Process Improvements in the Pesticide Program

Improvements in the Registration Process

Improving Application Quality

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. We encourage user comments, and in the past year, we have revised chapters in response to comments and suggestions from two pesticide trade associations to make it more useful to infrequent applicants. To ensure that users have access to the most recent information, the Manual is updated whenever new guidance or policies become available.

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.

In FY 2011, we enhanced the procedures and guidance for screening described in the FY 2009 report. In late FY 2010, we commenced a pilot to expand the screen using checklists for conventional chemicals to determine whether the data requirements were addressed in R300, R301 and R310 PRIA actions. The pilot also improved front end processing so that Product Managers receive applications identified as being deficient earlier in the process. Later, we expanded this enhanced screen to include all new biochemical and antimicrobial product applications and antimicrobial amendments. To assist applicants in addressing all of the data requirements and passing this screen, EPA checklists were posted to the Internet. Data requirements for conventional new products were posted in March, followed by the biopesticide and antimicrobial checklists in fall 2011. Links are provided within the checklists to the guidance on the conduct of each study to further assist applicants.

Study Profile Templates Based on DERs. The EPA encourages applicants to submit electronic summaries of their studies using the OECD/NAFTA templates with their applications to ensure that all reporting elements are addressed. The OPP Study Profile templates, user-friendly templates in Microsoft Word format, are available on the EPA website for most guideline studies. The templates were the outcome of a joint effort with Health Canada. Since the Study Profile template design is based on the EPA's existing Data Evaluation Record (DER) format, the EPA anticipates that the use of these templates will improve applications and expedite the review of submitted data. The initial focus of this effort was on conventional pesticide

applications. The Biopesticide and Pollution Prevention Division adopted data evaluation record templates similar to those submitted electronically to Canadian authorities. Existing templates for conventional pesticides are used for biochemical pesticide active ingredients, and new templates for microbial pesticides were finalized in 2011. Registrants can submit their data packages, using the templates, in electronic format. These harmonized templates should facilitate future data sharing, joint reviews, and concurrent registration actions with Canada and Mexico.

Efforts are underway to develop additional electronic tools to help applicants develop complete, high quality applications. Working with the EPA's Office of Research and Development, we are developing DER composers, which, through a series of questions and fields, will allow the user to enter the necessary information into an electronic format that can then be used to generate a DER or to transfer data to databases or to models. Composers have been developed so far for livestock and rat metabolism studies.

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. Processes described in past annual reports were continued in FY 2011 with some enhancements. The EPA developed an electronic negotiated due date form 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.

For the 21 day content screen, the application routing process was improved to enable Product Managers to quickly recognize and then act upon deficient applications within the 21 day period. Corrections are promptly made to the application by the registrant, thereby reducing the number of 75-day deficiency letters and decreasing the amount of follow-up required later in the process.

Pre-application Meetings. The EPA encourages applicants to discuss their application with agency staff prior to submitting it to help the application "pass" the 21-day content screen. For Global Joint Reviews, the EPA always meets with registrants prior to the application being submitted. These meetings benefit both the registrant and EPA. Forms and data requirements are discussed, and registrants learn how to format their packages for electronic submission so their submission will be compatible with EPA's IT systems. EPA also obtains advance notice of the submission that can be used in its workload planning.

As part of the registration process for biopesticides, companies have always been strongly encouraged to meet with staff prior to submitting an application to register a new pesticide product. The introduction of "pre-submission coordinators' has improved the process. In the past, the process of fitting a meeting in and the multi-step process of finalizing the meeting minutes could take months. Prospective registrants are now directed to work with pre-

submission coordinators to schedule the meetings, and meeting notes are provided at the end of the meeting to all participants. This small change has eliminated "overbooking" meetings and reduced the time involved.

For these meetings, the pre-submission coordinator sends the company an electronic "toolkit," with links to important information on the Web needed by applicants to develop a registration application (data requirements, forms, statutes, regulations, label manual, etc.) and a template for the pre-submission meeting. The template serves to document the meeting since it is filled in during the meeting with the information discussed and assists applicants as they prepare their application package. This process has improved the quality of the meetings by allowing better preparation in advance of the meeting date. The agency will arrange a Webinar for a pre-submission meeting with a prospective applicant so that the applicant will not have to travel to EPA. This may save the applicant significant travel costs and further encourage more pre-submission meetings which will result in better application packages.

To identify and communicate deficiencies early in the registration process, the biopesticides staff established a Submission Readiness Team, which reviews all submissions within two weeks after the division receives the complete application from document processing. The team looks closely at the application package to determine if the data are ready for review. If deficiencies are found, applicants are informed of these deficiencies immediately and must correct the deficiencies before the data can be put into primary science review. The team records its findings electronically, in real time, substantially reducing the time it used to take for the EPA to inform the applicant of obvious deficiencies. When the data are ready to go into review, the applicant is informed via letter and e-mail, and the contact information for the Regulatory Action Leader is provided. By detecting obviously deficient packages early, the Submission Readiness Team saves science reviewers time and improves the division's ability to meet a PRIA due date.

The biopesticides division also initiated an internal Document Review Team that ensures the quality, consistency, and clarity of the Biopesticide Registration Action Documents (BRADs). These documents communicate risk assessments and risk management decisions concerning all pesticide active ingredients registered in the division.

Streamlining the Health Effects Risk Assessment Document. The Health Effects Division (HED) revised its Risk Assessment Document to make it easier for division staff and risk managers to find and abstract information and thereby increase the efficiency and transparency of the registration process. Information needed for *Federal Register* Notices on new tolerances are more easily extracted from the risk assessment into the FR Notice template, and HED recommendations for label modifications are highlighted in the beginning of the document. The Risk Assessment Review Committee briefed the Registration Division on the risk assessment

modifications and encouraged staff to provide feedback as they receive new assessments to further improve these documents.

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. Revisions to the crop grouping substantially reduce the number of studies to be reviewed, 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. This revised crop group regulation saves considerable resources by reducing the number of required residue studies and facilitates the establishment of import tolerances. In FY 2011, activities included training EPA staff on new crop groups, updating the Index to Part 180 Tolerance Information, updating the EPA Food and Feed Commodity Vocabulary Website, developing the EPA/Codex Crop Group Commodity Comparison database, and publishing *Federal Register* Notices and Updates to Tree Nut and Stone Fruit Crop Groups.

Process Improvement for Adding or Changing a Fragrance. EPA initiated a two-year pilot that allows registrants to add or change a fragrance in a product formulation using the notification process. A *Federal Register* Notice providing guidance to registrants is available on the EPA pesticide website.

Improving Data Evaluation Records. The EPA is developing more DER templates for efficacy data reviews and secondary review of DERs. These standardized templates are being tested now and we expect them to increase the efficiency and consistency of the review process.

Improving the Confidential Statement of Formula (CSF). EPA and Health Canada discussed options for improving Confidential Statements of Formula and have made plans for workshops early in FY 2012 on future areas of harmonization, including development of a joint electronic product specification form (e-CSF).

Antimicrobial Program Improvements

Voluntary Disclosure of Antimicrobial Ingredient Information Pilot. Guidelines for the voluntary disclosure of all ingredients in an antimicrobial product were finalized and posted on the EPA website. This guidance describes ways that a company can present ingredient information about an antimicrobial product on its own website or on product labels. Information can be found at http://www.epa.gov/oppad001/voluntary-disclosure.html .

Product Performance Guidelines. The product performance test guidelines for air, textiles and water (Section 810 Guidelines) were issued for 90 days public comment on September 14, 2011. We expect this second set of guidelines to be finalized in 2012. The first set, for sterilants,

disinfectants and sanitizers (810.2000 Series), should go final in early 2012. Registrants may follow these guidelines to conduct studies required under FIFRA for pesticide registration pursuant to 40 CFR 161.

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 2011 the agency approved the first products to be allowed to use 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. The agency launched a two year Pilot Program to assess the potential benefits of allowing "factual statements" regarding certain environmentally preferable characteristics of registered pesticide products. Biodegradability is a critical concern for products, such as household antimicrobials that typically go "down the drain" and can be aquatically toxic. More information can be found at: http://www.epa.gov/pesticides/regulating/labels/biodegradability-claims.html

Prions as Pests. EPA published a Notice of Proposed Rulemaking (NPRM) to clarify agency policy on products intended to control prions on January 26, 2011. A proposed Supplemental Prions Rule to clarify efficacy data required for "products with prion-related claims" published on November 17, 2011. Public comments were invited on the latter proposed rule until January 17, 2012.

Anthrax Test Guidance. The agency finalized guidance on efficacy testing required to support an anthrax-related claim. This final guidance will make it easier for companies to provide reliable anthrax control agents.

Interagency Agreement between EPA and USDA on Foreign Animal Disease (FAD) Disinfectant Efficacy Testing. USDA completed its work developing efficacy test methods and data requirements for generic chemicals used against foreign animal disease agents. USDA has published two scientific papers summarizing all of the testing and results for disinfectants applied against selected disease agents on nonporous and porous surfaces.

Educating Consumers about Pressure-Treated Wood. As part of an ongoing effort to educate consumers on proper handling for existing structures treated with chromated copper arsenate (CCA), staff of the Antimicrobials Division led a national EPA work group to assist in the production and review of the Consumer Product Safety Commission's inter-agency brochure titled, "CCA-Pressure Treated Wood: Guidance for Outdoor Wooden Structures." Although virtually all residential uses of CCA were canceled effective December 31, 2003, many existing structures are still in place and EPA, CPSC, and USDA continue to respond to a large number of

information requests from stakeholders. CPSC distributed thousands of copies throughout the US and the brochure is available online http://www.cpsc.gov/cpscpub/pubs/270.pdf.

International Workshops on Biopesticides

NAFTA Biopesticide Registration Improvement Course (BRIC). In April 2011, the Biopesticides and Pollution Prevention Division hosted a three day North American Free Trade Agreement (NAFTA) course with pesticide officials from Canada and Mexico, for pesticide registrants and consultants. Registrants and consultants were given building blocks for constructing a biopesticide registration application, and workshop leaders identified the major stumbling blocks that cause significant delays in registration decisions. Approximately 50 biopesticide registration applicants, consultants, researchers, and registrants attended the course in person, and a simultaneous webinar, broadcast over the Internet, reached over 70 additional participants. The recorded webinar is posted on EPA's website: http://www.epa.gov/oppbppd1/biopesticides/nafta-bric.html.

NAFTA Workshop on Biopesticide Regulation. The Pesticide Program hosted a one-day NAFTA workshop, "Biopesticide Regulation: Registration Approaches and Processes," in November 2011 in conjunction with pesticide officials from Canada and Mexico. This workshop evolved from the BRIC training earlier in the year to provide additional information to biopesticide registration applicants and consultants. The workshop covered biopesticide regulation in Canada, Mexico and the United States, organic agriculture in Mexico, joint reviews between the U.S. and Canada, and process improvements the EPA has made to facilitate biopesticide registration. The workshop agenda and links to the presentations are posted on EPA's website: http://www.epa.gov/pesticides/biopesticides/final-workshop-agenda-11-18-11.pdf.

U.S-Canada Workshop on Product Chemistry. EPA and Health Canada held a two-day workshop in November 2011 to work toward harmonization of product chemistry reviews to conserve resources. The workshop's objectives were to share and understand the approaches used by EPA and Canada's Pest Management Regulatory Agency in conducting product chemistry reviews, to agree on the similarities in approaches between the two agencies, and to identify the differences. Participants explored opportunities to further align chemistry assessments in future. Next steps include follow-up teleconferences to prioritize areas of possible alignment and work toward producing more harmonized chemistry assessments.

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.
- Arranged site visits to a food processing facility and a pulp and paper manufacturing plant. Both experiences enabled staff to gain practical knowledge of industries that utilize biocides as well as building positive relationships with the regulated community.
- Attended several national conferences, such as ASHES 2011 (American Society for Healthcare Environmental Services).
- Served on a panel for the ISES/SETAC Europe 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.

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 Canada, Australia, the European Union, and Japan. In global and joint reviews, EPA makes its own registration decision while sharing the study reviews and working toward harmonizing its regulatory decisions with other national authorities.

Conventional Pesticides. While no new conventional active ingredients were registered through the global joint review process in FY 2011, nine active ingredients were in review. Three actions were in review as work-share projects with Canada in FY 2011. In addition, Brazil, Japan, and Mexico have begun participating in the joint review process, increasing the number of joint

review partners. Other countries such as China, Korea, Taiwan and South Africa have expressed an interest in participating in the joint review process.

In FY 2011, Canada's Pest Management Regulatory Agency and the EPA continued implementing a work-share process for minor uses for those chemicals/crops that cannot be completed as a joint review. One minor use action on one commodity was completed as part of the US and Canada work-share program. Two joint reviews were completed in FY 2011 for three commodities. Fifteen additional minor use chemicals (29 commodities) are expected to be evaluated under the NAFTA joint review program and four chemicals (four commodities) are expected 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. Two microbial pesticide joint reviews were completed in FY 2011, and at the end of FY 2011, six were in progress – three biochemical and three microbial pesticides.

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. EPA staff made a presentation at the Informa Conference in Spain that discussed EPA's antimicrobial registration process and public participation process and held a follow-up meeting with members of the EU to discuss issues including treated articles and devices.