



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

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**MEMORANDUM**

Via E-Mail

DATE: October 2, 2007  
TO: Firm Clients and Friends  
FROM: Bergeson & Campbell, P.C.  
RE: PPDC PRIA Process Improvement Workgroup Meeting

On September 27, 2007, the U.S. Environmental Protection Agency's (EPA) Pesticide Program Dialogue Committee's (PPDC) Pesticide Registration Improvement Act (PRIA) workgroup met in Arlington, Virginia, to update workgroup members on projects and other activities under its purview, in advance of the full PPDC meeting scheduled for **October 17-18, 2007**. This memorandum summarizes information presented at the PRIA workgroup meeting.

**Advancements in Information Technology and Management**

*E-Submission Pilot with Industry*

Robert Schulz, EPA, Information Technology and Resources Management Division, presented an update of EPA's efforts to develop the capacity to receive materials submitted to EPA's Office of Pesticide Programs (OPP) in electronic format. One of the goals of this project has been to enhance EPA's ability to share pesticide data and enhance harmonization with North American Free Trade Agreement (NAFTA) members and members of the Organization for Economic Cooperation and Development (OECD). Reviewing EPA's long-term approach, Schulz stated that EPA is still working through submission approaches and technical aspects of the project.

Five companies are participating in a pilot project; these companies have collectively provided EPA seven electronic submissions. The submissions have involved Federal Insecticide, Fungicide, and Rodenticide Act Section 3 registrations, Experimental Use Permits, and distributor products.



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As a result of the project, EPA has identified to this point several issues, including the need for additional harmonization with Canada's Pesticide Management Regulatory Agency (PMRA) that would allow one submission to cover both EPA and PMRA. EPA will work to increase harmonization with NAFTA countries first, then will seek to increase harmonization with OECD standards. A member of the workgroup commented that it would be helpful to industry if EPA could decide on the electronic format for submissions in advance of the development of industry studies so that the studies' data and results can be formatted properly in advance of submissions to NAFTA and OECD organizations.

### ***PrePay Decision Tree Fee Determination Tool***

Dominique Rey-Carruth, EPA, Information Technology and Resource Management Division, demonstrated EPA's PrePay Decision Tree Fee Determination Tool. The Tool is a web-based interface that, through a series of questions, can be used to determine the fee registrants must pay when registering their products. The questions the Tool asks are related to the type of pesticide registration action involved and the action code associated with the registration action. The information associated with this Tool will be made available to the public via EPA's website as early as this month.

### **Electronic Pesticide Label Review Update**

Tom Harris, EPA, Registration Division, presented an update on EPA's efforts to improve EPA's E-labels review. Harris explained that EPA is currently capable of tracking, comparing, and commenting on labels electronically. EPA expects to expand its E-label review to include review of more of the structure of the label itself. EPA currently is able to provide comments directly onto a PDF label. Harris explained the key elements to ensuring that EPA is able to provide an E-label review for product labels. These elements include ensuring that the file name format is correct and that a clean label is used without columns.

The number of E-labels EPA has received has been increasing steadily in 2007. The largest impediment to greater adoption of EPA E-label review to this point has been staff adoption of the tools available. EPA will continue to encourage registrants to submit E-labels, and EPA will work to provide greater training for EPA staff.

In the future, EPA anticipates being able to allow submission via a web interface portal for registrants, including a drag and drop tool for file transferring. At this interface, registrants would also be able to check on the status of their registration submittals. EPA also is working to develop E-label tools that would address certain text-portions of labels.



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### **OPP Labeling Committee**

Donald Stubbs, Chair of OPP's Labeling Committee, provided an update on activities of the OPP Labeling Committee. He reviewed the Committee's charge, to serve as a clearing house for broad cross-cutting label issues, to manage the labeling-related website, and to revise and keep current the Label Review Manual (LRM). The Committee has been working to ensure EPA answers in a timely fashion the questions EPA receives via its Q&A labeling page. Answers EPA develops are posted on the EPA website. The Q&A webpage receives nearly 700 hits per month, and the labeling webpage and the LRM itself receive nearly 900 hits per month. The Committee is ensuring that new additions to the Q&A page will be date-stamped, new items will be flagged, and the Q&A page will be searchable.

A subgroup of the Committee has been working to update the LRM. The team is converting the LRM from Wordperfect to Word and revising the LRM for straightforward corrections and compliance with current policy. The first six chapters of the Revised LRM have been updated and posted. Additional chapters will be revised in the very near future.

OPP expects to publish in the *Federal Register* very soon an announcement of the draft Pesticide Registration (PR) Notice on Environmental Hazard General Labeling Statements on Outdoor Residential Use Products. The types of products covered by this PR Notice include liquid concentrates, broadcast granular products, dusts, and liquid ready-to-use products.

OPP also expects to release by mid-October 2007 a draft PR Notice on third party endorsements and cause marking claims.

### **Process Improvements for Inert Ingredients**

Karen Angulo, EPA, Registration Division, provided an update of EPA's efforts to improve the inerts review process. Angulo described how EPA is recommending consultation prior to submitting for an inert a petition to EPA for a new tolerance for that inert or for obtaining or retaining a tolerance for that inert in the absence of a pesticide registration. She suggested that EPA anticipates consulting with petitioners either through a meeting or conference call, to improve efficient use of resources on the part of all parties involved in an inert petition process. By forwarding materials to EPA in advance, a conference call or meeting can be used to identify any data gaps or areas of concern and next steps for moving the petition forward.

Angulo reviewed the EPA process for reviewing Confidential Statements of Formulas (CSF). EPA is working to reduce the resources spent on registration actions that



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cannot proceed due to problems with inert ingredients. EPA finds that about one-third of CSFs have problems, with most having one of the following problems: Chemical Abstracts Service (CAS) numbers and chemical names of listed inert ingredients do not match; trade names and chemical names of listed inert ingredients do not match; or inclusion of inert ingredients that are restricted in such a manner that they do not allow for the labeled use sites, among other problems. EPA is developing a process for working with registrants to address the more easily resolved problems through re-submissions, and the more difficult problems through reformulations, EPA-initiated exemptions, or petitions for tolerances.

Angulo summarized EPA's efforts to update the lists of approved inerts in the Code of Federal Regulations (C.F.R.) and on EPA's website. A comment was made that putting the approval list in the C.F.R. is a mistake because the list likely will become outdated well before it would next be updated.

Angulo also detailed EPA's efforts to add CAS numbers to listings of inerts that are subject to tolerances and exemptions from tolerances and also those listed as non-foods inerts, to help to eliminate uncertainties about approval status. EPA is also working to modernize the EPA inert ingredient webpage.

Angulo concluded by describing EPA's Fragrance Notification Pilot program for inerts in antimicrobial products. In this 120-day pilot program that ended in August 2007, EPA was investigating whether a notification process could be successful. EPA is evaluating the results of this pilot program.

### **Advancements in Environmental Exposure and Ecological/Endangered Species Risk Assessment Models and GIS**

Brian Anderson and Michelle Thawley, EPA Environmental Fate and Effects Division, updated workgroup members on various EPA models, model development, and capabilities in assessing aquatic exposure. The models reviewed included:

- Terrestrial Residue EXposure Model;
- Terrestrial Herpatofaunal Exposure and Risk Program Simulation;
- KOW (based) Bioaccumulation Model;
- Wildlife Drinking Water Exposure Model;



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- Terrestrial Investigation Model; and
- Surface Water Assessment Model for Pesticides.

Thawley outlined how EPA is moving away from generalized scenarios toward being able to be more spatially explicit in assessing exposures. She explained how EPA is modeling input data using a grid approach. Thawley used several examples to show how various fields of data can be overlaid using the grid approach to select stream catchments, field applications, crops, and drinking water intakes, for examples. EPA is currently undertaking quality assurance and quality control of data EPA is making available for exposure assessments using these models and tools. The work undertaken to this point is the beginning of what EPA anticipates will be a long process of developing improved risk assessments.

#### **Upcoming PPDC Meeting**

The next full PPDC meeting will be held **October 17-18, 2007**.

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