Risk Assessments

Ecological Risk Assessments: Screening Assessments

- Evaluate the results from pesticide exposure to ecological resources
- Based on
 1. Best available scientific and commercial data, and
 2. Sound scientific processes.
- Provide critical information to Agency regulators

Best Available Data

- Registrant submitted data for exposure and effects (CFR 40 part 158)
- Open literature data for effects
- Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) (6)(a)(2) data

Effects Data: CFR 40 Part 158

- Evaluates the acute and chronic effect of a pesticide
- Limited data set predicts toxicity levels to a large number of potentially exposed species
- Data includes birds, fish, plants, aquatic organisms and others
- Generally little or no data on reptiles, amphibians, and other taxa
- Data used are based on the most sensitive species tested
- Proposed expanding requirements to include additional species and routes of exposure

Other Sources of Effects Data

ECOTOX

- Locates publicly available chemical toxicity data for aquatic and terrestrial organisms
- Interim guidance issued outlining evaluation criteria to ensure the best available data are used

Section 6(a)(2) of FIFRA

- Requires registrants to submit adverse effects information about their products to the EPA
- Includes incident data and other adverse effects information

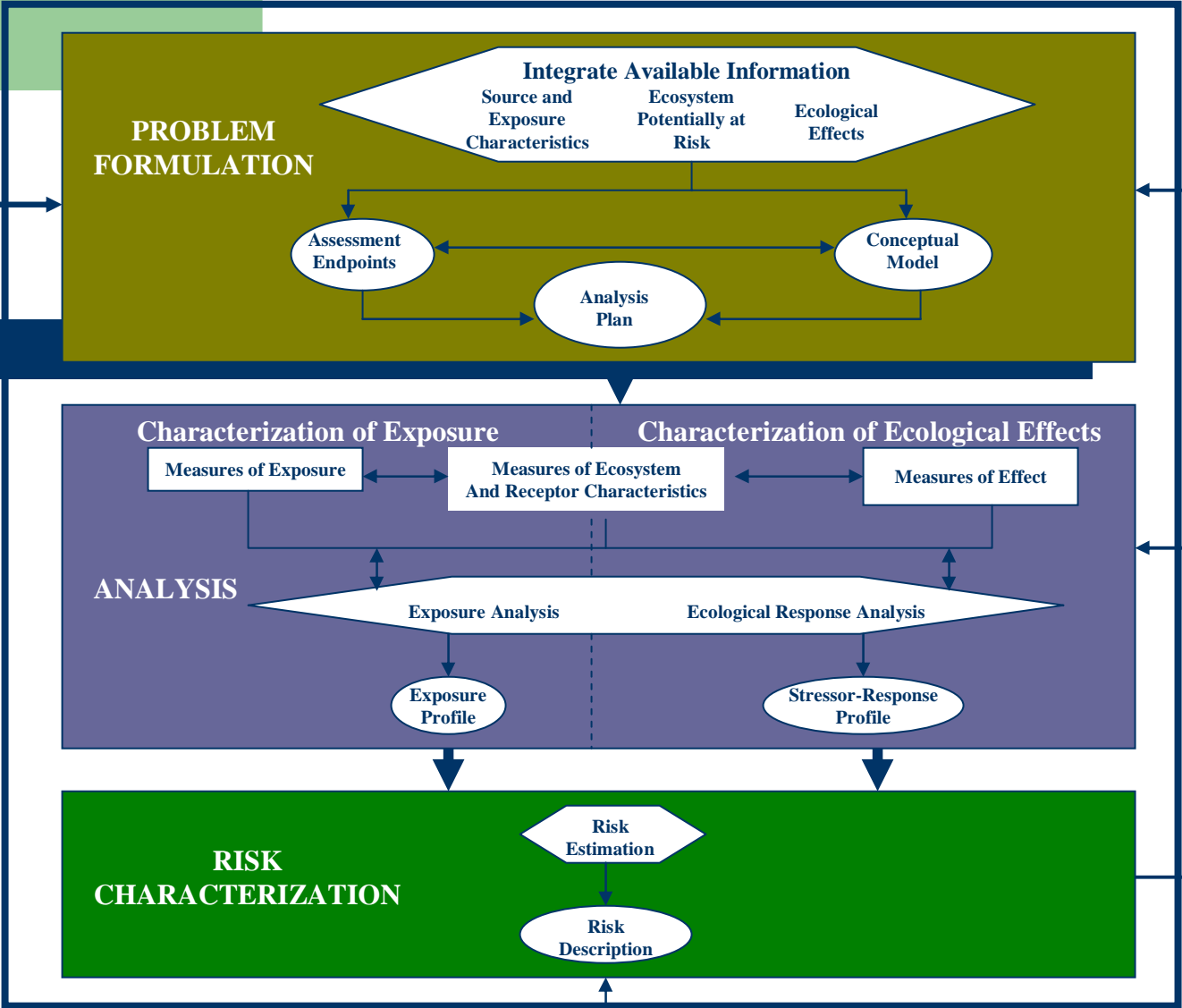
Exposure Data: CFR 40 Part 158

- Where and how the pesticide moves in the environment and how long it will persist
- What degradation products are produced, in what quantities and under what processes
- Includes chemical degradation, metabolism, mobility, and field studies
- No new tests! Just codifying current practices.

FRAMEWORK FOR ECOLOGICAL RISK ASSESSMENT

**Planning
(Risk Assessor/
Risk Manager
Dialogue)**

- 1. Management Goals
- 2. Management Options
- 3. Scope, Complexity, and Focus
- 4. Resources
- 5. Scheduling



As Necessary
Acquire Data,
Iterate Process,
Monitor Results

Communicating Results to the Risk Manager

Risk Management

5/18/

Planning a Risk Assessment: Planning Dialogue

- Distinct from the risk assessment process
- Occurs up front between risk managers and risk assessors
- Key steps are
 - Describing management goals
 - Identifying potential risk management options
 - Discussing the focus, scope, and complexity of assessment
 - Identifying resources and setting schedules

Basic Components of the Risk Assessment Process – Brief Overview

1. Problem Formulation

- Begins the scientific process
- Provides the foundation for the assessment
- Integrates available information and provides an early identification of data gaps
- Defines assessment endpoints and proposes conceptual model
- Concludes with an analysis plan

2. Analysis

- Review the available data
- Develop exposure characterization →
Measures of exposure: Describe the pesticide's existence and movement in the environment
- Develop effects characterization →
Measures of Effect: Describe the effect of the pesticide
- Evaluate uncertainty

3. Risk Characterization

- Represents the final step in the assessment process
- Integrates and synthesizes the effects and exposure characterizations into an overall conclusion
- Includes a description of assumptions, limitations, and uncertainties
- Is complete, informative, and useful for decision makers

3. Risk Characterization cont'd

- Risk Estimation
 - Integrates exposure and effects data
 - Accomplished by calculating a risk quotient (RQ)
 - RQ compared with a Level of Concern (LOC), the criteria used to indicate potential risk
- Risk Description
 - Provides interpretation of risks based on assessment endpoints
 - Informative for the risk manager, who will use the assessment to make a risk management decision

Final Thoughts

- Primary mission is to provide Agency regulators with scientifically sound ecological risk assessments
- Accomplished by
 - Following sound scientific processes in evaluating the available data from 40 CFR 158 and
 - In conducting the ecological risk assessments