Implementing the Pesticide Registration Improvement Act - Fiscal Year 2012

Ninth Annual Report

March 1, 2013

Process Improvements in the Pesticide Program

Improvements in the Registration Process

Improving Application Quality

Blue Book Updates. The EPA's updated Pesticide Registration Manual, posted to the Internet in March 2010, includes guidance on how to develop an application for a pesticide product registration. Links are provided directly to forms, statutes, guidance, references and background materials, and other application resources. In the past year, two chapters have been updated – Chapter 5, Registration Fees, and Chapter 14, How to Obtain an EPA Company or Establishment Number and Change of Address. More chapter updates are anticipated during FY 2013 to reflect changes in PRIA 3.

The Initial Screening. The EPA's initial screening of the contents of the application determines whether the application contains all the necessary forms, data, and draft labeling, formatted in accordance with EPA guidance. The screening must be completed within 21 days after receiving an application and the required registration service fee (FIFRA section 33(f)(4)(B)). If the application fails the screen and cannot be corrected by the applicant within the 21 day period, the EPA must reject the application.

At the beginning of FY 2012, PRIA applications identified as having deficiencies under the PRIA 21-Day Completeness Screen were being forwarded to the RD Product Managers for resolution. The Product Managers were expected to either resolve the pending issues or process a rejection letter. This year we changed the process for addressing deficient packages under the PRIA Completeness Screen as a result of recommendations from product managers. Now the PRIA Ombudsman receives deficient applications from the 21-Day Completeness Screeners. Under the new process, the ombudsman works with the applicant to resolve deficiencies. In the event that any unresolved deficiencies are deemed by the PM and the ombudsman significant enough to warrant rejection, the Ombudsman prepares the rejection letter for management and OGC review. The Office of General Counsel reviews the rejection letter before it goes to the Deputy Office Director of the Office of Pesticide Programs for approval. The Deputy Office Director approves and signs the letter that is then sent to the applicant. Revamping the current process allows the Product Managers and PM teams to focus their resources on those actions that have a path forward toward a registration decision.

Improving the Registration Process

The EPA's success in meeting PRIA due dates is a result of its continued monitoring of the status of decisions and identification of efficiency measures that conserve resources and time. We continued processes described in past annual reports in FY 2012 with some enhancements.

More Crop Grouping

Revisions continue in the crop group regulations, where crop group tolerances are established based on residue data from designated representatives within the group and then applied to all commodities within that group. Crop groups substantially reduce the number of studies needed to establish a crop group tolerance; for instance, instead of more than 30 separate reviews for individual crops in a crop group, only data for the representative commodities need to be reviewed, which may range from 2 to 5 reviews. Crop group regulations save considerable resources by reducing the number of required residue studies and facilitating the establishment of import tolerances. In FY 2012, activities included publishing the *Federal Register* final rule that established Stone Fruit Crop Group 12-12, Tree Nut Crop Group 14-12, training EPA staff on crop group updates, and updating the Index to Part 180 Tolerance Information. In addition, we expect that the new PRIA 3 code R175 that went into effect on October 1, 2012, will encourage registrants to submit more petitions that include conversions of existing approved crop group(s) to one or more revised crop groups.

Improving the Confidential Statement of Formula (CSF)

Efforts are underway to develop an electronic Confidential Statement of Product Specifications (eCSPS) that will eventually replace the Confidential Statement of Formula. We are working with Health Canada's Pest Management Regulatory Agency (PMRA) to develop an electronic form that can be used to submit applications to both regulatory authorities. We are conducting the e-CSPS project under the United States-Canada Regulatory Cooperation Council (RCC). The RCC has a two-year mandate to work together to promote economic growth, job creation, and benefits to our consumers and businesses through increased regulatory transparency and coordination. The Office of Pesticide Programs and PMRA have coordinated extensively and have reached agreement about the data fields on the form.

Electronic Negotiation Due Date Extension System Upgrade

In FY 2011 the EPA developed an electronic negotiated due date system that saves resources by allowing electronic routing and approval of PRIA due date extension forms. The forms are maintained in a database that will facilitate the EPA's analysis of the reasons for due date extensions. We upgraded the electronic PRIA Negotiation WebForms system to improved email notification and Division profiles. The improved email notification includes author's name,

chemical, form date, decision, registration, and petition numbers. This additional identification information allows the user to distinguish requests easily. A profile template was also customized for each Division with pre-populated review levels for group emails.

U.S-Canada Workshop on Product Chemistry

As a follow-up to a two-day product chemistry workshop in November 2011 the EPA and Canada's PMRA agreed to collaborate on joint EPA/PMRA chemistry guidelines/directives and to continue to work toward harmonization of product chemistry reviews to conserve resources.

Conventional Pesticide Registration Process Improvements

Label checklist: In FY 2012 RD implemented several process improvements developed by joint divisional (Registration Division, Health Effects Division, Environmental Fate and Effects Division) workgroups having to do with problem formulation, or identifying and communicating to the registrant critical data/information gaps early in the process such that the assumptions the EPA is making in its risk assessments accurately reflect the desired use pattern proposed by the registrant. One of these workgroups developed the label checklist, which lists the parameters that need to be specified on the label for the science divisions to conduct their risk assessment without using unnecessarily conservative assumptions. This checklist has been shared with Crop Life America (CLA) and it is hoped that the registrant community will eventually start providing this information routinely with their registration applications, in addition to using the checklist as a resource to provide more clarity on their labels regarding the proposed use pattern. We held team meetings for new active ingredient actions prior to FY 2012, but in FY 2012 we expanded this practice to include new use applications, such that RD, EFED, and HED team members all engage in the problem formulation process toward the front end of the PRIA decision review time frame. This will result in communication of deficiencies and concerns to the registrant much earlier in the review process, giving the registrant an opportunity to correct deficiencies and address concerns early in the risk assessment phase, rather than after the risk assessment is complete. This should result in a decrease in the number of negotiated PRIA due dates. Another benefit is making sure that all divisions involved in the review of the PRIA application have a common understanding of the use pattern being requested. The label checklist, along with the Label Use Directions Table, is a tool that is used to prepare for the first team meeting.

Biopesticide Registration Process Improvements

The Biopesticides and Pollution Prevention Division (BPPD) introduced several initiatives in 2011-2012 to improve its communications with registrants, consultants, and other stakeholders; the consistency and predictability of registration processes; and the quality of applications submitted for registration (especially the associated data submissions), with the goal that BPPD

would better meet its customers' needs and reduce the frequency and length of PRIA negotiated due dates.

Presubmission Meetings. As part of the registration process for biopesticides, companies have always been strongly encouraged to meet with BPPD staff prior to submitting an application to register a new pesticide product. These meetings were usually scheduled by "fitting in" a time for the meeting wherever one could be found, without considering BPPD's staff and management schedules. After the meeting, the visitors prepared a summary of the meeting, submitted it to BPPD, and the staff who had attended the meeting from BPPD would review the minutes, editing where necessary to clarify any questions or errors concerning the data needs, and the Regulatory Action Leader (RAL) would prepare a response letter to the prospective applicants with the changes for the Branch Chief's signature. This process could take months, which was understandably a problem for the prospective applicant. The two registering branches now direct prospective applicants to work with their presubmission coordinators to schedule the meetings, and meeting notes are provided at the end of the meeting to all of the participants. These small changes eliminated "overbooking" meetings and the often significant time delays caused by the old practice for preparing, editing and responding to the minutes.

To improve the quality of applications submitted for new registrations, the presubmission coordinator sends the company an electronic "toolkit" with links to important information on the Web needed by applicants for registration (data requirements, forms, statutes, regulations, label manual, etc.) and a template for the presubmission meeting. The template serves double duty since it is filled in during the meeting with information discussed that will assist the applicant as they prepare their application package. The presubmission coordinator sets up the meetings with staff and managers, being mindful of their schedules, workloads, and deadlines. This has improved the quality of the meetings by allowing better preparation of BPPD employees in advance of the meeting date. BPPD worked with OPP IT staff to have webinars with the prospective applicants to reduce the need for travel.

Electronic Data Submission Templates. BPPD participates in a North American Free Trade Agreement (NAFTA) joint-review process with Canada's PMRA for new pesticide products that are submitted to both countries. Since PMRA receives registration applications electronically, and all of the data required to support registration is submitted in OECD formats, BPPD adopted and developed data evaluation record (DER) templates similar to those submitted electronically to PMRA. The applicant submits the templates with the data packages in electronic format. This helps the applicants understand the specific content needed to determine the acceptability of the various required studies. Existing templates for conventional pesticides are used for biochemical pesticide active ingredients, and the templates for microbial pesticides were finalized in 2011. Since the templates are harmonized with the OECD format, which is accepted by Canada and

Mexico, we anticipate that this will facilitate future data sharing, joint reviews, and concurrent registrations.

Improved Communications: Timely Feedback on Application Deficiencies

A Submission Readiness Team was established in BPPD during 2011. The team reviews all submissions within two weeks after the division receives the complete application from document processing. They look closely at the application package to determine if the data are ready for review. If they find deficiencies, they inform applicants immediately, and applicants must correct the deficiencies before the data can be put into primary science review. The team records its findings electronically, in real time, communicating obvious deficiencies months sooner than under BPPD's previous review processes. When the data are ready to go into review, the applicants are sent a letter and email with contact information for the RAL. By detecting obviously deficient packages early, the Submission Readiness Team has saved science reviewers time further down the pipeline, has flagged gross deficiencies early in the process and has reduced PRIA renegotiations and the length of time it takes to register new products. After the success of the readiness team concept, all the OPP Regulatory Divisions have now adopted the process and we have written it into PRIA 3 as a technical screen allowing for 45/90 days of review. Under the law, an application can be rejected if it fails to pass the screen or cure any problems within a certain time frame.

Improving the Quality of BPPD Documents and Decisions

BPPD initiated an internal document review team to ensure the quality, consistency, and clarity of Biopesticide Registration Action Documents that communicate risk assessments and risk management decisions for pesticide active ingredients registered in the Division.

Training on the Biopesticide Registration Process

In April 2011, OPP hosted a three day NAFTA Biopesticide Registration Improvement Course with PMRA and pesticide officials from Mexico, for pesticide registrants and consultants interested in biopesticides. At the training course, registrants and consultants were given building blocks for constructing a biopesticide registration application. Trainers then identified the major stumbling blocks that cause significant delays in registration decisions. About 50 biopesticide registration applicants, consultants, researchers, and registrants attended the course in person, and more than 70 additional participants tuned in to the simultaneous webinar broadcast over the Internet. The recorded webinar is posted on EPA's website at http://www.epa.gov/oppbppd1/biopesticides/nafta-bric.html.

Antimicrobial Pesticides Process Improvements

Voluntary Disclosure of Antimicrobial Ingredient Information Pilot. OPP's Antimicrobials Division finalized guidelines for voluntary disclosure of all ingredients in an antimicrobial product posted them on the EPA website. This guidance describes ways that a company can present ingredient information about an antimicrobial product on its website or on an antimicrobial label. Information can be found at http://www.epa.gov/oppad001/voluntary-disclosure.html

Product Performance Guidelines. OPP finalized the product performance test guidelines for air, textiles and water (Section 810 Guidelines). Registrants may follow these guidelines to conduct studies required under FIFRA for pesticide registration pursuant to 40 CFR 161. Additional information can be found at http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series810.htm

Design for the Environment (DfE) Antimicrobial Pilot Program. This pilot project allows the use of a DfE logo as a marketing tool on qualifying antimicrobial pesticide labels. In 2012 the agency approved four products with the DfE logo. Additional information about the program can be found at: http://www.epa.gov/pesticides/regulating/labels/design-dfe-pilot.html

Pilot for Biodegradability Claims. This on-going Pilot Program assesses the potential benefits of allowing "factual statements" regarding some environmentally preferable characteristics of registered pesticide products. Biodegradability is a critical concern with "down the drain" products which can be aquatically toxic. AD approved two products with a biodegradable surfactant claim. More information can be found at: http://www.epa.gov/pesticides/regulating/labels/biodegradability-claims.html.

Prions as Pests. The EPA published a Notice of Proposed Rulemaking to clarify agency policy on products intended to control prions (proteinaceous infectious particles) on January 26, 2011. The EPA published a proposed Supplemental Prions Rule to clarify efficacy data required for products with prion-related claims on November 17, 2011. After obtaining a "non-significance" determination from OMB waiving comment on the final rule in July 2012, EPA notified Congress, HHS and USDA on July 27, 2012. Publication of the final rule is pending.

Exposure Studies and Protocols. AD reviewed and approved two Antimicrobials Exposure Assessment Task Force study protocols and one completed exposure study. The reviews of one protocol and the completed study were presented to the EPA's Human Studies Review Board in October 2011 and January 2012.

Registration Review Data Call-Ins (DCI). AD issued nine data call-ins. To minimize FOIA requests, AD began posting non company-specific (i.e., redacted) copies of registration review

DCIs to the public dockets on http://www.regulations.gov. In addition to posting the documents, the division distributed a one-page list of DCIs issued and links to the corresponding documents in the public dockets.

Reaching out to the Pesticide Registrant Community

The Antimicrobials Division made several formal presentations and participated on committees focused on improving stakeholder information and raising awareness of the antimicrobial registration process:

- Bi-monthly meetings with the American Chemical Council Biocides Panel and quarterly presentations at Consumer Specialty Products Association conferences.
- Participated in a webinar hosted by the Association for the Healthcare Environment (AHE). The webinar, titled "Regulatory Compliance: The Hidden Costs of Non-compliance" included hospital and long-term care facilities staff. The webinar helped AHE members better understand regulatory activities associated with antimicrobial pesticides and provided them with information on additional resources.
- Attended several national conferences, such as AHE 2012 (Association for the Health Care Environment).
- At the 15th Indoor Air Quality Association Annual Meeting, presented the regulation and use of antimicrobial products in HVAC systems, cleaning claims guidance and other antimicrobial topics of interest to this group.
- Served on a panel for the International Society of Exposure Science/Society of Environmental Toxicology and Chemistry (ISES/SETAC) Europe's 21st Annual Meeting in Milan, Special Session: "Emerging Exposure Science for Developing Chemical Regulatory Policy: REACh, Biocides, TSCA Reform." In an interactive panel format, European and North American regulators shared their views on key science needs for human and environmental exposure characterization for regulatory decision-makers moving forward within their legislative mandates. Panel members discussed barriers to addressing these needs, as well as opportunities for moving forward. The focus of the discussion was on exposure science needs.
- Presented at the Informa Conference in Spain a discussion of the EPA's antimicrobial registration process and public process.
- Held a follow-up meeting via video conference with members of the EU to discuss issues including treated articles and devices.
- Provided Support to the international Organisation for Economic Cooperation and Development (OECD) Test Methods and Guidance. AD supported the development of antifoulant, treated article, wood preservative and swimming pool documents. AD also

supported the OECD Biocide Method Implementation Work Group. Finally, AD supported the development of the OECD Quantitative Use Dilution Method.

The Registration Division meets twice yearly with CropLife America and quarterly with major conventional pesticide registrants and participates in meetings of the Chemical Producers and Distributors Association, the Consumer Specialty Products Association, Responsible Industry for a Sound Environment (RISE), the Armed Forces Pest Management Board, and the IR-4 Technical Working Group to discuss application status, upcoming submissions and application issues.

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 individual registration decisions while striving to harmonize regulatory decisions with other global partners.

Conventional Pesticides

During FY 2012, seven new conventional active ingredients were registered through the global and joint review process. Fourteen global and joint review active ingredients were in review during FY 2012. In addition, Brazil, Japan, and Mexico have continued their participation in the joint review process. Other countries such as China, Korea, Taiwan and South Africa have expressed an interest in participating in future joint review projects.

In FY 2012, Canada's Pest Management Regulatory Agency and the EPA completed work on 7 chemicals for 13 commodities under the minor use joint review program. Work was also completed on one active ingredient for two commodities as part of the US and Canada work-share program. During FY 2013 we expect to evaluate 17 additional minor use chemicals (38 commodities under the NAFTA joint review program and we expect five chemicals (six commodities) to be evaluated as work-share projects.

Biochemical and Microbial Pesticides

EPA also participates in a NAFTA joint-review process with Canada's PMRA for new biopesticide products that are submitted to both countries. BPPD completed three NAFTA joint reviews with Canada in FY 12. Four Joint Reviews are pending for 2013.

Antimicrobial Pesticides

The Antimicrobials Division meets on a quarterly basis with the Canadian Authorities on a range of issues including triclosan, wood preservatives and public health products. In FY 2012, Canada's Pest Management Regulatory Agency and the EPA completed work on two amendments for disinfectant products under the work-share program.