

US EPA ARCHIVE DOCUMENT

Pesticide Program Dialogue Committee (PPDC) PRIA Process Improvement Workgroup



December 13, 2010

Introductions and Announcements

Marty Monell
Deputy Director
Office of Pesticide Programs
December 13, 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).”

e-Dossier Builder Update and User Pilot

Robert Schultz

**Information Technology and
Resources Management**

Division December 13, 2010

What is the e-Dossier Builder?

- Software application for the creation of electronic submissions to OPP
 - For use by registrants
 - Download and install on users PC
 - Expands allowable submission type (future)
 - Requires modifications to internal EPA software
 - Uses a proprietary e-package format
 - Designed as an intermediate step toward larger scale electronic submission
 - Only for submissions to EPA

Development Process

- Announcement @ PPDC Process Improvement Workgroup October 1, 2009
- Stakeholder workgroup formed
 - 17 Participants
 - 14 Companies
- Used an iterative development process
 - Teleconferences
 - Webinars

Current State of Affairs

- Initial release date target July 2010
 - Intentionally missed!
 - Desire to synchronize with internal software modifications
 - User understanding concerns
- Version 0.81 ready
 - Adobe Flex/Flash
 - Adobe Integrated Runtime (AIR)
- Plan for a user pilot

e-Dossier Builder User Pilot

- Starting January 2011
- Continue with limited submission types
- Desire to work closely with registrants/agents
 - Gain a better understanding of user comprehension
 - Identify issues with the Builder
- Allows time to finish modifications to internal software

Future Thoughts

- Formal release of e-Dossier Builder
- Pre-assignment of _____ via Website
 - Root MRIDs
 - Registration numbers
 - Company numbers
- Electronic submission via Internet
- International harmonization of e-Submission package format (OECD)

Pilot Involvement

- e-Dossier Builder User Pilot
 - Contact Bob Schultz
 - Schultz.robert@epa.gov
 - (703) 308-8186
- Materials you'll receive
 - e-Dossier Builder v 0.81 installation file
 - e-Dossier Builder installation instructions
 - e-Dossier Builder User's Guide



E-Dossier Builder Demonstration

Streamlining the Risk Assessment Process in OPP

Toward Increasing Efficiency and
Reliability

Thomas Steeger
Brenda May
Robert Schultz
Office of Pesticide Programs
December 13, 2010

Furthering Efficiencies

- In March 2010, OPP staff members were invited to submit ideas for further efficiencies in OPP's process toward meeting PRIA deadlines while maintaining the integrity of the risk assessment and risk management decisions.
- The winning responses from OPP science divisions showed a concordance of opinion on improving the efficiency with which data evaluation records are completed.

Data Evaluation Records

- Data Evaluation Records (DERs) are the typical way that OPP records its evaluations of studies submitted to fulfill guideline test requirements under FIFRA.
- Some divisions within OPP have well established templates for each of the guideline studies (e.g., NAFTA Harmonized Templates).
- Typically, DERs are initiated by EPA contractors (primary reviewers) and are then completed by EPA science staff (secondary reviewers).

Data Evaluation Records

- Budget constraints have limited the extent to which contractors can complete primary reviews of acute toxicity studies. Chronic studies typically still rely on contractors to complete primary reviews.
- Whether primary reviews are conducted by contractors or EPA staff, this is a very time consuming and costly effort.

Data Evaluation Records

- The winning recommendation (s) from separate science divisions is to have registrants complete the initial version of the DER using the study profile template.
- EPA contractors then verify that the study information has been accurately transcribed (primary review).
- EPA science staff complete their secondary review as usual.

Data Evaluation Records

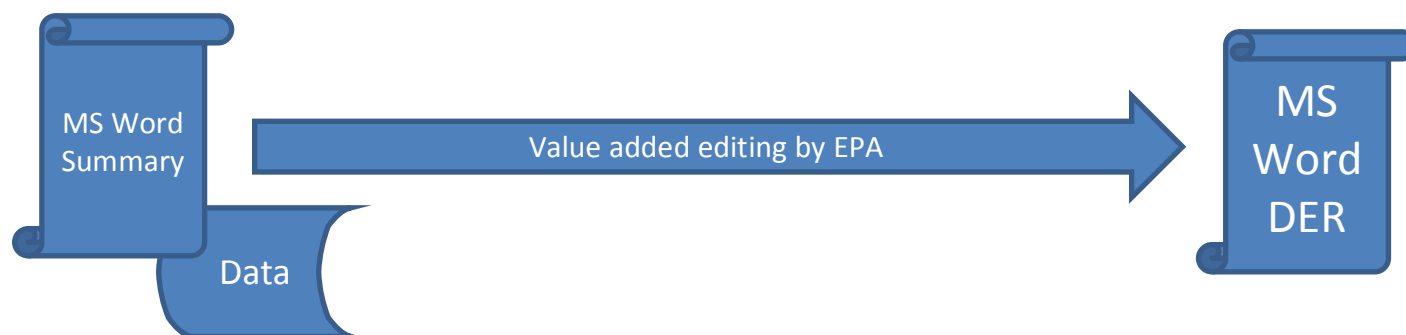
- Proposed recommendation is not substantially different that what is done for global reviews.
- Standardized templates exist for many of the studies (e.g., NAFTA, OECD Tier II, IUCLID). See http://www.epa.gov/pesticides/regulating/studyprofile_templates/studyprofile_templatelist.htm
- Proposed process would eliminate the costly and time consuming process for EPA to complete the initial study design template.
- EPA will continue to apply the same level of scrutiny to the data and its interpretation.

Increased Efficiency and Reliability

- What are the benefits?
 - Reduced costs associated with primary reviews
 - Quicker processing
 - Increased flexibility as process evolves
 - xml format would allow uploading to diverse databases
 - Increased potential for automating quality assurance steps and insuring accurate transfer of data to enhance database reliability.

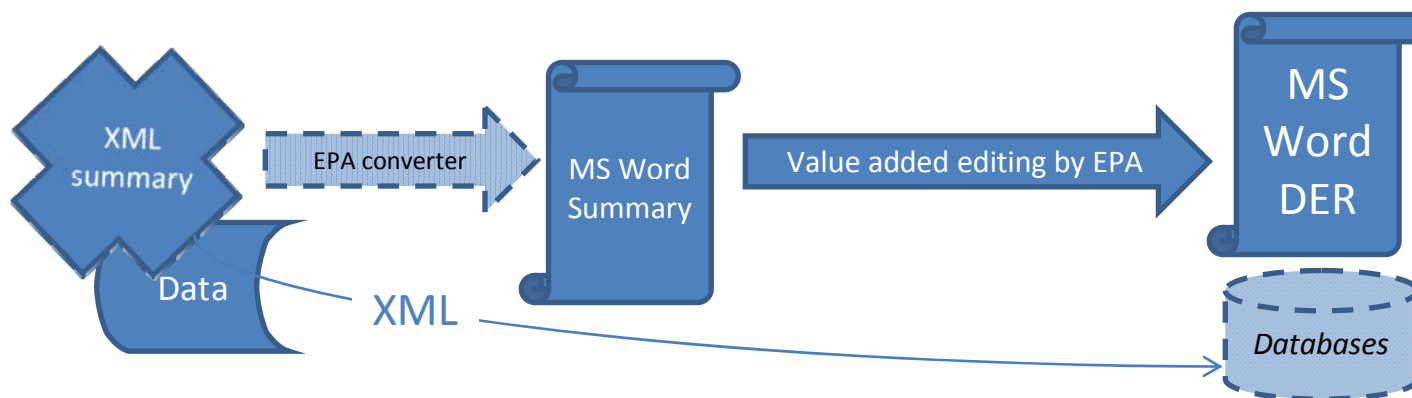
An Evolving Process

- Initially registrants may complete Microsoft® provide associated data in Microsoft Excel or SAS-transportable files.



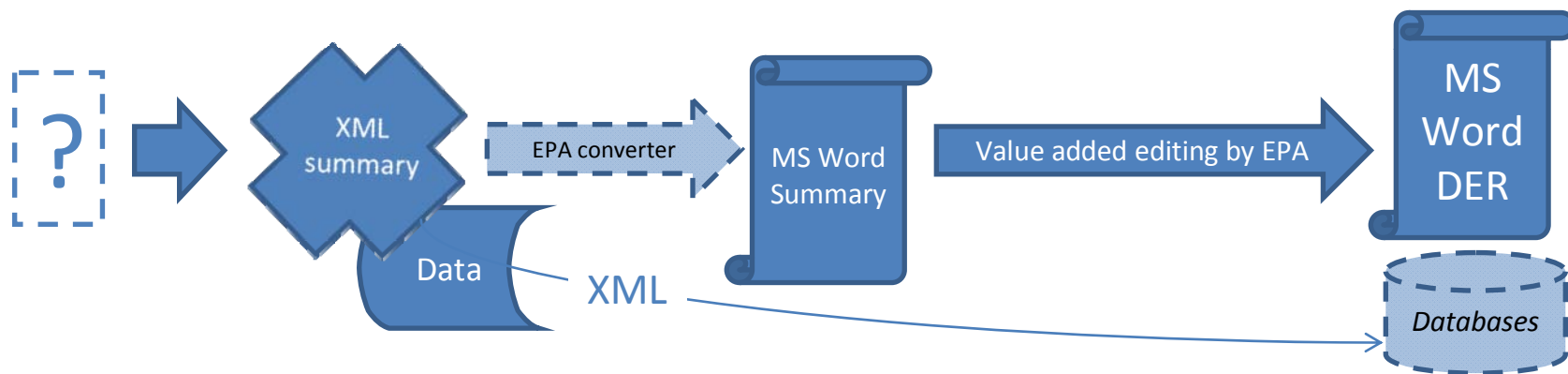
Extensible Markup Language

- XML will provide greater flexibility in how databases will be able to provide the capacity to generate Word files.



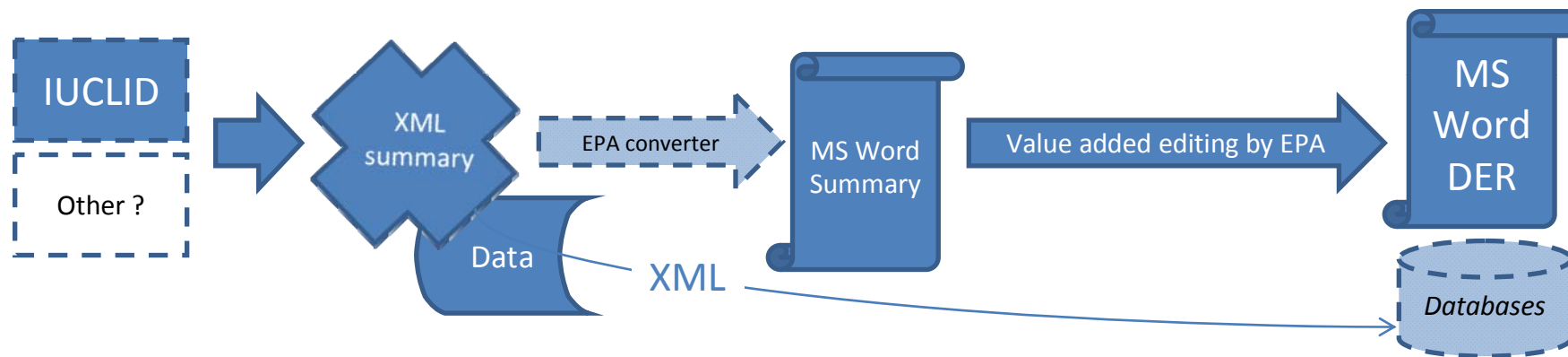
Starting Point

- The goal is to have a mechanism which allows
which allow ready analysis (transportability).



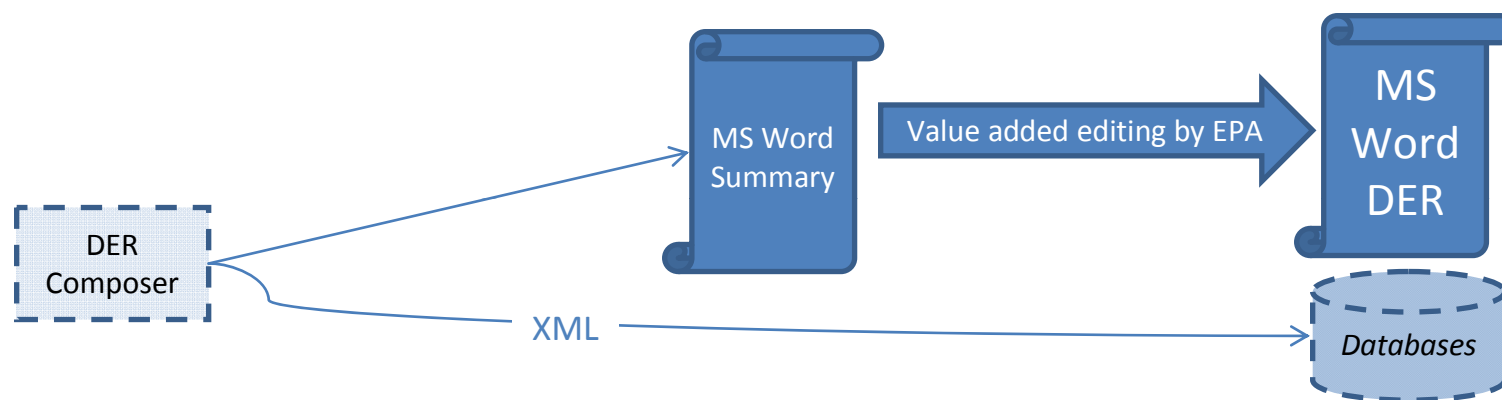
Options

- Existing tools to create the XML may already



Options

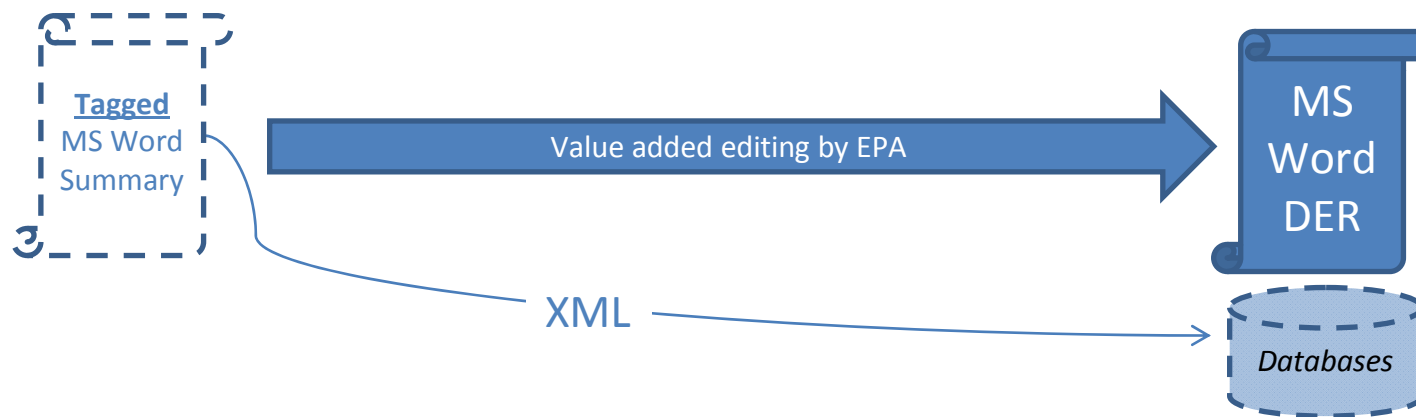
- Other alternatives are under development.



Options

- Using a properly built MS Word templates

mechanism.



Pesticide Registration Manual (Blue Book)

Elizabeth Leovey
Blue Book Committee
Office of Pesticide Programs
December 13, 2010

Blue Book Status

- Pesticide Registration Manual posted on the Pesticides Web site in March, 2010
 - Formerly “General Information on Applying for Registration of Pesticides in the United States”
 - General guidance on how to apply for a pesticide registration
 - Each Chapter is a separate Web page for easy updating
 - Date of last update shown
 - Supporting information and guidance are linked



Pesticides: Regulating Pesticides

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Pesticide Registration Manual (Blue Book)

You will need the free Adobe Reader to view some of the files on this page. See [EPA's PDF page](#) to learn more.

The Pesticide Registration Manual is a resource for companies and individuals who want to have their pesticide products registered for sale in the United States. The manual describes EPA's review and decision making process for registering a pesticide product and its use. Detailed information for pesticide registrants (the company or individual applying to register a pesticide) concerning their responsibilities before, during and after the review process is also included in the manual.

[Pesticide Registration Decision Tree](#) is provided to assist you in determining whether a product will require a formal review by EPA and to direct you to appropriate chapters of the Pesticide Registration Manual for additional information.

Title	Updated
Introduction	October 2010
Chapter 1: Requirements for Pesticide Registration and Registrant Obligations	March 2010
Chapter 2: Registering a Pesticide Product	March 2010
Chapter 3: Additional Considerations for Biopesticide Products	July 2010
Chapter 4: Additional Considerations for Antimicrobials Products	March 2010
Chapter 5: Registration Fees	July 2010

OPP Ombudsmen

- Conventional Chemicals
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- PRIA Conventional Chemicals (Acting)
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- Biopesticide Chemicals
[Brian Steinwand](mailto:steinwand.brian@epa.gov)
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Comments?

Do you have comments or technical issues about the Registration Manual?

Registration Resources

- [Label Review Manual](#)
- [Registration Forms](#)
- [Reduced Risk Pesticides](#)

Pesticides Home

Regulating Pesticides Home

Registration

Reevaluation: Pesticide Review

Pesticide-Producing Establishments

Laws and Regulations

International Issues

Adverse Effects Reporting

Storage & Disposal

Restricted & Canceled Uses

Pesticide Tolerances

Registration Information Sources

Local intranet

100%

Blue Book Status

- ACC Biocides Panel and Consumer Specialty Products Association reviewed and provided comments on June 4, 2010
- Revisions being made in response to the comments
- Response provided on how comments addressed to the trade associations when chapters/appendices are revised

Blue Book Status

- Revisions remaining
 - Revised Chapters 1, 6, 7 and 8 are in review
 - Chapter 2 is being rewritten
 - Appendix C being revised and revised B and C will be posted soon
 - Decision Tree will be the last item revised

Blue Book Status

- ACC Biocides Panel and CSPA commented on some of the revisions and these will be addressed after all chapters have been updated
- Hardcopy will be published when revisions have been completed
- Comments welcomed from other organizations and users to further improve it
 - Submit to bluebook@epa.gov
- Updated as new guidance is available

Product Reregistration Process Improvement

**Patricia Moe, Chief
Re-evaluation Management and
Implementation Branch V (RMIB V)
Pesticide Re-evaluation Division
Office of Pesticide Programs
December 13, 2010**

Background

- Reregistration Eligibility Decisions (REDs) completed in 2006
- Product reregistration implements RED decisions
- Goal : To complete product reregistration by 2014

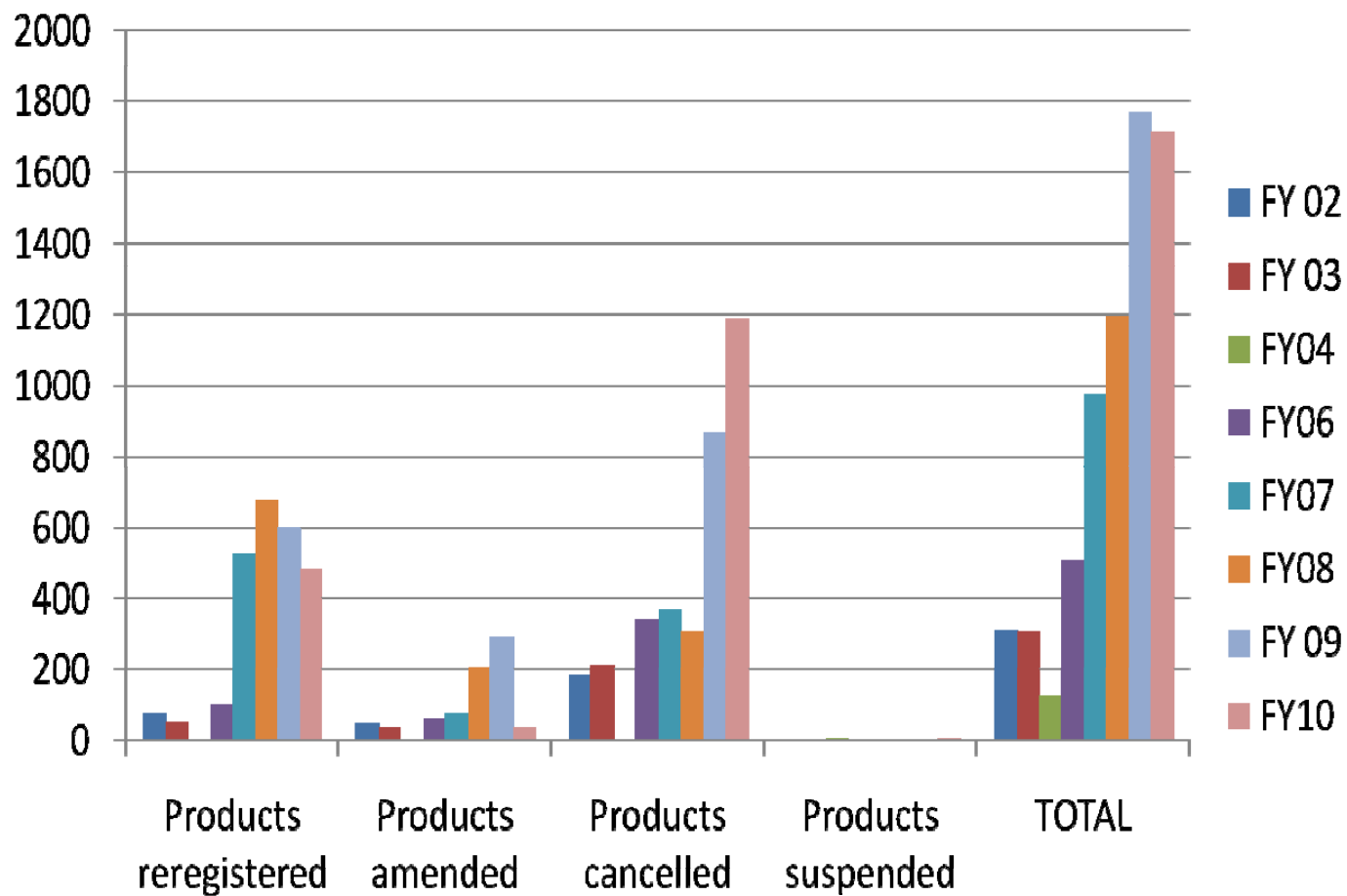
Opportunities

- Challenge: Resources
- Capitalize on product reregistration expertise in PRD
- Use AD contractor resources to enhance science review capabilities
- No additional resources; redistribution of existing resources

Memorandum of Understanding

- Defined roles for the Division, to ensure areas of responsibility were defined.
- AD finalized REDs, develops and clears DCIs
- PRD issues DCIs, tracks DCI responses, reviews product-specific data, performs preliminary label review
- AD conducts final label review and completes reregistration

Historical Product Reregistration Decisions



Other Measures

- Cross-trained staff for enhanced flexibility
- Share the workload across the Division
- Transition to registration review

Contact information

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Recent Changes on Inert Web Page

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Chief, Inert Ingredient Assessment Branch

December 13, 2010

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Pesticides: Regulating Pesticides



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- Registration Information Sources

Inert Ingredients Permitted in Pesticide Products

Listed below are inert ingredients permitted for use in pesticide products.

If you identify what may be an error in any of these listings or have questions or comments, please contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and provide specific information characterizing the problem.

- Process for new/amended inert ingredients:
 - [General Guidance for Petitioning the Agency for the Establishment of a New/Amended Food Use Inert Ingredient Tolerance or Tolerance Exemption](#) (46KB, 4pp., PDF)
 - [General Guidance to Petitioners for Low Risk Polymer Submissions](#) (51KB, 5pp., PDF)
 - [General Guidance for Requesting a New Nonfood Use Inert Ingredient](#) (39KB, 3pp., PDF)
 - [Open Literature Database Search](#) - Updated July 26, 2010 (63KB, 4pp., PDF)
 - [Inert Ingredient Frequently Asked Questions](#) (68KB, 8pp., PDF)

- [Nonfood Inert Ingredients](#) (93pp, 431KB, PDF) - Permitted for use in pesticide products applied to non-food use sites, such as ornamental plants, highway right-of-ways, rodent control, etc. [**Search Tip:** In Adobe Reader click EDIT on the menu bar, select FIND or SEARCH, then type either the name or CAS number]
- Food-Use Inert Ingredients - The only inert ingredients approved for use in pesticide products applied to food are those that have either tolerances or tolerance exemptions in the Code of Federal Regulations (CFR), 40 CFR part 180 (the majority

Inert Resources

- [Inert Disclosure](#)
- [Inert Ingredients Permitted in Pesticide Products](#)
- [About Tolerance Reassessment](#)
- [Federal Register and Pesticide Registration Notices on Inert \(other\) Pesticide Ingredients](#)

Resources

- [Guidance for Supporting the Inert Ingredients Subject to the Revocation Notice of 8/9/2006](#) (250KB, 5pp., PDF)
- [Inert Ingredient Frequently Asked Questions \(FAQ\)](#) (68KB, 8pp., PDF)
- [Fragrance Notification Pilot Program](#) (41KB, 6pp., PDF)
- [Fragrance Ingredient List](#) (2MB, 45pp., PDF)
- [Fragrance Formula Sheet](#) (19KB, .xls file)
- [Joint Inerts Task Force \(JITF\) Formed to Support](#)

Inerts Database



Search All Inerts (Food, Nonfood and Fragrance)



Food Use Data Entry Form



Nonfood Form



Fragrance Form



Food Use Report -- Entire List

Ingredient

Enter CAS number without any dashes

CAS - no dashes

PC Code

CFR

Fragrance

All fragrances are "Nonfood use" and must not exceed 0.1% of the formulation.

Food Use	CAS no dash	Ingredient	Limits	F
No	13837564	(.+.)-Tetrahydro-2,6,6-trimethyl-2-	Must not exceed 0.1% of formulati	
No	7785708	(+)-Pin-2(3)-ene	Must not exceed 0.1% of formulati	
No	68877292	(1,7,7-Trimethylbicyclo[2.2.1]hept-	Must not exceed 0.1% of formulati	
No	23726912	(2E)-1-(2,6,6-Trimethyl-1-cyclohex	Must not exceed 0.1% of formulati	
No	28069729	(2E,6Z)-Non-2,6-dien-1-ol	Must not exceed 0.1% of formulati	
No	81836137	(3a.alpha.,4.alpha.,6.alpha.,7.alpha.	Must not exceed 0.1% of formulati	
No	67845469	(4-Methylphenoxy)acetaldehyde	Must not exceed 0.1% of formulati	
No	3288991	(4-tert-Butylphenyl)acetonitrile	Must not exceed 0.1% of formulati	
No	20872576	(E)-1-(2,4,4-Trimethyl-2-cyclohex	Must not exceed 0.1% of formulati	

Record: 1 of 1534 No Filter Search

Food Use

Food Use	PC Code	Ingredient	CAS Number	CFR	Data Comp	Uses
Y	700187	alpha-Cyclodextrin	10016-20-3	950(e)		
Y	807504	Dysprosium Chloride (DyCl3)	10025-74-8	920		as tagging agent
Y	807505	Europic Chloride (EuCl3)	10025-76-0	920		as tagging agent
Y	872506	Yttrium chloride (YCl3), hexahydrate	10025-94-2	920		tagging agent
Y	844626	Decanoic acid, sodium salt	1002-62-6	910		Binder, emulsifier
Y	900332	Ferric sulfate	10028-22-5	910		as solid diluent, c

Record: 1 of 1337 No Filter Search

Non-Food

Some CAS numbers are not available, and are listed as "na" followed by unique identifier letters.

Food Use	PC Code	Ingredient	CAS Number	Commer
N	856301	p-Nitrophenol	100-02-7	
N	900343	Sodium dodecylphenyl polyoxyethylene phosphates	100092-50-0	(9CI)
N		alpha-Cyclodextrin	10016-20-3	
N		Nitrous oxide (N2O)	10024-97-2	
N		Sulfur chloride (S2Cl2)	10025-67-9	

Ingredient

Enter CAS number without any dashes

CAS - no dashes

PC Code

CFR

Search

Enter search term into one or more fields, click Search.

Fragrance

All fragrances are "Nonfood use" and must not exceed 0.1% of the formulation.

Food Use	CAS no dashes	Ingredient	Limits
No	13837564	(+/-)-Tetrahydro-2,6,6-trimethyl-2-	Must not exceed 0.1%
No	7785708	(+)-Pin-2(3)-ene	Must not exceed 0.1%
No	68877292	(1,7,7-Trimethylbicyclo[2.2.1]hept-	Must not exceed 0.1%
No	23726912	(2E)-1-(2,6,6-Trimethyl-1-cyclohex	Must not exceed 0.1%
No	28069729	(2E,6Z)-Nona-2,6-dien-1-ol	Must not exceed 0.1%
No	81836137	(3a.alpha.,4.alpha.,6.alpha.,7.alpha.	Must not exceed 0.1%
No	67845469	(4-Methylphenoxy)acetaldehyde	Must not exceed 0.1%
No	3288991	(4-tert-Butylphenyl)acetonitrile	Must not exceed 0.1%
No	20872576	(E)-1-(2,4,4-Trimethyl-2-cyclohex	Must not exceed 0.1%

Record: 1 of 1534 No Filter Search

Food Use

Food Use	PC Code	Ingredient	CAS Number	CFR	Uses
Y	700187	alpha-Cyclodextrin	10016-20-3	950(e)	
Y	807504	Dysprosium Chloride (DyCl3)	10025-74-8	920	as tagging agent
Y	807505	Europic Chloride (EuCl3)	10025-76-0	920	as tagging agent
Y	872506	Yttrium chloride (YCl3), hexahydrate	10025-94-2	920	tagging agent
Y	844626	Decanoic acid, sodium salt	1002-62-6	910	Binder, emulsifier, anticaking a
Y	900332	Ferric sulfate	10028-22-5	910	as solid diluent, carrier

Record: 1 of 1338 No Filter Search

Some CAS numbers are not available and are listed as "na"

Ingredient

Enter CAS number without any dashes

CAS - no dashes

PC Code

CFR

Search

The database will show matches from each of the four tables.

Fragrance

All fragrances are "Nonfood use" and must not exceed 0.1% of the formulation.

Food Use	CASnodash	Ingredient	Limits
No	107211	Ethylene glycol	Must not exceed 0.1% of

Record: 1 of 1 | No Filter | Search

Food Use

Food Us	PC Code	Ingredient	CAS Number	CFR	Uses
Y	800009	1,2-Ethanediol (9CA)	107-21-1	920, 1040	s antifreeze, deactivator
* Y					

Record: 1 of 1 | No Filter | Search

Non-Food

Some CAS numbers are not available, and are listed as "na" followed by unique identifier letters.

Food Use	PC Code	Ingredient	CAS Number
N		Ethylene glycol	107-21-1

Ingredient ethylene glycol

Enter CAS number without any dashes

CAS - no dashes

PC Code

CFR

Search

Fragrance

All fragrances are "Nonfood use" and must not exceed 0.1% of the formulation.

Food Use	CAS no dashes	Ingredient	Limits
No	107211	Ethylene glycol	Must not exceed 0.1% of the formulation
No	111762	Ethylene glycol monobutyl ether	Must not exceed 0.1% of the formulation
*			

Record: 1 of 2 No Filter Search

Food Use

Food Use	PC Code	Ingredient	CAS Number	CFR	Uses
*					

Record: 1 of 1 No Filter Search

Non-Food

Some CAS numbers are not available, and are listed as "na" followed by unique identifier letters.

Food Use	PC Code	Ingredient	CAS Number
N	811510	Ethylene glycol monethyl ether (List 1- Inert Ingredient of Toxicological Cc	110-80-5

Ingredient

Enter CAS number without any dashes

CAS - no dashes

PC Code

CFR

Fragrance

All fragrances are "Nonfood use" and must not exceed 0.1% of the formulation.

Food Use	CASnodash	Ingredient	Limits
No	67641	Acetone	Must not exceed 0.1%

Record: 1 of 1 | No Filter | Search

Food Use

Food Use	PC Code	Ingredient	CAS Number	CFR	Uses
Y	844101	Acetone	67-64-1	910	as solvent, cosolvent
* Y					

Record: 1 of 1 | No Filter | Search

Non-Food

Some CAS numbers are not available, and are listed as "na" followed by unique identifier letters.

Food Use	PC Code	Ingredient	CAS Number
N	844101	Acetone	67-64-1

Ingredient

Enter CAS number without any dashes

CAS - no dashes

PC Code

CFR

Fragrance

All fragrances are "Nonfood use" and must not exceed 0.1% of the formulation.

Food Use	CAS no dashes	Ingredient	Limits
*			

Record: 1 of 1 | No Filter | Search

Food Use

Food Use	PC Code	Ingredient	CAS Number	CFR	Uses
Y	811551	2H-Azepin-2-one, 1-ethenylhexahydro-, homopolymer	25189-83-7	960	
* Y					

Record: 1 of 1 | No Filter | Search

Non-Food

Some CAS numbers are not available, and are listed as "na" followed by unique identifier letters.

Food Use	PC Code	Ingredient	CAS Number
*			

Ingredient

Enter CAS number without any dashes

CAS - no dashes

PC Code

CFR

Search

Fragrance

All fragrances are "Nonfood use" and must not exceed 0.1% of the formulation.

Food Use	CASnodash	Ingredient	Limits
*			

Record: 1 of 1 No Filter Search

Food Use

Food Use	PC Code	Ingredient	CAS Number	CFR	Uses
Y	911344	C.I. Pigment Yellow No. 104	15790-07-5	930	as pigment in animal tag &
Y	900693	Octadecyl 3-(3',5'-di-tert-butyl-4'-hydroxyphenyl)propionate	2082-79-3	930	as thermal stabilizer/antioxid
Y	900377	2-(2H-Benzotriazol-2-yl)-4-methylphenol	2440-22-4	930	as ultraviolet light absorber/s
Y	800160	9-Octadecenoic acid (Z)-, ester with 1,2,3-propanetriol	37220-82-9	930	
Y	900008	Sorbitol	50-70-4	930, 950	930 - Antidusting agent.
Y	900416	Octyl epoxytallate	61788-72-5	930	as plasticizer component an

Record: 1 of 11 No Filter Search

Ingredient

Enter CAS number without any dashes

CAS - no dashes

PC Code

CFR

Fragrance

All fragrances are "Nonfood use" and must not exceed 0.1% of the formulation.

Food Use	CASnodash	Ingredient	Limits
*			

Record: 1 of 1 No Filter Search

Food Use

Food Use	PC Code	Ingredient	CAS Number	CFR	Data Comp	Us
Y	900514	Tridecyloxy poly(ethyleneoxy)* poly(propyleneoxy)*	61725-89-1	910, 930	Y Company 84913 (CST1)	as surfactants,
* Y						

Record: 1 of 1 No Filter Search

Database also useful for identifying inerts with data compensation issues.

Non-Food

Some CAS numbers are not available, and are listed as "na" followed by unique identifier letters.

Food Use	PC Code	Ingredient	CAS Number	Comme
N	900514	Tridecyloxy poly(ethyleneoxy)* poly(propyleneoxy)**-2-propanol *(9 moles)*	61725-89-1	
*				



Label Accountability Initiatives

Update for PPDC – PRIA Process
Improvement Workgroup

Jim Roelofs
OPP Labeling Committee
December 13, 2010

Background

- 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

In this report:

- Web-based training tool
- Phase II of Label Review Manual up-date
- Enhancements to the SLITS system
- Some issues from recent SFIREG meeting

Training for Label Reviewers

- 2009, a workgroup developed content of a basic training program.
- Contractor produced web-based program.
- We put it on OPP website in June
- All reviewers completed it by end of FY '10
- Available to anyone on OPP homepage under “Featured Sites”.

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.

Updating the Label Review Manual

- Workgroup up-dated all the chapters between 2006 and 2009.
- Now entirely a web document – accessible, links to supporting policy docs.
- SFIREG POM committee is commenting on groups of chapters;
 - Began in June; probably finish in January or Feb.
- Have SFIREG comments on 11 chapters so far

Updating LRM (continued)

- Also collecting public comments via web discussion forum (blog), since September.
 - Pesticides Web page – Participate – Join the Label Discussion Forum
- Also one or two chapters at a time – now on chapter 5 for December.
- No changes to LRM text yet – but may edit early chapters in Jan. or Feb.

Updating LRM (continued)

- What EPA wants from comments:
 - Editorial improvements: clearer language, better examples; more citations to supporting documents; needed up-dates.
- What EPA does not want (and generally can't do):
 - Policy discussions, requests for policy changes
 - for example, we can't just change "should" to "must".

LRM comment process

- Workgroup screens comments for usefulness, viability – then to Label Committee; Workgroup includes OGC and OECA, as does the LC.
- Difficult and time consuming to track down rationale or origin of LRM language

Enhancements to SLITS

- 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

- Enhancements designed with input from States (main users)
- Currently in testing in OPP
- Gave a demo of new features at SFIREG
- Main new features:
 - enhanced report function on many variables;
 - Ability to follow-up and track actions over time.

Label Committee

- Continues to operate public “label consistency” Q and A website.
 - About 400 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

- Full SFIREG committee met Dec. 6-7
- Issue Papers were discussed:
 - Supplemental Labels – want expiration date of 36 months (extension possible).
 - Will generate a letter to clarify for all SLA that “for professional use only” and its variants are not enforceable.
 - Will work with EPA to create examples of clear distinction in appearance or location of advisory versus mandatory language.

Public Participation for Registration Actions

Diane Isbell
Registration Division
Office of Pesticide Programs
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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.
- Process allows for comment on proposed decisions and risk assessments for certain registration actions.

Notice of Receipt

- 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.

Public Participation Process

- Actions included in the process:
 - new active ingredients;
 - first food use;
 - first outdoor use;
 - first residential use; and
 - other actions of significant 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.
- Sign up for automatic updates for individual dockets.

Registration Decision

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

Public Participation Process

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

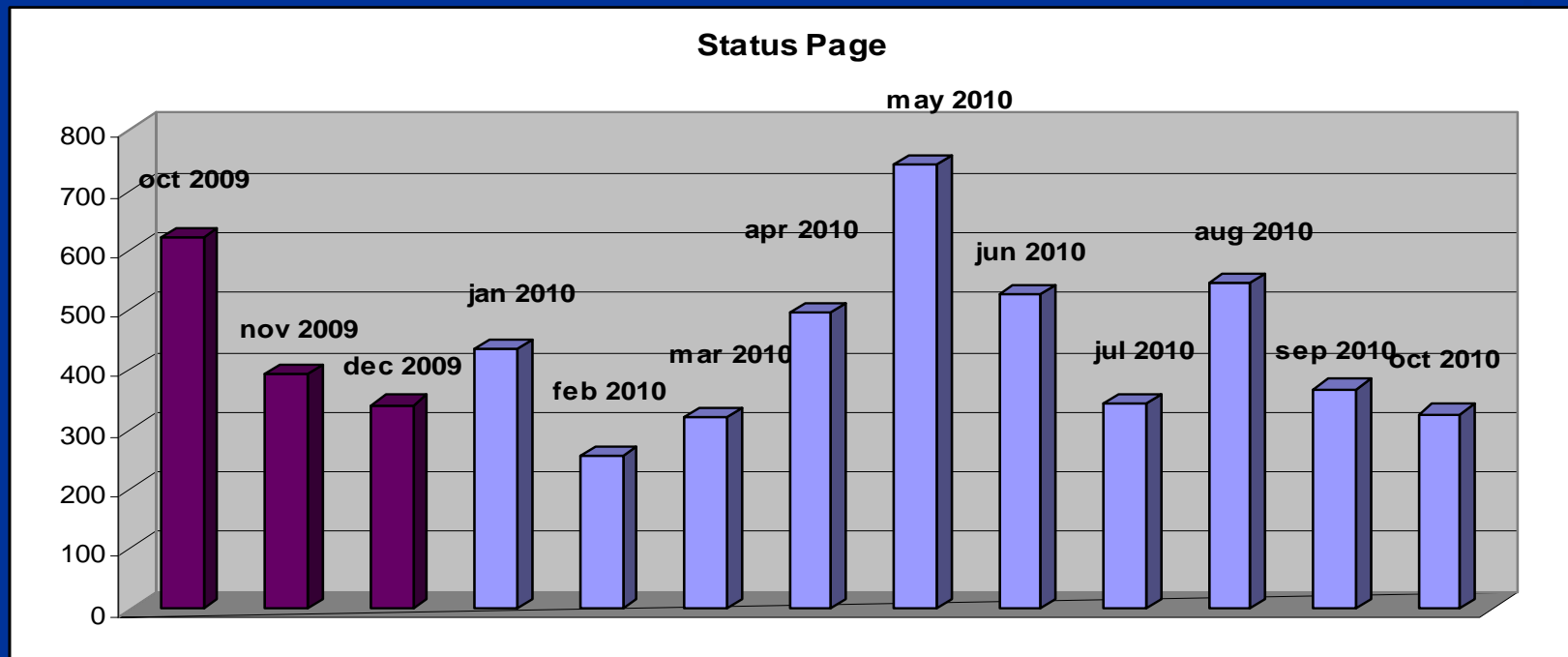
<http://www.epa.gov/pesticides/regulating/registration-public-involvement.html>

<http://cfpub.epa.gov/pesticides/comments.cfm>

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

Public Participation Website

The Public Participation Status Page has been visited 5,707 times between October 2009 and October 2010.



Public Participation Process Current Status

- 46 Public Participation Actions
(3 – AD, 31 – BPPD, 12 – RD)
- 11 Actions of Significant Interest

Public Participation Process Current Status

- New Active Ingredients:
29 (AD-2, BPPD-19, RD-8)
- First Food Use:
2 (BPPD-1, RD-1)
- First Outdoor Use:
2 (AD-1, RD-1)
- First Residential Use: 3 (RD-3)
- Other Actions of Significant Interest
(11 – BPPD)

Public Participation Process

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