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Keeping an Eye on Washington

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EPA Issues Draft PR Notice on Pesticide Spray Drift

On November 4, 2009, EPA announced the availability of its long-awaited draft PR Notice on pesticide drift labeling. Along with the draft PR Notice, EPA has issued a supporting guidance document entitled “Pesticide Drift Labeling Interpretation” that explains how the Agency intends for state and tribal pesticide regulatory agencies to interpret the recommended drift statements contained in the draft PR Notice. A second supporting document entitled “Draft PR Notice 2009-X: Additional Information and Questions for Commenters” contains background information on pesticide drift, a description of current and planned EPA actions to address drift, and a reader’s guide to the PR Notice including a description of the key terms and concepts, explanatory rationale, and specific questions on which EPA is seeking input from stakeholders. The draft PR Notice and supporting documents may be accessed at <http://www.regulations.gov/search/Regs/home.html#docketDetail?R=EPA-HQ-OPP-2009-0628/>.

The deadline for public comment was originally scheduled for January 4, 2010. However, EPA has recently decided to grant an extension of the comment period until March 5, 2010 (a *Federal Register* notice to this effect is expected to be published shortly). Comments may be submitted electronically at www.regulations.gov and must be identified by docket number EPA-HQ-OPP-2009-0628.

The draft PR Notice contains two types of statements for products with the potential to drift: 1) a generic drift statement containing a risk-protective standard which varies according to product type; and 2) examples of product-specific drift use restrictions along with a format for presenting these statements on product labeling. The draft PR Notice sets forth the procedures that registrants should use to amend their registrations to adopt these statements. EPA states that “the use of these statements and formats on labels will provide users consistent, understandable, and enforceable directions about how to protect human health and the environment from harm that might result from pesticide drift.” The labeling statements set forth in the draft PR Notice

would apply to most products labeled for outdoor use, including most agricultural, commercial, and non-commercial applications and sites.

EPA states that it does not intend to apply the draft PR Notice to products labeled solely for indoor use; products labeled solely for use in fully-enclosed greenhouses; products labeled solely for animal treatments; products labeled for direct application to people such as skin-applied mosquito repellents; fumigant products; or mosquito adulticide products labeled for wide-area application by ground or aerial equipment such as Ultra Low Volume (ULV) sprays or fogs. However, the PR Notice labeling recommendations do apply to home and garden use products which may list mosquitoes on the label, and/or to coarse non-ULV sprays intended for residual treatment of vegetation or other surfaces.

The Agency describes pesticide spray and dust drift as the physical movement of pesticide droplets or particles through the air from the target site to any non-target site. The Agency is proposing three different forms of the general drift statement, depending on the type of pesticide product. Products that currently bear Worker Protection Standard (WPS) statements should add the new general statement: “In addition, do not apply this product in a manner that results in spray [or dust] drift that could cause an adverse effect to people or any other non-target organism or site.” Labels for commercial-application products that do not bear WPS statements should add the new general statement and also the statement: “Do not apply this product in a manner that will contact workers or other persons, either directly or through drift.” Labels for products intended solely for non-commercial application should add the following statement to the label: “Do not apply this product in a way that could contact people, or that results in spray [or dust] drift that could cause harm to people, pets, property, aquatic life, wildlife, or wildlife habitat.” Products with specified application restrictions to minimize drift should also bear the following statement preceding the application restriction tables: “Applicators must meet the standard set by the general drift statement, in addition to complying with the following additional application restrictions.” The Agency notes that **for products with specified application restrictions that minimize drift, complying with the specified restrictions may not be sufficient to comply with the general drift labeling statement** (emphasis added).

EPA notes that it intends to assess the need for product-specific drift statements on a case-by-case basis. Product specific drift statements include, but are not limited to, restrictions on wind speed, application release height, spray droplet or particle size, and no-spray buffer zones around sensitive sites. EPA anticipates that, in most cases, the need for product-specific drift statements will be evaluated through registration review. The Agency explains that if the review indicates that current product labeling does not adequately address potential risks from drift and that additional or different drift mitigation is needed, the registrant will be required to add product-specific drift statements to the label, as appropriate, to address potential risks.

Registrants of products that have the potential for drift but currently have no existing drift labeling statements would be required to add the appropriate general drift

statements to the labeling within six months from the date of the final PR Notice. Registrants who adopt the exact wording of the appropriate general drift statements and make no other changes would be allowed to make these label revisions through the notification process. Registrants of products with existing drift labeling statements would be required to submit all drift labeling changes as an amendment to the registration within 12 months from the date of release of the final PR Notice. EPA states that products released for shipment after notification or approval of an amendment must bear the approved drift statements when new labels are printed or 12 months following the label's approval, whichever is earlier.

With regard to new products, EPA recommends that immediately after release of the final PR Notice, applicants for the registration of new products that are subject to the Notice include the appropriate general drift statement as part of the proposed labeling for their product.

Upon a preliminary review of the draft PR Notice, CPDA is concerned that the document is somewhat subjective in that it does not offer a clear definition of what would be deemed an "adverse effect" as related to pesticide drift reduction activities. In addition, CPDA believes that the draft PR Notice raises questions with regard to the potential liability that applicators and/or manufacturers may find themselves subject to in relation to the management of pesticide drift. CPDA continues to assess the EPA draft spray drift documents and welcomes the feedback of its membership in preparation for the submission of comments to the docket.

EPA Seeks Public Comment on Petition that Addresses Exposure of Children to Pesticide Drift

Concurrent with the release of the draft PR Notice on pesticide drift and supporting documents, EPA published for public comment a petition from Earthjustice and Farmworker Justice, filed on behalf of several other advocacy organizations, requesting that the Agency systematically evaluate children's exposure to pesticide drift and require interim prohibitions on the use of certain pesticides near homes, schools, and other places where children congregate. The petition asserts that EPA does not adequately consider the exposures of children to pesticide drift, especially children who live in agricultural areas. The petitioners are asking that EPA assess pesticide-specific exposures from drift to children in homes, schools, and other areas in which children congregate; determine if such exposures pose excessive risks; and implement measures to reduce any such risks. The petitioners further request that EPA immediately adopt specific interim restrictions on certain pesticides used near areas where children gather. Public comment on the petition was originally set for January 4, 2010 but was recently extended to March 5, 2010 (a *Federal Register* notice announcing the extension will be published shortly). Comments may be submitted electronically at www.regulations.gov and must be identified by docket number EPA-HQ-OPP-2009-0825.

CPDA and Other Industry Groups Secure 60-Day Extension of Comment Period on Draft Pesticide Drift Labeling PR Notice and Related Petition

In response to the publication of the draft PR Notice on pesticide drift labeling and the petition pertaining to children's exposure to pesticide drift, CPDA sent a letter to EPA requesting that the public comment period for both dockets be extended by an additional 90 days from January 4, 2010 to April 5, 2010. In its letter, CPDA emphasized that the myriad legal, scientific, regulatory, technical, public health, and enforcement issues surrounding the effective management of pesticide drift are complex and require considerable thought and analysis. CPDA stated, "Any potential change to pesticide labeling as related to the management of pesticide drift will have significant implications for farmers, professional applicators, members of the registrant community, and other regulated entities."

While expressing support for the Agency's overall goal of reducing off-target spray and dust drift and ensuring pesticide label consistency and clarity, CPDA cautioned that this mutually desired objective "can only be achieved by first giving extensive consideration to the broadest level of input from all segments of the stakeholder community." CPDA maintained that the current sixty-day comment period does not provide adequate time for affected stakeholders to analyze and identify key issues raised by the drift-related documents now published for public comment nor does it allow a sufficient opportunity to provide meaningful input that would help the Agency in its drift reduction efforts.

In addition, CPDA pointed out that drift reduction will be addressed in three important meetings scheduled to take place over the next few months. In December 2009, EPA will be convening a session of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA SAP) to consider and review scientific issues associated with field volatilization of conventional pesticides. In January 2010, the Association of Applied Biologists will hold a workshop in the United Kingdom that will focus on drift. Finally, in March 2010 the American Chemical Society will hold a pesticide symposium that will include presentations on drift reduction. CPDA emphasized that these three meetings will provide valuable and timely background information relevant to future EPA actions on drift-related issues.

As noted previously, at the time of this writing EPA had informed CPDA that it has agreed to grant an extension of the comment period from January 4, 2010 to March 5, 2010. Publication of a *Federal Register* notice announcing the change in the deadline for comment is imminent.

OPP Labeling Consistency Website Addresses Advertising on Pesticide Labels

The OPP labeling consistency web site includes a new post that addresses a question regarding the permissibility of advertising other products on the pesticide label. Specifically, EPA was asked whether a label may contain advertising for products such as

pictures of fertilizers and other pesticide products that the registrant may distribute. The Agency was also asked whether it was permissible for the registrant to include on the label a statement that directs the user to the company's web site to view additional lawn and garden products marketed by the company. EPA states that references to other products on the label are allowed as long as such reference is not false and misleading and does not detract from required label information.

The Agency reminds registrants that under FIFRA, a pesticide is misbranded if its labeling "bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular." To avoid a product becoming misbranded when references to other products (including pictures and/or website addresses) are added to the label, EPA recommends that registrants adhere to the following guidance as posted on the OPP labeling web site: *a) It should be very clear that those products are separate and distinct from the subject product, (i.e. such references to these other products should be clearly distinct from the required labeling of the subject product). It is especially important that reference to other products does not distract users from reading the labeled product's Directions for Use; b) The advertising should not contain mandatory language saying another specified product must be used in order to achieve control/relief. Any requirement that products be used in combination to achieve efficacy for a pesticide product must be part of the Directions for Use and must be evaluated by EPA as part of the granting of a registration; and, c) The registrant should understand that any reference to a website makes that website labeling and therefore subject to more searching EPA review than if it were not referenced. Future versions of a website referenced on a label will also be subject to the same review, though at this time the Agency does not require notification or approval of such changes.*

EPA adds that distributor products are not allowed to bear claims on the label that have not been approved on the parent product's label. As such, a distributor may not add advertising for its other products unless such advertising is also displayed on the parent product's label.

OPP Labeling Website Clarifies Situations When a Product is Exempt from FIFRA

The OPP Labeling Consistency website includes a new post that clarifies the exemptions under which a product may make limited pesticidal claims without requiring a registration. The Agency also describes categories of products that would not be deemed a pesticide by EPA as long as they make no pesticidal claims. EPA states:

"A pesticide is defined as a substance or mixture of substances intended to destroy, prevent, repel, or mitigate a pest (FIFRA Section 2(u), 40 CFR 152.3). A product that makes a pesticidal claim must either be registered or exempt from registration. Certain categories of products have been determined not to be pesticides because they are not deemed to be used for a pesticidal effect and therefore need not be registered unless they contain a pesticidal claim. These categories, found in 40 CFR 152.10, are: 1) Deodorizers, bleaches, and cleaning agents; 2) Products not containing toxicants, intended only to attract pests for survey or detection purposes, and labeled

accordingly; and 3) products that are intended to exclude pests only by providing a physical barrier against pest access, and which contain no toxicants, such as certain pruning paints to trees.

Further 40 CFR 152.20 describes certain pesticides or classes of pesticide that are exempt from any FIFRA requirements because EPA has deemed them to be adequately regulated by another Federal agency. These categories include certain biological control agents and non-liquid chemical sterilants. In addition, there are a number of exemption provisions described in 40 CFR 152.25 that allow products to carry limited pesticidal claims without requiring registration, when such products are intended for use, and used, only in the manner specified:

- 1. 152.25(a) allows an article or substance to make a pesticide claim if the article is treated with an EPA registered product that is registered for such use and the claim is limited to protection of the article,*
- 2. 152.25(b) exempts pheromones and identical or substantially similar compounds from registration if they are the sole active ingredient in a pheromone trap and they are labeled for use only in pheromone traps,*
- 3. 152.25(c) exempts embalming fluids and other products used to preserve animals or animal organs in mortuaries, laboratories, hospitals, museums and institutions of learning. Also exempt are products used to preserve the integrity of urine, blood, milk or other body fluids for purposes of laboratory analysis,*
- 4. 152.25(d) exempts food products that contain no active ingredient that are used to attract pests,*
- 5. 152.25(e) exempts natural cedar when it meets all of the criteria specified in that section,*
- 6. 152.25(f) exempts products containing certain minimum risk active ingredients listed in this section provided all of the criteria of the section are met.*

If a product makes a pesticidal claim and does not fit into one of the categories described above, then the product must be registered.”

OMB Responds to Congressional Criticism Aimed at EDSP Information Collection Request (ICR)

The Director of the Office of Management and Budget Peter Orszag has written a letter to Representative Edward J. Markey, Chairman of the House Subcommittee on Energy and Environment, in which he provides assurances that EPA alone makes the determinations about the quality of “Other Scientifically Relevant Information (OSRI)” and whether new research is necessary in making decisions under the Endocrine Disruption Screening Program (EDSP). In his November 16, 2009 letter, Orszag states, “...OMB does not question the scientific responsibilities and rigors put forward by the EPA. Scientific review is a rigorous process that must remain impartial.” Orszag emphasized that EPA must continue to have a “robust endocrine testing program” and that OMB “fully supports the EPA’s sole authority to make the scientific decisions related to this effort.”

OMB's letter responds to criticism voiced by Chairman Markey with regard to the approved Information Collection Request (ICR) in which OMB instructs EPA to encourage test order recipients to submit OSRI in lieu of performing all or some of the Tier 1 assays under the EDSP. As reported previously, on October 22, 2009, Chairman Markey wrote a letter to OMB in which he stated, "When one considers that lack of knowledge about possible adverse health effects with the numerous scientific reports that have come out in recent years on decreasing fertility, increased birth defects, greater rates of breast cancer, alterations in sex ratios and prevalence of miscarriages, not to mention the ability of some of these chemicals to accumulate in breast milk causing early infant exposures; it seems clear that there is a compelling public policy interest in empowering the EPA to collect the data needed to accomplish basic screening that would facilitate regulation of any chemicals that might pose a threat to the public and to manage the risk associated with such chemicals." Chairman Markey expressed his concern that the instructions to EPA contained in the ICR "could lead the agency to ignore or dilute the mandate of EDSP and could slow or eliminate the growth of our knowledge about the public health risks of endocrine disruptors."

OMB's response to Chairman Markey's concerns does not diminish EPA's obligation to adhere to the instructions set forth in the ICR – namely, the ICR requires the Agency to conduct a thorough analysis of the EDSP information collection to demonstrate "practical utility" or benefit, to re-estimate the "burden" of the program, and to explain the reasoning for concluding that existing data are insufficient to satisfy the test orders. It also requires public comment and peer review of the Agency's interpretation and use of the collected data.

House Passes Chemical Facility Security Measure

On November 6, 2009, the House of Representatives approved H.R. 2868, the Chemical and Water Security Act of 2009, by a vote of 230-193. The bill reauthorizes the U.S. Department of Homeland Security (DHS) to implement and enforce the Chemical Facility Anti-Terrorism Standards (CFATS) which are scheduled to sunset in October 2010 barring the enactment of legislation that would extend or make permanent these regulations. The bill also requires EPA to establish parallel security programs for drinking water and wastewater facilities. Among its provisions, H.R. 2868 contains IST mandates that require all tiered facilities to assess "methods to reduce the consequences of a terrorist attack."

In the weeks leading up to the House vote, CPDA worked extensively with members of the House Energy and Commerce Committee in an effort to dilute the language contained in several provisions of the bill. Several concessions were made at the last minute in an effort to address the concerns of CPDA members including: restricting citizen lawsuits to government entities only (as opposed to individual companies); narrowing the scope of facilities that fall under IST mandates; and a restriction on DHS to consult with industry "experts" during the review of all mandatory IST appeals.

In addition, CPDA reached out to Blue Dog Democrats to express concerns regarding the burden such provisions might have on small and medium-size chemical companies that could be left out of the concessions made to the bill. As a result of these discussions, Representative Debbie Halvorson (D-IL) authored language that was later added to the bill that provides smaller chemical companies – those with fewer than 350 employees – with the guidance, software and tools needed for compliance with the new rules. Representative Halvorson estimates that about 15% to 20% of chemical companies nationwide could benefit from this provision. “That’s a significant number of small businesses that we cannot forget as we move forward on security requirements,” Representative Halvorson stated. “It helps chemical facilities comply with security standards in an effective and profitable manner.”

Although the bill managed to pass the House, it still faces significant hurdles in the Senate. Senator Lautenberg (D-NJ) and Senator Susan Collins (R-ME) are both in the process of drafting their own versions of chemical facility security legislation expected to be introduced in the coming months. CPDA will shift its attention to the Senate to ensure that should the legislation gain momentum in that chamber, it moves in the right direction.

OMB Completes its Review of EPA’s Draft ANPRM on Inert Disclosure

On November 23, 2009, OMB completed its review of EPA’s draft Advanced Notice of Proposed Rulemaking (ANPRM) dealing with the public disclosure of inert ingredients deemed hazardous. Limited information posted online at www.reginfo.gov indicates that OMB has concluded that EPA’s draft initiative will not have any major adverse economic impact on the regulated community nor will it have a burdensome affect on small entities. Now that OMB has completed its review, it is expected that the ANPRM will be published in the *Federal Register* shortly.