Implementing the Pesticide Registration Improvement Act - Fiscal Year 2015

Twelfth Annual Report

March 1, 2016

Pesticide Registration Service Fees

Accomplishments -- Progress in Meeting Decision Times

Number of PRIA Actions Completed in FY 2015

Because each pesticide application package can require more than one decision, the EPA counts "decisions," rather than registration applications for tracking purposes. 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 2,111 decisions subject to PRIA during FY'15. FY'15 completions represent a 9% increase over the 1,931 decisions completed in FY'14. Among the FY'15 completed decisions, 319 (15% of total) were antimicrobial decisions, 154 (7%) biopesticide decisions, 960 (45.5%) conventional pesticide decisions, 56 (3%) inert clearances and 622 (29.5%) miscellaneous decisions. Table III (in Appendix A) titled "Number of PRIA Actions Completed in FY 2012, 2013, 2014 and 2015" summarizes the number of decisions completed by each PRIA category and compares the first three years under PRIA 3 (FY'13, FY'14 & FY'15) with the last fiscal year under PRIA 2 (FY'12).

An additional 114 applications were withdrawn – a decrease from the number withdrawn in FY'14 (153 applications) and FY'13 (138).

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 During FY'15 twelve applications were rejected/withdrawn for significant "content" deficiencies. In FY'14, FY13, and FY'12, nine, six, and four 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'15, Preliminary Technical Screens were completed for 1,807 PRIA 3 submissions. 139 10-day deficiency letters were sent out resulting in 87 applications being rejected or withdrawn. Forty-seven conventional chemical applications were withdrawn, and two applications were formally rejected. Eighteen antimicrobial packages were withdrawn, and three were rejected. Fifteen biopesticide applications were withdrawn, and two were rejected.

Reasons for applications being rejected or withdrawn as a result of the Preliminary Technical Screen include:

- Not substantially similar;
- Data deficiencies/missing data
- Inadequate efficacy data to support claims
- Uncleared inerts/missing inert data
- Inadequate acute toxicity data
- Waiver request missing or inadequate
- Unacceptable bridging arguments
- Data matrix/data comp issues
- Revised CSF significantly different from accepted CSF
- Deficient companion animal study
- Unregistered source for active ingredient

Rejected applications are not counted as completed decisions.

	Number **Decisions Completed** in Fiscal Year				Number **Withdrawn** in Fiscal Year			
Type of Pesticide	**2012**	**2013**	**2014**	**2015**	**2012**	**2013**	**2014**	**2015**
Conventional	1068	1039	895	960	95	87	89	65
Antimicrobial	333	329	287	319	18	43	34	29
Biopesticide	173	111	129	154	10	8	30	17
Inert		43	45	56		0	0	1
Miscellaneous		562	575	622		0	0	2
Total	**1574**	**2084**	**1931**	**2,111**	**123**	**138**	**153**	**114**

The EPA completed 98.4 percent of all decisions on or before their original or extended PRIA due date. In FY'15, 33 decisions (out of 2,111 completed decisions) were late. Decisions were typically delayed due to the need for additional time and data to address risk issues to ensure adequate protection of human health and the environment.

Average Decision Times

The average decision time for each PRIA category, shown in Table III in the Appendix, is the number of days it took the agency to complete a decision once the decision review time-period had formally begun. In some cases 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. Furthermore, meaningful comparisons of average decision

times can only be made for those fee categories with a significant number of completed decisions.

Due Date Extensions (Negotiated Due Dates)

Among the FY'15 completions, we extended due dates for 324 decisions (15.3%) by mutual agreement with the applicant. The percentage of decisions completed with due date extensions decreased somewhat in FY'15 from FY'14 (15.3% vs 17.6%). Extensions generally were needed due to missing or deficient data, risk issues, late risk assessments, MRL harmonization issues, delays due to global/joint reviews, public participation process, public interest findings, late FIFRA/FFDCA publication, and issues requiring additional review and coordination with other agencies such as antibiotic resistance. In FY'15 we extended due dates for 13.8%, 18.8%, and 23.9% of completed antimicrobial, biopesticide, and conventional decisions respectively, while in FY'14, the percentages we extended were 14.3%, 23.2% and 28.9% respectively.

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

	FY 2012		FY 2013		FY 2014		FY 2015	
Fee Category	Number due date extensions	Total	Number due date extensions	Total	Number due date extensions	Total	Number due date extensions	Total
Antimicrobial (A)	86	333	73	329	41	287	44	319
Biopesticide (B)	74	173	34	111	30	129	29	154
Conventional (R)	235	1068	205	1039	259	895	230	960
Inerts	-	-	1	43	9	45	18	56
Miscellaneous	-	-	-	562	1	575	3	622
Total Decisions	**395**	**1574**	**313**	**2084**	**340**	**1931**	**324**	**2111**

As discussed above, 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

Fee Category	FY 2012		FY 2013		FY 2014		FY 2015	
	Due Date Extensions	Total	Due Date Extensions	Total	Due Date Extensions	Total	Due Date Extensions	Total
Antimicrobial (A)	71	304	64	285	41	256	38	281
Biopesticide (B)	43	136	16	88	19	106	17	127
Conventional (R)	127	800	109	797	159	678	128	732
Inerts	-	-	1	43	9	45	18	56
Miscellaneous	-	-	0	562	1	575	3	622
Total Decisions	**241**	**1240**	**190**	**1775**	**229**	**1660**	**204**	**1818**

If only primary decisions are considered, 11.2% had due date extensions in FY'15 according to the agency's tracking systems, a decrease from the 13.8% in FY'14. Of the primary decisions, due dates for 13.5% of antimicrobial, 13.4% of Biopesticide, and 17.5% of conventional primary decisions were extended, in comparison to 16.0%, 17.9% and 23.4% respectively in FY'14.

The following general types of decisions involved due date extensions in FY'12 - FY'15:

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
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
2015	61	70	85	52	18	3	39	328

In FY'15 82% of completed new active ingredient decisions required due date extensions; 35% of completed new use decisions required due date extensions; 14% of completed new product decisions required due date extensions; 12% of completed amendment decisions required due date extensions; 32% of completed inert decisions required due date extensions; 37% 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
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
2015	14	26	78	40	18	3	25	204

In FY'15 67% of completed, new active ingredient, primary decisions required due date extensions; 37% of completed, new use, primary decisions required due date extensions; 13% of completed, new product, primary decisions required due date extensions; 11% of completed, amendment, primary decisions required due date extensions; 32% of completed, inert, primary decisions required due date extensions; 29% 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 2012		FY 2013		FY 2014		FY 2015	
Type	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total
New Active Ingredient	3	4	4	4	0	1	1	1
New Uses	2	8	6	14	4	10	2	7
New Products	46	200	35	173	18	131	19	151
Amendments	11	81	11	80	9	95	14	115
Other (tolerances, EUP protocols, etc.)	9	11	8	14	10	19	2	7
Total with Extensions	**71**	**304**	**64**	**285**	**41**	**256**	**38**	**281**

In FY'15 the percentage of antimicrobial primary decisions with a due date extension (14%) was down from FY'14 (16%).

Biopesticides

Comparison of Number of Primary Decisions with Due Date Extensions versus Total Number of Primary Decisions - Biopesticides

Fiscal Year	FY 2012		FY 2013		FY 2014		FY 2015	
Type	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total
New Active Ingredient	22	28	8	13	8	12	7	12
New Uses	2	2	0	0	1	14	1	4
New Products	14	65	6	41	7	51	4	66
Amendments	3	21	0	20	1	15	3	26
Other (tolerances, EUP,protocols, etc.)	2	20	2	14	2	14	2	19
Total with Due Date Extensions	**43**	**136**	**16**	**88**	**19**	**106**	**17**	**127**

In FY'15 the percentage of biopesticide primary decisions with due date extensions (13%) was down from FY'14 (18%).

Conventional

Comparison of Number of Primary Decisions with Due Date Extensions versus Total Number of Primary Decisions - Conventional Pesticides

Fiscal Year	FY 2012		FY 2013		FY 2014		FY 2015	
Type	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total
New Active Ingredient	11	12	6	9	6	7	6	8
New Uses	26	69	29	75	23	56	23	60
New Products	55	449	36	443	62	323	55	367
Amendments	29	236	26	221	43	229	23	238
Other (EUP, tolerances, protocols, etc.)	6	34	12	49	25	63	21	59
Total with Due Date Extensions	**127**	**800**	**109**	**797**	**159**	**678**	**128**	**732**

In FY'15 the percentage of conventional primary decisions with a due date extension (17%) was down from FY'14 (23%).

Note: Appendix A lists all applications subject to PRIA completed during FY'15 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'15 the agency issued 20 PRIA actions for public comment, of those, 1 was for an antimicrobial pesticide, 10 were for biopesticides, and 9 were for conventional chemicals. For additional information, please see http://www.epa.gov/pesticide-registration/about-pesticide-registration.

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 36 decisions in fee category A530 completed in FY'15, 7 (19.4%) were completed within 90 days and 16 (44.4%) were completed within the four month PRIA time frame, and 11 (30.6%) met their extended (renegotiated) due date, and 2 (5.6%) were completed late. Of the 33 other substantially similar or identical products in fee categories A531 and A532, 14 (42.4%) were completed within their PRIA time frames, 16 (48.5%) met their extended (renegotiated) due date, and 3 (9.1%) were late.

For new product decisions in fee category A540, the section 3(h) time frame is 180 days with a goal of reducing the review time to 120 days. The PRIA 3 time frame for this category is 150 days. Of the 84 FY'15 decisions in this category, 6 decisions (7.1%) were completed within 120 days (met the reduced 3(h) time frame); 24 (28.6%) were completed between 121 days and 150 days (met their original PRIA due date), 35 (41.7%) were completed between 151 days and 180 days (met the section 3(h) time frame), and 19 (22.6%) were completed after 181 days but within their extended PRIA due date.

For new product decisions in fee category A550, the section 3(h) timeframe is 180 days with a goal of reducing the review time to 120 days. The PRIA 3 timeframe is 210 days. Of the 8 FY'15 decisions in this category, 0 were completed within 120 days; 4 (50%) were completed within 180 days (met the section 3(h) time frame), and 4 (50%) met their PRIA due date (< 210 days).

Pesticide Incident Data System

Section 33(k)(2)(I) requires the EPA to report on progress in updating the Incident Data System (IDS) and making the data available to the public. The EPA has made improvements in the collection of and electronic recording of incident data received through FIFRA 6(a)(2) data as well as from consumer reporting. To improve data management and efficiency, the Ecological Incident Information System (EIIS), an EPA database that manages information on pesticide incidents of adverse field effects to non-target plants and animals, is currently being migrated into IDS. The Office of Pesticide Program's (OPP) incident website has been revised to better educate stakeholders on pesticide incidents and to make it easier to report incident data to the EPA. The EPA is working with a variety of organizations to improve incident data sharing (*e.g.*, through EPA's continued cooperative agreement with the National Pesticide Information Center at Oregon State University; via quarterly incident meetings with Canada's Pest Management Regulatory Agency; via a Memorandum of Understanding being developed with the US Fish and Wildlife Service; and through FIFRA cooperative agreements with states). Additionally, the EPA is working with a Pesticide Program Dialogue Committee (PPDC) Incident Workgroup to improve incident reporting. The first charge of the workgroup is to provide recommendations to the full PPDC on the types of information (*i.e.*, 'data elements') that are useful when reporting pesticide incidents. This is the first step in the EPA's efforts to move toward an electronic reporting system for incidents, and ultimately, to a publically available incident database. The EPA uses incident information when developing risk mitigation options during the risk assessment process to ensure the continued safe use of pesticide products. To help improve the use of incident data in risk assessment and risk management decisions, OPP is currently drafting an OPP incident guidance document. Also, trends in incident data can be used at any time to mitigate potential emerging concerns. To help improve the timeliness of responses that may be needed quickly, the EPA has recently established an Incident SWift Action Team (SWAT) that will screen incidents as they come into the Agency to identify those that may need immediate attention. Currently, the EPA provides 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/

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/Pages/default.aspx: 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 **i**s 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/: 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 2015

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, 2015 1,336 decisions subject to PRIA were pending in the agency's registration queue. Numbers pending at the end of FY'14 and FY'13 are shown for comparison and were, 1,330 and 1,102, respectively.

The number of antimicrobial decisions pending at the end of FY'15 (188) was greater than that at the end of FY'14 (159) and at the end of FY'13 (136).

The number of biopesticide decisions pending at the end of FY'15 (119) was less than that at the end of FY'14 (145) and FY'13 (135).

The number of conventional pesticide decisions pending at the end of FY'15 (938) was less than that at the end of FY'14 (962) but greater than that at the end of FY'13 (794).

The number of PRIA inert decisions pending at the end of FY'15 (44) was less than that at the end of FY'14 (51) but greater than that at the end of FY'13 (22).

The number of miscellaneous decisions pending at the end of FY'15 (47) was greater than that at the end of FY'14 (13) and at the end of FY'13 (15).