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MEMORANDUMVia E-Mail

DATE: October 21, 2008

TO: Firm Clients and Friends

FROM: Bergeson & Campbell, P.C.

RE: PPDC Holds Its Semiannual Meeting

On October 7 and 8, 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. These materials also may be available eventually at <http://www.epa.gov/oppfead1/cb/ppdc/>.

Endocrine Disruptors

William (Bill) Jordan, Senior Policy Advisor in the Office of Pesticide Programs (OPP) provided a status update for the Endocrine Disruptor Screening Program (EDSP). Jordan stated that the program was mandated by the Food Quality Protection Act (FQPA), which required EPA to develop an endocrine disruptor screening program using validated assays to test pesticide active ingredients, pesticidal inerts, and certain chemicals found in water for estrogenic and other endocrine effects that may affect human health. He described how, 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.

He then outlined the EDSP Tier 1 battery, which consists of 11 *in vitro* and *in vivo* assays that the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) recommended using in its June 11, 2008, report. He stated that these assays are intended to identify substances that have the potential to interact with estrogen, androgen, or thyroid hormone systems. According to the presentation, 10 of the 11 assays have completed the validation process. He stated that the EDSP Tier 2 battery, which is under development, will consist of a series of multi-generational tests intended to identify and establish



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a dose-response relationship for any adverse effects that might result from the interactions identified in Tier 1. According to the presentation, Tier 2 study development and validation is expected to continue into 2011.

Jordan noted that the draft list of chemicals for the initial round of Tier 1 screening was proposed on June 18, 2007 and the public comment period ended on February 11, 2008. According to the presentation, the draft final list has been submitted to the Office of Management and Budget (OMB) for review. In response to a question raised during the meeting, Jordan clarified that the list was compiled based on exposure-related criteria; no literature search for possible endocrine effects was completed, for example, to prioritize testing.

According to the presentation, EPA plans to issue test orders for the final list of chemicals in 2009 under the authority in FIFRA Section 3(c)(2)(B) and Federal Food, Drug, and Cosmetic Act (FFDCA) Section 408(p)(5). Jordan stated that EPA expects to manage the test orders like data call-ins and in particular to encourage the formation of consortia to respond to the orders. According to the presentation, the draft policies and procedures concerning the test orders, which were published on December 13, 2007, have been revised and submitted to OMB for review. During the meeting, PPDC member Jay Vroom, CropLife America (CLA) President and Chief Executive Officer, questioned how Tier 1 testing could proceed before validation of the final assay for estrogen receptor (ER) binding, which he described as “key;” Vroom also asked why validation for this assay has been delayed. Jordan commented that the ER binding validation simply has been a longer process, and that he was uncertain how its status would affect the test orders. After the first round of Tier 1 is complete, according to Jordan, EPA expects the Tier 1 battery may be refined based on the results; refinements could include a reduction in the number of tests and possible organization of testing into chemical classes with surrogate test materials. Eventually, according to the presentation, EPA expects that the testing will be merged with the registration review process.

Jordan also stated that EPA is in the process of responding to issues raised by stakeholders, particularly: a petition submitted by CLA on July 11, 2008; a Request for Correction submitted by the Center for Regulatory Effectiveness on July 10, 2008; and issues raised during a July 16, 2008, meeting between OMB and Physicians Committee for Responsible Medicine.

The presentation directs those interested in additional information to <http://www.epa.gov/endo>.



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Endangered Species

Donald Brady, Director of the Environmental Fate and Effects Division (EFED), introduced a presentation by Associate Director Arty Williams concerning the development of a process and timeline by which EPA and the U.S. Fish and Wildlife Service and/or National Marine Fisheries Service (the Service) would complete consultations, biological opinions (BO), and incidental take statements under the Endangered Species Act (ESA). Williams also addressed opportunities for stakeholder participation and discussed the experience with the first draft BO under this process.

Through schematics, Williams first explained that the consultation timeline will proceed in two parts; once an “action agency” (for the purposes of the meeting), EPA determines that a proposed EPA action (*e.g.*, product registration) may affect listed species or designated critical habitat, EPA would request the appropriate Service to initiate formal consultation. During the 90-day formal consultation period, the Service would prepare a draft BO and incidental take statement. During the subsequent 45-day “post formal consultation” period, EPA would sponsor a meeting between the Service and the applicant (*i.e.*, product applicant/registrant) as well as seek public comment on the proposed reasonable prudent alternatives (RPA) and reasonable prudent measures (RPM) in the draft BO. Based on feedback from these activities, EPA would develop and submit comments to the Service in time for the Service to issue a final BO and incidental take statement by the end of the overall 135-day period.

In the presentation, Williams stated that the Service Consultation Handbook provides the opportunities listed above for the Service to obtain input from the action agency and the applicant but no opportunities specifically for public participation. Williams stated that EPA is committed to soliciting public input through its website, where it intends to publish draft BOs, and through a docket, which was opened for a recent BO and which EPA plans to keep open on a continuing basis to collect comments on future draft BOs given the short period that EPA will have to respond to the Service.

Williams explained that the first BO under this process was not an ideal case study because it had a truncated, litigation-driven schedule; according to Williams, the truncated schedule was the reason there were no RPAs or RPMs in the draft BO and why EPA did not have opportunity to solicit much public input. At the end of the presentation, Williams in particular solicited input concerning the process for obtaining public input on draft BOs. Williams noted that prospectively, EPA expects to dovetail ESA assessment and consultation with the registration review process.



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Label Comparative Safety Statements

Marty Monell, OPP Deputy Director, gave an update concerning the newly formed PPDC Workgroup on Comparative Safety Statements for Pesticide Product Labeling. Consistent with the strong expression of interest during the PPDC semiannual meeting in May 2008, Monell discussed the high level of participation and strong interest in the issue of comparative safety and “green” claims by PPDC members. Monell discussed the first workgroup meeting in September, at which presentations were made by several EPA and third-party organizations, including EPA’s Design for the Environment and Energy Star programs, U.S. Department of Agriculture’s (USDA) National Organic Program, Green Seal, and TerraChoice’s EcoLogo.¹ According to Monell, during the meeting, break-out groups discussed whether this activity was one that a government agency should pursue and if yes, how it should do so; the workgroup concluded that EPA should pursue the issue, but no other consensus was achieved. During the second meeting, according to the presentation, the Federal Trade Commission (FTC) made a presentation to the workgroup regarding the FTC’s environmental marketing claims guidelines, which was followed by a discussion of potential overlapping jurisdiction for pesticide claims between EPA and the FTC. Prospectively, the workgroup is focused on the following three issues: (1) how to address the “common sense” desire to make factual statements (*e.g.*, reduced risk pesticide products currently cannot make related claims); (2) how an institutional/industrial products pilot program might be set up; and (3) what may be alternative approaches and issues associated with the approaches for achieving the overall goal (*e.g.*, logos vs. factual statements; EPA vs. third-party standards).

During a long discussion regarding the scope of the effort, Monell clarified that EPA currently is focusing on claims related to the product, not environmental footprint issues related to its packaging, transport, and so forth. Comments were diverse and included the following observations:

- Issues may be different for different product categories (*e.g.*, agricultural and antimicrobial);
- To the extent the initiative moves the market towards use of “more acceptable products,” consideration should be given to reduction in the number of pesticides and possible resistance issues;

¹ Information about the workgroup, including the meeting agenda, is available at <http://www.epa.gov/oppfead1/cb/ppdc/compara-safety/index.html>.



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- Whether a product is “safer” typically is dependent on the user following the use direction and other label precautions; and
- Choosing between products often involves trade-offs: a product may pose less mammalian risk but increased environmental risk, for example.

Debbie Edwards, OPP Director, concluded the discussion by emphasizing that EPA does not care about imparting marketing benefits and will only pursue the initiative if it has the potential to contribute to overall risk reduction.

Pesticide Program Resources/Funding

Monell also chaired the discussion regarding OPP’s funding and provided a detailed comparison of OPP’s funding and budget allocations for fiscal years (FY) 2008 and 2009. Monell stated that there is a decline in EPA’s budget from 2008 to 2009 that corresponds with a personnel reduction of 20, measured in full-time equivalents. Monell stated that EPA hopes to make up for the reduced appropriation through Pesticide Registration Improvement Renewal Act (PRIA 2) fees, to the extent the work is registration-related. 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 reviewed budget allocations for contractors, which are largely either information technology and public outreach related, and environmental stewardship grant programs.

In the presentation, Monell reported on the revenue in FY2008 from registration service or PRIA 2 fees (\$15.8M) and maintenance fees (\$22.0M). Monell stated that there was an unexpected increase in PRIA 2 fees from FY2007 to FY2008; she stated that OPP has not yet figured out the reason for the increase but speculated that it may be related to EPA’s retention of 25 percent of the fees for withdrawn applications. Monell clarified that PRIA 2 fees can only be used to fund registration and tolerance petition work, as well as set asides for specific grant programs. Maintenance fees can only be used to fund the reregistration and registration review programs.

Finally, Monell provided FY2008 performance measures from registration and reregistration programs. For the registration program, these measures included registration of 20 new active ingredients and 327 new food uses. For the reregistration program, these measures included the completion of 27 reregistration eligibility decisions (RED), and according to the presentation, “all 613 non-food use reregistration cases have now completed the RED decision making process.”



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Performance/Outcome Measures

MaryAnn Petrole, Chief of the Financial Management and Planning Branch, gave a presentation about EPA's development of and progress toward meeting its FY2006-2011 Strategic Measures. As examples of strategic measures already met, Petrole listed: avoid \$1.5 billion in crop loss; avoid \$900M in termite structural damage. PPDC members posed questions concerning the context and details of some of the reported metrics and provided comments on how EPA could improve communication of its successes. Generally, PPDC members applauded EPA's strides toward measures that linked EPA's actions to improvements in public health and the environment. Petrole's presentation also discussed activities related to strategic measures revision and improvement, and listed additional goals for 2009 and beyond that will be subject to measurement, including reducing children's exposures to rodenticides and developing measures for registration review efficiency.

USDA Updates

USDA attendees gave the following program updates.

NASS

Mark Miller, from the National Agricultural Statistics Service (NASS), USDA, gave a presentation concerning NASS' data collection activities, particularly its collection of chemical usage data. In short, Miller reported due to budget cuts, NASS chemical use surveys would be curtailed significantly in upcoming years. PPDC members stated that it is a "travesty" to lose this information, on which EPA and states rely, particularly because the program's budget is relatively small and the value of the data substantial.

Pesticide Safety Education Program

Presenters Amy Brown, Pesticide Safety Education Program (PSEP) Coordinator at the University of Maryland, and James Parochetti, PSEP National Program Leader, Cooperative State Research, Education, and Extension Service (CSREES), USDA, gave a presentation that included an overview of PSEP's history, mission, funding, and recent accomplishments. According to the presentation, PSEP trains both occupational and consumer pesticide users, as well as other educators and the health-care community, on a wide range of pesticide-related topics, including toxicity and potential effects, pest control strategies and tactics, and federal and state regulations and policies. Funding and in-kind contributions, according to the presentation, are provided by EPA, USDA, state, and other sources. The presentation highlighted several examples of innovative teaching initiatives, including "regional



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fly-in workshops” for aerial pesticide applicators that included aircraft testing/inspections, an online “virtual spray table,” which enables the user to see the effects of different nozzles, pressure and wind speed on spray pattern and drift, and master gardener education on a range of pesticide issues, which information is expected to be passed on by the master gardeners to consumers. While not required, a majority of state PSEPs track adoption of improved pesticide handling as a result of the training; illustrative data from trainee feedback also was included in the presentation. Additionally, a handout was distributed that provides funding and accomplishment information about EPA’s and CSREES’ partnership to provide training to certified applicators of restricted-use pesticides.

IPM-PIPE

Martin Draper, National Program leader, CSREES, USDA, gave a presentation about an online pest tracking tool, specifically, integrated pest management (IPM) pest information platform for extension/education (PIPE). Developed to track soybean rust, IPM-PIPE allows the user to detect pest occurrences on a national level and supports response-related decision-making. Draper commented that continuation and expansion of IPM-PIPE is funding-dependent and also stated that the program is relatively inexpensive to run. PPDC members shared their views that the program offered high value in that it leveraged a relatively low budget to provide valuable information.

Pollinator Protection

The following updates were provided on pollinator issues.

Pollinator Issues

Thomas Steeger, a Senior Advisor in OPP’s EFED, discussed efforts EPA is taking to address pollinator population decline as the issue relates to pesticides. In the presentation, Steeger stated that no correlation has been found between the population decline and a change in pesticide use; nonetheless, Steeger stated that EPA is focused on the issue. Steeger described EPA’s tiered testing approach for honeybee toxicity and efforts to refine Tier 3 field pollinator study protocols to detect a range of chronic and sub-lethal effects on both adult and brood bees. Other related regulatory activities include discussions concerning an approach for ecological risk assessments for pollinators and revisions to bee precautionary pesticide product labeling. Steeger also discussed research, voluntary stewardship, and communication/outreach programs to reduce risk to pollinators supported by EPA.



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CCD Update

Jeffery Pettis, Research Leader at the USDA Agricultural Research Service's (ARS) Bee Research Lab, started his presentation by stating that there have been many reports concerning declines in pollinator populations, but the most consistent data are for honeybees. According to Pettis, the decline has created a significant demand for commercial pollinators, resulting in bees being moved around the country for pollination purposes and increasing interest in imported bees, all at significant cost to growers. Pettis stated that the decline in honeybees, and particularly "colony collapse disorder" (CCD), has been associated with the rapid loss of adult worker bees, with an excess of young bees in the hive but few or no dead adult bees. According to Pettis, while the cause of CCD is unknown, the current theory points to multiple contributing factors. Specifically, Pettis stated that according to the current theory, a primary stressor, such as a mutation, stresses associated with commercial management (*e.g.*, interstate shipment), pesticide exposure, habitat destruction, or even monoculture (resulting in a steady diet of just one pollen) may leave the bees in a weakened state and thus vulnerable to a secondary pathogen present in the hive. Pettis stated that hive infection by two parasitic mites during the 1980s and 1990s occurred at the same time as significant population decline. According to Pettis, as the honeybee genome is defined, there is ongoing research for genetic indicators of CCD causes. Other ongoing research has found associations between the pathogen load in a hive and CCD incidence, as well as a range of pesticide residues in pollen, the honeybee food source.

Incident Data

Anne Overstreet, Chair of OPP's Incident Workgroup, presented information concerning the workgroup's activities. The workgroup was formed to develop a strategic plan to improve EPA's management and use of incident data. Implementation of this strategy has included: development of/improvements in an electronic system for reporting, tracking, managing, and analyzing incident data; improving outreach to support more robust data collection; and use of data for risk assessment/management, performance accountability, and enforcement. Overstreet discussed one recent use of incident data concerning deaths among companion animals (largely dogs) related to metaldehyde exposure, which led to label warnings, plans to test the efficacy of the aversion agent in products, and a commitment by registrants to develop a detailed incident reporting system.

Molly Clayton, Special Review and Reregistration Division, provided a status update on the Pyrethrins/Pyrethroids Allergy/Asthma Workgroup. This workgroup was formed to evaluate whether exposure to currently registered pyrethrins/pyrethroids is associated with asthma or allergic effects in humans, and if so, whether any regulatory action is needed. Clayton stated that the workgroup's efforts are underway but no conclusions have been reached yet.



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Frank Davido, Information Technology and Resource Management Division, presented information about the National Pesticide Information Center (NPIC) and in particular its launch of the American Veterinary Medical Association reporting portal. The online portal was created to allow veterinarians to report adverse effects associated with an animal's exposure to a pesticide. The portal supports collection of robust, uniform information about the product, exposure, and effects in a central, national database. PPDC members applauded the work but noted the need for a centralized place for reporting human incident data as well.

Brief Pesticide Program Updates

Several brief updates were provided concerning activities within OPP.

Volatilization

Jack Housenger, Associate Director, Health Effects Division, gave a presentation concerning efforts related to field volatilization of agricultural pesticides. Housenger stated the objective of the efforts is to ensure post-application inhalation exposures in or near a treated field are considered in a pesticide's assessment. Housenger stated that OPP plans to take many related science issues to the SAP in December 2009.

Housenger also discussed the results of a recent Drift Catcher Report (September 2008) released by the Pesticide Action Network North America (PANNA) presenting data collected in Hastings, Florida, measuring concentrations of chlorothalonil, diazinon, endosulfan, and trifluralin. Housenger contrasted the results of risk assessments completed for endosulfan completed by EPA and PANNA based on the Hastings data.

Susan Kegley, PANNA, also presented slides on this topic, which raised some controversy. Kegley's slides contained tangential data related to chlorpyrifos from other PANNA studies that EPA appears not to have reviewed or agreed with.

Housenger stated that additional information on OPP's field volatilization work can be found at <http://www.epa.gov/pesticides/about/intheworks/volatilization.htm>.

Pesticide Usage Information

Rick Keigwin, Director, Biological and Economic Analysis Division, presented information about the role of use and usage data in OPP's regulatory processes. Keigwin clarified that use data typically refers to more qualitative information included in product use directions, whereas usage data refers to quantitative information regarding how much of the



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pesticide is applied. Keigwin stated that these data are valuable during registration and registration review processes, among other efforts, as input to exposure and risk assessment analyses. A handout also was provided listing sources of OPP use and usage data.

Resistance Management

Keigwin also gave a presentation concerning EPA's efforts concerning resistance management, including a recently initiated effort to assess more routinely resistance management issues. Keigwin clarified that resistance is "the significant and heritable decreased sensitivity of a pest to a pesticide." Resistance management was defined in the presentation as "both reactive strategies to mitigate existing pesticide resistance and proactive initiatives to prevent future pesticide resistance development." Keigwin stated OPP's Resistance Management Workgroup is, as next steps, examining international approaches to resistance management; identifying key resistance management issues; and developing a strategic plan for addressing these issues.

Regulatory Update

Bill Diamond, Director, Field and External Affairs Division, provided a status update on a wide range of regulatory issues. Among the points he addressed were the following:

- OPP is reconsidering the FIFRA Section 25(b) exemption for insect repellents and may develop efficacy data requirements for all skin-applied insect repellent products. Diamond stated a proposal may be published in 2010.
- OPP is proposing revisions to the antimicrobial data requirements. Diamond stated that EPA will hold a stakeholder workshop on November 6, 2008, and that the final rule is expected to be published in 2010.
- EPA expects to propose in 2010 revised Part 158 data requirements that will replace the existing two-generation reproductive toxicity study with an extended F1 one-generation reproductive toxicity study.
- EPA expects to publish by November 1, 2008, a one-year extension for compliance with EPA's pesticide container/containment rule, as well as changes to the required label language and clarification of available exemptions to the rule.



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21st Century Toxicology/New Integrated Testing Strategies

Vicki Dellarco, Senior Science Advisor, OPP, introduced a presentation given by Elizabeth Brown, Steptoe & Johnson, regarding the efforts of the PPDC Workgroup on 21st Century Toxicology/New Integrated Testing Strategies. Brown stated the workgroup is primarily focused on educating itself about the range of work being done in the scientific community concerning new ways of approaching toxicity testing and applying structure activity relationships (SAR), as well as outreach to communicate this information to all stakeholders. In the near term, the workgroup is hosting seminars regarding SAR and quantitative SAR (QSAR) modeling.

Web-Distributed Labeling

Bill Jordan returned to introduce an update on the efforts of the PPDC Workgroup on web-distributed labeling by several workgroup members. The workgroup recently formed to focus on issues associated with making labeling available by the Internet or alternative method. The concept appears to have wide appeal, as evidenced by the number of PPDC members who volunteered to serve on the workgroup (32); it also presents many issues that will need to be worked through before web-distributed labeling could be implemented. Issues identified included: lifespan of labeling; liability concerns; product eligibility for inclusion in the database; database hosting and maintenance; outreach and education; characterization of the potential impacts on and benefits for stakeholders; enforcement-related issues; and others. According to the discussion, the workgroup is working on several discussion papers. As stated by Jordan, "I predict we will be at this for a while."

Other

At the close of the meeting, Debbie Edwards led a discussion about topics for the next meeting, which she projected would be in late March or early April 2009. Not many specific topics were raised; instead, a debate ensued over the number and depth of topics that should be planned for the agenda. Also, PPDC members lamented the decline in participation by registrants in the PPDC.

In addition to the presentations discussed above, several handouts were made available during the meeting that provided updates on the following:

- Registration, reregistration, and registration review activities;



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- Accomplishments by the PPDC workgroups on (1) AZM transition issues and (2) PRIA 2 process improvement;
- Spray-drift related issues;
- EPA's withdrawal of the proposed Pesticide Registration Notice on "Label Statements Regarding Third-Party Endorsement and Cause Marketing;"
- The development status of a globally harmonized system of classification and labeling of chemicals;
- EPA efforts to harmonize ecological effects assessment methodologies under FIFRA and the Clean Water Act; and
- Strategic measures for water quality in urban watersheds.

Finally, also distributed were copies of a memorandum from Timothy Sherer, Program Manager, EPA Federal Advisory Committees, Office of Cooperative Environmental Management, to EPA Designated Federal Officers, concerning "EPA Policy Regarding Representative Federal Advisory Committee Members Meeting with Members of Congress or their Staff."

* * * * *

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