# Implementing the Pesticide Registration Improvement Act - Fiscal Year 2016

## Thirteenth Annual Report

*March 1, 2017*

# Process Improvements in the Pesticide Program

## Improvements in the Registration Process

### Improving the Registration Process

**Lean Process for labels – electronic submission and workflow.** During FY'16, the percentage of labels conforming to the LEAN e-stamping and electronic signature process exceeded 99.3%, a significant efficiency improvement in the registration process.

**Product Efficacy.** In FY'16, RD created a webpage to address commonly asked efficacy-related questions. This effort increased transparency and improved communication with registrants and will likely reduce both the number of registrant efficacy inquiries and the amount of unusable data submitted. RD also converted to a fully electronic efficacy package system in which packages are only received electronically and stored in a searchable repository. The Product Efficacy Review Committee continues to be yielding greater consistency in EPA's assessment of efficacy data.

**SmartLabel.** EPA's SmartLabel initiative continued its collaboration with stakeholders to refine the SmartLabel model, to develop the necessary vocabularies and processes, to standardize terminologies and to define validation rules for structured pesticide label submissions. In FY'16, EPA employees and registrants tested the SmartLabel Builder, which allowed us to further refine our user guidance. A production ready Builder is anticipated in FY'17.

**PRIA Coalition.** OPP worked with PRIA stakeholder groups within the PRIA Coalition to provide (a) technical advice on the development of new categories under PRIA 4, (b) needed amendments of existing categories, and (c) corresponding revisions to the PRIA Interpretations Document.

**Harmonized Product Chemistry Templates** [Work plan under RCC (Regulatory Cooperation council)]. OPP finalized the Harmonized Product Chemistry Templates, developed with Canada's Pest Management regulatory Agency (PMRA) and agreed to by all OPP regulatory divisions. Templates were introduced to the regulatory community via webinar on June 2, 2016. Use of templates will facilitate more efficient joint reviews as well as easier adoption of work share between the USEPA and Canada's PMRA. The templates address all OPP regulatory Divisions: RD, AD and BPPD.

**FY'16 QA/QC Procedure for the Pesticide Product Label System (PPLS).** Almost all labels and associated correspondence are being QA/QC'ed before they are posted to PPLS and released to the registrant. This process ensures greater consistency across AD and allows us to correct errors prior to approval and distribution of the label/correspondence to the registrant. Under the

old process, errors might be caught after issuance by contractors, registrants, state regulators, etc. which would require us the revise and reissue the label/correspondence to the registrant

**FY '16 Correspondence Templates.** AD has fully implemented the use of the OPP correspondence templates for communication with registrants for PRIA actions. This has resulted in increased consistency and significant time savings for AD staff and registrants.

**Pollinator Protection.** EPA partnered with USDA, the National Association of State Departments of Agriculture, and the Honey Bee Health Coalition to bring together stakeholders to share information and tools for developing managed pollinator protection plans. Managed honey bee populations play a crucial role in commercial crop pollination. Developing mitigation to prevent further loss of managed hives, as well as wild pollinators, is an important part of the pesticide registration process. EPA also drafted a final Acute Risk Mitigation Strategy for bees, responding to more than 100,000 public comments.

**21st Century Toxicity Testing.** EPA sent letter to registrants regarding OPP plan for alternatives to *in vivo* testing. OPP waived the requirement of acute dermal toxicity testing based on acute oral data. This will save considerable time in reviewing data, conducting studies and obviate unnecessary testing on thousands of animals. For labeling purposes, EPA has also agreed to accept *in vitro* alternative testing methods for eye irritation.

**Child Resistant Packaging. EPA c**ollaborated with the Consumer Product Safety Commission (CPSC) to harmonize child resistant packaging data under the Poison Prevention Packaging Act and FIFRA.

**White House Coordinated Framework (CF) on Biotechnology.** BPPD worked to modernize and streamline the regulatory system for biotechnology products. Under this White House led effort, BPPD and its government partners (OCSPP/OPPT, USDA and FDA) undertook to increase transparency, predictability and efficiency in its regulation of biotechnology products and to improve agency coordination. EPA, USDA and FDA held three public meetings across the country, received and analyzed almost 1,000 public comments and published a revised Coordinated Framework.

**Strategic Framework for Biotechnology.** BPPD and its government partners (OCSPP/OPPT, FDA and USDA) developed and published a long-term strategy to ensure that the federal biotechnology regulatory system is prepared for the future products of biotechnology. As part of this strategy, BPPD will assume responsibility from FDA for genetically engineered insects if the registrant is making pesticidal claims such as population control.

**Bt Corn Industry Agreement.** EPA negotiated and implemented new, more protective requirements governing all Bt corn registrant products. The new terms and conditions are designed to delay significantly corn rootworm (CRW) resistance to genetically engineered Bt corn. The agreement provides incentives for registrants and growers to implement proactive integrated pest management (IPM) measures such as crop rotation. BPPD also separately negotiated the rapid phase out of single trait Bt products that are vulnerable to resistance. These combined actions help ensure farmers will have safe, effective tools for years to come to control CRW, limiting the need to resort to conventional pesticides.

**Plant-Incorporated-Protectants (PIPs) Symposium. BPPD o**rganized and held the first public symposium tailored to small businesses and academia to explain the US regulatory system that applies to biotechnology and the data that are used to support PIP registrations. The symposium also covered the scope of the scientific review process that determines the safety of PIPs and the pesticide registration process as a whole. This symposium increased awareness, understanding, and transparency with respect to EPA's approach to regulating biotech products.

**Zika Response.** With the emergence of Zika as a major public health concern in FY'16, BPPD expedited the review and approval of biopesticide products determined to be of potential value in combating the mosquitoes that spread Zika. This included several non-PRIA fast track label amendments, the registration of a new active ingredient mosquito attractant, and an Experimental Use Permit for *Wolbachia pipientis* to test its effectiveness in suppressing Aedes aegypti mosquito populations. BPPD has also provided registration support to companies with promising products or technologies, and has several other pending actions we anticipate completing ahead of their PRIA due dates. BPPD also led OPP and ORD's input on the White House strategy for Zika response research and development.

**BPPD-AD Joint Product Review Pilot.** In FY'16, BPPD and AD began a pilot to streamline the 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 will be reviewed by a work-share between these Division. The goal is to provide "B" (for biopesticide) codes to all appropriate products and to leverage resources and expertise most 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 ≤ 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'16 Results under the Pre-decisional Determination Due-Date Process.**
The Antimicrobial Division completed 350 decisions in FY'16. Of the 350 antimicrobial completions, 3 were for applications submitted during PRIA 2, and 347 were for submissions made under PRIA 3. Of the 347 PRIA 3 completions, 336 decisions involved the approval of a new or amended product label that were subject to this new process.

The Registration Division completed 980 decisions in FY'16. Of the 980 conventional completions, 7 were for applications submitted during PRIA 2, and 973 were for submissions made under PRIA 3. Of the 973 PRIA 3 completions, 821 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'16** | 350 | 980 | 1,330 |
| **Completed PRIA 3 decisions in FY'16** | 347 | 973 | 1,320 |
| **PRIA 3 decisions involving label approvals** | 336 | 821 | 1,157 |

Of the 336 antimicrobial PRIA 3 completed decisions involving the approval of amended or new product labels, 1 (<1%) 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 821 conventional PRIA 3 completed decisions that involved the approval of amended or new product labels, <1% (9 decisions) were completed after the PRIA due date; 23% (188 decisions) were completed on the PRIA due date; 42% (346 decisions) were completed after the Pre-decisional determination due date but before the PRIA due date, and 34% (278 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** | 1 (<1%) | 9 (1%) | 10 (<1%) |
| **On the PRIA due date** | 132 (39%) | 188 (23%) | 320 (28%) |
| **Before the PRIA due date but after the pre-decisional determination due date** | 166 (49%) | 346 (42%) | 512 (44%) |
| **On or before the pre-decisional determination due date** | 37 (11%) | 278 (34%) | 315 (27%) |
| **Total** | **336** | **821** | **1,157** |

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, 71% 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'16, 2 new conventional active ingredients were registered through the global and joint review process, and 9 other global and joint review projects for new active ingredients were in review during FY'16. 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'16, under the minor use joint review program, Canada's Pest Management Regulatory Agency (PMRA) and the EPA completed work on 4 chemicals covering 4 commodities. Work-sharing also occurred for 2 chemicals covering 3 commodities.

### Biopesticides

In FY'16 BPPD partnered with PMRA in 2 ongoing joint reviews of new biopesticide active ingredients. Both were completed in FY'16. No new joint reviews were initiated in FY'16.

### Antimicrobial Pesticides

In FY'16 AD completed a joint effort with PMRA to harmonize labeling for 3 antimicrobial products used in both the US and Canada.