Implementing the Pesticide Registration Improvement Act - Fiscal Year 2012

Ninth Annual Report

March 1, 2013

Process Improvements in the Pesticide Program

Improvements in Information Management and Labeling

Pesticide Registration Improvement Extension Act IT Support

In preparation for the expected passage of the Pesticide Registration Improvement Extension Act (PRIA 3), the EPA Office of Pesticide Programs began to make changes to the sections of the Pesticide Registration Information System (PRISM) responsible for tracking PRIA-related activities. Included in these changes was updating the fee categories including the addition of ten (10) categories for inert ingredients and eight (8) for external reviews and miscellaneous actions. We gave special attention to the inclusion of these new fee categories and their interaction with other fee categories affecting fees and timeframes. Our IT experts also developed the 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 had to handle the new PRIA 3 categories and requirements, but also maintain PRIA 2 tracking capabilities for those pending actions submitted under PRIA 2.

Electronic Submission and Document Retention

The EPA is using information technology to improve the efficiency of the pesticide registration program and to reduce the paperwork burden on both the agency and the public.

In July 2008, the EPA's Office of Pesticide Programs announced it would receive pesticide submission packages in electronic form, or e-Registration submissions, following a pilot project conducted in FY 2007. The agency published a *Federal Register* Notice and provided guidance on the Web. The types of applications we currently accept electronically are Section 3 New Applications, Section 3 Amendments, Experimental Use Permits, Petitions for Tolerances, and applications for Supplemental Distributor Products.

As described in the FY 2011 PRIA Annual Report, the e-Submission Module of the Agency's tracking system, PRISM, supports the processing of the documentation required for pesticide applications. Early in the electronic submission effort, we recognized that the segment of the pesticide industry taking advantage of electronic submissions was typically the larger companies – those with Information Technology (IT) capability. The midsize and smaller companies – those without significant IT resources of their own – were not easily able to create the electronic packages in the needed format. To respond to this need, the EPA developed the e-Dossier Builder and made it available on the EPA's public website. The e-Dossier Builder is an application designed to help pesticide registrants create electronic submission packages in the format needed for submission to OPP. The software application is intended to be downloaded and installed on the user's computer and was developed with input from a workgroup of pesticide industry stakeholders, piloted during the middle of 2011, and formally released in November 2011. To assist the growing community of registrants taking advantage of electronic submission, we conducted webinars on the use of the e-Dossier Builder and the specifics of the e-submission process.

For FY 2012, OPP received 976 e-submission application packages out of a total of 7528 application packages submitted. A total of 10,884 documents (such as forms, correspondence, study reports, and labels) were associated with these 976 packages.

Number of FY 2012 e-Submissions Compared to Paper Submissions

Quarter	Number e-Submission Packages	Number of electronic Documents	% of all e-Submissions rejected*	Number ALL FEPU Submissions**	% e-Submissions of Total
1st	161	2109	58 / 36%	1652	10%
2nd	222	2377	54 / 24%	1764	13%
3rd	318	3518	91 / 29%	2093	15%
4th	275	2880	64/23%	2019	14%
Total	976	10,884	267/27%	7528	13%

*E-submissions were rejected because the XML file submitted could not be accepted into EPA's data systems.
**FEPU = Front End Processing Unit

As a result of scanning documents and storing e-Registration documents in Documentum, OPP currently has a Documentum library of over 305,900 documents available electronically (50,500 more documents than in FY 2011). Documents stored in the library consist of studies, forms, letters, and labels.

Electronic Label Review

Acknowledging the agency's efforts in this area, Congress required the EPA [under PRIA 2, FIFRA 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 submitting electronic submissions (including electronic labels) can be found at:
http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm

FY 2012 represents the third 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 2012 Labels Submitted*

Type of Product	# of labels submitted	# of e-labels	% electronic labels
Antimicrobial	1,594	159	10
Biopesticide	437	53	12
Conventional	4,771	1,753	37
Total	6,802	1,965	29

FY 2012 Labels Reviewed*

Type of Product	# of labels in e-format	% of e-labels reviewed electronically
Antimicrobial	151	36
Biopesticide	67	0
Conventional	1,862	51
Total	2,080	54

*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 2012 may not be reviewed until a later year. Conversely, label reviews completed in FY 2012 may have been submitted in an earlier year.

Conclusions:

1) Of approximately 6,800 labels submitted to the EPA in FY 2012, 29% included an electronic label. This percentage is almost a third higher than the percentage of labels submitted in electronic format in FY 2011.

2) Of the label actions completed by the EPA in FY 2012 that included an electronic label, 54% were reviewed electronically. This is double the percentage of electronic label reviews conducted in FY 2011.

Labeling Consistency

The agency formed a cross-program Labeling Consistency Committee in FY 2005 to address broad labeling issues and to oversee revisions to the Label Review Manual (LRM). The LRM provides guidance to EPA staff on reviewing labels. A Label Review Manual Team was formed to revise and update the LRM, completed in 2009. In 2010, EPA began to solicit comments on the LRM from state pesticide regulatory agencies and the general public. State agencies collected comments through the working committees of the State FIFRA Issues Research and Evaluation Group (SFIREG) and sent them directly to the committee. Public comments, primarily from pesticide registrants, were received through a Web-based discussion forum. The process of evaluating comments and making edits on all 18 chapters will extend through spring 2013. During 2012, 13 revised and edited chapters were posted to the on-line LRM. The purpose of asking for comments is to seek clarification of language, better examples and needed updates to make the LRM more useful to both the EPA and other stakeholders.

The Committee developed a Web site to communicate its activities and to address the public's general labeling policy questions forwarded through the website's e-mail address (OPP_labeling_consistency@epa.gov), a major activity of the committee. The committee receives about 75 to 100 questions per year and close to 600 questions since the site began. Answers to questions of general interest are posted, but all questions receive a direct response.

The committee from time to time publishes issue papers on its website. In 2012 a paper on the use of "new" as a label claim was posted. We also use the site to publish compact summations of selected policies that might otherwise be difficult for interested parties to locate, for example, the agency's policy on warranty and disclaimer statements.

To further promote consistency in labeling and conformity with guidance, the EPA has undertaken a number of label training initiatives. In September 2011, the Pesticide Program hosted a workshop on label quality issues and the principles of good labeling that was attended by 60 representatives of agricultural pesticide registrant companies, as well as EPA staff and state regulators. We put on a similar workshop focusing on registrants of consumer products on April 5-6, 2012. In 2013 we plan another round of in-house training on labeling quality for OPP staff who did not participate in earlier sessions.