# Implementing the Pesticide Registration Improvement Act - Fiscal Year 2018

## Fifteenth Annual Report

# Process Improvements in the Pesticide Program

## Improvements in the Registration Process

### Improving the Registration Process

**Antimicrobials Retreat.** During FY'18, the Antimicrobials Division (AD) held a half-day management retreat for managers and other senior staff. During the retreat, short- and long-term action items were identified for regulatory- and science-related processes including improvements in the consistency of product labels, transmittal of data packages for science review, data evaluation records, and registration review Data Call-ins (DCIs). Implementation of the revised processes are anticipated to improve the consistency and transparency of regulatory decision making for antimicrobial pesticides.

**Antimicrobials Efficacy *Candida auris*.** In FY'18, AD collaborated with the Centers Disease Control (CDC) and OPP's Biological and Economic Analysis Division (BEAD) to develop data for testing antimicrobial efficacy of products against the emerging pathogen *C. auris.* AD staff collaborated with CDC on revisions to the posted guidance for testing and labeling of products for *C.auris.* In addition, at CDC's request, AD worked to identify products that can be used in long-term care clinical settings around patients with respiratory challenges.

**Revision of Antimicrobial Product Performance Test Guidelines.** In FY'18, AD announced the availability of final efficacy test guidelines for antimicrobial product performance. The revised guidelines provide recommendations for the design and execution of laboratory studies to evaluate the effectiveness of antimicrobial pesticides that work against public health microbial pests. The revision reflects current science methodologies, provides clarity to previous language in the guidelines, and incorporates new OPP policies introduced since the 2012 publication. The Agency is continuing to work with stakeholders on the mandatory implementation of these guidelines including the development of Frequently Asked Questions (FAQs) to provide further clarification.

**Electronic Submissions.** In FY'18, the Registration Division (RD) worked successfully within OPP and with external partners to advance opportunities for electronic data submissions. The SMART label/OPPEL project is moving ahead and will support efforts for data quality and label review.

**Streamlined Drinking Water Assessments.** In FY'18, in collaboration with the Environmental Fate and Effects Division (EFED) and the Biological and Economic Analysis Division (BEAD), RD began implementing a streamlined drinking water assessment process for minor use petitions.

**Revised Respirator Language**. In FY'18, in collaboration with the Field and External Affairs Division (FEAD), RD completed training on new respirator language and began implementing label language requirements to improve worker protection.

**Label Workshop Collaboration.** In FY'18, working in partnership with CropLife America and RISE, RD provided training and a forum for industry and government to discuss label challenges.

**Performance Test Guidelines**. In FY'18, RD sought FIFRA Scientific Advisory Panel recommendations on two product performance test guidelines, one for red imported fire ants and one for premise treatments.

**Enhanced Reporting Template.** In FY'18, RD developed a template to collect enhanced reporting data for pet spot-on products and held a webinar to provide implementation support. Collection of data in a consistent format will improve the Agency's ability to evaluate safety of pet spot-on products.

**Reinvented Joint Review Pilot Process.** In FY'18, RD collaborated with Health Canada's Pest Management Regulatory Agency (PMRA) to pilot a process for Joint Reviews that would continue to assure harmonized tolerances/maximum residue levels (MRLs), and also increase efficiency and timeliness of new active ingredient reviews and decisions.

**Standard Operating Procedures Enhanced.** In FY'18, RD's Q/A team completed new Standard Operating Procedures (SOPs) that describe the approaches and requirements for the review of new products and the Bulletins Live system. The team also updated the SOP that characterizes how staff should accomplish reviews of fast track amendments

## 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'18 Results under the Pre-decisional Determination Due-Date Process.**
The Antimicrobial Division completed 328 decisions in FY'18. Of the 328 antimicrobial completions, 326 were for submissions made under PRIA 3. Of the 326 PRIA 3 completions, 315 decisions involved the approval of a new or amended product label that were subject to this new process.

The Registration Division completed 1,045 decisions in FY'18. Of the 1,045 conventional completions, 3 were for applications submitted during PRIA 2 and 1,042 were for submissions made under PRIA 3. Of the 1,042 PRIA 3 completions, 857 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'18** | 328 | 1,045 | 1,373 |
| **Completed PRIA 3 decisions in FY'18** | 326 | 1,042 | 1,368 |
| **PRIA 3 decisions involving label approvals** | 315 | 857 | 1,172 |

Of the 315 antimicrobial PRIA 3 completed decisions involving the approval of amended or new product labels, less than 1% (1 decision) was completed after the PRIA due date; 34% (106 decisions) were completed on the PRIA due date; 48% (152 decisions) were completed after the Pre-decisional determination due date but before the PRIA due date, and 18% (56 decisions) were completed on or before the Pre-decisional determination due date.

Of the 857 conventional PRIA 3 completed decisions that involved the approval of amended or new product labels, less than 1% (3 decisions) were completed after the PRIA due date; 19% (164 decisions) were completed on the PRIA due date; 50% (428 decisions) were completed after the Pre-decisional determination due date but before the PRIA due date, and 31% (262 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%) | 3 (<1%) | 4 (<1%) |
| **On the PRIA due date** | 106 (34%) | 164 (19%) | 270 (23%) |
| **Before the PRIA due date but after the pre-decisional determination due date** | 152 (48%) | 428 (50%) | 580 (49%) |
| **On or before the pre-decisional determination due date** | 56 (18%) | 262 (31%) | 318 (27%) |
| **Total** | **315** | **857** | **1,172** |

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.

## 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.

During FY'18, 1 new conventional active ingredient was registered through the global and joint review process (Afidopyropen), and 5 other global and joint review projects for new active ingredients were in review during FY'18 (Bixafen, Revysol, Tetraniliprole, Pethoxamid, and Brofanilide). 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'18, under the minor use joint review program, Canada's Pest Management Regulatory Agency (PMRA) and the EPA completed work on 2 chemicals covering 9 commodities. Work-sharing also occurred for 3 chemicals covering 26 commodities.

No international work-sharing activities for biopesticides or antimicrobials were initiated or completed in FY'18.