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***Keeping an Eye on Washington***

**May 30, 2008**

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**EPA Addresses New Toxicity Testing Paradigm**

The PPDC meeting held on May 21-22, 2008 at EPA's offices in Arlington, Virginia included a presentation on the National Research Council's Committee on Toxicity Testing and Assessment of Environmental Agents report titled "Toxicity Testing in the 21<sup>st</sup> Century: A Vision and a Strategy." The report was commissioned by EPA and calls for a shift in testing paradigm by combining in vitro testing and computational models to make predictions for in vivo outcomes and by using more targeted animal testing. The report states that a transformative paradigm shift is needed to: 1) provide broad coverage of chemicals, chemical mixtures, outcomes, and life stages; 2) reduce the cost and time of testing; 3) use fewer animals and minimize the suffering of those animals that are used; and, 4) develop a more robust scientific baseline for assessing health effects of environmental agents.

EPA's Office of Pesticide Programs (OPP) has embraced the recommendations of the National Research Council report and is partnering with the Agency's Office of Research and Development in developing an implementation blueprint for the new toxicology testing paradigm. As part of this effort, EPA has announced the formation of a new PPDC work group that will address this initiative. CPDA has asked EPA for a membership seat on this newly established PPDC work group.

**PPDC Meeting Includes Update on OPP Labeling Improvement Initiatives**

EPA's Anne Lindsay provided participants of the May 21-22, 2008 PPDC meeting an update on OPP labeling improvement initiatives. Lindsay told the group that the importance of good labeling is paramount and she noted that the label is the "distillation" of the Agency's pesticide program activities. She noted that labeling problems can interfere with the dissemination of risk mitigation information to the user and described the current labeling system as "antiquated" and encumbered with multiple goals that may not be compatible. EPA's overall approach to improving labels encompasses the following three initiatives that Lindsay describes as having a great detail

of synergies between them: 1) electronic submission and review of labels; 2) content improvement of the label; and, 3) electronic or web-based distribution of labeling.

Turning her attention first to the “e-submission” of labels, Lindsay reported that the Agency is in the process of creating a “Label Builder” software tool that would be similar to Turbo-Tax in function. Specifically, registrants would be able to input information corresponding to different parts of the label or fields and the software would then generate a completed label. As part of this effort, the Agency is identifying and categorizing labeling elements so that these may be captured in fields and subfields utilizing an elaborate XML format (presently, EPA is accepting the electronic submission of labels in a more simple PDF format).

In activities focused on the improvement of labeling content, EPA has created a Label Accountability Workgroup (LAW) that has made a number of recommendations some of which, such as the more frequent updating of the Label Review Manual, have already been implemented. EPA has also solicited input from its state and tribal partners and has established an ongoing dialogue with SFIREG on labeling issues.

Lindsay provided a brief description of several content focused initiatives now underway including the development of a draft PR Notice on spray drift that is expected to be released for public comment this summer. EPA is also expected to publish a document this summer that addresses the issue of cause marketing claims and third party endorsements on the label. Lindsay noted that EPA has been reviewing public response to its draft PR Notice on cause marketing following the comment period which closed at the end of March 2008. She signaled that nearly all the comments reviewed thus far have articulated serious concerns with EPA’s proposal to allow cause marketing statements on the pesticide label and have recommended that the Agency refrain from moving forward with this draft initiative. Lindsay also announced the Agency’s release of a final PR Notice that provides guidance on how to revise general environmental hazard labeling for outdoor consumer residential use products.

The EPA official concluded her remarks with an overview of the Agency’s proposal to initiate the web-based distribution of pesticide labeling. Lindsay stated that this initiative would make the most current version of pesticide labeling available to purchasers and users electronically on an EPA maintained web site. According to Lindsay, the proposed mechanism would be similar to the Agency’s web-based Endangered Species “Bulletins Live” system and would allow for more rapid updating of the label. As envisioned by EPA, a URL address would appear on the pesticide container label directing users to the web site. The container label would include all FIFRA mandated elements such as product name, registration number, net content, and ingredient statements. However, components such as “Direction for Use” would be found on the web site rather than on the container label.

In order to obtain the label, distributors, purchasers or users would visit the web site and enter the product registration number. Product labeling would then appear in a printable format. Individuals without Internet or computer access would have the option

of calling a toll-free number to request the label. Users would need to possess a copy of the labeling from the web site at the time of application. Labeling would be good for a specified duration of time, anywhere from six to eighteen months, from date of printing. An archival system would allow verification of the version of the labeling posted on any specific date (Lindsay noted that this feature would be a useful tool in conducting enforcement investigations). EPA has been engaged in early communications with a number of stakeholders on its proposal to allow for the web-based dissemination of labeling and has announced the formation of a PPDC work group to obtain additional feedback. In addition, the Agency hopes to conduct a small pilot on web-based distribution of labeling sometime in 2009 to be followed by an expanded pilot possibly in 2010 and 2011. Lindsay indicated that more detail on EPA's web-based labeling proposal and opportunity for comment will be included in a future *Federal Register* notice that may be published in 2009 or early 2010.

### **EPA Representative Addresses Web-Based Distribution of Pesticide Labeling**

The PPDC meeting devoted a stand-alone session to the issue of web-based distribution of pesticide labeling with a discussion led by EPA's Bill Jordan. He noted that in tandem with initiating stakeholder engagement on this issue, the Agency has formed an internal workgroup that includes representatives from the Office of Pesticide Programs, the Office of General Counsel, EPA's enforcement division, EPA Regional offices, and two state representatives (Jim Gray of the North Dakota Department of Agriculture and Carol Ramsay from Washington State University). Jordan told the PPDC group that before the proposed small scale test pilot on web-based labeling can be launched for the 2009 growing season, a number of questions need to be addressed. Among these is how to ensure that the required "culture change" in the user community takes hold. Specifically, users are accustomed to finding the pesticide label on the product container. The success of web-based dissemination of pesticide labeling will depend on users modifying their behavior by going "the extra step" and visiting the web site or calling the toll-free telephone number to obtain the label.

Jordan also raised other questions that will need to be addressed prior to the initiation of the proposed pilot such as:

- What information needs to be displayed on the pesticide container and what information should be made available on the web site?
- Should the web site include additional information such as the MSDS or a rate calculator?
- Should labels that are downloaded off a web site or obtained through a toll-free number have a discrete life span?
- Should the web site be hosted by EPA, industry, or a third party such as NPIRS?
- How should EPA synchronize labeling actions under this proposal with state pesticide registration activity?

In his other comments, Jordan emphasized that the web-based distribution of labeling proposal will be voluntary and that no company will be forced to participate. He also signaled that while web based distribution of labeling is feasible for products used in the course of a business enterprise, the Agency does not believe this system would work well for consumer products.

Some members of the registrant community have expressed concern that EPA's proposal raises potential liability issues for companies since it depends on the willingness of the user to go to a source, other than the product container itself, to obtain the label. Several PPDC meeting participants questioned whether a registrant will be subject to liability if the user does not go the extra step to download the label under this initiative. In other concerns, some PPDC members pointed out that the determination of the host of the web site could have major ramifications for registrants. Specifically, registrants have concerns related to the protection of company owned label copyrights and trademarks being made accessible on web sites over which they have no control.

Jordan reiterated that the Agency plans to publish a *Federal Register* notice in the future on its proposal to distribute pesticide labeling electronically and that EPA will continue to engage stakeholders on this issue. CPDA is seeking membership on the newly announced PPDC work group that is being formed to address web-based dissemination of labeling.

### **EPA Plans to Finalize EDSP Components and Issue Test Orders in August 2008**

EPA plans to move quickly over the summer of 2008 in finalizing all the different pieces of its Endocrine Disruptor Screening Program (EDSP) so as to clear the way for issuing test orders at the end of August 2008. Agency representatives told members of the PPDC that on August 4, 2008, EPA plans to publish in the *Federal Register* the final list of chemicals that have been selected for the first round of screening for endocrine effects. In addition, the Agency has targeted August 4, 2008 as the date on which it intends to publish in the *Federal Register* its final policies and procedures document that will set forth EPA's approach to EDSP implementation. A presentation made available at the PPDC meeting by EPA representatives includes the following timetable for related EDSP activities:

- June 24, 2008 – Information collection request (ICR) required to issue EDSP testing orders to be published in the *Federal Register*
- June 26, 2008 – Due date for the Science Advisory Panel report on the Tier 1 Battery of assays
- August 4, 2008 – Assays selected for the Tier 1 battery to be published in the *Federal Register*
- August 28, 2008 – Upon OMB approval of the ICR, the first orders for Tier 1 testing will be issued

## **PPDC Discussion Includes Update on International Pesticide Issues**

EPA Registration Division Director Lois Rossi appeared before PPDC meeting participants to present an update on international pesticide registration activities. Rossi told the group that in April 2008, EPA launched a trade irritant data base to serve as a central source of information on trade barriers confined to NAFTA. She also discussed several projects that have been launched by the NAFTA Technical Working Group (TWG) that are aimed at eliminating trade barriers on specific agricultural commodities. In her other remarks, Rossi reported that four NAFTA labels have been approved. A NAFTA label satisfies harmonized regulatory requirements and allows for cross-border movement of pesticide product. Rossi expressed her hope that there is potential for more active ingredients to be jointly reviewed and approved for a NAFTA label. Beyond its NAFTA partners, EPA is also working with other members of the international community on bilateral work-sharing initiatives in the review of pesticides.

## **Agricultural Business Security Tax Credit Act Provisions Become Law**

The provisions of the Agricultural Business Security Tax Credit Act, legislation strongly supported by CPDA, have now become law as part of the Farm Bill conference agreement to accompany H.R. 2419, the Food, Conservation and Energy Act of 2008. The provisions of the Agricultural Business Security Tax Credit Act provide eligible agricultural businesses a modest tax credit to help offset the spiraling costs of implementing on-site security measures. This language will provide manufacturers, formulators, and distributors of agricultural products and inerts used in agricultural formulations a tax credit equivalent to 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. For nearly the past five years, CPDA has worked closely with its partners in the agricultural industry in support of legislation to establish this important tax credit. The enactment of the Agricultural Business Security Tax Credit Act as part of the Farm Bill signifies a major achievement for CPDA and its member companies.

The Farm Bill conference report was originally passed in the Senate on May 15, 2008 by a vote of 81 to 15 and in the House on May 14, 2008 by a vote of 318 to 106. President Bush, however, vetoed the measure objecting that the measure lacked program reforms and cost savings sought by the Administration. The measure was then sent back to Congress where on May 21, 2008 the House overturned the President's veto by a vote of 316 to 108. The Senate followed suit on May 22, 2008 with a vote of 82 to 13 to override the Presidential veto. With the recent House and Senate action, 14 of 15 titles of the Farm Bill have now been enacted into law. The trade title of the Farm Bill was included in the original Farm Bill conference report passed by Congress but was inadvertently omitted from the official copy of the measure that was sent to President Bush. Congress intends to deal with this glitch in the near future.

## **Update on H.R. 21 – Legislation to Establish a National Ocean Policy**

On April 23, 2008 the House Subcommittee on Fisheries, Wildlife and Oceans amended and approved H.R. 21, the “Ocean Conservation, Education, and National Strategy for the 21<sup>st</sup> Century Act.” The expansive reach of the current language would establish a National Ocean Policy (“NOP”) and could well be viewed as a “super statute” as it requires all federal agencies to review their policies and regulations to implement the NOP and ensure that all activities they fund, authorize or carry out are consistent with the NOP if they “may significantly affect ocean waters, costal waters, and ocean resources.” The NOP would subordinate all federal actions – such as pesticide registrations – for the goal of protecting and restoring marine ecosystems. The geographic reach of the NOP extends 200 miles out from the nation’s shorelines and includes activities in upstream watersheds without any defined limit.

This potential “super statute” will, at a minimum, affect implementation of the National Environmental Policy Act, the Clean Water Act, the Clean Air Act, the Endangered Species Act, the Resource Conservation and Recovery Act; the Federal Insecticide, Fungicide and Rodenticide Act; the Coastal Zone Management Act, the Marine Mammal Protection Act, and a litany of laws governing public lands, transportation, energy, housing, recycling, mining, and other natural resource matters.

The language used for the specifying principles of interpreting and applying the NOP are even more troubling as the bill, instead of a risk-based approach founded on real world data and hard science, takes the controversial “precautionary approach” when the potential impacts of a project are incomplete or unknown.

CPDA is actively working with a broad coalition to fight this piece of legislation. Efforts of the Oceans 21 Coalition have included a meeting with Chris Kearney of the Department of Interior, as well as a meeting with Troy Phillips, Senior LA to Congressman Sam Farr (Chairman of the House Ocean Caucus). CPDA is working on drafting written comments and scheduling meetings with Member of the Committee on Natural Resources before a full committee mark-up is scheduled. Sources on the Hill have implied that a mark-up could take place in the next few weeks as there is alleged leadership support for a vote on this bill by the full House before the end of the year.

### **CSPA to Host Workshop on Sourcing from Abroad and Importing Pesticide Product Ingredients on June 18-19, 2008**

On June 18-19, 2008, the Consumer Specialty Products Association (CSPA) will host a day and a half workshop on “Successful Strategies for Locating and Importing Pesticide Products and Active Ingredients” (day one), and “Data Compensation, Data Protection (North America and EU) and Update on Inert Regulation (U.S.) (day two). The meeting will be held at the law offices of McKenna Long and Aldridge, located at 1900 K Street, N.W., Washington, D.C. Major topics of the meeting will include sourcing and importing pesticide

products and active ingredients from abroad, data compensation and data protection in North America (U.S. and Canada) and the EU, and inerts disclosure and data compensation.

To register, go to <http://www.cspa.org/public/events/import.html>. Should you have any questions, please contact Beth Law at CSPA at (202) 833-7307 or [blaw@cspa.org](mailto:blaw@cspa.org).