Implementing the Pesticide Registration Improvement Act - Fiscal Year 2015

Twelfth Annual Report

March 1, 2016

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's major IT development project for PRIA during FY'15 was the implementation of the Pesticide Submission Portal (PSP). The Pesticide Submission Portal replaces the CD/DVD-based process by which pesticide registrants can submit applications electronically to EPA. Phase 1 of the PSP was released September 1, 2015, and now provides the ability to submit applications for all PRIA fee categories electronically via the Internet. The portal leverages the EPA's Central Data Exchange (CDX) to provide secure log-in authentication and other CROMERR requirements. New with the portal submission capability is support for PRIA 'Pre-application" submissions and inert ingredient clearance requests. 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'15, 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 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/pesticide-registration/electronic-submission-labels.

FY'15 was the first 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 # Packages Submitted	# Paper-Only Packages Submitted	# Electronic-Only Packages Submitted	Both paper & Electronic packages Submitted	% Paper Submission	% Electronic Submission	% both Paper & Electronic Submission
Conventional	2,864	1,504	684	676	52%	24%	24%
Antimicrobial	1,132	735	249	148	65%	22%	13%
Biopesticide	405	315	49	41	78%	12%	10%
total	4,401	2,554	982	865	58%	22%	20%

Conventional pesticide submissions had the highest percentage of electronic submissions while biopesticide submissions had the lowest. All three types of products show a significant number of submissions for which the applicant submitted both electronic and paper, which may indicate some confusion. While old EPA forms indicate that multiple paper copies are required, OPP's web site clarifies that the paper copy requirement only applies to paper submissions. If the applicant submits electronically, no copies are required.

Further examination of submissions by type of action provides some additional insight .

Stakeholder Submissions by Type of Action [Percentage Submitted Electronically]

Type of Action	Antimicrobial	Biopesticide	Conventional
New AI	67%	49%	92%
New Use	17%		95%
New Product	38%	20%	25%
Amendment	59%	16%	30%
Non-PRIA	12%	4%	16%

The most complicated packages involving new AIs for the most part have the highest percentage of electronic submissions across the three regulatory divisions while the non-PRIA submissions (fast track amendments and notifications), which are usually the least complicated submissions, have the lowest percentage.

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 agency's new system for tracking electronic reviews of labels depends on the reviewer voluntarily answering a prompt which essentially asks the question "Did you review this label using electronic comparison software?" "If not, why not?" There are legitimate reasons why a label cannot be reviewed electronically. If it is a new product, the initial label would not have any previously-reviewed label for comparison, requiring the reviewer to review it manually.

What the tables below show is that for a significant number of label reviews in each division, the reviewer failed to answer the prompt. For 49% of the labels reviewed in BPPD, the reviewer did not answer the prompt; in AD 45%; and in RD 27%. This has created a substantial amount of uncertainty, which is captured by providing an upper bound estimate and a lower bound estimate of the percentage of labels reviewed electronically in each division. The upper bound estimate relies only on those label reviews where the reviewer answered the prompt. The lower bound estimate includes those label reviews where the reviewer did not answer the prompt and assumes that an electronic review did NOT occur whenever the reviewer ignored the prompt.

FY'15 Electronic Label Reviews for Antimicrobials

Descriptions	Totals
Label reviewed electronically	229
Label not reviewed electronically	31
Label not reviewed electronically because electronic review not possible	24
Reviewer did not answer prompt	214
Number of labels that could have been reviewed electronically	236
Percentage of labels that could be reviewed electronically that were reviewed electronically (Excludes all decisions where reviewer did not answer the prompt)	97.03%
Percentage of labels which could have been reviewed electronically that were reviewed electronically (Assumes no electronic review for all decisions where reviewer did not answer the prompt)	50.89%

FY'15 Electronic Label Reviews for Biopesticides

Descriptions	Totals
Label reviewed electronically	62
Label not reviewed electronically	20
Label not reviewed electronically because electronic review not possible	2
Reviewer did not answer prompt	79
Number of labels that could have been reviewed electronically	80
Percentage of labels that could be reviewed electronically that were reviewed electronically (Excludes all decisions where reviewer did not answer the prompt)	77.50%
Percentage of labels that could be reviewed electronically that were reviewed electronically (Assumes no electronic review for all decisions where reviewer did not answer the prompt)	38.99%

FY'15 Electronic Label Reviews for Conventionals

Descriptions	Totals
Label reviewed electronically	1,995
Label not reviewed electronically	394
Label not reviewed electronically because electronic review not possible	224
Reviewer did not answer prompt	890
Number of labels that could have been reviewed electronically	2,165
Percentage of labels that could be reviewed electronically that were reviewed electronically (Excludes all decisions where reviewer did not answer the prompt)	92.15%
Percentage of labels that could be reviewed electronically that were reviewed electronically (Assumes no electronic review for all decisions where reviewer did not answer the prompt)	65.30%

Since the new tracking system allows for the tracking of electronic reviews down to the reviewer level, those reviewers who have been ignoring the prompt have been identified, and their management is pursuing more training in an effort to significantly reduce the percentage of labels reviewed where the reviewer ignores the prompt.