Implementing the Pesticide Registration Improvement Act - Fiscal Year 2013

Tenth Annual Report

March 1, 2014

Process Improvements in the Pesticide Program

Improvements in Information Management and Labeling

Pesticide Registration Improvement Extension Act IT Implementation Support

The EPA Office of Pesticide Programs completed changes to the sections of the Pesticide Registration Information System (PRISM) responsible for tracking PRIA-related activities to accommodate the new requirements of the Pesticide Registration Improvement Extension Act (PRIA 3). We updated the fee categories including the addition of ten (10) categories for inert ingredients and eight (8) for external reviews and miscellaneous actions. Special attention was given to the inclusion of these new fee categories and their interaction with other fee categories affecting fees and timeframes. Our IT experts also developed a mechanism for tracking the particulars of the "clean labels/2-day label review" and the 45/90-Day Technical Screen. The tracking system not only has to handle the new PRIA 3 categories and requirements, but also maintain PRIA 2 tracking capabilities for those pending actions submitted under PRIA 2.

Progress in Implementing PRIA 3 IT Set-Asides

PRIA 3 provided for $800,000/year in Maintenance Fee funds to be set aside 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 timeframe 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.

The EPA has begun the implementation of these by prioritizing the work over the course of the PRIA 3 timeframe and in accordance with OPP's strategic planning initiatives. During FY'13, efforts focused on developing the initial capabilities for improvements to the tracking ability of the IT systems for both registration actions and conditional registrations, enhancements to the ability to review pesticide labels electronically, and enhancements to the Endangered Species Knowledge Base.

Working in conjunction with stakeholders, OPP identified seven key milestones typical of most registration applications that are subject to PRIA fees and timeframes. As the first phase in developing a robust tracking capability for registration actions, we initiated enhancements to the IT systems to automatically send email notification messages to registrant-specified email addresses at each of the seven milestones for each PRIA 3 action. At the time of writing of this report, 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 is ongoing. In subsequent phases OPP intends to upgrade this tracking to allow for stakeholder interactive queries into the tracking

data base. Since this phase will be part of a more comprehensive set of IT improvements, OPP does not yet have a budget or timeframe for completion.

OPP is moving to implement the PRIA 3 requirement to establish a system for tracking conditional registrations. In the first phase, OPP established management controls and an office-wide process to track the status of submission and review of data required in connection with the conditional registration of pesticides containing new active ingredients. OPP has instituted more specific definitions within the list of allowable options available to the registering staff. These options will now clearly indicate which section of the FIFRA statute applies when making a conditional registration determination. All registration staff have been trained in the use of these new options by both Office of General Council and IT personnel. OPP has also compiled a consolidated spreadsheet that covers all new pesticides conditionally registered 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. The office is 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. The office is also monitoring the review of conditionally required studies to determine whether the new data would warrant changes in the terms of the registration. The office will make this compilation of information public via the OPP website on conditional registration in early 2014. In subsequent phases, the office intends to upgrade its information technology systems to automate the tracking of study submission deadlines and internal review due dates. Because better capabilities for tracking conditional registration data requirements will be part of a more comprehensive set of IT improvements, the office does not yet have a budget or schedule for completion of these later phases.

The first step in improvements to 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 considered critical, as a first step, to support the PRIA 3 requirement of two-day label review timeframes. Future work in this area will require OPP to begin in earnest to develop a formal structured label specification along with the acquisition of software to support both the creation of the structured label files by registrants and for the internal processing of those files by OPP.

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 endangered species – information that is typically reused across 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 fiscal year 2013, we refined our ability to catalog and retrieve this information.

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

FY'13 was the fourth 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 2013 Labels Submitted*

Type of Product	# of labels submitted	# of e-labels	% electronic labels
Antimicrobial	718	182	25
Biopesticide	324	28	9
Conventional	3,357	1,482	44
Total	4,399	1,692	38

FY 2013 Labels Reviewed*

Type of Product	# of labels in e-format	% of e-labels reviewed electronically
Antimicrobial	185	8
Biopesticide	28	14
Conventional	1,672	36
Total	1,885	33

*Note: The number of labels *submitted* versus the number of e-labels *reviewed* should not be compared to each other since they may count different labels. Labels are usually not reviewed until all studies submitted with an action have been reviewed. Therefore, labels submitted in FY 2013 may not be reviewed until a later year. Conversely, label reviews completed in FY 2013 may have been submitted in an earlier year.

Conclusions:

1) Of approximately 4,400 labels submitted to the EPA in FY 2013, 38% included an electronic label. Compared to the average of the previous three years (the period for which data has been collected), the percentage of labels (in any format) submitted in FY 2013 has decreased 55% but there has been a 70% increase in the percentage of labels submitted in electronic format.

2) Of the label actions completed by the EPA in FY 2013 that included an electronic label, 33% were reviewed electronically. Compared to the average of the previous three years (the

period for which data has been collected), the percentage of labels reviewed electronically in FY 2013 decreased 10%. This is partially due to problems with the old label comparison software. In 2012 a new release of the electronic label comparison software in use at the time was installed. Unfortunately, the comparison function took a step backward and did not work as well as previous versions. Frustration with the software resulted in a decline in usage by staff. Over the winter of 2012 – 2013 OPP staff researched and tested replacement label comparison software. New label comparison software was purchased in April and installed in June 2013, and staff were trained in its use over the summer. The statistics for FY 2014 will indicate if the replacement software has increased electronic label reviews.

Labeling Consistency

To further promote consistency in labeling, the Labeling Consistency Committee undertakes label training initiatives. In April 2013, the Committee hosted a workshop on label quality issues designed for OPP staff that had not attended earlier events. The workshop had about 100 OPP staff in attendance. Further in-house training is planned for 2014.