Application of RISK21 for ecological risk assessment (ERA) from the perspective of pesticide registration in the United States

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Syngenta Crop Protection, LLC.
HESI Risk21 Risk Assessment Summit: Challenges and Applications
Date: 18-19 February 2020
Washington, DC, USA.

FIFRA as the backdrop for the presentation

Who

Public stakeholders

What

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

Where

Global implications

When

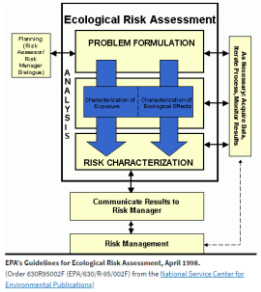
October 1, 2022

Why

What is intended purpose of the ecological risk assessment?

How

Framework for Ecological Risk Assessment



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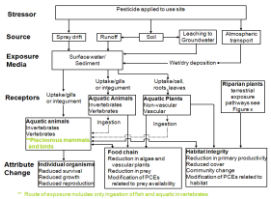
Understanding the FIFRA ERA paradigm:

Overview of technical foundation/workings

Guidance for the Development of Conceptual Models for a Problem Formulation Developed for Registration Review

https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-development-conceptual-models-problem



Final Test Guidelines for Pesticides and Toxic Substances

https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/final-test-guidelines-pesticides-and-toxic

Series No.	Series Name	Docket ID No.
810	Product Performance Test Guidelines	EPA-HQ-OPPT-2009-0150
830	Product Properties Test Guidelines	EPA-HQ-OPPT-2009-0151
835	Fate, Transport and Transformation Test Guidelines	EPA-HQ-OPPT-2009-0152
840	Spray Drift Test Guidelines	EPA-HQ-OPPT-2009-0153
850	Ecological Effects Test Guidelines	EPA-HQ-OPPT-2009-0154
860	Residue Chemistry Test Guidelines	EPA-HQ-OPPT-2009-0155
870	Health Effects Test Guidelines	EPA-HQ-OPPT-2009-0156
875	Occupational and Residential Exposure Test Guidelines	EPA-HQ-OPPT-2009-0157
880	Biochemicals Test Guidelines	EPA-HQ-OPPT-2009-0158
885	Microbial Pesticide Test Guidelines	EPA-HQ-OPPT-2009-0159
890	Endocrine Disruptor Screening Program Test Guidelines	EPA-HQ-OPPT-2009-0576

Models for Pesticide Risk Assessment

https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment

Terrestrial Models		Aquatic Models
BeeRex	T-REX	PWC
MCnest	TIM	KABAM
SIP	TerrPlant	PFAM
STIR	T_HERPS	Tier 1 Rice Model

Technical Overview of Ecological Risk Assessment: Risk Characterization

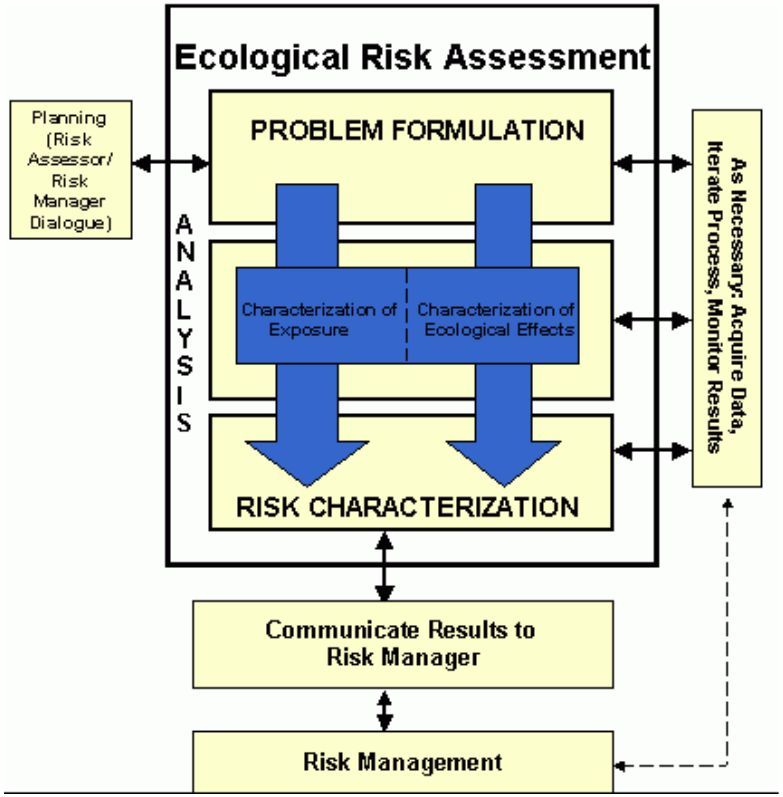
https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/technical-overview-ecological-risk-assessment-risk

Risk Presumptions for Aquatic Animals

Risk Presumptions for Aquatic Animals
Aquatic Animals

Risk Presumption	RQ	LOC
Acute High Risk	EEC/LC_{50} or EC_{50}	0.5
Acute Restricted Use	EEC/LC_{50} or EC_{50}	0.1
Acute Endangered Species	EEC/LC_{50} or EC_{50}	0.05
Chronic Risk	EEC/NOAEC	1.0

Ecological Risk Assessment for Pesticides: Technical Overview



https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/ecological-risk-assessment-pesticides-technical

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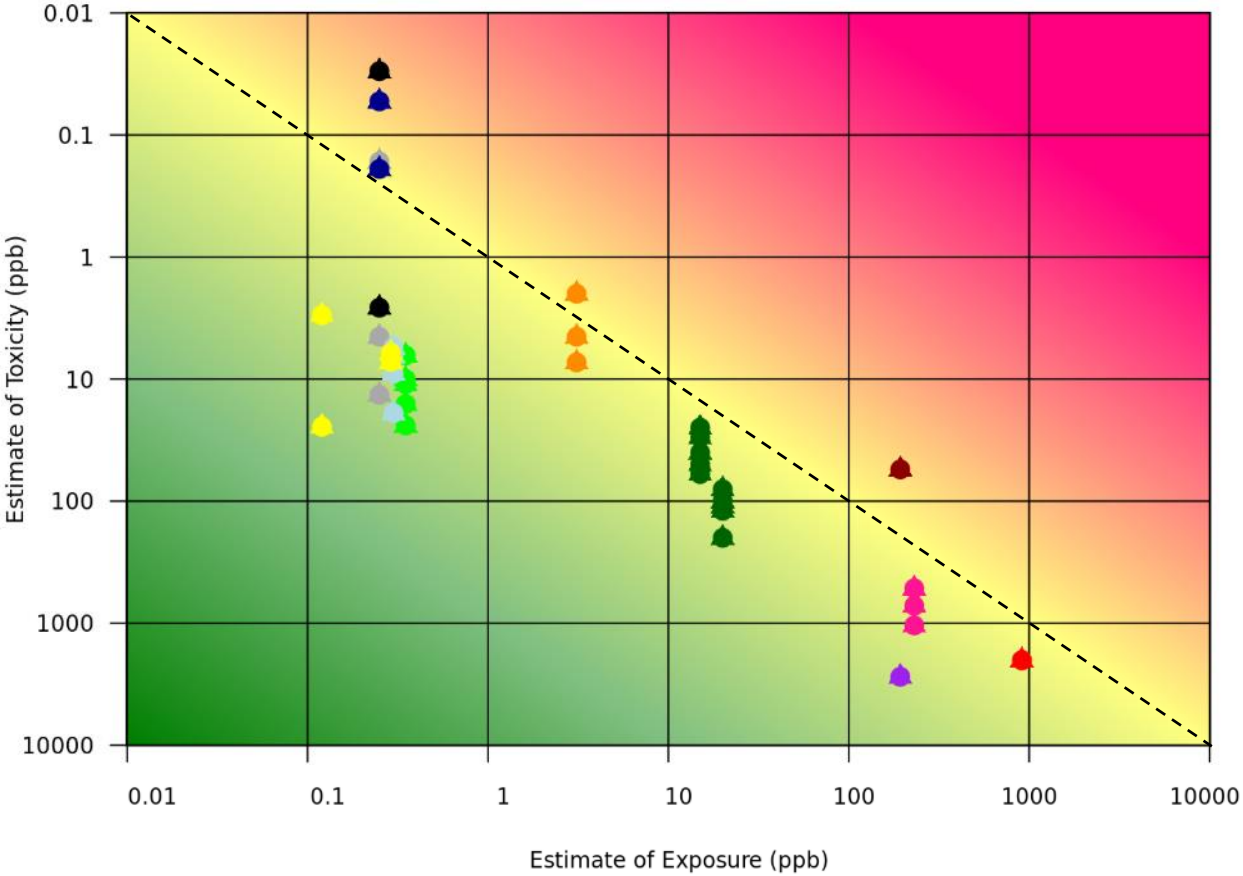
Understanding the FIFRA ERA paradigm:

Risk21 webtool visual of a screening level risk assessment



Study type	# species or studies
Aquatic plant	5
Invertebrate acute	3
Invertebrate chronic	2
Invertebrate benthic	3
Fish acute	4
Fish chronic	2
Terrestrial plant	10
Pollinator	5
Bird acute oral	3
Bird chronic	2
Mammal acute	1
Mammal chronic	1

Precision to make the decision?

What does the screening level risk assessment tell us?
What role does the risk assessment play in the regulatory decision?

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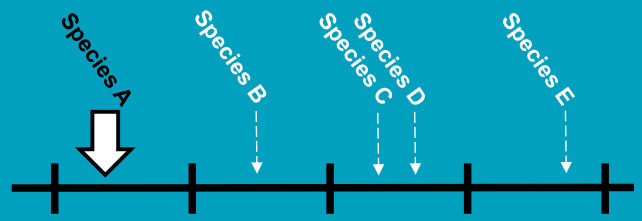
Understanding the FIFRA ERA paradigm:

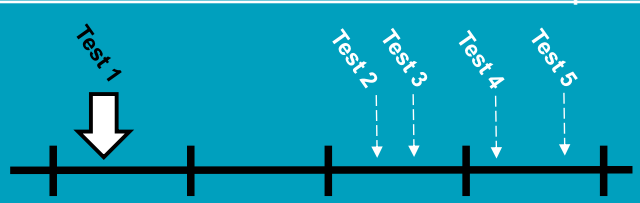
Why conservatism makes sense for a screening level assessment

HAZARD CHARACTERIZATION

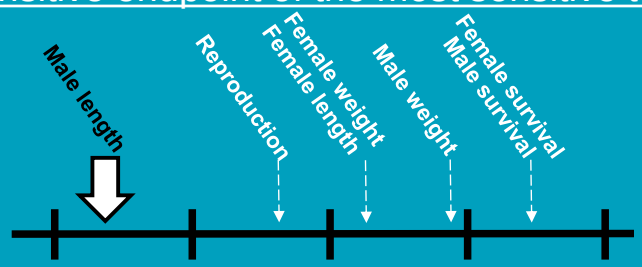
Most sensitive test species in a taxon



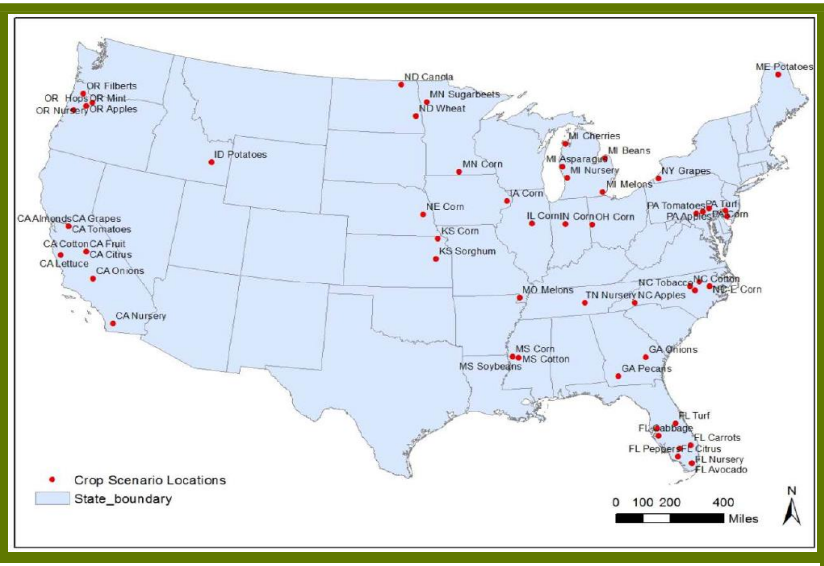
Most sensitive test of the most sensitive species



Most sensitive endpoint of the most sensitive test



EXPOSURE CHARACTERIZATION



Efate inputs	Efate half-life inputs based on upper 90th centile Propagates conservatism
Drift	Ecological = Aerial 5%, Ground 1% Drinking water = Aerial 16%, Ground 6.4%
Runoff/ erosion	Scenarios have soil properties favoring transport Rates of soil loss not sustainable
Simulations	1 hectare pond surrounded by 10 hectare field 100% treated at maximum label rate
Pond	Static waterbody Absolute depth (water and sediment never removed)
EEC values	Maximum value for each year during 30 year simulation EEC value = 90th centile of the 30 year max distribution

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Understanding the FIFRA ERA paradigm:

What is the regulatory decision?

FIFRA defines the term "unreasonable adverse effects on the environment" to mean: "(1) 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, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act."

HUMAN RISK ASSESSMENT

Is the pesticide safe when all major routes of potential exposure are considered?

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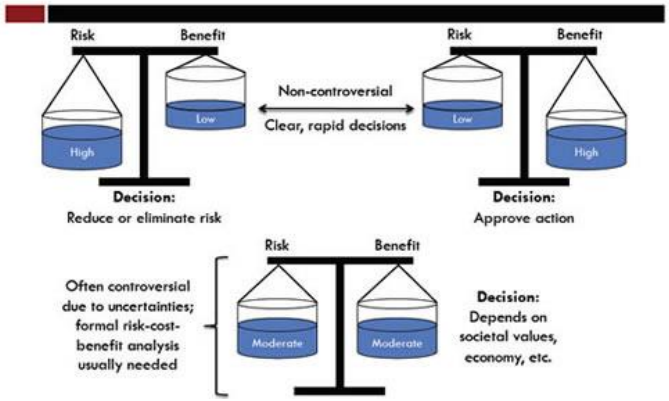
ECOLOGICAL RISK ASSESSMENT

Does the specified use of a pesticide pose unreasonable risk relative to overall benefit?



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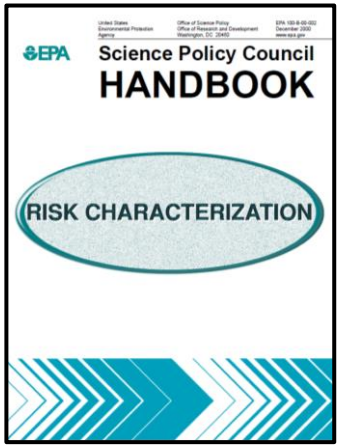
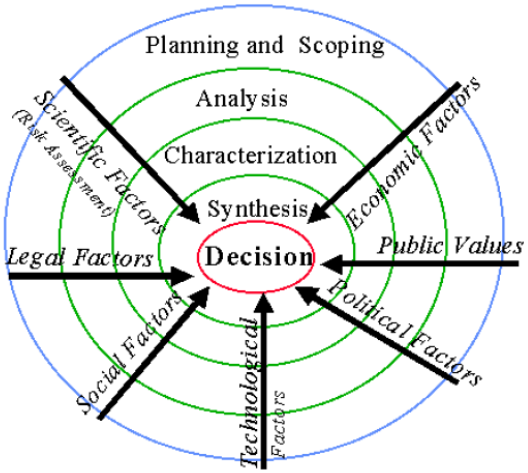
Understanding the FIFRA ERA paradigm:

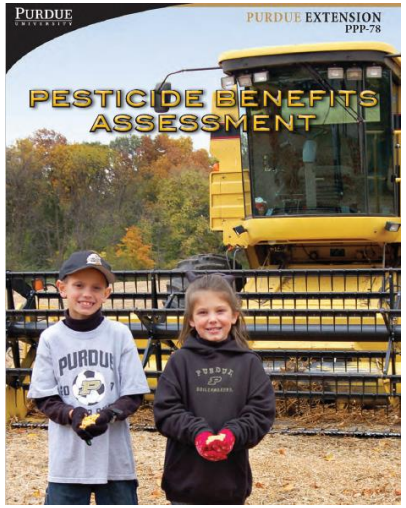
Risk management decision and associated considerations

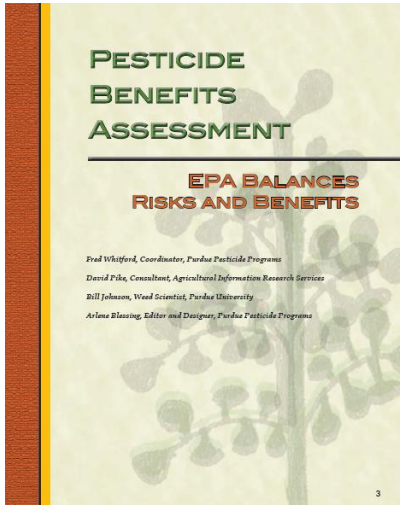
The EPA Science Policy Council Handbook "Risk Characterization" is a management decision making tool.

https://www.epa.gov/risk/risk-characterization-handbook









Purdue University Agricultural Extension developed an information package providing an overview of EPA's approach for balancing risk and benefits of pesticide use.

https://ppp.purdue.edu/wp-content/uploads/2016/08/PPP-78.pdf

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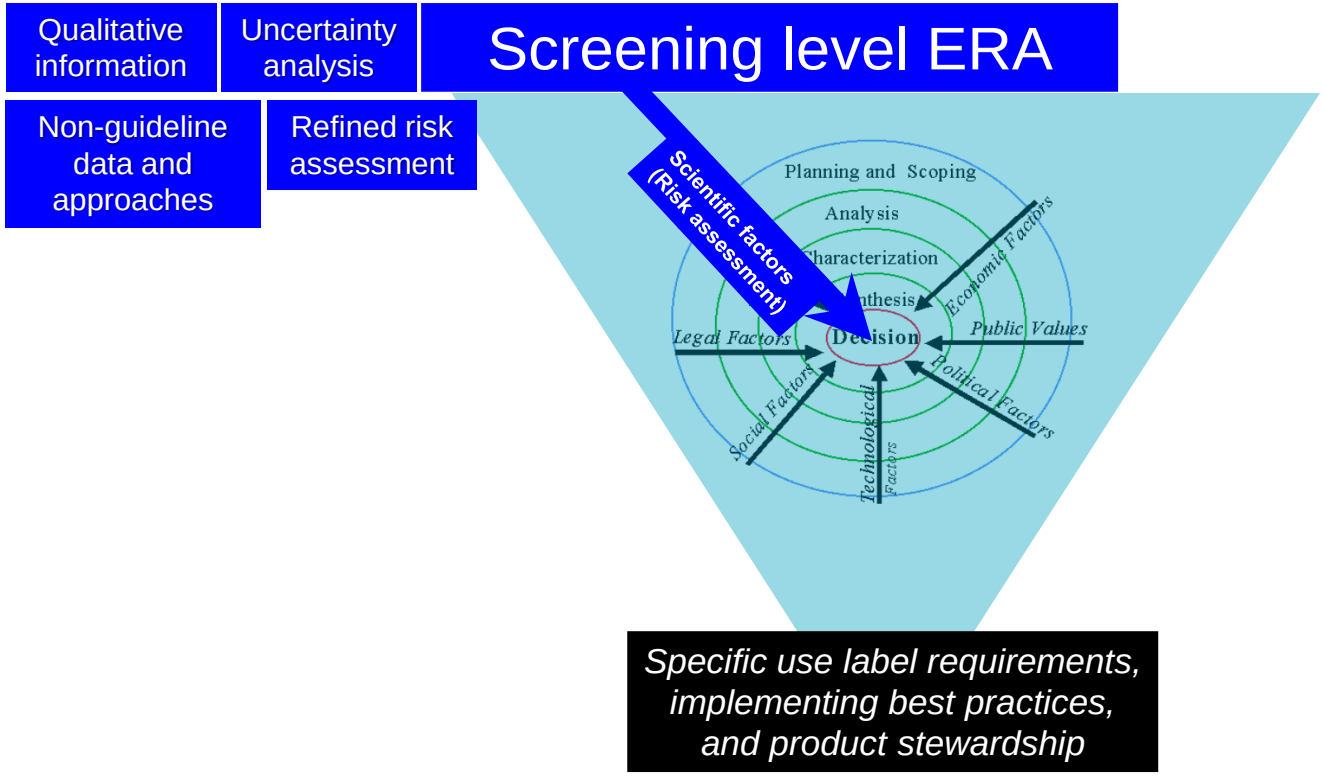
Understanding the FIFRA ERA paradigm:

Role of the screening level assessment in the regulatory decision

Risk conclusions from a screening level FIFRA **Ecological Risk Assessment (ERA)** with risk quotients exceeding level of concern do not exclusively answer whether specified use(s) of a pesticide will cause unreasonable adverse effects on the environment.



While the screening level risk assessment plays an important role, the overall regulatory decision is quite complex as various other factors are also considered.

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Understanding the FIFRA ERA paradigm:

Reaching alignment on "Fit for Purpose"

2017 Workshop on Innovation and Regulation in Agriculture

Overcoming the Challenges of Incorporating Higher-Tier Data in Ecological Risk Assessments and Risk Management of Pesticides

Integrated Environmental Assessment and Management — Volume 00, Number 00—pp. 1–12
Received: 19 September 2018 | Returned for Revision: 14 November 2018 | Accepted: 28 May 2019 1

Workshop Synthesis

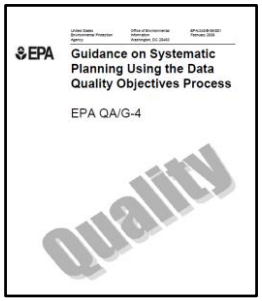
Overcoming Challenges of Incorporating Higher Tier Data in Ecological Risk Assessments and Risk Management of Pesticides in the United States: Findings and Recommendations from the 2017 Workshop on Regulation and Innovation in Agriculture

Steven L Levine,†‡ Jeffrey Giddings,§ Theodore Valenti,|| George P Cobb,# Danesha Seth Carley,†† and Laura L McConnell‡‡*

"More effective and open communication among registrants, USEPA risk assessors, and risk managers is needed earlier in the registration and registration review processes to clarify specific protection goals, assessment endpoints, and measurement endpoints to address areas of concern."

"Study design should be carefully considered to minimize complexity and to provide high value to the risk assessment and risk management process."

"the need for additional higher tier ecological data may be supplanted by mitigating risks via changes to label requirements, implementing best practices, and product stewardship."



https://www.epa.gov/quality/guidance-systematic-planning-using-data-quality-objectives-process-epa-qag-4

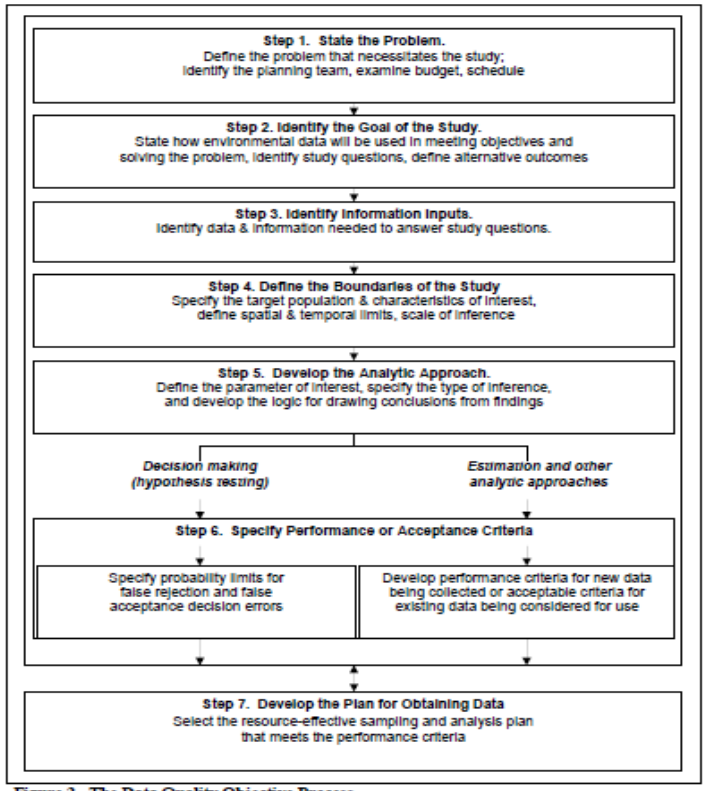


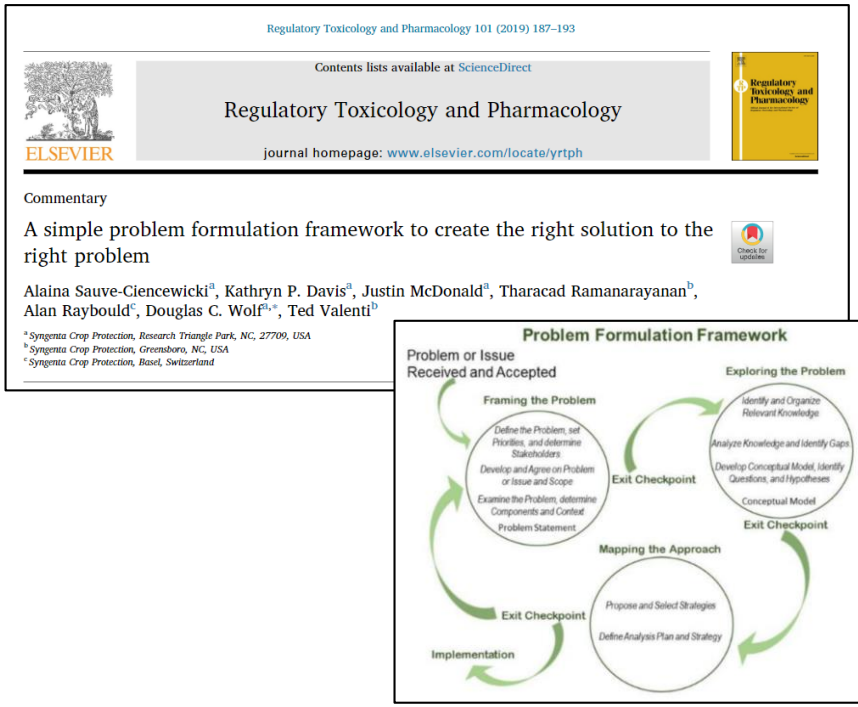
Figure 2. The Data Quality Objective Process

Application of Risk21 concepts for ERA:

Use of the webtool to facilitate discussion and align concerns

What is the problem/concern?

Stakeholder alignment



Regulatory Toxicology and Pharmacology 101 (2019) 187–193

Contents lists available at ScienceDirect

Regulatory Toxicology and Pharmacology

journal homepage: www.elsevier.com/locate/yrtph

ELSEVIER

Commentary

A simple problem formulation framework to create the right solution to the right problem

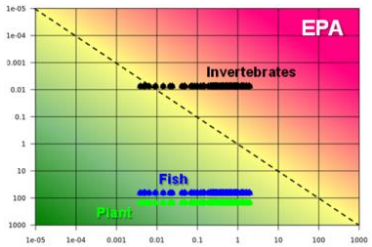
Alaina Sauve-Ciencewicki[a], Kathryn P. Davis[a], Justin McDonald[a], Tharacad Ramanarayanan[b], Alan Raybould[c], Douglas C. Wolf[a,*], Ted Valenti[b]

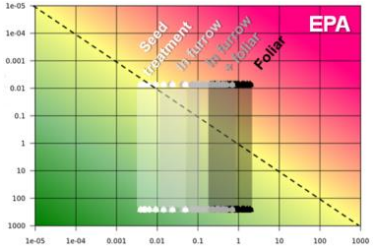
[a] Syngenta Crop Protection, Research Triangle Park, NC, 27709, USA
[b] Syngenta Crop Protection, Greensboro, NC, USA
[c] Syngenta Crop Protection, Basel, Switzerland

HESI-coordinated ecoRisk21 strategy team

Ongoing work using the HESI Risk21 webtool (https://risk21.org/webtool/) to develop "Batch" templates for various scenarios/examples.

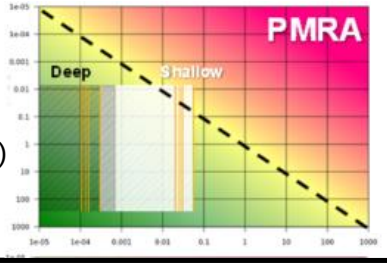
Example showing prioritization of concern for various aquatic taxa based on available information.





Example showing the landscape of risk based on the full range of aquatic invertebrate data across different use types.

Example showing how planting depth impacts risk characterization for all seed treatment (gray and white shadow) as well as for a specific crop type (color line) across the full landscape of aquatic invertebrate data.



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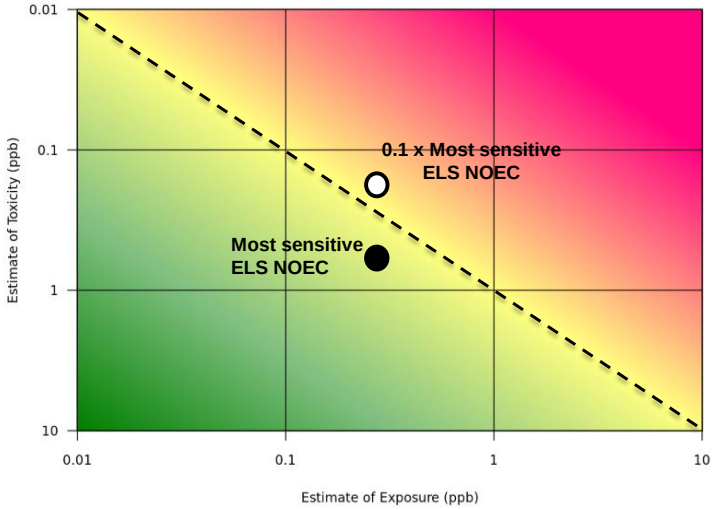
Application of Risk21 concepts for ERA:

Conditional trigger for Fish Full Life Cycle Toxicity Test

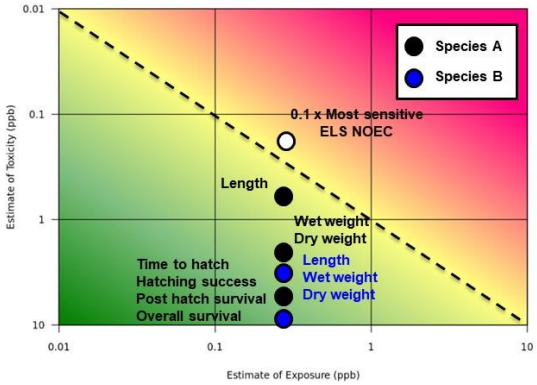
Guideline OPPT 850.1500- Freshwater fish full-life cycle (FLC) toxicity test is required if:

1) the estimated environmental concentration (EEC) is ≥ 0.1 of the no observed- effect level in the fish early-life stage or invertebrate life cycle test;
2) If studies of other organisms indicate that the reproductive physiology of fish may be affected.

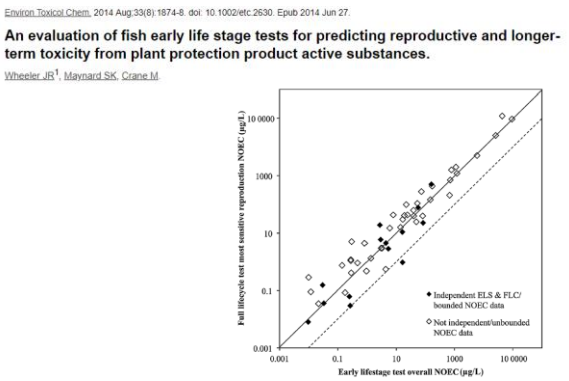


Should the decision also consider other lines of evidence?

Greater utilization of existing data



Bridging data from compounds

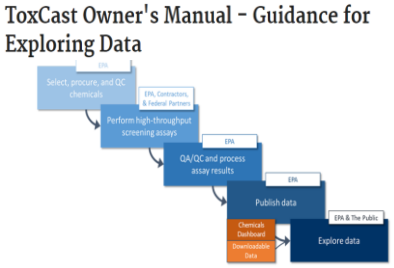

Environ Toxicol Chem. 2014 Aug;33(8):1874-8. doi: 10.1002/etc.2630. Epub 2014 Jun 27.

An evaluation of fish early life stage tests for predicting reproductive and longer-term toxicity from plant protection product active substances.

Wheeler JR[1], Maynard SK, Crane M.

Predictive science

Animal alternatives



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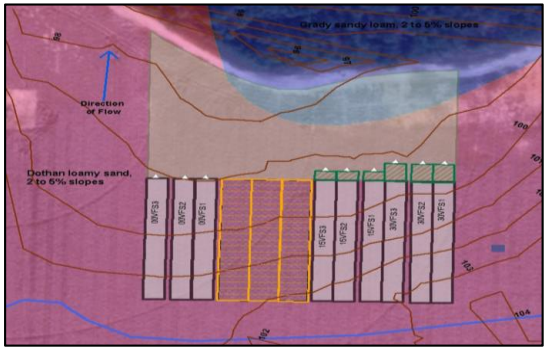
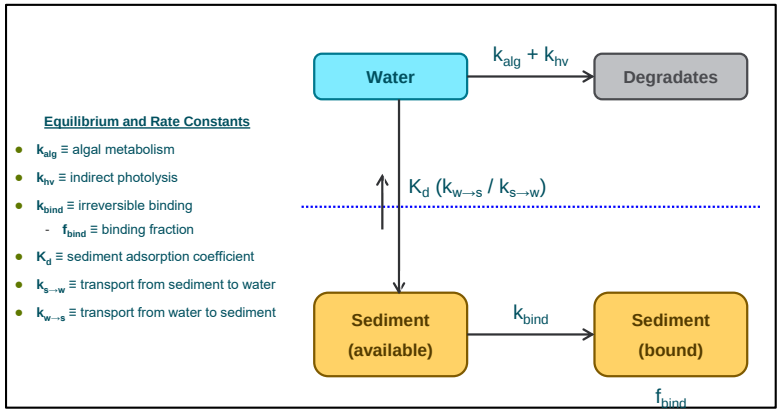
Application of Risk21 concepts for ERA:

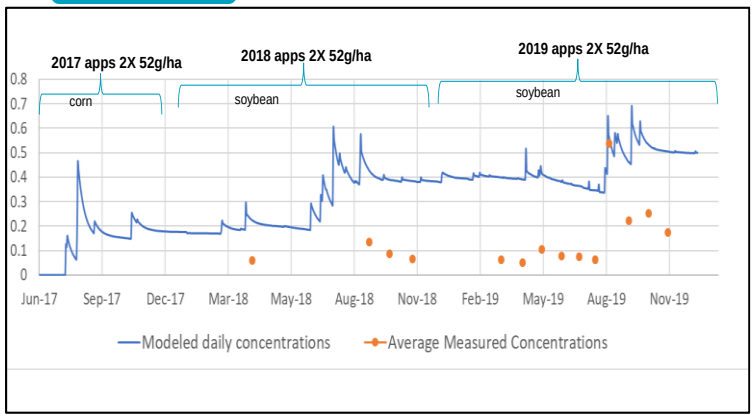
Non-guideline study to support registration



Field Studies

Lab Studies ⟷ **Model Simulations**





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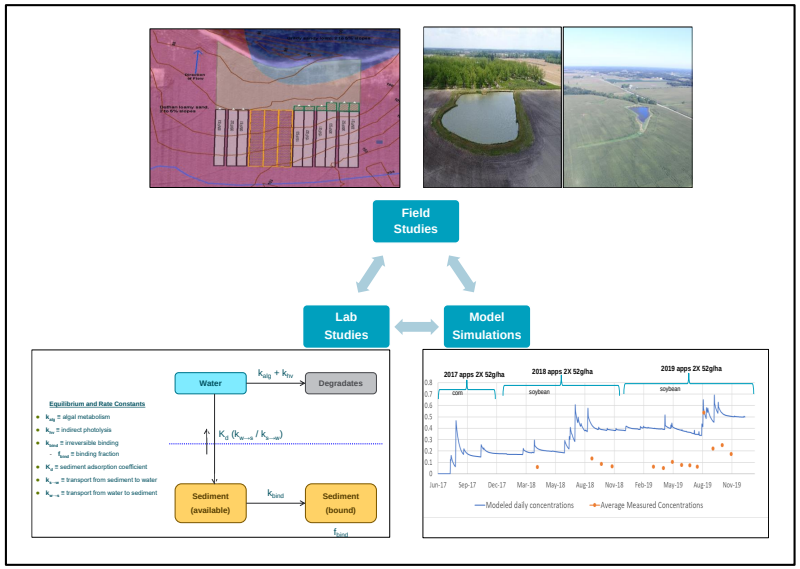
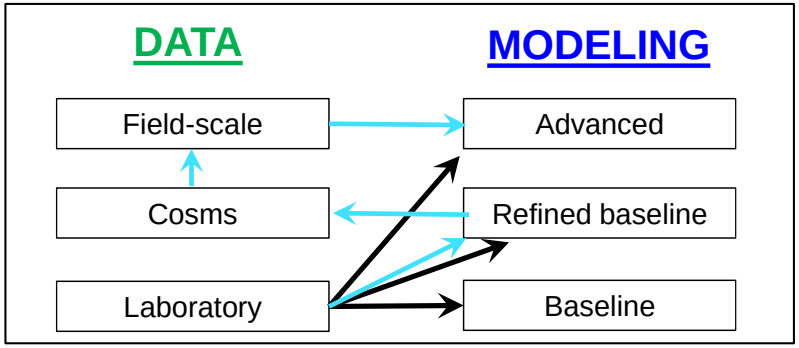
Application of Risk21 concepts for ERA:

The project exemplifies application of the Risk21 mindset





- Problem-formulation based
- Risk-based at each step of the process
- Use of prior knowledge
- Fit for purpose
- Value of information
- "Enough precision to make the decision"

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Concluding thoughts

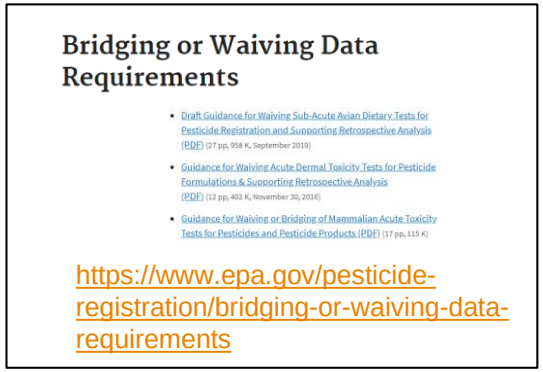
Principles and tools of Risk21 are applicable for both human and ecological risk assessment.

Many of these principles and tools are adaptable regardless of the regulatory paradigm.

Defining and communicating protection goals are critical for ecological risk assessment.

Protection goals should “anchor” risk characterization.

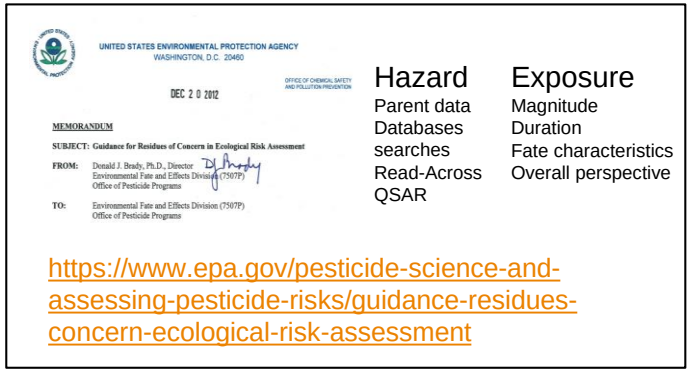
Past progress and potential foundations for the future.



Bridging or Waiving Data Requirements

- Draft Guidance for Waiving Sub-Acute Avian Dietary Tests for Pesticide Registration and Supporting Retrospective Analysis (PDF) (27 pp, 958 K, September 2019)
- Guidance for Waiving Acute Dermal Toxicity Tests for Pesticide Formulations & Supporting Retrospective Analysis (PDF) (12 pp, 402 K, November 30, 2016)
- Guidance for Waiving or Bridging of Mammalian Acute Toxicity Tests for Pesticides and Pesticide Products (PDF) (17 pp, 115 K)

https://www.epa.gov/pesticide-registration/bridging-or-waiving-data-requirements



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

DEC 2 0 2012

MEMORANDUM

SUBJECT: Guidance for Residues of Concern in Ecological Risk Assessment

FROM: Donald J. Brady, Ph.D., Director
Environmental Fate and Effects Division (7507P)
Office of Pesticide Programs

TO: Environmental Fate and Effects Division (7507P)
Office of Pesticide Programs

Hazard
Parent data
Databases
searches
Read-Across
QSAR

Exposure
Magnitude
Duration
Fate characteristics
Overall perspective

https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-residues-concern-ecological-risk-assessment

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THANK YOU

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