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***Keeping an Eye on Washington***

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**EPA Conducts PPDC PRIA Process Improvements Work Group Meeting**

On April 29, 2008, EPA convened a meeting of the PPDC PRIA Process Improvements Work Group where attendees received an update on the activities of the OPP Inert Ingredient Assessment Branch (IIAB). During the meeting, Agency personnel addressed the status of those inert ingredient tolerance exemptions that are the subject of an August 9, 2006 final rule calling for the revocation of a group of inert ingredient tolerance exemptions due to the lack of sufficient and reliable data to make the required safety determination under FFDCSA Section 408(c)(2) as amended by FQPA. The revocation of the listed tolerance exemptions are scheduled to become effective on August 9, 2008. EPA, however, has announced that it will allow for a one-year extension of the revocation date to August 9, 2009 for those tolerance exemptions for which industry has shown clear evidence of support. Of the 122 inert ingredient tolerance exemptions subject to revocation, 62 are being supported by industry (EPA notes that in some cases only portions of multi-chemical exemptions are being supported). Agency representatives state that a *Federal Register* notice will soon be published extending the expiration dates for the supported exemptions to August 9, 2009. The *Federal Register* notice will also call for studies to be submitted to EPA by December 31, 2008.

EPA is currently identifying pesticide products that contain revoked tolerance exemptions for which the Agency has not received any indication of support. Some of these products, EPA believes, are likely no longer being used. The Agency plans to contact registrants that hold product registrations formulated with inert ingredients that are not being supported to discuss "solution options" that could include reformulation or cancellation. The Agency states that registration actions that contain inerts with revoked exemptions will not be granted after August 9, 2008.

The Agency also continues to work on the drafting of an Advance Notice of Proposed Rulemaking (ANPRM) for food use inert ingredients which is expected to be released by the end of this year. As part of this effort, EPA is developing an Inert Ingredient Data Submitters List that will be made available for stakeholder review and comment. OPP representatives note that work on the ANPRM is moving forward in

coordination with the Agency's Endocrine Disruption Screening Program to ensure that data compensation provisions are compatible.

In other activities, EPA is hoping to soon publish a proposal in the *Federal Register* that will address a process for adding CAS numbers to existing tolerance exemptions listed in the CFR. The Agency contends that the addition of CAS numbers to the CFR will make it easier to identify currently approved food use inerts. In addition, EPA is expanding the Office of Pesticide Programs Information Network (OPPIN) to provide for better tracking of all inert ingredient requests, including mixtures, PRIA, and non-PRIA actions.

### **PPDC Work Group Meeting Includes Update on Labeling and e-Submission Initiatives**

At the April 29, 2008 PPDC PRIA Process Improvements Work Group meeting, EPA personnel reported that the Agency hopes to complete the update of its Label Review Manual (LRM) by the end of 2008. Thus far, eleven chapters of the LRM have been revised and posted on EPA's web site, two chapters are under review, and six chapters are currently being redrafted.

In related discussion, the PPDC work group meeting included a status report on EPA's e-Submission initiative. The Agency plans to launch its Pesticide Registration Information System (PRISM) e-Submission documentation module sometime during the summer of 2008. The module will draw on much of what the Agency learned in its June-July 2007 e-Submission pilot that was conducted with a group of registrants. In developing its PRISM e-Submission module, the Agency examined the components of incoming registration application packages including data and attachments in an effort to determine how PRISM could best accommodate the electronic submission of these individual pieces. EPA states that a move to a paperless environment and the use of electronic submissions will improve efficiencies, reduce errors, and promote regulatory harmonization with NAFTA and OECD. As part of its e-Submission initiative, EPA plans to make a help desk available to registrants needing assistance.

In other activities, EPA continues its work on developing an electronic version of the Confidential Statement of Formula (CSF). The Agency has completed the testing of a prototype of the electronic CSF which includes a drop down list as well as self-correction and helpful hints features. Finally, EPA staff report that the next PRIA related IT initiative will be the development of a registration tutorial web site page.

### **Industry Fees Coalition Meets with EPA Personnel to Discuss PRIA II**

On the morning of April 29, 2008, CPDA and other members of the pesticide industry fees coalition met with EPA Office of Pesticide Programs (OPP) personnel to discuss issues related to the implementation of the Pesticide Registration Improvement Renewal Act (PRIA II). One of the issues discussed at the meeting included registrations actions that are "approved with comments." As one Coalition member explained, a

registrant may get a label approved by EPA that is accompanied by a comments letter from the Agency that contains a change to the registration that was not anticipated by the applicant. Members of the industry fees coalition emphasized that a process needs to be developed whereby the registrant is able to rebut EPA final registration decisions that are “approved with comments.” Agency representatives recognized industry’s concerns. However, they emphasized that any process that is developed must ensure that closure and resolution of the problem are attainable. Otherwise, there is the potential for rebuttals and responses to rebuttals to continue indefinitely. OPP representatives intend to assemble a work group to address the issue of registration actions “approved with comments.” EPA has asked each trade association belonging to the PRIA Industry Fees Coalition to submit the name of an individual who will participate as a member of this work group.

Other discussion turned to EPA’s proposed approach in addressing the issue of primary and secondary registration actions under PRIA (formally referred to as the “parent-child” relationship). As reported previously, this issue focuses on fees that apply to submissions containing multiple labels supported with the same set of data. Under the Agency’s suggested approach, subsequent labels for new uses submitted within a 14-calendar day grace period of a primary submission will not be assessed a separate fee, provided no additional data associated with the secondary application are required or submitted. Moreover, the secondary application must qualify as a new use, fast-track amendment if submitted independently. EPA has prepared a draft document in which the Agency articulates its proposed policy on primary and secondary registration actions and has asked for input from Coalition members.

OPP representatives then told the group that the Agency continues to work on the PRIA fee category descriptors and hopes to convene a coalition meeting in the near future to discuss the draft interpretations.

Finally, in response to a question posed by one of the Coalition members, EPA personnel disclosed that statutory language to implement the President’s fee proposal as contained in the FY 2009 budget request has been developed. Agency representatives, however, did not know whether the language had been sent to Congress. It is extremely unlikely that the President’s fees proposal will gain any momentum in Congress. CPDA, however, will continue to monitor potential legislative developments related to pesticide fees as the EPA budget process unfolds.

### **Farm Bill Negotiators Reach Bipartisan, Bicameral Agreement but President Vows to Veto the Measure**

On the afternoon of Thursday, May 8, 2008, the principal Farm Bill negotiators convened a press conference during which they announced a conference agreement on the Food, Conservation and Energy Act of 2008. The agreement tightens the adjusted gross income eligibility test for farm commodity and disaster program benefit eligibility. The package also adds a new title on specialty crops, includes incentives for the production of cellulosic biofuels, provides new money for nutrition programs, and

promotes conservation initiatives. The Farm Bill conference agreement contains a set of tax reforms including the provisions of the Agricultural Business Security Tax Credit Act, legislation which has the strong support of CPDA. Originally introduced as S. 551 by Senators Pat Roberts (R-KS), Ben Nelson (D-NE), and Johnny Isakson (R-GA), the Agricultural Business Security Tax Credit Act would help eligible agricultural businesses to partially offset security expenses by providing a tax credit for 30 percent of the costs of security upgrades designed to increase protection of agricultural pesticides and fertilizers that are manufactured, distributed, or stored on site. The measure caps the tax credit at \$2 million annually per company and at \$100,000 per facility. The provisions of the Agricultural Business Security Tax Credit Act included in the Farm Bill conference agreement will provide a modest level of relief to agricultural businesses struggling with the exorbitant costs of protecting agricultural chemicals and pesticides from theft.

Farm Bill negotiators are awaiting the Congressional Budget Office (CBO) score of the language which is expected to be completed very shortly (by law, CBO must estimate the cost of the bill). After the score is made available, the measure will be posted on the House Agriculture Committee web site and the conference report will be filed. House and Senate floors votes on the Farm Bill conference agreement are planned for next Wednesday and Thursday, May 14-15, 2008. The conference report is not amendable on the floor of either chamber but instead is subject to a straight up or down vote.

While the Farm Bill agreement represents a bipartisan consensus that has emerged from what has been a long and arduous conference negotiation process, President Bush plans to veto the bill. In a statement released on May 8, 2008, USDA Secretary Ed Schafer criticized the Farm Bill compromise emphasizing that it “fails to include much needed reform and increases spending by nearly \$20 billion.” Secretary Schafer continued, “...For a year and a half, the Administration has been consistently clear that Congress needs to move forward with a good farm bill that the President can sign. They have failed to do so. This legislation lacks meaningful farm program reform and expands the size and scope of government. I have visited face to face with our President and he was direct and plain. The President will veto this bill.” Should President Bush deliver on his promise to veto the Farm Bill conference report, it would take 2/3 of both the House and Senate to override a Presidential veto (i.e., 290 votes in the House and 67 votes in the Senate).

Meanwhile, current Farm Bill authority remains in effect through a short-term extension bill that was signed into law by President Bush earlier this month and is scheduled to end on May 16, 2008. CPDA will monitor developments on the Farm Bill proceedings and will report on further news as it happens.

### **House Committee Postpones Tentative Hearing on Chemical Site Security**

The House Energy and Commerce Committee has postponed a hearing on chemical facility security legislation that was tentatively scheduled for May 15, 2008. The Committee had been expected to begin deliberations on H.R. 5577, the Chemical Facility Anti-Terrorism Act of 2008, introduced earlier this year by Representative

Bennie Thompson (D-MS), Chairman of the House Committee on Homeland Security. Chairman Thompson's bill was favorably reported out of the House Homeland Security Committee on March 6, 2008 by a vote of 15 to 7 and was referred to the House Energy and Commerce Committee for further consideration.

One of the more troubling aspects of H.R. 5577 is language that would require *any* covered chemical facility to include in its site security plan an assessment of methods to reduce the consequences of a terrorist attack. While H.R. 5577 does not make a specific reference to "inherently safer technology," the language of H.R. 5577 embodies the very concept or mindset of an IST mandate. Methods to reduce the consequences of a terrorist attack may include input substitution, changes or redesign of manufacturing and/or storage processes, technology modifications, or use of less hazardous substances among other options.

The House Energy and Commerce Committee has already secured two previous extensions of referral authority over the Thompson bill. With its current referral authority due to end on May 30<sup>th</sup>, it is possible that the Committee will seek yet another extension. Should an extension of referral authority beyond May 30<sup>th</sup> be granted, it is possible that the House Energy and Commerce Committee may consider alternative legislation introduced by Representative Albert Wynn (D-MD) titled the "Chemical Facilities Security Act of 2008" which would remove the October 2009 sunset date from the current DHS chemical site security regulations thus conferring permanent status to the rules. Unlike the Thompson bill, the legislation introduced by Representative Wynn does not include any language that seeks to establish an IST mandate. As such, Representative Wynn's legislation would ensure that chemical site security standards are not inappropriately diluted to include non-security related activities that fall within the environmental arena.

CPDA will continue to monitor further developments on the chemical facility security issue as they occur.

### **House Subcommittee Considers Bill to Establish National Ocean Policy**

On April 23, 2008, by a vote of 11-3 the House Natural Resources Subcommittee on Fisheries, Wildlife and Oceans favorably reported H.R. 21, legislation titled the "Ocean Conservation, Education, and National Strategy for the 21<sup>st</sup> Century Act." Full committee markup could occur before the end of May possibly as early as the week of May 19<sup>th</sup>. The bill would establish a "National Ocean Policy" and would provide broad regulatory authority to implement that policy. The measure defines ocean resources as "any living, nonliving, or cultural amenities in ocean waters or costal waters." Coastal waters would include the Great Lakes and their connecting waters, harbors, marshes, and water adjacent to shorelines such as sounds, bays, and ponds. The legislation is predicated on the principles that: 1) policies, programs, and activities should "recognize the interconnectedness of the land, atmosphere including climate, and oceans, and recognize that the actions affecting one of these, such as climate, are likely to affect

another, such as ocean resources;” 2) the lack of scientific certainty should not be used as justification for postponing action to prevent negative environmental impacts; and, 3) ocean waters, coastal waters, and ocean resources should be managed using “ecosystem-based management.”

The bill would require each federal agency to administer policies and regulations in accordance with the National Ocean Policy and it would create a National Ocean Advisor in the Executive Office of the President, a Committee on Ocean Policy, and a Council of Advisors on Ocean Policy. Under H.R. 21, each federal agency would be directed to interpret and administer policies, regulations and laws in accordance with the National Ocean Policy to “the fullest extent possible” and to the extent “not inconsistent with other laws.” Within two years, each federal agency would have to issue new or revised regulations to ensure consistency with the National Ocean Policy for any actions that may significantly affect ocean waters, coastal waters, or ocean resources. As part of this directive, each federal agency would be called upon to review existing regulations and applicable laws to identify inconsistencies that would preclude full implementation of the National Ocean Policy.

Members of the regulated community have expressed concern that the creation of a National Ocean Policy, as envisioned by H.R. 21, would subordinate all federal actions such as pesticide registrations and Clean Water Act permitting to the goal of protecting and restoring marine ecosystems. In addition, the measure would not only affect activities directly impacting ocean resources and ecology but would also affect activities in upstream watersheds. Moreover, regulated entities are troubled that in lieu of a risk-based approach founded on real world data and hard science, the measure embraces the use of a “precautionary approach” when the potential impacts of a project are incomplete or unknown.

CPDA is reviewing the provisions of H.R. 21 to assess its full potential impact and will keep its members informed of further developments as they occur.