United States
Environmental Protection
Agency

Prevention, Pesticides,
and Toxic Substances
(7506C)

EPA 735-R-95-001
January 1995

EPA

# Office of Pesticide Programs Annual Report for 1994

# Foreword

EPA's Office of Pesticide Programs (OPP) has been entrusted with an important responsibility: safeguarding the health of the American public and the environment from risks that may be caused by pesticides. OPP also must make sure that pesticides are regulated fairly and help ensure that effective measures for controlling pests are available. OPP has assembled a diverse and talented team of employees to manage these responsibilities. This report is intended to explain how OPP is using its resources to accomplish its mission.

From this report, several themes emerge:

- *Partnerships and Teamwork*: OPP cannot oversee pesticides by itself. EPA's regional offices and the state and tribal pesticide regulatory agencies have a fundamental role in implementing and enforcing pesticide policies and educating the public. Other important partners include the pesticide industry and users, environmental and public interest groups, the news media, additional EPA programs, and other federal and international agencies. And ultimately, all of us are partners because the personal choices that we make in using pesticides are important factors affecting pesticide risks.

- *Customer Service, Streamlining, and Reinventing OPP*: Many projects are underway to help OPP serve its partners and other "customers" more efficiently and effectively, and to better protect public health and the environment. OPP strives to make decisions openly, with public involvement, and in a sensible, understandable manner.

- *Sound Science and Data*: Sound science and data provide the foundation for OPP's decisions. OPP has required and reviewed thousands of studies on the potential effects of pesticides and their fate in the environment. OPP also gathers much data on the use, effectiveness, and economics of pesticides. OPP will continue to promote scientific excellence and ensure that scientific data are accessible and useful to EPA and the public.

- *Pollution Prevention*: OPP recognizes that it is neither economical nor effective to solve problems after they have been created. As a result, OPP is increasingly focusing on preventing risks from pesticides in the environment. Important elements of this approach include encouraging safer means of pest control, reducing pesticide use and exposure, and evaluating the effectiveness of protection efforts.

I hope this report will help you understand what we accomplished in 1994 and some of the many challenges that lie ahead.

Daniel M. Barolo, Director
Office of Pesticide Programs

**Dedication:** This first annual report is dedicated to the employees of OPP. They represent many disciplines, including scientists, administrative staff, environmental protection specialists, program analysts, and computer specialists. Although we have a few miles to go, everyone in OPP should feel proud of our efforts and, more importantly, the positive impact our actions have on our public health, environmental and worker safety goals.

# Introduction

Pesticides differ from other classes of chemicals regulated by EPA in several important ways. They are often intentionally applied in the environment, rather than occurring as a byproduct of industry or other human activity. They are used in a remarkably diverse array of products, from insect repellents to crop weed killers to household disinfectants to swimming pool chemicals, to name a few. In addition, they are likely to be found or used in nearly every home and business in the United States. Although improper pesticide use may pose health risks, many pesticides have public health benefits by killing potential disease-causing organisms found in food, water, and other settings.

Given the unique attributes of pesticides, EPA has found that protecting public health and the environment from the risks that pesticides may pose is a complex endeavor. To meet this challenge, the Agency has developed an array of programs to evaluate and reduce pesticide risks and promote safe pesticide use. These programs must be flexible enough to reflect the wide variety of existing pesticide products and uses, and must take into account the benefits that pesticides offer to society. State and tribal agencies and many other organizations, both public and private, have been vital partners in this effort.

This report describes many of the efforts and accomplishments of the Office of Pesticide Programs (OPP) during the 1994 fiscal year (October 1, 1993 to September 30, 1994). It also describes some of the opportunities and initiatives that OPP will pursue in 1995.

Annual Report Structure

While OPP staff are formally organized into eight divisions and a policy staff, this report is organized around the six major activity areas used in the budget process:

**1 - Registration**

Making decisions about the registration (licensing) of individual pesticide *products*, and assuring that decisions are consistent and up-to-date.

**2 - Reregistration**

Bringing the scientific data base for older pesticide *active ingredients* up to current standards, reassessing their regulatory status, mitigating their risks, and documenting new decisions. Assuring that products containing eligible active ingredients are supported by valid data, are labeled correctly, and are reregistered.

**3 - Special Review**

Conducting in-depth assessments of pesticides suspected of posing unacceptable risks to public health or the environment.

**4 - Field Implementation and Communications**

Working with EPA regional offices, states, and tribal organizations to implement pesticide programs, communicating with the public about pesticide issues, and supporting compliance efforts.

**5 - Policy, Regulations, and Guidance**

Developing pesticide policies and regulations, including improvement of the quality of scientific information used to make decisions.

**6 - Information and Program Management**

Managing pesticide information (including automated information systems, computers and computer networks, and paper and microfiche collections) and administering programs (including human resources, facilities, finances, and budget planning).

# Contents

**Foreword** ..... i

**Introduction** ..... 1

**Chapter 1: Registration** ..... 5

Overview Of Registration ..... 5
New Registrations in 1994 ..... 6
Reduced-Risk Policy ..... 7
Other 1994 Registration Achievements ..... 8
Ensuring The Effectiveness Of Antimicrobial Pesticides ..... 9
Retaining Minor Uses ..... 9
Proposed Measures To Reduce Risks From Total Release Foggers ..... 10
Addressing Risks From Spraying Pesticides Aboard Aircraft ..... 10
Water Protection Measures For New Pesticide Active Ingredients ..... 10
Efforts To Improve Pesticide Labels ..... 11
Pesticide Chemistry Laboratory Support For Registration ..... 11
Reducing Unnecessary Requirements For Pesticide Registration ..... 12
Agreement With California To Harmonize Pesticide Regulation ..... 12
Improvements to the Regulatory File System ..... 12

**Chapter 2: Reregistration** ..... 13

Steps In Reregistering Pesticides ..... 13
1994 Reregistration Progress ..... 14
Rejection Rate Analysis ..... 20
Pesticide Chemistry Laboratory Support For Reregistration ..... 20
Reducing Pesticide Spray Drift ..... 21
Reassessment Of Dioxin Risks ..... 21
Reducing Ecological Risks Under The "New Paradigm" ..... 22
The Label Use Information System (LUIS) ..... 22

**Chapter 3: Special Review** ..... 23

1994 Formal Special Reviews And Follow-up Activities ..... 23
Cancellation Of Mevinphos ..... 24
Other Negotiated Risk Reduction Efforts ..... 24
Other Cancellation Activities ..... 24
Tolerance Revocations ..... 25
Initiative To Reduce Risks To Birds (Avian Granular Initiative) ..... 25

**Chapter 4: Field Implementation and Communication** ..... 27

A. Field Programs ..... 27

Implementing The Worker Protection Standard ..... 28
Endangered Species Protection Program ..... 29
Protecting Ground Water ..... 29
Certification And Training Of Pesticide Applicators ..... 30
Disposal Of Suspended And Cancelled Pesticides ..... 30
Promoting Integrated Pest Management ..... 31
Guidance For Posting Of Outdoor Pesticide Applications ..... 31

B. Communications, Public Response, and Coordination ..... 31

Outreach And Communications Strategies ..... 32
Responding To The Public ..... 32
Congressional And Federal Coordination ..... 33
Public Meetings ..... 33
Pesticide Information Network ..... 33
Agency Risk Management Communication Group ..... 34
Scientific Presentations And Publications ..... 34
International Coordination And Integration ..... 34
Regional, State, And Tribal Liaison ..... 35
Improving Internal Communications ..... 36

C. Support For Compliance Activities ..... 36

Support For The Lab Audit Program ..... 37
Analysis Of Product Chemistry ..... 37
Other Laboratory Support ..... 37
Additional Support For Compliance Activities ..... 37

**Chapter 5: Policy, Regulations, and Guidelines ..... 39**

Follow-up To The National Academy Of Sciences (NAS) Children's Study ..... 40
Reduced Use/Risk Initiative ..... 40
International Harmonization And Regulatory Coordination ..... 41
Technical Assistance: AID/EPA Central American Project ..... 41
Biological Pesticide Policy Highlights ..... 42
Activities Related To Implementation Of The "Delaney Clause" ..... 43
Standards For Pesticide Containers And Containment ..... 43
Other Regulations Under Development ..... 44
Legislative Proposals ..... 44
Maintaining And Improving OPP's Science Base ..... 45

**Chapter 6: Information and Program Management ..... 47**

Operations, Maintenance And Integration Of The Primary OPP Information Systems ..... 47
Pesticide Incident Reporting/6(a)(2) Activities ..... 48
Ecological Incident Monitoring And Reporting ..... 48
Information And Records Management Activities ..... 49
Human Resources Management ..... 49
Resource Allocation And Financial Management ..... 50

**Chapter 7: Opportunities and Initiatives For 1995 ..... 53**

Biological Pesticides And Promoting Risk Reduction ..... 53
Opening Up OPP ..... 54
Reinventing And Streamlining OPP's Organization ..... 56

**How To Obtain More Information ..... 58**

**Pesticide Program Contacts ..... 59**

# 1

# Registration

This chapter describes the registration program, which provides the foundation for nearly all OPP activities related to pesticides. In addition to allowing the use of new pesticides, this program includes many activities related to the ongoing registration of existing pesticides, such as modifications to where and how they may be used in order to reduce risks or in response to requests by registrants. OPP also carried out a number of special registration programs in 1994, which are described in more detail in this chapter. These included encouraging the registration of reduced-risk pesticides, ensuring the effectiveness of antimicrobial pesticides, helping to retain important minor use pesticides, proposing measures to reduce the risks from total release foggers ("bug bombs") and from spraying of pesticides above aircraft, improving pesticide labels, reducing unnecessary registration requirements, and coordinating registration activities with the State of California.

## Overview Of Registration

EPA is responsible under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for registering new pesticides and ensuring that, when used according to label directions, they will not cause unreasonable adverse effects to human health or the environment. Pesticide registration decisions are based primarily on EPA's evaluation of the test data provided by applicants. EPA has established a number of requirements, such as the Good Laboratory Practice Standards, that apply to both registrants and testing facilities to ensure the quality and integrity of pesticide data. Depending on the type of pesticide, OPP can require more than 100 different kinds of specific tests.

Testing is needed to determine whether a pesticide has the potential to cause adverse effects to humans, wildlife, fish, and plants, including endangered species. Potential human risks, which are identified using laboratory tests in animals, include acute toxic reactions (such as poisoning and skin and eye irritation) as well as possible long-term effects (such as cancer, birth defects, and reproductive disorders). Data on the fate of pesticides in the environment are also required so that OPP can determine, among other things, whether a pesticide poses a threat to groundwater or surface water (lakes, rivers, and streams).

Most of OPP's testing requirements focus on "active ingredients" of pesticide products. Active ingredients are those substances that actually possess a pesticidal property — that is, they repel, destroy, or otherwise affect a pest. Most pesticide products also contain other ingredients that do not have pesticidal properties, such as solvents, carriers, aerosol propellants, and dyes. Ingredients that are not active as pesticides are called "inerts."

## New Registrations in 1994

OPP registered 31 new pesticide active ingredients in fiscal year 1994, more than half of which are considered to be reduced risk pesticides. Reflecting the trend of recent years, a high proportion of new ingredients — 15, or nearly half — were biological pesticides. Biological pesticides include "microbial pesticides," which are bacteria, viruses, or other microorganisms used to control pests, and "biochemical pesticides," which include pheromones (insect sex attractants), insect or plant growth regulators, and hormones used as pesticides. Biological pesticides generally pose less risk to health and the environment than chemical pesticides, and as a result OPP imposes fewer requirements on their registration. The following table describes the pesticide active ingredients registered for the first time in fiscal year 1994.

### New Active Ingredients Registered in Fiscal Year 1994

| Pesticide Name | Registrant | Pesticide Type | Use(s) | Biological or Other Reduced Risk Pesticide? |
|---|---|---|---|---|
| Acetochlor | Monsanto Agric. Co,; Zeneca Ag Products | Herbicide | Corn | |
| Ampelomyces quisqualis | Ecogen | Fungicide | Grapes, tomatoes, strawberries, apples | Yes (biological) |
| Bacillus subtilis (MBI 600) | Gustafson | Fungicide | Cotton, grains | Yes (biological) |
| C-9211 | Rohm and Haas | Mildewcide | Paints | |
| Castor Oil | Dinah Pickett | Repellent | Ornamental plants | |
| Checkmate CM pheromone | Consep; Bedoukian Research | Pheromone | Fruits and nuts | Yes (biological) |
| Corn Glutens | Gardens Alive! | Fungicide | Turf | Yes (biological) |
| Cyproconazole | Sandoz Agro Inc. | Fungicide | Turf | |
| Deltamethrin | Roussel Uclaf; AgrEvo Environmental Health | Insecticide | Feed | |
| Difenoconazole | Ciba-Geigy | Fungicide | Wheat | |
| DTEA | Dow Chemical | Antimcrobial | Water systems | |
| Floral Attractants (seven different compounds) | Micro-Flo | Pheromones | Corn | Yes (biological) (7 pheromones) |
| Flumetsulam | DowElanco | Herbicide | Corn and soybeans | |
| Gusano (Alfalfa looper virus) | Crop Genetics International | Insecticidal Virus | Vegetables | Yes (biological) |

## New Active Ingredients Registered in Fiscal Year 1994 (cont.)

| Pesticide Name | Registrant | Pesticide Type | Use(s) | Biological or Other Reduced Risk Pesticide? |
|---|---|---|---|---|
| Hexaflumuron | DowElanco | Insecticide | Termite control | Yes |
| Hydrogen Cyanamide | SKW Trostberg AG | Plant Growth Regulator | Grapes | |
| Imidacloprid (NTN) | Miles | Insecticide | Turf | |
| Igarol 1051 | Ciba-Geigy | Antimicrobial | Anti-foulant paints | |
| Methyl Anthranilate | PMC Specialties Group | Bird Repellent | Turf | Yes |
| Pseudomonas fluorescens Strain NCIB 12089 | Mauri Laboratories | Fungicide | Mushrooms | Yes (biological) |
| Puccinia canaliculate lagerheim | Tifton Innovation | Herbicide | All crops | Yes (biological) |
| RYH-86-A | Yoshitomi Pharmaceut. Industries | Slimicide | Paper mills | |
| Tebuconazole | Miles | Fungicide | Peanuts | |
| Tufted Apple Bud Moth Pheromone | Bedoukian Research | Pheromone | Apples | Yes (biological) |
| Turpentine | DLT Laboratories | Insecticide | Non-food uses | |

Summary Statistics:

- 31 new active ingredients registered
- 2 chemical active ingredients registered as "reduced-risk pesticides"
- 15 were biological/biochemical pesticides

## Reduced-Risk Policy

During fiscal year 1994, OPP implemented its voluntary Reduced-Risk Pesticide Initiative. Under this effort, OPP invites applicants seeking to register new pesticide active ingredients to provide information on how their pesticide presents opportunities for risk reduction. If OPP believes that the pesticide demonstrates such potential, OPP accelerates the registration process for the pesticide.

In March 1994, OPP registered the first pesticide under this initiative. Hexaflumuron, developed by DowElanco, has the potential to replace much larger amounts of the termiticide chemicals traditionally used. This product is used with a monitoring system so that the chemical is applied only after a termite problem has been identified. In September 1994, OPP registered the second reduced-risk pesticide, methyl anthranilate. This bird repellent, marketed by

PMC Specialties Group, is registered for use on turf. Methyl anthranilate is found in flower oils and in Concord and other grapes. This product solves bird pest problems where existing bird control toxicants and repellents cannot be used.

OPP will continue the voluntary initiative in its current form for at least one additional year. During this time, OPP will explore other types of incentives that could encourage the development, registration, and use of lower-risk pesticide alternatives. In addition, OPP will consider approaches for expanding the current pilot program to other types of registration applications.

## Other 1994 Registration Achievements

Registering new pesticides for the first time is only one of an enormous number of pesticide registration actions that OPP carries out each year. The decisions made in 1994 are summarized in the following table. Both approvals and denials of the requests received by OPP are included in the number of decisions.

### 1994 Registration Activities

| Registration Activity | Description of Activity | Number of Decisions |
|---|---|---|
| Registrations of new pesticides | First approval for use of pesticides not currently registered in the United States | 31 |
| Additional registrations for registered pesticides | Registrations for new products containing pesticide ingredients already approved for proposed uses | 782 |
| Amendments to existing registrations | Amendments, for example, to reflect revised labels and changed formulations for products already registered. | 3233 |
| New uses for previously registered pesticides | Approvals for uses of a pesticide (such as on particular food crops) for which it has never been registered | 56 |
| Emergency exemptions ("Section 18s) | Decisions on granting emergency exemptions to states or other federal agencies to allow use for a limited period of pesticides not registered for those particular uses. | 265 |
| Experimental Use Permits (EUPs) | Decisions on permits that allow pesticide producers to test new pesticide uses outside of the laboratory; generally required if more than 10 acres are to be tested | 104 |
| Tolerances | Decisions on approving tolerances, or maximum allowable levels of a pesticide in food or animal feed. Tolerances (or exemptions from tolerances) are required whenever a pesticide is registered for use on a food or feed crop. | 70 |
| Temporary tolerances | Decisions on approving tolerances for experimental purposes for an unregistered pesticide. | 26 |
| Special Local Need Registrations ("Section 24(c)s") | Registrations of pesticide products by state agencies for specific uses not federally registered. (The pesticides must be federally registered for other uses.) | 411 |

## Ensuring The Effectiveness Of Antimicrobial Pesticides

While all pesticide products are required to work as claimed by the manufacturer, EPA is particularly concerned about the effectiveness, or efficacy, of antimicrobial pesticides. Antimicrobial products are used to control "germs" such as bacteria and fungi (molds and mildews) that can cause odors, food spoilage, or infections. Not only are they used in homes, but also in hospitals, cafeterias, restaurants, and many other institutions. Over the past several years, EPA has implemented a comprehensive strategy to ensure the efficacy of antimicrobial pesticides, placing highest priority on those that have significant public health uses. Among these efforts, EPA has:

- Funded six cooperative agreements to develop new or revise existing test methods for determining the efficacy of antimicrobial public health products.
- Implemented a pre- and post-registration testing program. Six new sterilants were subjected to pre-registration testing this past fiscal year, of which one has been registered and the others are pending. Testing of hospital disinfectants and products with tuberculocidal claims is in progress.
- Administered the Antimicrobial Complaint System to receive inquiries and complaints from users and the public. The system received more than 4,000 calls from medical professionals and infection control personnel in 1994. This system also provides valuable information for assessing needed regulatory changes.
- Implemented comprehensive label improvement programs to upgrade the label claims and directions for products used against the AIDS virus (HIV-1) and for tuberculocidal, sanitizing, and pine oil products (household disinfectants).

## Retaining Minor Uses

Minor use pesticides are those that generate relatively little income for their manufacturers because they are used on limited acreages. Increased costs of pesticide registrations, especially the costs associated with reregistering pesticides, often result in registrants choosing to cancel minor use registrations and not pursue approval for new uses. However, minor use pesticides are of major importance to growers in producing many fruits, vegetables, and ornamental plants. In 1994, OPP continued to participate in several activities to help preserve important minor uses:

- **IR-4 Efforts**. OPP supports the efforts of the Interregional Research Project Number 4, or IR-4 program, which is jointly funded by the U.S. Department of Agriculture and the states. IR-4 has generated data for many minor use pesticides undergoing reregistration and has committed to providing residue data to support reregistration of an additional 250 high priority pesticide food uses. OPP supports increased IR-4 funding as the best way to protect minor uses without sacrificing health and safety data development and reviews.
- **Data deferrals/waivers**. OPP tries to be flexible on the data required for registration and reregistration of minor use pesticides, but must also ensure that pesticides do not pose unacceptable risks to people or the environment.
- **Crop grouping**. OPP has supported the establishment of tolerances (maximum approved levels in food) for multiple related crops based on residue data from a representative set of crops. This cuts the costs of registering minor uses.
- **Legislation**. In 1994, the Administration proposed legislative changes to help retain important minor uses, and encourage registration of new minor uses, as part of its Food Safety Initiative. This proposal embodies many elements from a proposal by the Minor Crop Farmers Alliance (MCFA).

## Proposed Measures To Reduce Risks From Total Release Foggers

Total release foggers — sometimes called "bug bombs" — are pesticide products containing aerosol propellants that release all of their contents at once to fumigate an area. They are used in homes to kill cockroaches, fleas, and other pests. On April 15, 1994, OPP proposed new labeling requirements for total release foggers based on information that demonstrated that total release foggers, as currently labeled, represent an unreasonable risk to users from fires and explosions. The proposed rule would require additional flammability label warnings and a standard graphic symbol, representing fire and explosion, to alert consumers to these potential dangers. In addition, pesticide labels for these products would include more detailed directions for proper use. The proposed rule encourages registrants to use other hazard communication mechanisms to reinforce the required precautionary language. OPP is reviewing comments on the proposal and expects to issue a final rule in 1995.

## Addressing Risks From Spraying Pesticides Aboard Aircraft

In late 1993, EPA became aware of several incidents in which airline personnel and passengers experienced adverse health effects after being exposed to an insecticide treatment aboard foreign-bound aircraft. Although the United States has not required spraying since 1979, several foreign countries do require the spraying of incoming aircraft, with passengers and crew present, prior to landing. Traditionally, passengers are *not* told that this treatment will occur until the spraying actually begins. The pesticide used in these treatments is known as sumithrin. Although EPA has data indicating that sumithrin is generally low in toxicity to humans, the Agency does not know how the chemical may affect susceptible sub-populations. EPA is particularly concerned that individuals who are chemically sensitive, or who suffer from respiratory problems or allergies, may have adverse reactions.

In March 1994, OPP issued a Data Call-In Notice to the two registrants that still held U.S. registrations for in-flight insecticide treatments requiring them to either develop new toxicity data or amend the pesticide label to delete the aircraft use. Since then, both registrants have removed the aircraft use from the label. Many countries, however, continue to require in-flight spray treatments. Recently, the U.S. Department of Transportation (DOT) issued a proposed rule to require notification to passengers at the time they purchase their tickets. EPA continues to work with the State Department and DOT to encourage foreign countries to rescind the airline spraying requirement. OPP is also preparing a notice to registrants to ensure that pesticide labels do not allow the use of other insecticides on board aircraft with passengers and crew present.

## Water Protection Measures For New Pesticide Active Ingredients

In 1994, OPP initiated a new approach for registering pesticide active ingredients that sets strong standards for ground and surface water protection. The approach establishes clear criteria that trigger voluntary suspension or cancellation of the registration if water quality is adversely affected. These criteria are based on an assessment of the chemical and physical properties of the pesticide and other factors indicating its potential to contaminate water resources. Acetochlor was the first pesticide registered using this approach. Highlights of the water protection approach include:

- Requirements for analytical methods to detect the presence of the pesticide in water, including a low-cost immunoassay.

- Early warning systems to prevent ground water emergencies, including monitoring of wells and surface water in several states.
- Product stewardship programs to foster proper use by customers and to prevent problems from occurring.

## Efforts To Improve Pesticide Labels

Labeling is one of OPP's most important tools for achieving its mission of protecting human health and the environment. No other pesticide document or publication has a more direct impact on risk reduction or the potential to prevent pollution. Over time, however, some labels have become cluttered and confusing. In response to needs expressed by OPP's customers and an internal evaluation process, OPP formed a Labeling Unit in July 1994. The goal of the unit is to ensure that product labels are clear, technically accurate, and consistent. In 1994 the unit accomplished the following:

- Introduced a process for tracking and resolving short-term labeling problems and issued responses to more than 50 requests for guidance.
- Established an electronic labeling policy directory which contains over 300 easily accessible documents.
- Established a Labeling Bulletin Board system for sharing information about labeling projects with internal and external customers.
- Helped finalize and release a comprehensive Label Review Manual for use by internal and external customers.
- Initiated projects to improve consumer labeling, test the electronic submission/review/storage of labels, and revise OPP regulations to allow certain information on labels that consumers need to make more informed choices.

## Pesticide Chemistry Laboratory Support For Registration

OPP's pesticide registration program is supported by two pesticide chemistry labs: the Analytical Chemistry Laboratory (ACL) in Beltsville, Maryland, and the Environmental Chemistry Laboratory (ECL) in Bay St. Louis, Mississippi. The labs support registration through the food tolerance and environmental chemistry methods validation programs, which ensure that pesticide residues can be properly measured in food and the environment.

The ACL has the lead responsibility for the food tolerance methods validation program. In fiscal year 1994, ACL validated a record 49 food tolerance methods for registration. The ACL's achievements also included the development of a method for detecting residues of multiple sulfonylurea pesticides in food using a new technology called capillary zone electrophoresis, which generated much interest among the scientific community. The ECL has the lead responsibility for the environmental chemistry methods validation (ECMV) program. The demand for environmental chemistry support for new pesticides grew substantially in 1994, with the primary emphasis being in the areas of environmental fate and exposure and ecological effects. The ECL completed seven ECMV requests for new pesticides in 1994, including a ten-fold lowering of the detection limit for the pesticide acetochlor, allowing it to be more readily detected in the environment. The ECL also continued to provide support to the new, low-cost technology for detecting pesticide residues known as immunoassay tests.

## Reducing Unnecessary Requirements For Pesticide Registration

In 1994, OPP continued to identify areas where pesticide regulations could be reduced, allowing OPP to better focus on high risk areas and preventing undue burdens on the regulated community. One area identified was the potential exemption of certain low-risk pesticides from registration requirements. In January 1994, OPP established an exemption from registration requirements under section 25(b) of FIFRA for natural cedar pesticides labeled to repel arthropods (other than ticks) or to retard mildew growth. OPP concluded that use of these pesticides poses negligible risks to human health and the environment and that, as a result, the burden imposed by regulation is not justified.

Subsequently, the Agency proposed a second rule (also under section 25(b)) to exempt 31 additional low-risk substances from regulation. Most of these were food items (such as cinnamon, garlic, and mints) or substances otherwise derived from natural sources. Under the proposal, to be eligible for exemption these substances could not be sold in formulations with other pesticides or chemicals of concern, and could not be labeled to control organisms posing a risk to public health. The labels would be required to list all ingredients. OPP will review comments received and determine how to proceed in 1995.

## Agreement With California To Harmonize Pesticide Regulation

OPP and the Department of Pesticide Regulation of the California Environmental Protection Agency began an initiative in 1994 to harmonize and simplify federal and California pesticide registration, and to exchange work products to reduce duplication of effort and expense. The first major milestone of this initiative was the signing of a Memorandum of Understanding (MOU) in May 1994. Under this MOU, the agencies agreed to share reviews of acute toxicology studies submitted by pesticide registrants. The agreement sets out a plan to reduce duplicative review of identical data, improve coordination, and reduce the workload of both agencies by allowing each agency to use acute toxicity data reviews generated by the other. Through this effort, products posing fewer risks will be registered much faster and at less cost, and older pesticides lacking adequate health data will be more quickly removed from the market.

## Improvements To The Regulatory File System

Among OPP's most important files are the regulatory "jackets" for each pesticide product that has been federally registered. During fiscal year 1994, the Regulatory File Area implemented several changes to improve service. In particular, a computerized system that provides OPP users with the ability to request jackets from their workstations was activated. The new system has been integrated with other OPP computer systems, and provides status information on each registration (such as cancelled, withdrawn, or suspended). Under this system, files can be more efficiently managed; for example, quick identification of cancelled files facilitates their removal to make room for new incoming files. 95% of file room users have been trained to use the new system and training will continue in 1995.

# 2

# Reregistration

The reregistration program is one of OPP's largest and most visible programs. OPP is required by law to reregister existing pesticides originally registered when the standards for government approval were less stringent than they are today. This comprehensive reevaluation of pesticide safety in light of current standards is critical to protecting human health and the environment. In 1988, Congress amended the federal pesticide law to strengthen and accelerate OPP's reregistration program. The "FIFRA '88" amendments apply to each product containing any active ingredient registered before November 1, 1984.

This chapter discusses the progress OPP is making in reregistering pesticides, as well as some related initiatives. These include efforts to reduce the number of studies rejected by OPP, reduce the risks posed by pesticide spray drift, more effectively assess and decrease ecological effects, help understand and control dioxin risks, and expand a database of label directions for pesticides undergoing reregistration.

## Steps In Reregistering Pesticides

OPP identified the pesticides to be reregistered and issued comprehensive data requests to registrants of those pesticides during Phases 1 through 4 of the accelerated reregistration process. Reregistration is now in its final phase, Phase 5, as OPP reviews the studies that are being submitted, examines the health and environmental effects of each reregistration case (group of related pesticide active ingredients), and attempts to mitigate effects of concern. This evaluation and risk management process is complete when OPP is satisfied that the pesticide, used in accordance with approved labeling, will not pose unreasonable risks to human health or the environment.

OPP's conclusion about whether a pesticide's uses are eligible for reregistration is presented in a Reregistration Eligibility Decision, or RED. About 14 months later, once certain product-specific data and revised labeling are submitted and approved, OPP begins reregistering products containing the eligible pesticide(s). A product will not be reregistered until OPP has determined that all of its active ingredients are eligible for reregistration.

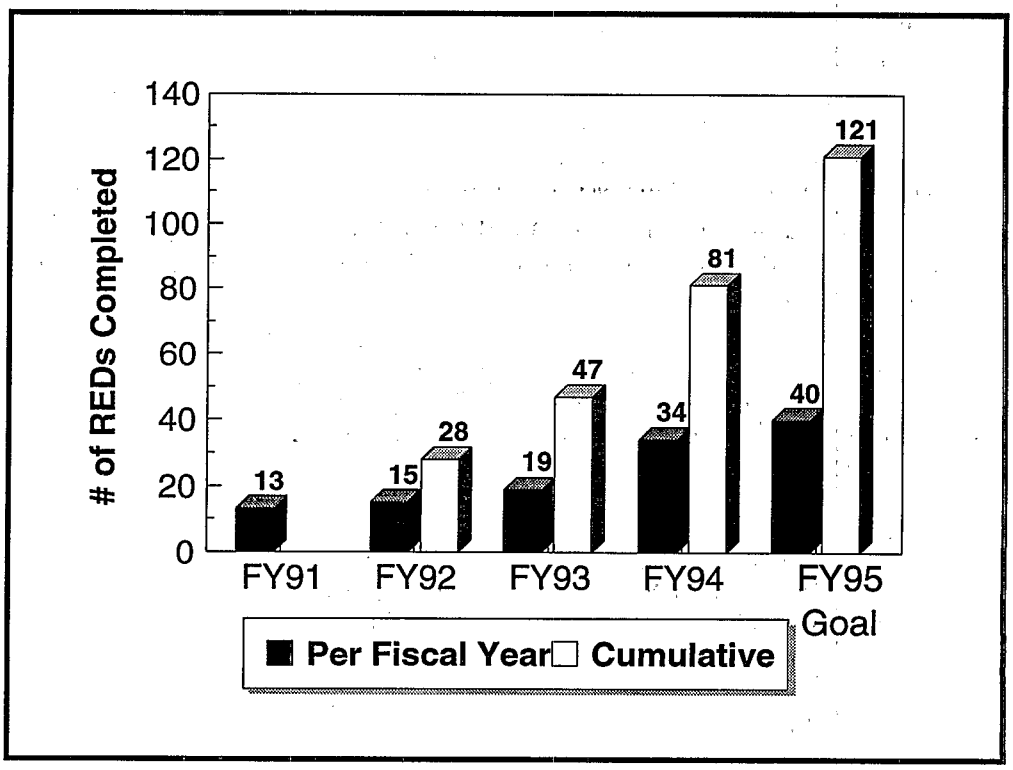
## 1994 Reregistration Progress

During fiscal year 1994, OPP made significant progress in administering the reregistration program. Many decisions were made resulting in significant risk reductions. The program's investment in people, computer systems and data gap identification is paying off with steady production of the decisions needed to complete the reregistration process.

Several different stages of reregistration offer opportunities to contribute to safer use of older pesticides. New risks identified during the reregistration process may be addressed by imposing interim risk reduction measures before the scheduled REDs. The next important stage for reducing risks occurs with the issuance of REDs. Many types of risk reductions are required through REDs, and OPP completed an unprecedented number of REDs this fiscal year, as detailed later in this chapter. Finally, perhaps the most comprehensive risk reduction impacts occur during the product reregistration stage. During fiscal year 1994, program emphasis began shifting toward product reregistration, as many more products became eligible. Product reregistration will become even more important during the next several years. Some of the principal accomplishments of the reregistration program during fiscal year 1994 and cumulatively are summarized below.

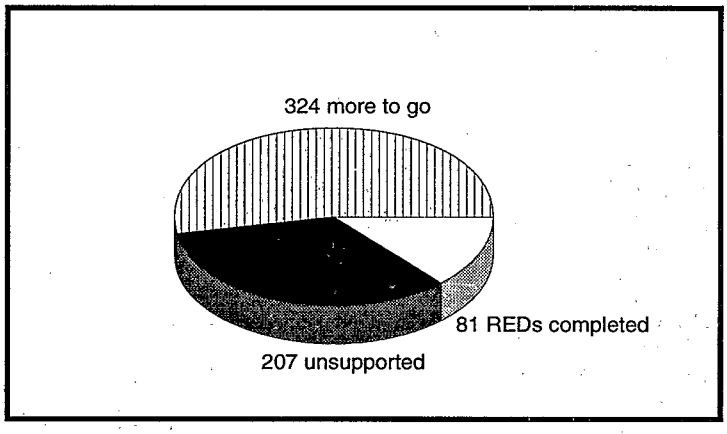
### Annual and Cumulative Completion of REDs

The number of REDs completed per fiscal year has been increasing steadily since the accelerated reregistration program began. This number reached 34 in fiscal year 1994 for a cumulative total of 81 completed REDs. A target of 40 more REDs has been set for fiscal year 1995.



### Status of Reregistration Cases

OPP has completed a total of 81 REDs, representing one fifth of the 405 chemical cases currently supported for reregistration. Meanwhile, 207 of the original 612 cases are unsupported (meaning that the registrants have decided not to complete and submit the studies required for reregistration). Cases that remain unsupported have been or will be cancelled.




### Anatomy of the 81 REDs Completed

*...Or, What "81 REDs Completed" Means...*

The 81 REDs completed cover 120 active ingredients, 3,521 products, and 500 tolerances. They represent 20% of all supported reregistration cases (a case consists of one or more related pesticide active ingredients); 17.5% of all currently registered pesticide products; 19% of food use pesticides (supported List A cases); and 9% of original List A tolerances reassessed. As described in the table below, the completed REDs represent about two-thirds of the quantity of pesticides used (by volume) in the United States, including about two-thirds of all homeowner-applied pesticides and 9 to 14% of all pesticides used in agriculture.*

**Amount of Pesticide Usage (by volume) Covered By REDs Completed***

| | Homeowner Applied | Agriculture | Commercial/ Industrial and Government | TOTAL |
|---|---|---|---|---|
| Fungicides | 50% to 55% | 55% to 60% | 4% to 7% | 40% to 48% |
| Herbicides | 4% | 4% to 7% | 16% to 30% | 6% to 10% |
| Insecticides | 10% to 15% | 1% to 2% | 1% to 3% | 4% to 10% |
| Antimicrobials | 99% + | 99% + | 99% + | 99% |
| TOTAL | 65% | 9% to 14% | 65% | 65% |

*Please note that the REDs completed for two antimicrobial cases — bleach (sodium and calcium hypochlorite) and chlorine — account for a large proportion of the usage of antimicrobials and the overall usage of pesticides covered by the REDs completed so far. Note, too, that pounds used may not indicate the relative percent of market share or number of applications.

## Risk Reductions Achieved

Each Reregistration Eligibility Decision (RED) document issued in 1994 involved changes to reduce the potential risks of the pesticide being evaluated. Risks can be reduced by cancelling products, declaring uses ineligible for reregistration, strengthening the requirements on product labeling, or limiting the amount of pesticide residues that may remain in food by establishing, reducing or revoking "tolerances" (enforceable maximum residue limits). Some of the risk reduction measures achieved in the 34 REDs completed this fiscal year are described in the following table:

| Number of REDs | Risk Reduction Measures Required By RED |
|---|---|
| 1 | All products and uses voluntarily cancelled (mevinphos). |
| 6 | Restricted Use Pesticide classification added or maintained, so that the pesticide may be used only by or under direct supervision of a certified applicator. |
| 19 | Personal Protective Equipment requirements for pesticide applicators strengthened or confirmed. |
| 10 | Restrictions that limit entry of workers into treated areas (including Restricted Entry Intervals) strengthened or confirmed. |
| 8 | Limits/reductions/specifications regarding the amount, frequency, or rate of application required. |
| 3 | Use Directions on labeling strengthened or made more specific. |
| 6 | Other user safety measures required. |
| 5 | Label Advisory or other measures to protect ground or surface water required. |
| 14 | Environmental Hazard statements to reduce ecological risks strengthened. |
| 8 | Tolerances revised (reduced, revoked, or newly approved). |

## Tolerances Reassessed

As part of reregistration, OPP is reassessing pesticide tolerances, or maximum residue limits in food and feed. A pesticide must have a tolerance (or be granted an exemption from a tolerance) for each different type of food or animal feed on which it may be used. The number of tolerances for the List A pesticides (which represent the most significant food use pesticides) was about 5,600 in November 1988, when the accelerated reregistration program began. Since then, about 500 (or 9%) List A pesticide tolerances have been reassessed as part of the reregistration process. About 600 more List A tolerances are associated with active ingredients no longer supported for reregistration; these active ingredients ultimately will be cancelled and their tolerances revoked. During the past several years, some new tolerances have been added for the List A chemicals, while others have been revoked. OPP estimates that approximately 4,500 tolerances for List A pesticides still need to be reassessed during reregistration.

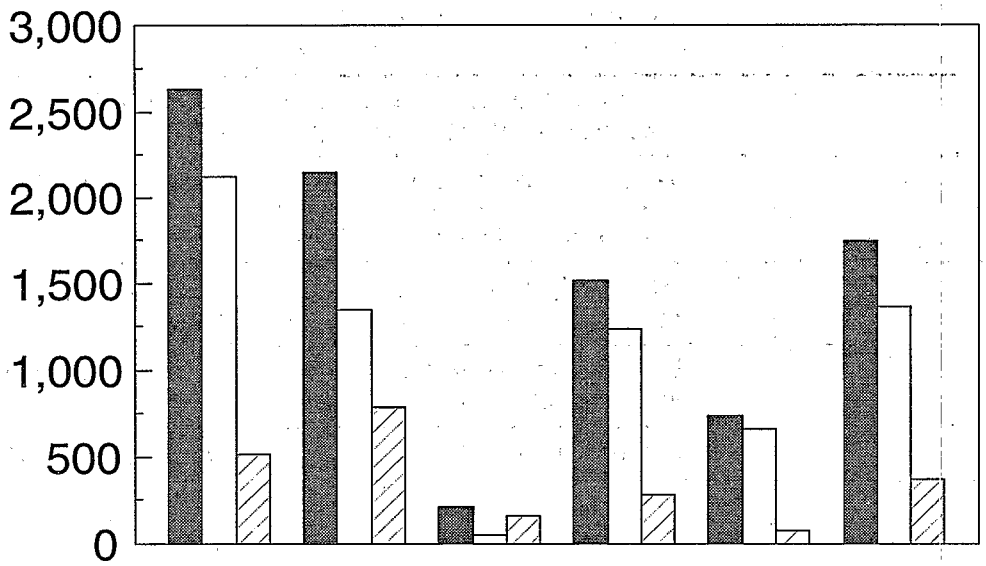
### Data Call-In (DCI) Notices

OPP has issued 453 comprehensive Data Call-In (DCI) notices under the reregistration program to obtain studies needed to assess potential health and environmental risks. As Phase 4 of reregistration has been completed, which involved issuing DCIs to complete pesticide databases, the number of DCIs issued per year has decreased. OPP issued 77 DCIs in 1994.

### Status Of Studies Received

Registrants have responded to DCIs and other requirements by submitting more than 19,000 studies in support of reregistration. Review of these studies is essential for making reregistration decisions. By end of fiscal 1994, OPP had reviewed more than 11,500 of the studies, including nearly 7,000 of the approximately 9,000 studies received for List A pesticides. The cumulative numbers of studies received, reviewed and awaiting review by scientific discipline are shown in the following figures for the List A pesticides and for all pesticides undergoing reregistration.

**Study Review Status For List A Pesticides**

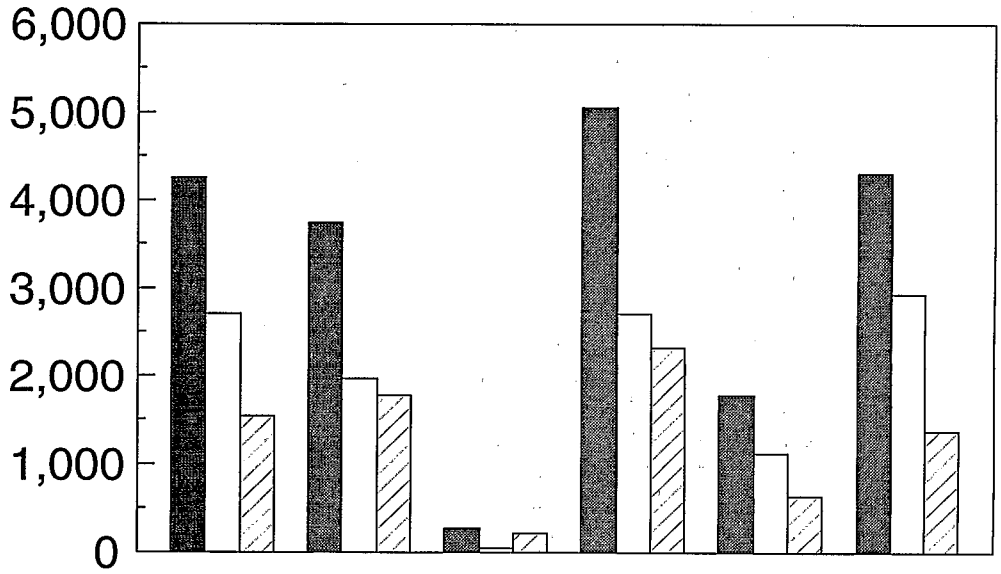



| | Residue Chemistry | Environ. Fate | Reentry Non-Dietary | Tox Non-CORT** | Tox-CORT* | Eco Effects |
|---|---|---|---|---|---|---|
| Received | 2,632 | 2,140 | 209 | 1,515 | 738 | 1,742 |
| Reviewed | 2,118 | 1,349 | 51 | 1,238 | 658 | 1,365 |
| Awaiting Review | 514 | 791 | 158 | 277 | 80 | 377 |

* Tox-CORT - Chronic feeding, carcinogenicity (oncogenicity), reproduction, and developmental toxicity (teratology) studies.

**Tox Non-CORT - Studies other than CORT studies that measure the toxicity of pesticides.

**Study Review Status For All Pesticides Undergoing Reregistration (Lists A, B, C, and D)**




| | Residue Chemistry | Environ. Fate | Reentry Non-Dietary | Tox Non-CORT | Tox-CORT | Eco Effects |
|---|---|---|---|---|---|---|
| Received ■ | 4,250 | 3,741 | 268 | 5,045 | 1,777 | 4,304 |
| Reviewed □ | 2,709 | 1,960 | 55 | 2,721 | 1,127 | 2,930 |
| Awaiting Review ▨ | 1,541 | 1,781 | 213 | 2,324 | 650 | 1,374 |

Tox-CORT - Chronic feeding, carcinogenicity (oncogenicity), reproduction, and developmental toxicity (teratology) studies.

Tox Non-CORT - Studies other than CORT studies that measure the toxicity of pesticides.

## Suspensions

When pesticide registrants fail to submit studies required for reregistration in a timely way, EPA's Office of Enforcement and Compliance Assurance (OECA) can issue Notices of Intent to Suspend (NOITS) product registrations. NOITS serve as an effective mechanism for bringing about compliance with EPA's data requirements for reregistration; in most instances companies comply with the NOITS by submitting the missing studies. If companies fail to comply by either submitting the required studies, voluntarily withdrawing their product registrations, or requesting a hearing, EPA can issue suspensions.

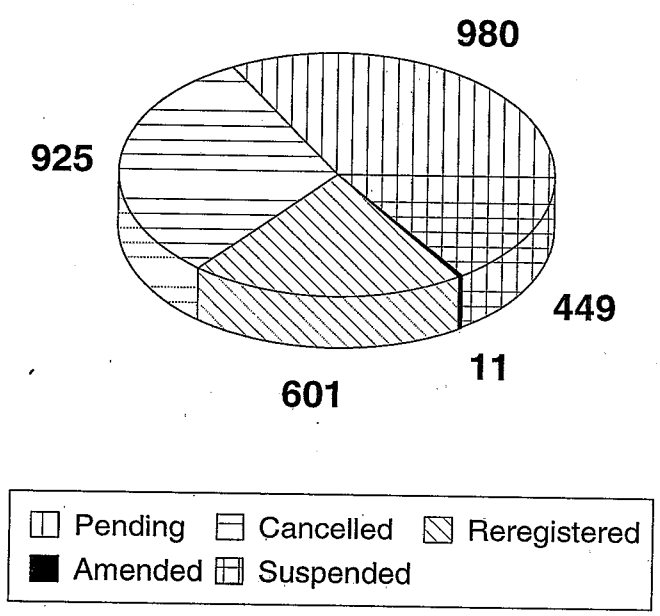
During fiscal year 1994, EPA issued NOITS to 179 companies. The Agency eventually withdrew 128 of these NOITS because the companies achieved compliance. However, EPA also issued 47 suspensions, and in four other cases is responding to requests for hearings to resolve questions about the Agency's data requirements. These fiscal year 1994 actions bring the total number of NOITS issued since 1989 to 779, and the number of suspensions to 301. In most of the remaining 478 cases, compliance has been achieved, while hearings continue to resolve remaining issues in some of the cases.

### Voluntary Cancellations

In some instances, registrants have responded to reregistration requirements by withdrawing support for pesticide active ingredients and products. Reregistration cases have dropped overall from 612 cases in 1988 to 405 today. Registered products declined during the early 1990s from approximately 45,000 to about 20,000 subject to reregistration. This initial decline represented pesticides with little or no use; more than 19,000 of these pesticides had not been produced in the three years prior to their cancellation. As product reregistration proceeds (please see below), a significant number of additional products are being voluntarily cancelled by their registrants.

### Product Reregistration

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. This occurs at least 14 months after a RED is issued because of the time required for registrants to submit product-specific data and labels and for OPP to review them. As of October 1994, OPP had reregistered over 600 products, granted a greater number of voluntary cancellations (925), amended 11 existing registrations, and suspended 449 products. Reregistration decisions are pending on a total of 980 products. Activity in this important area will increase dramatically during the next several years.



## Rejection Rate Analysis

In 1991, OPP discovered that the submission of unacceptable studies was the most significant factor delaying reregistration. Repeating studies can add years to the reregistration process, significantly increase the OPP's administrative and science review costs, and cost registrants millions of dollars. To address the high rate of rejection of studies submitted during reregistration, OPP developed the Rejection Rate Analysis.

OPP's analysis, which involves the active cooperation of the pesticide industry and the IR-4 program, is an intensive effort to identify and resolve the underlying problems that most frequently cause studies to be rejected. The resulting reports for each discipline — including Residue Chemistry, Worker Exposure, Toxicology, and Environmental Fate — are designed to make sure that future studies will be acceptable to the Agency.

By 1994, two years after the first Rejection Rate Analysis chapter was published by OPP, the quality of studies submitted to OPP was improving. For example, processing studies, which initially had the highest rejection rate among residue chemistry studies, improved from a 29% rejection rate before the analysis to a 16% rate afterwards. The second most often rejected study, plant metabolism, improved dramatically from a 27% rejection rate before the analysis to only 8% after. Improvements such as these will assist OPP in making reregistration decisions in a more timely way.

The next milestone in the Rejection Rate Analysis will be publication of the final chapter on Ecological Effects in 1995. EPA and industry scientists first met in April 1994 to improve understanding of factors leading to ecological effects study rejection. This effort became a forum for expressing divergent perspectives on the way risk to birds is assessed. The analysis discovered that rejection rates for some testing requirements have decreased over time, but that rates for others have not. On average, the rate at which OPP rejects ecological effects studies has declined from 36% prior to 1986 to the current rate of 20%.

While some testing issues have been resolved through the Rejection Rate Analysis, others remain to be addressed by future workgroups that OPP hopes will involve continued public participation.

## Pesticide Chemistry Laboratory Support For Reregistration

In addition to supporting pesticide registration (as described in chapter 1), OPP's two pesticide chemistry labs provide support for the reregistration program. The Analytical Chemistry Laboratory validated one food tolerance method for reregistration in 1994. Approximately five to ten methods are expected in 1995. The Environmental Chemistry Laboratory (ECL) completed four analytical method validations for pesticides in soil and water under the reregistration program in fiscal year 1994. In addition, the ECL developed a multianalyte method for detecting nine sulfonylurea pesticides in water. The ECL also prepared a draft of the new environmental chemistry methods manual, which will contain all of the EPA validated and non-validated soil and water methods.

## Reducing Pesticide Spray Drift

Aerial or ground application of pesticides may lead to drift off the site of intended application and result in exposure to workers, nearby residents, nontarget plants, and other ecological resources. To better understand the factors which affect spray drift, OPP worked closely in 1994 with the Spray Drift Task Force (SDTF), a coalition of 32 pesticide registrants. The SDTF is conducting extensive research into the factors that contribute to and can control spray drift. The information generated by the task force will greatly enhance OPP's ability to assess exposure resulting from spray drift, prevent excessive spray drift, and reduce risks caused by drift. These data will help fulfill requirements of pesticide registration. 1994 highlights include:

- EPA's Office of Research and Development (ORD), the U.S. Department of Agriculture (USDA), and the SDTF signed a Cooperative Research and Development Agreement in March 1994.
- OPP is providing input to spray drift modeling efforts under the cooperative research agreement. The models developed will enable optimal use of spray drift data and provide options for reducing drift and managing risk.
- A conference was held in June 1994 to discuss the SDTF's preliminary data on drift from airblast applications to tree crops and to identify additional research priorities. Orchard crop specialists from the United States and Europe attended.
- OPP reviewed the first official data submission of the SDTF.

## Reassessment Of Dioxin Risks

Dioxins comprise a group of chemically-similar, highly toxic compounds that are of concern to EPA. Because some pesticides have been found to be contaminated with low levels of dioxins, OPP has contributed to EPA's exhaustive reassessment of dioxin risks conducted since 1991. OPP's Environmental Chemistry Laboratory performed a number of analyses of animal tissue in 1994 as part of the reassessment, and helped review dioxin sampling and analysis methods. In September 1994, the Agency publicly released a draft version of the reassessment of dioxin risks and issued a voluntary call for additional information. The report highlighted not only cancer concerns but also possible reproductive, developmental, and immunological effects detected in animals.

OPP has taken several steps to ensure that pesticides do not contain dioxins at levels that pose unreasonable risks to public health or the environment. In 1987, OPP issued two data call-ins that applied to 161 active ingredients. Of those, 92 have been cancelled or are no longer being supported for reregistration. To date, OPP has reviewed submissions regarding the manufacturing processes of 43 of the supported active ingredients and determined that dioxins are unlikely to be formed. Through analysis of production samples, nine other active ingredients were found not to contain dioxin impurities. Thus, of the 161 originally subject to review, 144 are no longer of concern.

As of 1994, four of the remaining 17 active ingredients have been found to have manufacturing processes which produced levels of dioxins slightly above what is known as the Level of Quantification. Based on assessments using the "Toxicity Equivalent Factor" approach, OPP believes that the levels of dioxins in these four active ingredients pose a negligible risk to human health. OPP expects to complete review of the manufacturing processes of the remaining 13 chemicals by the end of 1995.

## Reducing Ecological Risks Under The "New Paradigm"

In March 1992, EPA established an internal task force to review and assess the role of ecological and environmental fate data in OPP's regulatory process. One of the task force's accomplishments was the development of an approach known as the "New Paradigm." This approach is intended to strengthen the Agency's efforts to prevent adverse effects to the environment from pesticides, while simultaneously accelerating pesticide reregistration. The strategy of this program is to reduce risks more quickly when the Agency receives information that pesticides may be causing adverse environmental effects, rather than requesting and waiting for additional studies to be submitted.

This emphasis led OPP to develop a paper providing preliminary guidance on risk reduction strategies and monitoring programs, including a format for registrants to follow when submitting mitigation and monitoring proposals. OPP then initiated a number of outreach activities related to risk mitigation and monitoring, such as presentations at workshops and scientific conferences and wide distribution of the document to pesticide registrants during the registration and reregistration processes. As a result of this effort, the regulated community has submitted improved mitigation proposals. Many are now following OPP's proposed format, which has led to the submission of more clearly defined and justified mitigation measures. In addition, OPP has incorporated environmental risk mitigation in almost half of the documents issued through the reregistration process. This approach of requiring risk mitigation and monitoring applies during the registration of new pesticides as well.

## The Label Use Information System (LUIS)

The Label Use Information System (LUIS) is a product-level database of pesticide label directions. It contains detailed information on registered sites, application methods, application rates, and limitations on the use of pesticides (e.g., preharvest intervals, reentry intervals). LUIS information can be reported by active ingredient to support chemical regulatory decisions; it can also be reported by product to monitor product compliance with regulatory decisions. In addition, the database can be used to help locate labels which match a specified parameter. In 1994, OPP completed initial entry of information for most pesticides undergoing reregistration. During 1995, OPP will complete initial data entry and begin expanding LUIS capabilities so it can support registration and Special Review as well reregistration. Eventually, it will be linked to other pesticide data systems and made available electronically to all OPP staff.

# 3

# Special Review

Special Review is EPA's formal process for determining whether the use of a pesticide poses unreasonable risks to people or the environment. In making this determination, EPA must consider the pesticide's risks and benefits. Special Review is designed to allow formal public input to the decision-making process. A Special Review can result in a decision to cancel, restrict, or continue the pesticide uses in question.

The Special Review process is set in motion when EPA has reason to believe that the use of a registered pesticide poses significant risks to people or the environment. Over 100 pesticides or groups of closely related pesticides have been evaluated through the Special Review process. While reregistration applies to all older pesticides, Special Review is applied to those pesticides of particularly serious concern.

## 1994 Formal Special Reviews And Follow-up Activities

**Inorganic arsenicals.** OPP concluded the Special Review for inorganic arsenicals by publishing a Notice of Final Determination. All affected uses (uses other than as wood preservatives and sealed ant baits) were voluntarily cancelled as a result of the Special Review. This action culminated a Special Review initiated in 1978 because of concerns about risks of cancer, reproductive and fetal effects, and mutagenicity (genetic effects).

**EBDCs.** OPP completed a Special Review for a group of fungicides known as the EBDCs in 1992 by cancelling a number of uses and placing restrictions on the remaining uses. Subsequently, a registrant requested a change in certain of the restrictions. In 1994, OPP helped support the hearing that responded to the request, which resulted in an amendment allowing the use of more than one EBDC on a crop during the course of the growing season, as long as the total amount of pesticide applied does not exceed the maximum amount allowable from any one EBDC application.

**Carbofuran.** OPP also revisited the Special Review for the granular formulation of the insecticide carbofuran when registrants requested an extension of uses for rice, corn, and sorghum. OPP published a proposal in the Federal Register which would allow for a maximum of two more years of use on rice but no more use on corn and sorghum. OPP began phasing out most uses of carbofuran in 1991 because of risks of bird poisonings.

## Cancellation Of Mevinphos

OPP continues to reduce risks by means other than the traditional Special Review process, particularly through negotiated settlements. The agreement to cancel all uses of the agricultural insecticide mevinphos — one of the most acutely toxic pesticides produced in the United States — exemplifies how such actions can achieve substantial protection of human health and the environment.

In response to planned actions by OPP and the State of California to remove mevinphos from the market, the registrant requested that its registrations be cancelled. The registrant also agreed to a voluntary recall of all product still in the channels of trade after sale and distribution of product was no longer allowed. The cancellation was based on OPP's determination that the risks to agricultural workers were unacceptable. Poisoning data from California and other states showed that even when workers followed stringent label restrictions, an alarming number of poisoning incidents occurred. From 1982 through 1992, California (where about half of U.S. use of mevinphos occurred) recorded 594 poisonings associated with the use of mevinphos alone and in combination with other pesticides. Mevinphos alternatives are significantly less risky to workers than mevinphos.

## Other Negotiated Risk Reduction Efforts

During fiscal year 1994, OPP successfully negotiated for the reduction of health risks associated with several pesticides in addition to mevinphos:

**PCNB.** Registrants agreed to lower levels of two carcinogenic contaminants, HCB and PCB, in their products, bringing dietary risk down to the negligible level.

**Metrex.** OPP negotiated a settlement with the registrant because of concerns about the risk posed by failure of this hospital sterilant to work properly. The settlement imposed label requirements for longer contact times with treated surfaces and higher treatment temperatures to ensure that treated medical instruments were adequately sterilized.

**Simazine.** Twenty-two registrations of simazine used as an algicide in swimming pools were voluntarily cancelled after OPP approached registrants about unacceptable cancer risk to swimmers. OPP subsequently cancelled the remaining swimming pool simazine products when their registrants declined to join the voluntary cancellation.

## Other Cancellation Activities

In addition to the negotiated settlements described previously, OPP handled several cancellation actions in 1994. Two (for TBT fluoride and mercury compounds used on turf) were voluntary actions prompted by the registrants' decision not to develop required data. OPP also amended the earlier cancellation notices for the herbicide methazole (to extend the existing stocks period) and for Wipeout, a medical sterilant containing glutaraldehyde (to add new risks of concern).

## Tolerance Revocations

OPP continued to propose or finalize revocations of tolerances (maximum residues allowed in food) for pesticides cancelled through Special Review or for other reasons. OPP generally revokes tolerances some time after the uses are cancelled to allow legally treated foods to move through the marketplace and to account for possible foreign use on imported food. OPP proposed or finalized tolerance revocations and revisions for eight active ingredients in 1994: arsenic acid, carbophenothion, DDVP, diallate, dicofol, PCNB, perthane, and ronnel.

## Initiative To Reduce Risks To Birds (Avian Granular Initiative)

OPP continued to track the progress of the voluntary risk reduction initiative begun in 1992 for granular pesticide formulations posing risks to birds. OPP prepared a progress report that describes the voluntary risk reduction proposals received from seven registrants. The proposals include lower application rates, reduced number of applications, and use of application methods designed to reduce the number of exposed granules in end rows. Granular pesticides can be eaten by birds feeding in agricultural areas.

# 4

# Field Implementation and Communication

The major regulatory areas discussed by the first three chapters — registration, reregistration, and Special Review — primarily involve interaction with pesticide registrants, though many other organizations are also affected by and involved with OPP's decisions in these areas. In this chapter, the emphasis shifts to regulatory programs directed at pesticide users and implemented in the field. This chapter also discusses how OPP shares information with pesticide users and the myriad of other organizations and citizens interested in pesticides. Finally, this chapter discusses OPP's support for efforts to ensure compliance with pesticide requirements. All of these efforts complement the pesticide regulatory programs described in the first three chapters by improving the safety with which pesticides are used, and by making the public aware of the risks and benefits of pesticides and the availability of alternatives.

## A. Field Programs

The major field programs that OPP implements, as described in more detail in this chapter, are the Worker Protection Standard, the Endangered Species Protection Program, ground water protection programs, certification and training of pesticide applicators, and disposal of suspended and cancelled pesticides (completed in 1994). Voluntary field efforts in 1994 included promoting integrated pest management (IPM) and drafting guidance for states for posting of residential and commercial pesticide applications.

## Implementing The Worker Protection Standard

OPP revised the Worker Protection Standard (WPS) for agricultural pesticides in 1992 and it became fully effective on January 1, 1995. The Standard represents a major strengthening of national efforts to safeguard agricultural workers. Agricultural employers are required to follow new measures to protect their employees, including safety training, notifications about pesticide applications, provisions for washing facilities, and maintenance of protective equipment. OPP believes that the WPS will substantially reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers.

In 1994, OPP carried out a number of Worker Protection activities in preparation for full implementation in 1995, many of which included the participation of EPA's ten regional offices. OPP:

- Worked with pesticide registrants to ensure that the labeling of all agricultural pesticides was revised to convey stronger worker protection requirements, such as restrictions on entry to treated areas and use of personal protective equipment.

- Continued to work with the states, USDA's Cooperative Extension Service, and the agricultural community to help employers obtain the information and assistance they need. Over 1.7 million copies of OPP's *Agricultural Worker Training Handbook* have been distributed, as well as thousands of the *How To Comply Manual* and the *Pesticide Handler Training Handbook*. A number of other publications, videos, and training materials are available.

- Developed a voluntary program to issue training verification cards to workers and handlers to promote safety training for agricultural workers and to make it easier for agricultural employers to ensure that their workers have been trained. To date, 40 states, Puerto Rico, and two tribes have agreed to participate in the program, with more expected to join.

- Met directly with more than 25 organizations affected by the WPS to resolve problems and improve implementation of the standard. EPA held workshops on the WPS and conducted periodic meetings and discussions with agricultural groups.

- Approved the first exception to the WPS. For a two-year period and under specified conditions, the exception allows early entry into pesticide-treated areas in greenhouses to harvest cut roses. The WPS establishes a process for OPP to approve requests for exceptions if the benefits of the exception outweigh the costs (including any health risks) attributable to the exception.

- Evaluated certain WPS provisions where change or flexibility may be needed to make sure that workers are protected and that the requirements are fair and achievable. OPP has proposed changes to the WPS in the following areas and, based on public comments, expects to finalize them in the spring of 1995:

  - Strengthened safety training requirements.
  - Reduced requirements for crop advisors.
  - Reduced restrictions for lower risk pesticides.
  - Reduced requirements for irrigation activities.
  - Reduced requirements for other activities that result in limited contact to pesticides.

## Endangered Species Protection Program

The primary goal of OPP's Endangered Species Protection Program (ESPP) is to protect federally listed threatened and endangered species from the direct and indirect impacts of pesticide use. As mandated by the 1988 amendments to the Endangered Species Act, this goal is to be accomplished while minimizing the burden on pesticide users. Currently, OPP is carrying out an interim, non-regulatory program to protect endangered species while finalizing an endangered species protection regulation.

The ESPP was very productive in 1994. OPP produced and widely distributed many materials supporting and promoting the voluntary program, and is currently distributing 240 county-specific pamphlets in 22 states and Puerto Rico that describe voluntary measures pesticide users can take to avoid affecting threatened and endangered species with pesticides. OPP also completed fact sheets about eight additional endangered species, such as the Bald Eagle and Whooping Crane, bringing the total number of species fact sheets to 45. OPP also continued the operation of a toll-free endangered species hotline to provide more information about the program.

In implementing the endangered species program in 1994, OPP worked closely with EPA regions, states, and other federal agencies, such as the U.S. Fish and Wildlife Service (FWS). This cooperation was exemplified by efforts to protect the Wyoming Toad, an endangered species known to occur in the wild only in Albany County, Wyoming. The Wyoming Department of Agriculture, FWS, EPA's Region 8 Office, and OPP forged an agreement with local landowners and officials to postpone pesticide use on land within the toad's range until the land could be surveyed for potential habitat. No new toad populations were found on private lands, and pesticide applications resumed in areas where the toad was not found. The case serves as a model for the cooperation of landowners and federal, state, and local governments to implement the Endangered Species Act.

OPP also provided extensive comments on the Fish and Wildlife Service's draft Biological Opinion, which addresses the potential impacts of all uses of 15 major agricultural pesticides. In addition, OPP has begun requesting endangered species data from registrants on particular registration requests. Registrants may form a task force to supply the necessary data to cover all pesticide use sites. The next major step is to announce the final regulation and program by publishing a Notice in the *Federal Register*. OPP spent much of 1994 working with FWS and the U.S. Department of Agriculture to develop the final plans for the ESPP.

## Protecting Ground Water

Ground water provides about one-fourth of all water used in the United States and is the source of drinking water for about half the U.S. population. It also is a vital component of the ecosystem. For example, ground water often flows into surface water systems that are habitats for fish, sustain wetlands, and support commerce. OPP has several programs in place to protect this critical natural resource from pesticide contamination.

The centerpiece of OPP's strategy is a cooperative effort to develop State Management Plans (SMPs) to prevent ground-water pollution from pesticides. An important step in this approach has been the development of "Generic" SMPs, which aim to create the capacity for protecting ground water regardless of the pesticide. Forty-six states have submitted draft Generic plans to the EPA regions, and the regions have provided comments on most of these plans.

Final regional concurrence on all Generic plans is expected January 1996. The next major step will be the requirement that states develop pesticide-specific SMPs for those pesticides found to leach into ground water. OPP has received comments on a draft rule for pesticide-specific SMPs from all ten EPA regions and expects to issue a Notice of Proposed Rulemaking (NPRM) during 1995. OPP also works closely with EPA's Office of Water to ensure that the pesticide SMP program will complement the Agency's Comprehensive State Ground Water Protection Program.

Another important feature of OPP's strategy has been to establish procedures during registration and reregistration to evaluate a pesticide's potential to contaminate ground water. In 1994, OPP began to implement a new approach that achieves early mitigation of ground-water risks. In cases such as the registration of acetochlor, OPP required that registrants better target the use of pesticides and conduct follow-up monitoring to protect ground water quality. OPP continues to track evidence of ground water contamination through its Pesticides and Ground Water Data Base.

Furthermore, OPP expects to issue a final rule in 1995 that would add criteria for classifying a pesticide for restricted use if any of its ingredients has the potential for contaminating ground water on a widespread basis. Pesticide products classified for restricted use may be purchased and used only by certified pesticide applicators or individuals under their supervision. OPP believes that a pesticide is less likely to contaminate ground water if it is used only by trained applicators.

## Certification And Training Of Pesticide Applicators

When OPP designates some or all uses of a pesticide as "Restricted," then the pesticide may be used only by or under the direct supervision of certified users. Certification Programs are conducted by states, territories, and tribes and are designed to ensure that users of the most risky pesticides are knowledgeable about their risks and uses. OPP sets national standards for the programs, which certify over one million applicators nationwide.

In 1994, OPP continued to work to revise its national standards to better ensure continued competency of certified applicators. To assist the state, territory and tribal governments in conducting certification programs, OPP also continued cooperative agreements and provided funding to 64 governments. OPP also provided funding to state extension coordinators through the U.S. Department of Agriculture to conduct certification training programs. Training covers general areas of pesticide use as well as specific uses for which a person wishes to become certified. For example, training to become certified to apply pesticides to structures (such as schools, houses, and office buildings) includes information about ventilating structures prior to re-occupation.

## Disposal Of Suspended And Cancelled Pesticides

In 1994, OPP completed its disposal program for suspended and cancelled pesticides, thus removing the risks posed by unused stocks of these pesticides. Prior to the 1988 revisions of the Federal Insecticide, Fungicide, and Rodenticide Act, OPP was required to accept suspended and cancelled pesticide products for disposal if requested by holders. 2,4,5-T and silvex pesticides were suspended and cancelled prior to 1988 because of concerns about dioxin contamination. OPP accepted about 300 tons of granular 2,4,5-T/silvex materials and 30,000 gallons of liquid materials from several hundred holders at a hazardous waste storage facility. On May 27, 1994, OPP disposed of the last of these 2,4,5-T/silvex stocks at a hazardous waste incinerator.

## Promoting Integrated Pest Management

Integrated Pest Management, or IPM, involves the carefully managed use of an array of pest control tactics — including biological, cultural, and chemical methods — to achieve the best results with the least disruption of the environment. IPM relies upon an understanding of life cycles of pests and their interactions with the environment. Biological control refers to using natural enemies of the pest, such as employing ladybugs to control aphids. Cultural control involves practices of cultivation, crop rotation, and other methods that prevent or control pests. IPM also involves the judicious use of chemical pesticides, if necessary.

OPP's IPM accomplishments extended to both the urban and agricultural sectors. In the urban arena, OPP published Pest Control in the School Environment: Adopting Integrated Pest Management. This creatively illustrated booklet, already in wide circulation, will be provided to every school district in the United States by the end of 1995. Companion training videos, produced in cooperation with Texas A&M University, should be finished during the spring of 1995. OPP also edited and published, through Lewis Publishing Company, *Integrated Pest Management for Turf Grass and Ornamentals*. This book is the most up-to-date and comprehensive publication on the subject and has already been widely accepted within the professional landscape community.

In the agricultural sector, OPP has hosted a series of commodity-specific workshops to inform growers about existing IPM techniques and help identify impediments to IPM adoption. The proceedings from this year's peanut, stored commodity, and potato workshops, along with those developed during 1993, are being used to help frame the Agency's position on agricultural legislation (such as the Farm Bill).

## Guidance For Posting Of Outdoor Pesticide Applications

During 1994, OPP began the development of draft guidance for states and local jurisdictions regarding "posting" of outdoor residential and commercial pesticide applications. Posting refers to the placement of signs at visible entry areas to inform bystanders that a pesticide has been recently applied. This guidance is being developed to help harmonize such state and local programs. OPP hopes that such guidance will help lead to better consumer awareness and understanding of posting, increased compliance with posting requirements, and reduced burdens upon lawn care professionals who sometimes must deal with a confusing array of differing requirements. OPP intends to publish a draft in the *Federal Register* for public comment in 1995.

## B. Communications, Public Response, and Coordination

Outreach to the public is vital to the mission of OPP. By the term "public," OPP means all constituents affected by or interested in pesticide issues — not only states, tribes, and EPA regions, but also citizens, environmental and public interest groups, industry and trade associations, pesticide users, Congressional staff, medical and health representatives, academia, international organizations, other federal agencies, and the media. This section describes several of the ways that OPP provides information to the public, responds to inquiries, and in turn obtains valuable public input.

OPP's approach to communications is to make information widely available, easily accessible, and suited to different public preferences. To accomplish this, OPP issues announcements and publications for both general and scientific audiences, provides information by telephone and electronic network, responds to written requests for information, maintains a public docket for walk-in visitors, holds public meetings, and presents speeches and Congressional testimony.

## Outreach And Communications Strategies

In 1994, OPP issued more than 50 announcements inform the public about OPP's major regulatory and policy decisions Each announcement is planned using a communications strategy, and often entails a press notice and additional outreach materials, such as fact sheets or questions and answers. OPP also made special efforts during the past year to make the public aware of available information resources and to provide general pesticide information. In June, OPP issued a Pesticide Regulation Notice (PR 94-3) that summarizes the many avenues one can take to obtain information from OPP. Another accomplishment this year was the preparation of OPP's first catalog of pesticide publications. OPP distributed both documents extensively, and they continue to be widely requested. OPP also continued to distribute other documents to the public with the help of the National Center for Environmental Publications and Information; for example, OPP distributed over 45,000 copies of the booklet *Healthy Lawn, Healthy Environment: Caring for Your Lawn in an Environmentally Friendly Way* and over 15,000 copies of the booklet *Citizen's Guide to Pesticides.*

Protecting children from pesticide poisoning continues to be an important focus of OPP's outreach efforts. Working with the Poison Prevention Council and the Consumer Product Safety Commission, OPP has participated over the past three years in the activities leading to Poison Prevention Week. Through this mechanism, each year OPP distributes thousands of copies of fact sheets on pesticides and child safety and on using insect repellents safely (both in English and Spanish) to medical establishments and the general public.

## Responding To The Public

### Freedom of Information Act Requests

OPP responds to specific technical or complicated information requests from the public under the Freedom of Information Act (FOIA). OPP continues to receive the highest number of FOIA requests of any program within EPA, and in fiscal year 1994 received 1,578 requests. Despite this heavy workload, OPP was able to reduce its backlog of FOIA requests by more than half. The majority of requestors receive all of the records they request, with the most common requests being for science reviews of registration data, administrative files for pesticide products, and product labels.

### OPP Public Docket

OPP has established four dockets, operated by a contractor, to house the regulatory notices, background documents, and public comments on OPP activities. These consist of the Federal Register, Special Review, Registration Standard, and Special Program Dockets. Thousands of requests were received in 1994 for docket information — by letter (over 1,000 requests), telephone (over 2,000 requests), and in person. Citizens account for the largest number of requests for docket information.

### National Pesticides Telecommunications Network (NPTN)

NPTN is a toll-free telephone service available to provide a variety of impartial information about pesticides to anyone in the United States, Puerto Rico, and the Virgin Islands. The service operates Monday through Friday from 8:00 a.m. to 6:00 p.m. (Central Standard Time). NPTN provided services to more than 25,000 callers during fiscal year 1994, including approximately 1,300 calls concerning pesticide incidents. The remaining calls were requests for general information on pesticide products and issues concerning health, safety, and use.

### National Pesticide Medical Monitoring Program (NPMMP)

The NPMMP, located at Oregon State University, provides information and referrals on the clinical toxicology of pesticides and analytical services for both biological and environmental samples. Consultations are given to both possible victims and health care professionals. NPMMP handles 200 to 300 cases per year.

### Letters

OPP also responded to a substantial number of letters to the Agency on pesticide-related issues, including letter campaigns on subjects such as food safety, pesticides and children, the Delaney clause, livestock predator pesticides, and worker protection.

## Congressional And Federal Coordination

Congressional interest and oversight in pesticide and food safety issues continues at a high level as OPP responded to almost 400 inquiries over the past year. OPP also prepared testimony and briefing materials for eight Congressional hearings concerning pesticide issues (such as pesticide exports/food safety and worker protection standards). During the past year, OPP assisted the General Accounting Office (GAO) and EPA's Inspector General (IG) office with seven ongoing evaluations of the pesticide program's activities: EPA's decision on carbofuran; a survey of EPA actions related to EBDC uses; EPA's process for reinventing tolerances for cancelled pesticides; EPA's collection of user fees; the Chief Financial Officer's audit of the fiscal year 1994 financial statement; environmental laws and regulations pertaining to agriculture; and the federal government's compliance with the Endangered Species Act.

## Public Meetings

OPP continues to seek ways to provide meaningful opportunities for the public to meet with the Agency and discuss pesticide issues of concern. OPP held several meetings during 1994, some on a quarterly basis, with a variety of constituent groups. OPP hosted regular meetings with environmental and public interest groups during the year, and set up several on topics of special interest, such as international issues and the farmworker protection program. OPP also held quarterly meetings with the American Crop Protection Association (formerly NACA). Additionally, OPP conducted two large-scale workshops in 1994 for a broad spectrum of participants, with one workshop focusing on general pesticide issues and the other on reducing pesticide use and risk. Looking ahead, OPP will seek opportunities for more in-depth discussions of critical program policies and issues with a cross-section of constituent groups.

## Pesticide Information Network

The Pesticide Information Network (PIN) is a computerized, on-line collection of files containing current and historic pesticide information. This system is designed to enhance OPP's data gathering efforts; aid state agencies and others in obtaining needed information on a timely basis, thereby improving their ability to respond to local pesticide situations and federal requirements; save OPP resources through automated dissemination and updating of public information; and enhance cooperative efforts between EPA and other federal agencies through a convenient method of information sharing.

In 1994, OPP worked to upgrade the system, and the revised PIN is expected to open in early 1995. The PIN will contain several different types of information. These will consist of the **Pesticide Monitoring Inventory (PMI)** (including the Pesticides in Ground Water Database), the **Ecological Incident Information System (EIIS)** (described in more detail in chapter 6), an **Environmental Fate and Ecological Effects** compilation, a **Regulatory Status** database, the **Certification and Training Bibliography**, and a **Biological Pesticides** data set.

## Agency Risk Management Communication Group

OPP actively participated during 1994 in the Agency Ecological Risk Management Communication Group, which was formed to address EPA's difficulties in using the assessments of ecological risks to properly manage those risks. The first major project of the Group, completed in 1994, was to write a document that would help risk managers throughout the Agency make decisions that include a consideration of ecological risk. The document is introductory in nature and contains a great deal of basic information about the value of ecological resources, determining what resources should be protected, understanding the involvement of a risk manager in the risk assessment process, and using a risk assessment for risk decision-making. The Group also hopes that experienced risk managers will benefit from the document.

## Scientific Presentations And Publications

OPP believes that sound scientific information is the cornerstone for assessing and managing risks, as will be described in chapter 5. OPP scientists continue to contribute to the development and application of their varied scientific disciplines, including hydrology, biology, agronomy, chemistry, toxicology, and many others. In 1994, OPP scientists presented several dozen papers and posters at a number of professional meetings of organizations such as:

- American Chemical Society
- American Society of Agronomy
- American Phytopathological Association
- International Union of Pure and Applied Chemistry
- Society of Environmental Toxicology and Chemistry
- Society of Quality Assurance
- Soil Science Society of America

OPP scientists served as editors for a book titled *Agrichemical Environmental Fate State of the Art*, which is scheduled to be released in May 1995. They also published a number of professional papers, including several that appeared in conference proceedings and symposiums of associations listed above and in journals like the *Journal of Invertebrate Pathology* and *Environmental Toxicology and Chemistry*. In addition, OPP scientists lectured at Clemson University, the University of Maryland, and other universities and organizations.

## International Coordination And Integration

This section describes OPP's efforts to inform foreign governments about the status of U.S. pesticides and OPP programs. The purpose of these efforts is to help foreign governments, especially those that have not yet developed extensive pesticide regulatory and information-gathering programs, make informed choices about the use of pesticides in their countries. Not only do these efforts benefit citizens of foreign nations, but they also benefit Americans by helping to ensure the safety of imported food and other commodities treated with pesticides. In addition, these efforts help to protect wildlife, like migratory birds, that cross international borders.

### Export Notification for Unregistered Pesticides

For all exports of pesticides not registered in the United States, federal pesticide law (FIFRA section 17(a)) requires the U.S. exporter to obtain a statement from the buyer acknowledging that the product is unregistered in the U.S. The exporter must then submit this statement to OPP, and OPP forwards a copy to the importing government. In 1994, OPP transmitted approximately 1,600 export notifications to the governments of importing countries.

### Information Exchange with Foreign Countries

Another provision of federal pesticide law, FIFRA section 17(b), requires OPP to operate an information-sharing program with health and environmental agencies in other countries. Through this program, OPP sends information notices to other governments on important regulatory decisions made in the United States related to pesticides, food safety, and pest management. In 1994, OPP transmitted several notices of major regulatory actions on specific pesticides, such as the voluntary cancellation of mevinphos, and other pesticide documents. Section 17(b) notifications are distributed directly to the pesticide regulatory authorities in approximately 140 countries.

### Prior Informed Consent (PIC)

EPA is a participant in this program developed by the United Nations Environment Programme (UNEP) and the U.N. Food and Agriculture Organization (FAO) to promote the safe management of chemicals. PIC establishes a mechanism whereby importing countries can receive information about pesticides and industrial chemicals and then determine whether to allow, restrict, or prohibit future imports of the chemicals. In 1994, EPA formally nominated mevinphos for inclusion on the UN list of banned pesticides because it was voluntary cancelled in 1994 (see the Special Review chapter for more information). In addition, work progressed internationally toward making PIC a legally binding instrument. Formal negotiations toward an international treaty are expected to occur during 1995 and 1996.

### International Visitors

OPP has an ongoing program to arrange meetings for foreign visitors to discuss U.S. pesticide policies and scientific evaluation procedures. During the past year, OPP received 95 visitors from 23 nations. The majority of visitors came from Japan, South Korea, and the People's Republic of China.

## Regional, State, And Tribal Liaison

### Regional Coordination

Staff in each of EPA's 10 regional offices are OPP's primary connection to state, territorial, and tribal governments. They negotiate cooperative agreements for OPP's field programs, assist the governments in developing and implementing programs, and oversee accomplishments and commitments made by the states, territories and tribes. Additionally, regional staff communicate OPP's programs and policies to the public and in turn provide OPP with information from the public. Clearly, OPP's regional counterparts are critical to the success of developing, implementing and communicating OPP programs and actions. Therefore, OPP works to ensure that the regional offices are involved in or informed of all OPP activities.

### State and Territorial Programs

States and territories are true partners with OPP in carrying out the functions of protecting human health and the environment. They assist in developing and implementing many of OPP's field programs, and they enforce OPP's regulations and pesticide labeling and use requirements. To ensure that programs are successful, direct communication among these governments is often necessary. To accomplish this, OPP in 1994 continued a cooperative agreement with the Association of American Pesticide Control Officials (AAPCO) to maintain the State FIFRA Issues Research and Evaluation Group (SFIREG). SFIREG meets periodically with OPP to develop pesticide programs and discuss implementation and enforcement issues of concern to the states and territories.

### Tribes

Native American tribal governments have sovereign rights and certain specific assurances from the federal government under treaties. A considerable diversity exists among the tribes. Some have land areas and populations comparable to many of the smaller states, whereas others have fewer than 50 tribal members and 100 acres of land. The capacity of the tribal governments to carry out environmental regulatory programs also varies significantly from tribe to tribe.

OPP's major effort with tribes has been to assist them in building the capacity to conduct regulatory and field programs for pesticides. In 1994, OPP participated in the Native American Environmental Conference to demonstrate different ways in which tribes can implement OPP programs. OPP also funded an environmental scholarship program to assist college students studying environmental sciences and interested in addressing Native Americans issues. OPP also addressed Native American issues by assigning one employee to work at the Administration for Native Americans and another to work with EPA's Office of Civil Rights.

In addition, OPP attempts to address specific issues uniquely affecting Native Americans. In 1994, OPP began a project involving other state and federal authorities to address potential pesticide exposure by members of the California Indian Basketweavers Association (CIBA). CIBA members expressed concern to the Agency about their potential exposure to pesticides from contact with native plant materials used in traditional basketweaving.

## Improving Internal Communications

The OPP Committee on Networking, Education, Communication, and Training Strategy (OPP CONECTS) made a significant effort in 1994 to improve internal communications. Based on recommendations of the committee to OPP management in June, two new initiatives are underway. *OPP PULSE*, a publication "by OPP staff, for OPP staff," began publication in September. The OPP LINKS series, in which each OPP division educates the others about its roles and responsibilities, often in innovative and creative ways, began in October. Both initiatives are helping OPP staff better understand the work of other divisions and gain a sense of how they fit into the larger picture. The two initiatives also give staff members the opportunity to share what they do and what they know with the rest of the program, making OPP a less impersonal workplace.

## C. Support For Compliance Activities

Compliance activities — such as helping regulated entities understand and meet applicable requirements, verifying that requirements are met, and taking enforcement action when they are not — are indispensable parts of EPA programs to protect public health and the environment. OPP provides support to Agency pesticide compliance activities, which are directed by the Office of Enforcement and Compliance Assurance (OECA). (Pesticide compliance activities formerly were coordinated by the Office of Compliance Monitoring, which was integrated into the newly-created OECA in 1994.)

## Support For The Lab Audit Program

OPP relies on data submitted by registrants to make regulatory decisions involving product registrations, tolerances, use restrictions and requirements, and other areas. EPA conducts a program to inspect and audit the laboratories that produce these data. Important components of the lab audit program are the Good Laboratory Practice Standards (GLPS), which are designed to ensure the quality and integrity of pesticide data.

In 1994, 43 GLPS inspections were conducted for OPP, and OPP scientists assisted in three of the inspections. Targeted areas included product chemistry, residue chemistry, environmental fate, toxicology, and antimicrobial testing. As a result of the inspections, EPA developed four GLPS enforcement cases involving four laboratories and thirteen registrants or sponsors, and revoked the registrations of two products.

## Analysis Of Product Chemistry

OPP's pesticide chemistry laboratories are essential for verifying the description and amount of active ingredients provided by registrants on pesticide product labels. During 1994, OPP analyzed a large number of new pesticide product samples, both for technical and end-use formulations, to verify registrant label claims. The methods used to perform the analyses are published in an EPA manual of methods by the Association of Official Analytical Chemists (AOAC) International and used by state agencies and other organizations.

## Other Laboratory Support

OPP's two pesticide chemistry labs often provide high priority support for other enforcement efforts. In 1994, OPP supported seven external EPA region/state projects: Craven Laboratories investigation with the Department of Justice; State of New York investigation of DCPA contamination of the Suffolk County drinking water supply; State of Florida's investigation of alleged benomyl damage in greenhouses; State of Oklahoma's analysis of dioxin/furan samples; EPA Region 5 and Region 7 investigation of the WTI incinerator in Ohio; Louisiana Board of Regents request to review technical proposals; and EPA Region 3's request to analyze samples for diatomaceous earth. The pesticide chemistry labs supported several other external projects, including the Central American Lab Project; Gulf of Mexico Project; U.S. State Department Project in Russia; two EPA Office of Research and Development Dioxin Projects; U.S. Army air samples from the Mideast (dioxins); and air samples from Croatia (dioxins).

## Additional Support For Compliance Activities

In addition to laboratory support, OPP often contributes expertise and records for compliance activities. One example of this in 1994 was OPP's work on the Raid Max Roach Bait enforcement case. In this case, EPA alleged that S.C. Johnson & Son, Inc., the manufacturer, began illegally marketing this product in new design packaging without first receiving EPA approval. This information contributed to EPA Region 5 issuing a Stop Sale, Use, or Removal Order to S.C. Johnson to immediately halt the sale and distribution of the product. EPA also requested that the company voluntarily recall all unapproved Raid Max Roach Bait products in the hands of consumers and in the channels of trade. Another example was OPP's work on the recall by the registrant of Natrapel Insect Repellent products because of potential bacterial contamination.

# 5

# Policy, Regulations, And Guidelines

OPP's fifth major program area involves developing regulations and other policies for pesticides. These efforts are intended to help develop and implement national legislation passed by Congress, to improve the quality of pesticide regulation (which can include both formulating new policies and streamlining existing ones), and to augment the quality of OPP's scientific information. In some cases, OPP finds that policies are needed to address newly-discovered concerns, or to keep up with technological advances in pest control, such as in the area of genetically-engineered biological pesticides. Wherever possible, OPP encourages public participation in the development of policies.

Federal policies can be regulatory (promulgated by regulation) or non-regulatory. Regulations are published in the *Federal Register* for formal public notice and comment and incorporated into the Code of Federal Regulations. Regulations proposed or finalized in 1994 and discussed in this chapter include those related to biological pesticides and pesticide containers. Non-regulatory programs, in general, are not directly mandated by law and do not impose legally enforceable requirements. A prime example, discussed in more detail below, is OPP's voluntary pesticide environmental stewardship partnership. Policies often include both regulatory and nonregulatory components, such as OPP's international coordination efforts and OPP's response to the National Academy of Sciences report on children and pesticides.

## Follow-up To The National Academy Of Sciences (NAS) Children's Study

EPA, the Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA) are working together to address the concerns identified by the June 1993 National Academy of Sciences report, *Pesticides in the Diets of Infants and Children*. The Academy concluded that exposure of children to pesticides is substantially different from that of adults and that the federal government should do more to address the unique risks posed to children. To provide additional measures of protection for children, the Academy recommended numerous changes to the way the federal government safeguards the nation's food supply.

OPP is moving ahead to implement many of the NAS recommendations. Additional toxicological studies will be included in the standard battery of testing requirements (known as the part 158 requirements) that are under revision. OPP plans to collect data on immune functions, nervous system development and toxicity, and visual systems. In addition, the OPP has completed an analysis of the utility of including *in utero* exposure in long-term toxicology studies. EPA and FDA have completed plans to standardize the reporting of pesticide levels in food and to store these data in a centralized National Pesticide Residue Monitoring Database, though additional funding is needed to proceed. OPP is working closely with USDA on the design of future USDA national food consumption surveys to ensure that the eating habits of infants and children are adequately represented. OPP is also exploring ways to combine the risks from multiple sources of exposure. These include combining the risks posed from chemicals with similar mechanisms of action as well as several routes of exposure, including both nondietary and dietary routes.

## Reduced Use/Risk Initiative

The Pesticide Use/Risk Reduction Initiative announced in June 1993 is a joint effort with EPA, USDA, and FDA to reduce the use and risks of pesticides. As part of the initiative, a voluntary program called "Pesticide Environmental Stewardship Partnership - PEST SMART" has been created to form partnerships with all affected interests (including commodity organizations and public interest groups) and develop plans which will reduce the risks posed by pesticides while maintaining cost-effective pest control methods.

In December 1994, the Administration announced the initial partners (grower groups and utility companies) in the program. In forming this partnership, the federal agencies and the participating groups and companies agree that environmental stewardship is an integral part of pest management practices. Specifically, the partners have agreed to a number of guiding principles that will shape pest management. In summary, the principles state that (1) pesticide users will continue to work towards pest management practices that reduce risks and to minimize the pesticide use where desirable and practicable; (2) users will continue to develop and implement regional pesticide environmental stewardship plans; (3) the federal government will seek to foster effective alternative pest management technologies and practices; (4) and the federal government will integrate the environmental stewardship plans into its agricultural and environmental policies and programs.

The partnerships represent a major step in the overall federal efforts to encourage environmental stewardship. OPP is actively seeking additional pesticide user groups, from both agricultural and non-agricultural sectors, to participate. The voluntary measures will help prevent pollution and reduce potential risks to both people and the environment from pesticides.

## International Harmonization And Regulatory Coordination

OPP's international harmonization projects aim to develop common or compatible international approaches to pesticide review, registration and standards-setting. The benefits of making pesticide regulatory programs more consistent internationally include improved safety of food imported into the United States, reduced regulatory burden on national governments, upgrading of supporting science, fewer trade problems, and reduced costs for registrants.

### OECD Pesticide Program

OPP worked closely with other member countries of the Organization for Economic Cooperation and Development (OECD) to establish a Pesticide Forum and pesticide work program. For the first time, the Forum brings government pesticide regulators together to address common problems and achieve greater harmonization of policies and procedures. The Pesticide Forum is working in five areas: reregistration, data requirements, risk reduction, test guidelines, and hazard assessment. Under reregistration, for example, the United States served as the lead country for the Pilot Project to Compare Pesticide Data Reviews. The pilot project has led to a number of follow-up activities to expand the exchange and use of national data reviews. As a result of Forum efforts, countries are gaining a much better understanding of each other's practices.

### Intergovernmental Forum on Chemical Safety

The United States participated in the June 1992 United Nations Conference on Environment and Development (UNCED) held in Rio de Janeiro, Brazil. The conference report "UNCED Agenda 21" made comprehensive recommendations for better coordination and management of environmental risks. Chapter 19 of Agenda 21 covers the environmentally sound management of toxic chemicals.

In May 1994, governments and international organizations meeting in Stockholm, Sweden agreed to continue the Intergovernmental Forum on Chemical Safety (IFCS) to improve the management of international chemical safety activities. The United States is working to implement the many Agenda 21 and IFCS recommendations, including the assessment of several hundred priority chemicals by the year 2000. These new assessments are intended primarily to meet the needs of developing countries. The IFCS is also moving to implement Agenda 21 recommendations for improvements in harmonization of classification and labeling, information exchange and prior informed consent, risk reduction, and strengthening national capabilities.

### Canada/U.S. Technical Working Group on Pesticides

The Canada-U.S. Trade Agreement (CUSTA) directs the countries to work toward equivalence of pesticide standards. To assist in this effort, CUSTA established a Technical Working Group on Pesticides, currently co-chaired by OPP and the Chemical Evaluation Division of Health Canada's Food Directorate. Pilot projects in progress in 1994 included: 1) parallel registration review of tebufenozide, an insect growth regulator, in Canada and the United States; 2) harmonization of maximum residue limits (tolerances) for four chemical/crop combinations; and 3) cooperative reevaluation of heavy-duty wood preservatives. Subgroups of the Technical Working Group have also been formed to address specific environmental, toxicological, and occupational exposure issues.

## Technical Assistance: AID/EPA Central American Project

The AID/EPA Central American Project is a pilot technical project involving EPA, the U.S. Agency for International Development (AID), FDA, and USDA. It is designed to enhance Central American efforts to improve pesticide safety and pest management practices. During 1994, EPA participated in regional technical workshops in Central America to provide information about integrated pest management, safe pesticide use practices, and U.S. pesticide/food safety import requirements. EPA implemented a short-term assistance program in El Salvador to identify and manage old pesticide storage sites. EPA also provided technical assistance to the Government of Ecuador to assist them in dealing with the "Taura Syndrome," a condition causing high shrimp mortality in shrimp farms in the Gulf of Guayaquil.

## Biological Pesticide Policy Highlights

EPA believes that many biological pesticides are less hazardous than traditional chemical methods of pest control, and in 1994 the Agency continued to take steps to encourage their development and use. This section summarizes those efforts. EPA expects that as biological and other safer pesticides are brought to market, they will displace an older generation of more toxic chemical pesticides.

### Pheromone Regulatory Relief Policy

Insect pheromones are a class of biochemical pesticides and are considered to be reduced risk pesticides. They are used to disrupt the mating of insect pests that infest agricultural crops. As part of its efforts to provide regulatory relief for pheromones, OPP published a final rule expanding the allowable acreage from 10 acres to 250 acres for testing without obtaining an Experimental Use Permit (EUP) from OPP. OPP also published an exemption from the requirement of a tolerance for certain formulations of pheromones and their inert ingredients based on low risks to people. These rules applied to solid matrix dispensers (such as those made of plastic) that can be retrieved from fields. OPP is considering further expanding the exemption for testing of certain groups of pheromones to include all broadcast formulations for experimental testing on up to 250 acres.

### Final Rule on the Testing of Microbial Pesticides

EPA published a final rule on September 1, 1994, that amends the Agency's experimental use permit regulations and modifies prior policy regarding small scale testing of microbial pesticides. Microbial pesticides consist of microorganisms such as bacteria, fungi, viruses, or protozoans used to control pests. The rule will codify existing policy that requires notification to OPP prior to initiating small-scale field tests with certain genetically modified microbial pesticides. This rule reduces the regulatory burden of testing microbial pesticides compared to existing policy, while preserving sufficient federal oversight to prevent unreasonable adverse effects from testing of microbial pesticides.

### Proposed Regulation Of Plant-Pesticides

The Agency has proposed a number of actions to regulate certain novel pesticidal substances genetically introduced into plants for the purpose of protecting them against pests and disease. These substances have been designated plant-pesticides. The proposed regulations, issued in November 1994, address plant-pesticides and not the plants themselves.

EPA is proposing to exempt three types of low risk plant-pesticides from registration requirements:

1) Plant-pesticides derived from a closely related plant (e.g., those taken from one corn plant and engineered into another corn plant).

2) Plant-pesticides that act primarily by affecting the plant (e.g., plants that have been engineered to produce a thicker, more pest-resistant outer layer of wax) rather than by having a direct toxic effect.

3) Plant-pesticides consisting of certain components of viruses called *viral coat proteins*, and the genetic material needed to create the coat proteins. Scientists are now able to transfer genes from a virus into the plant so that the plant can produce viral coat proteins. These proteins provide the plant with resistance to infection by disease-causing plant-viruses.

EPA is proposing to exempt three categories of low risk plant-pesticides (including associated genetic material) from the requirement to obtain a tolerance:

1) Plant-pesticides derived from closely related plants.

2) Plant-pesticides not derived from closely related plants, as long as the plant-pesticide would not result in substantially different exposure through food (e.g., those taken from a highly consumed crop such as corn and engineered into another crop such as eggplant).

3) Coat proteins from plant viruses.

## Activities Related To Implementation Of The "Delaney Clause"

In 1992, the Ninth Circuit Court of Appeals issued a decision in the Les *v* Reilly case mandating a strict interpretation of the Delaney clause of the Federal Food, Drug and Cosmetic Act (FFDCA). According to the court, the Delaney clause forbids EPA approval of food additive regulations if the pesticide has been found to induce cancer, regardless of the degree of risk to the public. (Food additive regulations are maximum residue limits, or tolerances, for processed food and are required if a pesticide is used or becomes concentrated in processed food.) The Delaney clause does not apply to tolerances for raw agricultural commodities. EPA has taken a number of actions to achieve full and continuing compliance with the Delaney clause, and in fiscal year 1994:

- ❑ Proposed to revoke food additive regulations for a number of pesticides found to cause cancer. OPP proposed the revocation of 26 tolerances of 7 pesticides on July 1, 1994. OPP expects to propose the revocation a number of other tolerances in 1995.
- ❑ Revoked tolerances for dichlorvos (DDVP) on bagged commodities, for dicofol on tea, and mancozeb on washed raisins. A temporary stay of the revocation is in effect for DDVP and dicofol.
- ❑ Issued a notice to registrants (PR Notice 93-12) explaining the revised policy that dried hops are a raw agricultural commodity (RAC), and therefore no longer subject to the Delaney clause. Two tolerances were subsequently established for dried hops as a RAC.
- ❑ Published in the *Federal Register* an updated list of pesticides potentially affected by the Delaney clause.
- ❑ Issued a Federal Register Notice explaining OPP's policy to delay action on pending petitions and registration actions subject to the Delaney clause until Delaney policy issues are resolved.

## Standards For Pesticide Containers And Containment

In February 1994, OPP proposed the "Standards for Pesticide Containers and Containment." These measures are intended to protect human health and the environment by reducing exposure to pesticides and reducing production of wastes when pesticide containers are stored, handled, and refilled. The standards are a result of Congressional amendments to FIFRA in 1988, which authorized EPA to issue regulations in two areas of concern: pesticide container design standards and residue removal standards. The proposed rule would establish standards for the removal of pesticides from the containers and the rinsing of the containers and would facilitate safe use, refill, and disposal of containers. The rule also would establish requirements for the containment of stationary bulk containers and pesticide dispensing areas.

OPP reviewed and summarized approximately 200 public comments and entered them into an issue-oriented data base. A workgroup is being re-established to finalize the rule, which is expected to take 18 months.

## Other Regulations Under Development

In 1994, OPP continued to develop a number of regulations designed to increase protection of human health and the environment.

### Tolerances and Food Safety

OPP is reinventing its processes for establishing tolerances and estimating risks to consumers (including children) from exposure to pesticide residues in food. Thus far, eight potential procedural changes have been identified. OPP is considering taking into account factors such as those known to reduce pesticide residues in foods between the time crops are harvested and eaten (e.g., storage, processing, washing, peeling, and cooking) when setting tolerances. The resulting tolerances would more closely reflect real exposure to pesticide residues in food. OPP expects to issue an Advance Notice of Proposed Rulemaking (ANPRM) in the spring of 1995.

### Revised Pesticide Registration Data Requirements (Part 158)

In 1994, OPP provided draft comprehensive revisions to data requirements for registering pesticides (Part 158 of the Code of Federal Regulations) to the EPA Scientific Advisory Panel (SAP) for review in preparation for proposed rulemaking in early 1995. Much of this proposed rule would implement changes already adopted in OPP in the course of registration and reregistration. The revisions would ensure that comprehensive data packages are supplied to OPP so that each pesticide can be evaluated using current health and environmental standards.

### Reporting of Pesticide Incidents (6(a)(2) Rule)

Section 6(a)(2) of federal pesticide law requires registrants to report to OPP incidents related to pesticide use or other information related to potential adverse effects of pesticides. This information is important in helping OPP decide if action should be taken to reduce the risks posed by a particular pesticide. In 1994, OPP worked to finalize the proposed 6(a)(2) rule, which would clarify the incident reporting obligations of registrants. OPP expects to publish the final rule in mid-1995. (Chapter 6 provides further discussion of 6(a)(2) activities during 1994.)

### Protecting Endangered Species and Ground Water

As described in more detail in chapter 4, OPP continued to work on a final regulation to protect federally listed threatened and endangered species from the impacts of pesticide use and to draft several regulations to further protect ground water resources.

## Legislative Proposals

OPP played a lead role in working with USDA, FDA and the White House domestic policy staff to draft comprehensive pesticide and food safety legislative reforms advanced by the Administration, preparing for Congressional hearings on the proposals, and conducting numerous communications and outreach activities. OPP also performed a preliminary cost analysis and analyzed other bills advanced in the 103rd Congress. The Administration proposals aim to provide authorities under both the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to enable regulatory agencies to take prompt action to reduce risks to health and the environment, and to promote development of safer methods of pest control.

Notably, the Administration's legislation would replace the "Delaney clause" of the FFDCA with a consistent, health-based standard for setting tolerances for pesticide residues in all types of food. Other FFDCA proposals respond to the recommendations of the National Academy of Sciences report *Pesticides in the Diets of Infants and Children*; call for a review of all existing

tolerances against the new, health-based standard; and enhance FDA's enforcement powers. FIFRA proposals include registration "sunset" provisions; incentives for development and registration of reduced risk and minor use pesticides; support for risk and use reduction and IPM activities; streamlined cancellation and suspension procedures; export restrictions; record-keeping for all agricultural pesticide use; additional fees to support FIFRA '88 reregistration; enhanced enforcement for FIFRA violations; and a number of other regulatory tools.

The Administration's proposals were introduced into the 103rd Congress, but no final action was taken before the close of the session. OPP expects a number of these issues to resurface in the next Congress, either as independent legislation or in the context of the 1995 Farm Bill.

## Maintaining And Improving OPP's Science Base

OPP's critical decisions rely upon the scientific information and judgment about those pesticides. OPP invests considerable effort in obtaining the best scientific information available and working with other experts within and outside of government to make sure its standards reflect the latest scientific thinking. This section describes some of OPP's efforts in 1994 to build upon its scientific base.

### Ecological Effects Pesticide Toxicity Database

Over the past two years, OPP has developed a database to provide a rapidly accessible source of ecotoxicity data for all pesticides in use nationwide. Ecotoxicity data consist of information about the toxicity of pesticides to birds, mammals, fish, plants, and other organisms. The database will track, record, and summarize OPP's vast library of toxicological data, which until now has been available only in paper format, and should prove to be an extremely valuable tool for assessing the risks associated with various alternative pesticide uses. OPP has already provided database information to EPA regions and other offices, USDA, the U.S. Fish and Wildlife Service, a number of state agencies, and others. The database will also allow OPP to more efficiently complete registration and reregistration actions. The database currently contains over 7,000 toxicity records for 300 major use pesticides and is about halfway completed. OPP plans to incorporate this database into the Pesticide Information Network (described in chapter 4) and other publicly available data sources.

### National Water-Quality Assessment Program

OPP scientists have worked closely with the U.S. Geological Survey's National Water-Quality Assessment (NAWQA) Program over the past several years. NAWQA is describing the status and trends in a representative part of the nation's ground and surface waters. One product from the joint efforts is the publication entitled *Summary of National Standards and Guidelines For Pesticides in Water, Bed Sediment and Aquatic Organisms and Their Application to Water-Quality Assessments*. This publication summarizes current national standards and guidelines, and provides definitions, originating agencies, statutory authorities, regulatory status, applicable sampling media, beneficial use and resource protected, and full citations of published documentation. An entire issue of *Reviews of Environmental Contamination and Toxicology* has been dedicated to the publication.

### EPA's Contaminated Sediment Management Strategy

OPP has actively participated in the Agency's Contaminated Sediment Management Strategy, published August 1994. OPP scientists have served on various Agency committees covering a wide range of topics from toxicity testing to use of sediment water quality criteria. They have also worked closely with EPA's Office of Pollution Prevention and Toxics to provide a Prevention, Pesticides and Toxic Substances policy, as well as a scientific position on the Strategy.

## Health Effects Research and Guidelines

OPP participated in a number of projects in 1994 to advance scientific knowledge and understanding of the health effects of pesticides. Some of these projects included:

- Drafting and sharing publicly the test guidelines for reproduction and developmental toxicity studies. OPP is finalizing the guidelines based on public comment. OPP has also developed Standard Evaluation Procedures (SEPs) for reproduction and developmental toxicity studies and is gathering public comment. These procedures should standardize how the studies are evaluated both by industry and EPA.

- Holding an Ocular Toxicity Workshop to explore testing options for the adverse eye effects associated with organophosphate pesticides. OPP and pesticide registrants discussed the protocols and feasibility of several proposed tests.

- Convening a workshop with leading researchers to obtain comment on draft revisions to the guidelines (known as the Subdivision K guidelines) for assessing pesticide exposure to people in both work and residential settings.

- Working with the International Life Sciences Institute (ILSI) to explore a number of contentious scientific issues. Among the most important ones are the significance of mammary and bladder tumors in laboratory animals and how to interpret certain effects in laboratory animals found at extremely high doses of pesticides (the Maximum Tolerated Dose, or MTD, issue).

- Drafting and distributing for preliminary comment revised guidelines for performing toxicology metabolism studies. The new guidelines will have a tiered system of testing. OPP plans to hold a workshop on the guidelines in May 1995.

# 6

# Information and Program Management

OPP's information and program management efforts are not as publicly visible as some of its other programs, but without them none of the other programs could operate. The buildings that OPP occupies, the supplies and equipment it uses, the funds it administers, the systems for processing and storing the vast amounts of information that OPP uses, and the staff itself — all of these critical program components are managed under this program area. This section describes some of the information and program management achievements during 1994.

## Operations, Maintenance And Integration Of The Primary OPP Information Systems

In 1994, OPP finished major parts of its automated information management infrastructure. All OPP employees are now equipped with personal computers linked via a high-speed local area network (LAN). Detailed and summary information about pesticide chemicals, products and their uses, registrants, registration action requests, tolerances, reregistration status, and other information is available through the LAN. Electronic mail (email), scheduling, word processing, spreadsheet, and other software packages are also available. This infrastructure is reliable and has greatly improved internal communication and data-sharing in OPP.

Additionally, OPP completed the integration of several computer systems used to manage the pesticide reregistration process into an improved system called the Chemical Review Management System (CRMS). OPP used CRMS

in preparing the Reregistration Report Cards sent to each registrant involved in reregistering a pesticide. Major improvements were also added to the Pesticide Regulatory Action Tracking System (PRATS), which OPP uses to help manage the flow of registration actions through the program. The improvements added capabilities for priority planning, scheduling, and performance analysis.

Other major improvements to the automated information management infrastructure in 1994 included upgrading the staff personal computers, completing the major preparatory steps for integrating all the OPP-wide computer systems into one umbrella system, aggressively pursuing electronic submission of detailed data critical to science studies, and adding more software to the network.

## Pesticide Incident Reporting/6(a)(2) Activities

Section 6(a)(2) of federal pesticide law requires registrants to report to EPA incidents, studies, or other information indicating new potential adverse effects of registered pesticides. This information is important in helping EPA decide if action should be taken to reduce the risks posed by a particular pesticide.

The number of 6(a)(2) submissions to OPP increased in 1994 to approximately 700 covering 4,500 individual incident reports. OPP's 6(a)(2) Team screened 755 adverse effects submissions, which were primarily studies and preliminary reports of possible adverse effects from studies not yet completed. As a result of screening, 20% of the submissions were determined to warrant expedited review. Of those, about 20% resulted in label changes to reduce risks, mostly in cases of new findings of acute toxicology studies, and 8% showed a new adverse effect that is being addressed by Special Review, an imminent reregistration decision, or risk mitigation measures. The remainder are in further stages of review or required no further action.

## Ecological Incident Monitoring And Reporting

In 1994, OPP completed the development of the Ecological Incident Information System (EIIS). OPP expects that this system will play an essential role in understanding how poisoning incidents involving nontarget species (unintentionally affected animals and plants) occur and will help OPP to reduce environmental risks. This database is a compilation of the information currently used for completing risk assessments. A total of 630 incidents have been entered into the database, including the most recently reviewed pesticide, carbofuran. Based on the data entered to date, over 101 active ingredients have caused adverse effects to 1,300 species of nontarget organisms.

In response to substantial interest in the EIIS, OPP has distributed the software to 175 state and federal agencies as well as to private industry. OPP contacted over 75% of the state agencies who are responsible for collecting the data. OPP has presented its efforts at professional meetings and to other federal agencies such as the National Biological Survey (NBS). OPP has also initiated cooperative agreement efforts between EPA, NBS, and the Fish and Wildlife Service and is developing a standardized protocol for ecological incident monitoring and reporting.

## Information And Records Management Activities

OPP receives and generates an enormous number of documents each year, such as studies submitted regarding the effects of pesticides and OPP's review of these studies. These records must be properly managed to ensure timely, appropriate decisions and for future reference.

Significant accomplishments were made in OPP's records management program in 1994. OPP conducted regular training for its network of records management liaison offices and drafted major changes to the records retention schedule for review by the National Archives.

## Human Resources Management

OPP's human resources efforts included hiring, training, and promoting staff. More than half of OPP employees received some form of technical, career, or management development training in 1994. Another human resource effort was that of the Cultural Diversity Task Force. The Task Force is committed to valuing OPP employees regardless of physical attributes, ethnicity, or sexual orientation. Three subcommittees have been formed: Communications, Planning, and Outreach. In 1994, the Communications Committee educated OPP staff on the mission of the task force. The Planning Committee determined that the task force should focus on recruiting and retaining minorities, developing careers for minorities, and ensuring unbiased reviews for minorities eligible for promotion. In 1994, the committee participated in drafting a Diversity Plan that should be finalized in early 1995. The Outreach Committee developed a database of potential applicants that will be made accessible to all managers to help them find qualified applicants.

## Resource Allocation And Financial Management

OPP resources are allocated in three distinct phases: budget formulation, planning, and execution. During any given year, OPP is formulating a budget two years in advance, planning a budget for the upcoming year, and executing a budget for the current year.

### Budget Formulation

Budget formulation is the process of developing the budget submitted by the President to Congress each year. During fiscal year (FY) 1994, OPP prepared the submission of the FY 1996 budget. OPP worked with the Administrator's office to develop the budget, investing in some areas and disinvesting from others, based on Agency priorities and objectives. OPP's major proposed areas of investment are ecological protection (including reducing pesticide use/risk and building tribal capacity), food safety, and implementation of the Worker Protection Standard. These investments are to be accompanied by disinvestments from registration and reregistration, by completion of some efforts, and by streamlining efficiencies. The budget will then be reviewed by OMB and ultimately become part of the President's Budget. After Congressional review and ratification, it becomes the Congressional Budget. Ideally, the final budget is approved with the signing of the Appropriations Bill by the President prior to October 1 (the beginning of the new fiscal year).

### Budget Planning

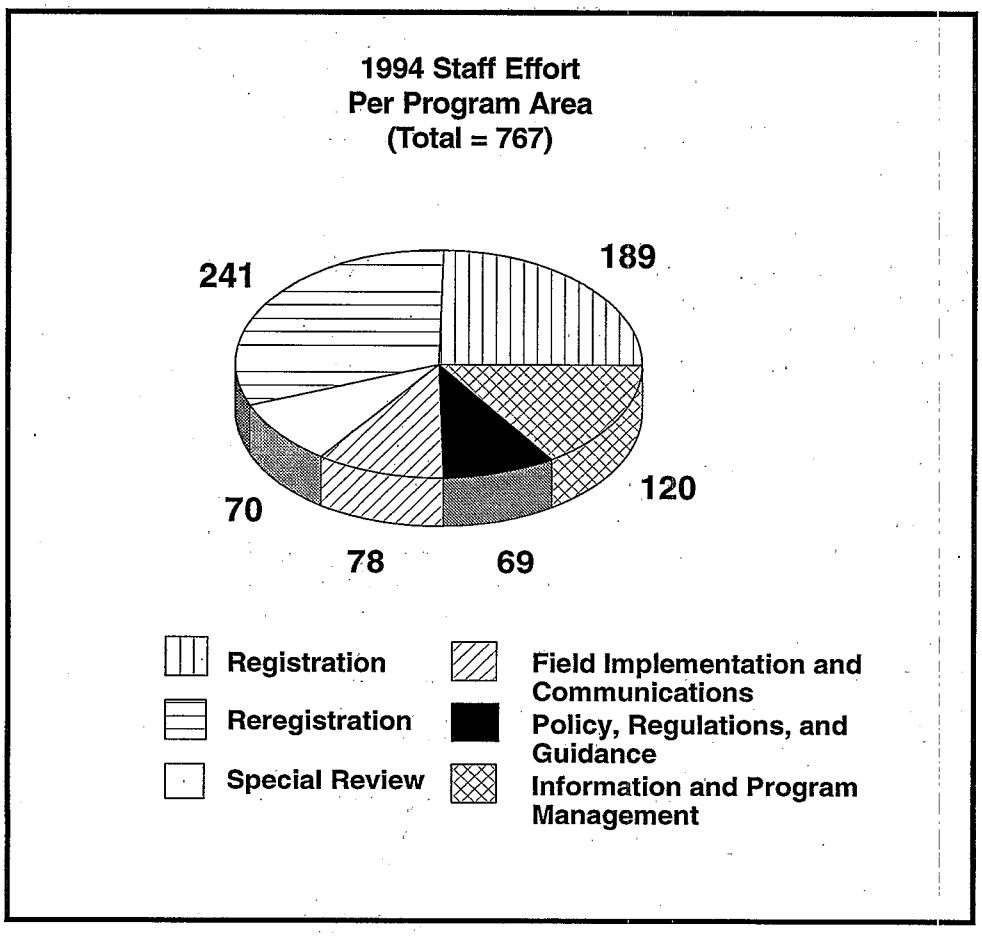
The planning process starts about nine to 12 months before funds are actually appropriated by Congress; OPP began FY 1995 planning in January 1994. The participants include a Senior Management Board, a Steering Committee, six Program Area Workgroups (PAWs), and coordinators from each of OPP's divisions. The PAWs identify resources needed to fund Program Area activities and prioritize those activities. The Steering Committee then makes recommendations based on the PAW efforts to the Senior Management Board, which integrates the area plans into the OPP Resource Management Plan. This plan describes the projects to be performed and their level of funding for the upcoming fiscal year.

For FY 1995, the OPP planning process allocated $18.2 million for headquarters contracts and grants, $3.3 million in expenses, and $52 million in salaries for approximately 785 employees. The planning process incorporated reductions requested by Congress, the conversion of some contractor functions to OPP staff, "buy-outs" to facilitate staff reductions, and implementation of the new pilot division. Nondiscretionary state grants and assistance, which are allocated outside of the OPP planning process, totalled $15 million.

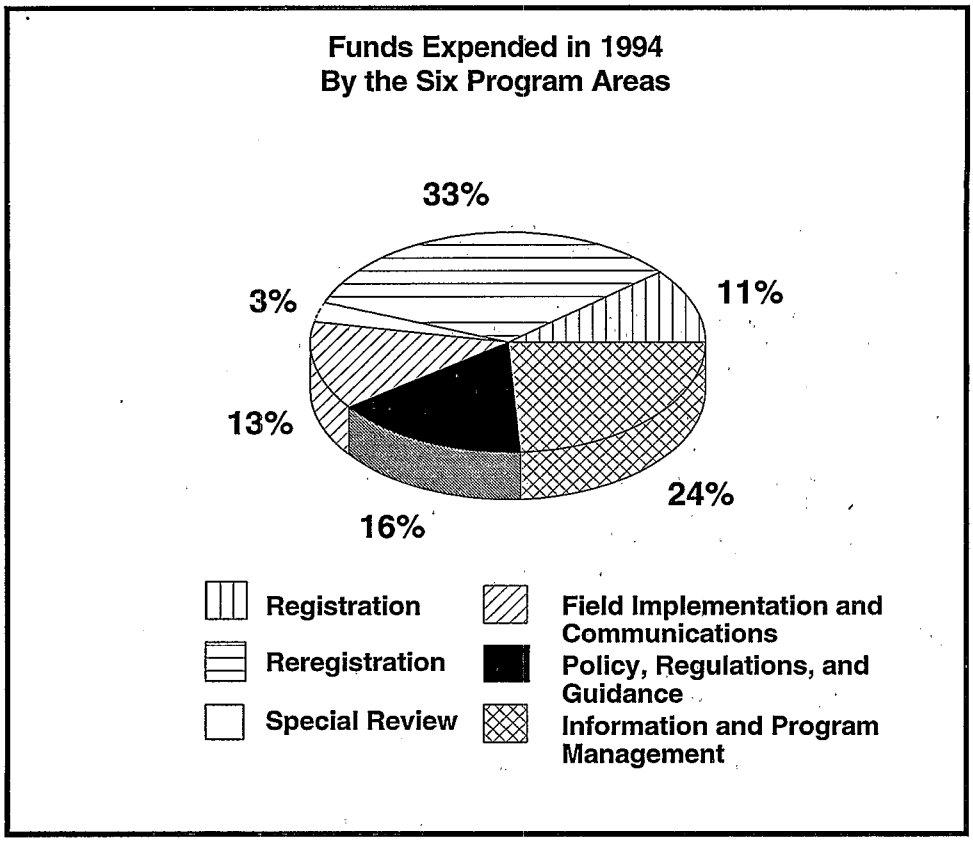
### Budget Execution

After the Appropriations Bill is signed by the President, the EPA Comptroller issues a new Operating Plan, which is executed by each Agency office. In executing the budget, OPP must carefully monitor expenditure of all funds, track compliance with budget plans, and coordinate appropriate Agency financial reports. During 1994, OPP obligated (spent) $93 million dollars. These funds consisted of $52 million in travel expenses and salaries for approximately 785 employees; $26 million for contracts, interagency agreements, grants, and expenses; and $15 million for grants and support to regions and states. In 1994, OPP continued to collect several types of funds from pesticide registrants, which supplement Congressional appropriations. The collected funds consisted of $2.1 million in tolerance fees, $14.1 million in annual registration maintenance fees, and $800,000 in reregistration fees. The collected fees are placed in revolving funds that may be used over multiple years, whereas most Congressional appropriations must be used within two years.

In 1994, OPP improved its systems for using the revolving funds and helped carry out financial management responsibilities, such as those under the Chief Financial Officer's Act and the Government Performance and Results Act. OPP also continued to fully use available resources to meet mission goals. The distributions of staff effort and discretionary funding among the six program areas are illustrated in the figures on the following two pages.




This chart indicates the approximate distribution of OPP staff effort to the six program areas. The chart is presented in terms of "Full-time Equivalents" (FTEs). One FTE represents the number of hours spent by one employee working full-time for one year. Because some employees work part-time, or are hired or leave part-way through the year, the actual number of employees in any given year exceeds the number of FTEs. Many employees divide their time among different program areas.




In 1994, OPP expended approximately $14.2 million allocated through the program area budget process. These "discretionary" funds were used for external contracts. This chart shows how these funds were distributed among the different program areas.

(Other major pesticide expenditures not reflected in this chart are travel expenses; salaries; grants and other assistance to states, regions, and other organizations; and set-asides for special projects, such as pesticide disposal.)

# 7

# Opportunities and Initiatives For 1995

In addition to continuing the work previously described throughout this report, OPP expects to pursue several important opportunities and initiatives during 1995. This section highlights some of those opportunities.

## Biological Pesticides And Promoting Risk Reduction

OPP is taking several measures to promote biological and other potentially safer pesticides, such as waiving data requirements, where possible, and placing a high priority on completing needed scientific reviews. OPP is also encouraging alternatives to pesticides and other ways of reducing pesticide use and risks. Two important new opportunities for continuing progress in these areas are the creation of a pilot division and the Memorandum of Understanding between EPA and the U.S. Department of Agriculture.

### Creation of the Pilot Division

EPA has established a pilot, multi-disciplinary division of 33 employees within OPP to promote reduced pesticide use, encourage development and use of safer pesticides, and accelerate registration of new biological pesticides. The Biopesticides and Pollution Prevention Division (BPPD) is responsible for: (1) all registration and reregistration actions for biological pesticides; (2) Integrated Pest Management

(IPM) programs and strategies; and (3) continued development of pesticide pollution prevention activities, including the Pesticide Environmental Stewardship Partnership.

In accordance with the Administration's National Performance Review (highlighted in the Vice-President's report on reinventing government), the pilot division will have a streamlined structure which exceeds the goal of 11:1 staff to management ratio. Small, self-directed and empowered teams are being formed as an alternative management structure. The approach is designed to promote staff development and OPP productivity for all science reviews and administrative processes for registration and reregistration actions, providing team leadership opportunities and allowing OPP to test and evaluate new methods of operation to assist with the overall streamlining of OPP scheduled for 1996.

### EPA/USDA Memorandum Of Understanding (MOU)

Under this MOU, signed in August 1994 by EPA Administrator Carol Browner and Department of Agriculture Secretary Mike Espy, the two agencies agree to work in collaboration to provide the agricultural community with pest management practices to reduce the risks associated with pesticides. The agreement will increase USDA research for alternative methods for pest control and establish practical means for transferring these tools to the farmer. Each year, USDA will identify those crop/pest/control combinations which are potentially vulnerable for the producer (i.e., situations where growers have few effective alternatives or where pest resistance limits effective pest management). Similarly, EPA will identify agricultural pesticides for which it is considering regulatory action that would affect their availability or use. Together, USDA and EPA will expedite research, development, education and registration, if necessary, to meet these priority needs.

## Opening Up OPP

OPP has several projects underway to "open up OPP" — that is, to allow everyone to obtain information from OPP more easily, and to participate in and understand OPP's decision-making process. OPP strongly believes that a well-informed public will make wiser choices involving pesticides and will help improve the quality of federal pesticide actions.

### Electronic Dissemination Of Information

OPP continues to experiment with innovative ways of making information available to affected organizations and the general public. The Agency's Email (electronic mail) Integration Pilot this year extended OPP's realm of communications to include EPA regional offices and made possible the exchange of Internet messages. Internet is a telecommunications system that connects thousands of computer networks and literally millions of computer users. Early in calendar year 1995, OPP expects to complete the process enabling all OPP personnel to easily communicate with anyone on the worldwide Internet. OPP has also begun to make some of its publications available on the Internet.

During fiscal year 1994, OPP also piloted the new Pesticide Special Review and

Reregistration Information System, an electronic bulletin board system (BBS) available free of charge to any member of the public who has access to a PC with a modem. This BBS contains recent Reregistration Eligibility Decision (RED) documents and all the RED fact sheets. Other files available for downloading include basic information explaining reregistration and Special Review, lists of pesticides under review and the appropriate Chemical Review Managers' names and telephone numbers, the Rainbow Report (or *Status of Pesticides in Reregistration and Special Review*), and *OPP Selected Terms and Acronyms*. Additional documents to be added soon include this Annual Report, the Rejection Rate Analysis chapters, and the quarterly *Pesticide Reregistration Progress Report*. To reach this BBS from a PC with modem, dial 1-703-308-7224. The BBS also can be reached on the Internet via *FEDWORLD.GOV*. EPA's "gopher server," *EARTH1.EPA.GOV*, is another source of these electronic files. The Sysop, or system operator, welcomes comments, questions and feedback.

### Public Involvement in Risk Decisions

Achieving risk reduction through negotiations with pesticide registrants can lead to quicker action than formal Special Review procedures; however, it has been criticized for not always providing an adequate opportunity for public involvement. OPP published a notice in the *Federal Register* in 1994 that described a number of ways OPP would be making the process more open, including a process for public comment on proposed agreements with registrants. OPP will continue this process in the coming year. OPP is also exploring avenues for expanding its efforts to include the public in pesticide registration decision-making.

### The Aquatic Risk Assessment And Mitigation Dialogue Group

To help implement the "New Paradigm" for pesticide regulatory decisions (described in chapter 2), OPP organized a workgroup known as the Aquatic Risk Assessment and Mitigation Dialogue Group with the joint sponsorship of the American Crop Protection Association (formerly NACA). The group consisted of representatives from the pesticide industry, academia, environmental groups, OPP, and EPA's Office of Research and Development (ORD). The group met seven times in 1993 and 1994 to promote an open scientific dialogue about the assessment and mitigation of risks to aquatic organisms posed by pesticides. The primary topics discussed by the Dialogue Group were ecological effects and exposure characterization, integrated risk characterization, and mitigation practices to reduce the risk of pesticides to aquatic resources. Subgroups researched a variety of topics, such as how to better employ existing data in risk assessments, how to improve pesticide risk assessment methodology, and cataloguing pragmatic short-term mitigation practices. Long-term needs for mitigation and monitoring were also discussed. The Group reached a number of conclusions and recommendations in a final report issued in November 1994.

## Reinventing And Streamlining OPP's Organization

As part of the efforts to "reinvent" and flatten the federal government structure and to increase responsiveness, OPP has undertaken twenty major streamlining projects in four main areas. Progress through fiscal year 1994 is summarized for each project in the table below. This broad range of activities is overseen by an OPP Streamlining Council, composed of the senior program managers, and an Employee Advisory Group, representing the staff.

### OPP Streamlining Projects

| Streamlining Project | Current Status |
|---|---|
| **Review and Evaluate OPP Program** | |
| Survey Customer Satisfaction | Preliminary test complete. Full surveys of regulated community and general public to begin in FY 95. Surveys of states/regions completed in FY 94. |
| Perform Outside Management Review | Pre-test complete. Interviews of 160 OPP staff began in mid-October 1994. Final report submitted in January 1995. |
| Upgrade Monitoring of Performance vs. Plan | Performance to be measured against FY 95 resource allocation plans. |
| **Revise Core Production Processes in OPP** | |
| Drop Activities Contributing Little to Risk Reduction | Identification of candidate processes complete. Winnowing process underway. |
| Increase Delegations and Empowerment | Many redelegations completed; others in progress. Allows quicker decision-making and fewer layers of review. |
| Streamline Correspondence Management | Project getting underway. |
| Pilot a "Living RED" | Test effort to maintain a continually updated, automated OPP regulatory and scientific position about a specific pesticide. Pilot pesticide selected, and prototype system under development. |
| Standardize Science Review Documentation | Pilot efforts completed in 1994. Two subgroups now focusing on review content and on technology for storing, indexing, and retrieving reviews. |
| Automate Product Manager Team Operations | Electronic letterhead and concurrence copies now used to simplify correspondence. Work to further automate correspondence underway. |
| Use Quality Circles in Health Effects Division | Pilot under development for non-supervisory quality management in science review division. |

**OPP Streamlining Projects (cont.)**

| Streamlining Project | Current Status |
|---|---|
| **Implement Human Resources Initiatives** | |
| Implement Diversity Initiatives | Draft OPP Diversity Plan completed and circulated for comment throughout OPP. Revisions in response to comment underway. First plan implementation in 1995. |
| Develop New Performance Appraisal System | OPP working jointly with Office of Pollution Prevention and Toxics. Staff survey planned for early 1995; full pilot to be in place for 1996 standards. |
| Appraise Supervisory Performance by Staff | Full OPP-wide implementation began in September 1994. |
| Establish Multiple Career Tracks | OPP effort, which depends upon Agency-wide progress, is in beginning stages. |
| Implement Administrative Support Career Management System | System approved and implementation underway. |
| Redefine Leadership Needs in Streamlined Organization. | OPP effort is in beginning stages. |
| Develop Staff Rotation Program | OPP effort is in beginning stages. |
| Develop Comprehensive Training Strategy | OPP-wide survey of training needs has begun. |
| **Streamline OPP Organization** | |
| Establish Biopesticides and Pollution Prevention Division | Pilot operations began in October 1994. |
| Realign Organization to Meet Streamlining Mandates | Divisional reorganization plans completed 3/94. Overall OPP streamlining plan to be developed by 2/95 by Streamlining Council. |

## Registration Streamlining

In September 1994, OPP released its plan for streamlining several aspects of the registration process. Two major areas for improvement identified are amendments to pesticide product registrations and other process changes. In the first area, OPP is proposing to expand the types of amendments which may be accomplished by notification. Under a notification system, a pesticide registrant may modify its pesticide label without prior approval so long as it notifies OPP of its action and fulfills OPP label requirements. This notification process will be limited to minor changes that do not increase risks. OPP is also proposing to simplify the notification process. Other potential areas for improving the registration process include streamlining the review of acute toxicity studies, self-certification by registrants for products with low acute toxicity, strengthening precautionary labeling statements, and expediting the review of products similar to products already registered ("me-too" registrations).

# How To Obtain More Information

The Office of Pesticide Programs (OPP) wishes to provide timely and consistent information to the public and offers a variety of ways to do so. If you would like additional information on subjects discussed in this report or other topics, here are some sources available to you:

OPP Public Docket — OPP's docket houses the regulatory notices, background documents and public comments on OPP activities. The Docket is open to the public from 8:00 a.m. to 4:30 p.m., Monday through Friday, and is located in Room 1132 of Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, Virginia (near the Crystal City subway station), telephone **703 305-5805.**

National Pesticides Telecommunications Network (NPTN) — NPTN is a toll-free telephone service which provides general information about pesticides and is available to anyone in the United States, Puerto Rico and the Virgin Islands (Monday-Friday, 8:00 a.m. to 6:00 p.m. CST) at **1 800 858-7378.**

Catalog of OPP Publications and Other Information Media — This catalog provides a listing of hundreds of pesticide publications, including science chapters, fact sheets, etc., and is available from **EPA's Public Information Center,** 401 M Street, S.W., Washington, D.C. 20460 (Telephone **202 260-2080**); or the **National Center for Environmental Publications and Information (NCEPI),** P.O. Box 42419, Cincinnati, Ohio 45242-2419 (Telephone **513 891-6561** or Fax **513 891-6685**).

Pesticide Regulation (PR) Notice 94-3 — This document provides general guidance for obtaining a variety of OPP records and publications. It provides key information and contacts for many resources available to the public (including Pesticide Dockets, Freedom of Information Act, the pesticide hotline, and on-line databases). Lists of OPP program contacts are included to help direct public requests regarding specific chemicals or policy issues. PR 94-3 can be obtained from:

Communications Branch, FOD (7506C)
Office of Pesticide Programs, U.S. EPA
401 M Street, S.W.
Washington, D.C. 20460
**(703 305-5017)**

Communications Branch — Recent announcements and copies of non-technical brochures and fact sheets on pesticide issues can be obtained from the Communications Branch, as listed above.

Electronic Availability of Pesticide Reregistration Documents — Many reregistration and Special Review documents are available through an electronic bulletin board system, which can be reached via modem at **1 703 308-7224.** They are also available through the Internet via FEDWORLD.GOV and via EPA's gopher server, EARTH1.EPA.GOV. A fact sheet describing these services can be obtained from the Public Docket, NCEPI, or the Communications Branch.

Pesticide Information Network (PIN) — The PIN is an interactive database containing current and historic pesticide information. It is free and operational 24 hours per day, seven days per week. It can be reached via modem and communications software at **1 703 305-5919.**

# Pesticide Program Contacts

The following is a listing of OPP's senior managers as of January 1995, as well as the managers of OPP's parent office, the Office of Prevention, Pesticides and Toxic Substances (OPPTS). All OPP telephone area codes are 703.

**Office of Prevention, Pesticides and Toxic Substances**

Lynn R. Goldman, M.D., Assistant Administrator ..... (202) 260-2902
Susan H. Wayland, Deputy Assistant Administrator ..... (202) 260-2910
James V. Aidala, Associate Assistant Administrator ..... (202) 260-2897

**Office of Pesticide Programs**

Daniel M. Barolo, Director ..... 305-7090
Penny Fenner-Crisp, Acting Deputy Director ..... 305-7092

Policy and Special Projects Staff

Anne Lindsay, Director ..... 305-7102

Biological and Economic Analysis Division

Allen L. Jennings, Director ..... 305-8200

Biopesticides and Pollution Prevention Division

Janet L. Andersen, Acting Director ..... 308-8712
Flora Chow, Acting Deputy Director ..... 308-8712

Environmental Fate and Effects Division

Anne L. Barton, Director ..... 305-7695
Paul F. Schuda, Deputy Director ..... 305-7695

Field Operations Division

William Jordan, Acting Director ..... 305-7410

Health Effects Division

Stephanie R. Irene, Acting Director ..... 305-7351
Richard D. Schmitt, Deputy Director ... 305-7351

Program Management and Support Division

Frank T. Sanders, Acting Director ..... 305-5440
Norman W. Chlosta, Deputy Director ... 305-5440

Registration Division

Stephen L. Johnson, Director ..... 305-5447
Lois A. Rossi, Acting Deputy Director .. 305-5447

Special Review and Reregistration Division

Peter P. Caulkins, Acting Director ..... 305-8000

☆ U.S. GOVERNMENT PRINTING OFFICE: 1995 – 620 - 830 / 82060

EPA

United States
Environmental Protection Agency
(7506C)
Washington, DC 20460

Official Business
Penalty for Private Use
$300