

**Report to the Membership**  
**Presented by Warren Stickle, President**  
**Chemical Producers & Distributors Association**  
**Harvey's Resort Hotel & Casino**  
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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.

Never before has the pesticide industry been at the crossroads where we find ourselves today. A number of critical issues are converging. The outcome of how these issues reach resolution will have a lasting impact on what direction the pesticide industry takes in the future.

Pesticide fees, continuing efforts to shape EPA policy regarding the implementation of FQPA, the Syngenta attack on the generic pesticide registration process, the development of a federal inerts policy, the new Data Quality Act requirements, and countless other issues rise before us as challenges that must be met. Now, more than ever, industry needs to take a proactive stance on these issues. Simply responding to the issue at hand is no longer good enough. Instead, members of the pesticide industry need to take a leadership role and head off potential crises before they develop.

CPDA and its member companies have strived to fill this leadership role. We at CPDA have dedicated ourselves to providing you with the best representation possible in Washington federal affairs. Your help and support in this regard 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.

**Pesticide Fees**

Over the last year, CPDA has focused its efforts on securing a long-term solution to the pesticide fees issue. To this end, CPDA has been working with a coalition of trade associations including the International Sanitary Supply Association, the Consumer Specialty Products Association, CropLife America, and the Responsible Industry for a Sound Environment in support of legislation, S. 1474, the Pesticide Maintenance Fees Reauthorization Act. This important legislation was introduced on September 26, 2001 by Senators Tom Harkin (D-IA), Chairman of the Senate Committee on Agriculture, Nutrition and Forestry, and Ranking Member Senator Richard Lugar (R-IN). S. 1474 provides for a five-year extension of maintenance fees at a new level of \$20 million per year with no cost of living adjustment (COLA). In other provisions, S. 1474 continues the current prohibition on registration fees as well as the current restriction on new

tolerance fees. S. 1474 also revises the definition of a small business contained in FIFRA and it requires that 1/7<sup>th</sup> of total maintenance fees collected be allocated for the review of “me-too” products. At the request of CPDA, inert ingredients were added to the expedited review category. The Harkin-Lugar fees bill was the culmination of extensive negotiations with House and Senate staff, EPA officials, the environmental community, and industry representatives.

For the better part of the past year, CPDA and other members of the industry coalition worked toward getting the provisions of S. 1474 included as part of the Farm Bill signed into law this past year. The industry coalition was successful in securing a streamlined, modified version of S. 1474 as a “placeholder” in the Senate passed version of the Farm Bill. Unfortunately, however, the final Farm Bill that emerged from a House-Senate conference did not include the industry supported provisions on pesticide fees.

Despite the merits and good policy inherent in this bill, House and Senate conferees were unable to resolve the issues surrounding the Congressional Budget Office (CBO) scoring of S. 1474. CBO scored the legislation at an estimated cost of \$214 million over five years. In calculating the scoring estimate, CBO counted as “lost” revenue some \$56 million in retroactive tolerance fees and \$25 million in pesticide registration fees. A focal point of the Bush Administration’s FY 2003 budget for EPA’s pesticide program activities hinges on the Agency’s proposed rule for the retroactive collection of \$56 million in tolerance fees and the Administration’s proposal to establish \$25 million in pesticide registration fees once the current prohibitions on new tolerance fees and registration fees lift on October 1, 2002. In addition, the CBO estimate did not credit the \$100 million in maintenance fees that would be generated over five years under S. 1474.

In the end, House and Senate Farm Bill conferees deleted the pesticide fee provisions of S. 1474 not on the basis of the policy approach adopted by this measure, but in response to budgetary constraints. The Bush Administration has pledged its commitment to providing \$73.5 billion in funding for domestic farm programs over the next ten years. While this amount is a large sum of money, it is important to recognize that the Farm Bill covers a broad, comprehensive array of commodity price support, nutrition, conservation, rural development, and energy renewal programs – all of which carry a considerable price tag and all of which are competing for priority.

In the Statement of Managers accompanying the Farm Bill, conferees question the legal basis of EPA’s proposal to impose tolerance fees retroactively and they also raise concerns with regard to the level of the Agency’s proposed tolerance fees. The conferees state that the retroactive imposition of increased tolerance fees, if imposed, could result in the unnecessary loss of valuable pesticide products for American farmers. The conferees strongly encourage the EPA to withdraw its proposed tolerance fee rule, and instead, “work with the appropriate oversight committees in the House of Representatives and the U.S. Senate to develop comprehensive pesticide user fee legislation.”

CPDA is now turning its attention to the FY 2003 VA, HUD and Independent Agencies appropriations bill that provides funding for EPA. Specifically, CPDA is supporting a one-year extension of maintenance fees at \$17 million per year, a one-year continuation of the prohibition on registration fees, and a one-year extension of the restriction on new tolerance fees. In the absence of Congressional action, EPA's authority to collect maintenance fees will end this September 30<sup>th</sup> which could lead to a serious shortfall in funding of EPA's FQPA implementation activities and could result in the loss of the jobs of some 200 Agency employees who are responsible for the reregistration of pesticides.

Similarly, the current restrictions on new registration fees and new tolerance fees will also lift this September 30<sup>th</sup>. In his proposed FY 2003 budget, President Bush has called for the establishment of \$26 million in pesticide registration fees without any specific funding for the registration program, without any accountability for EPA, and without any timetables for finishing the registration or approval process for pesticide products. Furthermore, the Bush budget proposal contains no provisions for waivers or exemptions for minor use, public health products, or small business nor does it distinguish between agricultural, non-agricultural, or public health pesticide products. In addition, the FY 2003 proposed Bush budget contains \$56 million in new tolerance fees to be generated by the implementation of EPA's draft rule. The Agency's proposal for tolerance fees is fundamentally flawed and will ultimately result in the loss of many products, particularly low volume, low sales minor use pesticide products, as well as a number of inert ingredients used in agricultural formulations. A number of legal questions exist surrounding EPA's authority to collect retroactive tolerance fees as the Agency is proposing to do in its draft rule. Moreover, the draft rule does not contain a workable mechanism to collect these fees or to determine how payment of these fees should be equitably divided among registrants and inert suppliers. Ultimately, the enormous fees that would be generated by this proposed rule would translate into higher product costs for U.S. farmers, ranchers, and growers at a time when American agriculture is struggling to remain competitive both domestically and in international markets.

Against this backdrop, CPDA and other industry trade groups have been working together in support of continuing the "status quo" for pesticide fees with one important exception. Namely, a total of 1/7<sup>th</sup> of the \$17 million in maintenance fees collected should be allocated to the funding of "fast track" or expedited review and the review of inert ingredient applications. This change is similar to S. 1474 and is different from the FY 2002 VA, HUD and Independent Agencies appropriations language that reduced fast track funding to 1/10<sup>th</sup> of total maintenance fees collected and did not specifically allow for the use of these funds to process inert ingredient applications.

CPDA has been meeting with Congressional staff of the VA, HUD and Independent Agencies Subcommittee of the House Appropriations Committee to lay the groundwork for the inclusion of pesticides fees language in the EPA spending bill. CPDA is also mobilizing its member companies with facilities in the states of New York and Texas to sign on to joint letters to Representatives James T. Walsh (R-NY),

Chairman of the VA-HUD and Independent Agencies Subcommittee, and House Majority Whip Tom DeLay (R-TX). The letters express support for the continuation of the status quo on pesticide fees with the exception of changes in fast track funding as described above. It is not yet clear when the FY 2003 VA, HUD and Independent Agencies appropriations bill will be taken up in the House subcommittee. Congressional sources indicate that a bill may not emerge from a House markup until next September or October. If a bill is not in place by September 30<sup>th</sup>, CPDA and other members of the industry coalition will seek a Continuing Resolution that extends the fee provisions adopted in last year's FY 2002 EPA spending bill.

While many questions remain surrounding the timing of the VA-HUD appropriations bill in the House, it is now becoming apparent that the Senate will move to mark up a bill prior to the August Congressional recess. As such, CPDA and other members of the industry coalition are working with the staff of Senators Harkin, Craig, and Bond – all of whom are members of the Senate Appropriations Committee – in an effort to secure placeholder language so as to ensure that the fees issue can be taken up in conference should the House choose not to address the fees issue.

In other activities, CPDA and other members of the industry fees coalition plan to meet with Dr. John D. Graham, Administrator of OMB's Office of Information and Regulatory Affairs (OIRA), in an effort to address the scoring problems that would once again present themselves should the Bush Administration include EPA's draft tolerance fee rule and \$25 million in pesticide registration fees as part of the FY 2004 budget. In essence, CPDA and other members of the industry coalition are hoping that it may be possible to dissuade the Administration from using these potential revenue sources as the basis for future pesticide budget proposals.

The EPA is presently planning on reproposing the tolerance fee rule sometime in mid-September, thus raising fundamental questions about its scope and parameters. The following are just a few questions that come to mind. What costs will be associated with tolerance actions? Will these fees be retroactive? How will the tolerance reassessment of inerts be addressed? In essence, how will EPA answer many of the comments and questions that CPDA posed back in 1999-2000.

Meanwhile, the ongoing negotiations and lobbying activities over a short-term fees fix has raised the possibility that discussions over a more comprehensive fee for service will resurface. CPDA members will recall that industry and EPA engaged in a fee for service discussion throughout much of 1999-2000. These discussions, however, slowed and ultimately ended in response to EPA's unwillingness to agree to firm deadlines for product review actions in return for the establishment of new fees. Nonetheless, EPA has continued to imply tacitly its long-standing desire for a fee for service package that would dramatically change the current fees structure. The CPDA Board of Directors will be looking at this issue closely during its July 14<sup>th</sup> meeting at Lake Tahoe.

## **The School Environment Protection Act**

Last year, CPDA and other industry groups worked with a coalition of environmental interests and Senators on legislation titled the “School Environment Protection Act of 2002” (SEPA) dealing with pesticide use in schools. The language would have established certain posting and parental notification requirements prior to the application of pesticides in publicly funded schools. SEPA would also require states to develop a School Pest Management Plan and submit it to the U.S. Environmental Protection Agency (EPA) for approval. The provisions of SEPA were included in the Senate passed version of the Farm Bill. However, the language was ultimately dropped during the House-Senate Farm Bill conference due, in large part, to strong opposition from members of the House Committee on Agriculture.

The provisions of SEPA were originally introduced by Senator Robert Torricelli (D-NJ) as an amendment to education reform legislation (H.R. 1/S. 1) during last summer’s debate on the reauthorization of the Elementary and Secondary Education Act. While the Torricelli amendment was adopted as part of the Senate education bill, the language was not included in the final House-Senate education reform bill. Among the House education conferees, the Torricelli amendment failed by a vote of 6-7. Among Senate education conferees, the vote was 14 to 11 in support of the language. The vote among both House and Senate education conferees was essentially a party line vote with Senator Mike DeWine (OH) being the only Republican conferee to cast his vote in support of the Torricelli language. Despite the fact that a majority of the conferees voted to approve the amendment (collectively, the votes were 20 for and 18 against), House education conferees refused to accept the Senate language. Ultimately, Senate conferees receded to the House position that did not include the SEPA amendment. Senator Kennedy, however, vowed that he would continue to push for SEPA legislation and he indicated that he would look for other vehicles in an effort to move the amendment forward.

The Torricelli amendment establishes a first time precedent for the federal regulation of pesticide use in schools. The legislation requires that all states develop a School Pest Management Plan and submit it to the U.S. Environmental Protection Agency (EPA) for approval. The bill also requires universal notification of parents three times per year (at the beginning of the school year, mid-year, and once for summer session). The amendment also establishes a registry for parents and school staff to sign up to receive 24 hour prior notification of a pesticide application. In its other provisions, the Torricelli amendment requires signs to be posted 24 hours before the pesticide application and to remain posted for 24 hours.

Given the fact that proponents of SEPA were not able to secure this legislation as part of the education reform bill or the Farm Bill, it is possible that similar amendments could be offered on the Senate floor as part of the debate over the FY 2003 appropriations measures. During the 106<sup>th</sup> Congress, Senator Barbara Boxer (D-CA) offered a series of amendments on the Senate floor during that chamber’s consideration of various appropriations measures aimed at effecting a reduction in the use of EPA

registered products. CPDA will be monitoring the appropriations process very closely for any possible amendments that would restrict the use of pesticides in schools or other locations.

### **Senate Passes Terrorism Risk Insurance Act**

The Terrorism Risk Insurance Act (S. 2600), passed the Senate on June 18, 2002 by a vote of 84-14. The measure would create a short-term federal backstop for terrorism insurance coverage. In the months leading up to Senate passage of this legislation, CPDA joined with other members of the Coalition to Insure Against Terrorism (CIAT) in signing on to a letter to Senate Majority Leader Tom Daschle and Senate Minority Leader Trent Lott. The letter urged the Senate leaders to move expeditiously and pass a terrorism insurance bill. CIAT represents business insurance policyholders throughout the construction, entertainment, manufacturing, real estate, retailing, energy, hospitality, wholesale distribution, and transportation sectors of the economy. The letter explained that due to last year's terrorist attacks, insurance for risks associated with terrorism is neither widely available nor affordable, and generally substandard when offered. Most states have permitted insurers to exclude terror insurance from their general property and casualty coverage. The Senate letter stated, "Those few insurance companies which continue to offer terror insurance today provide an inherently defective incomplete and all too expensive product. Importantly, biological, chemical and radiological incidents generally are left totally uncovered." The signatories to the letter urged Senators Daschle and Lott to pass legislation that would create a short-term federal backstop for terrorism insurance to facilitate "a return to normalcy in the insurance market and alleviate the downward pressure on economic activity that the insurance gap has created."

On November 29, 2001, the House passed the Terrorism Risk Protection Act (H.R. 3210) by a vote of 227-193. The bill establishes a one-year (plus an optional two years) risk-sharing loan program that would provide up to \$100 billion in aid. Under the legislation, the federal government would provide loans for 90% of the insurance industry losses between \$1 billion and \$20 billion attributable to a terrorist attack. The loans would be repaid ultimately through an industry assessment of 10% of a company's capital surplus and premiums and/or a policy surcharge depending on the magnitude of the loss.

The Senate's approval of S.2600 now paves the way for Conference consideration of the two measures. The White House has expressed its desire to have a final bill by August. However, White House officials have indicated that the final conference bill must include provisions on punitive damages.

In anticipation of the House-Senate conference, industry groups will be working collaboratively in an effort to clarify certain key issues related to the terrorism insurance measure. Among these, CIAT is seeking language that would clarify scope of coverage in the federal insurance program to include biological, chemical, and cyber attacks. CPDA will keep its members informed of further developments on this issue.

## **CPDA Takes Lead in Generic Pesticide/Metolachlor Issue**

On May 22, 2002, CPDA wrote to Governor Christine Todd Whitman, Administrator of EPA, expressing strong support for the Agency's recent decision to issue the generic registration for metolachlor and to preserve the generic registration process.

EPA's approval of the generic version of this chemical will have a long-range positive impact on future policies surrounding the registration of pesticide products that come off patent. CPDA applauds the Agency for recognizing the important role that generic pesticides play in making available to farmers, ranchers, growers, and consumers a wide array of effective, reasonably priced products.

In its letter, CPDA stated that it is important that follow-on generic manufacturers have an opportunity to register generic products after they come off patent. "The original registrant should not be allowed to cancel the product without giving other registrants an opportunity to register the product and compete in the marketplace, especially when the original registrant is aggressively working to try to convert the marketplace to one of its other proprietary products," CPDA stated.

CPDA explained that if generic manufacturers had been denied an opportunity to register a generic version of metolachlor, the original registrant would have been able to continue its monopoly over the marketplace and potential competitors would have been shut out. "Fortunately," CPDA stated, "EPA recognized the important role generic pesticides play in reducing farm input costs and granted the generic registration of metolachlor."

CPDA emphasized that the savings that derive from the use of generic pesticides is important to the farm and grower community, as well as other pesticide users and American consumers, especially in these times of rising input costs. "Price declines after the introduction of generic competitors of 20-30% are common, and price reductions following generic entry have been as high as 50%-60%," CPDA wrote. "It is estimated that generic products have yielded cost savings to farmers, ranchers and other consumers in the hundreds of millions of dollars *per year*."

A preponderance of existing federal case law upholds the principle that the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) provides a mechanism of data citation and data reliance so that registrants would not have to go through the lengthy and costly process of duplicating data. As such, the authors of FIFRA envisioned a streamlined, more expedient process for the registration of chemicals once they came off patent that would allow for greater competition and a wider array of lower cost product available to the user.

Moreover, Section 3(c)(5) of FIFRA clearly states that the Administrator shall not make any lack of essentiality a criterion for denying the registration of any pesticide. Where two pesticides meet the requirements for registration under FIFRA, one should not

be registered in preference to another.

“Over the years,” CPDA stated in its letter to Governor Whitman, “Congress has repeatedly refused to give EPA authority to phase-down or phase-out registered pesticides, clearly preferring product competition and asserting the belief that once products are adjudged by EPA to meet the safety requirements of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Food Quality Protection Act (FQPA), they should remain on the market. In fact, the Clinton Administration sought phase-down, phase-out authority during consideration of FQPA, but Congress rejected this proposal in the legislation.”

CPDA asserted that the lower cost of generic pesticide products will play an increasingly important role in the years ahead as farmers and growers struggle to remain competitive in the face of profit margins that continue to shrink, or, in some cases, disappear altogether. “Farmers and growers have long operated under the severe economic constraints and pressures wrought by softening commodity prices. The specter of continuing weak commodity prices adds a renewed sense of urgency highlighting the need to limit the spiraling increases in farm input costs. EPA’s approval of lower cost, effective, and proven generic pesticide products is a positive step forward in reigning in skyrocketing farm production costs,” CPDA stated.

CPDA explained to EPA that the availability of generic pesticide products will help farmers and growers remain competitive not only domestically, but in international markets as well. “It is especially important to recognize that many of the United States’ foreign trading partners do not have the same patent laws that exist in the U.S. As such, the availability of generic pesticide product is significantly greater in many foreign countries. Greater access to less expensive, generic product coupled with higher farm subsidies paid by foreign governments places American growers at an unfair disadvantage in international trading markets. It is now time to take steps to remedy this inequity by providing U.S. growers with a greater arsenal of generic pesticide products from which to choose,” CPDA wrote.

CPDA also pointed out the important role the use of generic pesticide products play in helping farmers and growers exercise responsible land stewardship. “For more than the past decade, generic registrants have employed new technologies in adopting more environmentally friendly packaging and application methods for these products. As such, generic pesticide products have an important role in the implementation of integrated pest management programs,” CPDA stated.

In addition to the letter to EPA, CPDA is encouraging agricultural and grower groups to weigh in on the importance of the generic pesticide registration process. CPDA has circulated a draft letter to EPA to more than 100 farm groups for signature. The letter reiterates many of the arguments set forth in CPDA’s May 22<sup>nd</sup> letter to Governor Whitman and emphasizes the important role generic pesticide products play in holding down farm input costs.

CPDA is also seeking Congressional support of the EPA's decision to register generic metolachlor. CPDA staff have been visiting with the offices of Representatives Ed Bryant, Bennie Thompson, and others in the hopes of securing a 'Dear Colleague' letter that would urge members of the House to sign on to a proposed joint Congressional letter to EPA concerning this issue.

Finally, in response to the recent lawsuit against EPA filed by Syngenta seeking to reverse the approval of generic metolachlor, CPDA will file an amicus brief in support of the generic registration process within the Agency. Other organizations have already indicated that they will support this effort.

### **CPDA Files Comments on EPA Draft Data Quality Guidelines**

CPDA has filed a set of comments with EPA on the Agency's draft data quality guidelines recently published in the *Federal Register*. EPA states that its proposed guidelines describe the Agency's policy and procedures for reviewing and substantiating the quality of information before EPA disseminates it. In its comments, CPDA emphasized that by focusing on pre-dissemination review, the Agency can conserve resources while reducing reliance on complaint and correction mechanisms. CPDA also maintained that by expanding and refining its existing procedures, EPA can maximize quality efficiently and effectively. In addition, CPDA stated that by providing the analytical factors the Agency uses to determine whether information is "influential," the EPA will create living Guidelines that can address developing areas of information. Finally, CPDA asserted that by implementing a "triage" system, the Agency can ensure that data causing the most harm can be addressed most expeditiously.

In its other comments, CPDA recommended that the Agency impose a uniform standard for information, *consistent with* its intended use. "Increasingly, the Agency's actions are based on externally-supplied information, but the Agency's decisions should not vary based on the *source* of information, but rather, the *quality* of information," CPDA stated. "That is, sound research methods and peer review are appropriate for all information underlying a rule-making. The Agency should impose standards based on the Agency's intended use for the information." CPDA also recommended that the bulk of the effort expended in ensuring and maximizing data quality should occur in the policy and procedures which occur before the Agency sponsors information, issues statements, or promulgates rules regarding information. CPDA stated, "The pre-dissemination emphasis utilizes Agency resources efficiently and reduces the need for complaints and corrections."

However, when an efficient recourse process is necessary, CPDA emphasized that the Agency should utilize a "triage" system upon receipt of requests for correction. While all requests should be handled within a specified time frame, the Agency should address more serious complaints, e.g., those alleging economic harm, in an immediate manner.

CPDA will continue to work with EPA as the Agency proceeds with further

revisions to its draft data quality guidelines. The Data Quality Act should be implemented on October 1, 2002.

### **CPDA Comments on EPA's Preliminary Organophosphate Cumulative Risk Assessment**

On December 28, 2001, EPA published in the *Federal Register* (66 FR 67249), a request for comment on its draft document entitled "Preliminary Organophosphorus Cumulative Risk Assessment ("POPCR assessment").

CPDA submitted a set of comments to the Agency emphasizing that it is absolutely essential that good science, with the use of the best available data, be utilized to develop good science policy on the POPCR assessment. CPDA stated that for many small-to-medium-sized generic pesticide producers, the OP products represent an important part of their product line. "In fact," CPDA stressed, "the OPs are the most widely-used insecticides in the United States, providing an effective and cost-efficient product to thousands of farmers, ranchers, and users across the United States. Many of these OPs are utilized for numerous minor use crops, especially fruits and vegetables, as well as public health uses, such as controlling mosquitoes. EPA's final assessment of the OPs could have an important impact on the continued use of these important products."

CPDA noted that since the assessment of the OPs represents the initial Agency effort to implement the cumulative risk assessment program, these Agency decisions will establish the precedents by which all other pesticide products will be judged, analyzed, and assessed. Consequently, it is important that EPA balance health protection with the requirements of the Food Quality Protection Act (FQPA) without exaggerating the exposure or risk of the OP products.

"By over-estimating the cumulative risk of some of the OPs," CPDA cautioned, "an unintended consequence could be the reduced availability of pesticide products, and certain food products such as fruits and vegetables, substantial increases in the cost of food products, and potential unavailability of certain public health product uses." CPDA warned that the cumulative effects of such decisions could be reduced public health and a less nutritious diet. "Too frequently we have a tendency to focus on the agricultural uses of the OPs, neglecting the non-agricultural uses (home, lawn, garden, and turf), as well as the public health benefits derived from mosquito abatement programs," CPDA explained. Thus, it is important to consider the comprehensive uses of the OPs, pursue an assessment based in sound science, utilize the best available exposure information and toxicological data, and make judgments that do not over-state risk and exposure."

CPDA expressed its general support for the efforts that EPA is taking toward the POPCR reassessment, especially by using available information on food and water consumption, residue levels, and residential exposure levels. By using reasonable extrapolation techniques, the Agency has been filling-in or bridging the existing data gaps and using distribution techniques, rather than worst case maximum assumptions. There appears to be sufficient data to evaluate drinking water exposure, and outdoor

residential uses, resulting in an initial EPA conclusion that there is no cumulative risk from exposure to OPs in these areas. The preliminary results also suggest that two uses of one pesticide – DDVP – make a significant risk for indoor residential exposure, leading the Agency to explore ways to mitigate the exposure. There are, however, other issues to be resolved.

CPDA has long supported the USDA Pesticide Data Program (PDP) for its ability to accurately test for residue on food by collecting residue data at the large agricultural distribution centers across the country. By using a large sample of multiple fruits, vegetables, milk, and other food products from a cross-section of states, PDP has collected important data on Organophosphate insecticides and their metabolites. EPA has used this USDA PDP information because it is representative of single serving samples, and we at CPDA support this interpretation.

PDP information has been collected over the last decade or more on a variety of crops, including fruits and vegetables. Rather than rely only on the most recent data, the EPA should also consider multiple years going back to the 1990s, thus providing a broader set of data over multiple years. At the very least EPA should run both models and compare the residue levels.

The PDP measures food residues on food collected at food distribution centers, prior to their arrival in grocery stores. It does not collect residues from fruits and vegetables grown for home consumption in backyard gardens. In fact, many homeowners do not use pesticides or OP insecticides. Malathion products, produced by some CPDA companies, are the only OPs still registered for home garden use. These products have specific label instructions for directions and use, as well as dose, application, and pre-harvest intervals, and these label instructions parallel commercial use for fruits and vegetables.

In its comments, CPDA stated that EPA’s assessment that there are no OP residues in human breast milk appears to be an accurate assessment of exposure. “The level of OP residue in baby food appears not to alter the outcome of the risk assessment,” CPDA noted. “During the last two years, EPA has taken numerous steps to eliminate residential uses of OP products, and has cancelled other products previously consumed as part of one’s diet. These products, therefore, should not be included in any cumulative risk assessment, thus allowing for correcting these past inaccuracies and replacement of old data with new data.”

CPDA commented that there is no evidence to demonstrate that seasonal consumption or regional consumption would result in substantial fluctuations in overall cumulative residue consumption. “We are fortunate to live in a society where food products, including most fruits and vegetables, are distributed nationally, and can be eaten year-round,” CPDA stated. “Even when we do occasionally eat some seasonal food, such as watermelon in July, we do not eat solely watermelon or even predominately watermelon, and therefore, there is no reason to anticipate a sharp rise in total OP residues.”

Since EPA has taken significant steps in the last several years to reduce OP use for outside residential areas, the Agency has announced that outdoor residential uses are not a significant risk contributor. It also appears that the only OP utilized for indoor use – DDVP – is being resolved as part of the aggregate risk assessment and therefore, will not influence the cumulative risk assessment.

CPDA emphasized the importance of continuing to collect valuable information from: 1) the Outdoor Residential Exposure Task Force (ORETF), and 2) consumer product use surveys that might provide a more accurate assessment of day-to-day use, and therefore, a better assessment of indoor exposure (non-dietary exposure). CPDA also noted that both the ongoing development of cumulative risk software, as well as assessments being put forth by The International Life Sciences Institute will be useful in developing an accurate and useful cumulative risk assessment.

CPDA told EPA that as well as assuring that data is collected from scientific sources, it is imperative that the Agency base its decisions on an accurate picture of product use patterns so as to assess the quality or biological probability of the data itself. “For example,” CPDA stated, “not only is a homeowner unlikely to use competing products to remedy the same problem, he/she is also unlikely to re-use competing products within a certain amount of time. EPA should consider seasonal aspects of pest management, as well as application methods and frequency to attain fact-driven data.”

In addition to refining the input data and risk assessment models utilized, CPDA recommended that EPA should offer a more detailed account of its tiered assessment procedures as well as an account of how output data are assessed. “We at CPDA commend EPA on its efforts to keep stakeholders informed about assessment processes, and we encourage EPA to be even more straightforward with the public as the cumulative risk assessment continues. Only when EPA’s sources and methods are identified can stakeholders understand and comment on the procedures.”

In putting together its cumulative risk model, the Agency has established dosages and risks at 99.9 percentile for acute dietary exposure. CPDA believes that at this exaggerated level, there is considerable uncertainty in risk management decisions. A more accurate level might well be 99.5 percentile. For calculating residential exposure, there are numerous variables important to these categories that do not support the 99.9 percentile exposures. CPDA believes that the 99.9 percentile cumulative risk exposure is misleading. If the Agency determines to move forward with the 99.9 percentile, it ought to devise a plan of action to take into consideration the over-estimation of risk that is inherent in this model.

We at CPDA are committed to working with the Agency on the issue of cumulative risk as the August 3, 2002 FQPA deadline for the evaluation of OPs draws closer.

## **CPDA Participates in Formation of Non-Agricultural Working Group (NAWG)**

In November 2001, CPDA appeared before the North American Free Trade Agreement Technical Working Group (NAFTA-TWG) in Mexico City to recommend that pesticide regulators from Canada, Mexico, and the United States establish an international stakeholder group of non-agricultural interests to work collaboratively as part of a collective effort to harmonize international pesticide regulations in the non-agricultural area. As envisioned, the focus of this international stakeholder group would center primarily on the regulation of non-agricultural pesticides including antimicrobials and inerts in Canada, Mexico, and the United States with the objective of devising uniform standards for these products across country boundaries.

The initial steps in the formation of this international stakeholder group came in March 2002 when representatives from several North American trade associations, including CPDA, held a preliminary organizational meeting and formally agreed to establish the NAFTA TWG Non-Agricultural Working Group (NAWG). In addition to CPDA, other members of the working group include ISSA, CSPA, RISE, the American Chemistry Council Biocides Panel, and the National Pest Management Association. NAWG also includes several North American companies.

Since the organizational meeting of March 2002, NAWG has held several meetings with the United States delegations, as well as the Canadian and Mexican pesticide regulatory delegations. During these meetings, members of NAWG have examined a number of challenges and opportunities in the non-agricultural area within the context of NAFTA. In this endeavor, NAWG is concentrating primarily on the need for harmonization of data requirements and risk assessments, the development of a NAFTA label for consumer products, methods for achieving greater efficiencies within limited government budgets, and innovative approaches to the removal of trade barriers and trade irritants. The group has reviewed the list of NAFTA TWG projects and has identified a detailed list of issues and priorities of concern. In addition, the group has identified five major non-agricultural areas of interest and has prepared a list of recommendations for submission to the Executive Board of the NAFTA TWG on Pesticides for consideration in development of that panel's five-year work plan.

The following is a summary of the NAWG priorities for non-agricultural pesticides including home, lawn, garden, and turf pesticides as well as rodenticides, pet products, and insecticides (repellants):

- Harmonization of risk assessment and data requirements including toxicological and environmental testing, post-application exposure modeling, and efficacy testing;
- Recognition of the public health benefits of non-agricultural products including residential use pesticides in NAFTA countries;

- Develop harmonized NAFTA labeling requirements for consumer, industrial, and institutional products;
- Identification of joint and/or shared reviews for certain new end-use products;
- Greater acceptance of field tests performed in each other's countries, especially in similar geographic areas;
- Electronic submissions;
- Steps to remedy the PCO non-agricultural minor-use problem in Canada (i.e., newer, safer, and more effective products registered in the U.S. are often not registered for use in Canada); and,
- Steps to enhance the professionalism of professional non-agricultural pesticide applicators in Mexico (i.e., increased training, enforcement, and IPM pilot projects).

The following is a summary of the NAWG priorities for inerts (both food and non-food use):

- Harmonization of risk assessment model/process for inerts in NAFTA countries, including list 2 inerts;
- Reciprocal approval process in Canada and the United States;
- Development of a list of approved inerts in Canada and the United States with CAS numbers;
- Given the need to generate new data for risk assessment models and tolerance reassessments, a uniform data compensation scheme for inerts must be developed in all NAFTA countries; and,
- Retention of present adjuvant policy in Canada, Mexico, and the United States.

CPDA believes that it is essential that the newly created NAWG be considered as part of the official NAFTA TWG on Pesticides stakeholder community, working in partnership with the three NAFTA governments to work on harmonization projects important to the non-agricultural pesticide industry. During the last three years, the NAFTA TWG has formed four subcommittees to work on a variety of issues. CPDA and other members of the industry working group have formally recommended to pesticide regulatory officials in the United States, Canada, and Mexico that an official fifth subcommittee on non-agricultural issues be created. We at CPDA will continue our efforts aimed at incorporating NAWG as a formal subcommittee of the NAFTA TWG and we will continue to keep our members informed of further developments.

## **Inerts Summary**

The 2001-2002 fiscal year was a very busy and challenging year for the CPDA Adjuvant and Inerts Committee with several issues taking top priority including inert disclosure, data protection for inerts, and EPA's proposed inert risk assessment methodology. The following is a brief description of CPDA's involvement in each of these areas.

**Inert disclosure:** The Inert Disclosure Working Group of the Pesticide Program Dialogue Committee (PPDC) has come to an end, but CPDA continues to take the lead on ensuring that health care providers have the information needed to diagnose and treat pesticide-related conditions. In achieving this objective, CPDA has been working with ASTM Committee 35 Subcommittee 22 on developing a standard vocabulary usable to consumers and health care providers. Use of this standardized, user-friendly vocabulary will make pesticide-information accessible to consumers and health providers through a releasable summary.

**Data Protection for Inerts:** Earlier this year, CPDA conducted a well-received, informative workshop with Piper Rudnick to illuminate current developments in the area of data protection. The workshop featured a number of legal experts who presented the perspectives of both the generic and proprietary registrant community concerning data rights. As a follow up to this workshop, CPDA established several internal committees and work groups that will examine the complex issues related to data protection and data compensation for inerts. First, the CPDA Board of Directors approved the formation of a Data Protection subcommittee, chaired by Carmine Sesa of Rhodia, to debate and examine the issues. CPDA would like to extend a special note of thanks to Dick Collier (Griffin LLC) for his time and input in helping the subcommittee develop a workable proposal for discussion.

Carmine Sesa and Bob Sielaty (Wright & Sielaty) also developed an inter-association proposal to address data protection under the upcoming Endocrine Disruption Screening Program (EDSP). CPDA is closely monitoring the EDSP issues, and is grateful for its members' participation in the Public Health Issues Coordination Group spearheaded by the American Chemistry Council.

**Inerts Risk Assessment Methodology:** On June 12-13, 2002, CPDA and CropLife America (CLA) co-sponsored a workshop on EPA's proposed Inerts Risk Assessment Model. The model was officially announced in the June 13, 2002 *Federal Register*. The workshop featured Kathryn Boyle and Kerry Leifer of EPA who presented the proposed process and procedures to implement the new methodology. Although the long-awaited Risk Assessment Model provides guidance on the process utilized by the Agency in reassessing inert ingredients, many uncertainties remain. Most notably, the new model lacks "bright lines" or mathematical thresholds that would enable registrants to predict in advance the costs associated with maintaining a product. In addition, the new model is predicated on a three-tiered system on the basis of available risk information. As such, the Agency has not identified a defined list of substances or

chemical families specific to Tiers 2 and 3. Rather, the tier system adopts a fluid approach whereby substances may move between tiers as new information supporting such moves becomes available. Without having a more definitive idea of what substances, or at least chemical groups or families, will be found in Tiers 2 and 3, registrants lack vital information for making research and product selection decisions.

In order to address the uncertainties described above, CPDA (working in conjunction with CLA) is forming an industry task force for developing models for using surrogate data in pursuit of tolerance reassessments. CPDA recently met with CLA staff to discuss the establishment of a task force Steering Committee that would oversee activities in the following areas: 1) developing and testing of models using surrogate data; 2) developing, maintaining, and protecting databases of model-generated data; 3) performing technical reviews of assumptions, methods, and analyses; and, 4) providing advisory support to the other work groups (i.e., members of government, universities, and industry retirees). It is CPDA's hope that a Steering Committee can be formed and that an initial organizational meeting can be conducted by the end of July in preparation for the submission of public comment to EPA on the new model due September 11, 2002.

### **Other CPDA Activities and Initiatives**

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

- 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.
- CPDA continues to work as part of an industry coalition known as The Endocrine Groups that addresses the many issues surrounding estrogenic effects and children's health issues.
- During the CPDA "Day on the Hill," held in conjunction with the 2002 Mid-Year Meeting, association representatives educated Hill staff about the importance of providing USDA's Pesticide Data Program full funding for 2003. 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.

### **CPDA Continues to be Industry Leader in Educational 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 2001-2002 fiscal year, CPDA held a series of regulatory workshops that addressed legal, labeling, and registration issues related to pesticides. In

addition, in conjunction with CropLife America, CPDA hosted a workshop on the EPA's proposed risk assessment model for inerts (see previous discussion). Earlier this year, CPDA hosted a Chemical Emergency Preparedness and Security Workshop in February 2002 that provided attendees with a glimpse of what precautions companies, particularly small and medium sized companies, should be taking in the aftermath of the tragic events of September 11<sup>th</sup>. CPDA also conducted a very successful Adjuvant and Inerts Workshop in Memphis, Tennessee this past May. This Memphis workshop presented an opportunity for distributors, formulators, and manufacturers to describe their interests and to examine global issues facing the adjuvant and inerts industry.

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. The CPDA staff encourages its membership to provide ideas on issues that would make for good workshops.

### **Conclusion**

Looking ahead, we face many challenges as the 107<sup>th</sup> Congress draws to a close and even greater challenges as we look ahead to the start of the 108<sup>th</sup> Congress. We at CPDA see the coming months as an opportunity to advance many of the initiatives of importance to our industry. To this end, we will call upon you to become involved with the activities of CPDA. In closing, the CPDA staff and I thank you for allowing us to serve you this past year.