Implementing the Pesticide Registration Improvement Act - Fiscal Year 2012

Ninth Annual Report

March 1, 2013

Pesticide Registration Service Fees

Accomplishments -- Progress in Meeting Decision Times

Number of PRIA Actions Completed in FY 2012

The EPA counts "decisions," rather than registration applications, and each application package can require more than one decision. The number of decisions that have to be made within an application depends on the number of product registrations and tolerance petitions in the application. For instance, in FY 2012, 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 1574 decisions subject to PRIA during the fiscal year, more than in FY 2011 (1554) and FY 2010 (1517). The small increase in the decisions completed in FY 2012 in comparison to FY 2011 was due to a 29% increase in biopesticide decisions completed. Among the FY 2012 completed decisions, 333 (21% of total) were antimicrobial decisions, 173 (11%) biopesticides and 1068 (68%) conventional pesticide decisions. An additional 123 applications were withdrawn – a decrease from the number withdrawn in FY 2011 (165 applications) and fewer than the previous three Fiscal Years under PRIA 2.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 2012, 4 applications were rejected; however, the contractor that performs these screens identified 136 applications with significant "content" deficiencies. In FY 2011, FY 2010, and FY 2009, eight, four and four applications, respectively, were rejected, generally for missing or incomplete forms or data. Rejected applications are not counted as completed decisions.

	Number **Completed** in Fiscal Year				Number **Withdrawn** in Fiscal Year			
Type of Pesticide	**2009**	**2010**	**2011**	**2012**	**2009**	**2010**	**2011**	**2012**
Conventional	1104	1069	1074	1068	129	145	121	95
Antimicrobial	342	310	346	333	24	28	24	18
Biopesticide	124	138	134	173	14	16	20	10
Total	**1570**	**1517**	**1554**	**1574**	**167**	**189**	**165**	**123**

The EPA completed 99.0 percent of all decisions on or before their original or extended PRIA due date . In FY 2012, 15 decisions (out of 1574 completed decisions) missed their statutory due date. Primarily, decisions were delayed to allow 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 2009, 2010, 2011 and 2012", summarizes the number of decisions completed by PRIA category and compares these last four fiscal years under PRIA 2. Decisions under both PRIA 1 and PRIA 2 were completed in FY 2012. 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 can be found in the FY 2007 PRIA Annual Report.

Over the last four years under PRIA 2, the number of PRIA decisions completed each year has been fairly consistent. For Fiscal Years 2009, 2010, 2011 and 2012 the number of completed decisions were 1570, 1517, 1554 and 1574 respectively.

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 an exemption was granted. The mandated time frame or decision review time-period changed from one fiscal year to another as prescribed by statute and depends on the fiscal year in which an application was received. 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 2011, average decision review times in FY2012 decreased for antimicrobial identical/substantially similar new products, for some biopesticide new active ingredients, and for some conventional new additional uses, identical/substantially similar new products and some other new end-use products. They increased for antimicrobial amended products and some new end-use products, for biochemical identical/substantially similar new products and amended products and some types of conventional new active ingredients applications.

Due Date Extensions (Negotiated Due Dates)

Among the FY 2012 completions, we extended due dates for 395 decisions (25%) by mutual agreement with the applicant. The percentage of decisions completed with due date extensions increased slightly in FY 2012 from FY 2011 (24%) but are significantly lower than in FY 2010 (31%). Extensions generally were needed because of missing or deficient data or information and risk issues. In FY 2012 we extended due dates for 26%, 43%, and 22% of completed antimicrobial, biopesticide, and conventional decisions respectively, while in FY 2011, the percentages we extended were 25%, 36% and 22%.

Number of Completed Decisions with Due Date Extension Compared to Total Completed								
	FY 2009		FY 2010		FY 2011		FY 2012	
Fee Category	Number due date extensions	Total	Number due date extensions	Total	Number due date extensions	Total	Number due date extensions	Total
Antimicrobial (A)	68	342	108	310	85	346	86	333
Biopesticide (B)	42	124	85	138	48	134	74	173
Conventional (R)	193	1104	277	1069	236	1074	235	1068
Total Decisions	**303**	**1570**	**470**	**1517**	**369**	**1554**	**395**	**1574**

As discussed previously, an active ingredient or a new use application package can include 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 designated 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 2009		FY 2010		FY 2011		FY 2012	
Fee Category	Due Date Extensions	Total	Due Date Extensions	Total	Due Date Extensions	Total	Due Date Extensions	Total
Antimicrobial (A)	60	284	89	268	70	292	71	304
Biopesticide (B)	35	105	62	108	31	112	43	136
Conventional (R)	125	881	156	811	153	880	127	800
Total Decisions	**220**	**1270**	**307**	**1187**	**254**	**1284**	**241**	**1240**

If only primary decisions are considered, 19% had due date extensions in FY 2012 according to the agency's tracking systems, a slight decrease from the 20% in FY 2011 and approaching the 17% in FY 2009. Of the primary decisions, due dates for 23% of antimicrobial, 32% of

Biopesticide and 16% of conventional primary decisions were extended, in comparison to 24%, 28% and 17% respectively in FY 2011 and 33%, 57% and 19% respectively in FY 2010.

The following general types of decisions involved due date extensions in FY 2009-FY 2012:

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
2009	17	93	123	52	18	303
2010	73	104	181	78	34	470
2011	21	111	154	64	19	369
2012	113	86	119	56	21	395

When only primary decisions are considered, the breakdown of decision types looks like this:

Number of Primary 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
2009	9	37	119	41	14	220
2010	20	37	170	53	27	307
2011	11	39	142	45	17	254
2012	36	30	115	43	17	241

In FY 2010, the agency and representatives of the pesticide industry's trade associations undertook an analysis of the reasons for extensions. Workgroups by pesticide type – antimicrobial, biopesticide and conventional – conducted the analysis. 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 decisions. The workgroups identified measures for improving the quality of submissions, including 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 that 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 2009**		**FY 2010**		**FY 2011**		**FY 2012**	
Type	**Number with Extensions**	**Total**	**Number with Extensions**	**Total**	**Number with Extensions**	**Total**	**Number with Extensions**	**Total**
New Active Ingredient	1	1			1	3	3	4
New Uses	5	27	7	21	2	6	2	8
New Products	39	156	55	149	47	162	46	200
Amendments	13	96	19	90	15	106	11	81
Other (tolerances, EUP protocols, etc.)	2	4	8	8	5	15	9	11
Total with Extensions	**60**	**284**	**89**	**268**	**70**	**292**	**71**	**304**

In FY 2012 the percentage of antimicrobial primary decisions with a due date extension was barely changed (down by .0062%) from FY 2011.

Biopesticides

Comparison of Number of Primary Decisions with Due Date Extensions versus Total Number of Primary Decisions - Biopesticides								
Fiscal Year	**FY 2009**		**FY 2010**		**FY 2011**		**FY 2012**	
Type	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total
New Active Ingredient	7	12	13	19	8	10	22	28
New Uses	4	6			5	7	2	2
New Products	16	41	36	65	11	48	14	65
Amendments	5	25	11	20	4	32	3	21
Other (tolerances, EUP,protocols, etc.)	3	21	2	4	3	15	2	20
Total with Due Date Extensions	**35**	**105**	**62**	**108**	**31**	**112**	**43**	**136**

The small increase in the percentage of biopesticide primary decisions that we extended from FY 2011(28%) to FY 2012 (32%) is attributable to an increase in the percentage of extensions for new uses.

Conventional

Comparison of Number of Primary Decisions with Due Date Extensions versus Total Number of Primary Decisions - Conventional Pesticides								
Fiscal Year	**FY 2009**		**FY 2010**		**FY 2011**		**FY 2012**	
Type	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total
New Active Ingredient	1	5	7	7	2	4	11	12
New Uses	28	76	30	70	32	60	26	69
New Products	64	511	79	492	84	524	55	449
Amendments	23	216	23	195	26	235	29	236
Other (EUP, tolerances, protocols, etc.)	9	73	17	47	9	57	6	34
Total with Due Date Extensions	**125**	**881**	**156**	**811**	**153**	**880**	**127**	**800**

The pattern of due date extensions for conventional actions between FY 2012 and FY 2011 remained fairly consistent with a slight decrease in the percentage of primary decisions (1.51%) in FY 2012.

Note: Appendix A lists all applications subject to PRIA completed during FY 2012 with the decision time for each decision.

Public Participation Process

Federal pesticide law includes only limited requirements for 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 2012, the agency issued 43 actions for public comment, of those, 3 were antimicrobial pesticides, 20 were biopesticides, and 20 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 one of 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 89 decisions in fee category A530 completed in FY 2012, 55 (62%) were completed within 90 days and 77 (87%) were completed within the three month PRIA time frame, and 12 (13%) met their extended (renegotiated) due dates. In comparison, 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 PRIA time frame. Of the 34 other substantially similar or identical products in fee categories A531 and A532, 28 were completed within their PRIA time frame of 4 months, and the remaining 6 met their extended (renegotiated) due dates.

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 76 FY 2012 decisions in these fee categories, all but two met their PRIA due dates or extended due dates. Of those, 34 (45%) were completed within 120 days, and 51 (67%) were completed within 180 days. In FY 2011, the percentages completed within 120 days and 180 days were 41% and 74% 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, 2012, 1143 decisions subject to PRIA were pending in the agency's registration queue. Numbers pending at the end of FY 2011, FY 2010 and FY 2009 are shown for comparison and were, 1217, 1151, and 1187 respectively.

The number of antimicrobial decisions pending (184) was lower than at the end of FY 2011 , FY 2010 and FY 2009, (191, 201 and 188 respectively).

The pending number of biopesticide decisions at the end of FY 2012 was less than that at the end of FY 2011 (110 versus 151).

Among conventional pesticide decisions, the number pending at the end of FY 2012 was 849, less than at the end of FY 2011 (875) but more than at the end of FY 2010 (796).