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MEMORANDUM

Via E-Mail

DATE: June 10, 2008

TO: Firm Clients and Friends

FROM: Bergeson & Campbell, P.C.

RE: PPDC Holds Its Semiannual Meeting

On May 21 and May 22, 2008, the Pesticide Program Dialogue Committee (PPDC) held its semiannual meeting in the U.S. Environmental Protection Agency (EPA) offices in Arlington, Virginia. This memorandum summarizes the presentations and topics discussed during the meeting. Copies of the slides and the handouts from the meeting are available upon request. Most of the slides also are available at <http://www.epa.gov/oppfead1/cb/ppdc/2008/may2008/may08.htm>.

A New Toxicology Testing Paradigm

Vicki Dellarco, Senior Science Advisor in the Office of Pesticide Program (OPP) and Steven Bradbury, Director of the Special Review and Reregistration Division (SRRD) presented EPA's response to the National Academy of Sciences' (NAS) 2007 report on *Toxicity Testing in the 21st Century*. This report recommends that toxicity testing move from purely "*in vivo*" testing to a regimen that includes "*in vitro*" testing and "*in silico*" (computer models) to make predictions for "*in vivo*" outcomes and guide more targeted animal testing. The goals of the new toxicity paradigm are:

- Use of fewer animals and less suffering for those animals used;
- Broader coverage of chemicals, end points, and life stages;
- Reduction of cost and time of testing with an increase in efficiency and flexibility; and
- Establishment of a more robust scientific basis for utilizing "*in vitro*" results in the regulatory process by providing modes of action and dosimetry information.



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Dellarco stated moving from “*in vivo*” testing to “*in vitro*” and “*in silico*” requires de-constructing the organism and then rebuilding it. Information databases are needed to look at molecular structures and the relativity of those structures at the molecular, cellular, organ and individual levels. The conversion from the present “*in vivo*” paradigm to the new paradigm will take many years to accomplish, according to Dellarco, because of the need to understand all the toxicity pathways and the effects of alternate pathways on the manifestation of toxicity. She further stated that much research and work needs to be carried out before the new toxicity paradigm is fully accepted and that it will require a sustained effort over many years. To begin the process of accepting the new toxicity paradigm, EPA and OPP have undertaken various activities:

- EPA has established and charged a cross-agency work group, the Future of Toxicity Testing Workgroup (FTTW) to develop an EPA strategy that will serve as a blueprint for ensuring a leadership role for EPA in pursuing the directions and recommendations of the National Research Council (NRC).
- EPA is promoting use of existing expert tools, such as Quantitative Structure Activity Relationship (QSAR) and others.
- OPP is developing a searchable relational database of all the toxicity data capturing effects and endpoints.
- OPP is carrying out retrospective analyses of data previously submitted to determine whether changes can be made to the protocols (*e.g.*, length of study, number of animals, etc.).

Bradbury presented the issues he believes EPA faces in moving towards the new paradigm. He acknowledged that there is a deluge of data that needs to be captured to allow the scientific and regulatory community to utilize fully the expert tools to arrive at the correct toxicity assessment. This process will be evolving, and will involve case studies, peer review, collaboration with international partners and other federal agencies, and the engagement of the stakeholders. EPA is partnering with international agencies on technology-based, hypothesis-driven effort to build capacity to prioritize, screen, and evaluate chemicals. EPA is assessing a proposal to establish a PPDC Workgroup on the New Toxicology Test Programs. The purposes of such a work group would be to:

- Improve understanding of the perspectives of all stakeholders regarding the new testing program;



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- Ensure input on key science products;
- Develop a common understanding for appropriate use of the new science and tools; and
- Provide advice to EPA (including how to best communicate this complex science to the general public).

Labeling Overview

Anne Lindsay, Deputy Director for OPP, presented an overview of OPP's labeling improvement initiatives. According to Lindsay, OPP recognizes that the present system of relying on paper-based labeling to convey its regulatory language is antiquated and conflicted. OPP realizes that the paper-based label system is labor intensive and slow to convey regulatory needs, often resulting in conflicting labels due to changing standards of acceptability. Today's pesticide labels, Lindsay stated, are too long and contain unenforceable, ambiguous, and/or inconsistent language. She further stated that the process of changing paper labeling is difficult and slow, leading to confusing and unclear labeling. In an attempt to solve the issues OPP believes to be associated with labeling, OPP has initiated a number of initiatives, which fall into three general categories: (1) electronic submission and review; (2) systematical improvement of content; and (3) electronic dissemination of labeling.

In the electronic submission and review category, OPP is working to develop a database system that will capture all the elements of an approved label and support label building software. OPP expects the electronic submission of labeling will replace the cumbersome "by hand" process, which will result in quicker routing of applications within OPP and allow automatic comparison with the prior version of the approved labeling, thereby resulting in a simpler, more efficient review and approval.

OPP has received feedback from many stakeholders (*e.g.*, advocacy groups, regulated industry, user groups, etc.) regarding problems with the content of current labels and the label review process, as well as proposed resolutions for these problems. To resolve many identified procedural problems, these stakeholders have recommended that OPP update and expand the Label Review Manual, develop a framework for quality assurance, establish mechanisms for priority setting, and increase the present stakeholder involvement. OPP also has a number of ongoing labeling-content initiatives that will result in proposed labeling improvement recommendations in the areas of spray drift, fumigation, mosquito control, and global harmonization, among others.



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According to Lindsay, electronic dissemination of labeling using a web-based system appears to be a promising vehicle for resolving the problems of conflicting language and slow communications in current regulatory labeling decisionmaking. Such a system would require a uniform resource locator (URL) address to be placed on the label. The electronic label could replace the Direction for Use on the physical container. Distributors, purchasers, or users would visit EPA's website to obtain a copy of the labeling. This label would be approved for a specified duration (*e.g.*, 6 to 18 months) from the date of printing. The archival system would allow verification of the version of the labeling posted on any date.

Lindsay indicated that the electronic submission and review is already under way in a simplistic form and a more elaborate form is anticipated after 2009. Activities to improve labeling content will begin this coming Spring 2009, with a pilot web distribution of labeling program anticipated to begin in 2009 and to be expanded in 2010 and in 2011.

Web-Based Labeling

Bill Jordan, Senior Policy Advisor in OPP, discussed the web distribution of electronic labeling. This system would make the current version of pesticide labeling available to purchasers and users electronically on an EPA maintained website. The system may allow for a more simplified label on the pesticide container and for rapid updating of the labeling. In developing this system, OPP has engaged a broad group of stakeholders to obtain their comments and has set up an internal EPA work group with state representation. There are a number of issues that are being considered in developing this system: state synchronicity; user, dealer, and registrant culture change; website host; container label language; mechanics of distribution; lifespan of label; database structure; and quality assurance. It is anticipated that a pilot program will begin in 2009 or shortly thereafter.

Endocrine Disruptors

Bradbury presented an update on the endocrine disruptors test assay validation. The endocrine disruptor program was mandated by the Food Quality Protection Act (FQPA), which required EPA to develop an endocrine screening program using validated assays to test pesticide active ingredients, pesticidal inerts, and certain chemicals found in water for estrogenic effects that may affect human health. In 1998, EPA adopted the recommendation of the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) for a two-tiered testing program that addressed estrogen, androgen, and thyroid effects in humans and wildlife and set priorities for chemicals to be tested.



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The two tier approach for testing included:

- Tier 1 -- *in vitro* and *in vivo* testing to detect potential to interact with the endocrine system; and
- Tier 2 -- multi-generation studies covering a broad range of taxa to provide data for hazard assessment.

For Tier 1, peer review has been completed for uterotrophic, Hershberger, adult male, female pubertal, male pubertal, AR binding, aromatase, amphibian metamorphosis, fish screen, steroidogenesis, and ER binding. The Scientific Advisory Panel (SAP) has reviewed the proposed Endocrine Disruptor Screening Program (EDSP) Tier 1 Screening Battery in March of this year and the SAP comments are expected later this year.

The Tier 2 assays are partially complete. The mammalian two-generation study is complete. The avian two-generation, the amphibial growth/reproduction study, fish two-generation, and mysid two-generation are not expected to be fully tested until 2010.

EPA anticipates, upon Office of Management and Budget (OMB) approval, the first orders for Tier 1 testing to be issued in August of this year.

Inert Ingredient Activities

P.V. Shah, Acting Branch Chief of the Inert Ingredient Assessment Branch (IIAB) in the Registration Division (RD) of OPP, reviewed IIAB's activities for 2008:

- ***Petitions for Inert Ingredients:***
 - 35 petitions are under review;
 - 10 food-use petitions have been approved to date;
 - 11 non-food-use inerts have been approved to date; and
 - 14 old petitions for food-use inerts have been voluntarily withdrawn.

EPA's inerts website has been updated to list all the approved inert ingredients, e-CFRs for locating food-use tolerance exemptions, all non-food listing of inerts,



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consolidation of Section 25(b) inert ingredients listing, and links to the United States Department of Agriculture's National Organic Program listing.

- ***Tolerance Revocation Update:*** On August 9, 2006, EPA proposed a notice to revoke 123 tolerance exemptions; exemptions are to expire on August 9, 2008, unless industry committed to supporting them with data. Also, on November 2, 2007, EPA published a notice indicating that 64 inert ingredients were being supported and 59 were not being supported.

EPA is working with a Joint Inert Ingredient Task Force, which is developing data in support of certain tolerance exemptions proposed for revocation due to lack of data. EPA will extend the revocation date for those inert ingredients where clear evidence exists that they are being supported. EPA anticipates publishing new tolerance exemptions for the supported chemicals that meet the FQPA standard of safety by August 9, 2009.

- ***Data Compensation for Inert Ingredients:*** FQPA provides for data compensation for food-use inert ingredients. An advance notice of proposed rulemaking for compensation of inert ingredients is expected to be published in the *Federal Register* by the end of the year. An Inert Ingredient Data Submitters List is being developed and will be circulated for comments. EPA has developed internal procedures for implementation of data compensation for food-use inert ingredients.
- ***Inert Disclosure on Pesticide Labels:*** In August 2006, 14 states and 22 environmental and health groups filed petitions with EPA for disclosure on pesticide labels of certain inert ingredients listed as hazardous under various authorities. OPP has been working with the Office of General Counsel to investigate the cited environmental statutes and standards used for such listing to determine consistency with Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authority.

Global Harmonization and International Activities

Lois Rossi, Director of RD, OPP, presented an update on the activities taking place internationally. Rossi stated that OPP has taken a leadership role in promoting joint registration reviews and harmonization efforts, to identify opportunities for collaboration and cooperation, and to promote dialogue between regulatory authorities and among all stakeholders. OPP's goal is getting reduced risk pesticides registered in multiple global markets and listed in



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international standards, such as Codex. Opportunities to achieve this goal arise from OPP's work with the Organization for Economic Cooperation and Development (OECD), under the North American Free Trade Agreement (NAFTA), through bilateral collaborations, and work on international committees. Information on the international efforts is available at <http://www.epa.gov/oppfead1/international>.

Rossi reviewed specific activities with Canada and Mexico under NAFTA. There have been four NAFTA labels approved, and more than nine additional products under review. She indicated that OPP is also working with Japan, Brazil, China, and Taiwan on sharing reviews and minimum residue level (MRL) documents. The issues and problems associated with these efforts are shared with other regulatory agencies in international committees on pesticide registration and MRLs.

Reregistration and Registration Review Overview

Bradbury discussed the activities taking place under the reregistration process and how those activities will change under the new review process mandated by FIFRA. Under the present reregistration process, OPP had completed 97 percent of all the reregistration cases: 366 Reregistration Eligibility Decisions (RED) are completed, 229 chemicals have been cancelled and 18 REDs are scheduled to be completed by October 3, 2008, deadline given in the Pesticide Registration Improvement Renewal Act (PRIA 2).

Under FQPA, OPP is required to review every established tolerance. In the last 10 years, OPP has reassessed 9,721 tolerances to ensure that all approved tolerances meet the new Federal Food, Drug, and Cosmetic Act (FFDCA) safety standard. This tolerance reassessment was completed in September 2007 and related risk management decisions are being implemented. OPP also reassessed the cumulative risk assessments for four groups of chemicals with common mechanisms of toxicity. These four groups are organophosphates (OP), N-methylcarbamates, triazines, and chloroacetanilides. Bradbury indicated that RED follow up and reregistration should be completed by 2014.

As a result of these extensive reviews, EPA has achieved significant enhancements in human health and environmental protection, according to Bradbury. Many OPs and other pesticides posing risk concerns have been voluntarily cancelled and/or their uses are being phased out. The reviews have resulted in elimination of many pesticide uses having unacceptable levels of residential or dietary risks, especially for children, and improvement to worker safety, as well as addressed important ecological risk concerns.



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A relatively new EPA program implementing FQPA requirements is the registration review program, which requires periodic review of each pesticide on a 15-year review cycle. This review process must be a flexible, transparent and open process including public participation. Bradbury stated that this process will ensure continuity in protecting human health and the environment by incorporating new societal and scientific issues that may have arisen since the last assessment, and allowing EPA to obtain new data/information necessary to address these issues. The schedule for review of chemicals has been published, and 42 public dockets with preliminary work plans (PWP) opened. Final work plans (FWP) have been issued for 26 cases, which include four FWPs for chemicals with no federal registration. Information on registration review is available at http://www.epa.gov/oppsrrd1/registration_review/index.htm.

OPP Resources

Marty Monell, OPP Deputy Director for Management, provided a detailed summary of OPP's budget and discussed trends in resource sources and allocations for the past few years, with projections for fiscal year (FY) 2009. Monell stated that there is a projected decline in EPA's budget. Consistent with a budget decline, EPA is planning on a reduction in personnel, measured in full-time equivalents. At the same time, the presentation showed an increase in EPA salaries; Monell stated that EPA finds it most cost effective to retain and compensate well trained, strong performing employees with institutional knowledge. Monell also stated that overall, PRIA 2 fees are lower than were projected and that PRIA 2 fees cover only approximately 20 percent of registration program costs.

Monell also provided OPP performance measures for FY 2007. Observing that the FIFRA program is a licensing program, Monell's presentation focused on the number and types of new pesticide active ingredients, uses, products registered, the number of REDs completed, and the number of products that have completed reregistration. In her subsequent comments on the presentation, PPDC member Jennifer Sass, Natural Resources Defense Council, encouraged EPA to include additional outcome measures in its performance measures report. As an example, Sass stated that she read a report that stated that OP residues in the top 10 consumed children's foods have been reduced from 28 million pounds to 12 million pounds. Stating that this is great progress, Sass commented that successes like these should be highlighted, and expanded upon, to identify, for example in this case, the specific foods and specific pesticide residues reduced.



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PRIA Process Improvements

Elizabeth Leovey, OPP Senior Advisor for PRIA Implementation, reported on the activities of the PRIA Process Improvement Workgroup. Among the Workgroup's accomplishments, Leovey discussed:

- Several labeling projects to improve the quality and consistency of product labels, based on stakeholder comments about the need for improvement in this area;
- Ongoing development of guidance and tools to improve the format and content of registration applications and data submissions, to increase the efficiency of review; and
- Identification and development of opportunities to increase the automation and use of electronic tools to expedite the registration process, including e-label review and electronic submissions.

Leovey stated that an in-depth summary of the Workgroup's prior accomplishments is included in the minutes of the PPDC October 18, 2007, meeting, available at <http://www.epa.gov/oppfead1/cb/ppdc/2007/oct2007/october07.htm>, as well as in the PRIA annual report, available at http://www.epa.gov/pesticides/fees/2007annual_report/pria_annual_report_2007.htm. For a summary of the topics discussed at the most recent Workgroup meeting, see our May 8, 2008, Firm Client and Friends memorandum, available at <http://www.lawbc.com/updates/050808-fifra.pdf>.

Endangered Species

Donald Brady, Acting Director of the Environmental Fate and Effects Division (EFED), introduced a lengthy presentation by Associate Director Arty Williams concerning EPA's efforts to meet its obligations under the Endangered Species Act (ESA). Williams started by stating OPP's overall goal of protecting listed species from the potential effects of pesticides while minimizing the burden on agricultural production and other pesticide users. Williams stated that time limitations precluded her from providing a historical overview of EPA's attempts to meet ESA requirements and related litigation. Prospectively, Williams discussed two actions that will support OPP's efforts to comply to ESA requirements:

- An agreement reached between EPA and the U.S. Fish and Wildlife Service and National Marine Fisheries Service (the Services), codified in 50 C.F.R. Part 402, Subpart D, that if EPA reaches a "not likely to adversely affect" decision, then



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consultation with the Services is not required as long as EPA has completed its ecological risk assessment according to agreed-to guidelines. EPA and the Services also agreed that Section 18 exemptions are considered emergencies for the purposes of ESA consultation.

- OPP's decision to address ESA compliance through the registration review process, which Williams stated will allow OPP to take advantage of the existing public participation process and make decisions that will address the potential risk to all listed species most efficiently.

Williams stated that PRIA 2 expanded EFED's ESA-related workload because it specified that registration review must not only be started but completed within the specified 15-year review cycle. She also stated that the analysis that has been completed as part of EPA's response to litigation brought concerning EPA's failure to meet ESA requirements has been far too resource-intensive to serve as a model for the analyses that will be completed as part of registration review. Accordingly, Williams explained that EFED has been working to design an assessment, consultation as needed, and implementation process that will achieve the desired goals within the specified time period. As part of this effort, EFED has been assessing automation possibilities, including database and model development, and coordinating these efforts with the Services.

PPDC members had several comments and questions concerning the presentation, including:

- EPA should look to state and local successes regarding endangered species protection efforts. One example raised involved growers in Michigan who were willing to move orchards and take other steps that allowed populations to reestablish quickly.
- EPA should consider how to monitor the outcome of its actions to assess whether they have been effective. For example, a commenter asked whether EPA's endangered species bulletins are used and effective.
- EPA should seek to leverage expertise, information and other resources beyond those housed within EPA and in the Services. Universities and the regulated community are two potential sources of data that could support EPA's efforts.



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October 2008 PPDC Meeting

In the last session of the meeting, OPP Division Director Debbie Edwards solicited ideas for topics to cover in the next PPDC semi-annual meeting, which is scheduled for October 8-9, 2008. The topics suggested included the following among several others:

- 21st Century toxicology;
- Web-based labeling;
- Pesticides and pollinators;
- Outcome-focused performance measures;
- Progress on endangered species ecological risk assessments and program planning; and
- Green/environmentally preferable labeling initiatives, as a subset of third party endorsements (a topic for discussion widely seconded by PPDC members).

PPDC members also suggested the possibility of having an ESA-related workshop before the next PPDC meeting, to allow discussion of issues and possible solutions or next steps that could then be presented during the PPDC meeting.

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We hope this information is helpful. As always, please call if you have any questions.