Implementing the Pesticide Registration Improvement Act - Fiscal Year 2013

Tenth Annual Report

March 1, 2014

Pesticide Registration Service Fees

Accomplishments -- Progress in Meeting Decision Times

Number of PRIA Actions Completed in FY 2013

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 2048 decisions subject to PRIA during FY'13. In addition, 36 non-PRIA inert clearances, which were submitted before inert clearances became a covered pesticide activity under PRIA 3, were also completed during FY'13 making the total number of completed decisions equal to 2084. FY'13 completions represent a 32% increase over the 1574 decisions completed in FY'12 and a 34% increase over the 1554 decisions completed in FY'11. This increase is attributed to the completion of 561 Gold Seal Letter decisions completed in FY'13 – a new PRIA 3 covered category. Among the FY'13 completed decisions, 329 (16% of total) were antimicrobial decisions, 111 (5%) biopesticides, 1039 (50%) conventional pesticide decisions, 43 (2%) inert clearances and 562 (27%) miscellaneous decisions. Table III titled "Number of PRIA Actions Completed in FY 2010, 2011, 2012 and 2013" summarizes the number of decisions completed by PRIA category and compares the first year under PRIA 3 with the last three fiscal years under PRIA 2.

An additional 138 applications were withdrawn – a slight increase from the number withdrawn in FY'12 (123 applications) but fewer than in FY'10 and FY'11.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'13 six applications were rejected/withdrawn for significant "content" deficiencies. In FY'12, FY11, and FY'10, four, eight and four applications, respectively, were rejected/withdrawn as a result of the 21-day content screen, generally for missing data or incomplete forms.

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'13, Preliminary Technical Screens were completed for 1,152 PRIA 3 submissions. 110 10-day deficiency letters were sent out resulting

in 22 applications being rejected or withdrawn. Twelve conventional chemical applications were withdrawn and five applications were formally rejected. Rebuttals were entertained for the five conventional chemical packages that were rejected which led to multiple phone conversations and meetings with the registrants; however, none of the rejections were overturned. Three antimicrobial packages were rejected and two were withdrawn.

Reasons for applications being rejected or withdrawn as a result of the Preliminary Technical Screen include:

- Not substantially similar;
- Lack of efficacy data to support a public health claim;
- Efficacy data tested above nominal concentration;
- Efficacy testing cited was inadequate;
- Inadequate rationale for changing signal word;
- Unacceptable bridging arguments;
- New product with multiple AIs where acute tox data were submitted on individual AIs and not on mixture;
- New AI rejected for the following deficiencies: hydrolysis data submitted not adequate, independent lab validation for aquatic field dissipation studies not submitted, mysid chronic tox study not submitted, fish early-life stage study not submitted, multi-residue methods study not submitted (registrant stated that the study was still ongoing at time of submission), product specific description of the production process not submitted;
- New AI withdrawn for the following deficiencies: photodegradation in soil, aerobic aquatic metabolism, anaerobic aquatic metabolism, freshwater invertebrate life-cycle, freshwater fish early life-stage, vascular aquatic plant, estuarine/marine invertebrate acute, estuarine/marine fish, terrestrial field dissipation, environmental chemistry method & independent lab validation.

Rejected applications are not counted as completed decisions.

	Number **Completed** in Fiscal Year				Number **Withdrawn** in Fiscal Year			
Type of Pesticide	**2010**	**2011**	**2012**	**2013**	**2010**	**2011**	**2012**	**2013**
Conventional	1069	1074	1068	1039	145	121	95	87
Antimicrobial	310	346	333	329	28	24	18	43
Biopesticide	138	134	173	111	16	20	10	8
Inert				43				0
Miscellaneous				562				0
Total	**1517**	**1554**	**1574**	**2084**	**189**	**165**	**123**	**138**

The EPA completed 98.8 percent of all decisions on or before their original or extended PRIA due date. In FY'13, 25 decisions (out of 2084 completed decisions) missed their statutory due date. Decisions were delayed due to mandatory furloughs, budget cuts and the need for additional time to resolve 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, 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'11, average decision review times in FY'13 decreased for antimicrobial amendment submissions, for some biopesticide new product submissions, and for some conventional new additional uses, new products and amendment submissions. Average decision review times increased for antimicrobial new uses, efficacy and some new product submissions, for biopesticide new active ingredients, some new product and some amendment submissions and some types of conventional new active ingredients, some new food use, and some new product submissions.

Due Date Extensions (Negotiated Due Dates)

Among the FY'13 completions, we extended due dates for 313 decisions (15%) by mutual agreement with the applicant. The percentage of decisions completed with due date extensions decreased significantly in FY'13 from FY'12 (25%). This percentage decrease is primarily due to the addition of Gold Seal Letters as a new PRIA 3 category which accounted for 561 completed decisions without a single renegotiated due date. Extensions generally were needed because of missing or deficient data or information and risk issues. In FY'13 we extended due dates for 22.2%, 30.6%, and 19.7% of completed antimicrobial, biopesticide, and conventional decisions respectively, while in FY'12, the percentages we extended were 25.8%, 42.8% and 22% respectively. [Note that the aggregate percentage of completions with renegotiated due dates for FY'13 reported above (15%) is less than that reported for each individual division due to the fact that the aggregate percentage also includes the new PRIA 3 Inerts and Miscellaneous categories which are not division-specific.]

Number of Completed Decisions with Due Date Extension Compared to Total Completed								
	FY 2010		FY 2011		FY 2012		FY 2013	
Fee Category	Number due date extensions	Total	Number due date extensions	Total	Number due date extensions	Total	Number due date extensions	Total
Antimicrobial (A)	108	310	85	346	86	333	73	329
Biopesticide (B)	85	138	48	134	74	173	34	111
Conventional (R)	277	1069	236	1074	235	1068	205	1039
Inerts	-	-	-	-	-	-	1	43
Miscellaneous	-	-	-	-	-	-	0	562
Total Decisions	**470**	**1517**	**369**	**1554**	**395**	**1574**	**313**	**2084**

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 Extension Compared to Total Completed								
	FY 2010		FY 2011		FY 2012		FY 2013	
Fee Category	Due Date Extensions	Total	Due Date Extensions	Total	Due Date Extensions	Total	Due Date Extensions	Total
Antimicrobial (A)	89	268	70	292	71	304	64	285
Biopesticide (B)	62	108	31	112	43	136	16	88
Conventional (R)	156	811	153	880	127	800	109	797
Inerts	-	-	-	-	-	--	1	43
Miscellaneous	-	-	-	-	-	-	0	562
Total Decisions	**307**	**1187**	**254**	**1284**	**241**	**1240**	**190**	**1775**

If only primary decisions are considered, 10.7% had due date extensions in FY'13 according to the agency's tracking systems, a decrease from the 19% in FY'12. Of the primary decisions, due dates for 22.4% of antimicrobial, 18.2% of Biopesticide and 13.7% of conventional primary decisions were extended, in comparison to 23%, 32% and 16% respectively in FY'12.

The following general types of decisions involved due date extensions in FY'10 - FY'13:

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
2010	73	104	181	78	-	-	34	470
2011	21	111	154	64	-	-	19	369
2012	113	86	119	56	-	-	21	395
2013	40	103	92	49	1	0	28	313

In FY'13 66.7% of completed new active ingredient decisions required due date extensions; 40.4% of completed new use decisions required due date extensions; 13.4% of completed new product decisions required due date extensions; 12.6% of completed amendment decisions required due date extensions; 2% of completed inert decisions and 34.7% of completed other (EUP, tolerance, protocol review, cancer reassessment) 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
2010	20	37	170	53	-	-	27	307
2011	11	39	142	45	-	-	17	254
2012	36	30	115	43	-	-	17	241
2013	18	35	77	37	1	0	22	190

In FY'13 69% of completed, new active ingredient, primary decisions required due date extensions; 39% of completed, new use, primary decisions required due date extensions; 11.7% of completed, new product, primary decisions required due date extensions; 11.5% of completed, amendment, primary decisions required due date extensions; 2% of completed, inert, primary decisions and 28.6% of completed, other (EUP, tolerance, protocol review, cancer reassessment), 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 2010		FY 2011		FY 2012		FY 2013	
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
New Uses	7	21	2	6	2	8	6	14
New Products	55	149	47	162	46	200	35	173
Amendments	19	90	15	106	11	81	11	80
Other (tolerances, EUP protocols, etc.)	8	8	5	15	9	11	8	14
Total with Extensions	**89**	**268**	**70**	**292**	**71**	**304**	**64**	**285**

In FY'13 the percentage of antimicrobial primary decisions with a due date extension (22.4%) was down slightly from FY'12 (23.4%).

Biopesticides

Comparison of Number of Primary Decisions with Due Date Extensions versus Total Number of Primary Decisions - Biopesticides								
Fiscal Year	**FY 2010**		**FY 2011**		**FY 2012**		**FY 2013**	
Type	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total
New Active Ingredient	13	19	8	10	22	28	8	13
New Uses			5	7	2	2	0	0
New Products	36	65	11	48	14	65	6	41
Amendments	11	20	4	32	3	21	0	20
Other (tolerances, EUP,protocols, etc.)	2	4	3	15	2	20	2	14
Total with Due Date Extensions	**62**	**108**	**31**	**112**	**43**	**136**	**16**	**88**

In FY'13 the percentage of biopesticide primary decisions with a due date extension (18.2%) was down from FY'12 (31.6%).

Conventional

Comparison of Number of Primary Decisions with Due Date Extensions versus Total Number of Primary Decisions - Conventional Pesticides								
Fiscal Year	**FY 2010**		**FY 2011**		**FY 2012**		**FY 2013**	
Type	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total
New Active Ingredient	7	7	2	4	11	12	6	9
New Uses	30	70	32	60	26	69	29	75
New Products	79	492	84	524	55	449	36	443
Amendments	23	195	26	235	29	236	26	221
Other (EUP, tolerances, protocols, etc.)	17	47	9	57	6	34	12	49
Total with Due Date Extensions	**156**	**811**	**153**	**880**	**127**	**800**	**109**	**797**

In FY'13 the percentage of conventional primary decisions with a due date extension (13.7%) was down slightly from FY'12 (15.9%).

The percentage of due date extensions for conventional primary decisions between FY'10 and FY'13 consistently decreased a small amount each year from 19.2% in FY'10 to 13.7% in FY'13.

Note: Appendix A lists all applications subject to PRIA completed during FY'13 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'13 the agency issued 24 PRIA actions for public comment, of those, 3 were antimicrobial pesticides, 12 were biopesticides, and 9 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 64 decisions in fee category A530 completed in FY'13, 20 (31%) were completed within 90 days and 40 (63%) were completed within the four month PRIA time frame, and 4 (6%) met their extended (renegotiated) due dates. In comparison, of the 89

decisions in fee category A530 completed in FY'12, 55 (62%) were completed within 90 days, and 77 (87%) were completed within the PRIA time frame. Of the 31 other substantially similar or identical products in fee categories A531 and A532, 27 were completed within their PRIA time frames, and the remaining 4 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 82 FY'13 decisions in these fee categories, all met their PRIA due dates or extended due dates. Of those, 18 (22%) were completed within 120 days, and 30 (37%) were completed within 180 days. In FY'12, the percentages completed within 120 days and 180 days were 45% and 67% respectively.

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. To date 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. The 6(a)(2) data have been migrated into a new system that enables EPA staff to query the database in the manner most relevant to their needs, such as: by location of the incident, by active ingredient, by product name, by registration number, etc. In addition, ecological and pet reporting portals were established through the EPA's cooperative agreement with the National Pesticide Information Center at Oregon State University. Other portals were established specifically for the reporting of bee kills. These portals bolster our data system by collecting detailed information from such sources as states, veterinarians, bee keepers and wildlife rehabilitation facilities. Increasing the availability of incident data to the public is part of a longer-term, ongoing EPA initiative. 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/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/PEST/Pages/purs_index.aspx#Annual_reports: 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/imperia/md/content/gfkkynetec/gfk_kynetec_sigma_final_12-3-09.pdf**:** 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 2013

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, 2013, 1102 decisions subject to PRIA were pending in the agency's registration queue. Numbers pending at the end of FY'12, FY'11 and FY'10 are shown for comparison and were, 1143, 1217, and 1151,respectively.

The number of antimicrobial decisions pending (136) was lower than at the end of FY'12, FY'11 and FY 2010 (184, 191 and 201 respectively).

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

Among conventional pesticide decisions, the number pending at the end of FY'13 (794) was less than at the end of FY'12 (849) and FY'11(875).

The number of PRIA inert decisions pending at the end of FY'13 was 22.

The number of miscellaneous decisions pending at the end of FY'13 was 15.