Implementing the Pesticide Registration Improvement Act - Fiscal Year 2014

Eleventh Annual Report

March 1, 2015

Pesticide Registration Service Fees

Accomplishments -- Progress in Meeting Decision Times

Number of PRIA Actions Completed in FY 2014

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, one conventional new non-food outdoor use application package required five 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.

EPA completed 1,919 decisions subject to PRIA during FY'14. In addition, 12 non-PRIA inert clearances, which were submitted before inert clearances became a covered pesticide activity under PRIA 3, were also completed during FY'14 making the total number of completed decisions equal to 1,931. FY'14 completions represent a 7% decrease over the 2,084 decisions completed in FY'13. This decrease is likely due to the government shutdown in October 2013. Among the FY'14 completed decisions, 287 (15% of total) were antimicrobial decisions, 129 (7%) biopesticide decisions, 895 (46%) conventional pesticide decisions, 45 (2%) inert clearances and 575 (30%) miscellaneous decisions. Table III titled "Number of PRIA Actions Completed in FY 2011, 2012, 2013 and 2014" summarizes the number of decisions completed by each PRIA category and compares the first two years under PRIA 3 (FY'13 & FY'14) with the last two fiscal years under PRIA 2 (FY'11 & FY'12).

An additional 153 applications were withdrawn – a slight increase from the number withdrawn in FY'13 (138 applications) but fewer than in FY'11.

FIFRA Section 33(f)(4)(B), "Initial Content and Preliminary Technical Screenings" first 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 content screen and cannot be corrected by the applicant within the 21 day period, the agency is to reject the application. During FY'14 nine applications were rejected/withdrawn for significant "content" deficiencies. In FY'13, FY12, and FY'11, six, four and eight applications, respectively, were rejected/withdrawn as a result of the 21-day content screen.

Second, the Preliminary Technical Screen directs the agency to screen the application to determine if the data are accurate, complete and consistent with the proposed labeling and/or tolerance. The technical screen is to be completed not later than 45/90 days after the PRIA start date, and if the application fails the technical screen and cannot be corrected within 10 business days, the agency is to reject the application. During FY'14, Preliminary Technical Screens were completed for 1,600 PRIA 3 submissions. 149 10-day deficiency letters were sent out resulting in 49 applications being rejected or withdrawn. Nineteen conventional chemical applications were withdrawn, and two applications were formally rejected. Ten antimicrobial packages were withdrawn, and five were rejected. Twelve BPPD applications were withdrawn, and one was rejected.

Reasons for applications being rejected or withdrawn as a result of the Preliminary Technical Screen include:

- Not substantially similar;
- Missing data;
- Data deficiencies;
- Inadequate acute toxicity data;
- Uncleared inerts;
- Waiver request for post-application exposure study denied;
- Unacceptable bridging arguments;
- Data matrix/data comp issues
- New AI rejected for inadequate characterization of the strain;

Rejected applications are not counted as completed decisions.

	Number **Decisions Completed** in Fiscal Year				Number **Withdrawn** in Fiscal Year			
Type of Pesticide	**2011**	**2012**	**2013**	**2014**	**2011**	**2012**	**2013**	**2014**
Conventional	1074	1068	1039	895	121	95	87	89
Antimicrobial	346	333	329	287	24	18	43	34
Biopesticide	134	173	111	129	20	10	8	30
Inert			43	45			0	0
Miscellaneous			562	575			0	0
Total	**1554**	**1574**	**2084**	**1931**	**165**	**123**	**138**	**153**

The EPA completed 85 percent of all decisions on or before their original or extended PRIA due date. In FY'14, 292 decisions (out of 1,931 completed decisions) were late due to the government shutdown in October 2013 and the "short term strategy" implemented by EPA to reduce the backlog created by the shutdown.

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 significant number of completed decisions. In comparison to FY'13, average decision review times in FY'14 seemed to increase across the board for new product submissions, most new active ingredient submissions, tolerances and most amendment submissions. Exceptions to this across the board increase in average decision review times would include several conventional new use

category submissions, and an AD amendment category submission where the average decision review times decreased. BPPD's major new active ingredient category submissions remained almost the same (i.e., increased on average by only one day).

Due Date Extensions (Negotiated Due Dates)

Among the FY'14 completions, we extended due dates for 340 decisions (17.6%) by mutual agreement with the applicant. The percentage of decisions completed with due date extensions increased slightly in FY'14 from FY'13 (17.6% vs 15%). Due to the government shutdown, FY'14 renegotiation percentages are somewhat of a special case. To deal with the backlog of PRIA actions which resulted from the two-week shutdown, OPP eschewed renegotiating PRIA due dates in favor of utilizing that time and resource to reduce the backlog. This was referred to as "the short term strategy". This strategy was in place from the middle of October 2013 to the middle of January 2014. In addition to the cascading effects of the shutdown, extensions generally were needed because of missing or deficient data or risk issues. In FY'14 we extended due dates for 14.3%, 23.2%, and 28.9% of completed antimicrobial, biopesticide, and conventional decisions respectively, while in FY'13, the percentages we extended were 22.2%, 30.6% and 19.7% respectively.

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

	FY 2011		FY 2012		FY 2013		FY 2014	
Fee Category	Number due date extensions	Total	Number due date extensions	Total	Number due date extensions	Total	Number due date extensions	Total
Antimicrobial (A)	85	346	86	333	73	329	41	287
Biopesticide (B)	48	134	74	173	34	111	30	129
Conventional (R)	236	1074	235	1068	205	1039	259	895
Inerts	-	-	-	-	1	43	9	45
Miscellaneous	-	-	-	-	-	562	1	575
Total Decisions	**369**	**1554**	**395**	**1574**	**313**	**2084**	**340**	**1931**

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, 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 Extensions Compared to Total Completed

	FY 2011		FY 2012		FY 2013		FY 2014	
Fee Category	Due Date Extensions	Total	Due Date Extensions	Total	Due Date Extensions	Total	Due Date Extensions	Total
Antimicrobial (A)	70	292	71	304	64	285	41	256
Biopesticide (B)	31	112	43	136	16	88	19	106
Conventional (R)	153	880	127	800	109	797	159	678
Inerts	-	-	-	-	1	43	9	45
Miscellaneous	-	-	-	-	0	562	1	575
Total Decisions	**254**	**1284**	**241**	**1240**	**190**	**1775**	**229**	**1660**

If only primary decisions are considered, 13.8% had due date extensions in FY'14 according to the agency's tracking systems, an increase from the 10.7% in FY'13. Of the primary decisions, due dates for 16% of antimicrobial, 17.9% of Biopesticide, and 23.4% of conventional primary decisions were extended, in comparison to 22.4%, 18.2% and 13.7% respectively in FY'13.

The following general types of decisions involved due date extensions in FY'11 - FY'14:

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

Fiscal Year	New Active Ingredient	New Uses	New Products	Amendments	Inerts	Misc	Other (EUP, tolerances, protocols, etc.)	Total with Due Date Extensions
2011	21	111	154	64	-	-	19	369
2012	113	86	119	56	-	-	21	395
2013	40	103	92	49	1	0	28	313
2014	47	79	95	67	9	1	42	340

In FY'14 80% of completed new active ingredient decisions required due date extensions; 40% of completed new use decisions required due date extensions; 18% of completed new product decisions required due date extensions; 16% of completed amendment decisions required due date extensions;

20% of completed inert decisions required due date extensions; 38% of completed other (EUP, tolerance, protocol review, cancer reassessment) decisions required due date extensions, and <1% of completed miscellaneous decisions required due date extensions.

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	Inerts	Misc	Other (EUP, tolerances, protocols, etc.)	Total with Due Date Extensions
2011	11	39	142	45	-	-	17	254
2012	36	30	115	43	-	-	17	241
2013	18	35	77	37	1	0	22	190
2014	14	28	87	53	9	1	37	229

In FY'14 70% of completed, new active ingredient, primary decisions required due date extensions; 35% of completed, new use, primary decisions required due date extensions; 17% of completed, new product, primary decisions required due date extensions; 16% of completed, amendment, primary decisions required due date extensions; 20% of completed, inert, primary decisions required due date extensions; 38.5% of completed, other (EUP, tolerance, protocol review, cancer reassessment), primary decisions required due date extensions and < 1% of completed miscellaneous primary decisions required due date extensions.

Antimicrobials

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

Fiscal Year	FY 2011		FY 2012		FY 2013		FY 2014	
Type	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total
New Active Ingredient	1	3	3	4	4	4	0	1
New Uses	2	6	2	8	6	14	4	10
New Products	47	162	46	200	35	173	18	131
Amendments	15	106	11	81	11	80	9	95
Other (tolerances, EUP protocols, etc.)	5	15	9	11	8	14	10	19
Total with Extensions	**70**	**292**	**71**	**304**	**64**	**285**	**41**	**256**

In FY'14 the percentage of antimicrobial primary decisions with a due date extension (16%) was down from FY'13 (22.4%).

Biopesticides

Comparison of Number of Primary Decisions with Due Date Extensions versus Total Number of Primary Decisions - Biopesticides								
Fiscal Year	**FY 2011**		**FY 2012**		**FY 2013**		**FY 2014**	
Type	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total
New Active Ingredient	8	10	22	28	8	13	8	12
New Uses	5	7	2	2	0	0	1	14
New Products	11	48	14	65	6	41	7	51
Amendments	4	32	3	21	0	20	1	15
Other (tolerances, EUP,protocols, etc.)	3	15	2	20	2	14	2	14
Total with Due Date Extensions	**31**	**112**	**43**	**136**	**16**	**88**	**19**	**106**

In FY'14 the percentage of biopesticide primary decisions with due date extensions (18%) was almost the same as in FY'13 (18.2%).

Conventional

Comparison of Number of Primary Decisions with Due Date Extensions versus Total Number of Primary Decisions - Conventional Pesticides								
Fiscal Year	**FY 2011**		**FY 2012**		**FY 2013**		**FY 2014**	
Type	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total
New Active Ingredient	2	4	11	12	6	9	6	7
New Uses	32	60	26	69	29	75	23	56
New Products	84	524	55	449	36	443	62	323
Amendments	26	235	29	236	26	221	43	229
Other (EUP, tolerances, protocols, etc.)	9	57	6	34	12	49	25	63
Total with Due Date Extensions	**153**	**880**	**127**	**800**	**109**	**797**	**159**	**678**

In FY'14 the percentage of conventional primary decisions with a due date extension (23%) increased substantially from FY'13 (13.7%).

Note: Appendix A lists all applications subject to PRIA completed during FY'14 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'14 the agency issued 20 PRIA actions for public comment, of those, 1 was an antimicrobial pesticide, 12 were biopesticides, and 7 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 3, antimicrobial substantially similar or identical products fall under one of three fee categories, A530, A531 and A532. PRIA 3 time frames were 4 months for an A530 and an A531 and 5 months for an A532. Of the 39 decisions in fee category A530 completed in FY'14, 10 (26%) were completed within 90 days and 20 (51%) were completed within the four month PRIA time frame, and 9 (23%) were completed late. In comparison, of the 64 decisions in fee category A530 completed in FY'13, 20 (31%) were completed within 90 days, and 40 (63%) were completed within the PRIA time frame and 4 (6%) met their extended (renegotiated) due dates. Of the 34 other substantially similar or identical products in fee categories A531 and A532, 28 were completed within their PRIA time frames, one met its extended (renegotiated) due date, and 5 were late.

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 58 FY'14 decisions in these fee categories, 0 were completed within 120 days; 38 (66%) were completed within 180 days; 10 (17%) were completed within their extended PRIA due date, and 10 (17%) were late.

In response to the government shutdown in October 2013, the Agency eschewed renegotiating PRIA due dates in favor of utilizing that time and resources to reduce the backlog created by the shutdown. This has been referred to as the "short term strategy" which was in place from the middle of October 2013 to the middle of January 2014. Consequently, the late completions described above should probably be considered in view of this "short term strategy".

Pesticide Incident Data System

Section 33(k)(2)(I) requires the EPA to report on the progress in updating the Incident Data System and making the data available to the public. The EPA has made improvements in the electronic recording of incident data received through FIFRA 6(a)(2) data as well as from consumer reporting. Through the EPA's cooperative agreement with the National Pesticide Information Center at Oregon State University, the more recently established ecological and pet reporting portals have been successful in providing more detailed information regarding incidents related to companion animals as well as bee kills from sources such as states, veterinarians, bee keepers and wildlife rehabilitation facilities. The EPA uses this incident information when developing risk mitigation options during the risk assessment process to ensure the continued safe use of pesticide products. Also, trends in incident data can be used at any time to mitigate potential emerging concerns. EPA provides this incident information to other federal agencies, states and EPA regions on a regular basis and provides information to public inquiries through the FOIA process.

Sources of Pesticide Usage Data

Section 33(k)(2)(J) requires the EPA to summarize the sources of publicly available pesticide usage data.

FEDERAL SOURCES

USDA Pesticide Usage Data Sources http://www.nass.usda.gov/About_NASS/index.asp

USDA National Agricultural Statistics Service (NASS): NASS conducts farmer surveys to collect pesticide-usage data on major field (e.g., corn, cotton, and soybean), vegetable, and fruit crops in states that account for the bulk of production of these crops. These data are collected based on surveys and updated at various frequencies determined by USDA.

Census of Agriculture: NASS also produces the USDA Census of Agriculture, which consists of uniform, comprehensive data on agricultural production and operator characteristics in each county and state, as well as the U.S. as a whole.

Crop Profiles: USDA produces Crop Profiles that provide information in narrative format about crop production, cultural practices, and pesticide usage. Each Crop Profile describes how a commodity is produced, with emphasis on critical pest management needs - including the role of pesticides in integrated pest management (IPM) and resistance management programs.

USGS - http://water.usgs.gov/nawqa/pnsp/usage/maps/: USGS provides pesticide-use maps showing the geographic distribution of estimated use on agricultural land in the conterminous United States for numerous pesticides.

STATE SOURCES

California Department of Pesticide Regulation http://www.cdpr.ca.gov/docs/label/labelque.htm: California Department of Pesticide Regulation collects usage information by conducting a pesticide-usage census in the state. Data collection is annual for all agricultural uses and offers site-specific information.

New Jersey – http://www.pestmanagement.rutgers.edu/njinpas/pesticidesurveys.htm: Through collaboration with Rutgers University, the New Jersey Department of Environmental Protection Pesticide Control Program (NJDEP) collects pesticide use information from private applicators in New Jersey. These surveys are conducted every three years.

New York - http://ai.psur.cornell.edu/: In collaboration with Cornell University, the State of New York collects Pesticide Use data from commercial applicators, who are required to report each pesticide application, at least annually.

Oregon - http://www.oregon.gov/ODA/shared/Documents/Publications/PesticidesPARC/PesticideusereportingsystemAnnualreport2006.pdf: Due to state budget constraints, Oregon discontinued its pesticide use surveys. However, pesticide usage statistics from 2006-2008 are available on the website.

PROPRIETARY SOURCES

GfK Kynetec - http://www.gfk.com/Pages/default.aspx: GfK Kynetec is a primary source of proprietary data for agricultural crops. The data are widely used by government entities as well as industry. These data are collected for a large range of row, vegetable, and fruit crops in the continental U.S. and include insecticides, fungicides, herbicides, nematicides, and growth regulators used by producers. Data are collected annually.

SIGMA- http://www.gfk.com/us/Pages/default.aspx: SIGMA, a subsidiary of GfK Kynetec, is the primary source for international pesticide usage data for fruits and vegetables. SIGMA provides an annual global study that quantifies the pesticide usage crop-by-crop and by target pest in more than 65 countries.

Kline and Company - http://www.klinegroup.com/: Kline usage data provides non-agricultural pesticide data profiles of home/garden and professional usage by class/market segment and chemical. Reports cover professional pesticides and fertilizers in the turf and ornamental markets.

Number of PRIA Applications Pending at the End of FY 2014

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, 2014 1,330 decisions subject to PRIA were pending in the agency's registration queue. Numbers pending at the end of FY'13 and FY'12 are shown for comparison and were, 1,102 and 1,143, respectively.

The number of antimicrobial decisions pending at the end of FY'14 (159) was greater than that at the end of FY'13 (136) but less than that at the end of FY'12 (184).

The number of biopesticide decisions pending at the end of FY'14 (145) was greater than that at the end of FY'13 (135) and FY'12 (110).

The number of conventional pesticide decisions pending at the end of FY'14 (962) was greater than that at the end of FY'13 (794) and FY'12 (875).

The number of PRIA inert decisions pending at the end of FY'14 (51) was greater than that at the end of FY'13 (22).

The number of miscellaneous decisions pending at the end of FY'14 (13) was about the same as those pending at the end of FY'13 (15).