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Keeping an Eye on Washington

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Special Review and Reregistration Division is Renamed the Pesticide Re-evaluation Division

The EPA Office of Pesticide Programs (OPP) has changed the name of its Special Review and Reregistration Division (SRRD) to the Pesticide Re-evaluation Division (PRD). The name change became effective September 13, 2009. EPA emphasizes that the new name more accurately describes the nature of the Division's present and future work responsibilities. In a statement released by EPA, the Agency notes, "...The pesticide program is moving toward closing out both the Special Review and the reregistration programs, for which SRRD was named. Only a few Special Reviews remain to be formally concluded. All Reregistration Eligibility Decisions (REDs) have been completed and are being implemented, while product reregistration is on a track to be completed within the next few years." EPA continues, "...Meanwhile, Registration Review is well underway, and the pace of this new program is increasing with more dockets opening, more Final Work Plans being completed every year, and registration review decisions being made. As the Division ramps up Registration Review and is completing Special Review and reregistration, the name Pesticide Re-evaluation Division better reflects its present mission and describes its ongoing work."

The Agency adds that although the Division and Branch names are changing, the Division's location, organization, projects and chemical assignments stay the same. The Division's mail code will remain 7508P. Updated Division contact information is available on EPA's web site at http://www.epa.gov/oppsrrd1/contacts_prd.html.

EPA Announces Pesticide Use Limitations Affecting Pacific Salmon and Steelhead

On September 11, 2009, EPA announced its plans to implement measures calling for new and significant limitations on the use of chlorpyrifos, diazinon, and malathion to protect endangered and threatened Pacific salmon and steelhead in California, Idaho, Oregon, and Washington. In announcing the implementation measures, OPPTS Assistant Administrator Steve Owens stated, "These limitations, developed as a result of the Endangered Species Act formal consultation process, will protect Pacific salmon and

steelhead while providing for appropriate pesticide use. These new limits are especially significant because they mark the first time that EPA and National Marine Fisheries Service have completed the consultation process under the Endangered Species Act in more than 20 years. This is a major step forward for both EPA and NMFS in meeting the requirements of the law. This process has been broken for too long.”

The Agency states that its measures will achieve the protection goals consistent with the following recommendations contained in the NMFS Biological Opinion (BiOp) that was issued on November 18, 2008: 1) a requirement for spray drift buffers, 2) a wind speed restriction, 3) a requirement for a non-crop vegetative runoff buffer, 4) a soil moisture/48 hour storm restriction, 5) a fish mortality incident reporting requirement, and 6) an effectiveness monitoring program for off-channel habitats. EPA intends to require changes to pesticide labeling to achieve the new use limitations.

EPA has adopted a spray drift buffer for aerial drift and overland runoff that differs in width compared to the limits recommended in the November 2008 NMFS BiOp. Specifically, NMFS recommended that use of the pesticides not be permitted within 500 feet of salmon and steelhead habitats when applied by ground nor within 1000 feet when applied by air. EPA states that the buffers it intends to impose will vary depending on application rate, spray droplet size, and water body size but in no case will be less than 100 feet to account for run-off in addition to drift. The Agency maintains that the buffers it has adopted will achieve risk reduction comparable to that estimated using the buffer distances and application assumptions NMFS used in their BiOp.

Similarly, EPA intends to adopt a 100 foot “no use” buffer adjacent to any surface waters that have a connection to salmonid-bearing waters in lieu of the NMFS recommended 20 foot non-crop vegetative runoff buffer. EPA notes that if they are maintained diligently, vegetative buffers can be effective in reducing pesticide runoff across land surface into a water body. However, EPA adds that if not maintained or managed properly, such buffers can also become conduits for pesticide runoff. The Agency states, “...Given the research and resulting literature relative to the effectiveness of vegetative buffers and maintenance thereof, EPA believes the minimum 100 foot application buffer effectively addresses NMFS concern regarding pesticide residues entering salmon and steelhead habitat from ground services.”

EPA has also departed slightly from NMFS with regard to the fish mortality reporting requirement recommended in the BiOp. NMFS recommended that EPA require pesticide users report all incidents of fish mortality that occur within four days of application and within the vicinity of the treatment area to the Office of Pesticide Programs. While the Agency intends to require that pesticide users report such incidents, rather than reporting these incidents to OPP, EPA will mandate that they be reported to the pesticide registrant who is already required to provide information regarding incidents to EPA pursuant to FIFRA Section 6(a)(2) adverse effects reporting obligations. “By approaching incident reporting in this manner,” the Agency explains, “EPA will avoid establishing a secondary system for receipt of such incidents and ensure appropriate treatment of all incidents reported.”

EPA adopted unchanged the NMFS recommendation that applications of the three pesticides not be permitted when winds are greater than ten miles per hour immediately prior to application. NMFS further recommended that applications adjacent to salmon and steelhead habitat commence on the side of the field nearest water and proceed away from the water.

Finally, EPA has adopted the NMFS recommendation calling for an effectiveness monitoring program for off-channel habitats to measure the effectiveness of the use limitations put in place. EPA states that it will work with NMFS to design a reasonable monitoring study that will allow the federal government to determine peak concentrations of the OP pesticides in vulnerable, off-channel habitats and at the same time provide data that might allow EPA to determine the effectiveness of its protection measures. The Agency will seek the input of the U.S. Geological Survey in developing the protocol for this monitoring program. EPA intends to require the registrants of the OP pesticides to fund and conduct the monitoring study and to submit the information collected to the Agency.

Detailed information on EPA's plans to implement the recommendations contained in the NMFS BiOp may be accessed at <http://epa.gov/oppfead1/endorsement/litstatus/wtc/nmfs-signedresponse.pdf>.

Senate Approves Nomination of Cass Sunstein as OMB/OIRA Administrator

On September 10, 2009, by a vote of 57 to 40, the Senate confirmed the nomination of Cass Sunstein to be Administrator of the Office of Management and Budget's Office of Information and Regulatory Affairs (OMB/OIRA). Sunstein's nomination generated some controversy largely due to his strong support for the use of cost-benefit analysis of regulations and his rejection of the use of the "precautionary principle." These positions have prompted some segments of the activist community to voice their concern that his appointment could erode environmental protections now in place.

As head of OIRA, Sunstein will play a major role in the promulgation of environmental, health and safety regulation. Created by Congress with the enactment of the Paperwork Reduction Act of 1980, OIRA reviews significant proposed and final rules as well as information collection requests prior to publication in the *Federal Register*. Coordinated review of agency rulemaking is necessary to ensure that regulatory actions do not conflict with the policies or actions taken or planned by another agency, are consistent with applicable law, the President's priorities, and the principles set forth in Executive Order 12866.

Sunstein was formerly a faculty member of Harvard Law School and he also taught at the University of Chicago Law School. The confirmation vote had remained stalled for months due to a series of holds that Republican Senators had placed on Sunstein's nomination due to concerns over his previous writings on such issues as

animal rights. However, on September 9th, the Senate voted 63-35 on a procedural measure to invoke cloture and end debate on the Sunstein nomination, effectively bypassing any holds placed on the nomination and clearing the way for an up or down confirmation vote.

EDSP Update

EPA has signaled yet again its intent to send out test orders before the end of this year as it proceeds with implementation of the Endocrine Disruptor Screening Program (EDSP). Industry has been actively engaged in discussions with the Agency and OMB over the questionable merits and significant costs to industry of the program. The test orders will cover 58 pesticide active ingredients and nine inert ingredients. Agency staff now estimate that as many as 750 test orders could be issued. This estimate significantly exceeds earlier EPA estimates that the total number of test orders issued would be approximately 380, 183 of which were for inert ingredients. EPA has indicated that most of the additional 350 plus orders will be sent to inert manufacturers or importers that do not sell into the pesticide market and will be exempt from the testing requirement. Regardless of the number, before EPA can move forward with the test orders, OMB must give final approval to the Information Collection Request (ICR) that authorizes the collection of EDSP screening and testing data.

The EDSP is a two-tiered screening and testing initiative established by the Food Quality Protection Act of 1996 and amends both FIFRA and the Safe Drinking Water Act. EPA contends that Tier 1 screening will identify chemicals that have the *potential* to interact with the endocrine system. Tier 2 testing is designed to determine if a pesticide chemical causes an adverse effect and establish the dose at which the effect occurs. EPA states that this tiered approach will enable it to gather the information needed to identify endocrine disruptors and take appropriate regulatory action. The Tier 1 battery consists of 11 assays (5 in vitro and 6 in vivo assays). The Tier 2 battery is comprised of 5 in vivo assays that have not yet been finalized or validated by EPA.

Agency personnel have indicated that test order recipients will have the opportunity to claim that existing information is sufficient for EPA to make a determination as to whether a particular chemical has the potential to interact with the endocrine system or causes adverse effects on the endocrine system and therefore should be exempt from duplicative testing under the Tier 1 screening battery. EPA intends to review on a case-by-case basis claims made by test order recipients that “other scientifically relevant information” (OSRI) or functionally equivalent data exist that satisfies all or part of a Tier 1 test order. However, EPA staff caution companies that test order recipients should be prepared to conduct the Tier 1 screening battery should the Agency decide that existing data does not provide sufficient information necessary to make a determination regarding a chemical’s potential to interact with the endocrine system. Industry has expressed concern that EPA has provided little to no guidance that would help companies evaluate whether existing data meets the criteria of what the Agency would consider to be “functionally equivalent.” Office of Pesticide Programs

Senior Policy Advisor Bill Jordan has indicated that if the Agency finds submitted data to be equivalent and that one or more assays may be waived, all test order recipients will be notified and will be exempt from conducting those assays. Another significant concern for industry is that EPA has not articulated what findings from the Tier 1 screen would automatically trigger a requirement for Tier 2 testing or preclude the need for Tier 2 testing. Tier 1 screening is estimated to cost at least \$1 million per chemical and Tier 2 testing is estimated to cost upwards of \$3-\$5 million. In addition, the Agency has signaled that it has considered the possibility that all manufacturers or importers of the nine listed inert ingredients may opt to discontinue sale into the pesticide market to avoid having to conduct the Tier 1 battery. Some registrant companies will be monitoring this situation very closely to see if there is evidence of such a scenario occurring.

In related developments, CPDA has sent a formal request to OMB for immediate access to any correspondence and supporting documentation submitted to OMB by EPA in response to the OMB request for information on the EDSP Information Collection Request. CPDA has also asked OMB to withhold its final decision on the ICR pending an opportunity for public review and response to this material once it is made available. In a September 17, 2009 correspondence to Kevin Neyland, Deputy Administrator of OMB's Office of Information and Regulatory Affairs (OIRA), CPDA President Sue Ferenc explained that the pesticide chemical industry provided substantial documentation to OMB in May of 2009 in response to the EDSP ICR that was forwarded to OMB for review and approval in April 2009. "It has come to our attention that subsequent to this submission," CPDA President Ferenc wrote, "OMB and EPA have exchanged written communications regarding several issues outlined by industry in its comments. Industry identified significant concerns regarding the ICR, including the lack of scientific validation of several of the assays in the Tier 1 Battery, and the significant underestimation by EPA of the actual \$70-\$100 million burden imposed on industry by this collection." She continued, "The Agency has failed to post any documents to the EDSP docket since June 15, the date for response to EPA on the OMB ICR review. Despite repeated requests to the Agency, we have been unable to obtain or review copies of the EPA response to OMB in this regard." CPDA President Ferenc concluded her email by requesting immediate access to the written exchanges between EPA and OMB concerning the ICR. CPDA will keep its members informed of further developments on this issue as they occur.

EPA to Conduct Public Webcast on NPDES Permitting Requirements for Pesticides

EPA will conduct a webcast to describe the Agency's efforts to develop a National Pollutant Discharge Elimination System (NPDES) general permit for discharges from the application of pesticides in the few remaining areas nationwide where EPA is the NPDES permitting authority. The free webcast will be held on October 7, 2009 from 1:00 p.m. to 3:00 p.m. (Eastern Time) and will be open to the public. A link to the webcast will be made available on EPA's NPDES training website at www.epa.gov/npdes/training prior to the scheduled date of this event. The webcast will cover the current legal status of NPDES permitting requirements for discharges from the

application of pesticides, the schedule for developing NPDES general permits for such discharges, and the agency's current thinking on the scope of the general permit as well as related issues pertaining to monitoring, reporting, and recordkeeping requirements.

As reported previously, 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 present in, over, or near waters. EPA expects the 45 states that are authorized as NPDES permitting authorities to use the Agency's general permit to guide them in developing and issuing their own permits.

CPDA and Other Members of the Pesticide Policy Coalition Urge Continued Support for USDA's Office of Pest Management Policy

CPDA and other members of the Pesticide Policy Coalition (PPC) have sent a September 25, 2009 letter to USDA Secretary Tom Vilsack urging his continued support for USDA's Office of Pest Management Policy (OPMP) and the appointment of a Special Assistant for Pest Management Policy. The industry group pointed out that since its inception, the OPMP has played a key role on significant issues such as providing critical data and analyses to other regulatory agencies, funding and coordinating vital research projects, promoting integrated pest management (IPM), and supporting USDA's risk assessments. Moreover, the letter emphasized that "OPMP's role is becoming increasingly important in ensuring that agriculture has a seat at the table as the intersection between agriculture and the environment has resulted in additional regulation by EPA, the Fish and Wildlife Service, and the National Marine Fisheries Service." CPDA and other members of the PPC explained that in order to accomplish these tasks, the OPMP must be fully staffed and adequately funded. The letter recommended the establishment of a permanent OPMP Director who would work across the various mission areas within USDA and who would report directly to the Secretary or a designee of the Secretary. In addition, the letter called for the appointment of a Special Assistant to the Secretary for Pest Management Policy.

The President's FY 2010 budget request for USDA proposed the transfer of the Office of Pest Management Policy to the Office of the Chief Economist within the Department. In its consideration of the FY 2010 USDA appropriations measure (H.R. 2997), the House Committee on Appropriations rejected the President's proposal and agreed to a funding level of \$1,700,000 for OPMP within the Agricultural Research Service. H.R. 2997 passed the full House on July 9, 2009 by a roll call vote of 266 to 160. Similarly, the President's proposal to transfer OPMP to the Office of the Chief Economist was rejected by the Senate Committee on Appropriations in its consideration of that chamber's version of the USDA spending bill, S. 1406. Report language accompanying S. 1406 states, "The fiscal year 2010 appropriation does not accept the

budget proposals to transfer the Office of Pest Management Policy to the Office of the Chief Economist or to decrease funds for property management.” The Senate adopted S. 1406 on August 4, 2009 by a roll call vote of 80 to 17. Differences between the House and Senate versions of the USDA spending bills must now be resolved in conference.

OPP Labeling Web Site Addresses Question Regarding Multiple Pesticide Products Packaged Together

The OPP labeling consistency web site includes a new post that addresses a question as to whether a pesticide, generally sold as ten one fluid ounce bottles in a box, can be removed from the box and sold as an individual bottle that does not bear the full label. The label, however, would be copied by the seller and provided to the purchaser. The question is phrased as follows: “A pesticide is sold as ten 1-fluid ounce bottles in a box. A do-it-yourself pest store is selling the individual 1-ounce bottles which do not have the full label. If they copy the full label and sell it with the bottle is this a violation?”

The Agency advises, “Unless the EPA registration allows and the registrant has authorized the do-it-yourself pest store to sell the bottles individually and to copy the label and provide it to the customer, the act of copying the label and providing it to the customer along with the individual bottle is considered production and sale of an unregistered pesticide. If the registrant authorizes the do-it-yourself pest store to open a box and sell individual bottles along with a copy of the full label and such sale is permitted under the registration, the do-it-yourself store would have to register as a producing establishment and file annual reports of their production. In addition, the individual bottles, if sold separately without the full labeling, are considered misbranded and it is a violation of section 12(a)(1)(F) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) to sell or distribute a misbranded pesticide.” To view other questions and Agency responses with regard to pesticide labeling, visit http://www.epa.gov/pesticides/regulating/labels/label_review_faq.htm.

CPDA and Other Industry Groups Voice Concern over Chemical Facility Security Bill to House Committee

CPDA and other members of a broad based coalition of industry groups representing chemical and agricultural interests, led by the U.S. Chamber of Commerce, have drafted a letter to the majority and minority leadership of the House Committee on Energy and Commerce expressing concerns over the Chemical Facility Anti-Terrorism Act of 2009 (H.R. 2868). In the letter addressed to Committee Chairman Henry Waxman (D-CA) and Ranking Member Joe Barton (R-TX), the group voiced its strong opposition to three specific provisions in the bill dealing with preemption, citizen suits, and “Inherently Safer Technology,” all of which could have damaging and disruptive impacts on ongoing security enhancement activities undertaken by the regulated community.

As reported previously, H.R. 2868 would make permanent the authority of the Department of Homeland Security (DHS) to regulate chemical site security. Currently, DHS exercises its regulatory authority over chemical site security through the Chemical Facility Anti-Terrorism Standards (CFATS) which are set to sunset in October 2009 in the absence of the enactment of reauthorizing legislation. On June 23, 2009, H.R. 2868 was reported favorably out of the House Homeland Security Committee, chaired by Representative Bennie Thompson (D-MS), and was subsequently referred to the House Energy and Commerce and House Judiciary Committees, both of which have jurisdiction over various provisions contained in the measure. The House Energy and Commerce Committee is expected to hold hearings on the bill on October 1, 2009 and proceed to a markup shortly thereafter. The letter signed by CPDA and its industry partners was drafted in anticipation of the upcoming hearing. The following is a summary of the concerns outlined in the letter.

Preemption (Section 2109): H.R. 2868 would permit state and local governments to adopt or enforce standards more stringent than federal standards now in place. The coalition emphasized that absent a set of consistent, uniform national standards, companies will be subject to a patchwork of confusing and possibly conflicting regulations that would burden industry and would do nothing to enhance the safety or security of chemical facilities. The industry group added that such a patchwork of state and federal regulation would be particularly problematic for the many companies that operate in multiple states and would be forced to “sort through a dizzying maze of potentially contradictory regulations.”

Private rights of action (Section 2116): This provision of H.R. 2868 would allow private rights of action, or “citizen suits,” to be brought by individuals, even if they have not suffered any harm, against regulated facilities or the Department of Homeland Security to enforce compliance with the Act. The industry coalition pointed out that the CFATS are performance-based and provide facilities the flexibility to decide which security measures or technologies to adopt. “Allowing layperson litigants rather than DHS security specialists to challenge a facility’s selection of security measures,” the industry coalition asserted, “will not enhance security in any meaningful way.” The group also expressed its concern that broad discovery rights in federal lawsuits could lead to public disclosure of classified or highly sensitive information, such as the types and amounts of chemicals stored at a facility, and that such information could assist terrorists.

Inherently Safer Technology (Section 2111): The bill would require all covered chemical facilities (risk Tiers 1 through 4) to assess “inherently safer technologies” (IST) and mandate that facilities assigned to risk Tiers 1 or 2 actually implement IST if ordered to do so by the DHS. The industry coalition emphasized that the current CFATS already provide chemical facilities with powerful incentives to implement enhanced safety measures, improve processes, and substitute safer chemicals. “Mandating adoption of government-selected ISTs would gut the core of the CFATS without reducing real risks,” the industry group warned. The coalition also objected that the cost of assessing ISTs would be “unduly burdensome” for smaller chemical facilities that would be required to retain expensive consultants and chemical safety engineers simply to assess the existence

and feasibility of ITSs. “These operations, already suffering from the ongoing economic crisis,” the industry coalition wrote, “will have even fewer resources to dedicate to actual security enhancements if forced to conduct costly IST assessments.”

While it is very unlikely that a comprehensive chemical facility security bill will be enacted during this session of the 111th Congress, it is expected that the current CFATS will be extended for a period of one year. As reported previously, the House and Senate have passed their respective versions of the FY 2010 appropriations measure for the Department of Homeland Security which includes language that would extend the current authority of DHS to regulate chemical facility security for one year until October 4, 2010. A conference committee is now meeting in an effort to reconcile differences in the House and Senate versions of the spending bill.

OMB Approves Renewal of Information Collection Request (ICR) to Accompany Rule on Intentional Dosing of Humans with Pesticides

OMB has approved the renewal of an EPA Information Collection Request (ICR) titled “Submission of Protocols and Study Reports for Environmental Research Including Human Subjects.” The ICR accompanies a January 2006 final rule to amend the Federal Policy for the Protection of Human Subjects (also known as the Common Rule). EPA’s final rule bans all third-party intentional dosing research on pesticides involving pregnant or nursing women and prohibits the Agency from conducting or supporting such research. The rule also extends new ethical protections to adult (non-pregnant, non-nursing) subjects involved in intentional dosing human studies for pesticides and adopts many of the recommendations from the National Academy of Sciences.

Study protocols involving the intentional dosing of human subjects to pesticides must be submitted to EPA and a “Human Subjects” institutional review board before such research is initiated so that the scientific design and ethical standards that will be employed during the proposed study may be reviewed and approved. In addition, respondents are required to submit information about the ethical conduct of completed research that involved human subjects when such research is submitted to EPA. The estimated total annual hour burden of the ICR is 20,572 and the estimated total annual cost is \$1,579,098.

PPDC Meeting Reminder

The Pesticide Program Dialogue Committee (PPDC) meeting will take place October 14-15, 2009 at OPP located at 2777 S. Crystal Drive (One Potomac Yard South), Arlington, Virginia. The PPDC meeting will include a discussion of EPA activities pertaining to the Endangered Species Act (ESA), the development of an NPDES general permit for pesticide applications near water, web-distributed labeling, comparative safety statements for pesticide products, plant health claims on pesticides, and other issues. EPA has posted a draft agenda on its web site which may be accessed at <http://www.epa.gov/pesticides/ppdc/2009/october/agenda.html>. In addition, EPA has announced the schedule appearing below for the PPDC Work Groups that will be

meeting in advance of the full PPDC. Scheduling updates may be found on EPA's web site at <http://www.epa.gov/pesticides/ppdc/>. Most, if not all of these meetings may be attended via conference call. CPDA will provide this information as it becomes available.

PPDC PRIA Process Improvement Work Group: October 1, 2009, 1:00 p.m. to 4:30 p.m., One Potomac Yard South, 2777 S. Crystal Drive, Arlington, VA, Lobby Level Conference Center

PPDC 21st Century Toxicology/New Integrated Testing Strategies Work Group: October 13, 2009, 2:00 p.m. to 4:00 p.m., One Potomac Yard South, 2777 S. Crystal Drive, Arlington, VA, Room N-4830

PPDC Web-Distributed Labeling Work Group: October 13, 2009, 1:30 p.m. to 4:30 p.m., One Potomac Yard South, 2777 S. Crystal Drive, Arlington, VA, Room S-4370-80

PPDC Comparative Safety Statements for Pesticide Labels Work Group: October 13, 2009, 1:00 p.m. to 4:30 p.m., One Potomac Yard South, 2777 S. Crystal Drive, Arlington, VA, Lobby Level Conference Center