

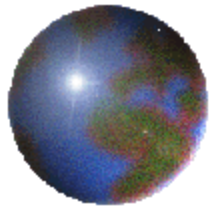


# LAPRW 2011

**3º Workshop Latinoamericano sobre Residuos  
de Pesticidas Alimentos y Medio Ambiente**

**Montevideo, URUGUAY, Mayo 8 a 11, 2011**

## ***Managing Pesticide Use to Protect Our Natural Environment***



**Ronald Parker, PhD  
Senior Environmental Engineer  
Office of Pesticide Programs  
US Environmental Protection Agency  
Washington DC**

**3rd Latin American Pesticide Residue Workshop:  
Food and Environment**



# Ecological Risk Assessment / Risk Management: Presentation Outline



- ✚ Ecological Risk Assessment (ERA): Why Do It? How Does It Work?
- ✚ Constraints to ERA Identified
- ✚ Possible Solutions Identified
  - ▣ Data Harmonization
  - ▣ Work-sharing
- ✚ Capacity-building; Capability-training
- ✚ User-friendly Exposure/Risk Assessment Methods & Tools
- ✚ Overall Goal: Risk Management

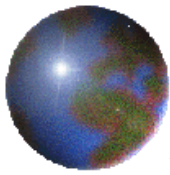


# Ecological Risk Assessment: Why Do It?

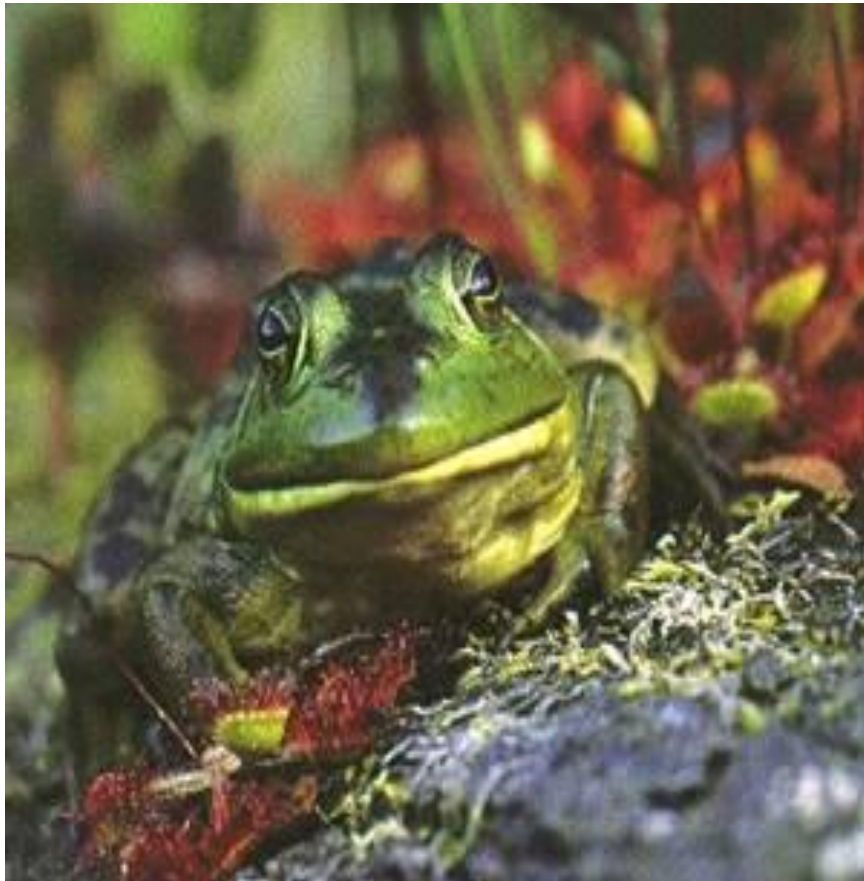


- ✚ Informs Pesticide Registration Decisions
- ✚ Informs Pesticide Risk Management Decisions
- ✚ Protects Wildlife
- ✚ Conserves Global Biodiversity
- ✚ Promotes Tourism

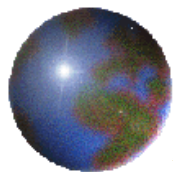




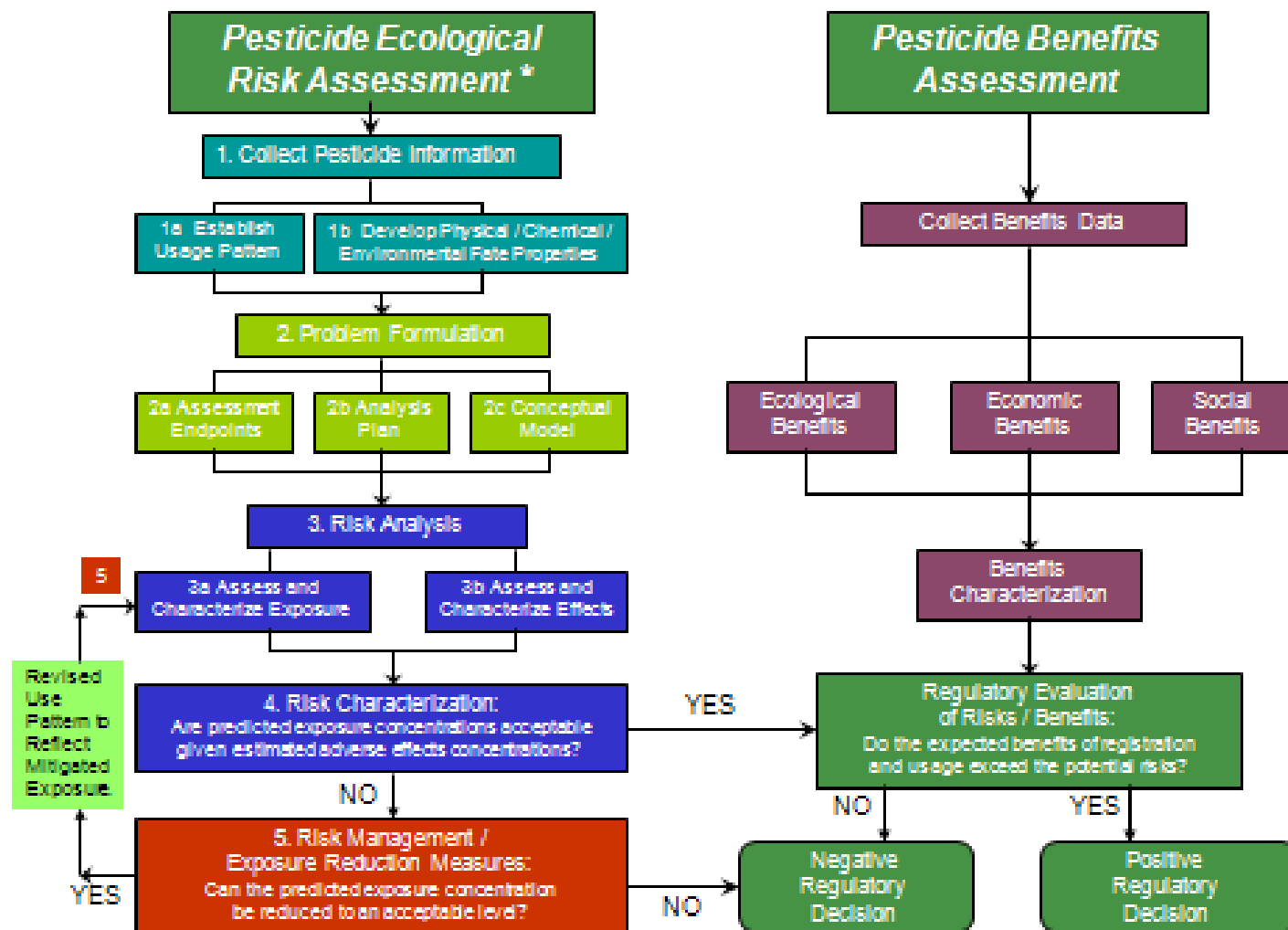
# Ecological Risk Assessment: How Does It Work?



- ✚ Estimates the Likelihood of Adverse Ecological Effects by Comparing Estimated Field Exposure to Measured Laboratory Toxic Effects Data
  - ⊞ Effects = Toxicity, hazard
- ✚ May Be Combined With Human Health Risk Assessment & Pesticide Benefits Assessment for an Overall Pesticide Risk / Benefit Evaluation



# Ecological Risk Assessment Decision Diagram



\* This diagram does not include human health risk assessment.



# Five-Steps of Ecological Risk Assessment

- Step 1: Data Collection
- Step 2: Problem Formulation
- Step 3: Risk Analysis
- Step 4: Risk Characterization
- Step 5: Risk Management

\*Based on USEPA *Guidelines for Ecological Risk Assessment* and EU Directive 91/414/EEC



# Step #1: Pesticide Data Collection



## ✚ Develop and Assemble Data Needed for the Risk Assessment

- ✚ Laboratory Physical / Chemical Data
- ✚ Laboratory Ecological-Effects (Toxicity) Data
- ✚ Laboratory and Field Environmental Fate and Exposure Data



# Types of Ecotoxicological Data



- ✚ The Most Data is Available for: Birds, Small Mammals, Fishes, Insects, Crustaceans, Mollusks, Vascular Plants, Algae
- ✚ The Fewest Data are Available for: Reptiles, Amphibians, Sponges, Protozoans, Fungi, Worms, Coelenterates & Plant Groups





# Number of Species Tested



- ✚ World Has Identified More than 1.3 Million Animal & Plant Species
- ✚ For New Chemicals, We Have Acute Toxicity Data for About 15 Species
- ✚ For Older Chemicals – We Have Data For About 50 Species
- ✚ For Herbicides, We Have Data for About 15 Plant Species

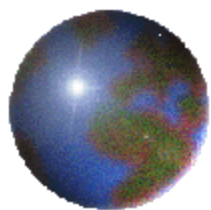


# Use of Indicator (Surrogate) Species



- ✦ 2 - 3 Species of Bird Represent 9,000 Species of Birds and 6,500 Species of Reptiles
- ✦ 2 – 3 Species of Fish Represent 22,000 Species of Fish and 4,000 Species of Amphibians
- ✦ 3 - 4 Invertebrate Species Indicate Sensitivity of 1 Million Species of Invertebrates
- ✦ 15 Plant Species Indicate Sensitivity of the Plant Kingdom
- ✦ 1 -2 Insect Species Represent Over 800,000 Insects





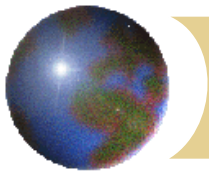
# *Web-ICE (Interspecies Correlation Estimation) Toxicity Estimation Tool for Ecological Risk Assessment*

Contact:

Sandy Raimondo, Deborah Vivian,  
Jill Awkerman, and Mace Barron

USEPA/ORD/NHEERL/GED





# *How well do ICE models work?*

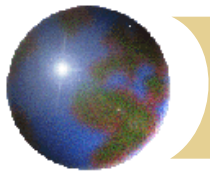
*Model uncertainty related to taxonomic distance*

**Aquatics in same order ~ 90% within 5-fold, 95% within 10-fold**

**Percentage of all datapoints in cross-validation category**

<b>Common level</b>	<b>Number datapoints</b>	<b>5-fold</b>	<b>10-fold</b>	<b>50-fold</b>	<b>&gt; 50 fold</b>
genus (1)	372	92	3	4	1
family (2)	1042	92	6	2	0
order (3)	280	89	6	4	1
class (4)	5622	79	9	8	4
phylum (5)	854	52	17	21	10
kingdom (6)	4524	50	16	22	12





# *How well do ICE models work?*

*Model uncertainty related to taxonomic distance*

**Wildlife in same order ~ 90% within 5-fold, 97% within 10-fold**

**Percentage of all datapoints in cross-validation category**

Common level	Number datapoints	5-fold	10-fold	50-fold	> 50 fold
genus (1)	48	100	0	0	0
family (2)	1452	92	6	2	0
order (3)	2238	90	7	3	0.3
class (4)	5706	85	10	5	0.2
phylum (5)	2402	76	13	9	1.5

Raimondo et al. 2003 Environmental Science and Technology (ES&T)



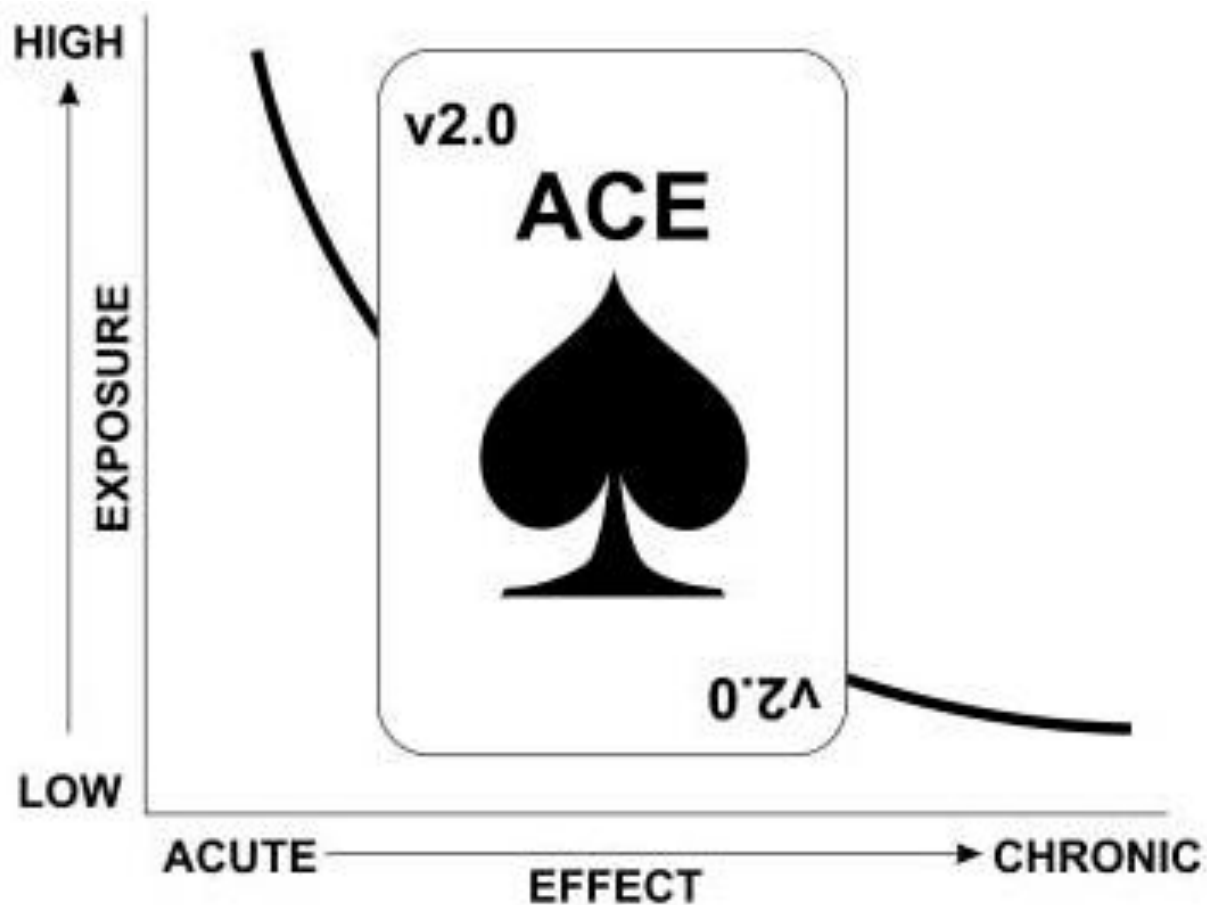
# Data For Chronic Risk Assessment

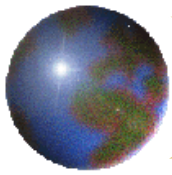


- ✦ 2 Species of Birds, 1-2 Species of Crustacea, and 1-2 Species of Fish Are Used to Represent Chronic or Sublethal Sensitivity of All Species in these Groups
- ✦ Limited Number of Chronic Endpoints Are Statistically Analyzed Under Controlled Laboratory Conditions

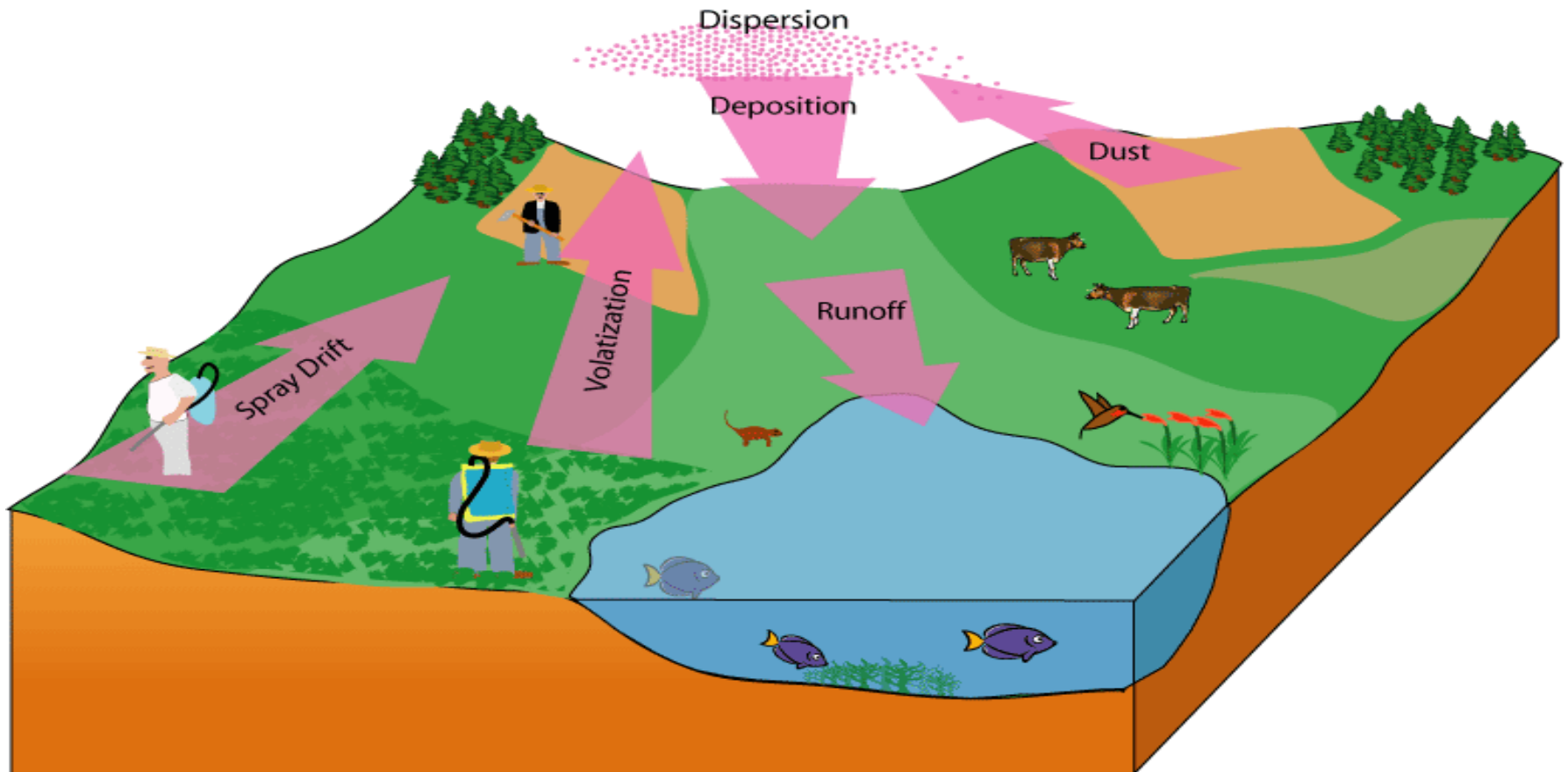


# Acute-to-Chronic Estimation (with Time - Concentration - Effect Models)





# Step #2: Problem Formulation: Every Pesticide is Different







# Step #2: Problem Formulation



- ✦ Generates and Evaluates Hypotheses About Reasons that Ecological Effects of Human Activities May Occur
- ✦ Evaluates the Nature of the Problem, Refines Objectives for the Analysis and Provides the Foundation for the Assessment.
- ✦ Develops a Plan For Analyzing Data and Characterizing Risk
- ✦ Responds to the Needs of the Risk Manager



# Step #3: Ecological Risk Analysis (1)



- ✚ Connects Problem Formulation Phase (Step 2) With the Risk Characterization Phase (Step 4 )
- ✚ Examines the Relationships Between the Two Primary Components of Risk, *Exposure & Effects*, and Between Them and Ecosystem Characteristics
- ✚ Provides the Ingredients Necessary for Estimating Ecological Responses to Pesticides Under Exposure Conditions of Interest





# Step #3: Ecological Risk Analysis (2)



- ➊ Assessment Endpoints and Conceptual Models Developed During Problem Formulation Provide the Focus and Structure for the Analyses
- ➋ Develops Summary Profiles that Describe Exposure and the Relationship between the Pesticide (Stressor) and its Effects (Response)
- ➌ These Profiles Provide the Basis for Estimating and Characterizing Risk

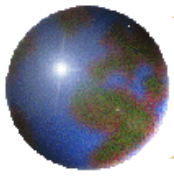


# Aquatic Ecological Risk Analysis



- ✦ Explicitly Assesses Fish and Invertebrates
- ✦ Implicitly Assesses Amphibians, Molluscs, etc
- ✦ Assesses Both Freshwater Organisms and Salt Water / Estuarine Organisms
- ✦ Always Assesses Direct Effects
- ✦ Sometimes Also Assesses Indirect Effects (e.g. Fish Food, Habitat, Predators, etc)
- ✦ Most Difficult Type of Exposure Assessment – Due to Inherent Variability of Aquatic Habitat





# Terrestrial Ecological Risk Analysis



- ✚ Explicitly Assesses Birds and Mammals
- ✚ Implicitly Assesses Reptiles
- ✚ Always Assesses Direct Effects
- ✚ Sometimes Also Assesses Indirect Effects (e.g., Availability of Food, Habitat, Predators, etc)
- ✚ Much Easier than Aquatic Exposure Assessment



# Step #4: Ecological Risk Characterization



- ✦ Risk Assessors Use Results of the Analysis Phase (*Exposure and Effects*) to Develop an Estimate of the Risks Faced by Animal and Plant Populations and Communities
- ✦ Allows Risk Assessors to Clarify the Relationships Between Pesticide Effects and Ecological Communities and to Reach Conclusions Regarding the Occurrence of Exposure and the Potential to See Adverse Effects
- ✦ Assessor Identifies and Summarizes the Uncertainties, Assumptions and Qualifiers in the Risk Assessment
- ✦ Reports the Conclusions to Risk Managers to Provide Clear Information for Environmental Decision Making





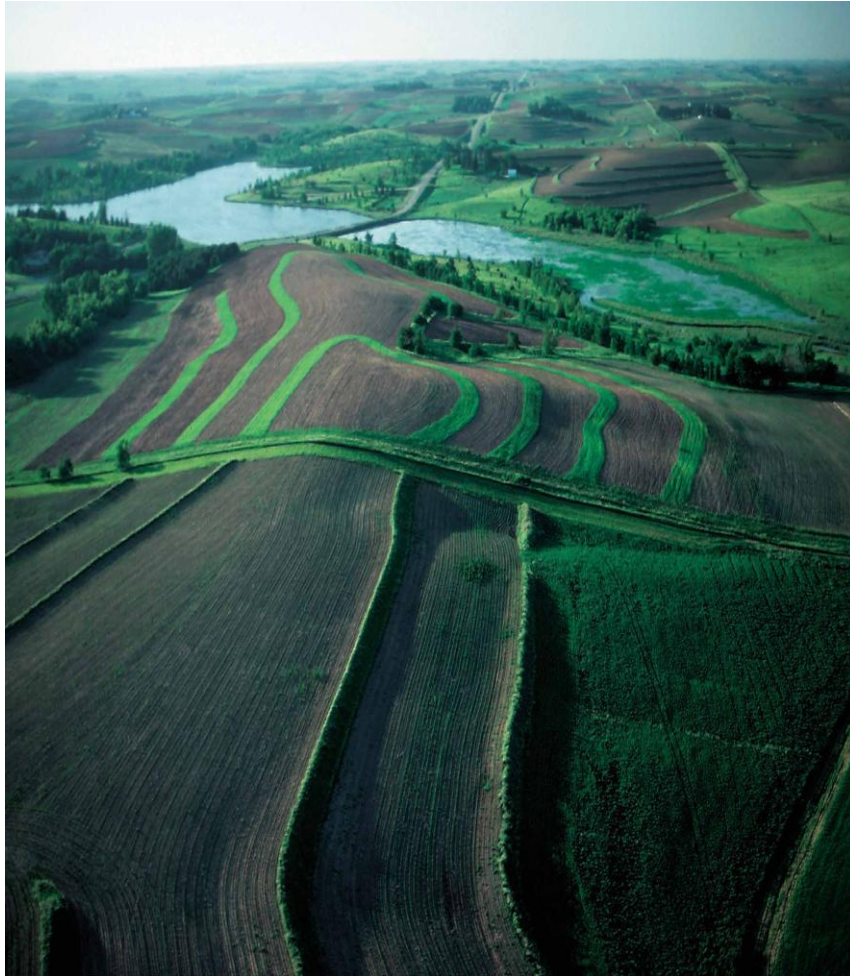
# Step #5: Ecological Risk Management: Possible Mitigation Measures



- ✿ Mitigation Measures Tailored to Local Conditions (e.g., Weather Limitations, Soil Type Limitations With Regard to Runoff, Sensitive Site Limitations)
- ✿ Pesticide Use Restrictions (Reduction In Application Rate and Number of Applications, Increased Time Between Applications, Acreage Limitation, Limits on Application Method, Requirement For Incorporation Into Soil)
- ✿ Separation Buffer Zones to Reduce Spray Drift to Vulnerable Sites
- ✿ Physical Barriers Such as Trees Along Waterways to Intercept Spray Drift
- ✿ Using No-tillage or Reduced Tillage Agriculture to Reduce Runoff and Soil Erosion



# Step #5: Ecological Risk Management: Possible Mitigation Measures

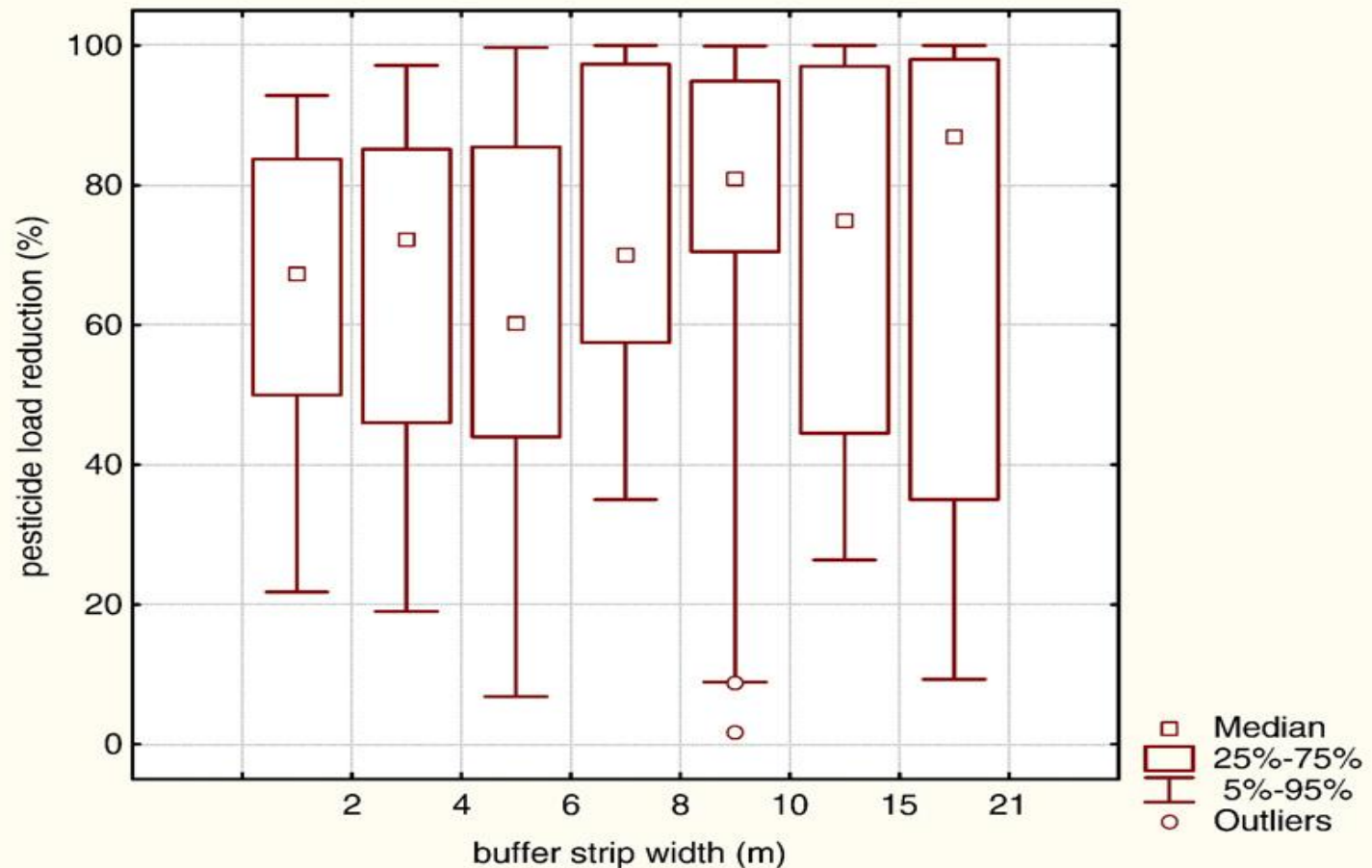


- ✚ Vegetated Buffer Zones to Reduce Offsite Runoff of Pesticide to Vulnerable Sites
- ✚ Use of Constructed Wetlands and Holding Ponds to Provide Time for the Pesticide to Degrade
- ✚ Application Restrictions (e.g., Method Type - Aerial Versus Ground, Field Tarps, Soil Compaction, Timing of Application)
- ✚ Equipment Cleaning and Maintenance Helps to Assure that the Target Application Rate Is the Rate that Is Actually Applied
- ✚ Restrictions on Locations at Which Equipment May Be Cleaned (Away From Waterways and Wells)
- ✚ Safe Disposal of Excess Product



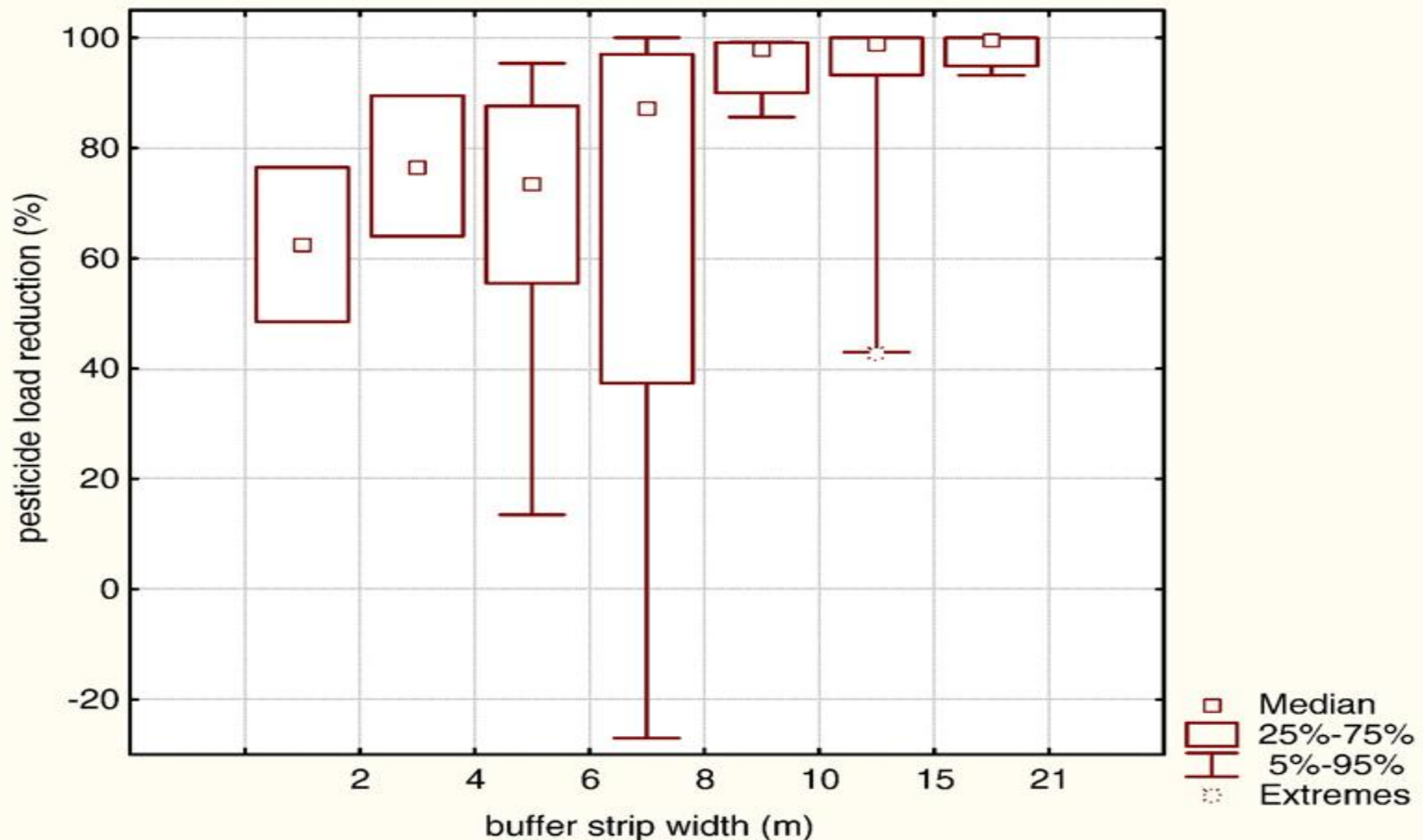


# Load Reduction for Field Buffers: Dissolved Pesticide





# Load Reduction for Field Buffers: Adsorbed Pesticide





# Making Ecological Risk Assessment Work: Addressing Major Constraints







# Ecological Risk Assessment: Constraints Identified in Central American Workshop



- ✚ Need For Better Coordination Among Ministries Within the Country and Between other Countries in the Region
- ✚ Short Legal Time-Frame for Collecting Data and Conducting Ecological Risk Assessment
- ✚ Inadequate Resources (Funding, Trained Staff, Laboratory Facilities)



# Risk Assessment Constraints Identified by Latin American Regulators



- ⊕ Limited Data on Local Non-Target Species Which May Need Protection
- ⊕ Environment Fate and Toxicity Data that were Developed for Temperate Climates & Species
- ⊕ Lack of Data For Exposure Assessment (Crops, Soil Properties, Water Resources, Weather History, etc)





# Risk Assessment is Scientifically Complex

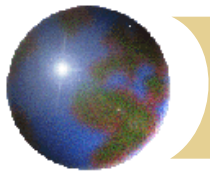


## ✚ ERA Requires Many Scientific Disciplines

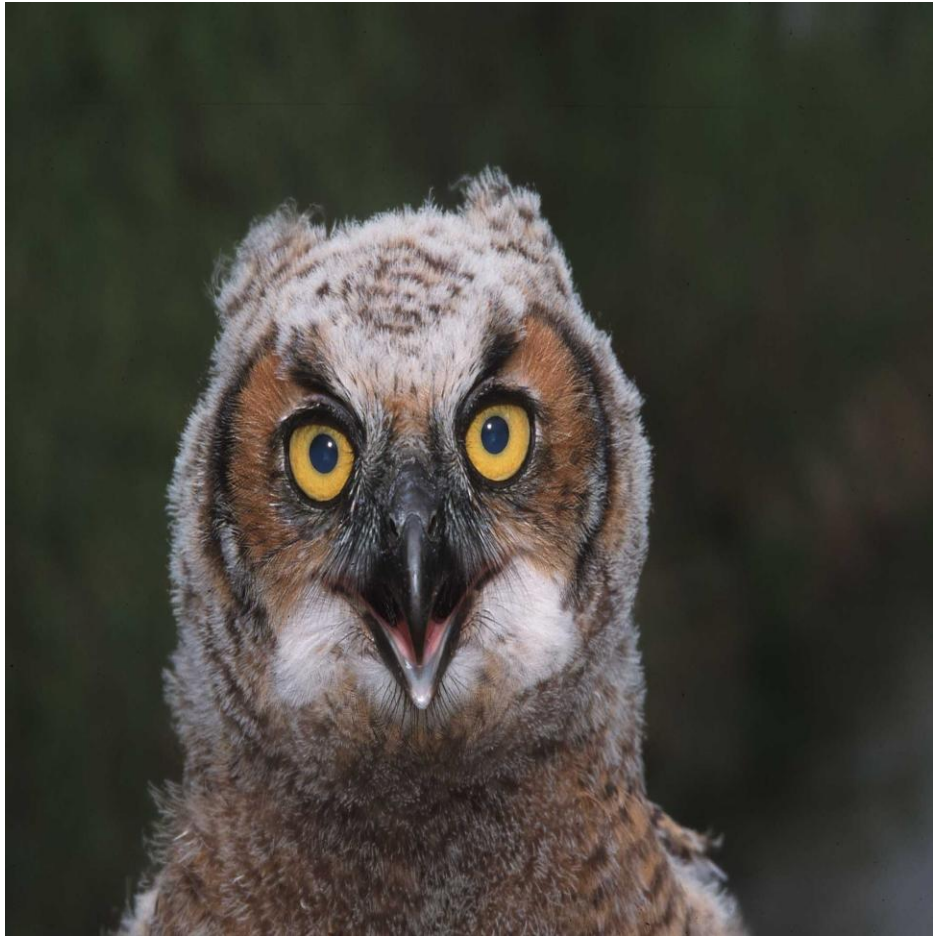
✚ Agronomy, Botany, Entomology, Ecology, Bacteriology, Toxicology, Public Health, Chemistry, Hydrology, Environmental & Agricultural Engineering, Crop Production, Farm Management, Economics, Statistics, Geology, Zoology, etc.

## ✚ ERA Requires Strong Management & Coordination Skills

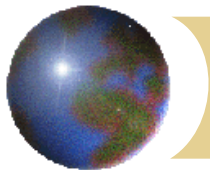




# Development of Ecological Risk Assessment – Risk Management Training Module (eVALUATE)



- ✿ OECD Working Group on Pesticides (WGP): International Pesticide Assessment Consultation
  - ✦ Held in Washington, DC in October 1998
  - ✦ Hosted by the USEPA Office of Pesticide Programs and the National Chemicals Inspectorate of Sweden
  - ✦ OECD, Non-OECD, NGOs: UN Organizations, Pesticide Industry
- ✿ Requests by Latin American Countries to USEPA/OPP for Training in Risk Assessment Methods



# Funding and Technical Support for eVALUATE



- ✦ Partially Provided by USEPA Field and External Affairs Division
- ✦ Partially Provided by IUPAC Division of Chemistry and the Environment
- ✦ Technical Support Provided by OPP EFED, Members of IUPAC Division of Chemistry and Environment & Industry Scientists
- ✦ Cooperation & Support from:
  - ✦ Joint International Atomic Energy Agency-Food and Agriculture Organization (IAEA-FAO) Pesticide Program
  - ✦ International Food Contaminant and Residue Information System (INFOCRIS) Pesticide “Distance Learning for Capacity-Building” (e-Learning) Website



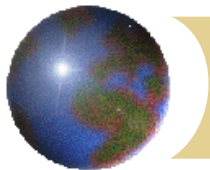


# Original OECD WGP Recommendations



- ✦ Provide Access to Examples of Completed Risk Assessments
- ✦ Encourage Harmonization, Work-sharing & Membership in Regional Groups
- ✦ Create a “Layman’s Guide” to the OECD Monograph Guidance Documents
- ✦ Standardize Definitions for Risk Assessment Vocabulary and Processes
- ✦ Identify Useful Sites on the World Wide Web

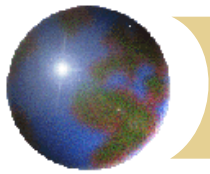




# OECD WGP Recommendations



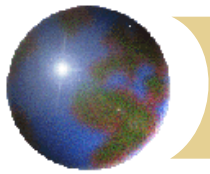
- ⊕ Assist in Technology Transfer of Risk Assessment Methods & Tools
  - ⊕ Provide Access to Tools for Estimating Pesticide Exposure
  - ⊕ Provide Access to Tools for Estimating Pesticide Toxicity
- ⊕ Encourage Participation in International Groups and Treaties (IFCS, PIC, POPS, IPCS, Montreal Protocol)



# OECD WGP Recommendations



- ⊕ OECD Should: Consider Ways in Which Data Developed for Temperate Climates Could be Adapted to Meet the Needs of Developing Countries with Arid & Tropical Climates
- ⊕ Pesticide Industry Should:
  - ⊞ Consider Ways to Facilitate the Flow of Information from Agencies in Developed Countries to those in Developing Countries
  - ⊞ Assist and Encourage National Regulatory Agencies in the Development and Adoption of a Common Data Submission Format

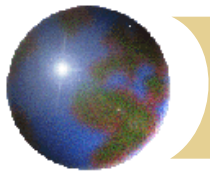


# Benefits of Work-sharing and of Harmonized Methods and Testing



- ✚ Work-sharing Among Countries
- ✚ Harmonization
  - ✚ Common Test Guidelines
  - ✚ Joint Data Development
  - ✚ Common Assessment Methods
- ✚ Joint Data Review
  - ✚ Reduces Costs
  - ✚ Increases Range of Expertise Available
  - ✚ Saves Time

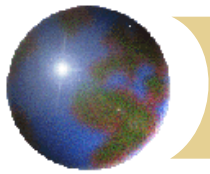




# Regional Harmonized Assessment Groups



- ⊗ European Union (EU)
- ⊗ North American Free Trade Agreement (NAFTA) Countries
- ⊗ Organizational For Economic Cooperation And Development (OECD) Countries
- ⊗ Andean Community Countries
- ⊗ Central American Countries:
  - ⊞ Central American Free Trade Agreement (CAFTA)
  - ⊞ Organismo Internacional Regional de Sanidad Agropecuaria (OIRSA)
- ⊗ West African Countries: Comité Sahélien Des Pesticides (CSP) – the Regional Registration Authority
- ⊗ Southern African Development Community (SADC) Countries
- ⊗ **MERCOSUR Countries (possible)**

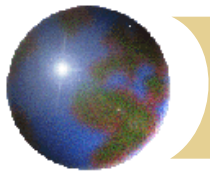


# Components of e-VALUATE Pesticide Risk Assessment & Training Module



- ✦ Step-by-Step Guidance
- ✦ Risk Assessment Process Diagram
- ✦ Risk Management Guidance
- ✦ Glossary of Terms & Process Descriptions
- ✦ Environmental Fate and Toxicity Databases
- ✦ Training Materials
- ✦ Exposure Models
- ✦ Internet Linkages



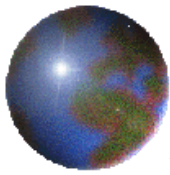


# User-friendly, Harmonized Aquatic and Terrestrial Exposure Models



- ✦ EXPRESS (EXAMS - PRZM Exposure Simulation Shell): User-friendly, Input/Output Shell to Estimate Pesticide Exposure to Aquatic Wildlife Using More Complex, Sophisticated Models
- ✦ T-REX (Terrestrial Residue Exposure) Model Is a More Complex, Spreadsheet-based Estimator of Terrestrial Ecological Risk Also Based on Potential Pesticide Residues on Avian and Mammalian Food Items Using the Fletcher-Kenaga (UTAB) Data Base, and
- ✦ RICE Models: Pesticide Environmental Fate and Transport, Water Quality Model that Estimates Pesticide Concentrations Within and Down-stream From Single or Multiple Rice Paddies.

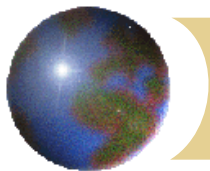




# EXPRESS (EXAMS - PRZM Exposure Simulation Shell)



- ⊕ EXPRESS (EXAMS - PRZM Exposure Simulation Shell) Is a User-friendly, Input/Output Shell to Estimate Pesticide Exposure to Aquatic Wildlife Using Much More Complex and Sophisticated Models
- ⊕ Simulations Using the Pesticide Root Zone Model (PRZM) and Exposure Analysis Modeling System (EXAMS) Are Used For a “Refined” Estimation of Pesticide Concentrations In Surface Waters Used as Drinking Water Sources and for Aquatic Ecosystem Exposure Assessments.



# T-REX (Terrestrial-Residue EXposure) Model for Avian / Mammalian Exposure Assessment

T-REX MODEL INPUTS	
These values will be used in the calculation of exposure estimates for foliar, granular, liquid and/or seed applications of pesticides.	
Chemical Name:	<input type="text"/>
Use:	<input type="text"/>
Product name and form:	<input type="text"/>
% A.I. (leading zero must be entered for formulations <1% a.i.):	<input type="text"/>
Application Rate (lbs/A):	<input type="text"/>
Half-life (days):	<input type="text"/>
Application Interval (days):	<input type="text"/>
Number of Applications:	<input type="text"/>
Note: Sources of wildlife diet are assumed to be available for less than one year for this model.	

- ✚ T-REX (Terrestrial Residue Exposure) Model Is a Spreadsheet-based Estimator of Terrestrial Ecological Risk
- ✚ Not Site or Region (or Country) – specific
- ✚ Based on Potential Pesticide Residues on Avian - Mammalian Food Items Using the Fletcher-Kenaga Database



# Additional Work on eVALUATE Still Needed



- ✦ Complete Translation into Spanish, Portuguese and other Languages
- ✦ Develop HTML Versions for the Internet
- ✦ Develop Crop-specific EXPRESS Scenarios
- ✦ Coordinate Module, Models, Manuals, and Materials with other Organizations
- ✦ Conduct National and Regional Training Workshops In Use of the Module