

**Report to the Membership  
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We at CPDA are proud of the many accomplishments realized over the past year. The centerpiece of the association's activities continues to be its strong legislative and regulatory affairs activities.

CPDA has dedicated itself to providing you with the best representation possible. Your help and support of the organization has allowed us to fulfill this goal. CPDA has made much progress during the past year on issues impacting the generic formulator and distributor and manufacturers of inert ingredients. I would like to take this opportunity now to briefly sketch out some of the milestones of which we are most proud and to touch on some of the challenges that lie ahead.

**Regulatory Affairs**

**Copyright Infringement of the Pesticide Label**

One issue that has jumped to the top of CPDA's priority list deals with copyright infringement of the label. In a disturbing trend, more and more follow-on generic registrants are finding themselves the target of litigation brought by original registrants contending that the EPA approved "me-too" pesticide label violates the copyright of the original product label. Recently, a U.S. District Court ruled in favor of a basic manufacturer that claimed a follow-on registrant had violated copyright infringement protections by copying verbatim the language of the original product label. The U.S. District Court issued a preliminary stop sales order that barred the me-too registrant from selling any product bearing the label alleged to have infringed on the original copyright.

This court decision contradicts a longstanding EPA policy that labels for follow-on or "me-too" products should be identical or virtually identical to the label of the corresponding product of the original registrant. When Congress passed the provisions of FIFRA Section 3(c)(3)(B), it envisioned a process of expedited review for "me-too" end-use products that have identical or virtually identical language to the originally registered product. This court decision has enormous implications for the generic pesticide industry and could trigger an onslaught of label submissions to EPA caused by follow-on registrants rushing to revise their product labels so as to avoid potential copyright infringement.

If such a scenario unfolds, it will create huge resource demands for the Agency and likely divert EPA's attention away from other pressing regulatory issues and statutory deadlines. Moreover, the court decision creates a confusing legal dilemma for follow-on registrants. On the one hand, the courts have ruled that labels that are identical or substantially similar to the original label are in violation of U.S. copyright laws.

However, FIFRA seemingly conflicts with U.S. copyright law by establishing a mechanism for expedited review based on me-too labels that are identical or substantially similar to the basic label.

CPDA has organized a working group of follow-on registrants to address this critical issue. On May 27, 2005 CPDA representatives met with Office of Pesticide Programs Director Jim Jones at which time they presented EPA with a letter outlining a number of concerns pertaining to the copyright infringement issue. The letter called upon EPA to publicly reaffirm its longstanding policy, consistent with the provisions and objectives of FIFRA, that labels for follow-on or “me-too” products should be identical or virtually identical to the label of the corresponding product of the original registrant.

As a follow-up to the meeting with Jim Jones, CPDA representatives held two separate meetings with OPP Deputy Director Anne Lindsay and OPPTS Acting Assistant Administrator Susie Hazen. During these meetings, CPDA representatives described the potential adverse economic impacts that could result from a deluge of label changes submitted to EPA by companies seeking to avert the possibility of copyright infringement legal action brought by the original manufacturer. Products would need to be recalled and shipped back for label revision. Companies would incur enormous costs in having to reprint thousands of labels. In addition, companies would bear the expense of hiring outside lawyers and consultants to resolve issues such as how to address those products already in channels of trade. CPDA emphasized that EPA resources and manpower would be strained by a substantially increased workload made up of label revisions. EPA would likely find it difficult to hire additional staff to handle this increased workload since PRIA does not provide for the collection of a fee for simple label amendments. In other possible impacts, farmers, ranchers, growers and other users would have fewer product options available to them as a result of the long and protracted delays associated with securing EPA approval of label changes and getting product onto the marketplace.

In an effort to quantify the potential monetary impacts that could result from the copyright infringement issue, CPDA is asking its members to provide examples of how their companies would be impacted economically if forced to change product labels.

CPDA is continuing to develop other strategies that may include additional meetings with EPA, possible legal action in the form of an amicus brief advocating the position that “me-too” product labels approved by EPA pursuant to Section 3(c)(3)(B) of FIFRA do not constitute a violation of copyright laws, and a review of the Hatch-Waxman Act Amendments that preclude generic drug labeling from U.S. copyright protections.

#### CPDA Succeeded in Convincing EPA to Revise its Atrazine Labeling Directive

CPDA played a key role in convincing EPA to issue a decision in September 2004 that allowed for the stickering of cartons containing two 2 ½ gallon jugs of atrazine pesticide products subject to a Memorandum of Agreement (MOA) between EPA and the Atrazine Technical Registrants. Initially, EPA had issued a directive that would have

required the stickering of each individual jug directing users to follow the directions for use as set forth on a supplemental label approved by the Agency pursuant to the MOA. In order to comply with EPA's original decision, each carton would have to be opened and a sticker would have to be affixed to each individual jug. The carton would then have to be resealed. This process would have been expensive, time-consuming, and labor intensive for a number of CPDA member company distributors, many of whom had anywhere from 50,000 to 75,000 cartons of the affected atrazine product situated in their warehouses. Moreover, the process of breaking open the outermost carton and then resealing it would have compromised the structural integrity of the box and would have led to an increase in accidental spillage and leakage. With weakened structural integrity, the cartons would have to be "flat-stacked" at warehouses – an unfeasible and unworkable option precluded by space limitations at distribution warehouses.

CPDA wrote a September 21, 2004 letter to OPP Director Jim Jones requesting that the Agency limit the stickering requirement for affected atrazine pesticide products to the outside carton or unit of sale rather than requiring the stickering of the individual jugs inside the box. CPDA asserted that as long as the supplemental label was distributed at the point of sale with each carton sold, the stickering of each individual jug was unnecessary. CPDA emphasized that the Worker Protection Standard (WPS) labeling initiative established a clear precedent for providing supplemental label information at the point of sale. Subsequent to the letter, CPDA conducted a conference call with participation from the EPA product managers and enforcement personnel and industry registrants. CPDA reiterated the concerns described above and was successful in convincing EPA to modify its original decision so as to limit the stickering requirement to the outermost carton along with distribution of the supplemental label at the point of sale. CPDA's efforts in persuading EPA to revise its initial directive resulted in a savings of hundreds of thousands of dollars for pesticide distributors.

#### EPA's Proposed Part 158 Regulations

On March 11, 2005, EPA published in the *Federal Register*, its long-awaited proposed rule to revise data requirements for conventional pesticides. In its draft rule, EPA is proposing to codify existing data requirements for product chemistry, toxicology, residue chemistry, applicator exposure, post-application exposure, nontarget terrestrial and aquatic organisms, nontarget plant protection, and environmental fate. The proposed Part 158 rule has been deemed by OMB to be a "significant regulatory action." On May 4-5, 2005, CPDA held an informative workshop on the proposed Part 158 data requirement revisions that explored the intricacies and potential ramifications of the sweeping draft changes. Subsequently, CPDA joined with several allied associations in seeking a 90-day extension of the comment period on the proposed rule to September 7, 2005.

In its request for an extension, CPDA emphasized that: 1) additional time is necessary to assess EPA's economic assumptions upon which the draft rule is predicated; 2) a meaningful discussion of EPA's proposed Part 158 rule needs to include an assessment of the alternative tiered risk-based toxicology testing schemes currently under

third-party development; and, 3) a structured process to provide for the formal involvement of stakeholders in addition to public notice and comment would allow for more meaningful input to the Agency in its consideration of revisions to data requirements for conventional pesticides.

Subsequently, EPA announced its decision to grant a 90-day extension of the comment period on the draft rule. CPDA will submit comments on the proposed Part 158 rule and encourages its member companies to provide our office with input on areas of special concern.

### Registration Review

Over the last year, CPDA has participated as a member organization of the Pesticide Program Dialogue Committee (PPDC) Registration Review Work Group. Under FQPA, EPA is required to review pesticide registrations on a 15-year cycle to ensure that over time they continue to meet the statutory standards for registration. As a member of this federal advisory committee work group, CPDA has advocated for a system that would eliminate any duplicative and unnecessary testing. CPDA has also recommended that EPA provide for an “easy-off ramp” for those products that have recently undergone a comprehensive FQPA review, products requiring only a limited review, and pesticides for which there are no data gaps. CPDA has suggested that the easy-off ramp could be utilized for low-volume, low toxicity, and reduced risk products as well as pesticides registered pursuant to Section 25(b) of FIFRA. CPDA also recommended that EPA utilize its current data call-in authority under FIFRA Section 3(c)(2)(B) of FIFRA if additional data is required. Throughout the deliberations of the PPDC work group, CPDA held firm in its position that registration review should not be used as a procedure for the evaluation of inert ingredients, especially those 2200 inerts utilized in non-food use products. CPDA maintained that these inert ingredients should be part of a comprehensive review of end use products.

On July 13, 2005, EPA published its long anticipated proposed registration review rule in the *Federal Register*. In its proposal, EPA discusses three options for managing the review of inert ingredients as follows: 1) establish registration review cases for inert ingredients; 2) review individual inert ingredients in a process that is separate from registration review; and, 3) focus on product hazards rather than reviewing individual inert ingredients. In its draft rule, EPA is proposing to utilize the second option for inert ingredients under which the evaluation of inerts would continue under a separate process and would not be formally incorporated into a registration review program. The Agency notes that the first option would not be practical in that the proposed criteria for establishing the baseline date for a registration review case would not work well for inert ingredients. EPA explains “...it is often difficult to determine when registrants began to use an inert ingredient in registered products.” The Agency also points out that other proposed procedures, such as public identification of the products that belong in a registration review case would not be appropriate for inerts. EPA states, “Registrants consider the identity of the inert ingredients in their products to be trade secret, so the Agency must not disclose the products that belong in an inert ingredient registration

review case. Thus, the Agency finds that it may not be practicable to establish a chemical case for an inert ingredient when it is not possible, for trade secret reasons, to identify products belonging to the case.” Moreover, EPA cites the conclusions of the PPDC Registration Review Work Group that inert ingredients are “cleared” for use in pesticides and, as such, are not registered and therefore not subject to registration review.

In other provisions of the proposed rule, EPA describes three possible avenues to implementation of registration review as follows: 1) a comprehensive approach modeled after reregistration; 2) a checklist approach that would focus on ensuring all data requirements are met and new risk assessments are performed only if new data warrants; and, 3) a tailored approach where the scope and depth of the review respond to the particular characteristics of the pesticide in question.

Among these three options, EPA favors the tailored approach for the implementation of registration review. The Agency explains that under the tailored approach, the scope and depth of the review would be commensurate with the complexity of the issues presented by the pesticide. The Agency states, “...The scope/depth decision and any accompanying DCI notice that might be needed is a critical output of the registration review process. By using a tailored approach, the Agency believes it will be able to make such decisions on approximately 1/15<sup>th</sup> of the total registration review workload each year. As a result of registration activity that will continue to occur during the 15-year registration review cycle, the Agency will receive new data and conduct new risk assessments for many pesticides. The Agency expects that the scope/depth decision that the Agency would make as part of registration review is likely to show that very little additional work would be needed to complete the registration review for such pesticides, at least in regard to non-occupational human health assessments.”

EPA’s proposed rule is accompanied by an extensive economic analysis of the estimated costs of registration review. The projected costs were extrapolated from data obtained in a study of 28 randomly selected chemical cases. Based on its analysis of these 28 chemical cases, EPA estimates that the costs would be approximately \$8.1 million for the checklist approach, between \$10 and \$12.8 million for the tailored approach, and at least \$24.1 million for the comprehensive approach.

The Agency has announced a 90-day comment period ending on October 11, 2005. It is very likely that industry groups will be seeking an extension of the comment period. We will be discussing the feasibility of sending a joint letter to EPA signed by CPDA, CLA, CSPA, ACC, ISSA, and other key industry groups formally requesting an extension of the comment period. In the interim, CPDA invites its membership to provide our office with input on EPA’s registration review proposal.

### Containers

CPDA has been invited by EPA to participate on the newly established Container Recycling Standard Development Committee. The committee will be considering the feasibility of establishing a national container standard that could have a major impact on

future decisions at the federal or state level concerning container disposal and recycling. The committee recently held its first “face to face” meeting in Washington, D.C. As a member organization of this committee, CPDA has voiced concern about broadening the scope and mission of the project to include non-registered products, such as adjuvants, surfactants, crop oils, and spreaders. CPDA believes that the committee lacks statutory authority to establish a federal program in this area since FIFRA Sections 19 (e)(f) and (g) apply only to pesticide containers. Furthermore, CPDA does not believe that the standards should apply to containers that hold non-agricultural pesticides, such as structural pest control products, lawn, garden, turf, and ornamental products. However, other member organizations on the committee counter that farmers and applicators make no distinction between containers based on what product is held. A segment of the committee maintains that stewardship practices should be applied to all containers (including those holding non-registered products) that are being collected for recycling. Several committee members suggest that unlike EPA’s proposed container regulations, which are limited to pesticide containers pursuant to FIFRA statutory authority, the recycling standard under development by the container committee does not have the same constraints and should apply to pesticide and non-pesticide containers as well as agricultural and non-agricultural containers (even containers holding bleach and antimicrobials).

The establishment of a national container recycling and disposal standard would have a major impact on pesticide formulators and distributors, particularly small and medium-sized companies. The success and growing popularity of voluntary pesticide container collection and recycling efforts throughout the country calls into question whether it is indeed necessary or appropriate to establish such a national standard. CPDA’s participation on this container committee will ensure that the concerns of its member companies are brought before EPA.

## **Legislative Affairs**

### **Pesticide Fees**

Long-range funding of EPA’s Office of Pesticide Programs (OPP) continues to be an important priority for the CPDA membership. The enactment of the Pesticide Registration Improvement Act (PRIA) has brought about a number of positive changes within OPP in the form of the establishment of product decision timelines, EPA accountability, and the implementation of new registration procedures that promise to increase Agency efficiencies. PRIA represents a carefully crafted, landmark legislative agreement, more than two years in the making, that brought together members of a broad coalition of divergent interests including members of the regulated community, environmental interests, agricultural commodity groups, farm worker advocates, and the EPA. However, in its Fiscal Year 2006 budget request for EPA, the Bush Administration requested \$26 million in pesticide registration fees and \$20 million in new tolerance fees as well as \$4 million in PMN fees under TSCA. In its consideration of the EPA spending bill for Fiscal Year 2006, the House and Senate rejected the Administration’s proposal to establish new pesticide fees and, in fact, directed EPA to find \$50 million from elsewhere

in its budget to make up for the offset in the President's pesticide programs funding request. House and Senate conferees will now begin the process of finalizing the conference report to accompany the FY 2006 Interior, Environment and Related Agencies appropriations measure.

Despite the fact that the House and Senate rejected the Bush budget proposal for \$50 million in new pesticide fees, the OMB has directed EPA to draft legislation that would establish these very same fees. The implementation of new registration fees and new tolerance fees would require an amendment to PRIA which presently prohibits the imposition of pesticide fees other than those specifically authorized under the statute. OMB has asked the Agency to draft language that would amend PRIA to remove the existing prohibitions on new registration and new tolerance fees, thus allowing EPA to raise \$50 million in new pesticides fees for FY 2006 (i.e., \$26 million in additional registration fees, \$20 million in tolerance fees, and \$4 million in PMN fees). The EPA has drafted letters to Speaker of the House Dennis Hastert (R, IL), and Vice President Richard Cheney, President of the Senate, asking for legislative action on fees language this year. OMB continues to be persistent in its quest for these additional monies and is expected to seek an amendment to the omnibus budget reconciliation bill that would lift the prohibitions on new tolerance fees and new registration fees. The legislative language on fees is expected to be introduced at the request of the Administration and will probably be referred to the Appropriations committees and the House and Senate Agriculture Committees. Congressional sources speculate that OMB's renewed push for pesticide fees may be an effort on the part of the Administration to influence the upcoming House-Senate conference negotiations over the FY 2006 EPA spending bill.

The outcome of the Administration's efforts to secure authorizing legislation to create new registration and new tolerance fees will certainly have a profound influence on the shape and nature of any future bill to reauthorize PRIA. CPDA and other pesticide industry fees coalition members are beginning the process of assembling a set of ideas and principles in anticipation of the reauthorization of PRIA. The enactment of fees legislation now being sought by the Administration at this juncture could derail the carefully crafted balance upon which PRIA was constructed.

Rising federal deficits coupled with the significant costs that will accompany new initiatives such as registration review and post-RED activities for food use pesticides will place significant strains on OPP's budget. In turn, increased pressures will bear down on industry to pay additional fees that may represent an even larger share of OPP's total budget compared to what industry is now paying in fees.

As discussions over "PRIA II" get underway, CPDA will fight to ensure that any new fee provisions are fair and equitable and do not place an undue economic burden on its member companies – particularly "me-too" registrants. In addition, CPDA will advocate for continued funding dedicated to the review of inert ingredient applications within EPA. Finally, CPDA will continue to work closely with other members of the Pesticide Industry Fees Coalition in efforts to prevent any Congressional action on

legislation, such as that now being pursued by the Bush Administration, to establish new pesticide registration and tolerance fees.

### CPDA Efforts to Eliminate the California LOA Requirement

Another major issue that ranks high on CPDA's agenda centers on legislative efforts in support of enactment of California legislation, A.B. 1059. A.B. 1059 would eliminate the Letter of Authorization (LOA) requirement in California whereby a generic pesticide registrant must receive written permission from the original data submitter before using that data in support of a generic registration. In so doing, A.B. 1059 would allow for consistency with the data compensation and product licensing mechanism set forth under FIFRA. Negotiations between follow-on registrants, basic manufacturers, the California Governor's office, and the California Department of Pesticide Regulation on the provisions of A.B. 1059 have been ongoing over the last several months. CPDA is playing a critical part in these discussions. The California Senate Committee on Environmental Quality is expected to take up the bill sometime in August 2005 after the state legislature completes its work on the Governor's budget. In anticipation of this action, CPDA has sent letters to every member of the Senate Committee on Environmental Quality urging quick passage of the legislation.

In its letter, CPDA stated, "The LOA requirement has served as a significant barrier to the entry of generic pesticide products into the California marketplace due to the long and protracted delays associated with issuance of the letter. In some cases, the time period by which generic pesticide registrants have been denied access to the California agricultural markets has spanned multiple growing seasons. Over the years, the LOA requirement has been misused as a means of keeping generic pesticide products off the market and thwarting competition within the pesticide industry. Such tactics result in higher pesticide costs for farmers, ranchers, growers, and other users of these chemicals."

CPDA continued, "In order to obtain a pesticide registration in the state of California, an applicant must either obtain a letter of authorization from the original data submitter or generate the necessary data in fulfillment of DPR requirements – a process that can cost hundreds of thousands or even millions of dollars and take one to two years or more to complete. A number of CPDA member companies have encountered situations whereby the original data submitter flatly refuses to issue a letter of authorization or provides a letter only after an inordinate amount of time has lapsed. In other cases, CPDA member companies have been forced to pay exorbitantly high data compensation costs to the original data submitter as a condition for receiving a letter of authorization."

In its letter, CPDA pointed out that the LOA requirement results in increased costs to generic registrants and discourages these companies from seeking entry into the California markets. The end result is a reduction in the market availability of lower-priced generic pesticides. "At a time when U.S. agricultural producers are struggling with the economic burden of substantially increased output costs for fuel, equipment, and

other farming materials,” CPDA stated, “A.B. 1059 represents an opportunity to provide the grower community with some level of financial relief by making lower-priced generic product more accessible. A review of marketing data indicates that when generic pesticides are allowed to enter the California market, the price of these products available to end users decreases by as much as 10% to 35%. The ultimate beneficiary of lower pesticide costs is the American family that enjoys a safe, plentiful, nutritious and very affordable supply of fresh fruits, vegetables, grains, and other foodstuffs.”

CPDA emphasized that A.B. 1059 will level the playing field for pesticide registrants in California by removing the artificial barriers that currently block many generic products from entering the marketplace. Moreover, the provisions of A.B. 1059 to abolish the LOA requirement will eliminate much of the litigation over data compensation and intellectual property rights in California that has diverted the resources of DPR away from its mission of protecting human health and the environment. CPDA stressed that the enactment of A.B. 1059 will free up limited DPR resources that are currently expended on “policing” compliance with the LOA requirement and will result in a significant savings in state taxpayer dollars.

In addition to CPDA’s letter writing campaign to members of the California Senate Committee on Environmental Quality, CPDA has contacted legislators on the California Assembly Committee on Agriculture to express support for a repeal of the LOA requirement. In fact, a delegation of CPDA representatives had the opportunity to visit with many members of the Assembly committee in April 2005 to discuss this issue. CPDA is hopeful that A.B. 1059 will be passed by both chambers of the California legislature and signed into law by Governor Schwarzenegger. CPDA remains committed in seeking the enactment of this important measure.

#### Agricultural Business Security Tax Credit Act

CPDA has been working closely with a coalition of allied trade associations in support of legislation (H.R. 713) introduced by Representative Ron Lewis (R-KY) titled the “Agricultural Business Security Tax Credit Act.” This important legislation would establish a modest tax credit to help agricultural businesses offset the expensive but necessary costs of on-site security upgrades. CPDA is currently engaged in a series of visits with members of the House in an effort to increase co-sponsorship of the bill. In addition, CPDA is reaching out to members of the Senate in seeking introduction of a companion bill in that chamber. The issue of chemical facility security has become subject to increased Congressional scrutiny. It is likely that mandatory chemical facility security legislation will be drafted and introduced within the next several months despite the voluntary initiatives now being taken by a number of companies in the chemical sector. The Senate Committee on Homeland Security and Governmental Affairs, chaired by Senator Susan Collins (R-ME), has held three hearings this year focusing on chemical facility security. Most recently, on July 13, 2005, the committee heard testimony from chemical industry representatives, government officials, and security experts about the need for federal regulation to make chemical facilities less vulnerable to terrorist attack. Should specific chemical facility security mandates be enacted, legislation such as H.R.

713 will help ease the associated economic burden that will be felt by companies in putting in place on-site security upgrades. CPDA will continue to push for enactment of a tax credit to help agricultural businesses defray such security costs.

### **Adjuvants and Inerts**

Over the last decade, CPDA has built a strong regulatory program focused on adjuvants and inerts. CPDA's Adjuvant and Inert Committee (AIC) is very proactive and meets regulatory with staff from the U.S. Environmental Protection Agency (EPA). Among its activities this year, the CPDA AIC is working with EPA in developing generic label language that could be used by pesticide manufacturers, formulators, and distributors in making a recommendation on their product label that the end use pesticide be used with a CPDA certified adjuvant product. Standardized approved EPA label language will eliminate several hundred versions of this language being used in pesticide labeling. In addition, the CPDA AIC continues to receive applications for products seeking certification pursuant to a voluntary set of labeling and performance standards for spray adjuvants and soil conditioners that was developed by CPDA. CPDA believes that these voluntary standards will benefit pesticide manufacturers, formulators, distributors, applicators, farmers, ranchers, and other users by improving product stewardship and helping to ensure the quality and integrity of adjuvants used in agricultural formulations.

In the area of inerts, the CPDA AIC continues to work with EPA on a number of initiatives that would establish alternative approaches to assessing inert ingredients of relatively low toxicity with the goal of streamlining and eliminating duplicative information and data requirements. For example, the CPDA AIC has provided input to EPA in the creation of clusters or families of inert ingredients of similar chemical composition. In other activities, at the urging of the CPDA AIC, EPA announced its decision to create a new, separate branch for inert ingredients within the Registration Division of the Office of Pesticide Programs that will address issues surrounding data requirements for inert ingredients and the elimination of the current backlog of products awaiting review.

CPDA has also assembled a group of its member companies under the umbrella of the Surfactants Task Force. The objective of the CPDA Surfactant Task Force is to: 1) facilitate the gathering of public information and public literature that can be used in the reassessment of some 120 inerts that are classified as surfactants; 2) prepare data summaries for each surfactant or surfactant cluster; and, 3) submit data summaries to EPA. The CPDA Surfactants Task Force has met several times during 2004-2005.

CPDA continues to work with CLA as co-chair of the Inerts Steering Committee (ISC). The ISC is working with EPA to develop and interpret various models for determining dietary risk assessment methodology for inert ingredients. Since registrants and inert suppliers have not done residue testing on each inert ingredient in their end use products used on multiple crops, it is important to develop alternative processes and models to address these issues. Otherwise, it is possible that EPA will require additional testing on inert ingredients, forcing registrants and inert suppliers to choose between

conducting additional testing or abandoning the inerts in question. EPA might be forced to use conservative models and surrogates to determine dietary exposure for inerts with a focus on active ingredients and application rates. The EPA could consider certain inert ingredients to be used only with specific active ingredients at specific rates rather than for multiple products and multiple crop uses.

The Inerts Steering Committee has also weighed in on the California VOC issue. Earlier this year, the California Department of Pesticide Regulation (DPR) issued California Notice 2005-03 that addresses VOC emissions from certain pesticides and the associated impact on air quality in California. In California Notice 2005-03, DPR issued its request for thermogravimetric analysis data on certain pesticides in an effort to make an accurate determination of total VOC emissions from certain pesticides. Representing the Inerts Steering Committee, CPDA and CLA submitted a set of comments to DPR on California Notice 2005-03 emphasizing that key physicochemical parameters, such as vapor pressure, that can influence the potential for a VOC to be present in air should be considered. The ISC stated, "...If it can be demonstrated that a pesticide formulation consists primarily of [low vapor pressure]-VOCs, it should not need the thermogravimetric analysis or the effort on the part of DPR personnel to review the data." CPDA will continue to monitor the California VOC issue as co-chair of the ISC.

Another important development is EPA's publication in the June 1, 2005 *Federal Register* of a draft proposal to revoke 34 exemptions from the requirement of a tolerance for 31 inert ingredients due to the fact that those substances are no longer contained in currently registered pesticide products requiring reassessment under section 408(q) of FFDCA. EPA states that it is general practice to revoke tolerances and tolerance exemptions for pesticide chemical residues (which includes both active and inert ingredients) for which there are no associated active registered uses under FIFRA, or for which there are no registered products to which the tolerance or tolerance exemption applies, or for tolerances or tolerance exemptions that have been superseded, unless a person commenting on the proposal indicates a need for the tolerance or exemption to cover residues in or on imported commodities or legally treated domestic commodities.

CPDA is encouraging all pesticide registrants, registrant suppliers, and adjuvant producers to: 1) review current pesticide product confidential statements of formula for presence of the affected inert ingredients; 2) review new products under development for plans to use any of these inert ingredients; 3) contact inert ingredient suppliers concerning the use of these ingredients in proprietary blends used to formulate their products; 4) review compositions of adjuvant products for presence of these ingredients; and, 5) review their new adjuvants under development for plans to use any of these ingredients.

### **Other Initiatives**

- Earlier this year, CPDA submitted comments to EPA on its Globally Harmonized System of Classification and Labeling of Chemicals (GHS) proposal. CPDA stated that while its members support a uniform structure to classify and label

hazardous chemicals, the requirement that pesticide labels carry essentially the same precautionary text and pictograms will diminish the importance of the label's precautionary message and result in consumer confusion. In addition, CPDA emphasized that EPA should finalize changes in the 40 CFR 156 regulations and the Label Review Manual to reflect GHS mandated changes before moving forward with GHS implementation. CPDA pointed out that if the regulations are not changed prior to implementation, a pesticide could be considered misbranded pursuant to Section 2(q) of FIFRA. CPDA believes that no registrants should be required to submit GHS label amendments for approval until the final rules have been established.

- In related GHS activities, CPDA and other members of the Coordinating Committee on International Harmonization have urged the Council on Environmental Quality (CEQ) to take a leadership role in coordinating the U.S. implementation of GHS.
- CPDA submitted comments to EPA in response to EPA's proposed rulemaking and notice of interpretive statement titled "Application of Pesticides to Waters of the United States in Compliance With FIFRA," as published in the *Federal Register* on February 1, 2005. In its comments, CPDA urged EPA to adopt in the final rule its long-standing operating approach that the application of all agricultural and other pesticides consistent with label directions shall not be subject to NPDES permitting requirements.
- Tackling the NPDES permitting issue from the legislative front, CPDA is working with other industry and agricultural groups in support of the Pest Management and Fire Suppression Flexibility Act (H.R. 1749), recently introduced by Representative C.L. "Butch" Otter (R-ID). The bill would codify EPA's established position that using agricultural and other pesticides according to label directions is not subject to permitting requirements under the Clean Water Act. On June 20, 2005, Senator James Inhofe (R-OK), Chairman of the Committee on Environment and Public Works, introduced a companion bill, S. 1269.
- On September 15, 2005, CPDA submitted comments to EPA on the Agency's proposed rule to establish standards for pesticide containers and containment. In its comments, CPDA expressed its concerns over the feasibility of meeting a proposed residue removal standard of 99.9999 percent. CPDA called upon EPA to agree to a more reasonable approach that would set a cleanliness standard for non-refillable containers between 99.99% and 99.9999%. In its other comments, CPDA reiterated its position that the proposed standards should exempt containers of five gallons or less from the design requirements for refillable, reusable, and returnable containers. CPDA also recommend that the EPA exempt from its proposed pesticide container standards any non-agricultural product, including household products, which contains less than 5% active ingredient. Finally, CPDA noted that until it is possible to derive a more accurate estimate of the number of farms nationwide that utilize on-site storage of bulk pesticides, it will

be difficult to finalize an appropriate federal regulatory approach that addresses this issue. CPDA recommended that EPA work jointly with state pesticide regulatory officials and industry in devising a method for the compilation of such data so as to arrive at an accurate figure of the amount of on-farm storage of bulk pesticides exists in the U.S.

- CPDA has joined with a coalition of the U.S. Chamber of Commerce and other business interests in support of legislation, the Terrorism Risk Insurance Extension Act (TRIA), that would ensure that the nation's workers and businesses will continue to be able to obtain adequate and affordable insurance coverage against terrorism. TRIA is set to expire at the end of 2005. Unless Congress acts to extend this important legislation, U.S. businesses will be at risk of substantial economic losses in the event of another terrorist attack on American soil.
- CPDA continues to work in support of full funding for USDA's Pesticide Data Program (PDP). PDP data is statistically reliable data used by EPA in making FQPA registration and reregistration decisions. In the absence of PDP data, EPA would be forced to use theoretical assumptions of maximum residues and exposure that could lead to the cancellation of literally hundreds of pesticide uses, particularly low volume public health and agricultural minor uses. On June 2, 2005, the House Appropriations Committee approved the Bush Administration's request for a \$584,000 increase in funding for the USDA Pesticide Data Program (PDP) during its markup of the FY 2006 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act. The appropriations measure was subsequently passed by the full House on June 8, 2005 by a roll call vote of 408-18.

The activities described in this report are just a few of the many initiatives CPDA is involved in. We encourage our member companies to provide us with input on any other issues that may be having an impact on their businesses. We look forward to serving you as we begin the 2005-2006 fiscal year.