Pesticide Risk Assessment Overview

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Office of Pest Management Policy, USDA

UMass IPM Evaluation Training

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Office of Pest Management Policy (OPMP)

- OPMP is responsible for:
  - Developing USDA policy on pest management, pesticides, and agricultural biotechnology;
  - Consulting with stakeholders on pest management related actions taken by EPA and other agencies; and
  - Intra- and Interagency coordination with USDA, EPA, FDA, and other federal and state entities.
- Our stakeholders include:
  - Growers (especially specialty and minor crops)
  - Pesticide registrants, retailers, and applicators
  - International, federal, and state agencies
  - Cooperative extension agents

https://www.usda.gov/oce/pest/about

What is Risk?

- EPA Definition: **Risk** is the chance of harmful effects to human health or to ecological systems resulting from exposure to an environmental stressor.

- A **stressor** is any physical, chemical, or biological entity that can induce an adverse response.
  - For our purposes, the stressor is a pesticide or pesticide metabolite

What is Risk Assessment?

- Risk Assessment is a scientific process.
- EPA uses risk assessment to characterize the nature and magnitude of health risks to humans and ecological receptors from pesticides uses.
- Risk depends on the following 3 primary factors:
  - How much of a chemical is present in an environmental medium (e.g., water, air, food)
  - How much contact a person or ecological receptor (e.g., fish, bird, plant) has with the contaminated environmental medium
  - The inherent toxicity of the chemical (hazard)

Risk = Exposure x Toxicity

What is Risk Assessment? (Cont.)

- Risk assessments should:
  - Be based on a very strong knowledge base
  - Discuss any uncertainties, including data gaps and model limitations
  - Include characterization of exposure and risk estimates
- Due to its regulatory statutes, EPA requires and receives extensive hazard and exposure data for pesticide registration purposes
  - Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
  - Federal Food, Drug, and Cosmetic Act (FFDCA)
  - Food Quality Protection Act (FQPA)

Risk Assessment Framework

- Problem Formulation / Scoping
- Conducting Risk Assessment
  - Effects / Toxicity
  - Exposure
  - Risk Characterization
- Risk Management and Communication

Risk Assessment Framework

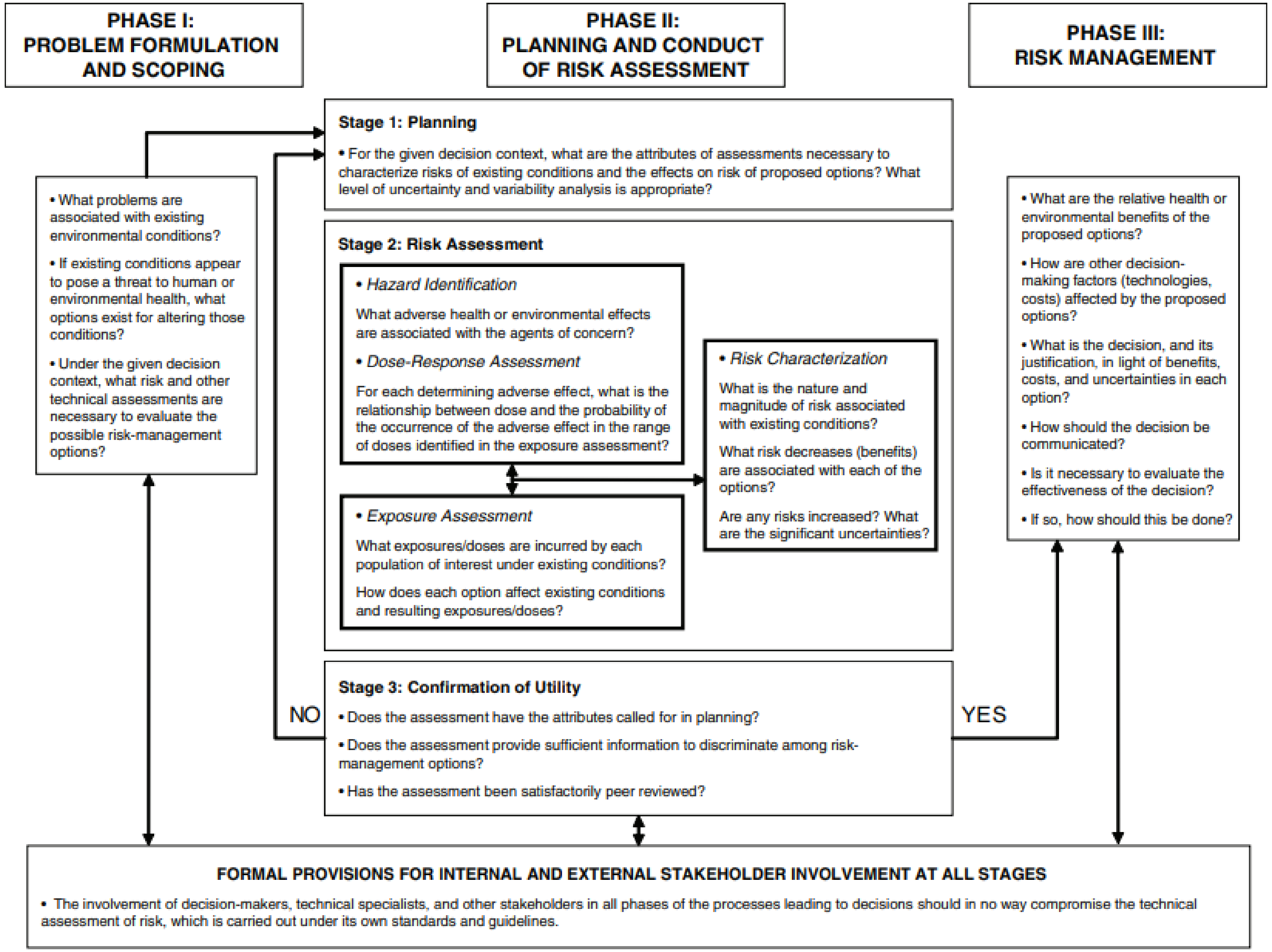
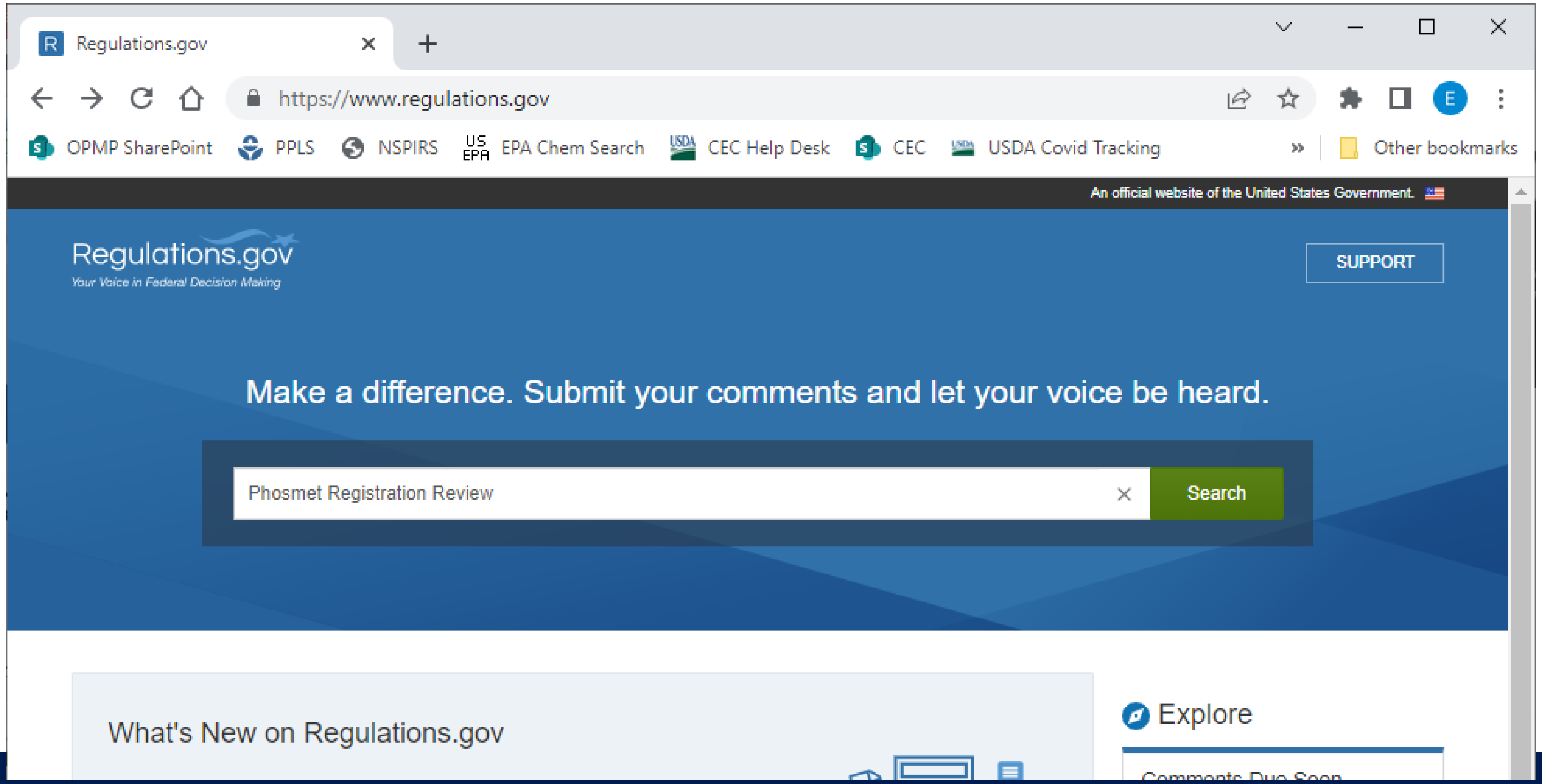


FIGURE S-1 A framework for risk-based decision-making that maximizes the utility of risk assessment.

Source: National Research Council. 2009. Science and Decisions: Advancing Risk Assessment. Washington, DC: The National Academies Press. https://doi.org/10.17226/12209

How to find EPA Risk Assessments

- EPA Pesticide Chemical Search: https://ordspub.epa.gov/ords/pesticides/f?p=chemicalsearch:1
- Federal Docket: https://www.regulations.gov/



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Reduced Risk Classification

- https://www.epa.gov/pesticide-registration/reduced-risk-and-organophosphate-alternative-decisions-conventional
- Reduced risk pesticides (**determined for each use**) are described in FIFRA section 3(c)(10), which establishes an expedited review for applications for registration for pesticides that "may reasonably be expected to accomplish **one or more** of the following:
    - Reduce the risks of pesticides to human health.
    - Reduce the risks of pesticides to nontarget organisms.
    - Reduce the potential for contamination of groundwater, surface water or other valued environmental resources.
    - Broaden the adoption of integrated pest management strategies, or make such strategies more available or more effective."

Ecological Risk Assessment

- **Exposure** is modeled based on environmental fate properties of the pesticide
  - Aquatic exposure: runoff and spray drift into water bodies
  - Terrestrial exposure: spray residue on food items or direct spray (plants, bees)

  EPA models: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment
- **Hazard** is determined based on laboratory ecotoxicity studies
  - Acute (mortality) vs. Chronic (mortality, growth, or reproduction)
  - Surrogate species
- Risk Quotient (RQ) = Exposure / Toxicity
  - RQs are compared to Levels of Concern (LOC)
  - RQ > LOC
- Risk Characterization – provides important context

More information: https://www.epa.gov/sites/default/files/2014-11/documents/ecorisk-overview.pdf and https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/ecological-risk-assessment-pesticides-technical

Ecological Risk Assessment

Risk Summary Table

Table 1-1. Summary of Risk Quotients for Taxonomic Groups from Current Uses of Phosmet.

Taxa	Exposure Duration	Risk Quotient (RQ) Range[2]	RQ Exceeding the LOC for Non-listed Species	Additional Information/ Lines of Evidence
Freshwater fish	Acute	0.03 – 0.74	Yes	Acute RQ values for freshwater fish range from 0.03 to 0.74 and exceed the acute risk LOC of 0.5 for phosmet use on cotton and walnuts.
	Chronic	0.26 – 2.14	Yes	Chronic RQ values for freshwater fish exceed the chronic risk LOC of 1.0 for use on cotton and walnuts. At the LOAEC, there was an 81% decrease in fecundity. Freshwater fish are considered as surrogates for aquatic-phase amphibians; however, if RQ for amphibians were based on the measured NOAEC for amphibians, chronic RQ values would be below the chronic risk LOC for aquatic-phase amphibians.
Estuarine/ marine fish	Acute	0.01 – 0.31	No	--
	Chronic	13 - 107	Yes	Chronic RQ values range from 13 to 107 and exceed the chronic risk LOC across all of the uses evaluated. Given that the chronic toxicity endpoint used to assess risk was estimated based on an acute-to-chronic ratio for freshwater fish, there is some uncertainty regarding the actual sensitivity of estuarine/marine fish. If RQ values were based on the 5^{th} quantile value of 0.28 µg ai/L for measured NOAEC values for dithiophosphate insecticides, the maximum RQ would be reduced from 107 to 7.6 (for walnuts) but would still exceed the chronic risk LOC.
Freshwater invertebrates	Acute	0.23 – 6.02	Yes	Acute RQ values for freshwater invertebrates exceed the acute risk to non-listed species LOC of 0.5 for all uses.
	Chronic	0.73 – 6.43	Yes	Chronic RQ values for freshwater invertebrates exceed the chronic risk LOC for all uses except blueberries.
Estuarine/ marine invertebrates	Acute	1.25 – 32.5	Yes	Acute RQ values for estuarine/marine invertebrates exceed the acute risk LOC across all of the uses evaluated.
	Chronic	1.49 – 13	Yes	Chronic RQ values for estuarine/marine invertebrates exceed the chronic risk LOC for all uses evaluated.
	Acute[1]	0.10 - 18	Yes	Other than for uses on almonds, blueberries, and pears, RQ values exceed the acute risk LOC of 0.5

Phosmet Registration Review Ecological Risk Assessment: https://www.regulations.gov/document/EPA-HQ-OPP-2009-0316-0045

Ecological Risk Assessment

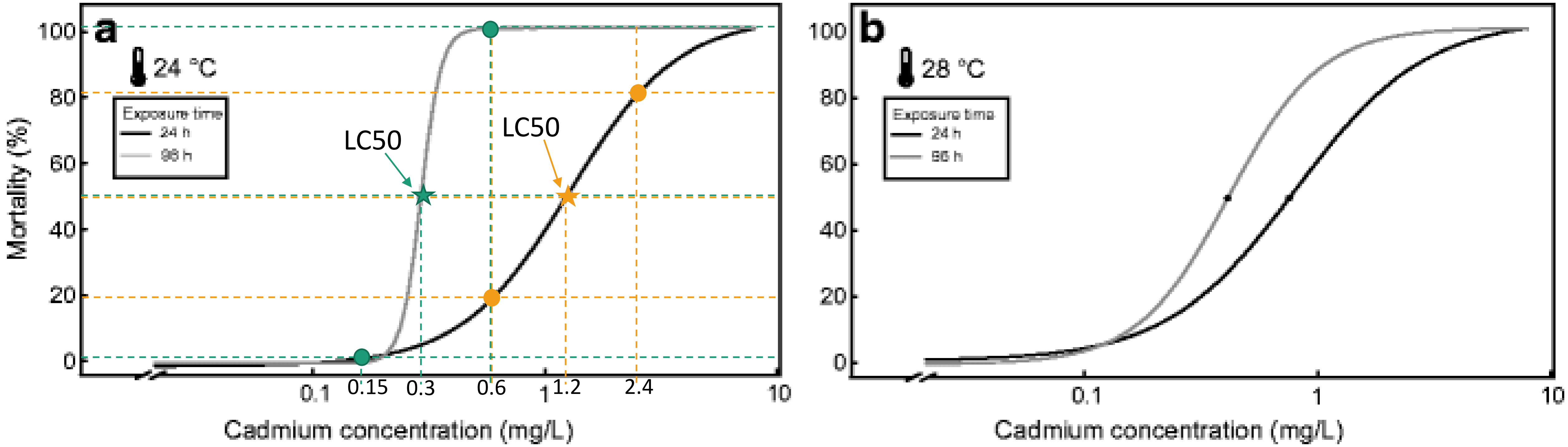
Risk Summary Table (cont.)

Taxa	Exposure Duration	Risk Quotient (RQ) Range[2]	RQ Exceeding the LOC for Non-listed Species	Additional Information/ Lines of Evidence
Birds	Acute Oral Acute Dietary	<0.01 – 2.42 0.03 – 4.40	Yes	Acute dose- and dietary-based RQ values for birds (exceed the acute risk LOC of 0.5 for non-listed species of small birds foraging on short grasses across all of the uses evaluated. Depending on the application rate, acute RQ values exceed the LOC for birds foraging on tall grass, broadleaf plants and arthropods.
	Chronic	Dietary: 0.28 – 36.8	Yes	Dietary-based RQ values exceed the chronic risk LOC of 1.0 across all of the use rates and the majority of forage categories evaluated. To get the dietary-based RQ below the chronic risk LOC, the maximum single rate would have to be reduced to 0.25 lbs ai/A. Even if the RQ was based on the LOAEC of 150 mg ai/kg (at which there was a 29% reduction in the number of eggs laid) at lowest rate for clover (*i.e.*, single application of 0.89 lb ai/A), the RQ (1.6) value for birds foraging on short grasses would still exceed the chronic risk LOC.
Terrestrial invertebrates	Acute Adult	≥2.45	Yes	At lowest application rate evaluated (1 lb ai/A), the acute risk LOC of 0.4 exceeded based on contact exposure. There are multiple bee-related incidents involving the loss of both individual honey bees and honey bee colonies.
	Chronic Adult	No data	No data	Not assessed due to lack of data.
	Acute Larval	No data	No data	
	Chronic Larval	No data	No data	
Aquatic plants	N/A	Vascular: <0.01 – 0.03 Non-vascular: 0.01 – 0.35	No	The sensitivity of plants to phosmet was based on analysis of aquatic plant sensitivity to other organophosphate insecticides (*i.e.*, naled and chlorpyrifos).
Terrestrial plants	N/A	Not calculated	No	No adverse effects detected in either monocotyledonous or dicotyledonous plants at application rates ≥6.07 lbs ai/A. However, phosmet labels contain advisory language regarding potential premature leaf drop from exposure to phosmet.

Phosmet Registration Review Ecological Risk Assessment: https://www.regulations.gov/document/EPA-HQ-OPP-2009-0316-0045

Comparing Risk - Acute

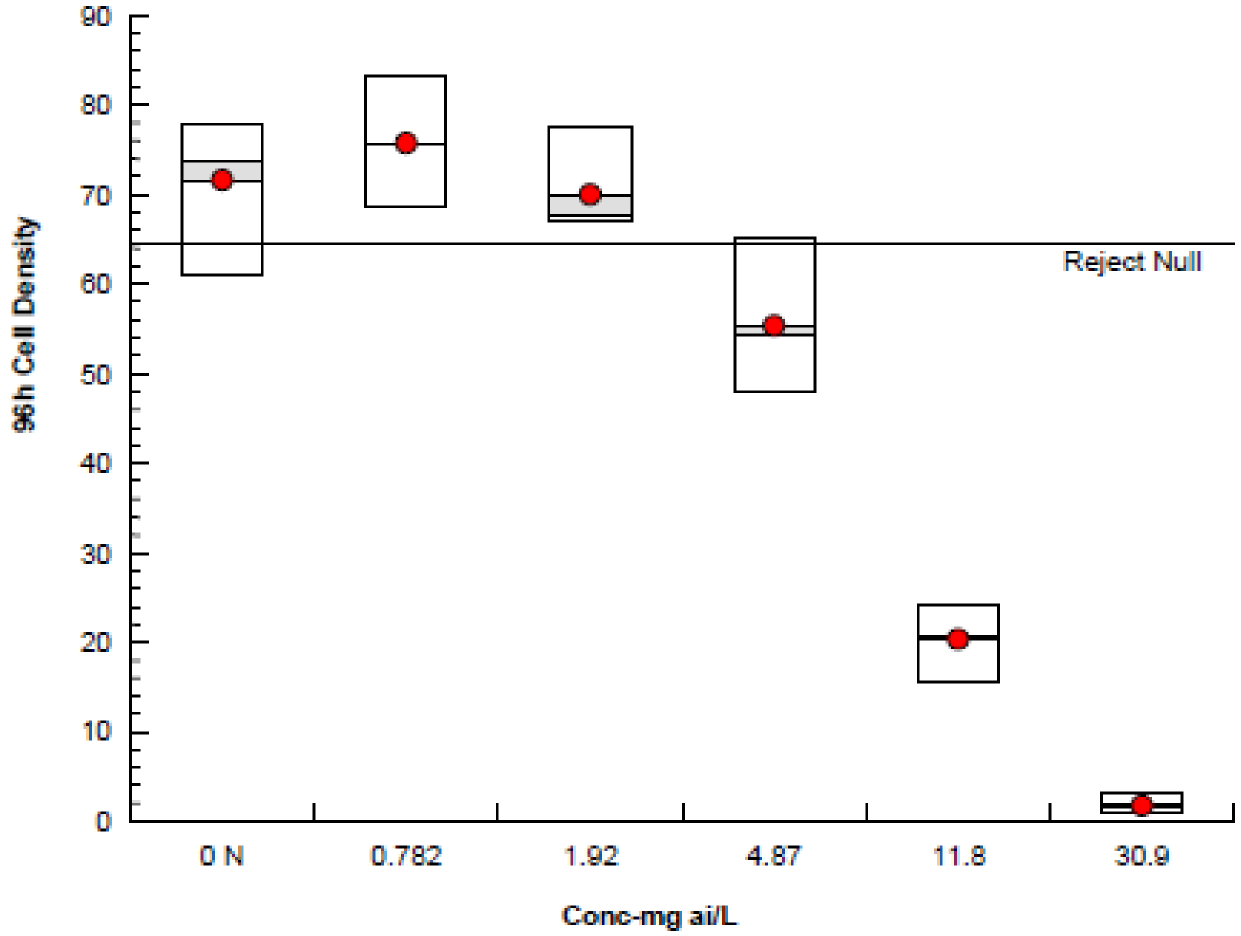
- Risk Quotients (RQs) are NOT directly comparable, especially for acute risk



RQ = 0.5 means that the exposure concentration is 0.5X the LC50
RQ = 1 means that the exposure concentration is equal to the LC50
RQ = 2 means that the exposure concentration is 2X the LC50

Comparing Risk - Chronic

- Chronic RQs are calculated using a NOAEC (No Observed Adverse Effect Concentration) based on survival, growth, or reproductive endpoints.
- The NOAEC is dependent on dose spacing chosen in the study design



Evaluating Ecological Benefits of IPM

- Ecological benefits can result from:
  - Less active ingredient applied
    - Fewer applications (e.g., as a result of using non-chemical methods)
    - Lower application rates
    - More targeted spraying / precision application
  - Moving from more risky to less risky pesticides
    - Can evaluate whether there are RQs exceeding the LOC or not for each chemical
  - Changing timing of pesticide applications
    - Applying near sunset or early morning to avoid actively foraging pollinators
    - Avoiding breeding times for bird species of concern in the local area
  - Decreasing movement of a pesticide offsite
    - Reducing spray drift (e.g., ground vs. aerial application, leaving buffers to edge of field)
    - Reducing runoff (tillage practices, cover crops, mulching, vegetative filter strips, etc.)
    - Holding time of water from flooded crops (cranberry, rice)

Human Health Risk Assessment

Risk = Exposure x Toxicity

Exposure: How Much?

- Dietary (Food/Drinking Water)
- Aggregate
  - Food
  - Drinking water
  - Residential
- Cumulative
- Occupational

Hazard: How Toxic?

- Acute
- Subchronic
- Chronic
- Carcinogenicity
- Reproductive/Developmental
- Neurotoxicity
- Genetics

Hazard Assessment

- Typically start with hazard identification and endpoint selection

- Terms
  - Hazard
    - Identification of harmful effects in toxicity database
  - Dose
    - Amount of pesticide (mg/kg/body weight)
  - Endpoint
    - Harmful effect(s) upon which the risk assessment is based
    - Relevant to the route, duration, and population(s) of concern
  - Point of Departure (POD)
    - Dose level used to quantify risk (generic)

- Dose selected for risk assessment is the No-Observed Adverse-Effect Level (NOAEL)
- Use of uncertainty and safety factors

Estimating Human Exposure – General Approach

Identify Use Pattern → **Identify Exposure Pathways** → **Estimate Exposure** → **Estimate Risk**

Identify Use Pattern

- Where it is applied
- How it is applied
  - Method
  - Rate
  - Frequency
  - Label restrictions
  - Post-application activity
  - Area treated, etc.

Identify Exposure Pathways

- Exposed Populations
  - Infants/Children
  - Adults
  - Workers
- Exposure Routes
  - Oral (food/water)
  - Incidental oral (Children)
  - Inhalation
  - Dermal
- Exposure Durations
  - Acute
  - Short-term
  - Intermediate-term
  - Long-term

Estimate Exposure

- Types of Assessments
  - Dietary (food/water)
  - Residential
  - Aggregate
  - Occupational
  - Spray drift, etc.
- SAP-Reviewed Models/Tools
  - DEEM-FCID
  - Water models
  - Residential SOPs
  - Occupational Pesticide Handler Exposure Calculator
  - Occupational Pesticide Re-entry Exposure Calculator, etc.
- Use of chemical-specific data

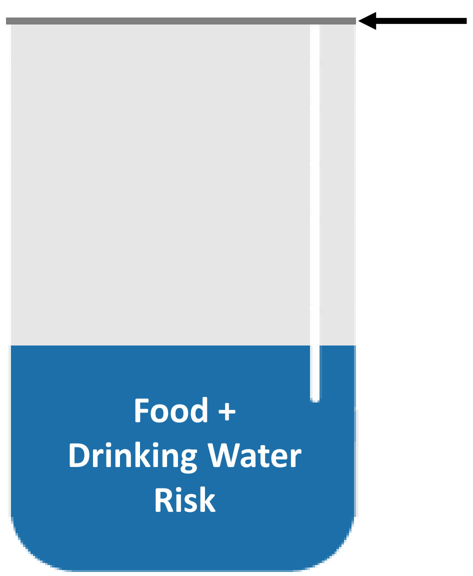
Estimate Risk

- Compare exposure estimate to PAD or LOC to estimate risk for specific exposure scenario
- Risk is not a number
- Characterize Assessment
  - Data gaps
  - Uncertainties
  - Potential limitations
  - Assumptions
  - Level of refinement, etc.

Estimating Dietary (Food + Drinking Water) Exposure and Risk

- Estimate food and drinking water exposure and risk for the general US population and population subgroups
- Data-driven approach
  - Use of consumption data and residue data to estimate dietary exposure
    - USDA’s National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA)
    - US EPA’s Food Commodity Intake Database (FCID)
    - Residue data – tiered approach
    - Modeled drinking water concentrations

- Dietary Exposure = Consumption x Residue
- Dietary Risk (% PAD) = (Dietary Exposure / PAD) x 100
- Characterization provides context for risk estimates



Acceptable Level
(aPAD, cPAD, etc.)

Dietary model

Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID)
https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/deem-fcidcalendex-software-installer

Water models

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

US EPA's Food Commodity Intake Database (FCID)

https://fcid.foodrisk.org/

Estimating Residential Exposure and Risk

- Non-occupational exposures
  - Handler exposure and risks (adults)
  - Post-application exposure and risks (adults and children)

- Data-driven approach
  - Chemical-specific studies (e.g., turf transferable residue (TTR) studies, etc.)
  - SOPs, unit exposures, etc. informed by Task Force data, surveys, scientific literature, US EPA's Exposure Factors Handbook, etc.

Residential Handler	Lawns/ Turf	Gardens and Trees	Outdoor Fogging/ Misting Systems	Insect Repellents	Indoor Environments	Treated Pets	Impregnated Materials	Treated Paints and Preservatives

- Residential risk is typically expressed as a Margin of Exposure (MOE)
  - MOE = NOAEL / Exposure
  - Compare MOE to a Target MOE (level of concern; LOC)
  - An MOE above the Target MOE indicates that the risk is not of concern
- Characterization provides context for risk estimates

Residential Exposure Assessment Tools
https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide

Estimating Aggregate Exposure and Risk

- Aggregate exposures when there is concurrent exposure from different pathways
  - Food exposure
  - Drinking water exposure
  - Residential exposure
- Aggregate across routes (oral, dermal, inhalation) when the toxic effect is the same
- Characterization provides context for risk estimates

More information: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/general-principles-performing-aggregate-exposure

Estimating Cumulative Exposure and Risk

- Considers the potential for food, drinking water, and residential exposure to “to more than one pesticide at a time from a group that share an identified common mechanism of toxicity”

- Groups with an identified common mechanism of toxicity:
  - Organophosphates (OPs)
  - N-methyl carbamates
  - Triazines
  - Chloroacetanilides
  - Pyrethrins / Pyrethroids

- Thiocarbamates and dithiocarbamates have also been examined, and it was determined that they do not share a common mechanism of toxicity

- Characterization provides context for risk estimates

More information: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides

Estimating Occupational Exposure and Risk

- Occupational Exposures
  - Handler exposure and risk
    - Exposure = Amount Handled x Unit Exposure Value
  - Post-application exposure and risk
    - Exposure = DFR x TC x Hours Per Day

- Data-driven approach
  - Chemical-specific studies (e.g., Dislodgeable Foliar Residue (DFR) studies, etc.)
  - SOPs, unit exposures, etc. informed by Task Force data, surveys, scientific literature, US EPA's Exposure Factors Handbook, etc.
  - Data to estimate impact of PPE on exposures

- Occupational risk is typically expressed as a Margin of Exposure (MOE)
  - MOE = NOAEL / Exposure
  - Compare MOE to a Target MOE
  - An MOE above the Target MOE indicates that the risk is not of concern

- Characterization provides context for risk estimates

Handler Exposure Examples

- Mixer/Loaders
- Applicators
- Mixer/Loader/Applicators
- Flaggers
- Loader/Applicator, etc.

Post-Application Exposure Examples

- Scouting
- Hand pruning
- Moving irrigation equipment
- Hand harvesting
- Hand thinning
- Weeding
- Packing/Sorting, etc.

Handler Exposure Assessment: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data
Post-Application Exposure Assessment: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-post-application-exposure

Evaluating Human Health Benefits of IPM

- Human health benefits can result from:
  - Less active ingredient applied
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    - Lower application rates
    - More targeted spraying / precision application
  - Moving from more risky to less risky pesticides
  - Decreasing movement of a pesticide offsite
    - Reducing spray drift (e.g., ground vs. aerial application, leaving buffers to edge of field)
    - Reducing runoff (tillage practices, cover crops, mulching, vegetative filter strips, etc.)
    - Holding time of water from flooded crops (cranberry, rice)

- Broadly – can reduce human exposure to both pesticides and pests

Conclusions

- Ecological and human health risk is a function of exposure and toxicity
- Risk Assessment is a scientific process that relies on various sources of data
- Characterization is an important part of risk assessment
- Comparing risks across pesticides can be complex and nuanced
- IPM can result in reduced ecological and human health risks resulting from pesticide use

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