



MEMORANDUM

Via E-Mail

DATE: May 21, 2007

TO: Firm Clients and Friends

FROM: Bergeson & Campbell, P.C.

RE: EPA Pesticide Program Dialogue Committee Meeting

The U.S. Environmental Protection Agency's (EPA) Pesticide Program Dialogue Committee (PPDC) met on May 9-10, 2007, in Arlington, Virginia, to discuss a host of issues facing EPA's Office of Pesticide Programs (OPP).

The PPDC, originally established in 1995, operates in accordance with the provisions of the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2 Section 9(c). The PPDC provides a forum for a diverse group of stakeholders to provide feedback to the pesticide program on various regulatory, policy, and program implementation issues. Topics of discussion at past meetings have included the following: inerts disclosure, registration review, spray drift, non-animal testing, antimicrobial pesticides, endangered species, reduced risk pesticides, labeling, minor uses, ecological standards, fees for service, experimental use permits, environmental marketing claims, outreach to the public, and several implementation issues emanating from the Food Quality Protection Act of 1996 (FQPA).

Membership to the PPDC includes environmental and public interest groups, pesticide manufacturers and trade associations, user and commodity groups, public health and academic institutions, federal and state agencies, and the general public. The PPDC meets two to three times a year and all meetings are open to the public. The May 9th meeting of the PPDC addressed the topics discussed below.

Session I -- Work Group on Spray Drift/NPDES

This session reported on the deliberations of the Spray Drift Work Group. In sum, there was no consensus of the PPDC about how to address or resolve the drift issue. Also, little mention was made of the National Pollutant Discharge Elimination System (NPDES) or ongoing litigation about the subject. The most contentious elements of the debate were reported



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to be the definition of “harm,” and whether there should be a performance standard approach (*e.g.*, drift did not occur if there was no unreasonable adverse effect) or some kind of design standard (*e.g.*, no drift, *i.e.*, no detectable level, should be allowed). The group reported explicitly that the definition of harm was the most contentious and area of widest disagreement.

The Work Group, however, did note a number of areas where there was broad agreement among the various groups, for example: better training, stewardship, and education, as well as updated and clearer label instructions, would help minimize drift and any adverse impacts.

EPA as chair thanked the Work Group for its efforts and declared the Work Group “done” -- with no indication of how EPA might proceed from this point forward on the subject of drift.

Session II -- Program Updates

OPP staff reported on a number of routine activities and briefly summarized updates on a number of program elements. A copy of the slides from these reports are appended.

Registration activity for fiscal year (FY) 2007 was reported with 14 new active ingredient registrations approved (five conventional pesticides, six biopesticides, and three antimicrobials). OPP also reported that since the start of the Pesticide Registration Improvement Act of 2003 (PRIA), more than 99 percent of decisions have been made within the PRIA deadlines, although this includes those cases where EPA renegotiated a later due date. It is worth noting that among the divisions responsible for registration activity, the Biopesticide and Pollution Prevention Division (BPPD) has proportionately far more renegotiated deadlines (136/448) when compared to the Registration Division (RD) (201/3,757). Similarly, “do not grant” decisions were made for more BPPD cases (16/448) compared to RD (12/3,757).

EPA reported that it had completed 92 percent of 613 reregistration cases and hoped to complete work on all food use reregistration decisions (seven cases) this FY (*i.e.*, before October 1, 2007). In its accounting of all 613 cases, EPA stated that it has completed 564 cases (92 percent), 49 cases remain (8 percent), and 229 cases (37 percent) had been voluntarily cancelled. EPA also noted that the remaining 84 tolerances, which have not been reassessed before the FQPA deadline, are due to be completed this FY when EPA completes the N-methyl carbamate cumulative risk assessment. The carbamates involved are: aldicarb, carbaryl, carbofuran, formetanate, and oxamyl. EPA also mentioned that the soil fumigants are on the FY 2007 schedule to be completed (this seems unlikely, however, given the current schedule for



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comment periods, public meetings, and general volume of information and complexity of the issues that will have to be evaluated before reaching any final decisions).

EPA used the meeting to update the group on efforts to harmonize pesticide use across the U.S. and Canadian border. This is an effort to respond to growers on the northern tier who believe the availability and price of certain pesticides is more attractive across the border. EPA's response has been to stress the development of a joint U.S.-Canada label to allow free movement of pesticide products between the two countries. OPP has been working on such a scheme for a number of years and is starting to approve some joint labels: one label has already been approved and seven more labels are expected to be approved in 2007. It is EPA's goal to have this joint label process obviate the need for a U.S. equivalent of any kind of personal use exemption program, like that available to Canadian growers under Canadian law, for cross-border movement of unregistered products.

Session III -- Budget

EPA used this session to articulate the results of the internal process used to match more closely its current budget categories to its declared mission areas. The old budget structure was to articulate the budget into registration, reregistration, and field programs. The new budget structure articulates the budget resources into the categories used in OPP's strategic plan: "protect public health, protect the environment, and realize value."

One result of the exercise has been to reduce the number of budget activities from 25, under the old budget structure, to a more manageable list of seven activities. No change in budget amounts is expected as a result of these changes in nomenclature or accounting units; any budget totals remain to be driven mostly by much larger forces, including reducing the federal deficit and other overarching priority goals of the President and Congress.

Session IV -- Work Group on PRIA Process Improvements

EPA has begun a number of initiatives designed to facilitate registration applications, especially in light of PRIA deadlines and the general commitment to improve the registration process.

EPA reported on electronic submissions of PRIA fees and registration packages (progress continues), a November 2006 paper issued on minimum application rates (only six comments were received), inert ingredients (continuing to attempt to untangle the old List 1, 2, 3, 4 structure as obsolete and review food use inerts), the beginning of a fragrance notification pilot



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program, and the move towards more geographically specific environmental fate reviews in light of advances in geographic information systems (GIS).

Most notable was a discussion of a new OPP Labeling Committee designed to be a clearing house for cross-cutting label issues. It has resulted in a dedicated website, which can be used to submit questions and to review the answers to questions submitted by users of the site. The web address is http://www.epa.gov/pesticides/regulating/labels/label_review.htm. Questions to the Committee can be addressed to OPP_labeling_consistency@epa.gov.

Session V -- Diagnostic Biomarkers

The PPDC discussed the need for diagnostic biomarkers -- a simple, relatively inexpensive tool that physicians can use to determine whether a person demonstrating certain symptoms has been exposed to a pesticide. Such tools, EPA believes, would lead to better medical treatment because pesticide exposure could be easily identified. In addition, EPA believes diagnostic biomarkers would improve risk assessments and risk management decisions. Presently, cholinesterase is the only diagnostic biomarker for pesticide exposure available, but its utility is limited since a baseline cholinesterase level is always needed to determine pesticide exposure.

While the entire PPDC was in agreement that diagnostic biomarkers are needed, some questioned to what extent OPP should be involved in their development. Several PPDC members suggested that the Centers for Disease Control and Prevention (CDC) or EPA's Office of Research and Development (ORD) are more experienced and better equipped than OPP for such a task. In addition, there were concerns, given OPP's limited resources, that biomarker development could distract OPP from its core function, *i.e.*, Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) registrations. Jack Housenger, Associate Director of OPP's Health Effects Division, welcomed these comments and pointed out that OPP was still in the problem formulation stage with regard to biomarker development and that OPP would keep the PPDC updated.

Session VI -- Work Group on Worker Safety

The discussion in Session VI began with an update from the Worker Safety Regulations Work Group, which reports substantial participation with most of the PPDC involved, and the formation of a subgroup to address antimicrobials. The Work Group plans to offer a final proposal on worker safety in **December 2008**. Following the Work Group report, discussion turned to specific proposals aimed at improving worker safety.



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It was noted that most certified applicators do business in several jurisdictions, leading to multiple certifications, and the associated costs compliance, in terms of both time and money. It was suggested that states might adopt reciprocity agreements with other jurisdictions, thereby allowing applicators to go through the certification process only once. In the alternative, the possibility was raised of a national certification program to address the problem of multiple certifications. At the very least, it was agreed that greater harmonization of the language used by state and federal regulators was needed.

Proposals to expand the scope of applicators subject to certification and training were discussed next. Some suggested that all employees, even those that do not apply restricted use products, should be certified. Others pointed out that such a dramatic increase in the scope of certification would be costly to both states and the regulated community. An alternative suggestion was to group employees in tiers, based on the risks associated with their work, so that the greater the risk, the more certification and training would be required.

Pesticide specific hazard communication was also discussed. It was agreed that applicators had the right to know the hazards associated with the products they are using, but it was unclear how such information should be communicated and at what cost. Numerous factors that need to be considered when developing hazard communications, including what information to provide, what language to convey that information (English versus native), the mode of presentation (written, oral, or pictorial), and the level of sophistication (technical versus plain language), were identified. It was suggested by one participant that OPP might look to the Occupational Safety and Health Administration (OSHA) for examples of workplace protections.

Session VII -- AZM Transition Issues Work Group

The session began with a presentation of background information. In November 2006, EPA announced its decision to phase-out azinphos methyl (AZM) by **September 30, 2012**, which provides in part for mandatory ratcheting down of annual application rates; larger buffer zones around water bodies; buffers around occupied structures; gradual elimination of aerial applications; post-application worker stewardship program; and transition to available safer alternative pesticides. The AZM Transition Issues Work Group is charged to provide advice, through the PPDC, to EPA and the U.S. Department of Agriculture (USDA) on the implementation of AZM phase-out, including identifying ways to improve understanding of critical grower needs; identifying programs/mechanisms to provide reduced-risk management strategies and techniques to growers; recommending ways to assist growers' efforts; and providing process recommendations to ensure that AZM transition progress is tracked and assessed and reported back to the PPDC.



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The AZM Work Group reports that, to date, it has created a rough outline of the basic transition strategy with components addressing four areas of concern: trade, regulation, research and implementation, and impact assessment. In addition, the Work Group has developed two matrices: crop/alternative approaches to pest management matrix and the regulatory matrix. Each matrix is under review by the Work Group. Finally, the Work Group has drafted two cases studies -- Ohio parsley and Washington apples -- each of which is being revised after an initial round of review and comment.

The Work Group intends to hold another meeting to flesh out the case studies; further develop the matrices; and work to reach consensus on components and contents of, and plans for, transition strategies. Ultimately, the Work Group will present the case studies and proposed advice to the full PPDC.

Session VIII -- Endangered Species Update

OPP's Endangered Species Protection Program (ESPP) gave an update on several topics. ESPP began by summarizing the current status of five completed assessments required under various settlement agreements, as well as four that will be completed in the next few months.

The status of the California red-legged frog stipulated injunction was discussed next. This requires EPA to develop and distribute a bilingual (English and Spanish) brochure, which was available at the PPDC meeting. In addition, it enjoins, vacates, and sets aside EPA's authorization of uses of 66 pesticides in certain parts of 33 counties in California.

It was noted that as of the PPDC meeting, ESPP has opened 12 dockets. ESPP has a draft work plan and will review past assessments. In particular, ESPP is considering data needs and assessment needs for the ecological risk assessment, including endangered species.

OPP also reports that it is working with other offices in EPA to develop geospatial tools, including a Terrestrial Action Area Development Tool (available now); a Use Site Development Tool (available later this summer), which will be linked to USDA agriculture census data to identify areas of potential agricultural use; an Aquatic Action Area Development Tool (available this fall); and a Spatial Framework for PRZM/EXAMS.

In addition, OPP is developing the following data repositories: OPP/Office of Environmental Information collaboration on a massive (~1 tera-bite) geospatial database to contain all OPP needs for geospatial data (available late this summer); a Tracking System for endangered species actions, including status and timelines; and a Knowledge Repository to



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contain both documents used for endangered species assessments and discrete pieces of relevant information.

Session IX -- Registration Review

This session began with a presentation of background information. The purpose of the Registration Review Implementation Work Group (RRIW) is to provide stakeholder input on several initial registration review dockets; advise the PPDC on registration review docket recommendations to give to EPA; and suggest improvements to EPA in the initial stages of this new regulatory program.

The RRIW made several recommendations for docket structure, including guidance on how to navigate/use the Federal Docket Management System dockets; organize dockets and identify documents better; provide more detail on incidents; include all available background documents if possible; and list the PRIA schedule.

In addition, the RRIW made several recommendations for summary documents, including more summary/highlighting of EPA conclusions up front; less jargon and clearer language; more consistency in format and better flow between sections; more usage information, including FIFRA Section 24(c) registrations; highlighting data requested or not requested with rationale, including product/trade names; providing information and Internet sites for analytical methods; and remaining aware of EPA's limited resources.

Finally, the RRIW made several general suggestions, including development of water quality benchmarks; development of diagnostic biomarkers for pesticide exposure; and clarification of when and how stakeholders could provide information for endangered species assessment in the registration review.

The RRIW also noted that OPP has made some initial docket improvements, including a dated signature page included on the front of the registration review summary document; lists of all product registration numbers in the summary document to facilitate label searches; and incident reports in the docket when available. OPP also has fixed the docket "basic search" function to enable searches on open dockets by pesticide name in addition to docket number. The RRIW will meet again this summer to consider biopesticide and antimicrobial dockets.



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Session X -- Performance Measures

This session began with a brief history of the Performance Measures Work Group, which was established at the May 2005 PPDC meeting. The Work Group presented its draft report to the full PPDC in November 2006, and has held comment sessions since that meeting. The Work Group presented a summary of the changes made as a result of these comment sessions.

- First, the Work Group suggested that OPP should not abandon all of its “old” output measures (*e.g.*, number of registrations per year) in moving to the new measures. Recognizing this, it is important for EPA to provide relevant detail regarding its quantifiable measures.
- Second, linkages between programmatic actions and performance measures should be clear.
- Third, there was concern that having measures that look at reductions in the levels of pesticides without any qualification of the statement could give the impression that current levels are unacceptable.
- Fourth, there was concern with the proper use of Poison Control Center Data, as some of the data may be fragmentary. Therefore, OPP should consider validating the data before they are used.
- Finally, EPA should consider using FIFRA Section 6(a)(2) incident reporting data and other objective sources, such as U.S. Geological Survey and Water Quality data, to demonstrate environmental benefits from the use of reduced risk pesticides.

Session XI -- Cause Marketing

This session provided the liveliest debate of the two-day meeting. It began with presentations from Clorox and the American Red Cross defending the practice of cause marketing -- allowing a non-profit to place their logos on a product in return for a donation from the product manufacturer. Clorox recently agreed to donate up to \$1 million to the American Red Cross when consumers purchase certain products labeled with the group’s logo. Several environmental groups petitioned EPA in February to deny the use of the labels as improper because they had the name or logo of a company other than the registrant. These groups argued that such labels could inappropriately imply that the products are safe and effective.



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While EPA has not officially responded to the petition, it has approved the labels. Dennis Edwards, OPP, said that according to Clorox market research, consumers were not misled. He said that the labels feature a disclaimer stating that the American Red Cross logo is not an endorsement and that all safety and usage instructions should be followed. In considering whether to approve similar labels in the future, Edwards said that EPA may ask third parties to study how the labels would influence various demographic groups' use of the products in question, as well as what the consequences would be if consumers are misled.

There was some debate about whether cause marketing was ever appropriate for pesticides. Some environmental and consumer advocates argued that the pesticide label was a legal document and therefore could not be used in this way. Industry advocates were quick to point out that only part of, not the entire, label is a legal document, and that it is common for other language to appear on a pesticide label.

Session XII -- Planning for Fall Meeting

It was reported that the charter for the PPDC is up for renewal this fall. A *Federal Register* notice will go out in June calling for submission of application for membership to the newly constituted committee. Any member of the public with an interest in, and experience with, pesticides is encouraged to apply. Existing PPDC members are not barred from applying.

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

[Attachment](#)