



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

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**MEMORANDUM**

Via E-Mail

DATE: October 8, 2008  
TO: Firm Clients and Friends  
FROM: Bergeson & Campbell, P.C.  
RE: PPDC PRIA Process Improvement Workgroup Holds Meeting

On September 23, 2008, the Pesticide Program Dialogue Committee (PPDC) Pesticide Registration Improvement Act (PRIA) Process Improvement Workgroup held its eleventh meeting in the U.S. Environmental Protection Agency (EPA) offices in Arlington, Virginia. This memorandum summarizes the presentations and topics discussed during the meeting. Copies of the slides from the meeting are available upon request.

**Process Improvement in the Health Effects Division**

Following introductory remarks from Marty Monell, Deputy Director, Office of Pesticide Programs (OPP), Tina Levine, Director, Health Effects Division (HED), discussed two reorganization efforts within HED intended to improve efficiency.

First, Levine stated that currently there are seven “production branches” within HED -- three risk assessment branches and four reregistration branches. Prospectively, Levine stated that under current plans all production branches will become risk assessment branches. According to Levine, this change will yield efficiency gains because most actions for a given chemical, whether related to registration amendments or registration review, will be worked on by a smaller number of people within one branch, leading to improved coordination of efforts. Also, the reorganization will support HED’s workload management efforts by facilitating reassignment of work to branches with capacity. Levine also stated that the change is expected to lead to more time for employee training and education, greater opportunity for employees to become knowledgeable about specific chemicals, and higher employee morale and productivity.

Second, Levine stated that HED plans to form a Toxicology Science Advisory Committee (ToxSAC) to provide a hazard assessment peer review before a risk assessment is conducted. By meeting early in the process to review endpoint proposals and critical data



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evaluation reports (DER), ToxSAC is intended to help to avoid oversights or errors that could otherwise result in a need to redo work if found later in the process, which could lead to delays. ToxSAC also is expected to help ensure consistency between the risk assessment branches. ToxSAC will be a standing committee of approximately six members, with rotating membership.

One commenter asked if ToxSAC will provide assistance to the Antimicrobials Division (AD) where, the commenter stated, similar benefits are needed. Monell said that the ToxSAC will provide assistance to the Registration Division only. Monell stated, however, that reorganization within AD, particularly with regard to science support, has been under consideration but has been delayed by the change in leadership from Frank Sanders to Joan Harrigan-Farrelly.

### **e-Submission Update**

Steve Robbins, Information Services Branch Chief in OPP's Information Technology and Resources Management Division (ITRMD), provided an overview of OPP's experience since OPP began accepting certain types of pesticide applications electronically on July 15, 2008. Robbins stated that to date, OPP had received 95 applications containing a total of 2,329 documents via e-submission, which constituted 14 percent of submissions for the time period. Approximately half (50) of the submissions had what Robbins described as "mostly minor" issues, such as file name errors and syntax issues. Robbins briefly reviewed the e-submission process and encouraged submitters to submit applications electronically, using resources EPA has made available, including the PRISM e-Submission Help Desk (1-866-612-8664) and information on EPA's website, which is available at <http://www.epa.gov/pesticides/regulating/registering/submissions/>.

### **PRIA 2 OPPIN Enhancements**

Dominique Rey-Carruth of EPA's ITRMD discussed how EPA's registration information tracking system has been expanded to track a wider range of registration actions, in part due to the expanded number of actions covered by the Pesticide Registration Improvement Renewal Act (PRIA 2). Rey-Carruth provided several examples of the expanded tracking capabilities, including tracking for new inert ingredient requests and pre-application activities such as study waiver requests and protocol reviews; these activities now can be tracked and linked to corresponding Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 3 applications. The system has also been updated to facilitate internal and external action-related communications, such as an e-mail notification to the registrant when pre-payment of a PRIA 2 fee has been linked to an application and the PRIA 2 start and due dates are assigned.



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### **e-CSF Demonstration Results**

Rey-Carruth also discussed the results of beta-testing seminars held earlier in the day for an electronic confidential statement of formula (e-CSF) builder program that EPA is developing. The software application prompts users to enter information typically included in a CSF in a series of input fields, which include features such as pull-down menus. The application then compiles the information into a final CSF. Feedback from the seminars appeared generally to be positive, but with suggestions for improvement. In particular, Rey-Carruth stated that the beta-test users did not find the edit feature intuitive, requested more automatic calculation features, and requested greater flexibility for entries in other fields. Reviewers did appear to appreciate the “Turbo Tax” approach of the application.

### **Registration Review Tracking**

Lance Wormell, of EPA’s AD, addressed changes to EPA’s information tracking system that are being implemented due to the changes in information needs as reregistration efforts decline and registration review efforts increase. Wormell stated that among the differences between reregistration and registration review is the increased through-put of chemical reviews (20 pesticides/year v. 45+ pesticides/year) which will require a well-designed status tracking and document management system. Wormell described the planned system as one that would support manager efforts to assign work, schedule meetings, track progress, and access work product, with a user-friendly interface that is integrated with OPP’s e-mail application. Among the benefits of the system, Wormell listed easy access to final documents, improved cross-divisional communication, and improved reporting and transparency, all ultimately supporting better management toward target deadlines. Eventually, according to Wormell, the system may support periodic status reports to stakeholders concerning the status of registration review. According to the presentation, the tracking system will be implemented in phases from now through 2009.

### **Upcoming Antimicrobial Guidance**

Dennis Edwards, Chief, Risk Management Branch I in the AD, provided a status update concerning two new antimicrobial policy documents that will be released soon. The first addresses regulatory jurisdiction issues between EPA and the U.S. Food and Drug Administration (FDA) for antimicrobial products used in the manufacture of ethanol fuel. According to the presentation, inquiries to EPA from companies concerning data requirements and labeling for such products led to communications between EPA and FDA. Edwards stated that, as at this time ethanol is predominantly produced from corn, FDA took the position that the contents of fermentation tanks used to produce ethanol fuel are “processed food or feed.”



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Edwards cited the definition of “pest” in 40 C.F.R. Section 152.5, which excludes from the definition microorganisms on or in processed food or processed animal feed. Edwards stated that a document addressing this jurisdictional issue will be posted on EPA’s website as soon as concurrence is reached with FDA on the document.

Edwards also stated that a draft policy in the form of a draft Pesticide Registration (PR) Notice concerning labeling requirements for products that control indoor mold growth would be released this winter or early spring. Edwards explained that there are more than 1,000 pesticide products registered to control mold growth; as these products were registered primarily for aesthetic purposes, EPA did not require registrants to submit efficacy data for review. According to Edwards, new data and increased concerns about the health concerns potentially posed by indoor mold have led EPA to change its approach to regulating these products. Edwards stated that possible options for registrants may include a choice to: submit efficacy data to support claims; add a label disclaimer statement such as, “This product is registered to control the growth of mold for aesthetic purposes only”; or remove the mold claim from the label. Edwards stated that the guidance would also discuss additional required label directions, such as for cleaning and to clarify or distinguish between remedial and preventative uses. Registrants may be required to submit additional efficacy data to support residual or preventative claims.

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