Pesticide Registration Service Fees

Accomplishments

Progress in Meeting Decision Times

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

Number of PRIA Actions Completed in FY 2011

The EPA counts "decisions," rather than registration applications, and each application package can have more than one decision. The number depends on the number of product registrations and tolerance petitions in an application and reflects the number of "decisions" that have to be made within an application. For instance, in FY 2011, one conventional new non-food outdoor use application package required six decisions, one for each product label being amended. One decision is designated as a "primary" decision, while the others are "secondary" decisions within the application package in the Agency's tracking systems. Generally each application categorized as a Fast Track, Non-Fast Track New Product, identical/substantially similar new product, new product, Non-Fast Track Amendment or label amendment submitted with data, contains a single product and is a single decision.

The EPA completed 1554 decisions subject to PRIA during the fiscal year, more than in FY 2010 (1517) and fewer than FY 2009 (1570). The small increase in the decisions completed in FY 2011 in comparison to FY 2010 was primarily due to the increase in antimicrobial decisions completed. Among the FY 2011 completed decisions, 346 (22% of total) were antimicrobial decisions, 134 (8.6%) biopesticides and 1074 (69%) conventional pesticide decisions while in FY 2010, 310 (20.4% of total) were antimicrobial decisions, 138 (9.1%) biopesticides and 1069 (70.4%) conventional pesticide decisions. An additional 165 decisions were withdrawn – a decrease from the number withdrawn in FY 2010 of 189 and consistent with other Fiscal Years under PRIA 2.

FIFRA Section 33(f)(4)(B), "Completeness of Application" directs the agency, not later than 21 days after receiving an application and the required registration service fee, to conduct an initial screening of the contents of the application, and if the application fails the screen and cannot be corrected by the applicant within the 21 day period, the Agency is to reject the application. During FY 2011, 8 applications were rejected, while in FY 2010, FY 2009, and FY 2008, four, seven, and fourteen applications, respectively, were rejected, generally for missing or incomplete forms or data. Rejected applications are not counted among the completed decisions.

	Number **Completed** in Fiscal Year				Number **Withdrawn** in Fiscal Year			
Type of Pesticide	**2008**	**2009**	**2010**	**2011**	**2008**	**2009**	**2010**	**2011**
Conventional	1243	1104	1069	1074	124	129	145	121
Antimicrobial	336	342	310	346	22	24	28	24
Biopesticide	98	124	138	134	10	14	16	20
Total	**1677**	**1570**	**1517**	**1554**	**156**	**167**	**189**	**165**

The EPA completed 98.2 percent of these decisions on or before their PRIA or extended due date. In FY 2011, 28 decisions missed their statutory due date for a number of reasons. Nine decisions were delayed because the chemical associated with these decisions was the subject of a lawsuit. Others were delayed to provide the necessary time to resolve risk issues and to ensure adequate protection of human health and the environment.

Table III titled "Number of PRIA Actions Completed in FY 2008, FY 2009, 2010 and 2011", summarizes the number of decisions completed by PRIA category and compares the first four fiscal years under PRIA 2. Decisions received under both PRIA 1 and PRIA 2 were completed in FY 2011. Decisions with a two-digit fee category are PRIA 1 actions (e.g., R01, A53) while three-digit fee categories represent PRIA 2 actions (e.g., R010, A530). "Secondary" decisions can be identified by the decision number in the column titled "Primary Decision". A summary of decisions completed under PRIA 1 is provided in the FY 2007 PRIA Annual Report.

Over the last three years under PRIA 2, the number of decisions completed each year has been somewhat consistent. The number of new product and amendment decisions completed increased, while new use decisions again decreased from FY 2010. These trends were observed among both conventional and antimicrobial completed decisions.

Average Decision Times

The average decision time for each PRIA category, shown in Table III, is the number of days it took the Agency to complete a decision once the application was received and payment was made or a fee waiver or exemption was granted. The mandated time frame or decision time review period changed from one fiscal year to another as prescribed by statute and depends upon the fiscal year in which an application was received. The dates that applications for decisions completed in FY 2011 were received ranged from 1994 (a pre-PRIA action for which a fee was paid to obtain a PRIA due date) to 2011, resulting in decisions completed within one fee category with varying mandatory time frames. Consequently, in many cases, the average decision time in the table cannot be directly compared to the PRIA time frames mandated for FY 2011. Statutory time frames under PRIA 2 for some identical or substantially similar and new products, however, have been somewhat consistent from one fiscal year to another.

Meaningful comparisons in average decision times can only be made for those fee categories with a large number of completed decisions. In comparison to FY 2010, average decision review times decreased for antimicrobial new uses, new products, and amendments, biopesticide identical/substantially similar new products, and conventional new active ingredients and some types of new products. They increased for biochemical new active ingredients and some types of conventional new use and amendment applications.

Due Date Extensions (Negotiated Due Dates)

Among the FY 2011 completions, due dates for 369 decisions (24%) were extended by mutual agreement between the applicant and the agency. The percentage of decisions completed with due date extensions decreased in FY 2011 from FY 2010 (31%). During FY 2008, and FY 2009, 18% and 19.3%, respectively, were extended. Extensions generally were needed because of missing or deficient data or information and risk issues. Due dates in FY 2011 were extended for 25%, 36%, and 22% of completed antimicrobial, biopesticide, and conventional decisions respectively, while in FY 2010, the percentages extended were greater 35%, 62% and 26%. In FY 2009, 20%, 34%, and 17.5% were extended.

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

	FY 2008		FY 2009		FY 2010		FY 2011	
Fee Category	Number due date extensions	Total	Number due date extensions	Total	Number due date extensions	Total	Number due date extensions	Total
Antimicrobial (A)	74	336	68	342	108	310	85	346
Biopesticide (B)	47	98	42	124	85	138	48	134
Conventional (R)	185	1243	193	1104	277	1069	236	1074
Total Decisions	**306**	**1677**	**303**	**1570**	**470**	**1517**	**369**	**1554**

As discussed previously, an active ingredient or a new use application package can have a number of decisions to account for the number of registrations and tolerances requested for the new active ingredient or new use. All of the decisions associated with these applications are linked to one decision that has been assigned as the "primary" decision with the rest termed "secondary" decisions. A new product or amendment application package will have only one decision in the Agency's tracking system, however, some new product and amendment applications are dependent upon the data submitted with another application, the primary decision, as described in the primary/secondary guidance. If there are data issues, the due dates for both the primary and all of its secondary decisions will be extended. Consequently, as described in the FY 2010 report, an analysis of due date extensions using decisions can only indicate trends from one fiscal year to another. To conduct a more detailed analysis, the agency focused on primary decisions.

Number of Completed Primary Decisions with Due Date Extension Compared to Total Completed								
	FY 2008		FY 2009		FY 2010		FY 2011	
Fee Category	Due Date Extensions	Total	Due Date Extensions	Total	Due Date Extensions	Total	Due Date Extensions	Total
Antimicrobial (A)	71	305	60	284	89	268	70	292
Biopesticide (B)	43	85	35	105	62	108	31	112
Conventional (R)	124	945	125	881	156	811	153	880
Total Decisions	**238**	**1335**	**220**	**1270**	**307**	**1187**	**254**	**1284**

If only primary decisions are considered, 20% had due date extensions in FY 2011 according to the agency's tracking systems, a decrease from the 26% in FY 2010 and approaching the 18% and 17% in FY 2008 and FY 2009, respectively. Of the primary decisions, due dates for 24% of antimicrobial, 28% of Biopesticide and 17% of conventional primary decisions were extended, in comparison to 33%, 57% and 19% respectively in FY 2010 and 21%, 33% and 14% in FY 2009.

The 369 decisions with due date extensions were the following general types of decisions.

Number of Decisions with Due Date Extensions by Type of Decision (All Decisions)						
Fiscal Year	New Active Ingredient	New Uses	New Products	Amendments	Other (EUP, tolerances, protocols, etc.)	Total with Due Date Extensions
2008	29	94	142	31	10	306
2009	17	93	123	52	18	303
2010	73	104	181	78	34	470
2011	**21**	**111**	**154**	**64**	**19**	**369**

When only primary decisions are considered, the 254 primary decisions with due date extensions were the following general types of actions. Of the 115 secondary decisions, over 60% were associated with new use applications.

Number of Decisions with Due Date Extensions by Type of Primary Decision						
Fiscal Year	New Active Ingredient	New Uses	New Products	Amendments	Other (EUP, tolerances, protocols, etc.)	Total with Due Date Extensions
2008	13	50	136	30	9	238
2009	9	37	119	41	14	220
2010	20	37	170	53	27	307
2011	11	39	142	45	17	254

In FY 2010, the agency and representatives of the pesticide industry's trade associations undertook an analysis of the reasons for extensions. The analysis was conducted by workgroups by pesticide type – antimicrobial, biopesticide and conventional. Common deficiencies identified included product chemistry failures, deviations from standard protocols, denial of toxicity waiver request and rebuttals to Agency reviews, efficacy data issues, and analytical method validation. Risk concerns and administrative issues also delayed completing decisions. Measures for improving the quality of submissions included earlier screening and timelier communication of identified data deficiencies. With the decrease in the rate of due date extensions in FY 2011 from FY 2010, further analysis was conducted to identify the types of applications which contributed to the decrease in the percentage of extensions.

Antimicrobials

Comparison of Number of Primary Decisions with Due Date Extensions versus Total Number of Primary Decisions – Antimicrobials								
Fiscal Year	FY 2008		FY 2009		FY 2010		FY 2011	
Type	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total
New Active Ingredient	3	3	1	1			1	3
New Uses	12	23	5	27	7	21	2	6
New Products	49	166	39	156	55	149	47	162
Amendments	7	110	13	96	19	90	15	106
Other (tolerances, EUP protocols, etc.)		3	2	4	8	8	5	15
Total with Extensions	**71**	**305**	**60**	**284**	**89**	**268**	**70**	**292**

On a percentage basis, the decrease in the percentage of antimicrobial primary decisions with a due date extension from FY 2010 was attributable to a decrease in the percentage of such extensions for new products and amendments.

Biopesticides

Comparison of Number of Primary Decisions with Due Date Extensions versus Total Number of Primary Decisions - Biopesticides								
Fiscal Year	**FY 2008**		**FY 2009**		**FY 2010**		**FY 2011**	
Type	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total
New Active Ingredient	7	10	7	12	13	19	8	10
New Uses	4	5	4	6			5	7
New Products	26	47	16	41	36	65	11	48
Amendments	2	11	5	25	11	20	4	32
Other (tolerances, EUP,protocols, etc.)	4	12	3	21	2	4	3	15
Total with Due Date Extensions	**43**	**85**	**35**	**105**	**62**	**108**	**31**	**112**

The decreased percentage of biopesticide primary decisions that had due date extension was attributable to a decrease in the number and percentage of extensions for new product and amendment decisions, similar to the trend observed with antimicrobial primary decisions.

Conventional

Comparison of Number of Primary Decisions with Due Date Extensions versus Total Number of Primary Decisions - Conventional Pesticides								
Fiscal Year	**FY 2008**		**FY 2009**		**FY 2010**		**FY 2011**	
Type	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total
New Active Ingredient	3	11	1	5	7	7	2	4
New Uses	34	132	28	76	30	70	32	60
New Products	61	580	64	511	79	492	84	524
Amendments	21	194	23	216	23	195	26	235
Other (EUP, tolerances, protocols, etc.)	5	28	9	73	17	47	9	57
Total with Due Date Extensions	**124**	**945**	**125**	**881**	**156**	**811**	**153**	**880**

The pattern of due date extensions for conventional actions between FY 2011 and FY 2010 remained somewhat consistent with an increase in the percentage of new use primary decisions

with a due date extension and decrease for new active ingredients and actions categorized as other (e.g., protocol reviews).

Note: Appendix A contains a list of all applications subject to PRIA completed during FY 2011 and includes the decision times for each decision.

Public Participation Process

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

This process increased the public's opportunities to comment on risk assessments and proposed registration actions. Both the EPA and the public benefit from a public participation process because the public can aid in understanding potential risks and benefits, contribute to meaningful protective measures, and improve the public dialogue on pesticide registration decisions. The public participation process is used for the following types of applications:

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

In FY 2011, the agency issued 36 actions for public comment, of those, 3 were antimicrobial pesticides, 29 were biopesticides, and 6 were conventional chemicals. For additional information, please see http://www.epa.gov/pesticides/regulating/registration-public-involvement.html.

Antimicrobial Time Frames

Section 33(k)(2)(E) directs the EPA 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. Under PRIA 2, antimicrobial substantially similar or identical products fall under three fee categories, A530, A531 and A532, and PRIA 2 changed the time frames to 3 months for an A530 and 4 months for an A531 and A532. Of the 55 decisions in fee category A530 completed in FY 2011, 36 (65%) were completed within 90 days and 49 (89%) were completed within the three month PRIA time frame, whereas in FY 2010, 75% were completed within the PRIA time frame. The remaining 6 met their extended due dates. Of the 34 other substantially similar or identical products in fee categories A531 and A532, 18 were completed within their PRIA time frame of 4 months and the remaining 16 had due date extensions. Only 4 of these latter actions were completed within 90 days.

For other new product decisions in fee categories A540, and A550, the section 3(h) time frame is 180 days with a goal of reducing the review time to 120 days. Of the 73 FY 2011 decisions in these fee categories, all met their PRIA due dates or extended due dates. Of those, 30 (41%) were completed within 120 days, and 54 (74%) were completed within 180 days. In FY 2010, the percentages completed within 120 days and 180 days were 34% and 52% respectively.

Number of PRIA Applications Pending at the End of FY 2011

Table IV summarizes the pending registration applications (counted as decisions) in each of the PRIA categories as required by FIFRA Section 33(k)(2)(v). As of September 30, 2011, 1217 decisions subject to PRIA were pending in the Agency's registration queue. Numbers pending at the end of FY 2010, FY 2009 and FY 2008 are shown for comparison and were, 1151, 1187 and 1129, respectively. The number of decisions received overall in FY 2011 was 6.4% greater than in FY 2010. The increase in conventional decisions received in FY 2011, compared to FY 2010 was 9.3%, contributing to the overall increase in the number received. The number completed and withdrawn did not offset this increase in the decision requests received, resulting in an increase in the number of decisions pending at the end of FY 2011.

The number of antimicrobial decisions pending (191) was lower than at the end of FY 2010 and more than at the end of FY 2009 and FY 2008, (201, 188 and 179 respectively), reflecting an increased number of completions while there was only a slight increase in the number of decisions received. More new product applications were pending at the end of FY 2011 than in past fiscal years under PRIA 2, reflecting an increase in new product receipts, while the number of pending amendments was the lowest at the end of a Fiscal Year under PRIA 2, reflecting a decrease in the number received and an increase in the number completed.

The pending number of biopesticide decisions was approximately the same as at the end of FY 2010 (151 versus 154), while receipts and completions were also approximately the same overall. By types of action, there was an increase in the number of new active ingredient decisions pending due to a decrease in the number completed. The time frame to complete a new active ingredient decision generally spans more than one fiscal year and, as reported in the FY 2010 report, approximately twice as many new active ingredient decisions were received in FY 2010 compared to FY 2009, and some of these actions will be due in FY 2012. Fewer new product decisions were completed and more were received in FY 2011, resulting in an increase in the number pending. The number of amendments pending was reduced, however, due to an increase in the number completed in comparison to FY 2010.

Among conventional pesticide decisions, the number pending at the end of FY 2011 was 875, more than at the end of FY 2010 (796) or FY 2009 (852). More new active ingredient and new use decision were pending at the end of FY 2011 than at the end of FY 2010. Fewer decisions were completed than were received, thus the increase in the number pending. The time frame for these decisions generally spans more than one fiscal year, and thus the decisions received in FY 2010 and FY 2011 will be due in FY 2012 or FY 2013. The number of pending amendments remained approximately the same, even though there was an 30% increase in the number received. The number of pending new products decreased in comparison to FY 2010 because of the greater number of these decisions completed. There was little difference between the number of new product decisions received in FY 2011 and FY 2010.