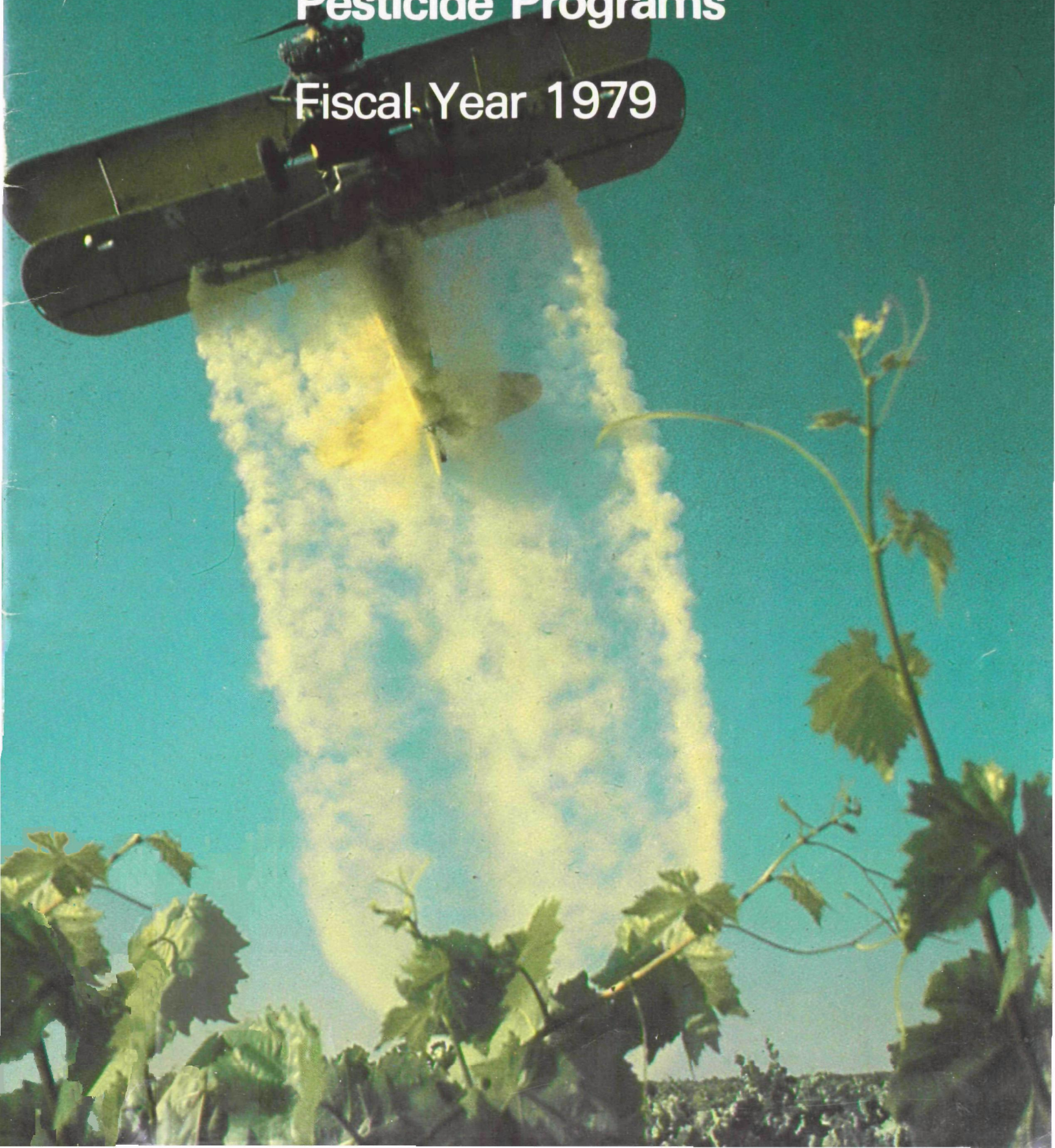




# Administration of the Pesticide Programs

## Fiscal Year 1979



Note: This report is for informational purposes only. Data contained in this report must be considered provisional and current as of the date of the report. Mention of trade names or commercial products in this publication does not constitute endorsement or recommendation for use by the Environmental Protection Agency.

OPP acknowledges the assistance of the Graphics and Photographic Services of EPA, especially that of Virginia Pulley.



## Foreword

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**T**oday the U.S. Environmental Protection Agency's Office of Pesticide Programs is making tougher, more consistently reliable and comprehensive pesticide decisions than ever before in the thirty years of Federal pesticide regulation. Our progress has resulted largely from internal administrative and organizational improvements designed to improve the coordination and management of pesticide activities.


Since the enactment of the 1978 amended FIFRA, the Office of Pesticide Programs has streamlined and further strengthened the review and registration processes of pesticide chemicals. Two of the more important changes have involved registration standards and the conditional registration processes, both of which were initiated and tested in Fiscal Year (FY) 1979.

The registration standards process, which was formerly in the procedure development mode, is now about to enter the production mode. Under this new approach to registration, the Agency will issue a comprehensive regulatory position for all products containing the same active ingredient. This means that the Agency will replace the traditional product-by-product review with a chemical-by-chemical review.

Because full data under today's requirements are not available for many chemicals entering the review process now and noting that all currently registered chemicals will take a decade or more to review, the Agency has implemented an interim process of conditional registration authorized by recent Congressional amendments. Under this system, the Office of Pesticide Programs (OPP) is able to process applications of new products which are identical or similar to previously registered products, thereby permitting new products to enter the market on an equal footing. Conditional registration may also be granted for new uses of old chemicals and for new chemicals if it is in the public interest.

In addition to implementing these two major initiatives, OPP has taken steps to strengthen its existing programs. After examining the processes and management systems in OPP, the Office has installed several formalized planning, management and information systems to coordinate the broad range of pesticide activities. Not only will these systems support OPP managers and decision-makers, but they will also provide outside individuals and groups with more accurate and timely information concerning the activities of this organization.

As you will see from reading this annual report, the Office of Pesticide Programs has made many significant advances and accomplishments in Fiscal Year 1979. These accomplishments, of course, represent the dedicated efforts of all the Office's employees and outside supporters who have contributed towards building a strong program. The continued success of this program will largely depend upon these talents and resources committed to the most important mission of safeguarding the health and the environment and upon the continued active interest, support and constructive criticism of user and environmental groups and the pesticide industry.



Edwin L. Johnson  
Deputy Assistant Administrator  
Office of Pesticide Programs

**W**ith conditional registration authorized by the Federal Pesticide Act of 1978, the Office of Pesticide Programs has dramatically increased the processing and approval rate for new pesticide applications in FY 1979. Receipt and approval rates for emergency exemptions also increased substantially (over 50%) in FY 1979 compared to FY 1978. During this fiscal year, the registration and special registration programs continued to give top priority to applications for environmentally safe and innovative compounds, such as new selective and safer chemicals, biologicals, and third-generation pesticides suited to integrated pest management programs. In conjunction with the newly authorized registration changes, OPP has implemented a more flexible approach to minor use tolerance data review and decision making.

Other significant gains of the fiscal year have occurred in the Rebuttable Presumption Against Registration (RPAR) Program which involves an intensive risk/benefit review of pesticide chemicals suspected of causing unreasonable adverse health or environmental impact. In FY 1979, the emphasis in the RPAR process shifted from the pre-RPAR phase (PD 1) to the post-RPAR phase (PD 2/3 and PD 4). Because of this policy shift, OPP completed proposed decisions for 7 RPAR chemicals, proceedings for 3 RPAR chemicals, and resolutions for 2 RPAR chemicals.

In FY 1979, the Agency issued its first emergency suspension action for major uses of two RPAR chemicals—2,4,5-T and Silvex. After this suspension action, the Agency reached agreements with major registrants to voluntarily cancel Silvex home and garden products. EPA is now arranging for appropriate and safe disposal of these pesticide products.

In the registration standards program, efforts were largely concentrated on the development and modification of registration standards procedures and on the data gathering and preparation phase (Phase 1) for 15 registration standards.

During Fiscal Year 1979 a prototype standard for metolachlor was designed to provide industry and the public with an example of a standard and to solicit their comments concerning it.

OPP continued to actively participate in regional and international programs in FY 1979, by responding to more than 10,000 external requests for pesticide related information from the regions and by attending international pesticide meetings. In addition OPP formally answered 700 Congressional inquiries, 100 inquiries from the Administrator's Office (including White House inquiries), over 400 general public inquiries, and 700 Freedom of Information requests. The Agency also analyzed 15,500 public comments on the registration guidelines.

Recognizing the need for improved planning, management, and control of its diverse activities, OPP initiated the development of the first large-scale Time Accounting Information System (TAIS) in EPA, a comprehensive Planning and Management System (PMS), and a registration tracking system. Both the TAIS and the PMS were implemented in the first half of FY 1980.

OPP has also initiated special projects and programs, including integrated pest management, farm and farmworker safety, classification by regulation, label improvement, advisory opinions, and other regulatory restrictions to deal with concerns about human exposure to off-target spray residues and drift. Through these special projects, OPP has continued to advance the development of innovative approaches for the regulation of pesticides.



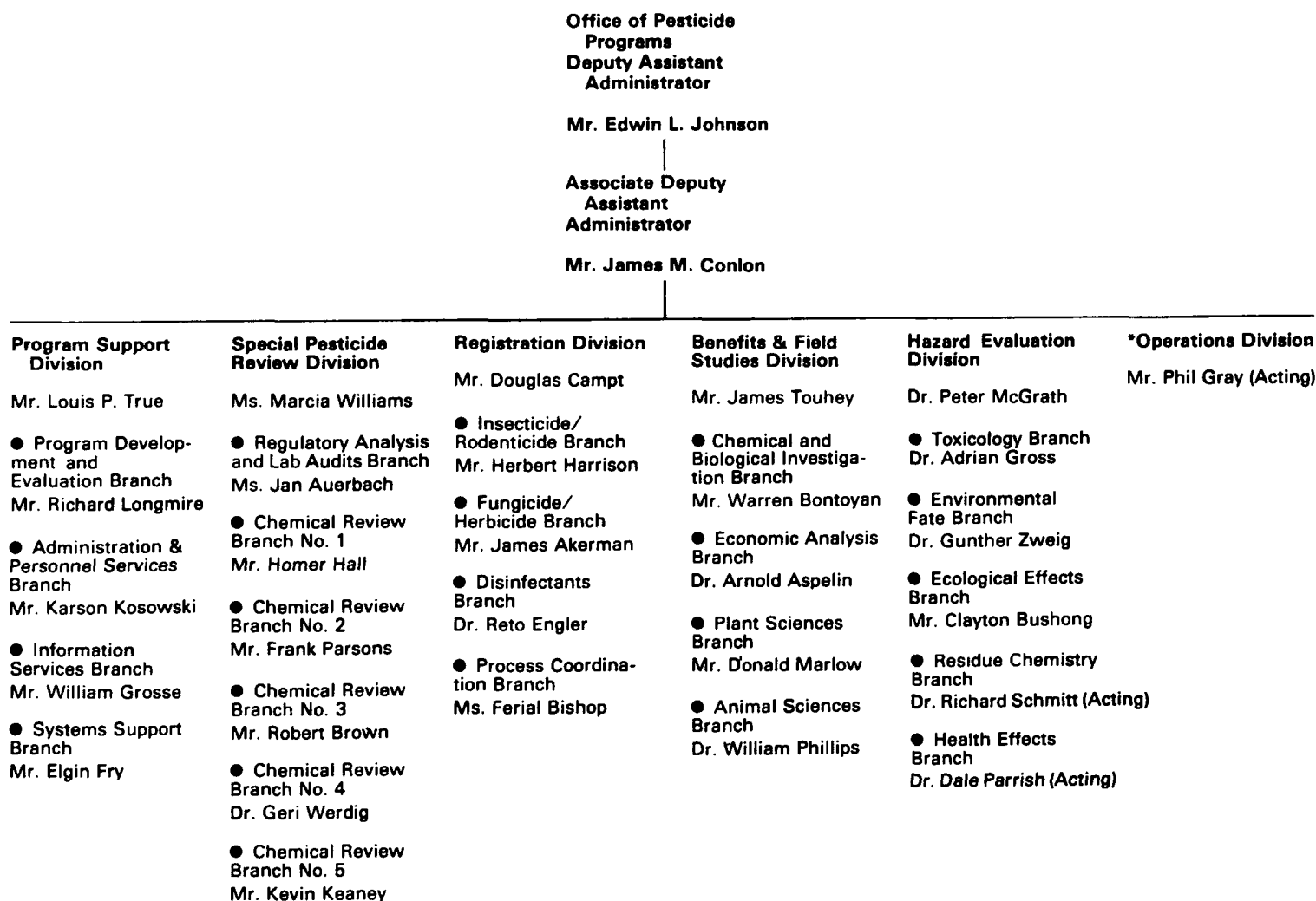


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# Introduction

## OPP FY 1979 Organizational Chart



\*In Fiscal Year 1980 the Operations Division was renamed the Regional Support Branch and transferred to the Program Support Division.



# Organization

**T**he Office of Pesticide Programs (OPP) consists of the immediate Office of the Deputy Assistant Administrator, three staff units (External Affairs Staff, Executive Support to the Scientific Advisory Panel, and Special Projects Staff), and the following six divisions: (1) Registration Division, (2) Special Pesticide Review Division, (3) Hazard Evaluation Division, (4) Benefits & Field Studies Division, (5) Program Support Division, and (6) Operations Division. To perform pesticide related functions in the field, the Office also maintains a staff complement of scientists at EPA laboratories in Beltsville, Maryland and in Corvallis, Oregon.

Because of the complexity of pesticide decision making, OPP has designed a management system which divides activities among regulatory teams (those processing registration or reregistration actions) and those teams providing scientific and technical support which are critical elements in making the regulatory decisions. The Registration Division and the Special Pesticide Review Division, as lead divisions, coordinate the complete review and evaluation processes for pesticide chemicals, while the Hazard Evaluation Division, the Benefits and Field Studies Division, and the Program Support Division provide technical and scientific support to the two lead divisions. This system requires a great deal of interaction and cooperation among the lead and support divisions; all are interdependent and share the program's objectives equally.

As one of the lead divisions in OPP, the Registration Division focuses on the registration of pesticides and the establishment of tolerance levels for pesticide residues on food and feed crops. The second lead division, the Special Pesticide Review Division, focuses on the review of pesticide chemicals which exceed specific risk criteria and on developing standards for active

ingredients for registration and reregistration of pesticide products. Both processes involve an intensive and open risk and benefit review and may result in continued registration, suspension, cancellation, or restrictions on uses of pesticides containing the chemical under review.

Both of the lead divisions use a project mode of operation to coordinate and expedite the review of pesticide chemicals. In support of these lead divisions, the Hazard Evaluation Division supplies the scientific and technical expertise for review of the risk data, while the Benefits and Field Studies Division supplies the technical and economic expertise for review of the benefit data associated with the use(s) of a particular pesticide. The Program Support Division supports all the divisions in OPP by providing technical information, literature and computer services, personnel and administrative assistance, as well as overall program, policy, planning, evaluation and budget guidance. (Appendix 1 lists the 1979 Appropriation for OPP).

## Function and Goals

**T**he EPA Pesticides Program has been established to regulate pesticides under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). The FIFRA, as amended, requires that EPA regulate pesticide compounds to ensure that they do not cause "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental cost and benefits of the use of any pesticide." Under the FFDCA, EPA is required to establish tolerance levels for pesticide residues on food and animal feed crops.

All pesticides marketed in the United States must be registered by the EPA prior to their sale or use. Pesticide producers are obligated to supply basic health and safety data on their products on a continuing basis as needed to support registrations. After the registrant submits safety data and in some cases

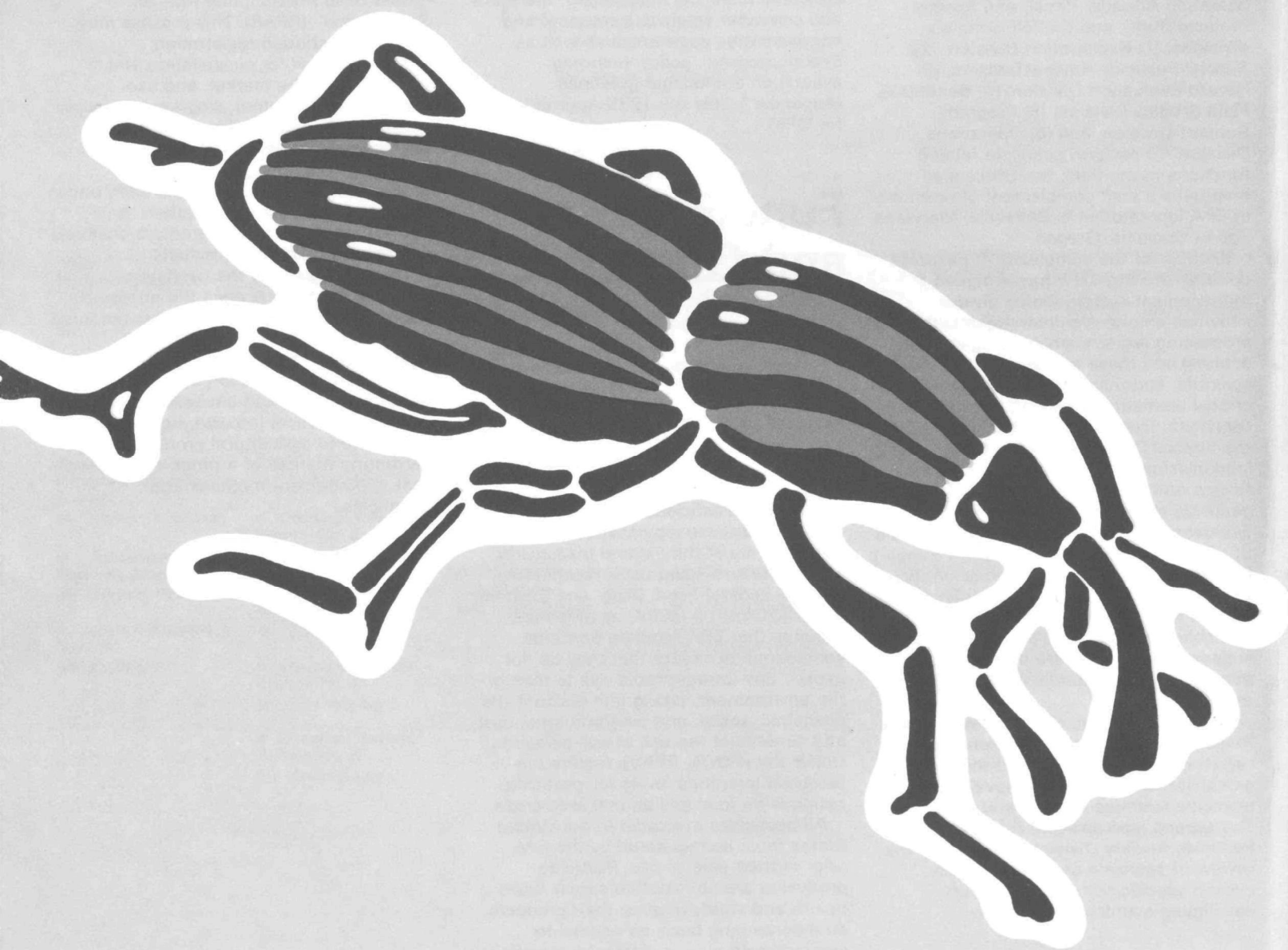
efficacy data, the Office of Pesticide Programs analyzes the data and recommends that the Agency either register a particular pesticide for general or restricted use or deny registration.

The amended FIFRA allows the Agency to grant specific exemptions from registration requirements for emergency pest control, to issue experimental use permit programs for generating data to support registration, and to supervise State registration for special local needs.

Under the legislation, the Agency has been mandated to review the registrability of all pesticide products on the market against more stringent and current scientific standards. Whenever data indicate that a pesticide chemical meets or exceeds certain measures of potential risk, EPA undertakes detailed risk/benefit decision-making through a process called "Rebuttable Presumption Against Registration" (RPAR). This process may result in continued registration, suspension and/or cancellation and removal from the market, and use restrictions. The other program for review of currently registered pesticides is the development of registration standards. Instead of examining each pesticide product on an individual basis, OPP, under the registration standard system, is evaluating each active ingredient chemical common to numerous products.

The basic goals of the pesticides program are to (1) protect the public health and the environment from potential unreasonable adverse effects from pesticide exposure, (2) contribute to environmental protection by facilitating the entry of new and environmentally safe pesticide products into the market, and (3) contribute to agricultural productivity by permitting the use of a range of effective pest management methods and chemicals.

# Principal Regulatory Programs



# Registration

**R**egistration or pre-market clearance of pesticides involves a comprehensive review of human and environmental risks and a limited review of benefits data submitted by industry. Risk is often quantified in terms of the number of or probability of certain health and environmental effects, while benefits are usually expressed in dollar valuations of such effects as increased crop yields, lower food costs, reduced chance of disease or the cost savings with respect to the use of alternative control measures. Data requirements for applicants seeking registration of pesticide products are outlined in the registration guidelines.

The Federal Pesticide Act of 1978, which amended FIFRA, authorized EPA to grant conditional registrations. Conditional registration is a necessary transition between old and new data requirements—it places registrants of similar products on an equal footing as far as data requirements are concerned. Before conditional registration was authorized, OPP routinely rejected new applications of products similar to those already on the market because the new data requirements had not been satisfied. Congress believed this put manufacturers of products already on the market at an unfair competitive advantage and authorized EPA to grant registrations to new producers, primarily on the "condition" that missing data would be provided by all registrants of like products at some future time to be specified by EPA.

Under this program, EPA is able to process applications of new products which are similar to ones already registered and new uses of old chemicals if sufficient information is available to evaluate the unique hazards posed by the new uses. New chemicals are also eligible

for conditional registration if EPA determines that the public interest would be served by registration, and if unreasonable risks will not be incurred during the period required to complete and submit additional studies.

Central to the conditional registration program is "incremental risk assessment." The amended FIFRA requires the Agency to focus its attention only on the *increased* risks or incremental risks resulting from the registration of old pesticides and new uses of old pesticides. Specifically, conditional registration of both identical and substantially similar products and uses and new uses is authorized only if the new use or product will not significantly *increase* the risk of unreasonable adverse effects on the environment.

Litigation challenging the constitutionality of trade secret and use of data provisions of the new amendments and the Agency's authority to consider all data for conditional registrations has been initiated by 17 pesticide manufacturers. Unless these lawsuits are resolved in favor of the amendments and EPA's implementation, they could have the effect of halting the conditional registration program and the registration standards development program.

In FY 1979 the registration program continued to give top priority to environmentally safe and innovative compounds and technologies, such as biorational compounds and other alternative means of pest management, and to substitute for cancelled or suspect chemicals. Out of the 59 new chemical



*Microscopic Examination of Pathology Slide  
Submitted by Industry in Support of  
Registration*



registration requests received in FY 1979, 23, or approximately 40% were approved. This represents a 100% increase over FY 1978 in the rate of approval of new chemicals received. During FY 1979, OPP experienced a two and a half-fold increase in the number of new chemicals received compared to FY 1978. In response to this increase, the registration program not only maintained an equivalent processing rate<sup>1</sup> but increased the quantity of new chemicals processed by 100% and the number of amendments by 30%. (See Table 1).

## Special Registration

The Special Registration Program was established to respond promptly and effectively to unexpected and temporary health and agricultural exigencies and to support state and local governments in registering pesticides for local or state use. Under the Special Registration Program, OPP issues emergency exemptions under Section 18 of the FIFRA, Experimental Use Permits under Section 5, and temporary tolerances to establish safe levels of pesticide residues in food and feed from pesticide use for experimental purposes.\* Minor use registrations or minor use/specialty crop petitions for tolerance submitted by public interest user-oriented groups, such as the Inter-Regional Project No. 4 (IR-4) based at Rutgers University, are a high priority. Under the Special Registration Program, OPP also monitors Section 24(c) registrations by states.

Experimental Use Permits (EUP's) allow registrants to perform large-scale experimentation needed for the development of data for new pesticides or new uses of currently registered pesticides. In cases where crops will not be destroyed after the experimental program is ended, a temporary tolerance for a safe residue level on the food or feed commodity must be established by the Agency before the EUP is issued. The Office of Pesticide Programs issues EUP's and establishes temporary tolerances based upon a case-by-case scientific determination of the human and environmental risks and benefits associated with the use of a particular pesticide.

Under the Special Registration Program, emergency exemptions may be granted to State or Federal agencies, authorizing pesticides to be used for purposes not included on registered labeling. Emergency situations which are deemed to justify granting of an emergency exemption must meet the following requirements: (1) A pest outbreak has or is about to occur and no pesticide registered for the particular use, or alternative method of control, is available to eradicate or control the pest, (2) significant economic or health problems will occur without the use of the pesticide, and (3) the time available from discovery or prediction of the pest



*OPP Meeting with Industry Representatives to Discuss the Registration of a Specific Pesticide*

*Table 1*

Registration Program <sup>2</sup>	Received	Processed	Approved	Disapproved
New Active Ingredients	59 <sup>3</sup>	42	23	19
Previously Registered Active Ingredients	1772	867	378	489
Amended Registrations	8835	6475	5349	1126
Supplemental Registrations	17,836	16,503	16,073	430

<sup>1</sup>The processing rate indicates the percentage of units received which are processed. In FY 1979, 59 new chemicals were received and 42 were processed, while in FY 1978 24 new chemicals were received and 21 were processed. The rates of processing for these two years (42/59 versus 21/24) did not change significantly. This indicates that the same percentage of demand was satisfied and the amount of output doubled, using the same level of resources.

<sup>2</sup>For a more detailed breakdown, see Appendix 2.

<sup>3</sup>This number includes total work units, including resubmissions.

\*Temporary tolerances submitted in support of EUP's allow for continuing pesticide research on agricultural crops used for feed or food.

Table 2

Special Registration Program	Received	Processed	Approved	Disapproved
Emergency Exemptions	282	*285	201	36
Experimental Use Permits	120	*176	143	33
Temporary Tolerances	36	32	27	5
State Registrations	1,086	1,080	1,069	17

\*These numbers include carryover from FY 1978

See Appendix 3 for a detailed breakdown

outbreak is insufficient for a pesticide to be registered for the particular use. In determining whether an emergency condition exists, OPP scientists and product managers carefully evaluate the benefits as well as the human and environmental risks associated with the use of such pesticides.

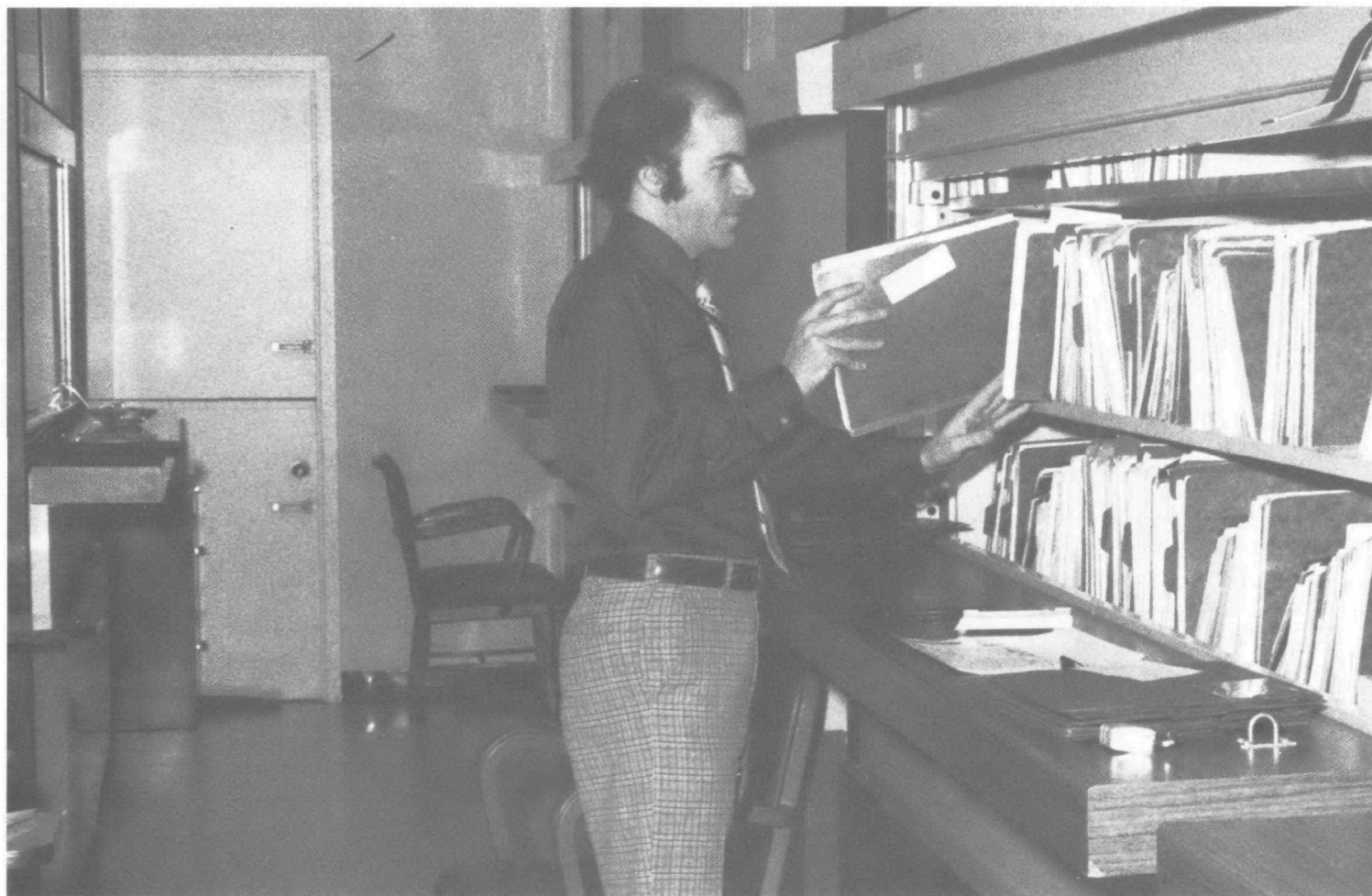
Because of the extremely broad authority provided under Section 18 of FIFRA regarding emergencies, these exemptions may include use of pesticides

on crops for which no tolerances have been established (approximately 95% fall into this category) and, in some cases, pesticides which have been cancelled for the proposed use. Granting of emergency exemptions results in reduced annual crop losses amounting to millions of dollars each year. The exemptions have spared growers catastrophic economic losses and have prevented the loss of millions of pounds of valuable food commodities. Emergency exemptions also have been

granted for various public health emergencies, such as rabies and plague, quarantine situations, such as witchweed and citrus black fly, and for protection of endangered species.

The Special Registration Program also includes approval or disapproval of state registrations of pesticides that are distributed and used only within a particular registering state. In conjunction with the state registration overview authority, OPP monitors the issuance of experimental use permits that are needed to support subsequent state registrations.

During Fiscal Year 1979, the Special Registration Program received 282 emergency exemption requests, 120 EUP applications, and 1086 Section 24(c) state registrations. This represents a substantial increase of approximately 50% in the receipt and approval rates of emergency exemptions compared to FY 1978. The approval rate for the total special registration requests averaged 90%. Table 2 summarizes the outputs for this program.



Information Retrieval System for Registration Documents

# Tolerances

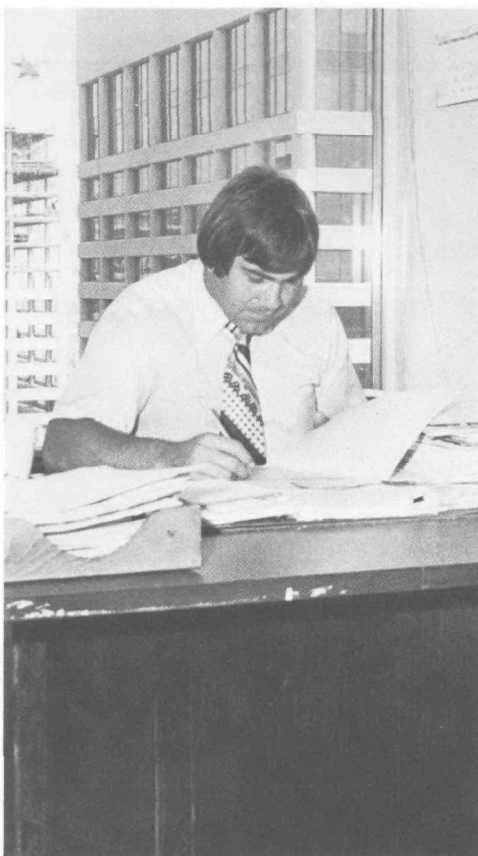
Under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended, the Agency is required to establish tolerance levels and exemptions from the requirements for a tolerance. These tolerance levels protect the public health while giving appropriate consideration to the production of an adequate, wholesome, and economic food supply. Determination of tolerances involves careful review and evaluation of residue chemistry and toxicology safety data to ensure that maximum residue levels likely to be found in food or feed are acceptable for human consumption. Included in this consideration is the cumulative effect of the respective pesticide and related substances with the same physiological activity.

In FY 1978, OPP initiated a review of the tolerance setting system by the Science Advisory Board (SAB) of EPA. The Science Advisory Board's Study Group on Pesticide Tolerances released a preliminary draft or working paper which has been reviewed by OPP and revised during FY 1979. The SAB will release their final report recommending changes in EPA's tolerance setting system in FY 1980.

In conjunction with conditional registration and other newly authorized registration program changes, OPP is implementing a more flexible approach to minor use tolerance data review and decision making. "Minor uses" are those

uses that are so small that the pesticide companies would spend more money in developing registration data and would incur more prospective liability claims than are warranted by sales for that use. However, these uses are of substantial economic significance to many growers. Thus, EPA and USDA through the IR-4 program have attempted to facilitate minor use tolerances and registrations.

During Fiscal Year 1979, OPP processed 247 tolerance petitions, 110 tolerance amendments, and 9 inert ingredient requests. Out of the total tolerance petitions processed, 30% of the total or 88 tolerance levels were established for pesticide residues on food and feed crops. (See Table 3)



Scientist Reviewing Registration Data

Table 3

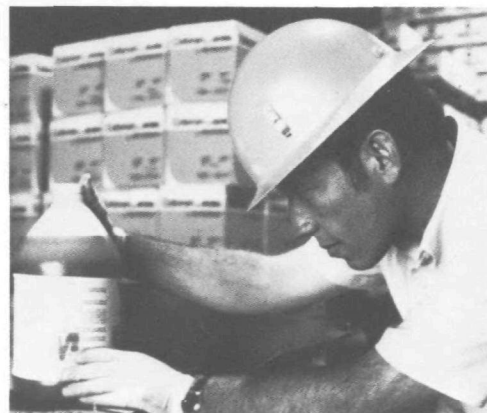
Tolerance Decision Unit	Received	Processed	Established	Disapproved
E Petitions (Government-Initiated Requests)	50	61	22	39
F Petitions (Raw Agricultural Commodities)	58	133	53	80
H Petitions (Processed Foods)	44	53	13	40
Amendments to Petitions	121	110	—	—
Inert Ingredient Requests	16	9	5	4

# Enforcement

The pesticides enforcement program is designed to insure user compliance with label directions and industry compliance with registrations, classification, and labeling requirements. Consistent with the 1978 amendments to FIFRA, most States have primary responsibility for enforcing the misuse provisions of FIFRA. During Fiscal Year 1979, the program has enhanced State involvement through Federal/State cooperative enforcement grants. Although most of these functions are located within the Enforcement Office of the Environmental Protection Agency, OPP maintains a small cadre of technical personnel who review enforcement pesticide referral cases. Table 4 illustrates the number of enforcement activities funded by OPP for Fiscal Year 1979.

Table 4

Activity	Number of Cases
Establishment Inspections	3910
Use/Reentry & Exp. Use Observations	7588
Market Place Investigations	9635
Import Investigations	215
Enforcement Case Reviews	801 Completed 816 Received



Enforcement Investigation



# Rebuttable Presumption Against Registration (RPAR)

**T**he RPAR process is an intensive risk/benefit review of pesticide chemicals suspected of causing unreasonable adverse health or environmental impact. OPP employees, with the support of other EPA offices and Federal agencies, develop recommendations for a regulatory position with regard to the registration, suspension, cancellation, or restriction on uses of pesticides containing the chemical under review.

The RPAR process begins when a suspected pesticide chemical is identified as posing a potential significant risk and is referred to the Special Pesticide Review

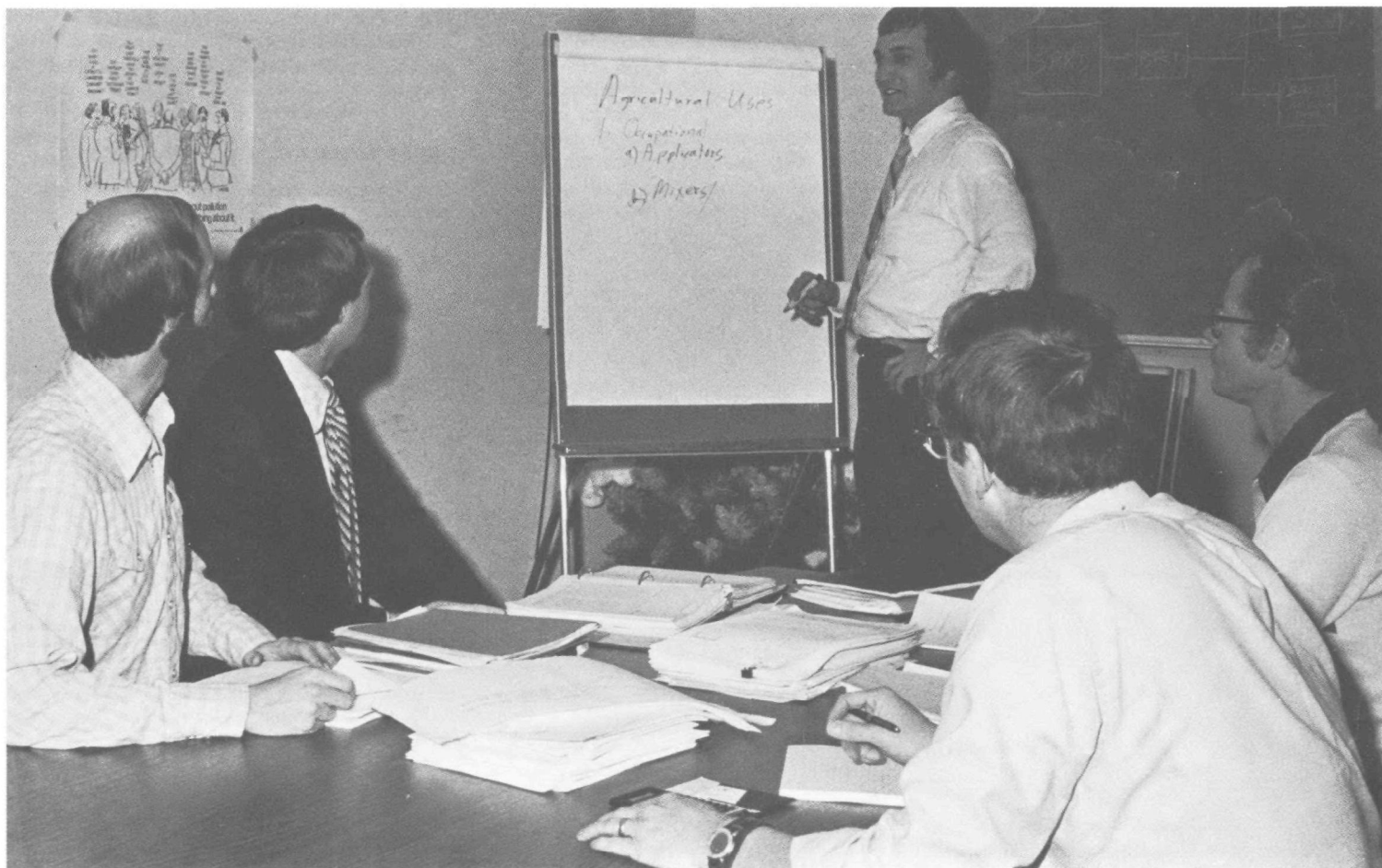
Division for consideration. Before this chemical is accepted as an RPAR candidate, data supporting the statement of risk must be scientifically validated. If accepted as an RPAR candidate, a project team is named and a comprehensive literature search is initiated for the pre-RPAR chemical. The first part of the RPAR process focuses on the development of a risk assessment, followed by a publication of the Agency's position on the pesticide chemical in the Federal Register. During the comment period, the public, manufacturers, and users are given an opportunity to offer evidence in rebuttal or in support of the presumption against registration.

If the comments do not rebut the risk presumption, the project team develops a risk/benefit analysis for each significant use of the RPAR chemical and for each of several regulatory actions which may be taken by the Agency. Representing the proposed Agency decision, the second Position Document (PD 2/3) is published in the Federal Register followed by a second public comment period. The tentative Agency decision and supporting data are reviewed by USDA and the EPA Scientific Advisory Panel (SAP). Their recommendations and appropriate public

comments are incorporated into the final regulatory document and forwarded to the Assistant Administrator for the Office of Pesticides and Toxic Substances for approval. After this comprehensive review and sign-off process is completed, EPA publishes the final decision in the Federal Register. The Agency may decide to register or reregister or restrict all or some of the uses of the pesticide.

In FY 1979, OPP initiated proceedings for three RPAR chemicals and completed proposed decisions (PD 2/3) for seven RPAR chemicals and final resolutions or decisions (PD 4) for two RPAR chemicals. Because the emphasis in FY 1979 shifted from the pre-RPAR phase to the post-RPAR phase, the number of proposed decisions and proceedings increased dramatically in comparison to FY 1978. Some of the more important RPAR decisions included the following chemicals:

● **Chlorobenzilate.** In February 1979, EPA announced the intent to cancel all non-citrus uses of the miticide chlorobenzilate. The cancelled sites included primarily cotton, fruits, nuts,



RPAR Project Team Meeting

melons, and turf grass, while non-cancelled uses included citrus crops in Florida, California, Texas, and Arizona. All cancelled uses of chlorobenzilate have registered available alternative chemical controls that will keep mite control at current levels. The Agency's decision is currently in appellate proceedings.

● **Endrin.** In July 1979, EPA announced the intent to cancel registrations for all uses of the insecticide endrin west of U.S. Route #35. Because endrin exhibited acute wildlife toxicity, labeling was amended to include warning statements and uses were restricted in areas where run-off and water contamination would be a problem. This decision was not appealed and is final.

● **DBCP.** Based upon carcinogenicity and reproductive effects in animals and man, several notices of intent and orders of cancellation and suspension have been issued concerning the nematocide, DBCP. These notices and orders culminated in Fiscal Year 1978 and continued into FY 1979 when EPA suspended all uses of DBCP except for pineapples in Hawaii. The notice of intent to cancel DBCP was reached in the early part of FY 80, followed by several requests for hearings. Cancellation hearings are expected to begin in the middle of FY 80 and continue into FY 81. After the completion of these hearings, the Administrator will issue a final decision for the cancellation and/or registration of specific uses for DBCP.

● **Trifluralin.** Two years ago, EPA was petitioned to suspend the registration of a herbicide trifluralin after findings indicated nitrosamine contamination in

the product. Informal hearings were held, and the suspension petition was denied. A comprehensive risk/benefit analysis for trifluralin indicated that the negative impact or loss of \$300 million/yr to agricultural producers exceeded the low long-term risks. In FY 1979 the Agency issued a proposed decision which would allow continued registration if the registrant amended the product's composition to include less than 1 ppm nitrosamine contamination.

● **Dimilin.** After an RPAR was issued because of potential oncogenicity, dimilin, an insect growth regulator, was subjected to a rigorous risk/benefit analysis. The results of this analysis showed that the overall risks posed by the use of dimilin were less than the risks for existing alternative chemicals. Furthermore, dimilin has been a favorable control in Integrated Pest Management Programs. In April 1979, the Agency issued a conditional registration for the use of dimilin on cotton only. During this five-year period of conditional registration, the registrants will be repeating a battery of chronic toxicity tests in animals and wildlife.

● **Pronamide.** After an extensive risk/benefit analysis, the Agency recommended the continued registration of the herbicide pronamide. In the final decision published in FY 1979, EPA required the registrants to amend the product labeling and to repackage the product in water-soluble bags. This innovative measure will protect the highest exposed group—the applicators—from dermal contact with the herbicide product.

● **BAAM (Amitraz).** Because of potential oncogenic effects in mice, the first of the unregistered pesticides, BAAM, was referred to the RPAR program in 1977. In Fiscal Year 1979, EPA published a preliminary notice of determination and a final notice which granted conditional registration for BAAM and set a tolerance of 3 ppm on pears. BAAM was found to be the only pesticide effective against the fungus, *Psylla*, on pears. Registration of BAAM for apples, however, was not granted because of the availability of safer effective, registered alternative chemicals.

● **2,4,5-T and Silvex.** For the first time in Agency history, on February 28, 1979, the Administrator issued an emergency order to suspend registrations for major uses of two toxic chemicals. The chemicals involved were 2,4,5-T and Silvex. This action was based upon evidence indicating a possible correlation between human miscarriages and the uses of these products as well as extensive animal data showing adverse reproductive effects, particularly with a dioxin contaminant of the products, TCDD, and positive oncogenicity results. After this suspension action, the Agency reached agreements with major registrants to voluntarily cancel Silvex home and garden products. The Agency is currently arranging for their safe disposal. The major manufacturer for 2,4,5-T is appealing the cancellation in ongoing hearings before an Administrative Law Judge.

#### FIFRA Scientific Advisory Panel

The Scientific Advisory Panel (SAP) was created by Section 25(d) of FIFRA, added in



Scientific Advisory Panel Meeting

1975. The SAP consists of seven expert scientists representing various fields and recommended by the National Institutes of Health and the National Science Foundation. (See Appendix 4 for a list of SAP members, disciplines and affiliations) The SAP members comment and advise OPP on the scientific validity of the data base used for regulatory decisions proposed in notices of intent issued under Section 6(b) (cancellations and changes in classification) and Section 25(a) (proposed and final regulations). The Agency also refers RPAR actions to the Panel for review, as well as special scientific issues as the need arises.

During 1979 the Panel held a total of twelve meetings where they discussed and made recommendations concerning the following pesticide regulatory initiatives:

- Interim—Final Regulations for Conditional Registration of Pesticides.
- Section 24(c) Proposed Regulations—State Registrations.
- Final Rulemaking for Classification of Pesticides—Group I.
- Proposed Rulemaking for Classification of Pesticides—Group II.
- Proposed Guidelines for Registering Pesticides, Subparts F, G, I, and J.
- Proposed Regulatory Actions for Amitraz (BAAM), Endrin, Benomyl, Treflan, Dimilin, Pronamide, DBCP, 2,4,5-T, and Silvex.

The Panel also assisted in the voluntary cancellation of a potent rodenticide (Vacor) which posed an acute poisoning threat to the public.

### Laboratory Audit Program

The Office of Pesticide Programs established a Laboratory Audit Program because of evidence that there were defects in basic industry submitted studies used to support pesticide registrations. The reliability of the data base is critical to all the basic regulatory programs in OPP, including removal or restriction of hazardous pesticides and development of registration standards.

In cooperation with the Food and Drug Administration and EPA's Office of Enforcement, OPP personnel have been managing systematic audits of

independent testing laboratories which generate toxicology data in support of the registration of pesticides. After conducting laboratory audits, OPP audit personnel recommend appropriate regulatory and/or judicial action.

During Fiscal Year 1979, OPP personnel conducted 33 on-site data audits and 190 reviews of registrant validations of possibly faulty lab data. The lab audit process identified several new suspect chemicals and four labs which had significant problems.

An early laboratory audit identified significant problems with data generated from Industrial Biotest Laboratory (IBT), a large independent laboratory which has generated data in support of registration of over 100 pesticide chemicals. In FY 1979, EPA launched an intensive investigation of all pivotal registration data generated by IBT. Registrants were required to submit validated and raw data on over 600 studies. Receipt and review of validated reports and raw data has continued through FY 1979. The IBT review program is being conducted jointly with the Government of Canada.

## Registration (Generic) Standards

The Registration Standards System, a new approach to registration and re-registration sanctioned by the 1978 amendments, will streamline these processes. Instead of reviewing for reregistration each of the 41,000 currently registered products on a case-by-case basis, the Agency is developing comprehensive registration standards for each active ingredient common to numerous pesticide products. Out of the 41,000 registered pesticide products, EPA will be concentrating its effort on the review of approximately 500 chemicals (active ingredients) representing the major pesticide chemicals produced. Overall, the registration standards system has been designed to create an open and well-documented decision-making process resulting in effective, efficient, and fair regulation of pesticides.

For every pesticide chemical and its formulations, safety criteria will be set, to which registrants must adhere, in order to register and reregister products. An intensive risk/benefit review will be conducted only for those chemicals which meet the "unreasonable adverse effects" criteria; all others will be based on a more qualitative risk/benefit judgment. In addition, standards for registration will state acceptable levels of exposure for food consumers, field workers, applicators, and other persons and organisms unintentionally exposed to pesticides.

In Fiscal Year 1979, efforts were largely concentrated on the development and modification of procedures for the registration standards process. Uncertainties caused by litigation challenging the constitutionality of basic FIFRA data use and disclosure provisions as well as the sheer magnitude, complexity, and unfamiliarity of this process have delayed progress in the development and publication of standards. However, the Agency is beginning to review systematically the data base upon which registration of current pesticides is based. During Fiscal Year 1979, OPP completed the data gathering and preparation phase for 15 Registration Standards.

In Fiscal Year 1979, OPP also developed a prototype standard for the chemical metolachlor which was designed to give industry and the public an example of a standard and to solicit their comments concerning the standard. It should be noted that this prototype standard is not the Agency's final regulatory position on metolachlor but rather a model that will enable OPP to improve future standard developments.

Other major accomplishments included the completion of an Advanced Notice of Proposed Rulemaking (ANPRM), announcing the Agency's plans for approaching registration standards development as well as a number of miscellaneous changes to the existing registration regulations. The ANPRM addresses the organization, preparation, content, and maintenance of a standard as well as the issue of its legal status and the order of development of standards.



Epidemiology  
Programs and  
Laboratory  
Support



# Epidemiologic Studies Programs (ESP)

Working through the Centers of Excellence, OPP's Epidemiologic Studies Program planned and coordinated several major health effect projects, including DBCP and EDP field studies, dimilin experimental use permit study, nitrosamine decomposition study, household pesticide usage and poisoning survey, 2,4,5-T study, and exposure of golf course applicators to cadmium.

**T**he Epidemiologic Studies Program (ESP) determines on a national basis the magnitude and the effect of human exposure to pesticides by monitoring residues and metabolites of pesticides in the general population and/or in specific populations. The Epidemiologic Studies Program is carried out by consultant specialists in the fields of veterinary medicine, toxicology, oncology, pathology, and related scientific disciplines directed from three Centers of Excellence. The projects directed by the Centers are located in twelve states and include eight universities and four state health departments. the ESP also provides consulting services for RPAR data validation, analytical methods development, farmworker reentry studies, and retrospective health effects studies.

Another part of the Epidemiologic Studies Program includes the Pesticide Incident Monitoring System (PIMS). The PIMS is an information and reporting system designed to provide accurate information on the number of pesticide incidents occurring nationally. the PIMS data provide information on causal relationships suitable for RPAR and Registration actions and for trend analysis. The PIMS also functions as an early warning system for the pesticide reregistration process.

In Fiscal Year 1979, 13,622 pesticide incident reports were submitted to the PIMS, of which 4,926 were submitted by the Epidemiologic Studies Program Projects itself. The Pesticide Incident Response Office managed OPP's response to approximately 150 reported pesticide incidents. The National Pesticide Telecommunications Network staff, using a toll-free number, answered 2,384 requests from physicians and health personnel.

## OPP Laboratory Support

**A** Chemical and Biological Investigations Laboratory is operated at Beltsville, Maryland to conduct special pesticide investigations and to provide technical assistance in support of pesticide regulatory programs. The laboratory

provides chemical, ecological, and biological data in support of the RPAR and registration processes and develops and applies analytical methods for detecting pesticides. Even though the burden of proof is on industry to demonstrate the safety of pesticides, the Beltsville Laboratory performs an important function in designing scientific methods when none exist, in providing technical assistance to the States, and in responding to emergency situations. The Laboratory also provides a quality control check by validating and verifying certain scientific methods used by industry in the generation of safety data.

Presently, the laboratory at Beltsville is divided into seven units: 1) Toxicology Unit, 2) Microbiology Unit, 3) Terrestrial and Aquatic Biology Unit, 4) Biology Resource Unit, 5) Chemical Residue Support Unit, 6) Petition Methods Validation Unit, and 7) Special Projects Unit.

Using mammalian systems, such as the rat and the rabbit, the Toxicology Unit in FY 1979 conducted numerous studies to determine the relative toxicity of over 40 pesticides. These studies included eye and skin irritation studies, acute oral toxicity and acute dietary studies.

In Fiscal Year 1979, the Microbiology Unit examined the effectiveness of over 150 health-related pesticide products such as water filtration products, disinfectants used as sterilizers, tuberculocidal, sporocidal, and virocidal



*Quantitation of the Number of Microbial Mutations Produced by the Ames Test*

products. These examinations required approximately 2,000 individual tests. In addition, this unit worked on several special efficacy projects and established 12 short-term cytogenetic methods for analyzing the mutagenicity of chemicals in microbial systems and in mammalian cell culture systems.

In Fiscal Year 1979, the Terrestrial and Aquatic Biology Unit developed seven laboratory testing methods and validated and reviewed several other bioassays for measuring acute toxicity and bioaccumulation of pesticides in estuarine and terrestrial organisms. They conducted and completed approximately 240 trout, bluegill, and daphnia LC<sub>50</sub> and EC<sub>50</sub> studies, 12 daphnia life cycle tests on 52 pesticide chemicals, and more than 200 rodenticide bioassays.

Using controlled greenhouse and field experiments the Biology Resource Unit developed eight plant-testing methods (bioassays) and conducted 16 special projects in FY 1979. Some of the more significant projects have included a five-year rotational crop study of carbofuran and its metabolites, a phytotoxicity study of picloram and 2,4-D in potatoes, and a study of the movement of encapsulated pesticide products through bee colonies.

The three Chemistry Units at the Laboratory provide a wide range of support to all the other Beltsville Units as well as to the Epidemiology Studies Program. Using the most sophisticated instrumentation available, these units identify and measure pesticides and their metabolites in plant, animal, air, and soil samples. In addition they develop and assess analytical methods and procedures used in support of regulatory actions.

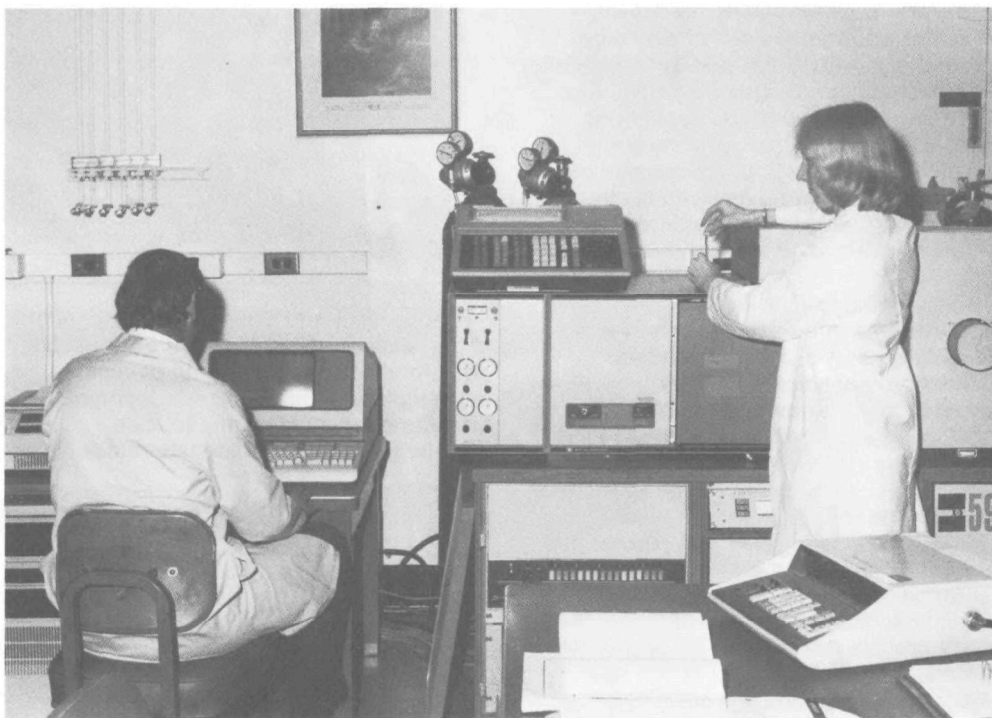
During Fiscal Year 1979, the Chemistry Section developed and reviewed six testing methods, completed the second edition of the EPA Manual of Chemical Methods for Analysis of Pesticides and Devices and reviewed the Pesticide

Formulation Section of the 1980 Association of Official Analytical Chemists (AOAC) Manual. In response to State/American Association of Pesticide Control Officials (AAPCO) requests, they distributed 539 pesticide standards and 78 analytical methods and provided technical information for 102 requests. The Chemistry Section also conducted several special projects, including analyses of dioxins, nitrosamines, creosote, pentachlorophenol, dibromochloropropane, carbofuran, and aldicarb.

Another part of the Pesticide Research Program includes the Northwest Biological Investigations Station (NWBIS) located on the campus of Oregon State University at Corvallis. Originally the NWBIS evaluated pesticides for

effectiveness and label compliance and developed efficacy methodologies. Because of the deemphasis of efficacy data development and review in the registration program, the laboratory program will be transferred to USDA in the near future where it can make significant contributions to the minor use program.

In Fiscal Year 1979, the NWBIS evaluated 14 minor use pesticide projects for efficacy and phytotoxicity on ornamental crops. The NWBIS staff also conducted special projects concerned with methods for evaluating plant fungicides, nematocides, and bacteriocides; methods for evaluating pesticide hand devices, and methods for estimating fungitoxicity and barrier action of tree wound paint.



*Chemical Analysis of Pesticides Using a Gas Chromatograph/Mass Spectrometer*



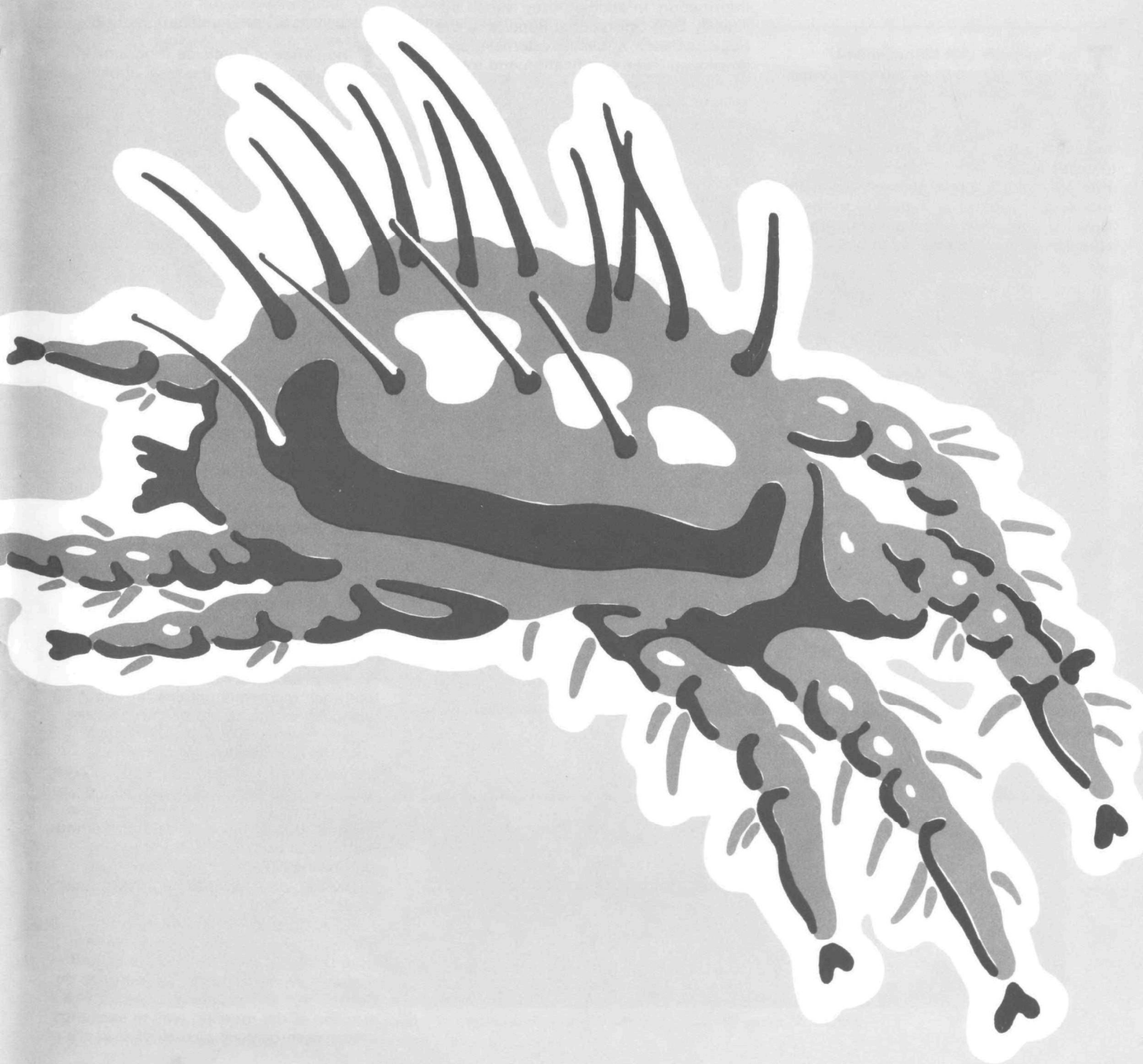
*Beltsville Laboratories*



*Northwest Biological Investigations Station at Oregon State University*



Regional and  
International  
Programs



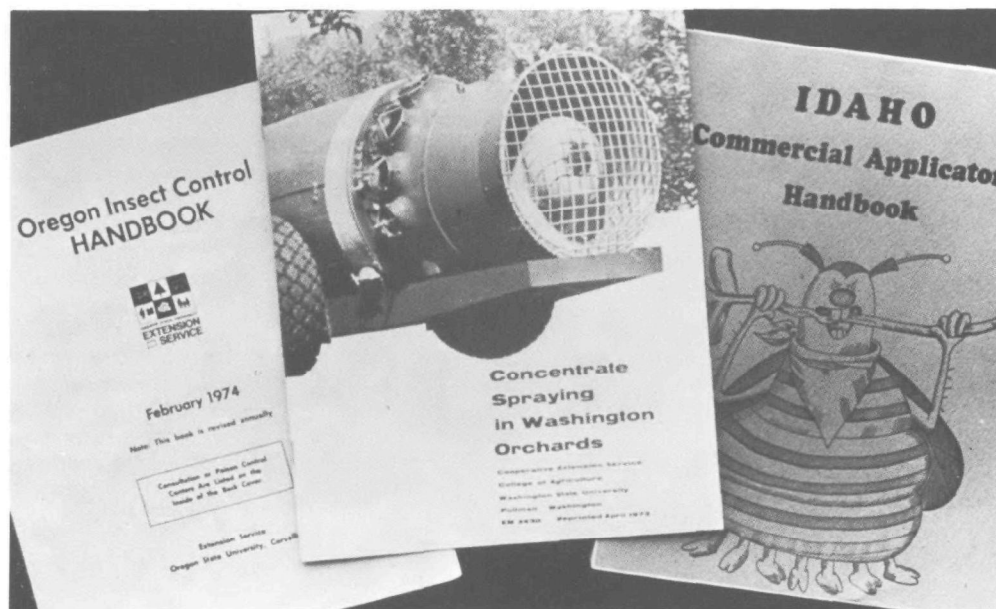


# Pesticide Use Management

programs and decisions. This program is conducted through 10 Regional Offices which oversee State pesticide programs, assist State pesticide regulatory officials in carrying out the aforementioned programs, and respond to public inquiries about EPA's pesticide programs.

As part of the Public Outreach Program, the pesticide use management staff in Fiscal Year 1979 responded to more than 10,000 external requests for pesticide related information, such as training materials, certified applicator standards, registration and use of pesticide information. In addition they issued 52 Weekly OPP Operational Reports to the Regions, States, and other external groups, developed three certification and training manuals, planned and coordinated the second National Certification and Training Meeting held in FY 1979 in Dallas, Texas, and provided the Regional Offices with detailed information concerning pesticide regulatory actions, such as RPAR's, classification by regulations, and advisory opinions.

**T**he Pesticide Use Management Program has been established to assist states in handling special pesticides incidents (fatal accidents, fires, etc.) and registration needs and to certify applicators to purchase and use restricted use pesticides. OPP's Pesticide Use Management Program provides technical assistance, guidance, and policy to the Regions, States and local governments concerning pesticide issues and Agency



*Pesticide Use Management Handbooks*

# International Programs

**T**he Office of Pesticide Programs in EPA believes that the most effective and appropriate means of reducing the adverse impact of pesticides on the global environment is through the efforts of all countries working together. For this reason, OPP actively participates in several international programs which have as their collective goal the harmonization of chemical testing standards and regulatory practices relating to pesticide use.

As part of the US-USSR Agreement on Cooperation in the Field of Environmental Protection, the Office of Pesticide Programs hosted a USSR delegation of scientists in Fiscal Year 1979. Scientists from both countries exchanged information about beneficial insect organisms used for control of agricultural pests, the regulatory and administrative measures needed for protecting environmental quality, and the genetic and biological effects of environmental pollution.

OPP also participates in the Codex Committee on Pesticide Residues (CCPR), one of the committees in the Codex Alimentarius Commission. This Committee develops and reviews international pesticide maximum residue limits (MRL's) or tolerances. During the eleventh annual meeting of the CCPR in the Hague, Netherlands, OPP representatives made tolerance recommendations for about 50 pesticide chemicals. After the meeting, together with USDA and FDA representatives, pesticide representatives drafted a U.S. response to over 400 Codex recommendations. This response included a discussion of various issues, such as classification of foods, sampling methods, methods of analysis, and methods of expressing MRL's for fat soluble pesticides, processed foods, and animal feeds.

In FY 1979, OPP representatives participated with other representatives from the U.S., Canada, and the United Kingdom in the Tripartite Conference on Pesticides held in Ottawa, Canada. The purpose of the meeting was to exchange information both on pesticides that are of

current interest and on subjects of more general nature, such as spray drift, pesticide disposal techniques, and exposure field studies and modeling.

OPP also participated in several subsidiary groups of the Environment Committee of the Organization of Economic Development, such as the Chemical and Toxicology Expert Groups. During Fiscal Year 1979, OPP representatives attended three OECD Meetings of the Expert Groups. The Short-Term and Long-Term Toxicology Groups discussed and drafted guidelines for toxicity testing. The Physical-Chemical Group drafted guidelines for 20 physical and chemical methods used to predict the

behavior of a chemical in the environment, e.g., volatility and melting point.

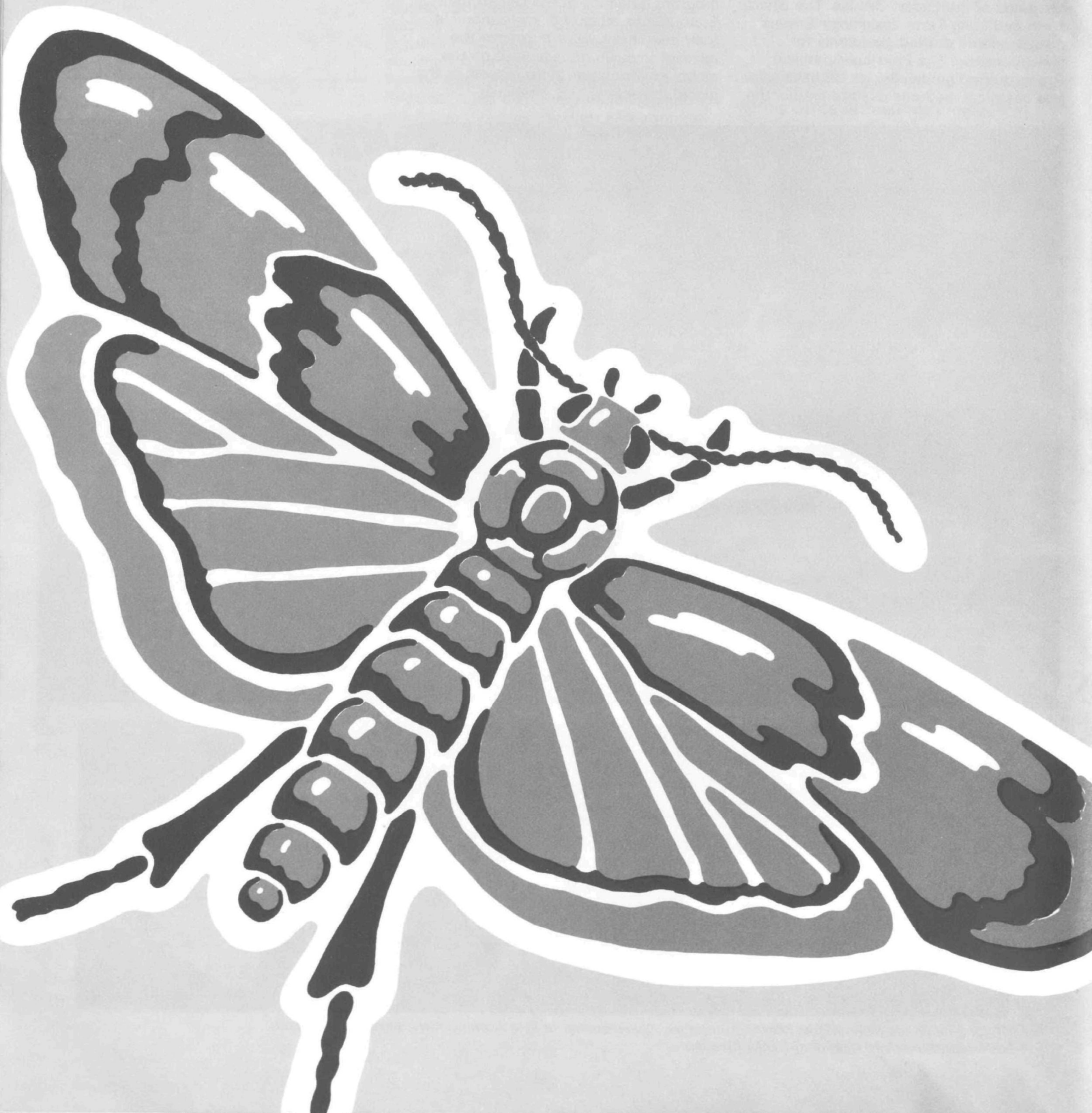
In cooperation with the National Committee for Man and the Biosphere and the U.S. Department of State, OPP participated in the U.S. Strategy Conference on Pesticide Management held in Washington, D.C. on June 7 and 8, 1979. The overall objectives of the conference were to provide policy and program guidance to the Department of State and to other U.S. institutions in their search for ways to reduce the adverse impacts of pesticides on the global environment. With respect to the global impacts of U.S. pesticide

regulations, Edwin L. Johnson, the Deputy Assistant Administrator for Pesticide Programs, described the recent changes in U.S. pesticide legislation and the impact that these amendments and EPA pesticide regulatory policies have on other countries. For a more detailed explanation of these international programs, see Appendix 5.



*OECD Environment Committee Meeting under the Chairmanship of EPA Administrator, Douglas M. Costle  
OPP Representatives Attending OECD Meeting*

# Program and Management Support





# Management and Information Systems

**A**s the largest headquarters office in EPA, the Pesticides Program recognized the need for improved planning, management, and information systems to coordinate and better manage the great diversity of pesticide activities. Several formal systems were designed to provide support for OPP managers and decision makers, and to provide EPA management with more accurate and timely information concerning the activities of the organization. During Fiscal Year 1979, OPP initiated the following systems:

- With the assistance of the Employee's Advisory Committee (a committee of 12 staff personnel representing each OPP division) and OPP managers, OPP system analysts and programmers designed a computer-based information system which records the time expenditure of personnel resources on a number of OPP activities, outputs, and chemicals. To date, this is the first large-scale time accounting information system installed in EPA's Headquarters. The Time Accounting Information System or TAIS (which is now fully operative) provides improved unit cost data to support OPP's external budget requests as well as biweekly data which enables OPP managers to better manage workloads and the impact of special projects on schedules and personnel resource allocations.

- A comprehensive Planning and Management System (PMS), now being implemented, was developed to improve the quality and timeliness of outputs within the allotted OPP budget. The PMS provides specific formats for assigning tasks, allocating resources for intra- and extramural projects and processes, and procedures for tracking, reporting, and

reviewing their progress. The uniformity provided in the system formats is intended to facilitate timely and continuing OPP-wide work coordination and adjustment, while permitting enough flexibility to allow appropriate treatment of the full variety of OPP work, situations, and management styles.

- The availability of real-time information on the status of product registration actions is essential for the timely assessment of program accomplishments. During FY 1979, an on-line computer system was under development to track the status and priority of registration actions and to provide necessary workload, time accounting, and activity reports for product managers and top management. This Registration Tracking System, when completed in FY 1980, will include the capability to accumulate aggregated descriptive statistics on registrations processed, completed, and pending.



OPP Computer Facilities



## Registration Guidelines

**U**nder the authority of FIFRA, the Office of Pesticide Programs develops proposed and final rules regarding guidelines for data and information to be submitted by applicants seeking registration of their pesticide products. These guidelines advise the applicants of what studies and tests are needed to provide acceptable data for registration, the standards for reporting the data and information, and guidance as to when such information and data are required or are not required, along with suggestions as to how to obtain or develop it. (See Appendix 8 for description of guideline subparts).

During Fiscal Year 1979, OPP received and analyzed over 14,000 formal public comments and 1,500 informal comments on subparts B, D, E, and F of the proposed guidelines. Subparts G, H, I, and J were completely redrafted and will be published in 1980 as proposed guidelines, as will worker safety (Subpart K) and Hazard to Non-Target Insects (Subpart L). Final guidelines are expected for Fish and Wildlife (Subpart E), Product Chemistry (Subpart D), and part of Human Hazard (Subpart F) in 1980.

## External Affairs Programs

**A** strong and effective program in OPP has been established to review and respond to Congressional and public inquiries. This program was developed to maintain intelligence on all Congressional pesticide-related activities and to provide comments on legislative proposals and pending bills. In addition to maintaining a liaison role with other offices in EPA and other Agencies and outside groups, this staff arranges for public appearances for top management and other OPP staff and prepares speeches, testimony, and briefing materials for such appearances.

During Fiscal Year 1979, the External Affairs Staff received and answered over 700 Congressional inquiries, 100 inquiries from the Administrator's Office (including White House inquiries), and over 400 general public inquiries concerning pesticide related matters. They coordinated and prepared over 20 public speeches and presentations for the Assistant Administrator and the Deputy Assistant Administrator.

This small staff successfully planned and coordinated the implementation of the 1978 FIFRA amendments. In addition, they coordinated the issuance of a policy

statement regarding minor use pesticide registrations and tolerances and a proposed policy statement on labeling requirements for export products and notification procedures.

Another part of OPP's public affairs program includes the Freedom of Information (FOI) Program. All pesticide FOI requests are coordinated and processed within the Program Support Division, while the other OPP divisions supply input for the requests. In Fiscal Year 1979, the Office of Pesticide Programs processed approximately 700 Freedom of Information requests.



*Deputy Assistant Administrator for Pesticides Program, Edwin L. Johnson, Addressing the Data Resources Agricultural Conference*



*Assistant Administrator for Pesticides and Toxic Substances, Steven Jellinek, Testifying before the House Subcommittee on Oversight and Investigation*

# Special Projects and Programs



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## Integrated Pest Management (IPM)

## Classification by Regulation

## Advisory Opinions

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**T**he Integrated Pest Management Program in OPP has been instrumental in the development, integration, and utilization of effective control techniques for managing pests, including biological and autocidal control agents, pest-resistant plant varieties and animal breeds, cultural practices, and improved pesticide application technology. Through the use of proper IPM strategies, OPP anticipates that the need for chemical pesticides will be reduced and pesticides will be used in a more judicious manner, resulting in sound environmental management.

In cooperation with USDA during 1979, OPP continued to support IPM research in the Land-Grant University system, in the initiation of demonstration pilot projects to promote farmer acceptance of IPM and to incorporate its approaches into applicator training. Working with HUD, USDI, and USDA, OPP developed and promoted urban IPM programs and advanced application technologies, such as the electrostatic application of pesticides. OPP played an active role in planning and participating in numerous IPM meetings, workshops, and demonstrations where IPM technologies were presented to farmers, industry, State and Federal agencies and other groups. The pesticides program also prepared IPM educational packages which promoted the benefits of pest management and detailed procedures for implementing IPM techniques and methods.

**A**s required by Section 3(d) of FIFRA, the Office of Pesticide Programs must classify pesticides for both general and restricted use. This classification process will occur by regulation prior to the completion of registration standards and will emphasize classification of uses/formulations for restricted use (to be used primarily by certified applicators).

During Fiscal Year 1979, OPP published a final rule classifying approximately 500 agricultural products for restricted use and published a proposed rule classifying the uses of an additional 400 products for restricted use, including many of the widely used granular insecticides. To date 2000 pesticide products have been classified for restricted use.

**I**nformation gathering hearings were held in Phoenix, Arizona as a result of complaints by Scottsdale residents that pesticides used on agricultural lands and in communities were causing adverse human health and environmental effects. Prior to these hearings the National Enforcement Investigations Center and the Texas Epidemiologic Studies Center had initiated an environmental monitoring and exposure program in the Scottsdale and Prescott areas of Arizona. The results of the information gathering hearings and of the monitoring program should help the Agency in making more effective regulatory decisions regarding pesticide drift.

The Agency has issued an advisory opinion outlining a series of recommended application practices for applying defoliants and desiccants in Arizona to cotton fields located next to or near sensitive areas. Following these recommended practices is expected to minimize pesticide drift into non-target areas and should not present any substantial countervailing costs or risks.

**T**he FIFRA requires that pesticides be registered and properly labeled prior to their shipment in commerce. The 1975 Regulations and the proposed Labeling Guidelines prescribe various labeling requirements relating to product identity, hazard, and use. When the regulations

During the interim period, there are certain critical labeling improvements which OPP plans to address. In an attempt to meet the requirements of FIFRA and the 1975 Regulations, OPP has developed an action plan describing the problems, factors, and issues to be considered in a label improvement program and several options for resolving the problems. Under the work plan schedule, the Registration Division in conjunction with other OPP Divisions, will evaluate various aspects of labeling which

The label improvement program is an *interpretive* program designed to help users better understand EPA's intent in permitting certain registered pesticide use patterns, and to provide better and clearer guidance to enforcers as to legal and illegal use. Through the LIP, the Office of Pesticide Programs hopes to make more explicit, information that will allow safe, lawful use of registered pesticides.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS  
(& DOMESTIC ANIMALS)

ANGER

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL  
HAZARDS

It is a violation of Federal law to use  
this product in a manner inconsistent  
with its labeling.

**CATEGORY OF APPLICATOR**

## STORAGE AND DISPOSAL

**RESTRICTED USE  
PESTICIDE**

**FOR RETAIL SALE TO AND APPLICATION ONLY BY  
CERTIFIED APPLICATORS OR PERSONS UNDER THEIR  
DIRECT SUPERVISION**


**PRODUCT  
NAME**

ACTIVE INGREDIENT:	_____	%
INERT INGREDIENTS:	_____	%
TOTAL:		<u>100.00 %</u>

THIS PRODUCT CONTAINS \_\_\_\_\_ LBS OF \_\_\_\_\_ PER GALLON

**KEEP OUT OF REACH OF CHILDREN**

**DANGER — POISON**



**STATEMENT OF PRACTICAL TREATMENT**

**IF SWALLOWED** \_\_\_\_\_

**IF INHALED** \_\_\_\_\_

**IF ON SKIN** \_\_\_\_\_

**IF IN EYES** \_\_\_\_\_

**SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS**

**CROP**

**CROP**

**CROP**

**CROP**

**WARRANTY STATEMENT**



# Farmer and Farmworker Safety Program

In April 1979, migrant farmworker groups led by the Migrant Legal Action Program (MLAP) and the National Association of Farmworker Organizations (NAFO) petitioned EPA to strengthen its voluntary pesticide incident reporting system and to promulgate rules requiring pesticide users to promptly report poisoning incidents. Spearheaded by this petition, earlier Congressional and SAP

hearings and data on hospitalized pesticide poisonings of farmers and farmworkers, the Office of Pesticide Programs established a Working Group to coordinate a program to protect farmers, farmworkers, and their families from unnecessary and unsafe exposure to pesticides.

The farmworker problem, which is perceived differently by the various interest groups, is extremely complex with on-the-farm pesticide exposure resulting from direct application of the pesticide, work-related contact from residues, and off-the-job exposure from contamination of dwellings and other areas. While EPA has clear authority to regulate some of these areas, it must rely upon the authorities and enforcement mechanisms of the Departments of Labor, Health and Human Services, Agriculture, and State organizations in other areas of pesticide exposure. (See Table 5).

In developing a farmer and farmworker safety action plan, OPP personnel have worked extensively with the aforementioned Agencies, the Office of Enforcement and the Office of Research and Development, EPA, the Migrant Legal Action Program, Rural America, and the National Association of Farmworker Organizations. The proposed farmer and farmworker action plan includes short term options, such as republishing worker standards, providing guidance to DOL on field reentry for pre-adolescents, and providing worker information on poisoning symptoms as well as long-term options for improving the understanding of the problem.

In order to define the risks associated with field reentry situations, the Epidemiologic Studies Program in OPP has initiated and completed several farmworker safety and health effects projects. One of these projects, the migrant worker study, was completed in FY 1979 and describes the exposure levels of migrant workers to pesticides during nine months of work and travel in the Atlantic Coast Migrant Stream. This is the first well-documented record of migrant workers' exposure to the use of pesticides and the migrant workers' dietary and social relationships which affect their overall susceptibility to pesticide illnesses.

Another major epidemiology study measuring human exposure from ultra-low-volume aerial pesticide applications was completed in FY 1979. Cotton applicators, flagmen, scouts, and local residents were monitored, as well as field foliage residues and pesticide drift. The report detailing this study is currently under Agency review.

At the request of the Department of Labor, OPP initiated an epidemiology study in Florida to monitor the potential exposure of pre-adolescents to pesticides in an agricultural environment. Pesticide residues are being monitored in air and soil samples, in house dust, on clothing, and in urine samples from 10-12 year-old children who harvest the tomato crop.



*Farmworker Safety Program*

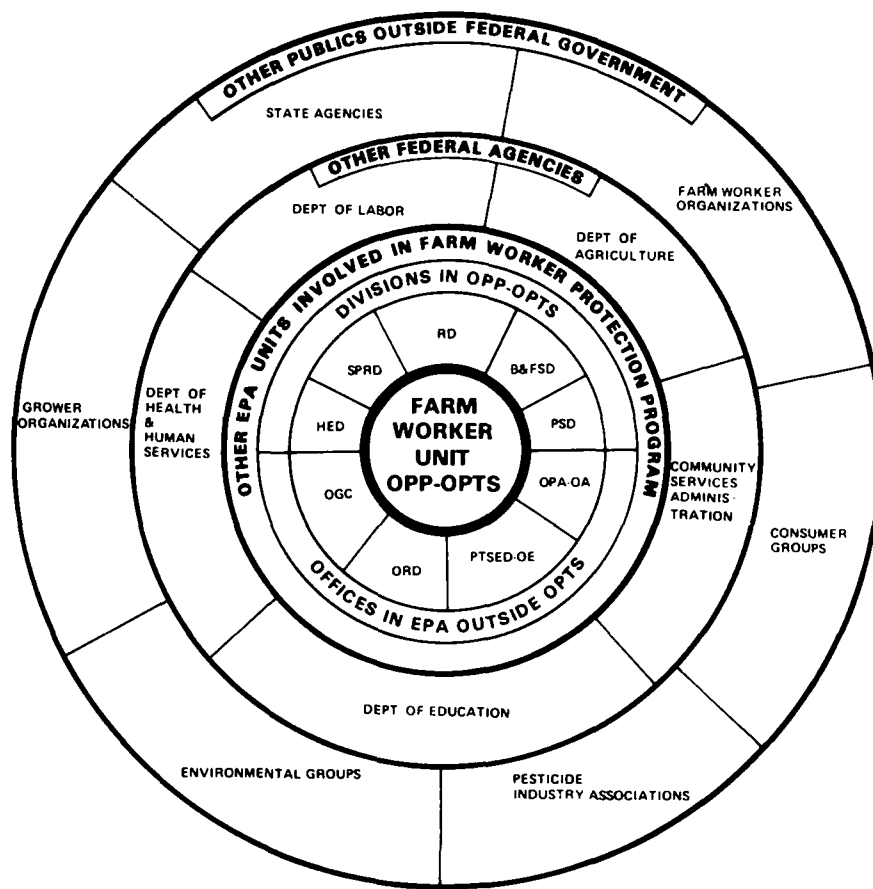
In addition to the above studies, several exposure studies are being conducted on toxaphene, iso-cyanuric acid, 2,4,5-T, carbaryl, EBDC, 2,4-D, lindane, DBCP, EDB, and dimilin. A study to measure occupational exposure to toxaphene was completed in FY 1979 and is currently under review.

Acting as the catalyst for the farmworker safety program, OPP in conjunction with other agencies and offices in EPA will continue to emphasize farm safety issues and to provide a focus for interagency and public farmworker activities in the 1980's. Under interagency agreements with several agencies, EPA will develop education, training, and informational materials and conduct training sessions and workshops throughout the farmworker community.

Table 5

**Farm Worker Program Coordination  
Key to Abbreviations**

OPTS	Office of Pesticides and Toxic Substances
OPP	Office of Pesticide Programs
HED	Hazard Evaluation Division OPP OPTS
SPRD	Special Pesticide Review Division OPP OPTS
BFSD	Benefits and Field Studies Division OPP OPTS
RD	Registration Division OPP OPTS
PSD	Program Support Division OPP OPTS
OE	Office of Enforcement
OA	Office of the Administrator
ORD	Office of Research and Development
PTSED	Pesticide and Toxic Substances Enforcement Division
OPA	Office of Public Awareness



**KEY TO ABBREVIATIONS**

OPTS	OFFICE OF PESTICIDES AND TOXIC SUBSTANCES
OPP	OFFICE OF PESTICIDE PROGRAMS
HED	HAZARD EVALUATION DIVISION OPP OPTS
SPRD	SPECIAL PESTICIDE REVIEW DIVISION OPP OPTS
BFSD	BENEFITS AND FIELD STUDIES DIVISION OPP OPTS
RD	REGISTRATION DIVISION OPP OPTS
PSD	PROGRAM SUPPORT DIVISION OPP OPTS
OE	OFFICE OF ENFORCEMENT
OA	OFFICE OF THE ADMINISTRATOR
OGC	OFFICE OF GENERAL COUNSEL
ORD	OFFICE OF RESEARCH AND DEVELOPMENT
PTSED	PESTICIDE AND TOXIC SUBSTANCES ENFORCEMENT DIVISION OE
OPA	OFFICE OF PUBLIC AWARENESS OA

## Appendices

### Appendix 1

<b>Appropriation</b>	<b>Actual 1979 (000)K</b>
Salaries and Expenses	\$32,369
Research and Development	7,401
Abatement, Control and Compliance	30,469
Total	\$70,239
Permanent Work-years	936
Full-time Equivalency	1,044
Outlays	58,210
Authorization levels	81,998

### Appendix 2

<b>Registration Program</b>	<b>Received</b>	<b>Processed</b>	<b>Provisionally Accepted</b>	<b>Approved</b>	<b>Disapproved</b>
New Active Ingredients					
Unconditional	41	33	14	14*	19
Conditional	18	9	9	9	0
New Products (Previously Registered Active Ingredients)					
Unconditional	187	245	209	166	79
Conditional	1,585	622	738	212	410
Amended Registrations					
Unconditional (Administrative)	5,613	4,594	3,216	3,995	599
Conditional (Technical)	3,222	1,881	795	1,354	527
Supplemental Registrations	17,836	16,503	—	16,073	430

\*Note: Figures reflect number of products (technical, formulate). Total number of new active ingredients is 17, of which 13 are unconditional and 4 are conditional.

### Appendix 3

<b>Special Registration</b>	<b>Received</b>	<b>Processed</b>	<b>Approved</b>	<b>Disapproved</b>	<b>Withdrawn</b>
Specific/Quarantine/Public Health Exemptions	254	237	201	36	10
Crisis Exemptions	28	48	—	0	0
Experimental Use Permits	120	176	143	33	4
EUP Follow-up Reports	419	419	—	—	—
EUP Revised Labels	56	49	47	2	0
Temporary Tolerances	36	32	27	5	—
SLN State Registrations (§24(c))	1,086	1,080	1,069	17	

**FIFRA Scientific Advisory Panel**

<b>Member</b>	<b>Affiliation</b>	<b>Speciality</b>
Dr. Dewayne C. Torgeson, Chairman	Program Director of Bioregulant Chemicals, Boyce Thompson Institute for Plant Research, Inc. Cornell University	Plant Pathology and Chemistry
Dr. John E. Davies	Chairman of the Department of Epidemiology and Public Health University of Miami School of Medicine	Epidemiology and Public Health
Dr. David E. Davis	Independent Consultant	Animal Ecology
Dr. John Doull	Professor of Pharmacology and Toxicology at the University of Kansas Medical Center	Pharmacology and Toxicology
Dr. Robert L. Metcalf	Professor of Entomology, Biology and Environmental Studies at the University of Illinois	Entomology and Biochemistry
Dr. Robert A. Neal	Director of the Center in Environmental Toxicology at Vanderbilt University School of Medicine	Toxicology and Biochemistry
Dr. Edward A. Smuckler	Chairman of the Department of Pathology, School of Medicine, University of California	Pathology

**US-USSR Environmental Agreement**

The US-USSR Agreement on Cooperation in the Field of Environmental Protection was signed in Moscow on May 23, 1972 by President Nixon and President Podgorny of the USSR. The Agreement covers 11 problem areas of environmental protection, including pollution associated with agricultural production.

As part of this agreement, a delegation of OPP representatives visited the USSR in 1976 to discuss Integrated Pest Management/crop loss determinations in development of alternatives to chemical pest control and to explore the status of chronic toxicological research. This meeting was followed by a visit to the United States by a USSR delegation as described in the text of the annual report.

**Codex Alimentarius Commission**

The Codex Alimentarius Commission (CAC) was established in 1962 as an international body concerned with protecting the health of consumers and ensuring fair practices in food trade. The CAC accomplishes these goals by developing international food standards under the joint Food

Standards Program of the FOA/WHO. As a participating member of the CAC, the Office of Pesticide Programs is primarily involved in activities of the Codex Committee on Pesticide Residues (CCPR). This Committee develops and reviews international pesticide maximum residue limits (MRL's) or tolerances.

The procedure for the elaboration or review of worldwide Codex standards involves an 11-step process where international governments and organizations comment on each draft and recommended standard for tolerance. At step 9 in the elaboration process, governments are requested to accept a recommended international tolerance or to provide reasons for non-acceptance. After the Commission has determined that the tolerance is appropriate, it will publish the recommended standard in the Codex Alimentarius as a world-wide Codex standard.

**Organization for Economic Cooperation and Development (OECD)**

The Organization for Economic Cooperation and Development (OECD) is the world's largest group of industrialized market-economy countries, comprising some 19 European nations, the U.S.A., Canada, Japan, Australia, and

New Zealand. The primary objectives of the OECD are to promote the economic growth of member countries, to eliminate barriers to trade, to aid developing countries, and to use concerted action in dealing with certain environmental problems.

In 1970, the Council of the OECD established the Environment Committee to serve as a forum for examining and discussing common problems related to protection and improvement of the natural and urban environment. This Committee also provides member governments with policy options or guidelines to prevent or minimize conflicts arising from the use of shared environmental resources.

A primary means by which the Environment Committee accomplishes its mission is through the efforts of subsidiary groups, such as the Chemicals Group. The Chemicals Group seeks to achieve international cooperation in the field of toxic substances regulation. In September 1977, the Chemicals Group of OECD established several Expert Groups which would prepare reports on

available test methods and provide information concerning the chemical characteristics and effects of toxic substances. The Office of Pesticide Programs participates in the Physical Chemical Expert Group, the Short-Term Toxicology Expert Group, and the Long-Term Toxicology Expert Group.



**Subparts of the Guidelines**

Subpart A	Introduction
Subpart B	Applicability of Data Requirements and Reader Guide
Subpart C	Registration Procedures
Subpart D	Chemistry Requirements
Subpart E	Fish & Wildlife Requirements
Subpart F	Human Hazard Requirements
Subpart G	Product Development
Subpart H	Label Development
Subpart I	Experimental Use Permits
Subpart J	Nontarget Plants
Subpart K	Reentry Data Requirements
Subpart L	Nontarget Insects
Subpart M	Biorational Pesticides