

**Chemical Producers & Distributors Association  
Legislative and Regulatory Accomplishments  
Fiscal Year 2002-2003**

The centerpiece of the association's activities continues to be its strong legislative and regulatory affairs activities. We at CPDA would like to take this opportunity to briefly sketch out some of the milestones of which we are most proud.

**Fees**

During the past year, CPDA has participated in a coalition of pesticide trade associations that have worked closely with EPA and members of the environmental community in developing a comprehensive, five-year package that will provide stability in funding of EPA's Office of Pesticide Programs (OPP). This package will bring greater predictability to the registration process by establishing deadlines and goals for product review time. In addition, it will provide for the equitable payment of fees by the agricultural and non-agricultural sectors of the industry. The enactment of this package will enable EPA to complete reregistration and tolerance reassessment in a timely manner as required under the Food Quality Protection Act (FQPA). Absent a fees bill, OPP's budget will be subject to future reductions in appropriations, thus resulting in longer review times and growing backlogs of new active ingredients and new uses.

Without question, many companies will experience increased fees under the coalition proposal. It is important to remember that all segments of the pesticide industry will "share" in this pain. Moreover, the economic impact of increased fees will be more severe under the President's budget proposal for fiscal year 2004. The President's budget for fiscal year 2004 calls for \$27 million in registration fees to go into the general Treasury. EPA would not benefit directly from any of these additional monies. In essence, registrants would be subject to a fee with no service. Moreover, the President's budget makes no allowances for the size or ability of the registrant to pay the fee; nor does it subject EPA to any standard of accountability.

In each of fiscal years 2000 through 2003, CPDA has worked closely with allied trade associations in blocking Administration budget requests that sought to significantly increase tolerance fees and to establish new registration fees. Collectively, over fiscal years 2000 through 2003, industry has saved a total of \$294,200,000 in fees that would have been paid had CPDA and allied trade associations not been successful in blocking annual Administration budget requests for EPA's pesticide program.

Congressional appropriators have sent a clear signal to industry that the fees issue can no longer be effectively addressed by attaching riders to the VA, HUD and Independent Agencies appropriations bills. Over the last four fiscal years, CPDA and other pesticide trade associations have successfully lobbied for the inclusion of appropriations riders that have provided for one-year extensions of the status quo with regard to the prohibition on new tolerance fees, the

restriction on new registration fees, and the continuation of maintenance fees. These riders provided a temporary, short-term fix to the fees problem but did not address the long-term funding needs of EPA's pesticide program. For these reasons, we at CPDA believe that the industry coalition draft language represents a fair, much-needed, comprehensive, long-term solution to the fees dilemma that will bring stability and predictability to the product review process. While each association at the table had to make some compromises in reaching consensus on the fees package, we are pleased to call to your attention the significant gains realized by CPDA in this proposal. Specifically, the package sets aside dedicated funding for new inert ingredients and increases the allocation of maintenance fee funding for new inerts and fast-track product applications. In addition, the fees package includes revisions to the definition of a small business under FIFRA long advocated by CPDA.

The following is a summary of some of the highlights of this important draft proposal:

- The language represents a five-year package with an effective date of October 1, 2003 and a sunset date of September 30, 2008.
- The language is expected to generate in excess of \$17 million in new registration service fees annually over five years and assumes additional monies will be collected through payment of voluntary fees for product applications submitted to EPA prior to October 1, 2003.
- The collection of tolerance fees is prohibited through September 30, 2008.
- The package provides baseline budget protection, an approach adopted by the Prescription Drug User Fee Act (PDUFA), whereby the assessment of registration service fees is prohibited unless the OPP allocation of appropriations equals or exceeds the fiscal year 2002 allocation level of \$114.6 million.
- EPA would receive an unconditional, across-the-board 5% increase or "bump" in registration fees effective in fiscal year 2006.
- The coalition proposal provides \$116 million in continued maintenance fees through September 30, 2008.
- Maintenance fees are front-loaded during the first three years of the proposal and then decline in the last two years.
- The proposal directs the Administrator to allocate about \$3.3 million in maintenance fees collected to the review of inert ingredients and fast track "me-too" products during fiscal years 2004 through 2006. In fiscal years 2007 and 2008 when maintenance fees decline, the allocation is set between 1/8<sup>th</sup> and 1/7<sup>th</sup> of total reregistration fees collected. As much as \$1 million in new monies could be dedicated to the processing of inert ingredients.
- The definition of a small business under FIFRA is revised to include companies with 500

or fewer employees and \$60 million or less in global gross revenue from pesticide sales (the current FIFRA definition uses a threshold of 150 employees and \$40 million in gross revenue from chemical sales). This revised definition will make the FIFRA definition of a small business more consistent with that used by the U.S. Small Business Administration.

- Small businesses would qualify for a 50% fee reduction. Fees would be waived completely for companies with \$10 million or less in sales.
- The proposal allocates 1/34<sup>th</sup> of the pesticide registration fees in an amount not to exceed \$500,000 annually during fiscal years 2004 and 2005 for the processing of new inert ingredients presently in a backlog dating back to 1994.
- The draft language allocates 1/17<sup>th</sup> of pesticide registration service fees each year during the life of the bill in an amount not to exceed \$1 million annually to fund EPA activities focused on enhancing worker protection.
- Label changes made in response to Agency initiated requirements or guidelines, such as PR Notices, would not be subject to registration service fees.
- Fast track label changes would not be subject to a fee.
- Fees for product applications other than new active ingredients submitted to EPA prior to October 1, 2003, could be paid on a voluntary basis, thus making these production submissions eligible for review under the new timeframes.
- The proposal allows fee waivers and reductions for minor uses and IR-4 product registrations.
- Supplemental registrations would not be subject to a fee.
- Registration fees would not be compensable under FIFRA data compensation requirements.
- The draft language allows for limited judicial review applicable to new active ingredients and new uses in situations where EPA does not meet the specified review time lines (prior to filing a lawsuit, an applicant must request a meeting with EPA to set an acceptable alternative time frame).
- The proposal includes EPA accountability and auditing provisions.
- The draft language establishes a two-year phase-out period: In the first fiscal year after sunset, registration fees are reduced by forty percent from the level in effect as of September 30, 2008. In the second fiscal year after sunset, registration fees are reduced by 70% from the level in effect as of September 30, 2008. The product review time lines

do not apply to registration applications submitted to EPA during this two-year phase-out period. EPA insisted on a phase-out period citing concerns that the Agency might be left with no residual fee authority should the package not be reauthorized at the end of five years. It is important to note that registrants who pay the full fee prior to the phase-out still get the benefit of the timeframe commitments.

CPDA and other members of the coalition recently presented the fees proposal to Office of Management and Budget (OMB) officials and are awaiting a response from the White House. In addition, the coalition has presented the proposal to staff of the House and Senate Agriculture Committees and will soon meet with staff of the Appropriations Committees. On September 30, 2003, the current prohibitions on new tolerance fees and new registration fees will lift. In addition, EPA's authority to collect maintenance fees will end at that time. As such, it is critical that the coalition fees package be enacted prior to this deadline. We at CPDA will devote our time and efforts during the coming months to working with the other coalition members in lobbying the Hill in support of this language with the goal of achieving its enactment by October 1, 2003.

### **Terrorism Risk Insurance Act**

CPDA is pleased to report that its efforts as part of the Coalition to Insure Against Terrorism (CIAT) successfully culminated in the signing into law of the Terrorism Risk Insurance Act of 2002. When President George W. Bush signed this legislation into law, it was a major step forward for any CPDA member company seeking to expand their facilities, open a new warehouse, or add to their production capability, especially for small to medium sized businesses in smaller financial markets. Banks will be less likely to discourage loans and insurance availability will be increased at more reasonable rates.

Following the terrorist attacks of September 11, 2001, insurance for risks associated with terrorism became scarce, unaffordable, and generally substandard when offered. Most states permitted insurers to exclude terror insurance from their general property and casualty coverage. The terrorism insurance legislation signed into law creates a short-term federal backstop for terrorism insurance to alleviate the economic pressures that ensued from the insurance gaps.

### **Chemical Security**

CPDA has recently joined with a coalition of industry and agricultural trade associations that have identified a number of concerns with regard to S. 157, the Chemical Security Act, introduced by Senator Jon Corzine on January 14, 2003. The Chemical Security Act would require EPA, in consultation with the Department of Homeland Security (DHS), to identify "high priority" chemical facilities and then require those facilities to assess vulnerabilities and hazards. The priority setting process would be based on factors including the severity of harm that could be caused by a chemical release, proximity to population centers, threats to national security or critical infrastructure, threshold quantities of substances of concern that pose a serious threat, and other safety or security factors that the EPA Administrator considers appropriate.

The measure would direct EPA and DHS to promulgate regulations requiring high priority facilities to: 1) conduct a vulnerability and hazard assessment within one year after the regulations are promulgated; and, 2) prepare and implement a response plan that addresses those vulnerabilities within 18 months after the regulations are promulgated. Chemical facilities would be required to work with local law enforcement and first responders, such as firefighters, in developing the assessments and plans. In addition, the response plans would be required to address the use of “inherently safer technology” in preventing or reducing the potential vulnerability of the chemical source to a release of a covered substance of concern.

The following is a summary of the concerns over the Corzine bill as identified by the coalition: 1) the requirements of the Corzine bill would disrupt ongoing security enhancements already underway; 2) the measure would dilute or “splinter” the security authority of DHS by creating new counter-terrorism authority within EPA; 3) EPA lacks security expertise and sufficient resources to ensure the security of potentially thousands of chemical facilities that would be covered under the bill; and, 4) the language pertaining to “inherently safer technologies” grants sweeping new authority that would allow EPA to mandate substitutions of all manufacturing processes and substances. Senator Corzine has signaled that he may attempt to attach his legislation as an amendment to other vehicles receiving Senate consideration.

In related developments, on May 5, 2003, Senator James Inhofe (R-OK), Chairman of the Senate Environment and Public Works Committee, introduced an alternative bill, S. 994, titled the Chemical Facilities Security Act of 2003. Co-sponsoring this legislation is Senator Zell Miller (D-GA). The measure requires chemical companies to conduct vulnerability assessments and to develop security plans for their facilities. In addition, the measure authorizes the Secretary of Homeland Security to reject those plans if they are deemed inadequate to protect plants against terrorism. The Secretary can require plant owners and operators to revise their plans and assessments to ensure adequate safety and protection. The bill would allow other agencies, including EPA, to provide the DHS with technical support. In addition, S. 994 would require DHS to perform routine oversight of facilities to ensure compliance with the law. For those that fail to comply, the Secretary of DHS would be able to petition the courts for injunctive relief which, in practice, could temporarily shut down a facility. The Secretary can also impose civil penalties of \$50,000 a day for each day a violation occurs and administrative penalties of up to \$250,000. The measure includes language that establishes confidentiality protocols for the use and maintenance of information that is obtained from owners or operators of chemical sources and provided to the Secretary of Homeland Security. The legislation has the support of the Bush Administration.

We at CPDA will monitor the chemical security issue closely and will continue to keep our members informed of further developments as they occur.

## **NAWG**

CPDA is working collaboratively with a coalition of several North American pesticide trade associations and companies from the U.S., Canada and Mexico as part of the NAFTA Non-

Agricultural Working Group (NAWG). NAWG was formed to pursue opportunities within the framework of the NAFTA Technical Working Group (TWG) on Pesticides to address antimicrobial and non-agricultural pesticide issues with the goal of reducing trade barriers and increasing access to products over NAFTA borders. As part of the NAWG, CPDA is playing a major role in providing input on: 1) the development of a North American label for consumer and institutional products; 2) the harmonization of efficacy standards for antimicrobial products; 3) the establishment of a consistent and uniform risk assessment model for inerts; and, 4) the creation of a uniform list of approved inerts, with CAS number, for use in Canada and the United States.

### **Endocrine Disruptor Screening Program**

In April of this year, CPDA submitted a set of comments to EPA on the Agency's proposed Endocrine Disruptor Screening Program, Proposed Chemical Selection Approach for Initial Round of Screening, as published in the December 30, 2002 *Federal Register*. In its comments, CPDA set forth a number of issues supporting the association's position that HPV/Inert chemicals not be included in EPA's proposed pilot EDSP initiative. CPDA pointed out that the potential costs for endocrine screening and testing for inerts could range from \$132 million to \$695 million, significantly high numbers in relation to the size of the inerts industry. CPDA also noted that the composition of inert is often complex and that these substances are largely found in mixtures. As such, a sound scientific foundation is lacking for designing and interpreting mixture studies for endocrine endpoints. Any list of potential candidates for screening and testing should be synchronized with the Agency's development of a screening and testing model. Moreover, CPDA asserted that before initiating an EDSP procedure for HPV/Inert Chemicals, a data compensation system (as provided for under FIFRA and FQPA) must be in place. CPDA also voiced concerns pertaining to the protection of confidential business information.

### **Endangered Species Protection Program**

This year, CPDA submitted comments to EPA on the Agency's approach for implementing the Endangered Species Protection Program (ESPP). In its comments, CPDA supported EPA's plan to implement Endangered Species Act (ESA) requirements through existing pesticide registration processes. CPDA noted that this approach represents an organized method for screening all pesticides, and allows for appropriate pesticide analysis based on exposure and toxicology.

CPDA also expressed its support for the annual updating of county bulletins observing that this type of approach will serve as a better method of enforcement than complicated, quickly outdated, ESPP claims on pesticide labels. CPDA added that distribution oversight of ESPP bulletins should rest with EPA. CPDA explained that registrants bear full responsibility to provide the Agency with data, including endangered species data the EPA requests, in order to secure a registration. The label, which may reference any relevant ESPP bulletins, and which must be approved by EPA in accordance with FIFRA, should conclude the registrant's role in disseminating ESPP information.

In other labeling issues as related to ESPP, CPDA voiced its concerns over EPA's proposal to consider a product "misbranded" if the label did not reference pesticide bulletins within the time frame specified in PR Notices. CPDA explained that the period for amending a pesticide label is usually at least a year or more. In addition, companies need additional time to determine how best to address existing product inventories that bear outdated labels. CPDA suggested that the Agency adopt an approach based on the development of a generic label statement for instructing pesticide users about endangered species protection.

### **Data Citation and Data Compensation**

During this past year, CPDA has been engaged in discussions with EPA concerning the timing of when an offer to pay data compensation has to be made as part of an application to obtain a generic registration. These discussions were prompted by the Agency's contemplation of a proposal that would require generic registrants to file a "notice of intent to apply" along with an offer to pay at the time of submitting the application to EPA. CPDA argued that such a requirement represents a significant departure from EPA's policy of the last 18 years that allows for the filing of the offer to pay anytime prior to EPA's granting of the pesticide registration. In comments submitted to EPA in response to the Agency's draft PR Notice on how to comply with data citation regulations as published in the Federal Register on November 13, 2002, CPDA asserted that the "notice of intent requirement" is unprecedented, undefined, and confusing. CPDA explained that EPA's proposed policy change, by implication, would require generic applicants to provide the data submitter with notification before the generic registration is filed (i.e., when the applicant only intends to apply, but has not yet applied for registration). CPDA maintained that current regulations clearly state that follow-on applicants may withhold their offers to pay until the application review process is nearly complete.

In addition, CPDA pointed out that practical considerations require that a proper offer to pay may only be submitted after EPA has determined that the follow-on product is identical or substantially similar to the existing registered product. In the case of applications utilizing the method of selective citation of data, EPA must determine that the data and studies cited support the registration submission. In its other comments, CPDA emphasized that by requiring "me-too" registrants to make data compensation offers to pay prior to processing of pesticide applications, the additional time involved will give the original data submitter more lead time to file petitions to deny follow-on registrations and could lead to a proliferation of such petitions. An increase in the filing of such petitions would consume EPA resources and lead to delays in the registration process. At a March 2003 meeting with CPDA, EPA officials announced that the Agency would not delay the processing of a follow-on application pending an offer to pay. We at CPDA are pleased to announce that EPA has signaled that it will continue to follow its long-standing policy. Although a "notice of intent" must be sent to the basic manufacturer before an application is filed, the actual "offer to pay" may be submitted at any time prior to approval of the pesticide registration.

### **Registration Review Under FQPA**

CPDA has been invited by EPA to serve as a member organization of the PPDC Registration Review Workgroup. The Workgroup will provide input to EPA as the Agency

proceeds with developing a program that implements the FQPA requirement that pesticide registrations be reviewed every fifteen years. CPDA and other members of the Workgroup will address such issues as risk reduction, agricultural and non-agricultural user needs, public health, and other issues related to the implementation of a registration review program. In addition to these activities as part of the PPDC, CPDA has formed an association subcommittee devoted to the registration review issue. The 15-year registration review requirement promises to take shape as the next major challenge facing the pesticide industry in the years ahead. We at CPDA invite our members to participate in the activities of this newly formed association subcommittee.

### **CPDA Adjuvants & Inerts Committee**

The CPDA Adjuvants & Inerts Committee (AIC) continues to be very active and is nearing completion of a project focused on the reformatting of the 40 CFR Part 180.1001 list to include a broad range of acceptable chemistry for each product grouping on the list including the alcohol ethoxylates. EPA has indicated that a reformatting of the list into family clusters will allow the Agency to more readily address industry petitions and questions and will bring clarity to the inerts process particularly in relation to tolerance reassessment. In other activities, the AIC continues to provide input to EPA on moving inerts from List 3 to List 4.

CPDA's AIC is working in partnership with CropLife America (CLA) to co-chair an industry joint steering committee that is monitoring the tolerance reassessment of inert ingredients. This group submitted comments to EPA in response to the June 13, 2002 *Federal Register* notice titled, "Methodology for Lower Toxicity Pesticides." In the comments, CPDA and other members of the coalition expressed support for EPA's approach that lower-toxicity pesticide chemicals, especially inert ingredients, can be found to meet FQPA safety standards with less data than would be needed for most traditional pesticide active ingredients.

Since submitting those comments, the Steering Committee surveyed the pesticide industry and submitted a list of "key inerts" used in pesticide formulations. OPP has incorporated this research into its inerts work plan. Currently, the CPDA-CLA Inerts Steering Committee, in collaboration with OPP, is developing an Exposure Assessment Model in order to facilitate the reassessment of Tier 2 and Tier 3 inerts based on surrogate residue data.

The CPDA AIC has also been working very closely with allied trade associations and EPA's Pesticide Program Dialogue Committee (PPDC) on a number of issues pertaining to inerts, including inert disclosure and data protection.

Finally, the CPDA Adjuvant Standards program – a voluntary self-certification program – has reached the take-off stage as all major distributors agree that the program has merit and should be implemented.

### **Product Liability Defense Group**

On Friday, May 16<sup>th</sup>, CPDA's Board of Directors approved the formation of an industry legal group to pool expert legal resources for the defense of product liability suits. Gary

Callahan, an experienced industry attorney, affiliated with Bergeson & Campbell, PC, will oversee the group's formation and mission. The group will not be affiliated with CPDA, but CPDA members are encouraged to participate.

The purpose of the group is to assist companies in their product liability defense efforts. Very often, company insurance companies encourage settlement, even in cases likely to favor the company. Gary Callahan will monitor developing case law and provide a monthly newsletter to member companies. Interested companies should contact Roger Unruh, of Nufarm, at (816) 676-9000 or [roger.unruh@us.nufarm.com](mailto:roger.unruh@us.nufarm.com).

### **Involvement in Legal Matters**

As a long-time champion of generic registrants' rights, CPDA is pleased to announce that we will submit an amicus brief in the Syngenta v. EPA litigation, which we usually refer to as the "Metolachlor case." About one year ago, Syngenta filed a suit against the EPA's decision to grant the generic registration of metolachlor, effectively launching an attack on the generic registration process. Syngenta alleges that the Agency should have granted the company's request to cancel the metolachlor registration in favor S-metolachlor, claiming reduced risk benefits. Syngenta claims that the metolachlor registration should have been cancelled, and that this cancellation should preclude generic registration of metolachlor. Syngenta's position attempts to block the marketplace from generic registrants. CPDA supports the Agency's decision to grant follow-on registrations for metolachlor and preserve the generic registration process, as it now exists. As such, we will continue to monitor and participate in cases that threaten the generic marketplace.

CPDA is also involved in another case, Chemical Producers v. Paul Helliker. CPDA takes the position that California's authorization letter requirement for follow-on registration is preempted by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since FIFRA addresses the issue of follow-on registration, the state of California should not be permitted to add additional burdens on applicants seeking generic registrations. Several basic manufacturers have intervened in the suit, asking that the suit be dismissed. The motion to dismiss has been denied, and the discovery is scheduled to take place over the next several weeks, ending on October 6<sup>th</sup>. If CPDA prevails, the generic industry will have achieved a significant victory over the obstacles generics face in California. More generics will have access to the California marketplace, providing choice and lower prices to farmers and consumers.

### **Other Issues**

The following is a brief synopsis of other activities and issues with which CPDA has been very involved during the past year:

- The CPDA Regulatory Committee has initiated quarterly meetings with EPA Registration Division staff during the past year in an effort to facilitate open discussion and to generate ideas on how best to improve the Agency's labeling procedures, the registration review process, and the streamlining of the inert ingredient approval process.

- CPDA continues to be an active member of the FQPA Implementation Working Group (IWG) and works in cooperation with other IWG members in support of the reasonable and fair implementation of FQPA based on sound science.
- During the CPDA “Day on the Hill,” held in conjunction with the 2003 Mid-Year Meeting, association representatives educated Hill staff about the importance of providing USDA’s Pesticide Data Program full funding for fiscal year 2004. 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 which could lead to the cancellation of literally hundreds of pesticide uses, particularly low volume public health and agricultural minor uses.
- CPDA continues to work as part of an industry coalition known as the Public Health Forum that addresses the many issues surrounding endocrine disruption and children’s health issues.

### **Meetings and Workshops**

In the area of meetings and conferences, CPDA continues to be the recognized industry leader in conducting informative “how-to” workshops that focus on specific regulatory topics. During the 2002-2003 fiscal year, CPDA held a “Registration 101” and “Registration 202” Workshop that generated a number of very positive comments from attendees regarding the excellent caliber of the speakers program. CPDA also sponsored a workshop on data compensation for inerts and a workshop on emerging regulatory issues – both of which were very well attended. In addition, CPDA hosted an Adjuvant & Inerts Workshop in Memphis, Tennessee that attracted more than 100 attendees.

We at CPDA are in the process of putting together a full slate of workshops for the coming year that will cover various topics of interest to the industry. Among the workshops CPDA is tentatively planning is a meeting that will address the long anticipated EPA changes to 40 CFR Part 158 data requirements for pesticide registration. We expect that an EPA proposal will be sent to OMB for review sometime this summer. Assuming there are no delays in EPA’s timetable, CPDA is looking at holding a Part 158 workshop in December 2003.

If revision of the EPA’s Label Review Manual is finalized in the summer of 2003, CPDA will host a workshop this fall on labeling. In addition, a full day update on data compensation, led by the law firm of Piper and Rudnick, will take place in the spring of 2004.