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Ecotoxicology, Risk Assessment and Risk Management in the U.S.

Topics

- Ecotoxicology Testing
- Ecological Risk Assessment in the U.S.
- Refinement of Risk Assessments
- Risk Mitigation
- Industry Research Activities

What is ecotoxicology?

- The study of the effects of stressors on the environment

- Rationale for ecotoxicology testing of pesticides:

  To obtain a registration, the registrant must demonstrate that the product **does not pose unacceptable risk** to non-target organisms in the environment

What is tested?

Aquatic organisms

Pollinators

Soil organisms, beneficial insects, & non-target plants

Birds & mammals

Studies generate endpoints (LD50, LC50, NOEC) to be used in risk assessments

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Basic Principles of Toxicity Testing

Indicator species

- Representative for different groups of species
- Ecologically relevant
- High sensitivity
- Easy to handle in the laboratory

Standard test protocols

- Internationally accepted guidelines (e.g. EPA-guidelines)
- GLP (Good Laboratory Practice)
- Different test types:
  - Acute vs. chronic
  - Laboratory vs. field

Why is Risk Assessment Important in the U.S.?

- Part of Regulatory Statute
  - will not cause any unreasonable risk to man or the environment

- No cut-off criteria based on toxicity or environmental properties

- No pass / fail; Registration decision are based on risks and benefits

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Basic principle of environmental risk assessment (US)

Hazard (toxicity)

„Which effects?“

Exposure

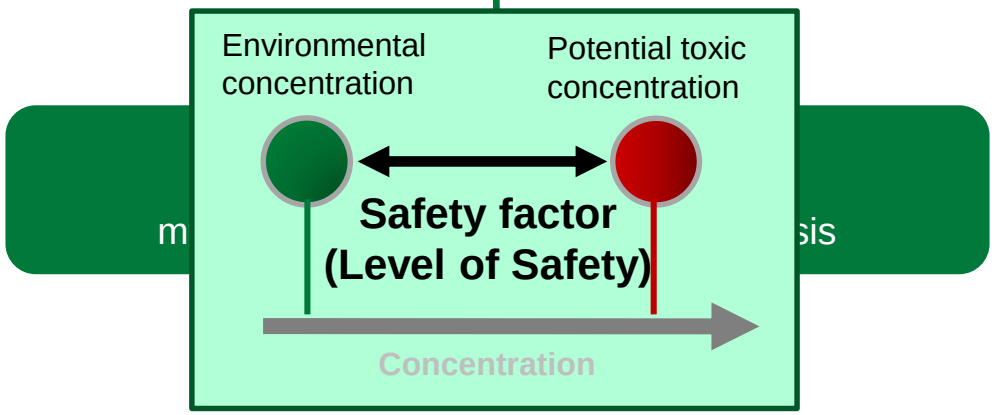
„How much?“

Risk assessment

= Toxicity vs exposure

Risk Quotient

$$RQ = \frac{\text{Exposure}}{\text{Toxicity}}$$



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U.S. EPA Exposure Models for Screening-Level Risk Assessments - Determine Estimated Environmental Concentrations (EECs)

- **Aquatic Organisms**
  - PWC (pesticide water calculator) - estimated concentrations in surface water (from surface runoff and spray drift)
  - KABAM – bioconcentration and food-web modeling
  - PFAM - estimated water concentrations after applications to flooded fields

- **Birds and Mammals**
  - T-REX - estimated concentrations on wildlife food items

- **Terrestrial Plants**
  - TerrPlant – estimated exposure to plant surfaces and soil

- **Pollinators**
  - BeeRex – estimated exposure on foraging bees and concentrations in pollen and nectar

Models all produce very conservative estimates of exposure and risk to screen out very low risk compounds

U.S. EPA Screening-Level Risk Assessment

$$RQ = \frac{\text{Estimated environmental concentration}}{\text{Toxicity Endpoint}}$$

RQ is compared to a defined **Level of Concern (LOC)** to identify low or high risk

Example of defined Levels of Concern – Aquatic Organisms

		RQ	LOC
Aquatic Animals	Acute Risk	EEC/ LC_{50} or EC_{50}	0.5
	Chronic risk	EEC/ NOEC	1
	Acute Endangered Species (Listed)	EEC/ LC_{50} or EC_{50}	0.05
Aquatic Plants	Acute Risk	EEC/ EC_{50}	1
	Acute Endangered Species (Listed)	EEC/ EC_{05} or NOEC	1

When LOCs are > values in the table there a **potential** of high risk

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What happens when screening-level LOCs are exceeded? Risk Refinement and Risk Mitigation Options

- Refine exposure estimates
- Refine effects (toxicity) endpoints
- Refine application directions on pesticide label to mitigate risks

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Exposure Refinement Options

- Higher tier models
  - probabilistic surface water exposure assessment (spray drift and surface run-off)

- Higher tier studies
  - spray drift / wind tunnel studies
  - surface water run-off studies
  - pollen and nectar residue studies
  - residue studies for bird food items

Effects (toxicity endpoint) refinement options

- Laboratory studies
  - test additional species – species sensitivity distribution (SSD)
  - modified exposure studies (e.g., pulse-dose studies)
  - modified test system (water/sediment vs. clean water system)

- Higher-tier modeling
  - McNest – bird nest productivity model
  - TIM – probabilistic effects model for birds
  - Population modeling – several under development

Effects (toxicity endpoint) refinement options

- Higher-tier semi-field and field studies

  - Honey bee tunnel studies

  - aquatic mesocosms

  - bird field monitoring

Effectiveness of higher-tier refinements

- Consultation with regulatory authorities is critical!

- Pre-submission meetings are important

What happens when there is still a high risk concern after refinements?

Risk mitigation through specific use directions on product labels

Risk Mitigation Options

- Pollinators
  - Do not apply during crop bloom
  - Apply late in the day or during the night

- Aquatic organisms
  - No spray buffer zones between treated field and water body
  - Employ spray drift reduction technology

- Birds
  - Do not apply in crops that are attractive to birds

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Labels that reflect the mitigation measures

Fastac™ EC
Insecticide

Vegetative Buffer Zone

Construct and maintain a minimum 10-foot-wide vegetative filter strip of grass or other permanent vegetation between the field edge and down gradient aquatic habitat (such as, but not limited to, lakes, reservoirs, rivers, permanent streams, marshes, natural ponds, estuaries, and commercial fish farm ponds).

Only apply products containing alpha-cypermethrin onto fields where a maintained vegetative buffer strip of at least 10 feet exists between the field and down gradient aquatic habitat.

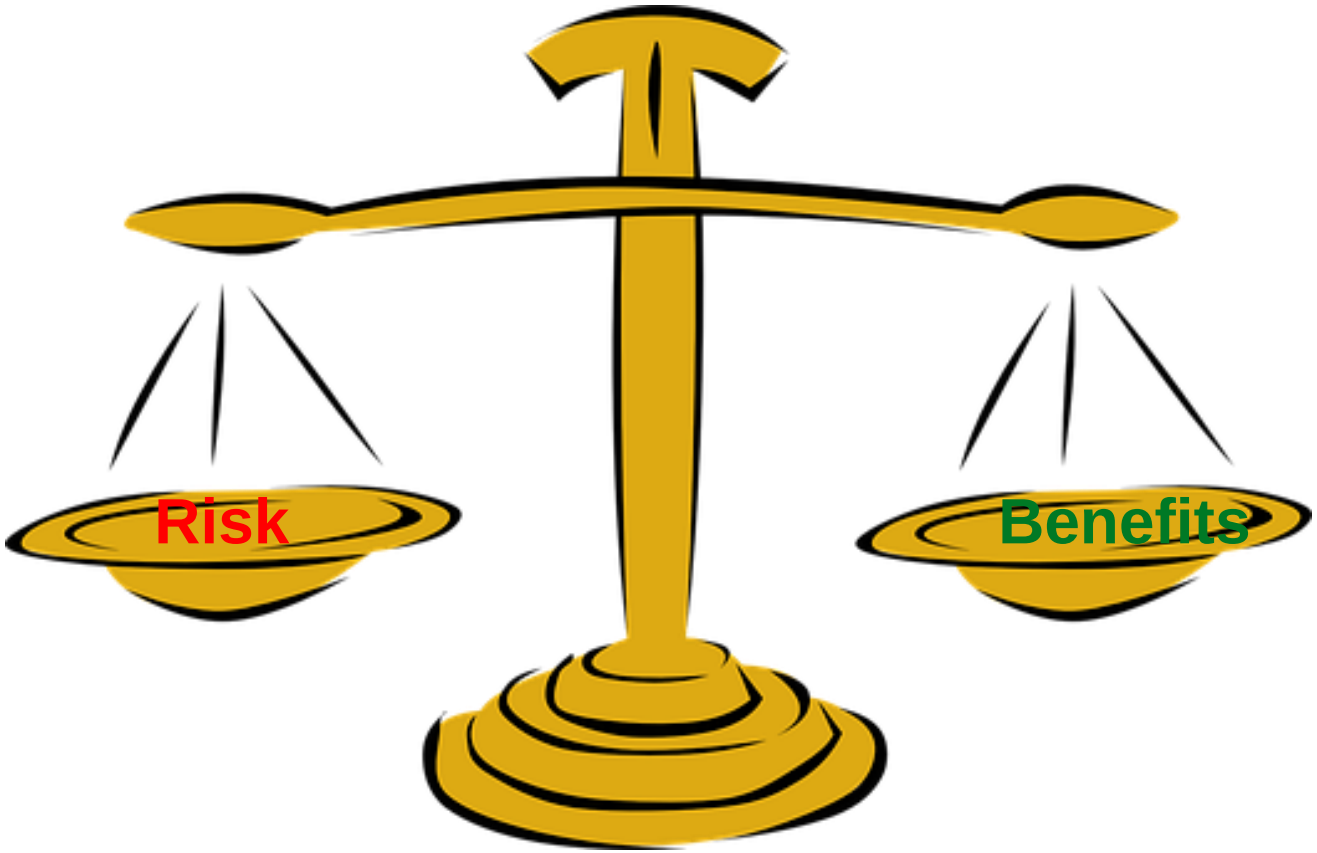
Buffer Zone

Buffer Zone for Ground Application (groundboom, overhead chemigation, or airblast)
DO NOT apply within 25 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, permanent streams, marshes, natural ponds, estuaries, and commercial fish ponds).

Buffer Zone for ULV Aerial Application
DO NOT apply within 450 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, permanent streams, marshes, natural ponds, estuaries, and commercial fish ponds).

Buffer Zone for Non-ULV Aerial Application
DO NOT apply within 150 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, permanent streams, marshes, natural ponds, estuaries, and commercial fish ponds).

Final Regulatory Decision by U.S. EPA



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Stakeholder activities to improve risk assessments

- CLA Spray Drift Issue Management Team
- Corn dust consortium
- Pollinator Research Task Force

PRTF Membership

- Arysta LifeScience
- BASF Corporation
- Bayer CropScience LP
- Dow AgroSciences LLC
- DuPont Crop Protection
- FMC Corporation
- Mitsui Chemicals Agro, Inc.
- Monsanto Company
- Syngenta Crop Protection, LLC
- Valent U.S.A. Corporation

PRTF Purpose

- Improve pollinator risk assessment process for regulatory decision-making in North America
  - Review and summarize existing knowledge
  - Develop new generic data sets
  - Develop/improve/validate test methods
  - Develop/improve/validate risk assessment tools
- Consult with US EPA on projects

Overview of Current PRTF Research Projects

- Chronic larval toxicity ring test
- Honey bee pollen and nectar consumption
- Honey bee colony winter survival modeling
- Guttation water and other water exposure
- Relative toxicity: a.i. *vs.* formulation
- Exposure assessment paradigm for non-*Apis* bees
- Improving the RT25 test
- Crop attractiveness as a factor in risk assessment
- Alternative solvent vehicles for use in bee toxicity tests

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