Pesticide Program Dialogue Committee PRIA Process Improvement Workgroup

Minutes of January 31, 2006 Meeting

Attendees:

Workgroup Members:

Kate Bouve, Information Technology and Resources Management Division (ITRMD)/Office of Pesticide Programs (OPP)
Sue Crescenzi, Steptoe and Johnson, on behalf of the American Chemistry Counsel (ACC) Biocides Panel
Dennis Edwards, Antimicrobial Division (AD)/OPP
Ted Head, NuFarm America, Representing the Chemical Producer and Distributors Association (CPDA)
James Kunstman, PBI/Gordon, Representing CPDA
Allen James, Responsible Industry for a Sound Environment (RISE)
Elizabeth Leovey, Office of Pesticide Programs, EPA
Ray McAllister, CropLife America (CLA)
Marty Monell, Office of Pesticide Programs
Sheryl Reilly, Biopesticides and Pollution Prevention Division (BPPD)
Amy Roberts, Technology Sciences Group, Representing the Biopesticide Industry Alliance (BPIA)
Julie Schlekau, MGK Company, Representing RISE
Julie Spagnoli, Clorox, Representing the Pesticide Program Dialogue Committee
Greg Watson, Syngenta Crop Protection, Representing CLA

Others in Attendance:

Linda Arrington, Registration Division (RD)/OPP
Darrel Barringer, MGK Company
Russell Dinnage, Pesticide and Toxic Chemical News
Phil Hutton, BPPD/OPP
Quentin Jones, ITRMD/OPP
Ed Jordan, BASF
Arnold Layne, ITRMD/OPP
Eric Mauer, Valent U.S.A
Michael Nieves, RD/OPP
Dominque Rey-Carruth, ITRMD/OPP
Robert Shultz, ITRMD/OPP
Diane Schute, CPDA
Karen Sheerer, Bayer
Donald Stubbs, RD/OPP

Dawn Stump, Syngenta
Arty Williams, Environmental Fate and Effects Division (EFED)/OPP

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Minutes

Information Technology/Information Management – PRIA Accomplishments and Plans for Next Three Years

Arnold Layne, Director of the Information Technology and Resources Management Division (ITRMD), provided an update on the Office of Pesticide Programs' information technology(IT)/management (IM) initiatives for the next few years. The Division has made substantial progress in improving its management of OPP's IT resources. The Program's current integrated database, OPPIN (Office of Pesticide Programs Information Network) was brought on line between 2003 and 2004. A coordinated IT/IM program was also created that resulted in an emphasis on configuration management, systems development and life cycle management, overall programmatic needs, strategic use of resources, and greater efficiency. A heightened awareness of security considerations and

plans for future enhancements and improvements that focused on OPP's needs are also emphasized. Decisions on IT investments are now made by the program's newly created Information Management Council comprised of OPP senior management.

Shortly after OPPIN was implemented, PRIA became effective and OPPIN was modified to allow the program to monitor due dates and maintain fee records. Each stage of a PRIA action is tracked and a number of management reports were developed to enable managers to monitor the status of each application. Modifications were also made in OPPIN to notify registrants when the Agency received their payments. The time required to complete initial application in processing conducted by the Division was reduced from 20 days to a goal of 10 days. In this process, each application is screened for compliance with PR Notice 86-5, application and study information are loaded into OPPIN, and files or "jackets" are created if needed for a new product.

Current challenges that are determining future IT investments are OPP's move to a new building, resource constraints, international harmonization activities focusing on electronic submission, evolving programmatic areas such as registration review, endangered species, and worker protection and IT/ITM expectations from OPP staff and stakeholders. For the short term, scheduled advancements include verifying the data in OPPIN for accuracy; scanning the documents in jackets to create e-jackets; addressing electronic submission and use of the government's Central Data Exchange (CDX); improving document management systems that are required for efficiencies in registration review and in conducting endangered species assessments; increasing the system's storage capacity; enhancing disaster recovery and security plans; expanding the use of business objects/management reports to all registration activities; standardizing the program's computers to decrease maintenance costs; and modifying OPP's web site for conformance with Agency's standards.

The Program's vision for the system of the future is one with a web based portal as the gateway to all pesticide related information. The new system, the Pesticide Registration Information System (PRISM), will integrate all of OPP's information to allow staff in their daily work to access whatever information or data they need at their desk and to interface with several EPA and governmental systems. Stakeholders will furthermore, have a single point of access to submit and obtain registration information. This system will meet government standards such as Section 508. In addition to the portal, primary components will address information submission and status, processing and workflow, information analysis and reporting, information interchange, document management, and geospatial information.

For FY2006, the Agency's pesticide IT/IM investments include a number of enhancements requested by organizations within the Office of Pesticide Programs. Electronic submission, systems support for PRIA, E-jackets, document management, and starts ups for registration review and CDX were also funded.

Stakeholders were interested in increased information on the status of an application within the Agency's registration process and had previously submitted a list of milestones of interest:

- Start of decision time review period (acknowledgement of certification of check).
- Date that submission passed chemical screening and was sent to Science Divisions, Technical Review Branch/RD, ARIA/RD
- Date of completion of primary reviews by HED, EFED, Technical Review Branch/RD, ARIA/RD, contractors
- Date of completion of secondary reviews by HED and EFED
- Dates for Peer Review Committees (HEXARC, MARC, CARC, RARC, etc.)
- Date of completion of risk assessments (HED, EFED, Endangered Species, etc.)
- Date of risk assessment outcome, HED/EFED reviews returned to the PM
- Date of EPA registration decision
- Date for publication of Notice of Filing and Federal Register Notice for tolerance petitions
- Date for completion of label review

The Agency will review the list and determine what may be feasible with OPPIN. Prior to the Agency making such information available, however, it needs to verify that the information in the system is accurate. The data is currently being evaluated and such accuracy is important in moving from OPPIN to PRISM.

Registrants requested a copy of the jacket of their own products or the scanned copy. A concern of registrants is that notifications may not always be filed in the jacket. The Agency commented that there may be additional information in the jacket than just information pertaining to a specific product and will consider the request.

Labeling Committee

Donald Stubbs, Associate Director, Registration Division and chair of the OPP Labeling Committee updated the workgroup on the Committee's activities. The Committee was formed at the suggestion of the workgroup and its purpose is to oversee cross cutting labeling policy issues, resolve them and communicate their resolution both internally and externally. Its members are representatives of the pesticide regulatory divisions, the Field and External Affairs Division and the Agency's Office of General Counsel and Office of Enforcement and Compliance Assurance. The Committee's charge is to revise and keep current the Label Review Manual (LRM) (http://www.epa.gov/oppfead1/labeling/lrm/), serve as a clearing house for broad cross cutting labeling issues, determine the scope and nature of cross cutting label policy needs, recommend solutions and measures for implementing solutions, and manage a web site (**http://www.epa.gov/pesticides/regulating/labels/label_review.htm**) devoted to labeling issues.

The Committee's draft Standard Operating Procedure (SOP) is available on its web site. The web site also provides an e-mail box for stakeholders and the public to submit their

labeling questions to the Committee. The Committee develops answers to these questions and posts them on the web site. As of this meeting, seven questions were being addressed.

To maintain the Label Review Manual, the Committee established a Label Review Manual Team that also developed a SOP. This procedure is an appendix to the Labeling Committee's SOP. The LRM Team is working its way though each chapter of the Manual, making straightforward corrections, and reviewing it for compliance with current policies. The Team is not considering policy changes at this time. Changes to the LRM web pages are also being evaluated to make it more user friendly and easier to navigate.

In response to a stakeholder question, the LRM will be a "living document" on the web. As changes are made, they will be posted. Stakeholders also commented that the Agency's web site is difficult to search particularly to find PR Notices and the regulatory status of a compound. PR Notices are posted and may be found on the site (http://www.epa.gov/PR_Notices/)

The Labeling Committee's issue paper on "For Use Only By…" was distributed and is attached. Examples of such label language intended to limit the use of the pesticide without a restricted use classification include "For professional use only", For use by veterinarians only", and "For use by pest control operators only". Comments could be submitted on the Labeling web site.

The Committee is conducting training sessions on PR Notice 2000-5, "Mandatory versus Advisory label language" for regulatory staff. The Office of General Counsel is updating the guidance on warranty statements to include additional examples of acceptable statements. Once updated, training sessions will be conducted for Agency staff and the examples will be available to stakeholders.

Application Deficiencies

Fee Waivers and PR 86-5

Study formatting and an update on processing waiver requests were presented by Kate Bouve, Chief of the Information Services Branch (ISB), ITRMD. In the initial in-processing of applications, ISB has observed that 12% of the studies submitted have formatting errors. These errors were further categorized as issues with CBI statements, 35%; mistakes in GLP compliance statements, 33%; problems with the documents themselves such as incorrect pagination, legibility, foreign language, etc., 19%; and other problems 13%. A stakeholder expressed a concern that a study that is not a guideline study may be rejected due to its GLP statement. GLP statements are required for both guideline and non-guideline studies. Examples of appropriate statements are included in PRN 86-5 and the GLP regulations. Data submitters can contact Teresa Downs (703-305-5363) if they need guidance on this or any other study submission issue.

Each year with a new maintenance fee billing cycle that begins January 15, companies must submit an updated and complete fee waiver request package. The package must contain three years of revenue information which if necessary, includes an estimate of the previous year's revenue. During FY05, EPA observed a slight increase in processing time during the January to March timeframe because applicants did not submit complete applications. For the subsequent quarters of 2005, average processing time to grant an application decreased to 21 to 24 days while the time it took to deny an application was consistently 50+ days. The increased time to deny an application reflects the increased time the Agency took in an attempt to obtain missing documentation.

Conventional Pesticides – Registration Division

On behalf of the Registration Division, Donald Stubbs described the Division's analysis of incomplete applications under PRIA. Only the front-end screen was examined. The Science Screen for new chemicals and new uses and science reviews were not subjects of this analysis. The Registration Division screened all incoming applications from the beginning of PRIA until the middle of August, 2005 and noted the results in a handout distributed during the meeting and attached. An estimated 10% of the applications were incomplete in obvious ways that could be caught in a cursory review when the application was received. Agency staff subsequently contacted the applicant to obtain the information and in some cases the PRIA due date was extended. Smaller companies had greater difficulty with the application process. The Division responds to all requests for application assistance. It would prefer to provide guidance prior to submission to assure that when submitted, the application is complete and can be processed efficiently. This is very important for actions or fee categories with a short timeframe such as 90 day Fast Tracks. Registrants were encouraged to ask questions prior to submission and to furthermore review their own records to determine whether any of their applications had extended due dates and then evaluate the reasons for the due date extensions.

The Division also announced that it had eliminated its FY05 Fast Track Amendment backlog and is processing approximately 80% of these applications within 90 days. Its goal is that no action should take longer than 120 days. To assure that completion time frames remain within its goal, the division reviews the status of these actions weekly.

For facilitating the review of new products, the Division has a new contract under which applications will be reviewed to determine whether the inerts listed in the Confidential Statement of Formula have been cleared. This process will also be examined to identify improvements. The long term goal is to automate it.

The PR Notice matrix mentioned during the last meeting of this workgroup was sent out electronically and is attached.

Antimicrobials –Antimicrobial Division

The types of deficiencies observed by the Antimicrobial Division in its review of applications were profiled by Dennis Edwards, Chief of its Regulatory Management

Branch 1. In general, 20% of all applications received had 86-5 deficiencies. Deficiencies included missing signatures, non-compliant GLP statements, inappropriate confidentially statements, poor copies, pages marked confidential in the middle of a study, and numbering problems. Forms such as offers to pay, the formulator's exemption and data matrix were missing from 35% of the applications. Data matrix problems, i.e. not all of the data requirements were addressed or incorrect MRID numbers were referenced occurred in 25% of applications.

Over a third (35%) of all applications reviewed by AD had data deficiencies. At times, justifications were not provided for data waivers. Product Chemistry deficiencies included no submitted analytical method, no submitted preliminary analysis, no GLP statement, incorrect CSFs, uncleared or more toxic inerts, and missing information on the unregistered source. In some applications, not all of the acute study requirements were addressed. Common problems were missing inhalation studies, the test material was not identified or the name of the product used in the study did not match the product that was the subject of the application. Efficacy studies had test material identify problems such as the number of the lots of the test material used was not identified. In addition, there were neutralization problems or neutralization was not addressed in the study report.

Biopesticides – Biopesticides and Pollution Prevention Division

The BPPD observed many of the same problems reported by the other divisions. Phil Hutton, Associate Director, provided an overview of its experience with deficient applications and an analysis conducted by the Division. Deficiencies are identified at three different points in processing Biopesticide applications: 1) during the in processing 86-5 review by ISB as previously discussed by Kate Bouve; 2) during an initial screen by BPPD staff for completeness, and 3) during scientific and/or regulatory review. If 86-5 deficiencies are observed, the Division sends the registrant a letter describing the deficiencies to be addressed and provides 75 days in which to address them pursuant 40 CFR 152.105. In some cases, if the PRIA due date precedes the end of the 75 day period, the Agency offers to extend the PRIA due date.

During the initial BPPD completeness screen, minor problems are corrected through e-mails or telephone calls. Major problems are handled through the 75 day notification process previously described. These problems are predominately associated with product chemistry and ecological effects studies. The same procedures are used if deficiencies are identified during scientific and/or regulatory review. Deficiencies during this later review include poorly conducted studies or problems with the label.e.g. the label and the studies do not agree. In some cases, the registration could not be granted under PRIA based on the information submitted and a PRIA Determination to Not Grant was made.

In an analysis of negotiated due dates or extensions in the due date, the Division observed that due dates for nearly 50% of all non-fast track new microbial and biochemical products were extended. A second or third extension, or negotiated due date was not uncommon. The Division presented these results to the Biopesticide Industry Alliance (BPIA) and will work with BPIA in findings way to reduce the number of due date

extensions. Both the Division and BPIA will take into consideration that many small companies are not members of trade associations.

Amy Roberts on behalf of BPIA requested a copy of BPPD screening checklists. (http://ir4.rutgers.edu/RWP/Checklist1.htm, http://ir4.rutgers.edu/RWP/Checklist2.htm)

Blue Book

One means of providing additional application guidance to help registrants develop better applications is to issue a revised "Blue Book" titled "General Information on Applying for Registration of Pesticides in the United States". Linda Arrington, Registration Division Ombudsman announced plans to hold a focus group meeting to discuss comments on a draft copy of the "Blue Book" and to brainstorm other ideas for making the registration process more transparent. Members of the focus group represent a cross section of applicants. The focus group meeting was scheduled for April 20, 2006.

Ecological Risk Assessments – Improvements and Endangered Species
Endangered Species

An overview of the challenges of conducting endangered species assessments and process improvements undertaken by the Environmental Fate and Effects Division were discussed by Arty Williams, Associate Director. While under the Federal Insecticide, Fungicide and Rodenticide Act, risk to non-target organism are considered against the benefits of using a pesticide, under the Endangered Species Act (ESA), the Agency is required to protect federally listed species and their habitats without regard to the benefits. This applies to all Federal Actions and includes new chemical decisions, reregistration actions, new use decision, Section 18's (including crisis declarations), etc.

The Division was recently reorganized to better integrate ecological assessments and endangered species assessments. An endangered species assessment is a component of an ecological risk assessment. A review to assess potential impacts to non-target organisms involves assessing the toxicity of a pesticide to surrogate species, characterizing the risks, developing a refined assessment and going beyond a refined assessment to considering the spatial and temporal inter-relationship of pesticide use and listed species. No further Agency action is needed if there is a "no effect" determination. If a conclusion is reached of "Not Likely to Adversely Affect", consultation with either or both the Fish and Wildlife Service and the National Marine Fisheries Service is not required provided the assessment is conducted following chapters 5 and 6 of the "Overview Document" or "Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U. S. Environmental Protection Agency" (http://www.epa.gov/oppfead1/endanger/consultation/ecorisk-overview.pdf). Formal consultation with the Services is required if a "Likely to Adversely Affect" conclusion is reached.

A majority of pesticides need to be evaluated for endangered species concerns. This will be a multi year task. The Agency will conduct approximately 100 new active ingredient

and 100 old ai reviews per year until approximately 2021. Unusual circumstances may require that a specific chemical be addressed earlier, for instance, in response to a lawsuit.

Endangered species assessments require best available data. Both laboratory and field studies submitted by registrants and the open literature are used. The Agency's ECOTOX database facilitates the program's review of the open literature. It contains both publicly available and not yet publicly available data and is updated on a schedule corresponding to the Division's assessment schedule.

Endangered species assessments must be spatially and temporally specific to a listed species. A challenge in conducting assessments is integrating land use, pesticide use and species locations to assess whether a specific endangered species would be adversely affected. The Agency is using land use/land cover data and developing GIS tools to enable assessments to be conducted efficiently. An assessment of the co-location of pesticide use with the habitat of the Barton Springs salamander was presented.

Since each ES assessment becomes species specific, information systems to capture and allow retrieval of species specific information are being developed by the Agency. Requirements are currently being developed for such a system.

The Agency has a number of scientific challenges, for instance, assessing pathways of exposure in the absence of inhalation and dermal exposure data and the extrapolation of surrogate species data to specific endangered species. Improved understanding of these challenges and state of the science are topics of meetings and public workshops with the FWS, NMFS and stakeholders. Tool development is discussed during monthly meetings with the Services. Carbofuran, the rodenticides and metolachlor are being taken through the consultation process with the Services to further define this process.

Bulletins will specify geographic limitations in pesticide use to protect endangered species with continued use of a pesticide in other areas. A reference to the bulletins will be placed on the pesticide label and the bulletins will be available on the web. Bulletins can then be readily accessible to users and easily updated by the Agency. Challenges in assuring compliance with the limitations are the pesticide users' knowledge of and understanding of the bulletins and of the limitations in place at any time particularly since bulletins will be updated continually. To improve the level of compliance, the Agency will develop and distribute educational materials, work with extension coordinators, and have "draft" bulletins reviewed at the state level. State and tribal regulatory and enforcement officials will have access to the historical information supporting the bulletins.

The Agency has made progress in implementing the ESA. Scientific review and assessment processes are in place. Significant improvement has been made in the development and deployment of tools. Registrants were encouraged to provide input on how processes could be further improved for greater effectiveness and efficiency.

Registrants were encouraged to provide relevant and valid data in their submissions and to avoid excessive and low value data. Data of interest are application and usage data.

In response to stakeholder questions, the Federal Endangered Species Task Force Information Management System has value in the screening level assessment as it provides county level information on pesticide use and in field implementation though there are limitations on data availability. State and public input on county bulletins will be a part of the bulletin development process. Registrants commented that they are interested in the format of an endangered species assessment as they are uncertain as to what information they should provide.

Future Activities/Projects - Priorities for Future Process Improvements

Greg Watson, on behalf of the Industry PRIA Coalition, distributed a list of improvement priorities from the first meeting of the workgroup. The EPA has addressed the first priority on the list, labeling, with the formation of the OPP Labeling Committee. The Agency was requested to share its priorities for process improvement during the next meeting of the workgroup.

To support electronic submission, another priority process improvement, a survey of registrants to determine what electronic forms they use was suggested. Examples of completed forms have already been developed for antimicrobial submissions to facilitate better submissions. Product Chemistry process improvements are a priority of the industry and Marty Monell reported that it is also a priority for the Agency. It will be a topic of discussion during the next meeting of the workgroup. Registrants were encouraged to update the product chemistry problem statement with specific examples of, for instance, the differences in reviews between the Registration Division and the Special Review and Reregistration Division.

Julie Spagnoli reported that PR 98-10 needs to be updated to reflect product labeling policy changes. She also noted that States do not accept notifications and that the notification process needs to be more visible.

The next meeting of the workgroup will be held in conjunction with the next PPDC meeting. Topics will include process improvements in product chemistry, the “Blue Book” focus meeting, and EPA updates.

"For Use Only By" Label Statements
1-4-06

Issue

Should the Agency allow labeling restrictions or recommendations such as "for use only by" for pesticide users outside of the restricted use pesticide category? What would be the value of allowing this? What are the problems associated with allowing this? Do States have the ability to restrict sale to certain types of users?

Discussion

Pesticides are classified as either General Use, those products which can be purchased and used by any person, or Restricted Use, those products that can only be purchased and used by certified applicators. Certified applicators must be trained in the proper use of restricted use products before they may purchase and use them. States usually train and certify applicators although in certain instances the federal government may train and certify applicators.

As the result of reviewing data on a chemical, usually through the registration or reregistration process, the Office of Pesticides Programs (OPP) often uses label language to mitigate the risks of a pesticide. One way of attempting to mitigate risks is to restrict the use of a pesticide to certain categories of applicators without actually classifying it as Restricted Use. This is usually done because the toxicity of the pesticide does not cause it to be classified as Restricted Use, yet there are risk mitigating advantages to only having certain applicators use the product. Alternatively, companies often restrict the use of a pesticide for marketing purposes which may or may not have risk mitigation advantages.

The Office of Enforcement and Compliance Assurance (OECA) has held that for the most part attempts to restrict the use of a chemical to certain categories of applicators, such as "For Professional Use Only" or "For Use Only by Pest Control Operators," without classifying the product as restricted use are ineffective from an enforcement standpoint and thus of questionable use for mitigation purposes. Through PR Notices in 1996 and 2005, OPP has limited the use of termiticides and certain mosquito control products respectively, without classifying products for restricted use. These limitations appear to be effective because the persons specified on the label to apply these products are clearly identifiable, either by a state credential other than certification (state license for termiticides) or by being employed by certain public agencies. It is important to note that the Agency cannot restrict the sale and distribution of a product without classifying it as a Restricted Use Pesticide.

Opportunity for Comment

In addition to this general request for public comments on the issue of limiting use of products without classifying them as restricted use, OPP is interested in comments on particular issues such as, should the Agency allow labeling that appears to restrict use of

pesticide products to groups of applicators who are neither certified nor clearly defined/credentialed? What is the value of allowing this? What are the problems or issues associated with allowing this? What is the value or need for having non-enforceable limitations on use/users? Do these types of limitations cause confusion? Do these types of limitations cause legal problems?

Please submit your comments within 30 days to: opp_labeling_consistency@epa.gov. To assist the Agency in responding to comments please include your name, organizational affiliation, and telephone number. Comments received will be made available to the public. Any personal information provided may be subject to disclosure. Do not submit information that you consider to be Confidential Business Information (CBI) or otherwise protected to opp_labeling_consistency@epa.gov.

Incomplete Applications--Missing Elements Identified in the Front-End Screening Process

The following information covers the time period from the beginning of PRIA until the middle of August 2005. It was collected from PRIA front end processing forms that are used to record information about the PRIA applications, primarily for billing purposes. This source would underestimate the problem, because the form does not require that information on why packages are incomplete be listed. However, many front end screeners use the remarks section of the form to record package deficiencies. Our best estimate using this data is that these types of problems are occurring in over 10% of the applications in RD.

Company	EPA Form 8570-27 Formulator's Exemption	EPA Form 8570-34 Certification with Respect to Citation of Data	EPA Form 8570-35 Data Matrix	Citation of Substantially Similar Product (somewhere in application)	Product Chemistry data	Acute Tox	Efficacy data	Comment
A	X				X			
B		X				X		
C		X	X					
D				X				
			X		X			
					X			
E			X	X				

Company name	EPA Form 8570-27 Formulator's Exemption	EPA Form 8570-34 Certification with Respect to Citation of Data	EPA Form 8570-35 Data Matrix	Citation of Substantially Similar Product (somewhere in application)	Product Chemistry data	Acute Tox	Efficacy data	Comment
F			X	X				Does not list generic data
					X			
	X							
					X			
G					X		X	
					X		X	
H		X	X	X				
I					X			
		X	X		X			
Company name	**EPA Form 8570-27 Formulator's Exemption**	**EPA Form 8570-34 Certification with Respect to Citation of Data**	**EPA Form 8570-35 Data Matrix**	**Citation of Substantially Similar Product (somewhere in application)**	**Product Chemistry data**	**Acute Tox**	**Efficacy data**	**Comment**

J				X	X	X		
K				X				
				X				
L					X			
					X			
M				X				
N					X			
O		X						
		X						
Company name	**EPA Form 8570-27 Formulator's Exemption**	**EPA Form 8570-34 Certification with Respect to Citation of Data**	**EPA Form 8570-35 Data Matrix**	**Citation of Substantially Similar Product (somewhere in application)**	**Product Chemistry data**	**Acute Tox**	**Efficacy data**	**Comment**
P					X			Incomplete application
Q			X					
R			X					

S					X			
T					X			
U			X		X			
Company name	**EPA Form 8570-27** **Formulator's Exemption**	**EPA Form 8570-34** **Certification with Respect to Citation of Data**	**EPA Form 8570-35** **Data Matrix**	**Citation of Substantially Similar Product (somewhere in application)**	**Product Chemistry data**	**Acute Tox**	**Efficacy data**	**Comment**
V							X	
W							X	
X						X		
Y					X			
Z					X			Undergoing 86-5 screen not with jacket

Company name	EPA Form 8570-27 Formulator's Exemption	EPA Form 8570-34 Certification with Respect to Citation of Data	EPA Form 8570-35 Data Matrix	Citation of Substantially Similar Product (somewhere in application)	Product Chemistry data	Acute Tox	Efficacy data	Comment
AA			X	X				
							X	
							X	
BB			X					
CC					X			
DD					X			Prod chem data cited, yet prod not a straight repack
		X						
EE					X			
Company name	**EPA Form 8570-27 Formulator's Exemption**	**EPA Form 8570-34 Certification with Respect**	**EPA Form 8570-35**	**Citation of Substantially Similar Product (somewhere**	**Product Chemistry data**	**Acute Tox**	**Efficacy data**	**Comment**

		to Citation of Data	Data Matrix	in application)				
FF							X	
							X	
GG					X			
HH					X			
					X			
II							X	
JJ				X				
KK				X				

Company name	**EPA Form 8570-27** **Formulator's Exemption**	**EPA Form 8570-34** **Certification with Respect to Citation of Data**	**EPA Form 8570-35** **Data Matrix**	**Citation of Substantially Similar Product (somewhere in application)**	**Product Chemistry data**	**Acute Tox**	**Efficacy data**	**Comment**
LL		X						
MM					X			
NN					X			

OO	X							
					X			
PP							X	
QQ	X							
				X				
	X							
RR				X				
Company name	**EPA Form 8570-27** **Formulator's Exemption**	**EPA Form 8570-34** **Certification with Respect to Citation of Data**	**EPA Form 8570-35** **Data Matrix**	**Citation of Substantially Similar Product (somewhere in application)**	**Product Chemistry data**	**Acute Tox**	**Efficacy data**	**Comment**
SS					X			
TT			X					Data matrix incomplete
UU					X			
VV					X			

WW	X							
Company name	**EPA Form 8570-27** **Formulator's Exemption**	**EPA Form 8570-34** **Certification with Respect to Citation of Data**	**EPA Form 8570-35** **Data Matrix**	**Citation of Substantially Similar Product (somewhere in application)**	**Product Chemistry data**	**Acute Tox**	**Efficacy data**	**Comment**
XX					X			
YY		X						
ZZ		X						
AAA							X	
BBB		X						
					X			
CCC				X			X	
	EPA Form	**EPA Form**	**EPA**	**Citation of**	**Product**	**Acute**	**Efficacy**	

Company name	8570-27 Formulator's Exemption	8570-34 Certification with Respect to Citation of Data	Form 8570-35 Data Matrix	Substantially Similar Product (somewhere in application)	Chemistry data	Tox	data	Comment
DDD				X	X			
Total 75								

COMPARATIVE MATRIX of Referenced PRNs Posted on the EPA Webpage (DRAFT V2.0)

THIS IS A DRAFT DOCUMENT - PLEASE SUBMIT ANY CORRECTIONS TO:

Michael Nieves
Registration Division
nieves.michael@epa.gov
703-308-6351

DRAFT 2 - Updated on Sept 20, 2005

PRN	Referenced PRNs	COMMENTS
2002-2	98-7, 97-2, 86-5	PRNs: 98-7, 97-2, 86-5 are on the EPA PRN webpage.
2001-6	98-10, 84-1, 83-3	PRN 2001-6 **supersedes** portions of the label instructions in PRN 83-3 & 84-1
2001-3	82-2	PRN 2001-3 states that registrants should submit final printed labeling in accordance with PRN 82-2, before distributing the product in commerce. PRN 82-2 is **NOT** on the EPA PRN webpage. PRN 82-2: Change in procedures for approval of applications
2001-1	2000-3	PRN 2001-1 **supersedes** PRN 2000-3. PRN 2000-3 in **NOT** on the EPA PRN webpage. PRN 2000-3: First Aid Statements on Pesticide Product Labels
2000-10	2000-1	PRN updates the “sell date” mentioned in PRN 2000-1.
2000-5	98-10, 95-2	PRN 2000-5 states that registrants may no longer add or change advisory labeling statements to existing products by notification as previously permitted by PR Notices 95-2 & 98-10. PRN 2000-5 **supersedes** those PR Notices concerning the use of notification for adding or modifying advisory statements.
2000-4	91-5	PRN 2000-4 **supersedes** PRN 91-5. PRN 91-5 is **NOT** on the EPA PRN webpage.

		PRN 91-5: Instructions for transmitting information to the Office of Pesticide Programs.
98-10	97-6, 97-4, 95-2, 94-2, 91-1, 84-1, 83-3, 82-2	PRN 98-10 **supersedes** PRN 95-2 **except** with regard to advisory statements. PRN 95-2: Notifications, Non-Notifications and Minor Formulation Amendments PRN 98-10 states: "If deletion of the use(s) is chosen as a response to a data call-in, the end product registrant should respond to the DCI and submit a notification for each changed product label rather than an amendment as described in PRN 91-1" PRN 91-1 is **NOT** on the EPA PRN webpage. PRN 91-1: Procedures for Voluntarily Requesting Deletion of Approval Uses from Registered Labels PRN 98-10 states: "Two (2) copies of final printed labeling must also be submitted to the Agency before a product, as modified, may be sold or distributed [PR Notice 82-2 and 40 CFR 156.10(a)(6)]. PRN 82-2 is **NOT** on the EPA PRN webpage. PRN 82-2: Change in procedures for approval of applications
98-7	97-3, 97-2	PRNs: 97-3, 97-2 are on the EPA PRN webpage.
98-4	98-3	PRN: 98-3 is on the EPA PRN webpage.
98-3		PRN 98-3 **supersedes** all previous policy statements pertaining to section 6(a)(2).
98-2	94-4	PRN: 94-4 is on the EPA PRN webpage.
98-1	92-5	PRN 98-1 states "This Notice **does not supersede** any regulations. Consistent with PR Notice 92-5, applicants need not submit summaries of color and odor of certain end-use products and, except as specified in PR Notice 92-5, the Agency will not request data on these properties. Applicants are advised, however, to summarize the results of color and odor for all MPs and the storage stability

		study for all MPs and EPs and, when requested, submit supporting data. Since PRN 92-5 calls for generating the storage stability data for certain EPs to be submitted upon request, as summary of this data should be included on this form." PRN 92-5 is **NOT** on the EPA PRN webpage. PRN 92-5: Product Chemistry Data Requirements for Registration and Re-registration of End-use Products
97-9	96-2	PRN: 96-2 is on the EPA PRN webpage.
97-8	96-7	PRN: 96-7 is on the EPA PRN webpage.
97-3	97-1, 93-9	PRN 97-3 states: "This PR Notice **supersedes** the reduced-risk criteria published in Federal Register notice 57 CFR 32140, July 20, 1992 and 58 FR 5854, January 22, 1993 and PR Notice 93-9, July 21, 1993". PRN 93-9 is **NOT** on the EPA PRN webpage. PRN 93-9: Voluntary Reduced-Risk Pesticides Initiative
97-2	95-4	PRN: 95-4 is on the EPA PRN webpage.
97-1	86-5	PRN: 86-5 is on the EPA PRN webpage.
96-1	88-5	PRN 96-1 **supersedes** PRN 88-5. PRN 88-5 is **NOT** on the EPA PRN webpage. PRN 88-5: Tolerance Enforcement Methods - Independent Confirmation by Petitioner
95-5	93-11, 93-7	PRN 95-5 discusses the WPS labeling changes in PRN 93-11. PRN 93-11 is **NOT** on the EPA PRN webpage. PRN 93-11: Supplemental Guidance for PR Notice 93-7 - Labeling Revisions Required by the Worker Protection Standard (WPS) PRN 95-5 discusses the Worker Protection Standard Applicability to Individual Products found in PRN 93-7.

		PRNs 93-7 is **NOT** on the EPA PRN webpage. PRN 93-7: Labeling Revisions Required by the Worker Protection Standard (WPS)
95-2	91-1, 88-6, 84-1, 83-3	PRN 95-2 states: "This PR Notice **supersedes** PRN Notice 88-6 (August 12, 1988) and the second edition of General Information On Applying For Registration of Pesticides In The United States (The Blue Book, Chapter 4, C, and D). This PR Notice also modifies parts of PR Notices 83-3 and 84-1 (Storage and Disposal Statements), and PR Notice 91-1 (Use Deletions)." PRN 88-6 is **NOT** on the EPA PRN webpage. PRN 88-6: Change in Registration Procedures - Agency Approval not Required for certain amendments
95-1	93-10	PRN 95-1 quotes effluent discharge statements found in PRN 93-10. PRN 93-10 is **NOT** on the EPA PRN webpage. PRN 93-10: Effluent Discharge Labeling Statements
94-8	91-1, 82-2	PRN 94-8 states: "WPS may not be deleted from a currently registered product except by amendment in accordance with PR Notice 91-1". PRN 91-1 is **NOT** on the EPA PRN webpage. PRN 91-1: Procedures for Voluntarily Requesting Deletion of Approved Uses from Registered Labels PRN 94-8 states: "For each product, final printed labeling should be submitted either as partof the notification or separately in accordance to PR Notice 82-2 before the product may be distributed or sold". PRN 82-2 is **NOT** on the EPA PRN webpage. PRN 82-2: Change in Procedures for Approval of Applications
94-7	83-5	PRN 94-7 discusses how in PRN 83-5, EPA summarized its historial policy regarding the use of rodenticide bait stations to isolate rodenticicde baits from nontarget animals. PRN 83-5 is **NOT** on the EPA PRN webpage. PRN 83-5: Tamper-proof Bait Boxes.

94-6	88-6	PRN 94-6 requires registrants to submit a Notification in accordance with procedures outlined in PR Notice 88-6. PRN 88-6 is **NOT** on the EPA PRN webpage. PRN 88-6: Change in Registration Procedures - Agency Approval not Required for certain amendments
94-1	91-8	PRN 94-8 announces withdrawal of PRN 91-8. PRN 91-8 is **NOT** on the EPA PRN webpage. PRN 91-8: Revised Policy To Provide Applicants Other Than Basic Manufacturers An Opportunity To Submit Generic Data And Receive Data Compensation For It
90-1	87-6	PRN: 87-6 is on the EPA PRN webpage.
86-5	86-4	PRN: 86-4 is on the EPA PRN webpage.
84-1	83-3, 83-2	PRN 94-1 clarifies the Agency's intentions regarding the Pesticide Label Improvement Program (LIP) for Farmworker Safety (PR Notice 83-2) and Pesticide Storage and Disposal (PR Notice 83-3) issues on March 26, 1983. PRN 83-2 is **NOT** on the web. PRN 83-2: Pesticide Label Improvement Program (LIP) for Farmworker Safety