Pesticide Program Dialogue Committee PRIA Process Improvement Workgroup

Minutes of September 27, 2007, Meeting

Attending:

Workgroup Members:

Kate Bouve, Information Technology and Resources Management Division (ITRMD), Office of Pesticide Programs (OPP)
Sue Crescenzi, Steptoe and Johnson on behalf of the American Chemistry Council (ACC) Biocides Panel
Ron Derbyshire, JohnsonDiversey
Susan Ferenc, Chemical Producers and Distributors Association (CSPA)
Ted Head, NuFarm
David Jones, Nice-Pak on behalf of International Sanitary Supply Association (ISSA)
Jim Kunstman, PBI/Gordon
Beth Law, substituting for Phil Klein, Consumer Specialty Producers Association (CSPA)
Elizabeth Leovey, OPP
Susan Little, CSPA
Marty Monell, 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 (PPDC)
Greg Watson, Syngenta on behalf of CropLife America (CLA)
Mae Wu, Natural Resources Defense Counsel (NRDC)

Other Participants:

Brian Anderson, Environmental Fate and Effects Division (EFED), OPP
Karen Angulo, Registration Division (RD), OPP
Teung Chin, US Department of Agriculture
Rebecca Clemmer, United Phosphorous Inc.
Mark Corbin, EFED, OPP
Steve Foss, Washington Department of Agriculture
Thomas Harris, RD, OPP
Mel Graven, MS Agro
Eric Johannsen, Washington Department of Agriculture
Cindy Loyd, Dow Agro Sciences
Bob Manfred, BASF Corp.
Debbie McCall, RD, OPP
Daniel O'Byrne, BASF Corp
Dominique Rey-Carruth, ITRMD, OPP

Robert Schultz, ITRMD, OPP
Tam Sheifer, Monsanto
Russ Schneider, Monsanto
Luann Shoemaker, Compliance Services International
Robert Sielaty, ToxCel LLC
Donald Stubbs, RD, OPP
Michelle Thawley, EFED, OPP
Nelson Thurman, EFED, OPP
Wendy Sue Wheeler, Washington Department of Agriculture
Ann Wick, Washington Department of Agriculture on behalf of AAPCO

Agenda

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VI. Recent Advancements in Environmental Exposure and Ecological/Endangered Species Risk Assessment Models and GIS - Update from November 2, 2006, meeting and plans for the future

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Minutes

Introductions and Announcements

After introductions, Marty Monell, Deputy Director, Office of Pesticide Programs, began the meeting by reminding participants of the Pesticide Registration Improvement Act (PRIA) provision on process improvement and that the Pesticide Program Dialogue Committee (PPDC) suggested the workgroup's formation. Since the last meeting on April 10, 2007, PRIA had been

reauthorized with the Pesticide Registration Improvement Renewal Act (PRIA 2) for an additional five years and through the efforts of the PRIA Coalition composed of industry, trade associations, and public interest groups. The process improvement provision was continued under PRIA 2 and expanded to include registration review, the next generation of reregistration. The Agency is required to annually report its recommendations for process improvements in the handling of registration review. During the workgroup's next meeting, expected in spring 2008, topics will include improvements in the registration process and in the registration review and product reregistration programs. Before that meeting, the Agency, with stakeholder input, will identify topics in these programs that would be of interest.

Advancements in Information Technology and Management

Electronic Submission

The Office of Pesticide Program's e-submission pilot was described by Robert Schultz of the Information Technology and Resources Management Division. The Agency's goal was to receive materials and documents in an electronic format, monitor the status of these submissions, and facilitate the exchange of information under the North American Free Trade Act (NAFTA) and as part of joint and shared review efforts with international organizations involved in pesticide regulation such as the Organization for Economic Cooperation and Development (OECD) and the European Union (EU). Once fully implemented, pesticide registrants would be able to submit their applications electronically through a secure portal directly into the Agency's data and tracking systems, and the Agency would then be able to review and distribute these materials electronically to a number of individuals concurrently, and potentially to a number of regulatory authorities. Under the current jackets system, a file can only be viewed by a single individual at a time. Electronic submission is expected to reduce the paper burden on both applicants and the Agency and streamline and increase the efficiency of the Agency's workflow and processes.

The Agency's preliminary approach was to expand the Pest Management Regulatory Agency (PMRA), Canada XML schema while still maintaining PMRA's naming conventions. Initially, submission would be by CD or DVD, with a zip file containing XML files and attachments. Guidance and a data dictionary would be provided by the Agency. An initial step was to conduct a pilot or "proof of concept" of the methodology and validate the benefits to submitters and the ability to exchange information with PMRA. The pilot also served to identify potential logic issues in the process, technical issues, and issues with OPP's existing processes.

Five registrants volunteered for the pilot, and of the seven submissions received, six were completed successfully. The submissions involved FIFRA Section 3 registrations, Experimental Use applications, and distributor products. Eventually, tolerance petitions will be another category of applications submitted electronically. Section 18s and SLNs were expected to be submitted in paper format. In the pilot, both paper and electronic versions were submitted of all materials, and the Agency coordinated the submissions. Issues in formatting of data, vocabulary, and the data dictionary indicated the need for additional guidance documents and style sheets. The pilot demonstrated that pre-assigned MRIDs and the ability to reference previous studies were required. Additional harmonization with PMRA and expansion of OPP's systems were

required to support the OECD and Canada's DACO identification scheme. Some supporting documents were submitted that may be required by other regulatory agencies though not required by EPA. The manner in which these documents were treated with regard to PRN 86-5 needed to be resolved.

The Agency anticipated implementation of electronic submission in early 2008, with documents submitted on either CD or DVD. Eventually, submissions will be received by transferring files through EPA's Central Data Exchange (CDX). Further in the future, a stand-alone application is expected that will help applicants create their XML files that will be harmonized with Canada's e-index builder and application package. After the Agency receives an application package, applicants will be able to monitor the status of their submission through the Web interface. Long term, an interactive system is anticipated that allows registrants to develop and submit their labels and Confidential Statements of Formula (CSFs) on-line. The CSF is expected to be an XML mark-up of the form. Immediate feedback would be provided to the user to avoid common mistakes. Harmonization with OECD and the CADDY XML system would be pursued.

Julie Spagnoli suggested that a translation function be available, as many retail outlets now require bilingual labels and asked whether paper copies will still be required. The Agency will consider this suggestion. The e-label tool was expected to help applicants avoid common errors such as the appropriate signal word through a series of questions. The Agency's 86-5 workgroup will discuss with its legal counsel the issue of whether a paper copy is required. An amendment to the regulation may be required.

Greg Watson emphasized that due to the time lag between development and submission of a study, and in the interest of harmonization, submission templates need to be developed soon. Mr. Schultz commented that at present the project is focused on harmonization of the software and the ability to share documents electronically between regulatory agencies. The Agency's priority was that any form of electronic submission could be accepted by its systems.

Mr. Watson reminded the workgroup that a priority process improvement for industry was the communication of milestones and requested an update on the status of this effort during the next workgroup meeting. Marty Monell reported that the Agency's priority was the second phase of PRISM and increased efficiency in processing registration actions. Communicating with registrants on the status of their submissions would be done; however, there was a timing issue. Mr. Watson suggested that the topic be addressed again during the next meeting of the workgroup.

PRIA Improvements – Fee Determination Tool

Dominique Rey-Carruth, Information Technology and Resource Management Division, demonstrated the Agency's PRIA Fee Determination Tool and described the results of a usability test conducted prior to this meeting. The tool is Web based and publicly available. It allows pesticide registration applicants to identify the correct type of their application, its fee category, and the amount of its fee through a series of questions and then to pay the fee prior to submitting the application to the Agency.

The usability test was conducted to identify any issues with the tool and determine its ease of use, level of user satisfaction, and general quality. Participants were eight registrants and others interested in the registration process. They commented that at times, there was a slight confusion about the use of the "select" button versus the hyperlinks to make a selection to move to the next question; however, once users navigated past the first question, the system became easier to use. Users requested that a fee category's decision review timeframe be displayed, and the Agency will consider this suggestion for future versions. The suggestion to link to the criteria for 50% and 75% fee waivers will be implemented. Additional definitions will be developed, for instance for inerts and food uses. Ms. Rey-Carruth will send the participants an e-mail listing their suggestions. In answering the usability questionnaire, four of the eight found it easy to use and four found it somewhat easy to use and in response to a question on satisfaction, three were very satisfied with the tool, four satisfied and one was somewhat satisfied. Participants recommended that the Agency implement the tool for PRIA 2.

In response to questions, the fee category PDF link led to a diagram of the decision tree and a list of all 140 PRIA 2 fee categories. Marty Monell reported that in a meeting of the PRIA Coalition in the morning, the feedback that the Agency received was that the tool was well received and that it should become publicly available the next week. Subsequent versions will be issued based on user feedback. Jim Kunstman commented that it was a nice system that will help the inexperienced applicant and would be appreciated.

Electronic Label Review

An update was provided by Thomas Harris, Registration Division, on the Agency's process in implementing electronic label review. Electronic labels submitted by applicants are being tracked in the Agency's systems, compared to past labels electronically to quickly identify revisions, and easily commented upon electronically by Agency staff with any corrections that need to be made. Applicants submit both paper and an electronic copy on a CD in a text PDF format with an affidavit that the electronic and paper copies were identical. Agency comments are e-mailed to the registrant and registrants can e-mail corrections directly to the label reviewer, which further speeds up the process.

As in past workgroup meetings, the need to name the file correctly, submit only in text.PDF, embed all fonts and avoid mark-ups and columns was again emphasized. The Agency expects to update the pilot guidance. When this project began, approximately 50% of e-labels submitted had incorrect file names. As a result of outreach efforts, this was reduced to 10 to 15% by September 2007. Labels with incorrect file names and even minor mistakes in the file name can not be entered into the Agency's tracking systems and therefore can not be electronically reviewed. Before submitting an e-label, applicants are advised to conduct their own e-label comparison to determine whether the Agency will have any problems with the file. Although, the number of e-labels submitted has increased, the number represents only a fraction of labels submitted and this has hindered the program's implementation. All regulatory staff have been trained in using the software and are adapting to the software as they have labels to review. Agency management strongly supports e-labels. With increased submissions and individual coaching, the Agency anticipates full implementation and greater efficiency in the label review process. The success of this effort, however, relies upon applicant submissions.

In response to questions from Julie Spagnoli and Sue Crescenzi, Mr. Harris stated that the first time an e-label is submitted it can be the proposed label as it is compared to past paper copies. Consequently, if previous labels were approved with comment, e-label review would accommodate such labels. Once changes were identified, Agency reviewers can determine whether they were made through notifications or amendments. To benefit from this effort, future labels have to be submitted electronically. Jim Kunstman asked about dating files. Mr. Harris responded that the date of the file can be used to differentiate different versions and if as a result of prompt e-mail responses, more than one version is generated on a single day, there is a field to denote the version. In response to Mr. Kunstman's question as to whether staffs are using the system, Mr. Harris responded that an issue for staff is learning and then entering the administrative information that enables the Agency to maintain and track e-labels. Don Stubbs encouraged registrants to submit e-labels. If submitted, he stated that the Agency will work with staff and have the labels reviewed electronically.

In response to a question from Mr. Watson on implementation in product reregistration, Mr. Harris noted that labels for conventional products are approved by the Registration Division and in fact many e-labels that he has reviewed were for product reregistration.

Marty Monell, in response to a question as to whether there were differences between the registering divisions in the implementation of e-label review, commented that the Agency will provide such information during the next workgroup meeting. Ms. Monell thanked Warren Stickle for his interest in e-label review. Mr. Stickle, recently deceased, advocated its implementation and, as a result of his interest, PRIA 2 contained two provisions requiring the Agency to report on its progress in implementing this program.

Labeling Committee

Labeling has always been of interest to the workgroup, and Donald Stubbs, Associate Director, Registration Division and Chair of OPP's Labeling Committee, reported on the status of the Committee's e-mail box, its Web site and follow-up to recommendations from the workgroup, updates to the Label Review Manual (LRM), and current projects. The Committee serves as clearinghouse for broad cross-program labeling issues and its members represent all of the regulatory divisions, the Office of Enforcement Compliance and Assurance, and the Office of General Counsel. As of September 6, the e-mail box (http://www.epa.gov/pesticides/regulating/labels/label_review_faq.htm) on the Committee's Web site (http://www.epa.gov/pesticides/regulating/labels/label_review.htm) had received 122 questions, of which 110 had been answered and 12 were being addressed. Answers were posted for 69 and the other 41 were referred elsewhere for answers since they were questions related to specific products or pesticides. Questions were organized into categories on the site, with topics that ranged from antimicrobial claims to containers. The main page of the Web site averaged 892 "hits" (individuals accessing the Web page) per month, the question and answer page averaged approximately 684, and the LRM (http://www.epa.gov/oppfead1/labeling/lrm/) averaged 921. The number of "hits" per month generally appeared to be constant, though a spike in "hits" was observed when new revised LRM chapters were posted. Based on recommendations from the PPDC workgroup, new answers contained the date of posting and

new items were identified with the word "New" in yellow for 30 days. Pages could be searched by "key words."

The Label Review Manual subgroup is converting the document from WordPerfect to Word and making minor corrections. As of September 2007 six chapters had been posted, Chapters 11 and 12 were being reviewed by the Labeling Committee, and Chapters 7 and 9 were expected to be posted shortly after the meeting.

Among the projects undertaken by the Committee was a review of the recommendations of the PPDC Consumer Pesticide labeling Improvement Workgroup on labeling outdoor residential products. The Committee made some minor changes and expected to publish an FR Notice announcing the availability of a PR Notice with a request for public comment. The products covered by the draft Notice included liquid concentrates, broadcast granulars, dusts, and liquid ready to use. A draft PR Notice was being circulated, and the FR Notice on cause marketing was expected to be published prior to the next meeting of the full PPDC.

Jim Kunstman commented that the PR Notice on labeling outdoor residential products will be helpful and that it was important for it to be implemented in reregistration and product reregistration. Mr. Watson noted that the Committee's response on supplemental labeling was surprising (http://www.epa.gov/pesticides/regulating/labels/label_review_faq.htm#supplemental) and that he appreciated the changes made to the Web site.

Inerts

Karen Angulo, Inert Ingredients Assessment Branch, Registration Division summarized the status of improvements to the inerts petition process, the Confidential Statements of Formula (CSFs) review process, and updates to the inerts lists in the Code of Federal Regulations (CFR) and on EPA's Web site, the revoked tolerance exemptions, and the fragrance notification pilot. As a process improvement, food use inert Notice of Filings are reviewed before publication to identify problems early in the review process. Problems such as incorrect chemical identifiers and missing data have been observed. The submitter or petitioner is informed of the issues and given the option of identifying other data, generating new data, or withdrawing the petition. This process has resulted in voluntary withdrawal of over 20 petitions and a substantial savings in the Agency's resources. Once a risk assessment is completed and the final rule published, the assessment is placed in the public docket and on OPP's inert Web site.

To assure that inert requests submitted for Agency approval are complete, petitioners are encouraged to consult the Agency before submission. To facilitate this consultation process, petitioners are encouraged to send a brief overview of the chemical to the Inert Ingredient Assessment Branch with a description of the requested use, the physical/chemical properties of the chemical, the available environmental fate, human and ecological toxicity data, and its exposure potential. Petitioners are then advised to schedule a meeting either in person or over the telephone. The Agency can then identify any data gaps or areas of concern and next steps during the consultation.

The Branch had a pilot within RD to screen all new CSFs to identify those submissions with

problems with inert ingredients. As of September 2007, approximately one-third of all CSFs had problems that included mismatches between the CAS number and the chemical name, the trade name and chemical name. In addition, non-food use or unapproved inerts were listed for food-use products and inerts were listed that are not allowed for the proposed use.

As a result of the Agency's experience with the pilot process, a permanent CSF screening process was developed within RD. As of this meeting, registrants are notified if their CSFs list unapproved inerts. Many of the problems are easily corrected -- for instance, incorrect CAS number or chemical, trade, alternate chemical, or mixture name. More difficult problems require a tolerance petition, reformulation, or an Agency initiated exemption. Options are discussed with the applicant on the best approach to correct the problems. The Agency had observed that many of the problems were due to the applicant's lack of understanding of how inerts are regulated, including use limitations. Increased understanding was needed of the differences between food and non-food uses, the existence of restrictions, the mixture clearance process, and how to correctly complete a CSF.

The inerts Web site and the Code of Federal Regulations (CFR) are being updated. The CAS number will be added to all inert tolerances, and exemptions, and non-food inerts. A new list of non-food inerts is available. A proposed rule to correct a number of other administrative errors in the CFR and a process to add CAS numbers to listings is being developed. This could solve many of the problems applicants have had identifying an inert or determining if an inert is approved. The Agency intends to modernize the inerts Web site. In the future, guidance on petitions and requests for approval of non-food use inerts, risk assessment documents, a list of non-food inerts with CAS numbers, and links to the electronic CFR for food use inerts and the list of inerts eligible for USDA's National Organic Program are expected. A "What's New" section will contain information on new inert activities over the preceding several months. Furthermore, the Agency is seeking suggestions for the making this site more helpful and user friendly and those with suggestions should contact Ms. Angulo.

As a result of tolerance reassessment, approximately 130 inert tolerance exemptions are to expire August 2008 unless the inert is supported, i.e. data submitted permitting reinstatement or development of a new exemption. The Agency has received a number of data development commitment letters and more are expected. Data has been submitted for a few exemptions. Some studies are under way and many are being initiated. The Agency expects to publish a list of tolerance exemptions being supported in the Federal Register (FR). Reinstatement of an exemption or a new exemption requires submission of a petition with a draft Notice of Filing. After publication in the FR, the public may comment on the Notice.

The results of the fragrance notification pilot are being evaluated, and additional information will be provided during the next meeting of the workgroup. This pilot ran from May to August 2007. Its goals were to streamline the fragrance approval process for antimicrobial products and to determine whether the notifications process could be used to approve a new fragrance, as suggested by the Fragrance Manufacturers' Association. The fragrances considered for this pilot notification process had to contain chemicals already approved by the Agency and on the Fragrance Manufacturers Association's list of fragrance components posted on the Agency's Web site. In addition, the notification could involve only a change in fragrance. Among the

issues identified in the pilot were that not all chemicals were listed and similar submissions from fragrance houses and registrants were inconsistent.

In response to questions, Ms. Angulo reported that the Agency anticipates posting the list of approved inerts on the Web in January. It will contain two lists. The one for food uses would be a link to the electronic CFR and the other would be a list of non-food use inerts. Regarding CFR modifications, the tolerance expression will not be changed and only the CAS number will be added under the name of a chemical. Ms. Angulo observed that revising the CFR proved to be more challenging than anticipated because previous versions of the CFR had to be referenced to obtain the full history of a tolerance expression. The previous lists categorizing inerts into groups 1, 2, etc., will be removed from the Web site.

Regarding publicly available inert lists, data owners will not be listed nor will components of a mixture. All components of a mixture such as a fragrance must be approved for the use, and only the mixture's manufacturer and the Agency will know the identity of its individual components. A participant suggested that since manufacturers tended to change the names of their mixtures routinely that mixtures be numbered for easy reference.

Jim Kunstman suggested that the section in the proposed blue book on inerts be expanded to include additional guidance on what to submit and how to use the e-CFR. The next version will provide this additional information, according to Ms. Angulo.

Mr. Watson recommended that the Agency publish the list of revoked tolerances as soon as possible and mentioned that an Inert Task Force had been formed to develop the data to support these inerts. He also thought that CAS numbers should not be published in the CFR because CFR changes requires rule making and publication on the Web was a better approach.

Recent Advancements in Environmental Exposure and Ecological/Endangered Species Risk Assessment Models and GIS

The Environmental Fate and Effects Division (EFED) updated the workgroup on its model and Geographical Informational Systems (GIS) advancements since the November 2006 meeting. Brian Andersen, EFED, discussed the terrestrial, aquatic, and probabilistic models, while Michelle Thawley provided the update on GIS. The Terrestrial Residue Exposure Model (T-REX) (http://www.epa.gov/oppefed1/models/terrestrial/trex_usersguide.htm) is a terrestrial exposure model that estimates pesticide residue concentrations on various food items, estimates daily doses to terrestrial animals that consume the food items, and then calculates risk quotients and LD50/ft2 for a risk assessment. The latest updates include (1) addition of a summary table that includes risk quotients and exposure and toxicity values and (2) addition of calculations used to more fully characterize risks from the application of granular pesticide formulations. Specific calculations include the number of granules that need to be consumed to result in a dose equivalent to the LD50 and the foraging area needed to result in a potential risk assuming various feeding efficiencies. The model allows consistent presentation of risk quotients in risk assessments and consistent and rapid characterization of risk from granulars.

Birds are generally used as surrogates in assessing risks to reptiles and terrestrial amphibians. T-REX was modified to reduce the uncertainties in estimates of exposure to these reptiles and amphibians. The modified model, T-HERPS (Terrestrial Herpatofaunal Exposure and Risk Program Simulation), addresses differences in diet and dietary intake and provides risk estimates in a rapid and consistent manner. This model is undergoing an internal quality assurance/quality control process and was used in an endangered species assessment for the red-legged frog.

A bioaccumulation model, KABAM (KOW based Bioaccumulation Model), estimates body burden of bioaccumulative pesticides in aquatic organisms that may be used to estimate potential exposures and risks to aquatic and terrestrial animals that feed on aquatic organisms. The model estimates tissue levels in aquatic animals and plants and the risk to terrestrial animals that then feed upon aquatic animals and plants. Bioaccumulation data and methodology from the peer review literature have been incorporated into the KABAM model and the model allows consistent estimates of risk to birds and mammals consuming aquatic organisms. This model is expected to be released in a year after a quality assurance/quality control process has been completed.

As for human risk assessments, in estimating exposures to wildlife, all sources of exposure must be considered, including drinking water. The Wildlife Drinking Water Exposure Model estimates exposure to terrestrial animals from the consumption of pesticide-contaminated water in puddles or dew. The model uses estimates of drinking water intake of mammals and birds coupled with a modification of EFED's rice model that estimates pesticide levels in puddles to estimate risk. The model is coupled with the Kenaga nomogram to estimate residues on foliage and a two-compartment equilibrium model to estimate exposure to pesticides contained in dew for purposes of estimating risk. Risk quotients are calculated based on dose-related estimated environmental concentrations of the pesticide and its significant metabolites in water and adjusted LD50s. This is a screening level tool that addresses uncertainty in risk estimates due to water consumption. This model is also expected to be released in a year after a quality assurance/quality control process has been completed.

The Terrestrial Investigation Model (TIM) is a probabilistic model that characterizes the likelihood and magnitude of pesticide effects to birds and has been updated following recommendations from the FIFRA Scientific Advisory Panel. A Monte Carlo approach is used to estimate avian acute mortality associated with pesticide applications by following 10,000 birds for a specified number of days. It accounts for variability and uncertainty by using distributions instead of point estimates for body weight, residues, etc. The output includes the probability of mortality. Recent updates include additional exposure routes, modified drinking water component, hourly time steps, and the ability to model multiple applications. The likelihood and magnitude of effects, variability of a number of parameters, and relative uncertainty of the estimates are expected to better inform risk managers of potential risks.

A probabilistic model, Surface Water Assessment Model for Pesticides (SWAMP), is being developed to provide estimates of the likelihood and magnitude of effects and the uncertainty of the effects and to characterize temporal variations in risk to aquatic organisms. In previous workgroup meetings, EFED mentioned that it was improving its aquatic models and was working on collapsing all components of an aquatic risk assessment into one software package

such that data would only have to be inputted once. This modification has been made to improve efficiency and the ability to track data and analyses.

A comparison was provided of the differences between Level I and Level II aquatic models. Level 1 involves specific use/site scenarios and point estimates, while Level II models are probabilistic and provide estimates of the probability and magnitude of risk, i.e., 20% of species would be affected 10% of the time.

Structure	Level I	Level II
Field Runoff	PRZM (Tier II)	PRZM
Field Drainage Area	10 ha	10 ha
Surface Water Dimensions	Depth: 2 meters Surface area: 1 ha Volume: 20,000 m3	Crop scenario specific
Surface Water Model	EXAMS (Tier II) - Fixed volume - No overflow/outflow - No evaporation	VVWM - Varying volume - Overflow - Evaporation
Drainage area to Volume Capacity	5 m2/m3 (1.5 acre/acre-ft)	Crop scenario specific
EECs used in risk estimates	90th percentile of annual maxima values	Full distribution
Species Sensitivity	Most sensitive	Distribution
Effect	Acute: point estimate (e.g., 96-h LC50)	Acute: Concentration-response distribution

Among the tier 1 models, the rice model has been recalibrated for ecological exposure and to evaluate drinking water exposure. PRZM has been updated to model crop irrigation and the shell (PE 5) revised to simultaneously run multiple initial application dates.

These revisions to the aquatic models are essential in moving from a scenario-based approach to generating spatially explicit exposure estimates in which exposure, particularly stressor distributions, are mapped across a landscape and compared with the range of the receptor to determine those areas in which a level of concern is exceeded. Michelle Thawley provided a summary of the improvements the Agency has made in its GIS capacity since the November 2006 meeting of the workgroup.

Under the Agency's "Big Decisions" project, a geospatial data repository is being developed that will include all publicly available Federal spatial datasets relevant to the assessments conducted by the Agency. It is being maintained in EPA's National Computing Center in Research Triangle Park, NC and directly accessible from GIS software as of September 2007.

Since November 2006 a prototype spatial aquatic modeling tool has been developed. A prototype national turf land use data set has been developed and will continue to be improved.

EFED is continuing to incorporate use of the National Hydrographic Plus Dataset (NHD+) as a modeling framework. The basin delineation component of the NHD+ was delivered in September 2007. With this tool, a catchment basin is automatically drawn upstream from a point such as a drinking water source. Also delivered in September 2007 were two additional NHD+-based data analysis tools designed to allow EFED to incorporate pesticide and/or land use information into a watershed-based analysis.

Improvements in the drinking water intake data include quality assurance and quality control of the SDWIS database. Drinking water intakes are being indexed to NHD+ and associated basins are being delineated. The next step is to complete the quality assurance/quality control effort related to indexing and catchment delineation through a cooperative effort with the USGS, anticipated to be completed in the fall of 2007.

Workgroup members and participants were encouraged to contact the following EFED staff if they had any additional questions. TREX & T-HERPS - Brian Anderson – anderson.brian@epa.gov ; KABAM – Kristina Garber – garber.kristina@epa.gov ; Wildlife Drinking Water Exposure – Shannon Borges – borges.shannon@epa.gov ; TIM – Ed Odenkirchen odenkirchen.edward@epa.gov ; Chris Salice - salice.christopher@epa.gov; SWAMP – Donna Randall – randall.donna@epa.gov ; Aquatic Models – Greg Orrick – orrick.greg@epa.gov ; Spatial Models – Michelle Thawley – thawley.michelle@epa.gov .

Sue Crescenzi inquired whether the data repository is publicly available. It is only available to Agency staff. The Agency's understanding is that industry groups have compiled their own databases using the same federally available datasets. The NHD+ is publicly available on the U.S. Geological Survey's Web site, and its tools will also become accessible. In response to Julie Spagnoli's question on use maps, Ms. Thawley responded that EFED obtains its own information from the Biological and Economic Analysis Division, OPP and it generally consists of NASS usage data that combined with cropping information is used to generate use maps. She encouraged registrants to submit such data if available. Maps of species locations are not available in a central repository. The data is obtained by the Agency from the Fish and Wildlife Service and NOAA on a species-by-species basis.

Mr. Watson commented that under FQPA, the Agency developed Standard Operating Procedures for human health risk assessments and the same effort was needed for modeling so stakeholders would be able to understand what was being done. The Agency's models, once ready, are reviewed by the FIFRA Scientific Advisory Panel.

Sue Crescenzi mentioned that a task force is conducting modeling for the reregistration of copper and asked where the modeling expertise was located within the Pesticide Program. Mr. Thawley responded that EFED takes the lead in aquatic modeling and has the data sets to support it. The Division would be willing to discuss the copper modeling effort with the task force.

In response to a question from Russ Schnieder on the validation of PRZM, Ms. Thawley reported that software was independently evaluated. The NHD+ was validated by USGS, and all tools developed by or for the program undergo a quality assurance/quality control review followed by a public review in a FIFRA Scientific Advisory Panel meeting. She mentioned in answer to

another question that spatial data has its own issues and needs to be considered in the context of how it will be used.

Public Comment

The issue of how to submit task force data was raised since OPP's data systems are designed to track registrant-specific submissions. The task force was given a company number to allow these data systems to track any information submitted by a task force in the Office of Pesticide Programs Information Network (OPPIN).

Small businesses have expressed a concern about that 25% of the PRIA fee that is non-refundable if the Agency rejects an application for content incompleteness, according to CSPA. CSPA suggested that the Agency provide information on the Web and through seminars or workshops to help applicants develop complete applications. Ms. Monell responded that the topic is being discussed with the PRIA Coalition. A workshop is contemplated and when information is available, it will be posted to the Internet. She encouraged trade associations to help their members with their applications. A suggestion was made to Web cast any workshops to make it convenient for small businesses to participate.

The next PPDC meeting will be October 17 and 18, 2007, and the workgroup will present a report. Marty Monell requested that members forward their suggested topics to Elizabeth Leovey and thanked everyone present and on the teleconference for participating in the meeting.