Implementing the Pesticide Registration Improvement Act (PRIA) - Fiscal Year 2010

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Contents

Seventh annual report. Report release date:

Under Section 33(k) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Environmental Protection Agency is required to publish an annual report, which must include certain items that describe the Agency's implementation of the Pesticide Registration Improvement Renewal Act (PRIA 2). The Act reauthorized the Pesticide Registration Improvement Act (PRIA 1) and is effective from October 1, 2007, to September 30, 2012. PRIA 1 was in effective from March 23, 2004, to September 30, 2007. The Act authorizes the Agency to collect two types of fees, registration service fees and maintenance fees, and establishes statutory time frames.

Section 33 of FIFRA, created by PRIA, is called "Pesticide Registration Services Fees" and describes a fee system for applications for specified new pesticide registration, amended registration, and associated tolerance actions, which set maximum residue levels for food and feed. Fees are charged for covered applications submitted to EPA and for certain pending applications received before March 23, 2004. EPA is then required to make a determination on the application within mandatory time frames, called decision time review periods.

Other sections of FIFRA were amended by PRIA, specifically section 4(i)(5), which reauthorized the collection of maintenance fees up to a prescribed level to support the Agency efforts in re-evaluating registered pesticides within statutory time frames to ensure that products met current safety standards. Maintenance fees are annual fees that maintain the registration of a pesticide product for another year.

This seventh annual report covers Fiscal Year (FY) 2010 – October 1, 2009, through September 30, 2010, the third Fiscal Year under PRIA 2. The report includes the items specified by Section 33(k) and discusses the Agency's implementation of PRIA's statutory provisions. It is organized into sections on Registration Service Fees and Maintenance Fees to associate accomplishments with the type of fee that funded the activity. Only changes in processes, practices and policies from FY 2009 are reported. Previous annual reports (2004, 2005, 2006, 2007, 2008, and 2009) are available on the Internet for comparison.

Pesticide Registration Service Fees

PRIA and registration service fee processes and procedures used by the Agency are described in Chapter 5 of the Pesticide Registration Manual.

Front-End Processing and Screening Procedures - FY 2010

Each of the 140 fee categories or types of application under PRIA 2 has a specific fee and a decision time frame. Under Section 33(b)(2)(D), the fee is due upon submission of the application. Section 33(b)(2)(F) directs the Agency to reject any application submitted without the required registration service fee. If certification of payment is not received within 14 days, the Agency will reject the application and invoice the registrant for 25% of the appropriate fee. Fees, time frames, and the front-end processing and screening procedures reported in FY 2009 continued in FY 2010. In FY 2008 and FY 2009, nine and two applications, respectively, were rejected, while in FY 2010, five applications were rejected for failure to pay a fee.

Guidance to help applicants identify the appropriate fee category and fee was revised in anticipation of the 5% fee increase required of Section 33(b)(6)(B), effective the beginning of FY 2011 (October 1, 2010). This guidance describes the type of application covered by a fee category and includes the Fee Determination Decision Tree for inexperienced applicants, a PRIA 2 fee table for experienced applicants and a PDF table that can be printed and used as a hardcopy reference. As required by Section 33(b)(6)(c), the Agency published a Federal Register Notice announcing the increase. The Agency also issued a Pesticide Program Update, announced the anticipated increase in conferences and workshops attended by potential applicants, and modified its tracking systems in FY 2010 resulting in an efficient implementation of this fee increase.

21 Day Initial Content Screen

Section 33(f)(4)(B), "Completeness of Application" directs the Agency, not later than 21 days after receiving an application and the required registration service fee, to conduct an initial screening of the contents of the application. In conducting this screen, the Agency must determine (1) whether the applicable registration service fee has been paid, or (2) at least 25 percent of the applicable registration service fee has been paid and the application contains a waiver or refund request for the outstanding amount and documentation establishing the basis for the waiver request and (3) that the application contains all the necessary forms, data, and draft labeling, formatted in accordance with guidance published by the Agency. If the application fails the screen and can not be corrected by the applicant within the 21 day period, the Agency is to reject the application. During FY 2010, four applications were rejected, while in FY 2009, 7 and in FY 2008, 14 were rejected generally for missing or incomplete forms and data.

The procedures and guidance described in the FY 2009 report were used to conduct this screen in FY 2010. A pilot was begun in late FY 2010 to expand the screen and conduct an in-depth screen for the data required for conventional new product applications. Checklists were developed and tested. An evaluation will be conducted in FY 2011 to determine whether to expand this screen to additional types of applications.

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 costs associated with review and decision-making for applications for which registration service fees have been paid. As of October 2007, fees are deposited into an account maintained by the U.S. Bank in St. Louis, Missouri, which informs the Agency when a payment is received. The later of date of payment or application receipt triggers the start of the PRIA decision review period, or time frame. On average, EPA has been informed of the receipt of a payment within 7.2 days of receipt by the bank consistent with past fiscal years.

The Agency encourages applicants to pay their fees by credit card or wire transfer using the Treasury Department's pay.gov system. In FY 2009, payments totaling $5,804,462 were made through pay.gov for 1,150 decisions while in FY 2010, payments totaling $8,425,487 were made

for 1,113 decisions representing 65% and 69% respectively of the total number of applications for which payment was received.

Financial Overview

During FY 2010, the Agency received $19.0 million in new registration service fees and, after subtracting $0.4 million in refunds (overpayments and withdrawals), net receipts were $18.6 million as of September 30, 2010. A balance of $7.0 million was carried forward from FY 2009, including recoveries of prior year unpaid obligations. From this total of $25.6 million, the Agency spent approximately $18.2 million, carrying the remaining balance of $7.4 million forward to FY 2011. A balance is carried forward to fund personnel and contractor support for applications with multi-year time frames and for which some or most of the work is performed in the next fiscal year. Without a balance at the beginning of a fiscal year, staff would have to be reassigned from PRIA work until more fees were collected. This would disrupt the process and possibly result in missed PRIA deadlines. Spending decreased by 2% in FY 2010, compared with FY 2009. The end of year remaining balance increased by 6% in FY 2010 from FY 2009. The decrease in spending was largely accounted for by the statutory reduction in the mandated Partnership Grants (reported under Worker Protection) related expenditures in FY 2010.

Under Section 33(c), interest earned and added to the PRIA Registration Fund is available to the Agency for spending. Interest in FY 2010 totaled $6,752.

Agency's FY 2004 through FY 2010 Expenditures from the Pesticide Registration Fund
Expenditures (in thousands)

For	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
Payroll	$2,535.3	$7,898.2	$5,819.8	$7,111.6	$7,556.4	$9,401.6	$9,401.3
Contracts	$1,591.3	$2,228.8	$4,013.1	$6,979.5	$7,168.1	$6,733.3	$6,485.7
Worker Protection	$430.0	$750.1	$750.0	$750.0	$2,250.0	$2,250.0	$2,000.0
Other Expenses	$455.8	$274.3	$221.6	$302.7	$205.8	$140.6	$309.9
Total	**$5,012.5**	**$11,151.4**	**$10,804.5**	**$15,143.8**	**$17,180.3**	**$18,525.5**	**$18,196.9**

Payroll expenditures were constant at $9.4 million in FY 2010 compared with FY 2009. Expenditures on contracts decreased to approximately $6.5 million in FY 2010, compared with $6.7 million in FY 2009. The balance between payroll and contract expenditures remained relatively constant from 2009 to 2010 (with payroll at 51% of expenditures in both FY 2009 and FY 2010, and contracts down slightly to 35% in FY 2010 from 36% in FY 2009). In addition to funds from the PRIA Pesticide Registration Fund, the registration program spent about $39.1 million from appropriated funds.

With spending on Partnership Grants reduced by the PRIA 2 statute, spending on mandated programs totaled $2.0 million in FY 2010 and $2.25 million in FY 2009. These mandated programs included worker protection ($1.0 million), partnership grants ($0.5 million), and the Pesticide Safety Education Program ($0.5 million). The percentage of expenditures going to the mandatory programs was 11% in FY 2010, and 12% in FY 2009. The Agency also continued to invest in upgrading its information management systems to track compliance with the PRIA review time frames, to meet reporting requirements, and to implement PRIA 2 requirements.

Other funds went primarily to pay for *Federal Register* printing costs associated with PRIA registrations.

Waivers of and Exemptions from Registration Service Fees

Section 33(b)(7) of PRIA authorizes the Agency to reduce or exempt the registration service fee for specified situations. The maximum fee reduction for small businesses with less than $10 million per year in global gross pesticide sales is 75% of the fee. A portion of all fees (25%) is non-refundable. A 50% reduction in the fee may be granted for a small business with less than $60 million in annual global gross pesticide sales. The Agency's guidance for small businesses on applying for a fee waiver was updated in FY 2010. Section 33(b)(7) also provides an exemption from a registration service fee for applications from Federal or State agencies and for applications solely associated with a tolerance petition submitted in connection with the Inter-Regional Project Number 4 (IR-4) that is in the public interest.

In FY 2010, the Agency granted 276 fee waivers and exemptions and denied 3 of the 284 fee waiver/exemption requests received as shown in the following table.

Waiver Type	Received	Granted	Denied	Withdrawn
75% Ultra Business	192	187	0	0
50% Small Business	71	68	3	5
IR-4	17	17	0	0
Minor Use	0	0	0	0
Federal State	4	4	0	0
Total	284	276	3	5

The average number of days required to grant a fee waiver in FY 2010 was the same as in FY 2009 (25 days). The average time to deny a waiver in FY 2010 (57 days) was greater than in FY 2009 (37 days) and reflects the extra amount of time that the Agency took in an attempt to resolve the issues.

The total fees waived and exempted in FY 2010 was $4.1 million, the lowest since the beginning of PRIA in March 2004 and due to a decrease in IR-4 fee exemptions. If the table below is compared with a similar table in the FY 2009 report, the amount waived and exemption for some past fiscal years has changed because once some applications were reviewed in-depth, the Agency determined that the application belonged to a different PRIA fee category.

Amount in Fee Waivers and Exemptions by Fiscal Year of Receipt and Type (in $1,000)

Fiscal Year/Type	Small Business	IR-4	Federal/State Agencies	Minor Use Waiver or Exemptions	Total
FY 2004	$3,699	$2,745	-----		$6,444
FY 2005	$3,006	$5,460	$15		$8,481
FY 2006	$1,497	$4,226	$40		$5,763
FY 2007	$2,162	$8,342	$924		$11,429
FY 2008	$1,287	$6,908	$28		$8,223
FY 2009	$935	$5,326	$471	$209	$6,952
FY 2010	$1,354	$2,353	$413		$4,120

Fee Reductions

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 March 2004. For fees required for pending new active ingredients and for applications pending prior to March 2004 where the registrant has offered to pay the registration service fee voluntarily, the Agency applied this refund provision as a credit toward the registration application service fee. In FY 2010, no voluntary payments were received.

PRIA and Pesticide Worker Protection

Under FIFRA Section 33(c)(3)(B), EPA is authorized to use 1/17 of the amount of the Fund (but not less than $1 million) to enhance current scientific and regulatory activities related to worker protection and approximately, $500,000 in each fiscal year, 2008 through 2012, for funding of the Pesticide Safety Education Program (PSEP).

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 the following focus areas: Prevention - Safety Training, Response - Poisoning Recognition, Sound Decision Data, and Inform - Risk Management. Table I lists the activities funded and their accomplishments in FY 2010. The efforts funded in FY 2009 with the Medical University of South Carolina, the National Institutes of Occupational Safety and Health and the Migrant Clinicians Network were funded in FY 2010 from other sources. The products developed under a completed cooperative agreement with the Pacific Northwest Agricultural Safety and Health Center will also be used by other institutions.

PRIA and Partnership Grants

Under PRIA 2, the amounts set aside for partnership grants in Section 33(c)(3)(B)(ii) were $750,000 each for fiscal years 2008 and 2009 and $500,000 each for fiscal years 2010 through 2012. In 2008, EPA augmented these funds with appropriated funds and awarded approximately $1 million in grants to fund five projects that use Integrated Pest Management (IPM) approaches to reduce pesticide risk with the funds to be spent over a two year period. In FY 2009, EPA augmented PRIA 2 funds with other EPA funds to award approximately $1.3 million in grants, funding six projects. Partnership grants funds were also augmented in FY 2010 with Advanced

Monitoring Initiative funds from EPA's Office of Science Advisor to fund a total of five projects. Table II provides a summary of this program's accomplishments with FY 2008 and FY 2009 funds and lists the projects awarded in FY 2010 after a competitive selection process.

The FY 2011 Request for Proposals and PRIA 2 Partnership Grants competition is targeted for February 2011. The Agency will award $500K in PRIA funds. The solicitation for proposals will include projects funded by the Office of the Science Advisor for approximately $400K. Additional information is available on the PRIA 2 Partnership Grants website.

Progress in Meeting Decision Times

Workplans are available on the Pesticide Internet Site to allow the public to monitor the Agency's progress in meeting due dates for certain types of applications. The multi-year workplan for new conventional chemical actions and new uses under PRIA is updated quarterly and to aid applicants with future submissions, the Agency continues to post risk assessments for new conventional pesticides. Schedules for new biopesticides are also updated at least once a quarter and Biopesticide Registration Action Documents (BRAD) are posted on the Web and include a review of the studies submitted to support the registration. The Antimicrobials FY 2010 Workplan for new antimicrobials and new antimicrobial uses was also published.

Number of PRIA Actions Completed in FY 2010

The Agency completed 1517 decisions subject to PRIA during the fiscal year, 53 (3.4%) fewer than the 1570 completed in FY 2009. Among the FY 2010 completed decisions, 310 (20.4% of total) were antimicrobial decisions, 138 (9.1%) biopesticides and 1069 (70.4%) conventional pesticide decisions. An additional 189 decisions were withdrawn; the number withdrawn has increased each fiscal year since 2007.

Type of Pesticide	Number Completed in Fiscal Year			Number Withdrawn in Fiscal Year		
	2008	2009	2010	2008	2009	2010
Conventional	1243	1104	1069	124	129	28
Antimicrobial	336	342	310	22	24	16
Biopesticide	98	124	138	10	14	145
Total	**1677**	**1570**	**1517**	**156**	**167**	**189**

EPA completed 99.7% percent of these decisions on or before their PRIA or extended due date. In FY 2010, five actions missed their statutory due date due to processing delays.

Table III titled "Number of PRIA Actions Completed in FY 2008, FY 2009 and 2010", summarizes the number of decisions completed by PRIA category and compares the first three fiscal years under PRIA 2. A summary of the actions completed under PRIA 1 are provided in the FY 2007 PRIA Annual Report.

Actions received under both PRIA 1 and PRIA 2 were completed in FY 2010. Actions with a fee category with two digits are PRIA 1 actions (e.g., R01, A53) while PRIA 2 actions have a three digit fee category (e.g., R010, A530). In reviewing the table, certain factors need to be considered. The Agency counts "decisions" and an application package can have more than one

decision. The number depends on the number of product registrations and tolerance petitions in an application and reflects the number of "decisions" that have to be made within an application. For instance, in FY 2010, one conventional new active ingredient application package required twenty decisions, one for each product registration requested. One decision is designated as a "primary" decision, while the others are "secondary" decisions within the application package in the Agency's tracking systems. Generally each application categorized as a Fast Track, Non-Fast Track New Product, identical/substantially similar new product, new product, Non-Fast Track Amendment or label amendment submitted with data, contains a single product and is a single decision.

The number of decisions completed each year increased steadily by over 20% per year from FY 2005 through FY 2007 under PRIA 1, increased by only 3.5% in FY 2008 and then decreased in FY 2009 and again in FY 2010. Fewer new use decisions and protocol reviews were completed in FY 2010. The number of new product decisions completed decreased again. New active ingredient decisions increased primarily because of the large number of product registrations for one new conventional active ingredient.

Average Decision Times

The average decision time for each PRIA category, shown in Table III, is the number of days it took the Agency to complete a decision once the application was received and payment was made or a fee waiver or exemption was granted. The mandated time frame or decision time review period changed from one fiscal year to another as prescribed by statute and depends upon the fiscal year in which an application was received. The dates that decisions completed in FY 2010 were received ranged from December 2004 to 2010, resulting in decisions completed within one fee category with different mandatory time frames. Consequently, the average decision time in the table can not be directly compared to the PRIA time frames mandated for FY 2010 for many decisions. Statutory time frames under PRIA 2 for some identical or substantially similar and new products, however, have been somewhat consistent from one fiscal year to another.

Comparisons in average decision times can only be meaningfully made for those fee categories with a large number of completed decisions. In general, average decision review times increased or remained the same in FY 2010 except for some specific types of applications. These included among conventional decisions, new reduced risk food uses, non-food outdoor experimental use permits, study protocols, and new manufacturing-use product applications with selective data citations. Among antimicrobial decisions, study protocols reviewed within the Antimicrobial Division, and certain new product decisions had decreased averages. The number of biopesticide decisions completed was too small to make any comparisons.

Due Date Extensions (Negotiated Due Dates)

Among the FY 2010 completions, due dates for 470 (31%) decisions were extended by mutual agreement between the applicant and the Agency. The percentage of decisions completed with due date extensions has increased each fiscal year. During FY 2008, and FY 2009, 18% and 19.3%, respectively, were extended. Extensions generally were needed because of missing or deficient data or information. Due dates were extended for 35%, 62% and 26% of completed

antimicrobial, biopesticide and conventional decisions respectively, while in the previous fiscal year, 20%, 34% and 17.5% were extended.

Number of Completed Decisions with Due Date Extensions Compared to Total Completed

	FY 2008		FY 2009		FY 2010	
Fee Category	Number due date extensions	Total Completed	Number due date extensions	Total Completed	Number due date extensions	Total Completed
Antimicrobial (A)	74	336	68	342	108	310
Biopesticide (B)	47	98	42	124	85	138
Conventional (R)	185	1243	193	1104	277	1069
Total Decisions	**306**	**1677**	**303**	**1570**	**470**	**1517**

As discussed previously, an active ingredient or a new use application package can have a number of decisions to account for the number of registrations and tolerances requested for the new active ingredient or new use. All of the decisions associated with these applications are linked to one decision that has been assigned as the "primary" decision with the rest termed "secondary" decisions. A new product or amendment application package will have only one decision in the Agency's tracking system, however, some new product and amendment applications are dependent upon the data submitted with another application, the primary decision, as described in the primary/secondary guidance. If there are data issues, the due dates for both the primary and all of its secondary decisions will be extended. Consequently, an analysis of due date extensions using decisions can only indicate trends from one fiscal year to another. To assess the reasons for the increase in extensions, the Agency focused on primary decisions.

Number of Completed Primary Decisions with Due Date Extensions Compared to Total Completed

	FY 2008		FY 2009		FY 2010	
Fee Category	Due Date Extensions	Total Completed	Due Date Extensions	Total Completed	Due Date Extensions	Total Completed
Antimicrobial (A)	71	305	60	284	89	268
Biopesticide (B)	43	85	35	105	62	108
Conventional (R)	124	945	125	881	156	811
Total Decisions	**238**	**1335**	**220**	**1270**	**307**	**1187**

If only primary decisions are considered, 26% had due date extensions in FY 2010 according to the Agency's tracking systems. This is an increase from the 18% and 17% in FY 2008 and FY 2009, respectively. Of the primary decisions, due dates for 33% of antimicrobial, 57% of Biopesticide and 19% conventional primary decisions were extended, an increase from the 21%, 33% and 14% in FY 2009.

The 470 decisions with due date extensions were the following general types of decisions.

Number of Decisions with Due Date Extensions by Type of Decision (All Decisions)

	New Active Ingredient	New Uses	New Products	Amendments	Other (EUP, tolerances, protocols, etc.)	Total with Due Date Extensions
2008	29	94	142	31	10	306
2009	17	93	123	52	18	303
2010	73	104	181	78	34	470

When only primary decisions are considered, the 307 primary decisions with due date extensions were the following general type of actions. Of the 163 secondary decisions, over 40% were associated with new use applications and 33% with new active ingredient applications.

Number of Decisions with Due Date Extensions by Type of Primary Decision

	New Active Ingredient	New Uses	New Products	Amendments	Other (EUP, tolerances, protocols, etc.)	Total with Due Date Extensions
2008	13	50	136	30	9	238
2009	9	37	119	41	14	220
2010	20	37	170	53	27	307

Because of the increase in the percentage of applications with due date extensions since the beginning of PRIA, the Agency and representatives of the pesticide industry's trade associations undertook an analysis of the reasons for extensions. The analysis was conducted by workgroups by pesticide type – antimicrobial, biopesticide and conventional.

Antimicrobials

Comparison of Number of Primary Decisions with Due Date Extensions versus Total Number of Primary Decisions - Antimicrobials

Fiscal Year	FY 2008		FY 2009		FY 2010	
Type	Number with extensions	Total	Number with extensions	Total	Number with extensions	Total
New Active Ingredient	3	3	1	1		
New Uses	12	23	5	27	7	21
New Products	49	166	39	156	55	149
Amendments	7	110	13	96	19	90
Other (tolerances, EUP protocols, etc.)		3	2	4	8	8
Total	**71**	**305**	**60**	**284**	**89**	**268**

The Antimicrobials Division (AD) organized several meetings with representatives of the pesticide industry and trade organizations. The primary focus of these meetings was to present AD's analysis of the due date extensions in the 1st and 2nd quarters of FY 2010 and to identify possible process improvements. The outcome of the analysis found: product chemistry failures, deviations from standard protocols, denial of toxicity waiver request and rebuttals to Agency reviews, to be the basis for most of the extensions. Suggestions were made on how to improve product chemistry submissions and provide additional training venues for pertinent stakeholders. The Agency is currently evaluating the suggestions and will continue to work with industry, through open communication and outreach efforts focused on providing additional guidance and making stakeholders more aware of requirements. In addition, the industry representatives decided to survey their individual members, to see if any additional information could be provided. Their report is expected in FY 2011.

Biopesticides

Comparison of Number of Primary Decisions with Due Date Extensions versus Total Number of Primary Decisions - Biopesticides

Fiscal Year	FY 2008		FY 2009		FY 2010	
Type	Number with extensions	Total	Number with extensions	Total	Number with extensions	Total
New Active Ingredient	7	10	7	12	13	19
New Uses	4	5	4	6		
New Products	26	47	16	41	36	65
Amendments	2	11	5	25	11	20
Other (tolerances, EUP protocols, etc.)	4	12	3	21	2	4
Total	**43**	**85**	**35**	**105**	**62**	**108**

The Biopesticide and Pollution Prevention Division (BPPD) convened a series of meetings with representatives from the biopesticide registrant community to evaluate the current trend in extension rates for PRIA actions in BPPD, and to discuss potential process improvements. The group found that the primary causes related to recurring data deficiencies and certain technical shortcomings of applications. Short term recommendations from the group included measures for improving the quality of submissions, earlier screening and timelier communication of identified data deficiencies. The group also encouraged EPA to provide additional guidance, complete the rulemaking on plant-incorporated protectant data requirements and the associated testing guidelines, and endorsed the proposal for EPA to conduct a biopesticide registration improvement course, currently scheduled for April 2011.

Conventional

Comparison of Number of Primary Decisions with Due Date Extensions versus Total Number of Primary Decisions – Conventional

Fiscal Year	FY 2008		FY 2009		FY 2010	
Type	Number with extensions	Total	Number with extensions	Total	Number with extensions	Total
New Active Ingredient	3	11	1	5	7	7
New Uses	34	132	28	76	30	70
New Products	61	580	64	511	79	492
Amendments	21	194	23	216	23	195
Other (tolerances, EUP protocols, etc.)	5	28	9	73	17	47
Total	**124**	**945**	**125**	**881**	**156**	**811**

The Registration Division (RD) met with industry representatives and trade organizations, focusing on the rationale behind the due date extensions for "new use actions," "new product actions," and "non-fast-track amendments," that occurred during the first two quarters of FY 2010. The rationales for the majority of extensions fell into the following categories: risk concerns, product chemistry concerns, efficacy data issues, analytical method validation, and administrative issues. In turn, the group developed a list of areas for improvement: consider ways to address analytical method validation; evaluate ways to bridge product chemistry between different formulations; conduct parallel review with Agency offices; provide guidance on bridging residue data within crop groups; and evaluate a preliminary science screen to identify concerns early. The Agency is currently evaluating the options presented and working to develop a method to identify concerns early.

Note: Appendix A contains a list of all applications subject to PRIA completed during FY 2010 and includes the decision times for each decision. (Microsoft Excel Viewer EXIT Disclaimer is needed to view this file.)

Antimicrobial Time Frames

Section 33(k)(2)(E) directs the Agency to review its progress in meeting the timeline requirements for the review of antimicrobial pesticide products under section 3(h). The timeline requirement under section 3(h) for substantially similar or identical products is 90 days. Of the 57 decisions in fee category A530 completed in FY 2010, 37 (65%) were completed within 90 days and 43 (75%) were completed within the three month PRIA time frame. The remaining 14 met their extended due date. Of the 27 other substantially similar or identical products in fee categories A531 and A532, 21 were completed within their PRIA time frame of 4 months and the remaining 6 had due date extensions. Only 4 of these latter actions were completed within 90 days.

Regarding other new product decisions in fee categories A54, A540, and A550, the section 3(h) time frame is 180 days with a goal of reducing the review time to 120 days. Of the 67 decisions

in these fee categories, all met their PRIA due dates or extended due dates and 23 (34%) were completed within 120 days, and 35 (52%) were completed within 180 days.

Number of PRIA Applications Pending at the End of FY 2010.

Table IV – Number of PRIA Decisions Pending at the End of Fiscal Year (FY 2008 - 2010) summarizes the pending registration applications (counted as decisions) in each of the PRIA categories as required by FIFRA Section 33(k)(2)(v). As of September 30, 2009, 1151 decisions subject to PRIA were pending in the Agency's registration queue. Numbers pending at the end of FY 2009 and FY 2008 are shown for comparison, 1187 and 1129, respectively. The lower number of receipts accounted for the decrease in the number pending from FY 2009 of 36 or 3%. In general, receipts were either similar or fewer in all categories of actions except new active ingredients and antimicrobial amendments in FY 2010 in comparison to the two previous fiscal years.

The number of antimicrobial decisions pending (201) was higher than in FY 2009 and FY 2008, (188 and 179 respectively), reflecting the decreased number of completions (310 versus 342 and 336), while there was a slight decrease in receipts (355 versus 379 and 382). There was an increase in the number of amendments received by the Agency, and a decrease in the number completed which contributed to the overall increase in the pending.

The pending number of biopesticide decisions was higher in FY 2010 (154 versus 147) while receipts were stable (163 versus 161); however, approximately twice the number of new active ingredient decisions were received in FY 2010 compared to FY 2009. The time frame to complete a new active ingredient decision generally spans more than one fiscal year.

Among conventional pesticide decisions, the number pending at the end of FY 2010 was 796, down from 852 at the end of FY 2009, primarily because of a decrease in overall receipts – from 1265 in FY 2009 to 1163 in FY 2010 and in the number of amendments, protocol reviews and tolerance requests received.

Process Improvements in the Registration Program

FIFRA Section 33(e) directs EPA to identify and evaluate reforms to the pesticide registration process with the goal of reducing decision review times for pesticide registration applications. Section 33(k) directs the Agency to report its recommendations for process improvements in the handling of and streamlining of registration review. The Agency continued to make progress during the fiscal year in improving its operations. The Agency will not compromise the scientific quality of its assessments as a means of reducing decision times. The Agency believes that the best way to gather 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 from pesticide registrant companies, pesticide trade associations, public interest groups, and Agency staff. Meetings are open to the public and are held approximately twice a year. Reports

of the October 1, 2009, and April 28, 2010, PPDC PRIA Process Improvement Workgroup meetings are posted on the internet.

The Agency works with all stakeholders to evaluate potential improvements in the registration and registration review processes. Future projects and efforts are identified through a dialogue between the Agency and stakeholders. During Workgroup meetings, stakeholders present their priorities for process improvement and the Agency discusses the status of its improvement projects; previews new tools and proposed changes in procedures and processes; presents analyses of specific processes; and reports on its successes. The Workgroup has been monitoring the Agency's efforts to develop electronic application and analyses systems, improve the consistency of labeling, provide inert ingredient guidance, and implement other enhancements to help applicants develop complete and quality applications and to streamline the Agency's processes.

Improving Application Quality

The Pesticide Registration Manual was published on the Internet in March 2010. This update of the mid-1990's publication provides guidance on how to develop an application for a pesticide product registration. Links are provided directly to forms, statutes, guidance, references and background materials, and other application resources. Stakeholders have been providing comments and suggestions for improvement, which the Agency is using to revise it. User comments are encouraged. The Manual is updated whenever new guidance or policies become available to ensure that users have access to the most recent information.

Electronic tools are being developed to improve applications. The Agency encourages applicants to develop study summaries using either the NAFTA (North American Free Trade Agreement) or OECD (Organization for Economic Cooperation and Development) templates to ensure that all report elements are addressed. OPP Study Profile templates are available on the EPA Website as user-friendly templates in Microsoft Word format for most guideline studies including:

- Product Chemistry: Series 830
- Environmental Fate: Series 835
- Environmental Effects: Series 850
- Chemistry: Series 860 - Residue Chemistry Test Guidelines
- Toxicology: Series 870 - Health Effects Test Guidelines
- Occupational / Residential: Series 875 - Occupational and Residential Exposure Test Guidelines

The development of the Study Profile templates was the outcome of a joint effort with Health Canada. Since the Study Profile template design is based on the Agency's existing Data Evaluation Record (DER) format, we anticipate that the use of these templates will expedite and facilitate the review of submitted data.

The Antimicrobials Division took a number of steps to make stakeholders aware of processes and policies, which included developing final guidance on antimicrobials used in the Fermentation of Fuel Ethanol; publishing final guidance on the use of disinfectants and sanitizers in Heating, Ventilation, Air Conditioning, and Refrigeration (HVAC&R) Systems; and

developing draft 810 Product Performance Test Guidelines, which will be finalized in 2011. The Antimicrobials Division also updated its Antimicrobials Testing Program Web pages.

In addition, AD developed a draft mold Pesticide Registration Notice, published a Prions Notice of Proposed Rule Making (NPRM), and supported the development of an OECD Quantitative Method, which will involve registrants and stakeholders in moving forward in its adoption. It hosted a summit attended by representatives of the American Hospital Association, D.C. Hospital Association, and several trade groups. The conference was designed to facilitate a discussion of infection reduction concepts and included topics such as scientific concepts, labeling, claims, guidelines, and educational programs. In an effort to better inform this stakeholder group, the Antimicrobials Division began distributing product efficacy news via a Hospital Newsletter distributed by the Region 1 Healthcare Sector Coordinator.

The Division made several formal presentations and also participated on committees focused on improving stakeholder information and raising awareness of the antimicrobial registration process, including:

- Bi-monthly meetings with the American Chemical Council Biocides Panel and quarterly presentations at Consumer Specialty Products Association conferences.
- Spring Conference of the Food, Drug, and Cosmetic Packaging Materials Committee (FDCPMC), a committee of the Society of the Plastics Industry (SPI). The committee develops SPI positions on food, drug, and cosmetic packaging issues, and other plastic food contact applications.
- Several national conferences, such as ASHES 2010 (American Society for Healthcare Environmental Services), APIC 2010 (The Association for Professionals in Infection Control and Epidemiology, Inc.), and the annual Informa LifeScience's Biocidal Products Directive, held in Lyon, France.
- FDA Food Code Subcommittee for Food Contact Sanitizers.

The Biopesticides and Pollution Prevention Division emphasizes pre-registration meetings to discuss how data requirements can be met and possible data waiver requests and provides the prospective registrant a detailed, step-by-step list of data requirements with a focus on product chemistry. To facilitate these meetings for biochemicals and microbial pesticides, a meeting coordinator arranges and conducts these meetings. Approximately 90% of meetings are now held within two weeks of a request. The Division continued quarterly meetings with the Biopesticide Industry Alliance to discuss PRIA and other common issues and with the United States Department of Agriculture (USDA) Inter-Regional Research Project Number 4 (IR-4) program, and monthly teleconferences with USDA's Animal Health Inspection Service and the Food and Drug Administration on Plant Incorporated Protectants.

The Registration Division meets twice yearly with CropLife America and quarterly with major conventional pesticide registrants and participates in meetings of the Chemical Producers and Distributors Association, the Consumer Specialty Products Association, Responsible Industry for a Sound Environment (RISE), the Armed Forces Pest Management Board, and the IR-4 Technical Working Group and with public interest groups to discuss application issues.

Through the PRIA Website, the public can submit questions regarding PRIA implementation. Questions are typically answered within 24 hours. Questions are also addressed by registration Ombudsmen. The Ombudsmen help applicants with issues related to identifying an application's fee and fee category, the implementation of PRIA 2, the registration process, and completing application forms.

Improving the Registration Process

The Agency's success in meeting due dates is a result of its continued monitoring of the status of PRIA decisions and identification of efficiency measures that conserve resources and time. Processes described in past annual reports were continued in FY 2010 with some enhancements. To decrease the amount of time spent in developing documents, Biopesticides staff developed templates for internal routing and decision documents and streamlined the Biopesticides Registration Action Documents into a more user friendly format.

Electronic Submission and Document Retention

The Agency is using information technology to improve the efficiency of the pesticide registration program and reduce the paperwork burden on both the Agency and the public.

In July 2008, EPA's Office of Pesticide Programs announced it would receive pesticide submission packages in electronic form or e-Registration submissions following a pilot project conducted in FY 2007. The Agency published a *Federal Register* Notice and provided guidance on the Web. The types of applications currently being accepted electronically are Section 3 New Applications, Section 3 Amendments, Experimental Use Permits, Petitions for Tolerances, and applications for Supplemental Distributor Products. The Agency also established an e-Submission Help Desk in May 2008 to assist applicants with their questions about formatting their e-submission and to provide step-by-step direction to ensure the validity of the submission.

The e-Submission Module of the Agency's tracking system, Pesticide Registration Information System (PRISM) supports the processing of the documentation required for pesticide applications. Traditionally, this paperwork has been submitted in hardcopy form. The E-Submission initiative helps EPA move toward a more paperless environment. The information exchange from industry to EPA is based on a harmonized XML schema adapted from Canada's Pest Management Regulatory Agency (PMRA). This harmonization ensures that a submission package submitted to one participating regulatory agency can likewise be submitted to any of the other participating agencies, thus increasing standardization and decreasing the burden on pesticide applicants. Once the package is received by EPA, its contents are parsed and validated, thereby promoting data quality. The data submitted are then used to pre-populate data entry screens in an effort to save processing time and decrease the burden on EPA. Finally, the e-Submission module is fully integrated with PRISM's core data repository for registration information and its document management repository. When the incoming package has been processed, the data and documents are seamlessly blended into other PRISM components (Document Management Workflow) for processing within the pesticide program. PRISM was enhanced to accept electronic registration (e-Registration) documents to make these documents available on-line at any time to the multiple users simultaneously processing registration actions. E-Submission/e-Registration will improve processing times, data quality and completeness;

reduce data entry and the number of data entry iterations; and improve document management. In addition, EPA is actively working with OECD to develop a common, globally accepted standard for the transport of electronic data to various international regulatory authorities. By conforming to a single standard, registrants will have to produce only one submission package for submission to multiple countries, reducing time and resources required for multinational submissions.

For FY 2010, OPP received 462 e-submission application packages. A total of 9894 documents (such as forms, correspondence, study reports, and labels) were associated with these 462 packages out of a total of 3888 application packages submitted.

Number of FY 2010 e-Submissions Compared to Paper Submissions

Quarter	Number e-Submission Packages	Number of Documents	% of all e-Submissions rejected	Number Paper Application Packages	% e-Submissions of Total
1st	58	715	12%	891	6%
2nd	150	3626	19%	656	19 %
3rd	139	3024	17%	794	15 %
4th	115	2529	27%	1085	10 %

As a result of scanning documents and storing e-Registration documents in Documentum, OPP currently has a Documentum library of over 220,322 documents available electronically, an increase of 36,847 documents from FY 2009. Documents stored in the library consist of studies, forms, letters, and labels.

Public Participation Process

Federal pesticide law only requires limited public participation in the pesticide registration process. In response to the President's directive on transparency and open government, EPA explored opportunities for expanding the openness of the process, and in October of 2009, began implementing a public participation process for certain registration actions.

By establishing this process, the Agency increased opportunities for the public to comment on risk assessments and proposed registration actions. Both EPA and the public will benefit from a public participation process because the public will help to inform the risk assessment and risk management processes associated with registration. Such input can aid in understanding potential risks and benefits, contribute to meaningful protective measures, and improve the public dialogue on pesticide registration decisions. The Agency intends to continue to use the outlined public participation process for the following types of applications:

- new active ingredients;
- first food use;
- first outdoor use;
- first residential use; and
- other actions of significant interest.

In FY 2010, the Agency issued 43 decisions for public comment, of that, 2 were antimicrobial pesticides, 31 were biopesticides, and 10 were conventional chemicals. For additional information, please see http://www.epa.gov/pesticides/regulating/registration-public-involvement.html.

Electronic tools are being developed to facilitate processing and to review applications. Improvements in tools used to conduct risk assessment are also expected to increase the efficiency of the registration process.

Maintenance Fees

Reregistration and Expedited Processing Fund

In FY 2010, $0.7 million (supporting 4.8 work years) from the Reregistration and Expedited Processing Fund (maintenance fees or yearly registration renewal fees) was used to carry out new inert ingredient reviews under section 4(k)(3). An additional $2.4 million from this fund was used to process fast track amendments and new products under FIFRA Section 3(c)(3)(B.

During FY 2010, the Agency's obligations charged against the Reregistration and Expedited Processing Fund to offset the cost of the reregistration and registration review programs and other authorized pesticide programs were $24.5 million and 143.0 work years. The Fund has two types of receipts: fee collections and interest earned on investments. Of the $22.1 million in FY 2010 receipts, more than 99.9% were fee collections.

Appropriated funds are used in addition to Reregistration and Expedited Processing Fund dollars. In FY 2010, the Enacted Operating Plan included approximately $40.0 million in appropriated funds for reregistration and registration review program activities. This supported 208.1 work years and $7.2 M in contract support, which included data reviews, systems maintenance and enhancements, and other expenses. The unobligated balance in the Fund at the end of FY 2010 was $1.7 million, including recoveries of prior year unpaid obligations.

Inert Ingredients

Pending Inert Ingredient Reviews at the End of FY 2010

FIFRA section 33(k)(2)(F) requires EPA to report the number of inert ingredients (inerts) pending review by the Agency. In FY 2010, one new petition for a food use inert was received as a PRIA action and an additional 30 new petitions were received as non-PRIA 2 actions. When PRIA was reauthorized, a request to approve an inert submitted with an application to register a conventional new product became subject to registration service fee requirements.

In FY 2010, 40 Final inert ingredient Tolerance Rules were published and six petitions were withdrawn due to deficiencies. At the end of FY 2010, there were 40 petitions in various stages of review. Inert ingredient tolerance petitions are reviewed in the order received. The Agency estimates that the average review time is 3-6 months for a polymer exemption petition and approximately 12 months (including data review, science assessment, decision document, and Final Rule) for a new inert petition. All new petitions are screened for deficiencies before being scheduled for review, and EPA works with petitioners to discuss the reliability and adequacy of

the data to meet the FQPA (Food Quality Protection Act) safety finding. In FY 2010, an additional 41 non-food use approval requests were granted and three non-food use requests were withdrawn or denied. Four non-food requests were pending at the end of FY 2010.

The Inert Ingredient Assessment Branch (IIAB), consisting of nine employees at the end of FY 2010, reviews inert ingredient actions. When needed, IIAB staff is supplemented with staff in other pesticide regulatory groups, particularly to review inert ingredients associated with biopesticide and antimicrobial products.

Process Improvement in Inert Ingredient Reviews

In 2010, IIAB published several guidance documents on the Web, including guidance for submitting food use tolerance petitions and non-food use requests, guidance for polymer exemption submissions and updated inert ingredient frequently asked questions. These documents will help individuals develop and submit inert ingredient approval requests as demonstrated by recent improvements in the quality of submissions. These improvements reduced the time spent by the IIAB staff working with the registrant in making necessary corrections. The IIAB has developed a computerized system to enable the public to find a list of approved inert ingredients. Currently, it is undergoing testing and will be made available to public in the near future.

Expedited Processing (FIFRA Section 3(c)(3)(B))

Under Section 33(k)(2)(A)(iv), the Agency is to report the number of applications completed for identical or substantially similar applications under section 3(c)(3)(B), including the number of such applications completed within 90 days pursuant to that section. There are two types of identical or substantially similar applications, new products and label amendments that require no data review. The former have been called in the past "Fast Track New Products" while the label amendments are still called "Fast Track Amendments".

Identical or substantially similar new products (formerly "Fast Track New Products") are subject to registration service fees, have mandated decision review time frames under PRIA and processing costs are also supported by maintenance fees. With the passage of PRIA 2, identical or substantially similar products, or Fast Track New Products, were further subdivided into additional fee categories, some of which have time frames greater than three months. The number of identical or substantially similar products with a three month time frame (A530, B660, B710, and R300) completed in FY 2010 was 346 of which 238 were completed within 90 days, 295 were completed within their three month PRIA time frame and the remainder had due date extensions. An additional 63 identical or similar new products with time frames of greater than three months (A531, A532 and R301) were completed (53 within the PRIA statutory time frame and 10 with due date extensions). In comparison to FY 2009, the number of decisions with a three month time frame completed in FY 2010 increased (346 versus 299) and was comparable to the 358 completed in FY 2008. The number of decisions completed with longer time frames decreased in comparison to FY 2009 (63 versus 74) though greater than the 37 completed in FY 2008. The percentage of three month time frame decisions completed within three months was 85%, less than in FY 2009 (92.6%) and FY 2008 (92.4%).

The time frame for "Fast Track Amendments", label amendments that required no data review, remained 90 days under PRIA 2 and these amendments are not subject to registration service fees. In FY 2010, the Agency completed 3384 fast track amendment decisions or actions (unaudited results - antimicrobial 1385, biopesticide 142, and conventional 1857), which was a substantial increase over the 2640 completed in FY 2009. The majority of the increase was due to the 60% increase in antimicrobial amendments (1385 versus 864). These "decisions" had 3947 submissions (1440, 207, and 2300, respectively). Each decision can have a number of submissions, each with a time frame of 90 days. Of these submissions, 3602 were completed within 90 days (1430, 125, and 2047, respectively).

Pesticide Reevaluation Programs: Product Reregistration and Registration Review

Status of Product Reregistration

Overall Accomplishments

Product reregistration is EPA's program for implementing reregistration eligibility decisions by ensuring that required risk reduction measures are reflected on pesticide product labels. EPA has completed its review of the safety of pesticide active ingredients first registered before November 1984 through the reregistration program. The results of EPA's reviews are summarized in Reregistration Eligibility Decision (RED) documents available on the Agency's Pesticide Reregistration Status Website. After the Agency completed a RED for a pesticide active ingredient and declared it eligible for reregistration, individual end-use products that contained the pesticide active ingredient still were required to be reregistered.

As of the end of FY 2010, 22,039 pesticide products were subject to product reregistration. EPA has completed decisions for 12,980 of these products and still must complete decisions for 9,059 products. EPA expects to complete product reregistration in 2014.

FY 2010 Progress and Goals

During FY 2010, EPA completed 1,718 product reregistration decisions, significantly exceeding its goal of 1,500 decisions. EPA's goal is to complete 1,500 product reregistration decisions in FY 2011.

Historical Product Reregistration Decisions

	FY 02	FY 03	FY 04	FY 05	FY 06	FY 07	FY 08	FY 09	FY 10
Products reregistered	77	53	78	104	169	529	679	603	484
Products amended	51	40	35	63	40	80	205	292	40
Products cancelled	186	213	14	342	297	370	309	869	1,188
Products suspended	0	5	0	0	0	0	3	5	6
TOTAL	**314**	**311**	**127**	**509**	**506**	**979**	**1,196**	**1,769**	**1,718**

REDs with Product Reregistration Decisions Completed

As of the end of FY 2010, EPA has completed product reregistration decisions for 220 REDs (out of a total of 384 REDs). These 220 REDs include 27 of the 31 organophosphates (OPs).

Status of Registration Review

Overall Status

EPA is continuing to meet all registration review targets consistent with overall program objectives. At the end of FY 2010, out of a universe of over 700 registration review cases including over 1,100 pesticide active ingredients, 216 cases are past the docket opening stage, 178 cases are past the Final Work Plan stage, and 22 registration review final decisions have been issued.

FY 2010 Accomplishments

During FY 2010, the pace of registration review continued to accelerate. 75 new dockets were opened by three OPP Divisions. These Divisions completed 70 Final Work Plans and 10 registration review final decisions.

Registration Review Progress FY 2007 – FY 2010

Fiscal Year	Dockets Opened	Final Work Plans Completed	Final Decisions Completed
FY 2007	25	13	--
FY 2008	46	34	3
FY 2009	70	61	9
FY 2010	75	70	10
Total	**216**	**178**	**22**

In FY 2010, EPA continued to open dockets for new registration review cases at the pace that must be maintained for the next seven years in order to finish the initial 15-year cycle on schedule in 2022. FY 2010 featured six additional registration review preliminary risk assessments, for the conventional pesticides urea sulfate, alliette, carbon and carbon dioxide, inorganic nitrates/nitrite, and sulfur. These preliminary risk assessments were published for public comment. The Agency and the Services (Fish and Wildlife Service and National Marine Fisheries Services) are continuing a collaboration to improve the process of preparing pesticide risk assessments for consultation under the Endangered Species Act, using clomazone as a pilot case.

Schedule for FY 2010 and Beyond

EPA plans to issue an updated schedule for the registration review program in early 2011. The schedule provides the timeline for opening dockets for the next four years, from FY 2011 to 2014, and includes information on dockets that opened in FY 2007 through FY 2010. The schedule reflects EPA's plan to open about 70 new dockets each year through 2017. This keeps

the Agency on track to complete the first 15-year cycle of registration review by October 1, 2022, for all pesticides registered as of October 1, 2007. EPA plans to continue to update the registration review schedule at least annually.

Registration review cases for which Final Work Plans have been developed are proceeding through the Data Call-In process toward the acquisition of data needed to produce risk assessments consistent with current science, policies and regulatory requirements. The Agency anticipates publishing additional preliminary risk assessments for public comment and completing additional final decisions during FY 2011.

Process Improvements in Pesticide Reevaluation Programs

The Agency continued to place a significant emphasis on improving the timeliness and overall productivity of the product reregistration program. As a result of these efforts, the Agency again significantly exceeded its product reregistration goal for the fiscal year and is making good progress toward meeting its long term goal of completing product reregistration in FY 2014. It is important that EPA complete product reregistration within the next few years so that mitigation measures required by REDs will be included on pesticide product labels, and so that the Agency can divert vital resources to the registration review program and ensure that we complete the first 15-year cycle of registration review by October 1, 2022.

The Office of Pesticide Programs (OPP) began successfully implementing a Memorandum of Understanding for Work-sharing on Product Reregistration, developed by two OPP divisions to increase their productivity in FY 2010 and beyond. The MOU, signed in October 2009 by the Antimicrobials Division and Pesticide Re-Evaluation Division (PRD), established the parameters of a mutually beneficial work sharing agreement for product reregistration. Through this agreement, PRD has been able to address a previous backlog of needed science reviews, while AD has obtained additional knowledgeable and experienced staff to help conduct product reregistration. By sharing existing resources and expertise and redistributing the workload, a mutually beneficial outcome is being achieved by these divisions at no greater expense to the Agency. Product reregistration decisions are being completed more quickly, speeding the delivery of risk mitigation measures and achieving important human health and environmental protection goals. Meanwhile, the work share arrangement has improved the consistency of science and label reviews across OPP. The agreement is an excellent example of applying innovative thinking in a resource-constrained environment.

An important step toward completing product reregistration was achieved by refining the number and status of products in the product reregistration universe. By identifying and including products that were canceled between the time when REDs were signed and product-specific Data Call-Ins (DCIs) were issued, the Agency has been able to more precisely define the universe of products that are subject to product reregistration. We can now more accurately track the status of all products undergoing product reregistration, describe the Agency's progress in meeting program goals, and solidify plans to complete the remaining product reregistration decisions during the next few years.

Process Improvements in the Pesticides Program

A number of process improvement activities support both the registration and the re-evaluation programs.

Electronic Labels

Acknowledging the Agency's efforts in this area, Congress required EPA [under PRIA 2, FIFRA Section 33(k)(2)], to report the number of label amendments reviewed using electronic means and to make recommendations for electronic submission and review of labels, including process improvements to further enhance the procedures used in electronic label review. The Agency's specifications and procedures for submitting electronic submissions (including electronic labels) can be found at: http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm.

FY 2010 represents the first full year that the Agency's tracking systems have been recording statistics regarding submission and review of electronic labels. A summary of this information is presented below:

FY10 Labels Submitted

Type of Product	# labels submitted	% electronic labels
Antimicrobial	2,491	5 %
Biopesticide	425	9 %
Conventional	7,362	19 %
Total	**10,278**	**15%**

Conclusions:

1) Of approximately 10,300 label actions submitted to EPA in FY 2010, 15% included an electronic label.
2) Of the label actions completed by EPA in FY 2010 that included an electronic label, 33% were reviewed electronically.

Note: The number of labels submitted versus the number of e-labels reviewed electronically should not be compared to each other since they count different labels. Labels are usually not reviewed until any studies submitted with an action have been reviewed. Therefore, labels submitted in FY 2010 may not be reviewed until a later year. Conversely, label reviews completed in FY 2010 may have been submitted in earlier years.

Since this was the first full year that these data were recorded it is difficult to compare them to the estimates reported for FY 2009 (which were estimated from data for one quarter). In general, the % of labels submitted in electronic format seems to be about the same but the % of e-labels reviewed electronically may have decreased. To increase the number reviewed electronically, registrants are encouraged to submit more labels in electronic format and more training will be provided to Agency staff to encourage use of the e-label review tools.

Labeling Committee

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 (LRM). A Label Review Manual Team was formed to revise and update the LRM, completed in 2009. In 2010, EPA began to solicit comments on the LRM from State pesticide regulatory agencies and the general public. State agencies collect comments through the working committees of the State FIFRA Issues Research and Evaluation Group (SFIREG) and send them directly to the Labeling Committee. Public comments, primarily from pesticide registrants, are received through a web-based discussion forum. Since the Agency has requested comments on one or two chapters of the LRM at a time, the process of commenting on all 18 chapters will likely extend into the spring of 2011. The purpose of asking for comments is to seek clarification of language, improved examples and needed updates to make the LRM more useful to both EPA and other stakeholders.

The Committee developed a Web site to communicate its activities and to address the public's general labeling policy questions forwarded through the Web site's e-mail address (OPP_labeling_consistency@epa.gov), a major activity of the committee. The Committee receives about 75 to 100 questions per year, with close to 400 questions since the site began. Answers to the majority of questions are posted, but all questions receive a direct response.

The Committee from time to time publishes issue papers on its Web site. For example an issue paper on Chemigation (PDF, 6pp, 63.8kb) was made available for comment in December 2008. The site is also used to publish compact summations of selected policies that might otherwise be difficult for interested parties to locate, for example, the Agency's policy on warranty and disclaimer statements .

Science Review Improvements

OPP Science Policy Council

The Agency continued to improve the scientific basis of its review of and decision-making on applications. OPP Science Policy Council has been operational for two years. The purpose of the council is to enhance the consistent use of the best available science in regulatory decisions and policies by providing a central forum that assists in identifying critical issues in pesticide safety, formulating solutions, and in transitioning new science, methodologies, and policies into the pesticide program. Over the next several years, the Agency will improve and transform its approach to chemical risk management by enhancing its ability to use integrated approaches to testing and assessment in a manner consistent with the 2007 National Research Council (NRC) of the National Academy of Sciences report on Toxicology Testing in the 21st Century. An integrated approach will enhance the quality and efficiency of risk assessment and risk management decisions. A priority of the Council is to promote this transition. In FY 2010, the Council focused on a number of cross-cutting science issues relevant to this objective including updating workplans on the development of new computational toxicology methods and providing input to the Office of Research and Development on priority research needs in the area of environmental risk assessment.

Ecological Risk Assessments

The Agency continued to improve its review and communication of ecotoxicity studies through the following efforts: joint review/work sharing of study reviews with other countries; harmonization of ecotoxicity endpoints with other EPA programs; verification of drift reduction technologies; development of new models; training, outreach activities, and development of risk assessment approaches for pollinators; development of harmonized approaches to estimate toxicity to aquatic life; and publication of peer-reviewed ecotoxicity values. Examples of these improvements include the following:

OECD Activities: Working with the Organization for Economic Cooperation and Development (OECD), the Agency identified more efficient means to conduct joint reviews and work sharing, thus reducing review times and workload.

The Agency also worked with OECD members to develop a survey to address issues related to pollinator declines, a topic of concern to OECD member countries. The EPA and the Canadian Pest Management Regulatory Agency (PMRA) took the lead in developing the survey instrument, with input from Germany and the European Food Safety Authority. In 2009, the survey was distributed by the OECD to member states. The final survey consisted of questions related to the importance of pollinators, including managed honeybees (*Apis mellifera*), in agriculture and observations on factors associated with pollinator declines, management of bee mortality incident information, regulatory toxicity testing requirements for pollinators, the range of potential regulatory responses to pollinator declines as they relate to the role of pesticides, and on-going research efforts related to declines in pollinator populations.

In 2010, the OECD published the results of this pollinator survey. A high percentage of respondents indicated that declines in bee populations have been documented in their country, and that declines have also been observed in other pollinator populations. Disease, parasites, winter losses, and pesticides were factors most frequently associated with the declines in pollinators. Most countries require reporting of honeybee-kill incidents; predominantly beekeepers themselves report this information. The incident information is mostly not accessible electronically. Almost half the countries indicated that they are considering expanding toxicity testing requirements to include studies on the toxicity of residues on pollen and in nectar and on potential effects on brood. The most frequently reported regulatory response to mitigate the potential effects of pesticides was label restrictions, rather than voluntary (non-mandatory) practices.

Based on the survey, there were a number of recommendations which a subgroup will explore in more detail. These include (1) developing options for efficiently communicating information on pollinator incidents among countries; (2) developing/enhancing study designs to better assess sub-lethal effects and potential effects of systemic pesticides on pollinators; (3) sharing risk management tools (e.g., labeling) and methods for testing the effectiveness of risk reduction measures for pollinators; and (4) establishing a communication "clearinghouse" on research efforts related to pollinator declines to facilitate coordination and collaboration of research activities.

OPP is also a member of the newly formed OECD Pesticide Effects on Insect Pollinators (PEIP)

sub-group of the Pollinator Expert Group. This sub-group will be examining the extent to which pesticides and other factors may be contributing to the phenomenon referred to as Colony Collapse Disorder (CCD) and pollinator declines in general and provide early alerts on key research findings to regulatory authorities. PEIP is intended to address four main goals:

(1) develop a mechanism for efficiently communicating accurate and necessary information on pollinator incidents among regulatory authorities of member countries;
(2) review study designs for pollinator toxicity tests to determine if they can be enhanced or if new tests are needed to better assess acute, chronic, and sub-lethal effects on pollinators and to develop such guidelines;
(3) develop a mechanism for sharing risk management tools, including precautionary labeling, use restrictions, technologies, training materials, best management practices, and integrated pest management practices used by different countries to mitigate pollinator risks and to recommend when and how tools should best be applied and characterize their effectiveness; and
(4) establish a communication "clearinghouse" on research efforts to facilitate coordination and collaboration of research activities.

Pollinator Issues: OPP continued to reach out to and meet with stakeholders who are involved in pollinator issues. These stakeholders included representatives of the National Honey Bee Advisory board (NHBAB), pesticide registrants, academic researchers, environmental groups, and officials from other federal and state government agencies and offices in EPA. OPP staff also participated in several seminars, conferences, and scientific meetings concerned with pollinator issues this year. In preparation for an upcoming Society of Environmental Toxicology and Chemistry (SETAC) Pellston conference in January 2011, OPP contributed to the development of white papers that lay the groundwork for advancing a global risk assessment process and test methodologies for pesticides with a particular emphasis on systemic pesticides. Finally, OPP sponsored training courses for science staff on bee biology in conjunction with USDA, the Xerces Society, and University of Maryland.

Birds and Mammals – Drinking Water Model: OPP implemented the Screening Imbibation Program (SIP v. 1.0) this year. The purpose of this drinking water model is to provide an upper-bound estimate of exposure of birds and mammals to pesticides through drinking water alone. The model, which is intended for use in the initial stage of risk assessments (i.e., problem formulation), is based on the solubility of the pesticide and the maximum daily intake of birds and mammals. More information about SIP can be found at: http://www.epa.gov/oppefed1/models/terrestrial/index.htm#sip.

Inhalation Exposure Screening: OPP developed the Screening Tool for Inhalation Risk (STIR), a model that estimates inhalation-type exposure based on various pathways by which birds or mammals may be exposed. This screening tool incorporates exposure from droplet inhalation immediately after pesticide application as well as vapor phase inhalation. Droplet inhalation exposure is calculated by determining the amount of pesticide sprayed over a defined area based on an assumed duration of time that the pesticide will remain in the air column. Using the application method and rate of application, modelers can compare exposure estimates with avian and mammalian toxicity data. STIR also addresses the potential volatilization of residues from the treated crop canopy and the soil by calculating the theoretical maximum air concentration at a specified distance above the treated field. This screening model is primarily used by science

staff within the Environmental Fate and Effects Division to determine if further data and analysis are needed to account for potential risks through inhalation.

Aquatic Life Benchmarks: In response to requests from FIFRA state lead agencies and state water quality agencies, EPA published 112 additional "benchmark" values for pesticides that can be used to interpret monitoring data and to identify and prioritize sites for further monitoring. The benchmarks, which are based on the most sensitive aquatic toxicity data, are estimates of the concentrations below which pesticides are not expected to harm aquatic life. The Agency has made benchmark values for 260 pesticides available to the public by posting them on its Aquatic Life Benchmark Web site and has developed a public docket providing easier access to the full ecological risk assessments for these pesticides. The Aquatic Life Benchmarks have been used by federal agencies, states, and others in interpreting monitoring data and in planning future monitoring efforts. EPA plans to update the webpage and accompanying docket annually, and to add to the number of chemicals represented. Information concerning these benchmarks can be found at the following web site:
http://www.epa.gov/oppfead1/cb/csb_page/updates/2007/aquatic-life.htm.

OPP/OW Harmonization of Aquatic Life Assessments: In response to concerns raised by states and other stakeholders, EPA's Office of Pesticide Programs (OPP) together with the Office of Water (OW) and the Office of Research and Development (ORD) developed documents that describe their initial thinking on a harmonized approach for assessing aquatic toxicity data in OPP and OW. In FY 2010, the three offices held six regional stakeholder meetings to solicit input from the public regarding methods, tools, and approaches for developing a consistent and common set of effects characterization methods for both programs. After the regional stakeholder meetings, the three EPA offices developed three white papers that explored methods for estimating aquatic toxicity data, approaches for deriving community-level benchmarks, and procedures for better integrating plant effects into community-level assessments. These white papers were presented at a national stakeholders meeting in Washington, D.C. on December 1, 2010. Input from the regional and national meetings will be used to develop an OPP/OW harmonized approach for assessing aquatic toxicity data. Additional information about this topic is available on the following web site:
www.epa.gov/oppefed1/cwa_fifra_effects_methodology/index.html

Drift Reduction Technologies: In FY 2010, the pesticide program continued to work with EPA's National Risk Management Research Laboratory (NRMRL) to identify and verify effective pesticide spray drift reduction technologies (DRTs). Under the Environmental and Sustainable Technology Evaluation (ESTE) program, EPA developed a draft verification protocol (DRT). The DRT testing protocol was adapted from standard test methods and regulatory methods used in other countries and describes the testing approach that will be used to generate high-quality, peer-reviewed data for DRTs, including test design and quality assurance aspects. Both low-speed and high-speed wind tunnel tests were completed this year using a reference nozzle and two test nozzles to evaluate the performance of the generic DRT testing protocol. By the summer of 2011, EPA plans to finalize this testing protocol based on the test results attained by EPA and stakeholders. As a next step, EPA intends to encourage equipment manufacturers to voluntarily use the protocol for testing their equipment. Additional information is available on the following web site: http://www.epa.gov/etop/etc_at_psdt.html.

Atrazine Monitoring Issues: In April 2010, OPP scientists participated in a FIFRA Scientific Advisory Panel meeting that focused on issues related to the Agency's review of mammalian *in vivo* and *in vitro* studies and approaches for evaluating drinking water monitoring frequency for atrazine. During the meeting, OPP scientists presented their approaches for evaluating water sampling strategies and frequency of monitoring, and statistical evaluation of sampling performance for estimating maximum concentrations of atrazine of different durations. They also presented the agency's artificial neural network modeling of atrazine occurrence patterns. Other issues that were presented and a summary of the meeting can be found at the following web site: http://www.epa.gov/scipoly/sap/meetings/2010/091410meeting.html.

In FY 2010, the Agency continued its efforts to incorporate tools in its aquatic risk and exposure assessments that will enable the Agency to identify specific geographic spatially explicit locations where risks may occur. As part of this effort, the Agency acquired and developed data, including the national-level SSURGO (Soil Survey Geographic) soils data, updating its land use data with the 2007 NLCD (National Land Cover Database), and deriving hydrograph data sets from the national NHD (National Hydrography Dataset) – as well as improving its tools to provide more accurate and relevant information about the potential effects of pesticides in the environment. These data and tools, which are being used in the Agency's risk assessments, allow EPA to more quickly identify the landscapes and water bodies that are most vulnerable to pesticide impacts on drinking water sources and on aquatic species, including endangered species. EPA plans to expand the use of these tools and data to endangered species assessments in 2011.

Human Health Risk Assessments

Science review committees. The Residues of Concern Knowledgebase Subcommittee (ROCKS) continues to lead the application of predictive Tox 21 tools for metabolites, residues, and environmental degradation products. In calendar year 2010, the Dose Adequacy Review Team (DART) met eighteen times on seventeen different chemicals. The Cancer Assessment Review Committee (CARC) met seven times on numerous chemicals, and the Toxicology Science Advisory Council (ToxSAC) met thirteen times in order to discuss and determine end-points of concern on thirteen different chemicals.

Integrative Testing and Assessment: A NAFTA Joint Integrative Testing and Assessment (IATA) Project has been formalized to include use of computational tools such as (Q)SAR and MetaPath. Included in this NAFTA project is the development of a guidance document for use of (Q)SAR in pesticide risk assessments. This is an on-going project which includes collaboration between EPA, PMRA, and FDA. The MetaPath project has been formally adopted as an OECD joint project under the Pesticide Working Group. A MetaPath Users Group (MUG) has been established to further explore opportunities to use MetaPath in global pesticide risk assessments and continue its database development, along with the customization of the MetaPath DER Composer. Current international collaborators include: Health Canada, PMRA, the European Food Safety Authority (EFSA), the Australian Pesticides and Veterinary Medicines Authority (APVMA), France, and Germany.

Many other projects reported in the FY 2009 report continued in FY 2010.

Other Activities

Use of Outside Reviewers

The Agency continued its work-sharing efforts with Canada's PMRA, APVMA, and the European Union (EU). In global and 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 national authorities. One new conventional active ingredient was registered in FY 2010 after a global review and ten others were in review. Six actions were completed as work-share projects with PMRA in FY 2010. In addition, Japan and Brazil began participating in the joint review process, increasing the number of joint review partners. Eight new biopesticide active ingredient joint PMRA/EPA reviews were pending at the end of FY 2010. An additional five are expected to begin in FY 2011.

In FY 2010, PMRA and EPA also implemented a work-share process for minor uses for those chemicals/crops that can not be completed as a joint review. Three minor use actions on six commodities were completed as part of the NAFTA work-share program. Two joint reviews were completed in FY 2010 for seven commodities. Nine additional active ingredient minor use chemicals (11 commodities) are expected to be evaluated under the NAFTA joint review program and four chemicals (6 commodities) are expected to be evaluated as work-share projects.

The Biopesticides and Pollution Prevention Division developed an internal Standard Operating Procedure for its staff on various aspects of the joint review process and how to approve a NAFTA label and established a work plan for these reviews. The document, "Updated Procedures for the Joint Review of Biopesticides" will inform applicants and other interested groups about the joint review process for microbial and biochemical pesticides.

EPA also continued working with the California Department of Pesticide Regulation (CDPR) to expand capacity to review residue chemistry studies and conduct dietary risk assessments in support of registration decisions. In FY 2010, CDPR reviewed the residue chemistry studies for two active ingredients and 10 representative commodities or crops.

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 the Agency's risk assessments. The level of contractor support in FY 2010 was approximately the same as in past fiscal years under PRIA 2, and approximately 80% of the Pesticide Program's active contracts or work assignments were performance-based, the same as FY 2009. 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.

Table I – PRIA Funded Pesticide Safety Education & Worker Protection Activities FY 2010		
Recipient & Mechanism	**Activity and Accomplishments**	**FY 2010 PRIA Funds**
U.S. Department of Agriculture - interagency agreement to pass funds to state cooperative extension services	PRIA funds provide partial support for state level pesticide applicator safety training (classroom, manuals, on line media) to develop competency for existing and future certified pesticide applicators in using restricted use pesticides safely. The training focuses on a population of applicators (approximately 900,000 commercial and private applicators) who can suffer high exposure and risk themselves, or subject others to high exposure and risk, if not trained to meet competency standards that help ensure safe pesticide applications. Through an interagency agreement with USDA, we transferred funds to state cooperative extension programs. The funds are distributed by formula based on the numbers of certified applicators reported by the states. With $800,000 in appropriated funds and $500,000 in PRIA funds, the national total to help support this activity was $1,300,000. The funds were allocated to state cooperative extension services by formula based on the number and type of certified applicators reported by the state regulatory agencies. The PRIA funding provides every state extension program with predictable additional resources to support their programs and help ensure that pesticide applicators receive adequate training to competently use restricted-use pesticides.	$500,000
U.S. Department of Labor - interagency agreement	PRIA monies funded the analysis of data and development of focused reports on the National Agricultural Workers Survey (NAWS), which contains the most comprehensive demographic information on agricultural workers. To assist with worker regulatory development and risk assessments, questions were developed on worker exposure for inclusion in the next extensive NAWS survey. PRIA funds help support the development of pesticide worker safety survey questions for the National Agricultural Workers Survey, as well as focused reports from the survey that aid in regulatory development and training materials development.	$100,00
Association of Farmworker Opportunity Programs (AFOP) - cooperative agreement	PRIA funds support a variety of the national affiliates of AFOP for pesticide worker safety training, education and outreach for farmworkers and farmworker families. This work increases protection for communities with environmental justice issues. These communities have: • a potential for high pesticide exposure, high risk • low literacy, non-English speakers, low income • high mobility • children at risk from take-home exposure A cooperative agreement with AFOP (supported by PRIA funds) helps support the following: • Project HOPE (Health and Outreach with Pesticide Education). AFOP has trained over 250 farm worker community outreach workers at 22 sites around the country on how to conduct pesticide worker safety training. These outreach workers are a main source of free safety training for workers.	$410,000

Table I – PRIA Funded Pesticide Safety Education & Worker Protection Activities FY 2010		
Recipient & Mechanism	**Activity and Accomplishments**	**FY 2010 PRIA Funds**
	• Project SAFE (Saving American Farmworkers Everywhere). Through an EPA / AFOP / AmeriCorps Program, AFOP trains AmeriCorps members as pesticide worker safety trainers. AmeriCorps members work in 15 AFOP affiliate sites and conduct hands-on, interactive training for farm workers and their families. Often the AmeriCorps members are adult children of migrant farm workers. • Project LEAF (Limiting Exposures Around Families). In response to research demonstrating higher levels of pesticides in farm workers' children and the effectiveness of simple mitigation measures, AFOP is delivering a program to prevent take-home pesticide exposure to farm worker children. • Spanish Radio Campaign to Protect Farmworker Children. AFOP works with Hispanic Communications Network to create a variety of radio messages on how to prevent pesticide exposure to farm worker children. The national radio campaigns, aimed at farm worker parents, cover 245 Spanish language radio stations that reach over 14 million listeners. • The Building Bridges Program. AFOP has partnered with Farmworker Justice to develop a project to assess pesticide safety training programs and other pesticide worker protection programs in Florida. The project works with key farm worker, grower and state stakeholder groups to develop model pesticide safety training programs to be used by farmers or agricultural service organizations. • Students Action with Farmworkers (SAF). AFOP worked with SAF (Duke University) to train 75 interns on how to conduct interactive pesticide safety education for farm workers and farm worker families.	
Abt, Associates - contract	Abt Associates, through an EPA contract, is conducting economic cost/benefit analyses and other regulatory analyses that are necessary to support the proposed amendments to the agricultural worker protection regulation and the pesticide applicator certification rule. Because of Executive Order requirements, Paperwork Reduction Act, and the Regulatory Flexibility Act, these analyses are required to quantify cost and benefits of the proposed regulatory changes. Abt provided analyses that supported the Small Business Regulatory Enforcement Fairness Act (SBREFA) panel analysis and report and developed new methodology to assess the benefits to be realized from the regulations' amendments. Their new methodology will be used in this analysis. Planned work includes aggregating the line item costs into total societal costs, performing sensitivity analyses and addressing the various regulatory analyses required by executive order and the Regulatory Fairness Act (RFA).	$490,000
	2010 Total	**$1,500,000**

Table II – Partnership Grants – Funding and Accomplishments		
FY 2008 – Partnership Grants (approximately $970K in grants ($750K in PRIA2 fees and additional appropriated funds) to fund five projects FY 2008 projects ran from October 2008 to September 2010)		
Recipient	**Project Title and Accomplishments**	**Funding**
California Department of Pesticide Regulation (Sacramento, CA):	**"Reducing Volatile Organic Compound Emissions from Pesticide Use in Nuts and Tree Fruit Orchards in California's San Joaquin Valley."** This two-year project, concluded in September 2010, applied PRIA funds to a reduction of pesticides in surface water runoff and volatile organic compound (VOC) emissions from almond, peach, and walnut orchards in California. Funding supported a multi-agency and grower group team of 12 organizations as project partners, project team meetings, development of a new Conservation Management Practices guide (CMP), development and demonstration of a Web-based "VOC Calculator" to end users. Team members gave seventeen presentations to over 500 farmers on how to use the CMP in conjunction with year-round IPM plans to reduce VOC emissions and pesticides in water runoff. They distributed 3700 copies of the CMP to 14 sites including California state and county agencies, USDA, and grower associations. Nineteen sessions to over 750 attendees demonstrated the use of the Web-based VOC Emissions Calculator for nonfumigant agricultural-use pesticides. The potential benefit of the CMP guide and VOC Calculator will extend to over 300,000 acres in California producing almonds, peaches, and walnuts.	$159,494
IPM Institute of North America (Madison, WI)	**"High-level IPM in All U.S. Schools by 2015."** This ongoing project supports establishing and verifying the adoption of integrated pest management (IPM) in public kindergartens through high schools across the country. This project promotes increased use of IPM tools by teaching IPM managers about pest biology, inspection and monitoring for both pests and pest-conducive conditions, and prevention through education, sanitation, and maintenance techniques. Two new measures (cockroach allergen levels and student absenteeism) will help evaluate the effectiveness of pest management practices. A national network of four regional work groups established 13 school demonstration sites (affecting 19,365 staff and 139,398 students) in seven states to promote IPM. The project's initial goal of establishing four new self-expanding coalitions to further expand IPM resulted in 13 new state coalitions (affecting 13,287 staff and 244,745 students). Work on identifying and measuring allergens in schools is continuing, as is an effort to build a network database of contacts that presently includes over 11,000 administrators, teachers, facility and grounds, food service, health care, and school business professionals. As a result of PRIA funding, IPM measures are now in place at a growing number of new school locations.	$250,000

Table II – Partnership Grants – Funding and Accomplishments		
University of Florida, College of Agriculture and Life Sciences (Gainesville, FL)	**"Reduced Pesticide Use for *Bermisia tabaci* and Greenhouse Whiteflies (GHWF) on Greenhouse Tomato using Protected Culture, IPM Techniques, Parasitic Wasps, and Papaya Banker Plants."** PRIA funds are promoting research, education, and adoption of a biological pest management system that reduces use of pesticides in greenhouses. Banker plants serve as a home base for parasitic wasps and predatory arthropods. In the case of Papaya banker plants, wasps feed on whiteflies, which are greenhouse pests of tomato plants. To achieve the project goal of demonstrating efficacy and adoption into production greenhouses, the presence of other pest species necessitated incorporation of additional biocontrol systems. The biocontrol of whiteflies is now being coordinated with the use of an expanded suite of similar banker plant biocontrol methods for aphids, mites, and thrips. Funds support demonstrating IPM approaches for controlling these pests and mitigating the spread of viral diseases using banker plants in greenhouses at five vegetable grower demonstration sites in Florida (4 cooperator owned, 1 University). Participants installed unique banker plant systems for mites, thrips and aphids, successfully demonstrating the banker plant approach. The project's success and outreach efforts have prompted University Extension agents to request development of systems for homeowners to help manage pest arthropods in vegetable gardens and landscapes. The potential impact for future use of biocontrols in tomato production includes greenhouse grown tomatoes representing 17% of the fresh market volume and 37% of grocery store sales in the United States.	$246,418
Michigan State University (East Lansing, MI)	**"Increasing Adoption of Reduced-Risk Pest Management Practices in Midwest Blueberries to Prepare for FQPA Implementation."** PRIA funds helped prepare the Great Lakes' blueberry industry for the phase-out of an organophosphate pesticide, azinphos-methyl (AZM), by increasing the adoption of reduced-risk alternatives and IPM methods. This two-year project, concluded September 2010, demonstrates the greater rain-fastness of alternative pesticides when compared to AZM. Thus, use of the alternatives leads to reductions in the number of pesticide applications during the growing season. Demonstration control programs at four commercial blueberry farms in Michigan successfully replaced AZM and pyrethroid based insecticides with reduced-risk alternative pesticides, achieving comparable or better control. Each year, workshops on IPM approaches were presented to groups of 50 to 75 attendees (including growers, crop consultants, and industry representatives). The weekly newsletter, *The Blueberry IPM Update,* had over 250 subscribers during each growing season. The Michigan Blueberry IPM Update Web page also updated project information for its readers. The Fruit and Vegetable Expo in Grand Rapids, Michigan offered the region's blueberry growers presentations of project results in 2009. Participants at the North American Blueberry Research and Extension Workers meeting also saw results from this research and education project. The impacts of this project continue as the principal investigators present talks on Blueberry IPM in 2011 at industry-led grower meetings, the next Fruit and Vegetable Days, and at the MSU Horticulture	$91,508

Table II – Partnership Grants – Funding and Accomplishments		
	Days.	
Central Coast Vineyard Team (CCVT) (Paso Robles, CA):	**"Reducing Pesticide Risk through the Adoption of Integrated Farming Practices in Central Coast Vineyards and Marketing Certified Sustainable Products."** PRIA funding initiated the adoption and implementation of IPM practices through CCVT's grower self assessment and the "Sustainability in Practice Vineyard Certification Program (SIP)." The program is now fully operational: for 2010 the results of 86 Self Assessments were sent back to participating growers. Funds also supported field research to demonstrate effective alternatives to pesticides currently used in vineyards. Participants installed 200 Argentine ant bait stations at four grower-cooperator research stations and worked with a grower cooperator to implement an IPM bait-station strategy to control mealybugs. CCVT delivered outreach programs to educate and guide growers on the use of integrated farming systems using "Certified Sustainable Standards" and educated the public and wine trade about the environmental and economic benefits of products that are "Certified Sustainable." As a result, SIP™ Certified labeled wines are a growing presence in the marketplace. Each label is evidence that IPM and stewardship practices are in use, growing grapes for wine. The team conducted workshops on pest identification (attended by 100 Spanish speaking participants) and training sessions in support of the SIP. Initially, twenty new vineyards applied to the SIP certification program in 2009. During 2010, CCVT engaged in outreach events with some 260 participants, including a Vineyard Pest and Disease Seminar, workshops on Irrigation and Water Management, Biodiversity and Conservation in the Vineyard, and an Oak Habitat Conservation Field Day. CCVT also worked with a bait-station grower-cooperator and other organizations to host a field day on ant and mealybug control. While this two year project ended in September 2010, the impact of PRIA funding continues as SIP reaches a broader audience.	$225,000

Table II – Partnership Grants – Funding and Accomplishments		
FY 2009 – Partnership Grants (approximately $1.3 million awarded ($750K in PRIA 2 Fees with additional funds from EPA's Office of the Science Advisor) to fund six projects, FY 2009 projects run from October 2009 to September 2011)		
Recipient	**Project Title and Accomplishments**	**Funding**
University of California (Berkeley, CA)	**"Implementing reduced risk alternatives for management of codling moth in walnuts"** This ongoing project includes: 1) a resistance management program for navel orangeworm and codling moth in walnuts; 2) reducing organophosphate and pyrethroid insecticide use by over 50%; and 3) demonstrating the effective use of a biopesticide (a pheromone that interferes with moth mating habits), currently used for apples, to replace azinphos methyl and other pesticides commonly used in growing walnuts. A reduction in the use of these pesticides also addresses concerns about water quality and runoff and resistance management in relation to controlling codling moth. Field research has been expanded to include three more cooperating partners, making a total of six orchards located in two different growing regions of California. Future impacts will come with: 1) the final development and registration of new pheromone delivery options for walnuts, currently grown on 240,000 acres in the US, 2) an increase in adoption in terms of total acres of walnuts using pheromone mating disruption, and 3) a corresponding reduction in use of organophosphates and pyrethroids in walnut systems.	$249,687
University of Wisconsin (Madison, WI)	**"Expanding and Improving the Use of IPM in Midwest Fruit Production"** PRIA funds are supporting adoption of IPM practices for apples, cherries, and grapes in Wisconsin and other nearby states to address water quality and runoff issues. The project team has trained 55 participants, including new IPM coaches, in how to use low-cost modifications to airblast sprayers to help growers in Wisconsin, Minnesota, Illinois, and Iowa use pesticides more efficiently and to reduce drift, risk, and water runoff. Impacts of the training will be assessed through a survey that compares prior year pesticide use to use in the year following the training. Up to 20 new coaches will be trained each year. In past performance this grantee has shown that adding new coaches leads to a reduction in pesticide risk by 50% and increased IPM adoption by 78% within 3 years. An extensive, four part IPM training course is under development for the second year of the project. This training promotes the use of reduced risk pesticides as well as biopesticides and pheromone technologies and will help growers and the Natural Resources Conservation Service with their IPM and Conservation Activity Plans for specialty fruit crops.	$202,027

Table II – Partnership Grants – Funding and Accomplishments		
Baltimore City Health Department (Baltimore, MD)	**"Safe Pest Management for Health (SPMH): An Initiative to Reduce Community Pesticide Use, Increase Integrated Pest Management (IPM), and Improve Environmental Health in Baltimore Through Public and Private Partnerships"** PRIA funds are supporting use of multiple IPM approaches that improve human health by controlling pests in residences, schools, day care facilities, and homeless service centers in Baltimore, Maryland. The Baltimore City Health Department is developing IPM training and site plans for target sites; developing and administering the nation's first IPM subsidization program for low-income families; coordinating pest control with six partner organizations; and implementing an educational IPM program for Baltimore's Latino community. They have leveraged their funds using a separately funded weatherization program to further incorporate IPM into urban structures. This project is ongoing and will train 5,450 persons (including, residents and city staff) and anticipates up to 75% reduction in pesticide uses. First year accomplishments include training for 400 city employees, action plans provided to 30 school sites, training for 275 school staff members, training for 25 weatherization assessors and contractors, completion of a model for subsidized IPM services for pest control to low-income families, 215 Latino community members trained in IPM, and 775 of the planned 2000 home visitations for IPM education.	$250,000
The Pennsylvania State University (University Park, PA)	**"Collaborative Design & Delivery of a Unified Training Platform for IPM in Buildings."** PRIA funds support a Penn State project to increase IPM in urban structures through a pilot training program and a collaborative network of housing entities in the Philadelphia metropolitan area that perform contract work in housing and commercial and public buildings. Funds support the development of educational modules for "IPM in Buildings;" first for the Philadelphia area and later for dissemination nationally via an internet-based training program. The modules, designed for service providers and their clients, address IPM in diverse building types and management systems. The ongoing pilot program will train 80 owners, 500 health outreach professionals, and 400 occupants. Accomplishments to date include successfully completing 5 cycles of the Urban IPM training for 60 entry-level employees (10 of whom are now IPM technicians and practitioners for local pest management companies in low-income neighborhoods of Philadelphia). A series of educational programs and materials were developed to educate students, parents, and building staff and management on bed bug control as part of a Penn State Campus IPM Team-initiated Centre County Bed Bug Coalition. To date, 60 people involved in housing on & off campus were educated through the Coalition. IPM training for School Facilities Managers resulted in 25 individuals educated to deal with bed bugs and to use this information to support Pennsylvania laws mandating IPM education in public schools. To date 20 Community Health Workers have received IPM training. Additional training for community housing is planned.	$249,770
University of Rhode Island (Kingston, RI)	**" Web-Based Decision Support Tools for Risk-Appropriate Tick-Bite Protection and Disease Prevention"**	$142,320

Table II – Partnership Grants – Funding and Accomplishments		
	Ticks are the main vectors for some of the most common vector-borne diseases affecting people in the U.S. Many effective tick control and tick-bite prevention strategies exist, but few effective decision support tools are available to guide people at risk in taking risk-appropriate actions. Funded by Advanced Monitoring Initiative funds (AMI funds from the Office of the Science Advisor), this project will develop a suite of unique, multi-media health promotion tools with customized action plans to support decisions for preventing tick-transmitted infections such as Lyme disease, human babesiosis, and human anaplasmosis. Expected products include a Tick Encounter risk calculator for homeowners and state and local decision-makers, which gives a quantitative measure of risk and tailored guidelines for minimizing and preventing risk, and training programs in Rhode Island and Massachusetts. As a result of this program, investigators expect to build homeowner demand for high quality, least toxic tick control. New IPM practices can be implemented at homes and in public areas.	
Washington University (St. Louis, MO)	**"Landscape Design Guidelines for Mitigating Human Risk of Exposure to Lone-Star Tick-Associated Pathogens"** Funded by Advanced Monitoring Initiative funds (AMI funds from the Office of the Science Advisor), this interdisciplinary study examines the consequences of landscape change on the emergence of tick-borne diseases in the St. Louis, MO metropolitan area. The objective is to explicitly quantify the effects of environmental changes on human health, and directly compare the level of risk between landscapes with varying degrees of man made change. Data will be integrated in a Geographic Information Systems framework to quantify the impacts of specific landscape changes and to develop predictive models of the potential impacts of future landscape change on human health. These tools will help generate recommendations for sustainable land management to mitigate human disease risk in Midwestern ecosystems. Project outputs will include a predictive risk model that can be used by land use planners to inform land management practices and community planning that benefits the environment and public health; and, new knowledge on disease risk dynamics that can inform the management of tick-borne diseases.	$237,439

Table II – Partnership Grants – Funding and Accomplishments		
FY 2010 – Partnership Grants (approximately $1 million awarded ($500,000 from PRIA 2 Fees and the remainder from of the Office of the Science Advisor) to fund five projects, FY 2010 projects run from October 2010 to September 2012)		
Recipient	**Project Title and Accomplishments**	**Funding**
IPM Institute of North America (Madison, WI)	**"Healthy School Communities Through IPM And Expanded Partnerships: Reducing Pest And Pesticide Risks, Improving Asthma Outcomes And Furthering Environmental Justice"** PRIA funds will address environmental justice concerns on many fronts, expanding the previous IPM Institute PRIA project (FY08) that established and verified adoption of integrated pest management (IPM) in public kindergartens through high schools across the United States. The FY 2010 project will: 1) expand self-sustaining school IPM coalitions in all states, where experienced school professionals recruit and mentor peers at other districts; 2) focus on childhood asthma and asthma triggers associated with cockroaches, rodents, and dust mites; 3) affect more than 49 million students served by 6.1 million staff including 3.1 million teachers in 14,383 public school districts in the US; and 4) expand a national working group to build effective new partnerships in fifteen target states. The project will develop a comprehensive set of metrics and online performance reporting for participating school districts, deliver fifteen new coalitions, deliver take-home educational materials about asthma and IPM in homes, develop a written business case for coalitions, provide training for site inspections in participating schools, produce monthly pest newsletters, support a listserv, produce presentations and webinars. Overall, this project will significantly expand use of advanced IPM methods in US schools.	$250,000
Michigan State University (East Lansing, MI)	**"Effective Soil-Based Biopesticide And Nutrient Delivery In Orchard Ecosystems"** PRIA funds will be applied to develop a biological IPM approach, through a beneficial nematode and compost system, to support the phase-out of the organophosphate azinphos methyl (AZM) and control the plum curculio; which is a pest of pome (apple) and stone (cherry) fruit found in the eastern US and in Utah. The project is based in the Great Lakes Basin where fruit growers rely on extensive broad-spectrum pest control methods that affect both target pests and nontarget insects, including many endangered species. PRIA funding is providing critical support to refining and further developing the biocontrol approach for plum curculio in the absence of alternatives because there are still no other organophosphate alternatives providing apple and cherry growers with adequate control of this pest comparable to AZM. The research and extension team will report the results of research projects to the tree fruit grower community and give them on-farm demonstrations, training workshops, internet, printed material, and weekly IPM updates. The project is expected to lead to a 25% increase in cherry and apple grower adoption of IPM, as well as a 50% reduction in chemical pesticides used to control plum	$249,939

Table II – Partnership Grants – Funding and Accomplishments		
	curculio on approximately 10,000 acres.	
Cary Institute of Ecosystem Studies	**"Landscape Epidemiology And Integrated Mgmt Of Tick-Borne Diseases"** Funded by Advanced Monitoring Initiative funds (AMI funds from the Office of the Science Advisor), this study will develop predictive models of landscape-level variation in the risk of Lyme disease, human anaplasmosis and human babesiosis; test how well ecological metrics of disease risk correlate with actual human incidence of tick-borne diseases; and use landscape variables to assess the likely impacts of development and land-use planning scenarios on the human risk of tick-borne diseases. These models can lead to the design of environmentally sound (non-chemical) strategies to reduce infectious disease transmission as part of an IPM strategy that also helps to minimize the use of pesticides (and their accompanying contamination of air, land, and water). Models will also inform forest ecosystem valuation and support management of forested landscapes, which can benefit public health.	$299,998
University of Washington	**"Pests, Predators, And Multiple Stressors In Agroecosystems"** Funded by Advanced Monitoring Initiative funds (AMI funds from the Office of the Science Advisor), this project will investigate the combined effects of pesticide use, land-use change, and climate change on working agricultural ecosystems in California's Central Valley. The main product will be a spatially-explicit population model to assess the effects of altered precipitation regimes, and land-use change on population size and distribution of rodent pests and a sensitive non-target species, the San Joaquin kit fox (natural predators of the rodent pests). The model will be used to prioritize lands for pesticide use under IPM and to inform guidance for IPM implementation.	$100,000
Oregon State University	**"Willamette Valley Pesticide Risk: an Alternative Futures Approach to Integrated Pest Management"** Funded by Advanced Monitoring Initiative funds (AMI funds from the Office of the Science Advisor), this project will develop a model-based tool to facilitate assessments of integrated pest management (IPM) strategies under a changing climate. The primary question is: How will the broad adoption of IPM strategies influence non-target pesticide concentrations and ecological risk? To connect the research results to IPM users, the team will coordinate the modeling work with a USDA National Institute of Food and Agriculture funded Extension-IPM program to quickly develop a mechanism to present results to a group of interested growers and other stakeholders. These presentations will be developed as part of already planned stakeholder meetings focused on IPM strategies.	$97,065

Table III – Number pf PRIA Actions Completed in fiscal year 2008, 2009, and 2010

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

Table III – Number of PRIA Actions Completed in fiscal year 2008, 2009, and 2010

PRIA Category	Description of Category	FY 2008		FY 2009		2010	
		Number of Completed PRIA Decisions	Average Decision Time in Days	Number of Completed PRIA Decisions	Average Decision Time in Days	Number of Completed PRIA Decisions	Average Decision Time in Days
R01	New Active Ingredient, Food Use	34	824	15	648	3	1106
R010	New Active Ingredient, Food Use			6	570		
R02	New Active Ingredient, Food Use, Reduced Risk	12	446				
R05	New Active Ingredient, Food use submitted after an EUP	12	175				
R06	New Active Ingredient, Non-food use, outdoor	1	541	1	753	4	1433
R060	New Active Ingredient, Non-food use, outdoor			1	245	29	686
R07	New Active Ingredient, Non-food use, outdoor, Reduced Risk	1	530				
R09	New Active Ingredient, Non-food use, outdoor, EUP submitted before application for registration	2	74				
R10	New Active Ingredient, Non-food use, outdoor, submitted after EUP					3	1199
R120	New Active Ingredient, Non-food use; indoor; reduced risk					2	755
R124	Conditional Ruling on Preapplication Study Waivers; applicant-initiated	1	100	15	153	2	179
R130	First food use; indoor; food/food handling	3	325				
R14	New Use, Additional food use, indoor Food/Food handling	2	627				
R15	New Use, First Food Use	7	776	9	642		

Table III – Number of PRIA Actions Completed in fiscal year 2008, 2009, and 2010

PRIA Category	Description of Category	FY 2008		FY 2009		2010	
		Number of Completed PRIA Decisions	Average Decision Time in Days	Number of Completed PRIA Decisions	Average Decision Time in Days	Number of Completed PRIA Decisions	Average Decision Time in Days
R16	New Use, First Food Use, Reduced Risk			3	555		
R17	New Use, Each Additional New Food Use	186	575	21	714	4	1146
R170	New Use, Additional food use	2	272	71	440	105	453
R18	New Use, Each Additional New Food Use, Reduced Risk	9	636	2	381		
R180	New Use, Additional food use; reduced risk			12	361	13	336
R19	New Use, Additional New Food Uses, Bundled, 6 or more	73	491	11	661	10	1829
R190	New Use, Additional food uses; 6 or more submitted in one application			23	419	36	464
R20	New Use, Additional New Food Uses, Bundled, 6 or more, Reduced Risk	3	1274				
R200	New Use, Additional food uses; 6 or more submitted in one application; reduced risk			14	336	19	324
R21	New food use, With EUP and temporary tolerance	1	360				
R220	New Use, Additional food use; EUP; crop destruct basis; no credit toward new use registration	1	96	3	108	1	181
R23	New use, Non-food, outdoor	15	447	3	402		
R230	New Use, Additional use; non-food; outdoor	1	285	14	372	13	441
R24	New use, Non-food, outdoor, Reduced Risk	6	403				
R240	New Use, Additional use; non-food; outdoor; reduced risk			5	331		
R25	New use, Non-food, outdoor with EUP (no credit toward new use registration)	1	180				
R250	New Use, Additional use; non-food; outdoor; EUP; no credit toward new use registration			1	182	4	158
R26	New Use, Non-food, indoor	1	361				
R260	New use; non-food; indoor			2	352	4	491
R270	New use; non-food; indoor; reduced risk					1	258
R272	Review of Study Protocol; applicant-initiated; excludes DART, pre-registration conferences, Rapid Response review, DNT protocol review, protocols needing HSRB review	12	82	48	68	20	64
R273	Additional use; seed treatment; limited uptake into Raw Agricultural Commodities; includes crops with established tolerances (e.g., for soil or foliar application); includes food or non-food uses					8	373
R274	New Uses, Additional uses; seed treatment only; 6 or more submitted in one application; limited uptake into Raw Agricultural Commodities; includes crops with established tolerances (e.g., for soil or foliar application);			1	359	2	586

Table III – Number of PRIA Actions Completed in fiscal year 2008, 2009, and 2010

PRIA Category	Description of Category	FY 2008		FY 2009		2010	
		Number of Completed PRIA Decisions	Average Decision Time in Days	Number of Completed PRIA Decisions	Average Decision Time in Days	Number of Completed PRIA Decisions	Average Decision Time in Days
	includes food and/or non-food uses						
R28	Import tolerance, New Active Ingredient or first food use					1	1155
R280	Establish import tolerance; new active ingredient or first food use			1	637		
R29	Import tolerance, Additional new food use	3	1000	1	1000		
R290	Establish import tolerance; additional food use			1	432	5	480
R292	Amend an established tolerance (e.g., decrease or increase); domestic or import; applicant-initiated	7	221	16	329	22	399
R293	Establish tolerance(s) for inadvertent residues in one crop; applicant-initiated			3	317		
R295	Establish tolerance(s) for residues in one rotational crop in response to a specific rotational crop application; applicant-initiated					1	506
R30	New Product, Me-Too, Fast Track	103	75				
R300	New product; identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data, or applicant submits specific authorization letter from data owner. Category also includes 100% re-package of registered end-use or manufacturing-use product that requires no data submission nor data matrix.	169	74	239	76	277	84
R301	New product; identical or substantially similar in composition and use to a registered product; registered source of active ingredient; selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy, where applicant does not own all required data and does not have a specific authorization letter from data owner.	21	116	43	122	36	123
R31	New Product, Non-Fast Track (includes review of product chemistry, acute toxicity, public health pest efficacy)	193	204	2	873		
R310	New end-use or manufacturing-use product; requires review of data package within RD; includes reviews and/or waivers of data for only: • product chemistry and/or • acute toxicity and/or • public health pest efficacy	100	166	236	194	167	204
R311	New product; requires approval of new food-use inert; applicant-initiated; excludes approval of safeners					2	406
R313	New product; requires amendment to existing inert tolerance exemption (e.g., adding post-harvest use);			4	416	1	654

Table III – Number of PRIA Actions Completed in fiscal year 2008, 2009, and 2010

PRIA Category	Description of Category	FY 2008		FY 2009		2010	
		Number of Completed PRIA Decisions	Average Decision Time in Days	Number of Completed PRIA Decisions	Average Decision Time in Days	Number of Completed PRIA Decisions	Average Decision Time in Days
	applicant-initiated						
R32	New Product, Non-Fast Track, new physical form (excludes selective citations)	14	349	3	513	1	797
R320	New product; new physical form; requires data review in science divisions	1	141	9	346	17	347
R33	New manufacturing-use product, Old Active Ingredient, Selective Citation	18	461	1	551		
R330	New manufacturing-use product; registered active ingredient; selective data citation			3	386	8	360
R331	New Product; repack of identical registered end-use product as a manufacturing-use product; same registrant uses only			1	77	4	72
R34	Amendment, Non-Fast Track (includes changes to precautionary label statements, source changes to an unregistered source)	64	119	1	421		
R340	Amendment requiring data review within RD (e.g., changes to precautionary label statements, or source changes to an unregistered source of active ingredient)	95	100	200	111	162	113
R35	Amendment, Non-Fast track (changes to REI, PPE, PHI, rate and number of applications, add aerial application, modify GW/SW advisory statement)	48	255				
R350	Amendment requiring data review in science divisions (e.g., changes to REI, or PPE, or PHI, or use rate, or number of applications; or add aerial application; or modify GW/SW advisory statement)	15	184	59	215	81	266
R37	Cancer Reassessment, applicant initiated	6	536			1	1185
A41	New Active Ingredient, Non-food use, outdoor, other uses	3	1252				
A42	New Active Ingredient, Non-food use, indoor, FIFRA sec. 2(mm) uses	2	998	2	920		
A44	New Use, First food use, with exemption	3	739	2	682		
A46	New Food Use, with exemption	3	470	2	492		
A460	Additional Food use; establish tolerance exemption			6	199	5	620
A470	New Food use, Additional food use; establish tolerance			1	436		
A48	New use, Non-food, outdoor FIFRA sec. 2(mm) uses	3	262				
A480	New use, Additional use; non-food; outdoor; FIFRA §2(mm) uses	1	20	1	391	3	356
A49	New use, Non-Food, outdoor, other uses	2	460				
A490	New use, Additional use; non-food; outdoor; uses other than FIFRA §2(mm)			3	454	1	363

Table III – Number of PRIA Actions Completed in fiscal year 2008, 2009, and 2010

PRIA Category	Description of Category	FY 2008		FY 2009		2010	
		Number of Completed PRIA Decisions	Average Decision Time in Days	Number of Completed PRIA Decisions	Average Decision Time in Days	Number of Completed PRIA Decisions	Average Decision Time in Days
A50	New use, Non-food, indoor FIFRA sec. 2(mm) uses	11	412	1	1002		
A500	New use, Additional use; non-food; indoor; FIFRA §2(mm) uses	3	228	22	263	19	309
A510	Additional use; non-food; indoor; uses other than FIFRA section 2(mm)					1	496
A520	Experimental Use Permit application			2	181	1	321
A521	Review of public health efficacy study protocol within AD; per AD Internal Guidance for the Efficacy Protocol Review Process; applicant-initiated; Tier 1	3	146	1	342	4	208
A522	Review of public health efficacy study protocol outside AD by members of AD Efficacy Protocol Review Expert Panel; applicant-initiated; Tier 2			1	234	3	797
A53	New Product, Me-too, Fast Track	25	102				
A530	New product; identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data, or applicant submits specific authorization letter from data owner. Category also includes 100% re-package of registered end-use or manufacturing-use product that requires no data submission nor data matrix.	45	73	49	95	57	97
A531	New product; identical or substantially similar in composition and use to a registered product; registered source of active ingredient; selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy, where applicant does not own all required data and does not have a specific authorization letter from data owner.	4	90	12	151	8	124
A532	New product; identical or substantially similar in composition and use to a registered product; registered active ingredient; unregistered source of active ingredient; cite-all data citation except for product chemistry; product chemistry data submitted	12	66	19	156	19	124
A54	New Product, Non-Fast Track, FIFRA sec. 2 (mm) uses	44	224	3	446	1	1261
A540	New end use product; FIFRA §2(mm) uses only	25	110	70	139	65	190
A55	New Product, Non-Fast Track, other uses	5	222	1	615		
A550	New end-use product; uses other than FIFRA §2(mm); non-FQPA product	2	172	4	180	1	270
A56	New Manufacturing use product, old active ingredient, selective citation	5	470				
A560	New manufacturing-use product; registered active ingredient; selective data citation	2	176	3	349	2	530

Table III – Number of PRIA Actions Completed in fiscal year 2008, 2009, and 2010

PRIA Category	Description of Category	FY 2008		FY 2009		2010	
		Number of Completed PRIA Decisions	Average Decision Time in Days	Number of Completed PRIA Decisions	Average Decision Time in Days	Number of Completed PRIA Decisions	Average Decision Time in Days
A57	Amendments, Non-Fast Track	55	115	1	454		
A570	Label amendment requiring data submission	78	105	136	123	120	145
B59	New Active Ingredient, Food Use, with exemption, Microbial/Biochemical	3	737			8	914
B590	New active ingredient; food use; establish tolerance exemption, Microbial/Biochemical			3	487	18	634
B60	New Active Ingredient, Non-food use, Microbial/Biochemical	6	980	6	732		
B600	New active ingredient; non-food use, Microbial/Biochemical			7	385	6	392
B61	EUP, Food Use with temporary tolerance exemption, Microbial/Biochemical	2	349				
B610	Food use; EUP; establish temporary tolerance exemption, Microbial/Biochemical			6	286	2	222
B620	Non-food use; Experimental Use Permit application			4	127		
B621	Extend or amend EUP, Microbial/Biochemical	3	62	3	101		
B63	New Use, First Food Use, with tolerance exemption Microbial/Biochemical,	8	459	4	541		
B630	First food use; establish tolerance exemption, Microbial/Biochemical			2	313		
B631	Amend established tolerance exemption, Microbial/Biochemical	1	270	3	242	1	471
B650	New use; Non-Food, Microbial/Biochemical			2	239		
B66	New Product, Me-Too, Fast Track, Microbial/biochemical	4	94				
B660	New product; identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data, or applicant submits specific authorization letter from data owner. Category also includes 100% re-package of registered end-use or manufacturing-use product that requires no data submission nor data matrix. Microbial/biochemical	9	79	6	73	11	106
B67	New Product, Non-Fast Track, Microbial/Biochemical	23	282	1	895		
B670	New product; registered source of active ingredient; all Tier I data for product chemistry, toxicology, non-target organisms, and product performance must be addressed with product specific data or with request for data waivers supported by scientific rationales, Microbial/Biochemical	7	161	9	282	11	188
B671	New product; food use; unregistered source of active ingredient; requires amendment of established tolerance or tolerance exemption; all Tier I data requirements for product chemistry, toxicology, non-target organisms, and product performance must be addressed with product-specific data or with request for data					7	529

Table III – Number of PRIA Actions Completed in fiscal year 2008, 2009, and 2010

PRIA Category	Description of Category	FY 2008		FY 2009		2010	
		Number of Completed PRIA Decisions	Average Decision Time in Days	Number of Completed PRIA Decisions	Average Decision Time in Days	Number of Completed PRIA Decisions	Average Decision Time in Days
	waivers supported by scientific rationales, Microbial/Biochemical						
B672	New product; non-food use or food use having established tolerance or tolerance exemption; unregistered source of active ingredient; no data compensation issues; all Tier I data requirements for product chemistry, toxicology, non-target organisms, and product performance must be addressed with product-specific data or with request for data waivers supported by scientific rationales, Microbial/Biochemical			12	280	11	404
B68	Amendment, Non-Fast Track, Microbial/Biochemical	7	115				
B680	Label amendment requiring data submission, Microbial/Biochemical	4	195	9	129	12	169
B681	Label amendment; unregistered source of active ingredient; supporting data require scientific review			3	244	7	227
B682	Protocol Review; applicant-initiated; excludes time for HSRB review (pre-application)			1	89	1	84
B690	SCLP, New active ingredient; food or non-food use	1	180	2	231	5	167
B700	SCLP, Experimental Use Permit application; new active ingredient or new use			1	134		
B710	SCLP, New product; identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data, or applicant submits specific authorization letter from data owner. Category also includes 100% re-package of registered end-use or manufacturing-use product that requires no data submission nor data matrix	3	93	5	94	1	92
B72	SCLP, New Product Non-Fast Track	2	194				
B720	SCLP, New product; registered source of active ingredient; all Tier I data for product chemistry, toxicology, non-target organisms, and product performance must be addressed with product specific data or with request for data waivers supported by scientific rationales			7	143	3	107
B721	SCLP, New product; unregistered source of active ingredient					5	185
B730	SCLP, Label amendment requiring data submission			3	72	2	129
B740	Plant-Incorporated Protectants (PIP), EUP; registered active ingredient; non-food/feed or crop destruct basis; no Scientific Advisory Panel (SAP) review required			2	135		
B75	PIP, EUP, with Temporary Tolerance or Exemption, No SAP review	1	269				
B77	PIP, EUP, New Active Ingredient, Set Temporary Tolerance or Exemption, SAP	2	517				
B771	Experimental Use Permit application; new active ingredient; establish temporary tolerance or tolerance					2	370

Table III – Number of PRIA Actions Completed in fiscal year 2008, 2009, and 2010

PRIA Category	Description of Category	FY 2008		FY 2009		2010	
		Number of Completed PRIA Decisions	Average Decision Time in Days	Number of Completed PRIA Decisions	Average Decision Time in Days	Number of Completed PRIA Decisions	Average Decision Time in Days
	exemption; no SAP review required						
B772	Amend or extend EUP; minor changes to experimental design; established temporary tolerance or tolerance exemption is unaffected	1	96	3	76		
B800	New active ingredient; establish permanent tolerance or tolerance exemption based on temporary tolerance or tolerance exemption; no SAP review required					1	357
B81	PIP, Register New Active Ingredient, Temporary Tolerance or Exemption Exists, SAP	3	539	3	587		
B810	New active ingredient; establish permanent tolerance or tolerance exemption based on temporary tolerance or tolerance exemption; SAP review required	1	538				
B84	PIP, Register New Active Ingredient, Set Tolerance or Exemption, SAP					2	1052
B86	PIP, EUP, Food Use, Amendment	5	208				
B880	PIP, New product; no SAP review required			2	382	20	395
B881	PIP, New product; SAP review required					1	697
B900	Amendment (except #B890); No SAP review required; (e.g., new IRM requirements that are applicant initiated; or amending a conditional registration to extend the registration expiration date with additional data submitted)	2	176	14	176	1	181
B904	Import tolerance or tolerance exemption; processed commodities/food only			1	103		
	TOTAL	1677		1570		1517	

Table IV– Number of PRIA Decisions Pending at the End of Fiscal Year (FY 2008 - 2010)

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

Table IV – Number of PRIA Decisions Pending at the End of Fiscal Year (FY 2008 - 2010)				
Progress in Meeting Decision Times – Number of PRIA Decisions Pending at End of Fiscal Year				
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of Fiscal Year**		
		2008	**2009**	**2010**
R01	New Active Ingredient, Food Use	24	5	1
R010	New Active Ingredient, Food Use	14	29	78
R02	New Active Ingredient, Food Use, Reduced Risk	6		
R020	New Active Ingredient, Food use; reduced risk		4	4
R040	Food use; Experimental Use Permit application; establish temporary tolerance; submitted before application for registration; credit $326,025 toward new active ingredient application that follows			2
R05	New Active Ingredient, Food use submitted after an EUP	1		
R06	New Active Ingredient, Non-food use, outdoor	5	3	
R060	New Active Ingredient, Non-food use, outdoor	11	45	2
R10	New Active Ingredient, Non-food use, outdoor, submitted after EUP	3	3	
R110	New Active Ingredient, Non-food use; indoor		3	3

Table IV – Number of PRIA Decisions Pending at the End of Fiscal Year (FY 2008 - 2010)				
Progress in Meeting Decision Times – Number of PRIA Decisions Pending at End of Fiscal Year				
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of Fiscal Year**		
		2008	**2009**	**2010**
R120	New Active Ingredient, Non-food use; indoor; reduced risk	2	2	
R123	New Active Ingredient, Seed treatment only; includes non-food and food uses; limited uptake into Raw Agricultural Commodities	2	2	
R124	Conditional Ruling on Preapplication Study Waivers; applicant-initiated	11	2	2
R13	New Use, First food use, indoor food/food handling	2	2	2
R14	New Use, Additional food use, indoor Food/Food handling	3		
R140	Additional food use; Indoor; food/food handling			6
R15	New Use, First Food Use	11	2	2
R150	New Use, First food use			11
R16	New Use, First Food Use, Reduced Risk	3		
R17	New Use, Each Additional New Food Use	67	31	11
R170	New Use, Additional Food Use	112	135	131
R18	New Use, Each Additional New Food Use, Reduced Risk	2		
R180	New Use, Additional food use; reduced risk	13	17	13
R19	New Use, Additional New Food Uses, Bundled, 6 or more	31	20	3
R190	New Use, Additional food uses; 6 or more submitted in one application	34	60	58
R200	New Use, Additional food uses; 6 or more submitted in one application; reduced risk	11	19	9
R21	New food use, With EUP and temporary tolerance	1		
R210	New Use, Additional food use; EUP; establish temporary tolerance; no credit toward new use registration	2		2
R220	New Use, Additional food use; EUP; crop destruct basis; no credit toward new use registration	2		
R23	New use, Non-food, outdoor	7	3	1
R230	New Use, Additional use; non-food; outdoor	25	23	25
R240	New Use, Additional use; non-food; outdoor; reduced risk	4		
R250	New Use, Additional use; non-food; outdoor; EUP; no credit toward new use registration	1	5	
R26	New Use, Non-food, indoor	1		

Table IV – Number of PRIA Decisions Pending at the End of Fiscal Year (FY 2008 - 2010)				
Progress in Meeting Decision Times – Number of PRIA Decisions Pending at End of Fiscal Year				
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of Fiscal Year**		
		2008	**2009**	**2010**
R260	New use; non-food; indoor	3	6	7
R270	New use; non-food; indoor; reduced risk		1	1
R272	Review of Study Protocol; applicant-initiated; excludes DART, pre-registration conferences, Rapid Response review, DNT protocol review, protocols needing HSRB review	7	9	3
R273	Additional use; seed treatment; limited uptake into Raw Agricultural Commodities; includes crops with established tolerances (e.g., for soil or foliar application); includes food or non-food uses		10	11
R274	New Uses, Additional uses; seed treatment only; 6 or more submitted in one application; limited uptake into Raw Agricultural Commodities; includes crops with established tolerances (e.g., for soil or foliar application); includes food and/or non-food uses	3	2	5
R28	Import tolerance, New Active Ingredient or first food use	1	1	
R280	Establish import tolerance; new active ingredient or first food use	2	3	5
R29	Import tolerance, Additional new food use	5	3	3
R290	Establish import tolerance; additional food use	2	9	5
B291	Establish import tolerances; additional food uses; 6 or more crops submitted in one petition			1
R292	Amend an established tolerance (e.g., decrease or increase); domestic or import; applicant-initiated	22	27	12
R293	Establish tolerance(s) for inadvertent residues in one crop; applicant-initiated	3		2
R295	Establish tolerance(s) for residues in one rotational crop in response to a specific rotational crop application; applicant-initiated	1	4	5
R300	New product; identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data, or applicant submits specific authorization letter from data owner. Category also includes 100% re-package of registered end-use or manufacturing-use product that requires no data submission nor data matrix.	51	73	60
R301	New product; identical or substantially similar in composition and use to a registered product; registered source of active ingredient; selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy, where applicant does not own all required data and does not have a specific authorization letter from data owner.	13	15	11

Table IV – Number of PRIA Decisions Pending at the End of Fiscal Year (FY 2008 - 2010)				
Progress in Meeting Decision Times – Number of PRIA Decisions Pending at End of Fiscal Year				
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of Fiscal Year**		
		2008	**2009**	**2010**
R31	New Product, Non-Fast Track (includes review of product chemistry, acute toxicity, public health pest efficacy)	4		
R310	New end-use or manufacturing-use product; requires review of data package within RD; includes reviews and/or waivers of data for only: • product chemistry and/or • acute toxicity and/or • public health pest efficacy	141	112	140
R311	New product; requires approval of new food-use inert; applicant-initiated; excludes approval of safeners		2	
R313	New product; requires amendment to existing inert tolerance exemption (e.g., adding post-harvest use); applicant-initiated	6	1	2
R32	New Product, Non Fast Track, new physical form (excludes selective citations)	5	1	
R320	New product; new physical form; requires data review in science divisions	9	15	25
R33	New manufacturing-use product, Old Active Ingredient, Selective Citation	1		
R330	New manufacturing-use product; registered active ingredient; selective data citation	3	8	6
R34	Amendment, Non-fast Track (includes changes to precautionary label statements, source changes to an unregistered source)	1		
R340	Amendment requiring data review within RD (e.g., changes to precautionary label statements, or source changes to an unregistered source of active ingredient)	63	55	66
R35	Amendment, Non-fast track (changes to REI, PPE, PHI, rate and number of applications, add aerial application, modify GW/SW advisory statement)	2	2	2
R350	Amendment requiring data review in science divisions (e.g., changes to REI, or PPE, or PHI, or use rate, or number of applications; or add aerial application; or modify GW/SW advisory statement)	63	76	55
R37	Cancer Reassessment, applicant initiated	1	1	
R370	Cancer reassessment; applicant-initiated		1	3
A380	New Active Ingredient, Food use; establish tolerance exemption	1	1	1
A400	Non-food use; outdoor; FIFRA section (2mm) uses		1	1

Table IV – Number of PRIA Decisions Pending at the End of Fiscal Year (FY 2008 - 2010)				
Progress in Meeting Decision Times – Number of PRIA Decisions Pending at End of Fiscal Year				
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of Fiscal Year**		
		2008	**2009**	**2010**
A41	New Active Ingredient, Non-food use, outdoor, other uses	2	2	2
A42	New Active Ingredient, Non-food use, indoor, FIFRA sec. 2(mm) uses	3	1	1
A420	Non-food use; indoor; FIFRA section 2(mm) uses		4	7
A44	New Use, First food use, with exemption	2		
A440	New Use, First food use; establish tolerance exemption	2	2	2
A46	New Food Use, with exemption	1		
A460	New Food Use, Additional food use; establish tolerance exemption	3	7	6
A470	New Food use, Additional food use; establish tolerance	1		
A480	New use, Additional use; non-food; outdoor; FIFRA §2(mm) uses	2	4	2
A49	New use, Non-Food, outdoor, other uses	1		
A490	New use, Additional use; non-food; outdoor; uses other than FIFRA §2(mm)	3	1	1
A50	New use, Non-Food, indoor FIFRA sec. 2(mm) uses	1		
A500	New use, Additional use; non-food; indoor; FIFRA §2(mm) uses	27	18	6
A510	Additional use; non-food; indoor; uses other than FIFRA section 2(mm)		2	1
A520	Experimental Use Permit application	1	3	2
A521	Review of public health efficacy study protocol within AD; per AD Internal Guidance for the Efficacy Protocol Review Process; applicant-initiated; Tier 1	2	2	3
A522	Review of public health efficacy study protocol outside AD by members of AD Efficacy Protocol Review Expert Panel; applicant-initiated; Tier 2	3	3	3
A530	New product; identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data, or applicant submits specific authorization letter from data owner. Category also includes 100% re-package of registered end-use or manufacturing-use product that requires no data submission nor data matrix.	15	18	21
531	New product; identical or substantially similar in composition and use to a registered product; registered source of active ingredient; selective data citation only for data on product chemistry and/or acute	5	2	14

Table IV – Number of PRIA Decisions Pending at the End of Fiscal Year (FY 2008 - 2010)				
Progress in Meeting Decision Times – Number of PRIA Decisions Pending at End of Fiscal Year				
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of Fiscal Year**		
		2008	**2009**	**2010**
	toxicity and/or public health pest efficacy, where applicant does not own all required data and does not have a specific authorization letter from data owner.			
A532	New product; identical or substantially similar in composition and use to a registered product; registered active ingredient; unregistered source of active ingredient; cite-all data citation except for product chemistry; product chemistry data submitted	6	7	3
A54	New Product, Non-Fast Track, FIFRA sec. 2 (mm) uses	4	1	
A540	New end use product; FIFRA §2(mm) uses only	32	48	41
A55	New Product, Non-Fast Track, other uses	1		
A550	New end-use product; uses other than FIFRA §2(mm); non-FQPA product	1		3
A560	New manufacturing-use product; registered active ingredient; selective data citation	4	6	6
A57	Amendments, Non-Fast Track	1		
A570	Label amendment requiring data submission	55	55	75
B59	New Active Ingredient, Food Use, Microbial/Biochemical, with exemption	12	8	
B590	New active ingredient; food use; establish tolerance exemption, Microbial/Biochemical,	19	31	63
B60	New Active Ingredient, Non-food use, Microbial/Biochemical	10	1	
B600	New active ingredient; non-food use, Microbial/Biochemical,	9	12	12
B610	Food use; EUP; establish temporary tolerance exemption, Microbial/Biochemical	2		2
B620	Non-food use; Experimental Use Permit application, Microbial/Biochemical			1
B621	Extend or amend Experimental Use Permit, Microbial/Biochemical			1
B63	New Use, First Food Use, Microbial/Biochemical, with exemption	7	3	3
B630	First food use; establish tolerance exemption, Microbial/Biochemical,	1	5	11
B631	Amend established tolerance exemption, Microbial/Biochemical	4	1	2
B650	New use; Non-Food, Microbial/Biochemical		1	3
B660	New product; identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data, or applicant submits specific authorization letter from data owner. Category also	2	4	2

Table IV – Number of PRIA Decisions Pending at the End of Fiscal Year (FY 2008 - 2010)				
Progress in Meeting Decision Times – Number of PRIA Decisions Pending at End of Fiscal Year				
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of Fiscal Year**		
		2008	**2009**	**2010**
	includes 100% re-package of registered end-use or manufacturing-use product that requires no data submission nor data matrix. Microbial/biochemical			
B67	New Product, Non-Fast Track, Microbial/Biochemical	1		
B670	New product; registered source of active ingredient; all Tier I data for product chemistry, toxicology, non-target organisms, and product performance must be addressed with product specific data or with request for data waivers supported by scientific rationales, Microbial/Biochemical	5	10	11
B671	New product; food use; unregistered source of active ingredient; requires amendment of established tolerance or tolerance exemption; all Tier I data requirements for product chemistry, toxicology, non-target organisms, and product performance must be addressed with product-specific data or with request for data waivers supported by scientific rationales, Microbial/Biochemical	6	6	
B672	New product; non-food use or food use having established tolerance or tolerance exemption; unregistered source of active ingredient; no data compensation issues; all Tier I data requirements for product chemistry, toxicology, non-target organisms, and product performance must be addressed with product-specific data or with request for data waivers supported by scientific rationales, Microbial/Biochemical	13	11	10
B680	Label amendment requiring data submission, Microbial/Biochemical	6	12	4
B681	Label amendment; unregistered source of active ingredient; supporting data require scientific review	2	5	2
B690	SCLP, New active ingredient; food or non-food use	2		
B710	SCLP, New product; identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data, or applicant submits specific authorization letter from data owner. Category also includes 100% re-package of registered end-use or manufacturing-use product that requires no data submission nor data matrix.	2		
B720	SCLP, New product; registered source of active ingredient; all Tier I data for product chemistry, toxicology, non-target organisms, and product performance must be addressed with product specific data or with request for data waivers supported by scientific rationales	1	1	2
B721	New product; unregistered source of active ingredient		3	2

Table IV – Number of PRIA Decisions Pending at the End of Fiscal Year (FY 2008 - 2010)				
Progress in Meeting Decision Times – Number of PRIA Decisions Pending at End of Fiscal Year				
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of Fiscal Year**		
		2008	**2009**	**2010**
B730	SCLP, Label amendment requiring data submission		1	2
B740	Plant-Incorporated Protectants (PIP), EUP; registered active ingredient; non-food/feed or crop destruct basis; no Scientific Advisory Panel (SAP) review required	1	2	2
B771	Experimental Use Permit application; new active ingredient; establish temporary tolerance or tolerance exemption; no SAP review required;		2	
B773	Amend or extend existing Experimental Use Permit; minor changes to experimental design; extend established temporary tolerance or tolerance exemption			2
B800	New active ingredient; establish permanent tolerance or tolerance exemption based on temporary tolerance or tolerance exemption; no SAP review required		5	4
B81	PIP, Register New Active Ingredient, Temporary Tolerance or Exemption Exists, SAP	3		
B84	PIP, Register New Active Ingredient, Set Tolerance or Exemption, SAP	2	2	
B870	PIP, New use			1
B880	PIP, New product; no SAP review required	2	19	2
B881	PIP, New product; SAP review required	1	1	5
B900	PIP, Amendment (except #B890); No SAP review required; (e.g., new IRM requirements that are applicant initiated; or amending a conditional registration to extend the registration expiration date with additional data submitted)	13		5
B901	PIP, Amendment (except #B890); SAP review required	1	1	

Appendix A: Decision Review Times for Actions Completed During FY 2010

As required by FIFRA Section 33(k), the following table (an Excel file) provides the decision times for each decision (application) completed during FY 2010. Decisions with a two digit PRIA code are PRIA 1 decisions (received by EPA between March 23, 2004, and September 30, 2007), while those with a three digit PRIA code are PRIA 2 decisions (received on and after October 1, 2007). Negative decision times occur when decisions are completed before the Agency has received full confirmation of payment or a fee waiver or exemption 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), or the Agency anticipates approval of a fee waiver based on past fee waiver approvals during the same maintenance fee cycle. If a decision number appears in the column, "Primary decision", the decision is a "secondary decision" dependent upon the primary decision in some manner.

Mandatory decision time frames depend on the year the application was received. Mandated time frames can be found in the fee schedules published in the Federal Register Notice on March 17, 2004, titled Pesticides; Fees and Decision Times for Registration Applications for PRIA 1 actions and for PRIA 2 decisions, and on October 30, 2007, titled Pesticides; Revised Fee Schedule for Registration Applications. As EPA improves its reporting capabilities, the Agency may update this table, as necessary.

Table of completed actions for FY 2010 Excel, 276 KB) (Microsoft Excel Viewer EXIT Disclaimer is needed to view this file.)