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Keeping an Eye on Washington

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CPDA Participates in PRIA Process Improvements Work Group Meeting

CPDA staff recently participated in a meeting of the PRIA Process Improvements Work Group (“Work Group”) in preparation for a meeting with EPA Office of Pesticide Programs (OPP) personnel tentatively scheduled for January 24, 2008. During its meeting, the Work Group identified issues that involve all three registering divisions (AD, RD, and BPPD) that registrants have encountered under the reauthorized statute.

One key issue involved EPA’s handling of new non-food use inert ingredient applications and the Agency’s use of monies dedicated from the annual maintenance fees to review these products. Under PRIA II, approximately \$3 million per year of the \$22 million in annual maintenance fees is earmarked for fast track submissions and new inert ingredient applications for each of fiscal years 2008 through 2012. Several members of the Work Group expressed their desire to see the development of a system that would provide greater transparency in how EPA utilizes these dedicated funds. While PRIA II provides funding from maintenance fees for these inert ingredient reviews, it does not set forth timelines for processing these actions. Therefore, some members of the registrant community believe some type of system is needed to ensure EPA acts in accordance with the principle of greater Agency accountability as set forth under PRIA II.

During this portion of the Work Group discussion, CPDA staff suggested that posting an inert ingredient work plan on EPA’s Inert Ingredient Assessment Branch (IIAB) website might serve as one avenue for bringing greater accountability to the inert ingredient review process. Posting would include the status of these submissions and should provide the registrant community with a means of measuring how effectively the Agency is using that portion of the maintenance fee dedicated to inert ingredient review.

In related issues, the Work Group discussed the potential merits of a proposal that would call for the publication of a list of approved inert blends by brand or trade name on EPA’s web site. This issue was also raised during a January 10, 2008 CPDA AIC Regulatory Committee meeting with EPA staff. At that time, EPA personnel indicated that the Agency would prefer to see the inclusion of the brand name of a proprietary inert mixture on the CSF if a mixture is to be used. The Agency is scrutinizing every pesticide

registration application to ensure that the inert ingredient cited in the CSF is approved for use. Listing an unapproved inert ingredient on the CSF can derail the pesticide registration application process and consume significant time and resources for both the applicant and product manager in seeking to resolve the problem.

In addition, new provisions contained in PRIA II require EPA to perform a 21-day content screen or completeness check of a pesticide registration application after receipt of the submission package and applicable fee. As part of the 21-day completeness check for conventional pesticides, the Registration Division Inert Team will check the CSF for food and non-food inert clearance. If EPA determines that the application does not pass the initial screen and cannot be corrected in 21 days, the Administrator will reject the submission no later than 10 days after making such determination. Moreover, PRIA II mandates that EPA retain 25% of the applicable registration service fee for any application that is rejected. The posting of approved inert blends by trade name on EPA's web site would help registrants determine if the inert mixture cited in the CSF has an Agency clearance. This initiative could help registration applicants pass the initial 21-day PRIA screen and avoid rejection of their submission and the associated loss of 25% of the applicable registration service fee.

In other discussion, the Work Group addressed the so-called "parent-child" relationship whereby EPA believes it has the authority under the revised statute to charge an additional fee of 25% for each new end use product added to the submission package. Under PRIA I, OPP created the parent/child relationship for reviewing one set of data to support multiple applications. The lead application with the data was charged a full fee while the other applications were given a reduced fee. The reduced fee in most cases was zero. All applications had the same due date. For instance, at EPA's November 27, 2007 PRIA workshop, Agency personnel noted by example a registrant submitting two applications for amendment at the same time with one set of efficacy data to support the amendments, the first application was assigned the full fee while the second application received a reduced fee. The rationale for this approach was that the data set only needed to be reviewed once to approve the application.

In contrast, under PRIA II, EPA has decided to charge the lead application with the data a full fee and a reduced fee (in most cases 25% of the full fee required) for the other applications. All applications will have the same due date. The Agency bases this policy change on Section 33(b)(2)(G) of PRIA II, which states that 25% of the registration fee is non-refundable. Several members of the Work Group contend that as long as the applications accompanying the lead application retain the same use pattern, the same rate pattern, etc., they should be treated as fast track amendments that are not subject to a registration service fee under PRIA II. The Agency's new policy represents a significant departure from past practice whereby the emphasis was placed on bundling applications together as much as possible. The parent/child dilemma could arise every time an applicant seeks to register multiple labels with the same set of data.

The Work Group also discussed whether a registrant can list a company website on a product label. It appears that EPA has told some members of the registrant

community that a company website address cannot appear on the product label unless the entire web site is FIFRA compliant. Apparently, the Agency is taking the position that such product label links provide access to product-related company information and is considered labeling. However, several members of the Work Group maintain that EPA should treat inclusion of a company website address on the label as it does in the permissible listing of toll-free telephone numbers on labels.

These issues will be addressed in further detail at the January 24, 2008 PRIA Process Improvements Work Group meeting with EPA. In preparation for the meeting, CPDA invites its member company representatives to provide our office with input on these and any other problematic issues related to implementation of PRIA II they may have encountered since the new law went into effect.

CPDA Seeks Extension of Public Comment Period on Draft EDSP Policies and Procedures Document

CPDA has submitted a formal request to EPA seeking a 90-day extension of the comment period on the Agency's draft policies and procedures for implementation of the Endocrine Disruptor Screening Program (EDSP). The draft policy document was published in the *Federal Register* on December 13, 2007 with a public comment period ending on February 11, 2008. In its January 14, 2008 letter to EPA, CPDA asked the Agency to extend the comment period to May 12, 2008. CPDA pointed out that the draft document presents a complex cost-sharing and data compensation scheme, procedures for handling confidential business information, notification procedures, a mechanism for seeking an exemption from EDSP screening, a process for contesting test orders, and a number of other provisions. CPDA emphasized that these are complicated issues that will have a far-reaching impact on the inert and pesticide industries, significantly affecting inert ingredient manufacturers and importers, pesticide registrants, and pesticide formulators. As such, it is essential that EPA allow adequate time for industry to conduct a thorough analysis of the potential impact of these policies and procedures so that the comments adequately address the many complexities presented in the draft document in a thoughtful and deliberative manner.

As reported previously, the public comment period for a related docket in which EPA has proposed the initial list of 73 chemicals for endocrine screening, ends on February 11, 2008. CPDA is not seeking an extension of the comment period on the draft list of chemicals. Should you have any questions on the EDSP issue or input you would like to provide CPDA, please contact our offices.

EPA Seeks Public Comment on Draft Guidance for Conducting Prospective Ground-Water Studies

EPA has issued for public comment draft guidance for conducting prospective ground water (PGW) monitoring studies. This study, which is conducted in a controlled setting and required on a case-by-case basis, provides EPA with data for evaluating the

impact of pesticide use on ground water quality. Comments on the guidance document, identified by docket identification number EPA-HQ-OPP-2007-1163, are due March 17, 2008 and may be submitted electronically through the federal government eRulemaking portal (www.regulations.gov). The Agency states that the PGW guidance document describes how to conduct a PGW monitoring study, milestones for consulting with EPA, and how to report results to EPA.

The Agency states that data generated from the PGW monitoring studies have proven valuable to EPA scientists and risk managers as they are specifically designed to relate pesticide use specified on the label to measurements of the pesticide and its degradates in ground water used as a source of drinking water. The Agency uses the results of the PGW monitoring studies to help it gather information on: 1) whether the pesticide will leach in portions of the use area that is similar to the study area; 2) how the pesticide residue changes over time; and, 3) the type of measures that might be effective in mitigating pesticide leaching.

EPA Posts Updated Chapters of the Label Review Manual on its Website

EPA has posted an update of Chapters 14 and 15 of the Label Review Manual on its website. Chapter 14 of the Label Review Manual addresses the inclusion of the EPA Registration Number on the product label and the EPA Establishment Number on the label or container. The EPA Registration Number indicates which company holds the registration for the pesticide product and in which sequence the product was submitted to EPA by the company. The Registration Number must appear on the label preferably on the front panel near the registrant's name and address. The Establishment Number indicates the final establishment at which the product was produced and may appear anywhere on the label or the immediate container. However, EPA advises that the Establishment Number must appear on the outer container or wrapper of the product if it cannot be read clearly through the outer container or wrapper.

Chapter 15 of the Label Review Manual addresses the inclusion of the company name and address on the pesticide label. EPA states that at a minimum, the company address must include the street address and/or post office box plus zip code or unique zip code of the location at which a particular organization may be found or reached. To access the online version of the Label Review Manual, visit <http://www.epa.gov/oppfead1/labeling/lrm/index.html>.