Overview of USEPA's Ecological Risk Assessment for Pesticides

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Statutory Standards

- Federal Insecticide Fungicide Rodenticide Act (FIFRA)

  "…will not generally cause unreasonable adverse effects on the environment." FIFRA defines the term ''unreasonable adverse effects on the environment'' to mean: any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide

- Endangered Species Act (ESA)

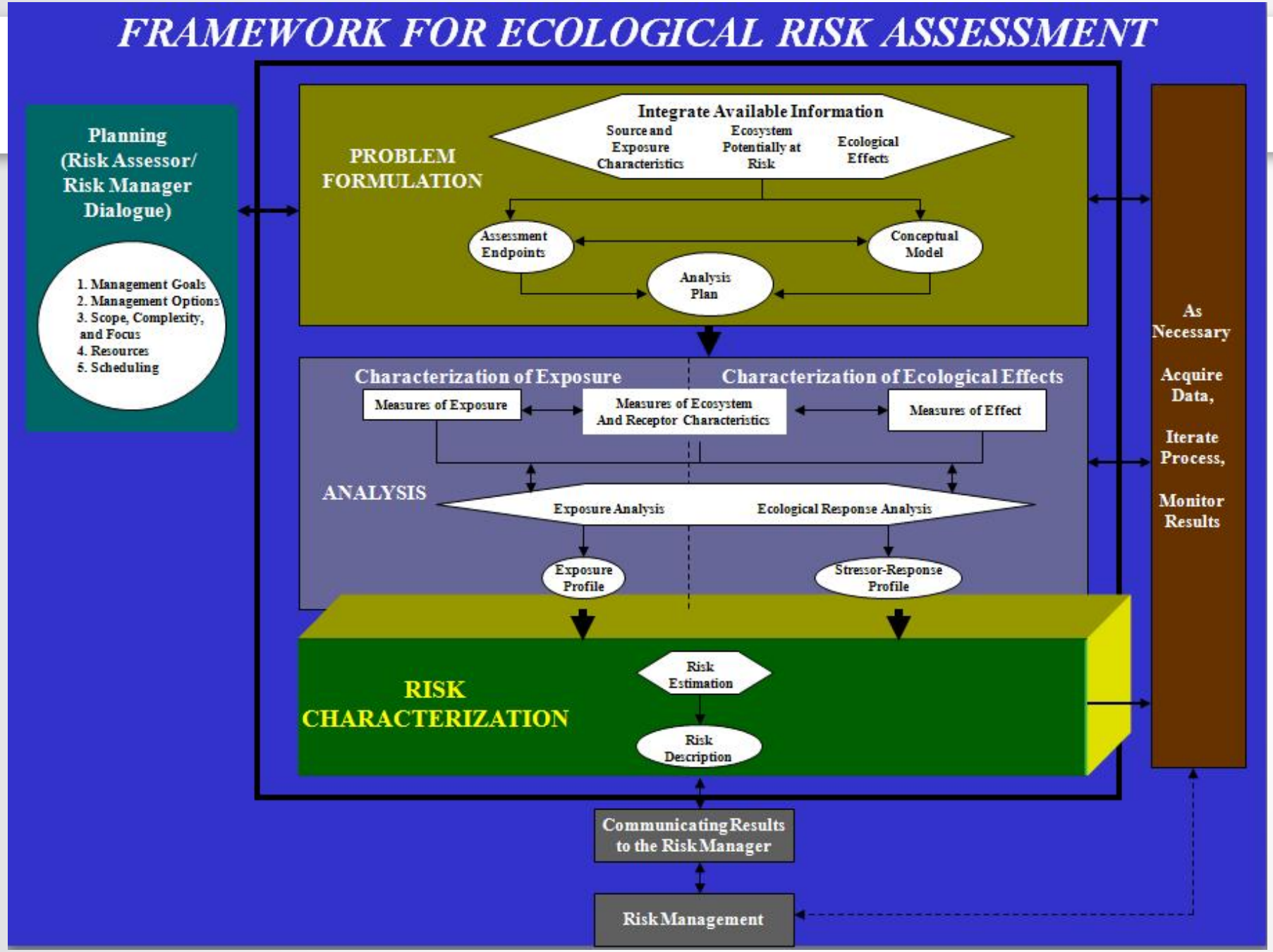
  "…is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat." (Section 7(a)(2))

Ecological Risk Assessments

- Objective: To evaluate the impacts of pesticides on non-target organisms
- Risk involves comparison of estimated environmental exposures to levels where effects may occur
- Requires an understanding of:
  - Toxicity
  - Exposure
  - Risk
  - Regulatory context
- Evaluate risks to aquatic and terrestrial wildlife and plants

Ecological Risk Assessments

- Tiered
  - Start out conservative and with lower effort
  - Increase in complexity and effort as needed
- May address risks at different scales
  - Individual – population – species – taxonomic group
  - Site-specific – county-level – nationwide
- Based on
  - Peer reviewed methods and models
  - Best available data
- Supports a regulatory decision
  - Registration Review
  - New chemicals
  - New uses of existing chemicals



Similar in structure to a scientific publication:

- '**Problem Formulation**' similar to '**Introduction**'
- '**Analysis**' similar to '**Methods**'
- '**Risk Characterization**' similar to '**Results**' and '**Discussion**'

Problem Formulation

- Provides the foundation for the risk assessment
- Describes the federal action (proposed use)
  - Based on proposed or existing labels
- Articulates the purpose of the assessment
- Explains the conceptual model and risk hypotheses
- Defines degradates of concern

Problem Formulation

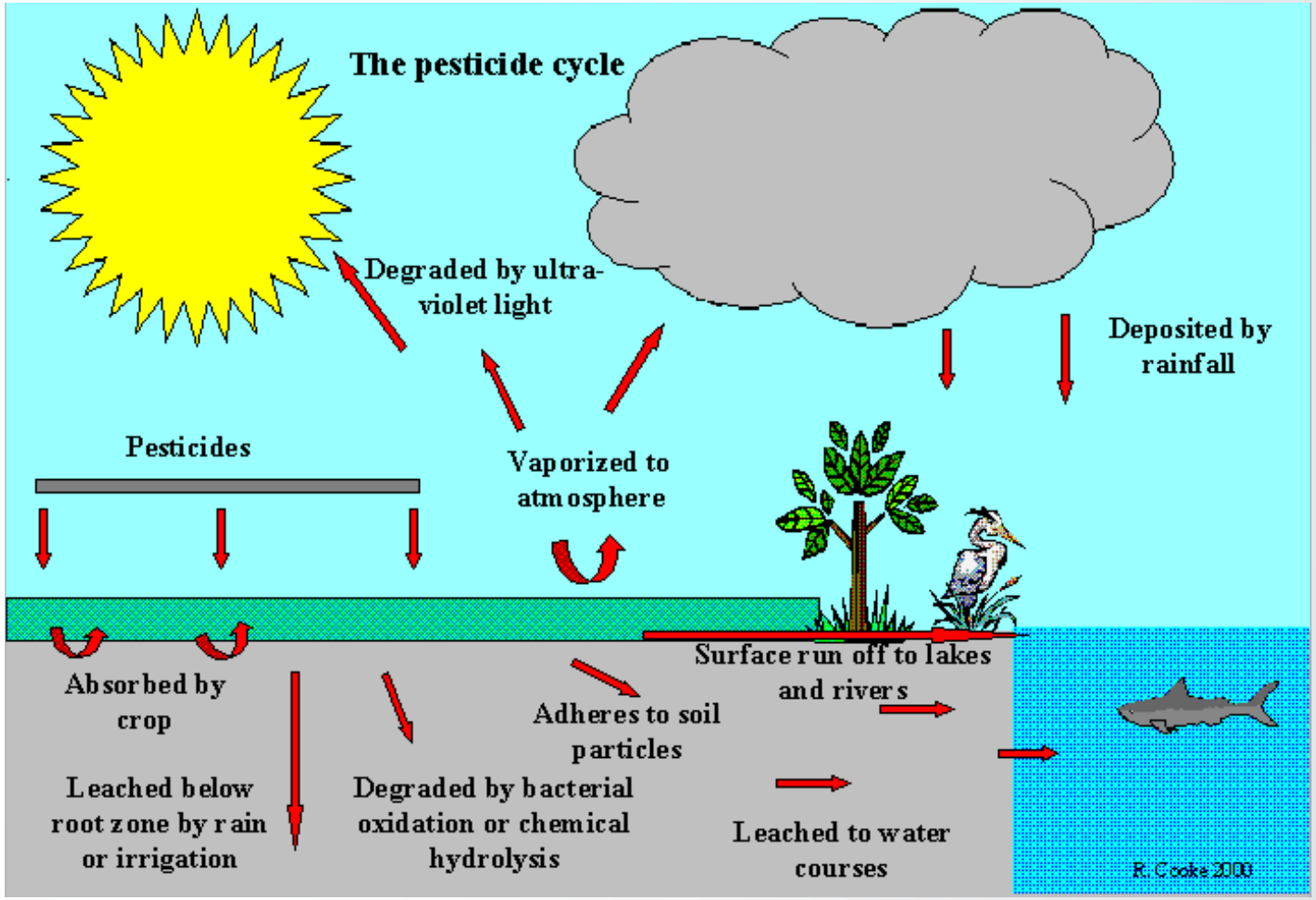
- Outlines a plan for analyzing risk, identifying:
  - Previous risk conclusions (if any)
  - Scope, complexity, and the focus of the assessment
  - Available data
  - Models
  - Data gaps
  - Uncertainties

Exposure Characterization

- Objectives
  - To characterize fate and transport of assessed pesticide in environment
  - To quantify exposure of pesticide and degradates of concern to non-target organisms
- Identify major transport and exposure routes for non target organisms
  - Direct application to field, spray drift, runoff, leaching, volatilization, bioaccumulation
- Degradation
  - Abiotic (hydrolysis, photolysis)
  - Biotic (aerobic/anaerobic, soil, water, sediment)
  - Identify major (>10%) degradates

Conceptual Exposure Model

- Driving Factors
  - Application/agronomic practices
    - Rate, method, timing
  - Environmental conditions
    - Weather, soil
  - Pesticide properties
    - Physical-chemical
    - Environmental fate



Analysis: Exposure

- Develop conceptual exposure model
- Identify residues and durations of exposure of concern
- Estimate exposure and characterize in a weight of evidence approach
  - Modeling (computer simulation derived concentrations)
  - Monitoring (measured environmental concentrations)

Exposure Models

- Terrestrial
  - Birds and mammals
    - T-REX model
    - Dietary exposure on field
    - Birds are surrogates for terrestrial-phase amphibians and reptiles
  - Bees
    - BeeREX model
    - Dietary and contact exposure
    - Honey bees are surrogate for other species
  - Terrestrial and wetland plants
    - TerrPlant model
- Aquatic
  - Fish, aquatic-phase amphibians, aquatic invertebrates, aquatic plants
    - Pesticide in Water Calculator
    - PFAM (rice and cranberry uses)
- Spray Drift
  - AgDRIFT
  - AgDISP

Analysis: Effects

- Objective
  - Quantify magnitude of effect of pesticide on survival, growth and reproduction of animals and plants

- Relies upon test species that represent surrogates for groups of organisms (referred to as “taxa”)
  - Terrestrial (birds, mammals, bees, plants)
  - Aquatic (fish, invertebrates, plants)

Effect Endpoints Represent

- Valued entity (the receptor; *e.g.,* a fish)
- Attribute or characteristic that is important to protect and is potentially at risk (*i.e.,* survival)
- Ecologically relevant
- Susceptible to potential stressor (pesticide)
- Relevant to risk management goals

Standard Endpoints: Animals

- Endpoints represent apical effects to non-target organisms
- Acute:
  - LD_{50} or LC_{50} or EC_{50} (lethal dose/concentration; 50%)
    - Based on survival or immobility
- Chronic:
  - NOAEL or NOAEC (no observed adverse effects level or concentration)
  - LOAEL or LOAEC (lowest observed adverse effects level or concentration)
  - Based on survival, growth (weight and/or length), and reproduction
- Effects on behavior, appearance, and/or developmental effects
  - *e.g.*, malformations
  - Can be used for risk characterization

Standard Endpoints: Plants

- Terrestrial
  - IC_{25} = concentration leading to 25% effect or decline in growth
  - NOAEC
- Aquatic
  - IC_{50} = concentration leading to 50% effect or decline in growth
  - NOAEC
- Endpoints include and represent apical effects
  - Survival/Emergence (terrestrial)
  - Biomass
    - Terrestrial plants: length and/or dry weight
    - Aquatic plants: cell density, frond number, dry weight
  - Growth rate (aquatic)

Incident Reports

- Incident = any exposure or effect from a pesticide's use *that is not expected or intended*
- *Categories*
  - Humans
  - Pet and Domestic Animals
  - Fish and Wildlife
  - Insect Pollinators
  - Plants
- Evaluated by OPP
  - Certainty category is assigned
  - Legality is described
  - Other pertinent details considered (*e.g.,* product applied, other active ingredients present)
- Discussed in risk characterization
  - Indicates that exposure pathway is complete
  - Line of evidence
    - Are effects observed consistent with other analyses?

Risk Characterization

- Risk Quotients = Exposure / Toxicity
  - Relies upon standard models and toxicity endpoints
  - Compared to Levels of Concern to determine if there is potential risk

- Tiered process
  - If RQ is below level of concern, risk is considered low
  - If RQ is above level of concern, additional refinement is carried out
    - Screening level is intentionally designed to be conservative
  - Refinements may include
    - Analysis of conservative assumptions and influence on risk conclusions
    - Probabilistic modeling
    - Field level exposure and effects data

Purpose of Screening Level Assessment

- The goal is to generate “reasonably conservative” estimates of pesticide exposures to organisms of interest

- Intended to distinguish between:
  - Pesticides that do not pose a risk and
  - Those that may need additional information

- Type I and II Errors
  - Tier I assessment should not conclude that there is no effect when there actually is (Type II)
  - It is more acceptable at the Tier I level to conclude that there is a potential effect when there is none (Type I)

Risk Characterization

- Starts with comparison of risk quotients to levels of concern
  - When RQs are above LOC, additional characterization is provided
- Evaluation of multiple lines of evidence
  - Quantitative and qualitative factors
- Discussion of assumptions and uncertainties and how they may impact risk conclusions
- Commonly evaluates alternative assumptions to inform risk mitigations
  - Aerial vs ground, application timing, drift buffers, etc.

Data Used in Ecological Risk Assessments

- Sources
  - Registrant submissions of unpublished studies
    - Code of Federal Regulations specify data requirements to support registration
    - Follow standard test guidelines
  - Open literature

- Data Review
  - EFED conducts independent reviews of unpublished and published studies
    - Statistical analysis of raw data
  - Evaluated according to Standard Evaluation Procedures (SEPs)
  - Completed Data Evaluation Record (DER)
  - Open literature is systematically reviewed for re-evaluation cases – Open Lit Review Summaries (OLRS)

Quality Assurance/Quality Control

- Models and Tools
  - Based on best available science and data
  - Undergo peer review
    - Internal EPA review by Senior Scientists
    - FIFRA Scientific Advisory Panel

- Ecological Risk Assessments
  - Written by EFED scientists
  - Reviewed by Senior scientists

Resources

- *Overview Document* (2004): http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/ecological-risk-assessment-pesticides-technical
- *Guidelines for Ecological Risk Assessment* (1998): http://www.epa.gov/risk/guidelines-ecological-risk-assessment
- Protecting bees and other pollinators from pesticides: https://www.epa.gov/pollinator-protection
- Protecting Endangered Species from Pesticides: https://www.epa.gov/endangered-species
- Models: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment
- ECOTOX database: https://cfpub.epa.gov/ecotox/
- Standard test guidelines for fate: https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-835-fate-transport-and-transformation-test
- Standard test guidelines for ecological effects: https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-850-ecological-effects-test-guidelines
- EPA Handbook on Risk Characterization: https://www.epa.gov/risk/risk-characterization-handbook
- EPA Peer Review Handbook: https://www.epa.gov/osa/peer-review-handbook-4th-edition-2015