

Implementing the Pesticide Registration Improvement Act - Fiscal Year 2017

Fourteenth Annual Report



March 1, 2018

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'17. 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 PSP introduces functionality to provide submission status information back to the submitter. While much of the PSP enhancement activity in FY'17 supports electronic submissions in response to Registration Review data call-ins, some enhancements were made to the overall user experience and to provide additional capability for registration actions. An example of the latter is the expansion of PSP to allow electronic submission of Gold Seal letter requests.

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'17, 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'17, OPP continued software development of the Electronic Confidential Statement of Formula (eCSF) Builder. This web-based tool will be located in the larger Pesticide Submission Portal (PSP) and provide the ability for registrants to enter information from the CSF and submit this information to OPP via the PSP as part of their application package. The information received will allow OPP to better support queries on product formulation data and to provide greater accuracy in the CSF review process than the current paper-based form. Deployment of the eCSF Builder into the Pesticide Submission Portal is being coordinated with the

development and deployment of the Smartlabel Builder expected in FY'18.

Electronic Submission of Product Labels

During FY'17, OPP began development of the Smartlabel/Use Index Builder. Similar to the eCSF Builder, the SmartLabel/Use Index Builder will be a web-based tool located in the larger Pesticide Submission Portal (PSP) and provide the ability for registrants to enter information contained on the product labels and to then, via the PSP, submit this information to OPP as part of their application package. The information received by OPP will be the same content as the current paper-based label. This will allow OPP to better support queries on product use data and to provide greater accuracy in the label review process. Deployment of the Smartlabel/Use Index Builder into the Pesticide Submission Portal is being coordinated with the deployment of the eCSF Builder to provide a unified experience for both registrants and OPP staff.

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: <https://www.epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>.

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 for FY'17 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	8,683	4,878	57	3,748	56%	1%	43%
Antimicrobial	2,589	1,046	32	1,511	40%	1%	59%
Biopesticide	1,105	633	26	446	57%	2%	41%
total	12,371	6,551	115	5,705	53%	1%	46%

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 following table shows the current percentage of labels reviewed electronically in each division.

FY'17 Electronic Label Reviews

% of labels reviewed electronically in RD	86% - 91%
% of labels reviewed electronically in AD	83% - 92%
% of labels reviewed electronically in BPPD	69% - 82%