



BERGESON & CAMPBELL, P.C.

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MEMORANDUM

Via E-Mail

DATE: May 8, 2008

TO: Firm Clients and Friends

FROM: Bergeson & Campbell, P.C.

RE: PPDC PRIA Process Improvement Workgroup Holds Its Semiannual Meeting

On April 29, 2008, the Pesticide Program Dialogue Committee (PPDC) Pesticide Registration Improvement Act (PRIA) Process Improvement Workgroup held its semiannual 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 and the handouts from the meeting are available upon request.

External Review of Product Registration

Peter Caulkins from EPA's Special Review and Reregistration Division (SRRD) presented the results from an external review, completed by a contractor, of EPA's product reregistration process, and in particular, focused on steps EPA could take to reduce the time between the publication of a Reregistration Eligibility Decision (RED) and the implementation of the RED recommendations. A summary fact sheet for the external review can be found at <http://www.epa.gov/evaluate/reports.htm> under the Office of Prevention, Pesticides, and Toxic Substances heading. Caulkins reported that EPA intends to make the entire report publicly available eventually.

In his presentation, Caulkins stated that for products that completed reregistration by the end of fiscal year (FY) 2006, the average time from the signature of a RED to final product reregistration was 54 months. Activities during the first 40 months included batching similar products, preparing and issuing the associated data call-in (DCI), generating and submitting data, reviewing the data and product labels, and summarizing the information to transfer it from SRRD to the registration divisions (primarily the conventional Registration Division (RD)). Activities during the final 14 months included review of the SRRD package by the RD product manager and working with registrants to make and approve applicable label revisions. Issues identified as delaying the process included:



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- EPA's need to meet statutory deadlines for issuing REDs, rather than implementing already completed REDs;
- Significant number of unknown errors, omissions, or other issues in REDs that have not been identified until implementation of RED conclusions;
- Lengthy justification process for approving DCIs; and
- Duplication of effort by SRRD and RD.

Caulkins listed the following efforts that currently are being pursued to reduce the time for implementing RED recommendations:

- Working with chemical task forces to duplicate the success in a pilot project with the 2,4-D Task Force, in which the Task Force provided information and coordination to support larger batching groups and matched existing data with the data requirements, resulting in a 50 percent reduction in the amount of data typically required with batching;
- Streamlining the materials sent to RD by SRRD, such as including only final data reviews and confidential statements of formula (CSF) and grouping the materials by similar products to facilitate RD's review; and
- Assigning a special SRRD team to assist RD for large groups of similar products, thereby allowing RD product managers to focus on PRIA actions.

Recommendations from the external review for a faster process included those listed above and others, such as: continuing to pursue electronic labels to expedite the label review process; obtaining more science support for the DCI justification process; and modifying the RED risk assessment formats to include rationale for each data requirement.

PRIA 2 Implementation

Elizabeth Leovey, Senior Advisor for PRIA Implementation, provided an update concerning several aspects of implementing the Pesticide Registration Improvement Renewal Act (PRIA 2). Among her points, she stated the following:



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- EPA's PRIA website is regularly updated with new information (<http://www.epa.gov/pesticides/fees/>). Recent updates have included information about Inter-Regional Project Number 4 (IR-4) exemptions and the 21-Day Initial Content Screen Review Worksheet.
- PRIA 2 pre-payment of fees is working well. Applicants are cautioned to use the correct form on <http://www.pay.gov> (*i.e.*, for pre-payment, not for payment following an invoice, which was used more regularly before PRIA 2), write the company number on the check if paying by check, and not combine payments for multiple registration actions into one.
- Revised fee category interpretations are being developed and will be incorporated into the Fee Determination Decision Tree; and
- Guidance on primary/secondary applications (a group of applications in which one or more secondary applications are linked to or dependent on the primary application, *e.g.*, because of a common data set; previously called "parent/child" applications) is being developed and will be posted on the web page when final.

Leovey along with the RD's ombudspople discussed the 21-Day Initial Content Review Screen process for each of the divisions that has been phased in since January 2008. Leovey noted that if an application does not pass the initial screening and the deficiencies cannot be corrected within the first 21 days of submission, then EPA must reject the application within 10 days. Linda Arrington, RD, stated that RD currently is conducting the screening, but this process will be conducted by contractors by September 2008. Michael Hardy, Antimicrobials Division (AD) stated that in AD, the team assigned to review incoming submissions daily (the "Mail Team") both assigns the PRIA code and completes the initial screening for completeness. The initial screening results are reviewed by the product manager, who then follows up with the applicant as needed. Hardy noted that, among steps being pursued to improve submissions, AD plans to post a list of current data requirements by use site on the Office of Pesticide Programs (OPP) website. Leonard Cole, Biopesticide and Pollution Prevention Division (BPPD) stated that the most common errors that have arisen during BPPD's initial content screening have been formulations containing inert ingredients not cleared for the proposed use and missing or incorrect data certification statements.



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RD Notification Status

Linda Arrington provided an update concerning the status of RD's management of notifications, including review of the existing backlog. Since October 2007, 334 backlog notifications were completed, with 523 still pending at the time the presentation was prepared. Arrington requested registrants to withdraw pending notifications if they are incorporated into and/or superseded by a subsequently approved registration amendment. Acknowledging that Pesticide Registration (PR) Notice 98-10 states that a registrant may proceed to make changes as soon as a notification is sent to EPA, Arrington stated that many registrants prefer not to proceed without a letter from EPA confirming the notification is appropriate. She also encouraged registrants to contact her directly if they have an urgent need for the confirmation letter. Finally, Arrington stated that notifications under PR Notice 2007-4 for the Container and Containment Rule have been coming in, and that RD has assigned two additional people to assist with their review.

Inert Ingredient Assessment Branch Update

Acting Chief of the Inert Ingredient Assessment Branch (IIAB) PV Shah provided an update of IIAB activities. Among the accomplishments to date for FY 2008, Shah included: a reduction in the backlog of petitions for new inerts, and an updated website with updated inert lists and useful links (<http://www.epa.gov/opprd001/inerts/lists.html>). He also stated that three PRIA 2 new inert food use petitions had been received, and encouraged registrants to meet with IIAB for input on what should be included in a petition.

Regarding the August 9, 2006, proposed revocation of 123 tolerance exemptions due to insufficient supporting data, Shah reported that EPA is working with the Joint Inert Ingredient Task Force. Shah stated that industry has informed EPA that it will support 62 of the 123 tolerance exemptions. For the inerts for which industry has submitted data and study development plans, EPA has extended the revocation date until August 9, 2009; a notice about this extension is scheduled to be published in the *Federal Register* soon. For unsupported inerts, Shah stated that EPA would be contacting registrants about options, including reformulation and cancellation.

Shah listed several ongoing efforts within the IIAB, including: the development of guidance for preparing inert ingredient petitions; an advanced notice of proposed rulemaking concerning the creation of a Inert Ingredient Data Submitters List for data compensation purposes, scheduled for publication by the end of 2008; extension of the Fragrance Pilot Project to include fragrances in antimicrobial products; and addition of Chemical Abstract Service



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(CAS) registration numbers to tolerance exemptions published in the Code of Federal Regulations.

Quality Improvement Workgroup and Product Chemistry

Tyron Aiken, from RD, reported that the Quality Improvement Workgroup, which supports all the OPP divisions, is developing web tools to assist registrants. These tools include a frequently asked question tool, a registration tutorial web page that focuses on common errors and solutions, and an electronic confidential statement of formula pilot project. Aiken invited registrants to test these tools as they are announced and send him comments at aiken.tyrone@epa.gov.

Labeling Committee Update

Leovey provided an update from the activities of the Labeling Committee, including: ongoing updates to the questions and answers section of the labeling web page, available at http://www.epa.gov/pesticides/regulating/labels/label_review.htm; the near completion of the review and update effort for the Label Review Manual, most of the updated chapters of which have been posted on the website; the near completion of the environmental hazard general labeling statements on outdoor residential use products; and review of comments on draft PR Notice 2007-B for third party endorsements and cause marketing claims.

Leovey also reported on the activities of the Labeling Accountability Workgroup (LAW), which was formed in July 2007 to address the issue raised by EPA regional offices of unenforceable label language. The LAW developed the following recommendations: develop and use training materials with EPA staff; develop and pilot test a quality assurance process; and eventually, adopt web-based distribution of labeling.¹

e-Submission Efforts Update

Oscar Morales and Dominique Rey-Carruth, from the Information Technology and Resource Management Division, discussed the status of ongoing efforts to develop electronic submission capabilities for pesticide registration applications. A successful e-

¹ Web-based distribution of labeling refers to a system that would make the most current version of pesticide labeling available to purchasers and users electronically on an EPA-maintained website. The system would simplify the label required to be affixed to the product container and allow for rapid updating of the label.



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submission pilot project was conducted in June-July 2007. Starting this summer, EPA will begin scanning registration submissions and distributing them to product managers electronically, to eliminate the need to manage and track paper copies, increase accessibility, and allow for parallel review of the same documents. Registrants are encouraged to submit submissions electronically, to expedite the in-processing of the submissions. Guidance on how to prepare a submission for electronic submission was distributed at the meeting; copies are available upon request.

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