

Implementing the Pesticide Registration Improvement Act - Fiscal Year 2016

Thirteenth Annual Report



March 1, 2017

Process Improvements in the Pesticide Program

Improvements in Information Management and Labeling

Progress in Implementing PRIA 3 IT Set-Asides

PRIA 3 provided for \$800,000/year in Maintenance Fee funds to be set aside (beginning in FY'13) to support enhancements of information technology systems to improve the review of pesticide applications. Included in these IT improvements over the course of the PRIA 3 statutory timeframes are (1) enhancing the information systems capabilities to improve the tracking of pesticide registration decisions by December 31, 2013; (2) implementing a system for tracking conditional registrations by December 31, 2013; (3) establishing the capability to electronically review labels submitted with registration actions; (4) enhancing the database for information regarding endangered species assessments for Registration Review; and (5) establishing the capability for electronic submission of Confidential Statements of Formula with registration actions by December 31, 2014. Section 33(k)(2)(G) requires EPA to report on the progress made on these enhancements.

Electronic Submission Portal for PRIA Electronic Submissions

OPP continued to improve the Pesticide Submission Portal (PSP) during FY'16. The Pesticide Submission Portal replaces the CD/DVD-based process by which pesticide registrants can submit applications electronically to EPA. In addition to electronic submission capability, the portal includes an initial foray into providing submission status information back to the submitter. Submitters can now see status changes as the electronic package is moved from the EPA CDX environment to that of OPP's internal tracking system. At this time, only the Milestone 1 notification status is identified in the Portal, however, future enhancements will allow for all PRIA Milestones to be reported back for submitter reference.

Enhancing the Database for Information Regarding Endangered Species Assessments for Registration Review

The Endangered Species Knowledge Base was developed to assist in our endangered species assessments by providing a single location for information on each of the designated endangered species – information that is typically reused for multiple assessments. We expect the availability of this information in a single location will allow staff to realize gains in efficiency when performing these assessments. For FY'16, incremental improvements were made to the Endangered Species Knowledge Base system to refine our ability to catalog and retrieve information and to allow users to add newly listed species to the database and to track when and by whom changes to the database were made.

Electronic Submission of the Confidential Statement of Formula (eCSF)

During FY'16, OPP began development of the Electronic Confidential Statement of Formula Builder. This web-based tool will be located in the larger Pesticide Submission Portal (PSP) and provide the ability for registrants to enter information contained on the CSF and to then, via the PSP, submit this information to OPP as part of their application package. The information received by OPP will be a more granular format than the current paper-based form. This will allow OPP to better support queries on product formulation data and to provide greater accuracy in the CSF review process.

Electronic Submission and Document Retention

The agency’s electronic submission portal allows for submission of all PRIA covered actions electronically. The agency’s specifications and procedures for electronic submissions (including electronic labels) can be found at:

<http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm>.

FY’16 was the first full year that the agency’s new PRIA submissions tracking report came on line. The system tracks the frequency of electronic submissions by stakeholders. A summary of this information is presented below:

Stakeholder Submissions by Type of Product

Type of Product	Total # of Submissions	# Paper Submissions	# CD/DVD Submissions	# of Portal Submissions	% Paper Submission	% CD/DVD Submission	% portal Submission
Conventional	9,145	6,277	192	2,676	69%	2%	29%
Antimicrobial	2,806	1,582	78	1,146	56%	3%	41%
Biopesticide	1,203	913	44	246	76%	4%	20%
total	13,154	8,772	314	4,068	67%	2%	31%

Antimicrobial pesticide submissions had the highest percentage of electronic submissions while biopesticide submissions had the lowest. All three types of products have shown increases in electronic submissions since the electronic portal opened.

Electronic Review of labels

Label reviews can be very labor intensive especially when the label is quite long. Electronic label reviews have been recognized in OPP as having critical efficiency gain potential. Recognizing how critical the agency’s efforts are in this area, Congress required the EPA [under Section 33(k)(2)], to report the number of labels reviewed using electronic means.

The percentage of labels reviewed electronically in each regulatory division continues to increase. The table on the next page shows the current percentage of labels reviewed electronically in each division.

FY'16 Electronic Label Reviews

% of labels reviewed electronically in RD	79% - 92%
% of labels reviewed electronically in AD	82% - 91%
% of labels reviewed electronically in BPPD	73% - 95%