Surface Water Protection Program Registration Evaluation Training

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California Department of Pesticide Regulation
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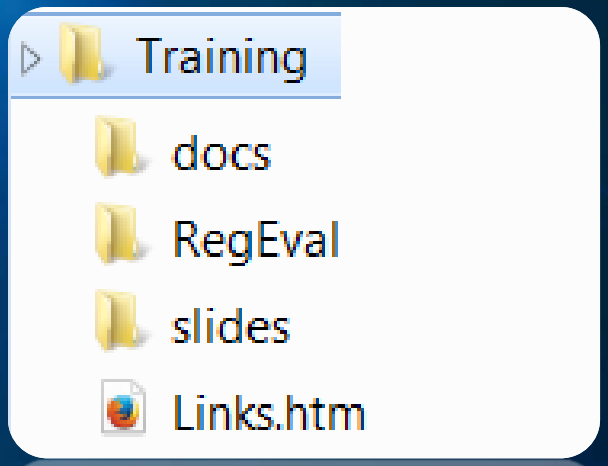
Setup

- Locate the training package in the share drive:
  \\dprhq01\SurfaceWater\Registration Evaluation\Training
  - Use the .bat in your email to map the drive as “X:”
  - Windows start menu, search for “\\dprhq01”
- Copy the “Training” folder to D:\, so you have a local folder as D:\Training
- Open “Links.htm”



Agenda

- Overview (Nan, 20min)
- Data preparation
  - Active ingredient (AI) data (Yuzhou, 20min)
  - Product label (Nan, 20min)
- Modeling & GUI demonstration (Yuzhou, 30min)
- Reporting (Nan, 20min)
- Q&A
- (sponsored by Kean)

- Overview (Nan)
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- Q&A

Registration Evaluation (RegEval)

- Why?
  - Per FAC, consideration of ecological effects is mandated into the CA registration process (CEQA equivalency)
  - An ideal opportunity to protect SW & prevent "significant adverse effects"
  - Even when registration is granted, will give us good idea of a.i.'s to watch for
  - U.S. EPA does similar review but we are CA centric (important since CA has many unique traits)

RegEval – What

- Registration evaluation for SW is a scientific review of relevant data to determine if the use of an a.i. and/or its resulting degradates will result in significant adverse effects to aquatic life in CA.
- Other stations are involved in their own areas of reviews
- All reviews result in a “recommendation” to Registration Branch

RegEval - Process

- Registration specialists manage submissions & data & route them to various stations
- SW is at the end of the queue
  - Need reviews from both Chemistry & F&WL stations
- Packets
  - Proposed label
  - Supporting info (sometime referencing registrant-submitted data volumes)
  - Other evaluations
  - Routing slip

Routing

- There is a criteria for routing (2012)
- All new a.i. except:
  - Microbial/biochemical
  - Pheromones
  - Bactericides/antimicrobials
  - Vertebrate pest control products
  - Plant growth regulators
  - Insect repellants/attractants
  - Bait/gel products or products for use in traps/baits
  - Use on bee hives & stored foods

Routing (cont.)

- Registration also routes products:
  - Directly applied to water
  - For use on rice
  - Antifouling paints & products for use on objects in & above water
  - Products designated by the Registration Branch Chief as needing evaluation by SWPP
- Separate tracking by me & Jackie
- Some packets are misrouted or don't need evaluations
- Those that make the cut & assigned based on staff background or areas of specialty & workload

RegEval - How

- SW Evals are focused on determining the risk from the use of a product/a.i. and the consequence of that use to sensitive aquatic life in CA receiving waters.
- Are the risks acceptable?
  - Significant vs. insignificant
- Two methods of evaluations:
  - Model-assisted
  - No model (good 'ol days… or not-so-good 'ol days)

RegEval - How (No Model)

- Model-assisted eval will be covered by Yuzhou
- What to do when products cannot be evaluated by the model (at this time…)???

1. Verify that product use pattern can't be simulated by RegEval Model
2. Read the label & get to know the product
3. Are there registered products w/ similar use patterns? If so, stop here.

RegEval - How (No Model)

4. Assess pathways for entering SW (e.g., direct, runoff, drift, stormwater, wastewater)
5. Can PEC be estimated quantitatively? (e.g., Zequanox)
6. Can loading relative to non-pesticide sources be established? (e.g., Cu, Ag)
7. Is product used in treating “articles?”
8. For wastewater, is treatment effective at removal?
9. Read the F&WL eval & assess aquatic toxicity. Is the lowest LC50 very low (e.g., < 1 ppb)?

RegEval - How (No Model)

10. Can a crude RQ be calculated?
    - If so, possible to use similar decision-making matrix as those in RegEval methodology
    - If not, can a clear case be made to deny the product? Will additional data get you there?
11. Are there degradate issues?
12. You are NOT limited to registrant-submitted data
13. Can look to older evals for guidance
14. Bottomline: case-specific, use your scientific mind…

RegEval – How (Model-based)

- In recent years, SWPP developed a methodology for modeling products w/ certain use patterns.
- Methodology has been extensively peer-reviewed & has been accepted even by industry
- It continues to evolve to better fit CA conditions

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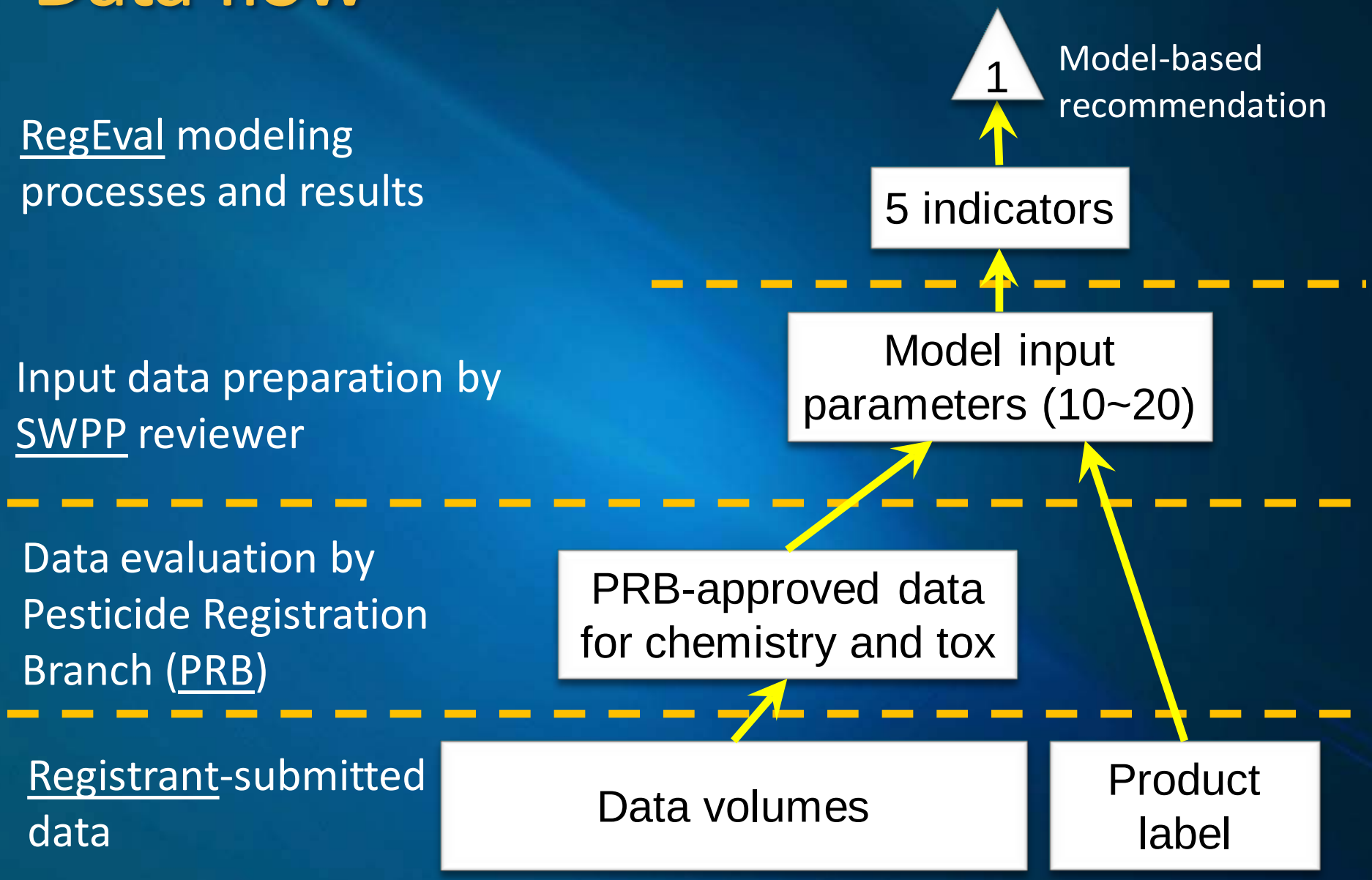
Data preparation: Part 1, AI-specific data (physiochemical properties and aquatic toxicity)

Guideline of data preparation (as an Appendix in the User's Manual, http://www.cdpr.ca.gov/docs/emon/surfwtr/review.htm)

Data flow


RegEval modeling processes and results
Input data preparation by SWPP reviewer
Data evaluation by Pesticide Registration Branch (PRB)
Registrant-submitted data
1
Model-based recommendation
5 indicators
Model input parameters (10~20)
PRB-approved data for chemistry and tox
Data volumes
Product label

Data sources for SWPP RegEval

- PRB-approved AI-specific data, indexed by a Tracking ID#:
  - Evaluation report(s) for chemistry data
  - Evaluation report(s) for fish & wildlife toxicity data
- Product label (product-specific data: use pattern, crops, application rate, interval, timing…)

AI data preparation

- Guideline of data preparation (Appendix in the User's Manual)
  - Training\docs\UsersManual.pdf, or
  - Links.htm -> "technical reports and user's manual"

- The guideline answers the questions
  1) Where to get the PRB evaluation reports
  2) Multiple versions of the reports
  3) Required input parameters
  4) General approach in data preparation
  5) Additional considerations

1) Get the PRB reports

- Registration Tracking System (http://registration/track/trackreps/trackreps.htm, or use the link in “Links.htm”)
- Log-in with the same account as for your desktop PC
- Have the 6-digit Tracking ID# ready

1) Get the PRB reports

- Exercise: "Protexio (V-10135) Fungicide" containing fenpyrazamine, tracking ID#249385,
  - Click "Evaluation History w/ Linked Reports"
  - "Find" by TRACKID=249385
  - Click the hyperlink for "REPORT(S)"
  - Reports
    - Chemistry data evaluation ("ce" in the pdf filename)
    - Fish and wildlife (toxicity) data evaluation ("fw")

2) Multiple versions of PRB reports

registration/track/evalreports/nw/249385/

registration - /track/evalreports/nw/249385/

[To Parent Directory]

Wednesday, February 06, 2013 12:39 PM	10112	249385_ce_02_04_2013.pdf
Thursday, March 07, 2013 2:40 PM	7413	249385_ce_03_04_2013.pdf
Tuesday, October 09, 2012 3:39 PM	78300	249385_ce_10_04_2012.pdf
Friday, September 06, 2013 10:18 AM	71824	249385_emgw_08_30_2013.pdf
Tuesday, September 23, 2014 4:36 PM	201131	249385_fw_09_23_2014.pdf
Tuesday, January 15, 2013 2:40 PM	165251	249385_mt_01_11_2013.pdf

Some reasons for "not/conditional support" in PRB data evaluation

	Description	PRB will…	SWPP will…
Missing data	for a specific test, submitted data are acceptable, but not sufficient	request additional data	use both originally and newly approved data
Unacceptable data	for a specific test, none of the submitted data are accepted	request verified/updated data	use approved data in the new evaluation report
Potential hazards	data meet the requirements, but indicate potential environmental risks	request label changes	This may not have effects on SWPP evaluation

3) Required input parameters

- Based on the general info of use patterns: terrestrial use? aquatic/rice? urban? e.g.,

PESTICIDE REGISTRATION - Evaluation History with Linked Reports

TRACKID:	249385 **N**
FIRMNO:	**59639** VALENT U.S.A. CORPORATION
EPAREG NUM:	59639-179-
PRODUCT NAME:	**PROTEXIO FUNGICIDE**
REGTYPE:	**3** REGISTRATION
GENERAL USE:	FOR THE CONTROL OF VARIOUS DISEASES SUCH AS BROWN ROT, BOTRYTIS BUNCH ROT, AND GRAY MOLD ON ORNAMENTALS AND CROPS SUCH AS ALMONDS, GRAPES, AND LETTUCE
ADDED USE:	

- Details in the guideline, table 5

4) General approaches

- For each of the required parameters, retrieve all relevant data approved in the PRB reports (multiple versions may be involved)

- Calculate the value for each parameter
  - For physiochemical properties: use the median value of all approved data
  - For acute toxicity data in water or in sediment: use the lowest value of all approved data

First stop: "Summary Table"

- Chemistry data: search (CTRL+F) "*groundwater*" or "*leaching*" in the report
- Toxicology data: may have multiple summary tables for
  - (Technical Grade) AI (← use this one)
  - End-use product
  - Metabolites
- Examples

5) Additional considerations

- With more details in the guideline…

Typical/recommended species, but not limited to…

Freshwater, water column: 48-hr EC50 and 96-hr LC50 data for • Rainbow trout (*Oncorhynchus mykiss*) • Fathead minnow (*Pimephales promelas*) • Water flea *(Daphnia magna)* • *Daphnia pulex*	**Freshwater, sediment**: consider ALL available (usually limited) data • *Hyalella azteca* • Midge larvae *(Chironomus dilutus,* formerly named as *Chironomus tentans*)
Saltwater, water column: 48-hr EC50 and 96-hr LC50 data for • Sheepshead minnow • Saltwater mysid (*Americamysis bahia*)	**Saltwater, sediment**: consider ALL available (usually limited) data • *Eohaustorius estuarius* • *Rhepoxynius abronius* • *Leptocheirus plumulosus*

Provided by Xin

Summary (AI data preparation)

- ONLY use PRB-approved data
  - STOP Don't use registrant-submitted data which are not reviewed/approved by PRB
  - STOP Don't use data from external databases or literature reviews
- Consider ALL approved data
  - Data in multiple versions of reports (e.g., approved KOC values in two reports, for penflufen, #254961)
  - Some physicochemical properties not in the summary table, but in the report main text (e.g., field dissipation, for fenpyrazamine, #249385)

Excepted changes in the near future

- Separation of freshwater and saltwater toxicity
- Data preparation for degradates

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Product-Specific Data
How to Read & Interpret the Label

What Do You Need from the Label?

- Labels are notoriously hard to read & decipher
  - You are NOT alone…
- You need to "mine" for critical pieces of info.
- Make sure you have the latest label
- Do a quick read of the <u>entire</u> label
- Now that you are thoroughly confused & stricken w/ a headache, take a walk outside or a few ibuprofen. Please come back & then take a deep breath.

Labels - Considerations

- Helps to make copy of label & highlight or scribble on the copy
- For new a.i.'s look at all proposed uses
  - but for label amendments & new products of registered a.i.'s, you need to I.D. new use(s)
- Look for various commodities/use sites that can be modeled in RegEval
- Focus in on highest application rate for each commodity & use site

Label - Info

- You will need the following info as inputs:
  - Max. rate of single application
  - Min. interval (days) between applications
  - Max. # of applications/year (or growing season)
  - Date of 1st application (default assumes Jan. 1st)
  - Can use max. annual application in some cases but above individual app info are preferred
- Beware of the rate units! Use rate calculator

Additional Label Info for Urban Uses

- The urban module requires more info about the products:
  - Residential, commercial/industrial, or rights of way
  - Granular or liquid
  - Application method (e.g., perimeter spray, broadcast, crack & crevice)
  - Adjustments for the effective application rate are allowed but usually will use default values

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SWPP modeling for registration evaluation (RegEval)

Technical reports
(http://www.cdpr.ca.gov/docs/emon/surfwtr/review.htm)

Objective and scope

- To develop a more consistent and transparent method for evaluating registration packages
- Developed for
  - Organic compounds
  - Pesticide applications with runoff potentials to surface water
    - Intentional applications
    - Unintentional applications (overspray, deposition)

Considerations in the development

- Mechanisms for pesticide fate, transport, and aquatic toxicology
- CDPR (or SWPP)-specific considerations
  - Availability of CDPR-approved data
  - Previously well accepted data analysis method (e.g., median of KOC, lowest LC50/EC50)
  - Indictors and factors frequently used in the best professional judgment based evaluation
  - Registration recommendations and additional data request (e.g., analytical method)
  - Consistent results for previous evaluated packages

Evolution

<u>Main program</u>
(generally consistent to USEPA approaches, especially for landscape phase of agricultural uses)

Project initialized April 2010

Stage I, 2011

Stage II, 2012

+Urban module, 2014

+Degradate module, 2014

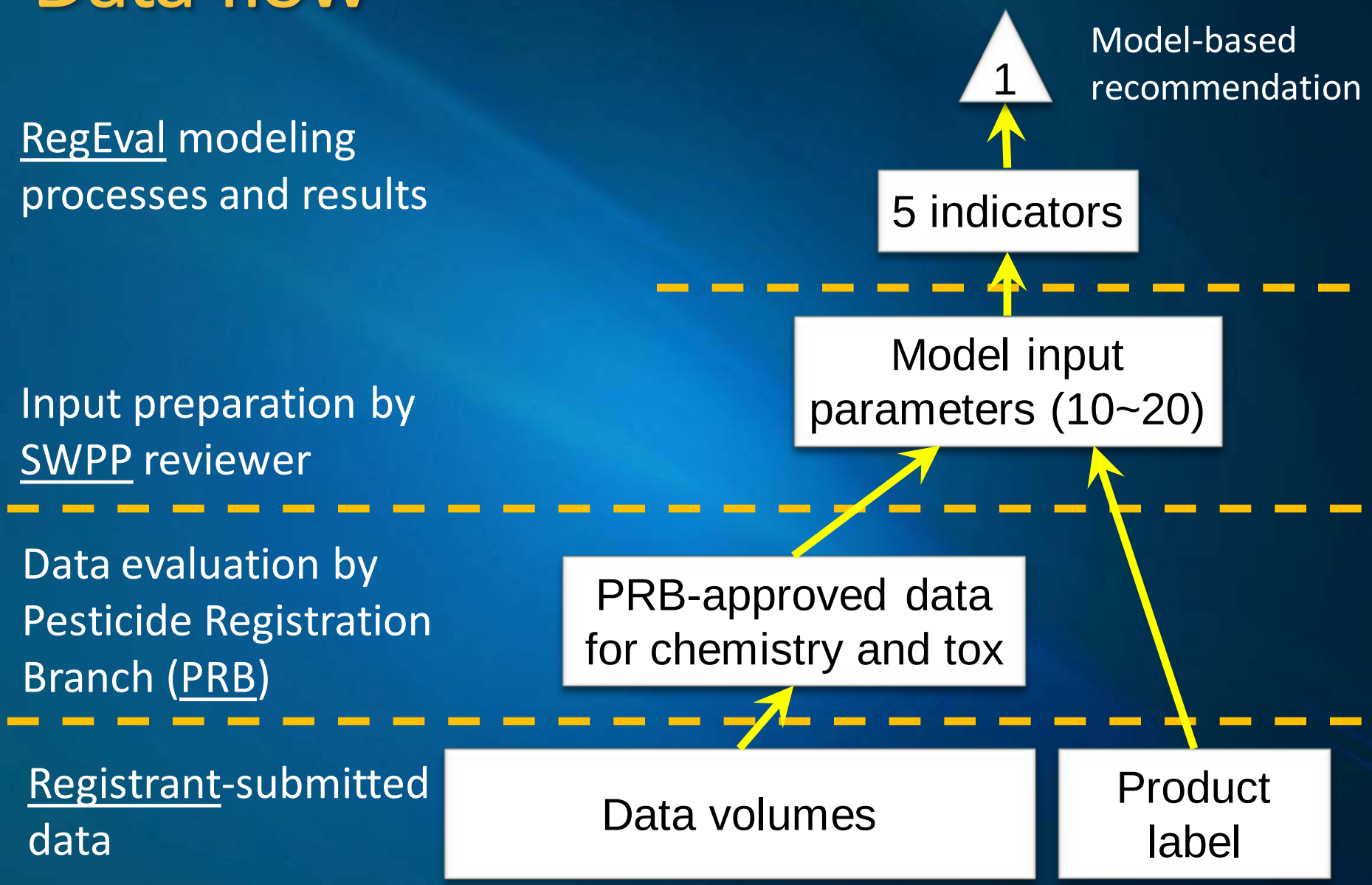
+Receiving water module

<u>Additional modules</u>
(When USEPA functionality is not available, or not suitable for California field conditions)

Modeling for receiving water body

- USEPA suggests a “standard farm pond”
  - Well accepted by USEPA and registrations
  - Not suitable for CA field conditions
- CA scenario of receiving water modeling is under development (Study 293 by Yina)
- Meanwhile, use USEPA pond:
  - incorporated in the development of new modules (urban, degradates, drift, etc.)
  - For agricultural uses, will consider if the SWPP model rejects the registration
- Will use CA scenario once it’s developed

Data flow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The five indicators

Indicators	Input parameters	Approaches
Soil runoff potential	Adsorption coefficient (KOC), field dissipation half-life (HL), solubility	USDA WIN-PST model
Aquatic persistence	HL's in water and in sediment	Critical values of 30 and 100 days of half-lives
Aquatic toxicity	Acute toxicity (LC50 or EC50) for the most sensitive species	▪ In water: USEPA criteria ▪ In sediment: SWPP criteria
Use pattern	Use pattern	Exposure risks investigated by DPR scientists
Risk quotient	Label rate, use pattern, KOC, soil metabolism HL's, toxicity	▪ USEPA PRZM, simplified ▪ USEPA Tier I Rice Model, modified

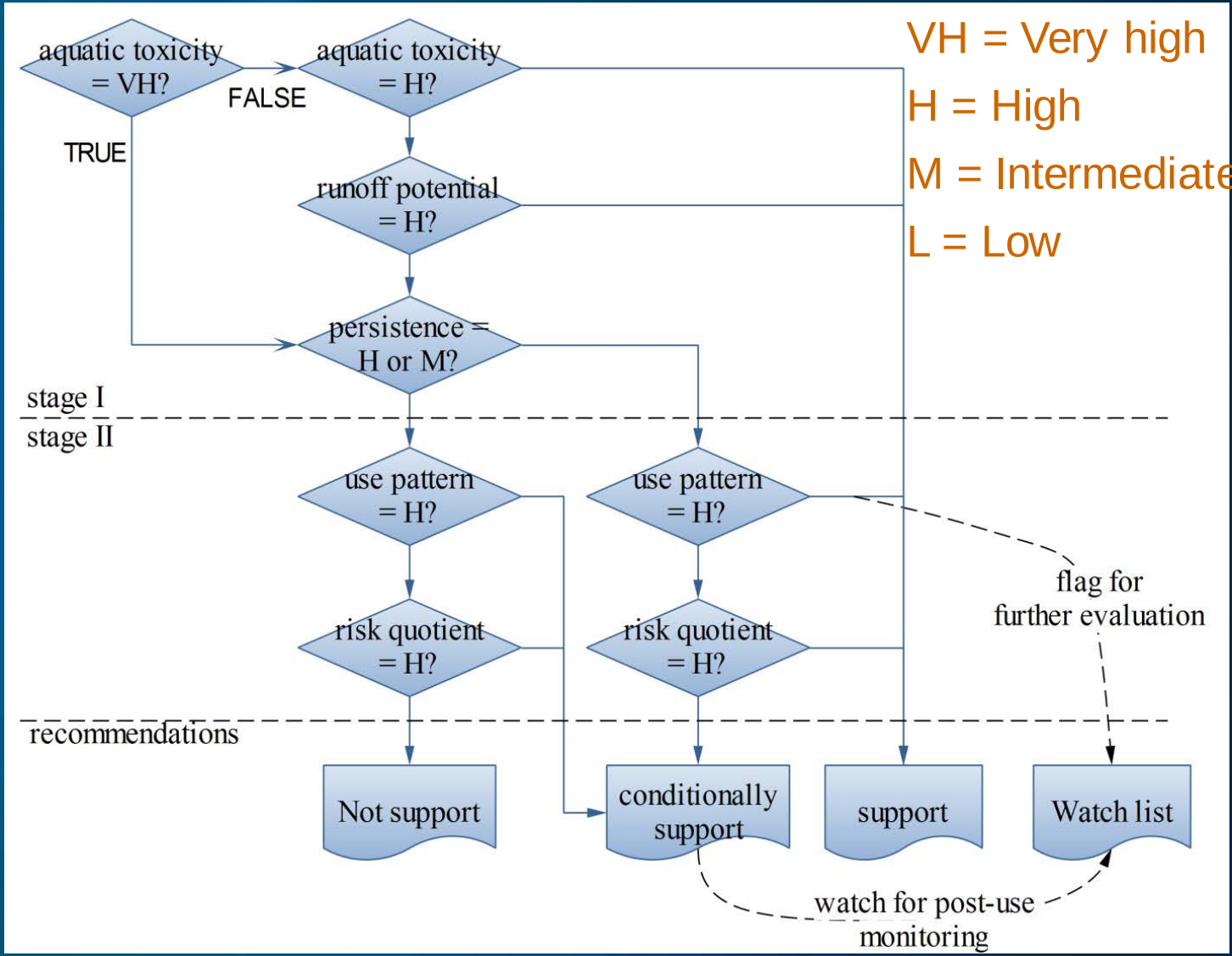
All indicators are expressed in categorical format (not numerical values), such as "low" (L), "high" (H)

The two-stage evaluation

- Stage 1 (initial screening)
  - Based on chemical properties and aquatic toxicology data of the **active ingredient** (AI)
  - Results: "support", or "need stage-2 evaluation"
  - *Model evaluation indicated: 11 of the 21 AI's were supported by the stage 1 (i.e., stage 2 not needed)*

- Stage 2 (refined modeling)
  - Based on risk characterization of the **product**-specific information (use pattern and application rate).

Decision-making flowchart



Runoff potential vs. use pattern

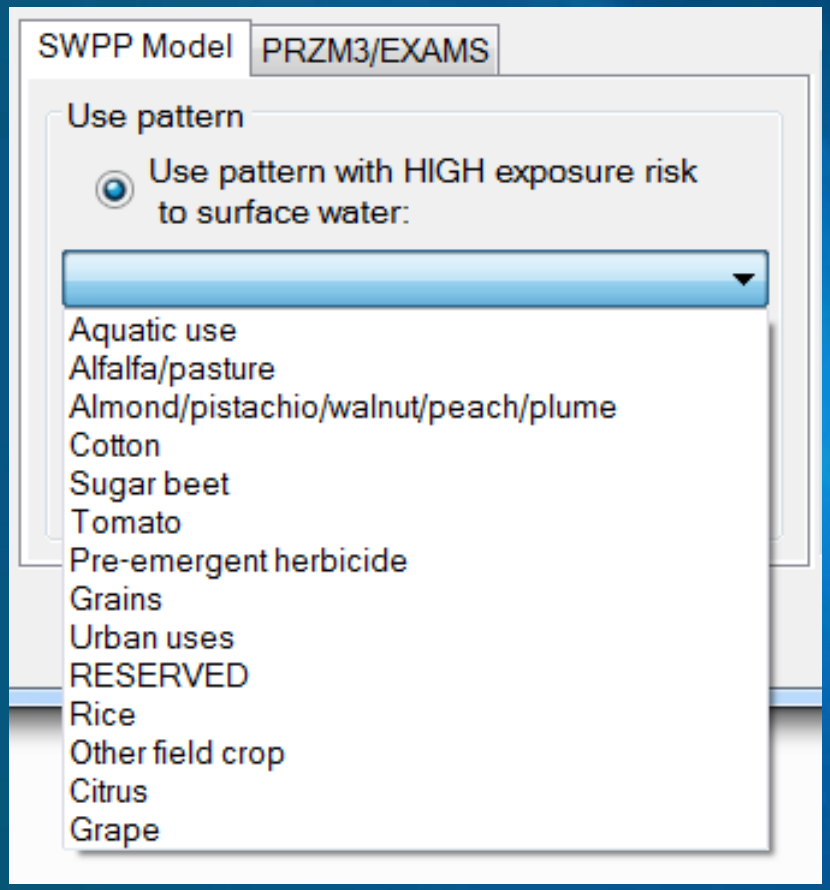
- Soil runoff potential: the mobility of the AI from the soils, indicated by solubility, adsorption coefficient, and field dissipation

- Use pattern: exposure risk to aquatic ecosystem according to proposed use pattern of the pesticide product, e.g.,
  - High exposure-risk use patterns: aquatic sites, hard surfaces, crops with gravity irrigation.

Use patterns with high exposure risk

- Aquatic applications (including rice pesticides)
- Urban/residential uses
- Crops with >50% gravity irrigation (alfalfa, corn, cotton, grains, pasture, sugar beets, dry beans, tomato)
- Winter rain season applications
- Pre-emergent applications
- Crops with top acreages in CA, if not already considered
- Nursery (*to be included*)

Use patterns with high exposure risk



DWR definition for "field crops" in California: corn, cotton, sugar beets, dry beans, safflower, flax, hops, grain sorghum, sudan, castor beans, sunflowers

Model validation and application

- Model evaluation (2008-2011)
  - 21 registration packages (new AI/label)

	Support	Conditionally support	Not support
Model-based	14	5	2
Best professional judgment based	14	6	1

Model validation and application

- Model evaluation (2008-2011)
- Model application (2011-present)
  - The first modeled: Prothioconazole (Oct. 2011)
  - Since that, there were 83 packages evaluated by SWPP (as of Oct. 2014)
    - 39 of them not require models at all (e.g., data review)
    - 44 new AIs or new labels
      - 33 modeled (75%), 2 of them "not support" (indoxacarb, tolfenpyrad)
      - 11 NOT modeled because of chemistry, uses, or both: inorganics, metals, microbial pesticides; antifouling paints (APF), consumer products, bait station

Other relevant models in EM

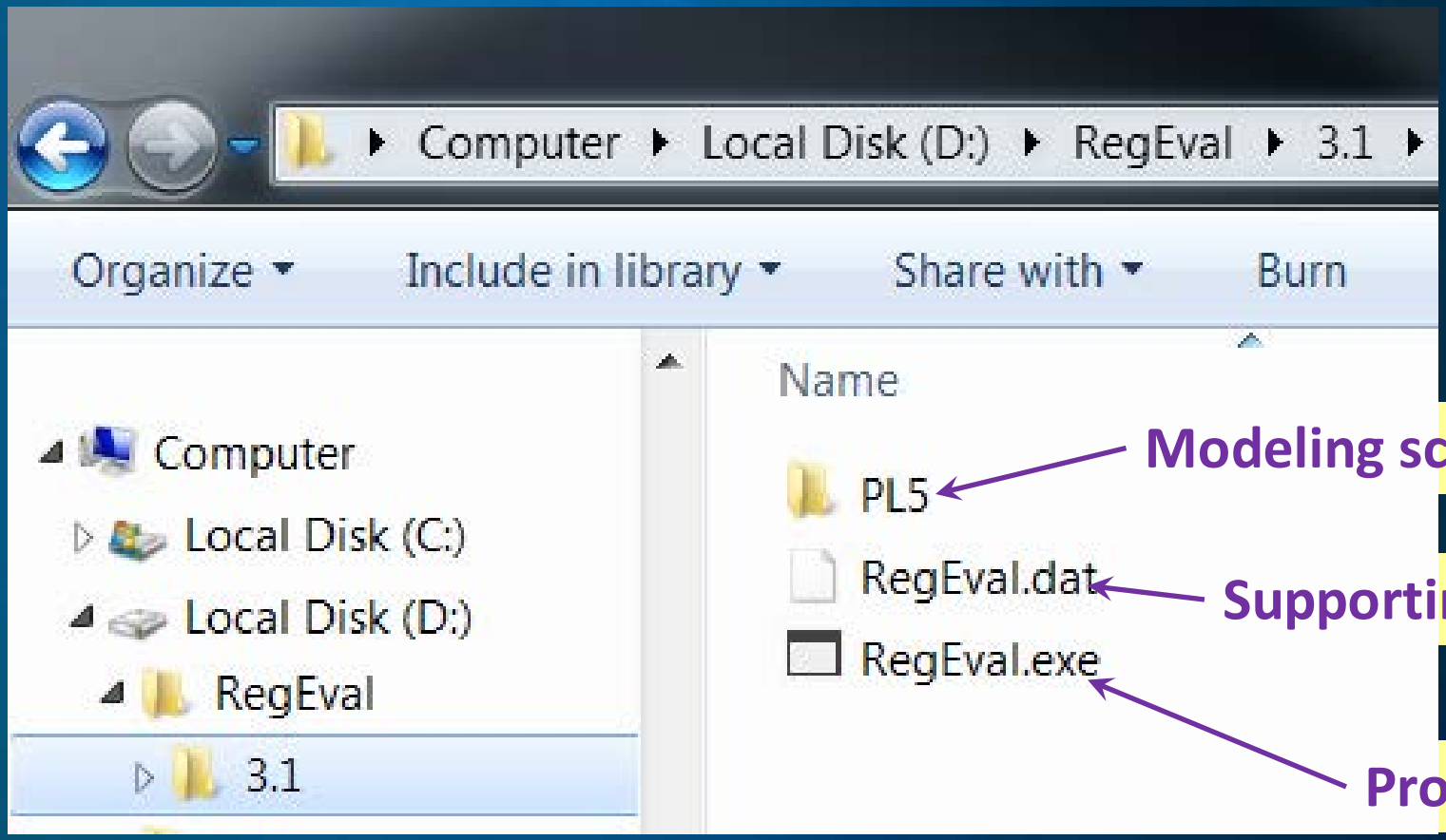
- USEPA AgDrift/AgDisp
  - for off-target spray drift to a surface
  - Example: "Zenivex E4 RTU" containing etofenprox, adult mosquito insecticide over agricultural areas
  - "*The AGDISP model predicted that about 37% of the applied a.i. settles onto surfaces.*" (#262551)
- MAM-PEC (marine antifoulant model to predict environmental concentrations) by Deltares (Netherlands)
  - Modeling scenarios defined (Xuyang &Nan, 2014)

Model Tutorial

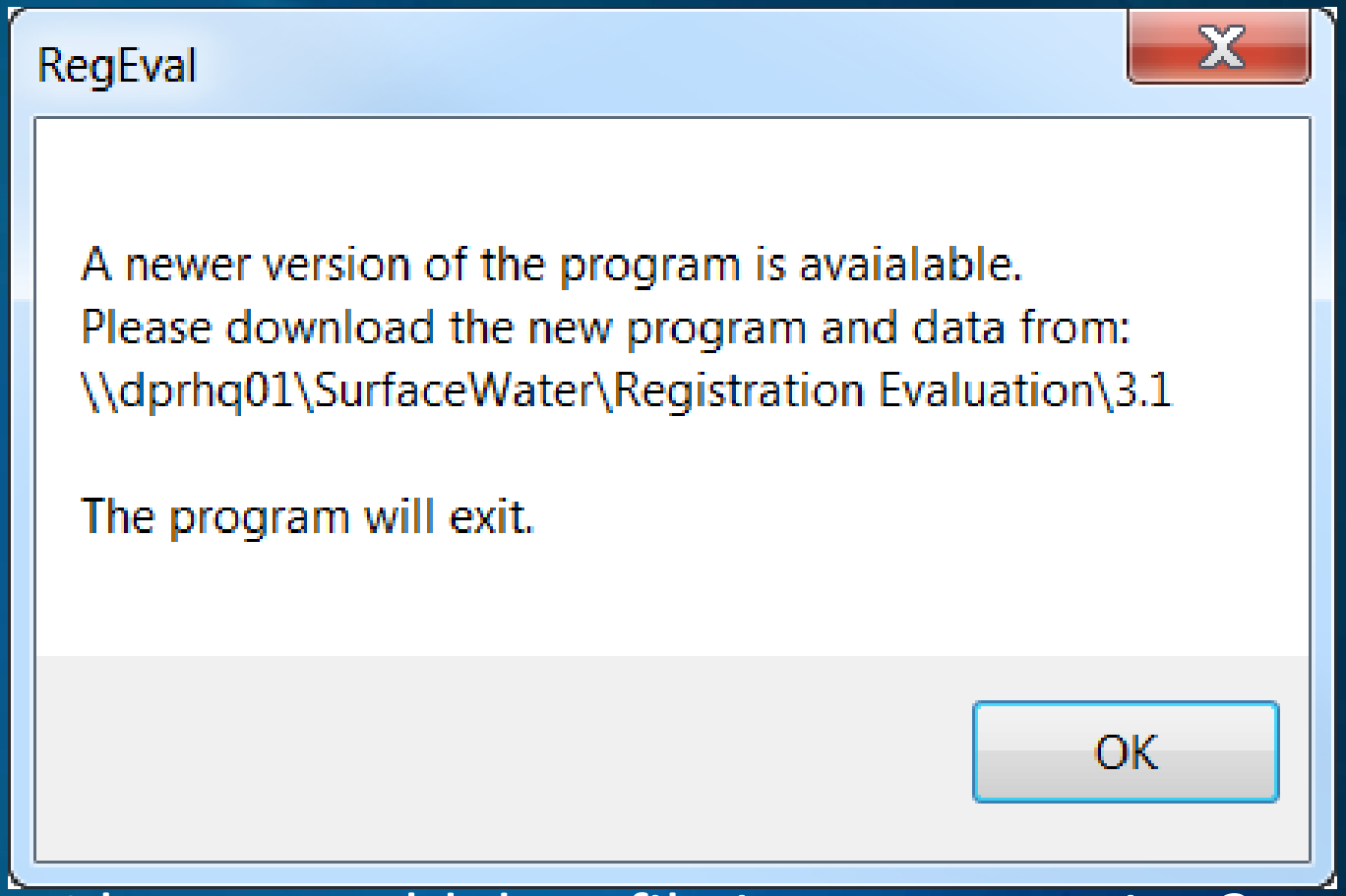
User's manual
(http://www.cdpr.ca.gov/docs/emon/surfwtr/review.htm)

File structure of the model

- Training\RegEval3.1\



Updating (if applicable)



- Can I keep my old date file in a new version?
  - Probably, if the upgrade is only for the program (not for data structure)
- So, save your old data. I can help for data migration

Demonstrations and exercises

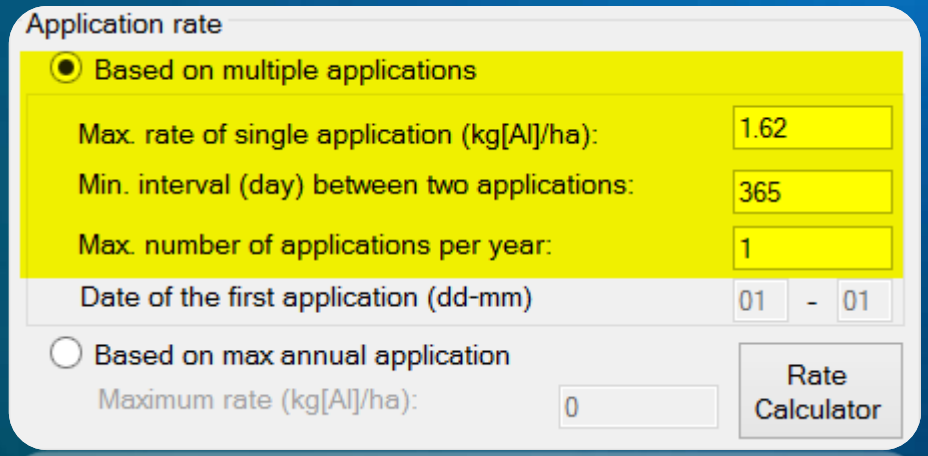
1) Add a new AI
2) A simple test
3) Urban evaluation

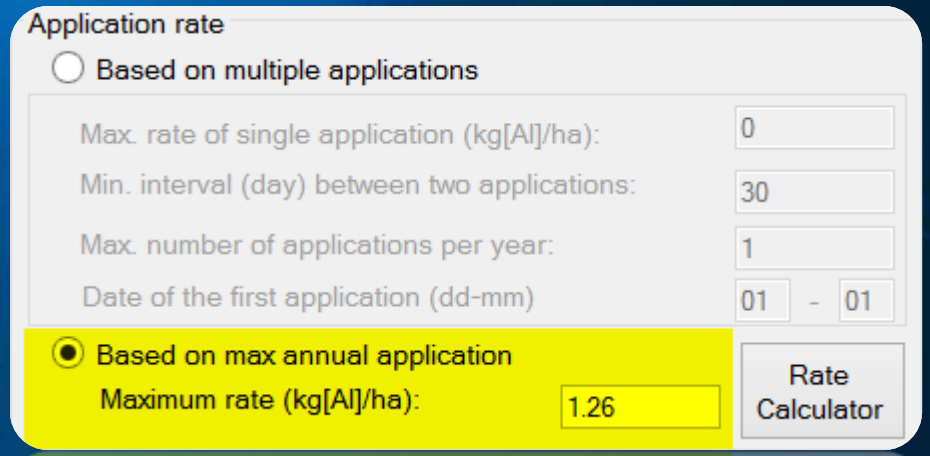
Exercise 1: add a new AI

- Create a new chemical (*any name*), with
  - SOL=20.4 (water solubility, mg/L)
  - KOC=421.5 (K_{OC}, L/kg[OC])
  - HYDRO=999 (hydrolysis half-life; 999 d for stable)
  - AERO=137 (soil aerobic metabolism HL)
  - ANAER=18.2 (soil anaerobic metabolism HL)
  - FD=8.65 (field dissipation)
  - TOX=660 (the lowest acute toxicity value, ppb)
  - Leave blank for other fields
- Save changes

Exercise 2: a simple test

- Chemical: the one you just created
- Use pattern: almond
- Application
  - Single application rate (kg[AI]/ha) = 1.26
  - Apply once per year
- Run





Exercise 2: results

```
Registration Evaluation for Surface Water Protection, Version 3.1
Modeling Input/Output Data Summary

Active ingredient: Fenpyrazamine
Modeling approach: SWPP Registration Evaluation
Product information: in the evaluation report

Inputs [1]: physiochemical properties and environmental fate data
================================================================
           20.4 | water solubility (mg/l)
          421.5 | OC-normalized soil adsorption coefficient (l/kg[OC])
   NA or stable | hydrolysis half-life (HL) (day)
            137 | aerobic soil metabolism HL (day)
           18.2 | anaerobic soil metabolism HL (day)
           8.65 | field dissipation HL (day)
   NA or stable | aerobic aquatic metabolism HL (day)
   NA or stable | anaerobic aquatic metabolism HL (day)

Inputs [2]: acute toxicity to aquatic organisms
================================================================
            660 | the lowest toxicity in water (ppb)
 NA or nontoxic | the lowest toxicity in sediment ([Mu]g/kg, 1%OC assumed)

Inputs [3]: use pattern and application rate
================================================================
           High | exposure risk to surface water (high/low)
Almond/pistachio/walnut/peach/plume | use pattern
           1.26 | the maximum application rate per year (kg/ha)

Outputs [1]: water column (dissolved phase)
================================================================
           High | runoff potential (based on solubility, KOC, field dissipation, and use pattern)
           High | aquatic persistence (based on aquatic half-lives)
           High | aquatic toxicity
            Low | risk quotient (based on label rate, use pattern, and toxicity)
          Watch | model-based recommendation

Outputs [2]: sediment (adsorbed phase)
================================================================
evaluation for adsorbed phase is not conducted.

Registration recommendation:
================================================================
data/information support conditional registration, and the AI will be placed in the watchlist for monitoring
```

Exercise 2: results

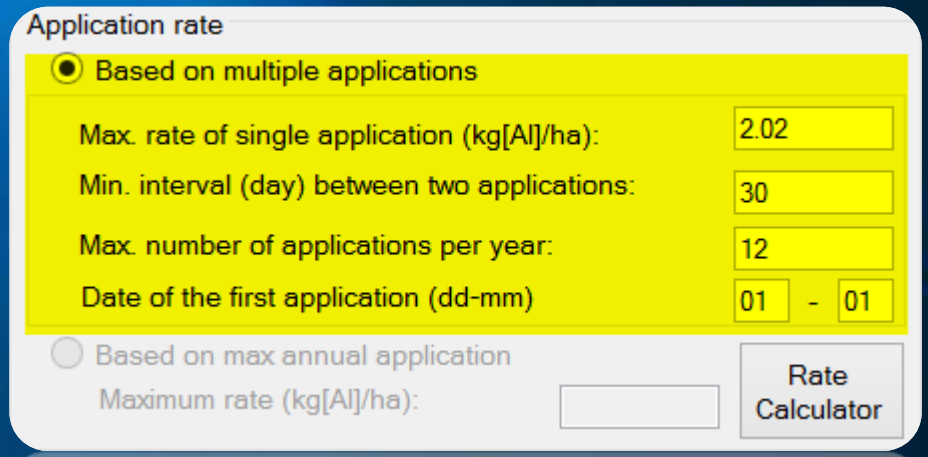
- Not just an exercise, you have (partially) finished a REAL evaluation!
- “Protexio (V-10135) Fungicide”(#249385) containing fenpyrazamine

Exercise 3: urban evaluation

- Urban module is recently developed, not used in any official SWPP evaluation
- Example
  - DuPont Arilon Insecticide, Indoxacarb, potential monthly applications to residential paved areas (#256184)
  - Input data mainly from a previous evaluation report (http://em/localdocs/pubs/rr_revs/rr1326.pdf)

Exercise 3 (cont'd)

- Select "indoxacarb" as the AI
- Use pattern: "urban uses"
- Application
  - Single application rate (kg[AI]/ha) = 2.02
  - Monthly applications (12 app's @ 30-d interval)
- Run



Exercise 3 (cont'd)

Additional data for urban evaluation

Label information for urban uses

Use pattern: Residential | Commercial/industrial | Rights-of-way

Product formulation: Liquid | Granular

Application method: Application on paved areas

Width of application (ft), if applicable: [1] ground= 0 [2] wall= 0 Update

Parameters (in area fraction) for calculating effective application rates

	Maximum	Suggested	Adjusted
[1] treated pervious suface, without dry-weather runoff	5 %	0 %	0 %
[2] treated impervious suface, without dry-weather runoff	74 %	0 %	0 %
[3] treated pervious suface, with dry-weather runoff	12 %	0 %	0 %
[4] treated impervious suface, with dry-weather runoff	9 %	9 %	9 %

Note: for [4] it's possible that [treated area]>[maximum area] with wall treatment. Submit

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Reporting & Finalizing

You have a Model Recommendation… Now What…?

- Put things in perspective. Model is to help you think.
  - Example: Clipper Aquatic Herbicide (Flumioxazin)
- Do you still have other concerns?
- Do you need additional data?
- Does modeling scenario make sense?
  - Example: Aproach Fungicide (picoxystrobin)
- Can overall modeling be improved?
  - Example: Zenivex Insecticide (etofenprox)

Recommendation = Support

- Aquatic risks are generally acceptable
- Generally for cases where:
  - Aquatic toxicity is low
  - Runoff potential is low
  - A.I. not persistent
  - Low risk use pattern
  - RQ ≤ 0.5
- Registrants are happy ☺…
- Note that we can deny or make conditional if very good reason

Recommendation = Deny

- Risks are not acceptable
- Generally for cases where:
  - Aquatic toxicity is high or very high
  - Runoff potential is high
  - A.I. is persistent
  - High risk use pattern
  - RQ > 0.5
- Registrants are not happy ☹
- Rebuttals will follow & that's okay…

Recommendation = Conditional

- For cases "in-between"
- Generally:
  - High or very highly toxic
  - Not persistent, but high risk use pattern
  - Persistent, but low risk use pattern
- Could potentially move off-site
- Registrants have mixed feelings…(?) but use <u>is</u> allowed
- A.I. placed on SW "watch list"
- Water & sediment method = core condition
- Remember we can still "deny" (e.g., flumioxazin)

Recommendation = Conditional

- You may choose to add additional conditions
- if registrant-submitted data & open literature are not enough
- Commonly asked = Degradate data
  - Field & aquatic dissipation
  - Aquatic toxicity data
- PLEASE add time allowance for data submission
  - Example, "…submit data within 6 months of the date of this notice."

What is Flagging?

- If first products with new a.i. are
  - Very highly or highly toxic
  - High runoff potential
  - Persistent
  - But… use patterns are categorized as “low risk”
- We add a “flagged” box & text in conclusion section on eval memo to notify Registration Branch staff (e.g., novaluron)
- [X] AI flagged for Future Surface Water Review

Eval Report

- See template in User Manual
- Blank memo template in share drive
- Try to keep the prescribed format
  - Background: Basic info on product, a.i., label, use pattern, target pests. Provide perspective & context
  - Evaluation: Model yes/no? Explain & justify what you did for various model inputs. Anything noteworthy should be discussed here. For multiple products, summary table good.

Eval Report

- Conclusion: Present your "recommendation." What are consequences? If conditional or deny provide some guidance to registrants
- References: Registrant-submitted studies, other evaluations, open lit.
- Appendices: Model input/output (multiple?).
  - Remember to change Mu/kg to µg/kg!
  - Helps to highlight key info in raw input/output file
  - One page = One input/output file

Eval Report Tips

- Consult w/ me or Yuzhou on your approach
- Consult previous SW evals
- Consult peers
- Consult “User Manual”
- Consult “Methodology” documents
- Is your eval clear, logical & can stand up to scientific scrutiny???
- Please proofread your draft before submitting to me
- Remember your memos are seen by many EYES…

Final Procedural Steps

- Fill out product/packet info as much as possible on memo
- Check the appropriate box(es)
  - Should match conclusions
- Once Branch Chief approves, goes to "Evalreports"
- After approval, sign original memo & make 3 additional copies & put them in packet
- Fill out packet's status sheet & give to Jackie
- I will have the memo posted internally

- Overview (Nan)
- Data preparation
  - Active ingredient (AI) data (Yuzhou)
  - Product label (Nan)
- Modeling & GUI demonstration (Yuzhou)
- Reporting (Nan)
- Q&A