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Keeping an Eye on Washington

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Updated "Blue Book" Now Available on EPA's Web Site

An updated version of the Pesticide Registration Manual, also known as the "Blue Book," is now available on EPA's web site. The manual describes EPA's review and decision making process for registering a pesticide product and its use. Detailed information for pesticide registrants concerning their responsibilities before, during and after the review process is also included in the manual. EPA is hoping to make available in the near future an electronic version of the "Blue Book" in PDF format. The Agency intends to make subsequent updates to individual chapters of the manual as needed. The "Blue Book" may be accessed at <http://www.epa.gov/opprd001/registrationmanual/>.

CPDA Comments on EPA's Draft PR Notice on Drift Labeling

On March 5, 2010, CPDA submitted comments to the docket in response to EPA's draft PR Notice on pesticide drift labeling. In its comments, CPDA expressed its opposition to the approach used by EPA in the draft document whereby the Agency seemingly attempts to substitute administratively a vague, unsupportable standard of "could cause adverse effects" [or harm] in lieu of the FIFRA risk-based "without unreasonable adverse effects" safety standard. CPDA maintained that EPA's proposed policy constitutes a *de facto* "no-drift" policy that presumes all offsite drift "could cause" adverse effects or "harm." CPDA recommended that EPA delay issuing the final PR Notice for a period of 6 to 12 months until after the Agency's new drift reduction technology (DRT) program is in place. Such a delay would give EPA an opportunity to ensure that its proposed policy is consistent with the goals and benefits of the DRT program. Moreover, the additional time would eliminate the potential for confusion among registrants, formulators, and distributors with regard to any final label changes that would be required pursuant to the PR Notice. Click [here](#) to read CPDA's comments.

EPA Assistant Administrator Steve Owens Addresses CPDA Spring Meeting

EPA Office of Prevention, Pesticides & Toxic Substances (OPPTS) Assistant Administrator Steve Owens addressed the CPDA Spring Meeting on March 1, 2010. Owens provided the CPDA group an overview of the three guiding principles of EPA

under the Obama Administration – namely, the Administration’s commitment to transparency and the need to provide more information to the public at large, a greater focus on the impact of EPA’s regulatory activities on children, and an emphasis on environmental justice by ensuring that any one Agency initiative does not have a disproportionate impact on one segment of the general population. In his other opening remarks, Assistant Administrator Owens announced that OPPTS would be renamed the Office of Chemical Safety and Pollution Prevention (the name change officially took effect on April 22, 2010, Earth Day).

The Assistant Administrator touched on several ongoing activities of specific interest to the pesticide registrant community. Among these was the Agency’s progress in developing an NPDES general permit for the application of pesticides to, over, or near waters of the United States. EPA has been working in an effort to develop a general permit following a Sixth Circuit Court of Appeals decision that struck down an EPA rule which held that a pesticide applied in or near water in accordance with the FIFRA approved label is not subject to NPDES permitting requirements under the Clean Water Act. A two-year stay of the Court’s decision remains in effect until April 9, 2011. In his comments to the CPDA audience, Assistant Administrator Owens explained that EPA is developing a permit that is broad-based and will cover those pesticide applications subject to the court ruling. The EPA official added that if an individual is not covered by the permit, he/she may be at risk of state enforcement action or possibly a citizen suit brought by a third party. According to Owens, the Agency is hoping to have a general permit finalized before the end of 2010.

Owens then addressed the assessment of pesticides for endangered species effects. He noted the need for an improved ESA consultation process between EPA and the Services in assessing the impact of pesticides on threatened species and habitats. Assistant Administrator Owens reported that he has been engaged in high level conversations at the political level with the Services in an effort to determine how the consultation process could be improved. Owens added that EPA is studying the possibility of providing the Services information in a more manageable format and perhaps defining more sharply the types of data the Services need to fulfill ESA obligations in assessing the effects of pesticides.

The EPA official concluded his remarks with his perspective on legislative efforts to reform TSCA. He signaled that any rewrite of TSCA must include several key components as follows: 1) a stricter hazard-based safety standard that chemicals should meet if they are going to be on the market; 2) an expeditious process that EPA could use in obtaining data in addressing any health or safety concerns associated with a chemical (Owens pointed out that at present, the Agency must conduct lengthy rulemaking if it determines it needs chemical specific information under TSCA); and 3) revisions to the statute should include a fee structure that would provide EPA the resources needed to implement the law.

OPP's Marty Monell Makes Presentation at CPDA Spring Meeting

OPP Deputy Office Director for Management Marty Monell spoke at the CPDA Spring Meeting on the morning of Wednesday, March 3, 2010. She provided an overview of EPA's proposed inert disclosure initiative and its potential impact on the treatment of Confidential Business Information (CBI), the Agency's pilot program that would allow the use of the Design for the Environment (DfE) logo on the label of qualifying antimicrobial pesticides that meet certain criteria, EPA's plans to conduct focus groups to gauge the effect that such pilots have on consumer behavior, and the impact of OPP's new pesticide registration decision transparency policy on PRIA deadlines.

In her summary of EPA's ANPR on inert disclosure, Monell stated that the Agency is seeking comment on whether disclosure should be limited to those inerts deemed to be hazardous under other statutes or whether disclosure should be applied more broadly to include all or most other inerts. Monell highlighted several specific questions included in the ANPR as follows: 1) whether the Agency should establish a *de minimis* threshold below which a potentially hazardous inert ingredient would not be required to appear on the ingredient statement; 2) whether a disclosure requirement should apply to classes of inerts such as fragrances or dyes (i.e., classes of ingredients would be identified only by the name of the class); and 3) whether EPA should list by rule specific chemicals used as inert ingredients that would trigger a disclosure requirement (in so doing, this option would require EPA to devise a process for revising such a list).

Turning her attention to EPA's pilot program that would allow the use of a DfE logo on certain qualifying antimicrobial products, Monell signaled that this initiative is on track to start May 3, 2010. She told the CPDA group that the pilot will consist of a two-step process. First, applicants must ensure that the product meets specific qualifying factors as established by OPP. Products must have an acute Toxicity Category III or IV classification and must not possess known reproductive issues or carcinogenic properties. In addition, products which have outstanding "conditional registration" data issues or require the use of personal protective equipment are ineligible for this pilot. Formulations submitted for DfE review must be identical to the Confidential Statement of Formula identified for the pesticide registration application. Finally, products may not have any issues pertaining to unresolved efficacy failures or FIFRA Section 6(a)(2) unreasonable adverse effects. Once the applicant ascertains that the product qualifies for the pilot, he or she must then review the DfE screening requirements to ensure that all necessary information is provided for the DfE review. Upon successful completion of the DfE review, the antimicrobial product must then be submitted to OPP's Antimicrobial Division as a PRIA action for which a fee will be required.

Monell then reported that EPA has conducted a preliminary market survey in an effort to obtain baseline information on consumer behavior. Specifically, the Agency is trying to determine whether a consumer might be willing to pay more money or be more likely to buy a product that bears a logo indicating that the product contains a "greener"

chemistry. Monell stated that EPA has now received permission from the Office of Management and Budget (OMB) to run a focus group to ascertain if pilot programs (such as the DfE initiative) have an influence on consumer behavior.

In her other comments, Monell announced that EPA is planning to revisit a draft PR Notice originally published in 2002 that attempts to clarify the rules regarding claims and names of products that may be confusing or misleading. As reported previously, CPDA along with CSPA, RISE, and CLA wrote a December 3, 2009 letter to Debbie Edwards, then Director of the Office of Pesticide Programs, which called upon the Agency to reissue for public comment its draft PR Notice 2002-X pertaining to false or misleading pesticide product brand names. The letter was prompted by EPA's unannounced implementation of a new policy of no longer allowing certain words to be used in pesticide product names. Specifically, during registration actions, EPA label reviewers began rejecting words such as "professional (Pro)," "maximum (Max)," "super," "plus," and "ultra" based on their potential to be false or misleading. Registrants would have to either remove the word or develop acceptable qualifying label language to minimize the potential for a brand name to be deemed false or misleading under FIFRA. The industry coalition asserted that this change in policy was inconsistent with the Agency's express commitment to bring increased transparency to the decision-making process given that it was not previously vetted with the regulated community. CPDA and its industry partners also expressed concern regarding the financial impact of EPA's new policy. In making the announcement that EPA would soon reissue the draft PR Notice for public comment, Monell added that the Agency intends to "finalize" the document this time around.

Finally, Monell offered some brief comments with regard to OPP's ability to meet its PRIA deadlines under the new registration decision transparency policy put in place by Assistant Administrator Steve Owens. This policy establishes a 30-day period that allows for public review and comment on risk assessments and proposed registration decisions for pesticides. This expanded process applies to all new pesticide active ingredients and first food uses, first outdoor uses, and first residential uses. (As reported previously, on October 1st, EPA began adding its risk assessment and proposed decisions to the public docket for a 30-day public comment period. Following the comment period, EPA will publish its decision and a response-to-comment document. EPA states that by focusing public access on new pesticide ingredients and first food, outdoor, and residential uses, the public will have the opportunity to comment on all major new exposure patterns for pesticide registration). Monell indicated that an internal analysis conducted by EPA suggests that renegotiations present a larger obstacle than the new transparency initiative with regard to the Agency's ability to meet its PRIA deadlines. She explained that there have been several occasions where EPA had to enter into renegotiations due to the 30-day comment period established under the transparency initiative. However, Monell added that for the most part, renegotiations are driven by data deficiencies. She clarified, however, that thus far the Agency has not received questions that had to be addressed during the 30-day public participation period. Monell stressed that if the Agency does receive meaningful questions of concern during the

public participation period, EPA will take appropriate steps to address these including the possible revision of the risk assessment for the product in question.

EPA's Bill Jordan Discusses Agency's Progress in Drafting NPDES General Permit

Speaking before attendees of the CPDA Spring Meeting, EPA's Bill Jordan signaled that the draft general NPDES permit that the Agency is developing will not include the agricultural application of pesticides. Jordan stated that the Agency is leaving it up to the agricultural community to decide whether the draft permit should be expanded to cover applications to corn, rice, soybeans, and other similar uses. Jordan indicated that the draft permit will be released for public comment in May 2010 and that one of the questions the Agency will seek input on is whether the scope of the permit should be expanded to cover agricultural applications. In developing the draft permit, EPA has been working closely with state regulators who, according to Jordan, have not given the Agency the impression that they are keen on extending their authorities under the Clean Water Act (CWA) to the agricultural application of pesticides. Jordan noted, however, that this could change in the future as the program moves forward. In his other remarks, Jordan pointed out that there is a great deal of litigation surrounding the phrase "waters of the United States" as used in the Clean Water Act. He explained that it is sometimes difficult to determine whether or not a water body meets the criteria of "waters of the United States" as set forth under the CWA.

State Pesticide Regulatory Official Discusses the Need for More Streamlined, User Friendly Labeling

Jim Gray of the North Dakota Department of Agriculture told attendees of the CPDA Spring Meeting that the current system of labeling is "fundamentally broken." In his discussions with stakeholders in his state, Gray indicated that an overarching theme heard repeatedly is the need for labels that are easy to understand. He expressed his support of EPA's proposal to initiate a virtual web distributed labeling (WDL) pilot. Gray explained that web distributed labeling is premised on the creation of a voluntary system under which the label will display "must-have" information and include a web site (URL) address where the user can find streamlined information. He explained that the intent of the WDL is to generate a streamlined, site specific, user friendly label that is no more than two to three pages long.

Joining Jim Gray in this discussion of WDL was EPA's Bill Jordan who told CPDA members that EPA will need to address three challenges surrounding this initiative: 1) the technological capability necessary to build a web site that generates a streamlined, user friendly label; 2) user access to the Internet; and, 3) the willingness of customers to use web distributed labeling. Jordan noted that the proposed virtual pilot will serve as a "customer acceptance" pilot that will help EPA gauge how users will react to web distributed labeling. Jordan concluded his comments emphasizing that web distributed labeling will offer registrants an opportunity to "enhance the user experience."

EPA Staffer Provides CPDA Members Update on EDSP

Gary Timm from EPA's Office of Science Coordination and Policy provided CPDA Spring Meeting attendees an update on the Agency's implementation of the Endocrine Disruptor Screening Program (EDSP). He reported that as mandated under the Interior and Environment Appropriations bill for Fiscal Year 2010 (enacted as Public Law 111-88 on October 30, 2009), EPA is required to issue a second draft list of no less than 100 chemicals for endocrine screening by October 30, 2010. EPA intends to issue 25 test orders per year for these chemicals and anticipates that an approved Information Collection Request (ICR) necessary before EPA can request the required data will be issued by October 2010. Timm stated that EPA is reviewing its policy and procedures document (issued in conjunction with the first list of chemicals selected for EDSP Tier 1 screening) with the hope that most of this document will remain intact with regard to its applicability to the second draft list of chemicals. However, Timm acknowledged that the policy and procedures document may likely have to be "tweaked" since the second list of chemicals will include substances found in drinking water.

State Official Highlights the Need for Additional NAFTA Labeled Agricultural Pesticide Products

Jim Gray from the North Dakota Department of Agriculture discussed the benefits of NAFTA labeling of pesticide products at the recent CPDA Spring Meeting. He explained that the price disparities in pesticide products seen across the U.S. and Canadian borders in 2000 highlighted the importance of NAFTA labeling for growers in the state of North Dakota. He told the CPDA audience that country-specific labels prohibit product from crossing the border unless it is relabeled. Gray emphasized that the purpose of NAFTA labeling is to eliminate any barriers to the free movement of product across the border. According to Gray, at present there are seven agricultural pesticide products that bear a NAFTA label approved by both the U.S. and Canadian governments. He noted that the current NAFTA label model is a basic container label which states that the product is registered for use in both the U.S and Canada. The user in the U.S. is required to follow the U.S. label and the Canadian user follows the label for its use in that country. The product may move across the border without the need for relabeling. Gray concluded his remarks by pointing out that there are no new products proposed for NAFTA labeling and he emphasized that more agricultural use pesticides need to be "volunteered" for this initiative.

EPA Announces "Rulemaking Matters!" Video Contest

EPA has announced on its web site its "Rulemaking Matters!" video contest, open to the public. The Agency is inviting the submission of videos that highlight the importance of participating in the federal regulatory process. Video submissions must be brief and must not exceed 90 second in length. The winner will receive \$2500 and will have his/her video submission posted on www.regulations.gov as well as on EPA's web

site. The deadline for submissions is May 17, 2010. Complete instructions on how to enter the contest may be accessed at <http://www.epa.gov/lawsregs/videocontest/>.

EPA Releases Open Government Plan

On April 7, 2010, EPA unveiled its “Open Government Plan” in response to the Obama Administration’s Open Government Directive. The plan discusses publishing EPA information online, improving the quality of the information, and creating a culture of open government. The Agency states that it will use its Open Government Plan to emphasize and expand on its culture of openness within a mission-focused framework for engaging stakeholders and the general public. EPA has made the Open Government Plan available on its web site which may be accessed at <http://www.epa.gov/open>. EPA will continue to address public comments and suggestions on its plan through a series of blog posts and with a video town hall meeting that will be held in early summer 2010. EPA states that it plans to review its Open Government Plan every six months as suggestions come in from the public. Information on how to comment on the Open Government initiative is available at <http://www.openepa.ideascale.com/>.

Early Reminder of Upcoming Increase in PRIA Fees

CPDA reminds its members that PRIA fees will increase 5% effective October 1, 2010. Actions need to be received by OPP’s mailroom no later than September 30, 2010, COB (4:00 p.m. Eastern Time) in order to avoid the increase.

EPA Releases Report that Addresses Climate Change Indicators in the U.S.

EPA has issued a report, “Climate Change Indicators in the United States,” which examines 24 key indicators described by the Agency as presenting “clear evidence that the composition of the atmosphere is being altered as a result of human activities and that the climate is changing.” EPA states that the data used in the report was collected by several government agencies, academic institutions, and other stakeholder organizations. In a press advisory announcing availability of the report, EPA summarizes its findings as follows:

- *Greenhouse gas emissions from human activities are increasing. Between 1990 and 2008, there has been about a 14 percent increase in emissions in the United States.*
- *Average temperatures are rising. Seven of the top 10 warmest years on record for the continental United States have occurred since 1990.*
- *Tropical cyclone intensity has increased in recent decades. Six of the 10 most active hurricane seasons have occurred since the mid-1990s.*
- *Sea levels are rising. From 1993 to 2008, sea level rose twice as fast as the long-term trend.*

- *Glaciers are melting. Loss of glacier volume appears to have accelerated over the last decade.*
- *The frequency of heat waves has risen steadily since the 1960s. The percentage of the U.S. population impacted by heat waves has also increased.*

The Agency notes that the information contained in the report will “help inform future policy decisions and will help evaluate the success of climate change efforts.” The report is available on EPA’s web site and may be accessed at

http://www.epa.gov/climatechange/indicators/pdfs/ClimateIndicators_full.pdf.

TSCA Reform Legislation Introduced in Congress

On April 15, 2010, Senator Frank Lautenberg (D-NJ) introduced legislation to amend the Toxic Substances Control Act of 1976 titled the “Safe Chemicals Act.” Concurrently, Representative Bobby Rush (D-IL) and House Energy and Commerce Committee Chairman Henry Waxman (D-CA) released a discussion draft of the Toxic Chemicals Safety Act of 2010. Both initiatives would require manufacturers to submit a minimum data set to EPA about the chemicals they produce instead of presuming substances are safe until proven otherwise. Further, EPA would have the authority when making a safety determination to require additional data as deemed necessary. The House and Senate language would require chemicals to meet a safety standard that provides “reasonable certainty of no harm” and takes into account aggregate and cumulative exposures, as well as potential exposures to vulnerable subpopulations. Both initiatives would establish an expedited process for EPA to reduce risk from exposure to certain chemical substances where the risks posed to health and the environment are well known. As such, EPA would be required to identify and prioritize chemicals in accordance with their likely risk. The provisions of the Senate bill and the House discussion draft would apply to new chemicals entering the marketplace as well as existing chemicals already in commerce.