

Information Exchange

Teaming Up for GLP Training

When the question was presented, where should we meet for this training? The answer was obvious...Orlando, which became the site for the 2004 Southern / North Central Region GLP Training.

Regional Directors, Marty Marshall (Southern) and Bob Hollingworth (North Central) opened the two and a half day program with a welcome and an exhortation to remain focused, despite the gorgeous weather.

The workshop was attended by over 80 people; mostly from the Southern and North Central regions, but also from the Northeast and

Western regions as well as Canada.

The workshop included topics such as SOPs, EPA audits, Field Data Book (FDB) changes for 2004, responding to QA audits, application equipment / demonstrations, and facility audits.

The first morning session began as an information lecture where key issues describing how to write, review and retire SOPs were discussed by Tammy White, the IR-4 HQ QA Manager. This session was followed by a "hands-on" exercise where participants were asked to review a FDB from an auditor's perspective. This exercise brought out many questions and gave participants a better appreciation for what to include in their own FDB.

IR-4's Kathryn Hackett-Fields (HQ QA) opened the afternoon sessions with a presentation on EPA audits. She commented that EPA inspections are the same with respect to the methods of notification, the general "pattern" of the process,



and the expectation of the Agency. She also emphasized that SOPs are critical for the inspection process. They explain to the investigator beforehand what to expect from the facility. The key areas to consider regarding an EPA audit are: SOPs, which should be present and up-to-date; equipment, which should be adequate for the task; and adequate test and reference substance storage.

responses. The audience appreciated this exercise because it helped them understand that whenever a "finding" is presented, an "action" needs to follow, not just an acknowledgment of the finding. This exercise also helped the QA auditors in the group to understand how to better state their findings for clarification. Most felt this was a good exercise and helped both

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From EPA Audits to QA Audits

Van Starner (pictured left below), IR-4 HQ Study Director and Chair of the Training Committee followed Kathryn with a lesson on Responding to QA Audits. "Perhaps the hardest thing to remember about QA audits is, it's not personal," stated Van. "If you can keep that in focus, you'll be better equipped to respond to the findings." Van went on to present actual FDB audit findings with actual FRD responses, and he asked for comments on adequacy of the



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Calendar of Events

June 7-9, 2004

GLP Training for
Lab Personnel
Michigan State University
Contact: Wayne Jiang at
517.432.3100 x 145

July 12-14, 2004

PMC Meeting
Traverse City, MI

August 17-18, 2004

Southern Regional Meeting
Wilmington, NC
Contact: Robin Adkins
352.392.1978

September 22-24, 2004

IR-4 Food Use Workshop
Orlando, FL
Contact: Cheryl Ferrazoli
732.932.9575 x 601

October 6-8, 2004

PMC-
California:
Location
TBD

October 26-27, 2004

National Research Planning
Meeting
North Brunswick, NJ
Contact: Cheryl Ferrazoli
732.932.9575 x 601

November 9-11, 2004

IR-4 Ornamentals Workshop
Orlando, FL
Contact: Cheryl Ferrazoli
732.932.9575 x 601



Training

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sides in communicating better.

Ken Samoil, IR-4 HQ Study Director, also gave a presentation on recent FDB updates and changes.

A Tour to Lake Alfred

The next afternoon, participants were given a tour of the University of Florida's Citrus Research and Education Center at Lake Alfred, FL. On the tour, Wayne Curry, who had given a presentation in the morning on the use of nozzles, was able to demonstrate test methods to determine the best nozzle for the job.

The research team from Texas A&M Research and Experiment station in Weslaco, TX brought along their portable Solo® backpack sprayer to demonstrate its use and convenience, and Robert Johnson, Mt. Dora, FL, demonstrated air blast sprayers, application, and calibration.



Ralph Morgan, Mechanical Maintenance Technician, Weslaco, TX demonstrates the ease of use and portability of a backpack sprayer.

The final day of training included a review of GLP requirements. Martin Beran, QA at UC Davis, discussed this along with plot maps, permanent markers, chemical storage, sample collection and maintenance logs. A survey of the training workshop was handed out to the participants and many said this training will help them perform their duties better. Others felt more interactive exercises are needed. The Training Committee was appreciative of the comments and will use them to help structure future training events.

A training for lab personnel is being planned for June 7-9, 2004, at MSU by the North Central region. The Western Region is planning a GLP training in March of 2005 at the U.C. Davis campus. ▲

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Participants look on as Wayne Curry of Weed Systems Equipment (r), uses an artificial plant, to demonstrate the spray distribution pattern of various nozzles.

Clearances

December 2003- February 2004

Product: Cyprodinil

Trade Names: Switch, Vangard
Crops: onion (dry bulb and green), strawberry
Federal Register: 12-31-03 (time-limited tolerance extended to 12-31-04)
PR# 05033, 06790

Product: Sulfuryl Fluoride

Trade Name: Vikane
Crops: Tree Nuts, Dried Fruit
Federal Register: January 23, 2004
PR# 06912, 06913

Product: Bifenazate

Trade Name: Acramite
Crop: Potato
Federal Register: February 4, 2004
(time-limited tolerance established, to expire on December 31, 2006)
PR# 08278

For more information, visit the IR4 web site at www.ir4.rutgers.edu

International Consulting Committee on Crop Grouping

IR-4 and EPA are joining together to form an International Consulting Committee on Crop Grouping. The purpose of the committee is to assist the IR-4/EPA Crop Grouping Working Group, whose members include Dr. Bernie Schneider & Dr. Yuen-shaung Ng of the EPA, and Dr. Hong Chen of IR-4, in clarifying data needs and providing crop information for crop grouping proposals. The committee will also review the crop monographs and crop grouping proposal data packages that are to be prepared by the Working Group.

The International Consulting Committee includes crop and regulatory experts from around the world. Many of whom participated in and contributed proposals that were the focus of the October 2002 USDA/IR-4 International Crop Grouping Symposium held in Washington, DC.

Dr. Bernie Schneider, Senior Plant Physiologist of the Health Effects Division of EPA/OPP stated, "We need help in completing the scientific information required to prepare the packages of proposals to the EPA. This committee will be able to provide their expert opinions on many U.S. and international agriculture issues related to pesticide registration, MRL, and international harmonization."

The 94 member committee includes participants from the US, Australia, Belgium, Canada, China, Japan, Korea, Lebanon, Netherlands, and UK. Besides representing their own countries, some of them also represent the European Commission and Codex Committee on Pesticide Residues. Their primary committee responsibility will be to provide feedback within one month of each inquiry. "Our goal is to complete the data packages for all the proposals produced from the USDA/IR-4 International Crop Grouping Symposium and submit them to the EPA, as well as assist in the regulatory procedures to bring the proposals to Federal approval," stated IR-4 HQ Crop Grouping Project Coordinator and Committee Chair, Hong Chen. "We also hope to assist the international harmonization of crop classification and determination of MRLs through our participation in US Delegation to the CODEX Committee on Pesticide Residues."

To learn more about the International Crop Grouping project, contact Hong Chen at 732.932.9575 x 627 or send her an email at hchen@aesop.rutgers.edu. ▲

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The simple answer is yes and no. According to the EPA, methyl bromide is a broad spectrum pesticide used in the control of pest



This trial was treated with Methyl Bromide and produces the results that IR-4 would like to see using Methyl Bromide Alternative products.

insects, nematodes, weeds, and pathogens. In the U.S., about 21,000 tons of methyl bromide are used annually in agriculture, primarily for soil fumigation. Anthropogenic methyl bromide has contributed a total of about 4% to ozone depletion over the past 20 years. Of this, about 2.5% can be attributed to agricultural fumigation activities. If it is not phased out, the continued use of methyl bromide as an agricultural pesticide may contribute 5-15% to future ozone depletion (as the contribution of chlorofluorocarbons (CFCs) diminish and the ozone layer heals). (www.epa.gov/spdpublic/mbr/qa.html#q2)

Because methyl bromide is highly effective, finding an alternative is no easy task. The U.S. Department of Agriculture

(USDA) states on their web site at www.ars.usda.gov/is/mb/mebrweb.htm, there is no known single alternative fumigant, chemical, or other technology that can readily substitute for methyl bromide in efficacy, low cost, ease of use, wide availability, worker safety, and environmental safety below the ozone layer. Research by the USDA indicates that multiple alternative control measures will be required to replace the many essential uses of methyl bromide. The effective application of a single alternative control measure or combination will generally be limited to a specific crop or use because specific crops have widely varying requirements and because of variations in target pests, soil types, climates, and state and local regulations.

Methyl bromide is being phased out in developed countries as follows: 25% reduction in 1999, 50% in 2001, 70% reduction in 2003, and complete phase out in 2005. In developing countries, consumption will be frozen in 2002 at 1995-98 average levels, followed by 20% reduction in 2005 and complete phase out in 2015. Exemptions for developed and developing countries include quarantine, critical uses and certain pre-shipment uses."

Since 1998, IR-4 has been focusing research on possible Methyl Bromide Alternatives (MBA) and with the phase out of methyl bromide imminent, research has been kicked into high gear. Recently, some positive results have shown promise, but with methyl bromide, it

Methyl Bromide Alternatives

Are We

is common to take two steps forward and one step back. A chemical that may show progress on one crop can easily destroy another. Finding what works and what doesn't takes time and money causing a unique collaboration from growers, researchers, registrants, and IR-4 to find solutions.

IR-4 Methyl Bromide Alternatives Manager, Jack Norton solicits participation from growers of nursery and tomato crops. On a recent visit in Florida, Jack met with Billie Caldwell and Butch Coward from Burdette Coward, a grower of cut flowers in Punta Gorda, FL. Burdette Coward contributes a number of plots for IR-4 MBA research. IR-4 arranges trials with the grower and together they decide on the number of treatments that would be required. Next, a chemical company representative visits the grower and assists with the treatment. IR-4 and the chemical companies provide the financing for the trial. "A lot of this year's trials were conducted under the worst seasonal conditions, when we got 50 inches of rain, so on a very stringent test under these conditions it's hard to separate weak from good," stated Burdette Coward production manager, Billie Caldwell. "Even though the conditions were bad, Multigard™ seemed to be a good product and K-Pam™ looks good on the heartier plants such as snap dragons, although, I couldn't use it on Asters or Queen Anne's Lace."

Growers have to be particularly conscious of the products that have been used on the site in previous growing cycles to make sure the results are actual and not due to residual methyl bromide that may have been leftover from an earlier growing season. If methyl bromide has a lasting effect, then growers should grow two or more crops without using it to feel confident about their results.

Some feel that once the phase out is complete there will be a mad scramble to find products that can be used as alternatives. One theory is to allow methyl bromide to be used on a two years to one rotation, thus giving the environment two years to recover from its use and allowing for extra research time to produce a more reliable MBA.

For now, the best we can do is use a combination of products to achieve our desired result. "The most difficult part of this research is figuring out the rate of product application for each crop. You can often get varying results with the amount of product applied," stated Dr. Rodriquez Kabana from Auburn University. He along with Dr. Jim Gilreath have been working on IR-4 research using test plots in Bradenton, FL. Dr. Gilreath has worked on over 30 products in the last ten years. Many have shown promise through early product screens; unfortunately when tested in the field, they fail. Drs. Gilreath and Kabana

"The IR-4 shows growers that a number of EPA registered products used in various combinations can replace methyl bromide based on crop yield and need to be economically and more needed to growers to use the consistent results."

- Burtleson Special Pest Management Policy, U.S. Dept. of Agriculture



This trial is an u



IR-4 HQ Special Projects Manager, Jack Norton discusses the results from a recent MBA trial with Burdette Coward Production Manager, Billie Caldwell.

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note that funding for this research is beginning to dry up. In 1990, there were 21 regional scientists working on these products, today, Dr. Gilreath works with five. He comments, "With limited funding, hard decisions are made and you must put the money with those products that are already known to have a higher probability of success and in doing so we may miss researching a better product because we have no prior research completed on that product." He continues, "The problem with finding an alternative among the products we know is, we just don't have a product that can do what methyl bromide does in terms of its ability to control a variety of pests under varying conditions. We just can't replace that, but using a more integrated approach and combining products in different stages of the plant growth cycle, seems to be providing positive results. We start by using products that have already been registered in order to eliminate the long registration process."

"The IR-4 data shows great promise that a number of EPA registered products can be used in various combinations as replacements for methyl bromide based on efficacy and crop yields," stated USDA Special Assistant for Pest Management Policy, Burleson Smith, "but we need to confirm their economic viability and more time is needed to familiarize growers on how best to use

them for consistently reliable results." Products that appear promising in many large scale strawberries and fresh market tomatoes IR-4 trials are Telone/ InLine or Chloropicrin EC. These trials are performed in the primary production areas of CA and FL and are applied as fumigants and coupled with EPA-registered weed control products like VAPAM or KAPAM (or other metam sodium based products) or the post emergence weed control products registered for weed control in tomatoes such as, Sandea from Gowan or Envoke from Syngenta. The later two products have received fast track regulatory reviews and EPA acceptances as a result of IR-4's MBA research. Performance consistency from VAPAM and KAPAM as stand alone products continues to improve as we learn better how to use these products. Smith adds, "In the interim, we need to look at research trials that rotate the cost-effective alternatives with methyl bromide treatments in order to determine whether we can achieve further reductions under the Montreal Protocol while maintaining adequate pest control."

Other products showing promise in IR-4 programs for soil application include:

- Fosthiazate from ISK Bioscience - For nematodes in tomatoes and strawberries.
- Basamid from Agro Kanesho - For weed control in combination with Telone/Inline for tomatoes and strawberries.
- MULTIGUARD™ PROTECT

from Agriguard Company, LLC - Registered in South America for control of nematodes in several crops. IR-4 trials have been directed against fungal pathogens and nematodes and unlike other products it may be applied post transplant for crop protection without causing crop injury. A label for greenhouse use of MULTIGUARD™ PROTECT is pending EPA approval. Overall performance from MULTIGUARD™ PROTECT is improved when it is applied in tank mixture with either VAPAM or KAPAM for improved weed control.

- Propozone from ABERCO - Propozone is a broad spectrum fumigant that shows promise for control of nematodes, fungal pathogens and weeds including yellow and purple nutsedge when proper rates are used. It may be applied either through drip tapes or by shanking the product into pre-formed beds.
- SEP-100 from American Pacific Corporation - A broad spectrum product but one that has given mixed results in the IR-4 trials until recently when optimal application techniques were determined.
- Iodomethane has broad spectrum pest control activity and may serve as a drop in replacement for methyl bromide.

IR-4 has also been involved in



the development of products for the protection of stored agricultural commodities. Propylene Oxide from ABERCO is a product that protects stored nutmeats, spices, and cocoa. Recently through the support of the IR-4 methyl bromide alternatives program, Propylene Oxide received EPA-accepted label amendments for the protection of stored in-shell nuts and cocoa beans. CDPR has subsequently approved these label amendments for use by California growers. Other label amendments are pending EPA-acceptance for Propylene Oxide that will benefit the spice industry by allowing a longer period of treatment exposure without increasing the amount of product used.

Are we there yet?

Not quite. While we have come a long way we still have a way to go, but advancements are coming through. The commitment of growers, registrants and funding from the industry and government will make it possible to find our way to alternatives that promote a healthy environment. To learn more contact Dr. Jack Norton, IR-4 Special Projects Manager at norton@aesop.rutgers.edu. 📍

Dr. Rodriguez Kabana (left) from Auburn University and Dr. James Gilreath, from University of Florida are pleased with the results they are seeing in this trial. However, due to growing conditions, and variability of pests, more trials need to show positive results before a successful alternative can be touted.



These two trials look promising. There is good nutsedge control behind the stake (left) where a cocktail mix of DUAL MAGNUM and ENVOKE are used for weed control and FOSTHIAZATE is used for control of nematodes. The trial on the right exhibits a broad spectrum treatment of MULTIGUARD™ PROTECT plus VAPAM.

"Fees" are the New Pesticide Registration Law at EPA

— by Sidney Jackson, Biologist Registration Division, EPA



The Office of Pesticide Programs (OPP) of the Environmental Protection Agency (EPA) previewed the new pesticide registration fee program at a one-day workshop held on March 11, 2004, in Arlington, Va. The fee program is mandated by the Pesticide Registration Improvement Act (PRIA) signed into law on January 23, 2004 by President Bush as part of the Consolidated Appropriations Act of 2004. PRIA prescribes pesticide registration fee amounts for 90 registration action categories and specifies maximum review times for each category. Provisions of PRIA began on March 23, 2004. EPA published a notice in the Federal Register, 69 FRI 2772, dated Wednesday, March 17, 2004 outlining the fees and decision time review periods established by PRIA. Steve Johnson, Acting Deputy Administrator of EPA, provided opening remarks at the workshop which was attended by an estimated 300 participants from government, industry, the public interest community and the public. Steve reiterated his long-standing support for the fee program, and stated he believes that, "PRIA serves everyone (EPA and pesticide registrants) and serves the American people well." He

emphasized the Agency's eagerness to take on the challenges of PRIA and urged all stakeholders to continue to work with EPA to implement the new statute.

Some provisions in the fee program include the following:

- Shorter decision time review periods for reduced-risk actions.
- Fee waivers for new registration actions submitted solely in connection with tolerance petitions received from the IR-4 program, provided the waiver is in the public interest.
- Fee waivers or fee reductions for some minor use actions and applications submitted by small businesses
- Fees range from \$475,000 for a new conventional active ingredient to \$50,000 for a new use of an already-registered active ingredient to the minimum fee of \$1,000 for some amendments
- Extension of the Agency's maintenance fee authority for an

additional five years, and providing funding to ensure that the tolerance reassessment and reregistration deadlines will continue to be met.

- Set-asides for worker protection and new inert ingredient review activities.

In an interview with Jim Jones, Office Director of OPP, he expressed enthusiasm about the prospects of smooth and efficient transition in implementing PRIA. He stated, "The fee program holds significant potential for increased pesticide registration program efficiencies including more predictability and increased accountability in registration decisions, and funding stability. Jim indicated that he fully expects this legislation will lead to more pesticide registration decisions being made in a more expeditious time frame. He added that, "OPP's staff and I look

forward to the challenges ahead in working with industry and other stakeholders to make the fee program effective and successful."

In addition to providing opportunity for EPA to introduce the fee program, the workshop allowed industry and public participants the chance to ask questions about the new law. Senior managers from each of the three OPP registering divisions - Antimicrobials, Biopesticides and Pollution Prevention, and the Registration Division - gave presentations on the impact of the law on their program area and answered questions from the audience. Additional workshops will be scheduled as implementation of PRIA evolves. For further information, contact the EPA "fees" website at: www.epa.gov/pesticides/fees or send an e-mail to: service.fees@epa.gov.

...waivers [will be extended] for new registration actions submitted solely in connection with tolerance petitions received from the IR-4 program, provided the waiver is in the public interest

Happy Retirement to a Good Friend

In February, IR-4 wished happy retirement to a good friend at a special dinner held in his honor. Hoyt Jamerson, the Minor Use Officer for the Environmental Protection Agency (EPA) retired at the end of December. During his 28 years of service with EPA, Hoyt helped build a valuable relationship with IR-4 that will remain a testament to his dedication.

From the beginning of his tenure, Hoyt was a

supporter of IR-4. In 1999, following the Food Quality Protection Act (FQPA), IR-4 Executive Director, Bob Holm and EPA Office of Pesticide Programs (OPP) Director, Jim Jones, agreed on forming a working group (the Technical Working Group [TWG]) for the purpose of expediting projects between the two organizations. Hoyt was appointed chair of TWG and upon the retirement of IR-4's George Markle,

Assistant Director, Dan Kunkel represented IR-4's interest. According to Dan, "Hoyt was a wizard of communications, networking and getting the right people to assist him. Additionally, his management gave him the support he needed to carry out his tasks. He also had an eye for detail, which made him very popular at the Federal Register Office." This ability allowed Hoyt to help IR-4 accomplish a significant number of successes toward its mission. This earned him a unique presentation of the IR-4 Hall of Fame Award, which is usually



EPA Minor Use Officer, Hoyt Jamerson (r) displays his Hall of Fame gift as IR-4 Assistant Director, Dan Kunkel wishes him a happy retirement.

given to someone associated directly with the IR-4 program. Some of his key successes include: coordinating OPP scientific and administrative review of all IR-4 tolerance petitions; providing technical and regulatory advice at IR-4 Food Use Workshops; playing a key support role in IR-4's Super Crop Grouping initiative; and working with IR-4 to address the challenges posed by the FQPA, resulting in over 2950 specialty crop clearances since 1998.

In retirement, Hoyt plans to spend a lot of time on his boat and he and his wife will move into their new home near the Pamlico Sound in North Carolina. Good Luck Hoyt! ▲

At ARS...

USDA/ARS Office of Minor Use Pesticides Staff Scientist, Paul Schwartz (pictured left in both photos) presents the Meritorious Service Award to Michael Klein at the ARS Liaison Representatives Committee meeting, held in Windsor Locks, CT. Leona Horst was the recipient of the Meritorious Technical Service Award, but was unable to attend. Paul (l) and IR-4 Associate Director Jerry Baron (r) congratulate Charles Krause who accepts the award on Leona's behalf. Both award winners are located at Wooster, OH. ▲



USDA-CSREES

Budget Cuts that Impact IR-4

In January, Congress reduced the IR-4 Program's CSREES budget by \$1,124,000 (from \$10,673,000 to \$9,549,000) for FY2004. This reduction came as a surprise to everyone and the Project Management Committee agreed to find ways to temporarily reduce expenses without impacting staffing levels. They agreed

that Headquarters and the four Regional offices would cut their operation expenses by \$741,640 each and the field research program budget would be cut by \$382,360. At this time, there will be no reductions in staffing due to recent attrition. However, without restoration of the budget

cuts received in FY 2004, staffing levels would have to be cut and this could occur as early as October 2004.

In the operational budget area, all parts of the program are reducing travel and other operational expenses such as supplies and equipment replacement. The impact

of these reductions will be reduced contacts with specialty crop growers and commodity groups on tours and meetings, which will impact our ability to learn about our stakeholder's pest control needs. This impact will be especially critical at the grass roots level where IR-4 will not be as able to

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Budget Cuts

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interface with liaisons and growers to obtain Project Clearance Requests, which will address their immediate crop protection concerns. IR-4 is a research service organization and the budget cuts will significantly affect the quality and quantity of our service to shareholders. Equipment purchases, especially for highly specialized analytical instrumentation, will be delayed as will upgrading equipment that is needed to detect ppm and ppb levels of crop protection products in EPA required GLP studies. Also, the

upgrading/replacement of sprayers, tractors and other important field equipment at the Field Research Centers which are part of the land grant Experiment Station system will be delayed, further postponing our GLP quality program improvements. Programmatic impacts will also be felt. The Biopesticide Research Program will be reduced \$50,000 impacting approximately 10 quality research proposals to integrate new biological products into IPM systems. The Field Research Program reduction will cut about

10 major projects that were given top Priorities (must do research) by our stakeholders at the Food Use Workshop. This will mean that over 50 crop protection chemical clearances will not be available for U.S. specialty crop growers in 2007. A new initiative with the Ornamental Program is being significantly scaled back with ornamental research being cut by approximately 40%.

The IR-4 Program is especially disappointed with the budget cut in a year when an all time record of 793 clearances were received from the EPA (a 40% increase from the previous record of 567 in 2000). In fact, the 2462 clearances obtained

the last 4 years (2000 to 2003) exceed the number of clearances granted the 20 years previous to 2000. In addition, the EPA's Section 18 data documented an economic loss avoidance of \$5.7 billion from IR-4 supported GLP programs from 1998 to 2002. A 2003 Peer Review Panel consisting of USDA, EPA, crop protection industry and commodity group experts gave the program high praise. It is IR-4's hope that these accomplishments and contributions to the specialty crop growers and their \$40 billion farmgate industry will be recognized by Congress for future funding consideration. ▲



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