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Office of Pesticide Programs Annual Report for 1996

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Foreword

I am particularly proud of the people in the Office of Pesticide Programs (OPP) this past year. They continue to safeguard public health and the environment from pesticide risks while ensuring that pesticides are regulated fairly and efficiently. In addition, OPP's partners in the regional offices, states and tribal pesticide regulatory agencies play an important role in implementing and enforcing pesticide programs and policies.

OPP's Fiscal Year 1996 achievements are especially significant in that they were accomplished amidst a government-wide shutdown, budget freezes, and the passage of a sweeping new law -- The Food Quality Protection Act of 1996. Moreover, the program continued extensive reinvention initiatives and planning efforts for a major realignment.

OPP made over 6,000 regulatory decisions during the year, including the registration of 22 new active ingredients and 27 Reregistration Eligibility Decisions. More than half of the newly registered active ingredients are considered safer or reduced risk pesticides, continuing the trend over the past few years. While the new law has undoubtedly affected the program's ability to make decisions on food-use chemicals and the shutdown and budget crises meant fewer resources for the program, this record of solid achievement clearly reflects greater efficiencies and a dedicated staff.

The new law, enacted August 3, 1996, and effective immediately, set in motion the creation of several teams to deal with immediate policy and program implementation needs, as well as long term issues. A high-level Food Safety Advisory Committee was established under the Federal Advisory Committee Act (FACA) to foster improved communications and understanding among stakeholders and to help provide strategic direction to the implementation efforts. In addition, a Pesticide Program Dialogue Committee was established under FACA this past year to deal with long-term pesticide policy and program implementation issues. Examples of other significant initiatives and accomplishments include: plans for a new Antimicrobial Division to reform and expedite the registration of antimicrobial products with priority for those that have significant public health uses; addition of more partners and supporters to the Pesticide Environmental Stewardship Program; deregulation of low-risk active ingredients (e.g., garlic); continuous improvement and expanded outreach and training in the Worker Protection program; and a redesigned Pesticides Program home page on the Internet.

The year ahead promises even greater challenges and opportunities as we implement the new law, realign our program to meet the requirements of an Executive Order mandating a streamlined organizational structure, and continue to deliver on our regulatory management obligations. The following pages provide a more in-depth look at the complexity and accomplishments of OPP. I hope this report will serve as an important communication and education tool and welcome your thoughts and recommendations on how we can improve it.

Daniel M. Barolo, Director
Office of Pesticide Programs

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Part I

The Office of Pesticide Programs: Meeting the Challenge

Introduction

The mission of EPA's Office of Pesticide Programs (OPP) is to protect public health and the environment from the risks posed by pesticides and to promote safer means of pest control. This is a challenging and complex undertaking. Pesticides differ from other classes of chemicals regulated by EPA because they are intentionally applied, rather than byproducts of industry or other human activity. Pesticide products and uses are likely to be found in nearly every home and business in the United States -- from insect repellents to weed killers to hospital disinfectants to swimming pool chemicals -- to name only a few. They also are used in schools, parks, and other public places.

The challenge for OPP, in carrying out its responsibilities, is to consider both the risks pesticides pose to human health and the environment and the benefits they offer society. Pesticides are useful because of their ability to kill or control disease-causing organisms that threaten humans, crops, ornamental and wild plants, domestic animals, and wildlife. By their very nature, however, most pesticides involve risks because they are designed to be biologically active and have a negative effect on living organisms.

OPP's programs and policies are designed to meet the challenge of evaluating and reducing pesticide risks and promoting safer means of pest control. State and tribal agencies and many other organizations, both public and private, are vital partners in this effort. Quite literally, pesticides and OPP's regulatory policies touch every one who eats and breathes. Meeting our challenge demands that we get input from and consider the needs of all Americans, without delaying the achievement of public health and environmental protection goals. We also must be conscious of the international implications of our decisions and policies, and work to advance public health and environmental protection on a global scale.

OPP's Fiscal Year 1996 Annual Report describes progress toward meeting these challenges over the past year. Part I of the report is organized according to three key themes underlying OPP's work: (1) adapting to key changes in our statutory framework, new scientific developments, new technologies and increasing global interdependence; (2) making significant strides in reducing pesticide risks to health and the environment; and (3) continuing progress in increasing OPP productivity.

Part II of the report presents the facts and figures on Fiscal Year 1996 activities, documenting measurable, concrete achievements over the past year. Finally, the Appendices provide details on how to obtain more information and the organizational structure of OPP.

The World of Pesticide Programs at a Glance (figures are estimated and rounded-off)

Active Ingredients (AIs)	620	Pounds of AI used in U.S./Year	1 billion*
Registered Pesticide Products	20,000	U.S. Pesticide Sales/Year	$9 billion
Tolerances (max. food residue limits)	9,000	Trained Farm Workers	2.5 million
Decisions/Year	6,000	Certified Pesticide Applicators	1.3 million
Publications Distributed/Year	400,000	Calls to the Pesticides Hotline/Year	20,000

* 1 billion pounds of conventional pesticides are used each year. Including wood preservatives and chlorine and other disinfectants, approximately 4 billion pounds of pesticides are used each year.

The Changing World of Pesticide Programs

Fiscal Year 1996 represented a year of significant change for the Office of Pesticide Programs. New legislation, new scientific developments and technologies, Administration initiatives to reinvent and streamline government, and the increasing globalization of pesticide issues have all spurred major changes in how OPP does business.

* Landmark pesticide legislation, the Food Quality Protection Act (FQPA), was signed by President Clinton on August 3. The new law established a single consistent, health-based standard for pesticide residues in food, with particular emphasis on safety for infants and children. Since many of the new statutory requirements were effective immediately, OPP initiated a major implementation effort that will require the dedication of significant OPP staff and "stakeholder" resources in the months ahead.

* Mechanisms for obtaining input from major stakeholders and the public in implementing the new law and improving OPP procedures included public meetings of advisory bodies focusing on strategic issues, consultation with expert scientific advisory groups, and continued reliance on the permanent Pesticide Program Dialogue Committee chartered in FY'96. The goal is to bring the expertise of all OPP constituencies to bear on major program issues.

* Complementing the new legislation, Administration initiatives to "reinvent" government also led to significant changes and productivity enhancements. OPP is creating two new divisions, the Antimicrobial Division and the Field and External Affairs Division, and is streamlining management structures throughout the program. The resulting structure will meet the needs of the new law and the Administration goal of more efficient and effective government programs. (See Appendix A for an outline of the planned new organizational structure.)

* Rising public and scientific concerns about the possible effects of pesticides and other man-made chemicals on the endocrine systems of humans and other species led to the creation of special initiatives to explore these issues further and work toward the establishment of a scientifically sound screening and testing program. While OPP worked with other EPA offices and public and private groups to begin this process even before enactment of new legislation, the FQPA contains ambitious new statutory deadlines to expedite screening and testing of chemicals for potential endocrine effects.

* Recognizing the importance of new technologies in revolutionizing communications and information dissemination, OPP continued efforts to take advantage of the Internet and other electronic mechanisms to help achieve program goals.

* Promoting global environmental protection and ensuring that international trade

initiatives and agreements are consistent with the high level of protection afforded by our pesticide laws required OPP to intensify efforts to promote the international "harmonization" of pesticide standards. Greater harmonization will reduce inconsistencies that raise both public and private sector costs for data development and review, and promote compliance with health and safety standards.

Managing and enhancing the pesticide regulatory system in this atmosphere of significant change presents major challenges. The following sections of this Chapter outline key initiatives aimed at meeting these challenges and improving public health and environmental protection for all Americans and throughout the world.

New Legislation: The Food Quality Protection Act of 1996

EPA worked throughout the year to secure the first major modernization of the nation's pesticide/food safety laws in over 30 years. OPP prepared and reviewed proposed legislation and participated in Congressional hearings. The new Food Quality Protection Act (FQPA) passed both the House of Representatives and the Senate unanimously in late July and was signed by the President on August 3, 1996.

This landmark statute amends both major pesticide laws: the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA) in many important ways. The most momentous reforms include: setting a single health-based safety standard for pesticide residues in food; providing for Consumer Right-to-Know information at the point of food purchasing decisions; and increasing assurance that children and other sensitive subpopulations are protected from pesticide risks.

The new law requires EPA to re-evaluate over 9000 existing pesticide tolerances (maximum food residue limits) within the next ten years to ensure that all tolerances meet the stringent standards of the FQPA. EPA also is charged with establishing a registration renewal program for updating pesticide registrations on a 15-year cycle, to keep the safety data supporting registrations up-to-date with current scientific standards.

EPA takes great pride in its work to enact the Food Quality Protection Act of 1996 with broad bipartisan support. The new law will help advance the scientific basis of risk assessment, promote sound risk management decisions, and ensure that the public is well protected into the next century.

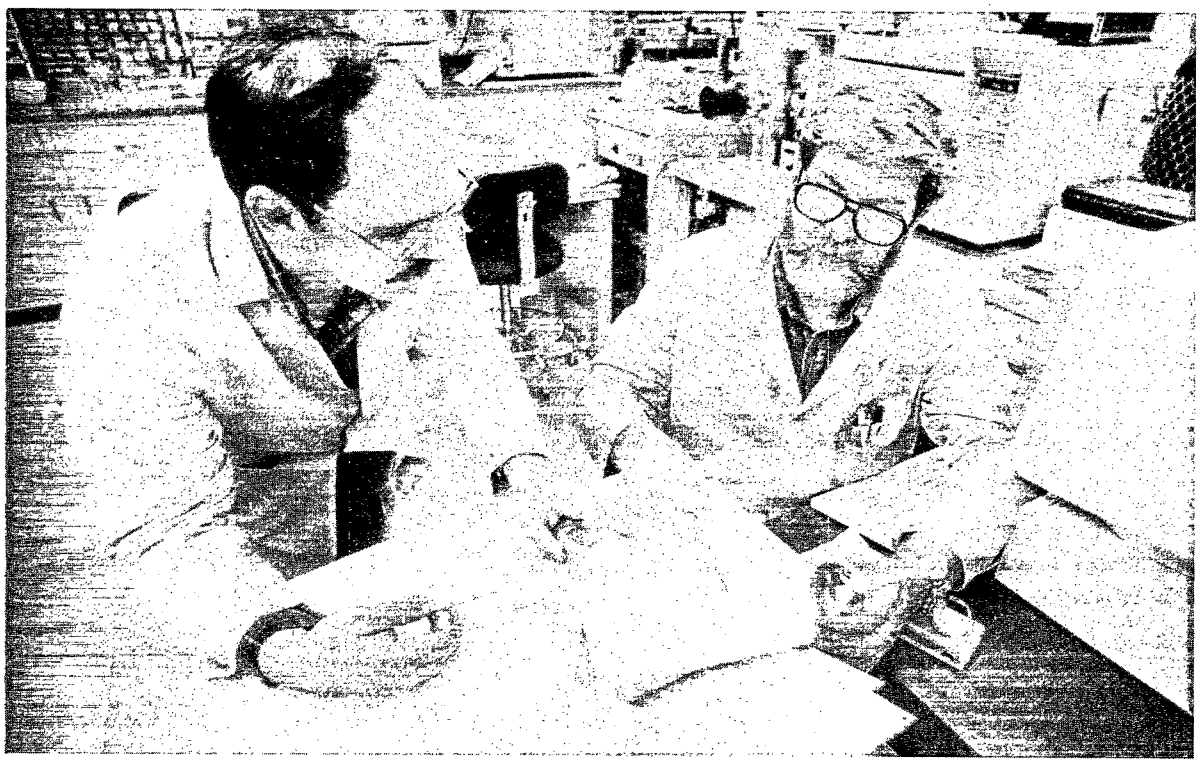
OPP has launched an ambitious initiative to expedite implementation, including the establishment of a new Food Safety Advisory Committee to secure stakeholder input on strategic issues and a number of implementation teams focusing on key issues in the short term. We will also rely on the continuing expertise of such standing advisory groups as the FIFRA Scientific Advisory Panel and the Pesticide Program Dialogue Committee, along with other mechanisms of obtaining public comment and expert input.

Establishing the Antimicrobial Division

As part of its overall streamlining efforts and in response to the FQPA of 1996, OPP is establishing a new Antimicrobial Division (AD) to manage the registration and reregistration of non-food use antimicrobial products. Division staff will include health and environmental scientists and risk assessors, as well as a core group of registration and reregistration specialists. This interdisciplinary approach will allow most registration and reregistration activities to be consolidated within a single division. The AD is expected to be in place by early 1997.

Among the first priorities of the AD will be implementing new requirements of the FQPA that pertain to antimicrobial products. These new provisions include establishing goals for review periods for registration applications and the development of new regulations clearly defining antimicrobial pesticides, describing their use patterns, and prescribing registration requirements. EPA will also be considering how to improve the cost-effectiveness of review mechanisms and the potential for expanding self-certification processes and notification procedures (in lieu of pre-market approval) for some types of actions.

The Division will report its progress each year in an annual report. Another provision of the FQPA exempts liquid chemical sterilants and disinfectants used on medical devices from regulation as pesticides and clearly places them under the control of FDA, eliminating potentially duplicative regulatory jurisdiction.



Endocrine Disruptors: Assessment and Analysis

There is growing evidence that a number of man-made chemicals may disrupt the endocrine systems of wildlife and humans. These endocrine or "hormone" disruptors may cause a variety of reproductive, behavioral, and developmental problems.

In FY 1996 OPP collaborated with other EPA offices to develop a report entitled *Environmental Endocrine Disruption: Effects Assessment and Analysis Document*. This document provides an overview of the current state of the science as it pertains to environmental endocrine disruption, including the identification of data gaps and high priority research needs to improve our understanding of the potential for pesticides and other chemicals to cause endocrine effects. The report articulates the Agency's interim policy regarding its interpretation of the existing data.

The Food Quality Protection Act (FQPA) also focused on endocrine effects and mandated work toward the expedited development of screening and testing programs. EPA convened a public meeting of experts to examine the issues even before the new law was enacted, and has formed a work group charged with implementing the FQPA provisions. In FY 1997, EPA plans to establish a formal advisory committee to aid in these efforts.

Pesticide Program Dialogue Committee

A Pesticide Program Dialogue Committee (PPDC) was established under the Federal Advisory Committee Act in late 1995 and held its first meeting in July 1996.

This committee was created as a forum for a diverse group of representatives with a broad range of interests and backgrounds to provide feedback to the pesticide program regarding regulatory, policy, and program implementation issues. As such, the Committee's function is to identify and evaluate proposed modifications to current pesticide program policies and procedures to reduce potential risks posed by pesticides, and to facilitate the exchange of ideas and information among stakeholders.

Membership includes environmental and public interest groups, pesticide industry, user and commodity groups, public health and academic institutions, federal and state government agencies, etc. The first meeting was held in July 1996. Discussion focussed on the following topics: endocrine disruptors; registration "fees for service"; resistance management; and public education and communications. The Committee intends to hold three or four meetings per year.

Pesticides Publications and Information on the World Wide Web

EPA is steadily expanding its electronic publishing via the Internet, and this past year began phasing out older approaches in favor of publishing on the World Wide Web. In FY 1996, OPP redesigned its "home page" web site, giving users a better guide to the information available and a better idea of the work OPP does. In order to make Internet publication a standard part of outreach and communication efforts, OPP established a network of staff throughout the program with responsibility for getting documents onto the Internet.

OPP's web site is accessed from the EPA home page address: **www.epa.gov/internet**. The types of information available via Internet include all *Federal Register* publications and press announcements, reregistration eligibility decisions (REDs), information on FQPA implementation efforts, and fact sheets and publications of general interest, such as the *Citizen's Guide to Pest Control and Pesticide Safety*, OPP's Annual Report, and the Catalog of OPP publications. Comments and suggestions about the web site, and what information OPP should post on the Internet, can be sent to the following e-mail address: **eidoc.opp@epamail.epa.gov**.

Two examples of the new information made available via the Internet in FY 1996 include the Pesticide Data Submitters List (PDSL) and company, chemical, and product information drawn from OPP's Pesticide Product Information System. The PDSL is a compilation of names and addresses of registrants who wish to be notified and offered compensation for use of their data by others seeking to market pesticide products. It was developed to assist pesticide applicants in fulfilling their obligations under FIFRA regarding ownership of data used to support registration.

As a result of collaboration with the California Department of Pesticide Regulation (CDPR), the public can now access some of OPP's Pesticide Product Information System. From CPDR's web site, visitors can search this database by company name, chemical name, product name, EPA registration number, and company numbers. Data are refreshed bi-weekly by OPP staff. Visitors to OPP's web site will find a link that will lead them to the CDPR site.

International Partnerships

OPP's international partnerships aim to develop common or compatible international approaches to pesticide review, registration and standard-setting. Partnerships with both developed and developing countries allow OPP to promote public health and environmental protection on a global scale, share the work of reviewing data with other countries, reduce trade barriers and regulatory burdens, and enhance assurance that food imported into the U.S. is safe. International partnerships can be grouped into three broad categories: (1) policy, (2) programmatic, and (3) capacity building.

Policy Coordination

By coordinating policies at global and regional levels, governments seek international harmonization on the sound management of chemicals. In FY 1996, the Intergovernmental Forum on Chemical Safety (IFCS) continued its work to build international consensus on the need to minimize use of twelve persistent organic pollutants (POPs), which are mostly banned by EPA but are still used in other countries. Action will be taken on these findings and recommendations early in 1997. IFCS also shaped the negotiating process for turning Prior Informed Consent (PIC) procedures into a legally binding instrument. PIC procedures relate to international information exchange on the export and import of banned and severely restricted chemicals.

OPP continued to provide support to the work of the Codex Alimentarius Commission, a joint program of the United Nations Food and Agriculture Organization and World Health Organization that sets international standards for pesticide residues in foods. Many countries rely on Codex in setting their own food safety standards, and the U.S. is working to improve the scientific basis and timeliness of Codex decisions, as well as to boost public participation in decision-making. OPP's work with Codex and in World Trade Organization committees focused on human, animal, and plant health protection standards, is designed both to promote harmonization and to ensure that international agreements are consistent with the high level of protection afforded by U.S. standards.

On a regional level, the North American Free Trade Agreement (NAFTA) Commission on Environmental Cooperation provided an important forum for EPA's efforts to deal with persistent organic pollutants. Canada, Mexico and the United States developed draft plans to reduce the use of DDT and chlordane throughout North America. These pesticides, which are canceled in the U.S. and Canada, continue to be used in Mexico in its malaria control program (DDT) and as a termiticide (chlordane). Residues are persistent and may be transported long distances in the atmosphere. These draft plans will serve as models for global risk reduction efforts.

Programmatic Activities

Policy coordination sets the stage for more concrete programmatic activities, based upon agreed-upon priorities and scopes of work. Through the Organization for Economic Cooperation and Development (OECD) and the North American Free Trade Agreement (NAFTA) Technical Working Group on Pesticides, OPP

made significant programmatic progress in FY 1996.

Organization for Economic Cooperation and Development (OECD). Building upon work by the European Union, OECD members are working to develop harmonized procedures for electronic data submission and documentation of the reviews that support pesticide regulatory decisions. Staff exchanges help scientists better understand each other's approaches to pesticide assessment and promote greater confidence in harmonization.

FY 1996 also marked a year of significant accomplishment in updating and harmonizing pesticide testing guidelines with those of the OECD. Final guidelines were issued on applicator exposure and post-application exposure, microbial and biochemical pest control agents, residue chemistry, and physical chemistry. Additional draft guidelines were prepared and are under review.

Also through OECD, OPP worked toward a three year risk-reduction program (1997-1999), harmonizing regulation of biocides (non-agricultural pesticides), and the establishment by the year 2000 of internationally harmonized labeling. The U.S. is participating in an OECD advisory group to develop proposals for a common hazard classification scheme that encompasses acute toxicity, reproductive effects, cancer, serious chronic effects, mutagenic effects, and aquatic toxicity.

The North American Free Trade Agreement (NAFTA) Technical Working Group. In 1996 Mexico became a full partner with Canada and the U.S. in harmonization activities through NAFTA. EPA is working with Mexico and pesticide registrants to establish reciprocal residue limits for pesticides used on peppers, strawberries, and squash.

U.S.-Canada cooperation produced a number of concrete advances: a bilateral agreement regarding the protection and exchange of confidential business information; a plan to allow residue field trial data from one country to be used by the other (a similar Mexican proposal is pending.); work sharing to review certain data on pheromones, microbial pesticides, and new active ingredients; coordinated reviews and decisions on three fungicides and the use of Integrated Pest Management (IPM) techniques to control late blight in potatoes; and the establishment of harmonized residue limits for several pesticides used on apples, potatoes, canola, carrots, cranberries and oats.

Capacity-Building Activities

To achieve global environmental protection goals, it is essential to work with developing countries to assist them in building their capacity to regulate pesticides and manage chemical production, distribution, use, and disposal. In cooperation with other U.S. and international agencies, OPP initiated a number of significant activities in FY 1996.

One major achievement was the development of a training course on the management and disposal of obsolete pesticides in developing countries. This course will be given first in a Central American country in early 1997.

Consistent with resources available from U.S. and international donor organizations, OPP also provides technical assistance on a bilateral and regional basis to build capacity in developing countries. For example, in FY 1996, EPA began work with the Indonesian Ministry of Agriculture on improving the regulation of pesticides in Indonesia. This partnership will form the basis for a regional pesticide information network to be shared by seven Asian countries. EPA also initiated a partnership with the Japanese National Institute of Health Sciences to improve global access to international sources of pesticide data and OPP data bases.

Safer Pesticides: Reducing Risks to Human Health and the Environment

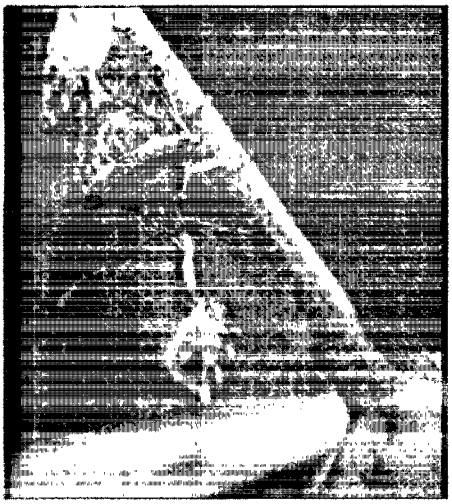
Over one billion tons of pesticide products are used each year in the United States. New, safer products are replacing older, more traditional pesticides on the farm, as well as in the backyard. A challenge for the Office of Pesticide Programs is to ensure that pest control and pesticide use become increasingly safer each year.

To meet this challenge, OPP is promoting safer pesticides and a pollution prevention ethic, creating public-private partnerships to reduce pesticide use and risk, and implementing risk-reduction through negotiated agreements, Special Review, and Reregistration Eligibility Decisions (REDs). Special emphasis is placed on potentially at-risk populations, including infants and children and agricultural workers. Many of these efforts have been given added impetus as a result of the Food Quality Protection Act, which specifically directed EPA to expedite safer pesticides and incorporate additional factors into pesticide assessments. OPP also is intensifying its efforts to educate pesticide users on the availability of alternative means of pest control, and on how to minimize pesticide risks to themselves and the environment.

A common thread running through many of OPP's initiatives to reduce pesticide use and risks is facilitating the development and adoption of *Integrated Pest Management* (IPM) strategies. IPM seeks to reduce the use of pesticides by taking advantage of all available alternative pest management options, substituting mechanical, physical, or biological pest controls for chemical controls whenever possible. IPM also promotes the adoption of safer, less environmentally persistent pesticides. More toxic pesticides are applied only as a last resort.

Biopesticides and Pollution Prevention

In FY 1996, OPP established a permanent, interdisciplinary Biopesticides and Pollution Prevention Division (BPPD), after evaluating BPPD's success as a pilot division in speeding review of safer, biological pesticides. Biopesticides include microbial pesticides (bacteria, viruses, or other microorganisms used to control pests) and biochemical pesticides, such as pheromones (insect mating attractants), insect or plant growth regulators, and hormones used as pesticides. Biopesticides generally pose less risk to human health and the environment than conventional chemical pesticides, because they are quite specific to the target pest.



Pheromone pesticides are used to attract the spined soldier bug, here seen feeding on a Mexican bean beetle larva, one of the most damaging soybean insect pests.

During 1996, ten new biopesticides and associated products were registered. An example of one such biopesticide is a nematicide that can replace some uses of methyl bromide, a highly toxic broad-spectrum conventional pesticide scheduled for phase-out under the Clean Air Act due to its potential to deplete stratospheric ozone.

Modern biotechnology has enabled the production of new plant-pesticides, for example, new types of agricultural plants that have been altered to produce proteins toxic to insects that destroy crops. In FY 1996, EPA registered corn and cotton plant-pesticides. Such plant-pesticides reduce the need for conventional pesticide applications, thereby reducing production costs as well as risks to workers and non-target insects, since only insects feeding on the crop are affected.

Pollution prevention is accomplished by reducing reliance on toxic broad spectrum pesticides. As IPM programs are more widely adopted, farmers and homeowners will be less dependent on the use of conventional pesticides to control disease and insect outbreaks. The use of biopesticides and the incorporation of IPM programs and other risk reduction measures is the basis of EPA's Pesticide Environmental Stewardship Program (PESP), as described in the following section.

Making A Difference Through Partnerships: The Pesticide Environmental Stewardship Program

The Pesticide Environmental Stewardship Program (PESP) was launched in December 1994. PESP is a *voluntary program* that forms partnerships with pesticide users to reduce health and environmental risk and implement pollution prevention strategies.

There are two categories of membership in PESP, "Partner" and "Supporter." Partners are agricultural producer organizations and other pesticide users who agree to devise and implement risk reduction strategies. Supporters include organizations that, while they are not pesticide users themselves, exert significant influence on pesticide use (for example, food processing companies who negotiate pesticide use restrictions in contracts with their suppliers). All PESP participants make a commitment to reduce pesticide risk and develop a strategy to achieve risk reduction goals. For a complete list of Partners and Supporters, see Part II, Page 40 of this report.

PESP partners and supporters are making a difference. For example, PESP participants in the Mint Industry Research Council are reducing risks through a number of innovative techniques, including reducing the spread of insect pests by promoting the use of disease-free rootstocks to establish new fields. Other PESP partners, such as the New England Vegetable and Berry Growers Association, are developing IPM standards and certification programs. The U.S. Department of Defense has made a commitment to develop alternative pest control strategies to reduce its pesticide use by 50% by the year 2000.

Through PESP, EPA also funds small "seed money" grants to partners and other organizations to foster the development and implementation of pollution prevention/risk reduction strategies. Eight PESP partner grants were awarded in FY 1996 through the National IPM Foundation for Education, and 14 EPA regional grants were awarded to support original research and promote IPM and PESP goals. Additional projects were supported through partnerships with the U.S. Department of Agriculture's "Agriculture in Concert for the Environment" program.

For more information on PESP, please call the PESP Infoline at 1-800-972-7717.

Safer/Reduced Risk Pesticides

In 1993, EPA launched a new initiative to expedite the review of lower risk pesticides. Under this program, OPP gives priority review to pesticides that satisfy criteria as likely to meet pest control needs and present lower risks to human health and the environment.

Since 1993, OPP has received 26 reduced risk pesticide applications. Of these, eight have been registered, with an average review time of 14 months, compared to 38 months for most conventional pesticides. Ten applications have been denied, and three are currently pending registration. (Reduced risk pesticides registered in FY 1996 are listed in Part II, Table I.) EPA is in the process of expanding its reduced risk initiative to include not only new pesticide active ingredients, but also new, safer uses of already-registered reduced risk pesticides.

The Food Quality Protection Act of 1996 explicitly mandates the continuation and enhancement of EPA's reduced risk pesticide initiative. The new law requires OPP to expedite review of new registrations and registration amendments that may reasonably be expected to reduce the risks of pesticides to human health or nontarget organisms; reduce the potential for contamination of groundwater, surface water, or other valued resources; or broaden the availability, adoption, or effectiveness of integrated pest management strategies. FQPA implementation will integrate these considerations into OPP's registration priority program.

Negotiated Risk Mitigation in Special Reviews

OPP continued to use negotiated agreements to expedite the reduction of pesticide risks in FY 1996. Following are three examples of the kinds of agreements achieved.

Cyanazine: In FY 1995, as the result of OPP's Special Review investigation into the potential cancer risks of cyanazine and other triazine compounds (atrazine and simazine), registrants agreed to implement worker protection safeguards and phase-out cyanazine sales and use by 1999. Based on these actions, EPA terminated its Special Review of cyanazine in July 1996. Special review of the other triazines is continuing.

Propargite: Based on studies showing that this miticide causes tumors in laboratory rats and residue data indicating unacceptable dietary risks to consumers, propargite registrants agreed to eliminate use on ten fruit and vegetable crops. These use deletions reduce risk to a negligible level and became effective in August 1996.

Molinate: In FY 1996, OPP successfully negotiated risk reduction measures for the rice herbicide molinate, based on concerns about reproductive risks to workers. The agreement requires more protective equipment (including chemical-resistant gloves, respirators, and coveralls) and handling systems that reduce exposure during loading. Additional studies have been required and may result in further restrictions.

Risk Reduction in Reregistration Eligibility Decisions (REDs)

Many older pesticides were first registered before today's stringent testing and safety standards were in place. In 1988, Congress required EPA to undertake a comprehensive reregistration review of all pesticides first registered before November, 1984, to ensure that they meet current standards. Reregistration Eligibility Decisions (REDs) summarize the findings of OPP's reregistration review of these older chemicals. (REDs completed in FY 1996 are listed in Part II, Table III.)

Nearly all REDs include some provisions to reduce risks to pesticide handlers, the public, or the environment. Among the 27 REDs completed by OPP in Fiscal Year 1996, the following are two examples of the kind of significant and innovative risk reduction measures being implemented through reregistration.

Coumaphos (pre-FQPA): An insecticide used on cattle, goats, horses, sheep, and swine, coumaphos is known primarily for its use by the Department of Agriculture (USDA) in dip vats located along the U.S./Mexico border, to control ticks that carry Texas Cattle Fever. EPA has been concerned about risks to pesticide handlers, wildlife, groundwater, and other ecosystem effects. Disposal of spent solution from these vats has been a long-standing environmental problem. Thanks to a new bioremediation method developed by USDA's Agricultural Research Service (ARS) and supported by the registrant, the risks associated with disposal of coumaphos waste are being effectively mitigated. The bioremediation process developed by ARS uses bacteria naturally present in dip vats to detoxify the waste. In the RED, EPA is requiring this process, or, as a second choice, the use of lined pits for spent dip vat solutions. To reduce risks to handlers of coumaphos, the RED establishes baseline protective equipment requirements. Other packaging and labeling requirements will lower risks to handlers, birds, and aquatic invertebrates.

Bromacil (post-FQPA): Based on the data required in reregistration, EPA was concerned about the effects of bromacil on pesticide handlers. A herbicide used on citrus and pineapple crops and for a variety of non-food uses, bromacil causes thyroid, adrenal, and thymus effects and is classified as a possible human carcinogen. Bromacil also has been detected in groundwater and may pose risks to birds, reptiles, and mammals. EPA's reregistration decision document for bromacil reduces application rates by over 50%, from a maximum rate of 32 pounds to 12 pounds per acre. To reduce risks to workers, the RED requires additional protective equipment, including chemical resistant gloves, and restricts the number of acres that may be treated in one day. Additional label warnings to reduce potential contamination of water resources and exposure of nontarget organisms are also required by the RED.

Special Populations: New Initiatives to Ensure Protection of Children and Agricultural Workers

Infants and Children

The Food Quality Protection Act of 1996 (FQPA) emphasizes the need to ensure protection of potentially sensitive or highly-exposed populations from pesticide risks, including infants and children. This issue will be a high priority for FQPA implementation. OPP currently analyzes food consumption and residue data to assess risks for more than twenty subpopulations, based on age, gender, ethnicity, and region.

In response to the 1993 National Academy of Sciences Report on *Pesticides in the Diets of Infants and Children*, the Agency continued to upgrade its testing requirements and analytical capabilities in FY 1996, including the issuance of a new policy for acute dietary exposure assessment.

Preparations also were made to determine the need for additional uncertainty or "safety" (margin of exposure) factors to protect children and the usefulness of *in utero* testing to detect possible effects of pesticide exposure "in the womb." These were presented to the FIFRA Scientific Advisory Panel in early FY 1997.

The new law mandates improved data collection efforts to support EPA decision-making. The quality and timeliness of the data supporting OPP's pesticide risk assessments remain of some concern in terms of dietary consumption patterns and actual residue levels. EPA will be working with the Departments of Agriculture and Health and Human Services and others to improve the quality of these data.

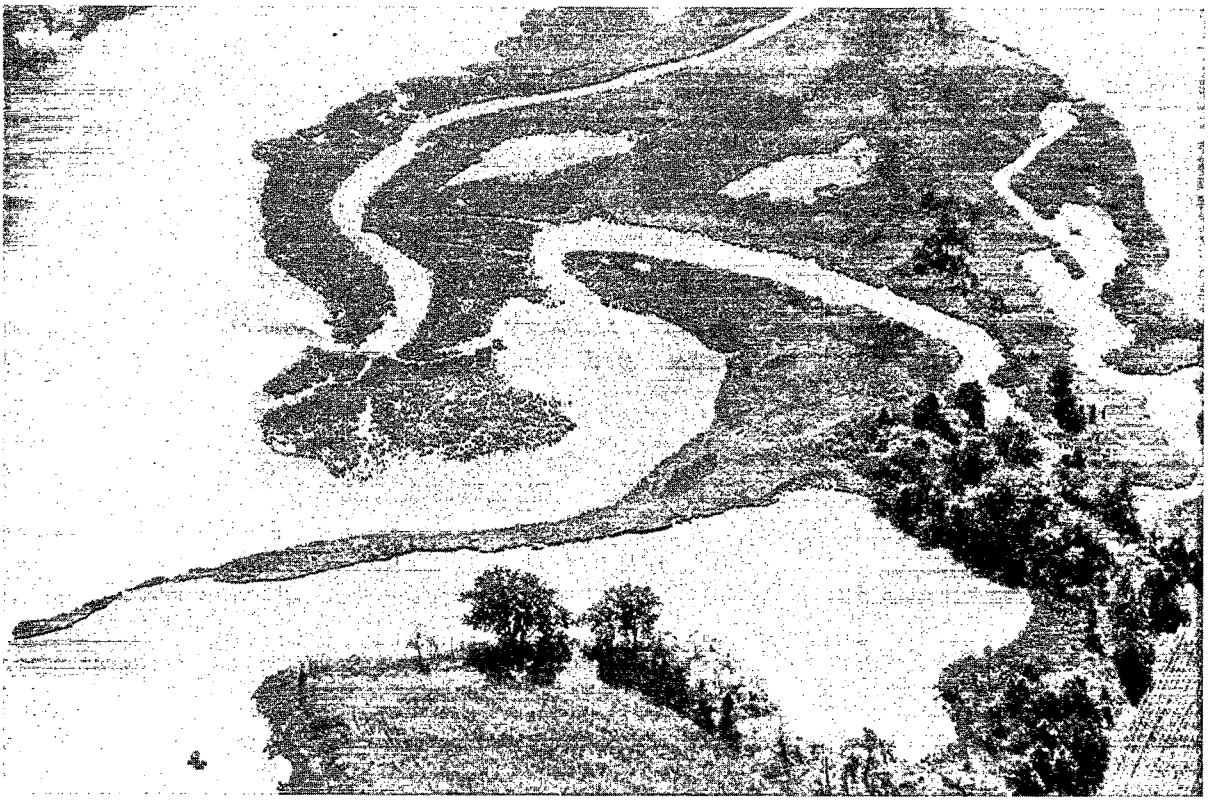
Agricultural Workers

EPA also continued to focus on pesticides that appear to pose the greatest risks to agricultural workers, using data from the State of California and the American Association of Poison Control Centers. These efforts resulted in the cancellation of all uses of mevinphos in FY 1995. In FY 1996, successful risk mitigation measures were negotiated for the pesticide methomyl, including reduced application rates, more precautionary label language, longer re-entry intervals after applications, and deletion of uses that accounted for disproportionate numbers of poisonings. EPA is continuing to work with registrants of carbofuran and methamidiphos to reduce worker risks.

Future Partnerships: Groundwater State Management Plans

OPP laid the foundation for a new approach to groundwater protection in FY 1996, issuing a proposed groundwater protection rule based on the adoption of State Management Plans (SMPs). The proposed regulation focused on five pesticides frequently found in ground water as initial SMP candidates. The SMP approach is based on the notion that states are knowledgeable and equal partners in designing and implementing risk-reduction measures for pesticides in ground water.

Groundwater SMPs will join an array of national measures to reduce the risks to humans from contaminated ground water. EPA expects to issue a final SMP rule in FY 1997.



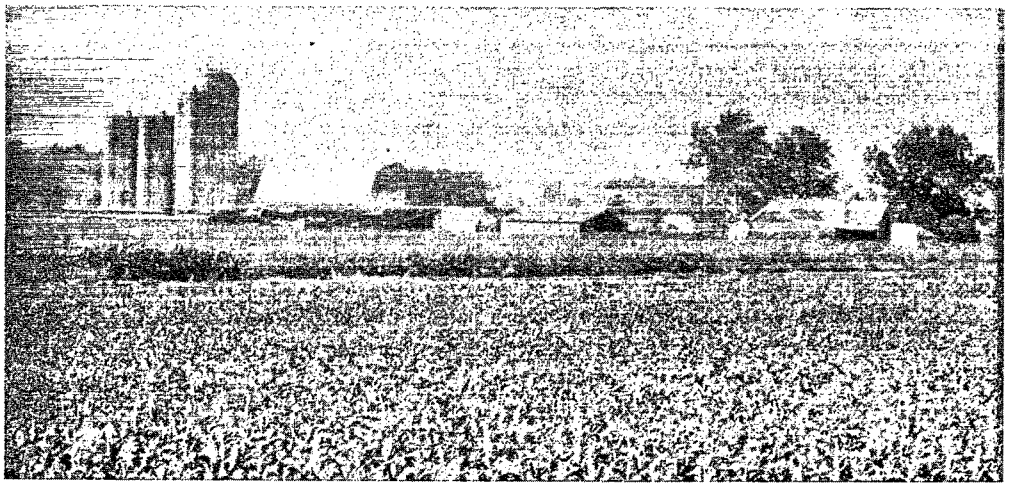
Continued Productivity Enhancements

Despite two prolonged government closings during the winter and new responsibilities following the passage of the FQPA in the summer, FY 1996 marked another highly productive year. The Office of Pesticide Programs registered 22 new pesticide active ingredients, more than half of which are considered reduced risk pesticides. These decisions include the approval of twelve new chemicals, including three reduced risk chemicals, and ten biopesticides. Overall, there were over 5,000 individual decisions concerning pesticide registrations.

OPP completed 27 Reregistration Eligibility Decisions (REDs), many of which included significant measures to reduce pesticide risks to human health and the environment. In addition, the Office met its target of completing 10 Special Review decisions in FY 1996.

More detail on these achievements is contained in Part II of this report. Wile these figures are lower than FY 1995's record high number of new active ingredients and REDs completed, they compare favorably with the program's historical levels of activity and reflect in part the need to adjust program policies to implement the new law. FY 1997 is expected to be a transitional year as new policies and procedures are implemented in a reorganized OPP.

FY 1996 also was characterized by continued "reinvention" efforts designed to streamline processes, build partnerships, and increase automation in ways that enable OPP to be more responsive and productive.



Reinvention Initiatives to Enhance Productivity

The Office of Pesticide Programs initiated many new projects aimed at reinventing registration and reregistration processes to provide services faster, smarter and more efficiently, resulting in benefits to registrants and the public. In fact, OPP was recognized for its success in simplifying the process of registering pesticide products when it received the prestigious "Hammer" Award from Vice President Al Gore's National Performance Review.

Streamlining Registration Reviews, Self-Certification and Exemptions

A number of important productivity gains were achieved in the registration program in FY 1996. Highlights included:

* OPP significantly expanded the categories of low risk, minor pesticide registration amendments that may be accomplished without waiting for formal EPA review and approval (self-certification) and created an accelerated process for Agency review of minor formulation changes.

* A final rule exempted 31active ingredients (in 71 products) under FIFRA Section 25(b) because of their low risk. The exempted products included many common food ingredients, such as garlic. They will no longer be regulated under FIFRA when they are used alone or in combination with inert ingredients that EPA has found to be safe.

* OPP also made great strides in expediting the review of the approximately 900 acute toxicity data submissions received each year, bringing the backlog down from 400 to nearly zero and reducing review times from 30 months to 4 months.

* Working with the California Department of Pesticide Regulation, EPA launched "work-sharing" programs for simple registration amendments and acute toxicity data. These activities aim to avoid unnecessary duplication of work by California and EPA and significantly shorten review times. EPA saved considerable resources by sharing the acute toxicity review workload with California (30 reviews in FY 96).

* A parallel review of a new pesticide active ingredient, tebufenozide, was conducted by EPA and Canada. The goal was to identify, through a real example, the similarities and differences between the Canadian and U.S. pesticide regulatory systems. Based on this cooperative review experience, EPA and Canada are exploring work-sharing opportunities under the NAFTA Technical Working Group, as described in Chapter 1.

Other internal efficiencies resulted from the continued activities of the Product Manager Automation Team (PMAT). PMAT helped implement electronic time-accounting for OPP staff, improving accuracy and reducing error rates. The group also enhanced staff performance by creating easily accessible templates and standard language for use in registration notices, fact sheets, and other frequently used forms and documents.

In the coming fiscal year, OPP expects to build on these achievements. The Agency will explore and seek public comment on additional opportunities for self-certification of, for example, product chemistry data. EPA also is collecting data on why applications for "me-too" products are found to be deficient, following the example of the successful rejection rate analyses performed in the reregistration program. ("Me-too" pesticides include registration applications and amendments that do not require data review and are identical or substantially similar to existing registered products in composition and labeling.) Once this analysis is complete, OPP will consider options for self-certification of "me-too" products.

Finally, OPP is considering proposing additional exemptions under FIFRA Section 25(b) to deregulate low risk chemicals and/or uses, such as antimicrobial products that claim only to eliminate odor-causing bacteria.

Reregistration and Special Review

RED Document Improvement. As part of a continuing effort to improve the format, content, and readability of RED documents, an OPP team developed and began piloting a user-friendly version of portions of the standard RED package. Others revised the RED document format and language to reflect the new FQPA provisions. Efforts to more clearly communicate worker protection aspects of our decisions are underway.

Special Review and Reregistration Division Peer Review Committee. This committee, comprised of both managers and staff, continued to review draft RED documents and Special Review Position Documents, considering cross-cutting policy and regulatory questions to ensure greater clarity and consistency.

State and Regional Review of REDs. OPP began an initiative to include States and EPA Regional Offices in the review of some draft REDs in order to make the best possible use of their expertise and interests, especially their familiarity with local pesticide use.

Coalition on Drift Minimization. OPP began participating in this new government/industry/user effort to identify and implement measures to reduce off-target spray drift through education, research, and regulatory means.

Improving Pesticide Labels and Labeling Procedures

Clear and effective product labeling is critical to protecting the public from pesticide risks. No other pesticide document or publication has a more direct impact on reducing risks, preventing pollution, and promoting safer use. OPP took several steps to improve both the labels themselves and the processes for their review and approval.

Consumer Labeling Initiative (CLI). The goal of the CLI, launched on March 22, 1996, is to foster pollution prevention, empower consumer choice, and improve consumer understanding through clear, consistent and useful environmental, health, and safety information on household consumer product labels.

The project is coordinated by a joint task force consisting of representatives from EPA, Food and Drug Administration (FDA), Consumer Product Safety Commission, Federal Trade Commission, and certain states. It also features partnerships with

interested companies and trade organizations. In FY 1996, CLI activities focused on qualitative research to improve our understanding of labeling issues and the development of a report and recommendations to Administrator Carol Browner.

Labeling Coordination. OPP issued a draft notice that would establish an annual compliance date for implementing most OPP-mandated labeling changes. The notice also described the Labeling Unit's role in coordinating labeling issues and related streamlining efforts. EPA is currently reviewing the comments received on the notice. In another effort to improve coordination and consistency in labeling policy, the Agency also began work to update the *Label Review Manual*, first issued in December 1994. A second edition should be available in early FY 1997.

Improving Accessibility and Updating Labeling Technology OPP converted its microfiche collection of pesticide product labels to compact disk format. The labels on compact disk, searchable by registration number and EPA company number, will be available to the public via the National Technical Information Service (NTIS). The collection will be updated quarterly to reflect newly registered products as well as label changes.

EPA also continued to maintain and post its electronic "on-line" Labeling Policy Directory on OPP's LAN. A listing of new documents is being sent to interested outside parties on a regular basis, and specific documents are made available upon request. Finally, EPA initiated a limited pilot project to test the electronic submission and review of labels.

Forming Partnerships to Monitor Ecological Incidents

OPP worked with other federal and state agencies and industry to develop the Fish and Wildlife Incident Monitoring Protocol. If accepted by the American Society of Testing and Materials, the protocol will be published and distributed world-wide to improve the rate and quality of incident reporting. OPP's Ecological Incident Information System (EIIS), which can be used to assess the ecological impacts of pesticides, is now available to the public on the World Wide Web. The address is: **www.epa.gov/indicator/county/pest/pest.html.**

Improving Customer Service

The Office of Pesticide Programs (OPP) is committed to improving the quality of service we provide to a broad spectrum of customers. We are improving communication with our customers, and we are enhancing our understanding of their needs and circumstances.

To assess current services, OPP conducted a series of baseline customer surveys. The surveys targeted the following groups: pesticide registrants; producers and formulators; environmental and public interest groups; the general public; and EPA regional offices and states. (The surveys by no means covered the entire spectrum of diverse customers affected by

pesticide regulatory and implementation issues, and OPP continues to assess customer satisfaction via other mechanisms, including stakeholder meetings and the Pesticide Program Dialogue Committee.) The information gained from these surveys assisted OPP in drafting new customer service standards. The Employee Advisory Group is developing a plan to implement customer service standards across OPP in 1997.

In addition, OPP worked closely with OPPT to complete the OPPTS *Community Based Environmental Protection Tools Catalogue*, which was distributed to Regional Offices to review and use. Designed to provide more effective cooperation with our partners in protecting human and ecological communities, this catalogue improves access to OPP's technical expertise, analytical tools, and data bases.

Continuing Strides in Agricultural Worker Protection and Applicator Training

Implementing The Worker Protection Standard

OPP's Worker Protection Standard (WPS) for agricultural pesticides represents a major strengthening of national efforts to safeguard agricultural workers. WPS requires agricultural employers to ensure that employees receive basic pesticide safety training and to notify them when pesticides are applied. Employers also must provide washing supplies if workers are likely to come into contact with pesticides, and provide and maintain protective equipment. Effective implementation of the WPS will substantially lower the risk of pesticide poisonings among agricultural workers and pesticide handlers.

To date, roughly 2.5 million agricultural workers have been trained. OPP created or funded the distribution of over 1 million compliance manuals for growers; nearly 3 million safety training booklets; 700,000 safety posters; 20,000 safety training videos; and 8,000 grower compliance video/slide sets. OPP also implemented a voluntary program to verify completion of WPS training.

In FY 1996, OPP conducted nine public meetings and 30 field site visits in major agricultural areas across the country (Florida, Mississippi, Washington, Texas, California, Pennsylvania, Missouri, and Indiana). Information from these meetings and site visits will be used to develop strategies to improve WPS administration.

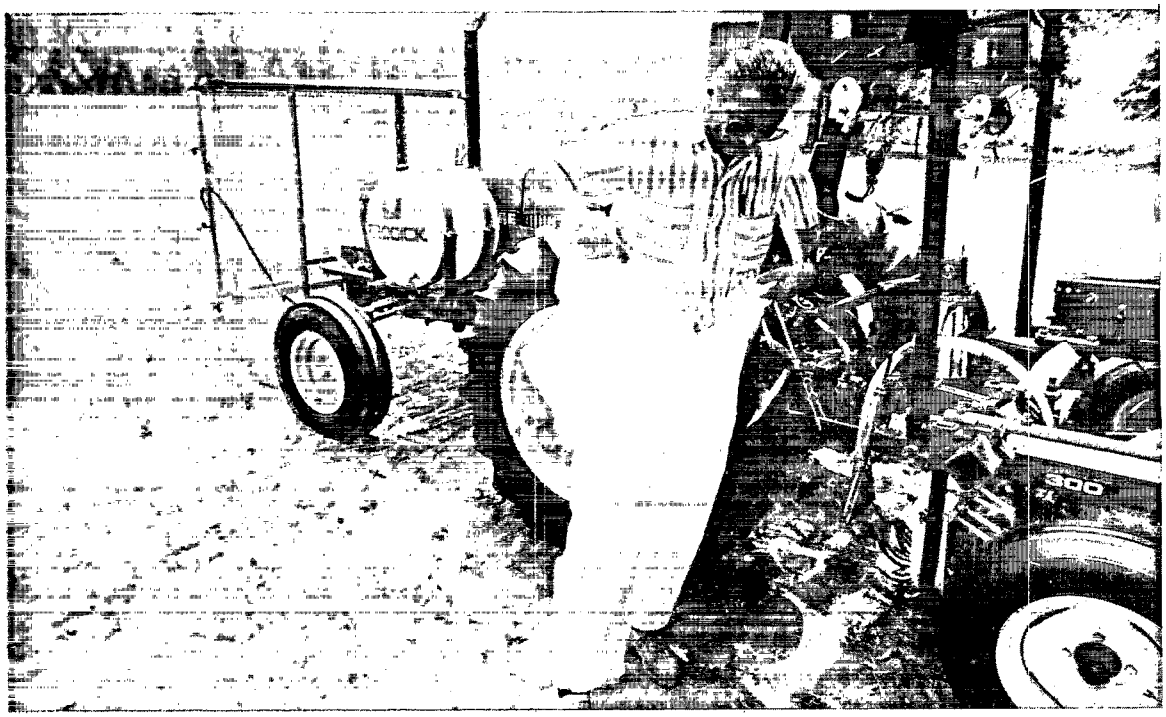
OPP also continued to modify WPS requirements to increase flexibility and remove unnecessary restrictions, issuing two proposed and two final regulation changes in the past fiscal year. Expanding efforts to reach diverse audiences more effectively, OPP worked with the Hispanic Radio Network in FY 1996 to develop and broadcast ten WPS safety information programs, reaching 120 market areas nationwide.

Certification And Training Of Pesticide Applicators

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

In 1995, the most recent year for which figures are available, over 81,000 private and 66,000 commercial applicators were certified; and more than 129,000 private and 121,000 commercial applicators were recertified.

In 1996, OPP continued to work to revise its national standards to ensure the continued competence of certified applicators. To assist state, territory and tribal governments in conducting certification programs, OPP funded 64 cooperative agreements and provided support to state extension coordinators through USDA. Other activities included "train-the-trainer" and pesticide applicator training workshops, development of training materials for improving pesticide drift management and application technology, and assessing behavioral and attitudinal changes in applicators as a result of certification and training programs.



Using Information Technology to Increase Access and Productivity

A key to increased productivity is the adoption of new computer technologies that allow OPP to respond faster to customer needs and improve both internal and external communication. Our increasing use of the World Wide Web, as described in Chapter 1, reflects OPP's commitment to these goals.

OPP is working with regulated industry to facilitate the electronic submission of pesticide registration documents and information. In the course of its investigations, OPP learned of a system called Computer Aided Dossier and Data Supply (CADDY) under development by the European Commission and the European pesticide industry. CADDY will rely initially on CD-ROM technology for submission of pesticide information to member countries. OPP is developing partnerships with Europe in the development and use of CADDY. In the long run, international harmonization of requirements, expectations and submission formats will benefit EPA, the private sector, and the public.

OPP is also standardizing electronic formats for some of the data in registration submissions in order to facilitate analysis by OPP scientific reviewers. The Office is moving more of its major data systems to the OPP local area network (LAN) to provide staff with more convenient access. In addition, OPP has adopted compact disk format as the archival medium for all studies, replacing microfiche.

In the future, OPP is planning to establish a Computer Resource Center to help keep OPP staff abreast of the latest technology. The center will consist of a fully equipped classroom for hands-on formal training and a room housing unusual or specialty software and equipment. In addition, a loan center will allow staff to borrow equipment, manuals, and training materials.

Part II

FY 1996 Accomplishments: Facts and Figures

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New Pesticide Registrations

In FY 1996, OPP registered 22 new pesticide active ingredients, more than half of which are considered reduced-risk pesticides. These decisions include the approval of ten biopesticides and twelve new chemicals, which include three reduced risk chemicals. The table on the following pages lists active ingredients for which decisions were made (and two where applications were withdrawn) in Fiscal Year 1996.

Table I. New Pesticide Active Ingredients Registered in FY 1996

Pesticide Name	Registrant	Pesticide Type	Use(s)	Biopesticide or Reduced Risk Pesticide?
Potassium Permanganate	Carus Chemical Company	Disinfectant	Manufacturing Use Only	No
Butanethiol	Bear Country Products	Repellent	Recreational Areas	No
Aztec	Bayer Corp	Insecticide Miticide	Corn	No
Sumilar	Sumitomo Chem Co.,Ltd	Insecticide Miticide	Farm animals, dogs, cats, non-food/feed storage areas	No
Maxim	Ciba-Geigy Corp.	Fungicide	Corn & Sorghum	Yes (RR)
Cadre	American Cyanamid	Herbicide	Peanuts	Yes (RR)
Mefenoxam	Ciba-Geigy	Fungicide	Fruits, nuts and melons	Yes (RR)
Fipronil	Rhone-Poulenc AG	Insecticide Miticide	Turf, dogs, cats, golf course turf	No
Cidex	Johnson & Johnson, Inc.	Disinfectant	Farm animals, pests, poultry, egg handling equipment, pulp & paper mills	No
Upbeet	DuPont	Herbicide	Sugar Beets	No
Promexal	Zeneca Ag Products	Miticide Fungicide	Preservative used in adhesives, coatings, paints, resin emulsions, metalworking cutting fluids.	No

Pesticide Name	Registrant	Pesticide Type	Use(s)	Biopesticide or Reduced Risk Pesticide?
Busan 1104	Buckman Labs	Microbiocide	Preservative used in adhesives, coatings, paints, resin emulsions	No
Bt Cotton	Monsanto	Plant Pesticide	Cotton	Yes
1-octen-3-ol	Armatron	Mosquito Attractant	Non-food	Yes
Jojoba oil	IJO Products	Insecticide	All terrestrial food crops	Yes
Oil of Melaleuca	Tuttle Apiary Laboratory	Miticide	(Application Withdrawn)	Yes
Bt (CRYMAX)	Ecogen, Inc.	Insecticide	All terrestrial food crops	Yes
Myrethecium verrucaria (killed fermentation solids and solubles of)	Abbott Laboratories	Nematicide	All terrestrial food crops and ornamentals	Yes
Meat meal	Lakeshore Enterprises	Repellent	Deer, rabbits and raccoons	Yes
Red pepper	Lakeshore Enterprises	Repellent	Deer, rabbits and raccoons	Yes
Verticillium lecanii	Abbott Laboratories	Insecticide	(Application withdrawn)	Yes
NK Bt corn	Northrup King	Plant pesticide	Field corn	Yes
Monsanto Bt corn	Monsanto	Plant pesticide	Corn (field, sweet and pop)--seed increase only	Yes
Lavandin Oil	S.C. Johnson & Sons	Repellent	Moths	Yes

Table II. Registration Decisions vs. Targets in FY 1996

CATEGORY	DESCRIPTION	TARGET DECISIONS	FINAL DECISIONS
Old Chemicals (Fast Track)	application for a new product containing an active ingredient (AI) contained in a currently registered product; requires no data review	595	701
Old Chemicals (Non-Fast Track)	application for a new product containing an AI in a currently registered product; requires data review	85	200
Amendments (Fast Track)	application to change an existing registration (e.g., formula or labelling); requires no data	2,150	3,104
Amendments (Non-Fast Track)	application to change an existing registration; requires data review	215	154
New Uses	application for registration of a use not currently included in the registration	50	117
New Chemicals	application for registration of a product containing an AI not contained in a currently registered product	24	24
Experimental UsePermits (EUPs)	permit required to conduct field trials (residue tests) to support the registration of a new AI	123	85
Tolerances	Safe pesticide residue level allowed on food	65	106
Temporary Tolerances	Tolerance for a pesticide under an EUP; must be established if the crop will be eaten	36	35
Inerts	approval of toxicology data for new inert ingredients to be used in pesticide products	13	38
Emergency Exemptions (Section 18s)	approval of a State's request to use an unregistered pesticide when no registered product is available	247	452
Special Local Needs (24c)	approval of a State's request for a specific use that is not currently registered	390	373
Biotech Notification	special EUP for a biological pesticide	5	5
TOTALS		**3,998**	**5,394**

Reregistration Progress

Overall Status of Reregistration

Of the 614 reregistration cases [1] (representing 1,138 active ingredients or AIs) that were eligible for reregistration in 1988, 232 are no longer supported (they have been suspended and/or voluntarily canceled). Reregistration Eligibility Decisions (REDs) have been completed [2] for 148 -- almost 40% -- of the 382 remaining cases. The 27 REDs competed in FY 1996 are listed below in Table III.

Figure I. Status of Original Reregistration Cases

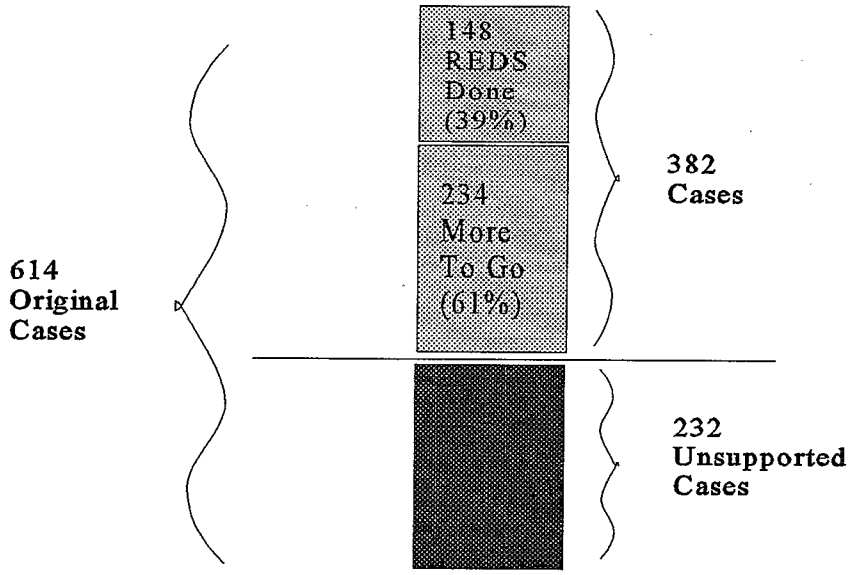


Table III. Reregistration Eligibility Decisions (REDs) Completed in FY 1996

Amitrole	4,4-Dimethyloxazolidine	Oil of Pennyroyal
Bacillus Popilliae	Furanone or Tanol Derivatives	p-Chloro-m-cresol
Bromacil*	Gibberellic Acid	Paraquat Dichloride*
Cloprop	Hydroxyethyl Octyl Sulfide	Phosphamidon
Colletotrichum gloeosporioides*	Hydroxypropyl methanethiosulfonate	Polyhedral Inclusion Bodies (NPV)*
Coumaphos	Mepiquat Chloride*	S-Kinoprene*
Cryolite	Methylisothiazolinone	Strychnine
Desmedipham	Mitin FF	Tridecenyl Acetates
Dibromodicyanobutane (DBDCB)	Norflurazon	Virelure*

[1] This number, originally 611 cases, rose to 614 when several active ingredients were separated to become individual cases.
[2] The 148 completed REDs include some cases voluntarily canceled as a result of the reregistration review.
* Indicates RED was issued after August 3, 1996, under the provisions of the FQPA.

Pesticide Usage Covered by REDs

The 148 REDs completed through the end of FY 1996 represent about 60% of the 4.2 billion pounds of pesticide active ingredients used annually in the United States. A significant portion of this volume is represented by chlorine, hypochlorites (bleach), pine oil, sulfur, petroleum oil, aliphatic alcohols, and coal tar/creosote.

REDs account for 30% of the remaining 1.6 billion pounds of conventional pesticides, antimicrobials, and wood preservatives used each year in the U.S. Looking at these conventional pesticides by market segment, completed REDs cover an estimated 33% of the consumer-applied pesticides, almost 24% of pesticides used in agriculture, and about 35% of pesticides applied by commercial applicators for residential and commercial pest control. This year's usage estimates are more accurate than previous years' because they are based on better data -- more categories of pesticides and data bases, and more recent and complete data.

Table IV. Amount of Pesticide Usage (by Volume) Covered by REDs Completed through FY 1996*

Type of Pesticide	Consumer Applied	Agricultural Use	Commercial Use	Total Percent
Antimicrobials/ Algicides	100 %	3 %	57 %	60%
Biologicals	100%	0 %	24 %	28%
Fungicides	1 %	6 %	3 %	5 %
Herbicides/Growth Regulators	24 %	37 %	30 %	36 %
Insecticides/Fumi-gants/Nematicides	12 %	>1 %	14 %	4%
Repellents	1 %	n/a	14 %	2 %
Rodenticides/ Molluscicides	65 %	0%	18 %	18 %
Wood Preservatives	0%	0%	0%	0%
TOTAL	33 %	24 %	35 %	30 %

* Excludes pine oil, chlorine, sodium and calcium hypochlorites (bleach), aliphatic alcohol, sulfur, petroleum oil, and coal tar/creosote. RED's completed account for 78% of these large volume pesticides. Also, pounds used may not indicate the relative percent of area treated or number of applications.

Risk Reduction Achieved Through FY 1996 REDs

The REDs completed in FY 1996 include many changes intended to reduce risks to human health and the environment. Some of the risk reduction measures achieved in these 27 REDs are summarized below.

Table V. Risk Reduction Achieved Through FY 1996 REDs

Number of REDs	Risk Reduction Measures Required by REDs
6	Voluntary Cancellation and/or Deletion of all or certain registrations, uses, or formulations. Includes **Amitrole** (voluntary cancellation of liquid formulation and deletion of ornamental plant nursery stock uses); **Bacillus popilliae** (all uses voluntarily canceled); **Cloprop** (all uses voluntarily canceled); **Oil of Pennyroyal** (last product voluntarily canceled); **Paraquat Dichloride** (some use patterns deleted); and **Phosphamidon** (all uses voluntarily canceled).
8	Use Reduction.
3	Restricted Use Pesticide classification added or maintained, so that the pesticide may be used only by or under the direct supervision of a certified applicator.
20	Personal Protective Equipment (PPE) requirements for pesticide handlers strengthened or confirmed.
11	Restricted Entry Intervals (REIs) limiting entry of workers into treated areas strengthened or confirmed.
21	Use Limits, Application Restrictions, Use Directions or Precautions added, strengthened, or made more specific.
16	User Safety Requirements or Recommendations added.
6	Special Packaging or Engineering Controls required.
4	Ground Water or Surface Water Safeguards required.
9	Spray Drift Labeling required.
14	Other Environmental Safeguards required to reduce ecological risk.
11	Tolerances reassessed (reduced, revoked, or newly approved).

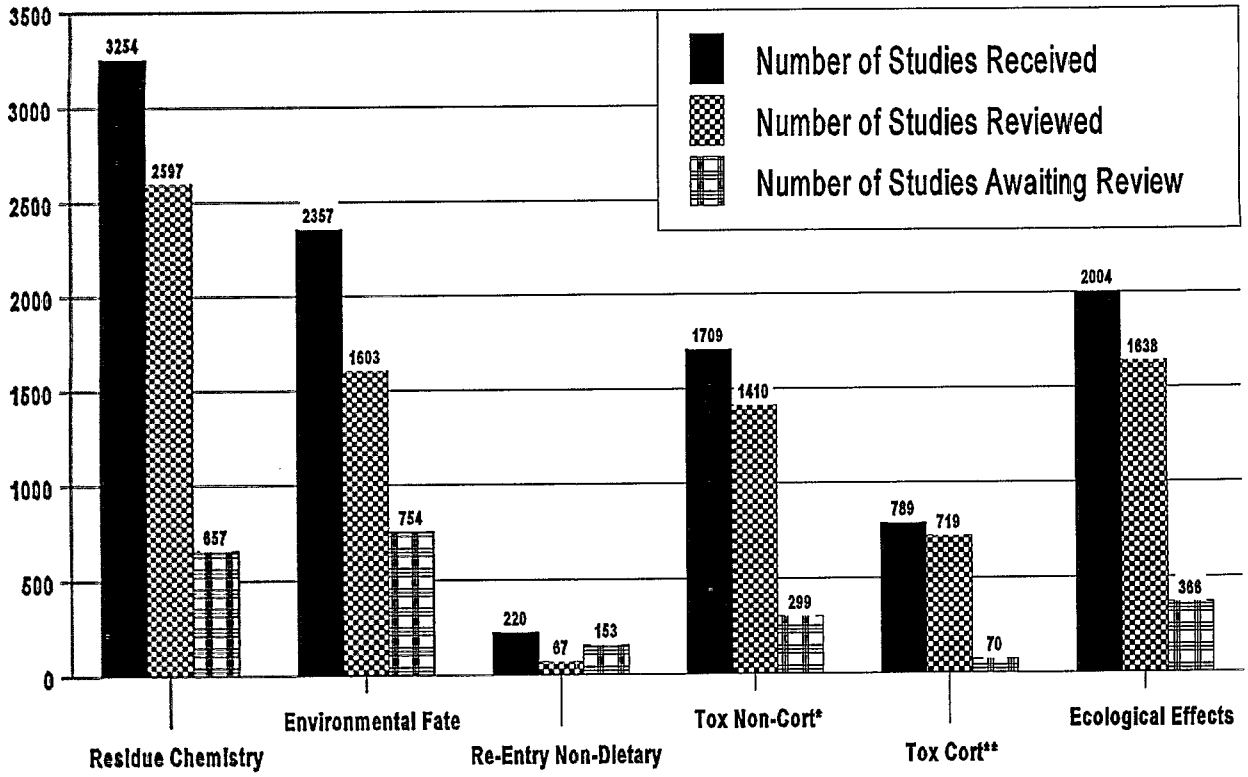
For more detailed information on the risk reduction measures achieved from each of the individual REDs completed in FY 1996, please refer to the *Pesticide Reregistration Progress Report for FY 1996.*

Status of Studies Received

Registrants have responded to Data Call In's and other requirements by submitting over 21,000 studies in support of reregistration. By the end of FY 1996, OPP had reviewed over 14,500 of these studies, including more than 8,000 of the over 10,000 studies received for List A pesticides (the most significant and/or food use pesticides). The numbers of studies received, reviewed, and awaiting review by scientific discipline are shown below for the List A pesticides.

Figure II. Review Status of List A Pesticides

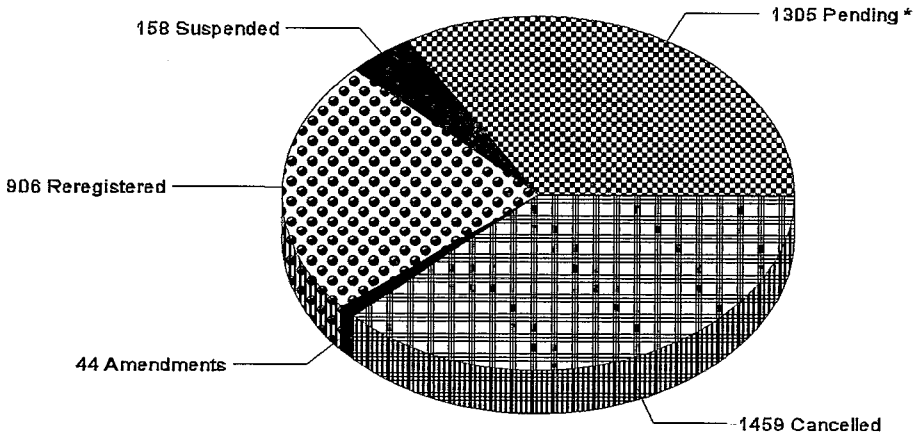
Number of Studies Received, Reviewed, and Awaiting Review



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. As of October 1996, about 2,500 products have completed this concluding phase. OPP has reregistered over 900 of these products, granted about 1,450 voluntary cancellations, amended 44 registrations, and suspended about 150 products. In addition, about 1,300 reregistration decisions are pending, and 1,370 products have recently entered this final phase.

Figure III. Product Reregistration Status for 148 REDs Completed as of October 1, 1996

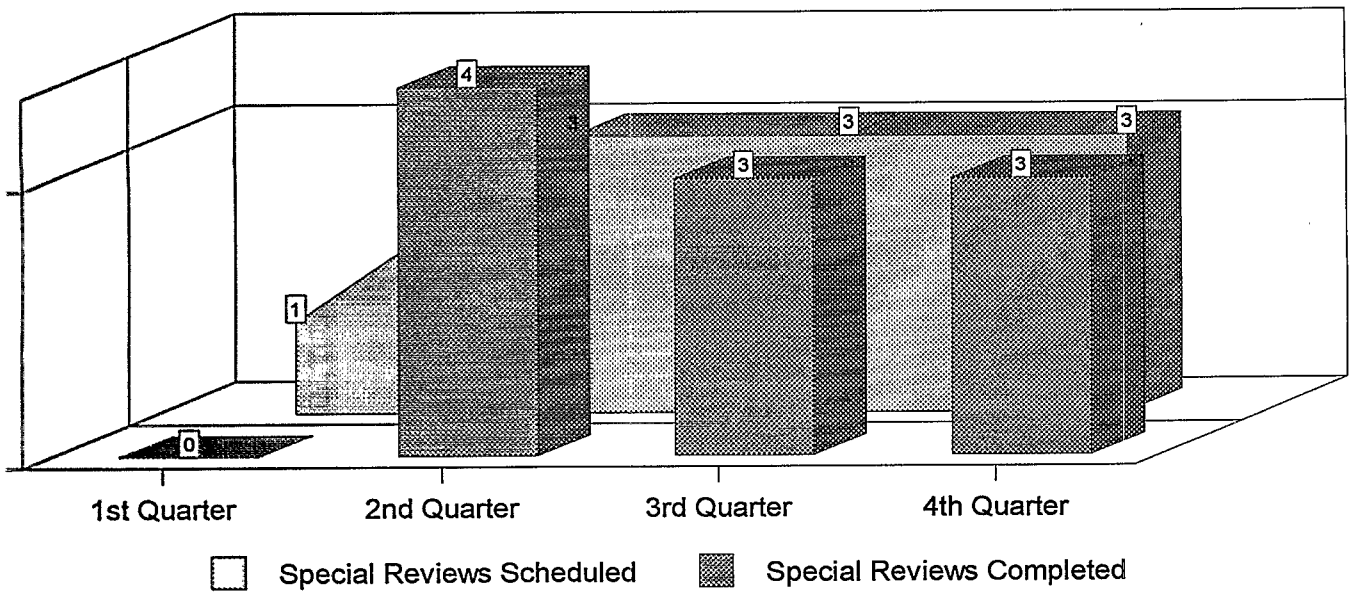


* An additional 1371 products are covered by REDs issued since August 1995, for which a product reregistration decision is not yet due under FIFRA.

Special Review

OPP completed a total of 10 Special Review decisions during FY 1996, meeting its target for the fiscal year.

Figure IV. Special Review Decisions vs. Targets in FY 1996



Risk Reduction Achieved Through Special Review

The following Special Review activities have resulted in risk reduction through label amendments, or provide information to OPP allowing the refinement of risk assessments to determine the need for further exposure reduction.

Table VI. Risk Reduction and Data Gathering through Special Review in FY 1996

Pesticide	Risk(s)	Use Reduction	New Restricted Use	Increased Preharvest &/or Reentry Intervals	Engineering Controls[1]	Additional Protective Clothing	Major Data Requirements	Special Review Ended
Cyanazine	dietary, worker; cancer, ground & surface water contamination	X			X			X
Iprodione	dietary; cancer			X			X	
Metam Sodium	to workers; developmental		X					
Methomyl	to workers; neurotoxicity	X		X		X		
Molinate	to workers; reproductive				X	X	X	
Propargite	dietary; cancer	X						
Propoxur	to workers & residents; cancer	X						X
Telone	to workers & residents; cancer	X			X	X		
Ag Reentry	to workers						X	

[1] E.g., mechanical and closed loading systems, application from within a closed cab, sealing fumigants in the soil with tarps, etc. Telone also included a buffer zone between treated areas and occupied buildings.

OPP Laboratory Accomplishments

Food Tolerance Method Validations (TMVs)

In order for FDA, USDA and the states to take appropriate regulatory action when residues exceed that which has been established by federal and state agencies, reliable chemical methods of analyses are required. Although the pesticide registrants are responsible for developing such methods, EPA determines if the methods are suitable for monitoring the nation's food supply. The Analytical Chemistry Lab, located in Beltsville, Maryland, is responsible for validating these methods. In FY 1996 the total number of TMVs completed at the laboratory increased by 66% from FY 1995. Of those, 27% of the TMVs were new uses of existing pesticides.

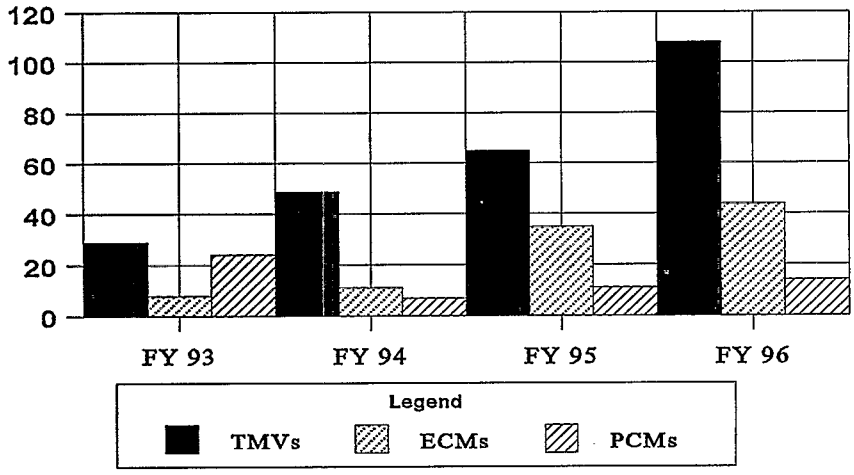
Environmental Chemistry Methods Validations (ECMs)

The Environmental Chemistry Laboratory in Mississippi determines the reliability and validity of pesticide soil and water residue methods. The environmental chemistry mthods (ECM) are used by the EPA regions and states to identify inadvertent pesticide residues in soil and water contaminated sites as well as being used for pesticide monitoring studies. There was a 26% increase in ECM validations completed in FY 1996 compared to last year's accomplishments.

Product Chemistry Method Validation (PCMs)

The Analytical Chemistry Laboratory in Beltsville, Maryland, periodically tests the composition of pesticide products. This testing is known as product chemistry method (PCM) validation. The lab completed 27% more PCM validations in FY 1996 than it completed last year.

Figure V. OPP Laboratory Accomplishments



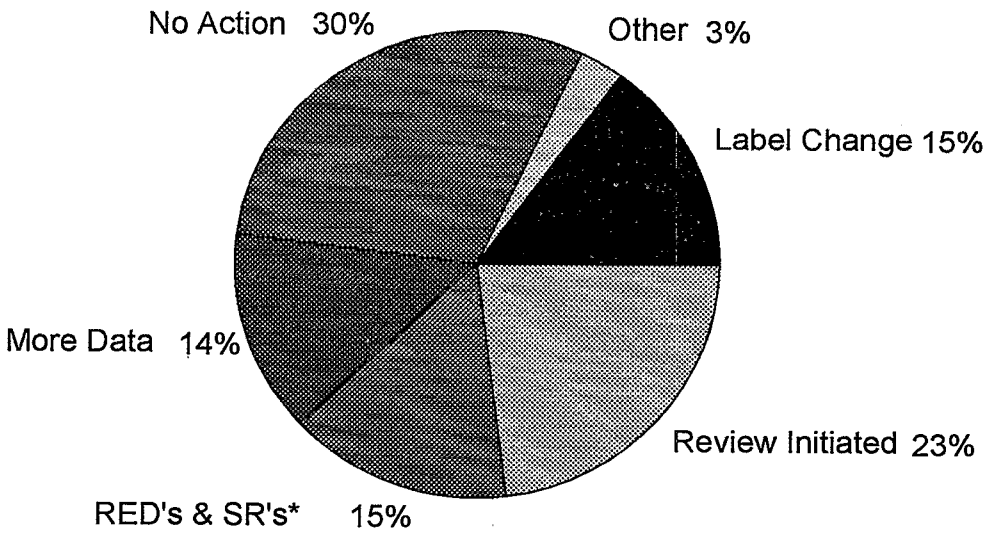
Pesticide Adverse Effects Reporting

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

Incidents. In FY 1996, the volume of reported incidents increased over the prior year. OPP received approximately 1500 submissions containing more than 9,200 incidents.

Studies. OPP screened over 400 adverse effects submissions consisting of studies and preliminary reports of possible adverse effects. Detailed information regarding the screening decisions and outcome of submissions warranting expedited review is available in the OPP Public Docket.

Figure VI. Outcome of 6(a)(2) Submissions Warranting Expedited Review



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

Pesticide Environmental Stewardship Program (PESP)

Table VII. PESP Partners and Supporters

Partners

American Association of Nurserymen
American Corn Growers Association
American Electric Power (AEP) Service Corporation
American Mosquito Control Association (AMCA)
Arizona Public Service
Atlantic Electric
California Citrus Research Board
California Pear Advisory Board
California Pear Growers
California Tomato Board
Carolina Power & Light
Cranberry Institute
Delmarva Power
Duke Power Company
Eastern Utilities
Edison Electric Institute
Florida Fruit & Vegetable Association
Global Integrated Pest Management
Golf Course Superintendents Association of America
Hawaii Agricultural Research Council
Hood River Grower-Shipper Association
Mint Industry Research Council
Monroe County School Corporation
National Potato Council
New England Vegetable & Berry Growers Association
New Orleans Mosquito Control Board
New York State Gas & Electric
Northern Indiana Public Service Company
Northwest Alfalfa Seed Growers Association
Oregon-Washington-California Pear Bureau
Oregon Wheat Growers League
Owen Speciality Services, Inc.
Pear Pest Management Research Fund
Pebble Beach Company
Pennsylvania Electric
Pennsylvania Power & Light
Pennsylvania Rural Electric Association
Pineapple Growers Association of Hawaii
Processed Tomato Foundation
Professional Lawn Care Association of America
Sun-Maid Growers of California
South Dakota Cattelmen's Association
Tennessee Valley Authority
Texas Pest Management Association
U.S. Apple Association (International Apple Institute)
U.S. Department of Defense
U.S. Public Health Service, Centers for Disease Control and Prevention
Utilicorp United
VA, MD, DE Association of Electric Cooperatives
Vegetation Managers, Inc.
West Virginia Power
Wisconsin Ginseng Growers Association
Wisconsin Public Service Corporation

Supporters

Aqumix, Inc.
Bay Area Stormwater Management Agencies Association
Campbell Soup Company
Del Monte
Farm*A*Syst/Home*A*Syst National Office
Gempler's, Inc.
General Mills, Inc.
Gerber Products Company
Glades Crop Care, Inc.
United States Golf Association

Appendix A. OPP Organization and Contacts

As part of its overall commitment to reinvention, the Office of Pesticide Programs (OPP) is "flattening" its organizational structure. This reorganization will reduce the number of layers of supervision and improve accountability for program performance. OPP is creating a new Antimicrobial Division, with the full range of functions needed to assess and regulate antimicrobial pesticides; merging the existing Policy and Special Projects Staff with the current Field Operations Division in a new Field and External Affairs Division; consolidating resources management functions in the immediate staff of the Office Director; and consolidating information management functions in a new Information Resources and Services Division. The general responsibilities of OPP's remaining divisions will change little, but structural changes below the division level will greatly increase reliance on interdisciplinary review groups. The new alignment will be in place early in calendar 1997. Below is a summary of division responsibilities in the new structure. OPP staff contacts follow.

Field and External Affairs Division (FEAD)

Program policies and regulations; legislation and Congressional interaction; International, Regional, State, and Tribal coordination and assistance; general food safety issues; ground water activities; publications and communications; endangered species; worker protection; certification and training

Information Resources and Services Division (IRSD)

Information support; Public Docket; records; computer support; FIFRA Section 6(a)(2) issues; pesticide incident monitoring, National Pesticides Telecommunications Network (NPTN)

Biological and Economic Analysis Division (BEAD)

Assessment of pesticide use and benefits; operation of analytical chemistry and antimicrobial testing laboratories

Biopesticides and Pollution Prevention Division (BPPD)

Risk/benefit assessment and risk management functions for microbial pesticides, biochemical pesticides, and plant-pesticides; Pesticide Environmental Stewardship Program (PESP)

Antimicrobial Division (AD)

Risk/benefit assessment and risk management for antimicrobial pesticides

Registration Division (RD)

Product registrations, amendments, reregistrations, tolerances, experimental use permits, and emergency exemptions for all pesticides not assigned to BPPD or AD

Special Review and Reregistration Division (SRRD)

Reregistration Eligibility Decisions (REDs); Special Reviews

Environmental Fate and Effects Division (EFED)

Environmental hazard, exposure, and risk assessments

Health Effects Division (HED)

Human hazard, exposure, and risk assessments

Key OPP Management Contacts

(All telephone area codes are 703)

Immediate Office Fax: 308-4776	Daniel M. Barolo, Director Penelope Fenner-Crisp, Deputy Director	305-7090 305-7092
Biological and Economic Analysis Division Fax: 308-8091	Allen L. Jennings, Director	308-8200
Biopesticides and Pollution Prevention Division Fax: 308-7026	Janet L. Andersen, Acting Director	308-8712
Environmental Fate and Effects Division Fax: 305-6309	Joseph Merenda, Director	305-7695
Health Effects Division Fax: 305-5147	Margaret Stasikowski, Director	305-7351
Information Resources and Services Division Fax: 308-5984	Linda Travers, Director	305-5440
Registration Division Fax: 305-6920	Stephen L. Johnson, Director	305-5447
Special Review and Reregistration Division Fax: 308-8005	Lois A. Rossi, Director	308-8000
Field and External Affairs Division (under development) Fax: 305-6244	Anne E. Lindsay, Director	305-7102
Antimicrobial Division (under development)	Frank T. Sanders, Director	305-5440

Appendix B. How to Obtain More Information

The Office of Pesticide Programs (OPP) wishes to provide timely and consistent information to the public. For additional information on subjects discussed in this report or other topics, the following sources are available to you.

How to Obtain Information from EPA's Office of Pesticide Programs (EPA 735-F-96-004)

This document, which was last updated in July 1996, 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. It can be obtained from

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

Communications Branch

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

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 metro station); telephone 703-305-5805.

Catalog of OPP Publications And Other Information Media (EPA 730-B-95-001)

Last updated in June 1995, this catalogue provides a listing of hundreds of pesticide publications, including science chapters and facts sheets. It is available from EPA's Public Information Center, 401 M Street, S.W., Washington, DC 20460 (Telephone 202-260-2080); or the National Center for Environmental Publications and Information (NCEPI), P.O. Box 42419, Cincinnati, OH 45242-2419 (Telephone 1-800-490-9198 or 513-891-6561; Fax 513-891-6685).

National Pesticides Telecommunications Network (NPTN)

Accessible by a toll-free telephone number, NPTN provides general information about pesticides. The network is available to anyone in the United States, Puerto Rico, and the Virgin Islands (Monday - Friday, 6:30 a.m. to 4:30 Pacific Time) at 1-800-858-7378.

Pesticide Information Network (PIN)

The PIN is an interactive database system containing current and historic pesticide information. It is free and operational 24 hours a day, seven days a week. It can be reached via modem and communications software at 703-305-5919.

OPP Home Page on the World Wide Web

OPP's web site is accessed from the EPA home page address: **http://www.epa.gov**.
The following information is available: *Federal Register* publications, reregistration eligibility decisions (REDs), information on registrants from the Pesticide Data Submitters List, company and product information from the Pesticide Product Information System, information on Food Quality Protection Act implementation efforts, and fact sheets and publications of general interest, such as the *Citizen's Guide to Pest Control and Pesticide Safety* and this report.

Appendix C. List of Acronyms

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

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

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