Implementing the Pesticide Registration Improvement Act (PRIA) - Fiscal Year 2009

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Contents

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The Consolidated Appropriations Act of 2004 established a new system for registering pesticides, called the Pesticide Registration Improvement Act, or PRIA. The new section 33 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), PRIA created a registration service fee system for applications for specified pesticide registration, amended registration, and associated tolerance actions, which set maximum residue levels for food and feed. Under PRIA, fees are charged for covered applications received on or after March 23, 2004, and for certain pending applications received before that date. The Environmental Protection Agency (EPA) is required to make a determination on the application within the decision times specified. The fee system was authorized until September 30, 2010. Due to the efforts of the PRIA Coalition of industry, trade associations, and public interest groups, PRIA was reauthorized on October 9, 2007 effective retroactively to October 1, 2007, the beginning of Fiscal Year 2008. The Pesticide Registration Improvement Renewal Act (PRIA 2) authorized the fee system to September 30, 2012.

Under FIFRA Section 33(k), EPA is required to publish an annual report describing actions taken under this section during the past fiscal year. The report must include several elements, including a review of the progress made in carrying out the Agency's obligations under the Act, a description of the staffing and resources associated with the review of and decision-making on applications, and a review of its progress in meeting the reregistration and tolerance reassessment timeline requirements. Additional PRIA 2 reporting requirements include information on electronic label review, a review of applications under section 3(c)(3)(B), and information on registration review that includes resource expenditures and recommendations for process improvements.

This sixth annual report covers Fiscal Year 2009 – October 1, 2008, through September 30, 2009, the second Fiscal Year under PRIA 2, and this report focuses on its continued implementation and impact. During FY 2009, the Agency improved its tracking systems, updated guidance, enhanced its application in-processing, and furthered the science of risk assessment.

PRIA 2 Enhancements in Application In-Processing

Previous annual reports (2004, 2005, 2006, 2007, and 2008) described the steps the Agency undertook to implement PRIA. When PRIA 2 became effective, the Agency modified its in-processing procedures and processes. PRIA 2 increased the fee categories from 90 to 140 and changed payment procedures and how applications are screened upon receipt. Advancements were made in the screening process and additional guidance provided during FY 2009 based on experience during the first fiscal year of PRIA 2.

Front-End Processing and Screening Procedures - FY 2009

When PRIA 1 was implemented in 2004, the Agency established an intra-agency workgroup that interpreted the 90 PRIA 1 fee categories to help applicants and the Agency consistently place each application in the appropriate PRIA category. These PRIA registration categories reflected the types of applications the Agency may receive and for which Congress had established a specified fee and a time frame. The time frame, or decision review time, is the amount of time the Agency is expected to take to review the application and reach a regulatory decision. The intra-agency workgroup modified these interpretations for PRIA 2 and developed interpretations for the additional 50 fee categories. PRIA 2 revised or expanded the description of some PRIA 1 categories, requiring modifications in the Agency's interpretation of these categories. The PRIA 2 interpretations are available on the pesticides Web site on the Fee Determination Decision Tree. In 2009, these fee category interpretations were revised to provide additional guidance on the type of application that fell into each specific fee category. Stakeholders reviewed the proposed revisions to ensure that the guidance could be easily understood and applicants

could accurately identify their fee category. The fee category interpretations were then posted on the internet. The Agency further modified its tracking system, Pesticide Registration Information System (PRISM), to improve its ability to track the new fee categories created by PRIA 2, to monitor fee activity, and to obtain the data needed to meet the additional PRIA 2 reporting requirements.

The Agency elected to invoice applicants instead of requiring payment at submission of an application under PRIA 1 because applicants were unfamiliar with the fee categories. Under this system, teams of EPA experts from the three registering divisions (conventional chemical, biopesticide, and antimicrobial pesticides) screened all incoming applications to determine whether they were subject to PRIA, assigned the application to a PRIA category if appropriate, and conducted a cursory screen of the application. The applicant was then invoiced for the appropriate amount with payment due within 45 days.

Certain provisions in PRIA 2 required the Agency to substantially modify this procedure. 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. Consequently, the invoicing system was discontinued except when an additional payment is required. A portion of the fee (25%) is non-refundable once an application is submitted per Section 33(b)(2)(G). If any fee is unpaid 30 days after the fee is due, under Section 33(b)(2)(H), it is treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code. A certification of payment is required with the application. Credit card or wire transfer payments can be made using the Treasury Department's pay.gov system, which provides an acknowledgement of payment. This acknowledgement of payment or a photocopy of a bank check serves as a certification of payment.

Since applicants have to identify the appropriate fee and pay it in advance of submitting an application (pre-payment) or upon submission to EPA, the Agency developed the Fee Determination Decision Tree and modified its tracking system, PRISM, to track payments and then match payments with applications, instead of with invoices. The Fee Determination Decision Tree is a tool that, through a series of questions and answers, allows pesticide registration applicants to identify an appropriate fee category and fee and was developed for inexperienced applicants. For experienced applicants, an "electronic short-cut" to the fee interpretations was also made available on the internet in FY 2009. The interpretations were also made available as a PDF table that included fees and time frames and can be printed and used as a hardcopy reference.

PRIA fees increased 5% effective October 1, 2008 and the Fee Determination Decision Tree and associated fee and payment guidance were revised by the effective date to reflect this increase. Payment information and a link to pay.gov for credit card and wire transfer payments are provided on the Decision Tree Web site. Once an application is received, the expert teams established under PRIA 1 screen the application and assign a PRIA 2 fee category. If the appropriate amount is not received, the Agency contacts the applicant and invoices the applicant for the unpaid portion, typically within 48-72 hours of receipt of an application.

The Agency treated the first quarter of FY 2008 as a transition period to provide enough time for applicants to become acquainted with the new payment procedures, and continued to send invoices requesting payment of the appropriate PRIA registration service fee if certification of payment was not received with the application. Beginning January 2, 2008, the Agency implemented a policy of not placing an application into the registration and review process if it did not contain certification of payment. The Agency would contact the registrant informing them that certification of payment was required together with the application. If certification of payment was not received within 14 days, the Agency would reject the application, and invoice the registrant for 25% of the appropriate fee. Nine applications were rejected in FY 2008 for failure to submit the appropriate fee while in FY 2009, only two applications were rejected for an unpaid fee.

21 Day Initial Content Screen

The cursory screen that the expert teams conducted under PRIA 1 had to be modified to implement Section 33(f)(4)(B), "Completeness of Application". This section 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 will reject the application.

The Agency phased in this screen. During a November 2007 PRIA 2 workshop, the Agency described its short term procedures for conducting this screen and its long term plans. Screening requirements were defined and a rejection process was developed by an intra-agency workgroup. Beginning January 2008, registering divisions assigned individuals or formed teams to conduct the screen of applications assigned to the division. A screening worksheet was developed, tested, and made publicly available on the pesticides Web site.

To ensure consistency across the pesticide program, the initial screen is now conducted by a contractor followed within 10 days by a review of the results by Agency employees. This review includes compliance with the Agency's formatting guidance, PRN 86-5 Based on the experience gained during FY 2008, specifications were developed for this contractor support and it was phased in beginning with biopesticide applications on November 24, 2008, conventional herbicide applications on December 22, 2008, conventional insecticides on February 17, 2009, antimicrobials on March 9, 2009, conventional fungicides on March 23, 2009, and the remaining applications on April 6, 2009.

The Agency also phased in a more detailed review of Confidential Statements of Formula (CSF) (form 8570-4) to identify unapproved inert ingredients during the 21 day screen. The 21 day screening contractor conducts a preliminary review to determine whether all of the inert ingredients are approved for the proposed uses using the lists of approved inert ingredients available on the Web. Staff in the Inert Ingredient Assessment Branch (inertsbranch@epa.gov) confirm the status of any contractor identified unapproved inert ingredient. If an unapproved inert ingredient is identified and a request to approve the inert is not a component of the application package, the registrant is informed that data and a request to approve the inert ingredient needs to be submitted or the ingredient replaced with an approved one for the application to be further processed. The 21 day initial content review worksheet on the internet was modified with additional guidance on the Agency's review for unapproved inerts. In an analysis of CSFs submitted with conventional new product applications, the number of inert ingredient issues decreased from 26% to 7% as a result of this screen.

During FY 2009, 7 applications were rejected generally for missing or incomplete forms and data. In FY 2008, 14 were rejected.

Funds Management and Utilization

Section 33(c) of PRIA established the Pesticide Registration Fund. Congress established this fund in the Treasury of the United States to carry out the provisions of PRIA. All registration service fees received by EPA are deposited in this fund, and expenditures from the fund can cover the costs associated with 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. The Agency has been informed of the receipt of a payment within an average of 7.2 days of receipt by the bank, and the Agency automatically sends an acknowledgment of payment to those applicants with an e-mail address on file.

The Agency encourages applicants to pay their fees by credit card or wire transfer using the Treasury Department's pay.gov system. These payments are more efficiently deposited with the U.S. Bank. In FY 2008, payments totaling $4,780,737 were made through pay.gov for 959 decisions. This represents 56% of the total number of actions for which payment was received. In FY 2009, payments totaling $5,804,462 were made through pay.gov for 1,150 decisions. This represents 65% of the total number of actions for which payment was received and an increase from 2008.

Under PRIA 1, EPA notified applicants when a payment was 45 days overdue for all PRIA fee categories except Fast Track applications (because of the short time frames for these actions). The notification gave the applicant 75 days to forward payment before the application was withdrawn by the Agency. In FY 2008 the Agency sent 59 such letters, resulting in 40 payments (totaling $400,312), 11 withdrawn applications, 4 fee waivers, and 4 determined to be secondary actions requiring no fee. These applications were received prior to PRIA 2's effective date. Applications received on or after October 1, 2008 are covered by PRIA 2's payment provisions: if payment is not received, the Agency rejects the application. In the case of a change in fee category to a higher fee during an in-depth review of an application, the Agency invoices the applicant for the difference and 75-day notices were sent if the payment was not received on the date due. In FY 2009, seven 75-day letters were sent resulting in one withdrawal and 6 payments totaling $56,726. In FY 2010, the Agency will no longer issue such 75-day notices and will reject an application if a payment is not received by the date due specified in the invoice.

Communications and Outreach

Communications and outreach efforts in FY 2009 focused on PRIA 2 implementation issues. Agency staff discussed PRIA 2 implementation during the Chemical Producers and Distributors Association Registration Workshop and annual meeting, meetings of CropLife America and the Consumer Specialty Products Association, with State and EPA Regional staff at the Pesticide Regulatory Education Program, and with the Armed Forces Pest Management Board. EPA provided updates on the status of PRIA actions received and summary statistics during meetings of the Agency's Federal Advisory Committee, the Pesticide Program Dialogue Committee (PPDC), PPDC Process Improvement Workgroup and meetings with the PRIA Coalition, composed of industry, trade associations, and public interest groups.

EPA also has quarterly meetings with the Biopesticide Industry Alliance to discuss PRIA and other common issues and with the United States Department of Agriculture (USDA) Inter-Regional Research Project Number (IR-4) program, and monthly teleconferences with USDA's Animal Health Inspection Service and the Food and Drug Administration on Plant Incorporated Protectants. The Agency has a standing bimonthly meeting with the Biocides Panel and Consumer Specialty Products Association to discuss issues such as those concerning antimicrobial applications and the due date extension process, international activities, the Primary Eye Irritation Pilot Program, Design for the Environment, factual statements, nanotechnology, guidance for evaluation of products against *Clostridium difficile* and 2009

Pandemic Influenza A H1N1. Presentations were made to the Association of American Pest Control Officials (AAPCO) and American Society for Healthcare Environmental Services (ASHES) on how antimicrobial pesticides are approved. A Webinar was held with Practice Greenhealth, a networking organization for the healthcare community to discuss the registration process for disinfectants and sanitizers with a focus on test methodologies.

Guidance on fee category interpretations, fee reductions resulting from related applications, and refunds were posted on the PRIA 2 web site and additional guidance was provided on the 21 day initial content screen review worksheet and in the form of questions and answers. 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.

Registration Program Workplans

The Agency's pesticide registering divisions continue to make their processes more transparent by providing additional information to the public on its Registering Pesticides Internet site such as workplans, schedules, and guidance. The multi-year workplan for new conventional chemical actions and new uses under PRIA is updated quarterly. These updates reflect new actions received under PRIA, actions completed, and changes to schedules. For a majority of the new chemical and new use actions listed, the time frame in which the Agency expects to complete its registration decision is shorter than that specified by PRIA. When possible, requests for new uses submitted by USDA's IR-4 program that are also being requested by registrants are merged to allow one risk assessment. Additional economies and time-savings were achieved where possible by folding new use assessments into assessments conducted for reregistration, and in the future, registration review. As they are registered, the Agency continues to post risk assessments for new conventional pesticides to aid registrants with future submissions. Human health and ecological risk assessments are attached to the new active ingredient fact sheets.

The 2009 and 2010 workplans for biopesticides are available on the Agency's pesticides website. The biopesticides workplan is updated at least once a quarter to reflect completed actions and changes to the schedule. Biopesticide Registration Action Documents (BRAD), posted on the Web for all new biopesticide decisions, give the basis for the Agency's decision, including a review of the studies submitted to support the registration.

The Antimicrobial's FY 2009 workplan for new antimicrobials and new antimicrobial uses was published and the FY 2010 workplan is anticipated in the near future.

Financial Overview

During Fiscal Year 2009, the Agency received $17.1 million in new registration service fees and, after subtracting $1.0 million in refunds (overpayments and withdrawals), net receipts were $16.1 million. A balance of $9.4 million was carried forward from FY 2008, including recoveries of prior year unpaid obligations. From this total of $25.5 million, the Agency spent approximately $18.5 million, carrying the remaining balance of $7.0 million forward to FY 2010. 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 increased by 8% in FY 2009, compared with FY 2008. The end of year remaining balance decreased by 26% in FY 2009 from FY 2008. As OPP staff time

grew in order to meet PRIA deadlines, the major factor that increased spending in FY 2009 was the 24% increase in payroll charges.

Under Section 33(c), interest earned and added to the PRIA Registration Fund is available to the Agency for spending. Interest in FY 2009 totaled $7,432.

Agency's FY 2004 through FY 2009 Expenditures from the Pesticide Registration Fund Expenditures (in thousands)

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

Payroll expenditures increased to $9.4 million in FY 2009 from $7.6 million spent in FY 2008. Expenditures on contracts decreased to approximately $6.7 million in FY 2009, compared with $7.1 million in FY 2008. Consequently, the balance between payroll and contract expenditures changed somewhat from 2008 to 2009 (with payroll at 51% of expenditures in FY 2009 compared with 44% in FY 2008, and contracts down to 36% in FY 2009 from 42% in FY 2008). In addition to funds from the PRIA Pesticide Registration Fund, the registration program spent about $37.7 M from appropriated funds.

As was the case in FY 2008, spending on mandated programs totaled $2.25 million in FY 2009 under PRIA 2. These mandates included worker protection ($1.0 million), partnership grants ($0.75 million), and the Pesticide Safety Education Program ($0.5 million). The percentage of expenditures going to the mandatory programs was 12% in FY 2009 compared to 13% in FY 2008 due to an increase in overall expenditures 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 under certain specified situations. The maximum that a fee can be reduced 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 for requesting a reduction of a registration service fee is available on the Web. 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 and in the public interest.

In FY 2009, the Agency granted 306 fee waivers and exemptions and denied 6 of the 320 fee waiver/exemption requests received as shown in the following table. The remaining 8 were pending review at the end of the fiscal year.

Waiver Type	Received	Granted	Denied	Withdrawn
75% Ultra Business	201	189	6	0
50% Small Business	77	76	0	0
IR-4	31	30	0	0
Minor Use	1	1	0	0
Federal State	10	10	0	0
Total	**320**	**306**	**6**	**0**

The average number of days required to grant a fee waiver in FY 2009 (25 days) was consistent with the time required in FY 2008 (24 days). The average amount of time it took the Agency to deny a fee waiver/exemption is greater due to the increased time that the Agency took in an attempt to resolve the issues. The time to deny a fee waiver/exemption ranged from 17 to 54 days and the average in each quarter is shown below. The average number of days to deny a fee waiver during a fiscal year decreased from 42 days in FY 2008 to 37 days in FY 2009. There were no denials in the 2nd quarter FY 2009.

Average Number of Days to Process Fee Waivers in a Quarter, FY 2009

Quarter	To Grant	To Deny
1st Q	28	36
2nd Q	24	--
3rd Q	24	31
4th Q	24	44

The total fees waived and exempted in FY 2009 was $6.9 million, which was consistent with past fiscal years except for FY 2007 ($11.4M). This amount may increase once the eight pending requests have been resolved. The amount reported for FY 2008 in the FY 2008 annual report was $7.85 million and it increased to $8.18 million during FY 2009 due to changes in fee category to one with a higher fee upon an in-depth review of the application and once the 16 requests pending at the end of FY 2008 were resolved. The majority of the FY 2009 fee waiver/exemption requests, 77%, were IR-4 exemptions, and approximately 13% were small business fee waivers. The total amount waived for small businesses decreased again from past fiscal years. An increased amount was exempted in FY 2009 for applications from federal and state agencies in comparison to FY 2008. The first minor use fee exemption was granted in FY 2009.

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	$1,247	$6,908	$28		$8,184
FY 2009	$879	$5,326	$471	$209	$6,885

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 past fiscal years, the amount of registration service fees that were reduced declined each year from $3.7 million in FY 2004 to approximately $3,500 in FY 2007. In FY 2008, no voluntary payments were received, while in FY 2009, one voluntary payment was received with a fee of $1,365.

Reregistration and Expedited Processing Fund

In FY 2009, the amount of money from the Reregistration and Expedited Processing Fund (maintenance fees or yearly registration renewal fees) used to carry out new inert ingredient reviews under section 4(k)(3) totaled $0.6 million. This supported 4.5 work years. An additional $2.4 million from this fund were used to process fast track amendments and new products.

During FY 2009, 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 $24.6 million and 153.9 work years. The Fund has two types of receipts: fee collections and interest earned on investments. Of the $21.8 million in FY 2009 receipts, more than 99.9% were fee collections.

Appropriated funds are used in addition to Reregistration and Expedited Processing Fund dollars. In FY 2009, the Enacted Operating Plan included approximately $38.3 million in appropriated funds for reregistration and registration review program activities. This supported 208.1 work years and $11.0 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 2009 was $4.1 million, including recoveries of prior year unpaid obligations.

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 2009.

PRIA and Partnership Grants

When PRIA was reauthorized, an amount from the fees collected were set aside for partnership grants in Section 33(c)(3)(B)(ii): specifically $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 again augmented PRIA 2 funds with appropriated funds to award approximately $950K in grants and fund four projects. Table II provides a summary of this grant program's accomplishments with FY 2008 funds and lists the projects awarded with FY 2009 funds which began in late 2009 after a competitive selection process. Fiscal Year 2009 grants support the demonstration of innovative IPM practices and technologies, as well as outreach and education, in California, Florida, Wisconsin, Maryland, Pennsylvania, and Michigan. Approximately 50% of the FY 2009 funds support IPM approaches in urban communities and residences.

The FY 2010 Request for Proposals and PRIA 2 Partnership Grants competition is targeted for early February 2010. For FY 2010, EPA will award $500K in PRIA funds, and the solicitation for proposals will include projects to be funded by the Office of Science Advisor for approximately $400K. Additional information is available on the PRIA 2 Partnership Grants website.

Progress in Meeting Decision Times

Number of PRIA Actions Completed in FY 2009

The Agency completed 1570 decisions subject to PRIA during the fiscal year, 107 (6.4%) fewer than the 1677 completed in FY 2008. Among the FY 2009 completed decisions, 342 (21.8% of total) were antimicrobial decisions, 124 (7.9%) biopesticides and 1104 (70.3%) conventional pesticide decisions. The decrease in the number of conventional actions completed (139) resulted in the overall decrease in actions completed as shown below. The number of antimicrobial actions completed has steadily increased, while the number of biopesticide actions varied from one fiscal year to another. An additional 167 decisions were withdrawn (24 antimicrobial, 14 biopesticides and 129 conventional), while in FY 2008, 156 decisions were withdrawn with 22 antimicrobial, 10 biopesticides and 124 conventional decisions withdrawn. The number withdrawn has increased yearly from 2007 to 2009.

Type of Pesticide	Number Completed in Fiscal Year			Number Withdrawn in Fiscal Year		
	2007	2008	2009	2007	2008	2009
Conventional	1189	1243	1104	77	124	129
Antimicrobial	308	336	342	35	22	24
Biopesticide	123	98	124	24	10	14
Total	**1620**	**1677**	**1570**	**136**	**156**	**167**

EPA completed 99.7% percent of these decisions on or before their PRIA or extended due date. In FY 2009, four actions missed their statutory due date by one or two days due to processing delays. Among the actions withdrawn, the Agency exceeded the PRIA due date for five decisions due to environmental risk issues and these actions were subsequently withdrawn. Another was withdrawn two days after the due date.

Table III titled "Number of PRIA Actions Completed in FY 2007, FY 2008 and 2009", summarizes the number of decisions completed by PRIA category and compares FY 2007, FY 2008, and FY 2009. FY 2007 was the last year of PRIA 1 and results from FY 2007 are shown for comparison to the first two years under PRIA 2. A summary of the actions completed in FY 2005 and 2006 are provided in the FY 2008 PRIA Annual Report.

Actions received under both PRIA 1 and PRIA 2 were completed in FY 2009, and both types of fee category codes are shown. 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. An application can have more than one decision. The number of decisions depends on the number of product registrations in an application. If a tolerance petition is included in the application, the petition is also assigned a decision number to allow the Agency to track it and ensure that it is completed by the PRIA due date for the application. For instance, in FY 2009, one conventional first food use application package had six decisions, one for the tolerance petition and five for the five products associated with the package. Information on the number of active ingredients and uses registered each year are reported during a meeting of the Pesticide Program Dialogue Committee, a Federal Advisory Committee. 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 actions (or 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 by 6.4%. Because more actions were received in FY 2009 than in either FY 2008 or 2007 and fewer actions were completed in FY 2009, the number pending at the end of FY 2009 was greater than at the end of FY 2008. In comparing completions in FY 2009 with FY 2008, there were 33 fewer new active ingredient decisions, 105 fewer new use decisions and 92 fewer new product decisions. The number of new product decisions completed has consistently decreased from FY 2007. The number of amendments completed increased (58) along with other types of minor actions such as study waivers, protocol reviews and tolerance decisions (59) between FY 2008 and FY 2009. These differences were due primarily to differences in the number of conventional decisions completed.

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 time frames mandated under PRIA 2 generally remained the same as the last fiscal year under PRIA 1 for similar fee categories. Exceptions were a reduction in the time frame for conventional reduced risk pesticides and an increase in the time frame for biochemical new products that required more than product chemistry data. For instance, the time frame for a reduced risk food use new conventional active ingredient decreased from 21 months to 18 months, while a non-reduced risk new conventional active ingredient's time frame remained 24 months. Under PRIA 1, time frames decreased from one fiscal year to another, e.g., for an R17 the time frame in FY 2006 was 22 months and it was reduced to 15 months for FY 2007 and FY 2008. A decision's time frame is based on the fiscal year in which the application was received. The date that decisions completed in FY 2009 were received ranged from October 2004 to 2009, resulting in decisions completed within one fee category with different mandatory time frames. Consequently, the average decision time or the number of days the Agency took to complete a decision in the table can not be directly compared to the PRIA time frames mandated for FY 2009 for many types of actions. Statutory time frames under PRIA 2 and for some identical/substantially similar and new products, however, have been somewhat consistent from one fiscal year to another.

For similar PRIA 1 and 2 fee categories, the average decision review time frames for PRIA 2 decisions were generally lower in FY 2009 than in FY 2008 except for a few categories of actions. The amount of time to complete actions for conventional new products, conventional label amendments requiring review within the Registration Division, and antimicrobial label amendments remained the same. These actions have short statutory time frames that remained consistent between PRIA 1 and 2. An increased amount of time in FY 2009 was required for decisions on antimicrobial products with unregistered sources or no letter of authorization and some biopesticide actions. The number of biopesticide actions completed was small and as observed in past annual reports, the number is too small to make adequate comparisons.

In the FY 2007 report, the average decision times for conventional reduced risk new food use active ingredients and new food uses were greater than those of non-reduced risk decisions. The number of reduced risk decisions was too small for the Agency to conduct an adequate analysis in 2007. In FY 2008 the average decision times for reduced risk new active ingredients were lower than those for non-reduced risk decisions and this trend continued in FY 2009, probably the result of reduced time frames for reduced risk actions under PRIA 2. Even though decision review time frames for conventional new use reduced risk decisions decreased, the average for these decisions completed in FY 2009 was greater than the statutory time frame because of due date extensions.

For those actions with consistent statutory time frames between PRIA 1 and PRIA 2, the average decision time review period for antimicrobial identical/substantially similar new products were greater than the statutory time frame. Among the PRIA 2 decisions, the average decision time review period for biochemical new active ingredients, and amendments, some conventional new product categories, certain antimicrobial protocols, and antimicrobial new products were greater than the statutory time frame.

Among the FY 2009 completions, due dates for 303 (19.3%) decisions were extended by mutual agreement of the applicant and the Agency. The percentage of decisions completed with due date extensions has increased each fiscal year. During FY 2006, FY 2007, and FY 2008, 11%, 13%, 18% of due dates, respectively, were extended. Extensions generally resulted from missing or deficient data or information. Due dates were extended for 17.5% of completed conventional decisions, while in the previous fiscal year, 14.9% % were extended. Twenty percent of antimicrobial and 33.9% of biopesticides were extended while in FY 2008, 22% and 48% respectively were extended.

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

	FY2007		FY2008		FY 2009	
Fee Category	Number due date extensions	Total Completed	Number due date extensions	Total Completed	Number due date extensions	Total Completed
Antimicrobial (A)	77	308	74	336	68	342
Biopesticide (B)	52	123	47	98	42	124
Conventional (R)	78	1189	185	1243	193	1104
Total Decisions	207	1620	306	1677	303	1570

The number of decisions with due date extensions was approximately the same in FY 2009 as in FY 2008, though the percentage of completed decisions with due date extensions increased in FY 2009 due to the decreased number completed. As discussed previously, a new use application package can have a number of decisions while a new product or amendment application package will have only one decision in the Agency's tracking system. Many new product and amendment applications, however, are dependent upon each other's data as described in the primary/secondary guidance and if there are data issues, the due dates for all of the affected applications will be extended. Consequently, an analysis of due date extensions using decisions can only indicate trends from one fiscal year to another. The 303 decisions with due date extensions were in the following general types of applications received by the Agency.

Number of Decisions with Due Date Extensions by Type of Decision

Fiscal Year	New Active Ingredient	New Uses	New Products	Amendments	Other (EUP, tolerances, protocols, etc.)	Total with Due Date Extensions
2007	28	18	121	35	5	207
2008	29	94	142	31	10	306
2009	17	93	123	52	18	303

Of the due date extensions in the different types of fee categories, new active ingredients, new uses, etc, new active ingredients continued to have the highest percentage of extended due dates. In FY 2008 and FY 2007 approximately 38% of the new active ingredient decisions completed had extended due dates and the rate was similar in FY 2009, 37%. Due dates were extended due to data deficiencies unique to each application. The percentage of new product decisions completed (both identical/substantial similar (fast track) and non-fast track new products) with due date extensions remained the same between FY 2008 and FY 2009 at approximately 17%, an increase over FY 2007's 14%. A common reason for these extensions was product chemistry data deficiencies. In the FY 2008 PRIA Annual Report, the Agency reported that the percentage of new use completions with due date extension increased substantially in FY 2008 (27%), compared to FY 2007 (7%) due to the time required to resolve risk issues. The percentage of new use completions with due date extensions again increased in FY 2009 to 39% and for the same reason. A smaller percentage of completed amendments 12% had due date extensions. This rate was higher than in FY 2008 (8.4%) and FY 2007 (9.5%).

Note: Appendix A contains a list of all application subject to PRIA completed during FY 2009 and includes the decision times for each application. (Microsoft Excel Viewer EXIT Disclaimer is needed to view this file.)

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 and have mandated decision review time frames under PRIA. 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 2009 was 299 of which 245 were completed within 90 days and 277 were completed within their three month PRIA time frame and the remainder had due date extensions. An additional 74 identical or similar new products with time frames of greater than three months (A531, A532 and R301) were completed (57 within the PRIA statutory time frame and 17 with due date extensions). In comparison to FY 2008, the number of decisions with a three month time frame completed in FY 2009 decreased (299 versus 358) while the number of decisions completed with longer time frames increased (74 versus 37). The percentage of three month time frame decisions completed within their statutory time frame was the same in FY 2009 (92.6%) as in 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 2009, the

Agency completed 2640 fast track amendment decisions or actions (unaudited results - antimicrobial 864, biopesticide 154, and conventional 1622) which had 3092 submissions (891, 209, and 1992, respectively). Each decision can have a number of submissions, each with a time frame of 90 days. Of these submissions, 2792 were completed within 90 days (884, 130, and 1778, respectively).

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 49 decisions in fee category A530, 41 (84%) were completed within 90 days and 42 (86%) completed within the three month PRIA time frame. The remaining 7 had due date extensions. Of the 31 other substantially similar or identical products in fee categories A531 and A532, 19 were completed within their PRIA time frame of 4 months and the remaining 12 had due date extensions. Only 3 of these latter actions were completed within 90 days.

Regarding other new product decisions in fee categories A54, A540, A55, and A550, the section 3(h) time frame is 180 days with a goal of reducing the review time to 120 days. Of the 78 decisions in these fee categories, all met their PRIA due dates or extended due dates and 48 (62%) were completed within 120 days and 64 (82%) were completed within 180 days. The remaining 14 decisions had due date extensions.

Number of PRIA Applications Pending at the End of FY 2009

Table IV summarizes the pending registration applications (counted as decisions) in each of the PRIA categories. As of September 30, 2009, 1187 applications subject to PRIA were pending in the Agency's registration queue. Numbers pending at the end of FY 2008 and FY 2007 are shown for comparison – 1129 and 1207, respectively. The number of applications received in FY 2009 was greater than FY 2008 and FY 2007. As observed in the FY 2008 annual report, receipts in FY 2008 were approximately the same as in FY 2007. Because of the increase in receipts, decrease in the completions, and only a slight increase in the number of decisions withdrawn, the number pending at the end of FY 2009 increased by 58 over that of FY 2008.

The total number of applications (counted as "decisions") received in FY 2009 increased by 75 from FY 2008. The difference in receipts between FY 2008 and FY 2007 was eight decisions.

	Difference in Number of Decisions Received between Fiscal Years		
Totals	**2007 and 2008**	**2008 and 2009**	**2007 and 2009**
New Active Ingredients	14	9	23
New Uses	-7	-9	-16
Experimental Use Permits	-6	15	9
New Products	-148	25	-123
Amendments	77	16	93
Other (protocol reviews, tolerances, study waivers)	78	19	97
Total	**8**	**75**	**83**

Receipts in all categories of actions except new uses increased in FY 2009 over FY 2008. The numbers of new active ingredient, amendment and other types of decisions received have continued to increase since FY 2007. Among the other types of decisions are the actions in the new fee categories created by PRIA 2, and the difference in the number of other decisions received between FY 2009 and 2008 was due to an

increase in the number of conventional protocols submitted for review. An increase in the number of conventional amendments (20) accounted for the general increase in amendments between FY 2009 and FY 2008. Conventional new product receipts have not rebounded after the substantial decrease in receipts (-124) experienced between FY 2007 and FY 2008. The increase in new product receipts between FY 2009 and 2008 was due to slight increases in the number of antimicrobial (13) and biopesticide (11) decisions received.

The number of antimicrobial decisions pending at the end of FY 2009 was approximately the same as FY 2008 (188 and 179, respectively), reflecting approximately level receipts (379 and 382), completions (342 and 336) and withdrawals (24 and 22). In considering decision type, the number of pending new uses (34 and 43) decreased while pending new products increased (82 and 68).

The pending number of biopesticide decisions was higher in FY 2009 (147 versus 127) due to increased receipts (161 versus 137). The difference in pending new product decisions accounted for the increased number of decisions pending in FY 2009 from FY 2008 (55 versus 33).

Among conventional pesticide decisions, the number pending at the end of FY 2009 increased from the end of FY 2008 (852 versus 823). The number of pending decisions was consistent between FY 2009 and FY 2008 for all types of actions except new active ingredient decisions indicating that the Agency was keeping up with conventional receipts. The number of new active ingredient decisions pending increased from 68 in FY 2008 to 96 in FY 2009 due to a decrease in the number completed (23 in FY 2009 versus 60 in FY 2008) and increase in receipts (54 in FY 2008 and 63 in FY 2009).

Pending Inert Ingredient Reviews at the End of FY 2009

FIFRA section 33(k)(2)(F) requires EPA to provide the number of inert ingredients (inerts) pending review by the Agency. In FY 2009, three new petitions for a food use inert were received as PRIA actions and an additional 45 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 2009, 40 Final Tolerance Rules were published; one petition was denied; and five petitions were withdrawn due to deficiencies. At the end of FY 2009, there were 47 petitions in review, which included four petitions with deficiencies and 43 in various stages of review. All inert ingredient petitions are scheduled for review on the workplan 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 prospective petitioners to discuss the reliability and adequacy of the data to meet the FQPA (Food Quality Protection Act) safety finding. In FY 2009, an additional 30 non-food use requests were granted and two non-food use requests were withdrawn or denied. Fourteen non-food requests were pending at the end of FY 2009.

The Inert Ingredient Assessment Branch (IIAB), consisting of seven employees at the end of FY 2009, reviews inert ingredient actions. When needed, IIAB staff are supplemented with staff in other pesticide regulatory groups, particularly to review inert ingredients associated with biopesticide and antimicrobial products.

Process Improvements in the Registration Program

Section 33(e) of FIFRA 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. A number of steps were undertaken, internal and external, to explore, develop, and implement improvements in registration and registration review processes.

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

Pesticide Program Dialogue Committee PRIA Process Improvement Workgroup

The PRIA Process Improvement Workgroup was created in FY 2004 under the auspices of the Agency's Federal Advisory Committee, the Pesticide Program Dialogue Committee, to evaluate process improvements for 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 April 20 and October 1, 2009, PPDC PRIA Process Improvement Workgroup meetings are posted on the internet.

Industry stakeholders and Agency staff identified many areas for improvement in the registration and registration review process, including labeling consistency, communication of schedules, use of electronic tools, application and submission guidance, and efficiencies in product reregistration and registration review. Many of the process improvements implemented by the Agency have addressed these issues. The Agency continues to work with all stakeholders to evaluate potential improvements to the registration and registration review processes. 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. Future projects and efforts are identified through a dialogue between the Agency and stakeholders.

Electronic Submission and Document Retention

The Agency is conducting a number of efforts to use 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 to broadcast this initiative. 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 adopted 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 within e-Submission, the data and documents are seamlessly blended into other PRISM components (Document Management Workflow) for processing within the pesticide programs. 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 the Organization for Economic Cooperation and Development (OECD) to develop a common, globally accepted standard for the transport of electronic data to the 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 fiscal year 2009, OPP received 386 e-submission packages. There were a total of 5177 documents associated with these 386 packages out of a total of 4020 submissions.

Number of FY 2009 e-Submissions Compared to Paper Submissions

Quarter	Number e-Submission Packages	Number of Documents	% of all e-Submissions rejected	Number Paper Submissions	% e-Submissions of Total
1st	95	1714	36%	743	11%
2nd	103	1339	41%	954	10 %
3rd	100	1161	42%	896	10 %
4th	88	963	32%	1041	8 %

To facilitate the 21-day initial content review, a Workflow Management tool was developed for the registration program and in FY 2009, it was modified to notify the 21-day screening contractor that e-Registration documents are available on line for their review. This feature allows the contractor and staff to work with all electronic documents on line.

As a result of scanning documents and storing e-Registration documents, a Documentum library of over 190,000 documents is available electronically, an increase of 40,000 documents from FY 2008. Documents stored in the library consist of studies, forms, letters, and labels.

Electronic Labels

Acknowledging the Agency's efforts in this area, under PRIA 2, FIFRA Section 33(k)(2), the Agency is required to report the number of label amendments reviewed using electronic means and make recommendations for electronic submission and review of labels, including process improvements to further enhance the procedures used in electronic label review. The Agency and stakeholders recognize that reviewing labels can be time consuming. Procedures for submitting labels in electronic format have

been in place for eight years. Registrants must format e-labels as text pdfs, name the file following a specific syntax, and submit the e-label either a) as a stand-alone file on a CD-ROM along with a paper application or b) as part of an XML file on a CD-ROM submitted without paper. Agency staff can then use Adobe Acrobat software to a) compare the proposed label against a previous version to identify changes and b) mark any required corrections on the e-label. Revisions of e-labels can usually be done using e-mail to exchange revised pdfs.

In the past, the Agency has been able to count the number of e-labels submitted but not the total number of label actions received in the same time period (and thereby calculate the percentages of paper and e-labels). To enable these statistics to be calculated, the Agency has been modifying its tracking system over the past two years to track electronic label submissions and to enable its staff to record when labels were reviewed electronically. This effort was completed at the beginning of July 2009. The statistics reported for FY 2009 are an estimate based on actual data from the fourth quarter, which were then multiplied by four to extrapolate to the entire year. Since label submissions are not necessarily constant throughout the year, these results are estimates and statistics reported in subsequent fiscal years can not be directly compared to these results.

FY09 Labels Submitted*

Type of Product	# labels submitted	% electronic labels
Antimicrobial	2,368	7 %
Biopesticide	540	7 %
Conventional	9,444	15 %
Unassigned	124	10 %
Total	**12,476**	**13 %**

* Data from the fourth quarter of FY09 was multiplied by four to reflect a full year of submissions.

FY09 Labels Reviewed*

Type of Product	# all labels reviewed	# e-labels reviewed	electronic label reviews	
			% of all labels	% of e-labels
Antimicrobial	2,664	160	5 %	80 %
Biopesticide	340	20	5 %	80 %
Conventional	8,156	780	6 %	58 %
Unassigned	48	8	8 %	50 %
Total	**11,208**	**968**	**5 %**	**62 %**

* Data from the fourth quarter of FY09 was multiplied by four to reflect a full fiscal year.

Based on these estimations:

1) Of approximately 12,500 label actions submitted to EPA in FY 2009, 13% included an electronic label.
2) Of approximately 11,200 label actions completed by EPA in FY 2009, 9% included an electronic label.
3) Of the label actions completed by EPA in FY 2009 that included an electronic label, 62% were reviewed electronically.

When considering the type of pesticide product, almost three quarters of the label actions submitted were for conventional products. Twice the percentage of conventional label actions was in electronic format as compared to antimicrobial and biopesticide label actions. However, of the electronic labels received, a higher percentage was reviewed electronically by antimicrobial and biopesticide staff than by conventional product staff.

Note: The two tables 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 2009 may not be reviewed until FY 2010. Conversely, labels reviewed in FY 2009 may have been submitted in earlier years.

Adoption of the e-label procedures by both registrants and EPA staff has been increasing slowly over the years. Registrant procedures for creating and submitting e-labels are detailed on EPA's website and have been presented and will continue to be presented in numerous industry meetings. All EPA label review staff were trained in the review of e-labels in 2007. Notification review staffs were trained in January 2010. Additional training classes for both registrants and Agency staff and one-on-one coaching are planned during 2010.

As a next step in improving electronic label submission and review, EPA prepared a comprehensive list of requirements for electronic labels (e-Label) in FY 2008. The objective of this effort is to improve the process of reviewing labels electronically and provide a tool for applicants to use in developing their labels. The general premise of the e-label is to identify all label content in a structured manner so that individual label elements can be processed with automated systems. Structured label content is expected to still further improve the efficiency of the label review process, allow for greater consistency of labeling content, and facilitate the distribution of product labeling via the Internet. Based on those requirements, the Agency is developing an XML schema definition that describes the technical specifications for the structured label content. Also under development is an application to load e-labels into the internal data system. The preliminary requirements for the "builder" application, to be used to create the needed e-label file, were gathered and the e-Label Loader application was developed in FY 2009. Once the other components of the structured e-label are finalized and implemented, the e-label builder and loader are expected to reduce the amount of time required for an applicant to prepare a label and for the Agency to review it.

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. A subgroup, the Label Review Manual Team, was formed to revise and continually update the Label Review Manual. During FY 2009 the Team completed its review and revisions to the Manual. All of the revised chapters have been posted to the Web; however, Chapter 13 will have some additional edits in the near future to reflect changes in storage and disposal regulations.

The Committee developed a Web site to communicate its activities and to address the public's labeling policy questions forwarded through the Web site's e-mail address (OPP_labeling_consistency@epa.gov). The Committee received 105 questions during FY 2009 (a total of 312 questions since the site began). Answers to the majority of these questions were posted while some received a direct response. The Agency reorganized the question and answer portion of the Web site to provide more useful subject matter categories. The reorganized Web page was posted during FY 2009. At the suggestion of stakeholders, the Agency now flags new questions and answers with the word "New" in yellow for 30 days. The date answers were approved by the Agency is now placed next to the associated question. To address concerns that responses being posted on the Web site might be perceived as requiring changes

to labels already on the market, the Committee placed a disclaimer of that intent at the beginning of the question and answer Web page.

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 is posted, and an additional policy summation regarding certain label claims for cleaning products is likely in the near future.

Product Chemistry

An analysis of the reasons for PRIA due date extensions in FY 2009 again showed that in each of the pesticide registering divisions up to 60% of the due date extensions involved product chemistry issues (including inert issues). Many common errors are made on the Confidential Statement of Formula (CSF) form on which registration applicants list the contents of a product. The Agency has developed a smart CSF form (e-CSF) for applicants' use that became available on-line in spring 2009. The smart form informs the applicant when a required portion of the form has not been completed or if the percent composition column does not add to 100%. The completed form can then be submitted in an electronic file format, which will reduce the Agency's reliance on paper and data entry required for the current paper-based process and make information readily available within the pesticide registration program. Improvements in the e-CSF builder have been suggested, such as identifying unapproved inerts and improving the "help" menu. These suggestions will be evaluated during FY 2010.

When the source of a conventional active ingredient is changed to a different manufacturer or source, the manufacturing or synthesis process may result in different impurities, which the Agency must assess for potential toxicological concerns. The Agency has a process in place involving the human health risk assessors to evaluate these impurities. This was due to an increase in the number impurities being noted associated with source changes and the additional or other impurities identified in the manufacturing (technical) product.

Process Improvements Implemented within the Pesticide Registration Program

The Agency's success in meeting due dates was a result of its continued monitoring of the status of PRIA decisions and identification of efficiency measures that conserve resources and time. Internal processes and tracking systems were modified to incorporate the 5% fee increase and to more effectively track and monitor study waiver requests and protocol submissions. All automated reports were then appropriately modified to monitor late applications and payments, and to report, for instance, the status of fee collections, rejections and due dates.

Agency staff continued to meet regularly to monitor workload and compliance with PRIA due dates and to resolve fee category and interpretation issues. For instance weekly staff meetings focus on the status of pending decisions, due date extensions, and refunds; identifying and resolving potential issues; resolving fee category questions; and coordinating schedules with science support organizations. During these meetings, staff identified PRIA 2 implementation issues and then discussed them with senior management during bi-weekly senior management meetings to ensure consistent implementation of PRIA across the pesticide program. Reasons for not granting, rejecting, or extending a due date are reviewed for consistency and to identify improvement opportunities such as incorporating additional reviews into the 21 day content screen. Senior managers continued to review justifications and make final decisions to extend or negotiate a PRIA due date and whether or not to issue a "PRIA Determination to Not-Grant" as under PRIA 1.

Staff reviewed policy decisions made during PRIA 1 for consistency with PRIA 2. This led to modifications in the questions and answers posted on the PRIA 2 web site and a detailed analysis of the manner in which discretionary refunds were given for applications dependent upon other applications which resulted in the related applications guidance posted on the internet. Inconsistencies in fee categories between A, B and R categories were identified particularly in how applications with an unapproved inert and requests to approve an inert were classified. This resulted in additional guidance on inert ingredients for the 21-day initial content review worksheet.

Pandemic 2009 H1N1 Influenza A Virus (Formerly Called Swine Flu)

The Agency published guidance to streamline the process for approving H1N1 Influenza A Virus claims on product labels. Typically, if registrants requested that this claim be placed on their labels, they would need to submit "virus specific" efficacy data under PRIA, a 120 day review process. The Agency worked with the Centers for Disease Control. By using the disinfection hierarchy, the Agency concluded that if a disinfectant product bears a label claim against human, avian, or swine influenza A virus, and efficacy data supported these claims, then a registrant may add Pandemic 2009 H1N1 Influenza A Virus to the product label via notification, a thirty day review process.

Science Review Improvements

OPP Science Policy Council

The Agency continued to improve the scientific basis of its review of and decision-making on applications. In June 2009 the Agency established the OPP Science Policy Council. 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. The Council focuses on cross-cutting science issues relevant across the program. The key functions of the Council are anticipating and proactively addressing emerging issues, providing research priorities, and transitioning new science policies and methods into its processes.

Over the next several years, the Agency will improve and transform its approach to pesticide 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.

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; implementation and analysis of a global survey on pollinators; development of alternative approaches to estimate toxicity to aquatic life; harmonization of testing guidance with other countries; refinement of ecological risk assessments for pesticides with persistent, bioaccumulative, and toxic characteristics; and publication of peer-reviewed ecotoxicity values. Examples of these improvements include the following:

Joint reviews with OECD members: 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 shared technical information with OECD countries and developed joint projects that will further improve the joint reviews of

ecotoxicity studies. Examples of these joint projects include the harmonization of the terrestrial field dissipation guidance with OECD and the development of a crosswalk of ecoregions between North America and European countries. The Agency is also beginning to work with China in developing harmonized pesticide risk assessment approaches, conducting two training workshops on human health and ecological risk assessment in 2009.

OECD pollinator survey: The Agency also worked with the OECD to develop and implement a survey on pollinator testing programs, research, risk mitigation activities, and communication/outreach efforts, including the reporting of incidents. Responses were received from 17 countries and a final survey report was developed in October 2009. A high percentage of respondents indicated that declines in bee populations have been documented in their countries, and that declines have also been observed in other pollinator populations. Initial recommendations based on survey findings were proposed in November 2009, and included developing a mechanism to facilitate reporting of pollinator incidents among countries, coordination in the development of additional studies on toxicity to pollinators, sharing information on effective risk mitigation methods used in different countries, and mechanisms for global co-ordination of research efforts related to pollinator declines to facilitate research.

[Q]SARs: In the registration review program, the Agency has developed an approach for identifying critical ecological effects data gaps early in the risk assessment process. The Agency has also proposed and implemented scientifically appropriate methods to conduct risk assessments by relying on alternative [quantitative] structure-activity relationships ([Q]SARS) tools such as ECOSAR (Ecological Structure Activity Relationships) and ASTER (Assessment Tool for the Evaluation of Risk) to estimate the toxicity of pesticides, their degradates/metabolites, and potential contaminants to aquatic organisms when measured values are not available. Using these alternative techniques reduces uncertainties, the workload, and review times for the Agency, and reduces the testing burden on registrants. If additional data are still needed after using alternative techniques, EPA will request additional testing from the registrants.

KABAM: EPA completed its quality assurance review of its bioaccumulation model called KABAM (KOW (based) Aquatic BioAccumulation Model) to estimate potential bioaccumulation of hydrophobic organic pesticides in freshwater aquatic food webs and subsequent risks to mammals and birds via consumption of contaminated aquatic prey. This model can also be used to estimate pesticide concentrations in fish tissues. The model is composed of two parts: 1) a bioaccumulation model estimating pesticide concentrations in aquatic organisms and 2) a risk component translating exposure and toxicological effects of a pesticide into risk estimates for mammals and birds consuming contaminated aquatic prey. In the bioaccumulation component, pesticide tissue concentrations in aquatic organisms are calculated for different trophic levels of a food web through diet and respiration. In the risk component of KABAM, pesticide concentrations in aquatic organisms are used to estimate dose- and dietary-based exposures and associated risk quotients for mammals and birds consuming aquatic organisms. The methods used in the risk component of KABAM are consistent with the pesticide program's current modeling approach for assessing risks to terrestrial mammals and birds described in USEPA 2004a (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs), as implemented in the T-REX model (version 1.4.1). More information concerning this model can be found at: http://www.epa.gov/oppefed1/models/water/kabam/kabam_user_guide_appendix_f.html.

Aquatic Life Benchmarks: In response to requests from FIFRA state lead agencies and state water quality agencies, EPA developed 78 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 148 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) continued to work with the Office of Water (OW) to develop a harmonized approach for assessing aquatic toxicity data. In 2009, OPP and OW developed a Scoping Document that describes the Agency's efforts to develop a consistent and common set of effects characterization methods for both programs. This document describes the Agency's initial thinking on integrating the approaches used by OW and OPP for characterizing effects of pesticides to aquatic life. The technical work to develop these approaches began in 2009 with a meeting that included scientists from the Office of Research and Development (ORD), OPP, and OW. An extensive program of outreach to stakeholders is planned in 2010, beginning with six public meetings, starting in January 2010 at locations throughout the U.S. In these public meetings, EPA will solicit input from regional stakeholders regarding methods, tools, and approaches being developed and evaluated by OPP and OW, as well as additional sources of data and types of values used by states for protecting aquatic life. 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 2009, the pesticide program continued to work with EPA's National Risk Management Research Laboratory (NRMRL) and Region 9 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 spring of 2010, EPA plans to finalize this testing protocol based on the test results performed 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.

Pesticides with persistent, bioaccumulative, and toxic characteristics: Standard pesticide risk assessment methods do not address the unique characteristics associated with pesticides that exhibit persistent, bioaccumulative, and toxic (PBT) characteristics. In October 2008, EPA convened a Scientific Advisory Panel (SAP) to review issues and methods for ecological risk assessment of PBT-like pesticides. This SAP peer review was an initial step in a process for making refinements to the Agency's ecological risk assessment practices for addressing pesticides with PBT profiles. Over the next years, EPA will return to the SAP for additional review of specific methods and tools related to ecological risk assessment of pesticides with PBT characteristics. Additional information about this SAP meeting can be found on http://www.epa.gov/scipoly/sap/meetings/2008/102808_mtg.htm.

EPA is also leading an OECD "PBT Expert Group" for harmonizing approaches for addressing PBT risk assessment issues. Current participants represent 7 countries and 2 international institutions. This group will be developing risk assessment guidance for pesticides with PBT characteristics. In addition, EPA is actively participating in the review of chemicals nominated for annexation into the Long-Range Transboundary Air Pollution (LRTAP)/ Persistent Organic Pesticides (POPs) Convention and the Persistent Organic Pollutants Review Committee (POPRC) of the Stockholm Convention. Recent technical review meetings with EPA participation included the LRTAP/POPs meeting June 2009 in Bulgaria and the Stockholm POPRC in October 2009 in Switzerland.

Atrazine Monitoring Issues: In December 2007, EPA presented the Comprehensive Aquatic Systems Model (CASM) to the FIFRA Scientific Advisory Panel (SAP). CASM was developed to determine a level of concern (LOC) that compares atrazine concentration and exposure durations from monitoring data to effects measured in a series of microcosm and mesocosm studies which were used in the original atrazine (IRED) assessment. During the May 2009 FIFRA SAP meeting, EPA presented new evaluations of the applicability of the revised CASM atrazine model to freshwater atrazine risk assessment and gave reasons for not supporting further development and application of this model. A simpler alternative to the CASM-based approach, Plant Assemblage Toxicity Index (PATI), was presented for relating atrazine surface water exposures to the microcosm and mesocosm effects. 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/2009/may/051209minutes.pdf.

In FY 2009, the Agency continued its efforts to incorporate tools in its aquatic risk and exposure assessments that will enable the Agency to identify specific geographic 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. For instance, the Atrazine assessment incorporates these technologies.

Human Health Risk Assessments

The Health Effects Division (HED) reorganized its registration and reregistration branches into 7 Risk Assessment Branches that perform both registration and registration review activities as discussed in the FY 2008 annual report. The reorganization has positively impacted the Division's work processes. Accountability and efficiency increased as a result of an individual overseeing the entire risk assessment process for a specific pesticide.

Regarding science review committees, the Residues of Concern Knowledgebase Subcommittee (ROCKS) is leading the application of predictive Tox 21 tools for metabolites, residues, and environmental degradation products. In calendar year 2009, the Dose Adequacy Review Team (DART) met seven times on six different chemicals to select doses for carcinogenic studies in rats and mice, and most recently, for immunotoxicity studies. The Cancer Assessment Review Committee (CARC) met four times on four different chemicals to establish cancer classifications on these chemicals, and the Toxicology Science Advisory Council (ToxSAC) met twenty-four times on twenty-six chemicals to determine end-points of concern.

Improvements in the Agency's pesticide human health exposure and risk assessments were focused in three major areas in FY 2009: 1) update and improve assessment methodologies and processes by incorporating recent scientific advancements and presenting these improvements to the FIFRA Scientific Advisory Panel (SAP) meetings for advice and comment; 2) advance assessment tools to increase the confidence of risk calculations; and 3) globally harmonize the tolerance (MRL) setting process. Significant progress was made in each area.

Worker Reentry Exposure and Risk Assessment: In December 2008, the SAP reviewed occupational post-application exposure monitoring studies conducted by the Agricultural Reentry Task Force (ARTF) and considered the Agency proposal for the duration of workday in exposure assessments. The SAP concluded that the studies were robust and useful for exposure assessment purposes and that the proposed use of individual studies to represent 'clusters' of similar occupational post-application reentry activities and the approach and inputs used – specifically for workday duration and for multi-day exposure assessments (i.e., short/intermediate-/ and long-term) were reasonable. The Agency will update its policy based on the Panel's advice and once implemented, better characterization of exposure and risk are expected.

Antimicrobial Exposure Assessment Task Force (AEATF): The AEATF was formed by a number of antimicrobial pesticide registrants to develop additional data to better represent actual exposure levels for a wider range of antimicrobial pesticide handler activities. The risk assessment process could be streamlined with a generic exposure database that can be used to assess new antimicrobials or new antimicrobial use requests. The AEATF is collecting data by monitoring dermal and inhalation exposures of applicators. In FY 2009, the field phase of the mop and wipe studies were completed. The aerosol study protocol was presented and accepted by the Human Studies Review Board (HSRB) in October 2009. Once studies are completed, the results will be reviewed by the HSRB.

Antimicrobial Exposure Joint Venture (AEJV): The AEJV is an industry group that has gathered in-home residential antimicrobial product use information. They are gathering information to answer the questions of when, where, how, and how often are antimicrobial products being used. These data will be reviewed and assessed by EPA for use in its risk assessments.

Pyrethroid Common Mechanism of Action: In June 2009, the SAP reviewed the Agency's evaluation of laboratory studies and other scientific information on the common mechanism of action of pyrethroid pesticides contained in a draft science policy document, "Proposed Common Mechanism Grouping for the Pyrethrins and Synthetic Pyrethroids". Synthetic pyrethroids are a class of insecticides structurally based on the pyrethrins, botanical insecticides extracted from *Chrysanthemum cinerariaefolium*. The potential exposure of the general public to these pesticides has increased over the past decade due primarily to the decreased residential use of organophosphates and *N*-methyl carbamates. The basis for a shared (i.e., common) mechanism of action for these compounds includes 1) shared structural characteristics and 2) shared ability to interact with the sodium (Na) channels. Two different neurotoxicity syndromes are expressed and the Panel agreed that these pesticides should be separated into two subgroups, Type I and II pyrethroids. After the policy is finalized, the naturally occurring pyrethrins and synthetic pyrethroids will be subject to cumulative risk assessments.

Integrative Testing and Assessment: The Agency initiated work on a long term vision for the application of Integrative Testing and Assessment (IATA) or computer-aided methods and integrated tools to better predict potential hazards and exposures. Activities have included a PPDC work group; a Web page to communicate with stakeholders on IATA issues; a computer model for predicting estrogenic activity; a pilot of the use of non-animal testing to address labeling requirements for pesticides; and development of a pesticide metabolism database (MetaPath). (Q)SAR-related

activities that support IATA include a project to enhance existing (Q)SAR models with pesticide-specific data, development of a QSAR guidance document, testing the predictive performance of (Q)SAR models on pesticides, integrating traditional studies with QSAR data and other information, and participation in the development of the proposed rule on the use of (Q)SAR to address data requirements for selected pesticides. For MetaPath, the Agency is populating the database with rat, plant, and environmental degradation metabolism data. These efforts have involved collaborations and partnerships within the Agency and with the US Food and Drug Administration and Canada's Pest Management Regulatory Agency (PMRA) experts on QSAR and MetaPath.

F1 Generation Study: The Agency is developing improved animal study designs to more reliably and efficiently address risks to children through its proposed enhanced F1 generation reproductive toxicity study as part of the greater IATA effort. The new enhanced F1 generation study will better target and more efficiently address potential toxicity on the reproductive, neurological, and immunological systems with the use of fewer animals. It is scheduled to be presented to the SAP in 2010.

Non-animal Testing for Eye Irritation for Certain Antimicrobial Products with Cleaning Claims: The Draize rabbit eye test is used to determine eye hazards and the required hazard labeling for pesticide products. The Agency initiated a pilot project in May 2009 with interested applicants, designed to evaluate the effectiveness of a specific alternative non-animal testing approach, as a potential replacement for the Draize rabbit eye test for labeling antimicrobial products with cleaning claims. The proposed testing strategy uses three assays; the Bovine Corneal Opacity and Permeability test (BCOP), the EpiOcular™ model (EO), and the Cytosensor Microphysiometer assay (CM).

The objective of this voluntary pilot project is to evaluate and gain experience with certain non-animal testing methods (*i.e., ex vivo* and *in vitro*). Data submitted under this pilot will be used in labeling decisions if the results are deemed by the Agency to be adequate and appropriate to support such regulatory decisions. Eighteen months after the start of the pilot project, the data will be compiled and analyzed and the final assessment document will be presented to OPP's Science Policy Council for their recommendations on this non-animal approach.

Global Harmonization of MRLs: A NAFTA-harmonized approach to establishing tolerances developed several years ago is currently being used by Canada, Mexico, and the U.S. to establish harmonized tolerances, which serves to encourage trade and minimize trade irritants among the NAFTA partners. To encourage such harmonization on a global scale, an OECD workgroup with EPA's participation and responsible for harmonizing the MRL-setting process among the OECD member states, is extending and expanding upon the previous tolerance harmonization work of the NAFTA Workgroup.

Section 33(k)(2)(A) directs the Agency to report its recommendations for the allowance and use of summaries of acute toxicity studies. To date no acute toxicity summary has been submitted to the Agency for review. However, if submitted electronically, they can be used to create a Document Evaluation Record (DER) or the Agency's review. Currently, OECD template study reviews submitted electronically with new active ingredient submissions are being used as a skeleton for the Agency's DERs.

Product Reregistration Progress and Accomplishments

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 Web site. 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 still were required to be reregistered.

As of the end of FY 2009, 22,122 pesticide products are subject to product reregistration. EPA has completed decisions for 11,262 of these products and still must complete decisions for 10,860 products. EPA expects to complete product reregistration in 2014.

FY 2009 Progress and Goals

During FY 2009, EPA completed 1,769 product reregistration decisions, significantly exceeding its goal of 1,275 decisions. EPA's goal is to complete 1,500 product reregistration decisions in FY 2010.

Historical Product Reregistration Decisions

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

REDs with Product Reregistration Decisions Completed

As of the end of FY 2009, EPA has completed product reregistration decisions for 214 REDs (out of a total of 384 REDs). These 214 REDs include 27 of the 31 organophosphates (OPs).

Process Improvements

During the past several years, as RED production work decreased, EPA has placed increased emphasis on post-RED work and product reregistration. As a result of an external review of the product reregistration process that was completed in 2006 – 2007, EPA has initiated a number of efforts to improve the timeliness and overall productivity of the product reregistration program. These efforts include, for example, use of a streamlined batching process, which has reduced the number of product-specific acute toxicity studies required; streamlining the Agency's internal work flow processes; and incorporating quantitative goals into performance standards for managers and staff. As a result of these efforts, the number of product reregistration decisions completed each year has increased significantly.

During FY 2009, EPA completed 1,769 product reregistration decisions, exceeding its goal of 1,275 decisions by almost 40%. The Agency completed almost 15 times as many product reregistration decisions in FY 2009 as it did five years earlier. To strive for continuous improvement, the Agency is again increasing its product reregistration goal for FY 2010.

EPA anticipates that a Memorandum of Understanding for Work-sharing on Product Reregistration developed in FY 2009 and signed in October 2009 between two divisions in EPA's Office of Pesticide Programs (OPP) will enable the Agency to further increase its productivity in FY 2010 and beyond. This MOU establishes the parameters of a work-sharing agreement for product reregistration between OPP's Antimicrobials Division and Pesticide Re-Evaluation Division (formerly the Special Review and Reregistration Division). The two divisions established the agreement to support meeting and exceeding EPA's product reregistration goals. EPA expects that through implementation of the agreement, the product reregistration program will be completed more quickly and risk mitigation measures implemented earlier thereby achieving important human health and environmental protection goals sooner.

Status of Registration Review

Overall Status

EPA is continuing to meet all registration review targets consistent with overall program objectives. Out of a universe of over 700 registration review cases, including over 1,100 pesticide active ingredients, over 140 cases are past the Preliminary Work Plan stage, and Final Work Plans have been completed for 108 cases. These totals include cases that were scheduled, but which were not required to go through registration review because there are no active domestic registrations.

FY 2009 Accomplishments

During FY 2009, the pace of registration review continued to accelerate. Seventy (70) new dockets were opened and 61 Final Work Plans completed.

Registration Review Progress FY 2007 – FY 2009

Fiscal Year	Dockets Opened	Final Work Plans Completed
FY 2007	25	13
FY 2008	46	34
FY 2009	70	61
Total	**141**	**108**

Fiscal year 2009 marked the point at which the Agency concluded ramping up the registration review process and began opening new cases at the pace that must be maintained for the next eight years in order to finish the initial 15-year cycle on schedule in 2022. FY 2009 also featured the first preliminary risk assessments for conventional chemicals under the registration review program. The preliminary risk assessments for clomazone and fomesafen were published and received public comments. The preliminary risk assessments were also provided to the Fish and Wildlife Service and National Marine Fisheries Services (the Services). EPA and the Services are collaborating 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 2010. The new schedule will provide the timeline for opening dockets for the next four years of the program, from FY 2010 to 2013, and will include information on dockets that opened in FY 2007 through FY 2009. 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 currently preceding 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, including one for urea sulfate, which was published during the first quarter of FY 2010.

Process Improvements in Registration Review

Section 33(k)(2)(D) requires that the Agency report its recommendations for process improvements in the handling of registration review under Section 3(g) and for streamlining the registration review process. Under the auspices of the PRIA Process Improvement Workgroup, stakeholders have met with Agency staff to identify process improvement opportunities in registration review in a process similar to the one used to identify improvement priorities for the registration process. Recommendations are anticipated in 2010.

In April 2009, EPA formed the Registration Review Listed Species Workgroup within the pesticides program, which is tasked with developing a nationwide risk assessment process to evaluate the impact of pesticide registration on endangered and threatened (listed) species and their critical habitats. This assessment process should be in compliance with the statutory and procedural requirements of section 7 of the Endangered Species Act (ESA) as well as FIFRA. This Workgroup is collaborating with the Services by working on a pilot assessment, focusing on developing a format and content acceptable to the Services. The Workgroup is also focusing on guidance development to allow deadlines to be met and to comply with the statutory mandate for Registration Review. The goal is an efficient and streamlined process that produces assessments consistent with the established agreements between the Agency and the Services (the "Overview Document"), the ESA, FIFRA, and implementing regulations and to efficiently use the Agency's and the Services' resources.

Agency senior staff is defining roles in the evolving registration review process. During FY 2010, the process from preliminary risk assessments through the public comment period and endangered species consultation will be refined based on initial feedback from the clomazone and fomesafen cases. The goal is to adapt the process to provide the public an opportunity to comment on the preliminary risk assessments and then provide a refined consultation package to the Services, while still maintaining a flow of work through the system to allow the Agency to complete registration reviews in a timely manner.

Other Activities

Use of Outside Reviewers

The Agency continued its work-sharing efforts with Canada's Pest Management Regulatory Agency (PMRA), the Australian Pesticides and Veterinary Medicines Authority (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 2009 after a global review and four others were in review. Five new biopesticide active ingredient joint PMRA/EPA reviews were pending at the end of FY 2009 and five more are anticipated in the future.

In FY 2009, 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. One minor use action was completed as part of the NAFTA work-share program. No joint reviews were completed, but three were pending at the end of FY 2009. Ten additional active ingredient minor use chemicals are expected to be evaluated under the NAFTA joint review program in 2009-2010 and six are expected to be work-share projects.

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 2009, CDPR reviewed the residue chemistry studies for three active ingredients and a total of 12 representative commodities or crops and completed dietary risk assessments for two active ingredients.

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 2009 was approximately the same as in FY 2008 and 2007, and approximately 80% of the Pesticide Program's active contracts or work assignments were performance-based, the same as FY 2008. 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 and Worker Protection Activities in FY 2009

Recipient & Mechanism	Activity and Accomplishments	FY 2009 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 potential certified pesticide applicators in using restricted use pesticides safely. The training focuses on a population of applicators (approximately 1,100,000 commercial and private applicators) who can suffer high exposure and risk themselves, or subject others to high exposure and risk, if not trained to competency standards that help to ensure safe pesticide applications. Through an interagency agreement with USDA, funds were transferred to state cooperative extension programs. The funds are distributed by formula based on the numbers of certified applicators reported by the states. The funding formula was revised in 2008 to more accurately reflect the actual workload related to certifying and recertifying Commercial and Private Applicators in each state. With $1.1 million in appropriated funds and $500,000 in PRIA funds, the national total to help support this activity was $1,600,000. The additional 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
Medical University of South -Carolina cooperative agreement	PRIA funds were used in 2008 to enter into a 2-year cooperative agreement with the Medical University of South Carolina to develop a 6th Edition of the Recognition and Management of Pesticide Poisoning. Additional funding was provided in FY 2009. The 5th edition was produced in 1999. The manual, in the English or Spanish version, is used internationally to provide health professionals with information on the health hazards of pesticides currently in use, and consensus recommendations for the management of pesticide poisonings and injuries. The fifth edition of this manual is a renowned quick-reference guide to help clinicians identify and properly treat patients with suspected pesticide-related illnesses. The fifth edition needs to be updated to reflect the most current consensus on the appropriate management of pesticide poisonings. The new manual will include a new chapter dedicated to Pyrethroids. The manual will also include more discussion on the health effects of long-term exposure to pesticides. Accomplishments in 2009 include: • Literature review completed for several chapters including neonicotinoids, pyrethroids, fipronil, cancer effects, chlorophenoxy herbicides, Pentachlorophenol, birth defects • New literature review: insect repellents, organophosphates, Paraquat/diquat • List of pesticides and their cancer classifications Drafts of new chapters: • Neonicotinoids section for other insecticides chapter. Status: completed	$40,040

Recipient & Mechanism	Activity and Accomplishments	FY 2009 PRIA Funds
	• Fipronil section for other insecticides. Status: completed • Cancer effects. Status: in progress Revisions of old chapters: • Pyrethroids (formerly found in "Other Insecticides"). Status: in progress. • Chlorophenoxy herbicides. Status: completed • Pentachlorophenol/nitrocresolic herbicides. Status: completed. • Paraquat/diquat. Status: in progress • Insect repellents. Status: near completion • Organophosphates. Status: near completion	
U.S. Department of Labor - interagency agreement	PRIA funds were used to fund the development and analysis of the data in, and for focused reports from, the National Agricultural Workers Survey (NAWS), which contains the most comprehensive demographic information on agricultural workers. Specific questions were developed on worker exposure to assist with worker regulatory development and risk assessments in FY 2008. Questions were pilot tested and revised in summer 2009 and will be included as part of the next extensive NAWS survey cycle. Support for the development of key pesticide worker safety survey questions for the National Agricultural Workers Survey and for focused reports from the survey were continued with remaining funds from the 2008 PRIA funds.	(continued use of 2008 PRIA funds)
National Institutes of Occupational Safety and Health - interagency agreement	PRIA funds support the goal of the NIOSH Sentinel Event Notification System for Occupational Risk (SENSOR) pesticides project to carry out acute pesticide-related illness and injury surveillance activities in the 12 participating states: California, Iowa, Michigan, New York, North Carolina, Texas, Washington, Arizona, Louisiana, Florida, New Mexico, and Oregon. The participating states use consistent criteria for ranking incidents (possible, probable, actual confirmed) and reporting. The confirmed incidents are tracked to medical resolution. The resulting data could be used by the Agency as indicators of the magnitude of incidents; signals of trends in exposures; insights into correctable causes of incidents; and data for the risk assessment and registration review processes. Through an interagency agreement with NIOSH, PRIA funds from EPA continue to support pesticide incident surveillance activities in Iowa, Texas, and Washington State. Since the inception of the current interagency agreement in 2005, PRIA funds have supported the expansion of the surveillance program from 9 participating states to 12 participating states. State surveillance work includes the identification, classification and documentation of pesticide poisoning cases. The states periodically perform in-depth investigations of pesticide-related events, and develop interventions aimed at particular industries or pesticide hazards. NIOSH supports these surveillance activities by providing funds and technical support to state health departments. Data submitted annually by each SENSOR state program is	$9,960

Recipient & Mechanism	Activity and Accomplishments	FY 2009 PRIA Funds
	aggregated to produce a national database consisting of acute pesticide-related illness and injury cases. The SENSOR-Pesticides program is valuable for providing depth of detail surrounding reported incidents, as well as for the timely identification of emerging trends involving occupational pesticide exposure. This surveillance program is unique in its potential to inform the Agency's Pesticide Program. This quarter, EPA requested that NIOSH provide incident reports for 11 EPA-registered active ingredients under regulatory review. An analysis of this type of incident data is useful in informing OPP risk assessments.	
Association of Farmworker Opportunity Programs (AFOP) - cooperative agreement	Support is provided to a variety of the national affiliates of AFOP for pesticide worker safety training, education and outreach for farmworkers and farmworker families. This work is targeted at increasing protections 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 PRIA funds were used for a cooperative agreement with the Association of Farmworker Opportunity Programs (AFOP) for the following: • Project HOPE (Health and Outreach with Pesticide Education). In a train-the-trainer effort, AFOP has trained over 150 farmworker community outreach workers in 22 sites around the country on how to conduct pesticide worker protection safety education for farmworkers. These outreach workers are, for farmers, a main source of free pesticide worker safety training. • Project SAFE (Saving American Farmworkers Everywhere). Through an EPA/AFOP/AmeriCorps Program, AFOP is training AmeriCorps members to become pesticide safety educators. AmeriCorps members work in AFOP affiliate sites to conduct hands-on, interactive pesticide safety education for farmworkers, farmworker families and other members of the agricultural community in 15 sites across the country. After AmeriCorps members, often grown children of migrant farmworkers, complete one or two years of public service, conducting worker protection pesticide safety trainings, they receive a scholarship award from AmeriCorps to continue or complete their education. • Project LEAF (Limiting Exposures Around Families). In response to research demonstrating higher levels of pesticide in farmworker children and the effectiveness of simple mitigation measures, AFOP developed a program to prevent take-home pesticide exposure to farmworker children. • Spanish Radio Campaign to Protection Farmworker Children. AFOP worked with Hispanic Communications Network to create and air a radio campaign on preventing pesticide	$385,000

Recipient & Mechanism	Activity and Accomplishments	FY 2009 PRIA Funds
	exposure to farmworker children. A national radio campaign aimed at farmworker parents on how to protect their children was aired in the peak of the 2009 growing season on 245 Spanish language radio stations that reach over 14 million listeners. Additional programs are being developed with new messages aimed at protecting farmworker children to reinforce AFOP's. These will be aired starting in spring, 2010. • Development of a Building Bridges Program. AFOP is partnering with Farmworker Justice to develop a project to assess pesticide safety training programs and other pesticide worker protection programs in Florida. The project will work with key farmworker, grower and state stakeholder groups to develop creative, model pesticide safety education programs to be used by farmers or agricultural service organizations to deliver pesticide worker safety training, as required by federal regulation. • Students Action with Farmworkers (SAF). AFOP worked with SAF (Duke University) to train 75 interns on how to conduct interactive pesticide safety education for farmworkers and farmworker families.	
Pacific Northwest Agricultural Safety and Health Center (PNASH) -cooperative agreement	As part of the EPA's health care providers' initiative, support is provided to the University of Washington's Pacific Northwest Ag Safety and Health Center to develop projects to improve the training of health care providers in the recognition, diagnosis, treatment, and prevention of pesticide poisoning among those who work with pesticides, through the development of curricula in several medical, nursing, and public health schools. Generally nurses and physician's assistants may be the first and only health care provider that pesticide workers see. The health care providers' initiative continues to raise awareness among clinicians and nurses nationwide on the recognition and appropriate treatment of patients with symptoms of a pesticide-related illness. PNASH continues to work to incorporate guidance for assessing pesticide exposure into the medical and nursing school curricula. Accomplishments in FY 2009 include the following: **Module Development:** The Problem Based Learning (PBL) case module targets health care workers in a rural clinical setting, but could be adapted to different audiences. It contains instructional information and resources (readings, literature references, online resources, graphic materials, an instructor's guide, and an evaluation process). The module is available to both the UW campus nursing faculty and students. It is being incorporated into the UW Public Health website and will be integrated into the Public Health Medicine site. **Curricula Insertion Points:** Training modules inserted into the following courses Seattle Pacific University Registered Nurse Undergraduate program: • Home Assessment – Environmental Home Assessment Tool • Hospital Survey: Clinical Site Harmful Substances Evaluation	$132,500

Recipient & Mechanism	Activity and Accomplishments	FY 2009 PRIA Funds
	University of Washington - Physicians Assistant Program • Problem Based Learning – A Pesticide Suicide Attempt • Oral Herbicide (Diquat) Exposure • A Pyrethroid Inhalation from a Crop Duster • Occupational and Environmental Health History University of Washington – Family Nurse Practitioner Program • Assessing Pesticide Exposure Risk – A Farmworker's Toddler • Occupational and Environmental Health History University of Washington – Nursing • Paresthesias – Is it Diabetes? • Farmworker Housing and Exposure – A Community Case Study Washington State University – Nursing • Organophosphate Exposures – Implications for Nursing Practice • Children's Home Exposure to Pesticides **Website Development and Testing:** • Website structure internally approved at the spring quarterly meeting • The informational components of the website and the learning modules are now in place • The core organizational concepts are flexible and intuitive • PNASH met with Migrant Clinicians Network in order to harmonize materials between the two projects to allow PNASH to put lectures and presentation materials on their network • PNASH conducted a webinar demonstration of the website for MCN and EPA staff	
Migrant Clinicians Network - cooperative agreement	As part of EPA's National Strategies for Healthcare Providers: Pesticide Initiative, funding through a five year cooperative agreement, begun in 2006, is provided to Migrant Clinicians Network to improve the recognition and management of pesticide poisoning by healthcare providers in the practice setting. The agreement was formulated in recognition of the need for increased provider competency in environmental and occupational health, in order to support agricultural worker health and safety. For the target populations to be served by the migrant clinicians' network, nurses and physician's assistants may be the first and only health care provider that pesticide workers see. The primary goals of the agreement are to provide resources and training to practicing clinicians, and to develop a model program to incorporate environmental and occupational health (EOH) into the primary care setting. In the fourth year of the agreement, emphasis continued to be placed on a variety of training and presentation activities, resource development, dissemination of pesticide-related health information, and the recruitment of additional	$132,500

Recipient & Mechanism	Activity and Accomplishments	FY 2009 PRIA Funds
	health care centers to participate in the program. Throughout Year 4, MCN trained 3 additional health centers to participate in the program, recruited an additional site in Puerto Rico for Year 5, and provided support to ongoing clinical programs. MCN has so far recruited and partnered with 7 clinics to participate in expanded guidance for clinicians to help prevent pesticide related illness. The two additional clinics recruited for Year 5 will bring the total number of programs to 9. MCN continues to stress to participating clinics the importance of incorporating patient occupational exposure histories into the standard clinic procedures in order to identify potential health concerns. Through the past year MCN has also provided extensive local, regional and national training sessions on pesticide related issues, reaching over 400 health care providers through 13 clinical sessions, highlighting pesticide exposure management for farmworkers. Additionally, MCN provided 5 general trainings on the issues facing migrant and seasonal farmworkers including overviews of educational materials to reduce risk (153 attendees) and 2 intensive EOH specific sessions (33 attendees). Additionally, MCN has continued to reach its goals of establishing extensive networks linking providers with EOH specialists, and broadened recognition of the health care provider initiative through organization of strategic meetings and presentations at key conferences. Through trainings and other partnerships, MCN distributed a total of 12,560 pesticide-related educational materials and clinical resources for providers and 8,500 patient education materials. 10,800 copies of MCN's bimonthly publication, containing an EOH/pesticide section, were distributed over the fiscal year. MCN continues to maintain its website as a key resource for clinicians seeking information on farmworkers and pesticide exposure, and recorded 20,863 downloads of pesticide related materials. The influence and reach of MCN has increased awareness of the potential health impacts of pesticides among providers, through training and distribution of materials such as EPA's Recognition and Management of Pesticide Poisonings manual.	
Abt, Associates - contract	Abt Associates, through an EPA contract, is conducting economic cost/benefit analyses and other required regulatory analyses that are necessary to support the proposed amendments to the agricultural worker protection regulation and the pesticide applicator certification rule. Because of requirements under Executive Orders, Paperwork Reduction Act, and the Regulatory Flexibility Act, these analyses are required to quantifying cost/benefits of the impacts of proposed regulatory changes. In the past year, 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).	$300,000
	2009 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 run 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."** Funds are being used to reduce both pesticides in surface water runoff and volatile organic compound (VOC) emissions from almond, peach, and walnut orchards in California. Funding supported: creation of a multi-agency team of project partners, project team meetings, demonstration of a web-based "VOC Calculator" to potential end users, development of a new Conservation Management Practices guide (CMP), and training for farmers on how to use the CMP in conjunction with Year Round IPM plans to reduce pesticides in water runoff and VOC emissions.	$159,494
IPM Institute of North America (Madison, WI)	**"High-level IPM in All U.S. Schools by 2015."** PRIA funds are being used to establish and verify adoption of integrated pest management (IPM) in all public kindergartens through high schools in the United States by 2015. This comprehensive approach promotes use of more than presently implemented 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. Funds have supported the implementation of two new measures (i.e., cockroach allergen levels and student absenteeism) to evaluate the effectiveness of the pest management practices. Funding was used to establish a national network of professionals in five states for promoting proven IPM tools and methods. This goal was exceeded with the addition of nine partner states to the network, four more than originally expected.	$250,000
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 being used to promote adoption of a biological pest management system that reduces continuous use of pesticides in greenhouses. Papaya banker plants serve as a home base for parasitic wasps. The wasps feed on whiteflies that are greenhouse pests to tomato plants. The funds support demonstrating an IPM approach for controlling both whiteflies and the spread of viral diseases by placing papaya banker plants in tomato greenhouses at four (cooperator owned) demonstration sites in Florida.	$246,418

Recipient	Project Title and Accomplishments	Funding
Michigan State University (East Lansing, MI)	**"Increasing Adoption of Reduced-Risk Pest Management Practices in Midwest Blueberries to Prepare for FQPA Implementation."** PRIA funds are being used to prepare the Great Lakes' blueberry industry for the phase-out of broad-spectrum pesticides, including azinphos-methyl, by increasing the adoption of reduced-risk alternatives as well as IPM methods. Accomplishments include determining the rain-fastness of nine alternative pesticides in a laboratory; establishing three demonstration field sites with high pest pressure and then field testing three pest control programs that replace Guthion and pyrethroid based insecticides. Preliminary results of the field tests show comparable or better control with reduced-risk alternative pesticides. Two workshops were presented to groups of 50 and 75 attendees (including growers, crop consultants, and industry representatives) on IPM approaches. Throughout the 2009 growing season, 21 weekly newsletters were sent to over 450 recipients. Additional field demonstrations and training will be conducted in a second year of this project.	$91,508
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 is furthering adoption and implementation of IPM practices through CCVT's grower self assessment and the "Sustainability in Practice Vineyard Certification Program (SIP)." Funds also support in-field research to demonstrate effective alternatives to pesticides currently used in vineyards by installing four grower cooperator research stations with Argentine ant bait stations and by working with a grower cooperator to implement an IPM bait-station strategy for the control of mealybugs. CCVT is delivering outreach programs to educate and guide growers on the use of integrated farming systems using "Certified Sustainable Standards," and to educate the public and trade on the environmental and economic benefits of products that are "Certified Sustainable." Funds were used to conduct two workshops on pest identification attended by 100 Spanish speaking participants and to conduct training in support of the SIP. Twenty new vineyards applied to participate in the SIP certification program in 2009.	$225,000

FY 2009 – Partnership Grants

(approximately $950,000 in grants awarded ($750K in PRIA 2 Fees with additional appropriated funds) to fund four 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"** Funding for this new project supports demonstrating the effective use of a biopesticide (pheromone) 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 OPP's concern for water quality and runoff issues and resistance management in relation to controlling codling moth.	$249,687

Recipient	Project Title and Accomplishments	Funding
University of Wisconsin (Madison, WI)	**"Expanding and Improving the Use of IPM in Midwest Fruit Production"** PRIA funds will be used to support adoption of IPM practices for apples, cherries, and grapes in Wisconsin and other local area states to address water quality and runoff issues. Funds will be used to train new IPM coaches on the use of low-cost modifications to airblast sprayers to help growers in Wisconsin, Minnesota, Illinois, and Iowa use pesticides more efficiently and reduce drift and water runoff. This training will be comprehensive and include the use of reduced risk pesticides as well as biopesticides and pheromone technologies.	$202,027
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 will be used to address multiple IPM approaches to improve human health by controlling pests in residences, schools, day care facilities, and homeless service centers in Baltimore, Maryland. Funds will support 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. PRIA funds will also be leveraged by an ongoing separately funded weatherization program to further incorporate IPM into urban structures. This project is projected to train 5,450 persons (including, residents and city staff) and anticipates up to 75% reduction in pesticide uses. Project findings will be disseminated to Baltimore city and national stakeholders through a regional IPM summit, workshops, conferences, journal articles, community presentations, partnership meetings, and web-based materials.	$250,000
The Pennsylvania State University (University Park, PA)	**"Collaborative Design & Delivery of a Unified Training Platform for IPM in Buildings."** PRIA funds will be applied to increasing IPM in urban structures through a pilot training program. Education modules will be developed for "IPM in Buildings" to be first used in the Philadelphia area and later disseminated nationally via an internet-based training program. The modules will address IPM in diverse building types and management systems and developed for service providers and their clients. The pilot program is expected to train 80 owners, 500 health outreach professionals, and 400 occupants.	$249,770

Table III. Number of PRIA Actions Completed in FY 2007, 2008 and 2009

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

PRIA Category	Description of Category	FY 2007		FY 2008		FY 2009	
		Number Completed PRIA Decisions	Average Decision Time in Days	Number Completed PRIA Decisions	Average Decision Time in Days	Number Completed PRIA Decisions	Average Decision Time in Days
R01	New Active Ingredient, Food Use	17	648	34	824	15	648
R010	New Active Ingredient, Food Use					6	570
R02	New Active Ingredient, Food Use, Reduced Risk	10	738	12	446		
R03	New Active Ingredient, Food Use, Experimental Use Permit (EUP) submitted simultaneously with application for registration	1	634				
R04	New Active Ingredient, Food Use, EUP with temporary tolerance, submitted before application for registration	3	195				
R05	New Active Ingredient, Food use submitted after an EUP			12	175		
R06	New Active Ingredient, Non-food use, outdoor	7	864	1	541	1	753
R060	New Active Ingredient, Non-food use, outdoor					1	245
R07	New Active Ingredient, Non-food use, outdoor, Reduced Risk	0		1	530		
R08	New Active Ingredient, Non-food use, outdoor, EUP request submitted simultaneously with application for registration	2	379				
R09	New Active Ingredient, Non-food use, outdoor, EUP submitted before application for registration	2	205	2	74		
R11	New Active Ingredient, Non-food use, indoor	4	832				
R124	Conditional Ruling on Preapplication Study Waivers; applicant-initiated			1	100	15	153
R130	First food use; indoor; food/food handling			3	325		

PRIA Category	Description of Category	FY 2007		FY 2008		FY 2009	
		Number Completed PRIA Decisions	Average Decision Time in Days	Number Completed PRIA Decisions	Average Decision Time in Days	Number Completed PRIA Decisions	Average Decision Time in Days
R14	New Use, Additional food use, indoor Food/Food handling	4	715	2	627		
R15	New Use, First Food Use	1	456	7	776	9	642
R16	New Use, First Food Use, Reduced Risk					3	555
R17	New Use, Each Additional New Food Use	153	646	186	575	21	714
R170	New Use, Additional food use			2	272	71	440
R18	New Use, Each Additional New Food Use, Reduced Risk	7	865	9	636	2	381
R180	New Use, Additional food use; reduced risk					12	361
R19	New Use, Additional New Food Uses, Bundled, 6 or more	36	691	73	491	11	661
R190	New Use, Additional food uses; 6 or more submitted in one application					23	419
R20	New Use, Additional New Food Uses, Bundled, 6 or more, Reduced Risk	0		3	1274		
R200	New Use, Additional food uses; 6 or more submitted in one application; reduced risk					14	336
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
R23	New use, Non-food, outdoor	23	632	15	447	3	402
R230	New Use, Additional use; non-food; outdoor			1	285	14	372
R24	New use, Non-food, outdoor, Reduced Risk	7	538	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)	2	205	1	180		
R250	New Use, Additional use; non-food; outdoor; EUP; no credit toward new use registration					1	182
R26	New Use, Non-food, indoor	13	507	1	361		
R260	New use; non-food; indoor					2	352

PRIA Category	Description of Category	FY 2007		FY 2008		FY 2009	
		Number Completed PRIA Decisions	Average Decision Time in Days	Number Completed PRIA Decisions	Average Decision Time in Days	Number Completed PRIA Decisions	Average Decision Time in Days
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
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					1	359
R28	Import tolerance, New Active Ingredient or first food use	2	688				
R280	Establish import tolerance; new active ingredient or first food use					1	637
R29	Import tolerance, Additional new food use	2	597	3	1000	1	1000
R290	Establish import tolerance; additional food use					1	432
R292	Amend an established tolerance (e.g., decrease or increase); domestic or import; applicant-initiated			7	221	16	329
R293	Establish tolerance(s) for inadvertent residues in one crop; applicant-initiated					3	317
R30	New Product, Me-Too, Fast Track	301	73	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

PRIA Category	Description of Category	FY 2007		FY 2008		FY 2009	
		Number Completed PRIA Decisions	Average Decision Time in Days	Number Completed PRIA Decisions	Average Decision Time in Days	Number Completed PRIA Decisions	Average Decision Time in Days
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
R31	New Product, Non-Fast Track (includes review of product chemistry, acute toxicity, public health pest efficacy)	337	183	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
R313	New product; requires amendment to existing inert tolerance exemption (e.g., adding post-harvest use); applicant-initiated					4	416
R32	New Product, Non-Fast Track, new physical form (excludes selective citations)	8	356	14	349	3	513
R320	New product; new physical form; requires data review in science divisions			1	141	9	346
R33	New manufacturing-use product, Old Active Ingredient, Selective Citation	20	472	18	461	1	551
R330	New manufacturing-use product; registered active ingredient; selective data citation					3	386
R331	New Product; repack of identical registered end-use product as a manufacturing-use product; same registrant uses only					1	77
R34	Amendment, Non-Fast Track (includes changes to precautionary label statements, source changes to an unregistered source)	179	111	64	119	1	421

PRIA Category	Description of Category	FY 2007		FY 2008		FY 2009	
		Number Completed PRIA Decisions	Average Decision Time in Days	Number Completed PRIA Decisions	Average Decision Time in Days	Number Completed PRIA Decisions	Average Decision Time in Days
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
R35	Amendment, Non-Fast track (changes to REI, PPE, PHI, rate and number of applications, add aerial application, modify GW/SW advisory statement)	45	380	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
R37	Cancer Reassessment, applicant initiated	3	785	6	536		
A41	New Active Ingredient, Non-food use, outdoor, other uses	6	879	3	1252		
A42	New Active Ingredient, Non-food use, indoor, FIFRA sec. 2(mm) uses	2	644	2	998	2	920
A44	New Use, First food use, with exemption	1	41	3	739	2	682
A46	New Food Use, with exemption	6	497	3	470	2	492
A460	Additional Food use; establish tolerance exemption					6	199
A470	New Food use, Additional food use; establish tolerance					1	436
A48	New use, Non-food, outdoor FIFRA sec. 2(mm) uses	1	261	3	262		
A480	New use, Additional use; non-food; outdoor; FIFRA §2(mm) uses			1	20	1	391
A49	New use, Non-Food, outdoor, other uses	2	436	2	460		
A490	New use, Additional use; non-food; outdoor; uses other than FIFRA §2(mm)					3	454
A50	New use, Non-food, indoor FIFRA sec. 2(mm) uses	7	253	11	412	1	1002
A500	New use, Additional use; non-food; indoor; FIFRA §2(mm) uses			3	228	22	263
A520	Experimental Use Permit application					2	181

PRIA Category	Description of Category	FY 2007		FY 2008		FY 2009	
		Number Completed PRIA Decisions	Average Decision Time in Days	Number Completed PRIA Decisions	Average Decision Time in Days	Number Completed PRIA Decisions	Average Decision Time in Days
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
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
A53	New Product, Me-too, Fast Track	80	108	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
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
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
A54	New Product, Non-Fast Track, FIFRA sec. 2 (mm) uses	75	178	44	224	3	446
A540	New end use product; FIFRA §2(mm) uses only			25	110	70	139
A55	New Product, Non-Fast Track, other uses	10	254	5	222	1	615
A550	New end-use product; uses other than FIFRA §2(mm); non-FQPA product			2	172	4	180

PRIA Category	Description of Category	FY 2007		FY 2008		FY 2009	
		Number Completed PRIA Decisions	Average Decision Time in Days	Number Completed PRIA Decisions	Average Decision Time in Days	Number Completed PRIA Decisions	Average Decision Time in Days
A56	New Manufacturing use product, old active ingredient, selective citation	5	418	5	470		
A560	New manufacturing-use product; registered active ingredient; selective data citation			2	176	3	349
A57	Amendments, Non-Fast Track	113	129	55	115	1	454
A570	Label amendment requiring data submission			78	105	136	123
B59	New Active Ingredient, Food Use, with exemption, Microbial/Biochemical	9	654	3	737		
B590	New active ingredient; food use; establish tolerance exemption, Microbial/Biochemical					3	487
B60	New Active Ingredient, Non-food use, Microbial/Biochemical	6	485	6	980	6	732
B600	New active ingredient; non-food use, Microbial/Biochemical					7	385
B61	EUP, Food Use with temporary tolerance exemption, Microbial/Biochemical	5	251	2	349		
B610	Food use; EUP; establish temporary tolerance exemption, Microbial/Biochemical					6	286
B62	EUP, Non-food use, Microbial/Biochemical	1	196				
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,	2	356	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
B65	New Use, Non-Food, Microbial/Biochemical	2	337				
B650	New use; Non-Food, Microbial/Biochemical					2	239
B66	New Product, Me-Too, Fast Track, Microbial/biochemical	14	69	4	94		

PRIA Category	Description of Category	FY 2007		FY 2008		FY 2009	
		Number Completed PRIA Decisions	Average Decision Time in Days	Number Completed PRIA Decisions	Average Decision Time in Days	Number Completed PRIA Decisions	Average Decision Time in Days
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
B67	New Product, Non-Fast Track, Microbial/Biochemical	35	184	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
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
B68	Amendment, Non-Fast Track, Microbial/Biochemical	28	122	7	115		
B680	Label amendment requiring data submission, Microbial/Biochemical			4	195	9	129
B681	Label amendment; unregistered source of active ingredient; supporting data require scientific review					3	244
B682	Protocol Review; applicant-initiated; excludes time for HSRB review (pre-application)					1	89
B69	Straight Chain Lepidopteran Pheromones (SCLP), New Active Ingredient, Food or Non-Food Use	1	235				
B690	SCLP, New active ingredient; food or non-food use			1	180	2	231

PRIA Category	Description of Category	FY 2007		FY 2008		FY 2009	
		Number Completed PRIA Decisions	Average Decision Time in Days	Number Completed PRIA Decisions	Average Decision Time in Days	Number Completed PRIA Decisions	Average Decision Time in Days
B700	SCLP, Experimental Use Permit application; new active ingredient or new use					1	134
B71	SCLP, New Product, Me-Too, Fast Track	5	75				
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
B72	SCLP, New Product Non-Fast Track	6	209	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
B730	SCLP, Label amendment requiring data submission					3	72
B74	Plant-Incorporated Protectants (PIP), EUP, Non Food/feed or crop destruct No Scientific Advisory Panel (SAP) review	1	318				
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	2	268	1	269		
B77	PIP, EUP, New Active Ingredient, Set Temporary Tolerance or Exemption, SAP			2	517		
B772	Amend or extend EUP; minor changes to experimental design; established temporary tolerance or tolerance exemption is unaffected			1	96	3	76

PRIA Category	Description of Category	FY 2007		FY 2008		FY 2009	
		Number Completed PRIA Decisions	Average Decision Time in Days	Number Completed PRIA Decisions	Average Decision Time in Days	Number Completed PRIA Decisions	Average Decision Time in Days
B81	PIP, Register New Active Ingredient, Temporary Tolerance or Exemption Exists, SAP	3	635	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		
B86	PIP, EUP, Food Use, Amendment	1	147	5	208		
B880	PIP, New product; no SAP review required					2	382
B90	PIP, Amendment, Non-Fast Track	2	179				
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
B904	Import tolerance or tolerance exemption; processed commodities/food only					1	103
	Total	**1620**		**1677**		**1570**	

Table IV. Number of PRIA Applications Pending at the End of Fiscal Year (FY 2007 through FY 2009)

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

Progress in Meeting Decision Times – Number of PRIA Actions Pending at End of Fiscal Year				
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of Fiscal Year**		
		2007	**2008**	**2009**
R01	New Active Ingredient, Food Use	48	24	5
R010	New Active Ingredient, Food Use		14	29
R02	New Active Ingredient, Food Use, Reduced Risk	18	6	
R020	New Active Ingredient, Food use; reduced risk			4
R05	New Active Ingredient, Food use submitted after an EUP	17	1	
R06	New Active Ingredient, Non-food use, outdoor	6	5	3
R060	New Active Ingredient, Non-food use, outdoor		11	45
R07	New Active Ingredient, Non-food use, outdoor, reduced risk	1		
R09	New Active Ingredient, Non-food use, outdoor, EUP submitted before application for registration	2		
R10	New Active Ingredient, Non-food use, outdoor, submitted after EUP	3	3	3
R11	New Active Ingredient, Non-food use, indoor	2		
R110	New Active Ingredient, Non-food use; indoor			3
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
R13	New Use, First food use, indoor food/food handling	2	2	2
R14	New Use, Additional food use, indoor Food/Food handling	5	3	

Progress in Meeting Decision Times – Number of PRIA Actions Pending at End of Fiscal Year				
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of Fiscal Year**		
		2007	**2008**	**2009**
R15	New Use, First Food Use	18	11	2
R16	New Use, First Food Use, Reduced Risk	3	3	
R17	New Use, Each Additional New Food Use	255	67	31
R170	New Use, Additional Food Use		112	135
R18	New Use, Each Additional New Food Use, Reduced Risk	11	2	
R180	New Use, Additional food use; reduced risk		13	17
R19	New Use, Additional New Food Uses, Bundled, 6 or more	93	31	20
R190	New Use, Additional food uses; 6 or more submitted in one application		34	60
R20	New Use, Additional New Food Uses, Bundled, 6 or more, Reduced Risk	4		
R200	New Use, Additional food uses; 6 or more submitted in one application; reduced risk		11	19
R21	New food use, With EUP and temporary tolerance	2	1	
R210	New Use, Additional food use; EUP; establish temporary tolerance; no credit toward new use registration		2	
R220	New Use, Additional food use; EUP; crop destruct basis; no credit toward new use registration		2	
R23	New use, Non-food, outdoor	24	7	3
R230	New Use, Additional use; non-food; outdoor		25	23
R24	New Use, Non-food, outdoor, Reduced Risk	6		
R240	New Use, Additional use; non-food; outdoor; reduced risk		4	
R25	New use, Non-food, outdoor with EUP (no credit toward new use registration)	1		
R250	New Use, Additional use; non-food; outdoor; EUP; no credit toward new use registration		1	5
R26	New Use, Non-food, indoor	4	1	
R260	New use; non-food; indoor		3	6
R270	New use; non-food; indoor; reduced risk			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
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

Progress in Meeting Decision Times – Number of PRIA Actions Pending at End of Fiscal Year				
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of Fiscal Year**		
		2007	**2008**	**2009**
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
R28	Import tolerance, New Active Ingredient or first food use	1	1	1
R280	Establish import tolerance; new active ingredient or first food use		2	3
R29	Import tolerance, Additional new food use	9	5	3
R290	Establish import tolerance; additional food use		2	9
R292	Amend an established tolerance (e.g., decrease or increase); domestic or import; applicant-initiated		22	27
R293	Establish tolerance(s) for inadvertent residues in one crop; applicant-initiated		3	
R295	Establish tolerance(s) for residues in one rotational crop in response to a specific rotational crop application; applicant-initiated		1	4
R30	New Product, Me-Too, Fast Track	85		
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
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
R31	New Product, Non-Fast Track (includes review of product chemistry, acute toxicity, public health pest efficacy)	189	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
R311	New product; requires approval of new food-use inert; applicant-initiated; excludes approval of safeners			2

Progress in Meeting Decision Times – Number of PRIA Actions Pending at End of Fiscal Year				
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of Fiscal Year**		
		2007	**2008**	**2009**
R313	New product; requires amendment to existing inert tolerance exemption (e.g., adding post-harvest use); applicant-initiated		6	1
R32	New Product, Non Fast Track, new physical form (excludes selective citations)	17	5	1
R320	New product; new physical form; requires data review in science divisions		9	15
R33	New manufacturing-use product, Old Active Ingredient, Selective Citation	21	1	
R330	New manufacturing-use product; registered active ingredient; selective data citation		3	8
R34	Amendment, Non-fast Track (includes changes to precautionary label statements, source changes to an unregistered source)	58	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
R35	Amendment, Non-fast track (changes to REI, PPE, PHI, rate and number of applications, add aerial application, modify GW/SW advisory statement)	48	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
R37	Cancer Reassessment, applicant initiated	6	1	1
R370	Cancer reassessment; applicant-initiated			1
A380	New Active Ingredient, Food use; establish tolerance exemption		1	1
A400	Non-food use; outdoor; FIFRA section (2mm) uses			1
A41	New Active Ingredient, Non-food use, outdoor, other uses	5	2	2
A42	New Active Ingredient, Non-food use, indoor, FIFRA sec. 2(mm) uses	5	3	1
A420	Non-food use; indoor; FIFRA section 2(mm) uses			4
A44	New Use, First food use, with exemption	5	2	
A440	New Use, First food use; establish tolerance exemption		2	2
A46	New Food Use, with exemption	4	1	
A460	New Food Use, Additional food use; establish tolerance exemption		3	7
A470	New Food use, Additional food use; establish tolerance		1	
A48	New use, Non-food, outdoor FIFRA sec. 2(mm) uses	4		
A480	New use, Additional use; non-food; outdoor; FIFRA §2(mm) uses		2	4

Progress in Meeting Decision Times – Number of PRIA Actions Pending at End of Fiscal Year				
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of Fiscal Year**		
		2007	**2008**	**2009**
A49	New use, Non-Food, outdoor, other uses	2	1	
A490	New use, Additional use; non-food; outdoor; uses other than FIFRA §2(mm)		3	1
A50	New use, Non-Food, indoor FIFRA sec. 2(mm) uses	10	1	
A500	New use, Additional use; non-food; indoor; FIFRA §2(mm) uses		27	18
A510	Additional use; non-food; indoor; uses other than FIFRA section 2(mm)			2
A520	Experimental Use Permit application		1	3
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
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
A53	New Product, Me-too, Fast Track	22		
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
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 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.		5	2
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
A54	New Product, Non-Fast Track, FIFRA sec. 2 (mm) uses	41	4	1
A540	New end use product; FIFRA §2(mm) uses only		32	48
A55	New Product, Non-Fast Track, other uses	4	1	
A550	New end-use product; uses other than FIFRA §2(mm); non-FQPA product		1	
A56	New Manufacturing use product, old active ingredient, selective citation	5		
A560	New manufacturing-use product; registered active ingredient; selective data citation		4	6

Progress in Meeting Decision Times – Number of PRIA Actions Pending at End of Fiscal Year				
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of Fiscal Year**		
		2007	**2008**	**2009**
A57	Amendments, Non-Fast Track	50	1	
A570	Label amendment requiring data submission		55	55
B59	New Active Ingredient, Food Use, Microbial/Biochemical, with exemption	11	12	8
B590	New active ingredient; food use; establish tolerance exemption, Microbial/Biochemical,		19	31
B60	New Active Ingredient, Non-food use, Microbial/Biochemical	14	10	1
B600	New active ingredient; non-food use, Microbial/Biochemical,		9	12
B61	EUP, Food Use with temporary tolerance exemption, Microbial/Biochemical	2		
B610	Food use; EUP; establish temporary tolerance exemption, Microbial/Biochemical,		2	
B63	New Use, First Food Use, Microbial/Biochemical, with exemption	11	7	3
B630	First food use; establish tolerance exemption, Microbial/Biochemical,		1	5
B631	Amend established tolerance exemption, Microbial/Biochemical		4	1
B650	New use; Non-Food, Microbial/Biochemical			1
B66	New Product, Me-Too, Fast Track, Microbial/biochemical	4		
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		2	4
B67	New Product, Non-Fast Track, Microbial/Biochemical	27	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
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

Progress in Meeting Decision Times – Number of PRIA Actions Pending at End of Fiscal Year				
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of Fiscal Year**		
		2007	**2008**	**2009**
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
B68	Amendment, Non-Fast Track, Microbial/Biochemical	6		
B680	Label amendment requiring data submission, Microbial/Biochemical		6	12
B681	Label amendment; unregistered source of active ingredient; supporting data require scientific review		2	5
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	
B72	SCLP, New Product Non-Fast Track	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
B721	New product; unregistered source of active ingredient			3
B730	SCLP, Label amendment requiring data submission			1
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
B77	PIP, EUP, New Active Ingredient, Set Temporary Tolerance or Exemption, SAP	1		
B771	Experimental Use Permit application; new active ingredient; establish temporary tolerance or tolerance exemption; no SAP review required;			2
B80	PIP, Register New Active Ingredient, Temporary Tolerance or Exemption Exists, No SAP	1		
B800	New active ingredient; establish permanent tolerance or tolerance exemption based on temporary tolerance or tolerance exemption; no SAP review required			5
B81	PIP, Register New Active Ingredient, Temporary Tolerance or Exemption Exists, SAP	7	3	

Progress in Meeting Decision Times – Number of PRIA Actions Pending at End of Fiscal Year				
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of Fiscal Year**		
		2007	**2008**	**2009**
B84	PIP, Register New Active Ingredient, Set Tolerance or Exemption, SAP	2	2	2
B86	PIP, EUP, Food Use, Amendment	3		
B880	PIP, New product; no SAP review required		2	19
B881	PIP, New product; SAP review required		1	1
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) (2)		13	
B901	PIP, Amendment (except #B890); SAP review required		1	1

Appendix A: Decision Review Times for Actions Completed During FY 2009

As required by FIFRA Section 33(k), the following table (an Excel file) provides the decision times for each decision (application) completed during FY 2009. Decisions with a two digit PRIA code are PRIA 1 decisions, while those with a three digit PRIA code are PRIA 2 decisions. Decisions received by the Agency on or after October 1, 2007, are PRIA 2 decisions. Decision times indicated in red with an asterisk are decisions completed before the Agency received payment or a waiver was granted. Completion of a registration action before payment is received typically occurs in situations where a voluntary fee payment has been offered for an application that was pending with the Agency prior to March 23, 2004 (the PRIA effective date), or the Agency anticipates approval of a fee waiver based on past fee waiver approvals during the same maintenance fee cycle.

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. The Agency's target due date for completing a decision or action under PRIA 1 was based on 30 days in a month. The time frames specified in the Consolidated Appropriations Act of 2004 are in months. In the table, if the PRIA due date was met, while the Agency's target date was not, a date was entered in the column labeled PRIA Due Date. After PRIA 2 was implemented the Agency modified its tracking system to calculate due dates in months. As EPA improves its reporting capabilities, the Agency may update this table, as necessary.

Table of completed actions for FY 2009 (Excel, 276 KB) (Microsoft Excel Viewer EXIT Disclaimer is needed to view this file.)