Implementing the Pesticide Registration Improvement Act-Fiscal Year 2006

Third annual report. Report release date: March 1, 2007.

The Consolidated Appropriations Act of 2004 established a new system for registering pesticides, called the Pesticide Registration Improvement Act, or PRIA. The new section 33 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), PRIA creates a registration service fee system for applications for specified pesticide registration, amended registration, and associated tolerance actions, which set maximum residue levels for food and feed. Under PRIA, fees are charged for covered applications received on or after March 23, 2004, and for certain pending applications received before that date. EPA is required to make a determination on the application within the decision times specified. The fee system is authorized until September 30, 2010, although the decision times under the system do not apply to applications received after September 30, 2008.

Under section 33(k) of PRIA, EPA is required to publish an annual report describing actions taken under this section during the past fiscal year. The report must include several elements, including a review of the progress made in carrying out the Agency's obligations under the Act, a description of the staffing and resources associated with the review of and decision-making on applications, and a review of its progress in meeting the reregistration and tolerance reassessment timeline requirements. This third annual report covers Fiscal Year 2006 -- October 1, 2005 through September 30, 2006.

FY 2006 Enhancements in Application In-Processing

The first annual report released in March 2005, described steps the Agency undertook to implement PRIA during its first nine months. These included front end processing and screening, waivers, funds management, and communications. In Fiscal Year 2005, these procedures were further refined as described in the second annual report. Additional enhancements during FY 2006 are described below.

Front-End Processing and Screening Procedures

To facilitate the implementation of PRIA, the Agency established front-end screening procedures for new pesticide applications in FY 2004. An intra-agency workgroup interpreted the 90 PRIA registration categories to help both applicants and the Agency consistently place each application in the appropriate PRIA category. These PRIA registration categories reflect the types of applications the Agency may receive and for which Congress has established a fee and a time frame. The time frame, or decision review time, is the amount of time the Agency is expected to take to review the application and reach a regulatory decision. The Agency intends to update these interpretations in FY 2007 based on its experience and suggestions provided by stakeholders.

Teams of EPA experts from the three registering divisions (conventional chemical, biopesticide, and antimicrobial pesticides) screen all incoming applications to determine whether they are subject to PRIA and to assign the application to a PRIA category (if appropriate). The experts do a cursory screen of the submission for completeness, thus saving both the registrant and the Agency valuable time. Typically within 48-72 hours of receipt of an application, the registrant is sent an invoice requesting payment of the appropriate PRIA registration service fee.

The Agency's internal tracking system, known as the Office of Pesticide Programs Information Network (OPPIN), underwent additional modifications during 2006 to enable the Agency to identify the status of an action. Management reports monitor due dates and interim milestones more efficiently. These modifications built upon the previous modifications developed for the regulatory process and support data review and risk assessment. Expected to be in full production by March 2, 2007, the detailed status

reports will allow more efficient monitoring of the stages and phases of the regulatory science review process.

The Agency enhanced its existing data management contract for the initial data screen in FY 2004 to reduce study processing time to 10 days, thus ensuring that complete data packages are ready to enter the review process at the beginning of the decision review period if the applicant has correctly formatted the data submission. During FY 2006, the average study processing time for the front end screen was 9.6 days while in FY 2005 it was 4.6 days. This increase in the average was due in part to delays in processing in May and June, 2006 as a result of OPP's move from Crystal Mall #2 to Potomac Yard. Excluding these two months, the average study processing time was about 7 days.

Funds Management and Utilization

Section 33(c) of PRIA established the Pesticide Registration Fund. Congress established this fund in the Treasury of the United States to carry out the provisions of PRIA. All registration service fees received by EPA are deposited in this fund, and expenditures from the fund can cover the costs associated with the review and decision-making for applications for which registration service fees have been paid. In FY 2004, the Agency worked with the Mellon Bank to establish the fund and create billing procedures and to coordinate communications on fee receipts between the bank and the Agency. Communication of the date the fee is received is critical as it triggers the start of the PRIA decision review period or timeframe. The Agency has been informed of the receipt of a payment within an average of 7.2 days of receipt by the Mellon Bank, and since May 17, 2005, the Agency automatically sends an acknowledgment of payment to those applicants with an e-mail address on file.

Beginning October 1, 2005, the Agency implemented a 5 percent fee increase required under Section 33(b)(6) for all covered applications as announced in the Federal Register of June 2, 2005. (Pesticides; Revised Fee Schedule for registration Applications (PDF) (9 pp, 85 KB, About PDF)). In September 2005, the Agency sent an electronic reminder of this fee increase to over 4,000 individuals and organizations as an "OPP Update". Invoices and financial databases were modified to reflect this fee increase. Reports were developed to monitor fee waivers, refunds, and the status of invoices and payments.

In July 2005, EPA began notifying applicants when a payment is 45 days overdue for all PRIA fee categories except Fast Track applications (because of the short time frames for these actions). The notification provides the applicant 75 days to forward payment before the application is withdrawn by the Agency. In FY 2006, the Agency sent 94 such letters, resulting in 30 withdrawn applications, 41 payments, 12 fee waivers, and 13 that were subsequently determined not to be PRIA actions. For Fast Track applications, the Agency currently informs applicants in an invoice that they have 30 days in which to pay a fee or submit a fee waiver. If neither is received, the application is rejected.

In September 2006 EPA began working with the Treasury Department to implement collection of PRIA fees via electronic fund transfer and credit card. Implementation of this enhancement began November 1, 2006.

Waivers and Fee Reductions

Section 33(b)(7) of PRIA authorizes the Agency to reduce or waive the registration service fee under certain specified situations. The Agency in FY 2004 developed and posted on the internet guidance on how to apply for waivers of the registration service fee. In FY 2006, the Agency reviewed 379 applications and reduced the average number of days to grant a fee waiver to 21 days at the end of fiscal year. The Agency also established formulas for reducing certain registration service fees (7 p 369.16) based on work completed by the Agency prior to the effective date of PRIA. Section 33(b)(8)(C) authorizes EPA to issue discretionary refunds, including instances where the Agency had completed portions of the review of an application before the PRIA effective date. For fees required for pending new active ingredients and for applications where the registrant has offered to pay the registration service fee voluntarily, the Agency applied this refund provision as a credit toward the application registration service fee. During FY 2006 the

Agency reduced registration service fees by $0.8 M based on work completed by the Agency on pending applications prior to the PRIA effective date. The amount in FY 2005 was $1.6 million and in FY 2004, $3.7 million.

Information Management

During FY 2006, enhancements were made in systems configuration and security. The Agency invested in Documentum to improve its document management systems. A prototype of the document management system has been developed and is expected to be tested in FY 2007. As an initial step in retaining and managing all of the Agency's pesticide documents electronically over 25,500 regulatory files containing over 5.2 million pages were imaged. Registrants are encouraged to submit applications on electronic media to support this effort. Investments were also made in the Agency's Central Data Exchange (CDX), a web based portal which will handle all electronic documents submitted to the Agency. Eventually, the Agency's current data management system, OPPIN, will be replaced with Pesticide Registration Information System (PRISM), a single system that covers many aspects of the registration process from on-line electronic submission of applications through CDX to document archival, retrieval and analysis. Systems requirements for electronic submission have been developed. The Agency is working closely with Canada and will build upon the Pest Management Regulatory Agency's e-Index.

Communications and Outreach

In 2006, the Agency continued with meetings and other outreach efforts. Agency staff discussed the status of PRIA implementation during the Chemical Producers and Distributors Association Registration Workshop, with State and EPA Regional staff at the Pesticide Regulatory Education Program, and with the Armed Forces Pest Management Board. During the annual meeting of the Consumer Specialty Products Association, EPA and the Natural Resources Defense Council discussed PRIA implementation. EPA provided updates on the status of PRIA actions received and summary statistics during meetings of the Agency's Federal Advisory Committee, the Pesticide Program Dialogue Committee (PPDC) and monthly meetings with the PRIA Coalition composed of industry, trade associations and public interest groups. EPA also has quarterly meetings with the Biopesticide Industry Alliance to discuss PRIA and other common issues and with the United States Department of Agriculture (USDA) IR-4 program.

The Agency has established a website dedicated to PRIA implementation. Through this website, the public submits questions regarding PRIA implementation. Questions are typically answered within 24 hours. Questions are also addressed by registration Ombudsmen. The Ombudsmen also help applicants with issues related to the registration process and completing application forms.

Financial Overview

During Fiscal Year 2006, the Agency received $14.6 million in new registration service fees and after subtracting $0.73M in refunds (overpayments and withdrawals), the net was $13.9 million. A balance of $9.2 million was carried forward from FY 2005. From this total of $23.1 million, the Agency spent approximately $10.8 million, carrying the remaining balance of $12.3 million forward to FY 2007.

Agency's FY 2004 through FY 2006 Expenditures from the Pesticide Registration Fund			
For	**FY 2004 Expenditures (per thousand)**	**FY 2005 Expenditures (per thousand)**	**FY 2006 Expenditures (per thousand)**
Payroll	$2,535.3	$7,898.2	$5,819.8
Contracts	$1,591.3	$2,228.8	$4,013.1
Worker Protection	$430.0	$750.1	$750.0
Other Expenses	$455.8	$274.3	$221.6
Total	$5,012.5	$11,151.4	$10,804.5

FY 2006 was the second full fiscal year under PRIA, following the half year represented by the FY 2004 initial implementation year. In FY 2006, data review output through contracts continued to increase while the funds spent on payroll costs represented a smaller majority of funds spent compared with FY 2005. Payroll expenditures decreased to $5.8 million in FY 2006 from $7.9 million spent in FY 2005. The payroll decrease was offset by a comparable increase in contract spending. Expenditures on contracts increased up to approximately $4.0 million in FY 2006 compared with $2.2 million in FY 2005. The end result of this shift was a better balance between payroll and contract expenditures under PRIA in FY 2006 (with payroll at 54% of expenditures in FY 2006 compared with 71% in FY 2005; and contracts up to 37.2% in FY 2006 from 20% in FY 2005). The amount spent on worker protection was $750,000 in contract/grant expenditures. The Agency continued to invest in upgrading its information management system, OPPIN, to track compliance with the PRIA review time frames and to meet reporting requirements. Other funds went primarily to pay for Federal Register printing costs associated with PRIA registrations.

Waivers of Registration Service Fees

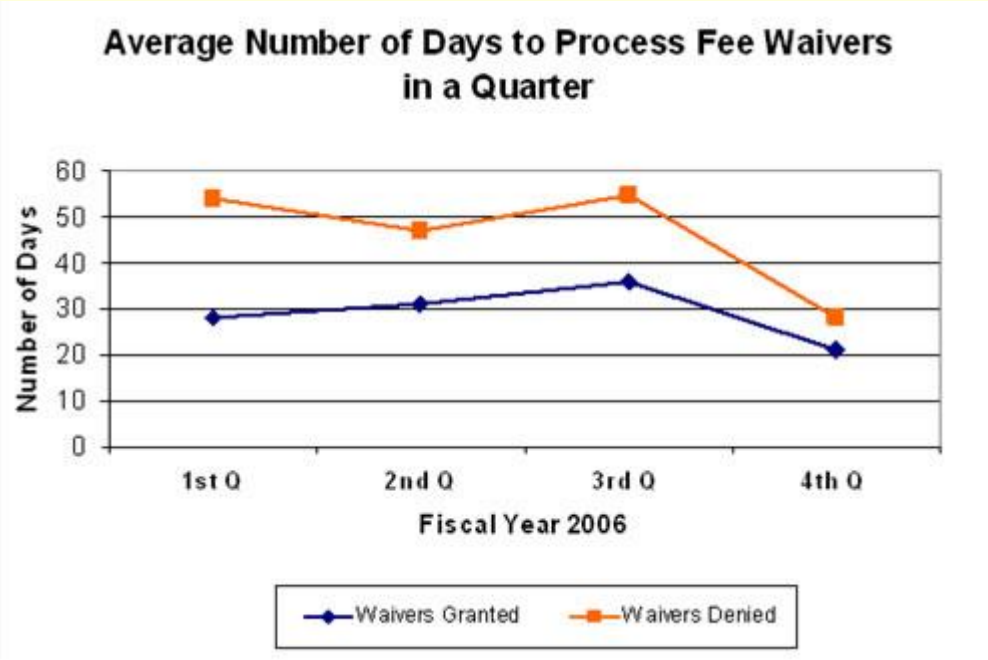
In response to requests for fee waivers and fee reductions, as authorized by PRIA, the Agency waived $5.8 million in registration service fees in FY 2006. The Agency reviewed 379 waiver requests, granting 336 and denying 35. The time for the Agency to reach a decision to grant a waiver was 21 days at the end of FY 2006, while the time to deny a waiver request was previously within 50 to 54 days. The time required to deny a waiver reflects the time the Agency took to obtain missing information in an attempt to be able to grant the fee waiver. The table below summarizes the number of the 100 percent and 50 percent waiver requests received in FY 2006. In addition to these waivers, the Agency processed 44 100% fee waivers requested by the USDA IR-4 program.

Small Business Waiver Requests -- FY 2006				
Waiver	**Submitted**	**Granted**	**Denied**	**Withdrawn**
100%	254	225	24	0
50%	76	64	10	0

Small Business Waiver Requests -- FY 2006				
Waiver	**Submitted**	**Granted**	**Denied**	**Withdrawn**
Total	330	289	34	0

The average number of days EPA took to grant or deny a fee waiver in FY 2006 is summarized in the table and illustrated in the graph below. In general, processing times decreased between the beginning of the year and its end. There was a slight increase in the second quarter of FY 2006 when applicants were required to submit complete and updated financial information. The increase in average processing times in the third quarter was due to a move to a new building when application in-processing was delayed. Once in the new building, applications were quickly processed and in the fourth quarter, the average number of processing days was the lowest for the fiscal year.

Average Number of Days to Process Fee Waivers in a Quarter, 2006		
Quarter	**To Grant**	**To Deny**
1st Q	28	54
2nd Q	31	47
3rd Q	36	55
4th Q	21	28



Worker Protection

Under Section 33(c)(3)(b), EPA is authorized to use 1/17 of the amount of the Fund (but not more than $1 million and not less than $750,000 for any fiscal year) to enhance current scientific and regulatory activities related to worker protection. The Agency worked closely with worker safety stakeholders through the Agency's Federal Advisory Committee, the Pesticide Program Dialogue Committee (PPDC), to determine which activities to enhance with PRIA funds. Based on the advice of the PPDC, the Agency decided to develop enhancements within focus areas characterized as: Prevention - Safety Training; Response - Poisoning Recognition; Sound Decision Data; and, Inform - Risk Management. Within these areas, PRIA funds were used to achieve the following accomplishment in FY 2006:

- Partnered with AmeriCorps and local farmworker service organizations to give hands-on, interactive pesticide safety training to 75,000 farmworkers and their families.
- Expanded the scope of a multi-year cooperative agreement with the Association of Farmworker Opportunities Programs (AFOP), which leverages the Agency's funds through agreements with AmeriCorps and local service organizations to provide safety training at 26 sites in 18 states.
- Completed a pilot study and report "Evaluation of the Effectiveness of Symbols and Hazard Communication Materials for Migrant Farm Labor.
- Supported the National Agricultural Workers Survey to gather critical demographic data on farm workers and their families by adding questions to the national survey to focus on handler tasks information and farm family exposure potential.
- Supported development of a report through the Department of Labor specifically focused on children and youth in agriculture, as well as child labor's exposure to pesticides. As of January 2007, a draft is being reviewed within the Agency.
- Funded the creation and reproduction of pesticide worker safety training and compliance material to be distributed through the National Agricultural Compliance Center and printed
    - 47,000 CDs of "How to Comply with the Worker Protection Regulation" manual,
    - 17,000 copies of the "Pesticide Worker Safety Training Handbook" (English and Spanish),
    - 12,000 copies of the "Pesticide Handler Safety Training Handbook" (English),
    - 5,000 copies of "Pesticide Handler Safety Training Handbook" (Spanish), and
    - 16,000 copies of "Steps to Protect Yourself from Pesticides" booklet (English and Spanish).

- Supported the Migrant Clinicians Network (MCN) to develop, test, then evaluate and promote a training model for primary health care providers in practice settings that incorporates key practice skills for the recognition and treatment of pesticide poisonings. In the first year of the 5 year cooperative agreement, the focus was on developing strong partnerships with key clinical and health care centers, associations, clinical networks, health professionals, and organizations and agencies dedicated to the migrant population.
    - Partnering with the Northwest Regional Primary Care Association, MCN implemented a clinician scholarship program, providing 5 scholarships to community health center physicians to attend the Western Stream Migrant Forum.
    - MCN promoted environmental occupational health (EOH) training with an emphasis on pesticide-related issues through 7 training sessions for health care providers (125 attendees), 5 EOH specific sessions (90 attendees), and distribution of 300 pesticide-related resources to at least 120 community health workers. At the trainings, the three part EOH modules were piloted, which are being developed for use in this project.
    - MCN updated and maintained its website for access to pesticide-related resources and links to partners, expanded their bimonthly publication to include 6 pesticide-related articles and distributed 10,800 newsletters.
    - MCN recruited 2 health centers to participate in the program.

- Under the Pesticides and National Strategies for Health Care Providers Initiative, an effort to improve the training of health care providers in the recognition, diagnosis, treatment, and prevention of pesticide poisoning among those who work with pesticides. Tests of educational materials were conducted at Heritage University which included:
    - poisonings illustrations for use as a teaching tool.

    - Outreach materials: informational flyer, and poster with support fact sheet. Poster includes project objectives, goals, and pesticide risks background/history and partner information. The fact sheet serves as a supplementary handout at conferences and/or meetings.
    - A Web-page for participants which includes resources and materials to be inserted into a university curriculum for health care providers. The web page will continue to be updated as materials are developed.

- PRIA Funds were used to increase the number of states in the National Institute of Occupational Safety and Health Sentinel Event Notification System for Occupational Risk (SENSOR) Program and to expand occupational illness and injury surveillance capacity within state health departments in areas of the country with sizable agricultural worker populations.
    - From 2001-2006, the following ten states reported occupational pesticide illness and injury cases to the surveillance program: Arizona, California, Florida, Louisiana, Michigan, New Mexico, New York, Oregon, Texas, and Washington. The SENSOR program has been expanded to include occupational pesticide illness reports from Iowa and North Carolina.

Progress in Meeting Decision Times

Number of PRIA Actions Completed in FY 2006

The Agency completed 1347 decisions subject to PRIA during the fiscal year, an increase of 249 (23%) over the 1098 reported in the FY 2005 annual report. EPA completed 99.9 percent of these decisions on or before their due dates. Two actions missed their date due. One was missed due to confusion over a holiday. The other was due to the Agency requiring additional time to reach a regulatory decision. The table below summarizes the number of decisions completed by PRIA category and compares FY 2005 to FY 2006. FY 2005 was the first full fiscal year under PRIA.

In reviewing the table, certain factors need to be considered. An application can have more than one decision. The number of decisions depends on the number of product registrations in an application. For instance, in FY 2005, one new antimicrobial active ingredient (A2) was registered that required two decisions. Information on the number of active ingredients and uses registered during a year can be found in the Office of Pesticide Program's Annual Reports and should be used in determining whether there are differences in these types of applications between fiscal years. Generally each application categorized as a Fast Track, Non-Fast Track New Product, and Non-Fast Track Amendment contains a single product and is a single decision. In comparing FY 2005 with FY 2006, an increase in the number of conventional new use (80) and product (105) and antimicrobial non-fast track amendment (42) decisions accounted for the majority of difference between these two fiscal years.

The average decision time for each PRIA category is shown in days and is the number of days it took the Agency to complete a decision once payment was made or a fee waiver was granted. The time frames mandated under PRIA decreased for some categories of decisions in FY 2006. For instance, a conventional new product, R31, had a statutory timeframe of 8 months in FY 2005 and a 6 month statutory time frame in FY 2006. A decision's time frame is based on the fiscal year in which the application or decision was received. Even though a fee was paid or a fee waiver was granted in FY 2006, an action received in FY 2005 received a FY 2005 PRIA timeframe. Actions in the same PRIA category completed in FY 2006 may therefore have different mandated timeframes. Consequently, the average decision time or the number of days the Agency took to complete a decision in the table below can not be directly compared to the PRIA time frames mandated for FY 2006.

While many new active ingredient and new use applications appear to have been completed in substantially less time than the decision time frame provided under PRIA, some of these actions were submitted prior to March 23, 2004, PRIA's effective date and benefited from work completed before the effective date. We expect decision times for these actions, such as R1 to R29, to be greater in future years as more recently received decisions are completed. Average decision times for completing these actions in general were greater in FY 2006 than FY 2005, as predicted.

Among the FY 2006 completions, due dates for 153 (11 percent) were extended upon mutual agreement of the applicant and the Agency. Extensions generally resulted from missing or deficient data or information. In FY 2006, over half (94 or 61%) of the extended due dates were for non-fast track new product decisions. A total of 492 new product decisions were completed in FY 2006 and accounted for 37% of the total completed. The majority of these actions (378) were conventional chemicals. Of the 492 total, 19% had extended due dates (41% of antimicrobials, 47% of biopesticides, and 12% of conventional chemicals).

Comparing the number of decisions with extended due dates with the total number completed in a category, a high percentage of antimicrobial new active ingredients (41%) and new uses decisions (33%) were extended. A similar pattern was observed for biopesticides. A smaller percentage of non-fast track amendments (7% of antimicrobials, 8% of biopesticides, and 6% of conventional chemicals) and fast track new products (14% of antimicrobials, 0% of biopesticides, and 3% of conventional chemicals were extended.

Key to the table

- R - Conventional Pesticides
- A - Antimicrobial Pesticides
- B - Biopesticides
- EUP - Experimental Use Permit
- PIP - Plant-Incorporated Protectants
- SAP - FIFRA Scientific Advisory Panel
- SCLP - Straight Chain Lepidopteran Pheromones

Progress in Meeting Decision Times

PRIA Category	Description of Category	Number of PRIA "Decisions" Completed in FY 2005	FY 05 Average Decision Time in Days	Number of PRIA "Decisions" Completed in FY 2006	FY 06 Average Decision Time in Days
R1	New Active Ingredient, Food Use	16	365	4	286
R2	New Active Ingredient, Food Use, Reduced Risk	8	180	0	
R6	New Active Ingredient, Non-food use, outdoor	0		3	423
R7	New Active Ingredient, Non-food use, Outdoor, Reduced Risk	0		0	
R8	New Active Ingredient, Non-food use, outdoor, Experimental Use Permit request submitted simultaneously with application for registration	0		1	77
R9	New Active Ingredient, Non-food use, Outdoor, Experimental Use	1	354	0	

Progress in Meeting Decision Times					
PRIA Category	**Description of Category**	**Number of PRIA "Decisions" Completed in FY 2005**	**FY 05 Average Decision Time in Days**	**Number of PRIA "Decisions" Completed in FY 2006**	**FY 06 Average Decision Time in Days**
	Permit (EUP) submitted before application for registration				
R14	New Use, Additional food use, Indoor Food/Food handling	2	360	1	489
R15	New Use, First Food Use	1	410	0	
R17	New Use, Each Additional New Food Use	5	262	47	429
R18	New Use, Each Additional New Food Use, Reduced Risk	11	190	31	617
R19	New Use, Additional New Food Uses, Bundled, 6 or more	1	45	18	384
R20	New Use, Additional New Food Uses, Bundled, 6 or more, Reduced Risk	5	57	2	357
R23	New use, Non-food, Outdoor	9	281	12	555
R24	New use, Non-food, Outdoor, Reduced Risk	2	115		
R25	New use, Non-food, Outdoor with Experimental Use Permit (EUP) (no credit toward new use registration)	2	148	6	112
R26	New Use, Non-food, Indoor	6	200	7	585
R28	Import tolerance, New Active Ingredient or first food use	0		7	746
R29	Import tolerance, Additional new food use	0		2	395
R30	New Product, Me-Too, Fast Track	222	70	231	68

Progress in Meeting Decision Times					
PRIA Category	**Description of Category**	**Number of PRIA "Decisions" Completed in FY 2005**	**FY 05 Average Decision Time in Days**	**Number of PRIA "Decisions" Completed in FY 2006**	**FY 06 Average Decision Time in Days**
R31	New Product, Non-Fast Track (includes review of product chemistry, acute toxicity, public health pest efficacy)	267	232	342	224
R32	New Product, Non-Fast Track, new physical form (excludes selective citations)	5	346	16	450
R33	New manufacturing-use product, Old Active Ingredient, Selective Citation	10	216	20	405
R34	Amendment, Non-Fast Track (includes changes to precautionary label statements, source changes to an unregistered source)	188	130	136	116
R35	Amendment, Non-Fast track (changes to REI, PPE, PHI, rate and number of applications, add aerial application, modify GW/SW advisory statement)	17	130	66	480
R36	Non-fast track, Isomers	0		2	577
R37	Cancer Reassessment, applicant initiated	1	508	3	455
A38	New Active Ingredient, Food use, with exemption	0		1	350
A41	New Active Ingredient, Non-food use, Outdoor, Other uses	0		4	288
A42	New Active Ingredient, Non-food use, Indoor, FIFRA sec. 2(mm) uses	3	296	12	622
A46	New Food Use, with exemption	0		2	392

Progress in Meeting Decision Times					
PRIA Category	**Description of Category**	**Number of PRIA "Decisions" Completed in FY 2005**	**FY 05 Average Decision Time in Days**	**Number of PRIA "Decisions" Completed in FY 2006**	**FY 06 Average Decision Time in Days**
A47	New Food use, with tolerance	0		1	431
A48	New use, Non-food, Outdoor FIFRA sec. 2(mm) uses	0		1	390
A50	New use, Non-food, Indoor FIFRA sec. 2(mm) uses	2	216	5	282
A51	New use, Non-Food, Indoor, Other uses	0		3	369
A52	Experimental Use Permit	1	36	1	270
A53	New Product, Me-too, Fast Track	79	74	72	83
A54	New Product, Non-Fast Track, FIFRA sec. 2 (mm) uses	55	147	48	173
A55	New Product, Non-Fast Track, Other Uses	5	190	9	243
A56	New Manufacturing use product, old active ingredient, selective citation	0		6	481
A57	Amendments, Non-Fast Track	64	121	106	107
B59	New Active Ingredient, Food Use, with exemption			9	475
B60	New Active Ingredient, Non-food use, Microbial/Biochemical	6	293	7	363
B61	Experimental Use Permit, Food Use with temporary tolerance exemption, Microbial/Biochemical			1	263
B62	Experimental Use Permit, Non-food use, Microbial/Biochemical			3	27

Progress in Meeting Decision Times					
PRIA Category	**Description of Category**	**Number of PRIA "Decisions" Completed in FY 2005**	**FY 05 Average Decision Time in Days**	**Number of PRIA "Decisions" Completed in FY 2006**	**FY 06 Average Decision Time in Days**
B63	New Use, First Food Use, Microbial/Biochemical, with tolerance exemption	2	96	5	490
B65	New Use, Non-Food, Microbial/Biochemical	1	143	0	
B66	New Product, Me-Too, Fast Track, Microbial/biochemical	4	74	7	50
B67	New Product, Non-Fast Track, Microbial/Biochemical	40	196	43	221
B68	Amendment, Non-Fast Track, Microbial/Biochemical	14	127	18	122
B69	Straight Chain Lepidopteran Pheromones (SCLP), New Active Ingredient, Food Use or Non-Food Use	1	179	4	172
B70	SCLP, Experimental Use Permit, (New Active Ingredient or New Use)	3	6	0	
B71	SCLP, New Product, Me-Too, Fast Track	8	85	0	
B72	SCLP, New Product Non-Fast Track	3	189	6	130
B73	SCLP, Amendment, Non-Fast Track	11	144	0	
B75	Plant-Incorporated Protectants (PIP), EUP, with Temporary Tolerance or Exemption, No Scientific Advisory Panel (SAP) meeting	2	265	2	408
B80	PIP, Register New Active Ingredient, Temporary	1	360	2	498

Progress in Meeting Decision Times					
PRIA Category	**Description of Category**	**Number of PRIA "Decisions" Completed in FY 2005**	**FY 05 Average Decision Time in Days**	**Number of PRIA "Decisions" Completed in FY 2006**	**FY 06 Average Decision Time in Days**
	Tolerance/Exemption Exists, No SAP				
B81	PIP, Register New Active Ingredient, Temporary Tolerance/Exemption Exists, SAP	3	330	0	
B86	PIP, Experimental Use Permit, Food Use, Amendment	3	111	3	84
B88	PIP, New Product	2	364	2	349
B90	PIP, Amendment, Non-Fast Track			7	124
	TOTAL	1098		1347	

Note: Appendix A contains a list of all applications subject to PRIA reviewed during FY 2006 (Excel, 192 KB) and includes the decision times for each application. (Microsoft Excel Viewer EXIT Disclaimer is needed to view this file.)

Number of PRIA Applications Pending at the End of FY 2006.

The following table summarizes the pending registration applications (counted as decisions) in each of the PRIA categories. As of September 30, 2006, 1256 applications subject to PRIA were pending in the Agency's registration queue. At the end of the preceding year, FY 2005, 1178 were pending and are shown for comparison. The number pending at the end of a fiscal year does not reflect the number received, since some PRIA categories have multi-year timeframes. Actions are furthermore sporadically received throughout the year, and for decisions with short timeframes, an increase in the number pending at the end of September may reflect additional applications received close to the end of the fiscal year.

A factor in the higher number pending at the end of FY 2006 was an increase in the number of conventional new active ingredients submitted to the Agency (28 in FY 2005 versus 55 received in FY 2006). The decision review time mandated under PRIA for conventional new active ingredients decreased in FY 2006. For instance, the statutory decision review time for an R1 was 34 months in FY 2005, while for applications received on or after October 1, 2005, the timeframe is 24 months. An increase in the number of antimicrobial amendments (83 received in FY 2005, versus 123 received in FY 2006) also contributed to the increased number of actions at the end of the year.

Key to the table

- R - Conventional Pesticides
- A - Antimicrobial Pesticides

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Progress in Meeting Decision Times			
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of FY 2005**	**Number of PRIA Decisions Pending at the End of FY 2006**
R1	New Active Ingredient, Food Use	27	54
R2	New Active Ingredient, Food Use, Reduced Risk	10	22
R3	New Active Ingredient, Food Use, Experimental Use Permit (EUP) submitted simultaneously with application for registration	0	1
R4	New Active Ingredient, Food Use, Experimental Use Permit with temporary tolerance, submitted before application for registration	0	2
R6	New Active Ingredient, Non-food use, outdoor	10	10
R7	New Active Ingredient, Non-food use, outdoor, reduced risk	1	0

Progress in Meeting Decision Times			
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of FY 2005**	**Number of PRIA Decisions Pending at the End of FY 2006**
R8	New Active Ingredient, Non-food use, outdoor, Experimental Use Permit request submitted simultaneously with application for registration	0	2
R9	New Active Ingredient, Non-food use, outdoor, Experimental Use permit submitted before application for registration	0	1
R11	New Active Ingredient, Non-food use, indoor	4	6
R14	New Use, Additional food use, Indoor Food/Food handling	3	6
R15	New Use, First Food Use	2	9
R17	New Use, Each Additional New Food Use	214	278
R18	New Use, Each Additional New Food Use, Reduced Risk	39	11
R19	New Use, Additional New Food Uses, Bundled, 6 or more	64	81

Progress in Meeting Decision Times			
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of FY 2005**	**Number of PRIA Decisions Pending at the End of FY 2006**
R20	New Use, Additional New Food Uses, Bundled, 6 or more, Reduced Risk	6	4
R21	New food use, With Experimental Use Permit and temporary tolerance	0	1
R23	New use, Non-food, Outdoor	44	43
R24	New use, Non-food, Outdoor, Reduced Risk	1	7
R25	New use, Non-food, Outdoor with Experimental Use Permit (no credit toward new use registration)	3	0
R26	New Use, Non-food, Indoor	17	15
R28	Import tolerance, New Active Ingredient or first food use	12	4
R29	Import tolerance, Additional new food use	9	10

Progress in Meeting Decision Times			
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of FY 2005**	**Number of PRIA Decisions Pending at the End of FY 2006**
R30	New Product, Me-Too, Fast Track	45	62
R31	New Product, Non-Fast Track (includes review of product chemistry, acute toxicity, public health pest efficacy)	221	204
R32	New Product, Non Fast Track, new physical form (excludes selective citations)	17	11
R33	New manufacturing-use product, Old Active Ingredient, Selective Citation	25	21
R34	Amendment, Non-fast Track (includes changes to precautionary label statements, source changes to an unregistered source)	57	68
R35	Amendment, Non-fast track (changes to REI, PPE, PHI, rate and number of applications, add aerial application, modify GW/SW advisory statement)	85	55
R36	Non-fast track, Isomers	2	0

Progress in Meeting Decision Times			
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of FY 2005**	**Number of PRIA Decisions Pending at the End of FY 2006**
R37	Cancer Reassessment, applicant initiated	6	5
A38	New Active Ingredient, Food use, with exemption	1	0
A41	New Active Ingredient, Non-food use, Outdoor, Other uses	12	9
A42	New Active Ingredient, Non-food use, Indoor, FIFRA sec. 2(mm) uses	14	5
A44	New Use, First food use, with exemption	0	3
A46	New Food Use, with exemption	6	6
A47	New Food use, with tolerance	1	0
A48	New use, Non-food, Outdoor FIFRA sec. 2(mm) uses	1	0
A49	New use, Non-Food, Outdoor, Other uses	0	3

Progress in Meeting Decision Times			
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of FY 2005**	**Number of PRIA Decisions Pending at the End of FY 2006**
A50	New use, Non-Food, Indoor FIFRA sec. 2(mm) uses	5	15
A51	New use, Non-Food, Indoor, Other uses	3	3
A52	Experimental Use Permit	1	0
A53	New Product, Me-too, Fast Track	24	23
A54	New Product, Non-Fast Track, /FIFRA sec. 2 (mm) uses	28	36
A55	New Product, Non-Fast Track, Other Uses	10	7
A56	New Manufacturing use product, old active ingredient, selective citation	7	6
A57	Amendments, Non-Fast Track	42	56
B59	New Active Ingredient, Food Use, Microbial/Biochemical, with exemption	17	13

Progress in Meeting Decision Times			
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of FY 2005**	**Number of PRIA Decisions Pending at the End of FY 2006**
B60	New Active Ingredient, Non-food use, Microbial/Biochemical	11	13
B61	Experimental Use Permit, Food Use with temporary tolerance exemption, Microbial/Biochemical	2	2
B62	Experimental Use Permit, Non-food use	0	1
B63	New Use, First Food Use, Microbial/Biochemical, with exemption	10	2
B65	New Use, Non-Food, Microbial/Biochemical	0	3
B66	New Product, Me-Too, Fast Track, Microbial/biochemical	0	2
B67	New Product, Non-Fast Track, Microbial/Biochemical	30	29
B68	Amendment, Non-Fast Track, Microbial/Biochemical	8	13

Progress in Meeting Decision Times			
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of FY 2005**	**Number of PRIA Decisions Pending at the End of FY 2006**
B69	Straight Chain Lepidopteran Pheromones (SCLP), New Active Ingredient, Food Use or non-Food Use	0	1
B70	SCLP, Experimental Use Permit, New Active Ingredient or New Use	0	0
B71	SCLP, New Product, Me-Too, Fast Track	0	2
B72	SCLP, New Product Non-Fast Track	3	3
B73	SCLP, Amendment, Non-Fast Track	0	0
B75	Plant-Incorporated Protectants (PIP), EUP, with Temporary Tolerance or Exemption, No Scientific Advisory Panel (SAP)	2	2
B77	PIP, Experimental Use Permit, New Active Ingredient, Set. Temporary Tolerance or Exemption, SAP	1	0
B80	PIP, Register New Active Ingredient, Temporary Tolerance/Exemption Exists, No SAP	2	0

Progress in Meeting Decision Times			
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of FY 2005**	**Number of PRIA Decisions Pending at the End of FY 2006**
B81	PIP, Register New Active Ingredient, Temporary Tolerance/Exemption Exists, SAP	2	3
B84	PIP, Register New Active Ingredient, Set Tolerance/Exemption, SAP	1	0
B86	PIP, Experimental Use Permit, Food Use , Amendment,	2	0
B88	PIP, New Product	5	0
B90	PIP, Amendment, Non-Fast Track	3	2

Pending Inert Ingredient Reviews at the End of FY 2006

PRIA section 33(k) (2) (A) (ii) also requires EPA to provide the number of inert ingredients pending review by the Agency. In FY 2006 11 Final Rules were published and 13 new petitions for tolerance exemption were received. As of September 30, 2006, the Agency had 28 petitions pending. Since then and to February 2007, one Final rule has been published, one is in signature, and three are in final review. Five petitions have been voluntarily withdrawn, one petition was rejected for no data, and two polymer petitions were rejected for not meeting the polymer exemption eligibility requirements. All inert petitions are scheduled for review by date received, with oldest petitions scheduled first on the workplan, thus eliminating backlogged petitions. The Agency estimates the current average review time as 3-6 months for a polymer exemption petition and 6-18 months (including data review, science assessment, decision document, and Final Rule) for a new inert petition. At this time, all new petitions are screened for deficiencies before being scheduled for review and EPA works with potential petitioners to discuss the reliability and adequacy of the data to meet the FQPA safety finding.

Process Improvements in the Registration Program

Section 33(e) of PRIA directs EPA to identify and evaluate reforms to the pesticide registration process with the goal of reducing decision review times for pesticide registration applications. The Agency has made considerable progress during the fiscal year in improving its operations. We have undertaken a number of steps, both internal and external, to explore, develop, and implement improvements in the registration process.

In identifying process improvements, the Agency will not compromise the scientific quality of its assessments as a means toward reducing decision times. The Agency believes that the best means of gathering recommendations for process improvements is through the Federal Advisory Committee Act (FACA) process.

Pesticide Program Dialogue Committee PRIA Process Improvement Workgroup

The PRIA Process Improvement Workgroup was created in FY 2004 under the auspices of the Agency's Federal Advisory Committee, the Pesticide Program Dialogue Committee, to evaluate process improvements in the registration program. The workgroup is composed of members of registrant companies, pesticide trade associations, public interest groups, and Agency staff. Meetings are open to the public and are held approximately 2 to 4 times a year. Reports of the January 31, 2006, and June 14, 2006, PPDC PRIA Process Improvement Workgroup meetings are posted on the internet.

Industry stakeholders identified many areas for improvement in the registration process, including labeling consistency, communication of schedules, and difficulties with the application process. Many of the process improvements proposed by the Agency addressed those issues. The Agency continues to work with all stakeholders to evaluate these and other potential improvements to the registration process.

Labeling Committee

Both stakeholders and the Agency recognized that labeling issues should be addressed. The Agency formed a cross-program Labeling Committee in FY 2005 to address broad labeling issues and to oversee revisions to the Label Review Manual. A subgroup, the Label Review Manual Team, was formed to revise and continually update the Label Review Manual. During FY 2006, the Team revised the first three chapters of the Manual and posted them on the Web. Additional chapters will be posted as they are updated.

The Committee developed a web site to communicate its activities and to address the public's labeling policy questions forwarded through the web site's e-mail address (OPP_labeling_consistency@epa.gov). At the end of September 2006, the Committee had received 60 questions. They posted answers to the majority of these questions while a few required a direct response. Due to the increasing number of questions and answers, the Agency has reorganized the web site. Questions are now organized in categories to facilitate web searches.

In early 2006, the Committee requested public comment on an issue paper "For Use Only By...", and thirty responses were received. A synopsis of the comments and the Agency's response was posted on October 24, 2006. The Committee, as part of its mission to ensure consistency on labeling issues, conducted two internal training sessions with approximately 100 Agency employees on the use of mandatory versus advisory language. The Agency has compiled historic warranty statement guidance into a guidance document that now includes examples. This revised guidance was made available in October 2006 on the labeling Web site. Two training sessions were then held in early FY 2007 to inform Agency staff of this revised guidance.

The Committee is incorporating labeling recommendations from the Pesticide Program Dialogue Committee's Consumer Label Improvement Workgroup into a Pesticide Registration (PR) Notice. A number of issues will be considered in FY 2007, and as issue papers are developed, the Committee will place them on the Web site for informal public comment. An issue paper on "Minimum Use Rates" has been posted.

Product Chemistry

Product chemistry issues continue to be a problem for both the Agency and registrants. Most recently they were a key area addressed by the PRIA Process Improvement Workgroup. As a result the Agency formed an internal Product Chemistry Team to address these issues. This team decided that a more systematic method was needed to ensure that the Agency understood what the exact issues were and how to best address these issues and thereby effectively target the real problems. As a result the team reanalyzed not only the questions that had been presented by the PPDC Workgroup but also information on the reasons for extending PRIA due dates.

In summary, the team found that across the pesticide registration program, product chemistry issues (including issues with inert ingredients) accounted for over one-third of the PRIA due date extensions. This analysis included all extensions since the beginning of PRIA through mid-August 2006. The count included decisions where there were multiple issues (in addition to product chemistry). The analysis revealed the following information about the extensions due to product chemistry:

- Involved mainly small businesses
- Likely resulted from a lack of complete understanding of the requirements for product chemistry
    - Data requirements
    - How to correctly complete CSFs
    - For biopesticides, issues with the manufacturing process, product identity, and composition or starting ingredients
- Frequently included registrants looking for a product identical or similar to the one cited in the application
    - Extra time was needed to find an alternate product to cite
    - Extra time was needed to generate data
- Often involved issues with inert ingredients

As a result of this analysis the team concluded that the best approach to address these issues was to develop a detailed addendum to the "Blue Book – General Information on Applying for Registration of Pesticides in the United States", which would systematically address Product Chemistry and Inert Ingredients issues. The "Blue Book" is a basic "how-to" guide for pesticide registration and the addendum is scheduled to be published in FY 2007. This addendum will also be placed on various Websites. The Blue Book Addendum serves as a supplement to the Standard Operating Procedure for Product Properties. TheInerts tip sheet has been posted. The biopesticide and antimicrobials tip sheets are expected to be posted in March 2007. Areas for improvement for product chemistry reviews will be discussed during the next antimicrobial workshop in FY 2007.

Process Improvements Implemented within the Pesticide Registration Program

The Agency made a number of process improvements to monitor workload and ensure that PRIA due dates are met. New reports monitor the status of due dates and help managers identify priority actions. In FY 2007, the Agency will analyze the business processes for the conventional registration process to identify additional improvements and efficiencies.

The Agency has begun to post risk assessments for new conventional pesticides registered during FY 2006 to aid registrants with future submissions. Human health and ecological risk assessments are attached to the new active ingredient fact sheets and in the future, will be posted when finalized.

Reviewing labels can be time consuming. An Electronic Label Review work group has been established to make the process more efficient and accurate by using an electronic comparison tool. In 2006, the work group updated the Agency's guidance to registrants on how to submit electronic labels. In addition, it drafted guidance for internal use on how to compare electronic labels, make notes on electronic labels and file them in an electronic label file. This guidance will be finalized in early March, and the work group will start training label reviewers in late March and April 2007. Revised guidance for registrant's will be tested and posted by the end of March. We expect to have the staff trained and using electronic label reviews by May. Registrants are currently submitting and the Agency is reviewing e-labels. Registrants are encouraged to submit them in an electronic format (.pdf) to take advantage of these efficiencies.

An analysis of the biopesticides registration process led to the formation of a Notifications Response Team and a Straight Chain Lepidopteran Pheromones (SCLP) team. By improving the overall efficiency of the biopesticide registration process, the Agency met PRIA due dates more effectively. The Notifications Response Team eliminated a backlog and the SCLP Team expedited new product applications.

The Agency reviewed its procedures and identified which Standard Operating Procedures and additional guidance was needed to ensure consistency within the antimicrobial registration program which resulted in an emphasis on product chemistry review. This information will be included in the Agency's continued work with stakeholders on application guidance. Checklists that registrants can use to ensure that their applications are complete were a product of this effort. The Agency began consultation with the Center for Disease Control to develop a hierarchical model that will facilitate the Agency's review process so that antimicrobial products will be available when needed to combat new pathogens.

The Agency's many program analyses are examples of the activities EPA undertook to reduce the amount of time required to complete decisions. Numerous internal Agency meetings monitor workload and compliance with PRIA due dates. Throughout the pesticide registration program, weekly meetings are held to review the status of pending decisions, due date extensions, and refunds; to identify potential issues and target their resolution; to resolve fee category questions; and to coordinate schedules with science support organizations. Senior managers review justifications and make final decisions to extend or negotiate a PRIA due date and whether or not to issue a "PRIA Determination to Not Grant" a registration. On a bi-monthly basis, progress in meeting PRIA due dates and the short term pending workload are evaluated across all involved organizations and periodically shared with stakeholder groups.

Registration Program Workplans

The multi-year workplan for new conventional chemical actions and new uses under PRIA is updated quarterly. These updates reflect new actions received under PRIA, actions completed, and changes to schedules. For a majority of the new chemical and new use actions listed, the time frame in which the Agency expects to complete its registration decision is shorter than that specified by PRIA. When possible, requests for new uses submitted by USDA's IR-4 program that are also being requested by registrants are merged into one risk assessment. Additional economies and time-savings were achieved where possible by folding new use assessments into assessments conducted for reregistration and tolerance reassessment.

The FY 2006 and FY 2007 workplan for new biopesticide active ingredients are also available. The biopesticide workplan is updated at least once a quarter to reflect completed actions and changes to the schedule. Schedules for new antimicrobials and new antimicrobial uses are described in a posted current year workplan for all antimicrobial activities.

Progress of Inert Ingredients Assessment Branch

Since the creation of the Inert Ingredients Assessment Branch in August 2005, the branch has successfully completed the tolerance exemption reassessment effort and created a website where the reassessment documents are located. A complete list, with CAS registry numbers, of all food and non-food use inert ingredients is being compiled for the website. When this list is posted, the "old" list of inert ingredients will be removed. The Agency is developing a process for reviewing data submissions in support of the revoked tolerance exemptions. These tolerance exemptions were revoked for lack of data necessary to meet the FQPA safety finding. The petition backlog has been reduced, and assessment documents are being developed for all new approved inert petitions and placed in the public docket.

Science Review Improvements

By taking advantage of geospatial data and analytical techinques, risk assessors can provide better, more accurate, and more relevant information about the potential effects of pesticides in the environment. In FY 2006, the Agency initiated an effort to advance its ability to apply geospatial techniques to its aquatic risk and exposure assessments. The developing framework is based on current modeling approaches that operate under a geospatial umbrella and take advantage of maps of land cover, soils, crops, watersheds, drinking water utilities, and other features. Using this framework, the Agency will be able to assess the spatial distribution of pesticide exposures relative to the presence of non-target organisms and drinking water utilities. An important milestone reached during FY 2006 improved the efficiency of the pesticide exposure model to run over a grid representing thousands or millions of scenarios in a matter of hours as opposed to days in the past. Additionally, results from these spatially explicit model runs can be represented graphically to better communicate modeled exposure to risk managers. The next steps in the geospatial risk assessment arena are to peer review the Agency's enhanced exposure model ("fast exposure model"), and to integrate additional geospatial tools and data layers into the modeling environment. Efforts begun in FY 2005 continue integrating aquatic and terrestrial exposure models to allow data to be entered only once and used in a number of modeling environments.

The pesticide human health risk assessment process has been streamlined over the last two years, and electronic storage and desk-top retrieval of science reviews have facilitated the work. We have consolidated review committees and delegated endpoint selection decisions to assessment teams so a single risk assessment is developed. In the past, peer review and end point selection committees required separate documents focused on each discipline. Now the draft risk assessment is the sole document that undergoes internal peer review. This consolidation and the reduction in the number of review committees have reduced the timeframe for conducting assessments. The Agency will continue to evaluate this process to identify still further improvements.

The Dose Adequacy Review Team (DART) met to discuss dose selection for registrant conducted cancer studies for five pesticides during FY 2006. An agreement on doses before the studies are begun insures that the doses are adequate. In the past, detailed discussions about dose selection were necessary after the study had been conducted, and now, these discussions and the need to repeat studies have been eliminated.

In FY 2004, in response to an industry request, the Agency established a waiver decision process for certain studies used for hazard identification. Waivers may be granted if evidence is submitted showing that the additional test is not needed to identify the nature of the hazard. The Agency received 13 requests for waivers to inhalation toxicity studies in 2005-2006; of the 13, waivers were granted for 7 chemicals and denied for 6.

Progress in Meeting Tolerance Reassessment and Reregistration Timelines

FY 2006 Accomplishments

During Fiscal Year 2006, the Agency completed a major milestone in the implementation of the Food Quality Protection Act by reassessing 9,721 (99% of) pesticide food tolerances and is well on it way to completing reregistration by October 2008. In FY 2006 alone, the Agency completed 59 Reregistration Eligibility Decisions (REDs) and 4 Interim REDs (IREDs) and issued tolerance reassessment eligibility decisions (TREDs) for 19 active ingredients. These decisions and others resulted in the completion of 1,820 tolerance reassessment decisions.

Status of Reregistration

To the end of FY 2006, the Agency has completed 330 REDs and must issue 54 more REDs to complete reregistration by October 3, 2008. EPA's goal is to complete 7 remaining REDs during FY 2007 for pesticides with associated food uses or tolerances, and to complete another 47 REDs in FY 2007 and 2008 for pesticides with no food uses or tolerances. This will satisfy PRIA requirements and support the Agency's tolerance reassessment and reregistration goals. EPA's schedule for completing these decisions can be found on the Agency's website.

Status of Tolerance Reassessment

Through the end of FY 2006, the Agency has completed a total of 9,637 tolerance reassessment decisions, addressing over 99 percent of the 9,721 tolerances that require reassessment. EPA is accomplishing tolerance reassessment through both the registration and reregistration programs by revoking tolerances for pesticides that have been canceled, by reevaluating pesticides with pre-FQPA REDs, and through other decisions not directly related to reregistration or registration.

More specifics on the Agency's progress in meeting its performance measures and goals for pesticide reregistration will be published in the Federal Register, as required by section 4(l) of FIFRA.

Other Activities

Use of Outside Reviewers

During FY 2006 the Agency continued its work sharing efforts with Canada's Pest Management Regulatory Agency (PMRA) and the California Department of Pesticide Regulation (CDPR). Two minor use actions were completed as part of the Joint Review Program under the North American Free Trade Agreement (NAFTA). In addition, the international work sharing efforts were expanded to a trilateral basis, adding Australia and the European Union (EU) to our work sharing partners. To date, two active ingredients (conventional chemicals) are being jointly evaluated by EPA and PMRA as part of the NAFTA Joint Review Program. Two more active ingredients (conventional chemicals) are being jointly evaluated by the EPA, PMRA, and the Australian Pesticides and Veterinary Medicines Authority (APVMA). Another active ingredient (conventional chemical) is being jointly evaluated by EPA, PMRA and the EU. Six minor conventional use joint reviews are also in progress. Two biopesticide joint review decisions were completed in FY 2006. No new ones were initiated this year, but two potential NAFTA joint biopesticide reviews are being considered. In joint reviews, EPA makes its own registration decision while sharing the study reviews and the risk assessment work and harmonizing its regulatory decisions with other authorities.

EPA also continues to work with CDPR to expand its capacity to review residue chemistry studies and conduct dietary risk assessments in support of registration decisions. During FY 2006, 27 crop combinations were reviewed through this joint effort.

Preliminary evaluations of laboratory and field studies submitted in support of registration decisions are conducted early in the assessment process by many regulatory organizations to identify major flaws in experimental procedures, which could increase the uncertainty of the risk assessments. During the later part of FY 2006, the Agency began using the scientific screens developed by NAFTA and OECD partners during joint reviews of data and submitted for environmental/ecological risk assessments of conventional pesticides. As a first step, the Agency conducted a side-by-side comparison of the science screens for a number of joint reviews during the NAFTA and OECD review process to ensure consistency. The result of this effort was "equivalency" among the participating countries such that for future joint reviews only one country needs to conduct a science screen, thereby saving resources.

The Agency has also begun to use the in-depth screens for missing information used by PMRA in conducting human risk assessments for conventional pesticides. Recently an Austrian science screen was used in a joint review. As joint reviews expand to other countries, the Agency anticipates expanding the use of external screens to avoid a duplication of effort.

Performance-Based Contracts

Contractors tasked with the review of hazard and exposure data continued to assist the Agency in the selection of endpoints and characterization of hazards for human health and ecological risk assessment. These contractor services enhanced the production of our risk assessments.

To date, approximately 75% of the Pesticide Program's active contracts or task orders/work assignments are performance based. Performance based contracts tend to be contracts with routine and predictable work assignments. Areas covered by these contracts include information management, records management, on-site computer leasing and support, outreach, and as appropriate, data review and risk assessment.

Appendix A: Decision Review Times for Actions Completed During FY 2006

As required by Section 33(k) of PRIA, the following table (an Excel file) provides the decision times for each decision (application) during FY 2006. Note that decision times indicated in red with an asterisk are decisions completed before the Agency received payment or a waiver was granted. Completion of a registration action before payment is received typically occurs in situations where a voluntary fee payment has been offered for an application that was pending with the Agency prior to March 23, 2004 (the PRIA effective date). Mandatory decision time frames changed for some PRIA action codes and fee categories between FY 2005 and FY 2006. A decision's time frame is based on the fiscal year in which the application is received. Mandated time frames can be found in the fee schedule published in the (Pesticides; Fees and Decision Times for Registration Applications, March 17, 2004), Federal Register. The Agency's target due date for completing a decision or action is based on 30 days in a month. The time frames specified in the Consolidated Appropriations Act of 2004 are in months. In the table, if the PRIA due date was met, while the Agency's target date was not, a date was entered in the column labeled PRIA Due Date. As EPA improves its reporting capabilities, the Agency may update this table, as necessary.

Table of completed actions for FY 2006 (Excel, 192 KB) (Microsoft Excel Viewer EXIT Disclaimer is needed to view this file.)