Implementing the Pesticide Registration Improvement Act - Fiscal Year 2017

Fourteenth Annual Report

March 1, 2018

Pesticide Registration Service Fees

Accomplishments -- Progress in Meeting Decision Times

Number of PRIA Actions Completed in FY 2017

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 2,026 decisions subject to PRIA during FY'17. FY'17 completions represent a 7% decrease over the 2,174 decisions completed in FY'16. Among the FY'17 completed decisions, 338 (16.7% of total) were antimicrobial decisions, 163 (8.0%) biopesticide decisions, 937 (46.2%) conventional pesticide decisions, 42 (2.1%) inert clearances and 546 (26.9%) miscellaneous decisions. Table III (in Appendix A) titled "Number of PRIA Actions Completed in FY 2014, 2015, 2016 and 2017" summarizes the number of decisions completed by each PRIA category and provides a comparison of the five years under PRIA 3 (FY'13, FY'14, FY'15, FY'16, & FY'17).

An additional 144 applications were withdrawn – an increase from the numbers withdrawn in FY'16 (142 applications) and FY'15 (114).

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 During FY'17, zero applications were rejected/withdrawn for significant "content" deficiencies. In FY'16, FY'15, FY14, and FY'13 seventeen, twelve, nine and six applications, respectively, were rejected/withdrawn as a result of the 21-day content screen.

The Preliminary Technical Screen then 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'17, Preliminary Technical Screens were completed for 1,639 PRIA 3 submissions. 149 10-day deficiency letters were sent out resulting in 32 applications being rejected or withdrawn. Eleven conventional chemical applications were withdrawn and six were rejected; eight antimicrobial packages were withdrawn, and one was rejected. Six biopesticide applications were withdrawn.

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
- Unacceptable bridging arguments
- Data matrix/data comp issues
- Revised CSF significantly different from accepted CSF

Rejected applications are not counted as completed decisions.

	Number **Decisions Completed** in Fiscal Year				Number **Withdrawn** in Fiscal Year			
Type of Pesticide	**2014**	**2015**	**2016**	**2017**	**2014**	**2015**	**2016**	**2017**
Conventional	895	960	966	937	89	65	97	83
Antimicrobial	287	319	353	338	34	29	36	40
Biopesticide	129	154	152	163	30	17	7	15
Inert	45	56	49	42	0	1	0	4
Miscellaneous	575	622	654	546	0	2	2	2
Total	**1,931**	**2,111**	**2,174**	**2,026**	**153**	**114**	**142**	**144**

The EPA completed 99.1 percent of all decisions on or before their original or extended PRIA due date. In FY'17, 18 decisions (out of 2,026 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. Meaningful comparisons of average decision times can only be made for those fee categories with a significant number of completed decisions, and such comparisons are complicated by the fact that many individual submissions are broken down into multiple component decisions for tracking purposes weighting different submissions unequally.

Due Date Extensions (Negotiated Due Dates)

Among the FY'17 completions, we extended due dates for 263 decisions (13.1%) by mutual agreement with the applicant. The percentage of decisions completed with due date extensions in FY'17 decreased from that in FY'16 (13.1% vs 15.7%). Extensions generally were needed due to missing or deficient data; risk issues; late risk assessments; MRL harmonization issues; and delays due to global/joint reviews, public participation process, public interest findings, publication of notices in the Federal Register, and issues requiring additional review and coordination with other agencies. In FY'17 we extended due dates for 8%, 13.5%, and 21.3% of completed antimicrobial, biopesticide, and conventional decisions respectively, while in FY'16, the percentages extended were 8.8%, 14.5% and 27.4% respectively.

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

	FY 2014		FY 2015		FY 2016		FY 2017	
Fee Category	Number due date extensions	Total	Number due date extensions	Total	Number due date extensions	Total	Number due date extensions	Total
Antimicrobial (A)	41	287	44	319	31	353	27	338
Biopesticide (B)	30	129	29	154	22	152	22	163
Conventional (R)	259	895	230	960	265	966	200	937
Inerts	9	45	18	56	21	49	16	42
Miscellaneous	1	575	3	622	2	654	0	546
Total Decisions	**340**	**1931**	**324**	**2111**	**341**	**2174**	**265**	**2026**

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 all 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 2014		FY 2015		FY 2016		FY 2017	
Fee Category	Due Date Extensions	Total	Due Date Extensions	Total	Due Date Extensions	Total	Due Date Extensions	Total
Antimicrobial (A)	41	256	38	281	23	272	26	282
Biopesticide (B)	19	106	17	127	12	126	16	145
Conventional (R)	159	678	128	732	118	691	100	745
Inerts	9	45	18	56	21	47	16	42
Miscellaneous	1	575	3	622	2	652	0	546
Total Decisions	229	1660	204	1818	176	1788	158	1760

If only primary decisions are considered, 9.0% had due date extensions in FY'17 according to the agency's tracking systems, a decrease from the 9.8% in FY'16. Of the primary decisions, due dates for 9.2% of antimicrobial, 11.0% of biopesticide, and 13.4% of conventional primary decisions were extended, in comparison to 8.4%, 9.5% and 17.1% respectively in FY'16.

The following general types of decisions involved due date extensions in FY'14 - FY'17:

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
2014	47	79	95	67	9	1	42	340
2015	60	70	85	51	18	3	37	324
2016	31	170	60	29	19	4	28	341
2017	34	108	62	26	16	0	19	265

In FY'17 64% of completed new active ingredient decisions required due date extensions; 53% of completed new use decisions required due date extensions; 9.3% of completed new product decisions required due date extensions; 6.4% of completed amendment decisions

required due date extensions; 38.1% of completed inert decisions required due date extensions; 17.3% of completed other (EUP, tolerance, protocol review, cancer reassessment) decisions required due date extensions, and 0% 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
2014	14	28	87	53	9	1	37	229
2015	14	26	78	40	18	3	25	204
2016	15	48	53	21	20	3	16	176
2017	13	33	60	22	16	0	14	158

In FY'17 59% of completed, new active ingredient, primary decisions required due date extensions; 49% of completed, new use, primary decisions required due date extensions; 10% of completed, new product, primary decisions required due date extensions; 5.9% of completed, amendment, primary decisions required due date extensions; 38.1% of completed, inert, primary decisions required due date extensions; 14% of completed, other (EUP, tolerance, protocol review, cancer reassessment), primary decisions required due date extensions and 0% 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 2014		FY 2015		FY 2016		FY 2017	
Type	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total
New Active Ingredient	0	1	1	1	5	6	1	1
New Uses	4	10	2	7	0	3	0	1
New Products	18	131	19	151	1	143	17	151
Amendments	9	95	14	115	5	108	7	117
Other (tolerances, EUP protocols, etc.)	10	19	2	7	3	12	1	11
Total with Extensions	**41**	**256**	**38**	**281**	**2 3**	**272**	**26**	**282**

In FY'17 the percentage of antimicrobial primary decisions with a due date extension (9.2%) was up from FY'16 (8.4%).

Biopesticides

Comparison of Number of Primary Decisions with Due Date Extensions versus Total Number of Primary Decisions - Biopesticides								
Fiscal Year	**FY 2014**		**FY 2015**		**FY 2016**		**FY 2017**	
Type	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total
New Active Ingredient	8	12	7	12	8	19	6	19
New Uses	1	14	1	4	1	4	1	7
New Products	7	51	4	66	2	75	6	67
Amendments	1	15	3	26	0	13	3	31
Other (tolerances, EUP, protocols, etc.)	2	14	2	19	1	15	0	21
Total with Due Date Extensions	**19**	**106**	**17**	**127**	**12**	**126**	**16**	**145**

In FY'17 the percentage of biopesticide primary decisions with due date extensions (11%) was up from FY'16 (9.5%).

Conventional

Comparison of Number of Primary Decisions with Due Date Extensions versus Total Number of Primary Decisions - Conventional Pesticides								
Fiscal Year	**FY 2014**		**FY 2015**		**FY 2016**		**FY 2017**	
Type	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total
New Active Ingredient	6	7	6	8	2	3	6	6
New Uses	23	56	23	60	54	82	32	58
New Products	62	323	55	367	41	354	37	391
Amendments	43	229	23	238	17	193	12	222
Other (EUP, tolerances, protocols, etc.)	25	63	21	59	12	59	13	68
Total with Due Date Extensions	**159**	**678**	**128**	**732**	**126**	**691**	**100**	**745**

In FY'17 the percentage of conventional primary decisions with a due date extension (13.4%) was down from FY'16 (18.5%).

Note: Table V in Appendix A lists all applications subject to PRIA completed during FY'17 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'17, the agency issued 21 PRIA actions for public comment. Of those, 2 were for antimicrobial pesticides, 9 were for biopesticides, and 10 were for conventional chemicals. For additional information, please see https://www.epa.gov/pesticide-registration/public-participation-process-registration-actions.

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 42 decisions in fee category A530 completed in FY'17, 13 (31%) were completed within 90 days and 29 (69%) were completed within the four month PRIA time frame. There were zero decisions requiring negotiation of the due date or completed late. Of the 19 other substantially similar or identical products in fee categories A531 and A532, 18 (95%) were completed within their PRIA time frames, 1 (5%) met its extended (renegotiated) due date, and zero 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 85 FY'17 decisions in this category, two (2.4%) were completed within 120 days (met the reduced 3(h) time frame); 34 (40%) were completed between 121 days and 150 days (met their original PRIA due date), 33 (38.8%) were completed between 151 days and 180 days (met the section 3(h) time frame), and 16 (18.8%) 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 3 FY'16 decisions in this category, zero were completed within 120 days; zero were completed within 180 days (met the section 3(h) time frame), and 3 (100%) 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. The Office of Pesticide Program's (OPP) incident website continues to be revised on an annual basis 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). The EPA uses 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. To help improve the timeliness of responses that may be needed quickly, the EPA is implementing a process 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

- **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.
  https://www.nass.usda.gov/Surveys/Guide_to_NASS_Surveys/Chemical_Use/

- **Pest Management Strategic Plans:** USDA produces Pest Management Strategic Plans (PMSP) that focuses on pest-by-pest management practices for a crop in a state or region. The usage information included in a PMSP is generally a qualitative narrative of current and potential pest management practices, including the use of pesticides. http://www.northeastipm.org/ipm-planning/pest-management-strategic-plans/

- **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. https://agcensus.usda.gov/Publications/2012/

- **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. http://www.northeastipm.org/ipm-planning/crop-profiles/

United States Geological Survey (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/pur/purmain.htm: California Department of Pesticide Regulation collects usage information by conducting a pesticide-usage census in the state. Pesticide usage reports are published annually for all agricultural uses and some non-agricultural uses.

New Jersey – http://www.nj.gov/dep/enforcement/pcp/pcp-pubs.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 typically 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/PesticideusereportingsystemAnnualreport2008.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

Kynetec - https://www.kynetec.com/ 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-: SIGMA, a subsidiary of GfK, 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. http://www.joy-consulting.com/sigmaCP_Prospectus_HY2014v2_10October2014_Word.pdf

Kline and Company - http://www.klinegroup.com/: Kline provides non-agricultural pesticide usage data profiles of various market segments including but not limited to consumers, professional pest management, turf and ornamental, biopesticides, mosquito control and industrial vegetation management by chemical type. Reports cover sales and use of pesticides in these markets.

Number of PRIA Applications Pending at the End of FY 2017

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, 2017, 1,613 decisions subject to PRIA were pending in the agency's registration queue. Numbers pending at the end of FY'15 and FY'16 are shown for comparison and were, 1,330 and 1,173, respectively.

The number of antimicrobial decisions pending at the end of FY'17 (171) was greater than that at the end of FY'16 (152).

The number of biopesticide decisions pending at the end of FY'17 (217) was greater than that at the end of FY'16 (140).

The number of conventional pesticide decisions pending at the end of FY'17 (1,019) was greater than that at the end of FY'16 (841).

The number of PRIA inert decisions pending at the end of FY'17 (37) was greater than that at the end of FY'16 (35).

The number of miscellaneous decisions pending at the end of FY'17 (169) was more than that at the end of FY'16 (5).