Pesticide Program Dialogue Committee PRIA Process Improvement Workgroup

Minutes of the April 20, 2009 Meeting

Workgroup Members Attending:

Donna Bishel, BioSafe Systems on behalf of BioPesticide Industry Alliance (BPIA)
Kate Bouve, Information Technology and Resources Management Division (ITRMD), Office of Pesticide Programs (OPP)
Sue Crescenzi, Steptoe and Johnson on behalf of the American Chemistry Council Biocides Panel
Dennis Edwards, Antimicrobial Division (AD), OPP
Laurie Flanagan, DC Legislative and Regulatory Services on behalf of the International Sanitary Supply Association (ISSA)
Ted Head, Ecolab
Jim Kunstman, PBI/Gordon, on behalf of the Chemical Producers and Distributors Association (CPDA)
Beth Law, Consumer Specialty Producers Association (CSPA)
Elizabeth Leovey, OPP
Ray McAllister, CropLife America (CLA)
Marty Monell, OPP
Steve Robbins, ITRMD, OPP
Amy Roberts, Technology Services Group on behalf of BPIA
Julie Schlekau, Valent on behalf of Responsible Industry for a Sound Environment (RISE)
Julie Spagnoli, FMC on behalf of the Pesticide Program Dialogue Committee (PPDC)
Greg Watson, Monsanto on behalf of CLA
Mike White, CPDA

Agenda

I. Introductions and Announcements

II. Changes in Application In-processing and 21 Day Content Screen

III. e-Submission and e-Confidential Statement of Formula Update

IV. e-Label Review

V. Labeling Committee

VI. Quality Assurance of Labels

VII. Workgroup Discussion – Pesticides Web Site Improvement

VIII. Public Comment

IX. PPDC Meeting and Next Meeting of the Workgroup

Introductions and Announcements

The meeting began with introductions and by Marty Monell reminding workgroup members and participants of the provision in the Pesticide Registration Improvement Renewal Act (PRIA 2) on process improvements and of the Pesticide Program Dialogue Committee's recommendation that a subcommittee be formed to publicly discuss these improvements. She also announced that the FY 2008 PRIA Annual Report had been posted on the Pesticides Web site before March 1, 2009 (http://www.epa.gov/pesticides/fees/2008annual_report/pria_annual_report_2008.html), the statutory due date. Additional guidance on unapproved inert ingredients became available on the 21 Day Initial Content Review Worksheet (http://www.epa.gov/pesticides/fees/questions/pria21day_wrksht.pdf) in April. Guidance on multiple applications was also posted on the Web on http://www.epa.gov/pesticides/fees/related-apps.html in April.

Changes in Application In-processing and 21 Day Content Screen

Steve Robbins, Chief, Information Service Branch, ITRMD informed the Workgroup of a change in the 21 day initial content screening process. Initially, Agency employees were conducting the screen after PRIA 2 became effective. As of April 6, 2009, a contractor under the direction of EPA is conducting an initial 21 day content screen on all PRIA covered applications. This change in process was phased in and began with biopesticide applications in November, 2008. The contractor uses the worksheet available on the Web (http://www.epa.gov/pesticides/fees/questions/pria21day_wrksht.pdf) to conduct this screen and contacts the applicant at least twice with any issues. Approximately 14 to 15 days into the 21 day period, the results are forwarded to the appropriate regulatory division for additional follow-up and a decision on whether to recommend to the Office Director that the application be rejected.

Issues identified by the contractor that required contacting an applicant have included differences between the Certification and the Data Matrix in the selection of the citation type, missing forms, insufficient information on the inert ingredients such as the CAS number did not match the chemical's name, and inaccurate contact information. Mr. Robbins reminded participants that any information submitted to the Agency during the 21 day initial content screen should be sent to the individual identified and an Agency employee and not directly to a contractor.

In response to questions, the contractor is cleared to handle Confidential Business Information and an e-mail confirmation is send when an applicant is contacted by telephone. The contractor does use the lists of approved inert ingredients posted on the Web. Workgroup members commented that the Inert Ingredient Assessment Branch has their own internal lists of approved mixtures and questioned why these lists were not on the Web. Members were concerned that not all of the CAS numbers were correct on the Web site. In addition, some inert ingredients had limitations on their use and these limitations should also be posted on the Web. Marty Monell responded that the Agency will consider these suggestions.

e-Submission, e-Confidential Statement of Formula and e-Label Review Update

Robert Schultz, ITRMD and Thomas Harris, RD updated the workgroup on electronic pesticide registration. E-registration consists of a number of electronic tools and processes to reduce the paperwork burden on both the Agency and the regulated community and to increase the efficiency of the registration process. Applications may be submitted electronically using an XML structure, labels may be submitted as a PDF file, PDF versions of application forms may be completed and the Agency recently developed the Confidential Statement of Formula (CSF) builder. In the future, XML study summaries may be submitted and tools will be available to develop labels and structure the electronic version of an application. Currently, electronic submissions are received on CD or DVD, though the Agency is developing the necessary systems to allow application packages to be transmitted and signed electronically. At this time, PDF text labels may be simultaneously reviewed electronically by multiple Agency reviewers. Progress is underway to enable labels to be stamped or approved electronically and then distributed via the Web (Web based labeling).

Electronic submission (http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm) of certain types of applications was described in previous process improvement meetings (http://www.epa.gov/pesticides/ppdc/pria/sept08/minutes.pdf). Such submissions are received on CD or DVD via courier. The Agency is working through the OECD to harmonize electronic submission internationally; develop an XML schema and an e-PRISM/e-Dossier builder; and expand the types of applications that can be submitted electronically. Applicants will be able to submit OECD XML study summaries in summer 2009.

In April, the Agency placed the e-CSF builder on its Web site (http://www.epa.gov/pesticides/regulating/registering/submissions/#ecsf). It may be downloaded by an applicant as an aid in completing the form. Once completed, a printed and signed copy can be sent to the Agency. This tool underwent two usability tests of two sessions each. One test was conducted prior to the previous workgroup meeting (http://www.epa.gov/pesticides/ppdc/pria/sept08/minutes.pdf) and the other was conducted during a CPDA registration workshop. Updates are planned particularly to enable applicants to submit the form as an XML file which will enable the Agency to directly transfer data into its databases.

The workgroup was updated on the status of electronic labels. The number being submitted has steadily increased with the majority being submitted for conventional chemicals. A greater number were submitted for herbicides than for the other types of pesticides. The Agency encourages applicants to submit electronic labels as it facilitates the review and approval process. Applicants can respond and revise their labels via e-mail. Instructions for formatting an electronic label may be obtained on http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm. To further enhance this activity, the Agency is in the early stages of developing a tool, the e-label builder. The contents of a label are being broken down into structured fields that will allow data to be automatically entered into the Agency's databases. The builder is also expected to increase efficiency and consistency and improve the quality of the data in these databases.

Workgroup members observed that adjustments may need to be made in the e-submission guidance for anti-microbial products and that the American Chemical Council was willing to work with the Agency in developing the necessary tools. To increase the number of biochemical applications being submitted electronically, a pilot with the biopesticide registrants was suggested. The majority of the e-submissions currently being received by the Agency are from the registrants that participated in the e-submission pilot (http://www.epa.gov/pesticides/ppdc/pria/september07/sept-minutes.pdf)..

Workgroup members suggested that submission of e-labels for the product reregistration process be encouraged which may require additional staff training. In response to questions, the Agency's tracking systems are being further modified to allow the Agency to determine the number of e-labels submitted and reviewed. The e-label builder is expected to have an impact on Web distributed labeling. Workgroup members also observed that approximately 90% of the requirements for the e-Dossier Builder have been defined and the application is expected to be available at the end of the year or early next year.

OPP Labeling Committee Update

Jim Roelofs, Chair, Labeling Committee, Office of Pesticide Programs updated the workgroup on the Committee's activities. Its charge is to serve as a clearing house for broad cross-cutting label issues, to manage a Web site devoted to labeling issues, to revise and maintain the Label Review Manual and to elevate as needed issues to its Steering Committee of Division Directors and senior managers in the Office of Pesticide Programs. The number of questions and answers on its Web site (http://www.epa.gov/pesticides/regulating/labels/label_review.htm) and submitted by the public using the e-mail box (OPP_labeling_consistency@epa.gov) have increased from that reported in April 2008 from 175 reviewed, 165 answered, and 100 answers posted to 263 received, 225 answered and 130 answers posted. The average number pending tends to be eleven. To make it easier to search for a specific topic, the site's subject categories have been revised and as previously described, the site contains a disclaimer in response to workgroup comments (http://www.epa.gov/pesticides/regulating/labels/label_review_faq.htm).

In developing answers, the Committee assigns a question to one member to draft a response. The answer is then reviewed by the whole Committee. Once the Committee reaches a consensus, the answer is circulated within the Office of General Counsel's Pesticides and Toxics Substances Legal Office for final comment before it is either posted on the Web or forward directly to the questioner. General responses are posted on the Web whereas answers to specific questions particularly involving a product are replied to directly.

The Label Review Manual Team (http://www.epa.gov/oppfead1/labeling/lrm/) has completed its update of all but two chapters. These last two chapters should be complete within a couple of months. A contact point or Website will be available later this summer for comments and suggestions. Chapters will be updated as needed.

Recently the Committee received 17 comments on its chemigation discussion paper posted on its Web site (http://www.epa.gov/pesticides/regulating/labels/projects.htm). As of this meeting, the Committee has no immediate plans for other issue papers.

In response to questions, approximately 30% of the questions in the e-mail box are from state regulators, the LRM is a "living document" that will be updated as needed, and the State Label Information Tracking System (SLITS) is currently being updated to monitor the Agency's responsiveness in addressing the States' questions.

Label Accountability Initiatives

In introducing the panel describing the Agency's pesticide label quality assurance initiative, Jim Roelofs, Chair, Label Accountability Workgroup (LAW) described the results of the LAW's 2007 analysis of the impact of labeling problems. The 2008 recommendations are currently being implemented and include label review training, improved problem and response identification such as using SLITS as a feedback and management tool for identifying certain labeling issues and label review quality assurance (QA). Agency staff training and enhancements to SLITS are being developed. A focus has been developing a label review quality assurance program to ensure that labels are consistent with EPA policy, clear, accurate and enforceable. Each pesticide registration division has developed a QA process unique to its organization.

The divisional QA processes were described by Meredith Laws on behalf of Karen Angulo for the Registration Division, Dennis Edwards, Antimicrobial Division, and Robert Forrest, Biopesticides and Pollution Prevention Division.

Registration Division's Label Accountability Team (LAT)

The mission of the Registration Division's Label Accountability Team (LAT) is to provide the Registration Division (RD) with a QA/QC process that ensures consistency within RD and with policy and guidance such as the LRM. The QA process supplements a branch's internal quality control process. For the Division level process, a random sample of new fast track labels, both retrospectively and prospectively, from across the spectrum of the type of pesticide regulated by RD are reviewed by the LAT. The LAT is composed of a representative from each product branch and of different levels of experience. Membership is rotated approximately every two months. It was organized in March and recently began reviewing labels.

The LAT meets every week to thoroughly review a random sample of new fast track amendments to identify any errors in the entire label (including the requested changes) prior to approval. Labels are compared to previous labels to ensure no other changes have been made other than what was requested in the fast-track amendment. The requested changes are verified against the LRM. The basic label format and standard statements are reviewed along with the clarity and enforceability of non-standardized language such as the directions for use.

The reviews are provided to the branch chiefs in RD to consider in conducting their own internal reviews. Significant policy and enforcement issues will be elevated to the Product Managers and/or Branch Chiefs for resolution and RD management will be provided regular reports.

AD Label Quality Improvement Program

The Antimicrobial Division's Label Quality Improvement Plan was signed February 18, 2009 with the goal of increasing the overall quality of antimicrobial labels; specifically, to ensure that agency policies are fully reflected in labeling, labels for similar products are consistent and all applicable requirements are met. Its process elements include peer review, branch-level quality assurance and Product Manager (PM) Reviews.

In the peer review process, all reviewers, PMs and AD Branch Chiefs randomly review selected pending labels in a weekly peer review meeting. The Division's goal is to review 5% of all pending actions. The entire label is reviewed and records are maintained of the issues identified and their resolution. Since all reviewers participate, these sessions also provide an opportunity for additional training. At least 10% of completed actions are reviewed in an intensive branch level QA review. Labels are chosen from a pool of completed actions and multiple labels are selected for each reviewer each month. The results of these reviews are used in staff performance reviews and to identify and resolve any issues.

In conducting these QA reviews, AD has a Label Review Checklist. The structure of the label is reviewed in addition to its clarity and readability. Decisions made during peer and branch reviewed are captured and are used to identify training needs. Training in general is a key component of the label quality program and is provided during peer review meetings and covers both OPP-wide and division specific topics. The label quality program has been integrated into staff performance standards. Performance measures include the number of issues identified and policies/guidance clarifications required, average label quality scores and the number of consistency complaints.

BPPD Label Quality Improvement Program

The Biopesticides and Pollution Prevention Division conducts its quality assurance program in bi-weekly meetings attended by all of its label reviewers. A variety of labels with different directions for use are discussed in a round table format. Reviewers use standard operating procedures, checklists, Pesticide Registration Notices and the LRM as references to identify deficiencies and issues. This review also focuses on label readability and acceptability. When issues arise, participants determine the Division's next steps.

In the general discussion following the panel presentations and in response to a question on how changes across product lines would be handled, Meredith Laws observed that the States may identify any changes in a specific label and then may ask about the other similar labels. She commented that fairness and a level playing field are a challenge when reviewing labels; however this concern is not going to prevent the Agency from requiring corrections. Workgroup members commented that registrants could be involved in identifying labeling problems. BPIA requested that BPPD's labeling checklist be made available to registrants, that registrant be notified if their label was the subject of an audit, that the division keep track of deficiencies and that reasons be provided when there was a request to change a label. Rob Forrest suggested that registrants contact him for the checklist when it is available.

Meredith Laws observed that directions for use are sometimes difficult to follow and tend to be general on some labels. A workgroup member commented that agricultural products generally

involve large acreages resulting in general label directions and that the quality assurance process was good. Additional discussion on the fairness issue would be helpful. Another member recommended that divisions inform registrants of endemic issues identified during audits.

Improving the Pesticides Public Website

Nikos Singelis, Chief, Internet and Training Branch, ITRMD announced that EPA is moving all of its Websites to a new "Content Management System (CMS)" technology. Currently, the Pesticides Web site is scheduled to make the transition in the spring 2010. The Agency will use it as an opportunity to improve its Web sites, remove outdated material and reorganize its contents to make it easier for the public to search for a specific topic or document. The Pesticides Web site (http://www.epa.gov/pesticides/) is one of the largest in EPA and receives over 20 million "hits" a year. In an analysis of the most searched items, the majority of searches over the last couple of years have been for individual active ingredients. The Pesticides Web site is also very large and contains over 6,000 HTML pages and 10,000 PDF files, some of which are out of date. Prior to 2010, the OPP will identify and remove out of date and repetitive/duplicative information. The schedule for this transition is to conduct the "clean-up" during summer 2009 while the information architecture is being developed, complete coding by February, 2010 and launch the new site in April 2010 followed by continued refinement and usability testing through the rest of calendar year 2010.

During the presentation, workgroup members were requested to provide their thoughts on what they liked and did not like about the Pesticides Web site and how they used it. In general, workgroup members noted that EPA generally does a good job of providing information on the Web and should now focus on displaying and organizing information in a more user friendly manner. Many members use bookmarks to readily retrieve information as navigating the Pesticides Web site is often difficult. They requested that the Agency consider providing the training, particularly labeling training, conducted for EPA employees to registrants. Some commented that the current registration review page was satisfactory and that they used tools and guidance such as the Fee Determination Decision Tree and the Label Review Manual. They would like to see the "Blue Book" on the Web and commented that the docket process is an improvement; however the documents in a docket need to be better organized.

In additional comments, members would like information on active ingredients in one location so they can see the most recent information for a chemical. Navigation pages in some cases listed too many choices. "Hot" topics should be consistently utilized and are currently posted on different sections of the Web pages (right versus bottom) and some topics are no longer "hot". Cleaning the site of outdated and duplicative material is a good idea. Recent changes to the EPA pages (main Agency pages) have been confusing and items are now harder to use. Members requested a better way to organize or flag items that are open for comment. A participant noted that it took approximately 90 minutes to find information on the public participation process and consequently a search tree would be helpful for locating policy and guidance documents. Participants noted that they use mainly Google and not the Agency's search engine to conduct searches. Posting effective dates and publication dates would be helpful. Improvements could be made to the list of approved inert ingredients such as listing their limitations. The labeling Web site's Question and Answer page was helpful.

Public Comment

The public comments were captured in the discussion on improving the Pesticides Public Web site.

PPDC Meeting and Next Meeting of the Workgroup

The topics suggested for the next meeting of the workgroup included labeling training; tips for improving submitted labels; the notification policy and process specifically improvements in the Agency's feedback on the acceptance of a notification within 90 days and changes to Pesticide Registration Notice 98-10; changes in the definition of fast track amendments; document tracking; follow-up to problems identified during label audits particularly the fairness issue; product chemistry; and the checklists used by the Agency to determine whether data requirements have been met.

For the April 22 to 23, 2009 PPDC meeting, a summary of this meeting will be available to the PPDC members prepared by Elizabeth Leovey.