



**BERGESON & CAMPBELL, P.C.**

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**MEMORANDUM**

Via E-Mail

DATE: April 21, 2009  
TO: Firm Clients and Friends  
FROM: Bergeson & Campbell, P.C.  
RE: PPDC PRIA Process Improvement Workgroup Meeting

This memorandum summarizes the presentations from the Pesticide Program Dialogue Committee (PPDC) Pesticide Registration Improvement Act (PRIA) Process Improvement Workgroup (Workgroup) meeting held yesterday, April 20, 2009. A copy of the presentations is available upon request.

Following introductory remarks by Marty Monell, Deputy Director, Office of Pesticide Programs (OPP) and Elizabeth Leovey, the Workgroup Chairperson, the following subjects were discussed.

**21-Day Content Screen**

Steve Robbins, OPP Information Technology and Resources Management Division, presented the following information.

- On a phased-in basis over the last four to five months, the U.S. Environmental Protection Agency (EPA) has outsourced this initial review of registration submissions for content to a contractor.
- In a recently revised guidance document/worksheet concerning the 21-day screening review, EPA advises registrants to verify that a new inert ingredient is approved for a product's intended use(s) before submitting an application and obtain the necessary inert approval first if it is not. Otherwise, the application may be rejected. The worksheet is available at [http://www.epa.gov/pesticides/fees/questions/pria21day\\_wrksht.pdf](http://www.epa.gov/pesticides/fees/questions/pria21day_wrksht.pdf).



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BERGESON & CAMPBELL, P.C.

Memorandum to Firm Clients and Friends  
April 21, 2009  
Page 2

- The EPA contractor will review the inert ingredients in submissions to the Antimicrobials Division (AD) and the Biopesticides and Pollution Prevention Division (BPPD); this review continues to be completed by the Registration Division (RD) for conventional chemicals.

There were many comments from attendees about the need for a complete/timely-updated publicly-available reference for inert ingredients, which would include their Chemical Abstracts Service (CAS) Registry numbers and the uses for which they are approved.

### **Electronic Submissions**

Bob Schultz and Tom Harris, OPP, presented the following information.

- Schultz and Harris first clarified that there are several electronic components to pesticide registration that are in various stages of development, including electronic applications, electronic transmission of applications to EPA, and electronic label distribution. The most developed area is preparation of electronic submissions, which was the focus of this discussion.
- EPA began accepting electronic submissions in July 2008, in a format based on Canada's Pest Management Regulatory Agency (PMRA) system. There are ongoing efforts to expand the system to accept additional regulatory submissions (*e.g.*, Section 18 applications, submissions related to registration review) and to harmonize with the Organization for Economic Cooperation and Development (OECD) system.
- The EPA electronic Confidential Statement of Formula (e-CSF), on which EPA previously has provided training, has been published on EPA's website within the last week. EPA currently is still requiring registrants to print, sign, and submit hard copies. More information about the e-CSF is available at <http://www.epa.gov/pesticides/regulating/registering/submissions/#ecsf>.



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BERGESON & CAMPBELL, P.C.

Memorandum to Firm Clients and Friends  
April 21, 2009  
Page 3

### **Electronic Label Review**

Harris also presented the following information.

- EPA is encouraging registrants to submit electronic copies of final approved labels. Once a registrant makes any changes required as part of a registration or amendment approval and sends EPA a final label electronically, EPA will verify the label is correct and keep it in its files. The objective is to facilitate a subsequent amendment review process, when proposed label revisions are submitted electronically. EPA can at that point use the compare documents feature to confirm what is changed on the proposed revised label, thereby reducing review time. More information about this process is available at <http://www.epa.gov/pesticides/regulating/registering/submissions/#labels>.
- EPA also is working on a structured e-Label program, in which a registered label would be a database file. Certain data fields -- particularly those with prescribed EPA language -- could more easily include standardized language. EPA states it expects this program would promote more efficient reviews, improved EPA files (with automated data entry from the electronic structured label to EPA's electronic files), and facilitate a more level playing field by using the same regulatory language on similar products.

### **OPP Labeling Committee**

Jim Roelofs, Chair, OPP Labeling Committee, provided the following status update concerning the Committee's ongoing efforts.

- The online Pesticide Labeling Consistency Questions & Answers document has recently been updated (March 4, 2009), based on the questions received; it is available at [http://www.epa.gov/pesticides/regulating/labels/label\\_review\\_faq.htm](http://www.epa.gov/pesticides/regulating/labels/label_review_faq.htm). Jim Roelofs stated that 30 percent of questions received are from state regulators.
- The Label Review Manual (LRM) review and update is nearly complete. Of the two remaining chapters to be completed, Chapter 18, Unique Product Labeling, will be published "momentarily"; Chapter 10, Worker



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BERGESON &amp; CAMPBELL, P.C.

Memorandum to Firm Clients and Friends  
April 21, 2009  
Page 4

Protection Labeling, addresses “more complex” issues and hopefully will be complete within a few months. EPA intends the LRM to be a living document prospectively. Attendees suggested that updates to the LRM be coordinated prospectively with any new Pesticide Registration (PR) notices.

- Seventeen comments were received on the recent chemigation discussion paper. The discussion paper was prepared at the behest of the State Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Issues Research and Evaluation Group (SFIREG). Roelofs stated the next step would be to take the comments back to SFIREG for discussion.

### **Label Accountability Initiatives**

Meredith Laws, Dennis Edwards, and Robert Forrest from, respectively, RD, AD, and BPPD presented the following information concerning label review improvement processes within the registration divisions. As a result of recommendations in 2008 by the Label Accountability Workgroup, the registration divisions have developed training and quality assurance procedures for label review. RD, AD, and BPPD each have developed their own programs, but with many commonalities:

- Reviews are done prospectively for proposed amendments and new applications, as well as retrospectively for existing language. RD is implementing this process with a focus on fast-track amendments. AD and BPPD are randomly picking a set percentage of labels to review.
- Review teams include new employees for training purposes, as well as existing staff, who offer their expertise as well as benefit from refresher training.
- For RD, participants serve for two months on a rotating basis. In AD and BPPD, all reviewers, Product Managers, and Branch Chiefs participate in regular meetings to vet each others labels.



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BERGESON & CAMPBELL, P.C.

Memorandum to Firm Clients and Friends  
April 21, 2009  
Page 5

### **Web Site Improvement**

Nikos Singelis, Chief, Internet and Training Branch, Information Technology and Resources Management Division, OPP, presented the following information.

- EPA is migrating all of its website content to a new management system, which reportedly will improve search results by making information from all the offices available to one search and improve EPA's ability to remove outdated information.
  
- The Pesticides webpages, which constitute perhaps the largest set of content of all the EPA offices, are scheduled to transition to the new system in Spring 2010. All existing bookmarks will become obsolete.

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