Surface Water Protection Program's Registration Evaluation - Using Models to Predict Aquatic Risks Posed by Pesticides

DTSC Seminar – July 2016

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Part I: DPR Registration Process & SWPP Registration Evaluation

Nan Singhasemanon

DPR's Registration Process – What is it?

- DPR's scientific evaluation & licensing process of new pesticide products that come into CA
- Pesticides include many types of products!
  - ~14,000 products registered, ~1,000 active ingredients
- Managed by Pesticide Registration Branch (PRB)
  - a core function of DPR
  - types of registrations… FIFRA Section 3 , 18, 24c
- Granted functional equivalency to CEQA - EIR
- Have to 1st be registered w/ U.S. EPA before DPR can grant registration

Steps for Product Registration

Mail Intake and Data Log In

Tracking Identification Number and Indexing Data

Submission Evaluation

Checks for completeness

Verifies label compliance

Formal Scientific Review

Does data support registration?

More data needed?

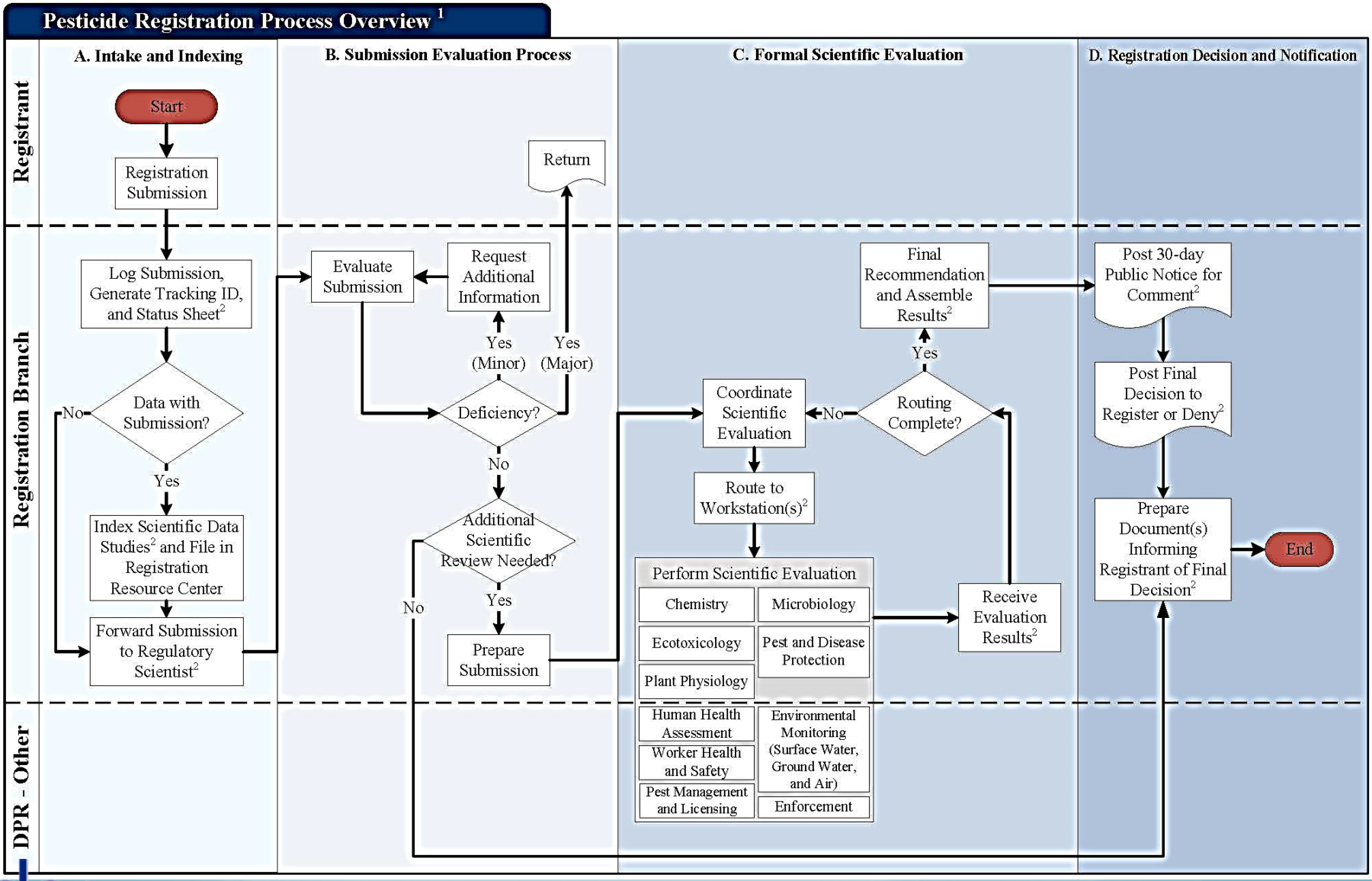
Registration Decision and Notification

Management Reviews & Decides

Public comment period

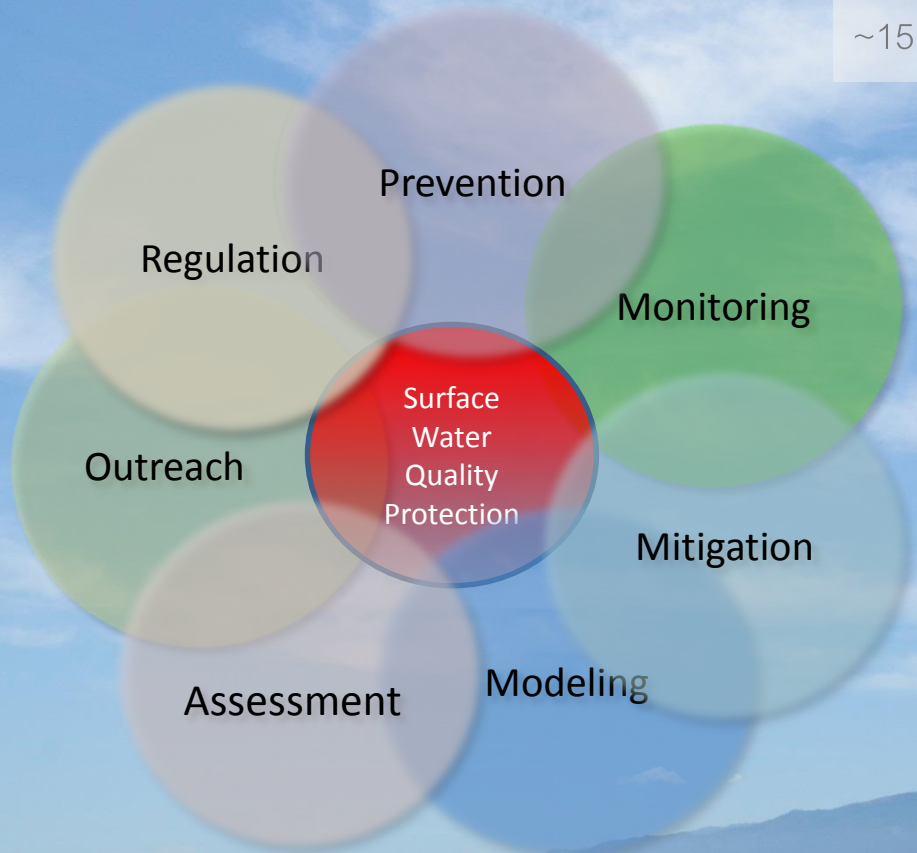
License for Registrants to Sell

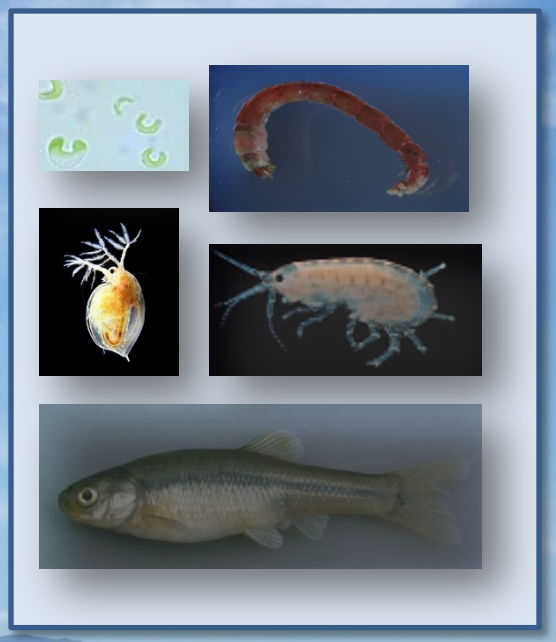
Steps for Product Registration



SWPP areas of activities

~15 fulltime & handful of intermittent staff





What Types of Products are Evaluated by SWPP?

- We don't review ALL products.
- Routing Criteria (last updated in 2012):
  - All new active ingredients (a.i.) in outdoor use products
    - Some exceptions (due to low risk a.i.'s or use patterns)
  - Direct application to water
  - Use on rice
  - Antifouling paints
  - Products designated by PRB Chief as needing evaluation by SWPP
- Routing criteria will change….

SWPP Evaluation Overview

- Main preventative tool for protection of water & sediment quality
- Two methods for evaluations:
  - Model-assisted
  - No model (best professional judgement)
- Prior to 2012 – NO MODEL
- Today doing both but modeling capabilities increasing
- Since 2009, ~35 product evaluations/yr.
- Program review (me & Yuzhou) & Branch Chief approval

Pesticide Registration Evaluation Model (PREM)

- PREM relies on label info, physico-chemical, e-fate & toxicity data
- Risk based
  - PEC/lowest aquatic LC50 or EC50 = RQ
  - RQ vs. Levels of Concern → model recommendation
- Predict water column & sediment risks
- Note modeling relies on data required by EPA/FIFRA
  - Chemistry & ecotoxicity studies & data must be approved by PRB
  - Data input CRITICAL
- Periodic staff training & user manual

Model Results

- Support, Conditional or Deny
- Can also FLAG a.i.'s for future routing
- Model recommendation strongly considered but actual SWPP recommendation could differ…
  - Example: degradate concerns
- Conditional often involves analytical method request, but sometimes more
  - Additional toxicity tests, e-fate studies
- SWPP also has monitoring prioritization model + we conduct MONITORING
  - "safety net" → continuous evaluation

Some Thoughts…

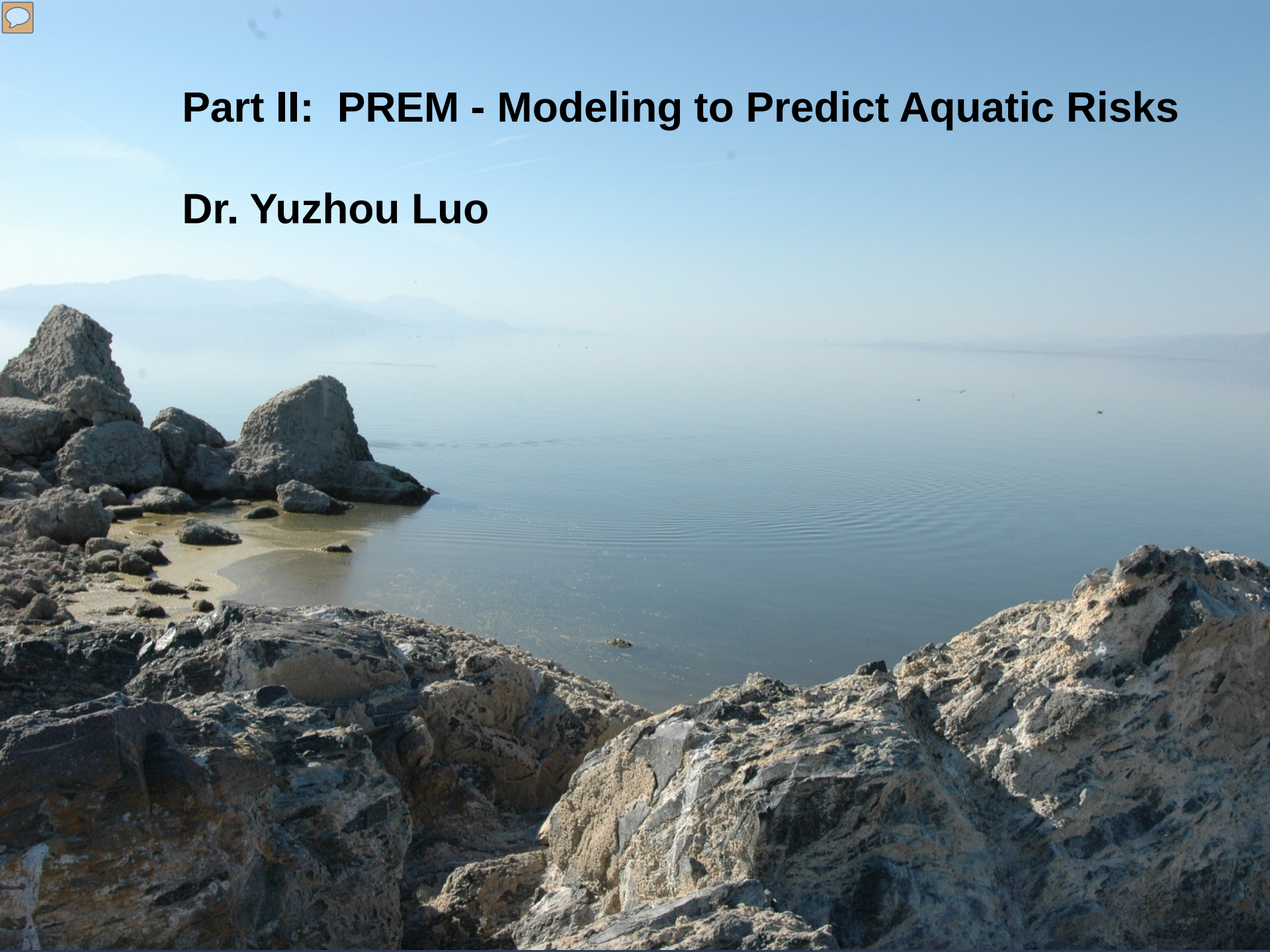
- PREM continually evolving
  - Striving for evermore realistic & CA-centric predictions
  - Degradate module (recently completed)
  - CA receiving water module (coming)
  - Wastewater module (coming)
- Eventually anyone could run model
  - Including registrants prior to submission of product labels to DPR
  - Hope to shape development of future product labels

More Thoughts…

- SWPP evaluations & PREM:
  - Consistently & reliably identify adverse risks of products to water quality & aquatic life
  - Avoid involved, costly & protracted post-registration efforts to develop & implement mitigation or regulations
  - Successful resolution between DPR & registrants (data needs, label changes) reinforces the usefulness & importance of SW registration evaluations & PREM

Part II: PREM - Modeling to Predict Aquatic Risks

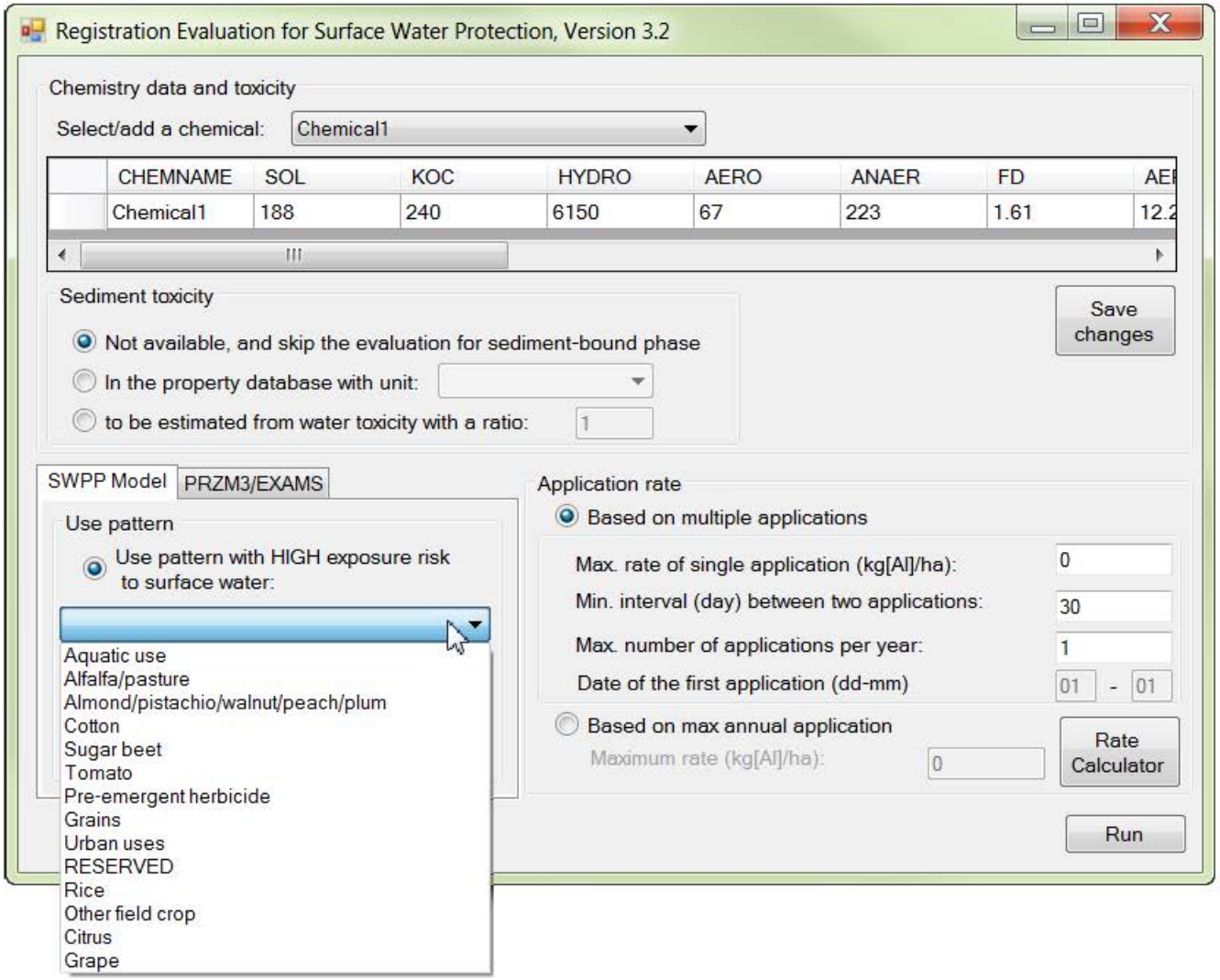
Dr. Yuzhou Luo



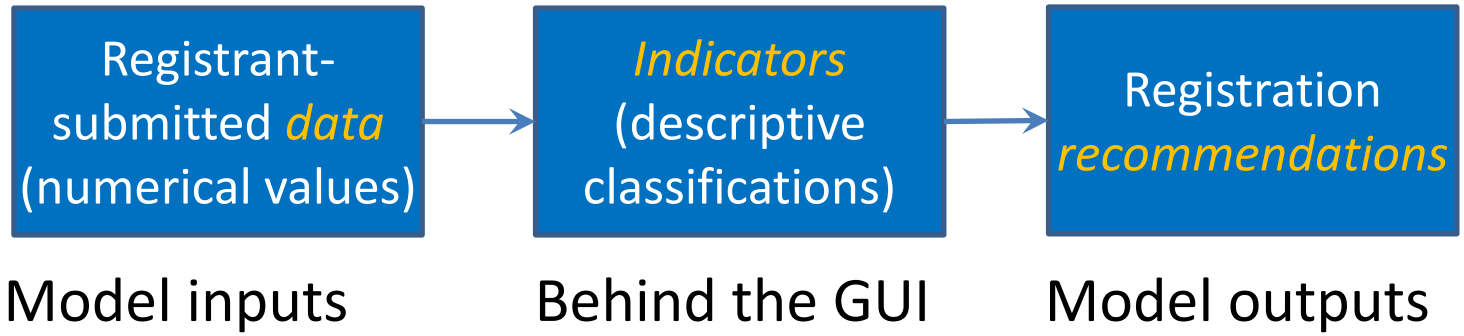
Introduction

- Pesticide registration evaluation model (PREM) for surface water protection
- Early versions released in 2011
- Current stable version (3.2) in 2014
- A new version under approval

Graphical User Interface



Modeling procedure



Model homepage

PREM (Pesticide Registration Evaluation Model)

PREM is used to evaluate aquatic impacts of pesticide products submitted to California for registration. It assesses potential toxicity of the products to aquatic organisms and protects the aquatic environmental & human health.

- Documents for modeling framework development
  - Initial Screening, PDF (342 kb). Yuzhou Luo and Xin Deng. January 26, 2012
  - Refined Modeling, PDF (266 kb). Yuzhou Luo and Xin Deng. January 26, 2012
  - UPDATED Methodology for Screening Pesticide Products with High Exposure Potentials to Marine/Estuarine Organisms, PDF (557 kb). Yina Xie and Yuzhou Luo. March 25, 2016
- Documents for functional module development
  - Module for Urban Scenarios, PDF (593 kb). Yuzhou Luo. February 28, 2014.
  - Module for Pesticide Degradates, PDF (350 kb). Yuzhou Luo, Nan Singhasemanon, and Xin Deng. May 3, 2016.

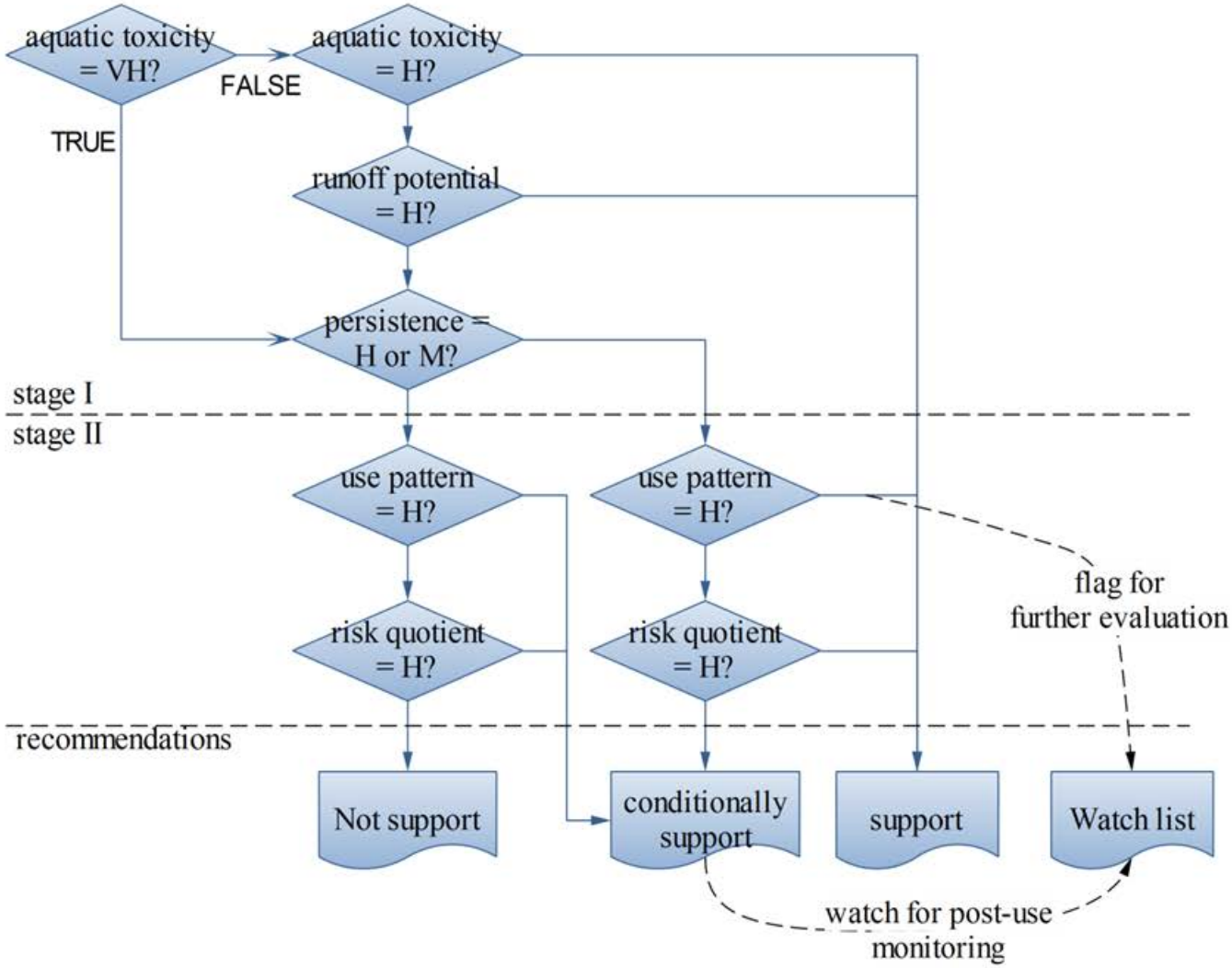
http://cdpr.ca.gov/docs/emon/surfwtr/sw_models.htm

Variables for evaluation

Indicators	Input parameters	Approaches
Soil-runoff potential	Adsorption coefficient (KOC), Field dissipation half-life, Water solubility	USDA WIN-PST model, modified by DPR
Aquatic persistence	Half-lives in water and sediment	Critical values of 30 and 100 days of half-lives
Aquatic toxicity	Acute aquatic toxicity (LC50, EC50) for sensitive species	USEPA classifications
Use pattern	Use pattern	High-risk use patterns identified by DPR
Risk quotient	Chemical property, use pattern, label rate, etc.	USEPA models (PRZM, VVWM, PFAM)

Note: Variables are presented as descriptive classification, e.g., high (H), low (L), intermediate (M)

Decision-making flowchart



Descriptive classification: L=low, M=intermediate, H=high, VH=very high

Model development

1. Modeling framework
   - Evaluation variables and their integration (the flowchart)

2. Functional modules
   - Modeling scenarios to parameterize an evaluation variable under certain conditions. For example, “urban module” is developed for estimating Risk Quotient with urban pesticide uses

Model results

- Registration recommendations (for a product)
  - Support registration
  - Support conditional registration and request analytical methods
  - Do not support registration
- Watch list and flagging (for an active ingredient)
  - 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-risk use pattern

Pesticide use pattern

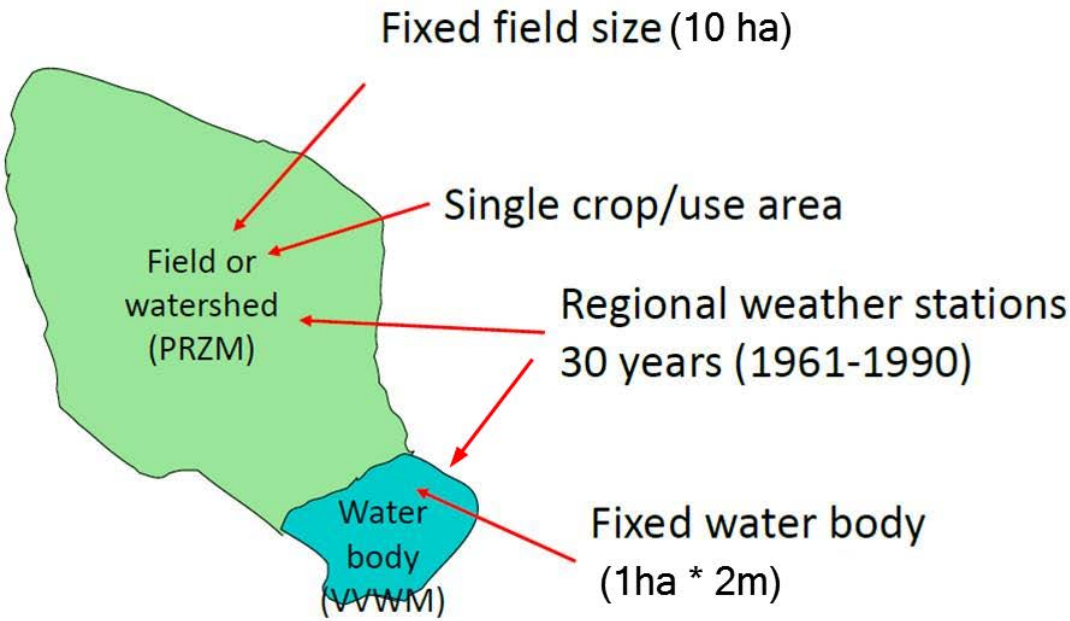
- Pesticide use patterns with high-risk potentials to surface water:
  - Aquatic and rice pesticides
  - Urban/residential uses
  - Crops with gravity irrigation
  - Winter rain season application
  - Pre-emergent application
  - Crops with top acreages in California
- Other use patterns: low-risk potentials

Risk quotient (RQ)

- Evaluated for high-risk use patterns only
- $$RQ = \frac{EEC}{TOX}$$
  - EEC (estimated environmental concentration) = *f*(chemical property, use pattern, label rate)
  - TOX = the toxicity value (LC50 or EC50) for the most sensitive species
- RQ is compared to the LOC (level of concern)
  - High risk quotient, if RQ>0.5

EEC modeling

- USEPA models
  - PRZM (Pesticide Root-Zone Model)
  - VVWM (Varying Volume Water Model), and PFAM (Pesticide in Flooded Application Model)



Ref: EPA-HQ-OPP-2015-0424-0036

EEC modeling

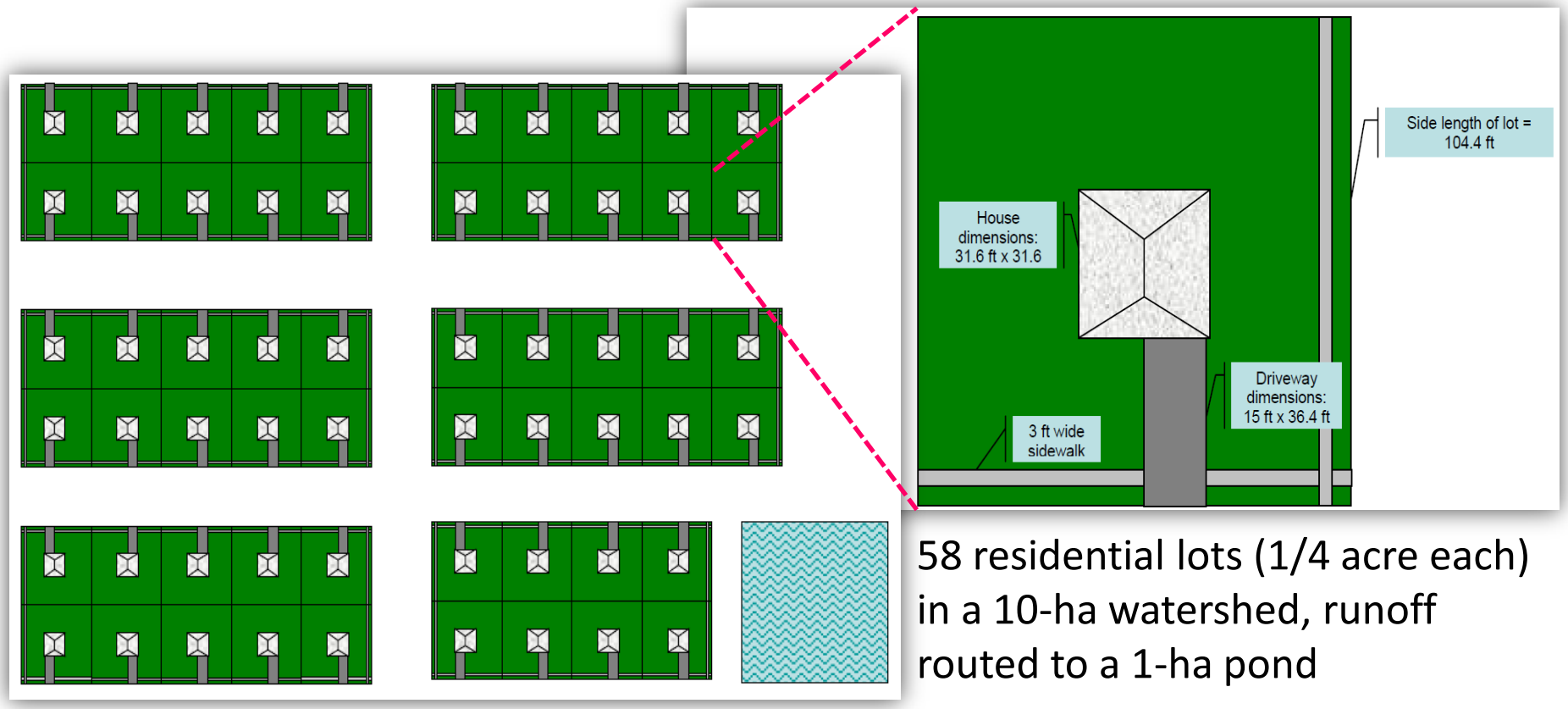
- USEPA models
  - PRZM (Pesticide Root-Zone Model)
  - VVWM (Varying Volume Water Model), and PFAM (Pesticide in Flooded Application Model)
- Modeling scenarios
  - USEPA scenarios for agricultural uses
  - DPR scenario for urban outdoor uses
  - DPR scenario for degradate evaluation
  - USEPA/DPR scenario for rice pesticides
  - DPR scenario for receiving water (under development)
  - …

Recent development by DPR

- Urban module (2014)
- Degradate module (2016)
- Use of toxicity data to marine/estuarine species (2015; updated in 2016)

- Under development
  - Receiving water module
  - Down-the-Drain module

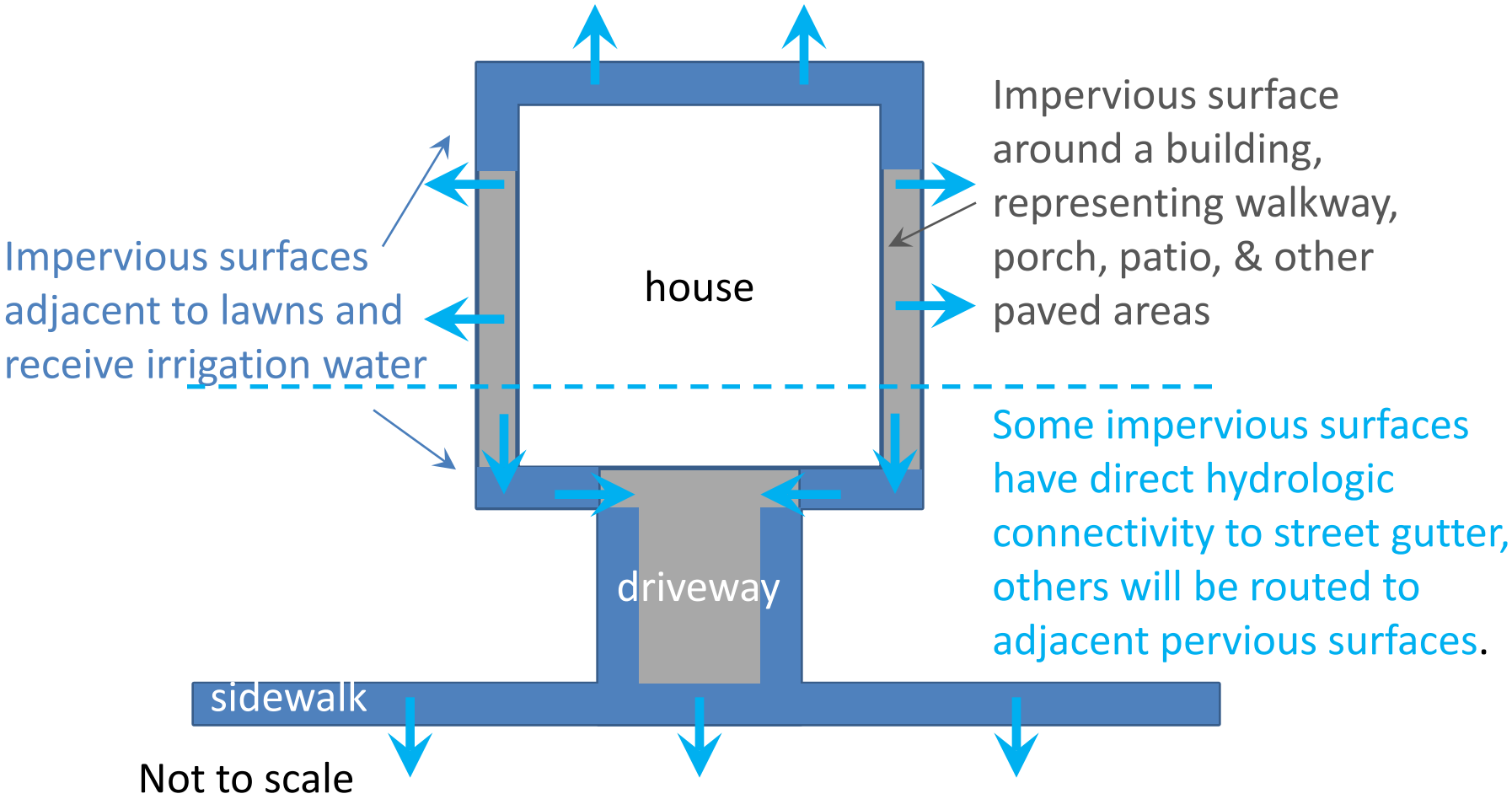
Urban module: USEPA residential settings



58 residential lots (1/4 acre each) in a 10-ha watershed, runoff routed to a 1-ha pond

Ref: USEPA, 2007, https://www3.epa.gov/pesticides/endanger/litstatus/effects/redleg-frog/carbaryl/determin-memo.pdf

Urban module: DPR landscape description



Urban module: DPR simulation design

Water source:

Precipitation only
(no dry-weather runoff)

Precipitation + irrigation
(dry-weather runoff)

Permeability:

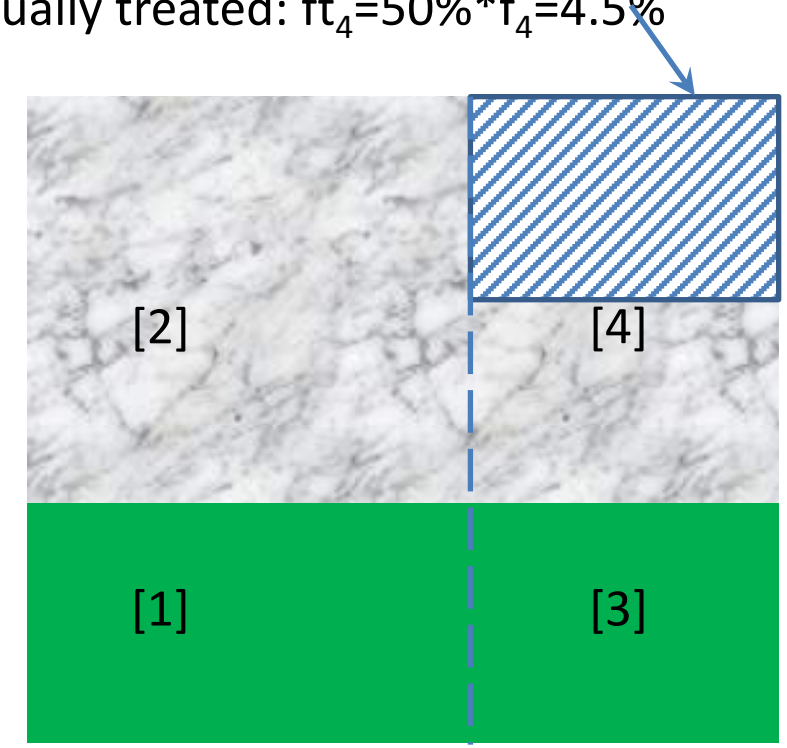
impervious, and
pervious surfaces

Not to scale

Urban module: DPR simulation design

Treated fraction, "ft" factors

For example, 50% of the surface [4] is actually treated: ft_4=50%*f_4=4.5%



Not to scale

Area fraction, "f" factors

[1] pervious, no dry-weather runoff (e.g., native vegetation)

- f_1=5%

[2] impervious, no d.w.r. (road, roof, part of driveway)

- f_2=74%

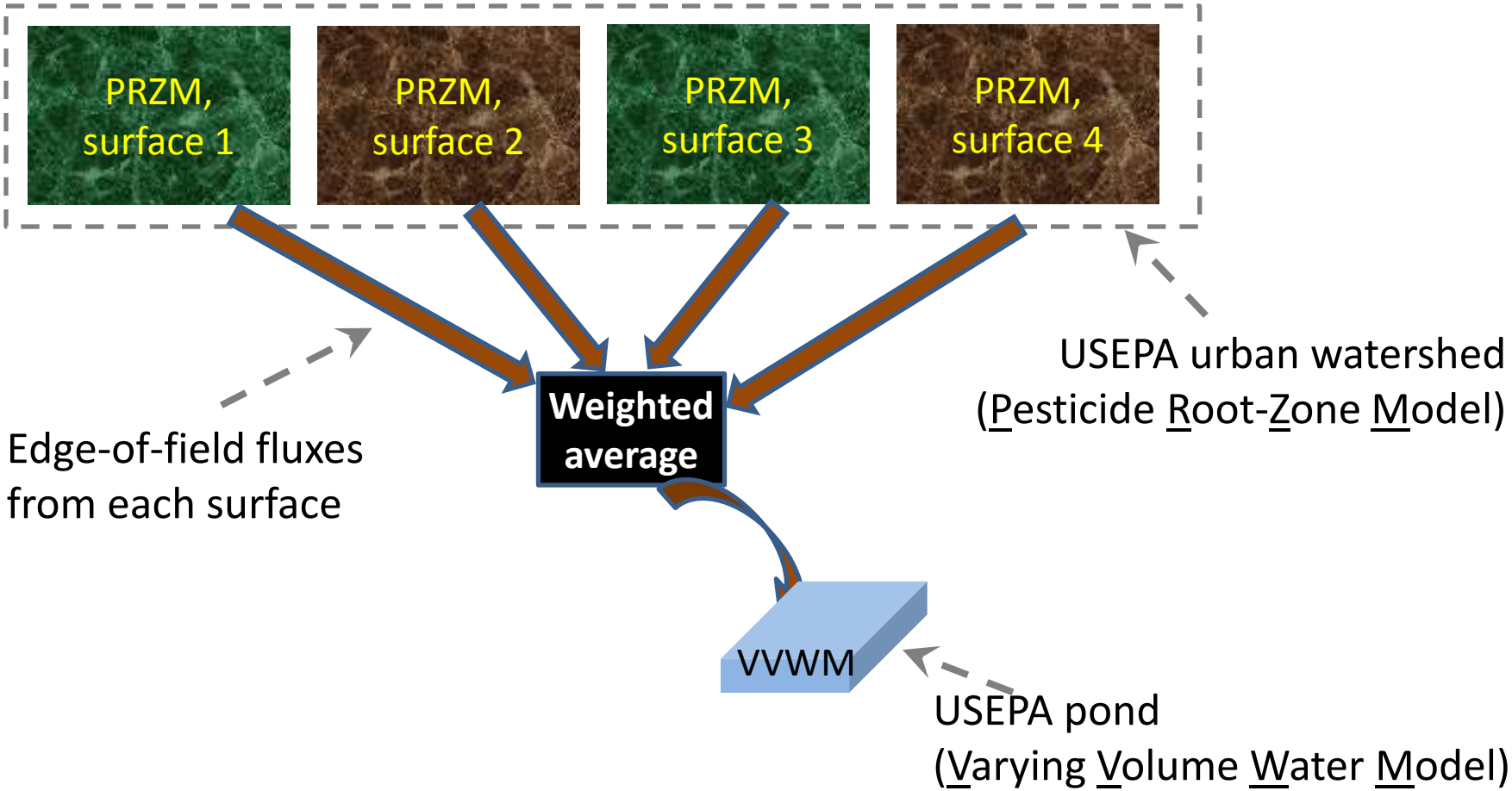
[3] pervious, with d.w.r. (lawns)

- f_3=12%

[4] impervious surface, with d.w.r. (driveway, walkway, sidewalk adjacent to lawns)

- f_4=9%

Urban module: Computer implementation



Ref: Luo, 2014 (http://cdpr.ca.gov/docs/emon/surfwtr/sw_models.htm)

Degradate module: background

- USEPA has no official data requirements and evaluation approaches for degradates
- DPR have evaluated degradates and requested additional data, on a case-by-case basis
- Objective of the degradate module: to standardize the processes for data request and evaluation

Degradate module: initial screening

- Only some of the major degradates will be modeled, based on "initial screening":
  - **Group [A]**: products of parent's quick degradation
    - Require evaluation if a degradate is very highly toxic
  - **Group [B]**: the parent is very highly toxic
    - Require evaluation if a degradate is even more toxic.

"Identified" degradates, a subset of "major"

Degradates to be modeled, a subset of "identified"

Notes: "quick degradation": Half-life <1d for photolysis or <5d for others;
"very highly toxic": TOX<100 ppb

Degradate module: modeling

- Input data
  - Acute toxicity tests
  - E-fate data: from lab tests and models (e.g., EPI Suite)
  - Conservative assumptions
- Risk characterization: total risk quotient (RQ) of the parent compound and degradates

$$Total\ RQ = RQ(P) + \sum_{i=1}^{n} RQ(Di)$$

P = the parent, D = degradates to be modeled, n = # of degradates

Ref: Luo, Singhasemanon, and Deng, 2016
(http://cdpr.ca.gov/docs/emon/surfwtr/sw_models.htm)

Toxicity to marine/estuarine species

- The evaluation variable of “aquatic toxicity” (TOX)
- Previous approach
  - TOX= the lowest of acute toxicity values to <u>all</u> (freshwater, marine, and estuarine) species
- Proposed approach
  - for products *with high exposure potentials to marine/estuarine species*: follow the previous approach
  - with *low* exposure potentials: <u>only</u> use toxicity data to freshwater species

Toxicity to marine/estuarine species

- Identification of high-exposure products
  - *(Spatial analysis)*: applications to major landuse/crops in California coastal areas
    - Aquatic, urban, alfalfa, broccoli, strawberry, celery, corn, cotton, grain/hay, outdoor nursery
  - OR,
  - *(E-fate data analysis)*: potential for long-distance transport
    - High "soil-runoff potential" AND intermediate-to-high "aquatic persistence"

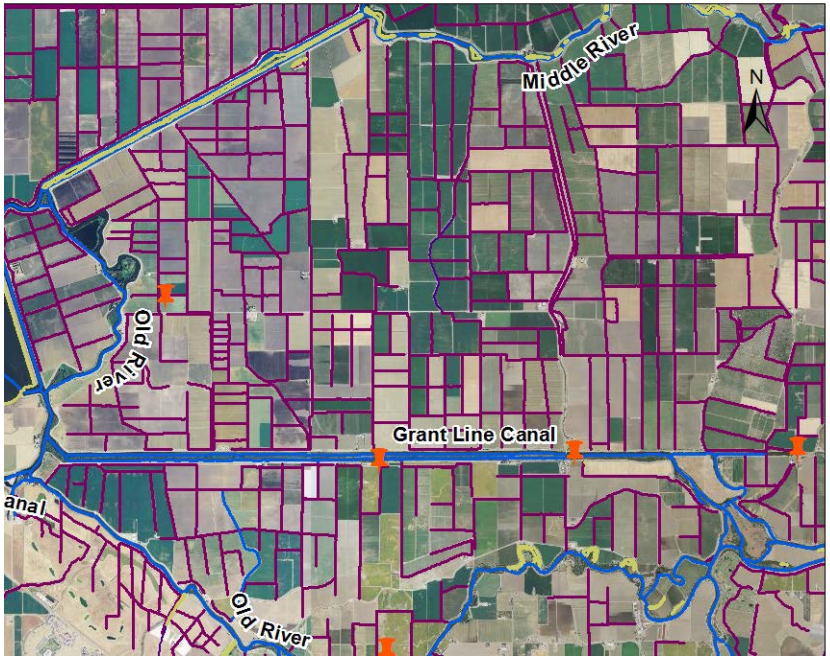
Ref: Xie and Luo, 2015 (updated in 2016)
(http://cdpr.ca.gov/docs/emon/surfwtr/sw_models.htm)

Receiving-water module

- Motivation
  - The USEPA scenario for receiving water (1ha, 2m) is based on typical agricultural ponds in Georgia

Georgia

California



Receiving-water module

- Motivation
- Objectives
  - Literature review: existing models and scenarios (AGRO, TOXSWA, VVWM)
  - Development: modeling scenarios for California conditions (discharges from agriculture, urban, and POTW)
  - Validation with monitoring data
- DPR Study #293 (study protocol by Xie, 2014, http://cdpr.ca.gov/docs/emon/pubs/protocol.htm)

Down-the-drain module

- Objectives
  - predict environmental concentration of a pesticide active ingredient from residential indoor uses
  - as an enhanced, California-specific implementation of USEPA model of E-FAST (Exposure and Fate Assessment Screening Tool)
- Study protocol under development
- Related studies in DPR
- Collaborations with USEPA

Contacts

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