Pesticide Program Dialogue Committee
PRIA Process Improvement Workgroup

Minutes of the April 19, 2011 meeting

Workgroup Members Attending:

Jerry Baron, IR-4, Rutgers University
ShaRon Carlisle, Antimicrobial Division (AD), Office of Pesticide Programs (OPP)
James Kunstman, PBI/Gordon on behalf of Croplife America (CLA)
Beth Law, Consumer Specialty Products Association (CSPA)
Elizabeth Leovey, Office of Pesticide Programs (OPP)
Ray McAllister, CLA
William McCormick, Clorox, on behalf of American Chemistry Counsel (ACC) Biocides Panel
Marty Monell, OPP
Sheryl Reilly, Biopesticides and Pollution Prevention Division (BPPD), OPP
Amy Roberts, Technology Services Group on behalf of BPIA
Julie Schlekau, Valent on behalf of Responsible Industry for a Sound Environment (RISE)
Robert Schultz, Information Technology and Resources Management Division (ITRMD), OPP
Julie Spagnoli, FMC
Allison Starmann, ACC Biocides Panel
Abigail Trueblood, Dow on behalf of ACC Biocides Panel
Greg Watson, Monsanto on behalf of CLA
Mike White, Chemical Producers and Distributors Association (CPDA)

Agenda

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Minutes

The powerpoint presentations were posted on the internet on http://www.epa.gov/pesticides/ppdc/pria/index.html.

Introductions and Announcements

Marty Monell began the meeting by reminding participants of the statutory provision in PRIA 2 on process improvements. She observed that the Workgroup had been successful in using the registrant community's and Agency staff's suggestions to improve the pesticide registration process. For this meeting, there were as many registrant presenters as OPP presenters, representing a first for a workgroup meeting.

Chemical Searches on OPP Web

Nikos Singelis, Chief of the Systems Design and Development Branch, ITRMD updated the Workgroup on two OPP Web pages, Chemical Search and the Pesticide Product Label System (PPLS). In previous meetings as the chief of ITRMD's Web branch, he discussed the EPA's plans for improving both of these sites. Chemical Search will be a "one-stop shopping" search vehicle for the public to obtain all of the information on the EPA web on a specific pesticide. After internal EPA testing, the beta version is expected to be available this summer. PPLS is being transformed into a new, more user friendly database to allow searches by company name and product name in addition to a product's registration number. All labels will be available as a PDF having been recently converted from TIF files. After resolving issues on providing transfer information, the new PPLS is also planned for this summer.

Workgroup members complimented the Agency on these advances and for making these searches easier to perform.

Fragrance Notification – Implementation

Dr. SanYvette Williams, AD, announced that EPA had published a Federal Register Notice on April 15 requesting comments on the OPP Pilot Fragrance Notification Program (PFNP) with comments due in 30 days. In 2007, EPA initiated a three month effort to examine both the completeness and accuracy of the Fragrance Ingredient List (FIL) and gain experience with a potential notification process for certain fragrance formulations. At that time, EPA did not request public comment on the process. The objectives of the current PFNP are to improve public transparency, reduce the amount of paperwork required of the company and decrease tracking.

Currently, a change in fragrance requires that the registrant submit an amendment. In the PFNP, the registrant or fragrance supplier would certify that all of the fragrance's ingredients are on the FIL when submitting a notification of the change in fragrance using form 8570-1. The

fragrance must be less that 1% of the formulation and individual fragrance components can be no more than 0.1% of the formulation. Only non-food use products are eligible for the program and amendments must still be submitted for insect repellents, bait products and antimicrobial aerosol products with public health claims. Self certifications must then be submitted annually and a product's registrant must contact the fragrance supplier twice a year to ensure that the annual self certification has been submitted. OPP will conduct a yearly audit. New fragrances will still be reviewed individually by the Inert Ingredient Assessment Branch in the Registration Division.

In response to questions from the workgroup, registrants filing a fragrance notification will be responsible for submitting Form 8570-1, the fragrance supplier certification letter and the CSF. The PFNP will be implemented for two years and assessed after that time. Components of proprietary blends commonly used in conventional products will continue to be reviewed by the current process. Registrants are considering fee categories and decision review timeframes for new fragrances and inert ingredients in antimicrobial products for PRIA 3.

Registrant Developed Tools – FESTF example

Ashlea Rives Frank, Compliance Services, described FESTF (FIFRA Endangered Species Task Force), its history and its tools. Using the tools, data are provided on the location of endangered species relative to land use information. This effort began in 1997 with the objective of developing a system to provide the Agency with information on the proximity of listed species to pesticide use sites that could be used in the pesticide reevaluation process. As a result of discussions with the Agency and a pilot assessment, the system evolved from a static report to an information management system that stores, retrieves and documents data on endangered or listed species. Data are purchased from NatureServe on species locations on a sub-county level for some species and are available through a portal, the FESTF MJD. Data obtained from public sources such as NOAA and USFWS and coupled with land cover data from the USGS and cropland data from the USDA are available through the FESTF IMS, a data warehouse. The FESTF IMS aggregates data on a county level consistent with EPA's ESA assessments. The data are updated regularly. The MJD allows users to map species locations relative to land use and calculate distances from species locations to land use categories and if the data are available, to specific crops. Additional cropping information is being considered. FESTF outputs are designed for use in developing county bulletins and for EPA risk assessments. The Task Force is interested in greater use of this system in risk assessments as it may result in efficiencies in the registration review process. Suggestions for further modifications to meet this need and make better use of the data are welcomed.

Label Review Manual – Comment Process and Comments

Jim Roelofs, Chair, OPP Labeling Consistency Committee, reported that after revising the Label Review Manual, the Label Review Manual Team was soliciting comments from the SFRIEG Pesticide Operations Management committee and using a Web discussion forum, from the public. As of April 19, SFRIEG had commented on 16 chapters while 10 chapters had been reviewed by the public. Generally, one to two chapters are reviewed at a time and with two different audiences reviewing the web based document, the LRM team expects that the revisions will further improve its clarity. The comments are being compiled and tracked on a spreadsheet.

The Team expects to begin editing the document in the near future. Comments are screened to determine whether the suggested changes are editorial. Non-editorial comments or substantial changes are "parked" for later consideration since most deal with policy changes outside the purview of the Committee. The Labeling Consistency Committee continues to address questions on pesticide labeling and posts the answers on its Web site. Approximately 400 questions have been received, most from small registrants or consultants, all are addressed and if of general interest, the answer is posted to the web site after all of the members of the Committee and the pesticide attorneys in EPA's Office of General Counsel have concurred on the answer.

In response to a workgroup member's question, the Team finds that concise comments tend to take less time to analyze. Even though the comment period may have closed on a chapter, comments can still be sent to EPA for its consideration. All comments and the response to comments are tracked on a spreadsheet which details the changes made and the reasons for any changes.

DocuProof and E-Label Review

Because of the possible time savings, the Agency has been encouraging registrants to submit electronic labels that could be reviewed using a document comparison tool. The Agency's current tool can be cumbersome for some staff and Doug Soper, PBI/Gordon, described how his company used Docu-Proof to proof and compare their labels. His company has approximately 240 registrations with 20 different types of labels, and labels in different electronic media. Reviewing labels is a detail oriented and time consuming activity. After reviewing a number of tools, his company decided to use Docu-Proof and he demonstrated how he uses it to review labels and commented that for him, it was simple to use as it clearly displayed differences character by character and specific sections can be selected for comparison. An advantage for his company will be the ability to use the comparison software to review distributor labels. From his experience, because the proofreading process becomes faster, there is more of a tendency to proof more of the document than actually needed. With less time spent on proofreading, labels can go on marketed products faster resulting in cost savings for his company.

E-Submission Preparation – Registrant Quality Checks

Robert Manfre, Global Regulatory Services, BASF and Chair of the CLA E-submissions Working Group, described how his company prepared their electronic submissions and the different quality checks that were performed to comply with the EPA guidance on electronic submissions. BASF has been submitting these applications to the EPA since 2001, and most since 2008. The company has gained substantial experience with e-submissions and developed its own software for assembling them; a JAVA based application, the BASF XML Builder. This "Builder" includes all of the elements of EPA's E-PRISM data dictionary, has controlled vocabulary, drop-down menus with commonly entered data, and OECD data points, and interfaces with the same software used by the Agency. The software performs checks to assure that data fields are properly completed. Documents are reopened manually after a CD is developed to assure that there are no problems and proofed for completeness and compliance with PRN 86-5.

The CD's label or a transmittal letter is sent in to be "pin-punched" by the Agency as documentation of receipt.

In response to questions from the workgroup, EPA is using the PDFs and word summaries. Robert Schultz, ITRMD/OPP reported that 30% of the studies submitted were in an electronic format and this has been a substantial savings for the Agency. These submissions tend to be new active ingredients and uses and large submissions by the major companies. OPP would like more electronic submissions. Its current IT system limits electronic submissions to specific types of applications.

DER Generator Demo

Pat Schmieder, Office of Research and Development, EPA, demonstrated the DER Composer. The Data Evaluation Record (DER) is EPA's review summary of a required study. The Composer will allow an applicant to develop an electronic draft summary of a study by filling out a DER template with structured XML data fields. The template has all of the data entry fields needed for a DER. A Word document can then be printed in the standard DER format. After reviewing a study report, EPA reviewers can edit the draft DER and enter their conclusions regarding the study and note any deficiencies. In addition to being exported into a Word document, the data can be used to populate other EPA databases (*e.g.*, MetaPath and ECOSAR). Data could also be transferred into public databases after EPA review. With the applicant developing an initial draft of the DER and the ability to transfer data directly into Word documents and relational databases, EPA will be able to save time keying in information, avoid data entry errors and facilitate quality assurance/control (QA/QC) as data are automatically exported into electronic databases.

Currently, DER composers have been developed for the rat metabolism (OCSPP 870.7485) and nature of residues in animals (OCSPP 860.1300) studies; these composers generate Word versions of the DERs and the metabolism data are also exported into MetaPath, a relational database used to capture metabolism pathway data and identify degradates of concern for risk assessment purposes. Metapath allows chemical structures to be drawn and metabolic pathways to be displayed two dimensionally. Ultimately, MetaPath will be integrated with the Organization of Economic Cooperation and Development (OECD) quantitative structure activity ([Q]SAR) toolbox which enables users to estimate the effects (activity) of a compound based on structural similarities to other chemicals.

DER composers are being developed for nature of residues in plant studies (OCSPP 860.1300) and are planned for environmental degradate data (OCSPP 835 series) as well. DER composers are planned for the Tier 1 test order data required under the Endrocrine Disruptor Study Program (EDSP; OCSPP 890 series); the data captured in these composers will be used to populate newly developed databases used in determining whether chemicals will be subject to more definitive Tier 2 testing for endocrine disruption. Eventually, composers are planned to capture all toxicity studies.

Workgroup members could contact Tom Steeger, Environmental Fate and Effects Division, OPP for a demonstration of the DER Composer and its ability to generate Word versions of DERs. Workgroup members asked whether the DER composer was consistent with the OECD

templates since applicants submit to multiple countries at the same time and want to develop only one application package. Mary Manibusen, Pesticide Re-evaluation Division, assured the workgroup that harmonization with OECD was a goal and that the DER Composer was being reviewed to assure that it contained the necessary data fields to achieve consistency with OECD. The advantage of the composer is that it can contain data fields that do not necessarily appear in a Word document and that the software can be manipulated to produce a final document in whatever format may be needed. In response to a question, Marty Monell emphasized that EPA scientific review of submitted studies will not be diminished and the same level of scrutiny will be applied to electronic submissions as with hardcopy submissions. Tom Steeger commented that currently, OPP uses the electronic OECD Tier II data summaries that are developed by the applicant.

Industry Training Seminars and Webinars

Beth Law, Consumer Specialty Products Association, described some of the efforts that her association had undertaken to provide training opportunities for their members so they could develop better applications. The association had conducted a workshop for new applicants in 2009. She has found that short term training was preferred. CSPA conducted 5 to 6 pilot webinars on such topics as PRN 98-10, data requirements and compensation, audits and self-policing, supplemental registrations and the Pesticide Registration Notice on false and misleading labeling statements. Based on feedback, the webinars were successful. These webinars were a service provided by CSPA to its members so that when they submitted an application to the Agency, it could be processed efficiently.

In answer to Marty Monell's question on whether the outcome of the negotiation analysis would be used to develop further training opportunities, Ms. Law responded that in developing webinars, CSPA tries to pick topics that are an issue for either EPA or industry, are timely, topical and can be presented in 90 to 120 minutes. The Association will continue to look for recent guidance from which they can develop webinars. In response to another question on the role of EPA staff in the webinars, EPA staff did participate. In general, CSPA relies on outside attorneys and OPP staff to conduct these webinars. A workgroup member commented that as a participant in one of the webinars, she appreciated the format with a specific topic covered in a short period of time. She found it difficult to get away from the office and participate in a two day workshop. She suggested that webinars be held for industry's marketing staff.

Process Improvements in the Biopesticides and Pollution Prevention Division

Sheryl Reilly, Chief of the Microbial Pesticides Branch, BPPD, described a number of initiatives that BPPD has undertaken to improve the quality and completeness of applications submitted for registration, and to make its initial processing of PRIA applications more efficient. These activities are an outcome of an analysis of PRIA negotiation rates and causes conducted with representatives of the biopesticide industry in 2010.

Just prior to this meeting, BPPD, under NAFTA, hosted the Biopesticides Registration Improvement Course from April 13 to 15, 2011. BPPD and Canada's Pest Management Regulatory Agency (PMRA) described their registration processes in detail (including risk assessment and risk management), and focused on the most common problems observed in

registration applications. Each country identified areas where improvements were needed, and recommended that applicants address the problem areas prior to submitting an application. The course also highlighted the benefits of NAFTA joint reviews. Most of the bases for renegotiations observed in the PRIA negotiation analysis were identical to problems encountered by PMRA in pesticide application packages. The most common deficiencies in packages included incomplete administrative documents and unfulfilled data requirements (for instance, the CSF is incomplete or inaccurate). The cost of developing new data to satisfy the data requirements for registration of a pesticide is expensive, so to decrease costs, applicants often submit data generated with an active ingredient or product that is similar but not identical to their proposed products. Applicants also submit requests to waive data requirements that are not sufficiently supported. While alternative sources of data are often appropriate, unless the active ingredients or products are shown to be nearly identical (physical/chemical properties, toxicity, etc.), there is a risk that a decisions on an application may be delayed or that it will be not granted or denied. In order to satisfy data requirements, a new study or additional data may be required, and the PRIA decision due date will have to be extended; otherwise, the decision may be to not grant or deny the application unless the applicant chooses instead to withdraw their application.

BPPD recommends that all applicants meet with the Agency prior to submitting an application to discuss the data requirements and how they plan to satisfy them. BPPD provides guidance on the appropriate PRIA fee category for their action. Applicants develop meeting minutes, and BPPD attendees review them and provide corrections where necessary to assure that the guidance provided is accurately documented. BPPD advises applicants to carefully review an application prior to submission for completeness. This includes making sure that the appropriate administrative forms are completely filled out, signed and dated, the draft label prepared in accordance with the guidance provided in the on-line Label Review Manual, and the data volumes are formatted as described in PR Notice 86-5. Applications should be submitted far enough in advance of when the applicant would like an EPA decision, to allow for potential delays. Subsequent follow-up is encouraged while applicants develop their application packages, and Dr. Reilly emphasized that questions asked before submission "cost" far less than delays caused by a deficient application.

BPPD is piloting a Submission Readiness Team to provide an in-depth screen of an application following the 21 day initial content screen. When deficiencies are identified during this screen, a 75 Day letter is issued to the applicant, and the application does not proceed to the next level of review. Marty Monell observed that similar efforts are being conducted by RD and AD in response to the EPA/industry analysis of the reasons for due date extensions. The Agency's proposals for PRIA 3 may include increasing time frames for certain types of actions, and implementing a more in-depth deficiency screen following the initial 21 day content screen to identify obvious missing data and other deficiencies that must be addressed before the application can proceed into formal review. She further commented that while application assistance is being provided by both the Agency and trade associations, some inexperienced registrants are not being reached to benefit from these efforts.

Public Comment

No public comments were received.

Summary and Next Workgroup Meeting

Marty Monell announced that there would not be a report from this meeting to the full PPDC meeting on April 20 and 21, 2011. She anticipated that the next discussion on the PRIA Process Improvement Workgroup to the full PPDC will coincide with a discussion on PRIA 3 during the fall PPDC meeting. There will be another workgroup meeting before that meeting.