Implementing the Pesticide Registration Improvement Act - Fiscal Year 2017

Fourteenth Annual Report

March 1, 2018

Process Improvements in the Pesticide Program

Improvements in the Registration Process

Improving the Registration Process

Electronic Stamping of Labels, QA/QC Procedure for the Pesticide Product Label System (PPLS). During FY'17, the LEAN e-stamping and electronic signature process was fully implemented. All pesticide labels and associated correspondence are now stamped electronically and are subject to quality control and quality assurance review prior to being uploaded to the PPLS webpage and released to the registrant. This represents a significant efficiency improvement in the registration process. This process ensures greater consistency and allows EPA to correct errors prior to approval and distribution of the label/correspondence to the registrant. Under the previous process, errors might be caught after issuance by contractors, registrants, state regulators, etc. which would require EPA to revise and reissue the label/correspondence to the registrant.

Product Efficacy. In FY'17, EPA published the new efficacy guideline "810.3900: Laboratory Product Performance Testing Methods for Bed Bug Pesticide Products." This document increases transparency and consistency in bed bug product testing and helps to ensure the generation of robust efficacy data to support product registrations. EPA also drafted two revised efficacy guidelines, "810.3100: Treatments for Red Imported Fire Ants" and "810.3500 Premises Treatments." These guidelines are scheduled for review by the Scientific Advisory Panel in May 2018. Finally, the Product Efficacy Review Committee continued to yield greater consistency in EPA's assessment of efficacy data and protocols.

SmartLabel. In FY'17**,** EPA's SmartLabel workgroup continued working with contractors to build the components needed for submission of an electronic pesticide label. Stakeholders input was used to refine the SmartLabel builder and modify the model, vocabularies, and enhance the functionality of the software. Significant progress was made in standardizing terminologies and defining validation rules for structured pesticide label submissions. A production ready Builder is anticipated to be released for voluntary submission of electronic labels in FY'18.

Coordinated Framework (CF) for Biotechnology. The Biopesticides and Pollution Prevention Division (BPPD) and its government partners (OCSPP/OPPT, USDA and FDA) implemented updates to modernize, streamline, and clarify the regulatory system for biotechnology products, including biotechnology-based pesticides. In particular, EPA worked extensively with FDA to negotiate the transfer of jurisdiction for genetically engineered mosquitoes intended for population control from FDA to EPA. In FY'17, FDA published for public comment their proposal to execute this transfer through Guidance for Industry #236. This transfer (completed in early FY'18) will streamline the Federal review process and increase predictability for industry by having timeframes and processes for decision-making under PRIA rather than FFDCA new animal drug authorities.

BPPD-AD Joint Product Review Pilot. In FY'17, BPPD and AD continued to pilot a joint review and registration process for products containing biopesticide active ingredients with antimicrobial uses. This type of product is subject to both BPPD and AD data requirements, and involves work-sharing between these Divisions. Lessons learned in 2016 and 2017 will be used to improve the process and increase efficiency for both OPP and registrants by leveraging resources and expertise most efficiently.

Public Process Decision Document Template. In FY'17, the Registration Division (RD) created a registration decision document template to be used when proposing and finalizing important registration decisions to be sent for public comment; the implementation of this template will ensure consistency and transparency in communicating our decisions to stakeholders.

New Active Ingredient Decision Memorandums Peer Reviewed by PRD. A new process was instituted between RD and the Pesticide Reevaluation Division (PRD) to improve the quality of decision memoranda associated with the new active ingredients. Under this process, a senior reviewer in PRD provides a peer review of the decision memorandum to RD before the decision is routed for division director review in RD.

SharePoint Site for Employee Training: In FY'17, RD established a Training SharePoint site which houses QA-related documents such as standard operating procedures (SOPs), guidance documents, tracking spreadsheets, links to mandatory EPA trainings, and a newly created Onboarding Package for new employees that includes a handbook and checklist. In addition, RD developed a Welcome Buddy program in which a new hire is assigned a peer "welcome buddy" who guides the new employee through his or her initial months in RD. These resources promote efficiency and consistency in RD by ensuring that all new hires receive the same training early on. In FY18, we are looking forward to completing the new product SOP and providing tips on how to use the electronic databases more efficiently.

Pre-decisional Determination Due Date

Under PRIA 3, the Agency established a Pre-decisional Determination Due Date for any covered application that requires approval of a new or amended label for the Registration Division (R codes) and Antimicrobial Division (A codes). The Pre-decisional Determination Due Date precedes the PRIA Decision Due Date by 2 weeks for PRIA categories with decision review times $\leq$ 12 months and by 4 weeks for PRIA categories with decision review times > 12 months.

The purpose of this new, earlier due date is to provide adequate time to reach agreement with the registrant on required label changes prior to the Agency approving the label. In the past, the Agency approved draft labels with comments specifying changes to be incorporated into a final label. Under this new process, only clean labels are approved (no comments) which makes it easier for the states, enforcement personnel, and other stakeholders.

If the Agency and the applicant cannot come to an agreement by the PRIA due date, the Agency will send a follow-up letter that will advise the registrant of the Agency's decision to close out the PRIA decision review time. That letter will provide the following three options for continuing the review of the application:

(a) Applicant agrees to all of the terms associated with the draft accepted label as revised by the Agency and requests that it be issued as the accepted final Agency-stamped label; or
(b) Applicant does not agree to one or more of the terms of the draft accepted label as revised by the Agency and requests additional time to resolve the difference(s); or
(c) Applicant withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee.

FY'17 Results under the Pre-decisional Determination Due-Date Process.
The Antimicrobial Division completed 338 decisions in FY'17. All of the 338 antimicrobial completions were for submissions made under PRIA 3. Of the 338 PRIA 3 completions, 330 decisions involved the approval of a new or amended product label that were subject to this new process.

The Registration Division completed 941 decisions in FY'17. Of the 941 conventional completions, 5 were for applications submitted during PRIA 2, and 936 were for submissions made under PRIA 3. Of the 936 PRIA 3 completions, 762 decisions involved the approval of a new or amended product label that were subject to this process.

Table 1: Completed Decisions Resulting in New or Amended Product Label Approvals

	Antimicrobial Decisions (A)	**Conventional Decisions (R) & Miscellaneous (M005)**	**Total**
Completed decisions in FY'17	338	941	1,279
Completed PRIA 3 decisions in FY'17	338	936	1,274
PRIA 3 decisions involving label approvals	330	762	1,092

Of the 330 antimicrobial PRIA 3 completed decisions involving the approval of amended or new product labels, 0 (0%) was completed after the PRIA due date; 39% (132 decisions) were completed on the PRIA due date; 49% (166 decisions) were completed after the Pre-decisional determination due date but before the PRIA due date, and 11% (37 decisions) were completed on or before the Pre-decisional determination due date.

Of the 762 conventional PRIA 3 completed decisions that involved the approval of amended or new product labels, <1% (6 decisions) were completed after the PRIA due date; 19% (143 decisions) were completed on the PRIA due date; 45% (336 decisions) were completed after

the Pre-decisional determination due date but before the PRIA due date, and 36% (277 decisions) were completed on or before the Pre-decisional determination due date.

Table 2: Timing for Completion of Label Reviews & Approvals

Timing for Completed Label Reviews & Approvals	Antimicrobial Label Reviews & Approvals	Conventional Label Reviews & Approvals	Total
After PRIA due date	0 (0%)	6 (1%)	6 (<1%)
On the PRIA due date	106 (32%)	143 (19%)	249 (23%)
Before the PRIA due date but after the pre-decisional determination due date	161 (48%)	336 (45%)	497 (45%)
On or before the pre-decisional determination due date	63 (19%)	277 (36%)	340 (31%)
Total	**330**	**762**	**1,092**

One of the purposes of this new PRIA 3 requirement was to provide applicants with adequate time to resolve label issues before the expiration of the PRIA due date forced a "take it or leave it" decision on the applicant. Quarterly PRIA Stakeholder meetings address on an ongoing basis whether stakeholders are receiving these pre-decisional determinations in a timely manner. Of the completed decisions that resulted in an approved label, 76% occurred before the PRIA due date indicating that this requirement has for the most part achieved its intended purpose. Also, this requirement results in clean labels which greatly facilitates state registrations.

As the table above indicates, the 2-day label review was not consistently achieved. Further training of staff in FY'17 will address these inconsistencies.

International Work-sharing

EPA is continuing global joint reviews and work sharing with counterparts in Canada, Mexico, Australia, and with other global partners. In global joint reviews, two or more national authorities evaluate a pesticide active ingredient at the same time, receiving the same submissions, developing a schedule, and dividing the work. At the conclusion of the effort, each national authority makes its own regulatory decision with the goal of harmonizing conclusions on potential adverse effect levels and allowable pesticide residues (MRLs). In work sharing, a national authority shares completed reviews with international counterparts who complete further work on their own schedule.

Conventional Pesticides

During FY'17, 5 new conventional active ingredients and one new use were registered through the global and joint review process, and 3 other global and joint review projects for new active ingredients were in review during FY'17. Countries that have participated in the global and joint review process (past or present), or that have observed the process or expressed an interest in participating, include Australia, Canada, Mexico, China, Brazil, Japan, Malaysia, Vietnam, India, Germany, the UK, France, New Zealand, the Netherlands, South Korea, and the Philippines.

In FY'17, under the minor use joint review program, Canada's Pest Management Regulatory Agency (PMRA) and the EPA completed work on 11 chemicals covering 24 commodities. Work-sharing also occurred for 2 chemicals covering 3 commodities.

Biopesticides

In FY'17 BPPD partnered with PMRA in screening for two joint reviews of new biopesticide active ingredients submitted late in the fiscal year. No other biopesticide joint reviews were initiated or completed in FY'17.