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Keeping an Eye on Washington

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EPA Seeks Comment on ICR Titled “Notice of Arrival of Pesticides and Devices”

EPA has published a notice in the December 9, 2008 *Federal Register* announcing that the Agency is inviting public comment on an existing Information Collection Request (ICR) titled “Notice of Arrival of Pesticides and Devices (EPA Form 3450-1).” The ICR expires on March 31, 2009. EPA intends to submit the ICR to the Office of Management and Budget (OMB) for review and approval. Comments on the ICR are being accepted until February 9, 2009 and may be submitted electronically at www.regulations.gov. Submissions must be identified by docket number EPA-HQ-OECA-2008-0809.

An importer of pesticides or devices brought into the United States is required to submit the “Notice of Arrival of Pesticides and Devices” form to the appropriate EPA regional office. Once the form is reviewed and approved, the EPA regional office returns it to the importer who, upon arrival of the pesticide shipment, must present it to the district director of the U.S. Customs and Border Patrol at the port of entry. U.S. Customs personnel compare the shipment entry documents with the information contained in the Notice of Arrival form and inform the EPA regional office of any discrepancies that may exist. If there are no discrepancies, U.S. Customs follows the instructions regarding the release or detention of the shipment. However, should U.S. Customs identify any discrepancy, EPA personnel are required to inspect the shipment to determine if the contents are adulterated, misbranded, or otherwise in violation of FIFRA. Depending on the results of EPA’s inspection of the shipment, the pesticide or device may be refused entry into the U.S.

EPA is soliciting public comment on whether the information required by the ICR is necessary for the Agency to perform its duties and whether the information will have practical utility. EPA is also seeking public comment on the quality and clarity of the information to be collected and the accuracy of the Agency’s estimate of the burden associated with the ICR (burden is described as the total time, effort, or financial resources expended to generate, maintain, retain, disclose, or provide required information to a federal agency).

Based on the comments received, EPA may amend the ICR before submitting it to OMB for review and approval. Once the final ICR package is sent to OMB, EPA will publish a notice in the *Federal Register* announcing another public comment period. A copy of the Notice of Arrival form as it is presently drafted may be accessed on EPA's web site at <http://www.epa.gov/oppfead1/international/noaform.pdf>.

EPA Plans to Consolidate Two Pesticide Fee Related ICRs

EPA has announced that it plans to submit a request to the Office of Management and Budget (OMB) to consolidate two existing Information Collection Requests (ICRs) that give the Agency the ability to process, grant, and collect pesticide registration fees and waivers. In so doing, EPA intends to establish a new, consolidated ICR entitled "Pesticide Registration Fees Program" that will consist of the following two currently approved ICRs: "Pesticide Registration Maintenance Fees" (scheduled to expire on November 30, 2010) and "Pesticide Registration Fee Waivers" (scheduled to expire on January 31, 2010). The Agency is inviting public comment on whether the proposed new, consolidated ICR will provide for greater clarity and ease of public review. In a supporting statement accompanying EPA's announcement, the Agency emphasizes that the consolidation of these ICRs into one document will help streamline its fee collection programs under PRIA. EPA points out that the new, consolidated ICR will not change any substantive parts of the two original ICRs.

In addition, EPA states that as part of its effort to reduce the burden associated with the maintenance fee filing form, the Agency will work with the U.S. Treasury Department to implement the electronic payment of maintenance fees via <http://www.pay.gov>.

Comments on EPA's proposal may be submitted electronically at www.regulations.gov and must be identified by docket number EPA-HQ-OPP-2008-0480. The deadline for comment is February 9, 2009. To access the supporting statement which addresses EPA's plans to issue a consolidated ICR, visit <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=EPA-HQ-OPP-2008-0480>.

Regulations Revising ESA Section 7 Consultation Process Finalized

On Thursday, December 11, 2008, the U.S. Department of Interior and the U.S. Department of Commerce finalized a proposed rule that makes certain narrowly crafted changes to the inter-agency consultation process under the Endangered Species Act (ESA). The rule becomes effective 30 days after publication in the *Federal Register*. The rule was originally published as a draft regulation on August 15, 2008 with a 30-day comment period. The comment period was subsequently extended for an additional 30 days. As reported previously, on October 14, 2008 CPDA submitted comments on the

proposal expressing support for the flexible approach to the consultation process envisioned by the draft rule. However, CPDA emphasized that EPA should be allowed to conduct “not likely to adversely affect” determinations without consulting the Services as consistent with the Joint Counterpart Regulations. The Joint Counterpart ESA Section 7 Consultation Regulations, published as final in the August 5, 2004 *Federal Register*, established a streamlined, efficient process for inter-agency consultation between EPA and the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (i.e., the “Services”) in determining the effects of a pesticide on a listed species or habitat. These regulations were intended to provide EPA with flexibility in the way it meets its obligations under the ESA by creating alternative consultation processes that more effectively utilize the Agency’s expertise in evaluating the ecological effects of pesticides.

Section 7 of the ESA requires federal agencies to ensure that actions they either fund, authorize, permit or carry out will not jeopardize the continued existence of a listed species or adversely modify designated critical habitats. To meet this obligation, federal agencies first determine if the proposed action may affect a listed species or critical habitat. If so, a federal agency must proceed with either formal or informal consultation with the U.S. Fish and Wildlife Service or National Marine Fisheries Service.

The recently promulgated rule clarifies the threshold for inter-agency consultation to occur. Under the final rule, federal agencies must still follow all existing consultation procedures, except in specific and limited instances where an action is not anticipated to adversely impact any member of a listed species and that action fulfills one of the following criteria: 1) the action has no effect on a listed species or critical habitat; or, 2) the action is wholly beneficial; or, 3) the effects of the action can not be measured or detected in a manner that permits meaningful evaluation using the best available science; or, 4) the effects of the action are the result of global processes and can not be reliably predicted or measured on the scale of species current range; or would result in an insignificant impact to a listed species, or are such that the potential risk of harm to a species is remote. Federal action agencies may still voluntarily engage in the informal consultation process. Moreover, the Department of Interior states that if a Federal agency has any limitations on its ability to make determinations under the ESA or believes that it does not have the scientific expertise to make an accurate assessment of the impact of its actions on listed species and critical habitat, it may avail itself of the expertise offered by the Services in exactly the same manner as under the current regulatory procedures.

The final rule sets forth timelines for informal consultation procedures. If during the course of informal consultation a federal agency determines that the action in question is not likely to adversely affect listed species or critical habitat, the consultation process is terminated and no further action is necessary as long as the Service concurs in writing. If the Service does not provide a written statement of concurrence within sixty days of the Federal agency’s request for such concurrence, the Federal agency may then, upon written notice to the Service, terminate consultation. The Service may, upon written notice to the Federal agency within the 60-day period, extend the time for informal consultation for a period no greater than an additional 60 days. If the Federal

agency terminates consultation at the end of the 60-day period, or if the Service's extension period expires without a written statement whether it concurs with a Federal agency's determination that the action is not likely to adversely affect a listed species or critical habitat, the consultation requirement in Section 7(a)(2) is deemed satisfied.

In its other provisions, the final rule includes language stipulating that a "biological assessment" may be a document prepared for the sole purpose of interagency consultation or it may be a document prepared for other purposes (such as an environmental assessment or environmental impact statement) containing the information required to initiate consultation. The rule states that the Federal agency is required to provide the Services a specific guide or statement as to the location of the relevant consultation information in any alternative document submitted in lieu of a biological assessment.

The rule also defines "cumulative effects" as those effects of future State or private activities (not involving Federal activities) that are reasonably certain to occur within the action area of the particular Federal action subject to consultation. Cumulative effects do not include future Federal activities that are physically located within the action area of the particular Federal action under consultation.

Shortly after the Department of the Interior announced promulgation of the final rule, the Center for Biological Diversity along with Defenders of Wildlife and Greenpeace filed suit in federal district court seeking to overturn the initiative.

In addition, Senate Committee on Environment and Public Works Chair Barbara Boxer (D-CA) issued the following statement: "These midnight regulations are part of a continuing effort by the Bush Administration to repeal our landmark environmental laws through the back door and weaken protections for our nation's endangered species. I believe they are illegal, and if similar regulations had been in place, they would have undermined our ability to protect the bald eagle, the grizzly bear, and the grey whale."

CPDA will continue to monitor the issue surrounding implementation of Section 7 of the ESA and will keep its membership apprized as further developments unfold.

Update on EPA's Policy on Repacks with Alternate Formulations

EPA is expected to schedule a meeting in the early part of 2009 to discuss a Registration Division (RD) policy that allows a registrant to register a 100% repack with alternate formulations. Under this policy which was established in 2005, applicants seeking approval of repacks that are alternate formulations do not need to submit data compensation forms provided the repack label only lists uses that are found on each of the alternate source products. If the label includes an additional use not found on the labels of all the source products the data compensation form must then be submitted to address data requirements for that use. The label may contain a subset of approved uses on the source product.

The RD policy stipulates that the label text may not change. As such, any alternate formulation that would necessitate a label change must be treated as a separate product. Registration Division personnel are advised that repacks with alternate formulations should be sent to the Technical Review Branch (TRB) for chemistry review to ensure formulations are similar.

Earlier this year, OPP staff considered changes to the policy described above due to concerns that a registrant could not ensure that its repack submission met the requirements for alternate formulations. In recent discussions with senior OPP staff, CPDA representatives pointed out that any changes to the policy on repacks with alternate formulations would create significant problems for registrants. In response, senior OPP managers have agreed to suspend further efforts to finalize any changes to the current policy on repacks with alternate formulations pending a meeting that will likely include representatives from CPDA, OPP staff across all three registering divisions, and the Agency's Office of General Counsel. In the interim, CPDA will keep its members informed of further developments as they occur.

President-elect Barack Obama Names Key Members of his Administration

President-elect Barack Obama has selected Lisa Jackson as his nominee to fill the post of Administrator of the U.S. Environmental Protection Agency. Jackson previously served as Commissioner of the New Jersey Department of Environmental Protection under Governor Jon Corzine. Jackson spent 16 years with the U.S. EPA working at both the Agency's headquarters office in Washington, D.C. and its Regional office in New York.

In his other environmental team picks, President-elect Obama named Nancy Sutley to Chair the White House Council on Environmental Quality. Sutley currently serves as Deputy Mayor for Energy and the Environment in Los Angeles. She has previously held environmental posts at the state level under former California Governor Gray Davis and at the federal level under former President Bill Clinton.

President-elect Obama also named Carol Browner to a new position in the White House where she will coordinate energy and climate policy. Browner was Administrator of EPA under the Clinton Administration. She has also served as Secretary of Florida's Department of Environmental Regulation and previously was Legislative Director for then-Senator Al Gore.

In related developments, President-elect Obama announced his choice of Senator Ken Salazar (D-CO) as nominee for the Secretary of the Interior and former Iowa Governor Tom Vilsack (D) as Secretary of Agriculture. Both Secretaries-designate are expected to play pivotal roles in the development of President-elect Obama's energy and environmental policies. Secretary-designate Salazar has stated that the reduction of U.S. dependence on foreign oil will figure prominently in the protection of national security

and in addressing the issue of global warming. Secretary-designate Vilsack has vowed to “promote American leadership in response to global climate change” and to “place nutrition at the center of all food programs administered by [USDA].”

In response to President-elect Obama’s nomination of former Governor Vilsack for Secretary of Agriculture, Senator Tom Harkin (D-IA) who chairs the Senate Committee on Agriculture, Nutrition and Forestry issued the following statement: “Tom Vilsack has a strong record in Iowa on building opportunities in renewable energy, conservation, food and nutrition, experience that will serve him well as Secretary of Agriculture. With our economy in a downturn, Tom Vilsack knows how to bring change that will rebuild rural economies and keep them vibrant. As someone who has been a supporter of Tom Vilsack from the time he ran for Governor to the time he ran for President, I believe he will be a strong Secretary of Agriculture and I expect a swift confirmation by the Senate Agriculture Committee.”

Staff Retirements at EPA and USDA

Don Stubbs, Associate Director of EPA’s Registration Division, will retire at the end of this year. Don tells CPDA that his last day on the job at EPA will be December 23, 2008. Over the years, CPDA has enjoyed a long working relationship with Don on a number of pesticide registration and labeling issues.

Other imminent EPA staff departures include Charles Auer, Director of the Agency’s Office of Pollution Prevention and Toxics, whose retirement will be effective January 2009. Auer has worked on such issues as the voluntary HPV Challenge Program, the TSCA Inventory Update Rule, and other important initiatives.

In other news, Al Jennings will retire from his post as Director of USDA’s Office of Pest Management Policy effective January 3, 2009. During the course of his career, Al has spoken at numerous CPDA meetings and workshops and has consistently demonstrated a solid understanding of the pesticide industry and the needs of growers.

Please join CPDA in recognizing these three individuals for the accomplishments they have achieved in their long government careers and wishing them well as they embark on new endeavors.

Mark Your Calendars

CPDA would like to take this opportunity to remind its members that the 2009 Mid-Year Meeting will take place March 10-11 at the Sheraton Crystal City Hotel located at 1800 Jefferson Davis Highway in Arlington, Virginia. Further details regarding the CPDA Mid-Year Meeting will be announced in the near future.