

US EPA ARCHIVE DOCUMENT

Pesticide Program Dialogue Committee PRIA Process Improvement Workgroup

Minutes of the September 23, 2008, Meeting

Workgroup Members Attending:

Sue Crescenzi, Steptoe and Johnson on behalf of the American Chemistry Council Biocides Panel
Dennis Edwards, Antimicrobial Division (AD), Office of Pesticide Programs (OPP)
Ted Head, NuFarm
Jim Kunstman, PBI/Gordon, on behalf of the Chemical Producers and Distributors Association (CPDA)
Beth Law, Consumer Specialty Producers Association (CSPA)
Elizabeth Leovey, OPP
Marty Monell, OPP
Kate Rosenfeld, on behalf of the International Sanitary Supply Association (ISSA)
Steve Robbins, Information Technology and Resources Management Division (ITRMD), OPP
Amy Roberts, TSG on behalf of BioPesticide Industry Alliance (BPIA)
Julie Schlekau, MGK on behalf of Responsible Industry for a Sound Environment (RISE)
Russell Schneider, Monsanto on behalf of BIO
Diane Schute, CPDA
Julie Spagnoli, FMC on behalf of the Pesticide Program Dialogue Committee (PPDC)
Greg Watson, Syngenta on behalf of CropLife America (CLA)
Michael White, CPDA

Agenda

- I. Introductions and Announcements
- II. HED Update on Branch Assessment Assignments
- III. e-Submission Update/Lessons Learned and Helpful Hints
- IV. PRIA 2 OPPIN Enhancements (Monitoring status of PRIA 2 applications)
- V. e-CSF Demo and Results of Morning Usability Test
- VI. Registration Review Tracking
- VII. AD Update on Recent Policies and Guidance
- VIII. Public Comment
- IX. PPDC Meeting and Next Meeting of the Workgroup

Minutes

Marty Monell began the meeting by reminding participants of the statutory provision in the Pesticide Registration Improvement Act (PRIA) on process improvement that led to the Pesticide Program Dialogue Committee's (PPDC) recommendation that the PPDC PRIA Process Improvement Workgroup be formed to provide a public forum in which to discuss improvements in the pesticide registration process. All workgroup meetings are open to the public and announced in the Federal Register. Agendas are posted on the pesticides Web site on <http://www.epa.gov/pesticides/ppdc/pria/index.html>. The Workgroup's scope was expanded to include registration review improvements when PRIA was reauthorized with the Pesticide Registration Improvement Renewal Act (PRIA 2). PRIA 2 requires the Agency in Section 33(k)(2)(D) to report its recommendations for process improvements in the registration review program. She also announced that the registration service fees would increase 5% effective, October 1, 2008, as specified by PRIA 2 and that the fees in the Fee Determination Decision Tree on <http://www.epa.gov/pesticides/fees/tool/index.htm> had been updated.

HED Update on Branch Assessment Assignments

Tina Levine, Director, Health Effects Division announced that the three HED Registration Action Branches and four Reregistration Action Branches have become seven Risk Assessment Branches, each conducting human health risk assessments for both registration and reregistration/registration review. With the completion of tolerance reassessment and the phase in of a reassessment program or registration review, the workload had changed within HED. Better workload management and efficiency gains are expected as a single branch will assess each pesticide. Staff will become knowledgeable about individual pesticides and coordinate their review with both the registration and registration review divisions.

The Division also formed a new intra-divisional committee, the Toxicology Science Advisory Committee (ToxSAC). Its primary function is to provide support to the risk assessment teams as they conduct their hazard assessments. The Committee will review the risk assessment team's endpoint proposal and critical study reviews (Document Evaluation Records (DERs)), provide guidance on time to effect, and assist in data interpretation and hazard characterization. Greater consistency in hazard characterization across the Division is expected as result of this Committee's peer review.

The Biocides Panel commented that the Antimicrobial Division (AD) would benefit from HED toxicology support and such support will increase consistency within the Office of Pesticide Programs. The Antimicrobial Division has a small staff and additional scientific resources will be needed for registration review. Furthermore, only in the last few years has AD conducted human health risk assessments. Marty Monell responded that OPP is reviewing AD's scientific resources and evaluating how to meet future risk assessment needs. The Health Effects Division will also consider what support it can provide AD, for instance, adding an AD representative to the ToxSAC.

HED was requested to update its process flowchart and present it during a future Process Improvement Workgroup meeting with an emphasis on the peer review committees and their roles in the process. In response to a request for a list of ToxSAC's members, Dr. Levine stated that Elizabeth Mendez is the chair of the six member committee and due to changes in personnel; its membership will change in the future. Greg Watson reported that the Dose Adequacy Response Team (DART) had been very helpful and requested that the DART and ToxSAC have common members. Dr. Levine responded that each Science Advisory Committee is represented on HED's Risk Assessment Review Committee (RARC) which reviews each draft risk assessment. BIO commented that HED's reorganization will increase consistency and efficiency as it will eliminate some of the redundancy in two branches conducting risk assessments on a chemical. CLA supported the reorganization particularly since registration review is an ongoing program in parallel with registration covering the same pesticides.

e-Submission Update/Lessons Learned and Helpful Hints

Steve Robbins, Chief, Information Services Branch, Information Technology and Resources Management Division (ITRMD) reported that as of July 15, 2008, the Office of Pesticide Programs had begun accepting Section 3 new applications and amendments, Experimental Use Permits, Tolerance Petitions and Distributor Product forms electronically on a CD or DVD. The PMRA/Canada E-Index Builder was used by ITRMD's Systems Development Branch to develop the consumption module that processes CD/DVDs for the Agency's use. All documents needed for the registration process may be submitted electronically. E-submission guidance is available on <http://www.epa.gov/pesticides/regulating/registering/submissions/> along with other registration application guidance on the Agency's web site (<http://www.epa.gov/pesticides/registrationkit/>). The Agency also has a help desk (703-308-8186 or OPP_e-Submission_Help_Desk_@epa.gov) to address any questions that applicants may have in developing their e-submission.

When the Agency receives an e-submission, the consumption module conducts a virus check and checks the XML syntax. The documents are then transferred to the electronic documents repository and data and information are moved into the Agency's tracking system, OPPIN. Experts in the regulatory divisions are notified by e-mail that an electronic submission is ready for them to assign a PRIA fee category. After the PRIA fee category is assigned, a tracking number (decision number) is created for the application. If correct payment has been received, the applicant is notified by e-mail. Individuals conducting the 21 day content screen are then notified by e-mail that a document is ready for their review in the document repository. Once this process is complete, the appropriate regulatory manager is informed that documents are ready for the next level of review, an in depth review which leads to a regulatory decision.

From July 15 to Sept. 23, the Agency received 95 electronically submitted applications containing 2329 documents which represented approximately 14% of all submissions. Fifty of these applications had minor issues which included inconsistent record counts (XML record did not match the attachments), XML syntax issues, no XML file, incorrect

field designations, or the XML file names did not match the PDF/Word document titles. For the future, the pesticides program is working with an OECD workgroup to harmonize the e-submission transport mechanism. Use of the e-submission help desk and information on the pesticides Web site were encouraged to enable applicants to develop correct and complete e-submissions.

Workgroup members encouraged the Agency to extend e-submission to antimicrobial and biopesticide applications and commented that staff in these regulatory divisions may need additional training in the use of e-submissions. E-submission should also be discussed in registrant training sessions such as the registration workshop sponsored by the Chemical Producers and Distributors Association in October, 2008. Mr. Robbins encouraged applicants to use the e-submission help desk to review their CD or DVDs to determine whether they had been properly formatted before submission to the Agency.

Workgroup members commented that the volume of e-submissions during this initial period was larger than expected and complemented the Agency on its outreach efforts and including applicants in the development process. One step of this process was the e-submission pilot discussed during the previous two Workgroup meetings. Since many of the e-submissions received were from registrants involved in the pilot, additional outreach was suggested such as distribution of another Pesticide Program Update and presentations to trade associations.

Workgroup members also observed that data input will be more efficient with e-submission which may help in scheduling work. Mr. Robbins responded that in this initial phase, most of the resource savings experienced with e-submission were in the front end or application in processing and in the future, additional resource savings could be expected as more reviews are conducted in parallel instead of in sequence. Marty Monell reported that the Agency's long term goal is to replace the manual systems used by the registering divisions to track scientific reviews with an automated system facilitated by e-submission that will notify applicants when milestones in the registration process are completed.

PRIA 2 OPPIN Enhancements (Monitoring status of PRIA 2 applications)

Enhancements being made in the Agency's tracking system, OPPIN, to implement PRIA 2 were described by Dominique Rey-Carruth, ITRMD. These enhancements will also allow the Agency to generate status reports and monitor additional activities to meet new PRIA 2 reporting requirements and will be implemented in fall, 2008. Seventy-five day deficiency notices per 40 CFR 152.105 sent by the Agency after an in-depth review of an application following the 21 day initial content screen will be tracked and monitored. All 75 day notices will be entered and the regulatory manager will be informed prior to the expiration of the 75 days that information is due from the applicant. Modifications to track tolerance amendments and to link Section 3 applications as a subordinate action to a tolerance petition will also be made.

Under PRIA, there are additional fee categories for protocols and study waivers. Since these actions are not associated with a registration or tolerance petition number, a separate administrative numbering system was developed which applicants should use when corresponding with the Agency. Applicants will be informed of this administrative number when they receive an acknowledgement of payment. OPPIN was modified to enable these types of actions to be tracked and linked to a Section 3 application once a Section 3 application is received. Protocol reviews will be closed out in OPPIN as “accepted”, “objections” or “accepted with comments”. Previously, inert ingredient approval requests and inert tolerance petitions were manually tracked. These will be tracked through OPPIN and by individual chemical and mixture names and by food and/or non-food use. Any limitations in an inert ingredient’s use will also be captured.

PRIA 2 requires the Agency to report the status of electronic label review and OPPIN will be modified to track the receipt of an electronic label and to require the reviewer to report whether it was reviewed electronically. If the electronic label is not reviewed, the reviewer must enter why it was not used. The workgroup had questions on the definition of the status indicators used by the Agency to describe the results of a label review and whether they were consistently applied. At the time of the meeting, the status indicators were “label deficiency”, “unconditional registration”, “conditional registration”, “unconditionally accepted with label comments” and “conditionally accepted with data requirements”. The Agency responded that it will consider the workgroup comments and provide a definition for each. Further review of the status indicators in OPPIN used to log out actions revealed that the following status descriptors could be used: “Unconditional registration”, “unconditionally accepted amendment”, “unconditional registration with label comments”, “unconditional accepted amendment with label comments”, “conditional registration with data requirements”, “conditionally accepted amendment with data requirements”, “conditional registration with data requirements and label comments”, and “conditionally accepted amendment with data requirements and label comments”.

As a result of these OPPIN updates, the e-mail notifying the applicant that the Agency has received both the application and payment will also include the date the PRIA time frame begins and ends. These e-mails are sent to both the e-mail address on file and any alternate e-mail addresses listed on the application. The e-mail will also contain a disclaimer that these dates are estimates for those applications that are accompanied with a fee waiver or exemption request or may change if the PRIA fee category is revised upon further review of the application. BPIA requested that the Agency send an e-mail to the applicant when a fee waiver or exemption is granted with the PRIA due date so that applicants do not have to manually calculate it once they receive the Agency letter granting the fee waiver or exemption.

All changes in PRIA fee categories will also be recorded and maintained in OPPIN to monitor whether applicants are correctly identifying their fee category. This information will be used to modify the Fee Determination Decision Tree and develop additional guidance.

OPPIN calculates the PRIA timeframe based on 30 days in a month. The new version of OPPIN will calculate the due date based on months as prescribed in the Congressional Record. Future enhancements to OPPIN will include automating the 21 Day content review process and implementing additional processes to facilitate the use of an electronic submission.

In response to questions, negotiated due dates are entered into OPPIN by individuals with the “rights” to enter them. The user must also enter the reason that the due date was extended to enable the Agency to identify issues that applicants may have with current guidance or with the registration process. Electronic labels in PDF are currently stored in a Lotus Notes Database and this database will eventually be migrated into OPPIN. The receipt and use of an e-label, though, are tracked in OPPIN. Staff in all of the pesticide regulatory divisions (Antimicrobial Division, Biopesticide and Pollution Prevention Division and Registration Division) have been trained to review e-labels electronically, however, applicants need to submit e-labels to enable Agency staff to gain experience with the software.

e-CSF Demo and Results of Morning Usability Test

The results of a usability test of a version of the electronic Confidential Statement of Formula (e-CSF) conducted on the morning of September 23, 2008 were described by Dominique Rey-Carruth, ITRMD. The e-CSF Builder allows a user to complete the CSF form electronically and the software will inform the applicant whether all fields have been completed and the % composition adds to 100%. Twenty-three individuals participated in two sessions to determine whether the version presented met the user’s needs and was easy to use. Users recommended that more auto calculation features be added such as percent by weight; that more than one country and establishment number could be entered; components of inert mixtures could be further listed; editing was easier; footnotes could be added; documents could be attached; additional parameters added to the drop down lists; and the PDF version of the form could be viewed while it was being completed. In response to a question, establishment numbers are optional, though they should be entered for technical products. Users agreed that the e-CSF builder should be made public after modification and suggested that the next version undergo another usability test, for instance during the October 29, 2008 CPDA Registration Workshop. The e-CSF Builder (<http://www.epa.gov/pesticides/regulating/registering/submissions/#ecsf>) will be made available spring 2009.

Registration Review Tracking

Lance Wormell, Antimicrobials Division, provided an overview of the Agency’s internal registration review tracking system that is expected to be deployed within the Office of Pesticide Programs during late fall 2008. Since the registration review program is an ongoing activity in which registered pesticides will be reviewed every 15 years and the program will have defined schedules and a larger number of reassessments each year than reregistration, a tracking system is being developed to manage the workload. It will be linked to the Agency’s existing tracking system, OPPIN/PRISM and any of its future

upgrades. Documents will be stored in the PRISM document management system. The system will also be integrated with the endocrine disruptor screening program's tracking system currently in development and linked to the Agency's e-mail system to enable notices to be sent to staff.

Both milestones and individual tasks will be monitored per case. An example of a milestone would be to create a summary document while the tasks associated with this milestone may include convening the first team meeting, creating a LUIS report, developing a problem formulation, and creating a scoping document, the Preliminary Work Plan and finally the Summary Document. For each task, the individual responsible will be identified and completed dates compared with target dates. All documents associated with a task will be accessible from the tracking system using the Agency's document management system. The system has been designed to be user friendly and easily integrated with existing information management systems and additional or future systems. The major benefits will be easy access to the status of each case's milestones and tasks and to relevant documents completed by Agency staff or submitted by stakeholders. The system will facilitate communication across the Office of Pesticide Programs on specific pesticides and improve reporting and the transparency of the program. Reports could be generated that will inform registrants and the public of the status of a specific case.

The Workgroup requested a presentation on any upgrades to LUIS during a future meeting of the workgroup. In response to questions, the registration review tracking system could be used to generate the master schedule. Only individuals with data entry rights will be allowed to enter and modify inputs and these rights will depend upon the electronic workflow process. The majority of data entries will probably be made by the registration review case manager.

AD Update on Recent Policies and Guidance

Dennis Edwards, Chief, Regulatory Management Branch I, Antimicrobials Division updated the Workgroup on the Agency's resolution of the jurisdiction of antimicrobials used in the fermentation of fuel ethanol. After discussions with FDA's Center for Veterinary Medicine, the content of a fermentation tank is processed food or feed and falls under FDA's jurisdiction consistent with the definition of a pest in 40 CFR 152.5 which excludes microorganisms on processed food and feed. Antimicrobials, though, that are applied to other than processed food or feed such as an empty tank require a pesticide registration. In developing such an application, the applicant should also consult FDA to determine if FDA has a concern and provide documentation to EPA of the consultation. Guidance describing the approach is being developed and after FDA concurrence, will be posted on the pesticides Web site.

The Antimicrobials Division has a draft Pesticide Registration Notice that presents the Agency's policy on labeling pesticide products developed to control mold growth in indoor environments. Previously, the Agency considered issuing an FR Notice with a request for comment and then issue a PR Notice. Instead, the Agency will request public comment on the draft PR Notice. The mold policy was a result of increased public

interest in mold control and of recent studies that have indicated that exposure to mold may pose a threat to human health. The over 1000 products registered to control mold growth are primarily registered for aesthetic purposes and while companies do generate efficacy data, they are not required to submit to the Agency for this purpose. Under the new policy, a disclaimer should be placed on a label that states the product is for aesthetic purposes, i.e. “This product is registered to control the growth of mold for aesthetic purposes only” or the applicant must submit efficacy data to support the mold claim or remove the mold claim from the label. Additional labeling directions will be needed on cleaning (for instance, use of protective measures) and reflect those adopted by the Office of Air. Existing directions will need to be clarified or supplemented to indicate whether the product is for remedial or preventive purposes. For residual or preventative mold claims, the Agency is moving in the direction of requiring efficacy data to support the claims. Six genera typically found indoors can be listed on a label provided the efficacy data supports the claim. This policy is anticipated to be issued during the first half of 2009.

A Workgroup member commented that the disclaimer does not communicate a product’s purpose clearly to the public, suggested that another term or phrase besides “aesthetic purposes” be used, and supported the adoption of the Office of Air cleaning directions. The Agency welcomes suggestions for alternative wording and suggestions can be provided when the draft PR Notice is available for public comment. The question of material preservation and its relationship to the mold policy could also be addressed during the public comment period.

Public Comment

In response to a question from Ray McAllister, CLA regarding web sites on labels, Marty Monell responded that the Agency is currently discussing the issue internally. Web based labeling in general will be discussed during the October, 2008 PPDC meeting along with the status of product reregistration.

PPDC Meeting and Next Meeting of the Workgroup

Marty Monell summarized the follow-up items from this meeting: The Agency will issue an OPP update announcing e-submission, will consider whether the scientific resources within the Antimicrobial Division are sufficient for peer review and the possibly of HED support, and will report on internal discussions to clarify the status descriptor entered in OPPIN when an electronic label review is completed. Another e-CSF usability test will be conducted during the October 29 and 30, 2008, CPDA Registration Workshop. This Workshop will provide training directed to small businesses on PRIA and on how to develop an application.

Topics suggested by Workgroup members for the next or future meetings included improvements in LUIS reports particularly the content of such reports. During the reregistration process, meetings were held to discuss pesticide use. Such meetings are not part of the registration review process which may lead to greater reliance on LUIS reports.

When the registration review tracking system is implemented, the Workgroup would like to discuss the types of reports that will be available to the public. Another topic of interest was the status of data call-ins. An update on inert ingredient approval lists and the process for obtaining an inert ingredient approval were also requested.

For the next meeting of PPDC, the Workgroup's report will be developed by Elizabeth Leovey and distributed as a hardcopy to its members. The PPDC meeting's agenda will focus on topics. The next meeting of the PPDC PRIA Process Improvement Workgroup will be prior to the next meeting of the full PPDC in spring 2009.