US ERA ARCHIVE DOCUMENT

Pesticide Program Dialogue Committee (PPDC) PRIA Process Improvement Workgroup



April 28, 2010

Introductions and Announcements

Marty Monell
Deputy Director
Office of Pesticide Programs
April 28, 2010

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)."

Updating the "Blue Book"

The Blue Book Committee

bluebook@epa.gov
April 28, 2010

Background on the "Blue Book"

- Original Title: General Information on Applying for Registration of Pesticides in the United States
- Provides a basic "how-to" guide to pesticide registration and regulation.
- Previous Version (Second Edition) issued in August 1992.
- New version reflects current-day regulations and procedures
- Pesticide Registration Manual Available on EPA Web on March 16, 2010 http://www.epa.gov/pesticides/bluebook/

Blue Book History

- Second Edition was updated prior to PRIA and then again in 2005/2006 to incorporate FQPA and PRIA changes, latest mailing addresses, in-processing procedures, etc.
- Edited
- To obtain comments a focus group of potential users was held April 20, 2006

Focus Group Members

- Industry Representatives
 - Russ Schneider, Monsanto
 - Ron Derbyshire, Johnson Diversey
 - Ted Head, NuFarm America
 - Maria Herrero, Valent Biosciences
 - David Jones, Nice-Pak
 - Jim Kunstman, PBI Gordon
 - Patrick McCain, Syngenta
 - Barbara Christianson, Acta Group

- Bob Stewart/Heather Bjornson, Technology Sciences Group
- Karen Warkentien, Lewis & Harrison LLC
- EPA Representatives
 - Elizabeth Leovey, OPP/IO
 - Michael Hardy, AD
 - Beth Edwards, RD
 - Linda Arrington, RD
 - Mike Mendelsohn, BPPD

Summary of Focus Group Meeting

- The Blue Book is one of the most helpful EPA publications for registrants.
 - Geared for smaller companies but useful to all registrants, large and small.
 - A condensed "Cliffs Notes" version of the regulations.
 - Provides basic information with links to statutes, regulations, and guidance documents.
 - Need to resist the urge to include too much information (becomes too voluminous and unwieldy).

Summary of Focus Group Meeting (continued)

- Specific Comments: Chapter Flow
 - Chapter flow needs to be addressed.
 - First chapter should introduce what will follow in remaining chapters.
 - More discussion of what is necessary prior to registration.
 - Is a registration required?
 - What needs to be considered?
 - Strengthen definition of terms
 - Make more user-friendly.
 - Utilize "highlight" boxes.

Summary of Focus Group Meeting (continued)

- Make more step-oriented (e.g., decision tree or similar)
- Briefly touch on the other aspects of registration
 - State registration
 - Recordkeeping
 - Enforcement and compliance
- Need to discuss status of PRIA (may be extended).
- Link to information on fee categories and fees.
- Discuss e-submissions
- Update links to CFR and other references.
- Include links for state and regional contacts.
- Explain when various forms are/are not required.
- Discuss data compensation obligations for both existing (FIFRA §3(c)(1)(F)) and future/ongoing (FIFRA §3(c)(2)(B)) studies.
- Include examples of completed forms and checklists.
- Show a complete application submission in appendices.

Blue Book History

- Revised per Focus group comments more examples included, tips on improving applications, and decision tree
- Reviewed again within OPP for "readability" and accuracy, i.e. ITRMD reviewed examples for compliance with 86-5
- OGC and then Deputy Director review (2006/2007)
- Electronic version was posted on a password protected site
- PRIA 2 passed in late 2007 requiring additional revisions
 - Some chapters were substantially revised, for instance, Chapters 3, 4, 5, 8 and 19
- OGC review of revisions started summer 2008

Blue Book History

- Once revised per PRIA 2 and updated, underwent an editorial review, fall 2009 – winter 2010
- OGC review of edits
- Web page revised for conformance with current EPA Web requirements, winter/spring 2010
- Published on a Web site with each chapter a Web page for easy revision
- Each chapter dated
- E-mail address provided for comments and suggestions – bluebook@epa.gov



Blue Book

- E-mail box answered by The Blue Book Committee
 - Linda Arrington
 - Jeff Kempter
 - Mike Mendelsohn
 - Erin Koch
 - Elizabeth Leovey
 - Nicole Williams
 - Rachel Holloman

Next Steps

- Trade associations requested to provide comments, corrections and ideas for improvement prior to developing a hardcopy and inform their members of Web address.
- Word documents developed for each HTML chapter to make revisions
- Develop PDFs from revised word document and posted along with HTML pages
- Registration Division will publish hardcopies to place in the registration kit available upon request

Your Comments Needed

- Pesticide Registration Manual Decision Tree
 ideas to improve it for the first time user
- Increased explanation or understandability of sentences, paragraph, sections, etc.
- Additional, incorrect, or inoperable links
- Additional appendices guidance documents, examples, etc.
- Additional "Registration Sources"
- Send to bluebook@epa.gov

Public Participation for Registration Actions

Diane Isbell
Registration Division
U.S. Environmental Protection Agency

Public Participation Process Overview

- Historically, limited opportunity for public involvement in registration actions.
- October 1, 2009, the Agency began implementing a public participation process for registration actions.
- The process allows for public comment on proposed decisions and risk assessments for certain registration actions.



 Publication of a Notice of Receipt is required for all new active ingredients and new uses.

 Only a subset of these uses will be subject to the public participation process.



- Actions included in the process:
 - new active ingredients;
 - first food use;
 - first outdoor use;
 - first residential use; and
 - registration actions with significant public interest.

Public Participation Process

- Docket opens with the Notice of Receipt published in the Federal Register, available for 30-day comment period.
- Risk assessments are completed.
- Contact registrants regarding CBI claims on submittals not made through the 86-5 process. If claims are made, they will have to be substantiated.

Public Participation Process

 Proposed decision, risk assessments, and proposed product labels are added to the docket and are available for a 30-day comment period.

 Public notified of open comment period through OPP website and OPP updates.

Registration Decision

- Announce final decision with publication of Notice of Issuance in Federal Register.
- Documents posted with final decision include: final decision memorandum; response to comments; registration notice; revised assessments (if needed); and product label.
- Actions posted to the same registration docket as the Notice of Receipt.



 Updates will be made to a new Registration Application Status page, linking to the docket.

 Public Participation Process for Registration Actions



http://cfpub.epa.gov/pesticides/comment s.cfm

http://www.epa.gov/pesticides/regulating/ registration-status.html

http://www.epa.gov/pesticides/regulating/public-participation-process.html

Status of Public Participation for Registration Actions

Rob Forrest

Biopesticides & Pollution Prevention Division

U.S. Environmental Protection Agency



Current Status

 14 New Active Ingredients (12 -BPPD, 2 – RD)

 3 Actions of Significant Interest (PIPs)



 Certain actions have been considered for concurrent, timelimited registrations.

- For these actions, the Agency may consider the following:
 - Risks associated with the chemical;
 - Public Interest Finding; or
 - Anticipation of no adverse comments.



 Five biopesticide actions have received time-limited registrations.

 Concurrent, time-limited registrations are converted to a Section 3 registration if no adverse comments are received.

PRIA Due Date Renegotiations

 Two actions not renegotiated, registrations granted by original PRIA due date.

 Five actions renegotiated due to data deficiencies, no time was added because of public process.

PRIA Due Date Renegotiations (Continued)

 Five actions were renegotiated due to data deficiencies, additional time was added for the public process.

 Five actions renegotiated due to data deficiencies. These actions were granted time-limited registrations, concurrent with the public comment period.

Comments Received

 17 PRIA actions posted to the public docket.

53 comments have been received.

 To date, all comments are associated with biopesticide PRIA actions (plant-incorporated protectants).

OPP's Efficiency Contest

Michael Hardy
Special Assistant
Office of Pesticide Programs

Background

- In an effort to further improve efficiencies and streamline the registration process in OPP, a contest was held to solicit suggestions from OPP staff.
- Staff was reminded that no efficiency gains would be achieved by compromising science or risk management decisions.



- There were 24 submissions for consideration.
- Ideas for efficiencies ranged from regulatory to science to information technology.
- An OPP Panel was created to review the submissions.

Next Steps

- The OPP Panel meets for the first time on Friday, April 30th.
- Members of the Panel are, Lois Rossi, Tina Levine, Oscar Morales, and Michael Hardy.
- Recommendations to be made to Marty Monell, deciding official.
- Selection of the winner(s) to take place in May.



Questions?

Electronic Label Review

Lois Rossi

Director

Registration Division

U.S. Environmental Protection Agency



 COMPARE - proposed label to last version to quickly identify changes

 COMMENT - mark any needed revisions and return to registrant for corrections

Submitting E-Labels

- INITIAL submission can be done two ways:
 - On CD ROM along with paper application
 - On CD ROM in XML format (no paper) [e-sub]

 CORRECTIONS - response to EPA corrections can be emailed directly to staffer



- Text .PDF (not scanned image)
- Embed fonts
- Follow file name syntax:
 Reg#.yyyymmdd.anything

Reg#.yyyymmdd.anything else.PDF

example: 090898-00012.20100401.container displosal.pdf

Full details on web:

http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm

Common Errors

File name not correct

Don't forget period after reg# and date

(syntax and periods used to automatically create label database record)

Reg#.yyyymmdd.anything else.PDF

CD-ROM unreadable

Remember to "finalize" CD so it is readable on other computers



THANKS!

To all of you who have been sending in e-labels over the years.

We have almost 7,000 labels in the e-label database.

Label Accountability Initiatives Update

Jim Roelofs
Field and External Affairs Division
Office of Pesticide Programs
April 28, 2010



 Label Accountability Workgroup (LAW) analyzed the impact of labeling problems, and developed recommendations in 2008.

 The Recommendations are all being implemented

The LAW Recommendations

- Finish updating Label Review Manual
- Develop Training for Label Reviewers
- Improve SLITS as a feedback and management tool
- Develop Divisional Quality
 Assurance procedures



- Plan for web-based training tool
- Up-dating the Label Review Manual
- Enhancements to the SLITS system
- Divisional Quality Assurance plans
- Some issues from recent SFIREG meeting

Training

- Last year we held "all hands" session on core principles of label quality.
- Rest of 2009, a workgroup developed content of a basic training program.
- Contractor produced web-based program, delivered it end of January.

Core Principles: What a Label Should Be

- Consistent with Agency Policies and Regulations
 - Guidance is not "just guidance" variations need to be justified by registrant and accepted by EPA.
- Enforceable/Advisory Intentions Clear
 - Critical to Regional and State partners as well as users.

What a Label Should Be (cont)

 Clear -- fully understandable to the user, in terms of language and organization.

Accurate –

- reflects EPA's science reviews.
- does not have errors in instructions for use.

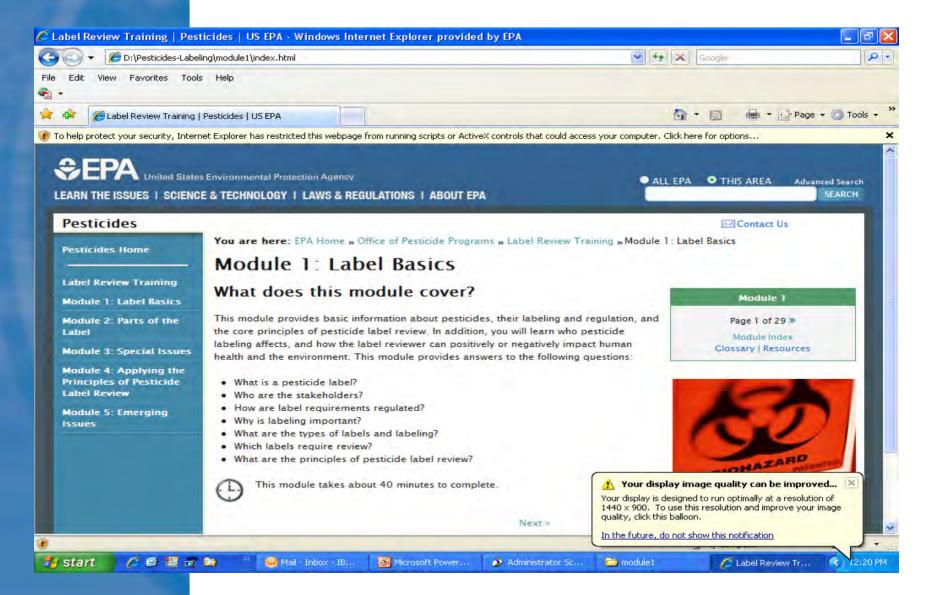
Web-based training tool for label reviewers

- Goal compact introductory basic training
 - What should a reviewer know on Day 1?
 - Not replace LRM, but a guide to its key parts.
- The core principles; importance of label to various stakeholders; the tools available to reviewers; how to resolve issues.

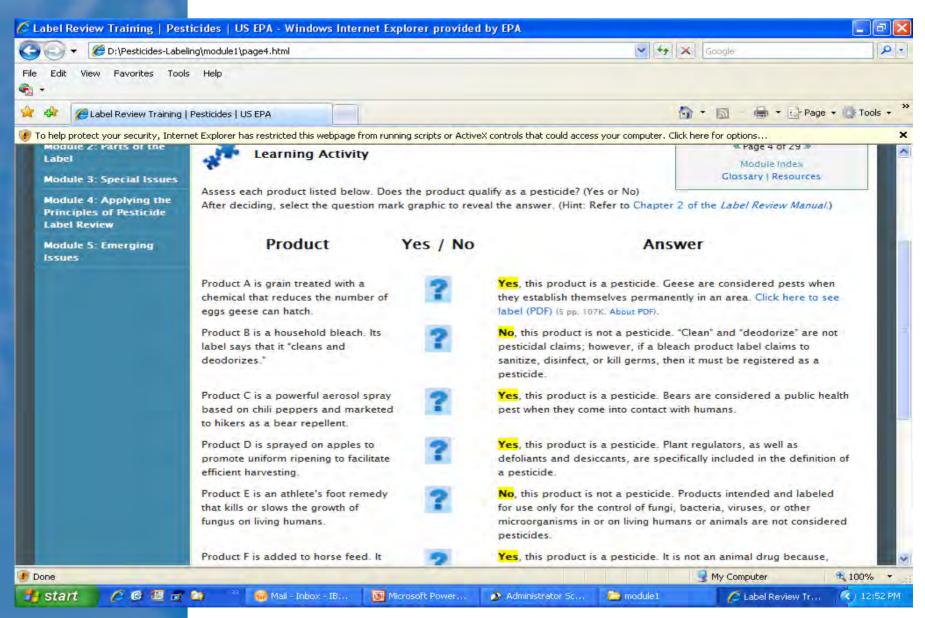


- About 3 hours in 4 modules
- Currently going through internal clearance process for posting to the web, and some minor tweaks to format.
- When this is made public, we encourage you to use it for your own label developers.

Opening page of module 1



Is it a pesticide quiz from Module 1



Updating the Label Review Manual

- Workgroup up-dated all the chapters between 2006 and 2009.
 - Not updating chapter 19 on Consumer Labeling Initiative
- Now entirely a web document accessible, links to supporting policy docs.
- Intent is to keep it "alive" open to improvement
- We will solicit comments soon a blog perhaps.
- SFIREG/POM committee also intends to comment on groups of chapters over the summer.



- State Label Issues Tracking System
 - Designed to ensure that a state (or Region) can direct a product specific question to right product manager
 - Get a timely answer
 - The answer is posted, so it is shared, others don't have to repeat it



SLITS continued

- Workgroup identified list of functional improvements.
- Have met with contractors; expect more user-friendly version soon.



- Each registering division came up with its own approach.
- Started putting into effect last year, as we described at the last meeting.
- Nothing new to report.



- Continues to operate public "label consistency" Q and A website.
 - About 350 received;
 - Revised the subject matter categories – hopefully easier to find relevant Qs and As
- No new issue papers published to LC website.

Label Issues raised by SFIREG

- Pesticide Operations and Management working committee – March 29 - 30
- Interested in reviewing LRM have a plan
- 3 Issue Papers submitted just before POM
 - Supplemental Labels want expiration date
 - Want EPA to stop allowing "for professional use only" and its variants.
 - Want clear distinction in appearance or location of advisory versus mandatory language.

Antimicrobial Efficacy Protocol Approval Process

Dennis Edwards
Antimicrobials Division



Tier 1 Protocols

 Tier 1 - Review of a public health efficacy study protocol within AD

A521

3 month review time line

\$2100

Tier 1 Protocols

- An application that requires the review of a modified protocol where only minor changes are made to an existing efficacy method (e.g. AOAC International, ASTM, AATCC) or an AD approved method described in A431).
- Examples of minor changes include:
 - varied test conditions (e.g., contact time, use of different hard surface carrier types [porcelain penicylinders vs. stainless steel penicylinders, or glass slide and/or wood surface]
 - modification of standard method to support additional microorganisms [e.g., Germicidal Spray Products test for spore-formers],
 - changes to support alternate application types [e.g., foams].

Tier 1 Protocols

- A draft label with proposed directions for use and use claims must accompany the application.
- A pre-registration meeting is recommended prior to submission of the protocol.
- The Agency will make every effort during the preregistration meeting to determine if the protocol is Tier 1.
- If during further review, the Agency determines that a Tier I protocol should be elevated to Tier 2 status, the applicant will receive notification prior to this change.



 Tier 2 – Review of public health efficacy study protocol outside AD by members of AD Efficacy Protocol Review Expert Panel

A522

1 year review

\$10,500

Tier 2 Protocols

- An application that requires the review of a new public health efficacy protocol, or a major change to an existing efficacy method (e.g. AOAC International, ASTM, AATCC, or an AD approved method described in A431).
- Applies to study design that requires review by external members of an AD Efficacy Protocol Review Expert Panel that will be created.

Tier 2 Protocol

- Examples of major protocol changes include
 - surrogate consideration,
 - field test component,
 - air sanitizers making public health claims
 - simulated or in-use testing,
 - changes in growth conditions [e.g., shaking vs. static for TB testing]
 - novel protocols for products with label claims that don't meet the conventional sterilant/disinfectant/sanitizer standards (e.g., treated materials, a new method,
 - different application method (fogging),
 - application to different surfaces (i.e., porous),
 - change in performance standard, copper alloy

Tier 2 Protocol

- A draft label with proposed directions for use and use claims must accompany the application, along with proposed performance measures
- A pre-registration meeting is recommended prior to submission of the protocol.
- The Agency will make every effort during the pre-registration meeting to determine if the protocol is Tier 2. Protocol review and approval must be completed before efficacy data is generated using the approved protocol and an application for registration is submitted to AD.



Protocol Process

- Tier 1
 - Protocol review conducted within the Antimicrobial Division within the 90 day timeframe

Protocol Process

- Tier 2
 - Review label and protocol to confirm need for outside review
 - Identify outside reviewers for panel
 - May be OPP reviewer (i.e., BEAD lab)
 - Other government employee (FDA, CDC)
 - Academia (university researcher)
 - User group (APIC, ASHES, SHEA)
 - Identify questions for outside reviewers to consider when reviewing the protocol

Protocol Process

- Identify review time
- Ensure ethics paperwork complete, if required
- Periodically check on status
- Obtain review
- Complete a secondary review of the comments
- Send review to company



Recent external reviews

- C. difficile wipes
- Anthrax
- H2O2 vaporizer to sterilize room

Issues with Conventional Substantial Similarity Actions

Lois Rossi
Director
Registration Division
U.S. Environmental Protection Agency

FIFRA's Definition of Substantially Similar

FIFRA Section 3(c)(7)(a)

"...the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment"

FIFRA Definition (cont.)

 also, "...approving the registration or amendment in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment."

Substantially Similar

OPP's interpretation of Regulation:

- Proposed product must have the same active ingredient(s), in substantially the same proportion, and chemical composition (solid, liquid, granular), and substantially similar approved inert ingredients as the registered product
- Additionally, substantially similar means the proposed product bears the same use patterns, signal words and precautionary statements on label

PRIA codes R 300 and R301 Conventional Substantial Similarity Actions

What Product Chemistry Data is Required?

Product chemistry data

 $830.1550 \rightarrow 830.1900 = Group A, 830.6302 \rightarrow 830.7950 = Group B$

Group A and B Data required unless the proposed product is identical (100% repack) to a registered product

Submission includes:

Confidential Statement of Formula (CSF)
Group A and B Product chemistry data
Data matrix

If unregistered source - reference the Reg no. where the Group A and B data was already reviewed by OPP

What Toxicity Data is Required?

Acute toxicity data

 $870.1100 \rightarrow 870.2600$

All 6 toxicity studies are required unless the product is identical (100% repack)

Submission includes:

Bridging argument or Waiver request

Data matrix

Proposed label

What Toxicity Data is Required?

Acute toxicity data

 $870.1100 \rightarrow 870.2600$

All 6 toxicity studies are required unless the product is can be determined to be substantially similar

Submission to include:

Bridging argument to use data from a product with lower AI and is substantially similar

Data matrix

Reasons for Need to Renegotiate

- Group A and B product chemistry data not submitted – registrant indicated "nearly identical"
- Data matrix missing or citing incorrect Registration Numbers
- Citing a cancelled product

Reasons for Need to Renegotiate (cont'd)

- Math errors in the nominal concentration
- Label and nominal concentration do not exactly match
- Citing a registered product with different A.I.s than proposed
- Certified limits outside of Agency standard with no justification provided



- Screening of inerts to assure clearance (already implemented)
- OPP considering a change to the 21 day screen procedures - a check to ensure all the data has been submitted
- Wider use of eCSF



Feedback needed

e-CSF

- Download from OPP web
- Version 1 was available spring 2009
- Does the software work for you?
- Exploring if registrants can supply the PC codes on the CSF's?

Renegotiation Stats R 300 & R 301

PRIA due dates: 2009

19 re-negotiations out of 283decisions (6.7%)

Product chemistry	9
Data matrix	8
CSF	7
Label	4
Inert not approved	3
Code Change	2
Rebuttal / not similar	1
Failure to respond	1

Improving Pesticide Product Label System (PPLS)

Nikos Singelis Information Technology and Resources Management Division April 28, 2010



Primary Issue

- PPLS Website is not very user friendly
- Labels can be retrieved only by company number and product number







- PPLS contains over 160,000 labels
- Stored as Tagged Image Files (TIF)
- TIF files contain no metadata or searchable text
- Difficult to open TIF files



Proposed Solutions

- Improve PPLS web application
 - Improve search criteria to include:
 - Product name
 - Company name
 - Common name
 - Provide information on product transfers

Proposed Solutions (Cont'd)

- Improve label collection
 - Convert collection to PDF format
 - Ensure addition of correct metadata
- Improve processing of new labels
 - Create PDF files of new labels
 - Ensure addition of correct metadata
 - Explore using the high quality PDF files from the Electronic Label Library (ELL, Tom Harris)

Future Possibilities

- Develop a Fully Integrated Labeling System
 - A "smart" input module for registrants for real electronic submissions
 - A review module for OPP staff that would allow comparison of label content
 - The ability to work collaboratively with registrants



Need More Information?

 Nikos Singelis, Chief Internet and Training Branch, 703-603-0164

 Mark Heflin, Internet and Training Branch, 703-605-0703

Chemical Search Utility

Issue

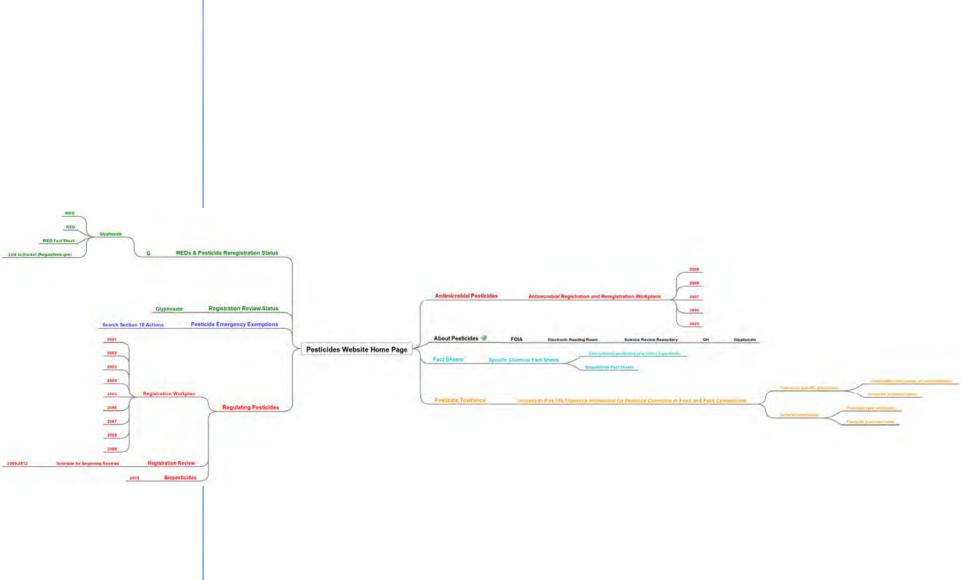
- Over time, OPP staff have created an ever increasing array of lists of chemicals/active ingredients
- We have identified 20 separate lists so far
- Each list addresses a facet of the regulatory process or an attribute of the chemical
- Lists are often subdivided into even more lists!



- Chemical Lists
 - Are created and maintained manually by the relevant Division and ITRMD's ITB
 - Are not linked to each other
 - Are hidden deep within the website
 - Are not consistently connected to regulations.gov and eCFR



- For the public (or even the regulated community):
 - Lists are difficult/impossible to find
 - Do not aid the public's understanding of our regulatory program or the latest information on a particular chemical
 - Create confusion/frustration



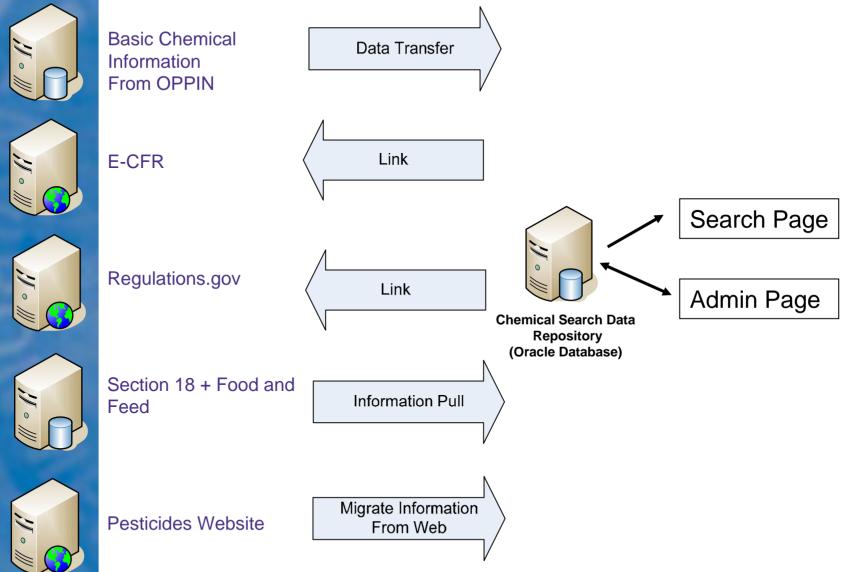


- Create a centralized location to display chemical information
 - Organize information so that it tells the "story" of a chemical
 - Create a one-stop shopping place that allows users to:
 - see all of what is available and
 - easily search and sort it

Proposed Solution

- Centralized chemical portal page
 - Simple and advanced search sort options
 - Page design that allows users to see the full range of information that is available on a chemical
 - Plain English explanations
 - Make use of existing data sources to eliminate duplication of data and effort:
 - OPPIN
 - Regulations.Gov (dockets)
 - eCFR (tolerance information)
 - Substance Registry System (metadata and synonyms)
 - Section 18 database and food and feed database
 - Document repository on website (REDs, fact sheets, etc.)

Proposed Solution





Project Phases

- Phase I
 - Active Ingredients
- Phase II
 - Inert Ingredients
- Phase III
 - Product and Label Integration



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