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Keeping an Eye on Washington

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EPA Seeks Comment on Draft ICR for NPDES Pesticide General Permit

In the November 3, 2010 *Federal Register*, EPA published a notice requesting public comment on a draft Information Collection Request (ICR) that calculates the burden and costs associated with requirements of EPA and State National Pollutant Discharge Elimination System (NPDES) permits for point source discharges from the application of pesticides to waters of the United States. The draft EPA Pesticide General Permit (PGP) responds to a United States Sixth Circuit Court of Appeals decision, handed down in January 2009, that vacates an Agency rule which held that a pesticide applied in, over, or near a receiving water of the U.S. in accordance with the FIFRA approved label is not subject to NPDES permitting requirements under the Clean Water Act. As a result of the Court's decision, on April 9, 2011 NPDES permits will be required for discharges to waters of the U.S. from application of biological pesticides and chemical pesticides that leave a residue.

Pursuant to the Paperwork Reduction Act, EPA must submit a request for a new ICR that estimates the burden of the Pesticide General Permit to the Office of Management and Budget (OMB) for review and approval. In an effort to evaluate the accuracy of its burden estimates, EPA is inviting input on specific aspects of the proposed ICR with a deadline of January 3, 2011 for the submission of public comment. The Agency notes that the estimates in the draft ICR will be revised based on the final PGP expected to be released in early 2011. Interested parties may submit comments on the draft ICR, identified by Docket Number EPA-HQ-OW-2010-0852, electronically at www.regulations.gov.

As reported previously, on June 4, 2010, EPA unveiled its proposed PGP for the areas where it is the NPDES permitting authority. At present, 44 states and the U.S. territory of the Virgin Islands are authorized by EPA to issue, administer, and enforce permits for discharges from pesticide application activities within their borders. EPA continues to be the permitting authority in the other 6 states and U.S. territories. The PGP covers the discharge of biological pesticides and chemical pesticides which leave a residue to waters of the U.S. resulting from the following use patterns: 1) mosquito and other flying insect pest control; 2) aquatic weed and algae control; 3) aquatic nuisance animal control; and, 4) forest canopy pest control. EPA states that the draft ICR uses the proposed NPDES PGP to estimate the burden from the State's general permits.

The draft ICR estimates an annual burden of 987,904 hours for 365,000 permittees at a cost of \$50,109,969 per year. The annual burden for permitting authorities (44 authorized states and the U.S. Virgin Islands) is estimated at 45,809 hours at a yearly cost of \$1,740,754. The proposed ICR estimates an EPA burden of 4,489 hours annually at an average cost of \$183,820. EPA estimates a total average number of responses for each respondent of 3.6. The frequency of responses is expected to vary from once every five years to occasionally as needed.

EPA states that the burden from its draft ICR will be consolidated in the existing ICR for the NPDES Program during the next standard renewal cycle. The current annual burden in OMB's inventory for the existing NPDES Program ICR is 30,943,308 hours. The Agency states that its proposed ICR will add 1,033,713 hours, increasing the burden by 3.3%.

At the close of the comment period, EPA will consider the comments received and amend the draft ICR as it deems appropriate. As noted above, EPA will also revise the burden estimates based on the final PGP. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA is expected to publish another *Federal Register* notice to announce the submission of the ICR to OMB and the opportunity for additional comment.

EPA Publishes Proposed Changes to Data Compensation and Exclusive Use Regulations

EPA has published a proposed rule in the November 5, 2010 *Federal Register* announcing proposed changes to the regulations contained in 40 CFR Part 152, Subpart E that govern the protection of exclusive use and data compensation rights of data submitters. EPA states that the proposed changes would update the regulations which have not been revised since they were originally promulgated in 1984. The public comment period on EPA's data compensation proposal closes on January 4, 2011. Comments may be submitted electronically at www.regulations.gov and must be identified by docket number EPA-HQ-OPP-2009-0456.

In a significant departure from current procedures, EPA's proposed changes would require applicants for registration to submit a General Offer to Pay Statement or Formulators' Exemption Statement to the Agency as part of the product application package in accordance with the Pesticide Registration Improvement Renewal Act (PRIA II). Current regulations allow applicants to submit the required forms related to satisfaction of data compensation obligations at any time prior to EPA's approval of the registration rather than at the time of application for registration. This proposed change would affect the timing of when a registrant must make an offer to pay data compensation to the data owner and is driven by the 21-day content screening requirement included in PRIA. Specifically, FIFRA as amended by PRIA requires EPA to determine within 21 days after receiving an application and the required registration service fee whether "the application contains all the necessary forms, data, and draft labeling, formatted in accordance with guidance published by the Administrator." The Agency states that information and forms required by Subpart E pertaining to satisfaction of data requirements are covered by this provision. Moreover, EPA must reject applications that do not pass the initial 21-day content screen. As such, EPA maintains that the information and forms required by Subpart E may no longer be submitted at any time prior to approval of the application but must be submitted at the time of application.

EPA is also proposing to revise the procedures for using the selective method of data citation by eliminating the current requirement that applicants use a Registration Standard (the EPA reregistration decision documents issued prior to 1988) as the default source of the listing of data requirements. Instead, EPA would refer applicants to the data requirements found in 40 CFR Part 158 and 40 CFR Part 161. The Agency explains that Registration Standards were superseded beginning in 1988 by Reregistration Eligibility Documents (REDs) which, in turn, will likely be updated by determinations made as Registration Review continues to be implemented. EPA also notes that on October 26, 2007, it amended its data requirements for conventional, biochemical and microbial pesticides. “Given the growth and evolution of the program’s systematic review of existing pesticides,” the Agency states, “EPA believes it should no longer identify by regulation a specific type of decision document as the source of data requirement listings. These documents are a snapshot of the data requirements at a particular review period, and are likely to become outdated over time as EPA’s risk assessments evolve and new types of data are needed.”

In other changes to the selective citation method, EPA is proposing to revise the data waiver provisions found in 40 CFR 152.91 to add Reregistration Eligibility and Registration Review decision documents as additional records that applicants may rely on in support of a waiver from a data requirement. EPA also proposes to specify that a denial of a waiver decision is deemed a final Agency action. Instead, the Agency intends to refer applicants to the data requirements in 40 CFR Parts 158 and 161.

The following is a summary of other revisions to current data compensation procedures as set forth in EPA’s proposal:

- The inventory of excepted actions not subject to data compensation, (such as minor amendments to composition and labeling, deletion of uses, clarifications of labeling content and presentation, and other actions of an administrative nature), that are specifically enumerated in 40 CFR Part 152, Subpart E will be replaced with a single reference to actions that may be accomplished by notification or non-notification. EPA states that this revision highlights the underlying principle that an action which does not require scientific review of data also does not require satisfaction of data requirements and therefore is not subject to data compensation. The Agency explains that the list detailed in the current regulations was not intended to be all-inclusive when promulgated but rather is merely illustrative of the wide variety of possible revisions to registration. EPA, however, reserves the right to make determinations on the need for scientific data on a case-by-case basis.
- The definition of “exclusive use study” would be updated to incorporate the exclusive use requirements contained in the Food Quality Protection Act of 1996 (FQPA). Specifically, FQPA provides for the extension of an original 10-year exclusive use period for up to three additional years when a registrant adds minor uses meeting certain criteria to the original registration for which the exclusive use data were submitted. In addition, FQPA creates exclusive use rights in data submitted by an applicant or registrant to

support an amendment adding a new use to an existing registration that does not retain any period of exclusive use, provided such data relate solely to a minor use of a pesticide.

- The certification and documentation procedures for claiming that a data gap exists will be eliminated. Currently, an applicant can satisfy a data requirement by documenting that no data have been submitted to fulfill the data requirement. The applicant does so by writing to data submitters and requesting verification that they have not submitted data to satisfy the data requirement. Data submitters are not required to respond to such requests but lose the right to later challenge the applicant's data gap claim if they do not respond. The Agency acknowledges that while there may be circumstances when an applicant may legitimately claim that a data gap exists, EPA generally believes that the data gap documentation mechanism is no longer needed given the refinement of its pesticide review processes and the volume of data acquired through reregistration. EPA adds that it will give close scrutiny of any data gap claims that are made given the significant amounts of data now available for most pesticides.

The proposed rule may be accessed at <http://edocket.access.gpo.gov/2010/pdf/2010-27906.pdf>. CPDA is in the process of preparing comments for submission to EPA on the proposed revisions and encourages its members to provide our office with any feedback or concerns they may have as related to the draft regulations.

EPA Publishes Second Draft List of Chemicals to Undergo EDSP Screening

On November 17, 2010, EPA published in the *Federal Register* a second draft list of chemicals and substances for which the Agency intends to issue test orders under the Endocrine Disruptor Screening Program (EDSP). The second list of chemicals expands the EDSP to include priority drinking water chemicals as authorized by the Safe Drinking Water Act (SDWA) and the House Appropriations Committee report for EPA's FY 2010 appropriations. EPA states that the list includes chemicals that have been identified as priorities under the Safe Drinking Water Act and may be found in sources of drinking water where a substantial number of people may be exposed. The list also includes about 50 pesticide active ingredients that are being evaluated under EPA's registration review program to ensure they meet current scientific and regulatory standards.

EPA ascertains that the data generated from the screens will help determine whether additional testing is necessary to address potential endocrine disrupting effects. The Agency had originally established a December 17, 2010 deadline for public comment on the draft list. However, in response to an industry request for a 30-day extension, the revised deadline for public comment is set for January 18, 2011. Comments should be identified by docket identification number EPA-HQ-OPPT-2009-0477 and may be submitted electronically at www.regulations.gov. The *Federal Register* notice containing the draft list of chemicals may be accessed at <http://edocket.access.gpo.gov/2010/pdf/2010-28818.pdf>. CPDA intends to submit comments to EPA on the second draft list.

EPA Proposes Draft Policies and Procedures to Accompany Second EDSP List of Chemicals

Concurrent with the release of the draft second list, EPA published its proposed policies and procedures document that sets forth the procedures for issuing and responding to EDSP test orders based on the Agency's authority for requiring Tier 1 screening provided under SDWA. EPA notes that the draft policies and procedures document accompanying the second list of chemicals is intended to supplement the existing EDSP policies and procedures that were published in the *Federal Register* on April 15, 2009. The procedures detailed in the document issued on April 15, 2009 were developed on the basis of considerations applicable to test orders for pesticide active and inert ingredients contained on the first list of chemicals that are subject to screening. However, EPA notes that some of the substances included on the first EDSP list may also fit the criteria to be considered a SDWA chemical and therefore the policies and procedures outlined in the just released draft document may be applicable to certain substances appearing on the first list as well. As such, EPA has proposed several modifications to its original policies and procedures that are intended to address issues unique to SDWA chemicals.

EPA states that it intends to use its authority under SDWA to require testing of SDWA chemicals that are not pesticide active ingredients and to require testing of SDWA chemicals that are also pesticide active ingredients if the initial FIFRA/FFDCA orders to technical registrants did not generate the required data. EPA states that in the event the FIFRA/FFDCA order recipients exercise the option to exit the pesticide market and the Agency subsequently sends such recipients a SDWA/FFDCA order, the recipient would be required to submit data or otherwise respond to the test order. The Agency explains that the basis for an order with respect to SDWA chemicals is that a substance may be found in sources of drinking water and a determination that a substantial population may be exposed to such substance. As such, EPA believes that SDWA procedures should not be unnecessarily tied to the use of the chemical in any given market and should instead focus on obtaining data from companies that might be expected to contribute to a chemical's actual or potential presence in drinking water.

According to EPA, the options for responding to a SDWA/FFDCA test order are similar to those established in the existing policies and procedures except that the option of exiting the pesticide market will not be available. EPA states, "The basis for a SDWA/FFDCA order is that a chemical may be found in sources of drinking water to which substantial populations may be exposed. Exiting any given market (e.g., the pesticide market) is not sufficient if the SDWA chemical is manufactured or imported for other uses because the chemical may still be found in sources of drinking water. Accordingly, if sufficient data on a SDWA chemical is not generated in response to a FIFRA/FFDCA order (e.g., all FIFRA/FFDCA order recipients exit the market or otherwise indicate that they are not providing data), a subsequent SDWA/FFDCA order may be issued."

The following is a brief summary of the options that would be available to test order recipients as described in the draft policies and procedures document:

- Test order recipients could choose to generate new data for each test specified in the order. The generation and submission of such data would need to comply with Good Laboratory Practices (GLP).

- Test order recipients would be allowed to submit or cite existing data or Other Scientifically Relevant Information (OSRI) they believe are relevant to one or more of the requests in the test order. EPA states that it intends to use a weight-of-evidence approach in assessing whether such information is sufficient to determine if a chemical has the potential to interact with the estrogen, androgen, or thyroid hormone systems. The Agency notes that under this option data compensation procedures may apply to data previously submitted.
- Test order recipients could opt to form or join a consortium to share in the cost of producing the required data. EPA intends to provide to every test order recipient a list of other manufacturers and/or importers (to the extent permitted by confidentiality constraints) that have also received an EDSP order for the specified SDWA chemical to help order recipients identify other companies with whom they could form consortia.
- Test order recipients could claim that they are not subject to the order because they do not manufacture or import the chemical identified for testing. Recipients could also claim that the order was erroneously sent. An explanation of the basis for such claims would need to accompany the initial response to the test order.
- Recipients of test orders could claim that they have discontinued all manufacture and import of the chemical. In seeking comment on this option, EPA again emphasizes, “Unlike the existing policies and procedures, which enable a manufacturer or importer of a pesticide chemical to comply with the FIFRA/FFDCA test order by discontinuing the sale of the chemical into the pesticide market, SDWA/FFDCA test orders cannot be satisfied in this manner. A chemical manufacturer or importer that receives a SDWA/FFDCA test order would need to cease all manufacture and import of that chemical. Simply exiting the pesticide market would not necessarily address the chemical’s potential presence in ‘sources of drinking water to which a substantial population may be exposed’ and it would therefore be inappropriate to allow companies to satisfy a test order with such a response.” EPA continues, “...given that past actions contributed to the source of the current exposure, the company should remain responsible for generating the data to allow the Agency to characterize the significance of that exposure.”
- Test order recipients could ask EPA to waive some or all of the testing if supporting data shows that the chemical is an endocrine disruptor and that additional Tier 1 screening is unnecessary or if supporting data shows that the chemical is not anticipated to produce any effect in humans similar to an effect produced by a naturally occurring hormone, or if the chemical was used by EPA as a “positive control” to validate one or more of the screening assays.

In a significant departure from current procedures, it would appear that EPA has removed an option whereby the recipient of a test order can request a waiver from the Tier 1 screen if existing data demonstrates that the chemical has the potential to interact with hormonal systems.

In other areas, EPA is soliciting public comment on whether and how to factor a chemical's persistence in the environment into EDSP policies and procedures. The Agency states, "...For persistent chemicals, past registrants, manufacturers, and importers (as well as processors and users) are likely to have contributed to current and ongoing contamination." EPA proposes one option where test orders would be issued to such manufacturers to ensure they share in the cost of generating the required data. Another option would be for EPA to issue orders to such parties only where the chemical is no longer manufactured or imported in the United States.

EPA is also seeking input on: 1) whether five years is the appropriate length of time that the Agency should continue to issue SDWA/FFDCA catch-up orders as a means of ensuring the equitable sharing of test costs, 2) the value of testing orphan chemicals (those for which test orders do not generate the necessary data), and 3) whether companies would prefer to receive electronic notification of a test order.

Public comment on the draft policies and procedures document must be received on or before January 18, 2011. Comments should be identified by docket number EPA-HQ-OPPT-2007-1080 and may be submitted electronically at www.regulations.gov. The draft document may be accessed at <http://edocket.access.gpo.gov/2010/pdf/2010-28812.pdf>. CPDA will submit comments to EPA on the draft policies and procedures and invites its members to provide us with any concerns or observations they may have as we develop a response.

EPA Releases Draft Addendum to Current EDSP Information Collection Request

In conjunction with its release of the second proposed list of chemicals selected for Tier 1 screening under the EDSP and the accompanying draft policies and procedures document, EPA has published a draft addendum to an existing approved Information Collection Request (ICR) as required under the Paperwork Reduction Act (PRA). EPA states that the focus of the draft addendum is on the modified Tier 1 screening activities and burdens related to the second list of chemicals and should be viewed as a supplement to the existing ICR. The Agency emphasizes that the addendum does not change the activities covered by the current ICR and is instead intended to seek approval of additional activities related to the Tier 1 screening of certain chemicals under the EDSP. The Agency adds that the addendum does not repeat verbatim descriptions in the existing ICR that remain applicable, yet unchanged. As reported previously, the existing ICR was approved by the Office of Management and Budget (OMB) on October 2, 2009. However, the accompanying terms of clearance requires EPA to conduct a thorough analysis of this information collection to demonstrate "practical utility" or benefit, to re-estimate the "burden" or costs of the program, and to explain the reasoning for concluding that existing data are insufficient to satisfy the test orders. It also requires public comment and peer review of the Agency's tools to be developed to interpret and use the collected data.

EPA is accepting public comment on the addendum to the current EDSP ICR through January 18, 2011. The Agency states it will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. EPA is required to publish a *Federal Register* notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. CPDA is in the process of reviewing the draft addendum and will submit comments on this document. Association

members wishing to submit comments may do so electronically at www.regulations.gov. Comments must be identified with docket number EPA-HQ-OPPT-2007-1081.

EPA Announces Availability of a Draft Weight-of-Evidence Guidance Document for Evaluating Results of EDSP Tier 1 Screening

In the November 4, 2010 *Federal Register*, EPA announced the availability of a draft document titled: “Weight-of-Evidence Guidance Document: Evaluating Results of EDSP Tier 1 Screening to Identify Candidate Chemicals for Tier 2 Testing.” EPA states that the draft guidance document provides a transparent scientific approach for broadly evaluating Tier 1 screening data to detect an interaction with endocrine, androgen, and/or thyroid hormonal systems and determine if additional Tier 2 testing under the EDSP is necessary. The draft guidance document responds to a directive contained in the House Appropriations Committee FY 2010 report which directed EPA to develop and publish criteria by October 30, 2010 for evaluating results of Tier 1 screening and determining whether a chemical should undergo Tier 2 analysis. The Agency has established a public comment period on the draft guidance document ending on January 3, 2011. Comments should be identified by docket number EPA-HQ-OPPT-2010-0877 and may be submitted electronically at www.regulations.gov.

In describing the criteria set forth in the draft guidance document, EPA explains that they are based in part on the Agency’s experience in developing and applying risk assessment guidelines involving cancer, reproductive and developmental toxicity, and ecological toxicity. The Agency states, “Important considerations include the use of expert judgment formed through the scientific process, current understanding of endocrine mechanisms of toxicity, and knowledge of other fields of toxicology (e.g., developmental, reproductive, neurological and immunological toxicology, and toxicokinetics). Principles articulated in this document are equally applicable to a Weight-of-Evidence evaluation of data from individual assays with multiple endpoints, as well as across the whole suite of assays in the EDSP Tier 1 screening battery. In addition, these principles would be generally applicable to the review of Other Scientifically Relevant Information (OSRI) submitted in response to test orders that request OSRI to be considered in lieu of designated screening assays in the Tier 1 battery.”

EPA is asking interested parties who comment on the draft guidance to estimate potential costs or burdens associated with the Agency’s proposed Weight-of-Evidence approach and to explain how they arrived at those estimates in sufficient detail to allow for it to be reproduced. The Agency is also requesting those individuals who comment to describe any assumptions, technical information and/or data, along with specific illustrative examples that would support suggested changes to the document.

The draft guidance document is posted on EPA’s web site and may be accessed at <http://www.epa.gov/endo/>. CPDA will submit comments to EPA on the draft guidance document and encourages its members to share their concerns with us as we prepare the association’s position.

CPDA and Other Industry Groups Voice Concerns over Web Distributed Labeling

CPDA joined with a coalition of 12 of its industry trade association partners as a signatory to a November 19, 2010 letter to EPA's Bill Jordan urging the Agency to suspend its efforts on the Web Distributed Labeling (WDL) initiative and to abandon the recently proposed "User Acceptance Pilot." As reported previously, EPA announced its intentions to conduct the pilot on August 18, 2010 and invited volunteers to participate in this endeavor. The Agency is hoping that the pilot will provide information on the feasibility and ease of utilizing the Internet to access product labeling and help EPA determine whether individuals would be willing to visit a website and download use-specific pesticide application information.

The signatories to the EPA letter voiced concern that the WDL initiative will do nothing to significantly enhance access to label information or to increase the understanding of labels by users. The industry coalition pointed out that there are several existing ways for stakeholders to obtain an electronic label and, as such, there is no need at this time for another mechanism to retrieve an electronic version of a label.

The industry group concluded, "At a time when all of us, including the Federal Government, face limits on our resources, we do not think WDL is a priority for industry, its customers, and other users and therefore should not be a priority for EPA. It is our recommendation that EPA suspend work on WDL at this time, including the recently proposed User Acceptance Pilot." The group noted that ultimately, some improved means of communicating label information might be needed. "Should that need arise," the coalition stated, "we would hope to work with EPA at that time."

CPDA and several members of the Pesticide Program Dialogue Committee (PPDC) Web Distributed Labeling Work Group reiterated the concerns set forth in the November 19th letter to EPA during a November 30, 2010 conference call that included Bill Jordan. Industry representatives cautioned that any WDL pilot must ensure the participation and input of those individuals that are the most uniquely qualified and equipped to provide EPA with feedback that would enable the Agency to assess the real utility and feasibility of web distributed labeling. Despite the concerns set forth by industry representatives, it would appear that EPA remains intent on moving forward with its pilot and continues to envision benefits that can be derived from a web distributed labeling initiative. CPDA will continue to work with EPA on this issue as an engaged member of the PPDC WDL Work Group and will report on related developments as they occur.

EPA Submits Draft Rule to USDA that Addresses Labeling of Pesticides for Export

EPA has forwarded to the Secretary of Agriculture for review a draft proposed rule that would clarify, restructure, and add specificity to existing labeling regulations for the export of unregistered pesticide products and devices. The draft proposed rule also includes a new requirement for the labeling of unregistered pesticide products and devices shipped between establishments operated by the same producer to ensure that they are clearly marked as unregistered products intended for export. EPA explains that this change would prevent such products from inadvertently entering the U.S. market. Pursuant to Section 25(a) of FIFRA, the

EPA Administrator is required to provide the Secretary of Agriculture with a copy of any proposed regulation at least sixty days before signing it for publication in the *Federal Register*. The draft proposed rule is not available to the public until after it has been signed by EPA. If the Secretary comments in writing regarding the draft proposed rule within 30 days after receiving it, the Administrator shall include the comments of the Secretary and the Administrator's response to those comments in the proposed rule when published in the *Federal Register*. If the Secretary does not comment in writing within 30 days after receiving the draft proposed rule, the Administrator may sign the proposed regulation for publication in the *Federal Register* anytime after the 30-day period.

Environmental and Fishing Groups File ESA Lawsuit Against EPA Over Pacific Salmonid

On November 29, 2010, a coalition of environmental and fishing groups filed a lawsuit in the U.S. District Court for the Western District of Washington alleging that EPA failed to implement the risk mitigation measures set forth in two Biological Opinions (BiOps) issued by the National Marine Fisheries Service (NMFS) that address the impact of six specific pesticides on endangered and threatened Pacific salmon and steelhead. The first of these biological opinions was issued by NMFS on November 18, 2008 and addressed the use of the organophosphate pesticides diazinon, malathion, and chlorpyrifos. The second BiOp was issued on April 20, 2009 and evaluated the potential ESA impacts of three carbamate pesticides including carbaryl, carbofuran, and methomyl. The lawsuit seeks a judgment declaring that EPA's failure to implement the recommendations contained in the two NMFS BiOps violates Section 7(a)(2) of the Endangered Species Act (ESA) and constitutes a taking of listed species in violation of Section 9 of the statute. The plaintiffs are asking the court to set aside EPA's authorization of the use of the six pesticides that do not comply with the risk mitigation measures recommended by NMFS until such time as the Agency has put in place permanent use restrictions that ensure against likely jeopardy to listed salmon and steelhead or adverse modification of their critical habitat. In addition, the lawsuit seeks an order compelling EPA to put such permanent measures in place within one year.

The lawsuit was filed by Earthjustice on behalf of the Northwest Coalition for Alternatives to Pesticides, Pacific Coast Federation of Fishermen's Associations, Institute for Fisheries Resources, and Defenders of Wildlife. In the suit, the plaintiffs contend that EPA has failed to implement the requirements of NMFS as articulated in the Reasonable and Prudent Alternatives (RPA) and Reasonable and Prudent Measures (RPMs) contained in the two BiOps. The RPAs and RPMs call for use restrictions such as the imposition of no-spray buffer zones to reduce the levels of pesticides in salmon-bearing streams. The plaintiffs further allege that EPA has failed to implement alternative protective measures that would avoid jeopardy and adverse modification. "EPA's failure to implement the RPAs and RPMs is allowing toxic pesticides to continue to contaminate the waters of Washington, Oregon, Idaho, and California; harm listed salmonids; and injure the commercial enterprises and communities that depend on salmonid fishing for their livelihoods," the plaintiffs state.

On July 2, 2002 the U.S. District Court for the Western District of Washington handed down a decision in *Washington Toxics Coalition v. EPA* which held that EPA was in violation of Section 7 of the ESA because the Agency did not consult with the NMFS to ensure that 54

registered pesticides would not jeopardize listed salmonid species. As a result of that court decision, EPA and NMFS initiated consultations to determine whether the registered pesticides threaten or endanger listed salmon and steelhead. Subsequently, NMFS became the subject of a lawsuit brought forward by activist groups in 2007 for its failure to complete any of the ongoing consultation proceedings. On July 31, 2008, NMFS entered into a consent decree in which it agreed to a schedule for the issuance of future biological opinions.

In the current legal proceeding, the plaintiffs state, "...2010 marks the second growing season since issuance of the biological opinions and the eighth year since this Court first held that EPA's pesticide registrations must comply with the ESA – and to date EPA has not required any on-the-ground changes in use of these pesticides to protect salmonids. EPA has not addressed its failure to implement the RPA and RPM requirements, nor has it implemented adequate alternative measures to address the continued harm that this delay is causing the species."

CPDA will keep its members informed of further developments surrounding the ESA consultation process between NMFS and EPA as it affects the registration of pesticides.

(Editor's Note: The upcoming issue of the "CPDA Quarterly" will include an article authored by guest contributor David B. Weinberg from the law firm of Wiley Rein LLP that will provide an analysis of recent ESA developments including the complaint filing discussed. His article will also address related activities taken by the registrants of the six pesticides in question in response to EPA's implementation of the use restrictions contained in the NMFS BiOps. Mr. Weinberg has generously agreed to share his insight on what is a very complex and far-reaching issue and we are excited that our members will have the opportunity to learn more about his perspective on ESA as it pertains to the registration and use of pesticides).

OPP Online Label Forum Focuses on Chapter 5 of the Label Review Manual During December

EPA's Office of Pesticide Programs online forum, known as "Enable the Label," will focus on Chapter 5 of the Label Review Manual for the month of December. In particular, the online discussion will examine the criteria for the determination of pesticidal activity, statement of concentrations, and inert ingredients. After the discussion thread closes at the end of December, OPP will review comments received and incorporate those it deems useful into future revisions of the Label Review Manual. As reported previously, EPA established its online discussion forum to facilitate the exchange of information and ideas related to the labeling of pesticides. The online forum features a monthly discussion that focuses on one or two individual chapters of the Label Review Manual along with several questions posed by EPA aimed at generating feedback on specific portions of the text that may be in need of further clarification or improvement. Forum participants are given the opportunity to post comments on the featured topics and provide input on any other subject covered in that month's discussion. The Agency states that the goal of the online discussion community is to improve the clarity and usefulness of the Label Review Manual for its users including pesticide manufacturers as well as state and federal pesticide regulators.

Senate Bill Introduced to Require Congressional Approval of Major Regulations Impacting the Economy

On September 22, 2010, Senator Jim DeMint (R-SC) introduced legislation, known as the REINS Act (Regulations from the Executive in Need of Scrutiny) Act, which would require Congressional approval of major regulatory actions. Specifically, S. 3826 would require that every new major rule proposed by federal agencies be approved by joint resolution passed by the House and Senate and signed by the President before going into effect. A major rule is defined as any regulation that the administrator of the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB) determines may result in a gross annual impact on the economy of \$100 million or more, a major increase in costs or prices for consumers, or significant adverse effects on the economy. A companion bill, H.R. 3765, was introduced on October 8, 2009 by Representative Geoff Davis (R-KY).

Food Safety Legislation Update

CPDA has posted on its web site an issue brief that provides an update on food safety legislation titled the FDA Food Safety Modernization Act (S. 510) and the Food Safety Enhancement Act of 2009 (H.R. 2749). To read the issue brief, please [click here](#).