



## BERGESON & CAMPBELL, P.C.

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### MEMORANDUM

#### Via E-Mail

DATE: December 3, 2007

TO: Firm Clients and Friends

FROM: Bergeson & Campbell, P.C.

RE: EPA Hosts PRIA 2 Workshop

On Tuesday, November 27, 2007, the U.S. Environmental Protection Agency (EPA) hosted a workshop in its Crystal City, Virginia, offices about pesticide registration service fees and changes introduced by the Pesticide Registration Improvement Renewal Act of 2007 (PRIA 2). The workshop was divided into a morning plenary session and three afternoon breakout sessions organized according to the three registration divisions. The slides and handouts for most of the presentations are available at <http://www.epa.gov/pesticides/fees/pria2workshop1107/index.htm>. Additional materials distributed but not available on EPA's website are available upon request.

#### **Plenary Presentations**

Following opening remarks by EPA Assistant Administrator for Prevention, Pesticides, and Toxic Substances James Gulliford, Office of Pesticide Programs (OPP) Deputy Office Director Marty Monell presented an overview of the provisions of PRIA 2. Her presentation included the following points:

- The provisions of PRIA 2 are effective as of October 1, 2007.
- PRIA 2 extends EPA's authority to collect annual maintenance fees to support the ongoing registration review program. EPA is authorized to collect \$110 million over five years (fiscal years 2008-2012). Approximately \$3 million is earmarked for review of fast track and new inert ingredient applications.
- PRIA 2 increases the number of registration service fee categories, thereby both refining distinctions between Pesticide Registration Improvement Act



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(PRIA 1) categories and expanding the types of actions covered by PRIA fees (*e.g.*, to include reviews of protocols and products with inert ingredients not previously reviewed).

- Fee payments must now be made at the time the registration action is submitted. Companies that may be eligible for a small business fee reduction now must pay at least 25 percent of the applicable fee, and submit that payment upfront with the fee reduction request. EPA may charge additional fees if the applicant identifies the incorrect fee category or if a fee reduction request is denied. If no payment is received 30 days after the fee is due, the fee will be treated as a claim of the U.S. Government according to 31 U.S.C. Chapter 37, subch. II. If an application is withdrawn within 60 days, EPA will refund 75 percent of the paid registration fee; after 60 days, the refunded amount will depend upon the amount of work completed but will not exceed 75 percent.
- As under PRIA 1, the decision review period begins 21 days after EPA receives the application as long as the fee payment has been received. During this time, EPA will perform an initial screening of the application both for format and content. If the application does not pass the initial screening review and deficiencies cannot be corrected by day 21, then EPA will reject the application within 10 days of the deficiency determination.
- PRIA 2 requires many annual reports concerning program progress to promote transparency.

Additional information about PRIA 2 is included in our October 12, 2007, memorandum available at <http://www.lawbc.com/updates/101207-fifra.pdf>.

John Jamula of EPA's Information Technology and Resources Management Division (ITRMD), Information Services Branch (ISB), discussed the available options for making fee payments. His presentation outlined the steps for making fee payments by paper check and online, as well as for making a partial fee payment along with a fee reduction request. Jamula stated that EPA will continue to issue invoices for registration actions through December 31, 2007, as registrants become familiar with the PRIA 2 changes, but after this transition period all fee payments must be made at the time an application is submitted to EPA.



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Dominique Rey-Carruth, EPA ITRMD Systems Design and Development Branch, discussed EPA's online Fee Determination Decision Tree tool. Through a series of questions, this online tool is intended to lead a registrant to the applicable PRIA fee category for any given action. The tool provides important guidance, particularly because a registrant must identify and pay registration service fees upfront, and EPA has stated that it is authorized to charge an additional fee if the registrant errs. Additional information about EPA's online PRIA 2 guidance is included in our October 22, 2007, memorandum available at <http://www.lawbc.com/updates/102207-fifra.pdf>.

Beverly Sjoblad, EPA ITRMD ISB, provided an overview of the requirements to be met to qualify for a small business fee reduction, noting that the requirements had not changed between PRIA 1 and 2. She recommended including the following in the fee reduction request:

- Voluntary Small Business Certification Form for Pesticide Registration Fee Waiver/Reduction, signed by an appropriate company official, who may include the company President, Vice President, or Comptroller. Sjoblad stated that an agent may not sign this certification;
- Financial documentation, including: completed tax forms for the preceding three years, 941-2 withholdings, a company financial report, and/or audited financial statements;
- An ownership structure chart that shows all entities related to the applicant, either directly or through a parent or subsidiary entity;
- Global gross revenue information for itself as well as for any affiliates; and
- Documentation regarding the number of applicant employees at the time of application (excluding employees of affiliates).

A presentation about the PRIA 2 application content screening process that takes place during the 21 days after submission was delivered by: Elizabeth Leovey, OPP Immediate office; Linda Arrington, Registration Division (RD); Michael Hardy, Antimicrobials Division (AD); and Linda Hollis, Biopesticides and Pollution Prevention Division (BPPD). The presentation included the following points:



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- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 33(f)(4)(B), as amended by PRIA 2, requires EPA to conduct a screening review of an application's content within 21 days of receiving the application and applicable service fee. If EPA determines the application is incomplete and cannot be corrected within the 21-day period, EPA must reject the application within 10 days of that determination. If EPA rejects the application, it will keep 25 percent of the registration fee.
- Each registration division is working out its own specific process for completing the 21-day content screening review. Short term procedures are in place for each division, and permanent procedures that generally involve assignment of the review to contractors are being developed.

In the final presentation of the plenary session, Linda Arrington discussed what she called the "parent/child dilemma." She stated that OPP has established a policy that when it reviews one set of data to support multiple applications, the lead or "parent" application with the data has been charged a full fee, while EPA used its discretionary fee reduction authority to reduce the fee for the other "child" applications. Under PRIA 2, EPA will continue this policy. According to Arrington, in most cases, the reduced fee will be the minimum 25 percent fee due according to FIFRA Section 33(b)(2)(G). Arrington's presentation is not posted on EPA's website; a copy is available upon request.

### **Individual Registration Division Breakout Sessions**

In the afternoon breakout sessions, each registration division (RD, AD, and BPPD) provided information about the procedures each division is following to implement PRIA 2. The handouts included draft interpretations of the PRIA 2 fee categories, as have previously been published for the PRIA 1. Some of these interpretations have been incorporated into EPA's online Fee Determination Decision Tree tool, but the documents have not yet been made available on EPA's website. Copies of the draft documents are available upon request. Each presentation reprised the morning plenary session by reviewing the main changes introduced by PRIA 2. Additional information from the breakout sessions is provided below.

### ***Registration Division***

The RD presentation discussed the new RD fee categories; examples include the following:



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- R121 -- Experimental Use Permit (EUP) for a new active ingredient for indoor use, and R271 -- EUP for a new, indoor, non-food use. Prior RD PRIA categories did not specifically cover EUPs for non-agricultural uses;
- R272 -- Protocol Review, for applicant-initiated protocol reviews;
- R331 -- New Manufacture Use Product, for a 100 percent repackaged end-use product for formulation purposes; and
- R311 -- and R312 -- Requests for approvals of food use and non-food use inert ingredients respectively. Inert ingredient applications must be accompanied by an application to register a product.

RD handouts included a bulleted chronology of RD's 21-day screening review, a copy of which appears on EPA's website. According to the chronology, RD will attempt to contact the registrant at least twice to correct any deficiencies identified during the 21-day screening review.

#### *Antimicrobials Division*

The AD presentation discussed the new AD fee categories; examples include the following:

- A431 -- New active ingredient (AI) that consists of a low-risk and low-toxicity food-grade AI not currently contained as an AI in any U.S. registered pesticide product, for non-food indoor uses;
- A521 -- Review of a public health efficacy study protocol that can be completed within AD, where the proposed protocol has only minor changes from an existing approved protocol;
- A522 -- Review of a public health efficacy study protocol that must be reviewed by members of the AD Efficacy Protocol Review Expert Panel, where the proposed protocol is new or represents a major change from an existing protocol; and
- A571 -- Cancer reassessment that is applicant initiated.



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The presentations described AD's 21-day screening checklist, as well as the regularly scheduled AD meetings during which active applications are discussed. The presentations distinguished between applications determined incomplete during the 21-day screening process and applications determined later to be substantively deficient. The latter will still result in a "75-day letter" consistent with 40 C.F.R. Section 152.105. The presentations also reviewed procedures and policies unchanged by PRIA 2, including the 75-day deficiency letters, PRIA review period renegotiations, and not-grant letters.

### ***Biopesticides and Pollution Prevention Division***

The BPPD presentations began with an overview of the recently revised microbial and biochemical pesticide data requirements. During the ensuing discussions, BPPD Director Janet Andersen and Associate Director Michael McDavit emphasized the importance of pre-submission meetings and discussed BPPD's informal data requirement waiver procedure. According to Anderson and McDavit, if during a pre-submission meeting, EPA concurs that certain data requirements may be waived for specific submission based on the information presented and this decision is captured in meeting minutes that are approved by EPA, then the approved meeting minutes may be included in the registration application in lieu of the data or formal written data waiver requests.

The BPPD presentation discussed the new BPPD fee categories; examples include the following:

- B631 and B641 -- for amending established tolerance exemptions and tolerances, respectively, including temporary ones associated with experimental use permits;
- B681 -- for a label amendment requiring data review, including product chemistry (*e.g.*, to support an unregistered technical source), toxicity, efficacy, or other data;
- B682 -- for an applicant-initiated protocol review. During the presentation, Microbial Pesticides Branch Chief Sheryl Reilly noted that the PRIA review period did not include time for any Human Studies Review Board review if required; and
- Many new categories for plant-incorporated pesticides (PIP).



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The BPPD presentations also addressed BPPD's 21-day screening process, pre-submission/pre-registration meetings, data waiver requests, and use of unregistered sources. Some of the presentations and handouts are not available on EPA's website; copies are available upon request. The data waiver request presentation was accompanied by a draft guidance document, complete with detailed examples, prepared by BPPD Senior Biologist Russell Jones; the draft guidance document is available at the EPA website linked at the beginning of this document.

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