Pesticide Program Dialogue Committee PRIA Process Improvement Workgroup

Minutes of April 10, 2007 Meeting

Attending:

Workgroup Members:

Dennis Edwards, Antimicrobial Division (AD), Office of Pesticide Programs (OPP)
Ted Head, NuFarm on behalf of the Chemical Producers and Distributors Association (CPDA)
David Jones, Nice-Pak on behalf of International Sanitary Supply Association (ISSA)
Jim Kunstman, PBI/Gordon
Elizabeth Leovey, OPP
Michael Mendelsohn, Biopesticides and Pollution Prevention Division (BPPD), OPP
Marty Monell, OPP
Sheryl Reilly, BPPD, OPP
Amy Roberts, TSG on behalf of BioPesticide Industry Alliance (BPIA)
Julie Schlekau, MGK on behalf of Responsible Industry for a Sound Environment (RISE)
Julie Spagnoli, FMC on behalf of the Pesticide Program Dialogue Committee
Warren Stickle, CPDA, ISSA
Greg Watson, Syngenta
Mae Wu, Natural Resources Defense Counsel (NRDC)

Other Participants:

Rebecca Ashley, DuPont
Linda Arrington, Registration Division, OPP
Aboubacar Camara, Pest Management Regulatory Agency (PMRA)/Health Canada
Susan Casoni, Pesticide.Net
Chris Davis, FMC
Cynthia Doucoure, Biological and Economic Analysis Division (BEAD), OPP
Tim Formella, United Phosphorus
Thomas Harris, RD, OPP
John Jamula, Information Technology and Resources Management Division (ITRMD), OPP
Richard Keigwin, BEAD, OPP
Blair McRae, PMRA/Health Canada
Elizabeth Mendez, Health Effect Division (HED), OPP
Larry Pearl, Pesticide and Toxic Chemical News
Karen Shearer, Bayer
Charles Stafford, BEAD, OPP
Donald Stubbs, RD, OPP
Philip Villaneuva, HED, OPP
Pauline Wagner, RD, OPP

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Minutes

Introductions and Announcements

Marty Monell began the meeting with introductions and then reminded the audience of the PPDC's recommendation that this workgroup be formed to obtain stakeholder input for the Agency's implementation of the statutory provision in the Pesticide Registration Improvement Act (PRIA) on process improvements. The provision encouraged the Agency to improve its processes and decrease PRIA Decision Time Review Periods or timeframes.

She announced that 40% of the PRIA fee payments were being made through pay.gov, the government's system to collect payments by credit card or wire transfer. This innovation began on November 1, 2006 (http://www.epa.gov/pesticides/ppdc/pria/november06/november06.htm).

It reduced some of the Agency's transaction costs and with more efficient payment, the PRIA time frame or decision review period began sooner. The Agency's next effort was to explore with pay.gov, payment prior to and at the time of application. While PRIA contemplated payment at application, the Agency decided to invoice or bill applicants after the Agency determined the PRIA fee category because applicants, at that time, were unfamiliar with the 90 fee categories.

Publication of the "Blue Book" or *General Information on Applying for Registration of Pesticides in the United States* had progressed since the last workgroup meeting with 18 of the 21 chapters reviewed by the Agency's Office of General Counsel. The remaining chapters were expected to be reviewed within three weeks with the appendices and glossary taking an additional two weeks or more. After concurrence within the Pesticides Programs, the document was expected to undergo the Agency's "Product Review" process which OPP will try to expedite.

During the next meeting of the workgroup, progress on pre-payment and information management will be highlighted.

Labeling Committee

The Labeling Committee was one of the successes of this stakeholder workgroup. Its chair, Donald Stubbs, Associate Director, Registration Division updated the workgroup on its recent activities. The Committee's charge included serving as a clearinghouse for cross-cutting labeling issues, managing a web site (http://www.epa.gov/pesticides/regulating/labels/label_review.htm) and e-mail box (http://www.epa.gov/pesticides/regulating/labels/label_review_faq.htm), and revising and keeping current the Label Review Manual (LRM). As of March 30, the web site had received 89 questions. The Committee answered 83, and was addressing 6. Of the completed questions, 29 were addressed directly and answers to 54 were posted on the web site. The web site averaged 655 "hits" per month and the question and answer page averaged 184 while the LRM averaged 827.

The LRM Team under the auspices of the Labeling Committee was converting the Manual from WordPerfect to Word and making non-policy corrections. The first three revised chapters were posted on the LRM web site (http://www.epa.gov/oppfead1/labeling/lrm/) and Chapters 4, 5, and 6 were being reviewed by the Committee.

Progress on the projects (http://www.epa.gov/pesticides/regulating/labels/projects.html); "Contains the same Active ingredient", "Minimum Application Paper" and general environmental hazards statement on outdoor residential products was reported. The Committee developed a guidance paper on the issue of adding statements such as "contains the same active ingredient as …" on labels by amendment. The guidance provided information on how to reference the other product; the statement's placement on the label, its font size and type; and disclaimers.

The Minimum Application Paper received 6 responses after being posted on the web for comment. Based on a review of the comments and the statute, the Agency concluded that minimum application rates may be placed on a label when the reduced application rate may result in increased pest resistance to the pesticide and when there was documentation that a product's efficacy may be substantially compromised. For these circumstances, minimum application rates would be mandatory. If the bases for a minimum application rate could not be documented, the rate should be stated in advisory language.

The PPDC's Consumer Pesticide Labeling Improvement Workgroup previously presented its recommendations to the PPDC (http://www.epa.gov/pesticides/ppdc/labeling/index.html) on general environmental hazard labeling for outdoor consumer residential (homeowner) use products. The recommendations were reviewed by the Labeling Committee and after some minor modifications; OPP anticipated issuing a PR notice on the recommended labeling language and how to incorporate the language on a label. Comments would be taken on the PR Notice. Four categories of statements were recommended based on the type of formulation:

> Liquid Concentrate: Do not apply near water, storm drains or drainage ditches. Do not apply when windy or when heavy rainfall is expected. Rinse applicator equipment over the lawn or garden area that was treated, and away from storm drains,
>
> Broadcast Granular: Do not apply near water, storm drains or drainage ditches. Do not apply if heavy rainfall is expected. Apply this product only to your lawn/garden, and sweep any product that lands on the driveway, sidewalk, or street, back onto the treated area of your lawn/garden.
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> Dust: Do no apply near water, storm drains or drainage ditches. Do not apply when windy or when heavy rainfall is expected.
>
> Liquid Ready to Use (RTU): Do not apply near water, storm drains or drainage ditches. Do no apply when windy or when heavy rainfall is expected.

In response to questions, the final PR Notice when published was expected to provide the final recommended label language and registrants and applicants could then proceed to revise their labels. The policy on "contains the same active ingredient" will be issued as policy on the web site and comments will be accepted.

Greg Watson commented that the Labeling web site was a good site and suggested two improvements: 1) key word searches to quickly locate a topic of interest and 2) notice whenever changes or additional information were posted on the site. Mr. Stubbs reported that the number of questions and answers were increasing and additional web categories were needed. The Committee will consider the suggestion on key word searches. Policy papers were announced on the web site and with an "OPP Update" distributed to over 6,000 e-mail addresses.

Julie Spagnoli inquired whether the LRM's objective will be changed from guidance to OPP label reviewers to guidance to label developers. Mr. Stubbs observed that it may be slowly

moving in that direction, however, he did not know whether it would eventually become solely registrant guidance.

Developing a Toxicological Reference Database for Pesticides

A goal of the Agency was to reduce, refine and replace animal usage. Elizabeth Mendez, Toxicologist, Health Effects Division, reported the status of an analysis of data submitted to the Agency by registrants to identify efficiencies in its review and use. By focusing on the toxicity of the compound, new testing paradigms could be developed to reduce the number of animals used and tests conducted. HED's ongoing retrospective analyses included the Dog Chronic and Subchronic, Rat Multi-generation Reproductive, Prenatal Rat and Rabbit Developmental, Rodent Cancer and Rat Neurodevelopmental Toxicity (DNT) studies. The Agency's Office of Research and Development (ORD) National Center for Computational Toxicology (NCCT) was assisting in the analysis of some of these studies and of other required studies such as the 28 and 90 day oral toxicity, dermal toxicity, inhalation and chronic rodent studies.

From the lessons learned, a new hypothesis driven testing paradigm would result that allowed more efficient and reliable use of data from the existing required studies and would be more responsive to the Agency's risk assessment and management needs. Testing improvements expected include reduced and refined animal usage, optimized study design, flexibility, and generation of sufficient, credible, yet not an overwhelming amount of data. Reduced cost and time for registrant development and for Agency review and analysis of the data were also expected.

The Dog Toxicity retrospective analysis and public comment on the analysis were completed. The Agency was reviewing the comments and expected to have a report in a few months. In collaboration with NCCT, the Rat Multi-generation Reproductive retrospective was underway with the first 130 chemicals expected to be completed by the end of the summer. The chemicals represented a broad range of chemical classes. Parallel with the Rat Multi-generation study and in collaboration with NCCT, the retrospective analysis of the prenatal developmental toxicity studies in Rat and rabbits was also underway. The rodent cancer and rat DNT analyses were expected to begin in the fall of 2007.

In collaboration with NCCT, a relational database and predictive tools were being developed. The ToxRef Database was in the process of being populated by OPP. The animal toxicity data will be linked to a variety of other domains including genomic data, chemical structures, and high throughput screening information to develop predictive tools that will eventually allow the Agency to develop a more hypothesis-driven testing paradigm that incorporated knowledge of toxicity pathways. This effort was being expanded through collaborative relationships with the EU and Canada.

In response to a question from Greg Watson, Ms. Mendez reported that the ILSI, Agricultural Chemical Safety Assessment Workgroup's efforts were related and on the same track as OPP's efforts with NCCT. Greg Watson commented that for the relational database to be of benefit to the registrant community, it had to be coordinated internationally particularly under North American Free Trade Agreement (NAFTA) and with the European Union (EU) and Japan. The

registrant community understood that it will take time. As a result of China's Codex chairmanship, the Pacific Rim countries should be included in international collaborations. Ms. Mendez responded that this was a long term effort and discussions had been undertaken with Canada and the EU. Mr. Watson reported that the DNT analysis conducted by the Agency was very helpful to registrants and should be an ongoing process. It was an animal intensive and expensive study and the study should be directly useful in end point selection and risk assessment. Ms. Mendez responded that since this analysis, approximately 50 studies had been received and their analysis would be added to the previous study.

MRL Calculator

Philip Villanueva, Health Effect Division, discussed the status of the Maximum Residue Limit (MRL) Calculator and the activities of the North American Free Trade Agreement (NAFTA) MRL Harmonization Workgroup. In the US, MRLs were called tolerances. Prior to this project, MRLs were established independently by the NAFTA members and similar data sets were sometimes used to establish different MRLs. To reduce trade barriers and facilitate joint review and work sharing, a common, harmonized approach was needed. A workgroup was formed to develop a statistically-based, scientifically defensible methodology which could be universally used to set a common MRL and to develop a Standard Operating Procedure that described this methodology to be used by non-statisticians to permit a more coordinated and harmonized approach. Workgroup members included the US and Canada with contributions from the EU's European Food Safety Authority (EFSA) and the California Department of Pesticide Regulation (CDPR).

Prior to this effort, individual reviewers and analyst set a MRL on a case by case basis, not on a statistical basis. Generally, the MRL was based on the highest residue level with some consideration of the sample size and was dependent upon the judgment and subjectively of the reviewer. The MRL calculator was based predominately on accepted statistical principles and methods, was reasonably simple to use by non-statisticians and had become widely accepted. It incorporated information about sample size and variance, resulted in consistency in an analysis across data sets, and effectively accomplished appropriate "balancing", i.e. the level was not too high nor too low to result in an enforcement case of over tolerance residues if the pesticide was used according to the directions on the label.

Since 2005 and after training was conducted for both EPA and Pest Management Regulatory Agency (PMRA)/Canada reviewers, the MRL Calculator had been used by PMRA and EPA to set tolerances. MRL calculations were reviewed by an advisory committee of senior chemists which for joint reviews included PMRA staff. Any technical questions were addressed by the NAFTA Workgroup members. An example was shown of how the MRL calculator was used to set a tolerance for Boscalid on carrots. The calculator presented the residue information graphically and then presented the reviewer with a spreadsheet with the analysis conducted by a number of statistical procedures. While easy to use, the user needed to understand the SOP.

The calculator was discussed during the August, 2005 National Meeting of the American Chemical Society, the August, 2005 meeting of the International Union of Pure and Applied Chemistry Pesticide Chemistry Congress, the December 2005 NAFTA Stakeholder meeting, the

September 2005 and October 2006 meetings of the Joint Meeting on Pesticide Residues (JMPR), and the December 2006 Fresenius Conference. A statistical white paper with the technical details, simulations and rational for selecting various methods was available on the PRMA website for external comment during April and May and was expected to be distributed to the JMPR in August or September. Once the NAFTA executive Board reviewed and approved the white paper scheduled for late 2007/early 2008, the revised White Paper, SOP, and spreadsheets will be released. The spreadsheet (http://www.pmra-arla.gc.ca/english/pdf/mrl/method_calc.xls) and guidance/SOP http://www.pmra-arla.gc.ca/english/pdf/pro/pro2005-04-e.pdf (English version)
http://www.pmra-arla.gc.ca/francais/pdf/pro/pro2005-04-f.pdf (French version)
were available on Health Canada's PMRA website. The White Paper will be available on the internet.

Greg Watson commented that since the Calculator became available, it had become standard practice within the registrant community to use it in developing a proposed Notice of Filing.

Analytical Chemistry Branch's Streamlined Procedure for Validating Food Tolerance Enforcement Methods.

The Analytical Chemistry Branch, Biological and Economic Analysis Division streamlined its procedure for validating food tolerance enforcement methods. Charles Stafford, ACB, BEAD summarized this procedure as a two tiered approach in which during the first tier the method underwent a data review by the Health Effects Division and ACB and then only select methods went to the second tier 2, a laboratory validation in which the laboratory repeated the method to determine whether it could achieve the same level of performance as reported by the registrant. Since the early 1980's, methods submitted with all new active ingredient applications with food uses and with the first food use of a registered active ingredient underwent a laboratory validation. The approach was problematic because validations were resource intensive for the Agency. As a result of advances in technology and the need for specialized reagents and columns, new supplies and in some cases equipment had to be purchased with each method. Substantial time was also required to set up the equipment and then conduct the method.

To identify improvements in this process, the laboratory examined the statutory requirements for conducting these validations. Residue methods were discussed in 40 CFR 158.240 in footnote A, as "A residue method for enforcement of tolerance is needed whenever, a numeric tolerance is proposed ...Analytical methods used to enforce residue limits ..must be available for use by enforcement agencies and thus may not be claimed as confidential business information ". Residue methods were used by FDA (food), USDA (meat, milk, poultry, eggs. etc.) and State regulatory laboratories for enforcement while other method users included State laboratories under USDA's Pesticide Data Program (PDP) and other laboratories such as academic, foreign, research and contract laboratories. Enforcement methods also had been submitted with supporting data as described in 40 CFR 158.202(c)(3): "Residue Chemistry data are also needed to support the adequacy of one or more methods for the enforcement of the tolerance.." Method performance guidance was available in the "Pesticide Assessment Guideline, Subdivision O, Residue Chemistry", October, 1982 and the "Residue Chemistry Test Guidelines, OPPTS 860.1340, Residue Analytical Method", August 1996. This guidance specified, for example, an

acceptable background of no more than 20% of the proposed tolerance and recoveries of between 70 and 120%.

The Branch also reviewed its experience in conducting laboratory validations and observed that during the 1980's and early 1990's, approximately 20% of the submitted methods failed validation. Reasons for this historical failure rate included poorly or incompletely written procedures, mistakes in the procedure's description, no performance data for the commodity of interest, and no performance data at the Level of Quantitation (LOQ). Reasons for not approving the method for enforcement purposes included the method LOQ was higher than the proposed tolerance, poor or erratic recoveries and matrix interference. In response to the high rate of method deficiencies, the Agency issued PR Notice 88-5 and then PRN 96-1 which provided guidance for an independent laboratory validation in which a registrant validated the method in another laboratory. As a result of an improved understanding by registrants of OPP's guidance and the independent laboratory validation program, methods submitted for food tolerance enforcement dramatically improved. Considering this improvement and that tolerance enforcement efforts were most efficiently performed using multiresidue methods, rather than single-analyte methods, OPP was shifting its laboratory resources from single-analyte method validation to better focus on multiresidue methods development and other priority OPP projects.

As part of the current effort to further improve the process, a Standard Operating Procedure (SOP) for validations was developed. Validation was defined by the Guidance for Developing Quality System for Environmental Programs and ANSI/ASQC E4-1994 as "confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use have been fulfilled. In design and development validation concerns the process of examining a product or result to determine conformance to user needs." Using this definition, the history of the program in validating data and assuring that public health would be protected, the following SOP was developed and was being reviewed by HED and the Registration Division: After ACB received a Tolerance Method Validation request from HED, ACB consulted the HED review chemist to identify potential method issues or deficiencies and performed a Tier 1 validation or data review. Upon consultation with HED of the results of this review, selected methods underwent Tier 2 validation with a laboratory trial of the method. Criteria for recommending that a Tier 2 validation be conducted were more risk based than in the past and included:

1. Difficulties were experienced by the independent laboratory during the independent laboratory validation;
2. The method used new or novel technology;
3. The active ingredient was the first of a new class of chemicals proposed for registration;
4. The proposed tolerance was lower than the validated recovery data submitted by the registrant;
5. The method did not appear to be based on sound scientific principles;
6. The parent pesticide or major residue was not recovered by any of the commonly used multiresidue methods;
7. HED had identified potential dietary risks of concern;
8. There was a high likelihood of quantifiable residues in treated crops that were the risk drivers in the risk assessment; and
9. Random selection of the method for laboratory validation.

For additional information, Frederic Siegelman (siegelman.frederic@epa.gov) or Charles Stafford (stafford.charles@epa.gov) should be contacted. Other sources of publicly available method information included

Registrant single-analyte food tolerance enforcement analytical methods
http://www.epa.gov/oppbead1/methods/ramindex.htm
Registrant single-analyte environmental (soil/water) analytical methods
http://www.epa.gov/oppbead1/methods/ecmindex.htm
FDA Center for Food Safety & Applied Nutrition analytical methods
http://vm.cfsan.fda.gov/~lrd/pestadd.html
USDA IR-4 single-analyte food analytical methods
http://ir4.rutgers.edu/Other/Analytical%5FMethods/
EPA Forum on Environmental Measurements analytical methods
http://epa.gov/osa/fem/measmethod.htm

A workgroup member applauded the streamlining approach presented and observed that as a result of FQPA and quantitative dietary assessments, registrants had developed more sensitive methods with lower LOQs and consequently, a greater number of detections were being reported. The context for the increased number of detections was, however, not being reported and communication of the impact of improved technology on detections to the general public could be enhanced.

Estimating Project Percent Crop Treated: BEAD's New Approach

When the Agency conducted chronic and acute dietary risk assessments for new pesticides or new uses of registered pesticides, it considered the percentage of the crop grown in the US treated with the active ingredient of interest. Cynthia Doucoure, presented the Agency's latest approach for estimating percent crop treated. Percent crop treated (PCT) was defined as the ratio of base acres treated (acres that received one or more applications of a specific pesticide) to acres planted or grown, expressed as a percentage. In the past, such projections of market share or (PCT) were submitted by the registrants and reviewed by the Biological and Economic Analysis Division (BEAD). The data submitted often varied because of the lack of standardized procedures or methodologies.

The Division developed the market leader approach to improve the quality of Projected Percent Crop Treated (PPCT) estimates. The market leader approach was defined as the use of (1) PCT data on market leaders and (2) other relevant factors to project the PCT of the new chemical or new use of a registered chemical. Market leaders were chemicals with the highest PCT for specific pesticide type (e.g., insecticide, fungicide, and herbicide) and crop or site. The underlying assumption of this approach was that the PCT of the new chemical or use was not likely to overtake the PCT of the market leader for that pesticide type and relevant crop within the first five years following registration. This conclusion was based on the Division's analysis of historical PCT data where they observed that in 186 out of 190 pesticide reregistration cases (98%) for the period of 1996 to 2005, the maximum PCT of the new chemical or new use did not exceed the average PCT (of the yearly maximum PCTs) of the market leader. This observation

was appropriate for chronic risk assessment. In cases appropriate for acute risk assessments, the maximum PCT of the new chemical or new use did not exceed the maximum PCT of the market leader in 326 out of 339 cases (96%). BEAD's analysis of the limited situations in which the PCT of new pesticides surpassed the PCT of market leaders suggested that Section 18 Emergency Exemption uses were a factor.

Three steps were described in the market leader approach. The first step was to derive the projected percent crop treated estimate by identifying the maximum percent crop treated for the market leaders for the same crop and chemical type for the three most recent years using data from USDA's National Agricultural Statistics Service (NASS). An average of the yearly maximum PCT provided the average PPCT used for chronic dietary risk assessments while the maximum yearly PCT of the three yearly maximums provided the PPCT for acute dietary assessments. In the next step, BEAD examined other relevant factors, such as Section 18 Emergency Exemptions and pest resistance (factors examined during the historical analysis) as well as factors such as pests controlled by a new pesticide, alternatives, the mode of action of the pesticide, its costs, and if available, data submitted by the registrant. Once this analysis was completed, BEAD delivered a description of (1) the methodology used for estimating the PPCT and (2) the review of the relevant factors examined in developing the estimates to the Registration Division for insertion in the Federal Register Notice of the Final Rule. This new approach had advantages because it was documented (based on an analysis of historical data), was comprehensive in providing estimates for both chronic and acute dietary exposure assessments, considered relevant information, was open and transparent, and involved the Health Effects Division and the Registration Division.

In response to questions raised following the presentation, BEAD noted the following:

- Calculations of PPCT estimates based on the pest and pest pressures were considered in a Tier II analysis, which was not discussed during this presentation.
- Maximum PPCTs were used for new chemicals to satisfy the FQPA requirement for 'reasonable certainty of no harm' determinations.
- USDA NASS data was used rather than proprietary data because NASS was publicly available, whereas proprietary data was not publishable
- For registration review, the PCT analyses will be placed in the docket.
- Multiple applications were not considered in calculating PCT since PCT was the percentage of the crop with residues based on the number of acres treated.

Inerts

Three new processes within the Inerts Assessment Branch, Registration Division, were reported by Pauline Wagner, its Branch Chief. Prior to publishing a Notice of Filing for a new inert petition, the Branch reviewed the submission to determine if the data submitted were adequate. If the data were inadequate, the petitioner was informed that they could identify suitable data from the literature, generate suitable data or withdraw the petition. This review was expected to save processing time and publication costs. In addition, the risk assessment will be placed in the docket when the Final Rule was published and on the inerts website to improve transparency and provide a historical record of the assessment.

In the fragrance notification pilot, a database developed by the Fragrance Manufacturers Association of 1500 compounds found in fragrances will be evaluated by the Agency. The database was expected to decrease the effort required to approve fragrance changes. If registrants certified that the fragrance change was the only change in the formulation, any fragrance in the database will be automatically cleared. The pilot began in May and was expected to run for 120 days. An announcement was placed on the inerts web site in mid-April (http://www.epa.gov/opprd001/inerts/). If successful, the Agency will make the process permanent.

The Inerts Assessment Branch was also reviewing Confidential Statements of Formula submitted with Fast Track Amendments early in the review process to verify the proper use of inert ingredients. If acceptable, the entire package was returned for chemistry review and if not, it was returned to the Product Manager to contact the registrant. During this process, the Branch tabulated common errors. Errors identified as of April, 2007 included: the Chemical Abstract Service (CAS), chemical name and/or trade name did not match; there was a non-food use or unapproved inert listed for a food use product; and an inert with restrictions was used inappropriately, i.e. the exemption was only for growing crops while the product was proposed as a post-harvest treatment. A form was developed to document this review which may be sent to the registrant if an issue was identified.

The Branch was considering a change in procedure for processing new registration actions. Proposed CSFs would be reviewed in an upfront screen for proper use of inerts. An early screen will allow the Agency to notify the registrant immediately if there were non-cleared inerts.

Jim Kunstman asked whether the Agency was considering on-line completion of a CSF that would immediately notify the registrant if all of the inerts had been cleared. Ms. Wagner reported that the Agency had been discussing such a system and as indicated by Marty Monell, during the next workgroup meeting, the Agency will report its progress on electronic submission. In response to a question from Julie Spagnoli, Ms. Wagner reported that an inert supplier could inform the Agency of name or CAS number changes and these will be entered in the Office of Pesticide Programs Information Network prior to any submission to facilitate processing future registration actions. Placing a list of cleared inerts on the web was a high priority for the Branch. In response to Amy Roberts' question that resulted from a request from BPPD to provide inerts information, Ms. Wagner suggested that such information be sent to both BPPD and the Inerts Assessment Branch. BPPD did have access to the inerts databases.

Greg Watson complemented the Inerts Assessment Branch on the substantial progress made since its formulation and presented some thoughts on future improvements. A uniform approach between the three registering divisions for the review and approval of new inerts would benefit both the Agency and registrants. Since the tolerance exemption process was similar for inerts in 40 CFR 180.910 and 180.920, the two sections should be combined. Since all of OPP employees used the same computer platform, an electronic format that allowed easy inert searches was suggested and Master Files could be updated by suppliers. He emphasized that publication of a list of cleared inerts was a high priority for industry. This was supported by Warren Stickle on

behalf of ISSA. Julie Spagnoli suggested that the list be organized in a hierarchy based on potential residues and exposure.

Product Chemistry

Product Chemistry was a topic of a number of workshops over the last ten years and some registrants, particularly smaller companies, continued to have difficulty submitting complete applications as reported by Don Stubbs. Smaller companies did not attend workshops nor belonged to trade associations. Product chemistry issues resulted in a third of the negotiated due dates and accounted for 18% of fast track amendment resubmissions. As reported in past workgroup meetings, the blue book was being updated as one mechanism to help new registrants. The Agency also considered developing a tutorial that will provide step by step guidance on how to develop a complete product chemistry submission and a "smart" CSF that will help submitters complete the application and indicate whether the contents summed to 100%. These, however, were only partial solutions and trade associations were encouraged to help reach the smaller companies through their web pages.

Warren Stickle on behalf of CPDA and ISSA, inquired whether there was any data to indicate whether completing the voluntary product chemistry form resulted in fewer errors. If it did, he suggested that trade associations could encourage its use and the form could also be made mandatory. Mr. Stubbs did not know whether such data had been obtained and that the Agency would look into it. According to Amy Roberts, tutorials and templates would be of help, however, they would need to be specific to the registering division since reviews differed. Julie Spagnoli asked whether the Agency was revising the CSF form. The instructions were not user friendly particularly the directions on how to calculate nominal concentrations. Mr. Stubbs reported that the Agency will revise the instructions on the back of the form. Ms. Spagnoli observed that reaching the smaller companies will be a challenge considering the number of generic products on the market.

Greg Watson on behalf of Ron Derbyshire presented the industry coalition's observations:

1) Develop a web based application similar to those used by the public to prepare IRS tax returns. As a result of such software, the public was more familiar with such applications. The CSF template should be the same for all registering divisions.
2) A greater proportion of fee waived applications had errors or were incomplete. In PRIA II, as proposed, everyone will pay some fee which may encourage complete applications.
3) Whenever a new company number was requested, the Agency should automatically send the company a copy of the label review manual and registration kit with the updated Blue Book.

E-Label Review

Thomas Harris, Registration Division, updated the workgroup on the status of electronic label review. In e-label review, an applicant will send a proposed label on a CD in text PDF and the Agency will compare it to past electronic labels, comment on it and link it in OPPIN's tracking system to maintain a permanent electronic record. During an informal training session conducted in the morning of the workgroup meeting. Mr. Harris emphasized that the file should be named according to the Agency's guidance (registration filename = registration

#.yyyymmdd.anything else.PDF) to assure proper routing and storage. In submitting an e-label, furthermore, the usual paperwork had to be submitted along with the CD with an affidavit that the electronic copy was the same as the paper copy. Corrections and revised labels could be sent by e-mail in text.PDF to the Agency's reviewer or branch gatekeeper. The SOP/guidance was being reviewed with comments due at the beginning of May. Agency staff training was expected to be completed by the end of June

Greg Watson observed that e-label review was an important PRIA process improvement that considering the number of labels reviewed, was expected to save the Agency resources. For the next meeting of the workgroup, a presentation on performance measures on the implementation of electronic review was suggested. In response to Julie Spagnoli's question on how approval with comment will be handled under e-label review, Mr. Harris noted that it will depend upon the reviewer and that because e-label review will make it easier to make corrections, the number of approvals with comment was expected to be reduced. Don Stubbs stated that he preferred that the Agency move away from label approval with comment. In response, Greg Watson commented that to provide enough time for a registrant to respond to comments, the Agency would have to complete its review in a timeframe that will allow the registrant to make the appropriate changes. Amy Roberts observed that this was the practice in BPPD. Only final labels were approved, though there was a question as to whether e-label review will be used in the notifications process. In the Registration Division, the notifications team was expected to use e-label review to speed up its process of determining whether the proposed label change could be implemented through notification.

In response to a question from Jim Kunstman, more than one label may be submitted on a single CD, however, each label must be easy to identify to facilitate processing by the front end or in processing staff. All applications associated with these labels should also be submitted simultaneously. If both electronic labels and electronic studies were submitted simultaneously, they had to be on separate CDs. As a follow-up question, Ms. Roberts inquired whether the front end staff was familiar with CDs and moving them through the process. According to Mr. Harris, the front end staff was familiar with the process. Over 1,000 labels had been stored and the front end staff maintained the original CDs.

Process Improvements

Fast Tracks and Notifications in the Biopesticides and Pollution Prevention Division

To process the label amendments resulting from the 2003 First Aid and Disposal PR Notice, BPPD formed the Label Review Team which successfully processed these actions. As a result of this success and the implementation of PRIA, Mike Mendelsohn, BPPD, reported that the Biochemical Pesticides Branch within BPPD adopted a team approach and formed the Science, Fast Track, Non-Fast Track, and New Active Ingredients Teams to efficiently process actions within PRIA timeframes. The Fast Track team initially processed fast track label and CSF amendments, fast track registrations, final printed labels and notifications for the Biochemial Pesticides Branch. In 2006, the Fast Track Team expanded its scope to all of BPPD and notifications processing was moved to the Notifications Response Team. The Notification Response Team was formed in spring 2006 to process notifications within 30 days of receipt and determine if the proposed label and/or formulation changes were within the scope of PR Notice

98-10. This team developed standard template response letters to inform the registrant whether the notification was within the scope of PRN 98-10, and if not, that it could be processed as a fast track amendment or that it needed to be resubmitted as a label amendment (the difference between the latter two responses was the complexity of the amendment, for example, if data were needed or if the changes involved new uses, etc.).

The teams significantly reduced average decision times. The average decision time for fast track label amendments was reduced from 146 days in 2003 to 78 in 2006. Similar decreases were noted for fast track formulation amendments; 148 days in 2003 to 71 days in 2006 and fast track new product registrations, 207 days in 2003 to 37 days in 2006. Few fast track lepidopteron pheromone registrations were processed with the average decision time at 126 days in 2006 for two actions. The Division was taking steps to reduce this average.

Amy Roberts, on behalf of the Biopesticide Industry Alliance, complemented the Division on the success of its Notifications Team, specifically reduction of the backlog and improved response times. She suggested that the standard letter also be sent by e-mail to the applicant to further expedite communications. The template letters were very helpful, and if one was not received, she suggested that the applicant contact the Agency after 30 days to find out the status of their action.

Notifications and Minor Formulation Amendment Processing in the Registration Division

Linda Arrington, Team leader, Notification Team, Registration Division, discussed the changes undertaken by her team in processing notifications and minor formulation amendments (MFA). Changes to the label that could be made by notification included; primary and alternate branch names, packaging changes, storage and disposal statements, use of symbols and graphics, redundant labeling statements, warranty statements, and other minor changes. Changes to the CSF that could be made through notification included; source of the active ingredient (one registered source to another registered source), source of the inert ingredient(s), nominal concentrations (within range), certified limit changes, formulation process, and other minor product chemistry changes as described in PRN 98-10 Minor formulation amendments that could be made by changing the CSF included; 1) Adding, deleting or substituting colorants, (amounts not exceeding 1%), 2) Adding, deleting or substituting fragrances (amounts not exceeding 1%), and 3) Adding, deleting or substituting one or more inerts (carriers, emulsifiers, surfactants, etc.). These were the only three formulation changes that could be made by amendment, though the Agency did receive other CSF changes that had been proposed as MFA and were not.

As of October, 2006, the procedure for processing a notification was
1. The team leader identified which actions were notifications or MFAs and distributed the actions to the team's members weekly,
2. The team member logged the submission into OPPIN,
3. Team member reviewed the submission and then prepared the appropriate response,
4. The letter with the response was reviewed, signed and dated by the team leader and returned to the assigned team member,

5. The team member closed the action out in OPPIN as a completed notification with the date stamped on the letter,
6. The team member mailed the letter and filed a copy along with the notification, and
7. The team leader ran monthly reports when available from OPPIN.

Adapting BPPD's process, an applicant received one of three responses, that the request was within the scope of PRN 98-10 and was a notification; that further investigation was required and the request did not fall within the scope and could be processed as a fast track amendment; or that it was not a notification and had to be withdrawn and then resubmitted as an amendment. CSF with MFA changes were reviewed by the team's chemist to reduce the burden on RD's Technical Review Branch. If the CSF did not quality as a MFA, it was handled as a notification and the registrant was notified. The MFA backlog was rapidly decreasing as a result of this improvement. After training on electronic label review, labels will be compared electronically to reduce processing times. The team was exploring mechanisms to inform registrants when to submit their label modifications electronically.

In response to questions, the goal was to review a notification submission within 30 days and an MFA within 45 days. The standard template letters were not in the correspondence file in OPPIN though such access was being considered. If a registrant had not received a response from the Agency concerning a notification or MFA since October, 2006, the submitter should contact Linda Arrington at (arrington.linda@epa.gov).

Notification Processing Procedures and Hierarchy Project in the Antimicrobials Division

The Antimicrobials Division's notification process was described by Dennis Edwards, Branch Chief, Antimicrobials Division and was consistent with FIFRA section 3(c)(9);

> "Notification and Disapproval – (i) Notification – A registration may be modified under subparagraph (A) if (I) the registrant notifies the Administrator in writing not later than 60 days prior to distribution or sale of a product bearing the modified labeling and (II) the Administrator does not disapprove of the modification under clause (ii)."
> Under clause (ii) "Disapproval – not later than 30 days after receipt of a notification under clause (i), the Administrator may disapprove the modification by sending the registrant notification in writing stating that the proposed language is not acceptable and stating the reasons why the administrator finds the proposed modification unacceptable."

In AD's process, each notification was reviewed to determine if it fell within the scope of PR Notice 98-10 and if it did not, it had to be resubmitted to the Agency as an amendment. A letter was sent to the applicant within 30 days either accepting the notification or rejecting it. Minor formulation changes were not reviewed in 45 days; however, they were reviewed within the timeframe specified in the Food Quality Protection Act of 90 days.

If the Centers for Disease Control (CDC) identified an emerging pathogen, the organism was generally not identified and thereby could not be tested in an efficacy study required under FIFRA for a public health use. To enable products to be marketed against these pathogens and meet the standard for registration under FIFRA, the Antimicobial Division undertook a disinfection hierarchy project in cooperation with CDC. Its purpose was to utilize an organism

hierarchy to identify effective products for use against emerging pathogens and to permit registrants to make limited label statements regarding product efficacy against such pathogens. Only enveloped viruses that had acceptable efficacy data previously reviewed by the Agency (such as for HIV) and only hospital and general disinfectant products registered with EPA would be considered. The product had to have at least one enveloped virus listed on its label prior to a request to add a claim for the emerging enveloped virus. The application would be considered a label amendment and not a PRIA action unless efficacy data was submitted with the application. The Agency expected to complete its review within ten to 30 days and the label amendment would be a one year conditional registration unless otherwise specified by the Agency.

The example of an acceptable label claim presented was "Respiratory illnesses attributable to Severe Acute Respiratory Syndrome ("SARS") are caused by a Corona virus. Product XXX is a broach-spectrum hard surface disinfectant that has been shown to be effective against other similar viruses." An unacceptable label claim would be any claims regarding the emerging pathogen that in any way stated or implied a disease reduction (e.g. reduces the spread of SARS; reduces the transmission of SARS; eliminates SARS cross contamination, etc.).

The Agency was working on a memorandum of understanding with the CDC and the criteria for non-enveloped viruses were under review.

Public Comment

None

Future Activities/Projects, Next Meeting of Workgroup and Pesticide Program Dialogue Committee

Marty Monell announced that the major topic of the next meeting will be information management and information technology and OPP's plans for the future. Areas identified during this meeting included electronic notification which the Agency will consider. Requirements for electronic submission had been developed which was facilitated by the Agency's establishment of a web based portal to receive electronic submission. The pilot project with CropLife involved submissions on a CD and the results of this pilot will be incorporated into the electronic submission project. A major effort and a priority for the program continued to be document management. Participants with suggestions for topics for the next meeting were to e-mail them to Elizabeth Leovey (leovey.elizabeth@epa.gov).

During the next meeting of the PPDC, the workgroup will present a progress report and the Agency will identify a couple of topics to showcase from among the many that have been the subject of workgroup meetings.

For the next workgroup meeting, Greg Watson suggested 1) a report on posting the list of approved inerts, 2) the status of the implementation of e-label review with data on the number submitted, reviewed and not in conformance with submission guidance, and 3) progress on pre-payments through pay.gov. Marty Monell mentioned that the inerts list and e-label review were a high priority for the program and were receiving management attention.

Jim Kunstman observed that there were a number of ongoing electronic labeling projects such as the NPRIS project and electronic distribution and was interested in how these different projects meshed together.

Greg Watson complemented the Agency on the PRIA annual report. The information and summary statistics were appreciated and helpful in developing PRIA II.