



BERGESON & CAMPBELL, P.C.

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MEMORANDUM

Via E-Mail

DATE: March 17, 2004
TO: Firm Clients and Friends
FROM: Bergeson & Campbell, P.C.
RE: EPA Pesticide Fees Workshop

On March 11, 2004, the U.S. Environmental Protection Agency (EPA) presented a workshop on the Pesticide Registration Improvement Act of 2003 (PRIA) and EPA's plans to implement PRIA's requirements. The legislation is intended to provide more stable funding for EPA and greater predictability for industry concerning the time for EPA review of applications for a broad range of registration actions (including registrations, amendments, and other actions). The new requirements become effective **March 23, 2004**.

A significant portion of the workshop was devoted to an overview of PRIA's requirements. The major provisions of PRIA are discussed in our January 23, 2004, memorandum, which can be accessed at <http://www.lawbc.com/updates/012304-FIFRA.pdf>. This memorandum summarizes information of interest presented during the workshop, including information provided during question-and-answer exchanges.

Appended to this memorandum are three documents distributed during the workshop: the workshop agenda; a Q&A document dated March 11, 2004; and EPA contacts for more information about PRIA implementation. EPA has announced that the slides from the workshop, as well as other pesticide fees-related guidance and materials, will be available before March 23, 2004, at <http://www.epa.gov/pesticides/fees>.

General

- The workshop was well attended. Representatives from industry, EPA, and non-governmental organizations who participated in the negotiations that resulted in the legislation were introduced and commended.



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- EPA emphasized throughout the workshop that the details of certain implementation issues are still being worked out. EPA responded to questions during the workshop and encouraged stakeholders to pose future questions through the pesticide fees website, at the link provided above.
- This memorandum focuses on the new fee requirements for registration actions but the new law also raises maintenance fees for the next three years. The second invoice for 2004 will be mailed in May. For the years ahead, one invoice will go out in November or December of each year.
- After the workshop, most participants commented that it had provided a good overview of the new law and a general sense of how EPA plans to start its implementation. At the same time, it is clear that critical policies, processes, and implementation practices are still evolving.

Upcoming EPA Actions

EPA stated that new rulemakings and guidance documents related to the implementation of PRIA would be published soon. These actions include:

- a proposal to suspend current tolerance petition fee requirements;
- a clarification of the pesticide fee categories schedule, organized with the intent to make the fee schedule more user-friendly (*see* 69 Fed. Reg. 12771 (Mar. 17, 2004), available at <http://www.epa.gov/fedrgstr/EPA-PEST/2004/March/Day-17/p6001.htm>); and
- a guidance document addressing PRIA implementation issues, which was described as a “living document” that would be periodically updated.

Applicability

- The new fees schedule applies to all submissions that fit into one of the 90 registration action categories and that are submitted on or after March 23, 2004.
- The new fees schedule also applies to all pending registration applications for new active ingredients (AI) that were submitted prior to March 23, 2004, but that were not on the FY 03 work plan. (According to EPA, there



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were only three new AIs carried over from the FY 03 work plan. They are not subject to the new fees schedule.)

- EPA noted that registrants with pending applications for other than new AIs are not required to pay the new fees. EPA also noted, however, that if the registrants want to benefit from the predictability of the decision deadlines in PRIA, they voluntarily may pay the fee associated with the type of pending action. (*See* “Pending Applications,” below, for additional information.)
- If an application is submitted, the fee is paid, and EPA denies or otherwise returns the application, it may be resubmitted without a second fee.
- So-called “fast track” amendments are not covered by PRIA. As a result, there are no fees associated with these amendments.
- Similarly, requests for EPA review and comment on study protocols are not covered by the fee categories and therefore are not subject to the new fees. EPA noted during the workshop that a draft protocol might be reviewed faster if a registrant could link a requested protocol review with an application for which a fee had been paid (*i.e.*, the study is necessary to support the application).

Pending Applications

- Pending applications that are not required to pay fees (*see* “Applicability,” above) may volunteer to pay the fees to get the benefit of the new decision deadlines. If a registrant with a pending application decides not to pay the fee, the Registration and the Biopesticides and Pollution Prevention Divisions have pledged to continue to work on the pending applications in a timely fashion to the best of their ability. Decision deadlines established by the 1996 Food Quality Protection Act will continue to apply to pending applications in the Antimicrobial Division regardless of fee payments.
- For pending AIs that are required to pay the new fee (*see* “Applicability,” above), the clock on the decision period will begin 30 days after the PRIA effective date, or on **April 22, 2004**.



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- EPA may grant partial fee refunds based on the amount of work completed on a pending application prior to the PRIA effective date. EPA will make this determination and so advise the affected registrant. If a fee is paid voluntarily for a pending action that has a new tolerance associated with it, EPA will reduce the fee by the amount of the previously paid tolerance.
- For pending applications not on the current Division work plans, EPA encouraged submitters to notify it about whether they continue to want the applications reviewed, and if so, whether they plan to pay the fees voluntarily and into what fee categories they think the applications fall. Submitters should send this information to EPA's Document Processing Center (VOLPAY); "VOLPAY" is a special distribution code that indicates the communication concerns a voluntary fee payment.
- In response to a question, EPA stated that a registrant with a pending application could decide not to pay initially but change its mind and elect to pay the voluntary fee at a later date.

New Front-End Administrative Process and Fee Payment

- There are no new forms associated with the new fees program. Applicants should indicate on EPA Form 8570-1 (Application for Pesticide), in the explanation block of Section II, into which category the applicant believes its submission fits. New applications submitted after the effective date should be sent to EPA's Document Processing Center (REGFEE), where "REGFEE" is a distribution code that will alert EPA that the submission requires a registration fee category decision.
- EPA is creating a new master tracking database, "OPPIN," to maintain a record of each application, its associated decision timeframe, and its status in the review process.
- EPA plans on notifying an applicant within three days of receipt of the application of its decision concerning the fee category into which the application falls. EPA will send this notification and fee invoice by e-mail or telefacsimile if the appropriate contact information has been provided; it will also send a hard-copy notification and invoice by mail.



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- Applicants are not to send payment for the fee until receiving an invoice from EPA. Payments will be sent to the EPA Headquarters Accounting Operations Branch in Pittsburgh, PA. Payments will need to include a copy of the letter-invoice.
- The review period will begin 21 days after receipt of the application or when receipt of the fee payment has been confirmed, whichever is later. Applicants should make every effort, therefore, to pay the fee immediately upon receipt of EPA's invoice.
- Payments currently must be by check. EPA is in the process of making arrangements to accept other forms of payment, including credit card and wire transfer.
- EPA stated that payment must be made separately for concurrently submitted applications, for tracking and auditing purposes.
- When asked, EPA acknowledged that there will need to be a process whereby a submitter could discuss an application's fee if the application appears to have been assigned to an incorrect fee category, but this process has not yet been defined.

Fee Waivers

- Fee waivers apply to the new one-time registration fees, not to the annual maintenance fees. There are, however, maximum total caps to the annual maintenance fees payable by small businesses.
- An application with a successful fee waiver is treated the same as a comparable application for which the fee is paid. That is, the maximum length of the review period will be the same for two applications (one that paid and one that waived the fee) that fit into the same fee schedule category and that are submitted in the same fiscal year.
- The request for a fee waiver and all required supporting documentation must accompany the application when it is submitted to EPA. What constitutes "all supporting documentation" is still being refined, and EPA invited industry feedback on what types of documentation would suffice. For the small business waiver, one commenter urged EPA to consider that



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available financial records for non-U.S. companies are likely to be different than those available for U.S. companies.

- EPA may take up to 60 days to review a waiver request. The “clock” for the decision period does not start until the waiver request is accepted or, if rejected, payment is received.
- A commenter asked if a fee waiver request could precede the application, to reduce the effect of the 60-day waiver review period. EPA said that they might be able to accommodate this type of request eventually, but not initially. EPA also noted that the 60 days is a maximum review period for waiver requests, and eventually it hopes to complete waiver requests within 21 days.
- EPA stated that it is evaluating how to streamline the waiver request process. Workshop attendees urged EPA to develop a process that, for small businesses, would not require a *de novo* review of waiver eligibility for each subsequent submission.
- There are two tiers of fee waivers for small businesses:
 - For businesses with average annual global gross revenue from pesticides that does not exceed \$60 million, registration fees are reduced by 50 percent.
 - For businesses with average annual global gross revenue from pesticides that does not exceed \$10 million, registration fees are completely waived.
- The FIFRA definition of a small business has been changed.
 - A small business is one with 500 or fewer employees and average annual global gross revenue from pesticides that does not exceed \$60 million.
 - EPA currently defines “pesticides” for the purpose of calculating the average annual global gross revenue “from pesticides” to include pesticides and pesticidal devices.



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EPA acknowledged during the workshop, however, that this interpretation may be subject to further revision.

- EPA clarified the definition to include revenues from affiliated companies.

Miscellaneous

- If an application is withdrawn within the first 60 days after submission, the applicant is eligible for a refund of 90 percent of the paid fee. If an application is withdrawn after 60 days, the amount of the refund will be pro-rated based on the amount of work completed on the application.
- EPA clarified that once the clock begins for an application's decision timeframe, EPA cannot unilaterally "stop" the clock. An applicant may elect to negotiate with EPA to extend the clock, however, particularly if the alternative is an adverse decision.
- EPA expressed its hope to improve communication with industry such that submitters would share their schedule for future submissions for EPA planning purposes.
- EPA emphasized that the statutory decision deadlines are maximum timeframes and expressed its hope that (eventually) decisions would be made in less than the maximum time allotted.
- The Registration Division (RD) Director expressed her desire to make RD's work plan a "living" document that is readily available (*e.g.*, via the Internet). A commenter encouraged RD to consider adding status updates to the work plan, so a submitter could determine from the work plan at what stage of review an application was currently.
- The Biopesticides and Pollution Prevention Division announced that it was releasing its first public work plan. The work plan can be viewed at <http://www.epa.gov/pesticides/biopesticides/workplan.htm>.
- Consultations for effects on endangered species are among the actions that must be completed within the specified timeframes. EPA acknowledged



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that the process for completing these evaluations within the specified timelines has yet to be developed.

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

Attachments :

[PRIA Contracts.pdf](#)

[PRIA Q&A 31104.pdf](#)

[Agenda 31104.pdf](#)