MEMORANDUM

Via E-Mail

DATE: October 21, 2009

TO: Clients and Friends

FROM: The Acta Group, L.L.C.

RE: Pesticide Program Dialogue Committee Holds Semi-Annual Meeting

On October 14 and 15, 2009, 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, which were organized into seven sessions:

- National Permit Discharge Elimination System (NPDES) permit development for pesticides;
- Status of litigation-mandated endangered species biological opinions and their implementation;
- Short summaries of six hot topics, including inert ingredients disclosure and the Endocrine Disruptor Screening Program (EDSP);
- 21st Century toxicology issues;
- Two pilot programs in the Antimicrobials Division (AD) related to comparative safety statements;
- Web-distributed labeling; and
- Plant health claims on a registered fungicide.

Copies of the slides and handouts from the meeting are available at http://www.epa.gov/pesticides/ppdc/2009/october/october09.html.

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In his introductory remarks, Steve Owens, Assistant Administrator, EPA Office of Prevention, Pesticides, and Toxic Substances (OPPTS) listed three priorities and key considerations for OPPTS' ongoing work: effects on children's health; environmental justice; and climate change. Owens also highlighted recent and/or upcoming initiatives that would be discussed during the PPDC meeting: the announcement of the Endocrine Disruptor Screening Program test order schedule; EPA's recent response to petitioners and decision to move forward with a plan to require disclosure of pesticide inert ingredients; and EPA's establishment of a new public notice-and-comment period process for risk assessments and proposed decisions for certain registration actions. Following Owens, Debbie Edwards, Director, Office of Pesticide Programs (OPP) reviewed the two-day meeting agenda and initiated PPDC member self-introductions before introducing Steven Bradbury, Deputy Director for Programs, OPP, who started the first meeting session.

NPDES Issues

Bradbury introduced the NPDES issues session, along with Linda Boornazian, Director, Water Permits Division, Office of Water (OW). Earlier this year, the U.S. Sixth Circuit Court of Appeals[1] vacated EPA's 2006 rule[2] with which EPA had intended to clarify that applications of pesticides directly to water to control pests and over or near water, where a portion of the pesticides will be deposited to the water, do not require an NPDES permit under the Clean Water Act. As a result of the court's decision, EPA and delegated permitting authorities must develop NPDES permit(s) for these discharges. With the Sixth Circuit's grant of a two-year stay, the court's decision will take effect on **April 9, 2011**. Bradbury stated that EPA is in the process of developing a proposed prototype general permit for these discharges, which is scheduled for publication in **April 2010**. Boornazian explained that OW is working with OPPTS to obtain comments to help shape the proposed prototype general permit; she also reviewed coordination activities conducted to date and stated that a webcast had been held the previous week on this issue, in which 1,200 stakeholders had participated. Boornazian then introduced Allison Wiedeman, Chief, Rural Branch, OW. Referring generally to a detailed slide presentation that summarized the information covered in the webcast, Wiedeman briefly touched on a few points before opening the session for discussion by PPDC members. Among the points raised were the following:

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1 *National Cotton Council of America v. EPA*, 553 F.3d 927 (6th Cir.).

2 71 Fed. Reg. 68483 (Nov. 27, 2006) (to be codified at 40 C.F.R. § 122.3(h)).

- Many PPDC members encouraged EPA to host well-publicized public workshops on the issue, in addition to the recent webcast, noting that this is a complicated issue that affects many stakeholders. In particular, Michael Fry, American Bird Conservancy, stated that, given the many competing concerns, an adaptive management approach should be taken toward developing the permits that considers stakeholder input and makes appropriate refinements. Similarly, many commenters called for significant outreach and training for the regulated community once the permits were developed.

- Several PPDC members also expressed concern about the timeliness with which permitting could occur and emphasized that, particularly in the case of public health threats, delays in the availability of sufficient tools to combat the threats could result in significant increases in infestations and raise pesticide resistance issues (if multiple treatment options were unavailable).

- Related to timeliness and efficiency, several PPDC members suggested that EPA include opportunities for electronic submissions, electronic reporting, and similar technological solutions. These considerations could also reduce costs, which commenters remarked could be significant for the states when implementing the permitting program.

- Several commenters inquired about the definition of key terms, such as "integrated pest management," which likely will be the proposed basis for determining the Best Available Technology, and "near water," and the importance of clear written guidance.

Finally, Jay Vroom, CropLife America, while commending EPA for its hard work to date, reminded the meeting attendees that a legal challenge to the Sixth Circuit's decision is pending. During the public comment period at the end of the morning's presentations, each of the four commenters addressed one or more aspects of the upcoming NPDES permits and related requirements for pesticides, including the complexity of the issue and the likely attendant costs. The American Water Works Association also submitted written comments, copies of which were provided at the meeting.

Endangered Species Act

Donald Brady, Director, Environmental Fate & Effects Division (EFED), OPP, and Richard Keigwin, Director, Pesticide Re-evaluation Division, OPP, opened the session with brief remarks about EPA working with the U.S. Fish and Wildlife Service and National Marine Fisheries Service (the Service) to implement the requirements of the Endangered Species Act (ESA) in connection with registered pesticides. EFED Associate Director Arty Williams then reviewed the status of the ESA biological opinions required by legal settlements. Williams stated that three biological opinions were received from the Service in November 2008 -- for chlorpyrifos, diazinon, and malathion -- and three more in April 2009 -- for carbofuran, carbaryl, and methomyl. Williams also provided a schedule in her slides for receipt of the remaining litigation-related biological opinions, through **February 2012**. In response to a question concerning the schedule after **February 2012**, Williams explained that ESA consultations with the Service would occur as part of registration review. Williams next reviewed the steps EPA is taking to implement the November 2008 biological opinions, comparing EPA's decisions with the Service's recommendations. Williams also stated that product labels are being amended to reference the counties affected by the ESA-related restrictions and requirements, and to list the website on which the ESA protection bulletins have "gone live" and are accessible.[3] Finally, Williams reviewed the registrant's role in the consultation process, stating that once the Service begins work on a biological opinion, EPA will identify the relevant registrants and schedule a meeting between the registrants and the Service. The objective of such a meeting is to provide an opportunity for the registrant to submit information for consideration, and for the Service to discuss with EPA and the registrant the Service's review and evaluation, the basis for any finding in the biological opinion, and the availability of reasonable and prudent alternatives. EPA also will request a draft biological opinion from the Service and place it in a public docket to solicit comments.

Next, Dana Spatz, EFED, discussed two National Listed Species Assessments (NLSA) for two active ingredients -- clomazone and fomesafen. Spatz compared and contrasted the assessments with the assessments completed previously in support of Reregistration Eligibility Decisions. Spatz also discussed the differences in the assessment approaches for the two chemicals. According to Spatz, both methods used are consistent with overview methods. Fomesafen's assessment used standard geographical tools and taxa screening tools, but the assessment was refined with expanded biological characteristics. In contrast, clomazone's assessment used more refined geographical analyses from Federal Endangered Species Task

[3] The ESA protection bulletins are available at http://www.epa.gov/espp/bulletins.htm.

Force (FESTF)-developed products. Spatz concluded by discussing the lessons learned from the NSLA thus far, including the value of discussions with registrants early in the process to clarify the uses and formulations that will be supported, and identifying potential mitigation early in the process as well.

The session was then opened to discussion by PPDC members. Comments included the following:

- Clarification about EPA's methodologies (*e.g.*, how spray drift buffers are calculated). Similarly, PPDC members emphasized that the means for figuring out required buffers must be understandable and reasonable to use.

- Inquiries about the models and data used by EPA. Williams clarified in response that much of the information used by EPA is publicly available, but the FESTF database in particular is not because it is compensable data submitted to meet a data requirement. Williams also stated that EPA-prepared validation/quality assurance reports should be available for the FESTF data and information management system. Finally, in response to a related inquiry, Williams confirmed that EPA is communicating with the Service about ways to share resources and reduce redundancy.

- Approval about the efforts EPA is taking to involve registrants early in the process and a request to provide registrants with clear, specific guidance about what information would be useful for EPA and the Service to receive from registrants. Williams responded that specific information requests are included in the notification letters sent to registrants.

Hot Topics -- Brief Updates

During this session, EPA provided short status updates on six subjects. Edwards started with comments on EPA's recently announced revised process for new registrations, which includes opportunity earlier in the process for public review and comment. Edwards stated that for new chemicals and for first food use, first residential use, and first outdoor use, EPA will put its draft decision and risk assessment in a public docket for a 30-day comment period. Edwards stated that Pesticide Registration Improvement Renewal Act (PRIA 2) deadlines constrain the length of the comment period. Edwards also stated that EPA will respond to comments in its final decision document.

Keigwin stated that a team within OPP had been formed to consider how pesticide use may affect climate change and scope out related issues, considering among other things whether any changes to EPA's risk assessment methodology are warranted. Keigwin stated that OPP anticipates involving the Scientific Advisory Panel (SAP) in how a review of these issues might be conducted. Keigwin emphasized that OPP is in an early stage of this long-term effort and stated that OPP anticipates preparing a white paper concerning the state of knowledge on this subject for public comment.

Marty Monell, Deputy Director for Management, OPP, provided an overview on EPA's inert ingredient disclosure initiative. Monell explained that in response to two petitions, one from 15 State Attorneys General and one from a coalition of 21 non-governmental organizations, EPA is moving forward with a plan to disclose the identities of inert ingredients in pesticide products. Monell stated that EPA would be publishing an advanced notice of proposed rulemaking to solicit public comment about how to increase the publicly available information for inert ingredients.

Bradbury provided a status update concerning the EDSP. Bradbury in particular stated the following:

- ***Assays and Testing Protocols***: Bradbury stated that validation had been completed for the final Tier 1 testing assay, and that work on validation of Tier 2 testing assays would continue for another year or two. New information about the Tier 1 Screening Battery and copies of the testing guidelines are available at the following websites: http://www.epa.gov/endo/pubs/assayvalidation/tier1battery.htm and http://www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/890_Endocrine_Disruptor_Screening_Program_Test_Guidlines/index.html. A notice announcing the availability of this information is published in today's *Federal Register*, available at http://edocket.access.gpo.gov/2009/E9-25348.htm.

- ***Priorities***: Bradbury reviewed the list of active and inert ingredients, announced on April 15, 2009,[4] that are the subject of the first round of EDSP testing and stated that future prioritization would be based on

[4] 74 Fed. Reg. 17579 (Apr. 15, 2009).

exposure and effects. Bradbury stated that future review would be conducted in conjunction with registration review and also in cooperation with the OECD and other countries.

- ***Testing Process and Test Orders***: Bradbury stated that EPA has been working since April on the administrative process for initiating testing, and stated that a *Federal Register* notice would be published soon that will provide the schedule for sending out the test orders as well as describe how EPA wishes to receive other relevant scientifically valid information. This notice is available in today's *Federal Register*, available at http://edocket.access.gpo.gov/2009/E9-25352.htm.

Bradbury also provided a status update about a proposed Pesticide Registration (PR) Notice concerning spray drift label language. Bradbury reminded the PPDC that there had been a PPDC work group in 2006-2007 that provided information and recommendations to EPA concerning spray drift label language. Bradbury stated that EPA had completed the draft PR Notice, and it along with a related guidance document with 12 case studies and a *Federal Register* notice would be published shortly, by the end of October or beginning of November 2009.

Finally, Brady presented a status update and related hand-out concerning OPP and OW's joint efforts to assess the methods used by EPA to characterize the effects from pesticides on aquatic life. Brady stated that EPA plans to host six public meetings across the United States starting in **January 2010** to present EPA's "initial thinking on how to assure that effects are characterized consistently by both OPP and OW." Brady stated that EPA expects to publish related documents in anticipation of these meetings in November or December 2009. Brady also stated that after the public meetings, EPA plans to develop a set of white papers to describe new tools and analytical approaches that may be used by EPA, state pesticide and water quality agencies, and other stakeholders, and solicit public input through these white papers.

21st Century Toxicology/New Integrated Testing Strategies

Bradbury gave introductory remarks, accompanied by a short (six-slide) presentation. Bradbury explained that changes in how toxicology information is collected, interpreted, and analyzed have prompted EPA to consider how these changes will affect EPA's programming. The PPDC 21st Century Toxicology/New Integrated Testing Strategies Workgroup has been formed to assist OPP in thinking about the implications that evolving technologies in molecular, cellular, and computational sciences have for OPP policies and

practices. Bradbury stated the objective of these efforts is to get ahead of the curve for this emerging and rapidly evolving area of technology. Bradbury also stated that EPA is trying to communicate/coordinate with other organizations wrestling with similar issues, such as the U.S. Food and Drug Administration and the Organization for Economic Cooperation and Development. Bradbury introduced presentations by the Workgroup's three subgroups: Stakeholder Issues Subgroup; Biomarkers Subgroup; and Metrics of Success Subgroup. A summary of each of these presentations is provided below.

Stakeholder Issues

Kristie Sullivan, Physicians Committee for Responsible Medicine, presented on behalf of the Stakeholder Issues Subgroup. Sullivan explained that this Subgroup is assisting EPA to anticipate stakeholders' issues and to prepare to communicate with stakeholders concerning the status and progress of efforts in this area. To this end, Sullivan stated that the Subgroup is in the process of developing a Frequently Asked Questions (FAQ) document. The Subgroup does not plan to answer the issues raised in the document; instead, it is developing points for EPA to consider when EPA addresses these issues.

During the ensuing discussion, PPDC members inquired and provided many comments about the general and technical issues that would be addressed by the FAQs document, including what EPA will do if *in vitro* and animal test data contradict each other, and whether the emerging technologies are expected to make testing mixtures more cost effective.

Biomonitoring/Biomarkers

Vicki Dellarco, Senior Advisor, OPP, introduced the Biomarkers Subgroup presentation. Dellarco stated that with advances in knowledge about toxicological pathways, many are hopeful that this knowledge will provide better diagnostic indicators of pesticide exposure and susceptibility. PPDC members Matthew Keifer, University of Washington, and James R. (Jimmy) Roberts, University of South Carolina, then gave a presentation concerning the need for better diagnostic indicators of pesticide exposure to support diagnosis and treatment. The presenters raised as an issue whether EPA is authorized to require registrants to develop such diagnostic tools for their products. During the ensuing discussion, comments by PPDC participants were supportive. Cindy Baker, Exigent Company, suggested that registrants and doctors should find a way to work together and collectively brainstorm to address this issue.

Metrics of Success

Elizabeth Brown, Steptoe & Johnson, presented on behalf of the Metrics of Success Subgroup, stating that the Subgroup is at the beginning of its effort to help EPA consider how to measure and how to communicate about (1) progress toward implementation of integrative toxicological strategies and (2) success in their implementation. In her presentation, Brown listed considerations for developing all metrics, as well as proposed metrics for measuring both progress and success toward the goal of developing and adopting new integrated testing strategies. Brown encouraged PPDC members to consider these points and share comments with the Subgroup.

Edwards closed the session, commenting that OPP is perhaps the most data-rich regulatory environment in the world and accordingly is well situated to assess the developments in the toxicological sciences and their practical implications. Edwards stated that EPA intends to involve the SAP and others on the technical issues, but also stated that stakeholders too must be involved in the technical issues, both to provide input and for the purposes of transparency, so that the outcome of these efforts is understood and trusted. Edwards stated that she is hopeful for the potential offered by this change in paradigm, particularly for evaluating the health effects of mixtures and for evaluating potential chemical synergies.

Comparative Safety Statements

Monell introduced the Comparative Safety Statements session and explained that, in conjunction with the recommendations of the PPDC's Comparative Safety Statements or Logos for Pesticide Products Labeling Workgroup, OPP is planning two related pilot programs.

Jacqueline Campbell-McFarlane, AD discussed the first pilot program, the Design for the Environment (DfE) pilot, whereby a qualifying antimicrobial product could add the EPA Office of Pollution Prevention and Toxics (OPPT)'s DfE logo and website to its label. McFarlane explained the process would involve two steps: first, the product must complete the OPPT DfE program review; then, the registrant would submit a label amendment to the AD, which would fall into PRIA 2 category A570 with a 120-day timeframe and (currently) $3,308 fee. Eligible products, among other things, must not: (1) be in acute toxicity categories I or II; (2) contain known, likely, or suggestive carcinogens; (3) pose developmental, reproductive, mutagenic, or neurotoxicity issues; (4) have outstanding conditional registration data issues for the active ingredient; and (5) require personal protective equipment to use the product. McFarlane stated that the pilot will start in **May 2010**, and while originally was scheduled to run

for 18 months, has now been scheduled to continue until **May 2013** to accommodate state registration issues.

Michael Hardy, AD, discussed the second pilot program, which also will be available for antimicrobial products. Under this "Factual Statement" pilot, registrants will be able to add the following types of statements to its label: dye- and fragrance-free; certain product packaging-related statements; and references to corporate websites for limited corporate commitment statements (*e.g.*, commitment to sustainability). This pilot will begin on **January 2010** and also continue for 36 months. Hardy discussed other types of statements that AD had decided not to include in the pilot, including "ready biodegradability." In response later to many questions asked about a ready biodegradability statement, Hardy stated that AD is continuing to examine the science and available protocols for conducting ready biodegradability testing on mixtures, working with the OPPT DfE program.

The session was then open to discussion; comments included the following:

- Multiple PPDC members inquired how EPA will verify that false or misleading statements will not be included on registrant corporate commitment websites. Hardy stated that the content of websites included on product labels cannot have statements that are inconsistent with approved labels and cannot contain cause marketing. Hardy stated that, as an example, if a product is sold as a concentrate, and is in acute toxicity category 1 or 2 as a concentrate but 3 or 4 when diluted for use, the product is ineligible for the DfE program. The registrant could, however, discuss on its website how shipping a concentrate requires less packaging and energy. Finally, Hardy stated that the objective of the pilot is to explore these and other issues.

- Many commenters were supportive, and noted that such initiatives created incentives for development and marketing of lower toxicity products, though cautioned that EPA needed to be careful so that trust in the DfE logo is preserved.

- Several commenters inquired about how EPA would measure success for the pilot programs. Monell responded that metrics for the pilots are still being developed. Monell also stated that EPA had conducted a consumer survey concerning the state of knowledge of the DfE logo; according to

the survey, a significant number of consumers were more likely to buy and were willing to pay more money for products with the DfE logo.

Web-Distributed Labeling

William Jordan, Senior Policy Advisor, OPP, opened the session, remarking that significant progress has been made on this long-term issue and that EPA is sharpening issues on which it intends to seek public comment. Jordan then introduced Lance Wormell, OPP, who gave a presentation on the background and next steps for the web-distributed labeling effort. Wormell distinguished web-distributed labeling, in which container labels would be simplified and certain label elements such as use directions would be available via the Internet and other means, and structured- or e-Labeling, in which labels would be developed and submitted as databases (an effort on which EPA is working separately.) Wormell stated that EPA is developing a virtual pilot program that would allow users to search for and download mock labeling. The purpose for the virtual pilot is to test system functionality as well as user acceptability. Wormell stated that EPA wishes to confirm that the system functions exactly as intended before commencing a pilot with real labels.

The session was then open to discussion; comments included the following:

- Many PPDC members expressed interest in the effort because of the promise web-distributed labeling offers to provide labeling that is more targeted to a specific users needs (*e.g.*, rather than having to wade through pages of use directions that are inapplicable) and potentially available in multiple languages. Fry particularly noted that this effort along with the online ESA bulletins are potentially effective ways to deliver tailored information to users.

- James Thrift, Agricultural Retailers Association, stated his membership supports the effort. Thrift commented that the effort will only work if there is user certainty on where to find labeling, appearing to imply that the program should be mandatory. Thrift also suggested the program be phased in, with information available for a while on both container labels and online.

- Tyler Wegmeyer, American Farm Bureau Federation, and Cannon Michael, California Cotton Growers Association, both expressed reservations about the effort. Wegmeyer stated that only 59 percent of his

membership had Internet access, and less than half of that was high-speed. Wegmeyer also stated that his membership did not store what is expensive product, so the concern about old/out-of-date information on container labels may be misplaced.

- Many PPDC members commented on the tremendous interest and energy exhibited by the Web-distributed Labeling Workgroup, and the desire to continue the Workgroup to support this effort. The Workgroup will continue, with a focus on: liability issues; a survey of state stakeholders through the State-FIFRA Issues Research & Evaluation Group (SFIREG); the Virtual Pilot program; and structured labeling.

Toward the end of the session, Jordan stated that EPA realizes that web-distributed labeling has to offer net benefits to all stakeholders to be a success; if it is disruptive and difficult, EPA will not pursue it. Accordingly, Jordan stated, EPA is working on this issue cautiously. Jordan also stated that it is clear that users and other stakeholders want more information that is more accessible and easier to read.

Plant Health Claims

Lois Rossi, Director, Registration Division, delivered the presentation for the final meeting session. Rossi explained that an issue had arisen by way of a letter to EPA concerning a registered product, BASF's Headline product, that contains both fungicidal and plant health claims. The concern discussed during the meeting was whether these two sets of claims created a conflict, in that users may wish to use the product at greater than the prescribed use rates to achieve improved plant health, at the possible risk of creating resistance or pest infestation problems. The specific example given was use of a fungicidal product that killed beneficial fungi, leading to an increase in the insect population that the beneficial fungi otherwise controlled. The issue of product efficacy also was raised. Rossi and Edwards stated that EPA is soliciting information about this issue, and particularly data supporting the assertions from the letter's author, the American Bird Conservancy. During the public comment period immediately following this session, a BASF representative delivered prepared remarks which emphasized the efficacy testing that BASF has completed in support of all product claims.

The letter that raised this issue and EPA's response are included on the website with the meeting presentations.

Other

The following handouts, available at the website at the beginning of this memorandum, were distributed during the meeting but not discussed:

- Registration Review Update; and
- PRIA Process Improvement Workgroup Update.

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