

# Implementing the Pesticide Registration Improvement Act - Fiscal Year 2018

Fifteenth Annual Report



## **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) of FIFRA requires EPA to report on the progress made on these enhancements.

#### ***Electronic Submission Portal for PRIA Electronic Submissions***

EPA's Office of Pesticide Programs (OPP) continued to improve the Pesticide Submission Portal (PSP) during FY'18. 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'18 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.

#### ***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'18, incremental improvements were made to the Endangered Species Knowledge Base system to refine our ability to catalog and retrieve information.

#### ***Electronic Submission of the Confidential Statement of Formula (eCSF)***

During FY'18, OPP continued to refine the Electronic Confidential Statement of Formula (eCSF) Builder and initiated beta testing with nine registrants. This web-based tool will be housed in the larger Pesticide Submission Portal (PSP) and provide the ability for registrants to enter and submit information from the CSF 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 provide greater accuracy in the CSF review process than the current paper-based form. Deployment of the eCSF Builder into the PSP is being coordinated with the development and deployment of the OPP Electronic Pesticide Label Builder anticipated in FY'19.

### ***Electronic Submission of Product Labels***

During FY'18, OPP finalized software development of the OPP Electronic Pesticide Label (OPPEL, formerly named SmartLabel) builder. The OPPEL system provides a tool for building electronic pesticide labels that are then managed in electronic format within OPP. The electronic pesticide label, submitted as an .xml file, is validated in the portal; if any errors are detected, an error message is generated informing the submitter of the portion of the label that is incorrect. Once the label passes validation, it will be in-processed via the PSP. In addition to completing the builder and validator, OPP completed development of the tools needed to open the .xml pesticide label files and automatically load them into a database. OPP will then review the labels using an electronic review tool. OPP is launching a test of the OPPEL system to ensure the it works as intended prior to making the system available for submission of all pesticide labels.

### ***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 online. The system tracks the frequency of electronic submissions by stakeholders. A summary of this information for FY'18 is presented below:

### **Stakeholder Submissions by Type of Product**

<b>Type of Product</b>	<b>Total # of Submissions</b>	<b># Paper Submissions</b>	<b># CD/DVD Submissions</b>	<b># of Portal Submissions</b>	<b>% Paper Submission</b>	<b>% CD/DVD Submission</b>	<b>% Portal Submission</b>
Conventional	7,845	4,011	14	3,820	51%	<1%	49%
Antimicrobial	2,420	750	5	1,665	31%	<1%	69%
Biopesticide	1,110	481	44	585	43%	4%	53%
<b>Total</b>	<b>11,374</b>	<b>5,241</b>	<b>63</b>	<b>6,070</b>	<b>46%</b>	<b>&lt;1%</b>	<b>53%</b>

Antimicrobial pesticides had the highest percentage of electronic submissions while conventional pesticides had the lowest. All three types of products have shown increases in electronic submissions since the electronic portal opened and FY'18 was the first fiscal year in which the percentage of submissions submitted electronically through the portal exceeded 50%.

### ***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) of FIFRA, to report the progress made toward implementing the capability to electronically submit and review labels submitted with registration actions.

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'18 Electronic Label Reviews**

<b>% of labels reviewed electronically in the Registration Division</b>	<b>88% - 93%</b>
<b>% of labels reviewed electronically in the Antimicrobials Division</b>	<b>90% - 95%</b>
<b>% of labels reviewed electronically in the Biopesticide and Pollution Prevention Division</b>	<b>61% - 92%</b>