



MEMORANDUM

Via E-Mail

DATE: January 28, 2005

TO: Firm Clients and Friends

FROM: Bergeson & Campbell, P.C.

RE: Pesticide Program Dialogue Committee -- Pesticide Registration Improvement Act Workgroup Meeting Summary

On January 25, 2005, the Pesticide Program Dialogue Committee (PPDC) held a meeting of the Process Improvement Workgroup. The Workgroup discussed: (1) process improvements implemented in the U.S. Environmental Protection Agency's (EPA) Antimicrobials Division (AD); (2) issues from the October 2004 Workgroup meeting, which included industry proposals for broadening stakeholder input in the registration process and labeling issues; and (3) Workgroup interest in electronic submissions of registration applications.

Dennis Edwards, AD, outlined changes implemented by his division since enactment of the Pesticide Registration Improvement Act (PRIA). Among the changes Edwards outlined were the following:

- There is no more “clock stopping” in the review process under PRIA;
- There are now AD staff meetings on Tuesdays and Thursdays to discuss applications subject to PRIA, and AD management meetings on Wednesdays for the same purpose;
- Changes have been made to the review process to include cursory reviews. These cursory reviews allow reviewers to note what the application involves and what claims are proposed for the product, data and data compensation issues, and where the application needs to go for review.
- New “scope” meetings now occur. These meetings include the division director, associate directors, registration and science branch chiefs, and “science people” and their assistants. The meetings address the active



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ingredient, use pattern, and new ingredient review requirements. At these meetings, AD staff determine if further review (*e.g.*, scientific review or risk assessment) is required. Edwards noted that these meetings are “more focused on the kind of determination” and help expedite the review process.

Ron Derbyshire, Consumer Specialty Products Association, expressed concern, stating that although industry did not want to micromanage PRIA funds, it was important that maintenance fees reach the AD division because there is concern over AD’s lack of resources to complete timely reregistration reviews. He also noted that there needed to be “fine-tuning” of PRIA. He suggested that:

- Industry work with AD to expedite front-end review by getting information out to industry in the form of a registration/reregistration application template or checklist;
- AD and industry work with small nonmember companies who have problems with application rejections due to incomplete applications or other reasons, perhaps via registration seminars. He suggested that this would decrease mistakes that “bog down” the system. This idea was well-received.

Michael Mendelsohn, Biopesticides and Pollution Prevention Division (BPPD), outlined changes implemented in BPPD since PRIA’s enactment. He noted:

- BPPD has implemented a website for industry to use to report inconsistencies in reviews, labeling, registration issues, and data (<http://www.epa.gov/pesticides/biopesticides/>). Concerns can be e-mailed via the website, and a response will be posted within 2 weeks. The questions should be more “process” oriented, rather than chemical-specific registration questions, confidential business information issues, or similar issues.

Marty Monell and Rick Keigwin, Office of Pesticide Programs, ended the PRIA discussion:

- They noted the importance of consistency with regard to meeting PRIA deadlines. Monell stated that cross-agency consistency in handling incomplete application packages, negotiation of reregistration deadlines,



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and other registration-related deadline issues was important. Thus, the “Registration Divisions meet once every other week to review incomplete packages and discuss as a group” how to handle renegotiation dates, application withdrawals, and similar issues.

- At present, Monell approves all renegotiation dates. This is not permanent, but is being done now because “the agency is trying to build a history of how to handle these issues.” There was expression of support, however, for the review of applications in a consolidated manner (*i.e.*, Monell making decisions for renegotiation of timelines), rather than division by division reviews.
- The PRIA outlines what must be in the registration application, but fails to give EPA the ability to take action if the criteria are not satisfied. Also, the language of PRIA refers to a “determination” and a “final determination.” This language has allowed EPA to draw a distinction between denial of an application and a “determination to not grant” an application because the determination to not grant is not held as a “final determination.” While “this basically forces an applicant to withdraw their application and resubmit it,” it is not a denial of the application because the applicants are given 75 days to amend or fix it. There was concern expressed over this practice. Industry representatives fear a grey area could develop between these two determinations.
- There was a final discussion of billed versus collected monies. Over the past ten months of operations, under \$18 million has been collected, and \$4 million are outstanding.

Greg Watson, Syngenta, began the discussion of follow-up to the October meeting with a discussion of transparency and data/review availability. He noted:

- There is a desire to have data evaluation records (DER) placed in a public docket, in addition to related risk assessment information, for chemicals under registration review. He also stated that there are inconsistency issues with regard to how and when these data become available to registrants.
- Industry would like to have the DERs and related risk assessment information earlier. Watson stated that DERs and similar information can



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be important, even though they do not serve as “real” registration decisions, because DERs feed into risk assessment processes which feed into endpoint discussions. Two questions posed were: “Why not give documents to the registrant once EPA signs off, even before registration is completed?” and if the DER and other related documents are disagreed upon, is it not better to flesh this out before registration?

- Others stated that DER availability is necessary because the information they contain is essential when sending in registration information, considering state regulations, and understanding tolerance decisions.
- A desire for transparency in the public work plan regarding new uses and active ingredient listings was expressed. Watson suggested implementation of a database that notes PRIA completion dates and dates that EPA expects completion.

EPA staff members agreed that there is no unified process in the Registration Division (RD) addressing when, and if, DERs and risk assessments are to be provided to registrants. Lois Rossi, RD, noted the necessity of a standard operating procedure (SOP) or guidelines so that the inconsistency among what-goes-to-whom-and-when is resolved. Other EPA staff member comments included:

- In BPPD, DERs are available upon request. BPPD also conducts a secondary review, which summarizes the DER, is prepared like a Reregistration Eligibility Decision, and is posted on the Internet.
- Rossi expressed hesitancy about providing DERs before registration because DERs are treated as property of the registrant and can be obtained via Freedom of Information Act requests only after registration is complete. She also noted that, while DERs are valuable, a problem arises when people attempt to represent the DER as a study in and of itself.
- Another EPA staff member stated that it was not pragmatic to make a docket for all information because a significant amount of work and resources are required to put information into the system, and from her perspective, the docketed information usually elicits no public comments. Further, concern was expressed that a docket is time-limited in that subsequent changes require a new docket. One agency representative asked, “Where does the docket stop?”



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Watson, Julie Schlekau, Responsible Industry for a Sound Environment, and Julie Spagnoli, Bayer Healthcare, then opened a discussion on labeling issues, noting that large problems for EPA are unwritten policies and inconsistency. Discussion included the following points:

- A suggestion was made to design a website addressing what is not found in the label review manual, to catalog how to handle labeling issues that have no written answer. It was also suggested that, as each issue is resolved, a weblink should be added to keep information current and available. This would provide a place for registrants to go if they encountered grey area in policy or had questions that product managers (PM) could not answer.
- The Label Review Manual should be updated immediately and made into a “living document” for all three divisions -- AD, BPPD, and RD. At present, EPA does not keep the manual current, and due to new changes in labeling, the manual is in danger of becoming “archaic” and “outdated.” EPA also should address inconsistencies between the manual and the regulations. Areas where inconsistencies arise include dermal, inhalation, and eye statements, precautionary language, environmental hazards statements, product category inconsistencies (public health pests, seed treatments, turf use, aquatic use, and fertilizer combinations), and warranty statements.
- A database should be constructed to alert registrants to Pesticide Registration Notices that are no longer in effect, or to those that have been amended or superseded by more recent notices.

Rossi recognized the concern over inconsistency. She noted that different divisions might not agree on certain statements based on differences in review standards among divisions. She said that a PR Notice database had been completed, and would be available shortly. Monell acknowledged that a consolidated, consistent label review system would also help EPA to implement PRIA, because better labeling guidance could help expedite reviews, but that other concerns had overshadowed the label issue.

Monell closed the discussion by saying that “we have a lot of work to do,” and that “this is depressing.” She said that the suggestions from the meeting would need to be discussed internally, in order to “identify the most effective way to make appropriate information available” and “develop a path forward.” She asked for final thoughts on electronic submissions



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of registration applications, adding that it would be a major investment: the “developmental” cost for the system improvements required for registrants to be able to submit everything electronically would be \$900,000 for the first year, \$800,000 for the second, and \$400,000 for the third.

In response to her questions regarding whether electronic submissions are “a high-priority” and whether EPA should “enhance delivery of service with PRIA funds,” industry representatives stated:

- They would like an update on capability and savings estimates. They asked whether electronic submissions could be useful as a front-end screening tool or an electronic label review mechanism. They also asked whether industry could get percentages and an analysis of what the savings in time and effort would be. They additionally asked whether, if it increases efficiency, it will open up monetary funds for other projects.
- There was hesitancy regarding the use of PRIA funds, and industry representatives noted that, because the cost would impact the registrants, they would need to discuss the costs and benefits with a broader group of registrants.
- For electronic infrastructure to function effectively, “information needs to go in, in order to go out.” Industry representatives expressed concern that the infrastructure was distrusted by some PMs, which would continue to hinder the process. Industry representatives suggested that EPA implement a mechanism for tracking PMs and their ability/desire to use the electronic infrastructure.

The next PPDC meeting will be in mid-April. There will be a full PPDC report out by the mid-April meeting.

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