Implementing the Pesticide Registration Improvement Act - Fiscal Year 2013

Tenth Annual Report

March 1, 2014

Process Improvements in the Pesticide Program

Improvements in the Registration Process

Improving Application Quality

Label Review Manual. The EPA's Label Review Manual provides guidance to both EPA reviewers and the pesticide industry on what is required and recommended for each part of a pesticide product label in order for the agency to approve the label. In FY'13 one chapter has been updated – Chapter 13, Pesticide Storage and Disposal. The revised chapter is posted at http://www.epa.gov/oppfead1/labeling/lrm/chap-13.pdf.

Improving the Registration Process

Preliminary Technical Deficiency Screen. In addition to the PRIA 21-day Completeness Screen, which evaluates whether all components of the application are present but not the quality of the submission, PRIA 3 requires a Preliminary Technical Deficiency Screen to determine if the data are accurate, complete and consistent with the proposed labeling and/or tolerance. The Agency must conduct the screen and communicate to the applicant any significant deficiencies, which would likely result in the inability to make a regulatory decision or require renegotiation of the PRIA due date, all within a certain time frame:

- 90-days from the PRIA start date for actions with decision time frame > 6 months
- 45-days from the PRIA start date for actions with decision time frame <= 6 months

Deficiencies are communicated by letter to the applicant. The applicant has 10 business-days from receipt of the Agency's letter to provide their response addressing the deficiency. Deficient applications that are not corrected are rejected, freeing up agency resources for those applications that can proceed towards a regulatory decision. We believe that identifying deficiencies early in the process and requiring the applicant to correct these deficiencies will decrease the need for renegotiation of PRIA due dates.

The Agency has developed several new tools to help conduct the technical screens, described in the next section below.

Similarity Clinic. In FY 2013, to ensure consistency in the review of substantial similarity claims as a basis for citing product chemistry and acute toxicity data to support new product registrations, the Agency established the Similarity Clinic. We soon expanded the Clinic's

charge to develop toxicity profiles for 100% repacks of registered products, where that information is not readily available, and to evaluate the validity of acute toxicity data citations where no substantial similarity claim is being made. Product chemistry and acute toxicology experts from four risk management divisions (RD, AD, BPPD, and PRD) review the application, and if acceptable generate an acute toxicity review and forward the application to the product manager for full review. If the package is not substantially similar or if the product chemistry or acute toxicity data cited does not support the new product, we send the applicant a 10 business-day letter outlining the deficiencies and options for action. The applicant is given a second opportunity to identify a substantially similar registered product or another set of data to support their application. The Similarity Clinic evaluates the response, and if found not acceptable, the applicant is given the choice to withdraw the application or have it rejected.

Registrants are allowed only two attempts to find a substantially similar product. This limitation kicks out PRIA applications that are deemed deficient early in the process so that Agency resources are available to work on applications that have a legitimate path forward towards a regulatory decision. The Similarity Clinic also ensures consistency in the substantial similarity and product-specific citation evaluations (within and between each risk management division).

The Similarity Clinic received a total of 234 packages for review in FY'13, representing 12 PRIA codes, 88% of which were submitted in four PRIA 3 categories – R300, R301, R310 and R331. The Similarity Clinic is composed of 3 scientists from AD, 2 scientists from BPPD, 2 scientists from PRD, and 8 scientists from RD – all experts in either acute toxicology or product chemistry.

First Team Meeting/Label Checklist/Problem Formulation. For the Preliminary Technical Screen under PRIA 3, the Agency incorporated the existing problem formulation tools of the first team meeting and label checklist to identify and inform the registrant of critical data/information gaps early in the process and so that the EPA's assumptions in its risk assessments accurately reflect the registrant's proposed use pattern. The label checklist provides the parameters that need to be specified on the label for the science divisions to conduct their risk assessment without using unnecessarily conservative assumptions. The label checklist, along with Technical Screen Stakeholder Checklists developed by the PRIA Coalition, is posted on the PRIA webpage. We hope the registrant community will use these tools as resources to help provide more clarity on their labels regarding the proposed use pattern and to develop complete PRIA applications that address all of the elements the EPA needs for the preliminary technical screen. For new active ingredient actions and new use applications, the staff responsible for risk management and risk assessment engage in the problem formulation process within the first 60-days from the PRIA start date. Significant deficiencies identified in the first team meeting are shared with the registrant within 90-days of the PRIA start date and the registrant has 10 business days to address those deficiencies; otherwise, the application is rejected. Using this process the registrant learns of deficiencies and concerns early in the review process and has an opportunity to correct deficiencies and address concerns early in the risk assessment phase, rather than after the risk assessment is complete. These tools also ensure that

all risk assessment and risk management staff leads involved in the review of the PRIA application have a common understanding of the use pattern being requested.

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 or 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'13 Results under the New Pre-decisional Determination Due Date Process

The Antimicrobial Division completed 329 decisions in FY'13. Of these 329 antimicrobial completions, 165 were for applications submitted during PRIA 2, and 164 were for submissions made under PRIA 3. Of these 164 PRIA 3 completions, 159 decisions involved the approval of a new or amended product label that were subject to this new process.

The Registration Division completed 1,039 decisions in FY'13. Of these 1,039 conventional completions, 703 were for applications submitted during PRIA 2, and 336 were for submissions made under PRIA 3. Of these 336 PRIA 3 completions, 325 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	Total
Completed decisions in FY'13	329	1,039	1,368
Completed PRIA 3 decisions in FY'13	164	336	500
PRIA 3 decisions involving label approvals	159	325	484

Of the 159 antimicrobial PRIA 3 completed decisions that involved the approval of amended or new product labels, none was completed after the PRIA due date; 21% (33 decisions) were completed on the PRIA due date; 50% (80 decisions) were completed after the Pre-decisional determination due date but before the PRIA due date, and 29% (46 decisions) were completed on or before the Pre-decisional determination due date.

Of the 325 conventional PRIA 3 completed decisions that involved the approval of amended or new product labels, <1% (2 decisions) were completed after the PRIA due date; 11% (38 decisions) were completed on the PRIA due date; 27% (87 decisions) were completed after the Pre-decisional determination due date but before the PRIA due date, and 61% (198 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	0 (0%)	2 (<1%)	2 (<1%)
On the PRIA due date	33 (21%)	38 (11%)	71 (15%)
Before the PRIA due date but after the pre-decisional determination due date	80 (50%)	87 (27%)	167 (34%)
On or before the pre-decisional determination due date	46 (29%)	198 (61%)	244 (50%)
Total	159	325	484

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. 84% of the completed decisions that resulted in an approved label

occurred before the PRIA due date indicating that the Agency's implementation of this requirement has for the most part achieved its intended purpose.

PRIA 3 also requires the Agency to review and approve revised labels within 2 business days after receipt. There were only 2 decisions that went beyond the PRIA due date. Both times the PRIA due date came as PMs and registrants were very close to an agreement on the labels. The applicants sent the Agency their revised labels incorporating the Agency's comments and both were accepted as the final Agency-stamped label within 1.5 days (average).
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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 group regulations save considerable resources by reducing the number of required residue studies and facilitating the establishment of import tolerances. In FY'13, we completed review work on proposals for 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. We expect to publish the Proposed Rule for Phase IV of this project, which will include these five groups, in the Federal Register in the spring of 2014.

Improving the Confidential Statement of Formula (CSF)

OPP is continuing its effort 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. The e-CSPS project is being conducted 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. In FY 2013, OPP conducted an internal pilot project to complete the form. OPP is seeking OMB approval of the new form in FY 2014.

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'13, two new conventional active ingredients were registered through the global and joint review process. Twelve global and joint review projects for new active ingredients were in review during FY'13. In addition, Brazil, Japan, and Mexico have continued their participation in the joint review process, and other countries such as China, Korea, Taiwan and South Africa have expressed an interest in participating in future joint review projects.

In FY 2013, Canada's Pest Management Regulatory Agency and the EPA completed work on 4 chemicals for 11 commodities under the minor use joint review program. Along with the joint review for spirotetramat, under the pilot project for the RCC, both agencies completed work as a joint review to establish import tolerances for the other uses submitted to one agency and not the other. PMRA established import MRLs that align with the US tolerances established for pineapple, taro, watercress, coffee, pomegranate and banana and EPA established an import tolerance for sweet corn that aligns with the Canadian MRL. During FY 2014 up to 14 additional chemicals (27 commodities) may be evaluated under the NAFTA joint review program and six chemicals (seven commodities) may be evaluated as work-share projects.