Implementing the Pesticide Registration Improvement Act - Fiscal Year 2015

Twelfth Annual Report

March 1, 2016

Process Improvements in the Pesticide Program

Improvements in the Registration Process

Improving the Registration Process

Lean Activities. During FY'14 & 15 OPP conducted 6 Lean process workshops to improve efficiency and quality in the registration process. "Lean" activities are designed to identify and eliminate waste and improve the speed and quality of resulting products. The following processes were chosen for improvement: (1) label reviews, approvals and posting; (2) Federal Register publication processes for Notices of Issuance (NOI), Notices of Receipt (NOR) and Notices of Filing (NOF); (3) Front End process improvements to provide for enhanced electronic submissions; (4) centralizing storage of electronic jackets that are fully searchable; (5) registration review team interactions; and (6) timeliness of information collection for assessors.

In FY'15 we began implementing the Lean recommendations in the three pesticide registering divisions, AD (Antimicrobials Division), BPPD (Biopesticides and Pollution Prevention Division) and RD (Registration Division) and the Pesticide Reevaluation Division (PRD). Staff compliance with electronic label signatures and automated uploading into PPLS was reported at > 90% across AD, BPPD and RD. BPPD has also expanded electronic signatures to include decision documents and memoranda. We have batched together NOIs, NORs and NOFs across AD, BPPD and RD to reduce staff time and publication costs. Batching of registration review docket opening notifications for AD, BPPD and PRD also took place. The Pesticide Submission Portal (PSP) went live in September 2015 which allowed registrants to submit certain types of applications to EPA electronically using a secure, web-based portal. The PSP is the first step in a phased approach that will ultimately lead to EPA's ability to accept all pesticide applications electronically which will increase operational efficiencies and reduce paper waste.

24(C). We initiated a pilot with 5 states for electronic submission of Special Local Needs 24(C) requests in RD to improve efficiencies in this process.

Product Efficacy. In FY'15 RD created the Product Efficacy Review Committee (PERC) for efficacy-related registration actions. The PERC allows for greater flexibility in allocating reviewer resources in the three vertebrate/invertebrate branches to handle efficacy protocol reviews, new efficacy study submissions and registrant rebuttals. The PERC also provides greater consistency in agency decisions with regard to these actions.

SmartLabel. Collaboration with FDA and stakeholders continued on EPA's SmartLabel initiative. We completed a Phase I pilot with stakeholders which helped to refine the SmartLabel model, develop the necessary vocabularies and processes, standardize terminologies and define validation rules for structured pesticide label submissions. Phase II is ongoing in FY'16.

Workshop to Improve Registration Submissions. In September 2015 BPPD led a product chemistry session at the Biopesticide Industry Alliance (BPIA) Registration Workshop. The workshop goal was to improve the quality of product chemistry submissions from applicants to increase review efficiency, decrease the number of 10-day failure letters sent during the 45/90 day technical screening process and decrease time invested post-submission addressing problems discovered during data review. Over the past few years, BPPD has participated in the BPIA Workshop and has led several sessions in various disciplines, including product chemistry, toxicology and environmental fate and effects. BPPD led an overview of the regulatory session in which they provided detailed information on the registration process, the importance of electronic submissions, waiver requests, microbial toxicity and eco-toxicity testing, as well as continued discussions on developing successful rationales to meet data requirements and the PRIA classification process.

More Crop Grouping. . We continue to revise the crop group regulations. We establish crop group tolerances based on residue data from designated representatives within the group and then apply them to all commodities within that group. Crop group regulations save considerable resources by reducing the number of required residue studies and facilitating the establishment of import tolerances. In FY'15, we continued work on five new groups -- Leafy Vegetable Crop Group 4-14; Brassica Head and Stem Vegetable Crop Group 5-14; Stalk, Stem and Leaf Petiole Crop Group 22; Tropical and Subtropical Fruit, Edible Peel, Crop Group 23 and Tropical and Subtropical Fruit, Inedible Peel, Crop Group 24. We published the Proposed Rule for Phase IV of this project in the Federal Register on November 14, 2014. The proposed rule also sought to make minor editorial changes to commodities and subgroups, and revised 40 CFR § 180.40(f) and commodity definitions in 40 CFR §180.1 (g). Tolerances were identified for Subgroup/Group 4 and 5 tolerances and the tropical fruits grandfathered in. The crop grouping team prepared briefing memos and responded to public comments on proposed rules. We expect to publish the final rule in FY16.

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, 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'15 Results under the New Pre-decisional Determination Due-Date Process.
The Antimicrobial Division completed 319 decisions in FY'15. Of the 319 antimicrobial completions, 5 were for applications submitted during PRIA 2, and 314 were for submissions made under PRIA 3. Of the 314 PRIA 3 completions, 304 decisions involved the approval of a new or amended product label that were subject to this new process.

The Registration Division completed 961 decisions in FY'15. Of the 961 conventional completions, 19 were for applications submitted during PRIA 2, and 942 were for submissions made under PRIA 3. Of the 942 PRIA 3 completions, 770 decisions involved the approval of a new or amended product label that were subject to this new 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'15	319	961	1,280
Completed PRIA 3 decisions in FY'15	314	942	1,256
PRIA 3 decisions involving label approvals	304	770	1,074

Of the 304 antimicrobial PRIA 3 completed decisions involving the approval of amended or new product labels, 14 (5%) were completed after the PRIA due date; 35% (107 decisions) were completed on the PRIA due date; 43% (133 decisions) were completed after the Pre-decisional determination due date but before the PRIA due date, and 16% (50 decisions) were completed on or before the Pre-decisional determination due date.

Of the 770 conventional PRIA 3 completed decisions that involved the approval of amended or new product labels, <1% (3 decisions) were completed after the PRIA due date; 14% (104 decisions) were completed on the PRIA due date; 48% (369 decisions) were completed after the Pre-decisional determination due date but before the PRIA due date, and 38% (294 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	14 (5%)	3 (<1%)	17 (2%)
On the PRIA due date	107 (35%)	104 (14%)	211 (20%)
Before the PRIA due date but after the pre-decisional determination due date	133 (43%)	369 (48%)	502 (46%)
On or before the pre-decisional determination due date	50 (16%)	294 (38%)	344 (32%)
Total	304	770	1,074

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. Of the completed decisions that resulted in an approved label, 78% 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 being achieved. Further training of staff is being conducted in FY'16 to address these inconsistencies.

International Work-sharing

The EPA continued its work-sharing efforts with Australia, Canada, and Mexico. In global and joint reviews, each national regulatory authority shares study reviews. Each national authority makes its individual registration decisions while striving to harmonize its regulatory decisions with other global partners.

Conventional Pesticides

During FY'15, 5 new conventional active ingredients were registered through the global and joint review process. 13 global and joint review projects for new active ingredients were in review during FY'15. In addition, China, a new partner, participated in the global joint review of Oxathiapiprolin, which was registered in FY'15. Australia, Canada and Mexico have continued their participation in the joint review process, and other countries including Brazil, Japan and Vietnam have expressed an interest in participating in future joint review projects.

In FY'15, Canada's Pest Management Regulatory Agency (PMRA) and the EPA completed work on 5 chemicals for 10 commodities under the minor use joint review program. We currently have 9 chemicals for 16 commodities currently under review through the minor use joint review program. Additionally, during FY'16 up to 15 additional chemicals (26 commodities) are expected to be evaluated under the NAFTA joint review program, and 6 chemicals (7 commodities) may be evaluated as work-share projects.

Biopesticides

In FY'15 BPPD partnered with PMRA in 4 ongoing joint reviews of new biopesticide active ingredients. Of these four, work on three was completed in FY'15 or early FY'16 while one is still ongoing. No new joint reviews were initiated in FY'15.

Antimicrobial Pesticides

In FY'15 AD completed a joint effort with PMRA to review an application to harmonize labeling for 1 antimicrobial product used in both the US and Canada.