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**MEMORANDUM**

Via E-Mail

DATE: October 25, 2004

TO: Firm Clients and Friends

FROM: Bergeson & Campbell, P.C.

RE: Pesticide Registration Improvement Act Workshop

On October 13 and 14, 2004, representatives from the U.S. Environmental Protection Agency (EPA), industry trade groups, and several non-governmental organizations gave a series of presentations at the Pesticide Registration Improvement Act (PRIA) Workshop in Arlington, Virginia. The Workshop was convened to discuss the progress in implementing PRIA during the nearly seven months since its effective date, describe efforts underway to assess and make program improvements, and solicit input by attendees. Presentations were made in plenary and concurrent breakout sessions on a wide range of topics. The slides from the presentations are expected to be available shortly on the web pages of the sponsoring organizations.<sup>1</sup> A copy of the Final Agenda is attached to this memorandum.

PRIA was signed into law last January. The legislation was the culmination of considerable negotiation among EPA, industry, and activist groups on the issue of whether new user fees should be imposed to fund pesticide registration and reregistration activities. The legislation is intended to provide more stable funding for EPA and, as a result, greater predictability for industry with regard to the timing of reviews of their applications and products. Pesticide registrants will pay increased maintenance fees and new registration fees, and EPA will be subject to deadlines for the completion of reviews of certain pesticide products. Additional information about PRIA is provided at <http://www.lawbc.com/updates/012304-fifra.pdf> and <http://www.lawbc.com/updates/031804-fifra.pdf>. Additional detail on PRIA and key issues associated with its implementation are available at <http://www.epa.gov/pesticides/fees>.

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<sup>1</sup> The Workshop Sponsors were: CropLife America; Chemical Specialties Products Association; American Chemistry Council Biocides Panel; International Sanitary Supply Association; Chemical Producers and Distributors Association; Biopesticide Industry Alliance; and Responsible Industry for a Sound Environment.



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The following information was discussed during the two-day workshop.

- Introductory speakers, including Jay Vroom, CropLife America, Wesley Warren, Natural Resources Defense Council, and Jim Jones, Office of Pesticide Programs (OPP), EPA, briefly recounted PRIA's history. The speakers reminded the audience that PRIA is not exclusively about registration fees and application review deadlines, but is also intended to serve as a mechanism to earmark funds to facilitate inert ingredients review and develop worker protection programs.
- Marty Monell, OPP, EPA, discussed PRIA revenues raised thus far and the priorities for allocating PRIA resources to improve EPA's ability to meet the statutory review deadlines. Priorities include increasing staff through hiring and contractors and investment in information technology infrastructure to support records and data management. Phil Klein, Consumer Specialty Products Association, acknowledged the many participants whose work led to PRIA and discussed the on-going efforts of the PRIA Process Improvement Working Group formed under the auspices of the Federal Advisory Committee Act (FACA) Pesticide Program Dialog Committee.
- During a discussion about EPA pesticide-related guidance, presenters reviewed the wealth of information available at <http://www.epa.gov/pesticides>.
- EPA gave a presentation about the Office of Pesticide Programs Information Network (OPPIN), an information system under development prior to PRIA that is being adjusted eventually to accommodate many OPP information- and records-management needs. Currently, OPPIN is used for administrative organization and tracking of new registration applications.
- During a series of presentations about tolerance reassessment and reregistration, speakers questioned whether the August 2006 deadline would be met and how EPA intended to achieve this goal. In response, EPA reviewed the status of reassessment and reregistration and described the steps EPA is taking to ensure it meets its deadline.



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- EPA noted that the electronic submission of revised labels would be a useful way for industry to assist EPA.
- Particular focus was given to inerts reassessment. Lois Rossi, Director of EPA's Registration Division, OPP, described EPA's plans to complete the reassessment of existing inert ingredients while keeping pace with new applications. Rossi noted that EPA anticipates that not all inerts will meet the Food Quality Protection Act (FQPA) safety standard and plans to engage industry soon to develop an appropriate strategy. A Workplan for the 1st Quarter of FY2005 was distributed.
- During a series of presentations about the front-end screening process, EPA reviewed the requirements of Pesticide Registration (PR) Notice 86-5 and described common errors. EPA noted that proposed changes to 40 C.F.R. Part 158 that will supersede PR Notice 86-5 are being reviewed by the Office of Management and Budget. EPA recommendations for registration applications included:
  - Use a descriptive title;
  - Provide a summary of the main points and requested action;
  - Organize information in a way to facilitate routing to the different EPA reviewers;
  - Provide well-developed, science-based waiver justifications;
  - Provide bibliographic information for existing data cited; and
  - Carefully quality check applications for missing or illegible pages, missing signatures, and so forth.



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- Paul H. Gosselin, California Department of Pesticide Regulation (DPR), spoke and described registration reform efforts in California. In addition to ongoing efforts in workload sharing with EPA, enacted reform includes:

- Accepting EPA data evaluation reports (DERs) to expedite DPR's review; and
- Not requiring up-front submission of residue data.

Planned reform includes:

- Registration status e-notification;
- Clarifying "California conditions" requirement for environmental fate studies;
- Amending California's efficacy data requirements to only require efficacy data on a case-by-case basis; and
- Possibly repealing California's data ownership laws concerning letters of authorization.

- During a breakout session on small business issues, minor use, and IR4 fee waivers, the requirements for each type of waiver were reviewed and the following points were made:

- Small business fee waiver review can take up to 60 days and delays the start of the PRIA review period.
- In addition to PRIA registration fees, annual maintenance fees are also eligible for a small business waiver request.
- A Voluntary Small Business Certification Form is available on EPA's website.
- A process exists for expediting a small business waiver request for a subsequent application submitted in the same year.



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- During another breakout session, a set of presentations were made about the history and status of electronic pesticide registration submissions; the following points were made:
  - A few completely electronic registration applications have been submitted to EPA on a pilot-program basis.
  - Currently, ADOBE PDF is the acceptable standard e-format.
  - Benefits include aiding EPA to achieve faster review and eliminating the need to submit multiple copies.
  
- During a third breakout session about inert ingredients, several presenters discussed EPA changes to eliminate the backlog of inert tolerance exemptions and to review new inert ingredient petitions with PRIA funding.
  - An Inert Ingredients Branch is being formed in the Registration Division.
  - EPA intends to eliminate the backlog over the next three years, while also reviewing new petitions. A full review schedule has been developed and will be posted on EPA's website.
  - New inert petitions will be scheduled with timeframes consistent with the PRIA ones for active ingredients.
  - A low toxicity risk assessment model is undergoing development for use with inerts.
  - EPA encouraged Industry to support the inerts review effort by:
    - Notifying EPA of plans to submit new inerts petitions;



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- Supporting inerts undergoing tolerance reassessment (an example was given of an industry task force that is compiling and submitting robust summaries of published and unpublished existing data to fill data gaps and avoid a data call-in); and
  - Providing adequate data and information with new submissions, as well as a rationale for the use of surrogate data.
- EPA proposed a method for implementing inert data rights on April 17, 2003; several trade associations submitted a joint letter commenting on EPA's proposal.
- During a subsequent plenary session, the activities of the PRIA FACA Process Improvement Group were discussed. A set of 14 issue statements developed by the Group were distributed at the Workshop; the issues that have been identified and are being addressed by the Group include:
  - Benchmarking with Canada's new fee program and information systems;
  - Improving inconsistent label review and harmonizing inconsistencies between the Label Review Manual and other policies;
  - Improving communications between EPA and industry to expedite the review process, including automating communications about the status of pending applications and allowing direct communications between technical reviewer and registrant;
  - Improving access to DERs and other documents; and
  - Informing industry earlier of selected endpoints for risk assessment.



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Also distributed were detailed outlines of five new processes developed by the Registration Division for application review within PRIA timeframes (*e.g.*, “Process for Fast Track Actions” and “Schedule for New Active Ingredient/First Food Use”) that describe the interim steps and assignments of responsibility.

- In a session on worker protection, presenters discussed ongoing EPA worker protection programs and the priorities for the PRIA funds earmarked for worker protection. EPA stated the first priorities are worker protection, including incident prevention and training, and emergency response capabilities.
- During a breakout session for the Registration Division, the presenters reviewed the program changes thus far to implement PRIA and discussed the continuing process improvement efforts underway.
  - Voluntary payment (VOLPAY) actions for applications submitted prior to March 23, 2004, required much attention and presented many issues initially, but have largely been resolved.
  - Ongoing improvements to the PRIA front-end screening process include refinements to the fee category guidance and decision process, and processes for resolving billing issues and challenges to category assignments.
  - A new dynamic workplan has been developed and will be regularly updated; the sections of the workplan that will be posted on EPA’s website are under discussion.
  - The detailed outlines of five new processes developed by the Registration Division for application review within PRIA timeframes were also discussed.
  - In addition to the new Inerts Assessment Branch, a new Risk Integration Branch is being formed to support Section 18 actions and the new Internal Registration Division Analysis and Decision Making (IRAD) team; IRAD is composed of the Registration Division Branch Chiefs and Division Director to provide quick risk management



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decisions for simpler actions and to approve scoping level-of-effort decisions.

- Improvements to PR Notice 98-10 for notifications and self-certifications were also discussed.
- During a breakout session for the Antimicrobials Division, the following issues were discussed:
  - Front-end screening process improvements, including daily reviews and biweekly completeness meetings, to ensure a complete data package has been received, placed into the appropriate PRIA category, and moved on for full review;
  - PRIA fee categories, reviewing the requirements for and specific issues associated with each Antimicrobials Division category;
  - Common PR Notice 86-5 deficiencies, including errors on the Good Laboratory Practices (GLP) and Confidential Business Information (CBI) statements, improper pagination, and illegible copies;
  - The process for renegotiating the PRIA deadline if circumstances preclude completing the review of the pending application; and
  - Common technical errors in fast track applications.
- During a breakout session for the Biopesticides and Pollution Prevention Division (BPPD), the presenters reviewed the program changes to implement PRIA and the results thus far.
  - BPPD has developed its own tracking tool to supplement OPPIN.
  - Forty-five percent of BPPD actions include a fee waiver request.
  - PRIA Category review teams have been formed to promote consistency in determinations.



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- BPPD has developed internal PRIA review schedules, but have not made the detailed schedules publicly available. Generally, the steps are:
  - Phase 1: Front-End Screen, including a review for compliance with PR Notice 86-5 and a contractor-run preliminary screen to verify that all appropriate pieces of the submission are present;
  - Phase 2: Regulatory Action Leader Assignment and Administrative Preparation;
  - Phase 3: Primary Science Review, typically assigned to a contractor;
  - Phase 4: Secondary Science Review, completed by EPA scientists; and
  - Phase 5: Risk Management Decision, followed by label review, preparation of a Biopesticide Regulatory Action Document (BRAD), and related documents.
  
- Many expressed satisfaction with the workshop. One presenter suggested another workshop should be scheduled in a year to review the interim PRIA process improvements. EPA is considering the suggestion.

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We hope this information is helpful. If anyone would like a copy of the handouts, please call or e-mail Odeth Yalcin at [oyalcin@lawbc.com](mailto:oyalcin@lawbc.com).

[Attachment](#)