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***Keeping an Eye on Washington***

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**PRIA Fees to Increase 5% Effective October 1, 2008**

In the August 5, 2008 *Federal Register*, EPA published a notice announcing that as required under the Pesticide Registration Improvement Renewal Act, registration fees for covered applications received on or after October 1, 2008 will increase by five percent rounded up to the nearest dollar from the previous PRIA fee schedule published on October 30, 2007. With the 5% increase in PRIA fees, certain application categories will have shorter review periods. The August 5, 2008, *Federal Register* notice reminds registrants that fee payments must be submitted at the time of application. EPA will reject any application that does not contain evidence that the fee has been paid. Agency staff disclose that a number of pre-payments have been made by applicants prior to submission of the product package itself. EPA advises that the date the application package is received will determine whether or not an applicant must pay the increased fees that go into effect on October 1, 2008. Submissions received on or after October 1, 2008 will be subject to the new PRIA fees schedule and the applicant will owe an additional 5% even if he/she has prepaid the "old" fee. As such, registrants should make sure that their applications are received by the Office of Pesticide Programs (OPP) mailroom no later than 4:30 p.m. on Tuesday, September 30, 2008 to avoid paying the additional 5%. To access the *Federal Register* notice announcing the new PRIA fee structure for FY 2009, please visit <http://edocket.access.gpo.gov/2008/pdf/E8-17936.pdf>.

**CPDA Secures Membership Seat on Three Newly Formed PPDC Workgroups**

CPDA has secured a seat on three newly formed workgroups of the Pesticide Program Dialogue Committee (PPDC). One of these is the PPDC 21st Century/Toxicology/New Integrated Testing Strategies Workgroup which will focus on developing a blueprint for the implementation of a new testing paradigm that calls for combining in vitro testing and computational models to make predictions for in vivo outcomes by using more targeted animal testing. The workgroup will consider how best to communicate complex science to all stakeholders and how best to transition to the new testing paradigm.

CPDA has also been accepted as a member of the recently created PPDC Web-Distributed Labeling Workgroup. This workgroup will address several key issues pertaining to the web-based dissemination of pesticide labeling such as what type of information should be displayed on the container vs. the web site, what entity should be responsible for hosting the web site, concerns regarding the synchronization of EPA web-based labeling actions with state pesticide registration activities, and whether a downloaded web-based label should have a distinct life span.

Finally, CPDA has accepted EPA's invitation to participate as a member of the PPDC Comparative Safety Claims Work Group. The objective of this PPDC work group is to develop a set of recommendations to the full PPDC as to whether the government should pursue a policy and regulatory change in order to allow Agency third party endorsements/statements or logos on pesticide product labels regarding comparative product safety.

### **EPA Posts Risk-Based Prioritizations for 29 Additional Chemicals**

EPA has posted on its web site Risk-Based prioritizations and supporting documents for 29 additional chemicals that were sponsored under the High Production Volume (HPV) Challenge Program. For a given chemical or chemical category, each Risk-Based Prioritization presents an initial recommended level of concern based on information in the supporting documents, which include a Hazard Characterization, Exposure Characterization, and Risk Characterization. EPA uses these screening-level documents to evaluate chemicals and assign initial priority for future potential action based on the risk concerns presented by these chemicals in comparison with other HPV chemicals and in light of any uncertainties presented by gaps in the available data. To date, Risk-Based prioritizations have been posted for a total of 74 chemicals. The list may be accessed at [http://iaspub.epa.gov/opptppv/hpv\\_hc\\_characterization.get\\_report?doctype=1](http://iaspub.epa.gov/opptppv/hpv_hc_characterization.get_report?doctype=1).

The HPV chemical risk-based prioritization initiative is part of EPA's strategy for fulfilling its commitments in accordance with the North American Security and Prosperity Partnership (SPP). Under the SPP, the Agency has committed to assess and initiate any needed action on approximately 6,750 high and moderate production volume chemicals by 2012. To carry out this endeavor, EPA has developed the Chemical Assessment and Management Program (ChAMP).

### **EPA Announces Cancellation of Pesticide Registrations for Non-Payment of Maintenance Fees**

In the August 6, 2008 *Federal Register*, EPA published a list of 221 pesticide registrations that are being cancelled due to non-payment of maintenance fees required under PRIA. The statute establishes a January 15<sup>th</sup> statutory deadline for payment of maintenance fees.

EPA states that in late December 2007, all holders of either FIFRA Section 3 registrations or section 24(c) registrations were sent lists of their active registrations, along with forms and instructions on how to respond to the Agency. Registrants were asked to identify which of their registrations they wished to continue, and to calculate and remit the appropriate maintenance fees accordingly. EPA reports that most responses were received by the statutory deadline of January 15<sup>th</sup>. A notice of intent to cancel was mailed in mid-February to companies that did not respond to EPA's inquiry and to those companies that did respond but paid for less than all of their registrations. The Agency states that since mailing the notices, EPA has maintained a toll-free telephone number to answer questions from registrants regarding payment of the fees.

According to EPA, maintenance fees have been paid for about 16,116 Section 3 registrations, or about 96% of the registrations on file in December. Fees have been paid for about 2,212 section 24(c) registrations, or about 88% of the total on file in December. EPA states that cancellation for non-payment of maintenance fees affects about 191 Section 3 registrations and about 30 section 24(c) registrations.

Registrants will generally be permitted to sell and distribute existing stocks of canceled product for a period of one year following the statutory payment due date (i.e., through January 15, 2009). Existing stocks already in the hands of dealers or users may generally be distributed, sold, or used legally until they are exhausted. Existing stocks are defined as those stocks of a registered pesticide product which are currently in the U.S. and which have been packaged, labeled, and released for shipment prior to the effective date of the action.

The *Federal Register* notice identifying the products cancelled for non-payment of maintenance fees may be accessed at <http://edocket.access.gpo.gov/2008/pdf/E8-17928.pdf>.

### **EPA Posts Draft ESA Biological Opinion from NMFS on its Web Site**

EPA has received and posted to its web site a Draft Biological Opinion from the National Marine Fisheries Service (NMFS) that responds to requests for consultation under the Endangered Species Act (ESA) on the potential effects of three pesticides on Pacific salmon and steelhead. The Draft Biological Opinion is issued in response to a settlement agreement with the Northwest Coalition for Alternatives to Pesticides (NCAP), which sued NMFS for unreasonable delay in completing consultations with EPA on 54 pesticides subject to the Washington Toxics Coalition litigation dating back to January 2001. The Draft is the first of consultations on 37 active ingredients that are to be completed by NMFS over the next 4 years under this latest settlement agreement.

The Draft Biological Opinion available on EPA's web site focuses on three active ingredients – diazinon, malathion, and chlorpyrifos, for which the Agency initiated consultation on November 29, 2002, May 29, 2002, and April 14, 2003, respectively.

While the Draft Biological Opinion is specific to these three chemicals, it could set precedents for future ESA litigation and consultations for other products.

The ESA requires that Federal agencies assess their “actions” to determine whether species listed as threatened or endangered may be affected by those actions, or whether critical habitat may be adversely modified. The registered uses of a pesticide constitute an EPA “action” under the ESA. If EPA determines that a pesticide’s registered uses are likely to adversely affect a federally listed threatened or endangered species or modify its critical habitat, EPA initiates formal consultation with the U.S. Fish and Wildlife Service or the National Marine Fisheries Service as appropriate. In response to a Federal Agency initiating formal consultation, the Services develop a Biological Opinion in which they provide their opinion on whether the “action” is likely to jeopardize the continued existence of a listed species or is likely to adversely modify designated critical habitat and, if so, describes alternatives to avoid jeopardy.

NMFS has not invited input from the public on its Draft Biological Opinion. Instead, NMFS is limiting its interaction with EPA. As such, EPA has established a public docket [[EPA-HQ-OPP-2008-0654](#)] for this and future Draft Biological Opinions related to pesticides and Pacific salmon and steelhead. Comments received by EPA will be forwarded to NMFS as part of the Agency’s review of the Draft Biological Opinion. Once NMFS develops any alternatives or measures it believes are necessary to reduce risk, EPA will request public input on those remedies.

### **FWS and NMFS Accept Public Comment on Proposed Rule to Revise ESA Section 7 Consultation Requirements until October 14, 2008**

On Friday, September 12, 2008, the U.S. Fish and Wildlife Service (Department of the Interior) and the National Marine Fisheries Service (Department of Commerce) announced in the *Federal Register* a 30-day extension of the comment period on a proposed rule to revise the regulations governing implementation and applicability of the consultation requirements contained in Section 7 of the Endangered Species Act (ESA). The new deadline for public comment on the draft rule is October 14, 2008. Section 7 of the ESA requires federal agencies, including EPA, to consult with the Services to ensure that an agency action (such as the registration of a pesticide) is not likely to have an adverse impact on federally listed threatened or endangered species or habitats. The Department of the Interior states that such consultation may involve either a formal written request or an informal conversation between federal agencies.

The proposed rule to revise the ESA Section 7 regulations was originally published in the *Federal Register* on August 15, 2008. In unveiling the draft proposal, the Services noted that the proposed revisions respond to a 2004 Government Accountability Office (GAO) report which found that although significant improvements have been made in interagency collaboration during Section 7 consultations, the process remained burdensome and could still be improved. GAO recommended that the Services and other Federal agencies “resolve disagreements about when consultation is needed...”

As such, the draft rule sets forth changes that are designed to reduce the number of consultations under Section 7 of the ESA that federal action agencies deem unnecessary. According to the Department of the Interior, the proposed revisions would allow for more time and resources to be allocated to the protection of the most vulnerable species. Agency actions that could cause an adverse impact to listed species would remain subject to consultation.

The release of the draft rule follows the May 15, 2008 decision of the Department of the Interior to list the polar bear as a threatened species under the ESA. At that time, Interior Secretary Dirk Kempthorne conveyed the Bush Administration's position that the ESA was not the right tool to set U.S. climate policy or regulate green house gas emissions. The proposed rule articulates the Bush Administration's stance that it is not possible to draw a direct causal link between greenhouse gas emissions and distant observations of impacts affecting specific listed species such as polar bears.

The following is a brief summary of several key provisions contained in the proposed Section 7 regulations:

*Biological Assessment* – The draft rule stipulates that in lieu of creating a new biological assessment document, federal action agencies would be allowed to submit an alternate document created for another purpose (such as an environmental assessment or environmental impact statement) as long as it contained the relevant information regarding the likely effect of an agency action.

*Cumulative Effects* – The draft rule seeks to clarify that the definition under ESA of cumulative effects is narrower than that used under the National Environmental Policy Act (NEPA) which defines cumulative impact as the impact on the environment which results from the incremental impact of the action when added to other past, present, and “reasonably foreseeable” future actions. The ESA proposal would establish that cumulative effects do not include future federal activities. The draft rule also specifies that the standard of “reasonably certain to occur” is an essential factor for both cumulative effects and indirect effects.

*Effects of the action* – The draft proposal would establish a two-part test whereby an effect must both be caused by the action under consultation and must be “reasonably certain to occur” before it can be included in the effects analysis. The proposal would add language to the “effects of the action” definition to define “indirect effects” as those effects “for which the proposed action is an essential cause, and that are later in time, but still are reasonably certain to occur.” A conclusion that an effect is reasonably certain to occur must be based on clear and substantial information. The Services state that the intent of the proposed revisions is to clarify that there must be a close causal connection between the action under consultation and the effect that is being evaluated. The draft rule emphasizes, “...if an effect would occur whether or not the action takes place, the action is not a cause of the direct or indirect effect.”

*Applicability* – The draft rule would exclude from consultation those actions the effects of which are so inconsequential, uncertain, unlikely or beneficial that they are, as a practical matter, tantamount to having no effect on listed species or critical habitat. The proposal also seeks to exclude from consultation those effects of an action that are not capable of being meaningfully identified or detected in a manner that permits evaluation. In addition, the draft rule includes language that would allow a Federal action agency to make a “not likely to adversely affect” determination unilaterally without concurrence from the Services in limited circumstances. The proposed rule states, “...In light of the tremendous workload and consumption of resources that consultations require, the Services believe it is not an efficient use of limited resources to review literally thousands of proposed Federal agency actions in which take is not anticipated and the potential effects are either insignificant, incapable of being meaningfully evaluated, wholly beneficial, or pose only a remote risk of causing jeopardy or adverse modification or destruction of critical habitat.”

*Informal Consultation* – The draft rule adds timelines to limit the duration of the informal consultation process to sixty days with a one-time sixty day extension possible. If the Services do not provide a written determination within the prescribed timelines, the action agency may terminate consultation. In addition, the draft rule contains language that informal consultation can include “a number of similar actions, an agency program, or a segment of a comprehensive plan.” The Services hope that the proposed changes to the informal consultation regulations promulgated under Section 7 of the ESA will make for a shorter, more efficient and more predictable process.

*Formal Consultation* – The draft rule would eliminate the requirement for formal consultation any time that an action agency unilaterally determines that a project will have no adverse effect on listed species.

Comments on the proposed rule may be submitted electronically via the federal government’s eRulemaking portal ([www.regulations.gov](http://www.regulations.gov)) and should be identified by docket number FWS-R9-ES-2008-0093. The draft rule may be accessed online at <http://edocket.access.gpo.gov/2008/pdf/E8-18938.pdf>.

### **Proposed ESA Section 7 Rule Draws Criticism from Members of the Senate Majority**

In related developments, a coalition of Senators including John Kerry (D-MA), Barbara Boxer (D-CA), Chris Dodd (D-CT), Sheldon Whitehouse (D-RI), Hillary Clinton (D-NY), Bernie Sanders (I-VT), and Frank Lautenberg (D-NJ) sent an August 26, 2008 letter to Secretary of the Interior Dirk Kempthorne asking that the proposal to revise ESA Section 7 consultation requirements be withdrawn. In the letter, the Senators described the draft rule as “a significant departure from over three decades of ESA implementation.” The letter states, “The proposed changes are inconsistent with the letter and spirit of the ESA, contradicted by federal judicial precedent, and would reduce rather than strengthen protections for imperiled fish and wildlife.” Short of withdrawing the

rule in its entirety, the Senators called for a comment period of at least six months so as to allow for a comprehensive assessment of the potential consequences of the proposed rule.

Barring withdrawal of the draft proposal, the Senators called upon Secretary Kempthorne to extend the comment period for a minimum of at least six months.

In a separate letter to Secretary Kempthorne sent on August 15, 2008, Senator Boxer, Chair of the Committee on Environment and Public Works, asked him to appear before her panel on September 24, 2008 for an ESA oversight hearing. In her letter, Senator Boxer expressed her strong concerns regarding the draft rule. “Among the many serious flaws in the draft regulations,” she wrote, “is that they would allow federal action agencies to decide unilaterally that consultations with the U.S. Fish and Wildlife Service or the National Marine Fisheries Service are not necessary – consultations that are required by law and that have been important to the conservation and protection of endangered and threatened species.”

She continued, “It is vital that the Fish and Wildlife Service and the National Marine Fisheries Service, the nation’s primary wildlife agencies and the agencies with the most scientific expertise and experience, retain their responsibility in making such determinations. Instead, the proposal dramatically increases the likelihood that harmful agency actions will move forward without independent review by experts in the Services.”

Senator Boxer also questioned the timing of the release of the proposed rule given the fact that so little time remains before the current Presidential Administration’s term ends. She wrote, “...By proposing these considerable changes with only a short time remaining in the Administration's term, your office appears to be attempting, in effect, to make changes to the Endangered Species Act that the Administration has been unable to achieve through legislation. Indeed, some of these proposals were included in legislation that failed to pass during the 109th Congress. Instead of seeking to rewrite key provisions of the Endangered Species Act through last-minute regulations, changes to the Act, if any, must be made by Congress, after thorough review and consideration.”

CPDA will continue to monitor further developments on this issue and will be submitting comments on the draft rule. CPDA welcomes any input its member company representatives may be able to provide on the ESA issue.

### **EPA Announces Extension of Revocation Date for Food Use Inert Ingredient Tolerance Exemptions that are Being Supported**

On August 4, 2008, EPA published in the *Federal Register* a notice announcing a one-year extension of the effective date of revocation from August 9, 2008 to August 9, 2009 for those food use inert ingredient tolerance exemptions for which the Agency has received a firm commitment that the necessary data in support of the product will be

submitted. No extensions are granted for the revocation of tolerance exemptions where EPA has not received a demonstration of intent to support. As such, the revocation date for unsupported inert ingredient tolerance exemptions remains August 9, 2008. The revocation actions are limited to the use of these products in food use pesticides. Any current use of these inert ingredients in non-food use pesticide products is not affected.

According to the *Federal Register* notice, EPA is no longer accepting or processing applications for registrations for food use products containing an inert ingredient tolerance exemption that expired on August 9, 2008 unless accompanied by a petition for a new tolerance or exemption under PRIA together with all the necessary supporting data. EPA notes that all commodities containing residues of these revoked food use inert ingredients are adulterated under Section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) if the residues are the result of application of pesticide products made after August 9, 2008. The *Federal Register* notice may be accessed at <http://www.epa.gov/fedrgstr/EPA-PEST/2008/August/Day-04/p17457.pdf>.

### **EPA Personnel Update**

CPDA has learned that Karen Angulo, a long time staffer within the OPP Inert Ingredient Assessment Branch, has accepted a position as special assistant to Registration Division Director Lois Rossi. Please join us in wishing Karen all the best in her new role.

### **CPDA to Conduct October 29-30, 2008 Pesticide Registration Workshop**

CPDA is pleased to announce that it will conduct a two-day Pesticide Registration Workshop on October 29-30, 2008 at the offices of EPA located at 2777 S. Crystal Drive, One Potomac Yard, Arlington, Virginia. Personnel from the Office of Pesticide Programs (OPP) have agreed to staff the workshop and will be featured as presenters on a number of pesticide registration topics. It has been quite a while since CPDA last conducted a pesticide registration workshop and with the enactment of PRIA, much in the product submission and approval process has changed during this intervening period. We at CPDA strongly encourage our members to take advantage of this free, private training session and to learn about the latest process changes taking place in pesticide registration. To register for the meeting, please visit the CPDA web site at [www.cpda.com](http://www.cpda.com). Registration is open exclusively to CPDA members through September 16, 2008. After that time, registration will be made available to all interested parties on a space available basis. For more information, please contact CPDA at (202) 386-7407.