

**Chemical Producers and Distributors Association
1730 Rhode Island Avenue, N.W.
Suite 812
Washington, D.C. 20036
Telephone: (202) 386-7407
Fax: (202) 386-7409**

Keeping an Eye on Washington

October 2009

* * *

EPA Takes Significant Step Forward in EDSP Implementation

In the October 21, 2009 *Federal Register*, EPA published a notice that announces the Agency's schedule for issuing Tier 1 test orders under the first phase of the Endocrine Disruptor Screening Program (EDSP). EPA issued the first batch of test orders on October 29, 2009 and will issue subsequent groups of test orders on a rolling basis through February 26, 2010. The test orders are applicable to the final list of 67 chemicals (consisting of 58 pesticide active ingredients and 9 inerts) that are subject to the initial testing under the EDSP. The EDSP Tier 1 screening data required to satisfy an order are due within two years of the date of issuance of the order. EPA states that details on the status of the orders will be made available on its web site at <http://www.epa.gov/endo> including information on the order issuance date, the identity of the recipient(s) of the order, the response from each test order recipient, and the order due date. The Agency intends to update its web site with subsequent publications and postings as appropriate.

The October 21, 2009 *Federal Register* also includes an EPA notice that announces the availability of the EDSP Tier 1 battery of assays and the availability of test guidelines (protocols) for conducting the assays included in the battery. The *Federal Register* notice provides a summary of the peer review results for the battery and explains EPA's rationale for the selection and integration of the screening assays contained in the battery.

The *Federal Register* notice announcing the schedule for the issuance of the EDSP Tier 1 test orders may be accessed at <http://edocket.access.gpo.gov/2009/pdf/E9-25352.pdf>. The *Federal Register* notice announcing the availability of the EDSP Tier 1 battery of assays is posted at <http://edocket.access.gpo.gov/2009/pdf/E9-25348.pdf>.

OMB Approves ICR for EDSP

In related developments, on October 2, 2009 the Office of Management and Budget (OMB) approved the Information Collection Request (ICR) for the EDSP, a requirement for the issuance of the test orders subsequently announced by EPA. The trade associations representing manufacturers and registrants of these pesticide

ingredients worked diligently during the ICR review, collectively and individually, to provide OMB with science-based and economic evidence in support of our continuing concerns over the program. CPDA and others believe that the Agency: 1) has not demonstrated the “practical utility” or benefit of collecting the data in the Tier I battery; 2) did not adequately develop a weight-of-evidence approach for determining how the Agency will determine whether a chemical needs to continue on to Tier II testing based on results of the Tier I battery; 3) did not adequately estimate the “burden” or costs to industry to generate the data; and 4) has not identified how it will consider existing data that may preclude the need for some or all of the Tier I assays for some chemicals.

CPDA believes that the OMB notice on the EDSP ICR challenges the Agency to address each of these concerns before it will consider approval of a revised/new ICR for the testing of additional chemicals. It requires EPA to conduct a thorough analysis of this information collection to demonstrate “practical utility” or benefit, to re-estimate the “burden” 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 interpretation and use of the collected data. In order for this full analysis to occur before a subsequent round of EDSP screening, the screening of these initial chemicals must be all but concluded. If EPA is held to these requirements, future test orders may not be forthcoming for several years. The OMB notice may be viewed at http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=200904-2070-001.

House Member Criticizes OMB for its Instructions to EPA in EDSP ICR

Just as EPA is finally moving forward with the first phase of its EDSP, the Office of Management and Budget has come under attack by critics who charge that OMB is weakening EPA’s ability to collect the information necessary to make informed decisions on the possible endocrine activity of pesticides that could affect public health. In an October 22, 2009 letter to OMB Director Peter Orszag, House Subcommittee on Energy and Environment Chairman Edward J. Markey (D-MA) voiced his displeasure with the recently approved ICR in which OMB instructs EPA to encourage test order recipients to submit Other Scientifically Relevant Information (OSRI) in lieu of performing all or some of the Tier 1 assays. The ICR further directs EPA to accept OSRI as sufficient to satisfy the test orders to the greatest extent possible.

Chairman Markey writes, “...EPA has reported that it currently has little to no data on the effect that the roughly 87,000 chemicals produced today have on our hormonal system. When one considers that lack of knowledge about possible adverse health effects with the numerous scientific reports that have come out in recent years on decreasing fertility, increased birth defects, greater rates of breast cancer, alterations in sex ratios and prevalence of miscarriages, not to mention the ability of some of these chemicals to accumulate in breast milk causing early infant exposures; it seems clear that there is a compelling public policy interest in empowering the EPA to collect the data needed to accomplish basic screening that would facilitate regulation of any chemicals that might pose a threat to the public and to manage the risk associated with such chemicals.”

The Markey letter asserts that toxicological tests provide no information on endocrine modes of action. Congressman Markey contends that while traditional toxicological tests are designed to demonstrate whether there exists a high dose of a particular chemical that can be shown to cause acute health effects, endocrine disruptors are known to cause adverse effects at much lower doses over sustained periods of time. He concludes that the instructions to EPA contained in the ICR “could lead the agency to ignore or dilute the mandate of EDSP and could slow or eliminate the growth of our knowledge about the public health risks of endocrine disruptors.”

Congressman Markey has asked OMB to respond no later than November 12, 2009 to a series of questions that seek detailed information on the scientific assessments (including associated documentation) that OMB used in directing EPA to rely upon existing data and OSRI in its implementation of the first phase of the EDSP. OMB has also been asked to provide its opinion on whether the toxicological tests used for pesticide registration take into account possible endocrine effects on wildlife. Finally, Chairman Markey has called upon OMB to provide a detailed listing of any meetings or information received from outside parties that may have led to the instructions contained in the ICR.

Similar concerns regarding OMB’s role in reviewing the science related to EPA’s implementation of the EDSP were recently raised by several activist groups including the Center for Progressive Reform and the Pesticide Action Network North America.

EPA Announces Plans to Move Forward with Inert Disclosure Regulatory Action

EPA has announced its plans to move forward with an Advance Notice of Proposed Rulemaking (ANPR) that would seek input on a process for the disclosure on pesticide labels of the identities of inert ingredients deemed hazardous. The Agency has provided a draft of the ANPR to the Office of Management and Budget (OMB) for review and anticipates its publication before the end of this year. EPA’s decision to pursue rulemaking is articulated in its September 30, 2009 response to two petitions, one filed by the Northwest Coalition for Alternatives to Pesticides and one filed by a group of State Attorneys General, which identified a set of more than 350 pesticide inert ingredients as hazardous and requested that the Agency require the disclosure of these substances on the labels of formulations in which they are found. Both petitions were received by EPA on August 1, 2006.

In its response, EPA states that it will evaluate ideas to increase the disclosure of inert ingredient identities “to an even greater degree” than that requested by the petitioners and will consider the ramifications of a possible policy calling for full disclosure of all inert ingredients on the label, not only those deemed hazardous. In addition, EPA states that it is considering the feasibility of voluntary initiatives to achieve full disclosure. The Agency cites a number of issues that must be considered in pursuing regulatory action that seeks to achieve full public disclosure of inerts. Specifically, EPA

must establish the criteria for determining what inert ingredient identities should be made public, the extent to which disclosure independent of hazard can be supported under existing statute, whether a concentration threshold should trigger a disclosure requirement, whether public disclosure should be made on pesticide labels or through some other vehicle such as the Internet, and what form the disclosed ingredients should take (e.g., Chemical Abstract Service names, common chemical names, trade names, etc.). EPA states that the initiation of this regulatory initiative will affect a “sea change” in how inert ingredient information is made publicly available. For more detailed information regarding this issue, please click on the following: [Petition of the Northwest Coalition for Alternatives to Pesticides](#), [Petition of Attorney Generals](#), [EPA's Response to the Inert Disclosure Petitions](#).

EPA Announces New Review of Atrazine

EPA has announced that it is launching a new comprehensive evaluation of atrazine. The Agency states that based on this evaluation, it will decide whether to revise current atrazine risk assessments and whether new restrictions on use are necessary. During the first year of this evaluation, EPA intends to consider the potential for atrazine cancer and non-cancer effects, including data generated since 2003 from laboratory animal and human epidemiology studies. In conducting its re-evaluation of the human health effects of atrazine, EPA will seek the input of the independent FIFRA Scientific Advisory Panel (SAP). On its web site, the Agency has posted the following timetable and description of its planned atrazine review activities:

November 3, 2009 – EPA will present its plan for the new atrazine evaluation.

February 2010 – EPA will present and seek scientific peer review of its proposed plan for incorporating epidemiology studies into the atrazine risk assessment.

April 2010 – EPA will present and seek peer review of its evaluation of atrazine non-cancer effects based on animal laboratory toxicology studies, selection of safety factors in the risk assessment, and the sampling design currently used to monitor drinking water in community water systems.

September 2010 – EPA will present and seek peer review of its evaluation of atrazine cancer and non-cancer effects based on animal toxicology studies and epidemiology studies. According to EPA, this review is intended to include the most recent results from the National Cancer Institute’s Agricultural Health Study, expected to be published in 2010.

EPA states that at the conclusion of the evaluation of atrazine’s human health effects, it will ask the SAP to review atrazine’s potential effects on amphibians and aquatic ecosystems. The Agency adds that it intends to meet with interested groups to explore better ways to inform the public more quickly about results of atrazine drinking water monitoring.

EPA Unveils Preliminary Concepts for Draft NPDES General Permit

EPA held a webinar on October 7, 2009 during which Agency personnel presented their current thinking on a prototype for a draft National Pollutant Discharge Elimination System (NPDES) general permit that would be required for pesticide applications in, over, or near waters of the United States. The highlights of the webinar were summarized on October 14, 2009 during the first day of the Pesticide Program Dialogue Committee (PPDC) meeting held in Arlington, Virginia. As reported previously, on August 3, 2009, the U.S. Court of Appeals for the Sixth Circuit denied a petition for a rehearing of its January 2009 decision in *National Cotton Council, et. al. v. EPA* in which the Court struck down an EPA rule which held that a pesticide applied in or near water in accordance with the label is not subject to NPDES permitting requirements under the Clean Water Act. Meanwhile, a two-year stay of the Court's decision allows the EPA rule to remain in effect until April 9, 2011. After that time, NPDES permits will be required for pesticides applied directly to water to control pests and/or applied to control pests that are present in, over, or near waters. NPDES permitting authority is provided under the Clean Water Act which holds that all point sources discharging pollutants into waters of the U.S. must obtain NPDES permitting coverage from EPA or an NPDES-authorized state. EPA's pesticide general permit will cover areas where the Agency remains the permitting authority (i.e., Massachusetts, Idaho, New Hampshire, Alaska, and New Mexico as well as most territories, tribal lands, and certain federal facilities). During the two year Court approved stay that is now in effect, EPA will work closely with the NPDES authorized states to concurrently develop their permits. In addition, the Agency and the States will provide outreach and education to the regulated and environmental communities.

EPA staffers described the Agency's efforts to date in developing the prototype for the draft permit and noted that this initiative has involved the coordinated efforts of EPA's Offices of Water, Pesticide Programs, Enforcement and Compliance Assurance, Policy, General Counsel, Research and Development, as well as the Agency's Regional offices. As part of this process, EPA has established internal workgroups focusing on water quality, technology, and monitoring/reporting requirements associated with NPDES permitting. In addition, EPA is engaged in discussions with state regulatory officials and USDA representatives in an effort to solicit input on the proposed contents of its draft general permit.

At the PPDC meeting, EPA representatives outlined specific components of the general permit prototype as envisioned thus far. The Agency is considering the establishment of some threshold level of water-acre pesticide treatments as a trigger that would determine whether or not an NPDES permit would be required. If the projected pesticide application meets the threshold, the permit applicant would be required to file a "notice of intent" (NOI). Thresholds and triggers for an NOI could vary by pesticide use category. The NOI would include basic information on the discharger (contact information as well as whether the entity is a government body, homeowner association, applicator, etc.), the type of discharge (i.e., pesticide use patterns), and a description of

the receiving water body. EPA personnel are hoping that in most cases, the requirement to file an NOI would be limited to the organization that has the authority to decide whether or not to conduct the pesticide application, such as a mosquito control district or municipality, rather than the person actually performing the application. However, the Agency signals that many applicators would still likely be required to seek permit coverage. Pesticide applications performed in emergency situations prior to the submission of an NOI would be allowed as long as other conditions set forth in the permit are met. An entity filing an NOI would be covered starting ten days after receipt of a complete and accurate NOI form by the appropriate permitting authority. Filing an NOI would provide coverage for similar pesticide treatments applied subsequently within that geographic area for a period of five years. EPA states that for entities that are required to file an NOI based on the aggregation of water-acres treated in multiple applications, the NOI should be filed at any time the operator determines that it will exceed the trigger of “X” water-acre treatments per year (or per permit cycle).

EPA representatives told the PPDC that the general permit prototype calls for compliance with applicable water quality based standards and the implementation of Best Available Technology (BAT). Agency personnel explain that while the draft permit will not include specific effluent limitations, it will require permit applicants to adhere to nationally recommended ambient water quality criteria, state adopted numeric water quality standards, as well as narrative water quality standards such as “no toxics in toxic amounts.” The Agency is currently looking at the adoption of Integrated Pest Management (IPM) as a means of satisfying the BAT requirement within the draft general permit. Agency personnel note that technology-based standards will require professional judgment and would be described in narrative form within the permit application. EPA staff indicated that they might consider the inclusion of a definition of IPM within the permit so as to provide greater clarity on what would be considered acceptable technological standards. Several members of the PPDC encouraged EPA staff to also provide guidance on what the Agency considers to be “near waters.”

In its other components, the permit prototype would require visual monitoring to detect possible adverse effects on non-target organisms and it would set forth an annual reporting requirement that would include information on the names of pesticides applied, associated EPA registration numbers, jurisdictions where applied, descriptions of locations treated, quantify applied directly to, over, or near waters, and pests targeted.

EPA intends to release a draft permit for public comment in April 2010. The final permit will be issued in December 2010 and is expected to cover six use categories affecting surface water.

EPA Forms Work Group to Examine Impacts of Climate Change on Pesticide Registration Decisions

At the recent PPDC meeting, EPA officials reported that the Agency has formed an internal work group to examine how climate change may be affecting the use and behavior of pesticides. The Agency plans to meet with a group of scientists in 2010 to

further assess how climate change considerations might be adopted in pesticide risk methodology assessments. EPA plans to develop a white paper on this issue which will be released for public comment. While EPA representatives stated that the Agency is not on the verge of making any major changes in its pesticide risk assessment methodologies, they emphasized that EPA intends to continue to engage on this issue and recently met with a coalition of environmental groups who have encouraged the Agency to consider climate change impacts when making pesticide registration decisions. The concerns of this environmental coalition were initially raised in an April 1, 2009 letter to EPA Administrator Lisa Jackson and OPP Director Debbie Edwards. The signatories to the letter included the Sierra Club, the Center for Biological Diversity, the Pesticide Action Network, Defenders of Wildlife, the Center for Environmental Health, and the Natural Resources Defense Council. The coalition warned, "...Climate change will significantly alter the behavior and impacts of many pesticides, and EPA must move swiftly to address these new challenges. Addressing climate-linked pesticide impacts now is particularly appropriate because EPA is in the early stages of the registration review process...and so has an important opportunity to recalibrate its practices even as the climate crisis becomes ever more acute."

The letter stated that warming climates, altered precipitation regimes, and heightened carbon dioxide levels will put stress on agricultural systems and may favor pests and disease vectors. The coalition argued that this, in turn, may cause pesticide use levels now seen primarily in the south to appear in more northerly regions. The signatories added, "...It is worth noting, too, that this general increase in pesticide use will likely be quite complex on local and regional scales. Because the agricultural map of the United States may be quite different in a few decades, some regions will experience farming practices, including the use of some pesticides, which they presently do not. In other cases, novel combinations of pesticides will appear, as the present pattern of use shifts."

The environmental groups also asserted that likely weather patterns may "exacerbate" pesticide contamination of non-agricultural environments and may alter pesticide break-down pathways. The letter specifically cited the potential for enhanced pesticide spray drift and volatilization linked to higher temperatures and increased wind speeds. The signatories to the letter stated, "...with drier, warmer conditions, pesticides will likely travel further than they have before, with attendant ecological and human health risks." The coalition continued, "...new configurations of soil and atmospheric conditions implicate the break-down pathways of many pesticides. In some cases, formerly aerobic waters may become anaerobic; in others, soil composition may lead to new compounds coming into contact with toxins."

EPA Addresses Possible Ramifications of Use of "Plant Derived" Terminology on Labeling of Pesticide Products

At the recent PPDC meeting, OPP Registration Division Director Lois Rossi discussed the issue surrounding the use of the phrase "plant derived" that appears on the labels of certain pesticide products. EPA is concerned that while this phrase is not false,

it may inadvertently result in excessive use by individuals who are misled into thinking that there are no risks associated with the product simply because it is labeled as being “plant derived” as opposed to synthetically based. Proponents of Integrated Pest Management (IPM) fear that this false sense of security could lead to the application of such products at levels far exceeding the amount stipulated on the label. Furthermore, use patterns might shift so as to favor the application of “plant derived” pesticides in lieu of alternative crop protection products which, in turn, could adversely impact IPM practices that call for the use of a wide variety of tools available to the grower. Not only would such a trend have a negative impact on the effective implementation of IPM, it could unintentionally lead to adverse consequences such as a build-up of resistance to certain pests resulting from overexposure and overuse of one particular product. EPA has formed a resistance management work group which is engaged with USDA on this issue.

In related discussion, the PPDC meeting included a summary of OPP’s response to the recommendations put forward by a subset of the Comparative Safety Statements or Logos for Pesticide Product Labeling Work Group. This work group has been examining the parameters of a possible OPP policy that would allow for the expanded use of certain “factual statements” to appear on the labels of a select group of antimicrobial products that meet the eligibility criteria of the “Design for the Environment” (DfE) pilot program. Under this pilot, those antimicrobial products that have been accepted for participation would be permitted to carry a DfE logo. Among the statements that the PPDC work group considered for inclusion on the labels of products participating in the pilot were terms referencing products as being “plant derived” or “bio-based,” with some work group members expressing a clear preference for one phrase over another. However, OPP has rejected the use of either term for inclusion in the factual statements. In its response presented before the PPDC, OPP articulated its belief that the terms “plant derived” and “bio-based” may be false and misleading to the purchaser as they imply a level of “safety.” However, OPP did concur with the work group that factual statements such as “dye free” and “fragrance free” should be allowed under the pilot since such terminology may be verified with a review of the product CSF.

EPA Announces “Transparency Window” into Pesticide Registration Decisions

EPA has announced that it is establishing what it describes as a new transparent process that will allow the public to review and comment on risk assessments and proposed registration decisions for pesticides. This expanded process will apply to all new pesticide active ingredients and first food uses, first outdoor uses, and first residential uses.

In an October 1, 2009 statement, OPPTS Assistant Administrator Steve Owens emphasized, “This new process will give the public greater opportunity to participate and understand decisions about new pesticides. The Obama Administration’s emphasis on providing unparalleled transparency at EPA will increase credibility and strengthen the reputation of our pesticide registration program while improving the public dialogue surrounding controversial pesticide registration decisions.”

On October 1st, EPA began adding its risk assessment and proposed decisions to the public docket for a 30-day public comment period. Following the comment period, EPA intends to publish its decision and a response-to-comment document. EPA states that by focusing public access on new pesticide ingredients and first food, outdoor, and residential uses, the public will have the opportunity to comment on all major new exposure patterns for pesticide registration.

The Agency continues, "...Stakeholders now will get information sooner on reduced-risk pesticides being registered that can replace some of the older and often more toxic pesticides. The user community and the public will benefit from a broader understanding of the risk assessment and risk management processes associated with pesticide registration."

In an October 19th meeting with EPA, CPDA and other members of the PRIA Fees Coalition expressed concern that the Agency had moved forward with this new initiative without prior notice to the regulated community. The Coalition pointed out that this policy could adversely affect EPA's ability to meet its PRIA deadlines for some registration actions. EPA acknowledges that there will be some initial disruption, including missed PRIA deadlines, but intends to retain this new policy. EPA officials stated that the Agency expects to complete its response to public comments within thirty days after the comment period has closed. However, Agency representatives added that this timeframe could vary depending on the nature of the registration action in question and the scope of the public comments received by EPA. CPDA will continue to monitor EPA's implementation of this new initiative and will collaborate with its industry partners in assessing the ramifications of this policy on the Agency's PRIA obligations.

EPA Launches New Tolerance Search Capability on its Web Site

EPA has announced the launch of a new web page that enhances and replaces the Agency's current search feature for finding tolerance information. The web page contains indexes to Part 180 tolerance information for pesticide chemicals in food and feed commodities and is accessible at <http://www.epa.gov/opp00001/regulating/part-180.html>. The Agency states that this web page will allow individuals to find specific tolerance information by commodity, crop group, crop subgroup, pesticide common name, and pesticide types and families. EPA adds that this new web page will allow stakeholders to access detailed tolerance information published in the Code of Federal Regulations (40 CFR Part 180).

Chemical Facility Security Update

Activity on legislation that would make permanent the authority of the Department of Homeland Security (DHS) to regulate chemical site security is moving quickly through the House with a floor vote tentatively expected to take place the first week of November. On October 21, 2009, the House Energy and Commerce Committee approved an amended version of H.R. 2868, the Chemical Facility Anti-Terrorism Act of

2009, by a vote of 29-18. The measure has now been forwarded to the House Rules Committee which is expected to meet shortly to report a rule that may structure the amendment process for floor consideration of H.R. 2868. House members wishing to offer an amendment to H.R. 2868 must submit language to the Rules Committee no later than 6:30 p.m. (Eastern Time) on Monday, November 2, 2009 in order to be considered.

The measure marked up by the House Energy and Commerce Committee included changes made earlier by the Subcommittee on Energy and Environment that addressed the bill's provisions on methods to reduce the consequences of a terrorist attack. Specifically, the Subcommittee adopted language providing DHS with the authority to require companies assigned to risk tiers 1 or 2 to implement alternative manufacturing processes because they pose a risk of *release* [emphasis added] of a substance of concern. Methods to reduce consequences of a terrorist attack include substitution of chemicals (or forms of chemicals), changes in processes, storage or use of less of a substance of concern on site, and improvements in inventory control and handling of substances of concern. When DHS makes a determination that implementation is required at a tier 1 or tier 2 facility and that facility determines that it cannot comply, the facility must submit a written explanation to the Secretary within 120 days. The DHS Secretary shall then have 120 days after receipt to review the written explanation. Before making a final determination, the Secretary must consult with a range of technical experts. If the Secretary still determines that implementation is necessary, she/he must issue an order that contains the views of the technical experts with whom DHS has consulted as well as a timeline for implementation. In addition, the DHS Secretary must provide guidance, tools and technical assistance to farm supplies merchant wholesalers to streamline and simplify compliance with these requirements. The measure also allows the DHS Secretary to make funds available to facilities that are required to implement methods to reduce the consequences of a terrorist attack to help defray the cost of implementation.

In response to the recent flurry of House activity on H.R. 2868, CPDA and a broad cross-section of chemical and agricultural interests wrote an October 21, 2009 letter to House Energy and Commerce Committee Chairman Henry Waxman (D-CA) and Ranking Member Joe Barton (R-TX) expressing opposition to those provisions of the bill that would allow DHS to require the implementation of alternative manufacturing methods as described above. The letter stated, "...These provisions would be significantly detrimental to the progress of existing chemical facility security regulations...and should not be included in this legislation. DHS should not be making engineering or business decisions for chemical facilities around the country when it should be focused instead on making our country more secure and protecting it from terrorist threats. Decisions on chemical substitutions or changes in processes should be made by qualified professionals whose job it is to ensure safety at our facilities."

The signatories also pointed out that forced chemical substitutions might simply result in the transfer of risk to other points along the supply chain and do little, if anything, to actually reduce risk. The industry group then emphasized the potential economic hardship and burden that facilities could experience under the mandates of

H.R. 2868. The letter stated, "...Some of these forced changes are estimated to cost hundreds of millions of dollars *per facility*. Ultimately, many facilities would not be able to bear this expense."

Meanwhile, on October 28, 2009, President Obama signed into law the Fiscal Year 2010 Department of Homeland Security Appropriations measure which includes language that extends the current authority of DHS to regulate chemical facility security for one year until October 4, 2010.