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.