

Chemical Producers & Distributors Association
Legislative and Regulatory Accomplishments for Fiscal Year 2003-2004
Presented by Warren Stickle
President
Chemical Producers & Distributors Association
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Introduction

We at the Chemical Producers and Distributors Association (CPDA) would like to take this opportunity to present an overview of the activities of CPDA over the last year. The centerpiece of the association's activities continues to be its strong legislative and regulatory affairs program. CPDA is very involved in a number of issues impacting the registration of agricultural and non-agricultural pesticides by the U.S. Environmental Protection Agency (EPA). CPDA has embarked on a number of initiatives aimed at protecting the interests of generic pesticide registrants as well as small and medium-sized formulators and distributors. Included here is a summary of the highlights of CPDA's activities that have marked the 2003-2004 fiscal year.

Pesticide Fees

On January 23, 2004, President Bush signed into law the Pesticide Registration Improvement Act (PRIA) as part of the FY 2004 Consolidated Appropriations Act. The statute, which became effective on March 23, 2004, will provide EPA with \$15 to \$20 million per year in registration fees and a total of \$116 in maintenance fees over its five-year effective period. PRIA represents a comprehensive landmark consensus bringing together divergent interests and groups. Over the last year and a half, CPDA served as part of a broad coalition of pesticide trade associations that worked closely with EPA, members of the environmental community, and Congressional staff in developing the legislative language that was ultimately adopted as PRIA. This important legislation will provide stability in funding of EPA's Office of Pesticide Programs (OPP) and bring greater predictability to the registration process by establishing deadlines 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. CPDA believes that 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.

The fees language contains several important provisions that will benefit CPDA member companies. 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 brief summary of several of the key provisions of the fees legislation:

- PRIA 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 will receive an unconditional, across-the-board 5% increase or “bump” in registration fees effective in fiscal year 2006.
- 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 1/8th and 1/7th 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 1/34th 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 1/17th 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.
- The proposal includes EPA accountability and auditing provisions.

The focus of industry’s efforts on the fees issue has now turned to implementation. To this end, the pesticide fees coalition has established a Process Improvements Work Group that has been discussing areas related to improving the efficiency and timeliness of registration actions under PRIA. The industry fees coalition Process Improvements Work Group has held several internal meetings since its inception this past spring and has compiled a list of issues and

problem areas for further consideration and discussion. The following is a brief synopsis of some of the issues of most importance to CPDA member companies:

- EPA needs to develop a process that would ensure consistency in labeling and reduce the incidence of label rejection for minor issues related to grammatical wording or phrasing that could otherwise have been accepted with comment. In an effort to provide for greater consistency in labeling, EPA should revisit its Label Review Manual and reinstate its label policy unit along with adopting one annual date, such as October 1st, for the submission of EPA mandated label changes;
- CPDA and other industry associations believe that EPA should look to expand the universe of actions that could be done through notification and/or self-certification;
- The Agency needs to address situations where an inert may be approved under one CSF but rejected under another CSF; and,
- Minor requests such as gold seal labels or international certificates for South American registrations often languish at EPA while awaiting review.

The fees coalition Process Improvements Works Group has approached EPA with the recommendation that the Agency participate in this effort. EPA has responded positively to this suggestion and has indicated that this work group will be formally organized as a subcommittee under the umbrella of the Pesticide Program Dialogue Committee (PPDC) and will include representation from the Office of Pesticide Programs. The work group will focus on identifying and prioritizing process improvements that will have the greatest impact on efficiency of pesticide registration processes.

In related developments, on October 13-14, 2004, the pesticide industry fees coalition will conduct a workshop on PRIA implementation and process improvements. The workshop will be held at the Holiday Inn Rosslyn in Arlington, Virginia. We at CPDA encourage our members to provide suggestions on issues appropriate for discussion with EPA as part of the activities of the Process Improvements Work Group.

Small Business Relief from Pesticide Fees

The pesticide industry fees coalition has been working on a process whereby registrants that meet the definition of a small business under FIFRA (as amended by PRIA), could seek a fee waiver or reduction.

As required by the statute, EPA must determine whether to grant the fee waiver/reduction request no later than sixty days after receipt of the submission. The pesticide industry fees coalition has developed a draft voluntary self-certification statement that would allow companies to self-certify that they meet the revised definition of a small business. The draft statement seeks to streamline the level of documentation that a company would submit along with its application in support of its classification as a small business. CPDA and other members of the fees

coalition are urging the EPA to adopt a process that will not be overly burdensome to small businesses in terms of paperwork requirements.

On Monday, June 21, 2004, CPDA and other members of the pesticide industry fees coalition met with Rick Keigwin, Marty Monell, and Karen Brown from EPA to discuss the issue of small business fee waivers under PRIA. EPA staff told the group that the Agency has had internal discussions on the proposed voluntary small business self-certification statement for pesticide registration fee waiver/reduction requests that has been developed by the industry fees coalition. The statement allows registrants to self-certify, under penalty of perjury, that the documentation submitted in support of a fee waiver/reduction request is correct in all “material respects” and that previously submitted information being relied on is still valid.

One of the objectives of the proposed self-certification statement is to streamline and expedite the process for obtaining subsequent small business fee waiver/reductions for applications submitted to EPA during the same maintenance fee billing cycle after the initial small business fee waiver/reduction is granted. For example, in applying for its initial small business fee waiver/reduction, a registrant may have self-certified and provided documentation demonstrating that its total number of employees was 50. In submitting a second request for a small business fee waiver/reduction within the same maintenance fee billing cycle, the total number of employees may have increased to 52. This would not constitute a “material” change in the small business status of the registrant and thus would not require the resubmission of documentation pertaining to the company’s total number of employees as long as the second application was submitted within the same maintenance fee billing cycle.

EPA has made several additional revisions to the proposed voluntary self-certification statement. Additional changes in the future may be necessary as the registrant community and the Agency strive to further refine and streamline the process for obtaining a small business fee waiver or reduction under PRIA. Whatever process is ultimately adopted, CPDA believes it is important that small business pesticide registrants not be subjected to a 60-day delay with every registration submission. Such a scenario could unfold if EPA were to make a small business determination with each and every submission. The issue of timing is especially important for registrants of fast track submissions that have a 90-day statutory review deadline under FIFRA. The addition of a 60-day decision period on a request for a small business fee waiver would significantly increase the turnaround time for these actions and would serve as a disincentive for small business fast track registrants.

Moreover, CPDA believes that the final process for determining classification as a small business under PRIA must be in the spirit of the Paperwork Reduction Act and must not create new paperwork burdens for small companies.

Benefits of PRIA Small Business Provisions

Under the expanded small business definition set forth in PRIA, more companies will qualify as a small business. Registrants of biopesticides will enjoy the most benefits of the small business provisions, followed by antimicrobial registrants, and then agricultural product

registrants. Some companies previously classified as large businesses under FIFRA but now deemed to be small businesses could receive a refund of maintenance fees paid for fiscal year 2004. For example, a company that was considered a large company, would have already paid \$121,000 at the high cap. As a small company per the revised definition under the fees statute, that company would now owe only \$109,000 and would thus be due a refund of \$12,000. A company at the low cap would have already paid \$70,000 for FY 2004, but would owe only \$66,000 as a small company and would thus be due a refund of \$4,000.

CPDA believes that the small business provisions of PRIA will encourage product innovation and reduce costs. In addition, these provisions of PRIA will encourage competition in the marketplace and expedite the movement of product available to farmers, ranchers, growers, and other users of pesticides.

CPDA Continues to Monitor VA, HUD and Independent Agencies Appropriations Process

In related fees activities, CPDA continues to monitor the appropriations process for VA, HUD and Independent Agencies that provides funding for EPA. At the time of this writing, the FY 2005 VA, HUD and Independent Agencies appropriations measure was expected to be the subject of a House Appropriations Subcommittee markup. CPDA and other members of the pesticide industry fees coalition have been working together in support of proposed report language that would call upon EPA to refrain from promulgating a revised tolerance fee rule while PRIA remains in effect. In addition, the draft report language reiterates Congressional support for the continued prohibition on registration fees during the effective period of PRIA. The President's FY 2005 budget request for the Agency includes \$26 million in pesticide registration fees in addition to the new fee for service or enhanced registration service fee established by PRIA. In justification documents accompanying the FY 2005 budget request, EPA estimates that FY 2005 collections of enhanced registration fees under the recently enacted law will be \$19.4 million. This projected revenue underestimates the fees that will be generated because of the backlog payments.

As signed into law by President Bush, the Pesticide Registration Improvement Act specifically prohibits the imposition of any other pesticide registration fee through September 30, 2010. Removal of this prohibition would require an amendment to FIFRA. The justification documents accompanying the EPA FY 2005 budget request state, "...The Pesticide Registration Improvement Act rescinds the authority to collect pesticide registration fees to offset base program costs. This budget proposes amending the Act to allow collection of this fee. Collections are estimated at \$26,000,000."

The proposed language expresses the Committee's expectations that EPA will not work on a final tolerance fee rule or any other additional fee while PRIA remains in effect but instead will focus its resources on pesticide issues related to implementation of PRIA.

In the weeks and months ahead, CPDA will work with the industry fees coalition on related EPA appropriations issues such as protecting the baseline funding level for the Office of Pesticide Programs. As mentioned above, the assessment of registration service fees under PRIA

is prohibited unless the OPP allocation of appropriations equals or exceeds fiscal year 2002 levels.

CPDA and Other Members of the Pesticide Fees Industry Coalition Send Letter to OMB and EPA on Proposed Tolerance Fee Rule

In supplementing the legislative efforts described above, CPDA and other members of the pesticide industry fees coalition sent a letter to White House Office of Management & Budget Director Josh Bolton and EPA Administrator Michael Leavitt asking the Administration to refrain from taking steps to finalize a revised tolerance fee rule. The Coalition urged EPA to cease work on a draft tolerance fee rule and to focus instead on the implementation of the Pesticide Registration Improvement Act (PRIA).

PRIA prohibits the collection of tolerance fees while EPA collects the new registration fees. The Coalition letter emphasized that the promulgation of a tolerance fee rule would divert EPA resources away from PRIA implementation efforts such as meeting the timelines required for registration actions, developing registration process improvements, completing reregistration, enhancing current scientific and regulatory activities related to worker protection, and implementing the registration review provisions of FQPA.

The Coalition letter states, "...promulgation of a revised tolerance fee rule in the absence of any legal authority to charge such fees would have deleterious effects, since imposition of such fees cannot occur unless and until PRIA expires in 2008, at which time circumstances could be vastly different."

CPDA Joins With Industry Stakeholders in Supporting ESA Counterpart Regulations

On April 16, 2004, CPDA submitted comments expressing support for the proposal published in the January 30, 2004 *Federal Register* by the Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS) titled the Joint Counterpart Endangered Species Act Section 7 Consultation Regulations. This proposal will provide for a formal, streamlined consultation process between the U.S. Environmental Protection Agency (EPA) and the Services that will result in improved protection of wildlife and the continued availability of beneficial, EPA approved pesticides to farmers, ranchers, growers, consumers, and other users. CPDA is pleased that the Services and EPA are working to establish a framework such as that described in the proposal.

The Endangered Species Act (ESA) directs EPA to consult with the Services to ensure that the registration of pesticide products under FIFRA is not likely to have an adverse impact on the continued existence of federally listed threatened or endangered species or habitats. EPA should be designated the lead regulatory agency in making pesticide product risk assessment and risk management determinations as they relate to the potential impact on endangered species or habitats.

By providing EPA broad authority to make "not likely to adversely affect" decisions on

pesticide products, registrants will be able to negotiate label restrictions directly with EPA if they are necessary to protect endangered species, and thus eliminate the need to engage in lengthy consultations with the Fish and Wildlife Service and National Marine Fisheries Service. Such coordination of FIFRA and the Endangered Species Act will result in a more effective and expedient pesticide review process.

In the absence of such a procedural framework, efforts to protect listed species under the Endangered Species Act could be impeded and delayed by a proliferation of lawsuits. These lawsuits may result in indiscriminate bans or restrictions on pesticide use, may eliminate safe products because of insufficient data, may increase the costs of crop protection and public health products, and may spur additional “copycat” litigation. Such lawsuits would not be brought forward as the result of any physical harm or damage to a listed species or habitat. Rather, these lawsuits would be based on procedural grounds, specifically the lack of consultations in limiting the use of essential pest control products.

The consultation process set forth under the proposed Counterpart regulations will allow limited Agency resources to be focused on the protection of listed species pursuant to the ESA. At the same time, the proposal will ensure that pesticide users have continued access to beneficial pesticide products necessary for agriculture and the protection of public health. CPDA applauds the Services and EPA for their progress in developing a comprehensive, multi-agency review process as set forth under the proposed consultation regulations and urges its implementation.

CPDA Writes to Members of the House on ESA Issue

In related activities, CPDA wrote a letter to members of the U.S. House of Representatives requesting that they join with Representatives Frank Lucas and Tim Holden in signing on to a letter to Secretary of Interior Gale Norton urging her to finalize the January 30, 2004 proposed ESA counterpart regulations. The June 25, 2004 Congressional letter to Secretary Norton emphasized “the proposed regulation is an essential tool to protect endangered species while ensuring economical food and fiber production and protection from pests, diseases and weeds.”

The letter continued, “...Over the past four years, consecutive lawsuits have alleged that EPA has failed to consult with the Services (USFWS & NOAA Fisheries) as required by the Endangered Species Act, even though these suits did not actually claim a species had been harmed. Current court decisions and threats of additional litigation have created a piecemeal consultation processes, as well as use restrictions for pesticide products. The restrictions have seriously affected farmers’ abilities to provide Americans with safe, affordable, abundant food and fiber. These lawsuits have also cost taxpayers millions of dollars as EPA defends itself against a process that does nothing to improve protection for endangered species. Without the proposed counterpart regulation, the pesticide regulatory process will be subject to endless litigation.”

We at CPDA are pleased to report that a total of ninety-two members of the U.S. House of Representatives agreed to sign the letter to Secretary of Interior Gale Norton expressing Congressional support for finalizing the proposal.

Earlier, on May 6, 2004, House Agriculture Committee Chairman Bob Goodlatte (R-VA) and Ranking Member Charles Stenholm (D-TX) wrote a letter to Secretary Norton expressing their support for the proposal and urging that the draft rule be finalized as soon as possible. Representatives Goodlatte and Stenholm state, "...The current process of having the three separate agencies repeat the same work is both scientifically unnecessary and an expensive waste of government resources and taxpayer money."

The letter emphasized that the proposal will allow for the "continued registration of safe, effective pesticides" that farmers and growers need to "remain economically viable in providing safe, abundant and affordable food and fiber for our nation and for protecting public health."

CPDA and allied stakeholders are hopeful that the proposed counterpart regulations will be finalized in the near future.

EPA's Revised Spill Prevention, Control and Countermeasure Rule

On July 17, 2002, EPA issued a final rule amending the Oil Pollution Prevention regulation promulgated under the authority of the Federal Water Pollution Control Act. This rule addresses requirements for Spill Prevention, Control and Countermeasure Plans (SPCC) and some provisions may also affect Facility Response Plans (FRPs). The revised rule became effective August 16, 2002. On April 17, 2003, EPA published a final rule that extended by eighteen months the deadlines by which facilities must amend or prepare and implement their SPCC plans as set forth in the July 2002 revamped rule. Subsequently, on June 17, 2004, EPA announced in the *Federal Register* a proposal to extend by an additional twelve months the compliance deadline for the new SPCC requirements.

The revised SPCC rule requires integrity testing of 55-gallon drums serving as bulk storage containers (this requirement has always been a requirement for 55-gallon drums). EPA notes that for certain containers in which internal corrosion poses minimal risk of failure, which are inspected at least monthly, and for which all sides are visible (i.e., the container has no contact with the ground), visual inspection alone might suffice in accordance with the deviation provisions of Section 112.7(a)(2) of the revised rule, subject to good engineering practices. In such cases, the owner or operator of the facility must explain in the SPCC Plan why visual integrity testing alone is sufficient, and provide equivalent environmental protection. However, containers that are in contact with the ground must be evaluated for integrity in accordance with industry standards and good engineering practices.

In its other provisions, the revised SPCC rule requires a Plan amendment if a change in the contents that are stored in the container are deemed to be a material change. For example, changes of product involving a flammable product such as gasoline as opposed to combustible liquids (i.e., diesel) are material changes that substantially alter the conditions of storage and the

potential for discharge. The owner or operator must determine whether there will be a material change, and generally does so on a facility basis.

The revised rule requires containment areas to be “sufficiently impervious to contain oil” and the regulation assumes that secondary containment systems will be constructed of “impervious soil.” In accordance with these requirements, dikes, berms, or retaining walls must be capable of containing oil and preventing such discharges. Liners are an option for meeting the secondary containment requirements, but are not required by the rule.

We at CPDA are working with our member companies to ensure that they are informed of the new requirements set forth in the July 2002 revised final rule and to provide them with assistance in developing an amended SPCC plan.

EPA Reopens Comment Period for Proposed Container Regulations

On June 30, 2004, EPA published a *Federal Register* notice reopening the comment period on the proposed regulation establishing standards for pesticide containers and containment. Comments must be submitted to EPA under docket ID number OPP-2004-0049 by August 16, 2004. The original proposal titled “Standards for Pesticide Containers and Containment” was published in the *Federal Register* on February 11, 1994 and addressed refillable containers, non-refillable containers, labeling, and containment structures. On October 21, 1999, EPA published a supplemental notice that addressed proposed changes to the draft container standards that would: 1) narrow the scope of the proposed container/containment regulations based on toxicity category and container size; 2) exempt certain antimicrobial products from the container standards; and, 3) adopt and refer to several DOT standards. The supplemental notice also provided an alternative definition of small business for certain sectors of the pesticide industry. The overall effect of the notice was to focus on higher-risk pesticide products and to exempt lower- risk products from certain container standards in the 1994 proposed rule. The changes promoted the use of refillable containers and sought consistency within the federal packaging standards by adopting the DOT standards. It proposed a reduction in the number of pesticide products subject to the container requirements compared to the original proposal.

CPDA is reviewing the container proposal and seeks the input of its member company representatives on this important issue.

CPDA Surfactant Task Force

On April 13, 2004, an organizational meeting of the newly formed Surfactant Task Force was held and a follow up meeting was conducted on June 9th. The objective of the Task Force is to: 1) facilitate the gathering of public information that can be used in reassessment of the remaining surfactants; 2) prepare data summaries for each surfactant or surfactant cluster; 3) submit data summaries to EPA; and, 4) work with EPA as required.

The Food Quality Protection Act of 1996 (FQPA) classified inerts as pesticide chemicals

and mandated reassessment of tolerance exemptions. Completion of reassessment is required by August 3, 2006. To date, 410 inerts have been reassessed and 460 inerts are awaiting reassessment. Of those inerts for which reassessments are pending, 160 are classified as surfactants. Initial clustering has reduced the number of these products subject to reassessment to 100. It is possible that additional clustering can reduce this number even further. Last year, EPA published its FY 2004, 2005, and 2006 work plan for inerts and set dates for the reassessment of most of the surfactants widely used in pesticide formulations.

Endocrine Disruptor Screening Program

In April of 2003, 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.

An EPA work group has been established and continues to review the public comment received by the Agency on its proposed approach for selecting an initial list of chemicals for endocrine disruptor screening. Initially, EPA had projected publication in early 2004 of both a revised approach for selecting the first set of substances to undergo endocrine disruptor screening and a proposed list of chemicals based on application of that approach. However, EPA has now modified its timetable citing unavoidable technical delays that have occurred in validating a number of Tier 1 screens. Under the revised schedule, EPA now expects to publish its screening approach for establishing the initial list by the end of June 2004 and to publish a draft initial screening list of chemicals approximately one year before completing validation of the Tier 1 screening assays. EPA's target for publishing the draft chemical list would be about January 2005. EPA states, "...This sequence will allow the Agency to continue to consider and potentially refine the criteria for selecting the initial list of chemicals (for example, the Agency is exploring whether including particular chemicals for testing in the first group could provide helpful insight into determining what characteristics might lead to a conclusion that an untested chemical is or is not likely to have endocrine disrupting potential), as well as allow the Agency to use the most current data (exposure-related data and any other data that might be relevant to the selection criteria) in selecting that list. This approach will still allow the Agency to take public comment on the initial list and make whatever revisions to the list are appropriate in light of such comments without causing any delay in the commencement of testing."

Registration Review Under FQPA

CPDA is a member organization of the PPDC Registration Review Workgroup. The Workgroup provides 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 are addressing 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. As a member of the workgroup, CPDA is taking the lead in advocating that inert ingredients not be included in registration review. 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.

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.

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. Recently, the CPDA-CLA Inerts Risk Assessment Steering Committee developed a white paper detailing a proposed risk assessment model that will avoid residue testing on all inerts in all products for all uses, thus saving millions of dollars in research.

In other activities, the joint CPDA/CLA Inerts Steering Committee submitted a set of comments to EPA on June 18, 2004 (Docket No. OPP-2002-0296) which proposes an interim process to provide data protection mechanisms for inert ingredients that are newly approved for use in pesticide formulations or are subject to tolerance reassessment under FQPA while rulemaking is in progress.

In its comments, the joint Inerts Steering Committee stated that implementation of an inert ingredient data compensation process requires formal rulemaking through notice and comment and that an interim process is needed until such time as the rulemaking actions are complete. As part of this proposed interim process, the Inerts Steering Committee offered a set of recommendations with regard to EPA publication of a Data Submitters List for inert ingredients and the creation of a new “Certification with Respect to Citation of Inert Data” form. In addition, the comments drafted by the CPDA/CLA Inerts Steering Committee addressed issues surrounding the formulators exemption and data requirements as they relate to data compensation for inerts.

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.

In other developments, the AIC is pleased to report that EPA recently adopted an original CPDA proposal to establish a separate inerts branch within the Registration Division (RD). This branch will provide significantly increased personnel and resources devoted to the elimination of the current backlog of inerts and will facilitate the processing of new inert ingredients in a timely and efficient manner with increased accountability.

Finally, the CPDA Adjuvant Standards program – a voluntary self-certification program – has been launched and a number of major distributors have expressed their interest in participating in this exciting endeavor.

Chemical Security

CPDA has been working collaboratively with a coalition of industry and agricultural trade associations on the issue of chemical facility security. As part of this endeavor, CPDA has joined with other coalition members in voicing concern over S. 157, the Chemical Security Act, introduced in the 108th Congress. Specifically, CPDA and other members of the coalition are concerned that:

- The requirements of S. 157 would disrupt ongoing security enhancements already underway within industry;
- The measure would dilute or “splinter” the security authority of DHS by creating new counter-terrorism authority within EPA;
- 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,
- The language pertaining to “inherently safer technologies” grants sweeping new authority that would allow EPA to mandate substitutions of all manufacturing processes and substances.

It is very possible that chemical security legislation will be taken up in this session of the 108th Congress. We at CPDA believe that any measure pertaining to chemical security must take into consideration:

- Industry’s need for better threat information from law enforcement agencies including more specific information about potential threats in order to more effectively design security systems and protocols;
- The challenge faced by small and medium-sized businesses in achieving cost-effective security solutions that result in significant reduction of risk;
- An approach to chemical facility infrastructure protection geared to a “reasonable” level of security against known or suspected threats rather than in response to an extreme scenario that would be prohibitively expensive; and,
- The need for appropriate safeguards to protect sensitive information relating to chemical facility vulnerabilities and security that ensures such information is not inappropriately disseminated.

CPDA continues to work with stakeholders and members of Congress toward the goal of enacting comprehensive chemical facility security legislation that protects our nation from the risk posed by terrorist threat and addresses the concerns of industry described above.

Agricultural Business Security Tax Credit Act of 2004

On June 25, 2004, Representative Ron Lewis (R-KY) introduced H.R. 4718, the “Agricultural Business Security Tax Credit Act of 2004.” This important legislation would provide a tax credit to certain agricultural businesses to help offset the costs of facility security upgrades. Joining Representative Lewis as an original co-sponsor of the bill is Representative Ed Whitfield (R-KY).

Over the last several months, CPDA has been working with the Agricultural Retailers Association (ARA) in strong support of this important legislative initiative.

Under H.R. 4718, retailers of agricultural products as well as manufacturers, formulators, and distributors of food-use pesticides (including inerts used in agricultural formulations) would be eligible for a tax credit to help offset some of the costs of upgrading security at their facilities. The measure would provide a security tax credit equivalent to 50% of the aggregate amount paid on implementing security measures at covered sites and the dollar limit of the credit would be set at \$50,000 per facility (i.e., per location). Once a facility reaches the \$50,000 tax credit limit, a business must wait five years before that facility is eligible again to receive another tax credit.

The bill would establish a \$2 million cap per company for all covered entities. In addition, a business could only receive a tax credit for security costs incurred after the proposal becomes law.

H.R. 4718 will provide much-needed assistance to many small and medium-sized agricultural businesses to help defray the significant but necessary costs of enhancing on-site security measures. The cost of enhanced security measures at food-use pesticide manufacturing, formulating, and distributing facilities can spiral into the hundreds of thousands of dollars. H.R. 4718 is a fiscally responsible bill that will provide a modest level of tax relief to agricultural businesses and, in so doing, will encourage the implementation of more security measures.

CPDA has asked its member companies for help in contacting their Representatives and asking that they co-sponsor H.R. 4718. Your letters to Representatives in the House will help us in building a broad base of support for this legislation.

In recent years, there has been increased attention by the federal government, media and general public on the security of the nation's chemical, food processing and storage facilities. The heightened concern as to the vulnerability of these sites, in part, relates to the Oklahoma City bombing and the terrorist attacks on September 11, 2001. As a result of the *USA Patriot Act of 2001*, new federal hazardous materials (HAZMAT) transportation security regulations have been implemented that directly impact agricultural businesses. In addition, there are also several pieces of pending legislation (S. 994, S. 157 & H.R. 1861) in Congress that would make it mandatory for agricultural businesses with chemicals and fertilizers at their facilities to conduct a security vulnerability assessment, develop a site security plan and implement security measures.

The agricultural industry is committed to securing and protecting our nation's food supply. A top priority for agricultural businesses is to secure fertilizers and chemicals at their business operations. Some of the recent security-related actions include:

- *Asmark Security Vulnerability Assessment Model (ASVA)* – The Agribusiness Security Working Group announced the availability of a web-based, security-vulnerability assessment tool specifically designed for the retail agribusiness sector. It can also be useful for farmers and ranchers handling inputs on their operations. This tool meets the

criteria set by the Center for Chemical Process Safety.

- *USDA coordination with Farmers and Ranchers* – Production agriculture is working closely with the U.S. Department of Agriculture (USDA) to better secure inputs as well as other measures to address security concerns on the farm and ranch. These ongoing efforts are intended to increase producer-level awareness and participation in protecting the United States from terrorism.
- *Ongoing Industry Efforts* – Pesticide producers, distributors, and retailers are already working to do a security vulnerability assessment, as well as implementing some security measures at sites and facilities.

Agricultural businesses could spend over \$100,000 at a location on security measures such as fencing, alarms, lights, and security guards. Because of the high costs for security measures, the tax credit allowed under H.R. 4718 helps provide agricultural business owners with the necessary financial assistance to take expensive, yet necessary, security steps to better protect the American public from the potential threat of terrorism or any other illegal activities. The agricultural business community wants to address all security concerns. It is, however, a very expensive undertaking. The use of a security tax credit will provide economic incentives for agricultural businesses to install adequate security measures with its own resources, as opposed to being forced to comply with any un-funded federal mandates.

There are at least 3,500 agricultural retail facilities (out of a total of approximately 9,000) across the country with fertilizer and chemicals that will likely conduct a Security Vulnerability Assessment (SVA). The number of agricultural retail facilities that are likely to utilize this proposal may be as high as 6,000 since they store a considerable amount of the chemicals and fertilizers sold to farmers in the United States and have already or will spend a significant amount of money on security measures. This tax credit alone would help those agricultural retailers re-coup a portion of the costs for these security measures, which they are unable to recover from farmers.

Many pesticide manufacturers and formulators are preparing to conduct a Security Vulnerability Assessment (SVA). Perhaps as many as 500 producers are likely to spend monies on security measures. This tax credit would be particularly beneficial to dozens of chemical producers who are small businesses with low volume sales and low profits.

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 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 Pesticide Policy Coalition (formerly known as the FQPA Implementation Working Group) and works in cooperation with other industry members in support of the reasonable and fair implementation of FQPA based on sound science.
- CPDA supports 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.
- 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.
- CPDA is working with its member companies, EPA, and allied trade associations in developing a data compensation process for inert ingredients including a Data Submitters List.
- CPDA is monitoring the implementation of the Data Quality Act so that the EPA only releases activities and reliable information that is scientifically viable.

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 2003-2004 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, a workshop on emerging regulatory issues, and a labeling workshop – all of which were very well attended. In addition, CPDA hosted an Adjuvant & Inerts Workshop in Memphis, Tennessee that attracted 145 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. We are hopeful that the upcoming series of workshops will include a conference on Endangered Species. CPDA has been working with CLA in developing a proposed workshop that would address the recent *Washington Toxics Coalition, et. al. v. EPA* court case that has important implications for the pesticide industry. The court decision issued on January 22, 2004 by the United States District Court for the Western District of Washington establishes pesticide buffer zones adjacent to certain salmon-supporting waters in Oregon, Washington, and California. The proposed workshop would also focus on the proposed Joint Counterpart Endangered Species Act Section 7

Consultation Regulations providing for a formal, streamlined consultation process between EPA and the Services in making pesticide registration decisions. The workshop would also include presentations on EPA's ecological risk analysis process for making effects determinations, state initiatives pertaining to the Endangered Species Protection Program (ESPP), and a summary of practical issues that must be taken into account when integrating ESA with registration activities.

Among the other workshops CPDA is tentatively planning for the 2004-2005 fiscal year is a meeting that will address the long anticipated EPA changes to 40 CFR Part 158 data requirements for pesticide registration, a workshop focusing on the inert ingredient industry, a workshop addressing international requirements governing pesticide sales and distribution, and a regulatory workshop focusing on EPA's endocrine testing program and the Agency's plans for implementation of the FQPA registration review requirements. In addition, CPDA is planning to bring back its very popular Registration 101 and Registration 201 workshop. Finally, CPDA will again conduct an Adjuvants and Inerts Conference to be held in conjunction with next year's "Memphis in May" festival.

CPDA Establishes Toll-Free Telephone Number

In an effort to better serve the membership, CPDA has established a toll-free telephone number that companies may use when contacting our offices. The CPDA toll-free number is 1-866-671-CPDA (1-866-671-2732). We hope that the toll-free number will save our member companies money and make it easier for them to reach us.

Conclusion

CPDA has enjoyed a very busy year and we look forward to taking on even greater challenges as we begin 2004-2005. The staff of CPDA would like to express their gratitude and appreciation of having the opportunity to represent a growing and dynamic industry. We look forward to continuing to serve our member companies in the months ahead.