

US EPA ARCHIVE DOCUMENT

# Pesticide Program Dialogue Committee (PPDC) PRIA Process Improvement Workgroup



May 9, 2007

Marty Monell  
Deputy Director

# Statutory Provision

- “To the maximum extent practicable consistent with the degrees of risk presented by pesticides and the type of review appropriate to evaluate risks, the Administrator shall identify and evaluate reforms to the pesticide registration process under this Act with the goal of reducing decision review periods in effect on the effective date of the Pesticide Registration Improvement Act of 2003 for pesticide registration actions for covered pesticide registration applications (including reduced risk applications).”

# Topics and Panel Members

- On-line Payment of PRIA Fees and Electronic Submission – Oscar Morales, Director, Information Technology and Resources Management Division
- Labeling Committee and E-label Review – Donald Stubbs, Associate Director, Registration Division and Chair, OPP Labeling Committee
- Inerts – Pauline Wagner, Chief, Inerts Assessment Branch, Registration Division
- GIS and Environmental Assessments – Michelle (Shelly) Thawley, GIS Coordinator, Environmental Fate and Effects Division

# **On-Line Payment of PRIA Fees and Electronic Submission**

Oscar Morales  
Director  
Information Technology and  
Resources Management  
Division

# *Pay PRIA Fees On-Line*

- PAY.GOV
- Service Provided by the Treasury Dept.
- Free, Reliable, Secure
- Implemented for PRIA on Nov. 1, 2006
- 193 PRIA Payments (35% of Total)
- 55 Companies Have Paid On-Line
- \$705,135 Collected On-Line



Provided by the US Department of the Treasury

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## U.S. Environmental Protection Agency Office of Prevention, Pesticides and Toxic Substances

### Pesticide Registration Improvement Act Fee Payment

**Please fill in the form completely**  
**Click [Submit Data](#) to make your payment**

Company Name	<input type="text" value="My Company"/>	Contact Name	<input type="text" value="John Jamula"/>
Telephone Number	<input type="text" value="(703) 305-6426"/>	Email Address	<input type="text" value="jamula.john@epa.gov"/>
Decision Number	<input type="text" value="D-123456"/>	Registration Number	<input type="text" value="999999-88888"/>

Payment Amount



**Option 2: Pay Via Plastic Card (PC) (ex: VISA, Mastercard, American Express, Diners Club, Discover)**

Required fields are indicated with a red asterisk \*

Account Holder Name:  \*

Payment Amount: \$50,000.00

Billing Address:  \*






Billing Address 2:

City:


State / Province:

Zip / Postal Code:

Country:

Card Type:  \*     

Card Number:  \* (Card number value should not contain spaces or dashes)

Security Code:  \*  (On the back of your Card, find the last 3 digits) [Help finding your security code](#)

Expiration Date:  \* /  \*

Select the "Continue with Plastic Card Payment" button to continue to the next step in the Plastic Card Payment Process.

**Note:** Please avoid navigating the site using your browser's Back Button - this may lead to incomplete data being transmitted and pages being loaded incorrectly. Please use the links provided whenever possible.

# *e-Submission Goals*

- Facilitate submission process
- Improve processing time
- Lessen burden on industry
- Reduce iterations
- Improve data quality
- Harmonize internationally
- Standardize formats

# *e-Submission Pilot Goals*

- Demonstrate that e-Submission can work.
- Establish data exchange standards.
- Begin harmonization with NAFTA and OECD.

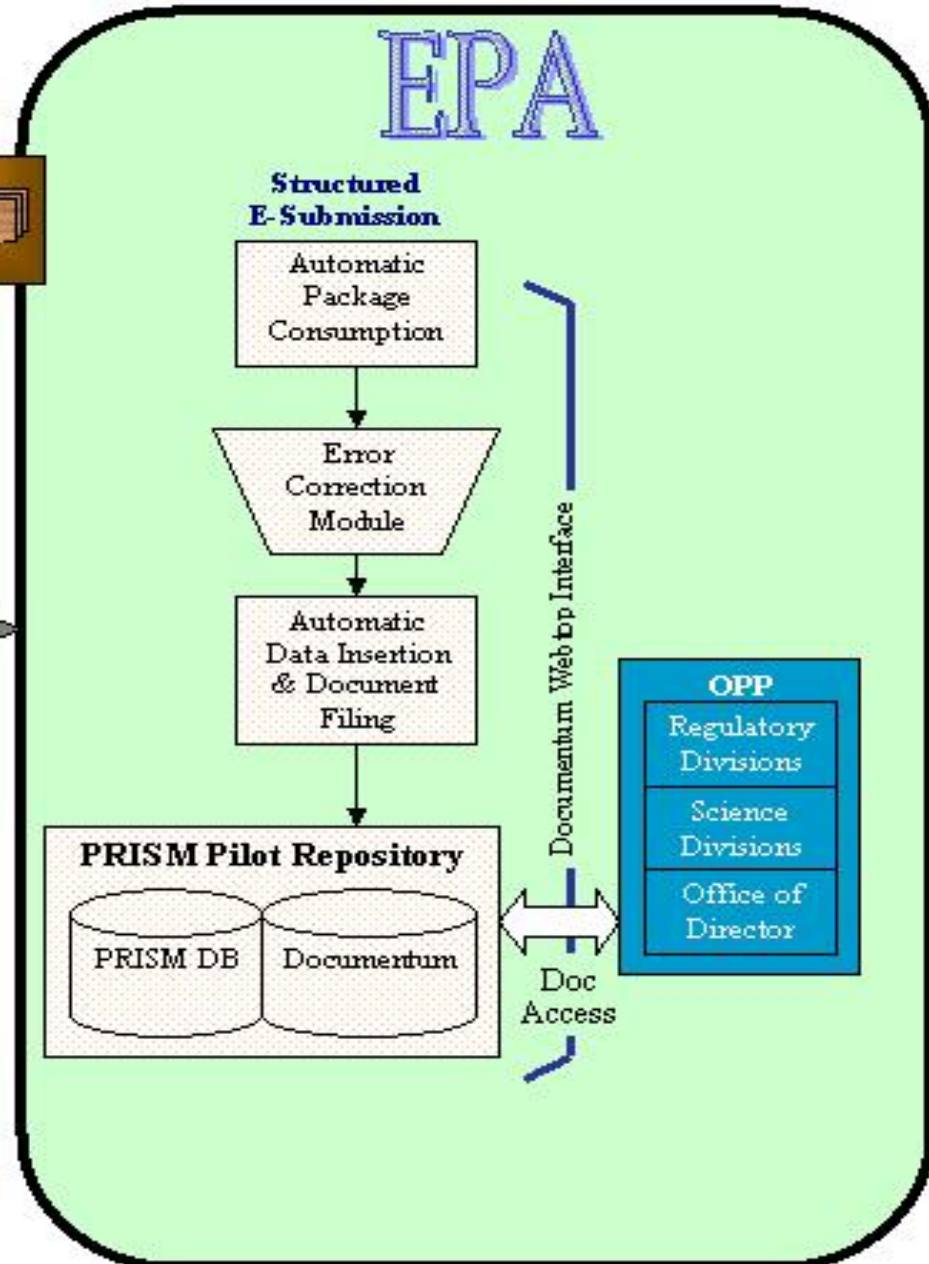
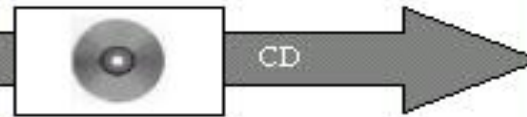
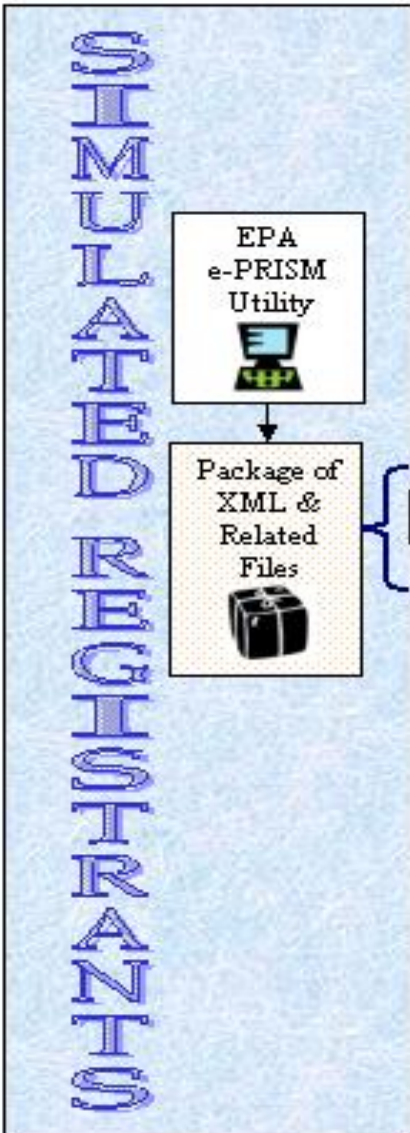
# *e-Submission Pilot Steps*

- Provide proof-of-concept for e-Submission methodology
- Validate benefits for industry
- Validate harmonization using one schema for multiple agencies
  - PMRA naming conventions are maintained
  - Potential harmonization with the CADDY XML system
- Identify technical issues

# e-Submission - Pilot

## To EPA:

1. Application Data (e-PRISM)\*
  2. Related Docs
    - Study Profiles\*
    - Studies
    - Prototype Label\*
- \* *Structured Data Format (XML)*



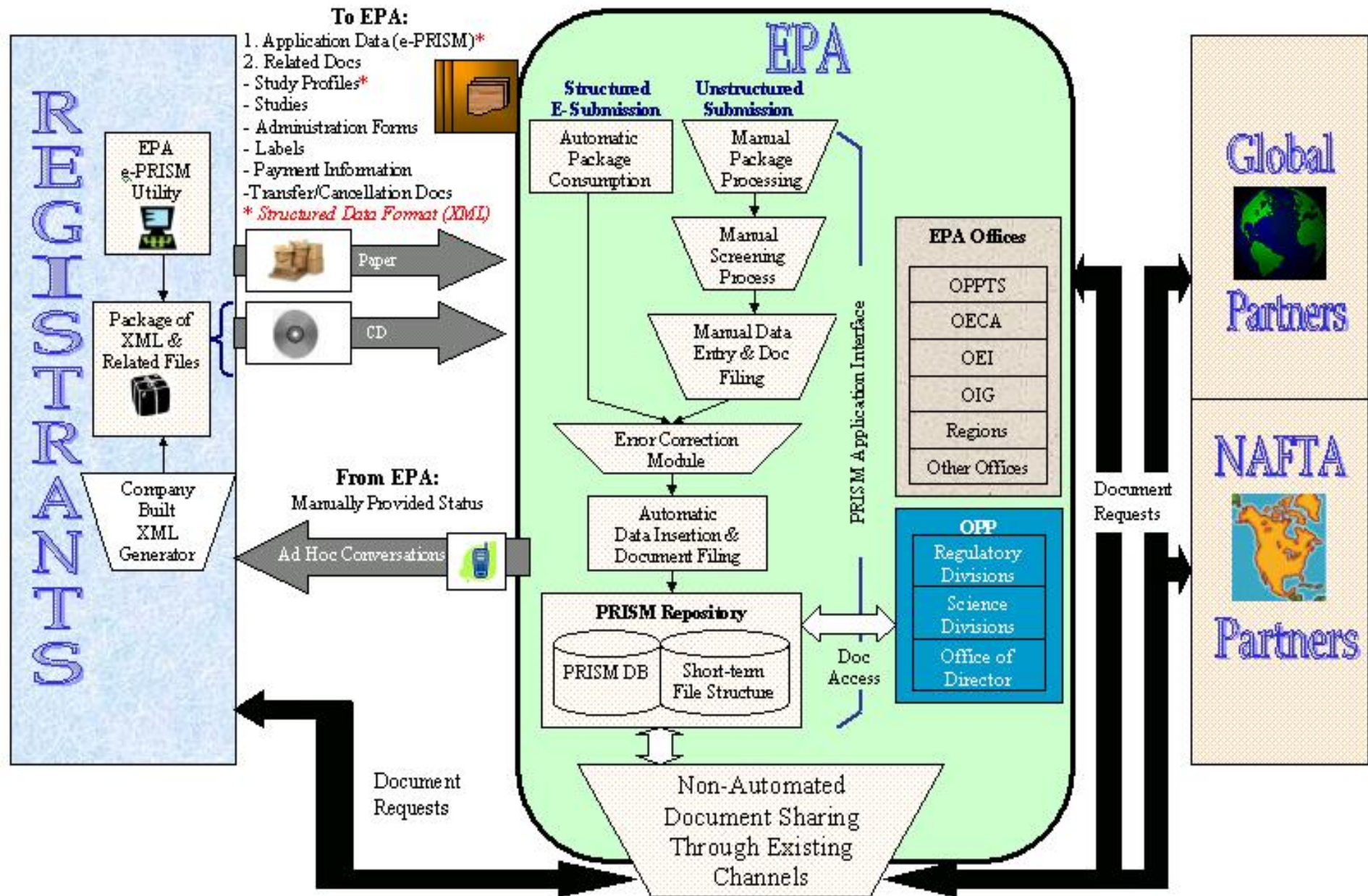
# *e-Submission Pilot Technical Approach*

- Provide a Data Dictionary
- Limited types of applications
  - Section 3 registrations
  - EUP
  - Distributor products
- Leverage existing PMRA XML schema
- Submission via CD or DVD
- Error Correction Module

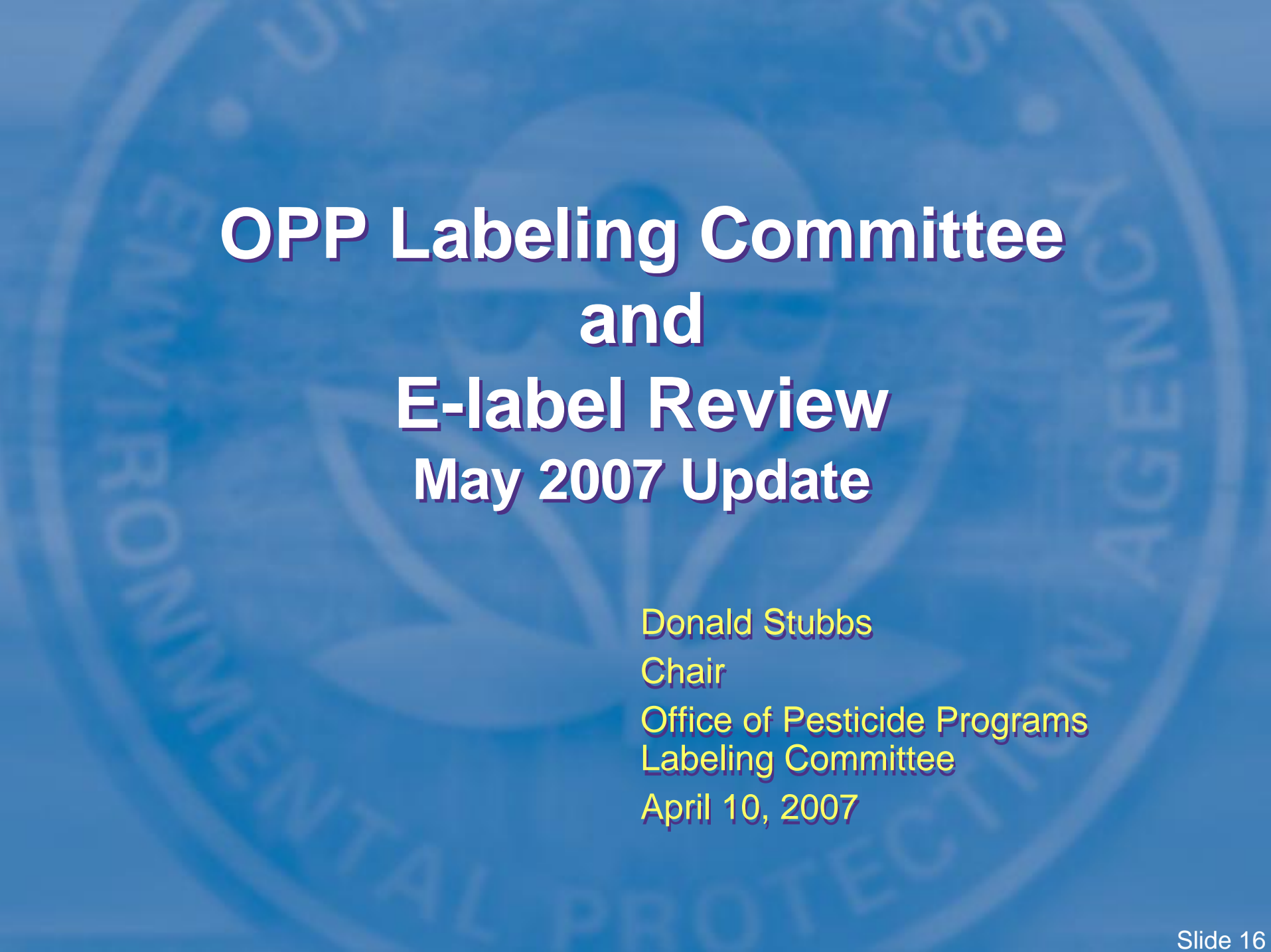
# *e-Submission Pilot Participants*

- BASF
- Bayer Crop Science (Submitted 5/2)
- Syngenta
- Keller & Heckman
- Valent

# e-Submission – Vision







# **OPP Labeling Committee and E-label Review May 2007 Update**

**Donald Stubbs**

**Chair**

**Office of Pesticide Programs  
Labeling Committee**

**April 10, 2007**

# Charge

- Serve as a clearing house for broad cross-cutting label issues
- Manage a web site devoted to labeling issues
- Revise and keep current the Label Review Manual

# Addresses

- E-mail box is available at:  
[OPP\\_labeling\\_consistency@epa.gov](mailto:OPP_labeling_consistency@epa.gov)
- Web page can be found at:  
[http://www.epa.gov/pesticides/regulating/labels/label\\_review.htm](http://www.epa.gov/pesticides/regulating/labels/label_review.htm)

# Questions and Answers

- Received 89 questions as of Mar 30
- Completed 83
- We are working on 6 questions.
- Referred 29 elsewhere in OPP/OECA
- Posted 54 Received

# Updating the LRM

- Created subgroup to work on updating the LRM.
- Team is converting LRM from *Wordperfect* to *Word* and revising the LRM for straightforward corrections and compliance with current policy
- First three chapters of Revised LRM have been updated and posted.
- Chapters 4,5 and 6 are being reviewed by the label committee

“Contains the same  
Active ingredient ...”

- Developed guidance paper
  - Can only add by amendment not notification
  - Other guidance deals with
    - Product referenced
    - Placement
    - Disclaimer
    - Font size and type

# “Minimum Application Paper”

- Posted in November for comment; received 6 responses to the paper
- Based on review of the comments and our statutes we believe there are times when labeling should have minimum use rates.

# “Minimum Application Paper”

- 1. When there is a risk that reduced application of the product may result in increased pest resistance to the active ingredient.
- 2. When there is documentation that a product’s efficacy is substantially compromised under a certain application rate.

If the bases for a minimum use rate cannot be documented, the minimum application rate should be stated in advisory language.



# Environmental Hazard General Labeling Statements on Outdoor Residential Use Products

- The PPDC Consumer Pesticide labeling Improvement Workgroup presented recommendations to OPP on general environmental hazard labeling for outdoor consumer residential use products.
- OPP will be issuing a PR notice in the near future giving guidance on how to revise labeling for general environmental hazard labeling for outdoor consumer residential use products.

# E-label Review

- Label review by comparing labels in PDF using the comparison abilities of Adobe Acrobat.
- Agency Staff are currently being trained – full implementation in June, 2007
- Next session how registrants should submit an electronic label will be held May 10 at 2:00 pm
- Registrants encouraged to submit their labels in PDF format

# Process Improvements for Inert Ingredients

Pauline Wagner  
Chief  
Inerts Assessment Branch  
Registration Division

# New Front-End Screening Pilot

- All Actions (PRIA and non-PRIA) will be screened by a member of the Inerts Branch
  - For PRIA Submissions
    - After PRIA code is assigned, application package will be screened for proper use of inert ingredients
    - If non-cleared inert ingredient is present, the process will stop and package returned to registrant
  - For non-PRIA Submissions
    - Same process except no PRIA code is assigned

# Options when uncleared inert ingredient is present

- Reformulate
- If food use product, petition for exemption from the requirement of a tolerance for the uncleared inert ingredient
- Withdraw

**INERT CLEARANCE STATUS FORM**  
**DP BARCODE No.: \_\_\_\_\_ D \_\_\_\_\_ ; ACTION CODE: 345**

Reviewer Name:			Request date:
Tel:	RGO.: IIAB/RD	CUBE:	MAIL CODE: 7505P

**A. COMMENTS:**

**B. PESTICIDE PRODUCT INFORMATION:**

EPA Reg. No/File Symbol:	Date on CSF:	Food-Use Pesticide: <input type="checkbox"/> Yes <input type="checkbox"/> No
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**C. INGREDIENT INFORMATION:**

Ingredient No.1	Tolerance Exemption(s)					
	910	920	930	940	950	960
Chem. Name:						
Trade Name:						
CAS Reg. No.:						
Comments:						

Ingredient No. 2	Tolerance Exemption(s)					
	910	920	930	940	950	960
Chem. Name:						
Trade Name:						
CAS Reg. No.:						
Comments:						

Ingredient No. 3	Tolerance Exemption(s)					
	910	920	930	940	950	960
Chem. Name:						
Trade Name:						
CAS Reg. No.:						
Comments:						

Ingredient No. 4	Tolerance Exemption(s)					
	910	920	930	940	950	960
Chem. Name:						
Trade Name:						
CAS Reg. No.:						
Comments:						

Completed By: \_\_\_\_\_

Date Completed: \_\_\_\_\_

**C. INGREDIENT INFORMATION:**

# Fragrance Notification Pilot

- New process for notification of formulation changes that involve only fragrances
- FMA Data base of fragrance components placed on website
- Registrants must certify proposed fragrance change is only change in formulation
- All fragrance components are on FMA database
- Pilot will run for 120 days, starting early May
  - Announcement of pilot is on the Inerts website
  - EPA will evaluate results
  - If successful, will be permanent change in procedure for fragrance changes

# The Lists

- Are on Inert website as Lists 1, 2, 3, 4a and 4b and tagged as obsolete
- Mixed food and non-food use inert ingredients
- All reassessed food use inert ingredients are automatically List 4b
- Inerts Branch is beginning to update Lists beginning with List 1
  - Time consuming
  - Must search by product for non-food uses
  - Some set of non-food use inerts are not currently in use
  - Will rescind permission to use these in the future if hazard profile warrants
- Will proceed to List 2, then List 3 and so on until review is complete



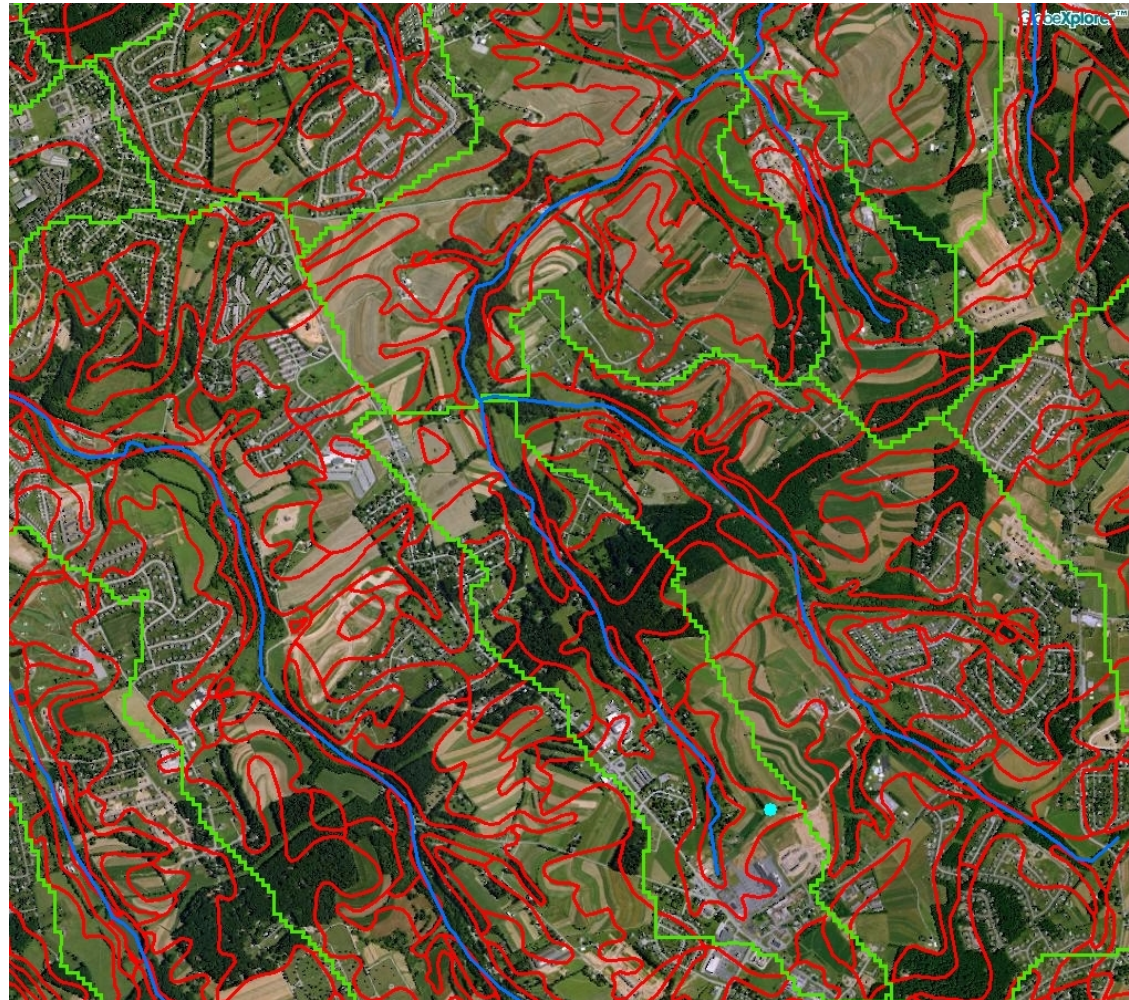
# **GIS and Environmental Assessments**

Michelle (Shelly) Thawley  
GIS Coordinator  
Environmental Fate and  
Effects Division

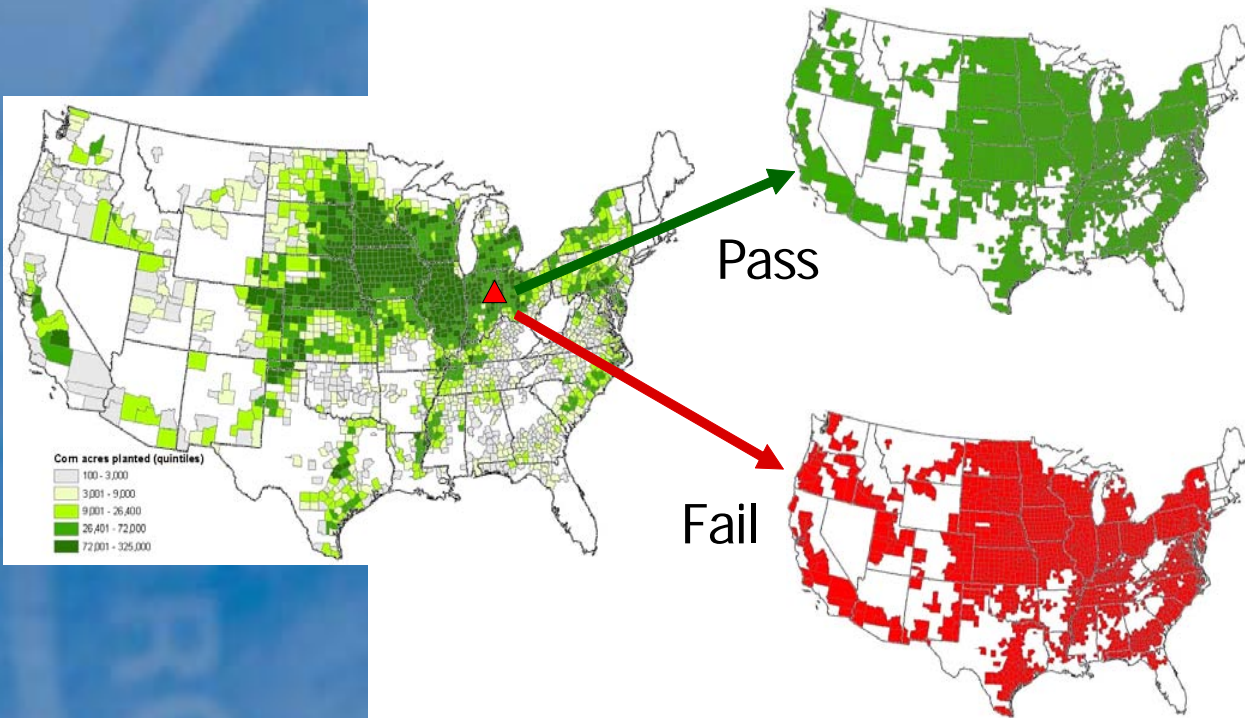
# Moving Away From Scenarios...



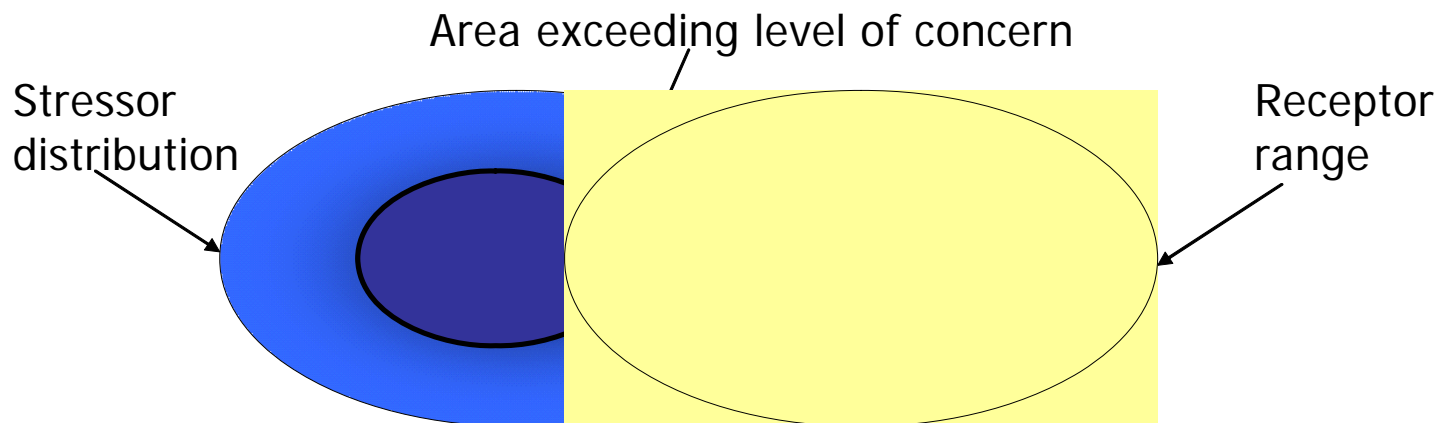
# Towards the Spatially Explicit



# Adding a spatial component



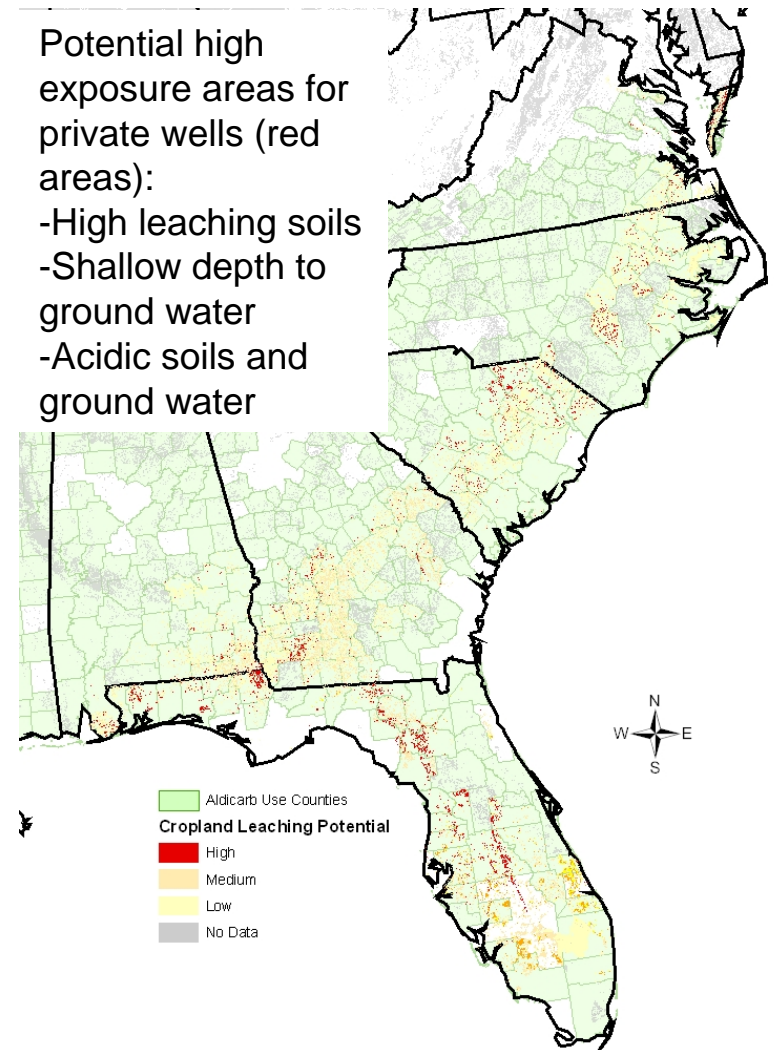
From single scenario screen to spatially-explicit assessment



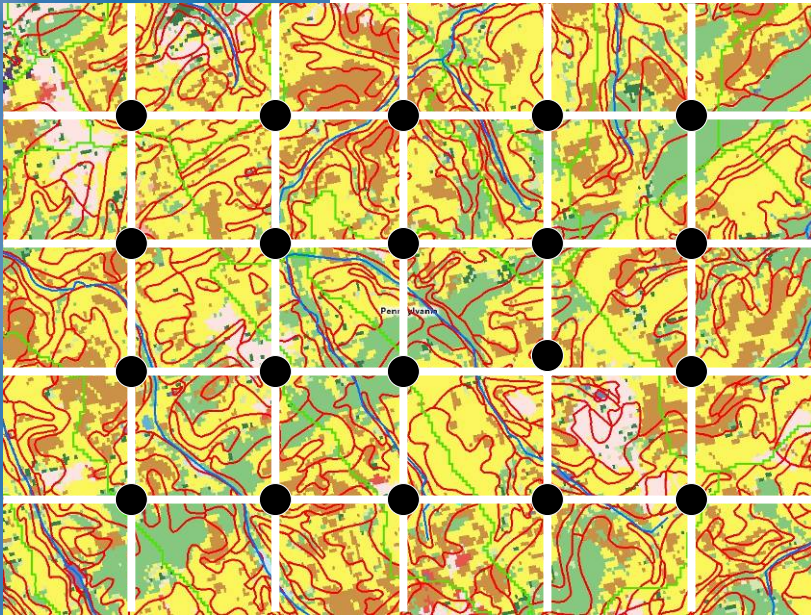
# Example: N-methyl carbamate assessment

Extrapolating to broader extent

- Lack of monitoring in other use areas
- Linked monitoring to soil and hydrologic characteristics
- Identified similar soil and hydrologic conditions elsewhere
- Limited by available data (soil, hydrology, land cover, monitoring)



# From Spatial Data To Model Input Grid Approach



There are various ways to approach a spatial model adaptation. The proto-type tool will begin with the grid approach:

- A grid is placed over the area of interest
- The resolution of the grid can be modified
- The exposure model is run for each grid point using input values from the specific location
- Results of point locations can be interpolated or summarized to a watershed or waterbody

# Update From Nov. '06 Workgroup Mtg.

- Enterprise GIS database to come on-line Sept. 2007
- Prototype spatial modeling tool in development
- Land Use Data Sets in Development
  - Ex. Urban uses, Turf, Non-ag. Uses
- Design Validation