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Keeping an Eye on Washington

February 2010

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EPA Extends Public Comment Period on Draft Inert Disclosure Initiative

EPA has announced a 60-day extension of the public comment period for its Advance Notice of Proposed Rulemaking (ANPR) on the disclosure of inert ingredients on the pesticide label that was published in the December 23, 2009 *Federal Register*. With EPA's announcement, the deadline for public comment has been extended from February 22, 2010 to April 23, 2010. In its ANPR, EPA seeks comment on two options aimed at increasing the public availability of the identities of inert ingredients in pesticide products. One option would limit mandatory disclosure to those inert ingredients deemed potentially hazardous. The other option would promote or mandate the disclosure of most or all inert ingredient identities, regardless of hazard. The Agency is also soliciting ideas for alternative approaches, both regulatory and non-regulatory. EPA's decision to pursue rulemaking was articulated in its September 30, 2009 response to two petitions, one filed by the Northwest Coalition for Alternatives to Pesticides and one filed by a group of State Attorneys General, which identified a set of more than 350 pesticide inert ingredients as hazardous. The petitioners called upon EPA to require the disclosure of these substances on the labels of formulations in which they are found. Both petitions were received by EPA on August 1, 2006.

The ANPR invites public comment on how a list of potentially hazardous inerts could be identified. To this end, EPA is considering three possible approaches: 1) EPA could develop a rule that would require the disclosure of the inert if it appeared on specified lists (the Agency notes that the petitioners identify a variety of statutory, regulatory, and other listings that in some way relate to hazard and serve as a useful starting point for discussion); 2) EPA could establish through rulemaking objective criteria that could be applied on an ingredient-by-ingredient basis in determining whether a particular substance is hazardous; and/or 3) EPA could by rule list specific chemicals used as inert ingredients that would trigger a disclosure requirement (in so doing, EPA would need to identify a process for revisions to such a list). In addition, EPA is seeking comment on such issues as: 1) whether there should be a *de minimis* threshold below which a potentially hazardous inert ingredient would not be required to appear on the ingredient statement; 2) whether the disclosure of the identities of hazardous inert ingredients on the label without further information would result in better informed consumer decision-making; 3) whether potentially hazardous impurities should be required to appear on the label and, if so, should there be a *de minimis* concentration

threshold such as 0.1% (the Agency notes that impurities below a concentration of 0.1% are not normally reported to EPA unless the impurity is of toxicological significance).

In addition to the hazard-based disclosure of inerts, EPA is seeking comment on broad-based disclosure that would be motivated not by hazard but by transparency. The ANPR includes a discussion of the Agency's handling of Confidential Business Information (CBI) under Section 10 of FIFRA. EPA explains that with certain limited exceptions, FIFRA Section 10(b) prohibits the Agency from disclosing information "which in the Administrator's judgment contains or relates to trade secrets or commercial or financial information obtained from a person and privileged or confidential." Among the exceptions to confidentiality in Section 10 is the requirement in FIFRA Section 10(d)(1) to make safety and efficacy data available to the public. However, FIFRA Section 10(d)(1) excludes three categories of information from the mandatory disclosure requirement for health and safety data including the identity or percentage quantity of inert ingredients. The Agency explains that this exclusion for inert ingredient information "has been taken by some to mean that any disclosure of inert ingredients is prohibited by statute, regardless of whether the information meets the confidentiality test in FIFRA Section 10(b)." EPA reiterates that information must meet the FIFRA Section 10(b) standard in order to be eligible for confidential treatment. The Agency asks for public comment on a number of confidentiality concerns including the merits of establishing unique procedures that would be applicable to products containing proprietary inert ingredients or proprietary mixtures of inert ingredients. EPA states, "...Because registrants may not know the identity of a proprietary inert ingredient or the identities of all the ingredients in a proprietary mixture of inert ingredients, there may be confidentiality concerns when informing registrants of new requirements applying to their pesticide products, and such registrants might face additional barriers to adjusting to a disclosure requirement. In addition, manufacturers of proprietary inert ingredients and proprietary mixtures of inert ingredients might raise confidentiality and other issues that do not apply to registrants."

Comments may be submitted electronically at www.regulations.gov and should be identified by docket number EPA-HQ-OPP-2009-0635.

Public Comment on EPA's Draft PR Notice on Drift Labeling is Due March 5, 2010

CPDA reminds its members that the deadline for public comment on EPA's draft PR Notice on pesticide drift labeling and supporting documents as well as the related petition that addresses the exposure of children to pesticide drift is March 5, 2010. As CPDA had notified its members previously, on Wednesday, December 9, 2009, EPA published a notice announcing a 60-day extension of the public comment period that was originally scheduled to end on January 4, 2010. The draft PR Notice, supporting documents, and the *Federal Register* notice announcing the extension are posted in the docket at <http://www.regulations.gov/search/Regs/home.html#docketDetail?R=EPA-HQ-OPP-2009-0628>.

A separate docket has been established for the petition dealing with the exposure of children to pesticide drift and may be accessed at <http://www.regulations.gov/search/Regs/home.html#docketDetail?R=EPA-HQ-OPP-2009-0825>.

The draft PR Notice provides recommended drift management statements to reduce off-target drift. The document also contains a *general prohibition* statement that applies to agricultural/commercial applications for drift that will contact people or could cause adverse health or environmental effects to people, non-target organisms, or sites, and another general prohibition that applies to non-commercial applications that could contact people or could cause harm to people and pets. It also contains product-specific statements, such as no-spray buffer zones and restrictions on droplet size and nozzle height, that would be required based on case-by-case risk assessment determinations.

CPDA will be commenting on the draft PR Notice and invites its members to provide our office with input relevant to this issue.

Environmental Group Files Notice of Intent to Sue EPA for Alleged ESA Section 7 Violations

On January 27, 2010, the Center for Biological Diversity (CBD) filed a notice of intent to sue the EPA for failing to adequately evaluate 394 individual pesticides nationwide for endangered species effects. The notice of intent alleges that EPA has failed to satisfy its Endangered Species Act (ESA) Section 7 consultation obligations that apply to pesticide registrations and reregistrations. The legal filing references 887 endangered and threatened species (including mammals, birds, fish, amphibians, reptiles, mollusks, crustaceans, insects, and plants).

The ESA requires EPA to consult with the U.S. Fish and Wildlife Service (FWS) and National Marine Fisheries Service (NMFS), i.e., “the Services,” in assessing the impact of pesticide registration actions on endangered species and habitats. At the completion of consultation, FWS or NMFS issues a biological opinion that determines if the action is likely to jeopardize the species or habitat. If so, the opinion may specify reasonable and prudent alternatives that will avoid jeopardy and allow the agency to proceed with the action. FWS and NMFS may also suggest modifications to the action during the course of consultation to “avoid the likelihood of adverse effects” to the listed species.

The recent CBD notice of intent to sue EPA is troubling given the Agency’s September 11, 2009 announcement of additional limitations on the use of chlorpyrifos, diazinon, and malathion to protect endangered and threatened Pacific salmon and steelhead in California, Idaho, Oregon, and Washington. These restrictions were issued as a result of a January 22, 2004 decision handed down by the U.S. District Court for the Western District of Washington in the case of *Washington Toxics Coalition (WTC) v. EPA*. The use limitations announced by EPA in September 2009 include pesticide buffer zones; application limitations based on wind speed, soil moisture and weather conditions; and fish mortality incident reporting requirements.

CPDA supports efforts to evaluate the effects of pesticides on threatened and endangered species provided the process is scientifically based and transparent. However, CPDA is concerned that lawsuits alleging that EPA’s methodology for assessing risks to endangered species is inadequate, have slowed the Agency’s efforts to assess potential pesticide risks to listed species, and have the potential to cripple the

country's vital food and fiber production through hasty use limitations. CPDA will continue its efforts in supporting a consultation process between the Services and EPA that is timely, transparent, and adheres to the framework contained in the ESA Section 7 Counterpart Regulations.

EPA Proposes Revisions to Tolerance Crop Grouping Regulations

EPA is proposing revisions to its pesticide tolerance crop grouping regulations which allow establishment of tolerances for multiple related crops based on data from a representative set of crops. The Agency states that the proposed revision would create a new crop group for oilseeds, expand existing crop groups by adding new commodities, establish new crop subgroups, and revise the representative crops in some groups. EPA maintains that the proposed revisions will promote greater use of crop groupings for tolerance-setting and will facilitate the availability of lower risk pesticides for minor crops both domestically and in countries that export food to the United States. Crop group tolerances are based on residue data applicable to designated representative commodities within the group. The selection of representative commodities is based on EPA's determination that they are likely to bear the maximum level of residue that occur on any crop within the group. Once the group tolerance is established, the tolerance level applies to all agricultural commodities within the group. The crop grouping proposal is based on a petition that was submitted to EPA by the Inter-regional Research Project Number 4 (IR-4) and developed with the input of the Canadian and Mexican governments. EPA's proposed rule is the second in a series of planned crop grouping revisions planned over the next several years.

The Agency describes its proposal as a "burden-reducing regulation" and emphasizes that crop grouping reduces testing costs by allowing the results of pesticide exposure studies for one crop to be applied to other, similar crops. EPA explains that new and expanded crop groups will likely reduce the number of separate risk assessments and tolerance rulemakings the Agency will have to conduct. EPA adds that further benefits will come from the international harmonization of crop classification and nomenclature, harmonized commodity import and export standards and increased potential for resource sharing between EPA and pesticide regulatory agencies in other countries. The Agency believes that its proposed crop grouping revisions will lead to reduced registration costs that will encourage pesticide manufacturers to register more pesticides for use on minor and/or specialty crops. Minor crop and specialty crop producers will benefit by having access to an increase in lower-risk pesticide options.

Public comment on the proposal is being accepted through March 8, 2010. The *Federal Register* notice announcing the proposed rule may be accessed at <http://edocket.access.gpo.gov/2010/pdf/E10-31397.pdf>.

EPA Extends Public Comment Period on Worker Risk Policy Paper

EPA has granted a 60-day extension of the comment period on its draft policy paper entitled "Revised Risk Assessment Methods for Workers, Children of Workers in Agricultural Fields, and Pesticides with No Food Uses." The deadline for comment, originally scheduled to end on February 8, 2010, is now set for April 12, 2010. The draft policy paper describes how the Agency will assess pesticide risks not governed by the

Federal Food, Drug and Cosmetic Act (FFCA). EPA states that it intends to apply risk assessment techniques developed in implementing the Food Quality Protection Act to any pesticide risk assessment, whether it falls under FQPA or not, as long as applying the risk assessment technique “is consistent with good scientific practice and is not otherwise prohibited by law.” Specifically, EPA is proposing to use the additional 10X safety factor to protect children. In addition, EPA proposes to consider aggregate exposures to pesticides from multiple sources and cumulative effects which may occur from exposure to multiple pesticides with a common mechanism of toxicity. Moreover, EPA is contemplating a proposed requirement calling for the reporting of potential risks for workers age 12-17 years and children taken into agricultural fields. The Agency emphasizes that the policy changes set forth in the draft paper have important environmental justice ramifications. The Agency states, “EPA’s commitment to environmental justice compels the Agency to act expeditiously, where consistent with statutory authority, to incorporate the risk assessment techniques developed in the implementation of FQPA in assessing pesticide risks under FIFRA.”

Comments on the draft policy paper may be submitted electronically at www.regulations.gov and should be identified by docket number EPA-HQ-OPP-2009-0889.

CPDA Submits Comments to OMB on Improvement of the Paperwork Reduction Act

On December 28, 2009, CPDA submitted comments to the Office of Management and Budget in response to OMB’s request for public input on how to improve implementation of the Paperwork Reduction Act of 1995 (PRA) as published in the October 27, 2009 *Federal Register*. The PRA requires federal agencies to minimize the public burden (cost) of collecting required information and to maximize the practical utility (benefit) of the collected information. The PRA regulations define burden to include certain activities, such as searching data sources and completing and reviewing the response, and federal agencies must estimate the time and resources needed to respond to a specific information collection request (ICR). OMB is concerned that agency estimates can produce imprecise and inconsistent burden estimates, which is of particular concern for ICRs involving burdens of tens of millions of dollars. OMB is also concerned that the practical utility of the information collected is not adequately considered, and is requesting public input on methods for ensuring information is collected in a manner that ensures the practical utility of the collection.

In its comments, CPDA emphasized its strong support for the PRA goal of minimizing the burden of federal information collections, especially on small entities, and the requirement to demonstrate that information has a practical utility. The comments point out that even though OMB regulations consider a burden to include the costs of “collecting, validating, and verifying information,” and that EPA guidance considers the actual costs of generating and collecting the information a part of the burden, OMB has not historically required EPA’s Office of Pesticide Programs to include those costs in burden estimates. CPDA used the recent ICR for the Endocrine Disruptor Screening Program (EDSP) to demonstrate how EPA significantly underestimated the burden of generating and submitting test data by excluding those costs from the burden estimate, and that EPA did not demonstrate the practical utility of the information it seeks

to collect. Finally, CPDA offered specific suggestions on how OMB can improve implementation of the PRA, easing the paperwork burden on small entities, and increasing the practical utility of large ICRs.

CPDA will continue to seek opportunities for providing OMB with information and suggestions on implementing the PRA in a manner that minimizes the burden on the pesticide industry.

Industry Coalition Addresses Issue of False or Misleading Pesticide Product Brand Names

On December 17, 2009, OPP Registration Division Director Lois Rossi signaled that EPA would temporarily suspend any Agency challenges to the listing of product brand names on the label that include such words as “professional (Pro),” “maximum (Max),” “ultra,” and similar words that might be construed as making a false or misleading claim in violation of FIFRA. EPA’s decision follows a December 3, 2009 joint association letter to Debbie Edwards, then Director of the Office of Pesticide Programs, signed by CPDA, CSPA, RISE, and CLA 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. “There are costs associated with removing words from pesticide labels but those costs pale in comparison to changing the brand name of a product. Some of these products have been in the marketplace for decades and our members have spent considerable sums of money on advertising to market the brand and build brand loyalty,” the coalition stated.

CPDA will continue to monitor further developments on this issue including the possible reissue for public comment of EPA’s draft PR Notice.

Endocrine Disruption Prevention Act of 2009 Introduced in the House

On December 3, 2009, Representative Jim Moran (D-VA) introduced H.R. 4190, the Endocrine Disruption Prevention Act of 2009. The bill seeks to amend the Public Health Service Act to authorize the National Institute of Environmental Health Sciences to conduct a research program on endocrine disruption “to prevent and reduce the production of, and exposure to, chemicals that can undermine the development of children before they are born and cause lifelong impairment to their health and function, and for other purposes.”

H.R. 4190 consists of four major components: 1) establishment of an Endocrine Disruption Prevention Program; 2) establishment of an Endocrine Disruption Program Panel; 3) transmission of certain findings to relevant agencies; and, 4) federal agency action (as well as a “citizen suit” provision included).

Within each of these components the bill orchestrates a highly elaborate program that will design and develop sensitive tests to screen chemicals using assays, address the full range of possible health outcomes, and consider additive and synergistic effects using a multidisciplinary approach to develop biomarkers of exposure to chemicals identified by the program’s Panel. If the Panel finds at least a minimal level of concern associated with a chemical’s potential to disrupt the human endocrine system, the Director shall transmit the Panel’s findings to each federal agency with authority to regulate the chemical or the route or source of human exposure to the chemical. Upon receipt of the findings, an agency must respond within 180 days listing their authority in connection with the chemical; any past or ongoing actions taken by the agency in connection with the chemical; and the proposed course of action to be taken by the agency in response to the Panel’s finding, including but not limited to further testing, issuance of regulations, orders, or public notices under the agency’s existing authorities. Within a year the agency must submit to Congress and shall publish a report summarizing the actions taken by the agency in response to the Panel’s finding, as well as proposed future actions to be taken by the agency.

The bill has been referred to the House Energy and Commerce Committee. A companion bill, S. 2828, was introduced in the Senate on December 3, 2009 by Senator John Kerry.

In related developments, on February 25, 2010 the House Subcommittee on Energy and the Environment held a hearing that focused on the science and regulation of endocrine disrupting chemicals in drinking water. Among the witnesses to appear at the hearing was Jim Jones, OPPTS Deputy Assistant Administrator. Jones provided the Subcommittee an update on EPA’s efforts to date in implementing the EDSP. He reported that EPA is now preparing a second list of no less than 100 chemicals for endocrine screening and he signaled that this draft list will be released shortly. Jones stated that the List 2 chemicals will be drawn from three sources: National Primary Drinking Water Regulations, the Contaminant Candidate List 3 (CCL3), and pesticides that are on the registration review schedule for 2007 and 2008. According to Jones’ testimony, the CCL3 List is a list of contaminants that are currently not subject to any proposed or promulgated national primary drinking water regulations, that are known or anticipated to occur in public water systems, and which may require regulation under the Safe Drinking Water Act Amendments of 1996 (SDWA). The CCL3 List includes pesticides, other chemicals used in commerce, and disinfection byproducts and degradates.

Chemical Facility Security Legislation Introduced in the Senate

Bipartisan chemical facility security legislation was introduced on February 4, 2010 by Senators Susan Collins (R-ME), Ranking Member of the Senate Homeland Security and Governmental Affairs Committee, Mark Pryor (D-AR), George Voinovich (R-OH) and Mary Landrieu (D-LA). Titled the “Continuing Chemical Facilities

Antiterrorism Security Act,” S. 2996 would reauthorize the current law that is set to sunset on October 4, 2010 for an additional five years through October 4, 2015. In so doing, the legislation would provide the Department of Homeland Security (DHS) with sufficient time to fully implement the Chemical Facilities Anti-Terrorism Standards program.

In a statement announcing the introduction of the bill, Senator Collins emphasized, “One of our nation’s greatest vulnerabilities is the threat of a terrorist attack against a chemical facility. The Department of Homeland Security has done a remarkable job developing a comprehensive chemical security program. This industry is vital to our country’s economy and important to advancements and innovations in critical fields such as science, technology, agriculture, medicine and manufacturing, but it can also be a dangerous threat in the event of a terrorist attack. That is why it is critical that we enable the Department to continue this important work.” Senator Collins added that chemical facility security legislation (H.R. 2868) passed by the House on November 6, 2009, would “unwisely bring this progress to a screeching halt.”

The “Continuing Chemical Facilities Antiterrorism Security Act” will be the subject of a March 3, 2010 hearing to be conducted by the Senate Homeland Security and Governmental Affairs Committee.

Meanwhile, CPDA continues its active engagement in the debate surrounding chemical facility security legislation and opposes provisions in the House passed legislation that reach beyond security protections by creating a mandate to substitute products and processes with a government-selected technology and allowing for third-party citizen lawsuits relating to chemical site security to be brought against DHS. On December 9, 2009, CPDA met with staff from the Senate Committee on Agriculture, Nutrition and Forestry to express industry’s concerns with the provisions contained in the House passed bill and to elaborate on the potentially adverse impacts this bill would have on agriculture if enacted. CPDA will continue its efforts on the chemical facility security issue and keep its members informed of further developments.