

# Implementing the Pesticide Registration Improvement Act - Fiscal Year 2014

## Eleventh Annual Report



*March 1, 2015*

## **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 Statement 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.

We are continuing implementation of IT set-aside improvements with the FY'14 effort focused on tracking of pesticide registration decisions, enhancing our ability to review pesticide labels electronically, and supporting LEAN activities surrounding OPP's business processes. LEAN is a collection of principles, methods, and tools that improve the speed and efficiency of any process by eliminating waste. The LEANing of OPP's business processes is a valuable and needed first step that will allow future IT enhancements to be more efficient and be more in tune with the Office's strategic goals.

#### **Enhancing Information Systems' Capabilities to Improve the Tracking of Pesticide Registration Decisions**

The long term vision for improved tracking of registration decisions includes the ability of pesticide registrants to securely submit needed materials to OPP and to receive back information such as the status of the application and other documentation from OPP electronically. As part of a multi-phased approach, in FY'14, OPP completed the first phase by enhancing OPP's existing internal tracking system to provide email notifications back to registrants at up to seven (7) milestones during the review process. As discussed in the FY'13 Annual Report, these milestones were developed in cooperation with stakeholders and are typical to most registration applications that are subject to PRIA fees and timeframes. The initial automated milestone email notification capability was implemented on December 27, 2013, and the system began tracking applications received after January 1, 2014. Additional improvements to consolidate email messages to improve clarity of the notifications for related registration actions (bundling of related decisions) was introduced a few months later.

The development of a web-based submission portal is a critical step in the realization of our long-term vision. In FY'14, OPP has been involved in discussions with the Canadian Pest Management Regulatory Agency (PMRA) to establish a joint effort for portal development. This effort will leverage our existing collaboration working toward a harmonized Confidential Statement of Product Specification form (currently Confidential Statement of Formula or CSF) with a goal of implementing a single submission portal usable for electronic submissions to either Agency. Preliminary discussions of technical and security concerns have begun, and we expect the bulk of the Portal development to occur in the coming year.

### **A System for Tracking Conditional Registrations**

In FY'14 OPP compiled a spreadsheet that includes the terms of all conditional registrations issued since October 1, 1999. It lists by active ingredient each of the data requirements imposed as a condition of registration and identifies when the data were due, when received, and the status of the agency's review. We are using this spreadsheet to ensure either that registrants submit data in a timely fashion or that EPA takes appropriate regulatory action under FIFRA sec. 6(e) to cancel products with delinquent data. We are also monitoring the review of conditionally required studies to determine whether the new data might warrant changes in the terms of the registration. We posted this information on OPP's conditional registration website in early 2014. The information on this spreadsheet was updated in December 2014. In subsequent phases, we intend to upgrade our information technology systems to automate the tracking of study submission deadlines and internal review due dates. These planned improvements to our tracking capabilities for conditional registration data requirements are part of a more comprehensive set of IT improvements.

### **Building the Capacity for Electronically Reviewing Labels**

The first step toward improving OPP's ability to review pesticide labels electronically was the acquisition of software to facilitate comparison of electronic label files – typically as PDFs. This software was a critical first step to support the PRIA 3 requirement of two-day label review timeframes. Since last year's Report, additional licenses of the comparison software have been purchased to extend this capability to more staff and increase efficiency. More than 15 separate training classes have been conducted for label reviewers on how to use "CompareDocs" and the Electronic Label Library.

OPP also embarked on process improvements and better IT tools to post approved labels to the Pesticide Product Label System (PPLS). Previously, paper copies of approved labels were physically stamped with the "accepted" stamp and then scanned into the PPLS resulting in less than optimal timeframes and utility of the resulting label PDF files. To increase efficiency and

reduce time to posting, OPP developed, through a LEAN workshop, a mechanism by which PDFs can be electronically stamped and automatically routed to the PPLS. During the FY'14 pilot, these improvements reduced the number of personnel required to post the accepted labels into the PPLS, reduced the time for those labels to move through the posting process, and yielded higher quality, text-searchable PDFs -- now available to the public.

### **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'14, incremental improvements were made to the Endangered Species Knowledge Base system to refine our ability to catalog and retrieve information including naming and storing all reference documents for automatic import into the database.

### **Establishing the Capability for Electronic Submission of Confidential Statements of Formula with Registration Actions**

Work with the electronic CSF continues with most of the recent effort being toward acquiring OMB approval on the new PMRA/EPA harmonized form (CSPS). OPP is working on getting a contract in place for the development of a “CSPS Wizard”. This work will be performed with the collaboration of PMRA and will support the capture of CSF/CSPS data so that structured CSF/CSPS data can be submitted to the respective agencies. The development effort for the e-CSPS Wizard will likely be followed closely by the development of the OPP Submission Portal.

### ***Electronic Submission and Document Retention***

Acknowledging the agency's efforts in this area, Congress required the EPA [under Section 33(k)(2)], to report the number of label amendments reviewed using electronic means and to make recommendations for electronic submission and review of labels, including process improvements to further enhance the procedures used in electronic label review. 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>.

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FY'14 was the fifth full year that the agency's tracking systems have been recording statistics regarding submission and review of electronic labels. A summary of this information is presented below:

### **FY 2014 Labels Submitted\***

<b>Type of Product</b>	<b># of labels submitted</b>	<b># of e-labels</b>	<b>% electronic labels</b>
<b>Antimicrobial</b>	1,280	401	31%
<b>Biopesticide</b>	386	79	20%
<b>Conventional</b>	4,677	2,616	56%
<b>Total</b>	6,343	3,096	49%

### **FY 2014 Labels Reviewed**

During FY'13 we discovered that the number of electronic label reviews completed was being systematically under-reported. During FY'14 we discovered that a programming error in the OPPIN tracking system was the likely culprit. This error was resulting in the incomplete collection of data regarding electronic label reviews. While the programming error was being corrected and tested, OPP conducted a survey of label reviewers in OPP. The survey indicated that 94% of respondents in RD reported using CompareDocs for electronic label comparisons, and these reviewers used the electronic comparison tool for 66 -70% of their label reviews. In AD the survey indicated that 75% of the respondents reported using CompareDocs for electronic label comparisons but only occasionally. In BPPD less than 25% of respondents reported using the CompareDocs software.

### **Conclusions**

1. Of approximately 6,300 labels submitted to EPA in FY'14, almost half included an electronic label. Comparing the statistics from FY'11 to FY'14 reveals a steady increase of approximately 10% each year in the percentage of labels submitted in electronic format.
2. The use of electronic label review software varies significantly across the three regulatory divisions with RD reporting the highest use, AD moderate use and BPPD the lowest use.