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# Office Of Pesticide Programs Annual Report For FY 1997





## **FOREWORD**

Fiscal Year 1997 was truly a transition year for EPA's Office of Pesticide Programs (OPP). Not only did our program take on the sweeping changes mandated by the passage of the Food Quality Protection Act of 1996 (FQPA), but we also successfully carried out a comprehensive reorganization and hiring plan to add over 100 new employees. These substantial changes to the pesticide program are setting the stage for us to chart new territory and make meaningful improvements to the way pesticides are regulated. In so doing, we will continue to work closely with our colleagues in the Regions and vital partners in the States, Territories, and Tribal Organizations to further advance our efforts to protect the environment and safeguard the health of the American public, especially infants and children, from pesticide risks.

Considering the extensive changes to the program's infrastructure and FQPA's mandate to immediately implement its numerous requirements, the program over the last year has completed an impressive number of regulatory actions. From the reregistration of 23 older chemicals to the registration of 21 reduced risk active ingredients, as well as the addition of new partners and supporters to the Pesticide Environmental Stewardship Program and advances in worker safety, the program continues to emphasize the importance of reducing both the risk from and reliance on pesticides. These activities and countless others are described in more detail throughout this report.

An important component of our efforts throughout FY 97 was to expand even further our outreach efforts with pesticide stakeholders through three separate advisory committees established under the Federal Advisory Committee Act. The Federal Insecticide, Fungicide and Rodenticide (FIFRA) Scientific Advisory Committee, the Pesticide Program Dialogue Committee and the Food Safety Advisory Committee held more than ten large public meetings over the past year to solicit advice and feedback regarding pesticide scientific, policy, and regulatory issues, including many of the early implementation mandates of FQPA. The program's commitment to timely and meaningful public involvement will continue through the advisory committee process.

Working in the Pesticide Program is a challenging and exciting endeavor. I encourage everyone to take the time to review this report and to take advantage of the enormous amount of information available on the World Wide Web (<http://www.epa.gov/pesticides>) describing our program's many efforts to protect public health and the environment from pesticide risks.

I am impressed with the caliber of people who are dedicated to the important goals of the pesticide program. I hope this report will help bring greater understanding about our accomplishments over the past year and provide a snapshot of the many challenges that lie ahead.

Stephen L. Johnson, Acting Director  
Office of Pesticide Programs

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## TABLE OF CONTENTS

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Foreword	<u>Page</u>
The Office of Pesticides Programs: Moving Ahead	1
Implementing the Food Quality Protection Act	2
Partnerships	4
Reorganization	10
Risk Reduction	12
Outreach	14
Strengthening EPA's Science Base	16
Field Activities	19
International Activities	22
Technology	24
Appendix A - Table and Figures Showing Fiscal Year 1997 Accomplishments	
Appendix B - OPP Organizations and Contacts	
Appendix C - EPA Regional Pesticides Programs	
Appendix D - List of Acronyms	

## THE OFFICE OF PESTICIDES PROGRAMS: MOVING AHEAD

The mission of EPA's Office of Pesticide Programs (OPP) is to protect public health and the environment from the risks posed by pesticides and to promote safer means of pest control. Pesticides differ from other substances regulated by EPA because they are intentionally applied to crops and other targets, rather than byproducts of industry or other human activity. Pesticides are likely to be found in nearly every home and business in the United States, from insect repellents to weed killers to disinfectants to swimming pool chemicals. They also are used in schools, parks, hospitals, and other public places. It is a challenging and complex undertaking to run a consistent and equitable regulatory program that achieves these goals.

The environment in which OPP operates is constantly changing: new active ingredients are developed for registration; new uses are proposed; new standards are applied to old pesticides; and new information is received about the behavior of pesticides in the field. Perhaps the most significant change in recent history was passage of a new statute, the Food Quality Protection Act of 1996, which dramatically redirected the program's priorities and provided a new standard for the assessment of pesticides used on our food crops.

State and tribal agencies and many other organizations, both public and private, are vital partners. Meeting our challenge requires that we get input from and consider the needs of all Americans, without delaying the achievement of public

health and environmental protection goals. We also must be conscious of the international implications of our decisions and policies, and work to advance public health and environmental protection on a global scale.

OPP's Fiscal Year (FY) 1997 Annual Report describes progress toward meeting these challenges over the past year. The report is organized according to several key themes underlying OPP's work: implementing FQPA, partnerships, reorganization, risk reduction, outreach, science, field programs, international programs, and technology. The Appendix presents the facts and figures on FY 1997 activities, documenting measurable, concrete achievements over the past year.



Photo By Steve Delaney

## IMPLEMENTING THE FOOD QUALITY PROTECTION ACT OF 1996

On August 3, 1996, President Clinton signed into law the FQPA, the most significant piece of pesticide and food safety legislation enacted in many years. FQPA amended the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), which covers pesticide registration, use and training, and the Federal Food, Drug and Cosmetic Act (FFDCA), which regulates pesticide residues in the food supply by requiring the setting of maximum levels (called tolerances) permitted in human and animal food.

Three important new changes in FQPA were: 1) the reassessment of all existing tolerances to ensure that they meet the new safety standard; 2) developing and implementing a program for screening and testing pesticides for endocrine disruption effects; and 3) improving the antimicrobials registration process.

### Tolerance Reassessment Under FQPA

A tolerance is the maximum legal amount of a pesticide residue permissible on food. FQPA requires that EPA reassess within 10 years over 9,000 tolerances to ensure that the tolerances meet the stringent new "reasonable certainty of no harm" standard, which includes consideration of:

- ! the aggregate exposure to the pesticide (including exposure from residential pesticide uses and drinking water and dietary intake);
- ! the cumulative effects from pesticides sharing a common mode of toxicity;

- ! whether infants and children are more susceptible to the pesticide; and
- ! whether the pesticide mimics naturally occurring estrogen, or otherwise disrupts the human endocrine system.

**FQPA AND PESTICIDES:** FQPA gave EPA unprecedented opportunities to provide greater health and environmental protection by requiring OPP to:

- ! apply more stringent safety standards for pesticide residues in food;
- ! improve protection for all consumers, particularly the young;
- ! maintain minor uses;
- ! give consumers greater access to information about pesticides;
- ! accelerate registration of reduced risk pesticides and complete the reregistration of older pesticides; and
- ! encourage Integrated Pest Management (IPM) techniques.

The law sets intermediate deadlines for reassessment of these tolerances: 33 percent by August 1999, 66 percent by August 2002, and 100 percent by August 2006.

In developing the reassessment schedule, EPA is placing a priority on pesticides believed to pose the greatest potential risk to public health. These pesticides are the organophosphates, carbamates, and probable and possible human carcinogens. Also included in this first phase are the organochlorine pesticides, high-hazard inert ingredients, and other pesticide chemicals for which reregistration is substantially complete.

#### Endocrine Disruptors

Endocrine disruptors are chemicals that mimic the behavior of natural hormones. There is substantial research and discussion within the scientific community regarding potential adverse impacts caused by these chemicals. Additional research is needed to determine the extent of risk and identify those chemicals that may present a problem. To address the information gap, FQPA requires that EPA establish a mandatory endocrine disruptor screening and testing program for pesticides by August of 1998 and implement the program by August of 1999.

To assist in developing an endocrine disruptor screening and testing program, EPA established the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) in October 1996, under the Federal Advisory Committee Act. EDSTAC, which includes representatives from industry, government, environmental and public health groups, labor, and academia, as well as other interested

stakeholders, is charged with recommending an endocrine disruptor screening and testing strategy responsive to the legislative mandates of FQPA. The EDSTAC report and recommendations are expected to be issued in Spring 1998.

#### Antimicrobials Division

Antimicrobial pesticides are used to control the growth of microorganisms. They include public health antimicrobial pesticides such as disinfectants used in hospitals, households, and drinking water; wood preservatives; pesticides that prevent deterioration and fouling of such materials as paint and metalworking fluids; and certain pesticides that help prevent food borne illness.

A turning point in improving the antimicrobial pesticide registration process occurred with creation of a self-contained Antimicrobials Division. This new division reforms all antimicrobial regulatory services.

With this new division, EPA reduced the antimicrobials registration backlog from 388 at the end of December 1996 to 87 at the end of October 1997, a decrease of 77%. At the same time, EPA met all the fast track review goals for antimicrobials mandated by the amended FIFRA, by creating an Expedited Review Team that ensures fast track actions are completed on time. These accomplishments were possible largely because the new Division controls its own workflow.

To continue its streamlining activities, EPA meets regularly with antimicrobial pesticide stakeholders to obtain their suggestions for lessening the

registration burden both on EPA and on registrants, while ensuring the continued safety and efficacy of registered pesticides.

## PARTNERSHIPS

States, tribes, territories, public health agencies, growers, and commodity groups are vital partners in ensuring the safe use of pesticides.

### States

State Lead Agencies (usually, but not always, state departments of agriculture) are vital partners in pesticide regulation. In FY 1997, through the use of federal/state funded cooperative agreements, states provided essential activities in developing and implementing the endangered species, groundwater, and worker protection programs, as well as in training and certifying pesticide applicators. EPA supported states for this work with about \$12 million in cooperative agreement funds (in addition to a roughly equal amount of funding for enforcement activities). In addition, states were involved in numerous special projects and investigations, including emergency response efforts resulting from widespread methyl parathion misuse, which is discussed later in this report.

### Tribes

OPP works closely with twenty tribes which currently operate pesticide programs, and with several tribes that use pesticides but currently lack a pesticide regulatory structure. In FY 1997, OPP:

- ! supported EPA's Tribal Lands Environmental Science Scholarship Program which provides scholarships to Native American college students working toward degrees in environmental fields;
- ! supported development of a pesticide integrated pest management course to be taught at the Haskell Indian Nations University in Lawrence, KS;
- ! funded a ground and surface water course at Flathead Lake Biological Station in Polson, MT, with participation by tribes;
- ! compiled a Tribal pesticide resource document, consisting of existing Tribal pesticide laws, memoranda of understanding, and examples of certification and training plans, to provide a reference for tribes which want to develop pesticide laws and programs.

### TRIBAL FACTS

There are:

- 562 federally recognized Tribes.
- 38 million acres of tribal land that are used for grazing.
- 8 million acres of tribal land that are farmed.
- 6 million acres of tribal land that are forested.
- 164,000 American Indians involved in farming.
- 20 Tribes with pesticide programs.
- 4 Tribes with EPA approved Certification



Denise Davis splitting willow at the California Basket Weavers Gathering. Photo by Hank Meals

**SPOTLIGHT ON TRIBES:** During FY 1997, EPA Region 9 and the California Department of Pesticide Regulation encouraged a dialogue among pesticide applicators, regulators, and Native Americans on the impact of pesticide spraying on plants important to Native Americans. Agreements were made to stop roadside spraying and move to mechanical control of weeds in certain locations. Meanwhile, EPA Region 8 awarded a Community-Based Tribal Pesticide Project to the Confederated Salish and Kootenai Tribes of the Flathead Reservation located in western Montana. Under this grant, the Tribes will identify and monitor possible pesticide residues on important cultural plants, specifically bitterroot and camas and formulate recommendations for minimizing pesticide applications near cultural plant communities.

### Territories

In FY 1997, OPP also provided financial and technical assistance to the U.S. Territories for developing and implementing various pesticide programs.

### Pesticide Program Dialogue Committee

In late 1995, the Pesticide Program Dialogue Committee (PPDC) was established under the Federal Advisory Committee Act. This committee provides a forum for a diverse group of stakeholders to provide feedback to the pesticide program on various regulatory, policy, and program implementation issues. Membership includes environmental and public interest groups, pesticide user and commodity groups, public health and academic institutions, federal and state agencies, and the general public. All PPDC meetings are open to the public.



The group met four times from its inception through the end of FY 1997 to discuss a wide variety of topics, including: reduced risk pesticides, labeling, measures of success, minor uses, tolerance reassessment, outreach, ecological standards, endocrine disruptors, fees for service, and several early implementation issues resulting from the FQPA. In addition, several PPDC work groups were established with PPDC members and other external parties to further facilitate the exchange of ideas and to develop recommended options for consideration at PPDC meetings.

A renewed two-year Charter for the PPDC was approved and membership to the PPDC is being renewed for many existing members, while additional members are being added to the group.

#### New Minor Use Program

Minor use pesticides are products used on agricultural crops or sites, livestock, or for protection of public health where the total acreage in the United States is less than 300,000 acres, or the use of which does not provide sufficient economic incentive to registrants to generate the data required by EPA to support registration. These pesticides are often of major significance to consumers and growers. Without these small scale but vital pesticide uses, many of the fruits, vegetables, and ornamentals that we enjoy in the U.S., worth billions of dollars, could not be grown successfully.

FQPA requires EPA to address minor uses in a coordinated fashion. Thus, in consultation with the Pesticide Program Dialogue Committee, U.S. Department of Agriculture, and growers concerned with

minor uses, EPA designed a new approach to minor use pesticides. Under the new program, EPA set up a team of representatives from throughout OPP which reports to the Director of OPP. The minor use team has three primary goals: 1) obtaining and using the best available data to support minor use tolerances; 2) working more closely with the minor use grower community early in the regulatory process, and 3) promoting the use of safer pesticides for minor uses by urging manufacturers to research and expedite registrations for lower risk pesticides.

#### Stewardship Program

The Pesticide Environmental Stewardship Program (PESP) is a voluntary partnership between the pesticide user community and EPA. Under PESP, participants prepare and implement strategies to reduce pesticide risk among their constituents. The PESP involves:

- ! partners, who develop educational programs on new, safer pest control techniques, and research areas that could lead to the development of safer technologies.
- ! supporters, who help partners by participating in research and providing pesticide educational information to the general public; and
- ! OPP, which provides both partners and supporters with a liaison in EPA to answer questions and address pesticide issues and other EPA activities.

**SPOTLIGHT ON PESP:** Measuring success of integrated pest management (IPM) strategies is a key component of PESP. For example, under one project, a three-year crop rotation system using sustainable IPM tactics will be compared to the traditional two-year cropping system for the northern plains wheat. The project, funded by EPA Region 7, will examine indicators of environmental health, including comparisons of pest density and estimates of arthropod and small mammal diversity and abundance in the test fields and in the surrounding area. Researchers will evaluate the economic feasibility of the different cropping systems and will coordinate closely with wheat growers and grower organizations. Results from this IPM project will have broad application for dryland wheat production in the northern plains, particularly for areas affected by the Russian wheat aphid.

The PESP program continued to expand in FY 1997, adding 28 more Partners and Supporters.



### METHYL PARATHION MISUSE

Since 1994, EPA has responded to several pesticide misuse incidents occurring in Midwestern and Southern states. Those incidents involved individuals who had illegally sprayed homes and other buildings with methyl parathion, a highly toxic agricultural pesticide registered for *outdoor*

*use only*. Investigators found high levels of methyl parathion residue in homes. Based on urinalysis of residents, about 3,400 people have been relocated from their residences.

Responding to this public health emergency, which is the largest single pesticide investigation ever undertaken by EPA and the impacted states, involved tremendous interagency cooperation

between city, county, state and federal agencies on a multitude of activities. Public agencies have spent well over \$72 million to date in responding to this emergency through environmental testing, biological testing, relocation, decontamination and restoration.

The widespread misuse of methyl parathion is a real public health threat, particularly to infants and children. Symptoms of direct exposure to high levels of methyl parathion include headache, dizziness, loss of coordination, muscle twitching, tremor, nausea, vomiting, abdominal cramps, diarrhea and general weakness, blurred vision, excessive perspiration and salivation.

In an effort to significantly reduce the likelihood that such widespread misuse will happen again, the multi-agency strategy is focussing on incident response, product modifications, outreach and prevention, and enforcement and deterrence.

#### Incident Response

Three separate EPA regional offices, seven state agencies, the U.S. Agency for Toxic Substances and Disease Registry and many county/local health officials were involved in finding and testing thousands of contaminated homes, conducting health evaluations of residents, cleaning up the homes, and relocating people. Information on the health effects of methyl parathion was distributed during the response and clean-up phase. This information can be found on the OPP Home Page on the Internet.

#### Product Modifications

In December 1996, Cheminova and other registrants of methyl parathion emulsifiable concentrate pesticide products agreed to:

- ! recall unopened containers of products in which methyl parathion is the sole active ingredient;
- ! add an odoring agent to discourage illegal indoor use;
- ! repackage the product into larger containers that require special equipment to access the contents;
- ! barcode packages for tracking purposes; and
- ! limit concentration of methyl parathion to five lbs per gallon or less in all products containing methyl parathion EC as the sole active ingredient.

#### Outreach and Prevention

Cheminova agreed to launch an education program to foster good product stewardship by dealers and applicators.

Other efforts are being initiated to prevent such widespread misuse from happening again. OPP led an effort with Regional Offices, ATSDR, Office of Enforcement and Compliance Assurance (OECA), and the Office of Communication, Education and Public Affairs to develop a communication and outreach strategy which will increase awareness of pesticide risks, available safer alternatives and sources of information. The outreach effort focusses

on medical professionals, grassroots groups, and consumers.

Several key accomplishments to date include:

- ! production by Cheminova, a methyl parathion registrant, of a widely-distributed public service announcement for radio and television that urges people to read labels, not use outdoor-only pesticides indoors, and to hire only licensed applicators.
- ! development of a poster and brochure promoting safer methods of roach control;
- ! a joint letter from OPP and OECA published in the National Pest Control Association newsletter, that asks for industry assistance in identifying unscrupulous pesticide applicators and;
- ! publication of an article in the American Academy of Pediatrics newsletter regarding methyl parathion as an aggravating factor of asthma in children.

Additional outreach efforts will be implemented in FY 1998, including working with the National Parent Teachers Association to communicate information on safer pest control methods.

#### Enforcement and Deterrence

To date, 23 individuals have been arrested for their illegal pesticide operations and face prison terms if convicted. One defendant has already received a six and one

half year sentence, the longest sentence ever issued in the United States for an exclusively environmental crime. EPA will continue to vigorously prosecute any person who places people at such risk.

OECA, in cooperation with Regions 4 and 5, developed a National Urban and Residential Pesticide Control and Enforcement Program that is currently being implemented by States nationally. This program is designed to prevent future diversion and illegal structural application of agricultural pesticides by detecting points of diversion of methyl parathion or other restricted use pesticides from the agricultural sector and initiating appropriate enforcement action against the culpable parties.

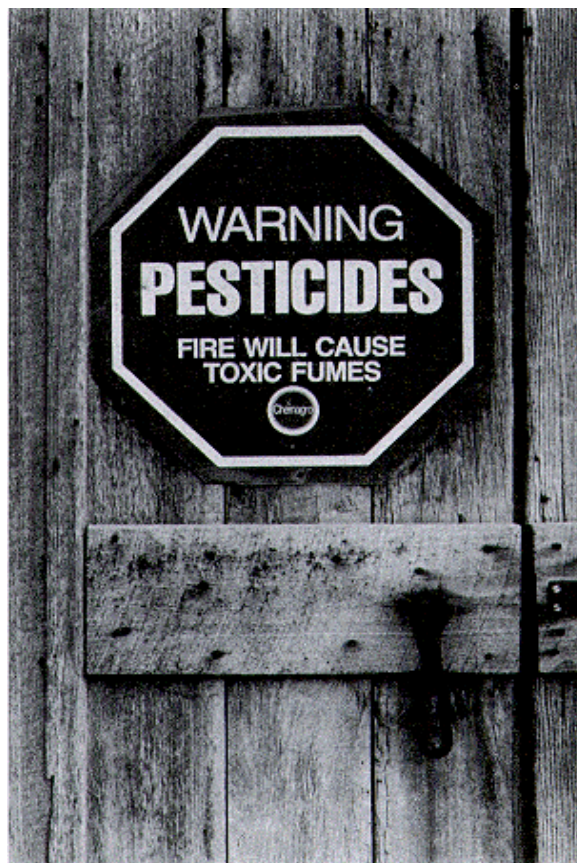


Photo by Steve Delaney



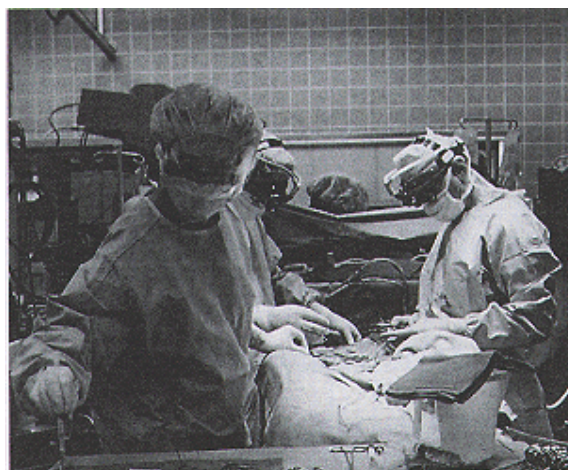
## REORGANIZATION

In FY 1997, OPP implemented the organizational realignment it had been planning for several years. Under this realignment, OPP:

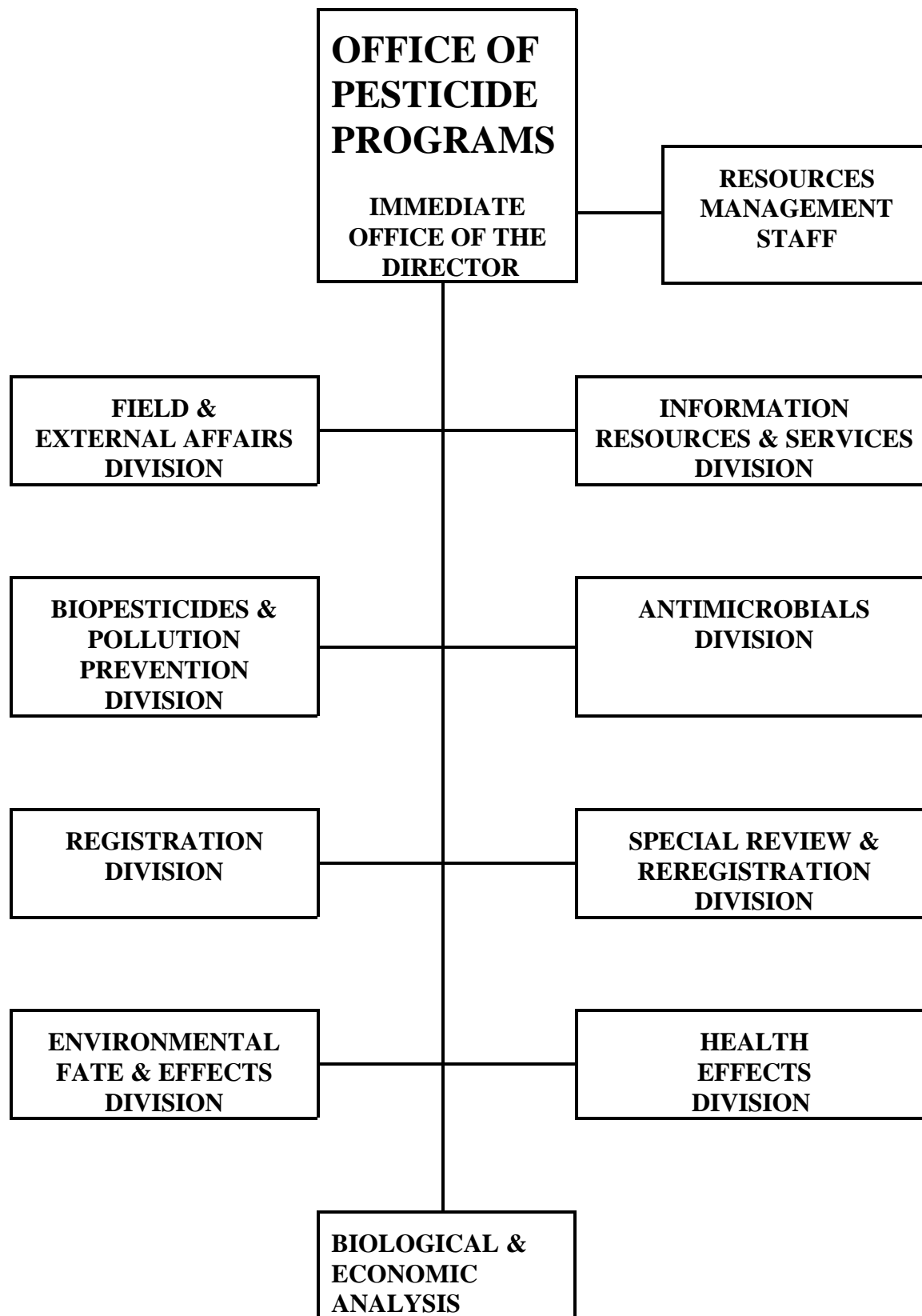
- ! reduced the number of supervisors by roughly half, with a reduction from four or five to only two levels of supervision within each division. Nearly all branches in OPP were recast at a new standard size of 12-15 employees, headed by a single supervisor. This flattening created new opportunities for additional branch chiefs while it eliminated the former branch subdivisions.
- ! created multi-disciplinary branches with a self-contained science review function. This puts the primary reviewers much closer to the regulatory decision process, reduces the number of pass-throughs and signoffs required to reach a decision, and encourages collaborative work among specialists in different disciplines.
- ! created a new Antimicrobials Division that combines risk assessment and risk management functions for antimicrobial pesticides in a single organization. The division carries out both regulatory and science functions. The new division has improved efficiency and accountability within the antimicrobials program, and it is continuing to work with stakeholders to achieve further streamlining improvements.
- ! defined a single team in each division to provide all administrative and support functions. This provides increased efficiency and increased career opportunities for specialists in administrative and support fields.
- ! consolidated information management functions in a new Information Resources and Services Division.
- ! combined the former Policy and Special Projects Staff with the Field Operations Division to form a new Field and External Affairs Division.

See the Appendix for a summary of each Division's area of responsibility.

In FY 1998, OPP is continuing to examine other ways to structure staff and processes to deliver services to the public.



The new Antimicrobials Division assures that disinfectants and certain sterilants used in operating rooms kill germs that cause infection. Photo by Steve Delaney

**OFFICE OF PESTICIDE PROGRAMS**

## RISK REDUCTION

In FY 1997, EPA continued to pursue pesticide risk reduction in a variety of ways, including expediting the registration of reduced risk products, placing conditions on registrations to reduce risk, re-registering older pesticides to meet today's safety standards, using special review authority to remove or change problem uses, and working with our partners in the field.

### Reduced Risk Products

EPA's emphasis on the registration of new reduced risk pesticides continued in FY 1997 with the registration of 19 reduced risk active ingredients.

Reduced risk pesticides fall into two classes - conventional reduced risk pesticides and biological pesticides. *Conventional reduced risk pesticides* are those that have low impact on human health, low toxicity to non-target organisms (birds, fish, and plants), low potential for groundwater contamination, lower use rates, low pest resistance potential, and are compatible with IPM. The number of conventional reduced risk pesticides registered by EPA has steadily increased each year. These include reduced risk fungicides, herbicides, and insecticides for a variety of crop and non-crop uses. Reduced risk pesticides are registered in about one-third the time required to register a conventional non-reduced risk pesticide. The average time required to register a new reduced-risk pesticide is about 14 months, compared to 38 months for a conventional pesticide.

*Biological pesticides*, naturally occurring substances with pesticidal properties, are considered reduced risk because they work by non-toxic means. In FY 1997, the average time required to register a biological pesticide was 11 months. Biological pesticides fall into three broad categories. *Microbial pesticides* contain a bacterium, fungus, virus, protozoan or alga as the active ingredient. Approximately 50 microbial pesticide active ingredients have been registered by EPA. The most widely known of these are varieties of the bacterium, *Bacillus thuringiensis* or Bt, which can control certain moths, beetles, and mosquitoes. *Plant-Pesticides* are pesticidal substances produced in a plant and contain the genetic material necessary for the production of those substances. To date, seven plant-pesticide registrations have been issued. *Biochemical Pesticides* include growth regulators and pheromones.

### Reregistration

Under FIFRA, EPA must review the human health and environmental effects of all pesticide active ingredients initially registered before November 1, 1984, to determine whether they meet today's standards. The reregistration process is addressing the potentially riskiest pesticides first. Those active ingredients that meet the standards are declared "eligible" for reregistration, as explained in a Reregistration Eligibility Decision (RED) document. REDs are designed to provide guidance to registrants for the reregistration of individual pesticide products, and usually spell out various mitigation measures that are required for the products containing a particular chemical to be reregistered. All 23 REDs completed this

fiscal year contain risk mitigation measures. For details, please see Table V.

The 171 REDs completed through the end of FY 1997 represent over 60% of the total volume of pesticide active ingredients used annually in the U.S. The remaining REDs are expected to be completed by 2002.

### Special Review

A Special Review is conducted on a pesticide when the Agency believes it poses an unacceptable risk to human health and/or the environment. In FY 1997, agreements were reached with the registrants of six chemicals through the Special Review program, in order to reduce potential pesticide risk.

These chemicals were:

- ! flowable carbofuran, a broad spectrum carbamate pesticide used against soil and foliar pests of field, fruit and vegetable crops;
- ! methyl parathion, an organophosphate insecticide used to control boll weevils and other biting or sucking insect pests of agricultural crops, primarily cotton;

**SPOTLIGHT ON SPECIAL REVIEW:** In response to EPA concerns about exposure of agricultural workers to **methamidophos**, an insecticide used on a variety of crops, Bayer Corporation and Valent USA, the methamidophos registrants, deleted all uses except cotton, potatoes, and tomatoes from methamidophos labels. The registrants also agreed to implement closed mixing and loading systems for all methamidophos products registered in the United States. EPA accepted these measures as interim risk mitigation; the remaining methamidophos uses will be evaluated during the reregistration phase. Also, in March 1997, Rhone Poulenc, in an effort to reduce dietary risk posed by **iprodione** on peaches, agreed to reduce the number of applications per use season from four to three, and to restrict application timing to the stage prior to petal fall, thereby increasing the post harvest interval (PHI) from 7 to 90 days. Although the reduction of risk resulting from these changes is not precisely quantifiable at this time, field data indicate that 99% of the residue is the result of the last application, and the company is conducting new field trials to reflect the new use rates. These label changes, as negotiated, were approved in April 1997, with relabeling of existing stocks to be completed by December 1997.

- ! copper and zinc naphthenate, which are wood preservatives;
- ! vinclozolin, a fungicide used for the control of several types of fungi in vines, strawberries, vegetables, fruit, and ornamentals. It is also used on turf grass;



- ! iprodione, a fungicide used on vegetables, ornamentals, root crops, cotton, and sunflowers; and
- ! methamidophos, an insecticide used on a wide variety of fruits and vegetables.

Risk reduction measures included voluntary cancellation of some/all uses, expanding the duration of the pre-harvest interval, special packaging and engineering controls, and spray drift labeling. (See the Appendix for all mitigation measures developed through the special review process in FY 1997).

## OUTREACH

Because the use of pesticides affects virtually everyone in the United States, it is especially important that EPA provide useful information to citizens about pesticide registration and use. In FY 1997 OPP expanded its outreach efforts by developing a consumer brochure, working on label improvements, and creating a Home Page on the World Wide Web.

### Consumer Brochure

OPP began work in FY 1997 on a brochure to inform consumers about pesticide residues on food as required by FQPA. This brochure is designed for supermarkets to distribute to the public. It will include basic information on the risks and benefits associated with pesticides and recommendations for ways consumers can reduce their dietary exposure to pesticide residues. In addition, the brochure will list benefits-based tolerances if they are set (tolerances that do not meet the "reasonable certainty of no harm" standard, but are retained because the loss of a particular use would pose even higher risks to public health, or the loss would significantly disrupt the food supply). The brochure will be available in August 1998 and annually thereafter.

As part of the development process, OPP is working with stakeholders through the Pesticide Program Dialogue Committee, and is conducting consumer research and focus groups.

### Better Pesticide Labeling

In FY 1997, EPA continued to work on improving pesticide labels, revising labeling procedures and increasing accessibility of label information.

## **IMPROVING PESTICIDE LABELS -**

The Consumer Labeling Initiative (CLI), a joint project with several Federal and State agencies, industry, and other interested parties, began in FY 1996. Its goal is to foster pollution prevention and improve consumer understanding of safe use, environmental, and health information on household consumer product labels. During its first year, the CLI conducted basic research on consumer behavior and attitudes, including one-on-one interviews with consumers; issued three Pesticide Registration Notices which permitted the use of chemical common names and phone numbers on labels; and tested revised First Aid statements with consumers.

**SPOTLIGHT ON OUTREACH:** Education and outreach to ordinary consumers can be an effective means of reducing risks from pesticide use. For example, runoff from urban and suburban users probably accounts for a significant portion of pesticide detection in wells and waste water plants. Proper use of pesticides, as part of an overall strategy of pest prevention, is crucial in order to decrease runoff of pesticides. The Fort Worth Water Department's Clean Water Program (FWWD) initiated an educational effort, funded by EPA Region 6, directed at urban residents to provide information about proper pesticide use and avoiding excessive application of pesticides. The Water Department met with area pesticide retailers to educate employees about IPM practices which they can convey to their customers to ultimately reduce pesticides. Also, brochures regarding pesticide alternatives were mailed to citizens with water bills. The FWWD has passed the water quality tests from November 1996 through September 1997. The Department credits this success to its education program.

## IMPROVING INFORMATION FLOW -

Pesticide label information must be accessible in order for it to be effective. Progress continued on a number of fronts in disseminating label information, including:

- ! revision of the Label Review Manual, which provides one source for existing regulations, policies, and other information concerning labels;
- ! creation of the Pesticide Product Label System (PPLS), which is a CD-ROM that provides users with a visual image of all EPA-stamped and accepted pesticide labels; and,

- ! announcement of the Labeling Change Coordination Policy which will help streamline the Agency's processing of labeling changes, improve the coordination of EPA's labeling activities, and lessen the economic impact on registrants and supplemental distributors who make labeling changes throughout the year.

## OPP and the Internet

OPP's Website continued to expand in FY 1997. The Website can be found at <http://www.epa.gov/pesticides>. The web is being utilized to provide practical information to consumers on the use of pesticides, as well as information to states, businesses, and children.

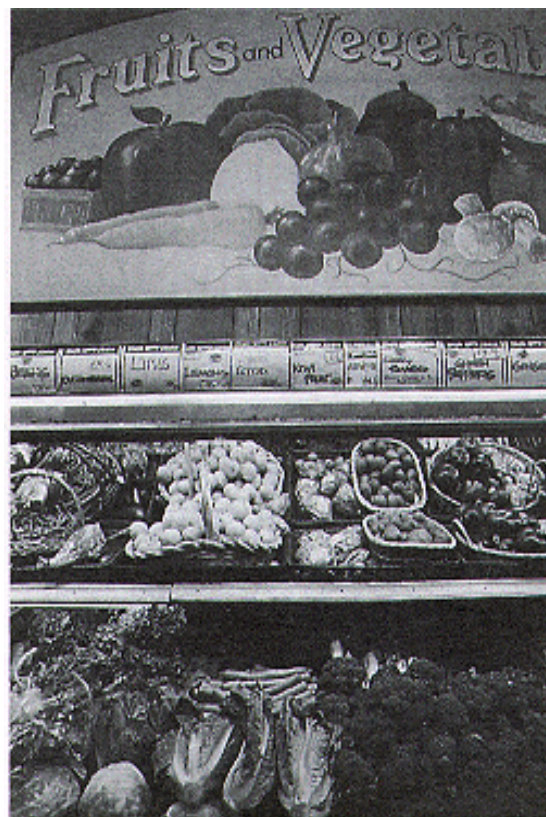


Photo by Steve Delaney

## STRENGTHENING EPA'S SCIENCE BASE

One of the Agency's core challenges has been to consistently improve the quality and soundness of the science used to support regulatory decision-making. In March 1995, EPA issued a policy committing the Agency to the core values of clarity, transparency, reasonableness, and consistency within the context of sound science and regulatory actions. In FY 1997, OPP implemented this policy in several ways.

### Ecological Risk Assessment Methods

In response to a recommendation from the FIFRA Scientific Advisory Panel (SAP), OPP began improving its ecological risk assessment by developing probabilistic risk assessments. Such an assessment would address the magnitude and probability of the expected impact as well as the uncertainty and variation involved in the provided estimates. OPP began a new initiative to achieve this goal by forming aquatic and terrestrial technical workgroups, which are composed of experts drawn from government agencies, academia, contract laboratories, environmental advocacy groups, and industry.

These workgroups will identify and develop probabilistic tools and methodologies for terrestrial and aquatic assessments. They will also identify developmental information and validation needs to ensure that the assessment process supports environmental decisions that are scientifically defensible, and will participate in nationally recognized professional meetings, such as the American Chemical Society and the Society for Environmental Toxicology and Chemistry.

### Human Health Risk Assessments

**AGGREGATE RISKS** - OPP developed interim guidance for performing aggregate exposure assessments for chemicals as required under FQPA. This guidance describes an approach to combining exposures to chemicals by multiple routes, from or through the diet, from water, and from other nonoccupational sources.

EPA's interim decision logic is based on the concept that the total level of acceptable risk to a pesticide is represented by the pesticide's Reference Dose (RfD). This is the level of exposure to a specific pesticide that a person could receive every day over a seventy-year period without significant risk of a long-term or chronic non-cancer health effect. The analogy of a "risk cup" is being used to describe aggregate exposure estimates. The full cup represents the total RfD and each use of the pesticide contributes a specific amount of exposure that adds a finite amount of risk to the cup. As long as the cup is not full, meaning that the combined total of all estimated sources of exposure to the pesticide has not reached 100% of the RfD, EPA can consider registering additional uses and setting new tolerances. If it is shown that the risk cup is full, no new uses could be approved until the risk level is lowered. This can be done by the registrant providing new data which more accurately represent the risk or by implementing risk mitigation measures.

While this explanation is focused on chronic non-cancer risk, the Agency will use a similar logic to assess acute risk and cancer risk.

This process was reviewed publicly by the SAP in March 1997. The SAP found the approach to be a good first step toward developing a policy. They provided several recommendations for next steps in the development process. OPP has continued to work toward development of a final policy on aggregate exposure, both internally and with the public and regulated community.

**CUMULATIVE RISK** - OPP also developed an approach to determine whether two or more pesticide chemicals are acting by a common mechanism of toxicity and thus are candidates for cumulative risk assessment. The proposed approach considers all available information on a group of candidate chemicals using a weight-of-evidence approach. OPP presented its approach and a case study clustering a group of structurally similar pesticides in draft form to the FIFRA SAP in March of 1997. This policy is being finalized.

**DRINKING WATER EXPOSURE** - As a result of FQPA, OPP is required to factor exposure to pesticide residues in drinking water into tolerance decision-making. During FY 1997 EPA developed and implemented an interim approach for addressing this pathway of exposure for those pesticides which have some potential to reach groundwater and/or surface water. The interim approach relies heavily on modeling (i.e., the estimation of pesticide concentrations in surface water and groundwater), because EPA lacks comprehensive drinking water monitoring data for most pesticides (comprehensive costs of collecting such data are enormous). OPP continues to evaluate options for improving its interim approach (so that its model-based estimates are more accurate), as well as options for obtaining additional drinking water monitoring data. OPP has presented its

interim approach to a Working Panel of the International Life Sciences Institute (ILSI) and is planning to present some options for improvement to the approach to the FIFRA Scientific Advisory Panel in December 1997.

**ACUTE DIETARY RISK** - OPP is currently reviewing probabilistic risk assessments of acute dietary risk from short term exposure. These assessments more closely approximate the likely risk to the public from acute dietary exposures to pesticides, by considering the probability of different combinations of exposure. The introduction of this methodology into worker and residential exposure assessments is also being explored.

**OTHER PROJECTS** - In FY 1997 OPP also:

- ! presented draft guidance on Data Requirements for Import Tolerances to the SAP;
- ! developed guidelines on conducting domestic animal safety studies, which are required prior to registration of a pesticide product proposed for direct application to domestic animals;
- ! drafted Residential Exposure Assessment Standard Operating Procedures for conducting residential exposure assessments for both handler and post-application exposures when pesticide-specific and/or site-specific field data are limited.



### EPA Analytical Support

**ASSISTANCE** - OPP assisted State and Federal laboratories with a variety of complex analytical projects. For example, in support of the Mediterranean fruit fly quarantine eradication program, OPP provided Florida State and USDA labs with water check samples to allow them to monitor for malathion and malaoxon in the environment. The laboratories also provided reference standards, analytical methods, and other assistance to state laboratory personnel. OPP laboratories also successfully responded to an urgent request for assistance from USDA and FDA to help discover the source of dioxin contamination in chickens which came from clay in feed.

### **THE ENVIRONMENTAL SCIENCE**

**CENTER** - Construction continued on a new EPA laboratory facility in Ft. Meade, Maryland. The Region 3 Annapolis laboratories, the OPP Beltsville Analytical Chemistry Laboratory, and the OPP Cincinnati Microbiology Laboratory will co-locate to the new facility upon completion in December 1998. The OPP wings will house the current operations of the two OPP laboratories as well as the analytical grade standards repository which will be transferred from the Office of Research and Development (ORD). This will result in cost savings and facility/equipment modernization.

**SPOTLIGHT ON ANALYTICAL METHOD DEVELOPMENT:** In FY 1997, reports surfaced in the Pacific Northwest that sulfonylurea (SU) herbicides were suspected of causing damage to non-target plant life. As a class, SU herbicides are effective in very small quantities, relative to other types of registered compounds. But, the fact that less active ingredient is being applied contributes to the difficulty in detecting the SUs in the environment. EPA formed a task force with industry to develop better analytical methods of detecting these effects on nontarget species, which will enable the EPA to better monitor the effects of the SUs on the environment. The task force developed five new analytical methods for soil and water. Responding to adverse effects through cooperative investigations with industry is a good example of public-private, cross-disciplinary efforts.

**EFFICACY TESTING** - Before EPA will register a public health pesticide, it reviews the submitted efficacy data to be sure that the pesticide will be effective. In FY 1997, work continued evaluating:

- ! technologies to more quickly determine efficacy of antimicrobial pesticides; and
- ! the efficacy of about 800 registered hospital disinfectants, 154 of which are registered for controlling the tuberculosis bacterium.

## FIELD PROGRAMS

EPA's Certification and Training, Endangered Species, Groundwater, and Worker Protection programs continued to be developed and implemented in FY 1997 by OPP, regional offices and state, tribal and territorial regulatory offices.

### Certification and Training

When OPP designates some or all uses of a pesticide as "restricted use," the pesticide may only be used by, or under, the direct supervision of specially trained, certified applicators. Certification programs are conducted in accordance with national standards set by OPP. All states require commercial applicators to be recertified, generally every three to five years. Some states also require recertification or other training for private, non-commercial applicators.

In 1997, OPP established the Certification and Training Advisory Group that completely reviewed the requirements for certified applicators. The group is reconsidering all aspects of applicator certification and will make recommendations for improvements on an annual basis. Other activities included the biennial pesticide applicator training workshop, and continued work on pesticide drift management and application technology.

In 1996, the most recent year for which figures are available, over 81,000 private and 66,000 commercial applicators were certified; and more than 129,000 private and 121,000 commercial applicators were recertified. There are a total of approximately 950,000 private and 360,000

commercial applicators currently certified nationwide.

In addition to traditional pesticide applicator training, the state Cooperative Extension Services initiate specialized training for various groups. For example, training is provided to private applicators on the proper use of personal protective equipment (PPE) and application equipment calibration, how to handle spill and injury situations, farm family safety, how to prevent drift and pesticide and container disposal. Other specialized training is provided to public works employees on grounds maintenance, pesticide control operators on proper insect identification and weed control for agribusiness.



Photo by Steve Delaney

**SPOTLIGHT ON ENDANGERED SPECIES:**

In the arid Trans-Pecos area of West Texas, two endangered fish, the Comanche Springs pupfish and the Pecos gambusia, are occasionally getting into the agricultural irrigation ditches near their natural habitat. As a result, EPA proposed pesticide use limitations for a fairly large area adjacent to the springs. A regional agriculture-wildlife team initiated a cooperative effort to prevent major impacts from these limitations to agricultural irrigation. The Team suggested creation of an artificial pond in Balmorhea State Park which would provide additional habitat for the endangered fish. The pond was constructed with tourism in mind. An underwater viewing area was installed to provide tourists the opportunity to safely view the endangered fish. Hundreds of thousands of endangered fish have propagated since the pond was completed. The project not only prevented extensive pesticide regulations while benefiting fish and wildlife, but it also stimulated a variety of economic and educational activities. A video documenting the approach used to develop the park was produced and is shown to other state, local and federal agencies as a success story of a cooperative team effort.

Endangered Species

The Endangered Species Protection Program, currently a voluntary program, is designed to protect endangered species from exposure to pesticides through the implementation of chemical-specific county bulletins. In FY 1997, OPP printed and distributed 89 bulletins and sent 22 draft bulletins to states for review. OPP also continued significant efforts with the

registrants' FIFRA Endangered Species Task Force to develop an information management system on endangered species that would markedly enhance endangered species risk assessments and species location data for registration and reregistration actions.

In addition to continuing work with risk assessors in OPP to address selected endangered species concerns, the program developed risk profiles on more than 300 listed plant species in FY 1997.

The Endangered Species Protection Program also has begun to provide information electronically on the Internet and through a faxback number (800-447-3813).

Groundwater

In FY 1997, states, tribes and EPA regions participated as equal partners in developing the ground water protection rule, which is intended to implement risk-reduction measures for pesticides in ground water. OPP always considers states and tribes to be its regulatory partners. However, in the past, states and tribes were not permitted to assist in regulation development after the close of the formal comment period, due to laws governing how the federal government develops regulations. With the Ground Water State/Tribal Management Plan Proposed Rule, OPP gained approval for states and tribes to work with us beyond the close of the comment period. In 1997, ten states and three tribes joined OPP's traditional regulatory review group.

**SPOTLIGHT ON COMPLIANCE:** A FIFRA cooperative agency since 1979, the New Mexico Department of Agriculture has long believed that the risks from potential or actual pesticide misuse are greater in the urban/suburban sector than in the rural/agricultural sector, due to the population density, but needed data to support that theory. Beginning in FY 1997, state inspectors used a standardized inspection checklist to cover FIFRA and State regulatory requirements, including compliance with label site, application within certification category, application rate and method, equipment integrity, and disposal. Overall, about 33 percent of all urban pesticide use inspections show some violation, although most are not “use”, or label violations. This compares to a violation rate of about 15 percent in the agricultural sector. The most common violations found in urban/suburban application sites are record-keeping (45%), unlabeled or mis-labeled rodenticide bait stations (17%), and unused or inadequate personal protective equipment (12%). Compliance Assistance activities designed to reduce these violations include training seminars for non-certified commercial applicators, state participation in training activities for certified applicators, and post-inspection reviews provided to applicators and service technicians by pesticide inspectors at the end of a formal inspection.

### Worker Protection Standard

OPP's Worker Protection Standard (WPS) for agricultural pesticides represents a major strengthening of national efforts to safeguard agricultural workers. WPS requires agricultural employers to ensure that

employees receive basic pesticide safety training and to notify them when pesticides are applied. Employers also must provide washing supplies if workers are likely to come into contact with pesticides, and provide and maintain protective equipment. Implementation of the WPS is lowering the risk of pesticide poisonings among agricultural workers and pesticide handlers.

In FY 1997, OPP issued the National Dialogue Report - Part I, a summary and transcript of the nine public meetings held in FY 1996. Part II, a strategic plan for the further efforts on the WPS will be issued.

OPP also continued to refine WPS requirements to increase flexibility and to remove unnecessary restrictions (e.g., issuing a proposal to modify glove requirements and an exception to rose growers for harvest activities).



Photo by Carol Parker



## INTERNATIONAL ACTIVITIES

OPP continued to provide leadership in FY 1997 in international efforts to harmonize pesticide standards and regulatory procedures. OPP's objective is to promote improved environmental protection world-wide and to ensure that international trade initiatives and agreements are consistent with the high level of protection afforded by EPA's pesticide laws.

In FY 1997, partnerships with both developed and developing countries allowed OPP to promote public health and environmental protection on a global scale, share the work of reviewing data with other countries, reduce trade barriers and regulatory burdens, and help ensure that imported food is safe. FY 1997 international efforts can be grouped into three broad categories: (1) policy, (2) programmatic, and (3) capacity building.

### Policy Coordination

**INTERGOVERNMENTAL FORUM ON CHEMICAL SAFETY (IFCS)** - In FY 1997, the IFCS continued to build international consensus on the need to minimize use of twelve persistent organic pollutants. Intergovernmental negotiations on a global control mechanism will begin in 1998. IFCS has also been instrumental in building consensus to turn the UN Prior Informed Consent (PIC) procedures into a legally-binding instrument. PIC procedures relate to international information exchange on the export and import of banned and severely restricted chemicals.

**CODEX** - OPP supported the work of the Codex Alimentarius Commission, a joint program of the UN Food and Agriculture

Organization and World Health Organization that sets international standards for pesticide residues in foods. Many countries rely on Codex in setting their national food safety standards. The U.S. is working with the organization to improve the scientific basis and timeliness of Codex decisions, and to boost public participation in the Codex decision-making process.

### **NORTH AMERICAN COMMISSION ON ENVIRONMENTAL**

**COOPERATION** - On a regional level, the North American Commission on Environmental Cooperation provided an important forum for EPA's efforts to deal with chemical pollutants of concern to Canada, Mexico, and the United States. The Commission approved regional action plans to reduce the use of DDT and chlordane throughout North America.

### Program Activities

In FY 1997, OPP expanded its harmonization and cooperation work through the Organization for Economic Cooperation and Development's (OECD) Pesticide Forum. Building upon work by the European Union, OECD members are developing harmonized procedures for electronic data submission and standardized data submission and evaluation formats. OPP began participation in a three-year OECD risk-reduction program (1997-1999), to harmonize the regulation of biocides and to establish internationally harmonized chemical classification and labeling by the year 2000.

Cooperative work with Canada and Mexico under the North American Free Trade Agreement Technical Working Group on Pesticides increased in FY 1997. The first joint review of a reduced risk chemical pesticide is currently in progress in the U.S. and Canada, and the joint review process has now been extended to microbial and pheromone products. Significant progress has been made in the harmonization of data requirements between Canada and the United States.

#### Capacity-Building Activities

To improve environmental protection world-wide, industrialized countries with well-established regulatory programs are working with developing countries to help improve their ability to regulate pesticides and to manage chemical production, distribution, use, and disposal. In 1997, OPP activities included:

- ! development of a training course on the management and disposal of obsolete pesticides in developing countries. The course was first delivered in Honduras in May 1997 and is expected to be used throughout Central America;
- ! working with the Indonesian Ministry of Agriculture to improve the regulation of pesticides in Indonesia. One objective of this work is to develop a regional pesticide information network to be shared by seven Asian countries;

- ! coordinating efforts with international development agencies in Central America for harmonizing pesticide standards and building institutional capacity for pesticide regulation; and
- ! helping Central American countries strengthen regulatory institutions for improved control over the importation, distribution, use and disposal of pesticides and promote policies for safe pesticide use practices.

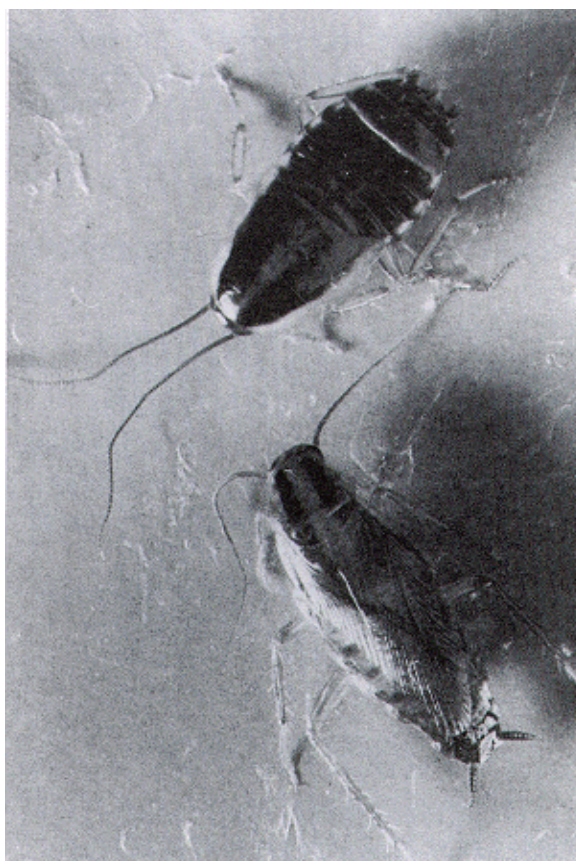


Photo by Steve Delaney

## TECHNOLOGY

In FY 1997, OPP continued to take advantage of innovations in technology in order to achieve greater efficiencies by purchasing state-of-the-art computers, integrating its numerous databases, and providing more opportunities for electronic submission by registrants and states.

### Computer Infrastructure Improvement

OPP invested significantly in improving its computer infrastructure. Approximately 50 percent of existing inventory was replaced by new Pentiums installed on desktops, and an additional 50 percent were upgraded with additional memory and enhanced operating systems. All Local Area Network (LAN) file servers, routers, and gateways were upgraded with new hardware. All file servers were reconfigured to conform to Agency standards.

### Database Integration

OPP made significant progress toward integrating its main databases containing information about pesticide products, chemicals, companies and studies. Groundwork has been laid to migrate this information from a mainframe computer to the Local Area Network, into a fully relational database, a step that will provide OPP staff with more flexible and more convenient access.

### Electronic Submission

OPP began work to develop computer software which will allow the electronic submission of pesticide registration documents and information.

This effort is being done in cooperation with the Canadian Pest Management Regulatory Agency, the Canadian Crop Protection Institute, the European Community and the European Crop Protection Association. EPA is adapting for Agency use a system called Computer Aided Dossier and Data Supply (CADDY) developed by the European Commission and the European pesticide industry.

### **SPOTLIGHT ON TECHNOLOGY:**

Under the federal certification program, all persons applying restricted use pesticides must be certified under an EPA-approved program, which is generally administered by states. Since thousands of people are certified annually, the states shoulder a large administrative burden. Technology is rapidly turning the certification process into a more manageable job. For example, upgraded software was distributed to Region 8's pesticide state lead agencies and pesticide coordinators (Extension Service) under the new title Parsystem. This new program is an integrated system designed to assist in the development of tests, scoring and analyzing of tests, maintaining records, managing grades, and tracking attendance. In addition, Virginia currently has similar technology in operation, and the remainder of Region 3 states are considering implementation of this system for private applicator testing.

**APPENDIX A****TABLES AND FIGURES OF OPP'S FISCAL YEAR 1997 ACCOMPLISHMENTS**

Table I	Pesticide Active Ingredients Registered in FY 1997
Table II	Registration of Safer Chemicals
Table III	Registration Decisions versus Targets in FY 1997
Figure I	Reregistration Eligibility Decisions (REDs) Issued in FY 1997
Figure II	Product Reregistration Status
Table IV	Risk Reduction Through Special Review
Figure III	Outcome of 6(a)(2) Submissions Warranting Expedited Review
Table V	Risk Reduction Measures Required in FY 1997 Registration Eligibility Decisions
Table VI	Pesticide Environmental Stewardship Program Partners and Supporters

**TABLE I**  
**PESTICIDE ACTIVE INGREDIENTS REGISTERED**  
**IN FY 1997**

Of the 28 new active ingredients registered, 19 are reduced risk pesticides (including 15 are biopesticides) and 2 are antimicrobials. (For purposes of this chart, reduced risk pesticides are those that have low risk to human health, low toxicity to non-target organisms (birds, fish, and plants), low potential for groundwater contamination, lower use rates, low pest resistance potential, are compatible with IPM, or are biopesticides; non reduced risk pesticides have been evaluated, they do not pose unreasonable adverse effects, but may have the potential to cause greater harm than reduced risk pesticides if not used properly.)

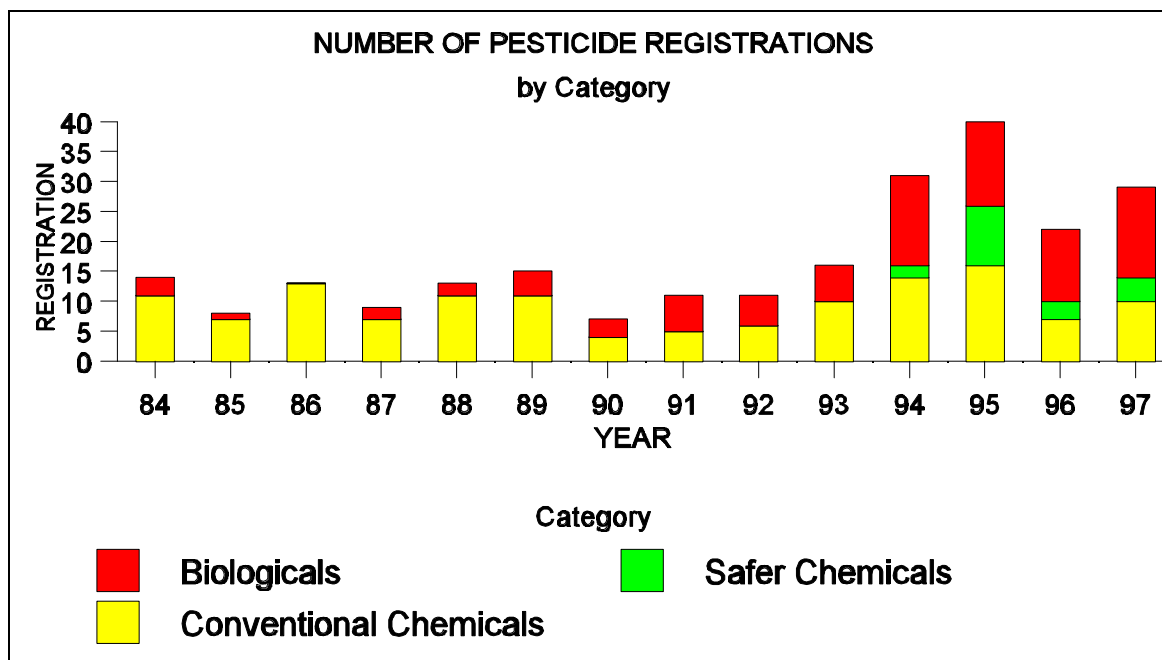
PESTICIDE NAME	TYPE	CLASS	USES	REDUCED RISK?
acetic acid	herbicide	biopesticide	ornamental turf	yes
alpha-metolachlor	herbicide	conventional	all metalachlor uses	yes
AVG	plant growth regulator	biopesticide	apples and pears	yes
azoxystrobin	fungicide	conventional	fruits and vegetables	yes
bacillus cereus	plant growth regulator	biopesticide	cotton	yes
Bt K	microbial insecticide	biopesticide	field crops	yes
burkholderia cepacia isolate	fungicide	biopesticide	vegetables/ornamentals	yes
cis-11-tetradecenyl acetate	pheromone	biopesticide	technical	yes
clofencoet	herbicide	conventional	wheat	no
copper octanoate	fungicide	conventional	field, fruit, and ornamentals	no
cyclanilid	fungicide	conventional	cotton	no
daza technical	insecticide	biopesticide	technical	yes
dekalb Bt corn	plant-pesticide insecticide	biopesticide	corn	yes
German cockroach pheromone	pheromone	biopesticide	cockroach control	yes
halofenozide	insecticide	conventional	turf	no
imazamox	herbicide	conventional	soybeans	yes
iron phosphate	molluscicide	biopesticide	home, gardens	yes
Lepinox-genetically altered Bt	insecticide	biopesticide	technical	yes
Plant Extract 620	plant growth regulator	biopesticide	fruits and vegetables	yes
polyoxin	fungicide	biopesticide	turf	yes
primicarb	insecticide	conventional	alfalfa	no
silver oxide	disinfectant	anti microbial	swimming pools	n/a
spinosad	insecticide	conventional	cotton, turf	yes
sulfentrazone	herbicide	conventional	soybeans	no
suttocide A	preservative	anti microbial	preservative	n/a
thiazapyr	herbicide	conventional	citrus	no
trans-11-tetradecenyl acetate	pheromone	biopesticide	technical	yes
Yieldgard Bt corn	plant-pesticide insecticide	biopesticide	corn	yes



TABLE II

## REGISTRATION OF SAFER CHEMICALS

The proportion of pesticide active ingredients that are considered to be safer (including biological chemicals) than conventional chemical pesticides has steadily increased over the past several years, as the chart below indicates.



**TABLE III**  
**REGISTRATION DECISIONS VERSUS TARGETS IN FY 1997**

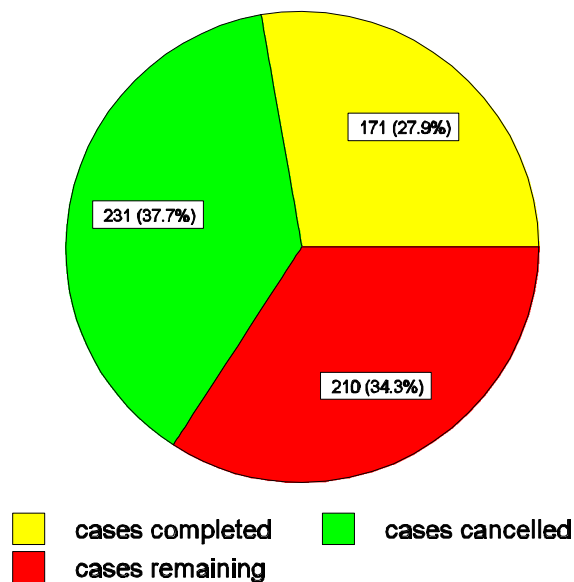
The following table summarizes, by action, the number of decisions that were made in the Office of Pesticide Programs versus the target, or goal that the program anticipated could be made. The target numbers are determined by anticipating market influences and taking into account past trends.

REGISTRATION CATEGORY	OPP TOTAL	
	Targets	Decisions
Me-too's (Fast Track) <sup>1</sup>	625	589
Me-too's (Non-Fast Track)	163	352
Amendments (Fast Track)	3100	3273
Amendments (Non-Fast Track)	141	387
New Uses	104	84
New Active Ingredients	21	28
Experimental Use Permits	66	14
Tolerances	67	43
Temporary Tolerances	40	2
Inerts (non-active ingredients)	33	25
Section 18 Decisions	398	384
Section 18 Tolerances	0	87
Special Local Needs	235	290
Biotech Notification	3	5
<b>TOTALS</b>	<b>4996</b>	<b>5564</b>

<sup>1</sup>The term "me-too" product refers to a pesticide product that is identical or substantially similar to another pesticide product that is currently registered by EPA.

**FIGURE I****REREGISTRATION ELIGIBILITY DECISIONS (REDs) COMPLETED IN FY 1997**

EPA presents the results of its reregistration reviews in Reregistration Eligibility Decision (RED) documents. EPA has completed REDs for 171 cases (groups of related active ingredients). Twenty-three of these REDs were completed during FY 1997. In addition, 231 cases have been canceled. Out of a universe of 612 reregistration cases, 402 cases (66%) have completed the process, leaving 210 REDs (34%) to be completed by the year 2002.



**FIGURE II****PRODUCT REREGISTRATION STATUS**

While REDs are OPP's major reregistration output, much of the real world impact of eligibility decisions and risk reduction requirements does not occur until products are reregistered. As of October 1997, OPP has reregistered 923 products, granted 1,818 voluntary cancellations, amended 55 registrations, and suspended about 146 products. In addition, about 2,500 reregistration decisions are pending, and 1,148 of these products have recently entered this final phase.

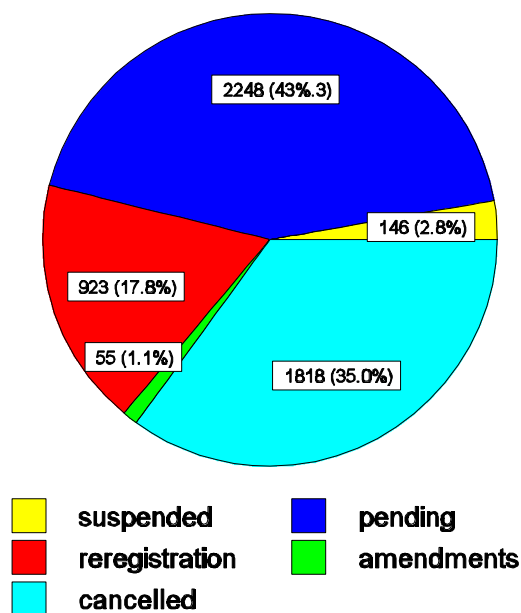


TABLE IV

## RISK REDUCTION THROUGH SPECIAL REVIEW

The following chart shows risk mitigation measures developed in FY 1997 through the special review process.

FY 97 RISK REDUCTION THROUGH SPECIAL REVIEW BRANCH						
Risks Mitigation Measures	Pesticide					
	Carbofuran (Flowable)	Copper & Zinc Naphthenate	Iprodione	Methamido-phos	Methyl Parathion	Vinclozolin
	Risks to workers and wildlife	Malodorous Off-Gassing	Dietary risk, especially on peaches	Risks to workers	Organophosphate, acute human poisoning risks	Dietary and residential risks
Use Reduction	X		X			X
Voluntary Cancellation, Some/All Uses	X			X		X
Post Harvest Interval Added			X			
Special Packaging/Engineering Controls	X			X	X	
Stronger Use Directions		X				
Spray Drift Labeling	X					
Environmental Safeguards	X					
Reduction of Risk to Children		X			X	X
Other Special Measures		X			X	



TABLE V

**RISK REDUCTION MEASURES REQUIRED IN  
FY 1997 REGISTRATION ELIGIBILITY DECISIONS**

<b>RED</b>	Voluntary Cancellation / Some Uses Not Yet Eligible	Limit Amount, Frequency, Timing of Use	Residential / Kids' Risks Addressed	Application Restrictions	Restricted Use Pesticide	Personal Protective Equipment/ Re-entry Interval	User Safety Requirements, Recommendations	Special Packaging; Engineering / Production Controls	Ground or Surface Water Safeguards	Spray Drift Labeling	Other Environmental Safeguards	Ecological Safeguards	Other	Tolerances Reassessed
<b>Bt</b>						✓		✓		✓	✓		*	✓
<b>Butralin</b>				✓		✓	✓							
<b>Dichlobenil</b>	✓	✓	✓	✓		✓	✓							✓
<b>Diffubenzuron</b>				✓		✓	✓		✓	✓		✓		✓
<b>Diphenylamine</b>				✓		✓	✓					✓		✓
<b>IPBC</b>	✓			✓		✓	✓				✓	✓		
<b>MBT</b>	✓			✓		✓	✓	✓			✓			
<b>Metribuzin</b>		✓		✓		✓	✓		✓	✓				✓
<b>Pendimethalin</b>		✓	✓	✓		✓	✓	✓		✓	✓			✓
<b>PNP</b>	✓✓			✓		✓	✓							
<b>Propoxur</b>				✓		✓	✓					✓		✓
<b>Rodenticides (6)</b>	✓✓		6 ✓	6 ✓	6 ✓		6 ✓						**	

RED	Voluntary Cancellation / Some Uses Not Yet Eligible	Limit Amount, Frequency, Timing of Use	Residential / Kids' Risks Addressed	Application Restrictions	Restricted Use Pesticide	Personal Protective Equipment/ Re-entry Interval	User Safety Requirements, Recommendations	Special Packaging; Engineering / Production Controls	Ground or Surface Water Safeguards	Spray Drift Labeling	Other Environmental Safeguards	Ecological Safeguards	Other	Tolerances Reassessed
Sulprofos	✓✓													✓
Terbacil				✓		✓			✓					
Thiobencarb				✓		✓	✓	✓		✓				✓
Triclopyr		✓	✓	✓		✓	✓		✓	✓				✓
Triethylhexa-hydro-s-triazine		✓		✓		✓	✓	✓			✓	✓		
Zinc Phosphide			✓	✓	✓	✓	✓				✓	✓	***	✓
TOTAL	6	5	10	21	7	16	20	5	4	6	6	12	3	11

✓ = Some Uses Not Yet Eligible (3)

✓✓ = One case, Pival, is Not Eligible (1)

✓✓✓ = Voluntary Cancellation of All Remaining Uses (2)

\* = Efficacy Data Required for Public Health Uses

\*\* = 2-Phase Program for Short and Long Term Risk Reduction

\*\*\* = 2-Phase Program as for Rodenticides

### FIGURE III

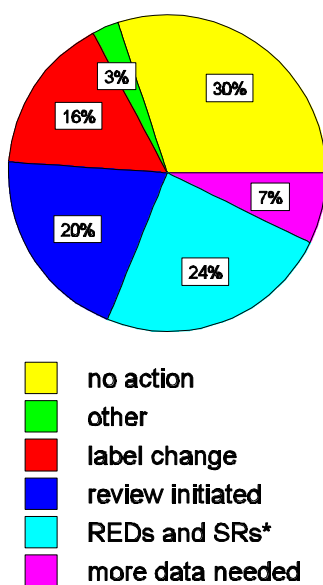
#### OUTCOME OF 6(A)(2) SUBMISSIONS

FIFRA Section 6(a)(2) requires registrants to notify OPP of any studies, incidents or other information indicating adverse effects of registered pesticides. This information helps OPP decide what action, if any, is necessary to reduce the risks posed by a particular pesticide

*Incidents.* In FY 1997, the volume of reported incidents increased over the prior year. OPP received approximately 1,800 submissions containing more than 12,000 incidents.

*Studies.* OPP screened 375 adverse effects submissions consisting of studies and preliminary reports of possible adverse effects. About 15 percent of these submissions warranted expedited review and are further tracked.

The outcome of expedited reviews since 1992 are as follows. About 40 percent will result, or has resulted, in regulatory action (either immediate through label changes, or long-term through re-registration eligibility decisions or special review), about 30 percent needed no action, and about 27 percent are still being reviewed for possible regulatory action. Detailed information regarding the screening decisions and outcome of submissions warranting expedited review is available in the OPP Public Docket.



\* The risk issues presented by these data are addressed by an upcoming Reregistration Eligibility Decision (RED) or Special Review.

**TABLE VI**  
**PESTICIDE ENVIRONMENTAL STEWARDSHIP PROGRAM**  
**PARTNERS AND SUPPORTERS**

**EXISTING PARTNERS**

American Corn Growers Association  
 American Electric Power Service Corp.  
 American Mosquito Control Association  
 American Nursery and Landscape Assoc.  
 Arizona Public Service  
 Atlantic Electric  
 California Citrus Research Board  
 California Pear Advisory Board  
 California Pear Growers  
 California Tomato Board  
 Carolina Power & Light  
 Cranberry Institute  
 Delmarva Power  
 Duke Power Company  
 Eastern Utilities  
 Edison Electric Institute  
 Florida Fruit & Vegetable Association  
 Global Integrated Pest Management  
 Golf Course Superintendents Association  
 Hawaii Agriculture Research Center  
 Hood River Grower-Shipper Association  
 Mint Industry Research Council  
 Monroe County School Corporation  
 National Potato Council  
 New England Vegetable & Berry Growers  
 New York State Gas & Electric  
 Northern Indiana Public Service Corporation  
 Northwest Alfalfa Seed Grower Assoc.  
 New Oregon Wheat Growers League  
 Owen Specialty Services, Inc.  
 Pear Pest Management Research Fund  
 Pebble Beach Company  
 Pennsylvania Electric  
 Pennsylvania Power & Light  
 Pennsylvania Rural Electric Association  
 Pineapple Growers Association of Hawaii  
 Processed Tomato Foundation  
 Professional Lawn Care Association of  
 American  
 South Dakota Cattlemen's Association  
 Sun-Maid Growers of California  
 Tennessee Valley Authority  
 Texas Pest Management Association  
 U.S. Apple Association

U.S. Department of Defense  
 Utilicorp United  
 VA, MD & DE Association of Electric Coop.  
 Vegetation Managers, Inc.  
 West Virginia Power  
 Winter Pear Control Committee  
 Wisconsin Ginseng Growers Association  
 Wisconsin Public Service Corporation

**EXISTING SUPPORTERS**

Aquimix, Inc.  
 Bay Area Stormwater Management Agencies  
 Campbell Soup Company  
 Del Monte  
 Farm\*A\*Syst / Home\*A\*Syst  
 Gempler's Inc

**NEW PARTNERS**

Almond Board of California  
 American Pest Management, Inc.  
 California Pistachio Commission  
 California Prune Board  
 Central Maine Power Company  
 Chevy Chase Village  
 City of Davis, CA  
 Delta Pest Control  
 Environ "Pest Elimination" Inc.  
 Filmore Citrus Protective District  
 Griggs County 319 Water Quality Project  
 Hawaiian Electric Company  
 Lodi-Woodbridge Wine Grape Comm.  
 Michigan Cherry Committee  
 New Orleans Mosquito Control Board  
 New York Berry Growers Association  
 Northwest Alfalfa Seed Grower Assoc.  
 New Oregon Wheat Growers League  
 Owen Specialty Services, Inc.  
 Pacific Coast Producers  
 Pear Pest Management Research Fund  
 Pennsylvania Electric  
 Pennsylvania Power & Light  
 Pennsylvania Rural Electric Association  
 Pest Police Pest Control  
 Pineapple Growers Association of Hawaii  
 Planet Pest Products Corporation  
 Processed Tomato Foundation

**Professional Lawn Care Association of Amer.**  
**Redi National Pest Elimination**  
**Reliable Pest Control**  
**Sanitary Exterminating Co.**  
**South Dakota Cattlemen's Association**  
**South Texas Cotton and Grain Association**  
**Sun-Maid Growers of California**  
**Sunkist Growers**  
**Tennessee Valley Authority**  
**Texas Pest Management Association**  
**U.S. Apple Association**  
**U.S. Department of Defense**  
**U.S. Public Health Service - CDC**  
**University of Georgia**  
**Utilicorp United**  
**VA, MD & DE Association of Electric Coop.**  
**Vegetation Managers, Inc.**  
**West Virginia Power**  
**Winter Pear Control Committee**  
**Wisconsin Ginseng Growers Association**  
**Wisconsin Public Service Corporation**

**NEW SUPPORTERS**

**Association of Applied Insect Ecologists**  
**Audubon Cooperative Sanctuary System**



## **APPENDIX B OPP DIVISIONS AND CONTACTS**

### **Office of the Director**

**703-305-7090**

**Marcia Mulkey, Director**

**Stephen Johnson, Deputy Office Director**

**Responsible for overall management of the Office of Pesticide Programs.**

### **Antimicrobials Division**

**703-308-6411**

**Frank T. Sanders, Director**

**William Jordan, Associate Director**

**Responsible for all regulatory activities associated with antimicrobial pesticides, including product registrations, amendments, and reregistrations.**

### **Biological and Economic Analysis Division**

**703-308-8200**

**Sherri Sterling, Acting Division Director and Associate Director**

**Responsible for assessment of pesticide use and benefits; operation of analytical chemistry and antimicrobial testing laboratories**

### **Biopesticides and Pollution Prevention Division**

**703-308-8712**

**Janet Andersen, Director**

**F. Kathleen Knox, Associate Director**

**Responsible for risk/benefit assessment and risk management functions for microbial pesticides; tolerance reassessment; biochemical pesticides; plant pesticide and Pesticide Environmental Stewardship Program**

### **Environmental Fate and Effects Division**

**703-305-7695**

**Joseph Merenda, Director**

**Denise Keehner, Associate Director**

**Responsible for evaluating and validating environmental data submitted on pesticide properties and effects.**

### **Field and External Affairs Division**

**(703) 305-7102**

**Anne Lindsay, Director**

**Jay Ellenberger, Associate Director**

**Responsible for program policies and regulations; legislation and Congressional interaction; regional, state, and tribal coordination and assistance; international and field programs; and communication and outreach activities.**

### **Health Effects Division**

**(703) 305-7351****Margaret Stasikowski, Director****Stephanie Irene, Associate Director****Responsible for reviewing and validating data on properties and effects of pesticides, as well as characterizing and assesses exposure and risks to humans and domestic animals.****Information Resources and Services Division****(703) 305-5440****Linda Travers, Director****Richard Schmitt, Associate Director****Responsible for information support; Public Docket; records computer support; FIFRA section 6(a) (2) issues; pesticide incident monitoring; and National Pesticides Telecommunications Network.****Registration Division****(703) 305-5447****Jim Jones, Director****Peter Calkins, Associate Director****Responsible for product registrations, amendments, reregistrations, tolerances, experimental use permits, and emergency exemptions for all pesticides not assigned to BPPD or AD.****Special Review and Reregistration Division****(703) 308-8000****Lois Rossi, Director****Jack Housenger, Associate Director****Responsible for Reregistration Eligibility Decisions (REDs), product reregistration; tolerance reassessment; and Special Reviews.**

**APPENDIX C**  
**EPA REGIONAL PESTICIDES PROGRAMS**

**EPA Region 1****JFK Federal Building****Boston, MA 02203****Telephone: (617) 565-3420****Fax: (617) 565-3415****EPA Region 2****2890 Woodbridge Ave****Edicson, NJ 08837****Telephone: (212) 637-3000****Fax: (212) 637-5046****EPA Region 3****841 Chesnut Building****Philadelphia, PA 19107****Telephone: (215) 566-5000****Fax: (215) 566-5103****EPA Region 4****Atlanta Federal Center - 12th Floor****61 Forsyth Street, S.W.****Atlanta, GA 30303-3104****Telephone: (404) 562-9900****Fax: (404) 562-8174****EPA Region 5****77 W. Jackson Blvd.****Chicago, IL 60604****Telephone: (312) 353-2000****Fax: (312) 353-1120****EPA Region 6****1445 Ross Ave****Dallas, TX 75202****Telephone: (214) 665-6444****Fax: (214) 665-2146****EPA Region 7****726 Minnesota Ave****Kansas City, KS 66101****Telephone: (913) 551-7000****Fax: (913) 551-7976****EPA Region 8****999 18th Street, Suite 500****Denver, CO 80202-2466****Telephone: (303) 312-6312****Fax: (303) 312-6363****EPA Region 9****75 Hawthorne Street****San Francisco, CA 94105****Telephone: (415) 744-1305****Fax: (415) 744-1073****EPA Region 10****1200 Sixth Avenue****Seattle, WA 98101****Telephone: (206) 553-0149****Fax: (206) 553-0163**

## APPENDIX D LIST OF ACRONYMS

<b>AD</b>	<b>Antimicrobials Division</b>
<b>ARS</b>	<b>Agricultural Research Service</b>
<b>BBPD</b>	<b>Biopesticides and Pollution Prevention Division</b>
<b>BEAD</b>	<b>Biological and Economic Analysis Division</b>
<b>CADDY</b>	<b>Computer Aided Dossier and Data Supply</b>
<b>CDPR</b>	<b>California Department of Pesticide Regulation</b>
<b>CLI</b>	<b>Consumer Labeling Initiative</b>
<b>DDT</b>	<b>Dichloro diphenyl trichloroethane (DDT)</b>
<b>EFED</b>	<b>Environmental Fate and Effects Division</b>
<b>EIIS</b>	<b>Ecological Incident Information System</b>
<b>FDA</b>	<b>Food and Drug Administration</b>
<b>FEAD</b>	<b>Field and External Affairs Division</b>
<b>FFDCA</b>	<b>Federal Food, Drug and Cosmetic Act</b>
<b>FIFRA</b>	<b>Federal Insecticide, Fungicide, and Rodenticide Act</b>
<b>FQPA</b>	<b>Food Quality Protection Act</b>
<b>HED</b>	<b>Health Effects Division</b>
<b>IFCS</b>	<b>Intergovernmental Forum on Chemical Safety</b>
<b>IPM</b>	<b>Integrated Pest Management</b>
<b>IRSD</b>	<b>Information Resources and Services Division</b>
<b>LAN</b>	<b>Local Area Network</b>
<b>NAFTA</b>	<b>North American Free Trade Agreement</b>
<b>NTIS</b>	<b>National Technical Information Service</b>
<b>OECD</b>	<b>Organization for Economic Cooperation and Development</b>
<b>OPP</b>	<b>Office of Pesticide Programs</b>
<b>PDSL</b>	<b>Pesticide Data Submitters List</b>
<b>PESP</b>	<b>Pesticide Environmental Stewardship Program</b>
<b>PIC</b>	<b>Prior Informed Consent</b>
<b>POPs</b>	<b>Persistent Organic Pollutants</b>
<b>PPDC</b>	<b>Pesticide Program Dialogue Committee</b>
<b>RD</b>	<b>Registration Division</b>
<b>RED</b>	<b>Reregistration Eligibility Decision</b>
<b>SRRD</b>	<b>Special Review and Reregistration Division</b>
<b>USDA</b>	<b>United States Department of Agriculture</b>
<b>WPS</b>	<b>Worker Protection Standard</b>