Pesticide Program Dialogue Committee
PRIA Process Improvement Workgroup

Minutes of the December 13, 2010 Meeting

Workgroup Members Attending:

Donna Bishel, Biosafe Systems on behalf of Biopesticides Industry Alliance (BPIA)
Sue Crescenzi, Steptoe and Johnson on behalf of the American Chemistry Council (ACC) Biocides Panel
Caroline Kennedy, Defenders of the Wildlife for the Natural Resources Defense Counsel
James Kunstman, PBI/Gordon on behalf of Croplife America (CLA)
Beth Law, Consumer Specialty Producers Association (CSPA)
Elizabeth Leovey, Office of Pesticide Programs (OPP)
Ray McAllister, CropLife America (CLA)
Marty Monell, OPP
Sheryl Reilly, Biopesticides and Pollution Prevention Division (BPPD), OPP
Kate Rosenfeld, DC Legislative and Regulatory Services on behalf of the International Sanitary Supply Association
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
Greg Watson, Monsanto on behalf of CLA
Mike White, Chemical Producers and Distributors Association (CPDA)

Agenda

I. Introduction and Announcements

II. E-submission Builder

III. DER Templates (Currently available and plans for the future)

IV. Blue Book Update

V. Product Reregistration – Antimicrobials

VI. Inert Ingredients - Recent Guidance

VII. Label Review Manual

VIII. Public Process After a Year

IX. Public Comment

X. Summary and Next Workgroup Meeting

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 and of the Pesticide Program Dialogue Committee's (PPDC) recommendation that the Agency form a subcommittee under the PPDC to obtain stakeholder input on these improvements. Initially, a focus was labeling initiatives followed by a shift to efficiency improvements identified by OPP. As an introduction to the DER templates project, Ms. Monell reminded workgroup members of OPP's process improvement contest in which EPA employees were solicited for suggestions for improving the efficiency of its registration process. More than one suggestion involved applicants submitting an electronic copy of a proposed DER following a template which could be reviewed and revised by EPA's contractor and then completed by an EPA employee. Due to the potential resource savings, the project was selected.

DER Templates – Streamlining the Risk Assessment Process in OPP

Thomas Steeger (Environmental Fate and Effects Division), Brenda May (Health Effects Division), and Robert Schultz (Information Technology and Resources Management Division) described efforts to develop data evaluation record (DER) templates and a DER generator. The DER represents the Agency's review of a study either from the open literature or submitted by an applicant or registrant to meet pesticide registration data requirements. These documents follow prescribed formats; many of these formats/templates have been harmonized under the North American Free Trade Agreement (NAFTA) [http://www.epa.gov/pesticides/regulating/studyprofile_templates/studyprofile_templatelist.htm]. Similar templates are utilized for global reviews conducted in conjunction with the Organization of Economic Cooperation and Development (OECD) member countries.

In EPA, the initial (primary) study reviews are typically conducted by EPA's contractors; these primary reviews are then reviewed by EPA science staff (secondary review) who in turn finalize the DER. In the European Union and for global (OECD) reviews in general, the registrant typically completes the initial DERs (referred to as Tier II summaries), and these are in turn reviewed and revised by member countries' regulatory science staff and are then finalized by the regulatory authority. For example, Tier II summaries are reviewed by EPA science staff just as thoroughly as if the primary review had been completed by an EPA contractor. Submission of partially completed DERs by the regulated industry has considerably reduced time and resources in developing the review and in keying-in information for global review efforts. At this time though, EPA typically completes DERs in Microsoft Word format and this format does not readily allow transfer of the information/data to relational databases. The goal is to develop DER templates in an XML format that would enable information to be efficiently and reliably transferred to various database. In the long term, automated quality assurance systems could be

employed to further reduce the amount of time and effort needed to insure thorough review of data/studies.

The Agency anticipates an evolving process in moving from paper Word-based DERs to fully electronic XML-based DERs. Initially, registrants could complete a Word version of a template and relay the electronic file to the EPA. This is similar to the process currently used for global reviews. Of more use to the EPA for transferring data into databases and avoiding transcription errors, would be a DER template in an XML format that could be used to generate Word files as well as populate relational databases. Current tools that could achieve this purpose are the International Uniform Chemical Information Database (IUCLID; http://www.oecd.org/document/46/0,3746,en_2649_34379_2501870_1_1_1_1,00.html) format, the DER generator and tagged Word documents. The DER generator uses a series of questions to develop the DER; responses to the questions are recorded in XML. A DER generator has been developed for the rat metabolism study and data from the DER are used to directly populate the data fields in the metabolism pathway expert system tool, MetaPath. While IUCLID allows data entry in XML, it does not currently accommodate SMILES codes. Alternatively, a tagged Word document with an underlying XML generator is an option that would be more familiar to users. The Agency would like feedback from potential users on the most desirable option.

Workgroup members commented that small businesses need a user friendly application due to their limited number of applications. Members recommended that the Agency discuss the project with testing facilities since in most cases, the facility developing the test report would also develop the draft DER. The observation was made that in some cases the DER was as long as the study report and it may be more efficient if one report were developed that could serve both purposes particularly for acute toxicity studies. Some companies currently require their contractors to develop draft DERs using the OECD/NAFTA/Tier II templates. While templates are available for some studies, they are not available for microbial and antimicrobial studies.

Industry would like a worldwide harmonized template to enable them to submit the same information to different regulatory authorities. Dr. Steeger mentioned that the Agency's proposal is similar to that of the OECD/NAFTA templates and Tier II summaries. The DER composer can accommodate chemical structure information (SMILES code) and is more compatible with the EPA implementation of the National Research Council's recommendations on toxicology testing in 21st century. Workgroup members commented that reducing the level of resources needed to develop DERs would be welcomed and they were interested in a demonstration of the DER generator during the next meeting of the workgroup.

Workgroup members were requested to forward their thoughts on the approaches suggested by the Agency for drafting DERs to Elizabeth Leovey.

E-Submission Builder

Robert Schultz, Information Technology and Resources and Management Division (ITRMD), Schultz.robert@epa.gov, 703-308-8186), gave a demonstration of the Agency's e-Dossier Builder discussed in a previous workgroup meeting and requested volunteers from among the registrant community to pilot test it. The Builder is a software application that applicants can use to create their electronic submissions to EPA and was developed as an alternative to using

Canada's e-Index application which, when used, requires additional editing of the resulting e-Index output for submissions to EPA. It is designed to be downloaded onto the applicant's computer. This initial application was developed with the help of a workgroup of potential users. The proposed release date was July, 2010; however, the Agency delayed its release to address potential user's concerns and software modifications to the Agency's systems. The user pilot is scheduled to begin January 2011. The current application is designed for a limited number of application types. In the future, EPA anticipates developing applications that allow pre-assignment of MRIDs, registration numbers and company numbers and eventually submission via the internet and harmonization with the e-submission standards of OECD.

In response to questions, the pilot will involve actual submissions to verify that the guidance is clear and that the software is easy to use before making it available on the internet. Due to regulatory requirements, documents that require a signature will need to be scanned. The program is looking into electronic signature. The types of submissions suitable for the pilot include new section 3s, amended sections 3s, experimental use permits and tolerance petitions. Smaller packages are preferred since it will be easier to individually help the applicant and potentially manually load the submission into OPP's tracking systems. New active ingredients are complex. All formatting requirements need to be met and the same as if the submission were in hardcopy. If the e-submission contains CBI, then at present, all of the submission is considered confidential. As to how the electronic submission is processed, EPA developed an electronic workflow which routes a submission appropriately and eventually to the Product Manager. Since the builder was developed with substantial input from the stakeholder/registrant community, the Agency anticipates few problems.

In responding to comments, MRID numbers need to be pre-assigned for e-submissions and applicants should contact Teresa Downs (downs.teresa@epa.gov, 703-305-5363)). Because of the number of keystrokes required to develop an e-submission, supplemental distributor forms were not considered for e-submission at this time. They would be suitable for an internet application and the Agency expects that MRID assignments, certain forms, and company and establishment numbers will eventually be obtained and completed via the internet.

Pesticide Registration Manual "Blue Book"

The Pesticide Registration Manual was published on the Pesticides Web site on March 16, 2010 as reported by Elizabeth Leovey, a member of the Office of Pesticide Programs' Blue Book Committee. It is an update of the previous document titled, "General Information on Applying for Registration of Pesticides in the United States" issued in August 1992. Each chapter is a separate Web page to easily update it and the date of the last update is shown. The ACC Biocides Panel and the Consumer Specialty Products Association provided suggestions to improve it. The Manual is being updated chapter by chapter. When a chapter is updated, the associations are provided a response to comments describing how their comments were addressed. Additional comments were provided on the updates which will be addressed after the first round of revisions has been completed. As of December, 2010, all of the chapters have been revised except the four chapters in review, one chapter being rewritten, and the appendices. The Decision Tree will be the last item revised. Users are encouraged to suggest improvements and the Manual will be revised whenever new guidance becomes available.

Workgroup members asked why a hardcopy version of the Manual will be published when it is available on the web and can be printed. In response, some applicants had requested a hardcopy that they could keep on their desks and the web version can be tedious to print.

Product Reregistration Process Improvement

Patricia Moe, Chief, Re-evaluation Management and Implementation Branch V, Pesticide Re-evaluation Division (PRD), discussed a redistribution of resources between the Antimicrobials Division (AD) and PRD to complete reregistration of antimicrobial products and all product reregistrations in 2014. In this revised process, AD develops the Data Call-Ins (DCI) required by the RED and obtains clearance. PRD then issues the DCI, manages the registrant responses and data submissions, reviews the product-specific data, and conducts a preliminary label review. The final label review and product reregistration are then the responsibility of AD. In exchange, PRD is using AD resources for additional data review of conventional products. This change in process was an outcome of a process flow analysis conducted to determine where efficiencies could be made to enable EPA to reduce its backlog of data reviews and to meet its reregistration goals. This redistribution of resources has allowed OPP to increase product reregistration productivity without any additional resources. The increased collaboration between the Divisions has improved consistency across OPP, an added benefit.

In response to questions, for reregistration, generic data are still being reviewed by AD while all of the product specific data are being reviewed by PRD. EPA is working on the DCI schedule and anticipates that they may be issued during calendar year 2011.

Recent Changes on Inert Web page

P. V. Shah, Registration Division (RD), described the recent changes to the Inert Ingredients Web page http://www.epa.gov/opprd001/inerts/. Guidance was posted on submitting food use tolerance petitions and requests for approval of non-food use inert ingredients and polymer exemptions. This guidance describes how to request EPA approval for the use of an inert in a pesticide product formulation. The inert ingredient frequently asked questions web page was developed and the questions are based on the questions asked of the inert ingredient review staff and during an inerts workshop conducted last year. The Inert Ingredient Assessment Branch observed that the inert approval process has become more efficient because of the guidance and the increased quality of applications.

The Branch, working with ITRMD, developed a pilot Inerts Database which will allow registrants and the public to search for specific ingredients and determine whether and under what conditions or limitations an ingredient has been approved for use in a pesticide formulation. It is an Access Database with a front end search engine. Ingredients may be searched by CAS number or PC Code and Dr. Shah described how to search for a specific chemical. The Branch receives approximately 1,000 e-mails per year via its e-mail box with inquires on the status of an inert ingredients. Once the database is public, these inquires should decrease. The Branch's workload at the time of the meeting was 30 food use petitions, 1 non-food approval request and 2 incomplete nonfood use approval requests and a typical workload.

In response to questions, the database may be available in February. For the fragrance notification program, a formulation component can not exceed 0.1% with the total amount of the

fragrance not to exceed 1%. If higher, the fragrance needs to be individually approved. The Branch is working with CropLife America and the Inerts Steering Committee to find a way in which mixture Trade Names can be made public without identifying the contents of the mixture to enable applicants to determine whether a mixture has been approved. Manufacturers are reluctant to provide such information due to CBI concerns. Trade names need to be in EPA's mixture's data base or the applicant needs to request EPA approval. Suppliers must also be approved. Workgroup members commented that the inert ingredient approval process could be a candidate for streamlining. Efforts between the Inerts Steering Committee and the Agency may streamline the process. The Steering Committee will propose lists of inert ingredients, mixtures, etc. which the Agency will review. Once an inert or mixture is approved, the information will be posted on the inert ingredients Web page.

Label Accountability Initiatives

Jim Roelofs, Chair, OPP Labeling Committee, updated the workgroup on EPA's progress in implementing the 2008 recommendations of the Label Accountability Workgroup. After the Label Review Manual was updated, the Agency requested comments from members of the State FIFRA Issues Research and Evaluation Group (SFIREG) Pesticide Operations and Management (POM) Committee. As of December, 2010, SFIREG had commented on 11 chapters. Comments on the LRM are also being received via a web discussion forum (blog) available to the public at the rate of one or two chapters at a time. The Agency is requesting comments that will improve the clarity and understanding of the information in the LRM. Policy changes will not be made through revisions to the LRM. In responding to comments, locating source or reference documents to link to the LRM has been more time consuming than originally anticipated. Comments are reviewed by the LRM Workgroup and then by the Labeling Committee. Both groups include staff from the Office of General Counsel and the Office of Enforcement and Compliance Assistance.

The State Label Issues Tracking System has been enhanced to improve reporting and tracking and is being tested within OPP. A feature has been added to track whether EPA had followed-up on a question.

The Committee's Q&A website has received approximately 400 questions and each is answered. Answers that will inform the public are posted on its web page. Issues papers being considered by the Committee were raised by SFIREG during its December, 2010 meeting and involve supplemental labels, use of "professional use only" and distinguishing between mandatory versus advisory language. States have been requested to provide examples of labels that provide a separation between mandatory and advisory language.

Workgroup members requested access to the SFRIG comments on the LRM to avoid duplicating them during public comment. Industry members observed that due to the short turnaround time for responding to SLITS questions, someone other than the label reviewer may address a question about a label which has lead to some confusion. Mr. Roelofs reported that in the Registration Division, reviewers are not held to the short turnaround times and answers are discussed among the RD Branch Chiefs and Product Managers and have to be approved by a Branch Chief before sending a response.

Public Participation Process for Registration Actions

Diane Isbell, Registration Division, summarized OPP's public participation process implemented as of October 1, 2009 to allow the public an opportunity to comment on proposed registration decisions and risk assessments. The types of actions that will undergo the public participation process are new active ingredients, first food uses, first outdoor uses, first residential uses and actions with potential significant public interest. A Notice of Receipt (NOR) is published in the Federal Register for all new active ingredients and new uses. A public docket is opened when a NOR is published. For those actions that will undergo the public process, information is available on http://www.epa.gov/pesticides/regulating/registration-status.html. When the proposed decision document, risk assessment and proposed product labels are available for comment, a Pesticides Update [http://www.epa.gov/oppfead1/cb/csb_page/form/form.html] is issued and the OPP webpage is updated. The final decision document, response to comments, registration notice, revised risk assessment (if revised) and product labels are posted to the public docket, a Pesticides Update is published and the webpage is updated. Final decisions are announced in the Federal Register with a Notice of Issuance.

Webpages devoted to the public process are updated as needed. The Web site was visited 5,707 times between October 2009 and October 2010. As of December, 2010, 46 actions underwent the public process which included 11 actions of significant interest. Questions concerning the public process should be referred to Caroline Klos, Antimicrobial Division (AD), Robert Forrest, Biopesticides and Pollution Prevention Division (BPPD) and Diane Isbell, RD.

In response to questions about the level of public comments, Robert Forrest reported that the majority of the comments received were on the Plant Incorporated Protectants (PIPs). Comments are being requested on all PIPs and approximately 75% of the comments have been significant. Some comments were received on conventional products and a number were received on a nano-silver. Comments have not impeded completing registration actions. Responses to comments are posted in the public docket. To conserve resources, Notices of Receipt and Issuance are being "batched", however, if needed, individual notices are being published..

Public Comment

No public comments were received.

Summary and Next Workgroup Meeting

Action items from this meeting include:

Workgroup members would like a demonstration of the DER composer and Amy Roberts reported that a couple of test laboratories would be interested in participating in testing this application. The workgroup emphasized that OPP should reach out to the stakeholders in developing this software.

Stakeholders and test facilities interested in testing the e-submission builder should contact Robert Schultz.

The Agency will consider sharing SFIRIG's comments on the LRM with stakeholders.