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Keeping an Eye on Washington

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U.S. Appeals Court Denies Request for Review of its Decision on NPDES Permitting Requirements for Pesticides

On August 3, 2009, the U.S. Court of Appeals for the Sixth Circuit denied a petition for a rehearing of its January 2009 decision in *National Cotton Council, et. al. v. EPA* in which the Court struck down an EPA rule which held that a pesticide applied in or near water in accordance with the label is not subject to NPDES permitting requirements under the Clean Water Act. Meanwhile, a two-year stay of the Court's decision allows the EPA rule to remain in effect until April 9, 2011. After that time, NPDES permits will be required for pesticides applied directly to water to control pests and/or applied to control pests that are over or near waters.

At the recent CPDA Annual Meeting held in Chicago, Illinois on July 19-21, EPA's Bill Jordan told the audience that the Agency will be developing, proposing, and issuing final NPDES general permits in unauthorized NPDES states, territories and tribes for pesticide applications subject to the January 2009 court decision. According to Jordan, EPA's general permits will cover pesticide applications in Massachusetts, Idaho, New Hampshire, Alaska, and New Mexico.

During the two-year stay, EPA will be working closely with NPDES authorized states to develop their general permits concurrent with the development of the Agency's general permits. Jordan noted that since the January 2009 appeals court ruling, EPA has been reviewing the 23 existing state pesticide application permits and has initiated data gathering. In addition, EPA is in the process of forming a state regulatory workgroup that will provide input and assist in the NPDES permitting effort. Jordan stated that EPA anticipates having two draft prototype general permits ready for informal review by stakeholders before the end of August 2009. One permit will cover mosquito adulticides and larvicides while the other will be applicable to herbicides used to control weeds in lakes and ponds.

AAPCO/SFIREG Pesticide Operations and Management Working Committee Will Meet on September 21-22, 2009

The AAPCO/SFIREG Pesticide Operations and Management (POM) Working Committee will meet on September 21-22, 2009 at the offices of OPP located at One Potomac Yard (South Building), 1st Floor South Conference Room, 2777 Crystal Drive, Arlington, Virginia.

Agenda topics will include updates to the Section 24(c) registration guidance document, a review of soil fumigant label tables, PRISM structured e-labeling, comparative safety statements on the label, and a variety of other issues. The *Federal Register* notice announcing the upcoming meeting may be accessed at <http://edocket.access.gpo.gov/2009/pdf/E9-19531.pdf>.

PPDC Meeting Scheduled for October 14-15, 2009

The next meeting of the Pesticide Program Dialogue Committee (PPDC) is scheduled for October 14-15, 2009 at EPA's offices located at 2777 S. Crystal Drive, One Potomac Yard, Conference Center, Arlington, Virginia. EPA announcements regarding the upcoming PPDC meeting will be posted on the Agency's web site at <http://www.epa.gov/oppfead1/cb/ppdc/>.

PPDC Workgroup Unveils Discussion Paper on Potential Benefits and Challenges of Web Distributed Labeling

EPA has made available on its web site a discussion paper prepared by the PPDC Web Distributed Labeling Workgroup in advance of its next meeting scheduled for September 17, 2009. Representing CPDA on this workgroup is Mike White, the association's Director of Regulatory Affairs. The paper identifies the potential benefits of web distributed labeling that will accrue to different stakeholder groups along with challenges and unresolved issues. The paper includes a discussion of some of the key benefits of web distributed labeling such as: access to state-specific and site-specific streamlined, easy-to-read labeling, labeling available in larger fonts, improved labeling compliance, web linkages to product stewardship information, reduced labeling costs and redistribution expenses to registrants, faster access to newly-registered uses, faster implementation of risk mitigation measures, and reduction in multiple versions of labeling in the marketplace.

The paper states that these potential benefits would be realized only for those registrants, users, and dealers of products that participate in the web distributed labeling initiative. Some of the challenges cited in the discussion paper include the lack of high speed Internet access in all areas of the country, the need for culture change in transitioning away from hard-copy container labeling, the establishment of expiration dates that are long enough to allow the majority of users to continue using product until the product is completely used but not so long that a user can continue using the downloaded labeling indefinitely, questions regarding the tort liability of registrants who

adopt web distributed labeling if users do not comply with FIFRA requirements to obtain labeling, and enforcement uncertainties pertaining to which entity would be responsible if the downloaded label is incorrect or if a product was not registered in a given state.

The PPDC discussion paper may be accessed on EPA's web site at <http://www.epa.gov/oppfead1/cb/ppdc/distr-labeling/sept09/potential-benefits.pdf>.

OPP Labeling Web Site Addresses Question Regarding the Listing of Active Ingredient Percentage for Diluted Formulations on Secondary Containers

The Office of Pesticide Programs (OPP) labeling consistency web site includes a new post that addresses a question regarding the percentage of active ingredient that must be listed on a secondary container holding diluted pesticide formulations. EPA advises, "A secondary container is a container used by an applicator to transport and store use dilutions of a pesticide for eventual use by the applicator. The percentage of active ingredient listed on the secondary container may be the same as that declared on the pesticide product, or if known, the percentage of active ingredient in the end-use dilution. Listing the percentage of active ingredient as reflected on the product label and indicating the product has been diluted as directed relieves the user from having to calculate the percentage of active in the dilute formulation. Such a calculation can be difficult for the average user when the directions for use call for a ratio of product to diluent, i.e., 1 part product to 64 parts diluent or 5 ounces of product to 128 ounces of water, and does not list the percentage of active ingredient in the finished dilution."

EPA adds that the secondary container is strictly for the use of the applicator and may not be sold or distributed. To view other questions and answers on the OPP labeling web site, visit http://www.epa.gov/pesticides/regulating/labels/label_review_faq.htm.

Senate Majority Leader Harry Reid Files Cloture Motion on Nomination of Cass Sunstein to Head the OMB Office of Information and Regulatory Affairs

On August 7, 2009, Senate Majority Leader Harry Reid (NV) filed a cloture motion seeking to end debate on the nomination of Cass R. Sunstein to be Administrator of the Office of Information and Regulatory Affairs (OIRA) of the White House Office of Management and Budget (OMB). The cloture motion is expected to be put to a floor vote sometime after the Senate returns from its August recess on September 8th and will require 60 votes to succeed. Should the cloture motion be adopted, Senate debate on the nomination of Cass Sunstein would end clearing the way for a floor vote. The Senate Committee on Homeland Security and Governmental Affairs approved Sunstein's nomination by voice vote on May 20, 2009. However, two Republicans – Senators Saxby Chambliss (GA) and John Cornyn (TX) – placed holds on Sunstein's nomination citing concerns over the Harvard professor's past writings on animal rights. While Senators Chambliss and Cornyn have subsequently lifted their holds, press reports indicate that a third unnamed GOP Senator has placed a hold on Sunstein's nomination which effectively delays a confirmation vote on the Senate floor. The cloture motion filed by Majority Leader Reid provides a parliamentary procedure by which Senate

consideration of the Sunstein nomination can move forward despite the hold. Meanwhile, the Senate's delay in holding a vote on Sunstein's nomination has hindered further action on President Obama's initiative calling for a revamping of Executive Order 12866 which sets forth the procedures the federal government must follow in promulgating health, safety and environmental regulations.

Republican Senators Question EPA's Analysis of House-Passed Climate Change Bill

Senators James Inhofe (R-OK) and George Voinovich (R-OH) sent a July 24, 2009 letter to EPA Administrator Lisa Jackson objecting that the Agency's analysis of House-passed climate change legislation, the Waxman-Markey American Clean Energy and Security Act of 2009 (H.R. 2454), provides an incomplete account of the bill's major provisions including how they overlap and how they impact consumers, households, and the economy. Senators Inhofe and Voinovich expressed their desire to work with EPA to produce what they described as a detailed, comprehensive, and objective analysis "to inform the upcoming legislative debate" on climate change in the Senate. The Senators requested that EPA provide the most up-to-date analyses, based on real-world assumptions, about energy production and use, the deployment of new technologies, and a complete account of the bill's cost to the economy.

In her response, EPA Administrator Jackson denied the GOP request citing an August 4, 2009 economic analysis of H.R. 2454 prepared by the Energy Information Administration (EIA). Administrator Jackson asserted that the EIA analysis incorporates many of the parameters requested by Senators Inhofe and Voinovich including scenarios in which low-carbon energy sources prove to be very expensive, the U.S. fails to deploy those sources beyond certain conservative limits, and no offsets become available from foreign countries. She also noted that Senator Barbara Boxer (D-CA), Chair of the Senate Committee on Environment and Public Works, plans to introduce an energy and climate bill in September. In preparation, Senator Boxer has asked EPA to perform an economic analysis of climate change legislative language now being drafted. Administrator Jackson urged Senators Inhofe and Voinovich to engage with Senator Boxer in a discussion of the "parameters, assumptions, and scenarios to be included in that analysis."

EPA Extends Effective Date of Revocation of Six Inert Ingredient Tolerance Exemptions

On August 7, 2009, EPA published in the *Federal Register* a direct final rule that extends the effective date of revocation of six inert ingredient tolerance exemptions that await a reassessment finding pending a review of supporting data that has been submitted to the Agency. The six products in question are among a group of 122 inerts that were slated for revocation pursuant to an August 9, 2006 final rule in which EPA determined that it lacked sufficient and reliable data to make the required safety determination for these products under FFDCA Section 408(c)(2) as amended by FQPA.

The effective date of revocation of the tolerance exemptions subject to the August 2006 rule was originally set for August 9, 2008. However, in a subsequent direct final rule published in the *Federal Register* on August 4, 2008, EPA announced a one-year extension of the effective date of revocation of certain inert ingredient tolerance exemptions from August 9, 2008, until August 9, 2009. EPA states that this determination was made based on requests for an extension of the revocation date from pesticide registrants and inert ingredient manufacturers who had demonstrated their intent to support certain inert ingredient tolerance exemptions and who had provided EPA with plans outlining a strategy and schedule for the development and submission of data to the Agency.

The Agency explains that in the case of six of the revoked tolerance exemptions, EPA has received petitions for the establishment of tolerance exemptions which included the submission of data for these inert ingredients. Notices of filing of these petitions were published in the *Federal Register* on March 25, 2009. EPA signals that it has not yet fully completed the risk assessments needed to evaluate these petitions and to make a safety finding. As such, EPA has concluded that additional time is necessary to complete the safety determinations for these six tolerance exemptions and that the effective date of the revocation of these tolerance exemptions should be moved by two months to October 9, 2009. The direct final rule published in the August 7th *Federal Register* may be accessed at <http://edocket.access.gpo.gov/2009/pdf/E9-19057.pdf>.

EPA Reminds Registrants of Label Regulations and the Agency's Position on Use of Terms Such as "Professional" and "Professional Grade"

EPA has posted on its web site a letter written by Registration Division Director Lois Rossi that reiterates Office of Pesticide Programs (OPP) policy regarding permissible claims on distributor products as well as the Agency's process for addressing misbranded pesticides bearing labels that include false and misleading statements. The letter specifically addresses the use of the terms "professional" and "professional grade" in product names and advertising claims. Under FIFRA it is unlawful to distribute or sell any pesticide which is misbranded. A product is deemed misbranded if its labeling bears any statement, design, or graphic representation which is false or misleading.

In its letter, the Agency states that it has become aware that certain pesticides are being sold and distributed under a brand name that includes the term "professional grade." The Agency has also learned that advertising claims for these unnamed products include phrases such as "professional grade results."

EPA explains that the use of the term "professional grade" implies a falsehood that pesticides are classified by grade (which they are not) and therefore constitutes a false or misleading comparison to other pesticides. EPA states, "... 'Professional Grade' implies or could well imply that the products are more efficacious than competitors' products. This is likely a false or misleading statement about the comparative effectiveness of the product under 40 CFR Section 156.10(a)(5)(iv)."

EPA adds that the use of the word “professional” is misleading in that it does not explain which professionals are being referenced. The letter states, “None of the products in question have ever been classified as restricted use...therefore, the sale or use of these products is not restricted to any particular group and the products are legally available for purchase by average consumers.”

The letter reminds basic registrants and supplemental distributors that only limited changes may be made between basic registered products and their supplementally distributed products. Specific claims may be deleted from distributor-product labels but they may not be added. EPA warns that when distributor-product names contain new claims that have not been accepted for the basic registration, the label is in violation of FIFRA and both the distributor and the basic registrant are subject to enforcement action. According to the letter, OPP will be reviewing supplemental distribution agreements more closely in an attempt to rectify improper brand names before they reach the marketplace. The letter is available on EPA’s web site at <http://www.epa.gov/pesticides/regulating/labels/product-labels.htm>.

International Society of Regulatory Toxicology and Pharmacology to Conduct Workshop on EPA’s Proposed Tier 1 Screening Assays for the EDSP

The International Society of Regulatory Toxicology and Pharmacology (ISRTP) is conducting a two-day workshop on September 9-10, 2009 that will focus on the details of EPA’s proposed Tier 1 screening assays that will be used to implement the Endocrine Disruptor Screening Program (EDSP). ISRTP is an educational organization dedicated to providing a forum for viewpoints on scientific, regulatory and related issues. CPDA President Sue Ferenc serves as a council member of the ISRTP.

The workshop will include a discussion of the strengths and weaknesses of each Tier 1 assay as well as the potential uses of data generated by those assays. The speakers program will also examine how existing data might be incorporated into the EDSP in an effort to avoid duplicative testing, whether EDSP screening data could potentially be used to trigger additional testing, and the types of limitations that could arise as a result of using EDSP data in conducting cumulative risk assessments.

In addition, CPDA Director of Regulatory Affairs Mike White will be moderating a panel discussion that will consider the legal and regulatory ramifications pertaining to EPA’s implementation of the EDSP. The workshop will take place at the National Institutes of Health, Lister Hill Auditorium, 8600 Rockville Pike, Bethesda, Maryland. To register for the workshop, visit <http://www.isrtp.org/ENDOCRINE%20WORKSHOP%202009/Endocrine%20Workshop%202009%20Online%20Registration%20Form.htm>.

EPA Launches Web Page that Sets Forth Strategic Direction for New Pesticide Testing and Assessment Approaches

EPA announced that it has launched a new web page that explains the development and evaluation of new technologies in molecular, cellular, and computational sciences to supplement or replace more traditional methods of toxicity testing and risk assessment.

This web page details the approach EPA is using to pursue new technologies that predict and characterize potential human health and environmental hazards and exposures from pesticides. EPA states that the web page describes the current status as well as future plans for “this rapidly changing area of research and regulatory science.” The web page contains links to a glossary of key terms, information on pesticides and the ToxCast™ Research Program, and a matrix of tools used for pesticide testing. The new web page may be accessed at <http://www.epa.gov/pesticides/science/testing-assessment.html>.