# Methodology for Evaluating Pesticides for Surface Water Protection

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# Objective

Develop a more consistent, transparent, and faster method for evaluating new AI registration packages

# History

- Approx 10 new active ingredient registration packets per year.

- All new active ingredient products labeled for use outdoors in agricultural or urban settings, except:

  Microbial and Biochemical pesticides, Pheromones, Bactericides, Antimicrobials, Vertebrate pest control products (repellents, rodenticides, etc.), Plant growth regulators, Products intended for use in bee hives, Insect repellants or attractants, Products intended for use on stored foods (fruit, grain, nuts, etc.), Products intended for use with a bait station or trap

# History

- No “official” process, system, or model.
- Professional judgment and experience from past assessment of the conditions and mechanisms responsible for offsite transport to surface water.

  Physical/chem props, Use patterns, Compare to known contaminants
- Toxicological impact on aquatic life.

# Problems

- Somewhat inconsistent, not transparent
- What is a “typical” surface water contaminant?
- Toxicity endpoint?
- Lengthy process

# Conditional Registration

- Process for AI's in the gray area.
- What additional data to ask for and how useful is it?
  - Toxicity tests
  - Edge-of-field monitoring
  - Ambient SW monitoring
  - Analytical method

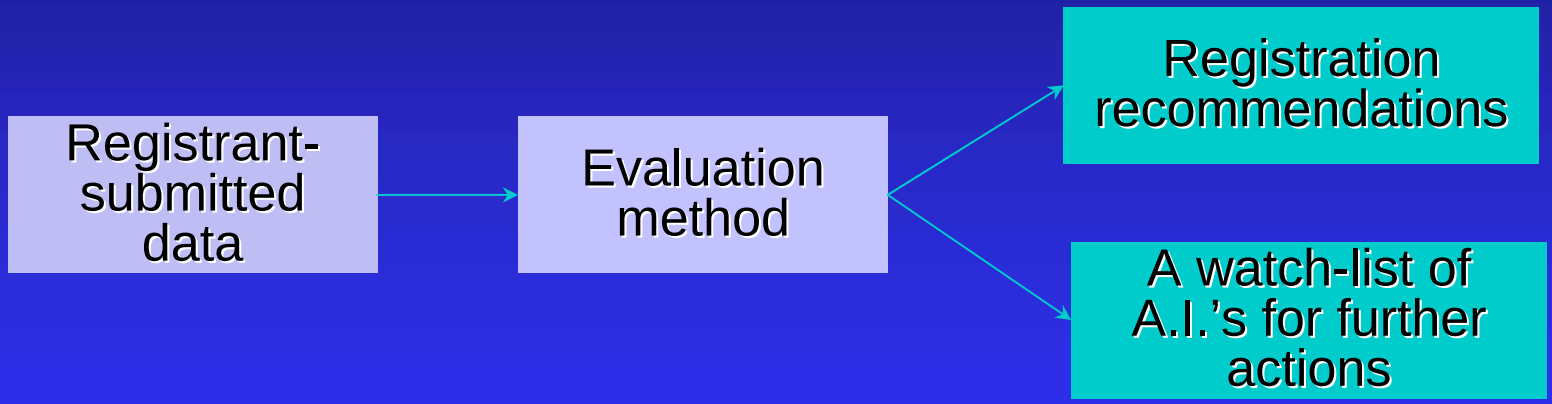
# Solution

- Systematic model less arbitrary
- Method to flag AIs of concern
  - -Monitoring
  - -Review of new products
- More transparent for registrants
  - -Easier to predict what AIs might be a concern for SW
  - -Easier to predict what additional data we might ask for.

# The Method

# General procedure

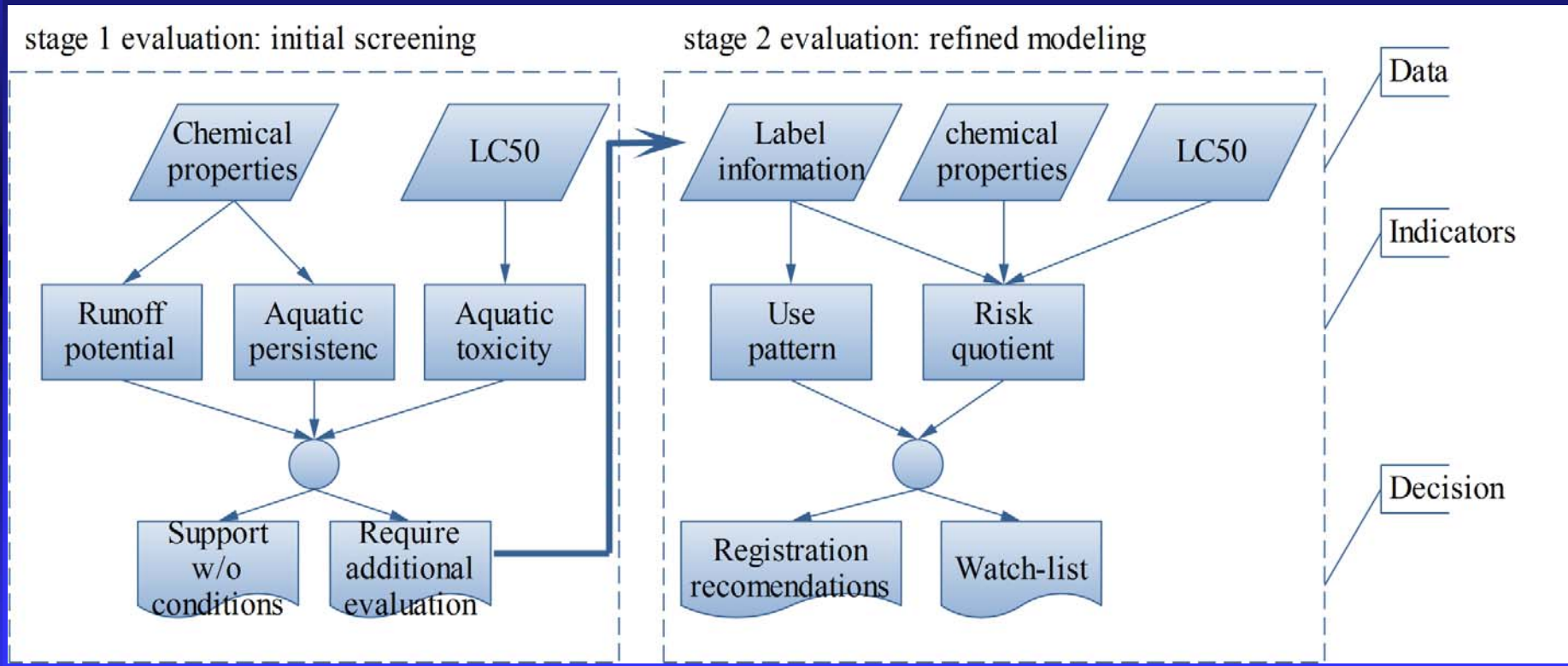
- A more consistent and transparent method for evaluating registration packages



# Development

| Procedure | Inputs/Methods | Results |
|---|---|---|
| Selecting *input data* | Registrant-submitted data | Chemical properties, toxicity data, label |
| Developing *indicators* | ▪ Well-accepted criteria & models<br>▪ Development & improvement | 5 descriptive indicators, as “high” (H), “intermediate” (M), and “low” (L) classes |
| Making *decisions* | Integrate indicators for appropriate decisions | ▪ Registration recommendations<br>▪ A watch-list |

# Two-stage procedure



# Indicators

| Indicators | Input parameters | Approaches |
|---|---|---|
| *#1 Runoff potential* | Adsorption coefficient (KOC), Field dissipation half-life, Water solubility | USDA model, modified for organophosphates and pyrethroids |
| *#2 Aquatic persistence* | HL's in water and sediment | Critical values of 30 and 100 days of half-lives |
| *#3 Aquatic toxicity* | Acute toxicity (LC50) for sensitive species | ▪ In water: USEPA criteria<br>▪ In sediment: DPR criteria |
| *#4 Use pattern* | Use pattern | High-exposure patterns identified by DPR scientists |
| *#5 Risk quotient* | Label rate, use pattern, KOC, aerobic soil metabolism half-life (AERO), LC50 | ▪ USEPA PRZM, simplified<br>▪ USEPA Tier I Rice Model |

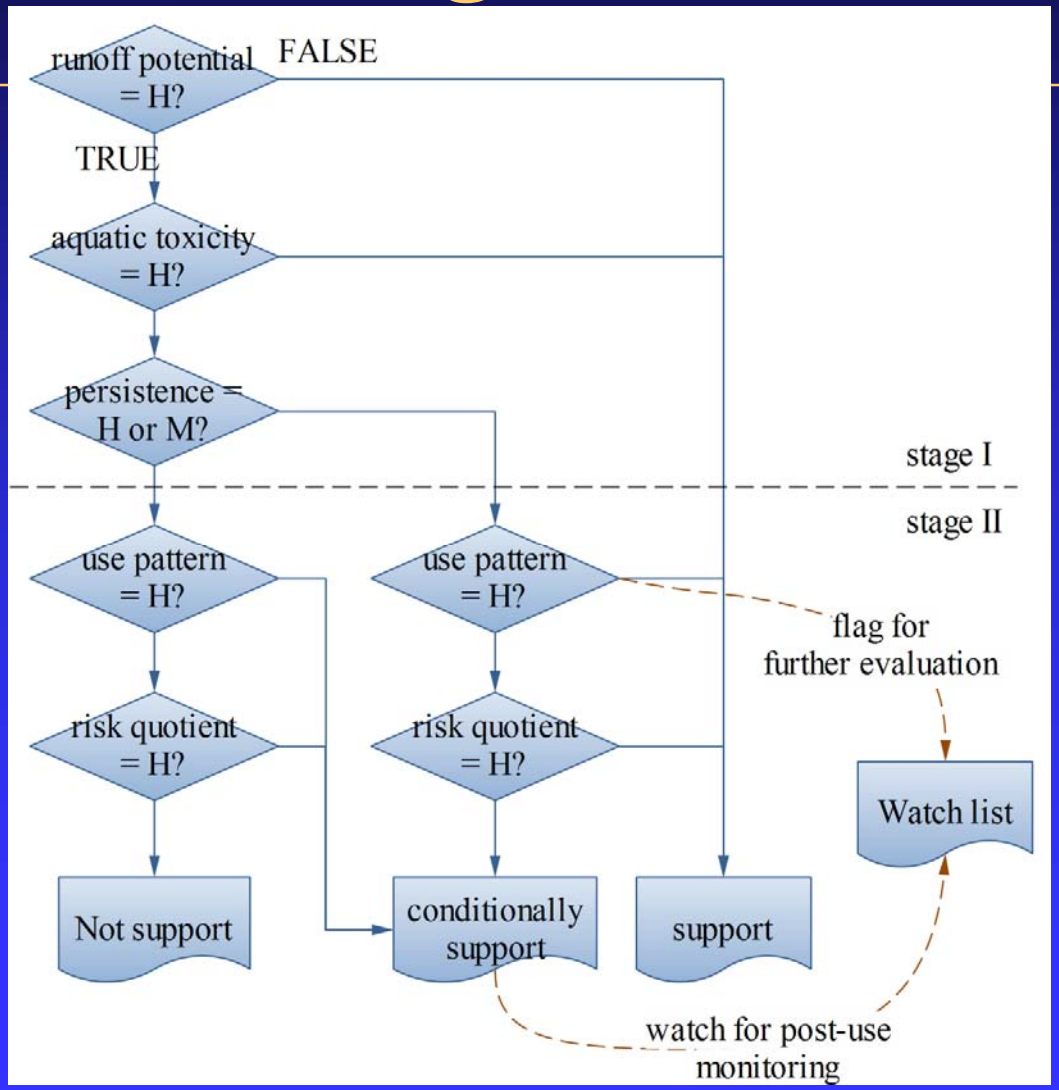
# Indicator #4: use pattern

- Pesticide use patterns with high exposure potentials to surface water:
  - *Aquatic* and *rice* pesticides
  - *Urban/residential* uses
  - Crops with *gravity irrigation* (DWR irrigation survey)
  - Crops with *top acreages* in California (PUR database and DWR land use survey)
  - *Winter* rain season application
  - *Pre-emergent* application

# Indicator #5: risk quotient (RQ)

- For high-exposure use pattern only
- RQ = EEC (estimated environmental concentration)/LC50; then compared to the LOC (level of concern) of 0.5
- EEC = *f*(label rate, chemical properties)
  - *Rice* pesticides: USEPA Tier 1 Rice Model
  - *USEPA tier 2 modeling scenarios*: "use-exposure relationships" based on USEPA PRZM
  - *Other* high-exposure use patterns not supported by regulatory models/scenarios: RQ is set as "High"

# Decision-making flowchart



# Decisions

- Registration recommendations (for a product)
  - Support registration without conditions
  - Support registration and request analytical methods
  - Do not support registration
- The watch list (for an A.I.)
  - Request analytical methods for the A.I. and watch it as a candidate for post-use monitoring
  - Flag the A.I. for further evaluation if a new label is associated with high-exposure use pattern

# Notes

- Dissolved and sediment-bound pesticides
  - Indicators are defined for both phases
  - Dissolved phase is always evaluated, while adsorbed-phase evaluation is only for pesticides with KOC>1000 (*USEPA, 2007, Data requirements for pesticide registration*)
  - (*for test run only*) if no data, LC50_sed (µg/kg[OC]) = LC50_wat (µg/L)*KOC
- Product with multiple use patterns
  - All labeled use patterns are evaluated
  - Professional judgment is required for final decisions

# Test run

- 21 new A.I.'s based on evaluations 2008-2010
- To compare decisions for pesticides in dissolved phase
- Criteria for methodology evaluation: comparable/equivalent decisions

| Model-based decisions | Professional judgment based decisions |
|---|---|
| Dissolved phase | |
| Support registration | Support registration |
| Support registration | Support conditional registration (sediment toxicity test) |
| Support conditional registration | Support conditional registration (runoff test) |

# Demonstration

- [W]= place into the watch-list
- [S]= Support registration
- [C]= Support conditional registration
- [N]= Not support registration

| A.I. | Product | Model-based decisions | | Professional judgment based decisions |
|---|---|---|---|---|
| | | Dissolved | Adsorbed | |
| A | A1 | [S] | [S] | [S] |
| B [W] | B1 | [C] | - | [S] |
| | B2 | [C] | - | |
| | B3 | [C] | - | |
| C | C1 | [S] | [N] | [C] (sed. tox & runoff ) |
| D | D1 | [S] | - | [S] |
| E | E1 | [S] | - | [S] |
| F | F1 | [S] | [S] | [S] |
| G [W] | G1 | [C] | [C] | [C] (runoff test) |
| H | H1 | [S] | [S] | [C] (sed. tox) |
| | H2 | [S] | [S] | |
| | H3 | [S] | [S] | |

| A.I. | Product (EPA Reg #) | Model-based decisions | | Professional judgment based decisions |
|---|---|---|---|---|
| | | Dissolved | Adsorbed | |
| I | I1 | [S] | [S] | [S] |
| J | J1 | [S] | [S] | [C] (sed. tox) |
| | J2 | [S] | [S] | |
| K | K1 | [S] | - | [S] |
| L | L1 | [S] | - | [S] |
| M | M1 | [S] | - | [S] |
| N [W] | N1 | [C] | - | [C] (runoff) |
| O | Q1 | [S] | - | [S] |
| P | P1 | [S] | [S] | [S] |
| Q [W] | Q1 | [C] | - | [C] (runoff) |
| | Q2 | [S] | - | |
| R | R1 | [S] | [S] | [N] |
| S | S1 | [S] | [S] | [S] |
| T | T1 | [S] | [S] | [S] |
| U | U1 | [S] | - | [S] |

# Summary

- Two-stage process
  - Active ingredient
  - Product
- Interpretation of evaluation results
  - Registration recommendations
  - The watch list of A.I.’s
- Model robustness and improvements
  - Development of indicators
  - Decision-making processes

# Selected references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