Implementing the Pesticide Registration Improvement Act - Fiscal Year 2014

Eleventh Annual Report

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Process Improvements in the Pesticide Program

Improvements in the Registration Process

Improving the Registration Process

Lean Activities. Over the past few years EPA and state environmental agencies have experimented with using Lean to improve government processes. Lean is a collection of principles, methods, and tools that improve the speed and efficiency of any process by eliminating waste. Although Lean originated in manufacturing operations, the tools have been successfully applied in organizations across all sectors, including the government.

OPP has employed this continuous improvement approach to improve some of our business processes, making them more efficient and consistent across the program. OPP has conducted Lean workshops for 6 processes. These Lean workshops included multidivisional teams and resulted in some immediate and short-term improvements. These implementation plans better utilize existing tools and resources, and get rid of unnecessary steps to allow us to more efficiently produce high-quality work.

1) Label review, approval, and posting process
    a. Reduced time from label approval to posting from 16 to 3 days on average by implementing electronic signatures, stamps and automated Pesticide Program label System (PPLS) uploads in all regulatory divisions
    b. Improved quality of labels posted to PPLS (fully searchable, color documents)
    c. Increase consistency of label approval letters by standardizing templates across regulatory divisions
2) Federal Register publication process for NOIs, NORs, and NOFs
    a. Reach a broader audience by publishing NOIs to OPP website in a manner similar to that used for Section 18s
    b. Increase number of polymer NOFs published on time by modifying FR batching process
    c. Reduce number of review cycles by revising FR review process
    d. Increase quality of notifications by formalizing process for updating FR templates
3) Front-end process
    a. Employ outreach and training to increase number of electronic submissions
    b. Catalogue common errors with current electronic submissions to inform future improvements
4) Creation, maintenance, storage, and retrieval process for jackets
    a. Reduce growth of paper jackets by eliminating redundant, unneeded documents from regulatory records

   b. Increase centralized storage of fully searchable electronic documents to create an electronic regulatory record
5) Optimizing chemical team interactions
   a. Streamline & accelerate registration review process for conventional & antimicrobial chemicals
   b. Provide earlier opportunity for registrant to weigh-in on uses being assessed
   c. Increase consistency of review process between chemicals to provide more level playing field
   d. Publish preliminary risk assessments earlier when additional data are not needed
   e. Capture registration review decisions in a database to inform decisions on similar chemicals
6) Risk assessment groundwork process
   a. Reduce time spent by assessors collecting information by consolidating and optimizing internal information systems
   b. Consolidate internal workload tracking systems across divisions

Delegation of authority in BPPD to Expedite Fast Track & Notification Actions. In conjunction with the LEAN activities, in FY'14 BPPD delegated signature authority for fast track actions and notification from the Branch Chief level to the team leader level. This process improvement brings consistency with the other registering divisions for these types of actions. This delegation has relieved a bottleneck at the Branch Chief level where a wide range of PRIA actions must be reviewed and approved. This process improvement has resulted in significantly shorter approval times for fast tracks and notifications. At the same time, BPPD reduced the number of actions in backlog status from 178 in July 2014 to 39 at the end of September 2014.

Workshop to Improve Registration Submissions. In September 2014 **BPPD** led several sessions at the Biopesticide Industry Alliance (BPIA) Registration Workshop. The workshop goal was to improve the quality of submissions from applicants to increase review efficiency and decrease time invested post-submission addressing problems discovered during data review. EPA-led sessions provided detailed information on the registration process, the importance of electronic submissions, product chemistry, microbial toxicity and eco-toxicity testing, developing successful rationales to meet data requirements, and the PRIA classification process.

Lower Certified Testing Guidance. In FY'14 the Antimicrobials Division released The Lower Certified Limit Testing Guidance, http://www.epa.gov/oppad001/lower-cert-limit-test-

guidance.pdf, to clarify scenarios under which efficacy testing at the lower certified limit (LCL) is needed. The LCL is the lowest amount of active ingredient a product can legally contain, and it is reported on the confidential statement of formula. Efficacy testing at the lower certified limit is necessary to demonstrate an antimicrobial product's ability to consistently perform as labeled. This guidance helps ensure that labeled products protect human health.

Antimicrobial Testing Program. EPA's Antimicrobial Testing Program (ATP) ensures that EPA-approved hospital sterilants, disinfectants and tuberculocides in the marketplace continue to meet stringent efficacy standards. Under the ATP, the agency collected and tested samples of EPA-registered products from manufacturers, distributors and sellers of hospital sterilants, disinfectants and tuberculocides. The ATP's efficacy test methods provide a rigorous challenge to the product. The EPA adopted this high standard to ensure that products will be effective even when extremely high pathogen levels are present. Following testing, issues were identified for a number of products. These products with outstanding issues were listed as "Agency Taking Action" on the agency's ATP website. In FY'14, the Antimicrobial Division greatly reduced the number of registered products where the agency was taking action. Reducing the total from over 120 to approximately 40 products (~66% decrease).

More Crop Grouping. Revisions to the crop group regulations continue, where crop group tolerances are established based on residue data from designated representatives within the group and then are applied 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'13, it was reported that work was completed on the review of five new groups for 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. However, publication of the Proposed Rule for Phase IV of this project was delayed during FY'14 in order to develop language to propose revisions to 40 CFR § 180.40(f). 40 CFR § 180.40(f) of the Crop Group Regulations was first promulgated in 1983. This section addresses the interaction of crop group tolerances with processed food tolerances and meat, milk, and egg tolerances. Based on a re-examination of § 180.40(f), EPA concluded that several changes were needed. Therefore, EPA will also propose to revise § 180.40(f) to more clearly enunciate the three principles originally included in the provision and to update these provisions in line with current practice. We expect to publish the Proposed Rule for Phase IV of this project, which will include these five groups and proposed revisions to § 180.40(f), in the Federal Register in the fall of 2014. We then expect to publish the Final Rule for Phase IV in the summer of 2015.

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 the label 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'14 Results under the New Pre-decisional Determination Due-Date Process.
The Antimicrobial Division completed 287 decisions in FY'14. Of the 287 antimicrobial completions, 15 were for applications submitted during PRIA 2, and 272 were for submissions made under PRIA 3. Of the 272 PRIA 3 completions, 259 decisions involved the approval of a new or amended product label that were subject to this new process.

The Registration Division completed 897 decisions in FY'14. Of the 897 conventional completions, 139 were for applications submitted during PRIA 2, and 758 were for submissions made under PRIA 3. Of the 758 PRIA 3 completions, 593 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	Conventional Decisions R & M005	Total
Completed decisions in FY'13	287	897	1,184
Completed PRIA 3 decisions in FY'13	272	758	1,030
PRIA 3 decisions involving label approvals	259	593	852

Of the 259 antimicrobial PRIA 3 completed decisions that involved the approval of amended or new product labels, 50 (19%) were completed after the PRIA due date; 25% (65 decisions) were completed on the PRIA due date; 37% (97 decisions) were completed after the Pre-decisional determination due date but before the PRIA due date, and 18% (47 decisions) were completed on or before the Pre-decisional determination due date.

Of the 593 conventional PRIA 3 completed decisions that involved the approval of amended or new product labels, 9% (56 decisions) were completed after the PRIA due date; 12% (71 decisions) were completed on the PRIA due date; 40% (239 decisions) were completed after the Pre-decisional determination due date but before the PRIA due date, and 38% (227 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	50 (19%)	56 (9%)	106 (12%)
On the PRIA due date	65 (25%)	71 (12%)	136 (16%)
Before the PRIA due date but after the pre-decisional determination due date	97 (37%)	239 (40%)	336 (39%)
On or before the pre-decisional determination due date	47 (18%)	227 (38%)	274 (32%)
Total	259	593	852

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. 71% of the completed decisions that resulted in an approved label occurred before the PRIA due date indicating that this requirement has for the most part achieved its intended purpose.

Due to the government shutdown in October 2013, the Agency eschewed renegotiating PRIA due dates in favor of utilizing that time and resource to address the resulting backlog caused by the shutdown. This was referred to as "the short term strategy". This strategy was in place from the middle of October 2013 to the middle of January 2014. The 12% of decisions that were completed after the PRIA due date (in Table 2 above) should be considered in light of this "short term strategy".

PRIA 3 also requires the Agency to review and approve revised labels within 2 business days after receipt. Only 1 decision went beyond the PRIA due date. The applicant and the Agency were able to resolve the label issues, and the revised label was accepted as the final Agency-stamped label within 7 business days, which exceeded the 2-day requirement.
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International Work-sharing

The EPA continued its work-sharing efforts with Australia, Brazil, Canada, the European Union, Japan, 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'14, four new conventional active ingredients were registered through the global and joint review process. Thirteen global and joint review projects for new active ingredients were in review during FY'14. In addition, China is a new partner and is currently participating in an ongoing joint review. Australia and Mexico have continued their participation in the joint review process, and other countries including Brazil, Japan, Korea, Taiwan, South Africa, and Vietnam have expressed an interest in participating in future joint review projects.

In FY 2014, Canada's Pest Management Regulatory Agency (PMRA) and the EPA completed work on 6 chemicals for 13 commodities under the minor use joint review program and completed a work-share project for another chemical on 1 commodity. We currently have 7 chemicals for 12 commodities currently under review through the minor use joint review program. Additionally, during FY'15 up to 13 additional chemicals (27 commodities) are expected to be evaluated under the NAFTA joint review program, and 3 chemicals (4 commodities) may be evaluated as work-share projects.

Biopesticides

In FY'14 BPPD partnered with PMRA in 6 joint reviews of new biopesticide active ingredients. Of these six, two were registered in FY'14 while the other four are ongoing.

Antimicrobial Pesticides

In FY'14 AD completed a joint effort with PMRA to review an application to harmonize labeling for 3 antimicrobial products used in both the US and Canada.