

Implementing the Pesticide Registration Improvement Act - Fiscal Year 2018

Fifteenth Annual Report



Pesticide Registration Service Fees

Accomplishments -- Progress in Meeting Decision Times

Number of PRIA Actions Completed in FY 2018

Because each pesticide application 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 2,206 decisions subject to PRIA during FY’18. FY’18 completions represent a 9% increase over the 2,026 decisions completed in FY’17. Among the FY’18 completed decisions, 328 (14.9% of total) were antimicrobial decisions, 215 (9.7% of total) were biopesticide decisions, 1,045 (47.4% of total) were conventional pesticide decisions, 39 (1.8% of total) were inert clearances and 579 (26.2% of total) were miscellaneous decisions. [Table III \(in Appendix A\)](#) titled “Number of PRIA Actions Completed in FY 2015, 2016, 2017 and 2018” summarizes the number of decisions completed by each PRIA category and provides a comparison of the past four years under PRIA 3 (FY’15, FY’16, FY’17 and FY’18).

An additional 137 applications were withdrawn – a decrease from the numbers withdrawn in FY’17 (144 applications) and FY’16 (142 applications).

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’18, one application was rejected for significant “content” deficiencies (none were withdrawn for this reason). Zero, seventeen, twelve, and nine applications, were rejected/withdrawn in FY’17, FY’16, FY’15 and FY’14, respectively, as a result of the 21-day content screen.

FIFRA Section 33(f)(4)(B) then directs the agency to conduct a preliminary technical screening of the application to determine if the data are accurate, complete and consistent with the proposed labeling and any proposal for a tolerance or exemption. The technical screen is to be completed not later than 45 or 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’18, Preliminary Technical Screens were completed for 1,639 PRIA 3 submissions. 200 10-day deficiency letters were sent out resulting in 85 applications being rejected or withdrawn. Six conventional chemical applications were withdrawn and three were rejected; one antimicrobial package was withdrawn and one rejected; and fifteen biopesticide applications were withdrawn, while fifty-nine applications were rejected.

Reasons for applications being rejected or withdrawn as a result of the Preliminary Technical Screen include:

- Data deficiencies/missing data, rationale, or waiver request
- Uncleared inerts/missing or invalid inert data
- Inert ingredient misidentified
- Data matrix/data compensation issues
- Inadequate efficacy data to support claims
- Unacceptable bridging arguments

Rejected applications are not counted as completed decisions.

Type of Pesticide	Number Decisions Completed in Fiscal Year				Number Withdrawn in Fiscal Year			
	2015	2016	2017	2018	2015	2016	2017	2018
Conventional	960	966	937	1,045	65	97	83	80
Antimicrobial	319	353	338	328	29	36	40	25
Biopesticide	154	152	163	215	17	7	15	31
Inert	56	49	42	39	1	0	4	0
Miscellaneous	622	654	546	579	2	2	2	1
Total	2,111	2,174	2,026	2,206	114	142	144	137

The EPA completed 99.7 percent of all decisions on or before their original or extended PRIA due date. In FY'18, 7 decisions (out of 2,206 completed decisions) were late.

Average Decision Times

The average decision time for each PRIA category, shown in Table 3 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'18 completions, we extended due dates for 379 decisions (17.2%) by mutual agreement with the applicant. The percentage of decisions completed with due date extensions in FY'18 increased from that in FY'17 (17.2% vs 13.1%). 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' 18 we extended due dates for 1.8%, 19.1%, and 29.7% of completed antimicrobial, biopesticide, and conventional decisions respectively, while in FY' 17, the percentages extended were 8.0%, 13.5% and 21.3% respectively.

Number of Completed Decisions with Due Date Extensions Compared to Total Completed								
	FY 2015		FY 2016		FY 2017		FY 2018	
Fee Category	Number due date extensions	Total	Number due date extensions	Total	Number due date extensions	Total	Number due date extensions	Total
Antimicrobial (A)	44	319	31	353	27	338	6	328
Biopesticide (B)	29	154	22	152	22	163	41	215
Conventional (R)	230	960	265	966	200	937	310	1,045
Inerts	18	56	21	49	16	42	20	39
Miscellaneous	3	622	2	654	0	546	2	579
Total Decisions	324	2111	341	2174	265	2026	379	2206

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 2015		FY 2016		FY 2017		FY 2018	
Fee Category	Due Date Extensions	Total	Due Date Extensions	Total	Due Date Extensions	Total	Due Date Extensions	Total
Antimicrobial (A)	38	281	23	272	26	282	5	267
Biopesticide (B)	17	127	12	126	16	145	18	120
Conventional (R)	128	732	118	691	100	745	150	818
Inerts	18	56	21	47	16	42	20	39
Miscellaneous	3	622	2	652	0	546	2	578
Total Decisions	204	1818	176	1788	158	1760	195	1822

If only primary decisions are considered, 10.7% had due date extensions in FY'18 according to the agency's tracking systems, an increase from the 9.0% in FY'17. Of the primary decisions, due dates for 1.9% of antimicrobial, 15.0% of biopesticide, and 18.3% of conventional primary decisions were extended, in comparison to 9.2%, 11.0% and 13.4% respectively in FY'17.

The following general types of decisions involved due date extensions in FY'15 - FY'18:

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
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
2018	55	170	75	27	21	1	30	379

In FY'18, 39.9% of completed new active ingredient decisions required due date extensions; 87.2% of completed new use decisions required due date extensions; 10.2% of completed new product decisions required due date extensions; 6.4% of completed amendment decisions required due date extensions; 52.5% of completed inert decisions

required due date extensions; 29.7% of completed other (EUP, tolerance, protocol review, cancer reassessment) decisions required due date extensions, and 0.2% of completed miscellaneous decisions required due date extensions.

When only primary decisions are considered, the breakdown of decision types is as follows:

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
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
2018	16	45	75	20	21	1	17	195

In FY' 18, 50% of completed, new active ingredient, primary decisions required due date extensions; 75% of completed, new use, primary decisions required due date extensions; 11% of completed, new product, primary decisions required due date extensions; 5.6% of completed, amendment, primary decisions required due date extensions; 52.5% of completed, inert, primary decisions required due date extensions; 20.7% of completed, other (EUP, tolerance, protocol review, cancer reassessment), primary decisions required due date extensions and 0.2% 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 2015		FY 2016		FY 2017		FY 2018	
Type	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total
New Active Ingredient	1	1	5	6	1	1	0	1
New Uses	2	7	0	3	0	1	1	5
New Products	19	151	1	143	17	151	2	125
Amendments	14	115	5	108	7	117	2	122
Other (tolerances, EUP, protocols, etc.)	2	7	3	12	1	11	0	14
Total with Due Date Extensions	38	281	23	272	26	282	5	267

In FY'18 the percentage of antimicrobial primary decisions with a due date extension (1.9%) was down from FY'17 (9.2%).

Biopesticides

Comparison of Number of Primary Decisions with Due Date Extensions versus Total Number of Primary Decisions - Biopesticides								
Fiscal Year	FY 2015		FY 2016		FY 2017		FY 2018	
Type	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total
New Active Ingredient	7	12	8	19	6	19	11	26
New Uses	1	4	1	4	1	7	0	2
New Products	4	66	2	75	6	67	3	52
Amendments	3	26	0	13	3	31	1	30
Other (tolerances, EUP, protocols, etc.)	2	19	1	15	0	21	3	10
Total with Due Date Extensions	17	127	12	126	16	145	18	120

In FY'18 the percentage of biopesticide primary decisions with due date extensions (15%) was up from FY'17 (11%).

Conventionals

Comparison of Number of Primary Decisions with Due Date Extensions versus Total Number of Primary Decisions - Conventional								
Fiscal Year	FY 2015		FY 2016		FY 2017		FY 2018	
Type	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total	Number with Extensions	Total
New Active Ingredient	6	8	2	3	6	6	5	5
New Uses	23	60	54	82	32	58	44	53
New Products	55	367	41	354	37	391	69	501
Amendments	23	238	17	193	12	222	17	203
Other (tolerances, EUP, protocols, etc.)	21	59	12	59	13	68	15	56
Total with Due Date Extensions	128	732	126	691	100	745	150	818

In FY' 18 the percentage of conventional primary decisions with a due date extension (18.3%) was up from FY' 17 (13.4%).

Note: Table V in Appendix A lists all applications subject to PRIA completed during FY' 18 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' 18, the agency issued 26 PRIA actions for public comment. Of those, 19 were for biopesticides and 9 were for conventional chemicals; there were no antimicrobial PRIA actions under the public participation in FY' 18. For additional information, please see <https://www.epa.gov/pesticide-registration/public-participation-process-registration-actions>.

Antimicrobial Time Frames

Section 33(k)(2)(E) of FIFRA directs the EPA to review its progress in meeting the timeline requirements for the review of antimicrobial pesticide products under section 3(h) of FIFRA. The timeline requirement under section 3(h) of FIFRA 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. Time frames under PRIA 3 were 4 months for an A530 and an A531 and 5 months for an A532. Of the 26 decisions in fee category A530 completed in FY' 18, 5 (19.2%) were completed within 90 days and 21 (80.8%) were completed within the four-month PRIA time frame. There were zero decisions requiring negotiation of the due date or completed late. Of the 24 other substantially similar or identical products in fee categories A531 and A532, all 24 (100%) were completed within their PRIA time frames.

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 69 FY' 18 decisions in this category, zero were completed within 120 days (the reduced 3(h) time frame); 34 (49.3%) were completed between 121 days and 150 days (met their original PRIA due date), 33 (47.8%) were completed between 151 days and 180 days (met the section 3(h) time frame), and 2 (2.9%) 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' 18 decisions in this category, none of them were completed within 120 days (the reduced 3(h) time frame) or 180 days (the section 3(h) time frame). All 3 decisions (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 pursuant to FIFRA section 6(a)(2) 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 periodic interactions 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) of FIFRA 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 focus 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. The PMSPs are under the “IPM Priorities” tab. <https://www.ipmcenters.org/crop-pest-data/>.
- **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. <https://www.northeastipm.org/ipm-planning/crop-profiles/>

STATE SOURCES

California Department of Pesticide Regulation

<https://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 – <https://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 -

<https://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 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, nematocides, and growth regulators used by producers. Data are collected annually. Kynetec is also a primary source for international pesticide usage data for field crops, fruits and vegetables via their sigma CP program which provides an annual global study that quantifies the pesticide usage crop-by-crop and by pest in more than 60 countries.

Kline and Company - <https://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' 2018

[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, 2018, 1,351 decisions subject to PRIA were pending in the agency's registration queue. Numbers pending at the end of FY' 16 and FY' 17 are shown for comparison and were, 1,173 and 1,613, respectively.

The number of antimicrobial decisions pending at the end of FY' 18 (140) was less than that at the end of FY' 17 (171).

The number of biopesticide decisions pending at the end of FY' 18 (174) was less than that at the end of FY' 17 (217).

The number of conventional pesticide decisions pending at the end of FY' 18 (986) was less than that at the end of FY' 17 (1,019).

The number of PRIA inert decisions pending at the end of FY' 18 (47) was greater than that at the end of FY' 17 (37).

The number of miscellaneous decisions pending at the end of FY' 18 (4) was less than that at the end of FY' 17 (169).