March 2007

Evaluation of the U.S. EPA Pesticide Product Reregistration Process: Opportunities for Efficiency and Innovation

Promoting Environmental Results

Through Evaluation

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List of Exhibits

Acronyms

AD	Antimicrobials Division
AI	Active Ingredient
BEAD	Biological and Economic Analysis Division
BPPD	Biopesticides and Pollution Prevention Division
CBI	Confidential Business Information
CFR	Code of Federal Regulations
CRM	Chemical Review Manager
CRS	Congressional Research Service
CSF	Confidential Statement of Formula
DCI	Data Call-In
EPA	U.S. Environmental Protection Agency
FEAD	Field and External Affairs Division
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA	Food Quality Protection Act
FR	Federal Register
FTE	Full-Time Equivalent
GAO	General Accountability Office
GPRA	Government Performance and Results Act
HED	Health Effects Division
HHDA	Hazard to Humans and Domestic Animals
IRED	Interim Reregistration Eligibility Decision
ISB	Information Services Branch
IMC	Information Management Council
ITRMD	Information Technology and Resource Management Division
MOA	Memorandum of Agreement
MRID	Master Record Identification Number
NRDC	Natural Resources Defense Council
OGC	Office of General Counsel
OIG	Office of Inspector General
OMB	Office of Management and Budget
OPP	Office of Pesticide Programs
OPPIN	Office of Pesticide Programs Information Network
OPPTS	Office of Prevention, Pesticides, and Toxic Substances
PARS	Performance Appraisal and Recognition System
PART	Program Assessment Rating Tool
PDCI	Product-Specific Data Call-in
PM	Product Manager
PPDC	Pesticide Program Dialogue Committee
PPE	Personal Protective Equipment
PPLS	Pesticide Product Label System
PRA	Paperwork Reduction Act
PRB	Product Reregistration Branch
PRIA	Pesticide Registration Improvement Act of 2003
PRN	Pesticide Registration Notice
PSB	Program Support Branch
RCS	Regulatory Coordination Staff
RD	Registration Division
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RUP	Restricted Use Pesticide
SEE	Senior Environmental Employment
SOP	Standard Operating Procedure
SRRD	Special Review and Reregistration Division
TRED	Tolerance Reassessment Eligibility Decision
USDA	U.S. Department of Agriculture
WPS	Worker Protection Standard

Acknowledgments

In Fall 2005 the U.S. Environmental Protection Agency (EPA) Office of Pesticide Programs (OPP) entered the EPA Program Evaluation Competition and was selected for an evaluation of its product reregistration process. This competition, jointly sponsored by the Office of Policy, Economics and Innovation and the Office of the Chief Financial Officer, encourages the effective use of program evaluation throughout EPA. As a subcontractor to Industrial Economics, Abt Associates conducted this evaluation under EPA contract EP-W-04-023.

The Abt Associates evaluation team gratefully acknowledges the input and guidance provided by Peter Caulkins, OPP Special Review and Reregistration Division, and Yvonne Watson, EPA Office of Policy, Economics, and Innovation, throughout the design and implementation of the evaluation. We also appreciate the time made available by OPP staff members to meet with the evaluation team, which provided us with critical information on their roles, responsibilities, and perspectives on product reregistration that would not have otherwise been available.

Preface

As a subcontractor to Industrial Economics, Abt Associates conducted this evaluation under EPA contract EP-W-04-023. This report reflects the information made available to Abt Associates either by EPA or through published sources. A substantial amount of the information is qualitative in nature and was collected through a series of interviews with EPA staff. The findings presented in this report are based on the information made available to the evaluation team. Further, the conclusions and recommendations presented in this report are those of the evaluation team and are not necessarily reflective of EPA's position.

Executive Summary

The U.S. Environmental Protection Agency (EPA) Office of Pesticide Programs (OPP) conducts a comprehensive review of pesticides initially registered before November 1, 1984, to ensure that they meet contemporary health and safety standards and labeling requirements. After the registrant signals its intent to reregister an active ingredient, EPA conducts science reviews, develops a risk assessment and publishes it for public comment, and issues a Reregistration Eligibility Decision (RED). EPA then must reregister each of the individual pesticide products that contains the active ingredient. This final step in the process – pesticide product reregistration – is the focus of this evaluation.

Product reregistration consists of three basic steps, which are completed by either the OPP Special Review and Reregistration Division (SRRD) or the Registration Division (RD): (1) SRRD sends registrants a Data Call-In (DCI) notice requesting the needed product-specific data. (2) SRRD receives and evaluates the requested studies from the registrants and conducts a preliminary label assessment. (3) RD reregisters a product if it was found to meet its standards by issuing a reregistration notice and stamping a revised label that includes the necessary mitigation.

Evaluation Purpose and Approach

There is considerable interest within EPA to streamline and expedite the product reregistration process. The purpose of this evaluation is to identify potential opportunities for innovation and streamlining of the product reregistration process in order to (1) ensure timelier implementation of the mitigation measures specified in the RED, and (2) make the process as efficient as possible in order to decrease the amount of time needed for product reregistration and use resources in the most effective manner. The evaluation was designed to answer the following questions:

- What components of REDs have caused delays in product reregistration?
- What problems, bottlenecks, or unnecessary duplication of efforts occur in the product reregistration process that are under the control of OPP?
- What innovations or streamlining in process could result in more timely implementation of mitigation specified in the RED and/or more efficient production of outputs?
- What are the pros and cons of each of the proposed innovations or streamlining measures?
- What is the optimal allocation of tasks between the Special Review and Reregistration Division and the Registration Division?
- Are any external entities or considerations impeding the product reregistration process?

The methodology employed several data collection methods, including interviews, document review, reregistration program data, case studies, and subject matter experts.

Product Reregistration Progress

Since beginning reregistration in the late 1980s, EPA has completed reregistration actions for 7,358 products. Reregistration actions for 11,948 products (conventional and antimicrobial)

were pending as of October 2006. Of the pending reregistration actions, the products are distributed through all phases of the pesticide reregistration process. Most of the products (9,088 or 76%) have not yet had the Data Call-in (DCI) approved by the Office of Management and Budget (OMB). The FY2006 REDs resulted in 6,722 products that will require DCIs.

On average, it took more than 54 months to reregister a product. On average, approximately 41 months were needed to transmit the reregistration package to the Product Manager (PM) in RD, and after the reregistration package had been sent to the PM, it took approximately 14 months to complete the reregistration process. The distribution of these data indicated that they are skewed such that the mean (average) is not adequate to represent the average duration of the process; the median time is more informative in this instance. The median time to complete product the product reregistration process was 30 months.

Product Reregistration Delays Associated with REDs

The Registration Eligibility Decisions (REDs) and subsequent activities were found to be a source of delay in product reregistration. REDs were often published before they are complete or before all outstanding issues were properly addressed. These documents represented a "snapshot in time" of the data made available to EPA, and registrants often provided additional data that warrant amending the RED. Some registrants were inclined to challenge the contents of a RED as a way to delay implementing mitigation. Also, some REDs did not represent decisions or included provisions for additional studies, such that product reregistration could not be effectively implemented after the RED was published. REDs sometimes contained small errors, most of which were straightforward and easy to address. The label tables often contained language that RD or SRRD Product Reregistration Branch (PRB) believe could been improved or that is not consistent with labeling for other products. Many of these issues only became apparent at implementation, which was during the product reregistration process.

Post-RED issues were not given high priority in work plans and adequate resources within the four SRRD reregistration branches, as statutory deadlines required continued focus on REDs. Staff from the reregistration branches were often unavailable to assist with post-RED issues. Given the length of time from when a RED was published, to when post-RED issues were addressed, to when product reregistration was conducted, the Chemical Review Manager (CRM) who wrote the RED was often no longer in that position.

Problems, Bottlenecks, and Unnecessary Duplications of Effort

Because of the length of the product reregistration process, as well as the delays that often occur, the mitigation identified in the RED is often not implemented for several years. This delay is particularly troublesome given that the universe of pesticides includes those that were registered prior to November 1, 1984. EPA has made several attempts to implement RED-specified mitigation as soon as possible, including through memoranda of agreement and requests to registrants. Even with regulatory action as a possible consequence of non-response, registrants did not submit amended labels for a substantial number of products.

There is substantial backlog in the number of DCIs that need to be approved by the Office of Management and Budget (OMB) and sent out by OPP so that product reregistration can begin. The review by OMB also results in substantial delay because the approval process takes an

average of nine to ten months. In addition, the format for the justification package has been and continues to be an issue, the needed information is not readily available in a suitable format, and OPP lacks an adequate tracking system for the DCI process.

One of the sources of delay in the product reregistration process are the registrant responses, which require a lot of time for the registrants to prepare and submit, as well as for EPA to receive, track, review, and respond to (if required). During the course of its reregistration program, EPA has initiated several efforts to increase the quality of data it receives from registrants so that data are not deficient, which requires additional time for the registrant to prepare and submit studies and for EPA to review them.

As currently designed, the Special Review and Reregistration Division (SRRD) conducts preliminary label assessments, and the Registration Division (RD) conducts full label reviews. The review by SRRD was intended to focus on mitigation required by the reregistration process, whereas RD focused on label amendments and content more generally. Despite this division of labor, the two reviews are duplicative and RD has not used many of SRRD's label assessments.

Efficient information management is an issue for all aspects of the product reregistration process. In 2000, EPA launched the Office of Pesticide Programs Information Network (OPPIN), which was intended to be an integrated, office-wide system. This system, which replaced existing systems to track reregistration on the product and active ingredient levels, failed to meet the needs of OPP with respect to product reregistration. In response, many staff have created one-off tracking systems in order to get their jobs done, making comprehensive, reliable status updates very difficult to retrieve. OPP again requested improvements to OPPIN in November 2006, but requests to modify OPPIN are often not granted due to competing demands and because OPPIN will be retired in September 2008. It is unclear the extent to which the new information management system, PRISM, will address the needs of product reregistration.

In its FY2007 reregistration work plan, SRRD allocates eight percent of its resources (full-time equivalent (FTE)) to product reregistration. This allocation is roughly equivalent to past staffing levels and SRRD expects the staffing level to remain fairly constant in the short term. SRRD intends to allocate funds to product reregistration at roughly the same level through FY2013. SRRD has predicted that it will complete product reregistration by the end of the 2012 calendar year.

Based on data provided by EPA, Abt Associates developed a conservative estimate as to when it believes OPP might complete product reregistration, assuming that the current level of activity and resource allocation continue. We estimate that product reregistration may not be completed for more than twelve years, or the end of FY2018. This is six years longer than EPA's current prediction, and five years longer than the period for which EPA has budgeted.

External Entities or Considerations

Two divisions of the Office of Pesticide Programs (SRRD and RD) are generally responsible for reregistering conventional pesticide products. However, other divisions participate in the effort, including the Field and External Affairs Division (FEAD) and the Information Technology and Resource Management Division (ITRMD). Both FEAD and the Office of Prevention, Pesticides,

and Toxic Substances Regulatory Coordination Staff participate in the preparation of DCI justification packages and facilitate communication with OMB. FEAD recently developed a streamlined template for the package to improve the process. FEAD also provides scientific and technical staff support to SRRD. ITRMD is responsible for information technology and management. ITRMD receives and responds to requests for data systems improvement, such as those to OPPIN. The science divisions also provide some support for product reregistration, as needed.

The Office of Management and Budget (OMB) reviews and approves DCI justification packages. This review period varies in length and often results in EPA responding to several rounds of questions and issues raised by OMB. A new OMB desk officer was recently assigned to pesticide DCI approvals, so the timeline and procedures for the review of DCI justification packages may change. As needed, the U.S. Department of Agriculture and other federal agencies consult on product reregistration issues.

Finally, the pesticide registrants play a key role in product reregistration and are also a significant source of delay. In response to a DCI, registrants provide both ninety-day and eight-month responses, which include amended labels, waiver requests, and requested studies. In addition to the time provided for response, additional time is required when registrants submit deficient studies that have to be repeated/upgraded. Also, the review of this material and the communication with the registrant consume a significant portion of OPP's time as well.

Recommendations to Streamline or Modify Product Reregistration

The reregistration program has evolved over time and in response to significant policy changes, including the Food Quality Protection Act, Pesticide Registration Improvement Act, and the public participation program. The pesticide reregistration program is required under the Federal Insecticide, Fungicide, Rodenticide Act, but the process is not codified in regulation. Although this arguably has its down sides, for purposes of this evaluation it means that EPA has the flexibility to modify and improve the process to better meet its desired outcomes.

Internally, OPP initiated a dialogue to improve the product reregistration program, including developing a "SWAT Team" approach to expedite product reregistration. In addition, recent management attention has raised the visibility of product reregistration in both RD and SRRD. Based on the results of the evaluation, the following recommendations are presented to further expedite product reregistration and/or implement RED-specified mitigation more quickly:

Recommendations of the Evaluation Team
RED Development
▪ Improve the Transition of Chemical Cases from Reregistration Branches to PRB ▪ Require More Participation by RD in the Development of Label Tables
Implementation of RED-Specified Mitigation
▪ Implement Mitigation in an Expedited Manner When Cost-Effective ▪ Pursue Additional Regulatory Action When Warranted ▪ Further Explore Self-Certified or Electronic Labels
DCI Justifications and Preparation
▪ Ensure that DCIs Are Prepared According to the Package Template ▪ Modify Format of Supporting Data in Risk Assessments
Streamlined Data Requirements
▪ Conduct Additional Analyses to Determine Value of Product-Specific Data ▪ Leverage Related Efforts for Process Improvements ▪ Expand Scope of Batching Approaches to Reduce Number of Requested Studies ▪ Encourage Use of Self-Certified Product Chemistry Data
Registrant Responses
▪ Create Incentives for Registrants to Provide Expedited Responses ▪ Establish Procedures and Pursue Suspensions ▪ Retain Data Review Functions within PRB
Label Reviews and the Role of the Registration Division
▪ Discontinue Label Assessments within SRRD ▪ Improve Transition of Chemical Cases from SRRD to RD
Management, Resources, and Staffing
▪ Reevaluate Allocation of SRRD Resources ▪ Maintain Emphasis on Product Reregistration ▪ Pursue SWAT Teams and Other Strategies to Reduce Backlog ▪ Obtain Support for DCI Preparation
Communication
▪ Improve Internal and External Communication about Product Reregistration
Performance Management
▪ Improve Performance Measures and Strategic Targets ▪ Incorporate Product Reregistration into PARS
Information Management
▪ Continue to Prioritize an Integrated Tracking System ▪ Maintain Web Site as a Repository of Reregistration Decisions

These recommendations are discussed in detail in the body of the report, including applicable pros and cons for each.

1. Introduction

To ensure the safety of older pesticides, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) amendments of 1988 required the U.S. Environmental Protection Agency (EPA) to conduct a comprehensive review of pesticides initially registered before November 1, 1984. Through its pesticide reregistration process, the EPA Office of Pesticide Programs (OPP) ensures that older pesticides meet contemporary health and safety standards and labeling requirements. Reregistration includes approximately 600 active ingredient cases and more than 20,000 pesticide products that contain these active ingredients.

The reregistration process is composed of several steps. After the registrant signals its intent to reregister a pesticide, OPP conducts science reviews, develops a risk assessment and publishes it for public comment, and issues a Reregistration Eligibility Decision RED). After OPP publishes a RED, it then must reregister each of the individual pesticide products that contain the active ingredient. This final step in the process – pesticide product reregistration – is the focus of this evaluation.

1.1 Purpose and Evaluation Questions

Risk assessments and mitigation requirements are incorporated in Reregistration Eligibility Decision documents (REDs) for each active ingredient; however, the mitigation for that active ingredient is not implemented in the field until the individual product labels have been changed. This is accomplished through the product reregistration process that follows the completion of the RED, a process that often spans several years and thus prolongs the implementation of environmentally protective measures specified in REDs. In addition, the recent signature of the REDs for food-use pesticides will next require OPP to reregister thousands of individual products. For these and other reasons, there is considerable interest within EPA to streamline and expedite the product reregistration process.

The purpose of this evaluation is to identify potential opportunities for innovation and streamlining of the product reregistration process in order to:

- Ensure timelier implementation of the mitigation measures specified in the RED, and
- Make the process as efficient as possible in order to decrease the amount of time needed for product reregistration and use resources in the most effective manner.

In order to focus the evaluation and establish a clear goal, Abt Associates and EPA identified several specific questions regarding the product reregistration process that were of particular interest. This evaluation was designed to provide the answers to the following questions:

1. What components of REDs have caused delays in product reregistration?
2. What problems, bottlenecks, or unnecessary duplication of efforts occur in the product reregistration process that are under the control of OPP?

3. What innovations or streamlining in process could result in more timely implementation of mitigation specified in the RED and/or more efficient production of outputs?
4. What are the pros and cons of each of the proposed innovations or streamlining measures?
5. What is the optimal allocation of tasks between the Special Review and Reregistration Division and the Registration Division?
6. Are any external entities or considerations impeding the product reregistration process?

1.2 Evaluation Audience

The findings, conclusions, and recommendations of this process evaluation will be of interest largely to the individuals responsible for or who participate in the pesticide product reregistration process. Thus, the primary audiences for this report are EPA managers and staff who will use the results of the evaluation as a management tool to identify issues related to the current process, including the extent/nature of the problems and possible modifications to the product reregistration process. The findings may further serve as a catalyst for innovation within the program, which will increase efficiency and reduce the product reregistration backlog, beyond the scope of what is recommended in this report.

Please note that due to the nature of the evaluation and the information contained within this report, this report and its supporting documentation is considered internal, EPA deliberative material, and therefore should not be cited, quoted, or distributed outside the Office of Pesticide Programs or the Office of Policy, Economics and Innovation unless otherwise approved by both the management of the Office of Pesticide Programs and the EPA Work Assignment Manager, Yvonne Watson.

1.3 Program Description

Product Reregistration for conventional pesticides is largely the responsibility of the EPA Office of Pesticide Programs (OPP) Special Review and Reregistration Division (SRRD), although the final end products – reregistration notices and stamped labels – are dependent upon the Registration Division (RD). In addition to product reregistration, SRRD is also responsible for reregistration eligibility decisions, tolerance reassessments, and special reviews. Reregistration of antimicrobial pesticides or biopesticides is the responsibility of the Antimicrobials Division (AD) and Biopesticides and Pollution Prevention Division (BPPD), respectively. This evaluation focuses only on conventional pesticide products because of the limited time and resources available and because conventional products are most common.

1.3.1 Statutory Framework

The Federal Insecticide, Fungicide, and Rodenticide Act, or FIFRA, as amended in 1988, authorized EPA to conduct a comprehensive pesticide reregistration program. Reregistration involves a complete review of the human health and environmental effects of older pesticides

originally registered before November 1, 1984. The reregistration process is finite and will conclude when all pesticides registered prior to November 1, 1984, have been reregistered (or cancelled). The reregistration requirements of FIFRA are not codified by rulemaking.

FIFRA specified five stages of reregistration and included provisions for collection of reregistration fees. Product reregistration is considered part of phase five, data review and reregistration (FIFRA section 4(b)). According to FIFRA section 4(g)(2)(b):

- Before reregistering a pesticide, EPA shall obtain any needed product-specific data regarding the pesticide and shall review such data within ninety days after its submission.
- EPA shall require that the data be submitted not later than eight months after a determination of eligibility has been made for each active ingredient of the pesticide, unless a longer period is required for the generation of the data (no more than two additional years).
- After reviewing its active ingredient(s) and product-specific data, EPA shall determine whether to reregister a pesticide. If eligible to be reregistered, EPA shall reregister such pesticide within six months after the submission of the product-specific data.

The Pesticide Registration Improvement Act (PRIA) of 2003 established pesticide registration service fees for registration actions. It also included specific deadlines for completion of specific aspects of the reregistration process:

- Complete all REDs for food-use pesticides by August 3, 2006
- Complete all REDs for non-food-use pesticides by October 3, 2008

EPA met its deadline to complete the 231 REDs for food-use pesticides, with the exception of aldicarb.[1] PRIA did not provide deadlines for completion of product reregistration.

Pesticides with food uses must meet the safety standards of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996. EPA must determine that pesticide residues remaining in or on food are safe. As amended by FQPA, FFDCA requires the reassessment of all existing tolerances (pesticide residue limits in or on food).

FQPA also amended FIFRA to require periodic review of pesticide registrations to ensure that all pesticides continue to meet statutory and policy standards over time. FIFRA section 3(g) specifies that EPA establish procedural regulations for conducting registration review on a fifteen-year cycle. This regulatory scheme, called registration review, was proposed for public comment in July 2005[2] and the EPA Administrator signed the final action on August 1, 2006.[3]

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[1] EPA Press Release, "U.S. Pesticide Safety Highest in the World," August 1, 2006, http://www.epa.gov/newsroom/

[2] 40 CFR part 155, Procedural Regulations for Registration Review, Proposed Rule, 70 FR 40251, July 13, 2005

EPA designed the program to address lessons learned from reregistration, including predictable schedules, sound science, transparency and public participation, flexibility, early stakeholder involvement, and using a docket system.[4]

1.3.2 Product Reregistration Process

Pesticides that meet current scientific and regulatory standards may be declared "eligible" for reregistration. To be eligible, an older pesticide must have a substantially complete database, and must not cause unreasonable adverse effects to human health or the environment when used according to EPA-approved label directions and precautions. EPA publishes its reregistration eligibility decision in one of two document types:

- REDs, or Reregistration Eligibility Decisions, for pesticides that have sufficient supporting data and whose risks can be successfully mitigated.
- IREDs, or Interim Reregistration Eligibility Decisions, for pesticides that are undergoing reregistration, require a reregistration eligibility decision, and also must be included in a cumulative assessment under the Food Quality Protection Act (FQPA) of 1996 because they are part of a group of pesticides that share a common mechanism of toxicity.

For pesticides that require tolerance reassessment decisions under FFDCA, but do not require a reregistration eligibility decision, or where the RED was completed prior to the passage of FQPA (1996), EPA publishes a Report on FQPA Tolerance Reassessment Eligibility Decision (TRED).

After EPA declares a pesticide reregistration case conditionally eligible for reregistration (the condition being that RED-specified mitigation is incorporated on the label), the individual end-use products that contain the active ingredient must be reregistered. This concluding part of the reregistration process is called "product reregistration." Product reregistration consists of three basic steps (Figure 1-1):

1. After issuing a RED for an active ingredient, SRRD sends registrants a Data Call-In (DCI) notice requesting any product-specific data needed to complete reregistration for each of the individual pesticide products covered by the RED.

2. SRRD receives and evaluates the requested studies from the registrants. It requests additional information, as needed, and conducts a preliminary label assessment.

3. Based on its review of the data and labeling, RD reregisters a product if it was found to meet FIFRA and FFDCA standards. The primary output of this step is a reregistration notice (issued to the registrant) and the stamped pesticide label, which includes any revised mitigation specified in the RED or during the product reregistration process.

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[3] 40 CFR part 155, Procedural Regulations for Registration Review, Final Rule, 71 FR 45719, August 9, 2006

[4] "Compare Registration Review to Reregistration," Presentation by Susan Lewis, Special Review and Reregistration Division

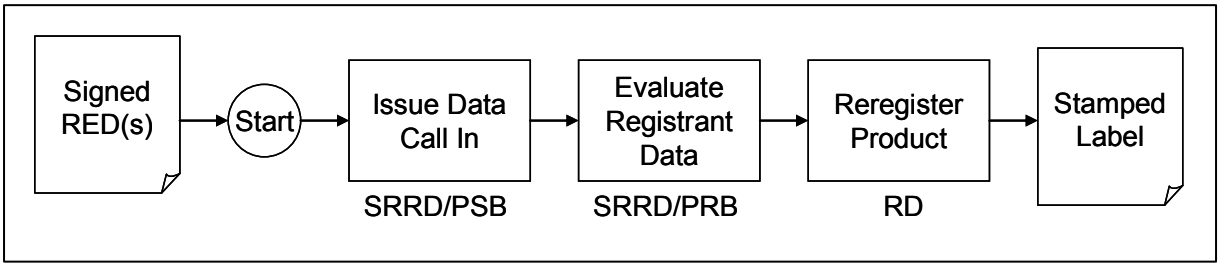


Figure 1-1. Overview of Product Reregistration Process. *(Source: OPP Enterprise Architecture Process Description: Special Review and Reregistration Division Product Reregistration, SRA)*

Issue Data Call-in

After a RED is signed, EPA collects both product-specific data and confirmatory data on the active ingredient as identified in the RED. EPA requests this information through Data Call-ins (DCIs) that are approved by the Office of Management and Budget (OMB) and then issued by EPA to the pesticide registrants. DCIs may either be generic (for confirmatory data) or product-specific (PDCIs). The Program Support Branch in SRRD is responsible for preparing the DCIs.

Evaluate Registrant Data

Registrants must respond to a DCI to indicate whether or not they intend to support a product within ninety days of issuance. If the product will not be supported, EPA publishes a cancellation notice in the *Federal Register*. If a registrant does not respond to the DCI, EPA has the option to initiate a suspension of the registration. Registrants continuing to support a product must submit study data to EPA within eight months of the DCI being issued. The Information Technology and Resource Management Division/Information Services Branch (ITRMD/ISB) reviews the study format, assigns a record number, and sends the studies to the Chemical Review Manager (CRM) in SRRD Product Reregistration Branch (PRB).

The SRRD CRM coordinates and tracks all activities and communication with the registrant. Product chemistry and acute toxicology studies are evaluated within PRB. If a study contains efficacy data, RD conducts the evaluation since PRB does not have in-house expertise in that area. If a study contains deficiencies, the CRM notifies the registrant and requests a corrected study. After all data have been reviewed, PRB conducts a label assessment and then sends the required documentation to RD for a label review and reregistration decision.

Reregister Product

Once RD receives the product reregistration package, the Product Manager (PM) reviews it for completeness and requests any missing data from PRB. In most cases, the label submitted by the registrant with the original reregistration submission is no longer current, so RD requests an updated label from the registrant. Any package inaccuracies are corrected at this time.

Once the amended label has been provided and is acceptable, RD develops a reregistration notice. If a product contains multiple active ingredients, EPA instead issues an amendment to the product's registration; a product with multiple active ingredients is not reregistered until the last active ingredient in its formulation is eligible for reregistration and its label has been

amended. The registrant receives a reregistration notice and a copy of the stamped label. The label is recorded in Pesticide Product Label System (PPLS), which is available on the OPP Web site. This concludes the product reregistration process.

For more information on the product reregistration process, please refer to "OPP Enterprise Architecture Process Description: Special Review and Reregistration Division Product Reregistration," SRA International, September 29, 2005.

1.3.3 Roles in the Product Reregistration Process

This section provides a brief overview of the key OPP divisions that play a role in product reregistration. Other OPP divisions sometimes contribute to product reregistration, as needed and/or requested.

Special Review and Reregistration Division (SRRD) is responsible for pesticide reregistration, tolerance reassessment, and registration review for conventional chemical pesticides.

- Reregistration Branches write the REDs, process confirmatory data on an active ingredient that are submitted in response to a DCI, and address post-RED issues.
- Program Support Branch (PSB) is responsible for preparing DCI justification packages and issuing DCIs.
- Product Reregistration Branch (PRB) tracks ninety-day and eight-month responses to product-specific data call-ins, processes product guidelines and identifies deficiencies, communicates with the registrant, conducts label assessments, and processes packages for RD.

Registration Division (RD) is responsible for product registrations, amendments, registrations, tolerances, experimental use permits, and emergency exemptions for conventional chemical pesticides. With respect to product reregistration, RD conducts label reviews, requests additional label changes (as needed), sends reregistration notices, and stamps (approves) labels.

Information Technology and Resources Management Division (ITRMD) is responsible for information support, dockets, the OPP Web site, computer support, budget, and personnel. With respect to product reregistration, ITRMD receives and processes the ninety-day and eight-month submissions and supports some of the information management databases (e.g., OPPIN).

Field and External Affairs Division (FEAD) is responsible for program policies and regulations; legislation and congressional interaction; regional, state, and tribal coordination and assistance; international and field programs; and communication and outreach activities. With respect to product reregistration, FEAD reviews the DCI justification package and facilitates communication with OMB and other federal agencies.

1.3.4 Product Reregistration Program Logic Model

The evaluation questions (see Section 1.1) were considered relative to the logic model for the pesticide product reregistration program (Figure 1-2). A logic model is a visual, systematic way to represent how a program works by illustrating the relationships between a program's resources, activities, outputs, and short-term, intermediate, and long-term outcomes. The model highlights the key connections between program components and outcomes, as well as providing some context in which the program operates.

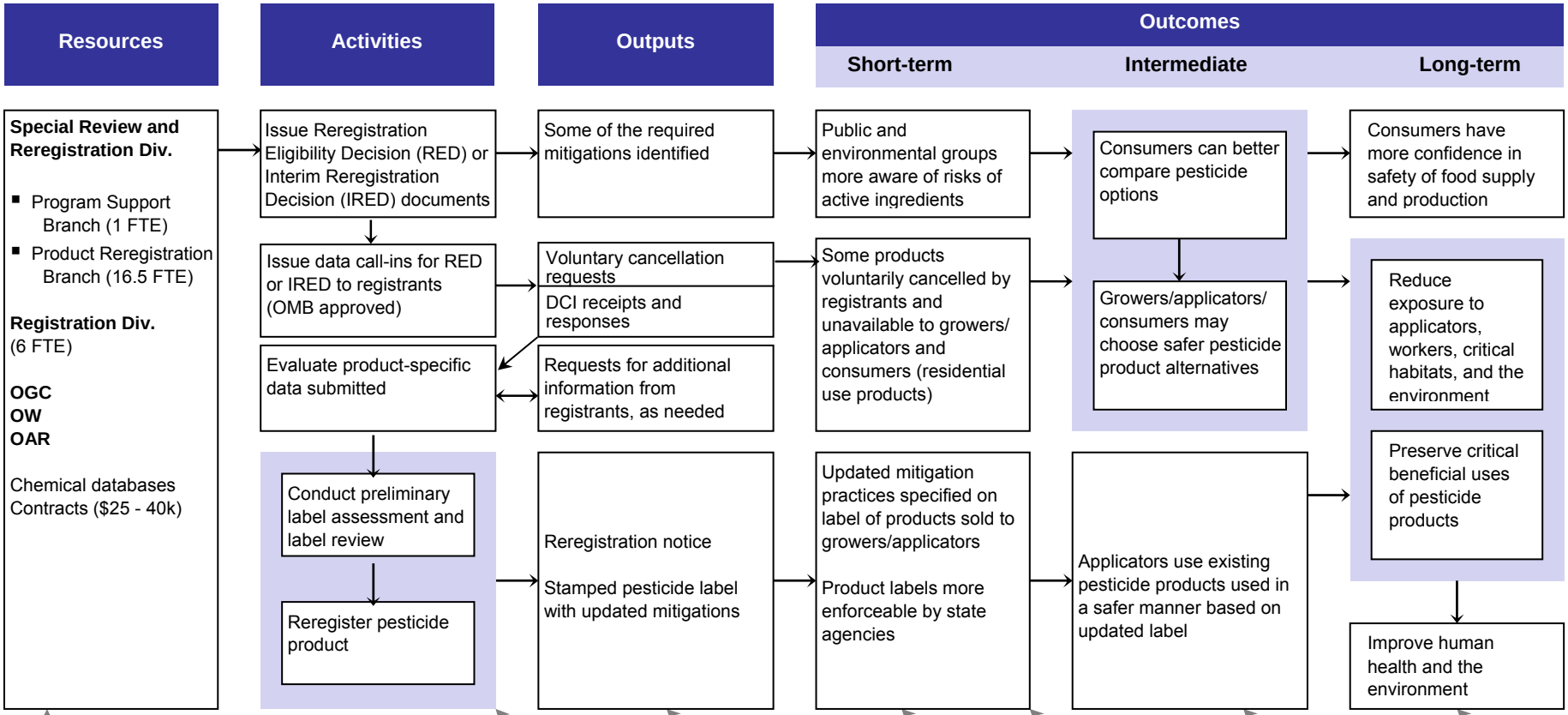
The program's logic model illustrates several key considerations regarding the product reregistration process:

- Issuing the RED does not directly result in mitigations appearing on the label. That is, the program cannot achieve its short-term outcome (updated mitigation practices specified on label of products sold to growers/applicators) until the completion of the entire product reregistration process.
- Product reregistration relies upon registrant-submitted data and receiving that data in a timely manner.
- OPP often has to request additional information from the registrant as it evaluates product-specific data, which results in delays as OPP requests data, the registrant develops the data, and OPP tracks and reviews (or re-reviews) additional submissions.
- Seven entities consult or participate in the product reregistration process, which removes aspects from the direct control of OPP. These organizations include other parts of EPA, other federal agencies, and the pesticide registrants (see "Partners that Consult or Participate").
- Several external factors affect program effectiveness, which influence resources, activities, outputs, and outcomes. These factors affect OPP's regulatory responsibilities, its priorities, the timeliness of information provided, and the resources available to complete product reregistration.
- Product reregistration has a variety of customers with different interests, concerns, and incentives.

Figure 1-2. Logic Model: U.S. EPA Office of Pesticide Programs Product Reregistration

Mission

To improve human and environmental health by ensuring older pesticide products are safe and to effectively manage and mitigate risk based on the best available science. The product reregistration program fulfills this mission by reviewing older pesticide products under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to ensure they meet current scientific and regulatory standards.



Partners that Consult or Participate

- Office of Management and Budget
- U.S. Department of Agriculture
- Regulatory Coordination Staff (EPA OPPTS)
- Field and External Affairs Division (EPA OPP)
- Information Technology and Resource Management Division /Information Services Branch
- Other Federal Agencies (FWS, NMFS, FDA)
- Pesticide Registrants

External Factors Affecting Program Effectiveness

- Oversight of Office of Management and Budget
- Responsiveness of Pesticide Registrants
- Level of budget allocation
- Implications of new legislation and regulations
- FIFRA Scientific Advisory Panel recommendations
- North American Free Trade Agreement requirements
- European Commission regulatory decisions

Customers

Pesticide Registrants develop and produce products

Growers/Applicators purchase, apply, and use products

Agricultural Workers work in areas where products are applied

Environmental Groups advocate a position and raise awareness of environmental issues to the public

General Public use residential products and consume food and other commodities that are treated with pesticides

State Agencies enforce pesticide labels

1.4 Review of Related Evaluations

Numerous entities have commented on reregistration and its shortcomings, though none have focused exclusively on product reregistration. Nonetheless, reviews conducted by the Government Accounting Office (now called the Government Accountability Office), the EPA Office of Inspector General, the Office of Management and Budget, and other entities illustrate the depth of the issues explored later in this report, as well as the striking similarities and marked differences between product reregistration and reregistration generally. In addition, OPP itself has also commented publicly on product reregistration, including in the recent rulemaking for its registration review program.

1.4.1 Funding and Accountability

In 1996, the Congressional Research Service (CRS) reviewed the Food Quality Protection Act, including reregistration and its related funding issues.[5] Reregistration is financed through a combination of appropriated funds and registration "maintenance" fees paid by pesticide registrants. EPA maintains that fee collections have been lower and costs higher than originally anticipated, and as a result maintenance fees have been extended. Pesticide registrants contend that historical funding levels had been adequate, and they questioned whether EPA had managed funds efficiently. One reason for higher than expected costs and reregistration delays has been late and deficient reregistration package submissions, according to EPA, and these problems are being addressed.

EPA requires manufacturers applying to register or reregister a pesticide to submit reports of scientific studies on pesticide toxicity and behavior in the environment. EPA requires that studies conducted by industry conform to EPA standards of scientific quality. Studies that do not meet EPA standards are rejected and must be repeated/upgraded and then reevaluated. Rejected studies contribute to the high cost of registration. While pesticide registrants have argued that EPA's scientific standards are excessive, EPA has insisted that registration decisions should be based on the best available science. Historically, EPA rejected approximately 30 percent of studies submitted. A 1991 analysis of factors contributing to late and deficient study submissions prompted a joint EPA-industry project to improve performance. Because of workshops, guidance, and registrant efforts, the study rejection rate in 1996 was half of what it was in 1993 and many submissions are timelier, according to EPA.

Some have argued that industries have little incentive to submit timely and adequate applications to maintain registrations of older pesticides; while a decision is pending about the safety of the older pesticides, manufacturers may continue to market them.

1.4.2 Reregistration Policy

In 1986, the Natural Resources Defense Council (NRDC) evaluated the reregistration program and related policies.[6] The reregistration process has its roots in the 1972 FIFRA amendments

[5] CRS Report to Congress: Pesticide Legislation: Food Quality Protection Act of 1996 (P.L. 104-170), 96-759 ENR, September 11, 1996, Linda Jo Schierow, available at http://ncseonline.org/nle/crsreports/pesticides/

[6] "Pesticide Reregistration: An Evaluation of EPA's Progress," Lawrie Mott, Natural Resources Defense Council, San Francisco, California, April 3, 1986

and in its 1986 report NRDC noted, "until recently reregistration was not even a high priority within EPA's pesticide program." Of NRDC's three key findings, one is particularly relevant to the premise of this evaluation: reregistration has not been expeditious. Two of the corresponding recommendations include:

- EPA should immediately issue final regulations establishing procedures for reregistration. Further, NRDC noted, "Without final regulations, EPA's reregistration program is operating on an ad hoc basis. Furthermore, absent a regulatory framework, the public cannot readily follow EPA's process."
- EPA should institute biannual public reports that identify which pesticides have been reregistered, etc. The public has no simple way to determine which pesticides have been reregistered.

Similarly, the Administrative Conference of the United States recommended that EPA adopt, whenever possible, rules setting clear standards for pesticide reregistration data and should communicate those standards to registrants.[7] In 2000, the EPA Office of Inspector General (OIG) concluded that EPA did not consider regulation development a high priority since the pesticide statutes are very prescriptive and the program is highly centralized.[8]

As it developed its registration review program, EPA and industry considered the shortcomings of its reregistration program.[9] In response to its proposal, industry commented that EPA should not implement registration review of end-use products until it fixes the problems with the review of end-use products in reregistration. Registration review and reregistration are likely to be similar and registration review might duplicate the effort of reregistration, especially when a product may undergo product-specific review several times. The commenters were concerned that if EPA does not achieve efficiencies in the review of end-use products, the fifteen-year registration review will extend to forty years.

In response, EPA stated that it expects reregistration to satisfy most product-specific data requirements and achieve many label improvements for end-use products. Although EPA does not expect it will routinely require product-specific data during registration review, it expects that registration review will be an important vehicle for the continuing update of labels. EPA agreed that the review of end-use product labels could benefit from process improvements, and that registrants and other stakeholders can help develop approaches to make this process more efficient.

1.4.3 Information Management

As early as 1980, GAO auditors determined that EPA was behind schedule, lacked a tracking system to identify problems, did not have a formal operating procedure for reregistration, and had not adequately monitored its overall progress in the reregistration program.[10] In 1991, GAO reported on the lengthy delays associated with reregistering pesticides and that such delays

[7] Recommendations of the Administrative Conference of the United States, 1 CFR part 305, Recommendation 93-5, Procedures for Regulation of Pesticides
[8] Pesticides: Follow-up Report on EPA's Pesticide Program, Report No. 00P00011, March 27,2000, EPA Office of Inspector General
[9] Pesticides; Procedural Regulations for Registration Review, Final Rule, 71 FR 45719, August 9, 2006
[10] Delays and Unresolved Issues Plague New Pesticide Protection Programs, GAO, 1980

stem, in part, from the inadequate support provided by EPA's information systems for reregistering pesticides.[11]

In 1992, GAO reported that after having invested $14 million over three years in data systems development, EPA could not easily assemble accurate, reliable, and complete information on chemicals in its reregistration process.[12] GAO concluded that these information management problems resulted from inadequate systems planning and poor data management. In addition, OPP employed nine separate data base systems to track or manage information about chemicals pending reregistration. Each of these data systems was designed and developed separately without taking into account a way of using them jointly. EPA staff entered information about pesticide studies numerous times into different systems, and data compilation is labor intensive and time consuming.

In 2000, the EPA Office of Inspector General (OIG) published a follow-up report to its 1994 evaluation of the pesticide program.[13] OIG found that the OPP Information Network (OPPIN) had been designed to address most of its information management concerns, but some of the original concerns still exist. OIG noted that OPP had not completed actions to improve information systems that contain inaccurate, incomplete, and duplicate data or that are not integrated.

1.4.4 Performance Management

In FY2005, the Office of Management and Budget (OMB) evaluated the reregistration program using its Program Assessment Rating Tool (PART).[14] The FY2005 Program Assessment indicated that the program was "adequate," and included the following conclusions:

- There is no evidence to indicate that a different program design would be more effective or efficient than what is currently used. The 1996 FQPA changes added clarity to science reviews and introduced higher visibility deadlines, which forced increase effectiveness.
- To help ensure the program is effectively targeted, statues establish criteria for prioritizing reregistration activities and sets specific deadlines and timelines for completion.
- The annual goals are output measures but are acceptable because it is a process-oriented licensing program that results in "products" (i.e., reregistrations).
- The annual output goals reflect activity required to meet statutorily required completion dates. The program did have difficulty meeting annual targets in the past, leading to changes in the statutorily required dates. The targets and baselines for the output measures are adequate.

[11] Pesticides: EPA's Information Systems Provide Inadequate Support for Reregistration, GAO/T-IMTEC-92-3, October 30, 1991

[12] Pesticides: EPA's Information Systems Provide Inadequate Support for Reregistration, GAO/IMTEC-92-3, October 30, 1991. Pesticides: Information Systems Improvements Essential for EPA's Reregistration Efforts, GAO/IMTEC-93-5, November 23, 1992.

[13] Pesticides: Follow-up Report on EPA's Pesticide Program, Report No. 00P00011, March 27,2000, EPA Office of Inspector General

[14] "Program Assessment: Pesticide Reregistration," expectmore.gov, accessed on July 11, 2006.

- The program uses multiple electronic methods to track information on the progress of reregistration actions and reports on the progress of activities are provided to program management weekly. OPPIN is a central database used to track activity, and it stores history that is easily retrievable.

A performance measure for pesticide product reregistrations was not included in PART, nor was product reregistration considered explicitly when evaluating the reregistration program.

In August 2006, the EPA Office of Inspector General (OIG) issued a critique of the Food Quality Protection Act.[15] OIG commented that although EPA has made progress in implementing the requirements of the FQPA, OPP has primarily measured its success and the impact of FQPA by adherence to its reregistration schedule rather than by reductions in risk to children's health. For FY2005, OPP used the following output measures to assess programs:

- Cumulative percentage of REDs completed
- Number of product reregistrations

OIG commented that the measures used by OPP generally indicate actions taken, instead of environmental or human health outcomes achieved. It concluded that OPP lacks outcome measures to assess the specific impact of those actions on the health of children and others.

1.5 Organization of Report

This report is composed of eight main chapters:

Chapter 1, Introduction, identifies the purpose of the evaluation and its audience, as well as key questions that will be answered. This section also includes a description of the program and a review of related evaluations.

Chapter 2, Methods, summarizes the approach for conducting the evaluation, and is based on the EPA-approved methodology.

Chapter 3, Progress on Product Reregistration, assesses the status of product reregistration and summarizes the duration of the processes.

Chapter 4, Reregistration Eligibility Decisions, discusses the issues associated with this part of the reregistration process that impact product reregistration. This section also discusses three case studies and alternative strategies used by EPA to implement mitigation.

Chapter 5, DCI Justifications and Preparation, addresses the current process for preparation and mail out of the generic and product-specific data call-ins by EPA and approval by the Office of Management and Budget, as well as associated issues and recent changes.

Chapter 6, Data Requirements and Review, summarizes some of the issues associated with registrant responses to the DCI, discusses an analysis of product-specific acute toxicity and product chemistry data, identifies strategies for batching data requirements, and discusses communication and management issues.

[15] Measuring the Impact of the Food Quality Protection Act: Challenges and Opportunities EPA Office of the Inspector General, Report No. 2006-P-00028, August 1, 2006, http://www.epa.gov/oig/reports/2006/20060801-2006-P-00028.pdf

Chapter 7, Label Assessments and Reviews, addresses the division of labor between SRRD and RD to revise pesticide product labels, discusses workload and other issues, and summarizes the current strategy to expedite product reregistration.

Chapter 8, Suggested Changes to Process Design and Other Recommendations, discusses the project team's recommendations for modifying specific aspects of the product reregistration process based on its findings presented in Chapters 3 through 8. This chapter also identifies specific areas where EPA may wish to modify its current program to better address product reregistration.

2. Methods

The evaluation of the product reregistration program is a process evaluation, which is defined by the Government Accountability Office (GAO) as one that "assesses the extent to which a program is operating as it was intended. It typically assesses program activities' conformance to statutory and regulatory requirements, program design, and professional standards or customer expectations."[16] Therefore, by design, this evaluation does not seek to determine the extent to which OPP achieves its intended outcomes (for instance, reduced exposure to pesticides) but only the activities that contribute to the outcomes.

In preliminary discussions, OPP identified a number of issues and concerns regarding product reregistration, including information management, the division of labor between SRRD and RD, issues in REDs, and information management. Abt Associates sought to examine these concerns and determine the extent of issues, as applicable, as well as identify other issues. This chapter summarizes the data collection methods, data collection approach, and analysis plan.

For more information on the approach taken for this analysis, please see "Identifying Innovations and Streamlining OPP's Product Reregistration Program: Program Evaluation Methodology," July 24, 2006.

2.1 Data Collection Methods

Abt Associates used a variety of methods to collect the information to answer the six evaluation questions. The data collection largely resulted in qualitative data, which we supplemented with quantitative data as needed and as available. Each data collection method used is described below along with the evaluation question(s) it helped answer. Limitations to each approach are identified. The following table summarizes each of the collection methods and the evaluation questions to which they will be applied (Table 2-1).

Table 2-1. Summary of Data Collection Methods

Evaluation Question	Data Collection Method				
	Interviews	Document Review	Program Data	Case Studies	Subject Expert
What components of REDs have caused delays in product reregistration?	•	•		•	•
What problems, bottlenecks, or unnecessary duplication of efforts occur in the product reregistration process that are under the control of OPP?	•	•			•
What innovations or streamlining in process could result in more timely implementation of mitigation specified in the RED and/or more efficient production of outputs?	•	•	•	•	•

[16] U.S. Government Accountability Office, "Performance Measurement and Evaluation: Definitions and Relationships," GAO-05-739SP, May 2005.

Evaluation Question	Data Collection Method				
	Interviews	Document Review	Program Data	Case Studies	Subject Expert
What are the pros and cons of each of the proposed innovations or streamlining measures?			•		•
What is the optimal allocation of tasks between the Special Review and Reregistration Division and the Registration Division?	•				•
Are any external entities or considerations impeding the product reregistration process?	•				•

The information collection activities above are governed by requirements under the Paperwork Reduction Act (PRA). Under PRA, EPA's information collection is limited to nine or fewer non-federal individuals or entities. Requests for similar information and/or similar questions must be limited to nine or fewer non-federal respondents. This evaluation was conducted in compliance with the PRA and other OMB rules on information collection requests.

Interviews

Abt Associates conducted a series of open-ended interviews (i.e., with no pre-determined response options) with numerous EPA staff. These individuals were accessible, have an interest in the results of the evaluation, and have a thorough understanding of the product reregistration process and its issues. In each interview, we characterized an individual's role in the reregistration process and solicited his/her perspective on the process in its entirety. Interviews with management focused more on the overall process, as well as the information flow between OPP divisions. Specific questions were prepared in advance of the interviews to ensure coverage of issues and to manage time (Appendix A).

Interview responses and comments are not referenced/attributed to specific individuals in this report or related discussions and presentations. A list of individuals interviewed or consulted is appended to this report (Appendix B). We believe that this approach increased the honesty of the answers and opinions provided in the interviews. All interviews were audio-recorded (with the permission of the interviewee), and the tapes were used to clarify issues and confirm the evaluator's notes.

This method of data collection was consistent with the statement of work, and also provided the opportunity to identify issues, solicit explanatory information, and understand the general functioning of the product reregistration program. This was appropriate given the process-improvement focus of the evaluation. Abt Associates sought to supplement the information gained in interviews with reregistration status, performance, and tracking data (where available), published documents, and additional information from OPP staff.

Although the perspectives of the registrants and the Office of Management and Budget (OMB) would be a helpful addition to this data collection, we limited our contact to EPA staff because of the limited time and resources available to complete this evaluation. However, in the document review and reregistration program data sections that follow, we identify sources from which we

obtained both published information on the roles of these two groups and their perspectives on product reregistration.

Document Review

Published documents available from EPA, the Government Accountability Office (GAO), the Office of Management and Budget (OMB), industry associations, and environmental groups served as another data source. Abt Associates reviewed these documents to determine the documented issues of reregistration, how reregistration is presented to the registrants and the general public, and how other external auditors perceive the program. These data sources were reviewed and cited, as appropriate, in Chapter 1 to summarize how reregistration has been characterized and/or criticized in the past.

Other documents informed this evaluation, including program descriptions and procedures. Under contract to EPA, SRA International developed a process flow diagram and accompanying report, which details the product reregistration process and its information management practices.[17] These materials summarize the process and its use, identify data sources and applications, describe execution of the process, estimate its duration, and identify potential improvements. The information management issues identified by SRA International were considered relative to other information collected during the evaluation. Abt Associates also reviewed additional documentation provided by EPA, including management briefings, fact sheets, and example tracking reports. These sources provided a further understanding of the process and areas of improvement.

Reregistration Program Data

Abt Associates used existing program data to characterize progress to date on the number of pesticide products reregistered, to establish the length of time it generally takes to reregister a pesticide product, and to consider the value of proposed data streamlining options.

To better define the problem, Abt Associates reviewed available data to determine progress made to date on product reregistration. The background materials developed by SRA International represent educated guesses and ideal conditions of the product reregistration process. For this evaluation, we sought to document in a verifiable manner the timeframe associated with product reregistration. Because of the estimated burden associated with this collection and the lack of a central data source, Abt Associates relied on information available from (1) the quarterly product reregistration briefing for Jim Jones, Director, Office of Pesticide Programs; (2) data pulls from OPP SRRD staff; and (3) Pesticide Reregistration Performance Measures and Goals for FY2005.[18]

As part of the evaluation, Abt Associates reviewed the draft findings of OPP regarding the added value of acute toxicity and product chemistry reviews on mitigation. EPA initiated this review to determine what mitigation is generally added to a product label during these two reviews compared to that specified in the RED. One possible way to streamline product reregistration would be to eliminate or streamline these two aspects of the process; however,

[17] SRA International, Inc., Support Documentation, "OPP Enterprise Architecture Process Description Special Review and Reregistration Division (SRRD) Product Reregistration: Support Documentation," Task 4: Baseline & Target Architecture Refinement, Task Order Number 5: OPPT Target Architecture Support, September 29, 2005, Contract Number EP-W-05-024

[18] Pesticide Reregistration Performance Measures and Goals for FY2005, 71 FR 36075, June 23, 2006

OPP had no analysis upon which to base this decision. For the draft analysis, EPA selected a random sample of pesticide products and determined the changes made to the mitigation statements as a result of the two review procedures. Because the original data are considered Confidential Business Information (CBI) and because of the time required to collect the data, OPP initiated this portion of the evaluation internally. Abt Associates reviewed the sampling technique and data collection and commented on the adequacy of the sample size. Abt Associates then audited a subset of acute toxicity data to confirm EPA's results. Because product chemistry data is considered CBI, Abt Associates did not audit those results.

Case Studies

EPA requested two types of case studies for evaluation – pesticides for which problems with the RED caused delays in reregistration and pesticides for which reregistration was expedited through Memoranda of Agreement (MOAs). These cases allowed Abt Associates to consider selected pesticides in a more in-depth manner to identify issues and possible solutions. This approach would have been far too resource intensive to complete for all active ingredients. However, this data collection method allowed us to highlight and/or validate perceived successes and failures of the product reregistration program. In order to complete the case studies, we relied on other data collection methods identified in this section, including interviews and document reviews.

By completing the RED case studies, we determined what problems in the REDs caused delays in product reregistration. With this information, OPP may be better informed and could change its procedures to avoid future issues. For the case studies of active ingredients for which an MOA was signed, these case studies illustrated one way that EPA tried to implement mitigation on the label in a timelier manner. The purpose of these studies was to inform recommendations on streamlining the product reregistration process, if possible, but without going to the effort of completing an MOA for each active ingredient. In addition, we considered products for which reregistration was streamlined, such as 2,4-D, by batching data requirements, to determine if this case could be used as a model.

Subject Matter Expert

As Abt Associates planned for the evaluation and developed the methodology, SRRD management provided assistance. Management identified background information and materials, answered questions, and clarified issues or concerns. This feedback allowed Abt Associates to understand issues regarding the product reregistration program prior to collecting information, and helped shape the evaluation questions and the development of the logic model.

This data source is particularly useful when the individual has a unique skill or professional background related to the issue being evaluated that helps the evaluator to better understand the issue and project participants. It is also useful given the internal, process-related orientation of the program evaluation. To ensure that the biases and opinions of a subject matter expert do not influence the data obtained or the conclusions made, Abt Associates challenged assumptions, collected supporting evidence, and/or identified counter-opinions or views.

Similarly, staff from the EPA Office of Policy, Economics, and Innovation served as a resource on evaluation design and implementation, in addition to administering the project.

2.2 Data Collection Approach

This section summarizes how Abt Associates applied each of the above data sources/collection methods to answer the evaluation questions. The data collection largely relied on interviews with OPP staff and managers, which allowed us to gain a full understanding of the product reregistration process and ways in which it could be improved or streamlined. We identified specific areas on which to focus, based on the evaluation questions, a review of background documents, and preliminary conversations with EPA staff.

Problems in REDs (Evaluation Questions 1 and 2)

Abt Associates collected and reviewed information for three case studies on REDs that caused delays in product reregistration: dicofol, captan, and the rodenticide cluster. These cases were selected because EPA is aware of issues with the RED that caused delays in product reregistration. Abt Associates could not make this selection independently, as it requires internal program knowledge and judgment. As the step immediately preceding product reregistration, the RED plays an important role in the information available for product reregistration. In the course of the evaluation, Abt Associates determined how often REDs cause issues in product reregistration by interviewing OPP management and chemical review managers. This review provided perspective for the sample selected for the evaluation.

Abt Associates reviewed RED documentation to become familiar with its contents and conclusions prior to meeting with OPP staff. Because REDs for food-use active ingredients were completed in August 2006, the extent to which RED-associated issues may be addressed in the future is limited. Thus, this part of the evaluation largely documents historical issues that may influence upcoming project work.

Implementation of RED-specified Mitigation (Evaluation Question 3)

Abt Associates reviewed information for two Memoranda of Agreement (MOAs) that allowed mitigation specified in the RED to appear on the label prior to the completion of product reregistration: chlorpyrifos and phosmet. These cases were selected because they are two of approximately ten instances in which EPA signed an MOA to expedite revising labels with mitigation. These set the precedent for implementing RED-specified mitigation prior to the completion of product reregistration and may serve as a model for a voluntary program in the future. Further, these two cases were selected because information is available both in the record and by interviewing staff who participated in the process. Both are organophosphate pesticides. Chlorpyrifos posed serious health risks and revised mitigation was placed on the label within a quick timeframe. Phosmet reregistration is ongoing and highlights the complexity of the issues and the considerations of the product reregistration program.

Abt Associates reviewed the MOA documentation to become familiar with its contents and conclusions prior to meeting with OPP staff. Abt Associates also considered the profile of each of the cases, the level of mitigation specified by the RED, and the number of products impacted. Similarly, OPP initiated a pilot project that uses the MOA as a model for implementing mitigation (propanil). The goal was to have registrants revise the label with the RED-specified mitigation prior to the completion of product reregistration. Abt Associates reviewed available information on propanil and interviewed staff about the success of the approach.

Data Requirements: Batching (Evaluation Questions 2, 3, and 4)

Abt Associates considered the case of 2,4-D as a model for how products may be further batched. Batching is one potential way to reduce the number of data requirements that the registrant needs to fulfill while still making the information available to EPA, as well as reducing the number of studies that OPP needs to review. We interviewed OPP staff to learn their experience with streamlining acute toxicity data requirements by batching products and using existing information about the products for storage stability.

Data Requirements: Acute Toxicity/Product Chemistry (Evaluation Questions 2, 3, and 4)

In order to determine the impact of product-specific acute toxicity reviews and product chemistry reviews conducted during product reregistration on the product label and confidential statement of formula (CSF), OPP analyzed the changes in product labels that resulted from these reviews over the period of its product reregistration activities. OPP initiated this review to determine what mitigation is generally added to a product label during these two reviews. Abt Associates verified the sampling procedure, assisted in data analysis, and audited a subset of OPP's results.

For more information on the approach for the audit, please see "Results of Audit – Evaluation of Acute Toxicity and Product Chemistry Review Findings," Memorandum to Yvonne Watson and Pete Caulkins, U.S. EPA, from Debra Kemp, Albert Acquaye, and Jason Sacks, Abt Associates Inc., January 30, 2007.

Label Reviews (Evaluation Questions 2, 3, 4, and 5)

As currently designed, the product reregistration process often includes label assessments/reviews by both SRRD and RD, which is perceived as a duplication of effort by some staff members. We determined why RD often conducts an extensive second review and identified possible alternatives through interviews of relevant staff.

In addition, a pilot project was designed to determine if the product reregistration process would be more efficient if SRRD conducted only product chemistry and acute toxicity reviews and if RD alone conducted label reviews. To determine this, both SRRD and RD conducted a label review independently of ziram products and determined if the two were consistent. Ziram was selected for this exercise because its products were in the appropriate stage of product reregistration for this pilot.

Relationship between SRRD and RD (Evaluation Question 5)

Although the responsibility of SRRD, RD contributes significantly to the product reregistration process by reviewing labels, issuing reregistration notices, and stamping revised labels. However, the two groups use different systems and have different management and unique cultures. Thus, through interviews we identified issues with the current division of labor and existing issues and proposed alternative means to divide the work, allocate resources, and communicate process information. Abt Associates first reviewed the product reregistration process flow diagram and relevant standard operating procedures (SOPs). We then interviewed staff and managers in both divisions to determine the current division of labor and any associated issues.

DCI Preparation and OMB Approval Process (Evaluation Question 6)

The preparation of the DCI is the first step in the product reregistration process. Despite approved SOPs, the SRRD contended that the DCI process is time-consuming and often evaluated by OMB against varying standards. OMB's approval of a DCI package was believed to be a source of delay in the product reregistration program. Thus, in this evaluation, Abt Associates explored the DCI preparation process and any associated issues.

Information Management (Evaluation Questions 2, 3, and 4)

One of the conclusions of SRA International was that, "EPA and participants of the product reregistration process could very much use an automated method of tracking the numerous products throughout the process. Currently, all tracking is done manually in PRB and only the CRM has direct access to the tracking data." To further support this conclusion, we considered shortcomings in information management, opportunities for improvement, and historical barriers to these improvements. Abt Associates interviewed SRRD, RD, and other OPP staff regarding product-level tracking for reregistration.

Management/Budget (Evaluation Questions 2, 3, and 4)

Although mandated by statute, OPP historically viewed reregistration (and particularly product reregistration) as less important than registration activities. The need to create SRRD in 1989 to focus specifically on reregistration in part reflects this problem. In addition, pesticide reregistration is a politically sensitive and high profile issue with both industry and environmental groups. Abt Associates interviewed OPP management and staff to identify management priorities, budget issues, and external influences.

Timeline for Product Reregistration (Evaluation Question 2)

The premise of this program evaluation was that product reregistration is a time-intensive and lengthy process. Abt Associates validated this assumption with the data available from OPP management briefings, annual reports, and internal databases.

2.3 Data Analysis

Abt Associates compiled and assessed a variety of information, both qualitative and quantitative in nature. For qualitative information obtained from interviews, Abt Associates referred to its notes and interview tapes to summarize the information provided. When and if a discrepancy was identified, we confirmed the information with a third source or with OPP management. As noted in the preface to this report, the findings are reflective of the information provided to the project team.

For quantitative information, Abt Associates used a standard software package and data analysis and presentation techniques to summarize the progress on product reregistration. To the extent that these data sources are limited in utility, we have identified these issues in this report. If data were missing or seemed inconsistent, we confirmed potential data issues with OPP staff.

Abt Associates documented its quality assurance procedures in its Quality Assurance Project Plan, which was approved by Abt Associates, Industrial Economics, and EPA in July 2006.

3. Progress on Product Reregistration

EPA originally estimated that reregistration would include approximately 600 active ingredient cases (consisting of more than 1,100 active ingredients) and approximately 20,000 pesticide products. The exact universe changes as REDs are published and estimates are refined. EPA projects that product reregistration will not likely be completed before the end of calendar year 2012.[19]

3.1 Status of Product Reregistration

Since beginning reregistration in the late 1980s, EPA has completed reregistration actions for 7,358 pesticide products. Reregistration actions for 11,948 products (conventional and antimicrobial) were pending as of October 2006. The overall product reregistration universe, both completed and pending, is presented in Figure 3-1. SRRD will also be responsible for product reregistrations that will follow completion of the 54 remaining, non-food use REDs[20] by October 2008.

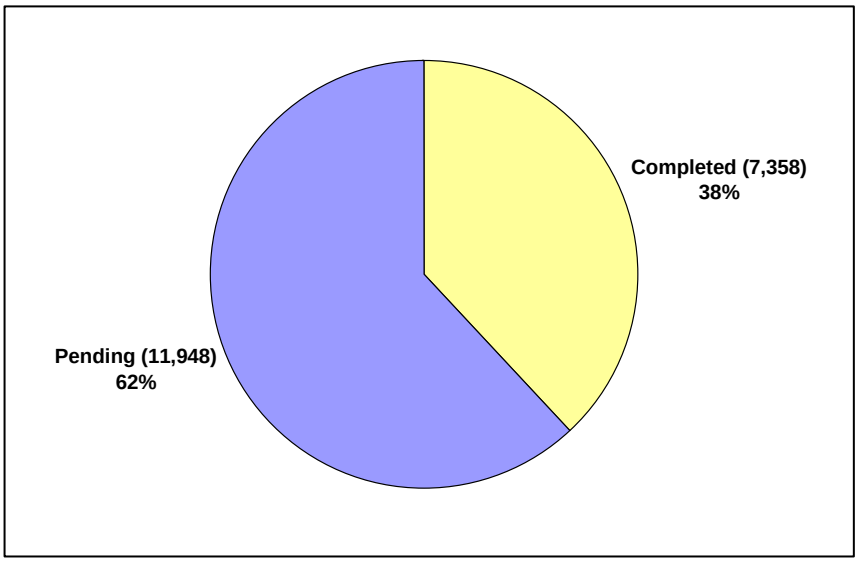


Figure 3-1. Universe of Pesticide Products at End of FY2006

Of the reregistration actions completed through the end of FY2006, the majority of the actions were cancellations (Table 3-1 and Figure 3-2).

[19] Pesticide Reregistration Performance Measures and Goals, Notice, 71 FR 36075, June 23, 2006
[20] http://www.epa.gov/oppsrrd1/reregistration/reregistration_facts.htm

Table 3-1. Cumulative Completed Reregistration Actions through FY2006

Action	Number of Products
Reregistered	2,070
Amended	563
Cancelled	4,695
Suspended	30
Total	**7,358**

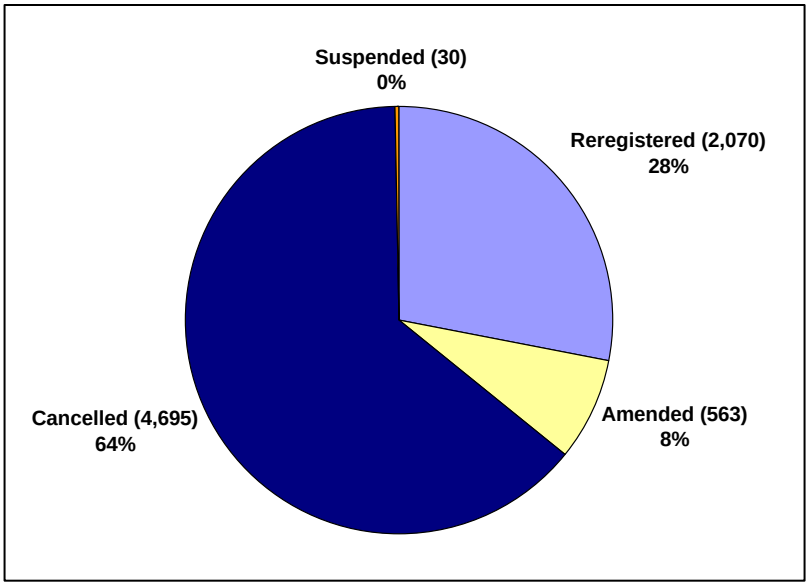


Figure 3-2. Distribution of Completed Actions through the End of FY2006.

Figure 3-3 shows actions (reregistrations, amendments, cancellations) completed from FY2002 through FY2006. (The EPA database was limited to actions completed since 2002, and older data were not readily available.) Note that summing annual actions would result in a greater number of completed actions than reported above since each individual product is potentially subject to multiple actions over time. Figure 3-4 shows actions completed in FY2006.

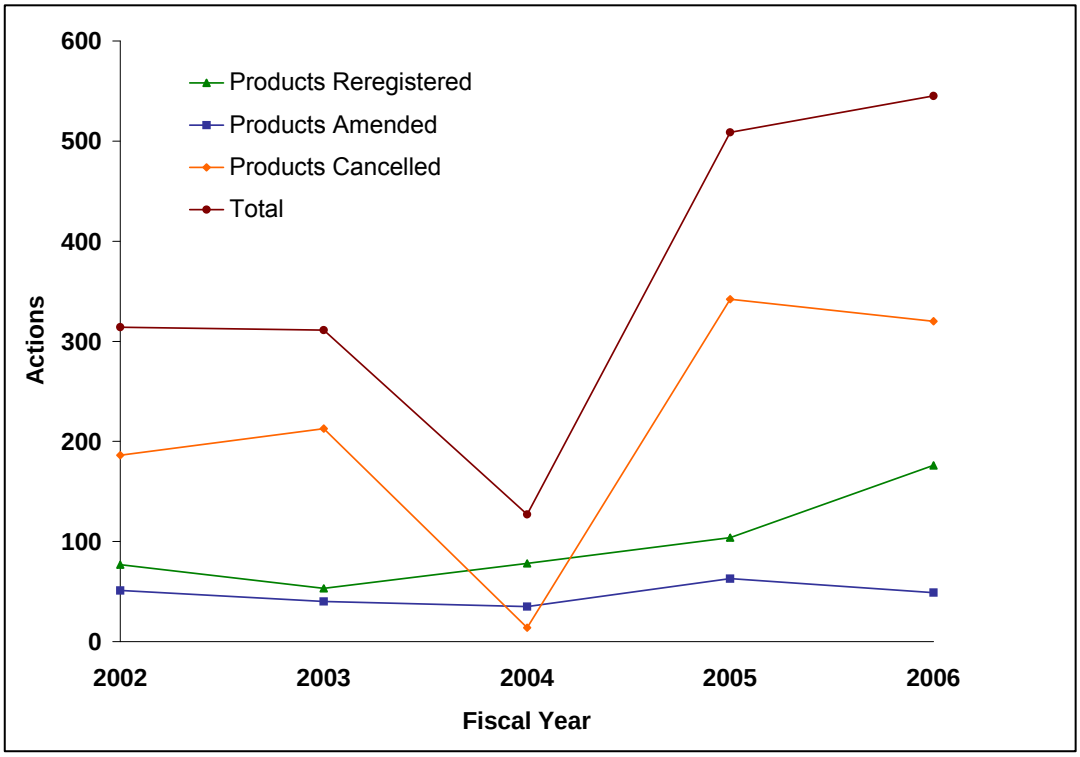


Figure 3-3. Actions Completed from FY2002 through FY2006

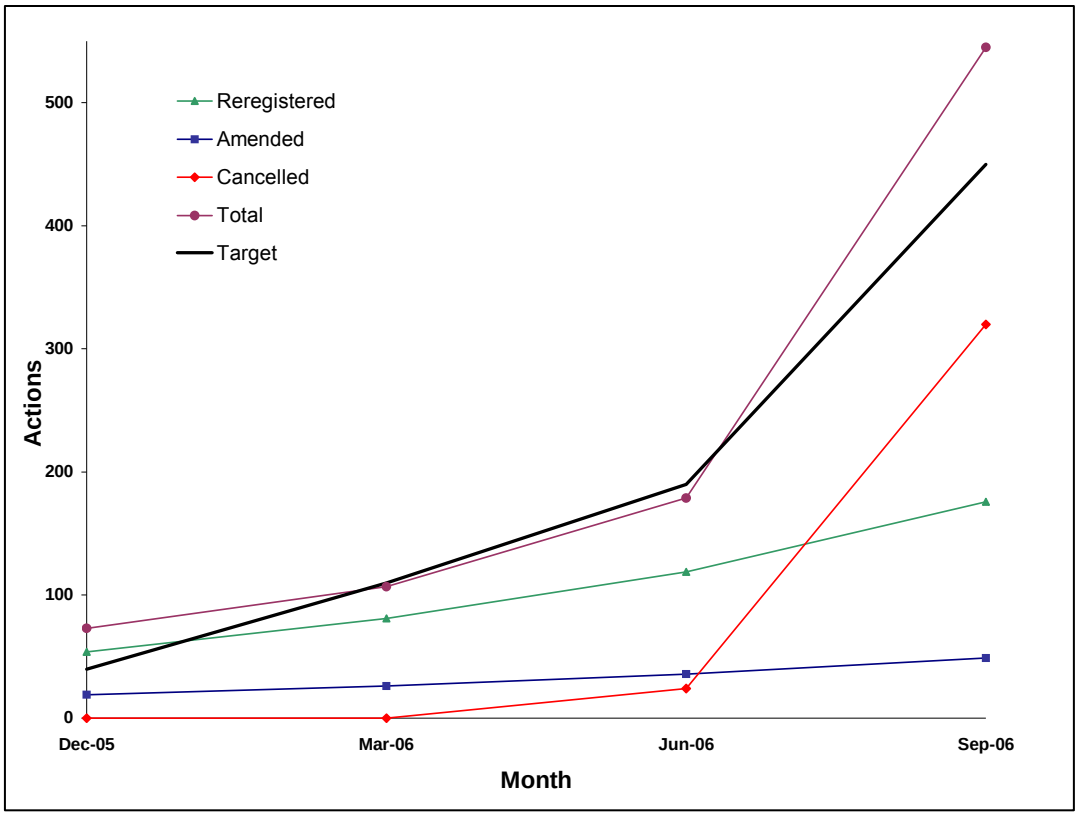


Figure 3-4. Actions Completed in FY2006 Compared to Target

Of the reregistration actions that were pending at the end of FY2006, the products are distributed through all phases of the pesticide reregistration process (Table 3-2). Most of the products (9,088 or 76%) have not yet had the data call-in prepared and/or approved by OMB. This is likely a function of the deadline to complete the REDs for the food-use pesticides by August 3, 2006, which increases the product reregistration backlog. The FY2006 decisions resulted in 6,722 products that will require PDCIs, in addition to remaining decisions from FY2004 and FY2005 that also require PDCIs.

Table 3-2. Products with Actions Pending at the End of FY2006

Location of Products in Process	Number of Products
Awaiting OMB approval – Antimicrobial pesticides	2,229
Awaiting OMB approval – Conventional pesticides	6,859
Awaiting issuance of PDCI – Antimicrobial pesticides	17
Awaiting issuance of PDCI – Conventional pesticides	1,096
Awaiting resolution of post-RED issues (in PRB)	143[a]
Awaiting registrant response to PDCI	318
In PRB process	437
In AD process	24
In BPPD process	53
In RD for reregistration	772
Total	**11,948**

[a] Includes eight products that are also included under "In PRB Process"

The 143 products awaiting resolution of post-RED issues are those for azinphos-methyl and the rodenticide cluster. There are 116 products in PRB and 446 in RD that were awaiting completion of the cumulative risk assessments for the organophosphates and the carbamates. The organophosphate cumulative risk assessment was completed in July 2006.

The FY2006 data source for this section was an internal EPA briefing.[21] These data will be further refined and audited by the EPA Office of Inspector General before being published in the *Federal Register* in 2007. By law, EPA must establish and publish in the *Federal Register* its annual performance measures and goals for pesticide reregistration, tolerance reassessment, and expedited registration. Performance measures and goals were published for FY2005 in the *Federal Register* on June 23, 2006.[22] Data on trends were obtained from OPP Chemical Review Managers.

3.2 Duration of the Product Reregistration Process

SRRD maintains a database, referred to as "STATUS," that includes basic tracking data for products in each of the reregistration cases. Although more detailed information is provided in individual "charts and tables" (in Microsoft Word format), these data are not centralized and

[21] Product Reregistration Quarterly Review, Briefing for Jim Jones, Associate Director of the EPA Office of Pesticide Programs, October 2006

[22] Pesticide Reregistration Performance Measures and Goals, Notice, 71 FR 36075, June 23, 2006

therefore not available for purposes of this analysis. Using the tracking data available, we determined the duration of the product reregistration process. From these data, we can distinguish three points in the reregistration process: (1) when the RED or IRED is issued; (2) when the reregistration package is sent to the product manager (PM) in RD; and (3) when the product is reregistered (decision date). Other milestones, including the date the DCI was sent to OMB, DCI was issued, data were reviewed, etc., are not available in this data source.

In the following tables and figures, we consider 124 REDs covering 1,639 products that were designated in the STATUS database as reregistered (reregistration code 22) and unconditionally reregistered with amendment or conditionally reregistered with amendment (reregistration code 17). Tables 3-3 and 3-4 and Figure 3-5 present the results for a combination of these two reregistration codes.

Table 3-3 shows that, on average, it took 54 months to reregister a product. An average of 41 months was needed to get the reregistration package to the Product Manager (PM) in RD, and after the reregistration package had been sent to the PM, it took an average of 14 months to complete the reregistration process.

With regard to a RED, on average, it took about 47 months to reregister all products covered by a RED. The average maximum time needed for reregistering all products covered by a RED was about 76 months. The average maximum time needed to get the reregistration package to the PM was about 53 months, and on average, once the reregistration package got to the PM, the maximum time to complete the reregistration process was about 33 months.

Table 3-3. Mean Duration of Process for All Products and by RED Case

Group	Mean Duration (months)		
	RED Signed to Sent to PM	Sent to PM to Reregistration Decision	RED Signed to Reregistration Decision
All Products	41	14	54[a]
By RED (case mean)	34	13	47[a]
By RED (case maximum)	53	33	76[b]

[a] Total process duration may not be the sum of the two phases because of rounding.

[b] Total process duration is not the sum of the two phases because we calculated the mean of the maximum length of time in each specific phase and for the entire process.

Table 3-4 presents the mean duration to complete all products for REDs by the number of products. On average, it took 36 months to reregister REDs that covered only one product, and 47 months to reregister all products under REDs that covered more than 70 products. REDs that covered between 14 and 26 products took the longest time (57 months) to complete the product reregistration process. Complete reregistration of the products in these cases also took the longest periods during both phases of the process.

Table 3-4. Mean Duration of Process for RED Case by the Number of Products

Number of Products per RED	Mean Duration (months)		
	RED Signed to Sent to PM	Sent to PM to Reregistration Decision	RED Signed to Reregistration Decision [a]
1	25	12	36
2 – 5	32	12	44
6 – 13	36	17	52
14 – 26	38	18	57
27 – 35	41	14	55
36 – 70	39	9	48
More than 70	40	7	47

[a] Total process duration may not be the sum of the two phases because of rounding.

A closer examination of the distribution of the duration of reregistration of all products shows that the mean does not represent the true picture of the duration of registration. Figure 3-5 depicts the distribution of products by the duration to complete the reregistration process. Figure 3-6 shows the distribution of products by reregistration phase.

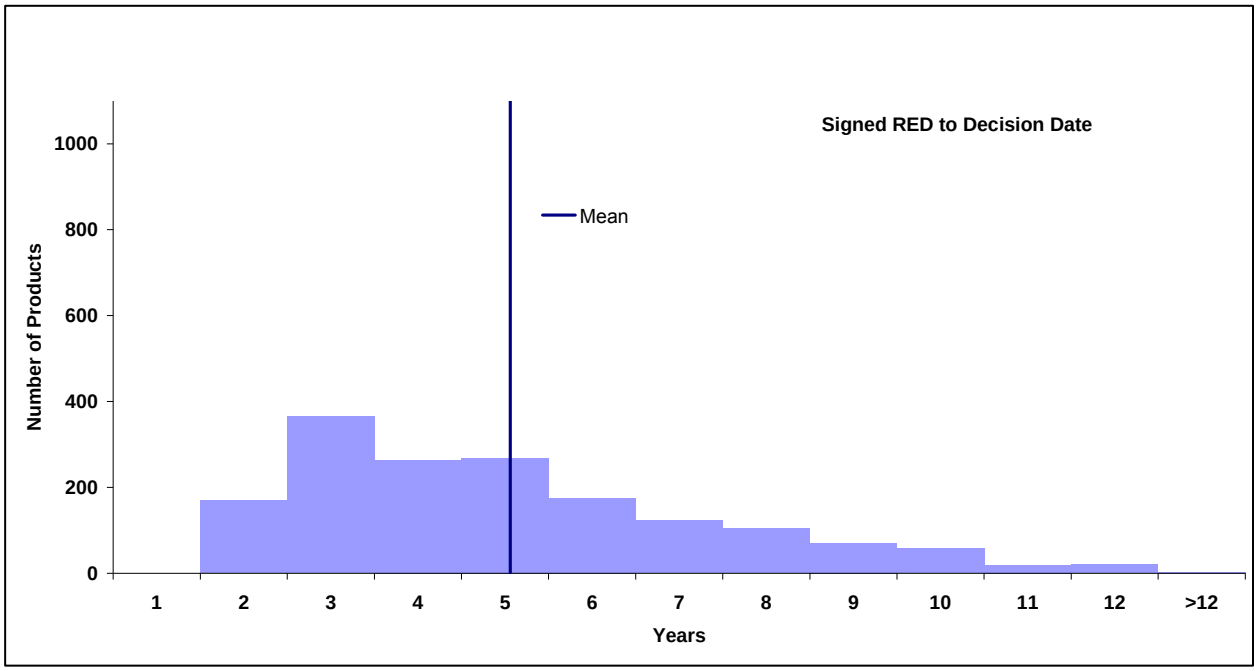
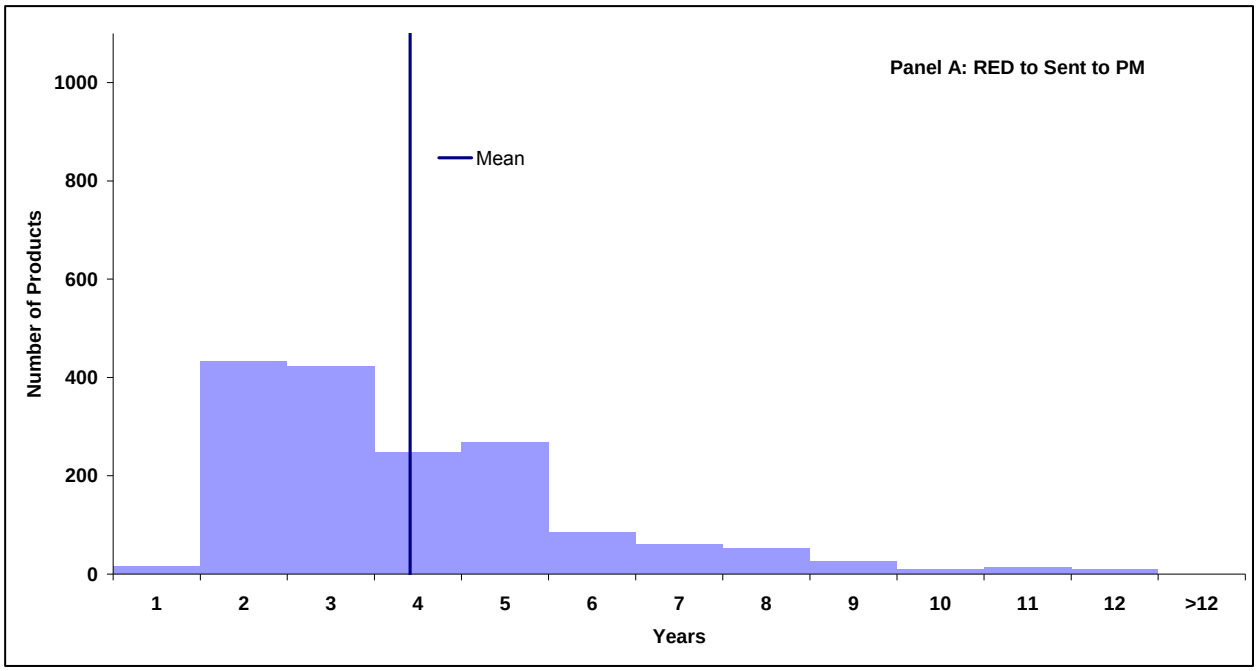


Figure 3-5. Duration of Product Reregistration Process for All Products (Reregistered and Conditional or Unconditional Reregistered Products)



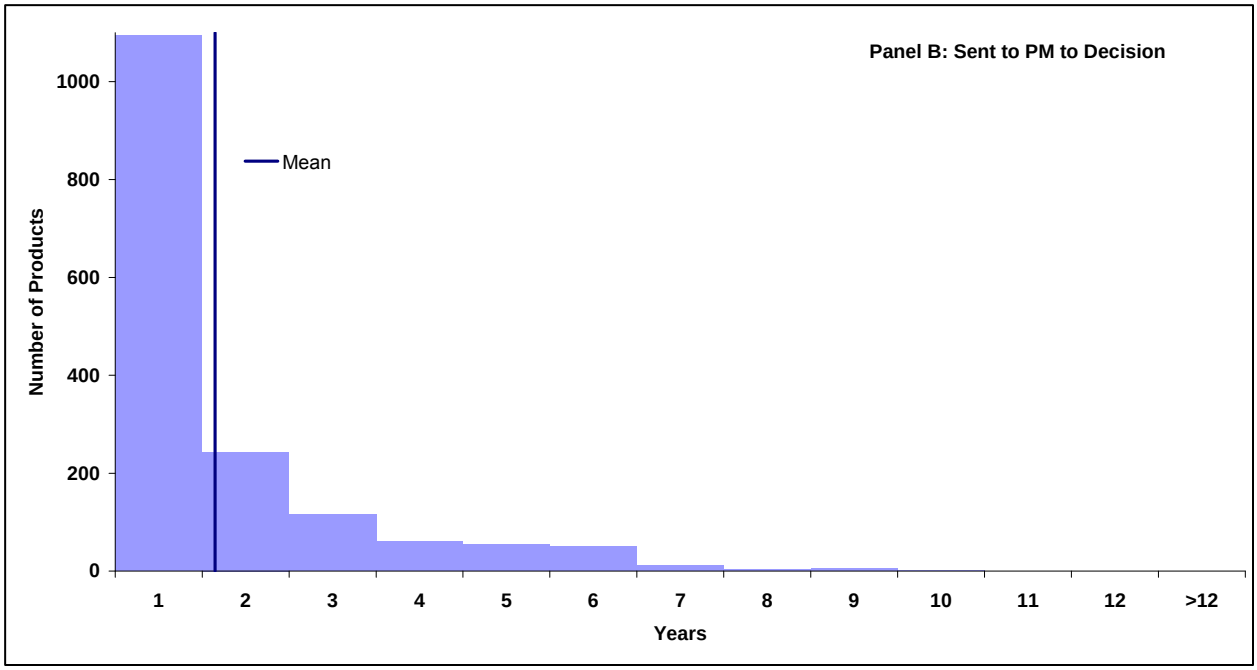


Figure 3-6. Duration of Period from RED Signature to Product Sent to PM (Panel A). Duration of Period from Sent to PM to Decision (Panel B). These graphs include all products (reregistered and conditional or unconditional reregistered products)

Figure 3-5 and 3-6 show that the average (mean statistic) is skewed by a small number of products. More often than not, the duration of the process was less than the mean. This is most obvious for the time needed to reregister a product after it has been sent to the PM. Of the 1,639 products covered in this analysis, 1,155 products, or 70 percent, were reregistered in less than 14 months (the mean time it took to reregister products) after the registration package was sent to the PM (Figure 3-6, Panel B). As such, we present the median time for each of the phases for all the reregistered products in Table 3-5 and the median time by the number of products per RED in Table 3-6 below.

Table 3-5. Median Duration of Process for All Reregistered Products and by RED Case

Group	Median Duration (months)		
	RED Signed to Sent to PM	Sent to PM to Reregistration Decision	RED Signed to Reregistration Decision
All Products	30	7	41
By RED (case mean)	29	9	41
By RED (case maximum)	46	17	69

[a] Total process duration may not be the sum of the two phases because of rounding.

[b] Total process duration is not the sum of the two phases because we calculated the mean of the maximum length of time in each specific phase and for the entire process.

Table 3-6. Median Duration of Process for RED Case by the Number of Products

Number of Products per RED	Median Duration (months)		
	RED Signed to Sent to PM	Sent to PM to Reregistration Decision	RED Signed to Reregistration Decision
1	30	6	35
2 – 5	28	6	39
6 – 13	30	10	37
14 – 26	30	13	57
27 – 35	38	10	55
36 – 70	30	8	36
More than 70	38	5	46

For the universe of products that have not yet completed product reregistration, but that have been sent to the PM in RD, the distribution of the time it took to reach this milestone is presented in Figure 3-7. Since being sent to the PM, the products have remained in RD anywhere from less than one month to more than 11 years. RD staff commented in interviews that many products are sent to them when there are still outstanding issues that need to be addressed.

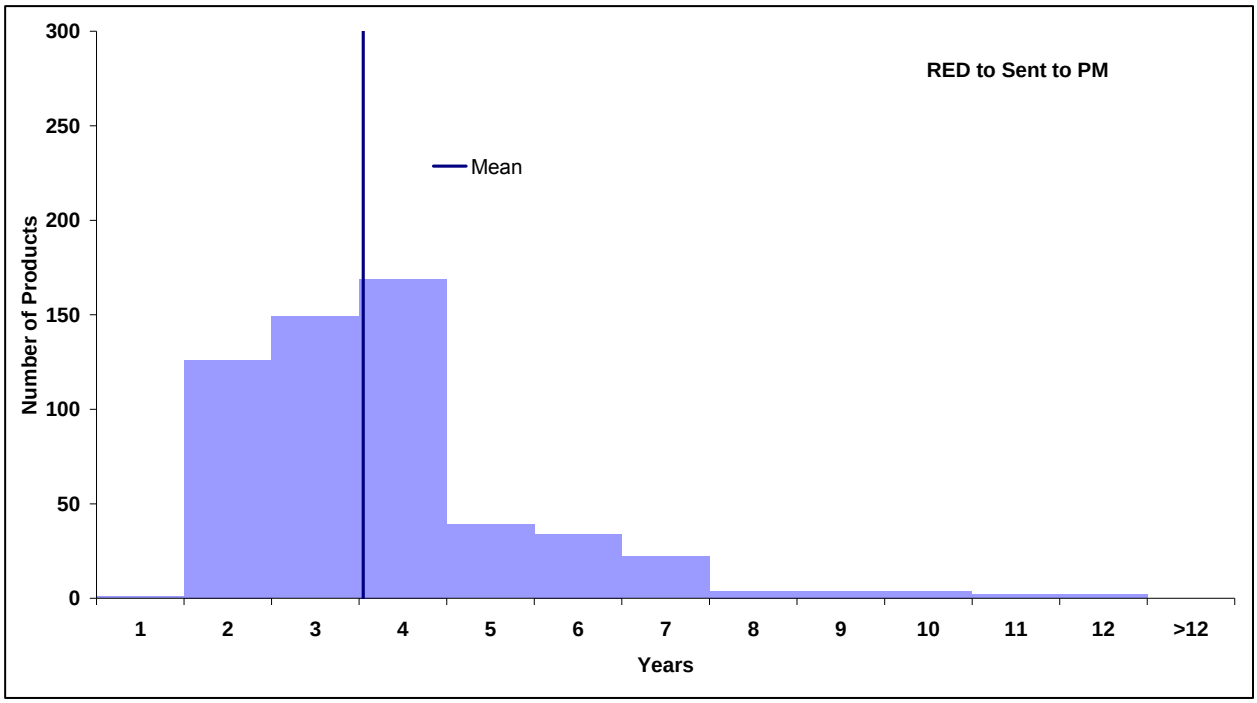


Figure 3-7. Duration of Period from RED Signature to Product Sent to PM for Products that are Not Yet Reregistered

The duration of the period from when the RED is signed to when the product is sent to the PM for reregistration includes several steps, not all of which are the responsibility of SRRD or even EPA. Part of this time includes the preparation and approval of the DCI justification package and the DCIs themselves (see Chapter 5). In addition, this period also includes the time for registrant responses (both ninety-day and eight-month), EPA review of the data submitted, and additional communication with the registrant. Thus, the estimates from the time the RED is signed to when the product reregistration package is sent to the Registration Division (RD) is not indicative of the time that SRRD Product Reregistration Branch (PRB) spends working on product reregistration (i.e., the time from the PDCI issued until the product reregistration package is sent to RD).

For the 755 products pending in PRB at the end of FY2006, SRRD data indicate that:

- 42 percent have been in PRB less than 12 months
- 36 percent have been in PRB between 12 and 24 months
- 20 percent have been in RPB between 24 and 36 months
- 2 percent have been in PRB more than 36 months

Table 3-7 presents the number and percentage of products completed for each fiscal year.

Table 3-7. Product Reregistration Completion Status by Fiscal Year

Fiscal Year	REDs/ IREDs Issued	Associated Products	Products Completed	Products Pending		
				Number	Percent	Location
1991	8	442	422	20	5	RD
1992	20	969	954	15	2	RD, AD, BPPD
1993	10	853	824	29	3	AD, RD
1994	22	729	717	12	2	AD, RD
1995	34	809	772	37	5	AD, RD
1996	42	1,050	970	80	8	AD, RD
1997	28	1,360	1,117	243	18	AD, RD, BPPD, PRB
1998	13	707	560	147	21	RD
1999	14	238	188	50	21	RD
2000	13	195	164	31	16	RD
2001	9	578	270	308	53	RD
2002	15	736	516	220	30	RD
2003	16	1,016	505	511	50	SRRD PRB
2004	17	713	126	587	82	SRRD PSB
2005 [a]	29	1,184	0	1,184	100	SRRD PSB
2006	41	8,693	1	8,692	100	SRRD PSB
Total	**331**	**20,272**	**8,106**	**12,166**	**60**	--

[a] The Fluazifop-p-butyl TRED required a PDCI.

Key: AD = Antimicrobials Division, BPPD: Biopesticides and Pollution Prevention Division, PRB = Product Reregistration Branch, PSB = Program Support Branch, RD = Registration Division, SRRD = Special Review and Reregistration Division

Source: "Status of Product Reregistration: Pending Products," December 12, 2006.

For purposes of implementing mitigation specified in the RED to reduce risks to human health and the environment, the overall length of the process – from the time EPA signs the RED to the time it stamps the label – is a key metric. However, for purposes of a process evaluation, determining the duration of each individual step becomes critical. Unfortunately, as currently managed, EPA data are of limited value for analyzing the time associated with each step in product reregistration. As explained in later sections, EPA does not track product reregistration data in a centralized database because the main OPP information management system (OPPIN) is not adequate.

4. Reregistration Eligibility Decisions

Reregistration Eligibility Decision (RED) documents include EPA's evaluation of the database for a chemical, its conclusions about the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. A RED also identifies the data and labeling requirements for products eligible for reregistration, as well as any additional confirmatory data needed on the active ingredient. Almost every RED includes some measures or modifications to reduce risks, e.g., declaring certain uses ineligible for reregistration; restricting use of products to certified applicators; limiting the amount or frequency of use; improving use directions and precautions; adding more protective clothing and equipment requirements; employing ground water, surface water, or other environmental and ecological safeguards; and other measures.

The "generic" chemical review managers (CRMs) in the reregistration branches of SRRD develop REDs based on available data and analyses conducted by the OPP science divisions. After a RED is signed, the Program Support Branch (PSB) and the Product Reregistration Branch (PRB) of SRRD initiate product reregistration. The "product" CRMs in PRB provide oversight for product reregistration. As needed, the reregistration branches are responsible for post-RED activities that arise after the RED is published and/or EPA receives product-specific and confirmatory studies.

4.1 Issues with REDs

This evaluation included three case studies where issues in the RED were believed to delay product reregistration. In addition to specific issues, several more general issues regarding the RED-development process became apparent. These include workload management, staffing, and division of labor, all of which are discussed in this section.

The generic CRMs in the four SRRD reregistration branches are responsible for writing a RED for an active ingredient. This part of the reregistration program faces public scrutiny, has ambitious deadlines, and demands a heavy workload. Over the years, this part of the reregistration program has evolved, particularly with respect to the FQPA requirements, scheduling, public participation, and transparency. However, the goal of this part of the process is to publish a RED by the given deadline. As a result, some REDs were published without addressing some outstanding issues. OPP also commented that virtually every RED likely has an issue or a hole because these may not be apparent until the RED is implemented (i.e., during product reregistration). Thus, REDs are sometimes amended to address outstanding issues or to include data that are submitted after the RED is signed. Sometimes EPA still initiates the data call-ins after the RED is signed, even if there are known outstanding issues. In these cases, the registrants are often contacted by both the reregistration branch and PRB.

For those REDs that did not have post-RED issues, generic CRMs indicated that they assumed that product reregistration happened as planned and were unaware of some of the delays and challenges. This is a source of frustration, as years of work to write a RED do not always result in environmental and human health protection as quickly as expected.

Post-RED issues were historically not given high priority in work plans and adequate resources within the four reregistration branches, as statutory deadlines required continued focus on

completing REDs. SRRD often looks to the science divisions for support with post-RED issues. Because there are no deadlines associated with post-RED activities, writing new REDs remain the priority. However, now that the August 2006 deadline to complete food-use REDs has passed, SRRD management has indicated a commitment to addressing post-RED issues (including product reregistration) in FY2007 and beyond.

REDs are not considered legally enforceable; EPA can only enforce DCIs and labels. Some registrants are inclined to challenge the contents of a RED to delay implementation of RED-specified mitigation. As EPA developed a more robust public participation process, registrants are more likely to be aware of upcoming eligibility decisions, which might reduce post-RED issues in the future and speed the product reregistration process.

Given the length of time from when a RED is published, to when post-RED issues are addressed, to when product reregistration is conducted, the CRM who wrote the RED is often no longer in that position. Typically, after about five years CRMs either are promoted or change positions. As staff leave, REDs that are in process need to be transitioned to other staff. As a result, institutional knowledge is often lost and new staff require additional time to become familiar with the issues.

Generic CRMs are responsible for identifying mitigation that needs to be included in revised labels as part of the RED development. Although the CRMs are knowledgeable of the issues of the case, some noted that they are not in the best position to draft label language. CRMs, although trained in writing labeling language, do not perform the task regularly enough to become extremely proficient at it, which sometimes results in problems when developing the label table. Generic CRMs commented that staff members in PRB and/or RD are better suited to determine how the language should read on the RED. Some within OPP believe the most efficient approach to drafting labeling language would consist of the decision-makers – PRB and RD – playing a more active role in the process.

4.2 Case Studies

To better understand how Reregistration Eligibility Decisions (REDs) sometimes cause delays in product reregistration, Abt Associates examined three REDs that were believed to delay product reregistration: the rodenticide cluster, captan, and dicofol. Each case study identified issues and challenges that arise throughout the reregistration process and, in particular, as a result of the contents of a RED.

4.2.1 Rodenticide Cluster

In July 1998, EPA published the RED for the rodenticide cluster, which included six active ingredients.[23] Rodenticides represent EPA's first attempt to cluster active ingredients, an approach that is also being used for fumigants. Since most of the rodenticides share similar use patterns, issuing reregistration decisions for one chemical at a time could shift the rodenticide market, perhaps to chemicals that pose greater risk but may be addressed later in the queue. EPA also intended this approach to maintain a level playing field. Levels of exposure to the varying rodenticides are generally similar, but they differ in toxicities. Thus, EPA expects to

[23] Reregistration Eligibility Decision: Rodenticide Cluster, U.S. EPA Office of Prevention, Pesticides, and Toxic Substances, EPA 738-R-98-007, July 1998

differentiate mitigation measures based on individual toxicities of the chemicals. Although clustering chemicals is more efficient for purposes of analysis, the number of issues and registrants involved complicates actual decisionmaking. In retrospect, EPA commented that it could have published concurrent but separate REDs for each chemical in the cluster and then made decisions for all the cases at the same time. By maintaining separate documents, EPA may have simplified the decision.

The rodenticide RED was incomplete and did not represent final regulatory decisions such that EPA could not implement much of what it included. Outstanding issues included human health (particularly accidental exposure to children) and ecological risks, and the RED included a two-phase approach for mitigating risk. The first phase would put into place short-term measures to identify, decrease, and monitor exposures largely through the use of bittering agents, dyes, and other measures. The second phase sought to reduce exposures in the long term by convening a stakeholder workgroup. EPA commented that the program has matured considerably since the rodenticide RED was published, and it is unclear why the RED was published in its final form. Under today's standards, EPA likely would not publish a document that did not provide actual reregistration eligibility decisions.

After convening a stakeholder workgroup, EPA changed its position on the requirements for bittering agents and dyes in 2004, which was subsequently challenged in a lawsuit. EPA was asked to reconsider this decision and develop a better record. Also, the rodenticide RED predated EPA's formal public participation process for reregistration. EPA is currently addressing the ecological risks of the rodenticide cluster. In January 2003, EPA released a preliminary ecological risk assessment for public comment; a revised assessment was published in September 2004.[24] EPA is formulating a mitigation plan to address these risks that it published for public comment in January 2007.[25]

Because of these outstanding issues, EPA has not yet completed pesticide reregistration for rodenticide products. After the RED was signed in 1998, EPA sent out DCIs, but they were put on hold in light of the outstanding issues. If EPA were to require bittering agents, this would require new product chemistry and acute toxicity studies, which makes it impractical to submit these data until the issue is resolved.

Because of these delays in reregistration, PRB encouraged registrants to voluntarily amend labels to incorporate some of the mitigation specified in the RED in advance of product reregistration. EPA also considered allowing registrants to have a master label that could be used on several different packages. This effort was largely unsuccessful and registrants would not voluntarily amend labels, although some voluntarily added bittering agents. For other reregistration cases, EPA has been successful in having registrants voluntarily amend labels.

Once the ecological risks are addressed through the forthcoming mitigation plan, SRRD expects to issue an amendment to the RED for public comment. EPA will then address any outstanding policy issues or regulatory activities. In the meantime, more than eight years have elapsed since the RED was signed without significant changes to the labels for the rodenticide cluster.

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[24] Rodenticides: Availability of Revised Comparative Ecological Risk Assessment, 69 FR 56756, September 22, 2004

[25] Proposed Risk Mitigation Decision for Nine Rodenticides, January 17, 2007, available at http://www.epa.gov/oppsrrd1/reregistration/rodenticides/rodenticides_mitigation_decision.pdf

This case study illustrates the challenge of clustering active ingredients that might have similar use patterns, but differ in toxicity and other characteristics. EPA staff noted that publishing separate documents concurrently could be a good alternative. This case cautions against publishing a RED without addressing all outstanding issues and not developing a solid record. Lastly, rodenticides shows that registrants are not always amendable to voluntary label changes.

4.2.2 Captan

In November 1999, EPA published the RED for captan, which included a determination that it was a probable human carcinogen based on the properties of a highly reactive but short-lived metabolite.[26] The risk assessment, however, indicated that this classification did not warrant additional mitigation. After EPA published the RED, additional data were submitted during the public comment period that led EPA to amend the RED in November 2004.

The RED pre-dated the formal reregistration public participation process that is in place now, which meant that early opportunities for public comment were more limited. EPA received additional data after the RED was signed that led EPA to recalculate certain re-entry intervals and margins of exposure for specific uses and applications. These new values were included in the RED amendment. The amendment also addressed a few minor inconsistencies that needed to be clarified (e.g., definition of a berry and seed treatment).

Also, after the RED was published in 1999, registrants requested that EPA consider a cancer reclassification for captan, presumably for marketing and other reasons. Because its current cancer classification did not warrant additional mitigation, EPA did not feel it was appropriate to use its limited resources on the analysis. The Captan Task Force, which is composed of captan registrants, voluntarily contracted with an independent body of scientists to review the data to support a mode of action determination for captan. The OPP Health Effects Division (HED) then reviewed this work. Based on the third-party review and subsequent HED review, EPA determined that captan acts through a non-genotoxic threshold mode of action. This determination, however, did not change the risk management conclusions or amend the RED. Overall, it took approximately two years to complete the cancer reclassification.

The cancer reclassification and the amendment to the RED were published for public comment in November 2004.[27] EPA received a modest number of comments, mostly on the cancer reclassification or issues un-related to the RED amendment. The captan amendment was less complex compared to other cases that have been amended. However, the process took considerable effort and was also not given top priority when compared to writing new REDs.

Because of the length of time between completing and subsequently amending the RED, EPA worked with the registrants and the Captan Task Force to amend product labels with RED-specified mitigation as soon as possible. The technical registrants, who were most interested in the cancer reclassification, were able to encourage the product registrants, who were most

[26] Reregistration Eligibility Decision: Captan, U.S. EPA Office of Prevention, Pesticides, and Toxic Substances, EPA 738-R-99-015, November 1999

[27] Captan; Cancer Reclassification; Amendment of Reregistration Eligibility Decision; Notice of Availability, 69 FR 68357, November 24, 2004

interested in the RED amendment, to revise their labels in an expedited manner. Registrants were also motivated by good environmental stewardship. The SRRD reregistration branch collected the labels in early 2005, which were then sent to the Product Reregistration Branch (PRB) for assessment. However, this approach resulted in confusion because two branches were in contact with registrants, and communication could have been better coordinated. EPA has since completed the product reregistration process for captan products. Reregistration for captan products took seven years from the time the RED was signed.

This case study reiterates that REDs represent the best data and analysis available at the time, and the need to engage registrants in the submission of new data. This case also included a creative solution for a third-party cancer assessment, which saved EPA resources. Lastly, the case illustrates that voluntary label changes can sometimes be successful.

4.2.3 Dicofol

In September 1998, EPA signed the dicofol RED and determined that products containing dicofol may be eligible for reregistration (as specified in the RED) contingent upon results of a dermal toxicity study that was due to EPA in December 1998.[28] In 2005, EPA published an addendum to the RED to establish re-entry intervals (which were not included in the RED) and solicited public comment.[29]

OPP maintains a strict, annual schedule for RED development and signature to meet the statutory deadlines in FQPA, and the deadlines are rarely (if ever) postponed or missed. In order to meet OPP's annual goals, these deadlines often correspond to the end of a fiscal year, which explains why a majority of REDs are signed in September. The dicofol RED was signed, although it lacked information on worker exposure, so that EPA could count dicofol tolerances toward the number of tolerances that were reassessed in FY1998. Staff commented, however, that given the significant data gaps, it would be unlikely that the dicofol RED would be published in that form according to current standards. Despite incomplete information on re-entry intervals, EPA mailed out DCIs in 1998 and received responses and amended labels from the registrant, but label review is pending the resolution of outstanding issues.

To address EPA's concerns with occupational exposure following the signature of the RED, the registrant submitted a dermal toxicity study and a chemical-specific dislodgeable foliar residue study approximately one year after the RED was signed. Given the use of the pesticide and the nature of the study, these data were submitted in a timely manner. However, the data indicate that a substantially longer restricted entry interval (REI) was warranted compared to the REI on the label at the time (more than 3 months compared to 24 hours). These data triggered the involvement of the OPP Biological and Economic Analysis Division (BEAD), who conducted an impact analysis to examine the current market and viable alternatives and met with the registrant. Other more minor issues in the RED, such as updating calculations to be consistent with a revised definition of "short-term exposure" from the OPP Health Effects Division (HED) were also addressed after the RED was signed.

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[28] Reregistration Eligibility Decision: Dicofol, U.S. EPA Office of Prevention, Pesticides, and Toxic Substances, EPA 738-R-98-018, November 1998

[29] Dicofol; Addendum and Closure of Reregistration Eligibility Decision; Notice of Availability, 70 FR 51794, August 30, 2005

Over time, interest in the dicofol case diminished, as other activities within OPP were given a higher priority and staff responsibilities were shifted (several generic CRMs have worked on the dicofol case). When dicofol again became a priority, EPA drafted and published the addendum to the RED for public comment. The growers indicated to EPA that the proposed REIs were unacceptable and maintained that dicofol was a much-needed miticide in the industry. EPA planned to release a second addendum to the dicofol RED after the August 3, 2006, FQPA deadline. This was pushed back further when staff became involved in registration review activities. However, in Summer 2006, the registrant announced that it intends to discontinue dicofol because it does not have sufficient market share.

Given the discrepancy over REI and the registrant's plans to discontinue the product, the registrant did not voluntarily revise its label to include any of the RED-specified mitigation and the labels remain unchanged. More than eight years have elapsed since the RED was signed without significant changes to the labels for dicofol.

The dicofol case study illustrates the issues that result from publishing a RED before it is complete, and that sending DCIs in such situations might not be appropriate. The case also highlights that new data sometimes delay product reregistration and require additional review and consideration.

4.3 Alternative Strategies for Implementing Mitigation

This section reviews two cases where EPA pursued implementation of RED-specified mitigation through signing a memorandum of agreement with registrants, as well as a current pilot project to achieving this same objective without the formal agreement.

4.3.1 Memoranda of Agreement – Chlorpyrifos and Phosmet

EPA uses Memoranda of Agreement (MOAs) as a mechanism by which registrants amend product labels to include RED-specified mitigation in advance of the product reregistration process and may also agree to provide data or take other action. Although used infrequently, EPA has used MOAs in approximately six to twelve instances, including the chlorpyrifos and phosmet cases. The following two cases highlight some of the successes and shortcomings of MOAs. These case studies provide support to the recommendations made later in this report.

In addition to MOAs, EPA has made efforts to amend terms and conditions of registrations to include RED-specified mitigation in a timelier manner. This approach requires fewer resources and does not commit EPA to anything. However, MOAs also provide a mechanism to get data, which is not possible only through amending the terms of conditions of a registration.

Chlorpyrifos

In June 2000, EPA signed an MOA with the chlorpyrifos registrants after several months of negotiation.[30] Under the MOA, registrants requested voluntary cancellation of their existing products and submitted applications for replacement registrations excluding those uses that were canceled (e.g., termite control, residential use). In return, EPA stated that it had no

[30] Memorandum of Agreement between the Environmental Protection Agency and Signatory Registrants Regarding the Registration of Pesticide Products Containing Chlorpyrifos, June 2000

intention to initiate cancellation or suspension proceedings and would act on replacement registrations within ten working days.

EPA was particularly concerned about exposures from residential uses of chlorpyrifos, and estimates that a chlorpyrifos product was in one in four households in the United States. As an organophosphate, chlorpyrifos posed acute risks and exposure and incident data indicated regulatory action was appropriate. In addition, a number of environmental groups published reports on risks of pesticides in food and in the home. This level of concern provided some leverage to convince registrants to take action.

In negotiations, registrants agreed to cancel residential uses. Both EPA and the registrants agreed that a recall of residential-use products was not necessary. There were approximately 10 million pounds of chlorpyrifos in homes, and a recall would pose logistical and disposal problems, including additional environmental and public health concerns. EPA's key objective was to develop an agreement that ensured that mitigation was placed on the label as soon as possible.

Chlorpyrifos is an interesting case because there were originally more than 900 products and extensive mitigation was required. EPA cancelled more than 300 products and amended approximately 100 labels. There are currently about 300 chlorpyrifos products. Because of the complexity of the agreement and the number of labels, EPA developed guidance and communications materials for the regulated community. In order to meet its obligations, EPA assembled a staff of six to eight people from the reregistration branches, PRB, and RD who worked full-time for five to six months on the case to process labels and voluntary cancellations. This work was mostly complete by January 2001, approximately eight months after the MOA was signed.

After having dealt with the residential uses, EPA focused its attention on agricultural uses and remaining regulatory issues, such as the Interim Reregistration Eligibility Decision (IRED) that was published in September 2001. Based on product-specific data, labels had to be reviewed and amended for formal product reregistration, but the product universe was considerably smaller because residential uses had been cancelled.

Several key aspects of the chlorpyrifos case made an MOA a particularly appropriate and successful tool: the registrant was a willing participant in negotiation, EPA was also committed to activities and deadlines, chlorpyrifos received public attention and required swift action, there were numerous products, and residential uses were of concern.

Phosmet

In 2001, EPA signed an MOA with Gowan Company, the only registrant of phosmet.[31] In 2001, EPA also published the IRED for phosmet. Although it is an organophosphate, phosmet does not exhibit the same risk profile of some of the others. There were some residential uses and some incident reports, and Gowan initiated voluntary cancellations for residential uses.

[31] Memorandum of Agreement between the Environmental Protection Agency and Gowan Company Regarding the Registration of Pesticide Products Containing Phosmet, October 2001

Growers expressed to EPA the necessity of phosmet, so EPA pursued an MOA to ensure that mitigation was put in place and worker protection issues were addressed as soon as possible.

The agreement required Gowan to amend all of its phosmet product labels based on the IRED and any modifications EPA considers necessary based on comments received during a sixty-day comment period. After June 30, 2002, products were required to bear labeling approved by EPA in accordance with the agreement. The agreement also required that all registrations of phosmet products labeled for specific crops would include the following terms and conditions:

- After October 30, 2006, products shall bear restricted entry intervals (REIs) specified in the MOA unless prior to that date EPA decided that another REI is appropriate.
- By October 30, 2005, the registrant would submit biomonitoring data, a feasibility study of gloves suitable for field workers, and data reflecting benefits and use patterns of phosmet.

EPA expected to receive revised labels from Gowan in May 2002 so that they could be reviewed and approved in advance of the June 30, 2002, deadline. Because of errors in the submissions, there were several rounds of label reviews and EPA did not approve amended labels until 2005. There were a number of issues that contributed to the delay: SRRD and RD disagreed whether or not the amended labels needed to be complete updates in light of relevant PR notices or if the labels only needed to have the mitigation specified in the IRED included. Note that the MOA stated that "each phosmet product must include on its product label in the Direction for Use section all of the labeling statements identified in the IRED…" SRRD maintained that a complete amendment conflicted with its intent to implement RED-specified mitigation as soon as possible and was beyond the scope of the exercise. Also, due to the substantial number of iterations of labels between OPP and the registrant, it took a long time to finalize the label amendments. There were only a limited number of phosmet labels that were affected by the MOA (ten to twelve) and EPA attempted to prioritize them.

Gowan completed the studies per the agreement and EPA reviewed the data. In 2004, phosmet was the subject of a lawsuit by farmworker organizations that challenged occupational exposure risks. EPA expected that the REIs would need to be lengthened, as was proposed in June 2006, which would require additional label amendments. In January 2007, EPA issued its final decision on nine uses of phosmet that will lengthen most REIs and impose additional mitigation measures. Generic and product-specific DCIs were issued on April 9, 2003. As of October 2006, the majority of phosmet products had not been reregistered.

Several key aspects of the phosmet case made an MOA a particularly appropriate and successful tool: there was only one registrant and there were additional issues beyond label mitigation to be addressed. This case also illustrates that an MOA does not necessarily guarantee timely implementation of all label changes.

4.3.2 Propanil Pilot Project

In an effort to implement the mitigation specified in the RED on the labels in a timelier manner, EPA initiated a pilot project for propanil. EPA published the propanil RED in September 2003 and mailed out DCIs in Spring 2006. SRRD provided the label table to RD at the same time that it issued the PDCI. RD sent a letter to the registrants in May 2006 to request that they

incorporate RED-specified mitigation while SRRD continues with the product reregistration process. This is similar to the approaches for chlorpyrifos and phosmet (above) but without the negotiation and signature of an MOA.

The Propanil Task Force responded to RD's request by questioning why EPA requested the amended label before the registrants responded to the DCI. The Office of General Counsel (OGC) prepared both a specific response to the Propanil Task Force and a generic letter for future use. The letters explained that EPA is working to reduce the amount of time between issuance of the RED and implementation of mitigation required in the RED. Registrants were given ninety days to provide a revised label. In the absence of the required label changes in the RED, EPA stated that the pesticide label does not have sufficient directions for use and/or a precautionary statement to adequately protect health and the environment (and could therefore be considered "misbranded" under Section 2(q) of FIFRA).

As of January 2007, of the 43 products: amended labels for 23 products were submitted to EPA and accepted with comments; 3 were pending in label review; 3 provided no response; and 14 products were voluntarily canceled. On average it took 6 months to receive and accept (with comments) amended labels, not including those that did not respond.

This pilot project illustrates that it is possible to implement RED-specified mitigation, although it will likely require a change in registrant culture as they become familiar with the new process. Given that half of the labels were not submitted, EPA will need to address the consequences of such actions moving forward. In addition, this approach does increase the burden on SRRD, so EPA will need to focus its activities appropriately.

5. DCI Justifications and Preparation

After a RED is signed, the preparation of the generic Data Call-In (DCI) or product-specific Data Call-In (PDCI) notice is the first step in the product reregistration process. Before the DCI can be issued to the registrant, EPA must prepare and receive approval of a DCI justification package from Office of Management and Budget (OMB). This DCI justification package lists all of the product-specific studies, as well as any confirmatory data, that the registrant must submit in order to complete reregistration for each of the individual pesticide products covered by the RED.

Several EPA offices and other agencies are involved in the preparation of a DCI justification package. The Program Support Branch (PSB) is responsible for preparing the DCI justification package and, once approved by OMB, for sending the DCI to the registrant. Several entities assist PSB in the development and review of the DCI justification package, including:

- OPP Field and External Affairs Division (FEAD),
- OPP Science Divisions: Environmental Fate and Effects Division (EFED) and Health Effects Division (HED),
- Office of Prevention, Pesticides, and Toxic Substances (OPPTS) Regulatory Coordination Staff (RCS), and
- SRRD Product Reregistration Branch (PRB).

The U.S. Department of Agriculture (USDA) also assists with DCI justification packages, particularly when high-profile chemicals and/or high-cost studies are involved. To ensure the DCI justification package complies with OMB standards, FEAD and RCS review it before submitting it to OMB.

5.1 Preparation of DCI Justification Package

Despite approved standard operating procedures (SOPs) for developing the DCI justification package, the process is time-consuming and often evaluated by OMB against varying standards. OPP believed that approval of a DCI justification package was a source of delay in the product reregistration program, and we explore this issue in this section.

5.1.1 Template for DCI Justification Package

In an effort to streamline and standardize the DCI justification package based on feedback from OMB on a DCI for the toxics program, RCS initiated changes to the format of the DCI justification packages. Through an iterative process, PSB and RCS re-formulated the template to include “boilerplate” responses for study rationale and intended data use. Despite the intent of streamlining the process, the first package PSB prepared using the template (submitted on May 22, 2006) was much lengthier than previous DCI packages because PSB included both the boilerplate language and standard elements from the old format. The lengths for the most recent packages are:

One year ago:	30 pages long for 26 chemicals
Most recent package:	80 pages long for 21 chemicals

In August 2006, OMB presented EPA with ten questions, which were mostly about process and therefore relatively easy to address (e.g., why is OPP requesting acute toxicity data from the registrant?). OMB approved that particular DCI package in October 2006, five months after it was submitted. It is unclear at this time whether the template changes will help expedite the review and approval of DCI justification packages by OMB.

5.1.2 Supporting Data

A lack of supporting data can lead to several delays in assembling the DCI justification package. First, the manner in which the OPP science divisions write the risk assessments (RAs) is viewed as problematic by several PSB staff. Currently, neither the RAs nor the REDs summarize or clearly identify upfront the rationale for new studies. Often, PSB staff need to review the entire RA to locate necessary information or contact the science divisions to help develop the rationale, both of which can be time consuming.

Second, in conducting the RA, the science divisions may conclude that the registrant needs to conduct "special studies" in order to generate sufficient confirmatory data for product reregistration. In practice, the science divisions delineate the basic parameters of these special studies but do not provide PSB with cost burden estimates. Since special studies fall outside of standard test cost estimates, PSB is responsible for estimating the cost burden for the DCI justification package, despite not being as familiar or knowledgeable as the science divisions about study components.

5.1.3 Tracking

Tracking, as it relates to the DCI preparation process, has several shortcomings. Due to the lack of an integrated tracking system and the multiple players involved in the DCI process, there are at least four tracking systems used by staff to meet different needs: the Office of Pesticide Programs Information Network (OPPIN), a Microsoft Excel-based tracking system, and several Microsoft Word-based tracking systems.

As one of the first steps in the DCI-related tracking process, the generic CRM or product-specific reregistration CRM generates the DCI or PDCI, respectively, in OPPIN. (In practice, PSB, not the generic CRM, typically generates the DCI.) OPPIN is not well suited, however, for detailed tracking of the DCI process because it does not include the needed data fields and reporting functions. Consequently, PSB uses a Word-based system to track the review periods of DCI justification packages by different EPA divisions (i.e., FEAD and RCS) and OMB. It then uses another system to track the return of green cards from registrants. Once PSB processes the product-specific green cards, it forwards them to the product reregistration CRM in PRB who tracks the ninety-day response for the PDCI in Charts and Tables. If the DCI also required generic, confirmatory data, PRB forwards a copy of the green cards to the generic CRM for tracking. The tracking system used for ninety-day and eight-month responses varies among CRMs on the active ingredient level – some use OPPIN; others use separate systems.

OPPIN, which is about five years old, was an attempt at creating a centralized, integrated information management system that would meet the needs of and be accessible to all OPP divisions. Multiple staff expressed dissatisfaction with OPPIN, citing it is not user-friendly, data are not current or complete, and lack of a "report-card" function (guideline status report) to

easily check the status of any given chemical in the post-RED process. CRMS, the predecessor of OPPIN for tracking reregistration of active ingredients, had this functionality, allowing the user to determine where an active ingredient is in the process (e.g., to check the status of submitted studies from a given registrant). Due to its design, CRMS also provided a level of staff accountability that OPPIN does not offer. A new system called PRISM is currently under development and intended to take over the functionality of OPPIN to address currently unmet needs. It is unclear at this time whether PRISM will have the "report card" function or something similar to it.

5.2 Resources and Staff Time

At this time, inadequate staffing in PSB contributes to bottlenecks and delays in the preparation of the DCI justification package. Currently, there are no senior scientists or senior science writers on PSB's staff roster. PSB currently relies on FEAD staff for preliminary reviews of supporting data and documentation. It is not uncommon for FEAD staff members to spend approximately ten percent to twenty percent of their time on DCI preparation and review.

Due to the statutory deadlines for reregistration, generic CRMs begin work on new chemical(s) after the RED is signed. By the time PSB commences the development of the DCI justification package, the CRMs are likely focusing on new chemicals. Consequently, answers to product-specific questions may be difficult to obtain due to the lapse of time between the RED signature and DCI preparation, as well as competing priorities among the CRMs. Moreover, since there are twenty-one CRMs at this time, PSB often must track down the right people to get information.

5.3 Approval of the DCI Justification Package

Since 2003, the total length of time for preparing a DCI (including OMB's review approval) has decreased from an average of 18 to 24 months to an average of 9 to 10 months; the shortest length of time being four months as OPP improved its procedures and developed its relationship with the previous OMB desk officer. A consistent source of delay in the DCI preparation process is OMB's review and approval, which can often span several months. Staff expressed the importance of building a relationship with the OMB officer, so both parties have a mutual understanding of the process. However, the turnover in OMB officers is relatively high: many officers serve for only two to three years.

6. Data Requirements and Review

Key aspects of the product reregistration process are the ninety-day and eight-month responses by the registrant, as well as the review of these data by EPA. Several issues are important to consider relative to the delays and issues with product reregistration, including data management, communication, management priorities, and staffing.

6.1 Data Management of Registrant Responses

Given the number of data guidelines, communications, and other pieces of information that correspond to each product, information management is key to the product reregistration process. Tracking of information is critical for DCI preparation and mail out, ninety-day responses, eight-month responses, data review, label assessment and review, and reregistration decisions. Overall, there are approximately forty-four discrete data elements that must be tracked for each product (i.e., six toxicity studies, twenty-eight product chemistry studies, efficacy studies (if required), waiver requests, study deficiencies, time extensions, and suspensions). Products that are combinations of active ingredients, which may or may not be conducted at the same time, further complicate tracking.

In 2005, SRA International developed a report that described and illustrated the product reregistration process and commented on the adequacy of its tracking systems.[32] SRA concluded, "EPA and participants of the product reregistration process could very much use an automated method of tracking the numerous products throughout the process. Currently, all tracking is done manually in PRB and only the CRM has direct access to the tracking data." Thus, for this evaluation, Abt Associates interviewed several OPP staff members to identify information management issues.

The Office of Pesticide Programs Information Network (OPPIN) was intended to be a centralized system to address the needs of all OPP programs. However, OPPIN is inadequate for purposes of product reregistration because it does not provide the required data fields or reporting functions. It also does not provide PRB the necessary reports to verify the data contained within OPPIN against other data sources, which is critical given the number of tracking systems used for product reregistration. Staff also noted that the concerns with OPPIN extend beyond those of reregistration. SRRD staff have requested modifications to OPPIN to address its shortcomings in tracking reregistration for both active ingredients and end-use products. Generally, requests related to the reregistration of active ingredients have been made more frequently, as many staff believed that those requests were more likely to be granted than those on the product level. OPP staff noted that information management needs for registration review are being addressed to their satisfaction. In addition, staff commented that PRIA actions accounted for most of the OPPIN maintenance budget.

In November 2006, SRRD management again requested several revisions from ITRMD, which reiterated SRRD's priorities from June 2004.[33] These revisions follow in priority order:

[32] OPP Enterprise Architecture Process Description: Special Review and Reregistration Division Product Reregistration," SRA International, September 29, 2005.

[33] Based on an e-mail message from Pete Caulkins, Associate Director, SRRD, to ITRMD, "Product Reregistration IT Development Projects," September 5, 2006

- RED Outcome Report at the Product Level, which would track by case name and chemical each product, the PDCI issuance date, ninety-day response date, eight-month response date, data review status, date sent to RD, and fields that track RD's interaction with the registrant.
- RED Outcome Summary Report that tracks the total number of products cancelled, reregistered, and amended. A key aspect to this report would be the ability to aggregate these data by chemical, branch, PM, etc.
- Guideline Status Report to track generic studies required by the RED.

These three features were promised to SRRD by ITRMD as part of the next revision to OPPIN.

The first report, RED Outcome Report at the Product Level, was available in the precursor system to OPPIN, which was called PRATS. PRATS was disabled in 2003 after OPPIN was launched. PRATS data are available in read-only format, but PRATS is no longer available for data entry. PRATS included specific fields for tracking product-specific studies (receipt, acceptability, review status, etc.), which is not available in OPPIN.

As a result, EPA has been forced to track outside the centralized system, which is counter to the intent of developing OPPIN. To track product-specific reregistration information, SRRD developed "charts and tables." Charts and tables are a Microsoft Word template that CRMs use to record product reregistration information. They include background information, such as RED date, case, code, PM contact, and number of products, as well as the status of responses in review, products suspended, products canceled, products in label review, products sent to RD, and letters out.[34] For each product, the document includes blowback requested/received, product chemistry data status, toxicity data status, due date for data, date sent to label review, and date sent to RD. It also summarizes contact with the registrant by product and identifies action items. Each CRM has some flexibility to modify the template according to his/her own style, and each file is not available to other CRMs or management because CRMs generally save these files on his/her personal drive. In addition, some CRMs are timelier than others in maintaining their charts and tables.

To provide tracking information to management, SRRD maintains two external databases in either Microsoft Access or Word: (1) STATUS includes information from the "bean sheet," which is a summary report submitted to RD with each reregistration package, and (2) REDS includes the chemical, CRM assignment, number of products, and how many products are reregistered, amended, or cancelled. These databases are only accessible to one SRRD PRB staff member, and serve as the data source for management reports and SRRD's annual performance report. Despite its disadvantages, OPPIN allows SRRD to track RD activities with respect to product reregistration. This helps SRRD maintain its STATUS database. Although there are some similarities between OPPIN and STATUS, OPPIN does not provide the proper reporting features such that PRB can access the needed information in a usable manner.

The third report that was requested, the Guideline Status Report (often referred to as a "report card") has been requested several times by SRRD.[35] This revision would largely benefit the

[34] Based on charts and tables for Trifluralin, September 15, 2005, provided by Pete Caulkins, Associate Director, SRRD.
[35] "OPPIN Generic Data Management Functionality Assessment," Patrick Dobak, May 2, 2005

reregistration branches that are responsible for tracking confirmatory data for active ingredients, as well as tracking DCI responses. Whereas PRB worked outside the system to develop charts and tables, the effort on the active ingredient side was not as coordinated. As a result, SRRD reregistration branches do not know where confirmatory data are in review nor if the guideline has been satisfied. RD also pursued the development of a database external to OPPIN to track generic data for registration.

Also, on the active ingredient level, staff noted that OPPIN was not well suited for tracking "special studies," which are those that are not included as standard guidelines. Similarly, PRB noted that it does not have a way to track voluntary letters, and Certitrack might be useful for this purpose. Certitrack is a database to track correspondence that was used by some PRB CRMs, but it is a DOS-based program that requires a dedicated printer. OPPIN also does not provide the proper capabilities for data management, as many of the corrections need to be made by a database administrator.

SRRD staff noted that improvements to OPPIN do not seem to be a priority given that OPP is developing PRISM, which will replace OPPIN in September 2008. PRISM, while still in the planning and acquisition phase, intends to use the basic table structures of OPPIN. PRISM, however, will supplement those tables with new and redesigned data structures as it is developed. The primary intention of PRISM is to provide OPP staff and management with an improved presentation layer, integrate currently missing applications and other improved software features, and provide new functional applications. Ultimately PRISM is intended to provide a more stable environment for the entire pesticide industry and, coupled with new technologies (Documentum, CDX, and J2EE driven applications), will enhance EPA's ability to meet its strategic goals.[36] Staff noted that OPP has not directly addressed how product reregistration will be addressed in PRISM.

Several staff members expressed that the ultimate success of PRISM hinges upon improved communication between management and staff. In particular, they currently play a mostly responsive role in maintaining and improving OPP tracking needs, e.g., they attend meetings when asked, or provide management with information when requested. These staff members expressed that they would be better able to anticipate and respond to tracking issues if open lines of communication between all staff are maintained. Several staff commented that ITRMD's visibility and involvement in programmatic activities is limited. Because ITRMD has taken a compartmentalized approach when developing both OPPIN and PRISM, staff noted a need to bridge communication within the office. One potential avenue is through the Information Management Council, which is comprised of all OPP division directors and provides a forum to advance IT needs.

As a result of the shortcomings of OPPIN and the current approach to data management, EPA unintentionally created a window of time for which data are not properly tracked because they are not available electronically or not available in a centralized format. The current approach means that PRB is unable to monitor progress in an effective and efficient manner, which wastes a lot of time and things are more likely to fall through the cracks.

[36] http://www.epa.gov/oamhpod1/admin_placement/0610113/qa1.doc

6.2 Acute Toxicity and Product Chemistry Analysis

SRRD conducted an assessment of the impact of product-specific acute toxicity and product chemistry reviews on label mitigation. The SRRD assessment sought to determine the impact of these reviews on revisions made to the product label during reregistration beyond what would be required by the Reregistration Eligibility Decision (RED). SRRD's preliminary analysis indicated that product-specific data had a significant impact on label mitigation. To confirm their findings, Abt Associates conducted an audit of the acute toxicity portion and assessed its utility for the evaluation of the product reregistration program. This section provides background on the data and guidelines and discusses the design of EPA's analysis and our conclusions regarding SRRD's analysis.

For more information on the approach and specific results of the audit, please see "Results of Audit – Evaluation of Acute Toxicity and Product Chemistry Review Findings," Memorandum to Yvonne Watson and Caulkins, U.S. EPA from Debra Kemp, Albert Acquaye, and Jason Sacks, Abt Associates Inc., January 30, 2007.

6.2.1 Background on Acute Toxicity and Product Chemistry Guidelines

The acute toxicity data required on end-use products for product reregistration include the acute oral, acute dermal, and acute inhalation studies, which evaluate systemic toxicity resulting from short-term exposure via the designated route. The remaining acute studies are the primary eye irritation, primary skin irritation, and the dermal sensitization studies. The eye and skin irritation studies assess potential irritation or corrosion from a single exposure, while the dermal sensitization study evaluates allergic contact dermatitis resulting from multiple exposures. These acute studies identify routes of concern, as each study is categorized based on degree of effect (categories 1 through 4), with Category 1 indicating the most severe effect and Category 4 representing the least severe effect. In addition, each category corresponds with specific label statements or requirements necessary to reduce exposure and protect against acute health effects. The resulting label statements/requirements vary significantly based on product-specific factors such as the formulation type and whether the use pattern is agricultural, occupational/industrial, or residential. Furthermore, label statements for agricultural and occupational use products may vary based on whether the product is subject to the Worker-Protection Standard (WPS).

Acute studies result in hazard communication directly to the user and/or medical professionals through the label sections and/or product classifications listed below.

1. Restricted-Use Pesticide (RUP) Classification
2. Signal Word/Skull and Crossbones Symbol
3. First Aid Statements
4. Note to Physician
5. Hazards to Humans and Domestic Animals (HHDA)
6. Personal Protective Equipment
7. Child-resistant Packaging

The product chemistry data required for product reregistration can be grouped into two categories: (1) product identity, composition, and analysis, and (2) physical and chemical properties. Product identity, composition, and analysis allow EPA to clearly define the product

formulation and identify any inert components of concern. The physical and chemical properties assess potential hazards posed by the formulation (e.g., flammability, corrosivity, and storage stability). Identification of these hazards allows the implementation of preventative measures. Some of the more basic physical and chemical properties evaluated allow EPA to respond to emergency requests for identification of unlabeled pesticides.

6.2.2 Design of Analysis

At the completion of FY2005, SRRD randomly selected a sample of 120 products (7 percent of reregistered products) of the 1,730 products had been reregistered. The sample size of 120 results in one product per RED listed on the OPP Web site with available batching tables at the time this assessment was performed. Abt Associates believes that a larger sample size would be better suited for this analysis, but understands the limited time and resources available to SRRD. SRRD noted that crosschecking labels with the results of the acute toxicity and product chemistry reviews was a lengthy process. Based on its description of how it identified a specific product from each of the 120 REDs, Abt Associates believes that the selection procedure SRRD described was objective and unbiased.

Although Abt Associates confirmed its sampling procedure, we believe that SRRD could have better designed its study and in turn provided a better answer to the issues at hand. For example, we would have suggested that EPA select randomly from among the entire universe of products for which product reregistration was completed or for which labels had been amended. This would have allowed SRRD to confirm that recommendations based on acute toxicity reviews were indeed placed on the final label. In addition, we would have suggested that EPA not constrain itself from sampling one product from each RED given how the number of products vary.

Also, Abt Associates did not believe that EPA's results were presented in a detailed enough manner such that the reader was left with a clear idea of what a "revised statement" means. By establishing criteria for each category or at least providing examples, the reader might have had a clearer idea of how substantive the revisions could be. Similarly, EPA could have made its categories more specific, including multiple categories for signal words (e.g., added, increased, decreased), first aid statements (skin/clothing, eyes, swallowed, inhaled), and individual categories for mitigation statements that appear most frequently and may therefore skew the results (e.g., having container available when calling poison control center, notes about cholinesterase inhibition, etc.).

Finally, the analysis did not provide a comparison of extent of mitigation identified by product-specific data as compared to extent of mitigation identified in the RED. We understand that RED-specified mitigation is generally more substantial. That said, some OPP staff members commented that the product-specific mitigation was negligible. Abt Associates believes that an analysis that identifies the mitigation required by the RED, as well as that specified by product-specific data would be informative.

6.2.3 Audit Conclusions

Although Abt Associates was generally able to confirm the majority of EPA's findings for each of the twelve products included in the audit, the audit revealed several discrepancies and other issues of concern. These discrepancies were identified in the above-referenced memorandum

to EPA. In addition, EPA seemed to be inconsistent in how it characterized Personal Protective Equipment (PPE) in its results. Generally, EPA included the discussion of PPE requirements in the Hazard to Humans and Domestic Animals (HHDA) section of its acute toxicity review memo; however, for purposes of its results sometimes these changes were considered revisions to PPE and sometimes revisions to HHDA.

Often, mitigation specified by the acute toxicity review did not appear on an amended product label. Note, however, that not all products have been reregistered. Similarly, amended labels often included additional mitigation beyond that recommended in the review memo or the label table from the RED. The source (e.g., registrant or RD) of such mitigation is unclear, as well as if mitigation specified by acute toxicity reviews may have otherwise been included on the label (e.g., updates to first aid statements based on current label review standards).

For these reasons as well as the shortcomings identified in the study design, Abt Associates did not feel it was appropriate to include EPA's analysis in its report.

6.3 2,4-D Streamlined Data Requirements

Through batching and citing existing data, OPP can substantially reduce the number of sets of product-specific acute toxicity data to be reviewed for each active ingredient, thus reducing the time required to re-register products. It may be possible to reduce the time required for acute toxicity reviews even further, if the batching process is streamlined. One such example of streamlining may be found in the case of 2,4-D. 2,4-D is an ingredient in more than 600 agricultural and home use products. It comes in multiple chemical forms, and is found in numerous products intended for use in a wide range of uses. The Industry Task Force II on 2,4-D Research Data worked with OPP to reduce product-specific acute toxicity data requirements by using existing data and streamlining the batching process. The Task Force included almost all registrants affected by the 2,4-D reregistration, including every company that had technical registrations for 2,4-D.

Batching allows registrants to use or cite acute toxicity data from a group of similar products to satisfy data requirements. Batching tables are included in the RED and group product formulations that, from an acute toxicity perspective, allow one set of acute data to be used to support the reviews of all products within the batch. Once batching tables are published in the RED, it is the responsibility of registrants to act upon them and submit data to OPP. For instance, after product A submits the required data to EPA, registrants of products B, C, and D that belong to the same batch as product A and want to use (cite) data for product A in support of their products, may pay or offer to pay the registrant of product A to cite its data.

Depending on the chemical and the formulations, OPP may not be able to batch all the acute toxicity data, instead requiring all registrants to submit individual acute toxicity data. This is usually the case for fertilizer products, which may result in individual eye irritation data being required and other acute toxicity data being batched. In many instances, registrants choose not to take advantage of the batches and rather chose to submit their own data, which EPA is obliged to review. Many registrants do not take advantage of the batching because the data already exist, they would prefer to submit their own data, or they do not want to pay data compensation fees. OPP estimates that typically between 20 and 30 percent of registrants take advantage of batching.

6.3.1 2,4-D Batching Approach

The level of success of batching varies from chemical to chemical, since formulations may be quite different. In the case of 2,4-D, a preliminary attempt at batching one of the formulations with the majority of 2,4-D products yielded about 50 to 60 batches. The Industry Task Force II on 2,4-D Research Data submitted a proposed batching scheme, although it was of limited value because it did not include information on inert ingredients, which is confidential business information. The acute data provided by the Task Force, however, were very useful in satisfying the data requirements for individual products and product batches, even though organizing and evaluating such a large volume of data was very time consuming.

This approach did, however, allow PRB to use the existing acute data provided by the Task Force to satisfy some or all data requirements for most of the product batches. This negated the need for a registrant to submit a waiver to cite what was already submitted to EPA. The formation of a task force specifically to address product-specific data requirements will likely result in greater participation in the batching groups by registrants. Also, because Task Force data were available during the batching process, they were used to determine product grouping. In some cases, this allowed for products with a larger range of active ingredient to be grouped together. As a result, EPA asked for only 1,027 acute toxicity studies out of a possible 3,618 studies, which will decrease the burden on the registrants, EPA, and OMB.

6.3.2 2,4-D Storage Stability Requirements

The Industry Task Force II on 2,4-D Research Data approached EPA with information and data to show that different formulations using the chemical are extremely stable under various conditions. For this reason, it was possible to eliminate the storage stability data requirements that are the most expensive ones for registrants and the longest for OPP staff to review. Registrants had over time submitted almost ninety storage stability studies to support registrations or in enforcement cases, all of which indicated that regardless of time, the product remains stable with up to five to seven years of shelf life. As a result, OPP waived the need for any more storage stability studies.

6.3.3 Pros and Cons of this Approach

In general, this approach will save time in reviewing data by identifying good studies that have been conducted properly to support the registration of large groups of products. This batching approach resulted in a 72 percent reduction in the amount of data required compared to getting a six-pack for each of the 603 products.[37] A six-pack for each of these products would have resulted in 3,618 individual studies required, while EPA is asking for 1,027 studies through the current approach. Typically with batching, however, many products use existing data (either from another company within the same batch, or previously generated product-specific data) to support product reregistration. Even if one-third of the 603 products used existing data, this approach would have resulted in a 57 percent reduction in the amount of acute data required.

This approach required registrant participation to determine the studies that may be used to support the reregistration of various product groups. The larger the number of registrants involved in a task force, the greater the degree of participation in batching since the formation of the task force provides an organizational structure to facilitate data sharing and minimize

[37] 2,4-D Batching Project Briefing, provided by Pete Caulkins, February 13, 2007.

registrant costs. Because all 2,4-D registrants were members of the Task Force, they were likely to participate.

Typically OPP would issue the data requirements and shift the responsibility to the registrant. By working with the Task Force, they were able to determine what they needed. OPP has learned from its 2,4-D experience. PRB developed a revised process for working with task forces that does not place as great a burden on its staff. OPP has targeted permethrin (1,185 products), MGK-264 (706 products), and PBO (1,704 products) as candidates for a revised, streamlined approach. This approach appears to be best suited for situations where a task force exists, which can provide the necessary infrastructure to coordinate responses among the various end-use product registrants, ensure their participation, and address data compensation issues.

6.4 Communication

Several entities are involved in product reregistration, including the SRRD reregistration branches following the publication of the RED and the Registration Division after data review is complete. Data collected through interviews indicate that there is a breakdown in communication at the transition of products to and from PRB.

Staff in the reregistration branches often operated on the assumption that the signature of the RED essentially concludes reregistration and that mitigation is implemented in a timely manner. Staff noted that the public and environmental and public health organizations often share this perception. Staff of the SRRD reregistration branches and the Registration Division admitted that they are not as familiar with the process or issues associated with product reregistration as perhaps is warranted.

Further, they recognize that communication with the registrant is not always productive because the registrants lack an incentive for product reregistration. Recently, SRRD has pursued avenues to prevent delays in registrant submissions, which often resulted from submitting comments or inadequate data later in the process. OPP staff also noted that the “stick” associated with product reregistration – suspension – has not been applied recently. SRRD is currently in discussion to reestablish the procedures for that process now that the EPA Office of Compliance is no longer involved in suspension actions.

At the end of each month, SRRD sends a status report to RD that identifies which products are currently with RD for reregistration. This is based on the STATUS tracking database that SRRD maintains external to OPPIN. Several RD staff noted that these reports could provide additional information to make them more useful, and some noted that they did not actively use the report for management purposes.

Whereas reregistration of conventional pesticide products is the responsibility of SRRD, other OPP divisions are responsible for reregistering products under their area of focus. SRRD staff noted the Biopesticides and Pollution Prevention Division (BPPD) has also commented on the inadequacy of OPPIN for product reregistration. However, SRRD staff noted that they were not familiar with the product-specific data tracking procedures within other OPP divisions (BPPD and AD).

6.5 Management and Staffing

As part of the overall reregistration process, product reregistration is only one of the priorities within either SRRD or RD. Historically, writing and publishing REDs was the priority for SRRD and registrations (particularly PRIA actions) were the priority for RD. Recent attention, however, is being focused on product reregistration through pilot projects, quarterly briefings for OPP Director Jim Jones, and regular SRRD/RD meetings on product reregistration. Most recently, the RD Director designed an approach for product reregistration moving forward (see Section 7.5 of this report). OPP management and staff are dedicated to seeing the RED-specified mitigation implemented on product labels, as well as addressing the vulnerability associated with the delays in product reregistration.

Despite attempts within FIFRA to establish deadlines for product reregistration (see Section 1.3.1 of this report), product reregistration has never been pushed and management focused on the front-end of the process. In addition to the impacts on OPP's backlog, a registrant also does not know when it will receive a reregistration decision after submitting an eight-month response. OPP has improved the process by which registrants submit data, including standard formats. OPP staff and management noted that product reregistration is one of the most inefficient processes in OPP, though that is not a result of the people, but the design of the system. To help address performance, SRRD sets goals for product reregistration annually, and these goals are met (see Figure 3-4). SRRD staff noted that because of end of fiscal year deadlines for REDs and other activities, product reregistration gets the most attention in October to January.

In its FY2007 reregistration work plan, SRRD allocates its FTE resources as follows:[38]

- 40 percent to completing non-food-use REDs
- 41 percent to post-RED issues
- 8 percent to product reregistration, which covers both SRRD PRB and RD
- 11 percent to registration review

Over time, a greater percentage of resources will be allocated to registration review. After FY2008, SRRD expects that funds will no longer be allocated for completing REDs, though it will continue to budget for post-RED issues. Funds are allocated for product reregistration through FY2013. The eight percent FTE allocation is roughly equivalent to past staffing levels and SRRD expects the staffing level to remain fairly constant in the short term.

Some staff members commented on the decrease in PRB staffing over time as a result of attrition and retirement. They maintain that it is a challenge for PRB to keep up in light of the workload and reductions in staff. PRB did recently hire a new product chemistry reviewer and a new CRM. Training for new staff is conducted on an ad hoc basis, and written procedures for product reregistration are not available.

[38] Personal communication with Pete Caulkins, January 2007

7. Label Assessments and Reviews

SRRD PRB and RD conduct label assessments and label reviews, respectively. SRRD's preliminary label assessment focuses on comparing the amended label to the label table in the RED to ensure that the label adequately captures the required mitigation. After SRRD's preliminary label assessment, RD reviews the label in its entirety and is responsible for stamping the final, approved version.

A brief overview of the reregistration process as it relates to the label review process is provided below:

- Registrants send OPP a revised label as part of the 90-day response to the DCI to incorporate mitigation on the RED;
- Registrants send OPP product-specific data and/or confirmatory (generic) data over the eight-month response period;
- SRRD evaluates the product-specific data, requests additional information as needed, and determines if additional mitigation is needed;
- After all study reviews are complete, the CRM assembles a label review package for the PRB Label Review Team;
- PRB Label Review Team develops a preliminary label assessment (see Section 7.1);
- The CRM assembles final review package ("bean sheet," all applicable science reviews, the preliminary label assessment, and the draft amended product label) and delivers to Product Manager (PM) in RD; and
- The PM in RD conducts final review of label (see Section 7.2) and requests additional revisions from the registrant, if required. Once approved, the PM stamps the final label and issues a reregistration notice.

7.1 Label Assessment – Special Review and Reregistration Division

The primary purpose of SRRD's preliminary label assessment is to determine whether the draft labels submitted in connection with product reregistration comply with amended labeling language specified in the RED/IRED.[39] To avoid duplication of effort between SRRD's and RD's label reviews, the preliminary label assessment does not comment on other aspects of the label, such as labeling requirements specified in 40 CFR part 156.10, Pesticide Regulation Notices (PRNs), and Criteria and Policy Notices. To assemble the preliminary label assessment and to maintain consistency, SRRD uses a template with the following sections: a scope statement, background, summary of findings (including recommended label changes), and an appendix with a checklist of whether the label changes made by registrants are acceptable or unacceptable.

The preliminary label assessment occurs once the CRM submits the label review package to the SRRD PRB Label Review Team. The label review package consists of the draft label

[39] PRB Preliminary Label Assessment. Memorandum provided to Abt Associates by Larry Schnaubelt, PRB.

submitted by the registrant, SRRD's review of the product-specific data, and the label table, which assists SRRD in comparing the label to the mitigation specified in the RED. The label included in the label review package is the most recent, hardcopy version submitted by the registrant as part of the eight-month response to the DCI. Over this same time period, however, the same registrant may have submitted drafts of amended labels to RD (e.g., to add a new use), and SRRD may be unaware of these label changes. Consequently, the label reviewed by SRRD as part of its preliminary label assessment may not be the most recent version. This problem is magnified by the long timeframes in which label reviews occur, as documented in Chapter 3 of this report. Once completed, the preliminary label assessment is submitted back to the CRM, who then assembles the final review package and delivers it to the appropriate PM in RD.

7.2 Label Review – Registration Division

After receiving the final review package from SRRD, the PM conducts the final label review and stamps the label. It is the responsibility of the PM to identify and address any outstanding labeling issues, including any remaining RED-specific issues, and to obtain the necessary label changes required for final product registration. To do so, the PM typically composes a letter to the registrant specifying necessary labeling revisions.

RD commonly finds issues with the labels that require additional revisions by the registrant (e.g., labels are not compliant with acute toxicity data) or prompt RD to re-conduct the label assessment performed by SRRD. For example, the preliminary label assessments commonly identify labeling issues but do not contain recommended solutions, requiring the PM to duplicate the part of the review related to RED mitigation. Another contributing factor is poor version control of labels between SRRD and RD. As mentioned previously, it is common for PMs to receive old labels as part of the final review package from SRRD, due to the fact that the PRB Label Review Team assesses the amended label submitted by registrants as part of the eight-month response. In these instances, PMs often conduct an entire label review from scratch, since the preliminary label assessment is based on an outdated label.

The OPP Label Review Manual was created as a way to help maintain consistency in RD's label reviews. Despite these guidelines, RD's label reviews are not always conducted in a consistent manner. For example, in instances where a registrant requests the addition of a new use to the label, and the product is still somewhere in the reregistration process, some (but not all) PMs will require that the registrant implement the mitigation stated in the RED at the same time as adding the new use to the label. These PMs will not stamp the new label until the mitigation stated in the RED is incorporated on the label.

Similarly, PMs vary in the way they use SRRD's preliminary label assessment. Several RD Branch Chiefs noted that the label assessments are especially beneficial to new PMs who are not experienced in conducting label reviews or who do not have an extensive knowledge of the product and its regulatory history. The majority of PMs, however, noted that they either entirely disregard the label assessments or only use them as a way to ground-truth their own label reviews.

7.3 Ziram Pilot Project

In Spring 2006, EPA initiated a pilot project using the ziram case where RD and SRRD conducted concurrent, independent label reviews for each of the products to determine how the two divisions assessed label changes. In March 2006, reviews were conducted for three products. There were no differences in the label reviews conducted by the divisions, except that RD had two, minor non-substantive additions that were a result of pesticide notices.[40] Note that two of the products were manufacturing-use products that typically do not require many label changes as a result of the RED.

Also in Spring 2006, SRRD and RD conducted label reviews for sodium acifluorfen using its standard process (i.e., a label assessment in SRRD and a label review in RD). Reviews indicated that the registrant had included a new use on the label, which was caught by both SRRD and RD reviewers.

Although these two reviews indicate the similarities in reviews between the two divisions, our preliminary conclusion is that two pilots are not an adequate sample from which to draw a conclusion. Further, we would have recommended that the reviewers not be told of the pilot project to better represent typical review conditions.

7.4 Workload Management and Other Issues

In some RD branches, products are assigned to PMs and their staffs based on chemical ownership. In other branches, one or two staff members are designated to conduct label reviews on a full-time basis. Many PMs and their staffs are currently juggling label reviews for product reregistration with PRIA and other registration work. Other personnel issues include frequent staff turnover and the likelihood of several PMs retiring in the near future.

With regard to managing workload, the number of review packages delivered by SRRD to RD is highly variable. Branch Chiefs and PMs in RD often do not receive a “heads-up” from SRRD about when to expect review packages. PMs may receive one hundred review packages at a time, or as few as one or two review package every few weeks to a month. The product reregistration backlog is also highly variably among the RD branches. For example, two branches have no backlog while the remaining branches have backlogs of one hundred or more products.

Several PMs expressed preference for receiving all product labels pertaining to one chemical at one time. This is advantageous because it allows the review teams to meet and discuss any issues, thus leading to greater consistency in the label reviews. The downside of batching is that SRRD may hold back a large number of completed packages while completing the remaining products, which delays implementation of mitigation and potentially results in outdated assessments for a significant number of products.

Several staff noted that there is very little collaboration or communication between SRRD and RD on the label assessments and reviews. For example, the PRB Label Review Team rarely

[40] Product Reregistration Quarterly Review, Briefing for Jim Jones, Associate Director of the EPA Office of Pesticide Programs, July 2006

receives feedback nor is asked questions by RD on the preliminary label assessment. Similarly, it is common for there to be little to no interaction between the SRRD CRM and the PM when the final review package is delivered to RD.

To facilitate the handoff of packages between SRRD and RD, OPP recently developed new standard operating procedures (SOPs) to provide RD with streamlined label review packages from PRB.[41] By providing only the critical documents used in PRB's label assessment, OPP expects that RD staff will be able to proceed with reregistering the product with less effort and in a shorter time period. A streamlined package would entail sending RD only the final acceptable review from each discipline (e.g., acute toxicity, product chemistry with acceptable confidential statement of formula, and efficacy), the label assessment, and one copy of the latest draft label (used in the label assessment). Previously, each CRM assembled packages differently and often provided more information than RD required. Both of these issues required RD to spend a significant amount of time reviewing and sorting materials in the package before conducting its label review.

7.5 Current Strategy to Expedite Product Reregistration

Recognizing the backlog in product reregistration, upper management in RD has placed an increased emphasis on product reregistration recently. In Fall 2006, the RD Director developed a plan to expedite product reregistration by forming "SWAT teams," which would include staff from both RD and SRRD and would focus on reducing product reregistration backlog. This is a promising approach because it bridges the divide between RD and SRRD, which will help to facilitate communication between the divisions.

Four categories of products were identified: (1) Products in RD for which the PM has communicated with the registrant but has not yet received a label that is in compliance with the RED, (2) Products in RD for which the PM has not yet taken any action, (3) Products in SRRD PRB for which the DCIs have been issued, and (4) Products in SRRD PRB for which the DCI has not yet been mailed.[42]

Products in Categories 1 and 2 will be addressed by RD staff exclusively. During our interviews, we found that some RD branches had taken the initiative to reduce its product reregistration backlog (as of September 2006), whereas others had not yet addressed products in their branch. Categories 3 and 4 will be addressed by SWAT teams (SRRD and RD).

To address Category 1 products, the PM will send a letter that outlines a registrant's obligations and allow a given amount of time to incorporate these changes before EPA takes action. To address Category 2 products, the PM will send a letter to the registrant requesting label changes as stated in the RED. The registrant must also send a letter that certifies that the only changes on the label were those required by the REDs.

In early October, SWAT teams were established to expedite product registration for Categories 3 and 4. Each team consists of about five SRRD and RD staff, each dedicating full-time, or close to full-time, to product reregistration over the next few months. The SWAT teams will

[41] SOP for Reregistration Packages sent to RD, provided to Abt Associates by Venus Eagle, September 2006

[42] Categories for Products in the SRRD-RD Pipeline, August 2, 2006

conduct label reviews, send letters to registrants about required label revisions, and initiate regulatory action when a registrant does not comply. Each SWAT team will be assigned about one to three active ingredient cases, covering about 100 products in total.[43] RD predicted that the SWAT teams would work for a period of two months.

The SWAT team approach is unique for several reasons:

- It includes ambitious internal deadlines for completing product reregistration
- Product reregistration was made a priority within RD (particularly with respect to products in Categories 1 and 2)
- RD will provide support to SRRD with products that have not yet completed the SRRD portion of the reregistration process.
- It includes strict deadlines for registrant responses, including 30 days for registrants to submit amended labels (Categories 1 and 2). OPP is also considering requiring registrants to amend labels with RED-specified mitigation in advance of product reregistration (Categories 3 and 4).

Preliminary information on the SWAT team approach indicates that each of the RD branches is implementing the approach differently. In any event, the management attention placed on product reregistration will ensure that product reregistration happens in a timelier manner. As the approach is further implemented, EPA will need to assess if the 30-day deadlines are being met, what the role for either division was, and compare number of actions completed in FY2007 to previous years.

[43] Details of Reregistration Process Categories (Draft), provided to Abt Associates by Pete Caulkins, SRRD, September 8, 2006

8. Suggested Changes to Process Design and Other Recommendations

Based on the findings and analysis presented in Chapters 3 through 7 of this report, this chapter presents our recommendations for improving the product reregistration process. As appropriate, we also present pros and cons for each recommendation.

8.1 RED Development

In August 2006, EPA completed the REDs for food-use pesticides as required by the Pesticide Registration Improvement Act. At that time, EPA only had 54 REDs to complete (9 percent). Thus, there are still opportunities to improve non-food-use REDs and to direct more attention to post-RED activities. Based on the case studies discussed in Chapter 4, Abt Associates identified the following issues or problems with REDs that contribute to delays in product reregistration:

- REDs were often published before they are completed or before all outstanding issues were properly addressed.
- The documents represent a "snapshot in time" of the data available to EPA, and registrants often provide additional data that warrant amending the RED.
- Some REDs did not represent reregistration decisions or included provisions for additional studies, such that product reregistration could not be effectively implemented after the RED was published.
- REDs sometimes contained small errors, most of which were straightforward and easy to address.
- The label tables often contained language that RD or PRB felt could be improved or that was not consistent with labeling for other products.
- Staff from the reregistration branches were often unavailable to assist with post-RED issues.
- When a case is transitioned to PRB, staff are often unfamiliar with the RED contents and issues.
- The implementation of REDs was often influenced by other issues, which may not have been directly related to the RED itself (e.g., the cancer reclassification for captan, the registrant's decision to discontinue dicofol, legal challenges, etc.).

With these findings in mind, Abt Associates provides the following recommendations regarding RED development.

8.1.1 Improve Transition of Cases from Reregistration Branches to PRB

The transition of a chemical case from the SRRD reregistration branches to PRB could be improved. One potential way to accomplish this would be to have a "hand-off" meeting that would be attended by the generic CRM, his/her branch chief, the PRB branch chief, and the product CRM. This would be an opportunity for the reregistration branches to brief PRB on the issues, particularly those that are outstanding, and improve the relationship and coordination

within SRRD. This would address the concerns of PRB that reregistration branches do not actively participate in many post-RED issues and also the concerns of the reregistration branches that product reregistration lacks visibility. A meeting would also help delineate roles and responsibilities, and signal a clear transition from one branch to another. Until this meeting occurs, the chemical case would remain the responsibility of the reregistration branches and help encourage them to address post-RED issues.

8.1.2 Require More Participation by RD in the Development of Label Tables

Based on our conversations with both RD and SRRD (reregistration branches and PRB), we believe that the development of the label table in the RED should be improved. This recommendation is based on comments from the reregistration branches that they do not have adequate expertise in labeling. Similarly, both the PRB Label Review Team and the RD PMs noted that label tables often include language that is written in a way that is not suitable for a label or that is inconsistent with other products containing the active ingredient. RD noted that PMs are invited to attend the meetings, but RD does not generally play an active role in the development of the label table. RD Branch Chiefs should ensure that PMs are invited to and attend these meetings. The involvement of both the PM and the RD Team Leader in the RED process will help ensure the quality and thoroughness of the label review as it relates to RED-specified mitigation. In addition, RD should be required to review and approve label tables before they are published to ensure consistency and appropriateness. Note that because of our recommendation to eliminate label assessments within PRB (below), the development and review of the label table would not be a role for PRB.

8.2 Implementation of RED-Specified Mitigation

Based on its review of Memoranda of Agreement (MOAs), pilot projects, and RD's SWAT team approach, Abt Associates identified the following issues or problems related to implementation of RED-specified mitigation:

- Because of the length of the product reregistration process, as well as the delays that often occur, the mitigation identified in the RED is often not implemented for several years. This delay is particularly troublesome given that the universe of pesticides products to be reregistered includes those that were registered prior to November 1, 1984.
- Even with regulatory action as a possible consequence of non-response, several registrants did not submit amended propanil labels to include RED-specified mitigation.
- In the case of phosmet, amended labels were not submitted in an expedited manner as specified in the MOA.

With these findings in mind, Abt Associates provides the following recommendations regarding the implementation of RED-specified mitigation.

8.2.1 Implement Mitigation in an Expedited Manner When Cost-Effective

With the goal of implementing RED-specified mitigation as soon as possible, OPP is considering requiring registrants to amend product labels after a RED is signed to include the required labeling changes. OPP is considering using this approach for all products because OPP

believes that identifying a subset of products would not maintain a level playing field among the registrants. By potentially adding an additional step into the product reregistration process, OPP needs to consider the additional staff time and resources this would require. Not only would OPP need to conduct an additional round of label review, but it would also need to track responses and maintain communication with the registrant.

Although we understand EPA's rationale for applying this policy to the entire universe of end-use products, OPP would have several options available to it if adequate staff and resources were unavailable:

- Identify subset based on risk characteristics based on the attributes of the product (e.g., market share, use patterns) or the level of mitigation required by the RED
- Select REDs that are likely to have issues that might delay product reregistration, including related regulatory activities, etc.

Any rationale for differentiating policies would have to be defensible and be consistent with applicable laws and regulations.

In addition, during the course of product reregistration, both RD and SRRD would be in contact with the registrant. RD would request a label amended with RED-specified mitigation, whereas SRRD would request ninety-day and eight-month responses. OPP would need to ensure that these efforts are consistent and coordinated to reduce confusion on the part of the registrant. Members of the regulated community, particularly smaller companies, are likely to miss the distinction between the two divisions and only focus on the Agency level. Note that this issue arose during the captan reregistration, where both the SRRD reregistration branch and PRB were in contact with the registrants at the same time. Moving forward with the proposed approach, OPP would need to establish better communication and coordination between the RD PM and the SRRD PRB CRM.

Alternatively, although it prolongs implementation of RED-specified mitigation, EPA could require the amended label with the ninety-day response, but instead of holding onto it until the product is ready for label review, PRB could immediately send the label to RD for review. This assumes, however, that the DCI is sent out in a timely manner because RD is considering having a PM send letters to the registrants independently of the DCI. As a benefit, issuing the letters prior to the DCI may allow OPP to identify products that would be cancelled before it goes to the effort of preparing and mailing a DCI.

8.2.2 Pursue Additional Regulatory Action When Warranted

As demonstrated in the cases of propanil and phosmet, several registrants did not submit amended labels despite the consequence of regulatory action or the conditions of the MOA. To ensure that mitigation is consistently implemented and that registrants are aware of the implications of noncompliance, EPA needs to be prepared to pursue the "additional regulatory action" to which it refers in its letters to the registrant. Without this aspect, the success of implementing RED-specified mitigation is limited.

8.2.3 Further Explore Self-Certified or Electronic Labels

As part of its approach to implement RED-specified mitigation sooner, EPA would require registrants to submit a letter that certifies that the only changes that were made to the label were those specified by the RED. Although this issue is outside the scope of this evaluation, Abt Associates suggests that EPA consider requiring a registrant to identify and certify the nature of label changes for all label amendments. This step would increase the transparency, and also reduce the burden on the PM for identifying label changes that may or may not be appropriate. Similarly, several staff noted that OPP has discussed but is not yet actively pursuing an electronic labeling system that would allow EPA to compare label amendments electronically (i.e., in a manner similar to document comparison features in word-processing programs). These two changes to program design would decrease label review burden generally and provide RD with significantly more time to address other issues, including product reregistration.

8.3 DCI Justifications and Preparation

Based on our findings in Chapter 5, Abt Associates identified the following issues or problems associated with developing Data Call-in (DCI) justification packages and mailing out DCIs that contribute to delays in product reregistration:

- The format for the DCI justification package has been and continues to be an issue. Based on the direction provided by the Field and External Affairs Division (FEAD), SRRD used a new streamlined template for the justification package, but it also supplemented the template with a substantial amount of information.
- Risk assessments and REDs often do not provide the necessary information to create the DCI justification package, which requires PSB to spend a significant amount of time collecting additional information.
- As with other parts of the product reregistration process, SRRD does not have the adequate tracking systems available to them and has been forced to develop external systems on an ad hoc basis.

With these findings in mind, Abt Associates provides the following recommendations regarding the preparation of DCI justification packages and DCIs generally.

8.3.1 Ensure that DCIs Are Prepared According to the Package Template

PSB should use the template for the DCI justification package to prepare the DCI package more effectively and efficiently. While it is important to anticipate the needs and questions of OMB, PSB should ensure that the DCI packages provide the essential information, not try to anticipate all of the information that OMB could (but may never) require at a later time. In turn, the DCI justification package template should be revised according to the comments and lessons learned from OMB on an ongoing basis.

8.3.2 Modify Format of Supporting Data in Risk Assessments

The RAs should contain an up-front description of the data gaps and the rationale for new studies so that PSB staff do not have to search for or re-create this information. As part of the

description, the science divisions should include cost burden estimates for "special studies," since they are in the best position to project the requirements and costs of special studies. As a next step, PSB and the science divisions should work together to identify what PSB routinely needs from RAs or REDs in order to construct the DCI justification package, and then how that information can best be presented and summarized going forward.

8.4 Streamlined Data Requirements

Based on EPA's analysis discussed in Section 6.2 of this report, Abt Associates expected to make recommendations for streamlining acute toxicity or product chemistry data requirements based on characteristics of end-use products. However, as described in that section of this report, Abt Associates concluded that the analysis was not designed in a manner that yielded results appropriate for this purpose. Without adequate data on which to base recommendations, Abt Associates is unable to make recommendations for streamlined data requirements. However, based on its research, Abt Associates provides the following recommendations regarding the product-specific data requirements.

8.4.1 Conduct Additional Analyses to Determine Value of Product-Specific Data

In order to provide data to inform an approach for streamlined data requirements, OPP could consider undertaking additional analyses that would be more informative and detailed than the one provided to support this evaluation. Such an analysis would involve randomly selecting from the entire universe of products for which product reregistration was completed or for which labels had been amended. This analysis would also not be limited to sampling one product from each RED. To increase the utility of the results, EPA should identify mitigation resulting from product-specific data in a more detailed manner and record these results in either Microsoft Excel or Access to facilitate analysis. We also believe that a comparison of RED-specified mitigation to that warranted by product-specific data would be informative.

8.4.2 Leverage Related Efforts for Process Improvements

In June 2006, the Pesticide Program Dialogue Committee (PPDC) PRIA Process Improvement Workgroup met to discuss issues with product chemistry studies.[44] The workgroup was formed in reaction to a provision in PRIA on process improvement. The workgroup includes members from EPA and industry, including the director of the Registration Division. Both EPA and registrants have noted that product chemistry studies are often provided as the rationale for extending decisions on registration actions under PRIA. Staff from SRRD participated in the workgroup discussion of product chemistry. Given the common interest in product chemistry studies, Abt Associates recommends that SRRD maintain its participation is these discussions and take full advantage of any procedures, guidance, or calculations that result from this related improvement process. This is also an opportunity for RD and SRRD management to leverage ideas and approaches that are applicable to product reregistration.

8.4.3 Expand Batching Approaches to Reduce Number of Requested Studies

For the case of 2,4-D, EPA worked with the Industry Task Force to identify storage stability studies and to further batch acute toxicity data based on existing studies. For this approach to

[44] http://www.epa.gov/oppfead1/cb/ppdc/pria/june06/june06-minutes.pdf

succeed, all (or almost all) registrants need to be involved. In addition, the number of 2,4-D products also justified the approach.

Due to the unwieldy amount of data received from the Task Force, OPP has decided that future efforts to reduce acute toxicity data requirements will not consider existing data during the batching process. Rather, PRB will provide the Task Force with the batching and allow them to identify acute data that support product batches, after which PRB will evaluate the data for acceptability. The acute toxicity profile and MRIDs for the studies available to support each batch will be identified in the final batching document. EPA should explore ways to engage the registrants early on in the batching process, perhaps by identifying windows of opportunity in the public participation process. This may help to address batching issues in a timelier manner.

EPA is currently considering ways in which product-specific acute toxicity and product chemistry data requirements could be further batched or streamlined for other cases, including PBO (1,704 products), pyrethrins (1,490 products), MGK-264 (706 products), and permethrin (1,185 products).

8.4.4 Encourage Use of Self-Certified Product Chemistry Data

In 1998 OPP issued Pesticide Registration (PR) Notice 98-1, Notice to Manufacturers, Producers, Formulators, and Registrants of Pesticide Products, which allows a "self-certification" program for certain product chemistry data for manufacturing-use products and end-use products. Applicants are allowed to submit a one-page summary of the products physical and chemical properties, but are no longer required to submit the studies upon which the summary is based. Registrants must submit the studies if requested by OPP. Based on our conversations with OPP staff, few registrants take advantage of this option for the purposes of product reregistration. If they did, OPP would likely request the supporting studies, particularly for storage stability. Thus, the benefit of this policy to registrants is not clear because they still need to complete the studies, prepare a summary (that imposes additional burden), and then respond to OPP inquiries. As such, this attempt at streamlining data requirements and submissions does not appear to be an effective one, and EPA should consider if it can provide an incentive for registrants to submit self-certified data or provide guidance that would yield storage stability studies that would not require OPP review.

8.5 Registrant Responses

One of the sources of delay in the product reregistration process is the registrant responses, which require a lot of time for the registrants to prepare and submit, as well as for EPA to receive, track, review, and respond to (if required). During the course of its reregistration program, EPA has initiated several efforts to increase the quality of data it receives from registrants. To ensure that registrants submit responses in a timely manner, or perhaps encourage registrants to submit responses more quickly than required, Abt Associates provides the following recommendations.

8.5.1 Create Incentives for Registrants to Provide Expedited Responses

As appropriate and permissible under applicable laws and regulations, EPA should consider if it could create incentives for registrants to submit data early or signal their intent to cancel a product. One potential approach would be to reduce registration maintenance fees or allow

additional flexibility. EPA would need to consider if these approaches would provide an adequate benefit to OPP relative to the cost (either in dollars or effort). This recommendation is based on the finding that registrants are often unwilling to voluntarily provide data and amend labels. This finding runs counter to the situation in RD where registrants want OPP to process registrations as soon as possible and registrants willingly submit information in a timely manner.

8.5.2 Establish Procedures and Pursue Suspensions

Recently, OPP has not initiated suspensions of product registrations because the procedures are under review. OPP also noted that suspensions require a significant amount of paperwork such that EPA often enters into negotiations instead. It is also difficult to lift a suspension. Because registrants lack an incentive for product reregistration to occur, as they often lose uses or must add additional mitigation to the label, EPA must make an aggressive effort to receive registrant responses. EPA is currently reviewing its procedures and signature authority for suspensions, and should consider suspending registrations of products for which the registrant is not submitting the required information. Despite the effort, this practice will send a clear message to the regulated community.

8.5.3 Retain Data Review Functions within PRB

Until 1989, product reregistration was the responsibility of the Registration Division. SRRD, and PRB specifically, was created specifically to address reregistration because it was not a priority within RD. Some have suggested that given the similarities between the two programs that product reregistration should again be the purview of RD. Although Abt Associates suggests in the next section that the label assessment in PRB should be discontinued, we believe that requesting, managing, and reviewing registrant submissions should remain the responsibility of PRB and be organizationally separate from registration. If these functions were moved to RD, they could be lost when combined with the competing priorities of registration. We believe there is a significant benefit to having dedicated product reregistration reviewers in PRB.

8.6 Label Reviews and the Role of the Registration Division

Based on our findings in Chapter 7, Abt Associates identified the following issues or problems associated with label reviews and assessments that contribute to delays in product reregistration:

- The label assessments are used by some of the registration branches, whereas others do not even consult the documents. Some product mangers commented that PRB information was out of date or inconsistent with related products containing that active ingredient.
- The goal of the PRB label assessment was to consistently implement product reregistration on product labels, but the consistency goal was subsumed by a broader effort for labeling consistency (e.g., Label Review Manual).
- The ziram pilot project did not provide enough information from which to draw conclusions.
- The procedures for the transition between SRRD PRB and RD have helped to streamline the package.

- SRRD and RD staffs generally do not communicate with each other and are generally unaware of the issues and procedures in either division.

With these findings in mind, Abt Associates provides the following recommendations regarding label reviews and the role of RD.

8.6.1 Discontinue Label Assessments within SRRD

While an effort was made to clearly divide roles and responsibilities between RD and SRRD, the preliminary label assessments and label reviews remain duplicative. As such, we recommend that that label review responsibility should reside within RD. This recommendation is based in large part on the finding that many PMs do not consult the preliminary label assessments because they are outdated (i.e., based on an outdated version of the label) or because the PMs regard them as unreliable or incomplete. Given their product-specific knowledge and familiarity with the label review process, PMs are arguably the best-qualified individuals to conduct the label reviews. While a label assessment in SRRD and a full label review in RD ensures that at least two individuals have reviewed the label, we believe that the efforts are redundant. In addition, PRB sometimes defers to RD on labeling decisions anyway (e.g., restricted-use pesticide classifications). Note that this recommendation does not preclude the participation of SRRD staff in the SWAT team approach developed by RD management.

8.6.2 Improve Transition of Cases from SRRD to RD

Better communication and collaboration are needed when SRRD delivers the final review packages to RD. Currently, many CRMs deliver final review packages to PMs without notifying them beforehand or clearly summarizing outstanding issues. We recommend that CRMs and PMs have “hand-off meetings” at this time so any unresolved issues can be flagged and discussed. The scheduling of hand-off meetings will also help PMs to better predict and manage their workloads.

8.7 Management, Resources, and Staffing

Abt Associates drew the following conclusions regarding management, resources, and staffing:

- The resource allocation has remained relatively stable and SRRD expects that will continue.
- The backlog of product reregistration actions to be completed increased after the completion of the food-use REDs in August 2006.
- Recent management attention has raised the visibility of product reregistration in both RD and SRRD.
- The SWAT team approach developed by RD management is a promising approach to accomplishing product reregistration.

With these findings in mind, Abt Associates provides the following recommendations regarding management, resources, and staffing.

8.7.1 Reevaluate Allocation of SRRD Resources

Despite the number of products yet to be completed, particularly following the completion of the food-use REDs in August 2006, Abt Associates believes OPP should reconsider its allocation of resources in FY2007 and in the future. In its FY2007 reregistration work plan, SRRD allocates eight percent of its resource allocation to product reregistration. The eight percent FTE allocation is roughly equivalent to past staffing levels and SRRD expects the staffing level to remain fairly constant in the short term. Funds are allocated to product reregistration at roughly the same level through FY 2013. EPA has predicted that it will complete product reregistration in 2012.

Based on the data presented in Chapter 3, we considered the work that SRRD has yet to complete with respect to product reregistration. In FY2006, EPA completed 545 actions, with 11,948 actions pending. Several active ingredients represent a large number of products: PBO (1,704 products), pyrethrins (1,490 products), MGK-264 (706 products), and permethrin (1,185 products). For purposes of the following calculation, these active ingredients were removed because we expect that EPA will develop unique approaches for these cases such that they may not follow the traditional reregistration process. Thus, we expect that approximately 6,903 actions remain exclusive of these chemical cases. We are working on the assumption that EPA completes 545 actions for FY2007 and beyond, based on stable resource allocation and the potential increased burden that would be associated with implementing RED-specified mitigation in advance of product reregistration. When considering 6,903 products and completing 545 actions per year, we predict that product reregistration may not be completed for more than twelve years, or the end of FY2018. This is six years longer than EPA's current prediction, and five years longer than the period for which EPA has budgeted. We understand that this calculation is rough and that there will also be FTE resources dedicated to the four major active ingredients identified above; however, given this workload and the necessity to complete product reregistration in a timely manner, EPA needs to reconsider its resource allocation.

8.7.2 Maintain Emphasis on Product Reregistration

The attention and emphasis placed on product reregistration by both SRRD and RD management have been critical to the recent improvements. It is important that this emphasis and attention be maintained, particularly as the office has competing priorities (e.g., registration review). In addition, OPP should use all opportunities to elevate issues related to product reregistration to OPP upper management, particularly when it comes to issues of staffing, resources, and policy concerns. Because SRRD and RD both share responsibility for product reregistration, upper management can help align the divisions and establish priorities. This continued emphasis on product reregistration is also important in the event that senior management in either division changes before product reregistration is completed.

8.7.3 Pursue SWAT Teams and Other Strategies to Reduce Backlog

As discussed in Chapter 7, the SWAT team approach developed by RD management is a promising avenue to reduce the product reregistration backlog. After reviewing the materials, Abt Associates believes that the SWAT team approach will be particularly effective at addressing products within Categories I and 2 because the approach requires action by both the PM and the registrant. The changes in process design that correspond to products in

Categories 3 and 4 are more dramatic and longer term. Moving forward, OPP should be mindful of the workload that corresponds to the SWAT team approach, the follow-up required, and the coordination between and roles of SRRD and RD.

Over the long-term, OPP should consider alternative strategies to reduce the product reregistration backlog over the next several years, including a performance-based contract for short-term staff support to assist EPA in the completion of product reregistration actions. The disadvantage of such an approach is that product reregistration requires a lot of internal communication and relies on institutional knowledge. However, some RD staff noted that newer staff or Senior Environmental Employment (SEE) employees are often assigned and successfully complete product reregistration tasks.

8.7.4 Obtain Support for DCI Preparation

The SRRD Program Support Branch (PSB) needs a senior scientist or senior science writer on staff. Although FEAD is a policy-oriented, not science-oriented group, PSB is relying on FEAD expertise in this area to assist in the development of the DCI justification package. This new hire would not only relieve FEAD's time commitment, but would also help expedite the development of the DCI justification package and provide needed scientific expertise. Alternatively, SRRD could shift existing staff to provide additional support in this area, particularly given the number of FY2006 decisions that will require DCIs in the short-term.

8.8 Communication

Based on its research, Abt Associates believes that communication regarding product reregistration could be improved both internally and externally. Elsewhere in this report, we note that the reregistration branches, PRB, and RD are unclear on each other's roles. In addition, PRB used to be physically separated from the rest of SRRD and the new office space seems to have helped facilitate communication. There are, however, opportunities for additional improvements by way of trainings, meetings, and brownbag presentations.

With respect to external communication, product reregistration is not mentioned in many OPP reports, such as the office's annual report.[45] In a recent addition to the EPA Pesticides Web page, "Pesticide Reregistration Facts,"[46] EPA highlighted and acknowledged product reregistration in its summary of the pesticide reregistration process and status. This discussion does not mention product-specific data and leads the reader to assume that product reregistration is a check to confirm that RED-specified mitigation appears on a label. It also notes that EPA "plans to complete the last product reregistration decisions several years after the last REDs are signed." In contrast, there was very little (if any) discussion on the EPA Pesticides Web page previously, and this information was included only within the REDs and *Federal Register* notices. Abt Associates believes that EPA could increase the transparency of the program by explicitly mentioning and addressing product reregistration. For example, to be more explicit and help the regulated community plan better, EPA could add reference to pesticide product reregistration in the "Status of Pesticide Reregistration" Web page along with schedules for REDs and registration review.

[45] http://www.epa.gov/oppfead1/annual/2005/05annualrpt.pdf
[46] www.epa.gov/oppsrrd1/reregistration/reregistration_facts.htm

8.9 Performance Management

Based on the measures reported under the Government Performance and Results Act (GPRA), Abt Associates believes there are opportunities to make these measures more meaningful for both internal and external stakeholders. Similarly, to address competing priorities within RD, we suggest that OPP incorporate individual performance goals for product reregistration.

8.9.1 Improve Performance Measures and Strategic Targets

As discussed in Section 1.4 of this report, for purposes of GPRA, EPA reports on the number of product reregistration actions completed. However, this type of output measure is not informative because it does not provide a measure of progress relative to the entire universe. Abt Associates recommends that OPP revise this performance measure to use a percentage, which would be more informative. We understand that the universe of pesticide products subject to reregistration is constantly in flux; however, a percentage measure might be more informative for internal purposes. In addition, Abt Associates would suggest that EPA examine its targets for the number of pesticide reregistration actions. Although the targets have increased annually, the targets might not be realistic or ambitious enough to ensure completion of product reregistration within EPA's desired timeframe.

8.9.2 Incorporate Product Reregistration into PARS

In order for the SWAT team approach and other product reregistration process improvements to be most effective, RD should place a continued emphasis on product reregistration. Currently, PMs have to manage their work based on the competing priorities of pesticide registration and reregistration. Until recently, however, RD management has not placed a high priority on product reregistration; for example, PMs have concrete job performance goals related to registration but not to product reregistration. To ensure that RD accomplishes product registration in an efficient, timely manner going forward, RD management should include product reregistration-specific goals in each staff member's Performance Appraisal and Recognition System (PARS). In turn, management should periodically review each PM's workload to make sure that workload is manageable and appropriately distributed among individuals.

8.10 Information Management

Abt Associates drew the following conclusions regarding information management with respect to product reregistration:

- Even though OPPIN was intended to be an integrated system, it has failed to meet the tracking needs of different components of the product reregistration process.
- Many staff have created one-off tracking systems in order to get their jobs done, making reliable status updates very difficult to retrieve.
- The current approach to information management not only contributes to inefficient and inadequate tracking, but also potentially makes EPA vulnerable.
- Information management is an issue in each of the product reregistration sub-processes.

With these findings in mind, Abt Associates provides the following recommendations regarding information management.

8.10.1 Continue to Prioritize an Integrated Tracking System

SRRD should continue to prioritize the development of an integrated tracking system that manages all of the data and information related to the DCI process. For example, the fact that the current tracking system does not adequately track the status of submitted studies and confirmatory data from registrants is a potential liability to EPA.

Assuming that PRISM is the predecessor of OPPIN, SRRD should ensure that PRISM has the necessary data fields and functionality for tracking all components of the DCI process because future programs (e.g., registration review) will use OPP's DCI authority. As an alternative to PRISM, it may be more practical and cost effective to develop a relatively simple tracking system in Access that staff can use for DCI-related tracking. This Access database would track, at a minimum, the following elements of the DCI process: (1) the submission and approval dates of the DCI justification by EPA (FEAD and RCS), (2) submission to and approval by OMB, (3) the outcome of the ninety-day response period whereby registrants specify their intent to comply, seek a waiver, or cancel their product, and (4) the status of submitted studies over the eight month response period. (Item #4, for example, would negate the need for the current "charts and tables" document that is maintained in Word for each PDCI.) Additionally, in developing the DCI tracking system, OPP should consult other EPA offices (e.g. Office of Pollution Prevention and Toxics) that issue DCIs to determine what tracking systems they use, if any, and share lessons learned.

Ideally, OPP would already have in place an integrated, centralized database that would track all remaining aspects of the registration process. Given that product reregistration is a finite process (anticipated completion being 2012), it may not be an effective use of OPP's time and resources to build a sophisticated system such as PRISM for the purposes of product reregistration. Depending on how far along PRISM is in its development phase, we recommend that OPP revisit its tracking needs to determine whether the potential benefits of PRISM will outweigh the negatives (e.g., cost, staff time, limited lifespan), and whether the work already done on PRISM can be transferred towards the creation of a simple, effective Access database. Although the utility of PRISM from strictly a product reregistration standpoint is questionable, PRISM will presumably benefit SRRD's upcoming registration review, which will continue past the complete of product reregistration. The development of any tracking system (whether it be PRISM or an Access database) should involve all relevant staff. CRMs, FEAD, management, and PSB (among others) all have different needs for tracking, and in turn, all groups need the opportunity to provide input on the final system. Since all OPP staff may not be familiar with Access, the database should be created with a user-friendly interface that makes data entry and analysis straightforward.

8.10.2 Maintain Web Site as a Repository of Reregistration Decisions

Both SRRD and RD staff rely on the OPP web site (www.epa.gov/pesticides) as a historical repository of reregistration documentation, including risk assessments, the RED and associated amendments, label tables, and other Federal Register notices. This reliance on the web site is an issue because OPP does not use a docket system for reregistration, nor does OPP publish REDs in hard copy anymore. Because several staff noted that amendments are not often

posted in a timely manner, it is essential that OPP remain attentive to its web site. This type of information is not available in OPPIN, but might be available in the Jacket. The Jackets, however, are not yet available electronically. These records will be critical for registration review.

Appendix A Interview Guide

The following interview guide was used for each of the interviews with OPP staff, including introductions, general questions, issue-specific questions, and conclusions. As appropriate, we also asked questions that arose during the course of the meeting or that related to comments made by the interviewer.

Introductions

"Good morning. I am _____ (introduce self).

This interview is being conducted to get your input about the implementation of the product reregistration program that you have been conducting/involved in. I am especially interested in any problems you have faced or are aware of and recommendations you have."

"If it is okay with you, I will be tape recording our conversation. The purpose of this is so that I can get all the details but at the same time be able to carry on an attentive conversation with you. I assure you that all your comments will remain confidential. I will be compiling a report that will contain a synthesis of all staff comments without any reference to individuals. If you agree to this interview and the tape recording, please sign this consent form."

"I'd like to start by having you briefly describe your responsibilities and involvement thus far with the product reregistration." *(Note to interviewer: You may need to probe to gather the information you need, including length of time individual has worked in the program).*

General Questions

"I'm now going to ask you some questions that I would like you to answer to the best of your ability. If you do not know the answer, please say so."

- In your opinion, what are the biggest challenges faced by product reregistration? How do these challenges influence your role in the process?
- What do you think are the main factors the influence the length of time that product reregistration takes? Which parts of the program are affected?
- How has the program changed over the time you have been here?
- Given your role, what would help you do your job better with respect to product reregistration?
- Which parts of product reregistration do you find the most time consuming? What are your suggestions for streamlining these portions?
- In what ways do you think product reregistration could be improved?
- What do you estimate would be a reasonable amount of time for reregistering a specific product after the RED is signed?

Problems in REDs

- We have been told that the RED for _____ caused delays in product reregistration. Do you agree with this assessment?
- What characteristics of the RED resulted in issues? For example, were parts incomplete, incorrect?

- If appropriate, in what ways was the RED incomplete? Incorrect?
- Did the RED contain any contradictory language?
- Were there any circumstances after the publishing of the RED that delayed product reregistration, for example, data made available, a risk assessment revised?
- How did these factors impact product reregistration? Were all products affected?
- Why do you think that this RED had these issues?
- Is this a high-profile case or of particular interest to the registrant or an environmental group?
- How did you address each of the issues with the RED?
- Who was responsible? What is the estimate of increased burden?
- What was the impact to the registrant?
- Are there ways that the problems with the RED could have been avoided or decreased?
- What needs to change to eliminate the problem?
- How could these changes be accomplished?
- Have you had (or heard of) similar experiences with other REDs? If so, which ones? How often?
- When does this occur (close to a statutory deadline, etc.)?

Implementation of RED-specified Mitigation

- How/why were the cases selected for MOAs? How many MOAs have been signed regarding product reregistration? Do they vary in scope?
- How quickly did mitigation appear on the product label?
- Please characterize communication with the registrant.
- What additional work did this approach require? Can you estimate the additional time?
- How do EPA, environmental groups, and the registrant perceive the case?
- In addition to the MOA, what other factors may be unique to this active ingredient?
- How did this MOA compare to others on which you have worked or about which you have heard?
- How or do you think that this approach could be modified to streamline product reregistration generally?
- What type of products (cases) may lend themselves to such an approach?

Propanil Pilot

- Why were the pilot cases selected?
- How did you approach the registrant? What was his/her reaction?
- What are the legal issues? How are they being overcome?
- Please describe the approach for categorizing products and the rationale for the approach?
- To which categories will EPA apply this option?
- How will these products be considered for product reregistration? Is there any benefit to the registrant for implementing mitigation on the label sooner?

- What is the estimated burden to EPA for this pilot? For the approach generally? What about to the registrant?
- What is the estimate for developing the option? The time required for registrants to respond? To complete the process?

2,4-D Batching

- Who initiated the batching alternative – EPA or the registrants?
- What role did EPA play in the alternative?
- What characteristics of 2,4-D made this alternative appropriate (number of products, etc.)?
- What documentation exists on this case?
- What was required of the registrants collectively?
- How were legal concerns or CBI issues addressed?
- How do registrants view the alternative? Would they characterize it as a positive experience?
- What is the estimated burden savings to EPA or the registrants?
- What are the biggest obstacles to implementing this alternative for other cases?
- In what circumstances would it be appropriate in order to result in the most burden savings?

Label Reviews

- What is the division of labor between SRRD and RD with respect to label reviews?
- How do SRRD and RD approach the task?
- What is the average time a label review takes? Is there a range?
- Knowing that RD stamps the label, what resources are available to RD that might not be available to SRRD as they review the label?
- How useful is the information provided by SRRD?
- What do SRRD and RD look for in the label tables? Could these reviews be reconciled?

Ziram Pilot Project

- Why was the pilot case selected? Were all the ziram products completed or just one?
- What information was given to both divisions? Were they aware that is was for a pilot?
- In your opinion, was this label review treated differently than the average case?
- What differences appeared on each label? How significant are they?
- As an individual, are you comfortable with this streamlining option? Why or why not?
- Do you think this option is a valid approach to streamline reregistration?
- How long did the review take? Is that a typical amount of time?

Relationship between SRRD and RD

- How different are the cultures within the two divisions?
- How is workload and communication coordinated?

- What procedures exist to govern product reregistration?
- What are the priorities for either division? Are they in conflict?
- In what ways could SRRD work better with RD? Vice versa?
- How effective is the SOP for handoff to RD? Pros/Cons?
- What RD resources are available to SRRD – are they coordinated/consistent?

DCI Preparation and OMB Approval Process

- How much time does it take to prepare the DCI? Receive approval?
- Do data exist to support this conclusion?
- Historically, how many DCIs (and DCI packages) are prepared annually? How many active ingredients? Products?
- What issues arise to slow the process?
- What are the issues with OMB? What efforts have been undertaken to address them?
- What tracking issues arise in this part of the product reregistration process?
- In what ways could this part of the process be streamlined?
- To what extent is OPP constrained by OMB in this part of the process?
- How effective are the SOPs in establishing roles and responsibilities for both EPA and OMB?
- When were the SOPs written and how current are they?
- Are there any parts of the process that are not covered by SOPs that should be?

Information Management

- On several occasions, GAO commented on the lack of infrastructure to manage reregistration data. What improvements have been made over the past 10-15 years generally? For products specifically?
- What tracking systems exist for product reregistration?
- Are there shortcomings in the way SRRD tracks product reregistration?
- What are the obstacles to improving this?
- Which data management needs are most important?
- What is the history of requests to improve tracking?
- How is tracking handled in the registration division?
- What is the functionality of OPPIN for product reregistration versus AIs?
- What changes are planned for OPPIN? Will they impact product reregistration?
- On what occasions are data pulls needed? How labor intensive is the process?
- Who needs access to the information?
- What tracking systems are maintained internally? How functional are they? How could it be improved
- What other information management tools have been developed? For what purpose? How could they be improved?

Management/Budget

- How have you seen priorities change within OPP and within the product reregistration program generally over time? How has funding for both OPP and product reregistration changed over time?
- From your perspective, how is product reregistration viewed within OPP? Within the Agency? By the registrants? Environmental and public health groups?
- How and to what extent does political pressure or media attention affect product reregistration?
- Which types of products receive increased scrutiny? Why?
- Are there aspects of product reregistration that receive less attention?
- What types of project planning exercises are completed for product reregistration (e.g., a work plan)? Is there a forecast for completing product reregistration?

Conclusion

- Is there anything else today that I have not directly asked that you think is important for us to consider in our evaluation?
- Is there anyone else that you think we should talk to about these or other issues?

Thank you for your time. We appreciate your thoughts and experiences with product reregistration. Over the coming weeks, we will be compiling responses. If necessary, would it be possible to contact you, if needed, for additional information or clarification?

Appendix B Individuals Interviewed or Consulted

Peter Caulkins	OPP Special Review and Reregistration Division
Pat Dobak	OPP Special Review and Reregistration Division
Venus Eagle	OPP Registration Division, Insecticide-Rodenticide Branch (on detail from SRRD)
Keenan Garvey	OPP Special Review and Reregistration Division
Richard Gebken	OPP Registration Division, Insecticide Branch
Cynthia Giles-Parker	OPP Registration Division, Fungicide Branch
Mike Goodis	OPP Special Review and Reregistration Division, Reregistration Branch 3
Katie Hall	OPP Special Review and Reregistration Division, Reregistration Branch
John Hebert	OPP Registration Division, Insecticide-Rodenticide Branch
Mika Hunter	OPP Biopesticides and Pollution Prevention Division
Marion Johnson	OPP Registration Division, Insecticide Branch
Karen Jones	OPP Special Review and Reregistration Division, Product Reregistration Branch
Dan Kenny	OPP Registration Division, Herbicide Branch
George LaRocca	OPP Registration Division, Insecticide Branch
Meredith Laws	OPP Registration Division, Insecticide-Rodenticide Branch
Susan Lewis	OPP Special Review and Reregistration Division, Reregistration Branch 1
Marianne Lewis	OPP Special Review and Reregistration Division, Product Reregistration Branch
Joanne Miller	OPP Registration Division, Herbicide Branch
Tom Myers	OPP Special Review and Reregistration Division, Reregistration Branch 2
Gary Mullins	OPP Special Review and Reregistration Division, Program Support Branch
Cathryn O'Connell	OPP Special Review and Reregistration Division, Reregistration Branch 2
Mark Perry	OPP Special Review and Reregistration Division, Product Reregistration Branch
Maria Piansay	OPP Special Review and Reregistration Division, Product Reregistration Branch
Linda Propst	OPP Special Review and Reregistration Division, Product Reregistration Branch
Margaret Rice	OPP Special Review and Reregistration Division, Reregistration Branch 2
Larry Schnaubelt	OPP Special Review and Reregistration Division, Product Reregistration Branch
Kelly Sherman	OPP Special Review and Reregistration Division, Reregistration Branch 2
Cameo Smoot	OPP Field and External Affairs Division
Jim Tompkins	OPP Registration Division, Herbicide Branch
Mary Waller	OPP Registration Division, Fungicide Branch