United States
Environmental Protection
Agency

Office of
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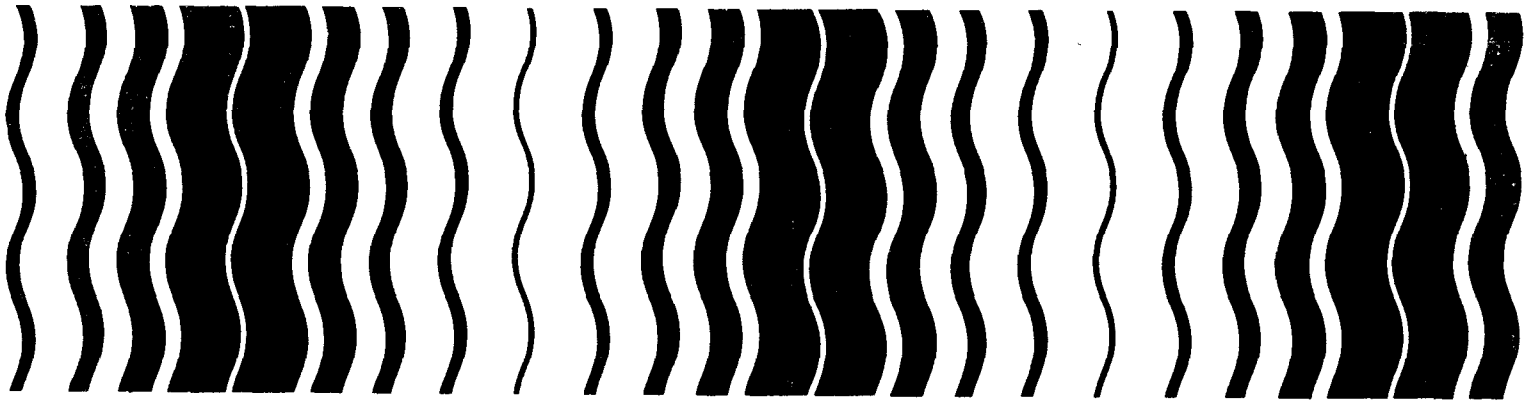
Pesticides

National Pesticides Monitoring Plan



National Pesticides Monitoring Plan

Table Of Contents

TABLE OF CONTENTS

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Introduction

INTRODUCTION

A. What is Monitoring Within the Context of Pesticide Regulation?

Monitoring is the systematic collection of information on the extent of human and environmental exposure to, and the effects of, pesticides and related compounds (such as metabolites or contaminants of toxicological concern). This definition encompasses the collection of exposure-related information (such as chemical use pattern and usage information), the documentation of pesticide-induced illnesses and contamination episodes, the determination of chemical concentrations in humans and the environment, and the collection of information on user and industry compliance with provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). FIFRA, sections 20(b) and (c), requires the Administrator to develop a national monitoring plan for pesticides and to conduct any pesticide monitoring activities necessary to implement the Act. Pesticide monitoring activities may also support Agency regulatory objectives under statutes other than FIFRA, since pesticides affect other environmental media such as water and air quality for which EPA has regulatory responsibilities.

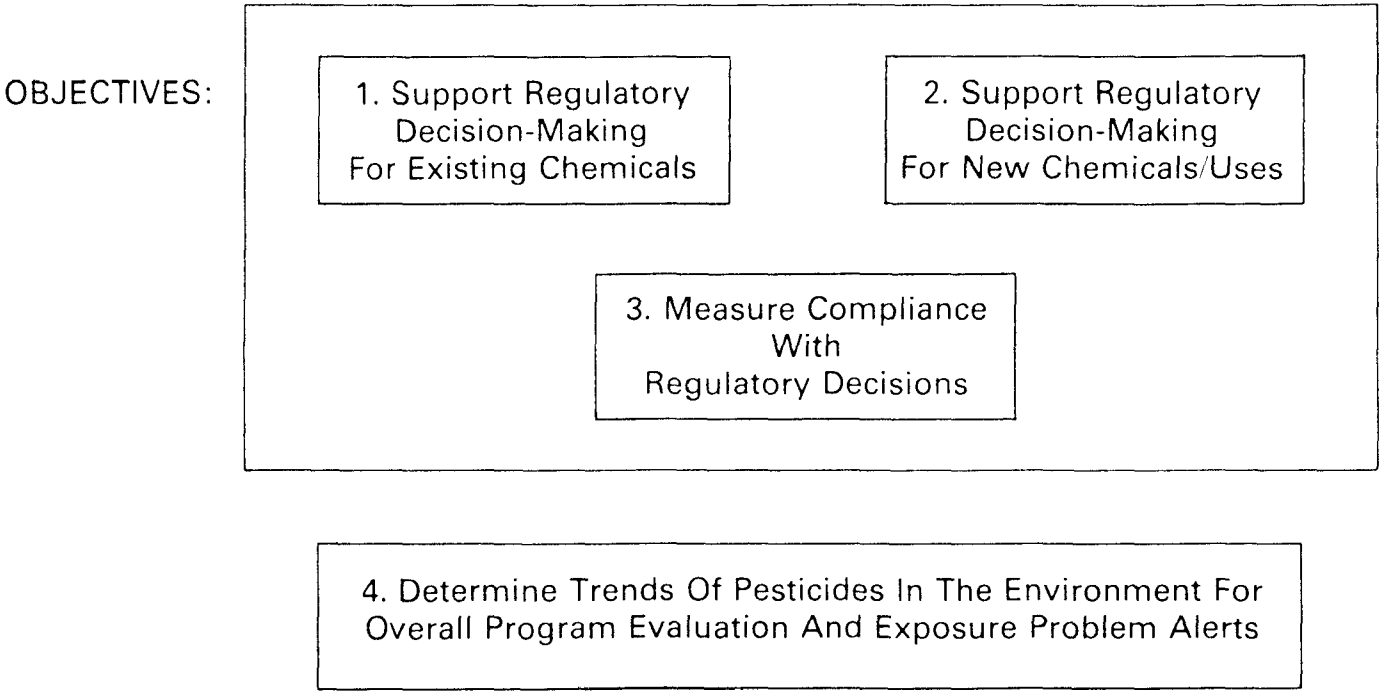
B. Why is Monitoring Important to Pesticide Regulation?

Pesticide monitoring serves four major objectives (Figure I). It provides data which assists EPA efforts to: 1) assess the risks posed by existing chemicals for specific registration decisions; 2) similarly, assess the risks posed by either proposed new chemicals or new uses of existing chemicals; 3) measure compliance with registration and related regulatory decisions that have been put into effect; and 4) determine the trends of pesticides in the environment to confirm expected outcomes of regulation and to alert EPA to unanticipated or emerging exposure problems.

Most significantly, monitoring can provide information on actual exposure and effects of pesticides on humans and the environment. Along with information on the toxicity of a pesticide, understanding of the likely degree and duration of exposure to the chemical is vital to assessing the risks posed by its use. Under EPA's pesticide registration process, monitoring data can be used directly to determine pesticide exposures and effects. More often, however, monitoring data is used to develop and validate predictive exposure models that EPA relies on for cost effective pesticide risk estimates.

Figure I
Pesticide Monitoring Goals And Objectives

Goal: Provide Information On Exposure And Effects To Assist
In Determining Risks And Benefits From Pesticide Use



Monitoring data may also be used to establish priorities for certain regulatory processes (primarily reregistration and special review). These data also may be used to measure the effectiveness or ineffectiveness of past pesticide regulatory actions (that is, to measure environmental results), and to alert EPA to future regulatory needs.

In summary, monitoring provides data on the consequences of pesticide use and on human and environmental exposure and effects which are vital to effective pesticide decision-making and regulation.

C. Who has Responsibility for Collecting Monitoring Data?

EPA has a leadership role in procuring pesticide exposure information. However, it is clear, both from the language of FIFRA and the risk assessment process which supports pesticide regulation that generating monitoring information on pesticides should be a cooperative effort. This is a responsibility which is shared by EPA, other Federal agencies, States, pesticide registrants, pesticide users, and other parties interested in the consequences of pesticide use.

Obtaining chemical-specific monitoring data to support the registration of a pesticide is the responsibility of the registrant. However, outside of the registration process, in developing data on a number of chemicals, EPA may have direct monitoring responsibilities, or at least the responsibility to work in cooperation with the pesticide monitoring efforts of other Federal or State agencies. The Agency determines what monitoring projects are necessary according to the extent to which they can assist the pesticide program in reaching regulatory decisions, or in determining the real world impact of regulatory decisions once implemented. Costs should be shared with registrants, States, and others concerned with the consequences of pesticide use. Similarly, compliance monitoring activities should be conducted cooperatively with the States under the guidance and oversight of EPA.

EPA plans to share the data generation burden primarily with four other sources:

1) Pesticide registrants - EPA will develop and impose monitoring data requirements on registrants, to support both new and existing pesticide product uses and registrations.

2) Other Federal agencies - The National Monitoring Plan will be implemented largely in cooperation with other Federal agencies. In developing this Plan, OPP has begun to investigate the existing monitoring activities in the U.S. Department of the Interior (USDI), U.S. Geological Survey (USGS), the Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and other agencies, to determine where pesticide analyses or information collection can be easily added or "piggybacked" without significant modification to the ongoing projects. Opportunities for "partnership" monitoring activities, where sampling mechanisms must be modified or cooperatively established, are also being explored.

3) The States - EPA recognizes that many States collect various types of monitoring data which could be very useful. OPP will investigate ways of accessing State-generated data, and will also investigate and pursue opportunities for cooperative monitoring (including both "piggyback" and "partnership" activities). EPA will also summarize and periodically review State-generated information to assist in the early detection of pesticide contamination problems. Listings of current pesticide monitoring activities will be developed by OPP and shared with the States.

   It should be noted that EPA's 10 Regional Offices play an important liaison role in the Agency's interactions with the States. Regional Offices may also directly assist in implementing some State monitoring programs. Although this Plan generally does not distinguish the specific roles of EPA Headquarters Offices, such as OPP, and the Regional Offices, cooperative projects and information sharing with States require Regional Office participation. OPP is working with the Regional Offices to ensure their effective involvement in monitoring program initiatives.

4) Private parties, groups and institutions - Pesticide monitoring data developed by private entities such as pesticide user groups and universities would also be useful to EPA, particularly if developed cooperatively with the Agency. Cooperative projects with several universities and associations are underway, and opportunities for expanding this data source will be investigated.

D. What Areas of Data Gathering are Important?

There are eight areas of data gathering which are particularly pertinent to pesticide regulation (see Figure II). These are

1) Use Pattern and Usage Data - descriptive information on how, when, where and why pesticide products are used (use pattern information) and quantitative data on the kinds and amounts of pesticides used (usage data);

2) Enforcement/Compliance Data - an important type of usage information needed to assess compliance status, trends, and emerging problems;

3) Direct Exposure Data: Applicators and Other Agricultural Workers - information on the levels of pesticides encountered by agricultural and other workers who apply pesticides or work in areas where pesticides have been applied;

4) Environmental Dispersal and Contamination - information on the type and extent of pesticide movement off the target site and into the general environment and the exposures that result;

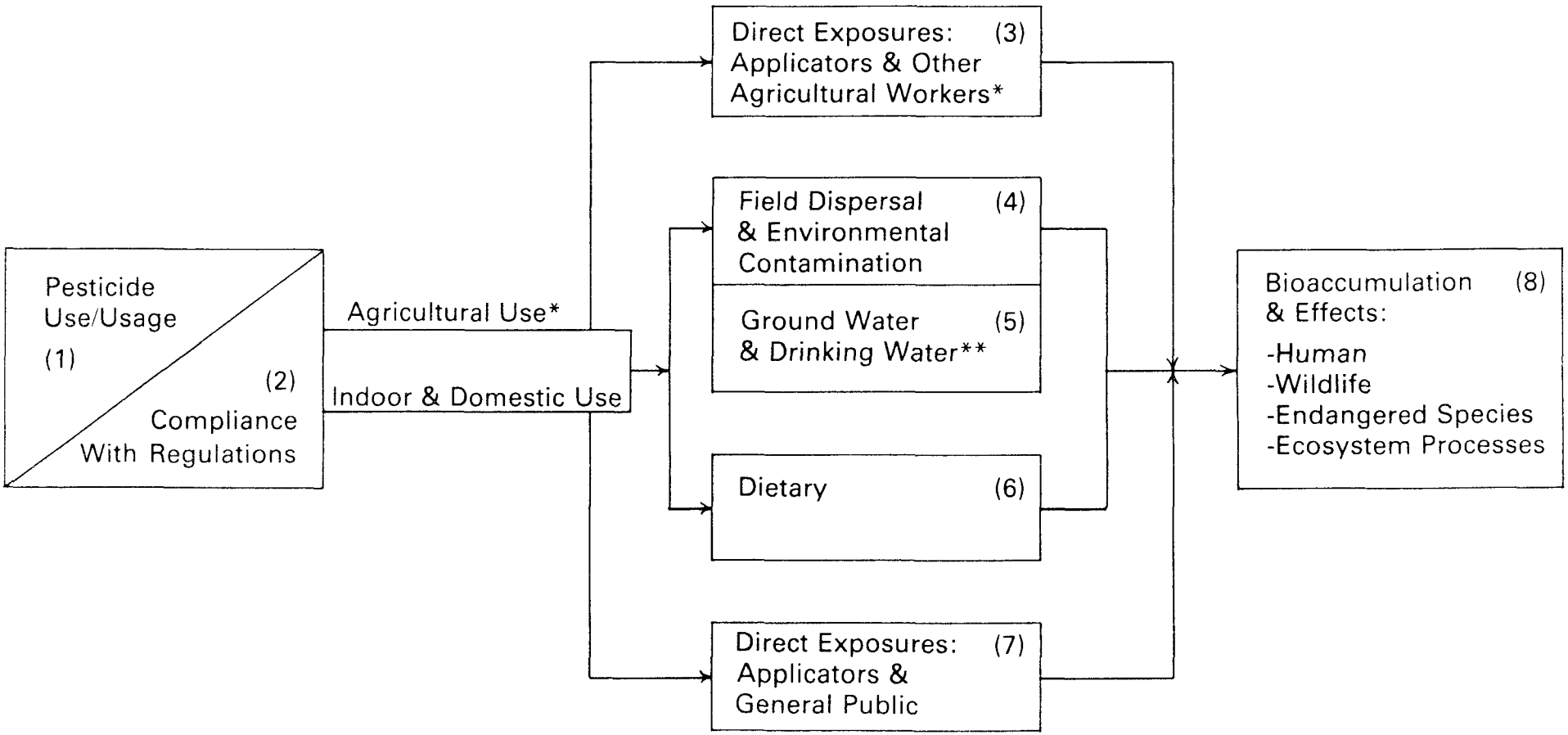
5) Ground and Surface Water Data - a particularily critical type of environmental dispersal information on the extent of water contamination by pesticides and estimated human exposures from drinking and other uses of contaminated water;

6) Dietary Residue Data - information on pesticide residue levels in food and feed commodities;

7) Direct Exposure Data: Indoor and Domestic Outdoor - information on the pesticide amounts to which individuals are exposed as a result of contemporary pest control practices, either in residences or from other home and garden uses; and

8) Body Burden and Effects Data - information on average pesticide residue levels in humans and various other organisms and data on pesticide-induced illnesses and other harmful incidents such as impacts on endangered wildlife species.

Figure II
Types Of Monitoring Information



*Includes Pesticide Use On Rangelands, Forests, And Rights-OfWay, As Well As Farmlands

**A Field Dispersal And Environmental Contamination Area Of High Concern

These primary areas of data collection are woven into the specific objectives discussed in this plan as they are called on to serve regulatory decision-making and Agency priorities.

E. What Does This Plan Do?

The present document is essentially an overview of current pesticide monitoring activities, rather than a long range plan. However, an important purpose is served by this first compilation effort. The present plan identifies numerous monitoring related projects and activities as a unified area of concern which needs to be integrated into the planning process for all major pesticides program activities. OPP is working now to ensure that monitoring needs are regularly considered in the process of planning pesticide program activities.

As monitoring considerations are integrated into program planning, the annual program and budget planning process will offer the opportunity to identify and plan for longer term monitoring goals which effectively support OPP's regulatory responsibilities and objectives. Thus, OPP expects to develop more long range monitoring plans over the next several years, and to up-date the National Monitoring Plan to reflect such developments as appropriate.

The National Monitoring Plan, Part II, discusses each of the four primary objectives of pesticide monitoring in detail. For each objective, the Plan identifies the specific regulatory needs to be served, the monitoring projects currently underway and planned to meet those needs, and additional projects and activities yet to be initiated. Part III of the Plan discusses the more mechanical aspects of implementing a monitoring strategy, including the physical and policy tools to be used by the Agency in carrying out a comprehensive, unified national pesticide monitoring program which broadly supports EPA's pesticide regulatory objectives.

Goal & Objectives

II. GOAL AND OBJECTIVES

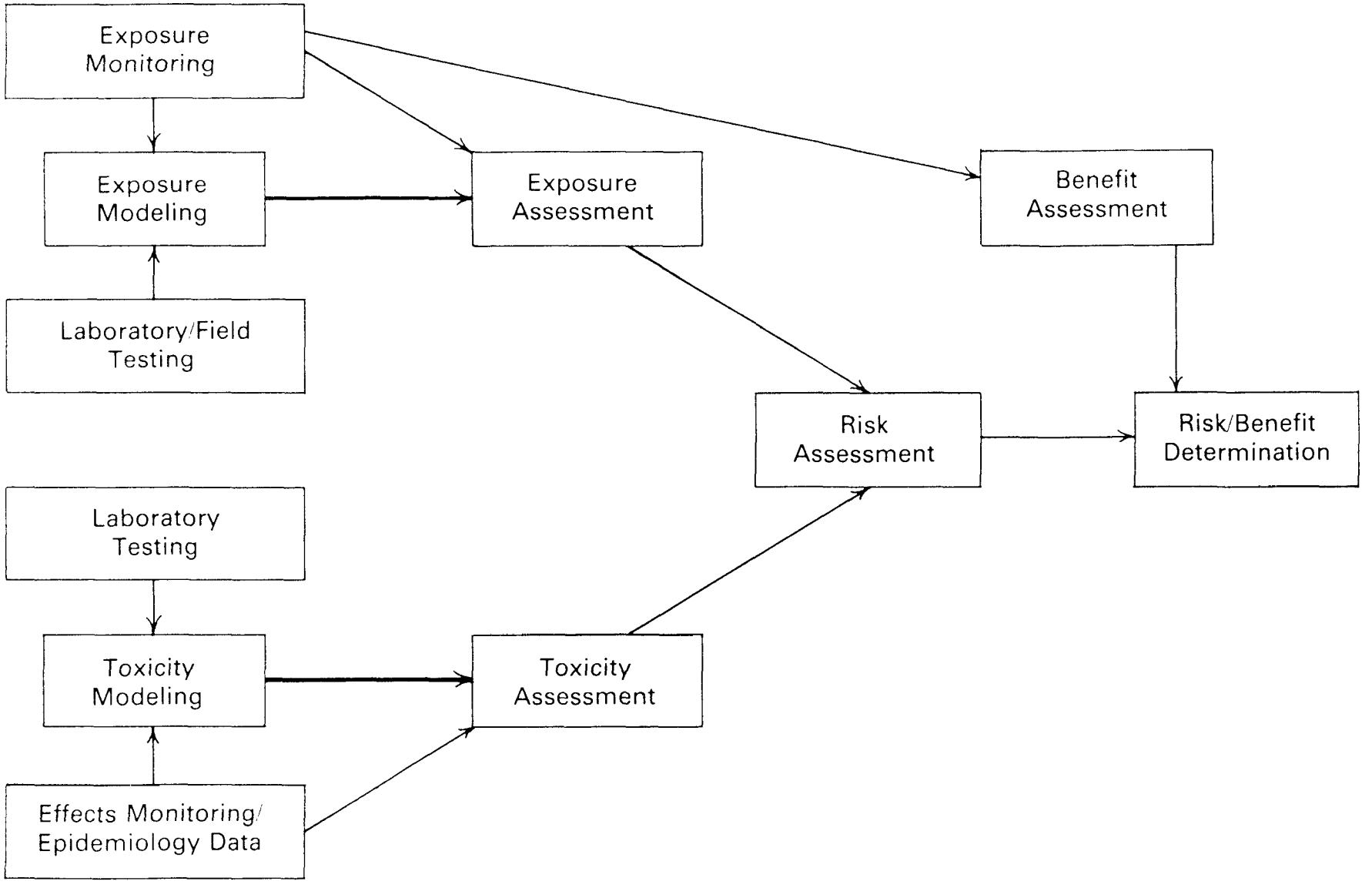
The primary goal of monitoring for pesticides is to provide information on exposure and effects to enhance the accuracy of pesticide risk assessments and thereby, improve the soundness of FIFRA risk/benefit regulatory decisions. Monitoring should also provide information that supports determinations of compliance with the Agency's pesticide regulatory decisions. Finally, EPA's pesticide monitoring efforts need to provide information to evaluate the ultimate effectiveness of its FIFRA programs in controlling unreasonable risks posed by pesticides.

Risk assessments are performed on any given chemical by calculating what is known about the inherent toxicity of the chemical in conjunction with the degree to which humans or other species are exposed to that chemical (see Figure III). Knowledge of the actual levels and duration of exposures and the subsequent effects resulting from the use of a pesticide can significantly enhance the accuracy of an assessment of the risks posed by that chemical's use.

In a world of limited resources, the Agency must make decisions carefully about where its monitoring dollars will be invested. The Agency must identify the kinds of regulatory decisions which can benefit most from increased exposure data, and among those regulatory decisions, which should receive highest priority attention.

As a first step, the Agency must decide if its information needs for a regulatory decision require a monitoring investment or whether these needs can be be fulfilled adequately by less expensive surrogate data or predictive modeling capabilities. As indicated in Figure III, predictive exposure modeling and effects (i.e. toxicity) determinations, based on laboratory testing, have come to play a key role in EPA's efforts to develop timely and cost-effective assessments. EPA has developed these predictive capabilities based upon years of scientific research and monitoring of pesticide environmental behavior and toxic effects. Today cost-effective estimates of exposures and effects can be predicted from laboratory data (e.g., animal toxicity testing and measures of a pesticide's chemical/physical properties) or surrogate data (e.g., use or application patterns similar to well-known pesticides). Monitoring continues to play an often crucial role in developing or validating these predictive capabilities. Also where confidence in

Figure III
Benefit/Risk Assessment In Opp



these capabilities is limited, monitoring information may provide the only evidence of exposure (e.g., ground-water contamination) or effects (e.g., declines in wildlife populations). With limited resources, the Agency must weigh the often increased confidence provided by monitoring data against the usually more cost-effective estimates provided by predictive models or surrogate data. The choice depends on the confidence in the available predictive tools and the significance of the decision to be made. In a number of cases, the costs of implementing a monitoring design capable of providing the needed information may be extremely prohibitive. In other cases, monitoring may be unethical (i.e., some human effects monitoring) or beyond our scientific capabilities.

Once the Agency has decided to obtain information on actual exposures or effects through pesticide monitoring, it must then decide if monies need to be expended by EPA or whether the data should be acquired by cooperating with other Federal agencies and the States or by imposing monitoring requirements on pesticide registrants. While EPA has a leadership role, it is clear that responsibilities for pesticide monitoring have been, and will continue to be, shared among various government and private entities.

This plan organizes EPA's monitoring information needs into four basic objectives (see Figure I). The first two objectives are derived from the primary pesticides monitoring goal of improving risk assessments and the FIFRA risk/benefit decisions based upon them. The third objective is to monitor for compliance with EPA's pesticide regulatory decisions. The final objective is to provide monitoring information that can be used to evaluate the ultimate effectiveness of the Agency's overall pesticide regulatory program and alert EPA to any unanticipated or emerging risks. These objectives are summarized below.

OBJECTIVE 1: ASSIST IN DETERMINING THE IMPACT OF OLD (EXISTING) CHEMICALS ON HEALTH AND THE ENVIRONMENT FOR SPECIFIC REGULATORY DECISION-MAKING

One of the Agency's priorities is to complete the job of reassessing the health and environmental impact of pesticides registered before today's registration requirements were put into place. Monitoring can contribute to that reassessment process by providing information on the actual exposure or effects resulting

OBJECTIVE 2: DETERMINE THE IMPACT OF REGULATORY DECISIONS TO PERMIT NEW CHEMICALS AND/OR NEW USES

The Agency needs to give explicit thought to whether monitoring requirements will be imposed as a condition to granting new uses. Part of this process will be to identify how to best monitor for new chemicals in response to the changing trends in types of chemicals themselves and in response to true innovation such as biologically-engineered microorganisms. Monitoring for pesticides permitted by past decisions can provide surrogate data useful in making decisions on new pesticides.

OBJECTIVE 3: MEASURE USER AND INDUSTRY COMPLIANCE WITH REGULATORY DECISIONS IN THE FIELD

One of the fundamental premises of any regulatory program is that decisions will be complied with in actual practice. Monitoring of compliance is thus needed to assure that the Agency's regulatory objectives are being met.

OBJECTIVE 4: DETERMINE TRENDS OF PESTICIDES IN THE ENVIRONMENT FOR OVERALL PROGRAM EVALUATION AND IDENTIFYING UNANTICIPATED OR EMERGING EXPOSURE PROBLEMS

In addition to reassessing the impact of specific chemicals in the environment, monitoring helps to analyze and understand the overall status of pesticides in the environment (e.g., use, exposures, and effects). These trends can assist the Agency in accomplishing one of its primary goals, which is to determine the real-world, environmental results of regulatory decisions. Trends analysis can also detect unanticipated emerging problems so that appropriate regulatory action can be taken to respond to the situation before a crisis develops.

These four objectives are explored in depth below. For each objective, the need for monitoring will be explored, the regulatory utility will be articulated, the entities responsible for monitoring will be identified, and a summary of planned monitoring activities will be presented. In other words, this document will address the questions WHY monitor, WHO will monitor, and WHAT monitoring will be undertaken. Monitoring of the environment necessarily reflects the environment's extremely complex interlinkages. Thus, any organization of monitoring information needs and its special uses will always be somewhat arbitrary. It is hoped that this presentation, organized in terms of basic regulatory program responsibilities, is an effective and logical structure for communicating EPA's pesticide monitoring plans.

Objective 1

Pesticide Monitoring Goals And Objectives

Goal: Provide Information On Exposure And Effects To Assist In Determining Risks And Benefits From Pesticide Use

OBJECTIVES:

1. Support Regulatory Decision-Making For Existing Chemicals

2 Support Regulatory Decision-Making For New Chemicals/Uses

3. Measure Compliance With Regulatory Decisions

4 Determine Trends Of Pesticides In The Environment For Overall Program Evaluation And Exposure Problem Alerts

A. OBJECTIVE 1: ASSIST IN DETERMINING THE IMPACT OF OLD (EXISTING) CHEMICALS ON HEALTH AND THE ENVIRONMENT

One of the top priorities of the Office of Pesticide Programs (OPP) is to re-examine the decisions made on pesticides registered over the past 30 years to ensure that they continue to meet the statutory requirement that no pesticide should be marketed which imposes unreasonable adverse effects on humans or the environment. The FIFRA requires the reregistration of previously registered pesticides. This entails the review of the data bases for all chemicals registered prior to 1977 when modern data requirements were imposed to (a) ensure that basic health and safety data have been developed and are of satisfactory quality to meet today's standards, (b) reconsider the current regulatory requirements and registration status of each chemical in light of modern data, and (c) set forth the standards and conditions under which that chemical will be registered in the future. There are approximately 600 active ingredients representing 45,000 products undergoing reregistration review. The outcome of the review is a registration standard which explains EPA's regulatory position on the use of a pesticide active ingredient and documents the information available to the Agency about the chemical. Registration standards include a chemical description and use profile, the Agency's regulatory position and rationale, the criteria for registration under the standard, acceptable product composition ranges and limits, tolerance reassessment information, what additional data need to be developed and when, and what restrictions and labeling changes will be imposed. The Program had completed 94 registration standards as of December 31, 1984, and is developing additional standards at a planned rate of 25 chemicals a year.

In some cases, the rereview of old data or the review of newly generated data will indicate that the pesticide, as currently marketed and used, may be posing unreasonable adverse effects to humans or the environment, that is, its risks may outweigh its benefits to society. In these cases, a special review may be initiated. A special review is an intensive review of the pesticide's risks and benefits. It is a public process in which the Agency first identifies and quantifies to the extent possible the human

health or environmental problems being posed and the benefits being derived from agricultural or other sectors' use of the chemical; second, proposes a regulatory position; and finally, issues a final position which may be to continue current uses, restrict some or all uses, or cancel some or all uses.

Monitoring data can assist the Agency in making both registration standards and special review decisions. Data indicating the extent to which existing pesticides are occurring in the environment can provide information on which to base realistic exposure assessments which in turn will lead to better assessments of the potential risk of a pesticide to humans and other nontarget life. Such exposure information is especially critical in making decisions on special review chemicals where the inherent toxicity has raised serious concerns about potential health impacts.

Monitoring data in the form of use and usage information is important not only in performing exposure assessments, but also in developing benefits analyses which are a critical part of special review decisions. In addition, monitoring data can assist the Agency in establishing priorities for special review. For example, if the Program is considering initiating special reviews for several chemicals because of potential toxicological concerns, and monitoring data indicate that one of these chemicals is more prevalent or persistent in the environment or in a certain key medium, such as ground water, that chemical will have higher priority for review in order to to determine if regulatory action is needed.

In general, then, monitoring data can contribute in several ways to assessing impact of existing pesticides in the environment, including:

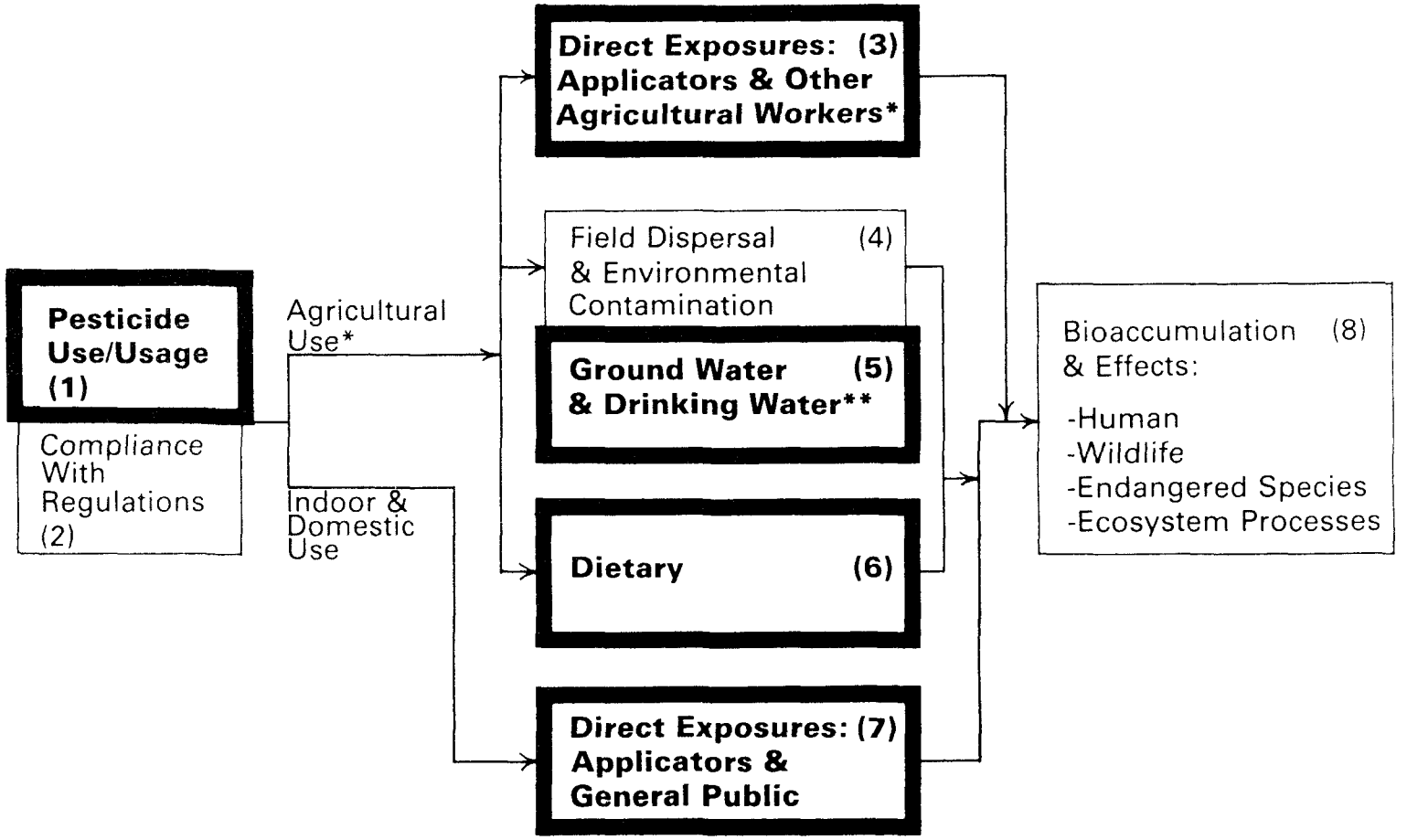
- development of exposure profiles for pesticides undergoing registration standards;
- development of labeling restrictions for pesticides undergoing registration standards;

- reassessment of permissible residue levels (tolerances) for pesticides undergoing registration standards or special reviews;
- setting priorities for chemicals which are candidates for special review;
- development of exposure and risk assessment for chemicals undergoing special review; and
- development of benefits analysis for chemicals undergoing special review.

There are five particular areas of monitoring activities which will assist in the review of existing chemicals. These are: developing use and usage data, monitoring to determine exposure to workers, monitoring ground and surface water, monitoring for residues in food and feed, and determining exposure from indoor and domestic outdoor application. Each of these areas is discussed below (see Figure IV).

As noted in Figure IV, several types of monitoring information are not specifically addressed under this objective. In some cases, these other information types can be of equal or more importance to existing chemical regulation decision making. They have been omitted from this section for several reasons. Compliance monitoring is completely addressed under a separate section, Objective 3. The Agency is increasingly looking at the likelihood of compliance or enforceability of its regulatory decision-making and the activities under Objective 3 will certainly provide information useful to meeting Objective 1. Environmental dispersion and contamination, other than for ground water and surface water, is primarily limited to aerial drift, volatilization and particle reentrainment. Aerial drift, while not discussed here, continues to be an important data requirement of registrants; it is also part of the work described under this objective for determining field worker exposures. Finally, monitoring information on body burdens and effects is certainly a very important consideration in the assessment of existing chemicals, particularly for special reviews. The general discussion of this type of monitoring information is found under Objective 4. However, much of the work discussed under Objective 1 on worker exposures is aimed at identifying body burdens and health impacts.

Figure IV
Monitoring Needs For Objective 1: Determining Impact Of Existing Chemicals



* Includes Pesticide Use On Rangelands, Forests, And Rights-Of-Way As Well As Farmlands

** Ambient Exposure And Environmental Contamination Area Of High Concern

SUBOBJECTIVE A: DETERMINE THE EXTENT OF USE OF PESTICIDES CURRENTLY BEING APPLIED

Pesticides are applied in virtually all geographic areas of the United States to some degree. About 10 percent of the total land area of the U.S. receives some type of pesticide application in any one year. These applications include agricultural pesticide use on hundreds of crops as well as applications of pesticides in urban and suburban settings for household, lawn and garden pest control. Given the great variety of pesticide use situations and the multitude of pesticide chemicals registered for use, the benefits and potential risks afforded to different segments of our population and environment vary widely. EPA needs information on the kinds, amounts and circumstances of pesticide use in order to better understand both the benefits provided and the extent of exposure, and ultimately risks, presented. Monitoring efforts to provide current pesticide use and usage data for both agricultural and nonagricultural sites are, therefore, an important component of the National Monitoring Plan.

WHAT DATA SHOULD BE COLLECTED: Qualitative data on how, when, where and why particular pesticides are used on given sites in given geographical areas, and quantitative data on pesticide usage, should be collected for both agricultural and non-agricultural pesticides and use sites. Currently, EPA has a reasonable amount of use and usage data, particularly for major agricultural crops, primarily from proprietary data bases available to the Agency on a subscription basis. In general, more usage data in the public domain would be useful to formally support program actions. Additional data are needed regarding:

- non-agricultural pesticide use and usage;
- "minor" or specialty agricultural crops;
- detailed (e.g., county-level) geographical breakdowns of agricultural pesticide use and;
- pesticide use patterns and product performance.

WHY: These data will permit EPA to better understand both pesticide benefits and exposures, and thus make better regulatory decisions on continued registration of pesticides now in use.

REGULATORY UTILITY: Pesticide use and usage data can provide a vital link between the Agency's initial regulatory assumptions made during the registration process, as reflected in product labeling, and the consequences of use (residues in environmental media, any observed adverse effects, etc.). Use/usage data help to elucidate the relationship between registration/conditions of registration and resulting consequences, in terms of both risks and benefits to society. By showing how benefits and exposures are occurring as a consequence of registered pesticide use, these data can permit the Agency to validate or invalidate its regulatory assumptions about use and use patterns. The data gathered are thus essential to the Agency's reevaluation of existing pesticide registrations.

Use and usage data support other monitoring activities in two ways. First, such data are needed to establish priorities and identify locations and media from which samples should be collected. Second, these data are required to properly interpret the significance of results from other types of monitoring activities.

In summary, then, use and usage data are needed by EPA to:

- help establish residue and effects monitoring priorities and design monitoring studies;
- help interpret the results of other types of monitoring activities;
- determine efficacy of pesticides in the field;
- perform routine exposure assessments; and
- perform benefits assessments.

WHO SHOULD COLLECT: EPA, several other Federal agencies, the States, pesticide registrants, private companies, user groups and trade associations all have various roles in developing and collecting pesticide use and usage data.

° EPA - has the Federal lead role in collecting pesticide use/usage data but relies on a wide variety of sources, as detailed below. EPA participates with USDA, FDA, the Bureau of the Census, State officials through the American Association of Pesticide Control Officials (AAPCO) and the State FIFRA Issues Research and Evaluation Group (SFIREG) and State land grant universities in an interagency planning group on pesticide use and usage data needs. That group has designated EPA responsible for conducting usage surveys on urban and non-farm sites.

° USDA - historically, has surveyed agricultural pesticide users and has been designated as responsible for continuing this function by the interagency group.

° Other Federal Agencies - are generating certain use/usage data consistent with their respective goals and responsibilities. EPA has formed interagency agreements with USDI, the Department of Defense (DOD) and others so that information of use to the Agency may be generated cooperatively.

° States - independently generate use/usage data, some of which are useful to EPA in decision-making.

° Pesticide Registrants - have a continuing responsibility to provide data as needed by EPA regarding their products' risks and benefits. EPA has recently requested detailed geographical use/usage data on a number of pesticides to defend existing registrations, and may do so for other pesticides.

° Private Subscription Data Bases - several companies collect data on pesticide usage that is used largely by pesticide producers in their marketing studies. EPA purchases such data bases, which provide wide crop coverage data at very reasonable cost. These data are useful to EPA as a back-up and for cross-checking purposes. However, these data are not a full substitute for data in the public domain which can be quoted and referenced in support of Agency actions.

° User Groups and Trade Associations - have cooperated with EPA in conducting usage surveys, and express an interest in working further on future surveys.

° EPA Regions - collect production and distribution data that are used as a proxy for usage data.

ONGOING/PLANNED ACTIVITIES AND PROJECTS: EPA's strategy is to continue to develop pesticide use/usage data for major agricultrual commodities. At the same time, however, increasing attention will be given to acquiring more information on minor crop use, household and domestic use, and other non-agricultural uses. Key activities designed to gather pesticide use and usage data include:

° Pesticide User Network

EPA is currently devoting resources to establishing and maintaining pesticide user networks representing major agricultural, public health and other non-agricultural uses. These national networks involve the pesticide user community in the development and analysis of OPP program activities, and provide a mechanism for obtaining pesticide benefits, exposure and product performance information directly from users. Timely and accurate benefits and exposure-related use information is essential to implementation of OPP's special review procedures. Information on product performance in the field is also potentially significant for evaluating the balance of risks and benefits involved in decisions for registration actions and emergency exemptions, as well as special reviews. The Agency is reevaluating the current policy of waiving the submission of product efficacy data for non-health related pesticide uses.

° Production and Import Data System Enhancement

EPA is continuing to devote resouces in FY 85 to a FIFRA section 7 data enhancement effort. Data on pesticide production and distribution are reported to EPA by each producer under section 7 of FIFRA. These data are vital to the Agency as they provide a proxy for usage data, and are often the only data available for certain minor agricultural and non-agricultural use sites. As such, they are used to prioritize problem chemicals, to identify chemicals of immediate regulatory concern, to provide a starting point for economic analyses used in the registration standards and special review programs, and to assist in planning monitoring projects.

This project will provide a needed overhaul of the existing section 7 and import data system so that it may be used more efficiently by Agency analysts.

° EPA Surveys on Urban/Non-Farm Sites

Consistent with our responsibilities as designated by the interagency planning group on pesticide usage surveys, OPP has conducted surveys of golf courses, nurseries and commercial applicator activities and has selected several additional categories of usage sites that would be feasible to study with appropriate funding (including usage by households, mosquito control districts and hospitals). As data from these surveys become available, EPA will begin to develop a comprehensive profile of pesticide usage in non-agricultural areas.

° USDA Surveys of Agricultural Sites

To increase the usefulness of the USDA surveys, EPA will negotiate an agreement with USDA to expand its efforts. (More frequent data collection, coverage of significant minor crops, and geographical detail down to county rather than regional levels are needed.) The trend in recent years has been toward more limited funding of USDA pesticide usage surveys. However, EPA will continue to try to work with USDA to enhance this important source of usage data.

° USDA's NAPIAP

The National Agricultural Pesticide Impact Assessment Program (NAPIAP) under USDA, was created in the late 1970's to contribute to benefits assessments for use by EPA in the RPAR or special review process, and will continue to serve as a liaison with EPA on pesticide use, exposure, and other regulatory matters. For example, the NAPIAP has been asked to provide use and exposure information for several special reviews this year. NAPIAP is partially funding a cooperative study with Oregon State University to examine benefits of forest vegetation management. NAPIAP may also continue to provide Pesticide Assessments by commodity.

° USDI Agreements

At present, there are two working agreements with the USDI: (1) an agreement with the Fish and Wildlife Service Labs in Denver, Colorado, to evaluate the effectiveness of vertebrate pest control agents, and (2) an agreement to develop programs for control of selected pests utilizing integrated pest management (IPM) systems.

° DOD Agreement

An agreement is currently in effect with the DOD Armed Forces Pest Management Board for the generation of certain non-agricultural use site information and specific information on public health pests.

° U.S. Forest Service (USFS) MOU

A Memorandum of Understanding (MOU) is currently in effect with the Forest Service to provide OPP with current as well as historical pesticide use information on Forest Service lands. The Forest Service will develop and provide: (1) yearly pesticide use reports, (2) project reports on efficacy trials of pesticides of current interest, (3) yearly listings of NAPIAP projects and project reports on exposure, and (4) current assessments of alternatives to specific pesticides of current regulatory interest to EPA.

° The States

Through SFIREG, EPA will continue to exchange information informally with the States on product performance. Also, we will continue to use certain pesticide usage surveys conducted by the States.

° National Pest Control Association (NPCA)

An agreement is currently in effect between OPP and the NPCA to obtain product performance and use data from field testing programs which include screening of currently registered devices, pesticides, or biorational agents intended for use in the professional urban pest control fields.

° American Mosquito Control Association (AMCA)

A Cooperative Agreement is being negotiated between EPA and the AMCA to provide: (1) data on use and effectiveness of pesticides used in vector mosquito control activities, (2) information on common vector control practice and integrated pest management practice, and (3) a forum of users on label improvement and similar items of interest.

° University of North Carolina (UNC)

OPP has a Cooperative Agreement with the UNC to assess the precision of the AOAC Use Dilution Test. This test is used as the efficacy test to register all hospital disinfectants and is used by Florida, North Carolina, Virginia, Mississippi, Canada, New Zealand, and Brazil for enforcement purposes. Additional microbiological tests to assess product performance are also being investigated under this cooperative agreement.

SUBOBJECTIVE B: DETERMINE THE EXTENT OF EXPOSURE TO WORKERS FROM PESTICIDE APPLICATION

Certain individuals are exposed to pesticides more than the general population. In particular, there are thousands of individuals who are exposed to pesticides through their work; mixers, loaders, farmers, pest control operators, and farmworkers. Some of these individuals are exposed when they reenter a field sprayed with pesticides to harvest crops. Determining the risks to those occupationally exposed to pesticides is an important component to regulating existing and new chemicals.

Monitoring occupational exposures is therefore a critical part of performing accurate risk assessments. In this sense, monitoring can encompass actual exposure studies, overall health effects studies, and personal risk mitigation measures.

WHAT DATA SHOULD BE COLLECTED: Field and personal impact residue studies, dermal absorption studies, epidemiological studies, and protective clothing research should be pursued.

WHY: These data will permit the Agency to understand actual exposures of more highy exposed populations, determine the health impact of pesticides to those who work with these chemicals on a regular basis, and identify practical risk reduction techniques for pesticide users.

REGULATORY UTILITY: Based upon the data gathered in this category, the Agency may:

- initiate a special review, cancellation or suspension based on potential unreasonable adverse effects to workers;

- restrict uses to certified applicators, or impose other restrictions, such as the requirement for applicators to wear protective clothing; set re-entry intervals for pesticides which specify the time required between the application of a pesticide before workers can reenter the field without special protective measures;

- develop protective standards through rulemaking, e.g., to reduce risks and/or ensure worker understanding of potential risks.

- develop special protections for children in field situations, e. g., longer reentry intervals, special clothing requirements.

In addition to assisting OPP in making direct regulatory decisions under FIFRA, worker-related monitoring data can assist the States and USDA in tailoring applicator training materials to educate applicators about potential risks and how to guard against them, and assist EPA, HHS, USDA, and the private sector in developing educational materials for agricultural field workers, or professional applicators.

WHO SHOULD COLLECT:

- OPP (EPA) - maintains a capability through the National Pesticide Hazard Assessment Program to perform a range of worker-related studies from residue studies to epidemiological studies. This Program operates through cooperative agreements with seven universities in various regions throughout the U.S.

- USDA - has a responsibility to assist in determining benefits of pesticides and, through the National Agricultural Pesticide Impact Assessment Program (NAPIAP), performs exposure studies for pesticides, especially those undergoing special review.

- National Institute of Occupational Safety and Health (NIOSH) - as the research arm of OSHA, performs studies relating to exposure to pesticides in a manufacturing setting, which may have applicability to understanding pesticide exposures.

- Department of Health and Human Services (HHS) - through the migrant labor clinics, is also in a position to collect and disseminate information on pesticide risks to the field worker labor force.

- Registrants - may also be required to collect applicator exposure data to support product registrations. The Agency is now exploring development of generic data requirements for this type of exposure data.

° Office of Research and Development (EPA) - has a major role in developing research on protective clothing, and may initiate health-related studies in special circumstances.

ONGOING/PLANNED ACTIVITIES AND PROJECTS: There are several special projects relating to worker exposure planned or underway:

° Field Worker Exposure Studies

OPP has a several field worker exposure studies planned for FY 85, including:

--- studies to determine adult and juvenile worker exposures in selected crops;

--- studies to determine whether the use of vegetable oils as diluents in applying pesticides increases the persistence of residues and thus increases exposures to field workers.

Results of these studies will permit the Agency to refine the methodology for establishing reentry intervals, determine if there are greater impacts of pesticides on children working in fields than adults, and determine if new policies are needed to address use of diluents, as well as provide more information on how pesticides behave in the environment which will assist in reassessing the risks of all outdoor use pesticides undergoing registration standards review.

° Protective Clothing and Devices

OPP is initiating additional field studies through the National Pesticide Hazard Assessment Projects (NPHAP) this fiscal year (and will continue these studies during FY 86 and 87) to monitor applicators wearing different types of garments during different types of spray operations. These studies will address performance of the garments in reducing exposure, as well as thermal comfort levels of the workers. ORD will begin testing the permeability of various types of glove materials to pesticides, and will fund garment

material testing at the University of Tennessee through a cooperative agreement beginning this fiscal year. ORD is coordinating this work for OPP with other personal protection research being conducted on behalf of EPA's Office of Toxic Substances (OTS) and the Office of Solid Waste and Emergency Response (OSWER).

The data developed through these field and lab studies will be used by OPP to develop protective clothing performance standards for purposes of risk reduction. A protective clothing and equipment guide for users will be completed by FY 88. The data will also be used to establish a consistent internal OPP policy on protective clothing and equipment that will be applied to every aspect of the regulatory process including registration and labeling, special reviews, registration standards, and farmworker protection standards.

° Studies of Applicator Exposure During Various Application Techniques

Through the NPHAP, OPP is conducting field and lab studies to formulate an applicator exposure data base for hand held, power train, chemigation, aerial and ULV techniques. These data will be used to fill significant data gaps and permit human exposure assessments and evaluations.

° Health Effects and Special Studies

OPP also has a variety of studies planned for FY 85 which involve determining the extent of human exposure to pesticides. These projects are also described in Objective IV. D, and they include:

> a study in Hawaii to monitor levels of heptachlor epoxide in mothers' milk;

> development of a technique to detect exposures to an organophosphate insecticide (parathion);

> a study of animal skin permeability to investigate dermal exposure potential; and

> statistical surveys of pesticide poisoning incidents.

SUBOBJECTIVE C: MONITOR FOR PESTICIDES IN GROUND WATER AND SURFACE WATER

Protection of ground water and surface water is a significant goal of the Agency and a major social and policy issue of the 1980's. The general public, as well as nontarget plant and wildlife species may be exposed to pesticide residues inadvertently through drinking and tap water, irrigation systems, etc. Ground and surface water can thus be seen as a significant potential route of human and environmental exposure to pesticides. Monitoring ground and surface water for pesticide residues is essential to understanding and limiting the risks of exposure presented to people and their environment. Such monitoring is therefore a significant component of the National Monitoring Plan.

WHAT DATA SHOULD BE COLLECTED: Ground water and surface water samples for pesticide residue analysis should be collected from a variety of sources around the country.

WHY: The resulting data will permit the Agency to assess the extent of contamination of water by pesticides, to better understand the relationship between use directions and residues in the environment, to understand which areas of the country may be more vulnerable than others to contamination, and to better determine the level of pesticide exposure to humans and wildlife through water sources.

REGULATORY UTILITY: Such data can provide the basis for:

- initiation of Special Reviews when chemicals of toxicological significance are found at levels of concern;
- Registration Standards and Special Review regulatory decisions including label restrictions or other modifications to existing registrations (including cancellation of certain pesticides, across the board or in key geographical areas);
- determination of extent of risk and need for treatment or clean-up;
- drinking water standards and health advisories;
- confirming and/or improving the models and methods used to predict the environmental fate of pesticides, and suggesting new directions for research;
- determination of the impact of recently introduced agricultural practices including no-till farming, and pesticide application through irrigation systems (chemigation) on the environment, which can lead to modifications on labels.

WHO SHOULD COLLECT: There are a variety of agencies and private entities who have a role in collecting data on pesticides in ground and surface water:

- USGS - has an overall mission in mapping and determining quality of surface and ground water; has expertise and ongoing activities in sampling water sources for a variety of contaminants.

- USDI - has a mission in protecting aquatic and endangered species which may be impacted by water quality and use of pesticides.

- States - have mission to both protect water quality and share with the Federal government the regulation of pesticides; State water, health and agricultural agencies involved in monitoring for pesticides.

- Office of Pesticde Programs (EPA) - has the lead responsibility for evaluating pesticide exposure information; OPP works cooperatively with other EPA Offices and other agencies to acquire data through specific water monitoring projects.

- Office of Drinking Water (EPA) - has a mandate to set standards for contaminants, including pesticides, in public water supplies, from either ground or surface water.

- Office of Water Regulations and Standards (EPA) - has a mandate to set standards for effluents, including pesticide chemicals, in surface waters from point sources. OWRS also provides guidance to States on Best Management Practices for controlling non-point sources of water contaminants.

- Office of Ground Water Protection (EPA) - has mandate to coordinate implementation of National Ground Water Protection Policy, including a Monitoring Plan.

- Office of Research and Development (EPA) - can collect monitoring data if mandated for special projects, and has a larger role in developing quality assurance measures and technologies to predict movement of chemicals to ground water.

- Pesticide Registrants - have a continuing responsibility to provide data to the Agency to demonstrate that their products do not pose unreasonable adverse effects to humans or the environment. For chemicals with a potential to leach to ground water or run off to surface waters, actual monitoring may be a key factor in determining whether the product poses unreasonable adverse effects.

ONGOING/PLANNED ACTIVITIES AND PROJECTS: OPP's strategy is to acquire information on specific chemicals of concern through several EPA-sponsored studies and by requiring monitoring by registrants. OPP will also undertake jointly with other EPA programs, Federal agencies, and the States, several ground-water monitoring surveys to identify general pesticide contamination and to develop predictive exposure modeling capabilities for this critical medium. Specific activities include:

° OPP/ODW Survey

The Office of Pesticide Programs and the Office of Drinking Water are jointly planning a national survey of drinking water from ground water sources to measure the presence of selected pesticides. The survey will be planned in FY 85 and executed, assuming that funding is forthcoming, in FY 86. The results of the study will provide information on the potential extent of contamination of drinking water in various parts of the country, which will allow the Agency to better assess the impact of certain pesticides on human health and may lead to label restrictions or possible cancellation of some products on the market.

° Data Call-In on Potential Leachers

OPP issued special data call-in letters in FY 84 requiring manufacturers of registered products to conduct and submit environmental fate data on over 100 pesticides known or suspected to leach to ground water. The data from this call-in will be submitted to EPA in FY 85 and FY 86. Pesticide registrants will develop these data. The results of these data will permit the Agency to determine what further field monitoring will be required of the registrant, and assist in developing exposure assessments for registration standards.

° Pilot Registrant Field Monitoring

OPP is requiring, as part of the registration standards process, registrants of at least four chemicals to conduct field monitoring of ground water as a condition of continued registration in FY 85. Pesticide registrants will be responsible for developing these data. The results of the pilot projects will permit OPP to refine its recently developed draft policy on imposing monitoring requirements during the registration standards process, help complete exposure assessments of the four chemicals in question, and permit the Agency to decide what labeling and/or restrictions need to be imposed on these registered products.

° ORD Aldicarb Survey

As a result of a special Congressional appropriation, ORD has been conducting monitoring for the pesticide aldicarb in Florida. This was a federally funded project conducted through a State university. Data from this project will assist OPP in reaching a conclusion on the future labeling or other restrictions of aldicarb during the already ongoing special review of the chemical. The registrant and several States are also continuing to monitor areas that may be vulnerable to leaching for aldicarb.

° Dougherty Plains Field Validation Study

ORD, with OPP support, has a 5-year study underway in Georgia to validate environmental fate models. The study, which is federally funded, is measuring pesticides in soil and water and comparing the actual presence with predictions of computer models. The results of the survey will permit the Agency to refine current models and to predict with more accuracy and confidence the potential for pesticides to move to ground water. This will in the long run lead to less expensive and more efficient decision-making to the extent that modeling can be used in lieu of field testing.

° U.S. Geological Survey Monitoring

OPP is planning to work extensively with USGS in FY 85 to ensure that ongoing USGS ground water programs are designed to collect data in ways which will assist OPP decision making. A particular project funded by OPP in FY 85 is designed to create an Interagency Agreement with USGS to help OPP collect data, and to identify areas of the country where pesticides are more prone than others to leach. This effort will assist the Agency in targeting label restrictions and further monitoring efforts. OPP will also work with USGS to investigate the possibility of a cooperative surface water monitoring program.

° States Monitoring

Many States are monitoring ground water sources for pesticides. States will continue to monitor for pesticides and other toxic substances as their resources permit. EPA and the States are working on ways to identify priorities and mechanisms for capturing the findings of State activities (see also Part III, Implementation).

SUBOBJECTIVE D. DETERMINE THE EXTENT OF PESTICIDE RESIDUES IN FOOD AND FEED

Most food and feed commodities commercially available in the U.S. today have been treated with pesticides at some time during their production, harvest, storage or processing. The Federal government is responsible for ensuring that potentially hazardous pesticide residues do not result in food and feed commodities travelling through the channels of interstate commerce. EPA establishes tolerances, or legally enforceable residue limits, for all pesticide food and feed uses, while FDA and USDA enforce those tolerances. While effective food and feed residue monitoring is essential to compliance programs (Objective 3), it is also directly relevant to EPA's pesticide risk assessment responsibilities.

WHAT DATA SHOULD BE COLLECTED: Residue data for pesticides in raw agricultrual commodities and in foods ready for consumption should be collected from different geographical areas.

WHY: Residue data on raw agricultural commodities determine whether pesticide tolerances are being exceeded, and permit EPA to determine whether tolerances are set at appropriate levels. Data on the extent of food contamination permit EPA to better evaluate human exposure to pesticides through food, and thus perform sound dietary risk assessments.

REGULATORY UTILITY: Dietary residue data are vital to EPA, FDA and USDA regulatory programs. Such data provide the basis for:

- Reassessment of tolerances in the registration standards process;
- Performing dietary risk assessments of chemicals undergoing special review or registration standards;
- Determining overall trends in dietary pesticide residue levels over time which contributes to the exposure profile in registration standards.
- Establishment of action levels in lieu of tolerances for pesticides whose registrations have been cancelled and tolerances revoked because of health-related concerns.

WHO SHOULD COLLECT: EPA, FDA, USDA, the States and pesticide registrants each have a role in collecting and developing dietary residue data.

- EPA - cooperates with and supports to some extent the FDA and USDA dietary residue data monitoring programs so that the data developed by those agencies will also serve our regulatory needs. EPA also conducts special food monitoring projects as needed to support special reviews, reregistration or cancellation proceedings (for example, several EDB cooking/baking studies were performed in FY 84).

- FDA - has the Federal lead in developing dietary residue data since it has enforcement responsibility for all food and feed (including milk and shell eggs) except for meat, poultry tissue and liquid eggs.

- USDA - shares the Federal lead for residue data development with FDA, as USDA is responsible for enforcing pesticide tolerances for meat, poultry tissue and liquid eggs.

- The States - often develop data on pesticide residues in food/feed produced and/or marketed within their boundaries, consistent with their pesticide regulatory and health protection responsibilities, and often have contracts with FDA and USDA to perform federal programs or portions thereof within their boundaries.

- Pesticide Registrants - have a continuing responsibility to provide data demonstrating that their products do not pose unreasonable adverse effects. For products used on food or feed crops, actual dietary residue and exposure data may be a key factor in determining whether the product poses unreasonable adverse effects.

ONGOING/PLANNED ACTIVITIES AND PROJECTS: EPA's strategy is to continue to work with FDA and USDA to increase the utility and availability of information. EPA will also be seeking more dietary residue data from registrants, and from State monitoring programs. Specifically, EPA is working on the following activities:

° FDA Monitoring/Surveillance

FDA, USDA and the States are continuing to carry out routine pesticide surveillance/compliance monitoring programs. FDA has made improvements in its monitoring program during the past four years which have made the data gathered particularly useful to EPA in asessing pesticide risks. USDA's National Residue Program is also being expanded, but closer cooperation with USDA is needed to increase the number of pesticides included and the tissue types analyzed for pesticides, so that USDA's data may be equally useful to EPA in developing dietary exposure and risk assessments.

° FDA Surveillance Index Project

OPP will continue to provide quantitative usage analyses and chemistry, toxicology and environmental fate summaries to FDA to support that agency's preparation of the Surveillance Index. That document presents FDA's method of ranking pesticides in order of monitoring priority based on potential health risk and potential for occurrence in the food supply. Currently about 140 pesticides/pesticide groups are included; another 50 should be added by the end of FY 85. OPP's data contributions to the Surveillance Index help to influence which pesticides are included in FDA's monitoring programs.

° Pesticide Analytical Manual (PAM), Volume II

OPP is providing updated analytical methods for use by FDA and USDA in dietary residue surveillance compliance monitoring programs through preparation of PAM Volume II. Availability of this updated manual will minimize conflicts in enforcement methods at the State and national level.

° On-Line Access to FDA and USDA Monitoring Data

If future resources permit, OPP will explore with FDA and USDA the possibility of establishing on-line access to those agencies' monitoring data bases, to speed up data access and make EPA's analyses of the data for exposure assessment more efficient. These data bases include Feedcon and Foodcon which enter data on contamination findings in food and feed sampling programs.

° Residue Data Call-In for Grain Fumigants

Out of concern with the ethylene dibromide situation, OPP has initiated a special Data Call-In for grain fumigants through which residue and other exposure data will be gathered. Letters requiring the data were sent in FY 84, and OPP expects to receive the data in FY 85. These data will allow OPP to make better informed reregistration and other regulatory decisions about the grain fumigants.

SUBOBJECTIVE E: DETERMINE EXPOSURE FROM INDOOR AND DOMESTIC OUTDOOR APPLICATIONS OF PESTICIDES

A large variety of pesticides are registered for domestic and indoor use by homeowners and others. The types of products available range from insecticide space sprays to bathroom disinfectants to pet flea collars to lawn and garden herbicides to mildew-resistant paints to insect repellants. The types of pests controlled range from insects and weeds to rodents to bacteria and mildew. Potential routes of exposure include inhalation, dermal absorption or ingestion (particularly for children), or combinations of those routes. Exposure settings range from the home and garden to offices, public buildings and meeting places.

Ten years ago, as OPP began the task of preparing registration data requirements and guidelines, regulatory priorities were, of necessity, set in favor of agricultural pesticide uses. As a result, special attention to nonagricultural pesticide exposures is needed at present. This is especially true regarding human exposure from domestic outdoor and indoor uses of pesticides, since the exposed population is obviously large. Thus, EPA is developing a program to monitor human exposure from domestic outdoor and indoor applications of pesticides.

WHAT DATA SHOULD BE COLLECTED: Initially, baseline and use patterns data should be generated through EPA- and registrant-sponsored studies. Specifically, air monitoring studies and combined or total exposure studies should be conducted, and use pattern data generated. In addition, the development and validation of simple test procedures are needed to generate data which can be used to estimate exposure from expanded uses of already-registered products or use of new pesticide products.

WHY: These data will enable EPA to learn what types and degrees of human exposure to pesticide residues are occurring in domestic and indoor settings as a result of current pesticide registrations and labeling. Conclusions about the safety of those exposures may then be drawn in a more precise way than in the past.

REGULATORY UTILITY: Monitoring data on domestic and indoor pesticide exposures may be used by EPA:

- to define baselines;
- to prioritize future data call-in activities;
- to detect unforeseen problems which require special regualtory consideration;
- to develop monitoring data requirements and guidelines for future registrant-sponsored studies;
- possibly, to set standards similar to tolerances for indoor air pesticide residue levels; and
- ultimately, to develop better risk assessments of existing chemicals.

These data will be useful to OPP in making registration, reregistration and special review decisions. They may also be useful to ORD and other Federal agencies interested currently in indoor air quality. OTS may find the data useful as that program shares OPP's interest in human exposure in the home and other indoor environments. EPA's Air Office may be able to use the data in its toxic air pollutant program (under section 112 of the Clean Air Act).

WHO SHOULD COLLECT: Several public and private parties have an actual or potential role in developing indoor and domestic outdoor exposure data.

- OPP - has the primary coordination function for indoor and domestic outdoor pesticide exposure data, and is planning to support some multi-residue, survey-type studies with ORD. This work will assist in developing monitoring guidelines for registrant sponsored studies.
- Other Federal Agencies - EPA participates with 14 other agencies in the Interagency Research Group on Indoor Air Quality. Some of the other participating agencies may develop data or methods that will be useful to OPP's monitoring and evaluation efforts.
- States - may develop useful indoor monitoring data consistent with their pesticide regulatory and public health protection responsibilities.
- Pesticide Registrants - have a continuing responsibility to provide data demonstrating that their products do not pose unreasonable adverse effects. For domestic or "home and garden" use products, actual indoor and domestic outdoor residue and exposure data may be vital in determining whether unreasonable adverse effects are posed.

ONGOING/PLANNED ACTIVITIES AND PROJECTS: EPA's strategy is to continue its in-depth study of termiticides while working with ORD/EPA on determining other potential indoor pesticide exposure problems. The following are the key activities planned or underway to generate data on exposures from indoor and domestic outdoor pesticide applications:

- Termiticide Studies

  In response to widespread concern about possible adverse health effects resulting from treatment of homes with termiticides, OPP initiated a special project several years ago to evaluate the risks of registered termiticides. The initial conclusion was that more exposure data were needed. EPA therefore required that registrants submit field monitoring studies defining dissipation curves for air levels in homes during the first ten years after treatment. OPP is in the process of reviewing the registrant's protocols for these studies.

  OPP also sponsored a field monitoring study through a cooperative agreement with Mississippi State University (MSU), focusing on air levels of termiticides in homes at intervals of 1, 30, and 90 days after treatment, the period when air levels are expected to be at their highest. The final reports of this study may serve as an independent validation of the air levels reported by the registrants.

  The exposure data provided by the termiticide studies will be used by EPA to complete its reevaluation of the risks posed by the registered termiticides. In addition, the test protocols developed may be incorporated into our monitoring guidelines, and the regulatory experience gained through the termiticide project may contribute to our development and imposition of routine indoor air monitoring data requirements in the future.

° Monitoring Study with ORD

OPP and ORD are working closely together to design a study of indoor human exposure to pesticides. ORD is managing in cooperation with OPP a Total Exposure Assessment Methodology (TEAM) study of exposure to pesticides used in and around the home. This study is supported by a $1 million Congressional appropriation in FY 85. The objective of the study is to estimate the frequency and distribution of exposures of an urban or suburban population to selected pesticides. The study will produce data on personal exposure which will be extremely useful to OPP in developing future exposure/risk estimates.

The monitoring, exposure and use habit data generated by this research project will be useful to OPP in defining baselines, prioritizing future data call-ins and further research activities, and detecting unforeseen problems which require special regulatory consideration.

SUMMARY OF OBJECTIVE I: Assist in Determining Impact of Old (Existing) Chemicals on Health and the Environment

DATA COLLECTION/GENERATION PROJECTS FOR IMPLEMENTATION UNDER THE NATIONAL MONITORING PLAN

Project Description	Responsible Party	Regulatory Objectives Supported	Current Status
Survey of Urban/ Non-Farm Sites	EPA (OPP)	Registration (including Standards development) Special Reviews.	Ongoing
Pest Control Efficacy	USDI	Determine efficacy of vertebrate pest control; determine effectiveness of IPM.	Ongoing
	DOD	Non-agric. use: Site information.	
Use of Pesticides in Forests	U.S. Forest Service	Efficacy feedback; usage data which can be used in Registration and Special Reviews.	Ongoing
Pesticide User Networks	Private Sector Groups (Users)	Determine impact of efficacy waiver policy; info on minor uses; comparative efficacy for Special Review process.	Funded for FY85 and to be continued in FY86
Enhancement of Production Data Reporting	EPA (OPP)	Prioritize Special Review and Registration Standards; target ground water monitoring	Funded for FY85; to be expanded in FY86
Professional Pest Control Practices in Urban Areas	Private Sector (National Pest Control Assoc.)	Efficacy Feedback	Ongoing
Use of Pesticides in Mosquito Control	Private Sector (Amer. Mosquito Control Assoc.)	Efficacy feedback; usage information which can be used in Registration and Special Review.	Agreement negotiated in FY85
National Agricultural Pesticide Impact Assessment Program (NAPIAP)	USDA	Use and benefits data for Special Reviews	Ongoing in FY85
Field Worker Exposure Studies	EPA (OPP-National Pesticide Hazard Assessment Projects)	Registration (label restrictions, re-entry intervals) and Special Reviews	Work ongoing in FY85 to be continued in FY8[illegible]

SUMMARY OF OBJECTIVE I: Assist in Determining Impact of Old (Existing) Chemicals on Health and the Environment

DATA COLLECTION/GENERATION PROJECTS (CONTINUED)

Project Description	Responsible Party	Regulatory Objectives Supported	Current Status
Applicator Exposure Studies	EPA (OPP)	Registration and Special Review-provide dermal and inhalation exposure for risk assessment	Ongoing: funded for FY85
Health Effects and Special Studies	EPA (OPP-through National Pesticide Hazard Assessment Projects)	Registration, Special Review, assist in risk assessments	Ongoing: Funded in FY85; to completed in FY86
Protective Clothing & Devices	EPA (ORD w/OPP Support)	Registration & Special Review-determine risk reduction protective measures.	Ongoing; funded for FY85
Dougherty Plains Field Validation Study	EPA (ORD w/OPP Support)	Will permit model validation; useful in determining likelihood of groundwater commination for Registration and Special Review purposes.	In 3rd year of 5-year project
Ground Water Vulnerability Assessment	USGS/EPA (OPP)	Target monitoring to vulnerable areas; assist label development in Registration and Special Reviews.	Funded for FY85
Ground Water Contamination Studies	USGS/EPA (OPP)	Assist in Evaluation of Results of OPP/ODW Survey; Registration - to develop label restrictions for ground water protection.	To be planned in FY85
OPP/ODW Drinking Water Survey	EPA (OPP & ODW)	Registration Standards, Special Reviews Drinking Water Standards	Planning funded for FY85; Implementation $ for FY86 pursued.
Data Call-In on Potential Leachers	Registrants	Registration, Special Reviews	Call-in letters complete; data arriving in FY85 and FY86.

SUMMARY OF OBJECTIVE I: Assist in Determining Impact of Old (Existing) Chemicals on Health and the Environment

DATA COLLECTION/GENERATION PROJECTS (CONTINUED)

Project Description	Responsible Party	Regulatory Objectives Supported	Current Status
Pilot Project: Registrant Monitoring for Ground & Surface Water	Registrants	Registration Standards Special Reviews Drinking Water Standards	Pilot initiating in FY85; Results in FY86/87
ORD Aldicarb Study	EPA (ORD)	Contribute to Special Review on Aldicarb	Draft reports available; completion date April 85
Food Monitoring and Surveillance	FDA and USDA	Registration (tolerance reassessment) and Special Review (dietary risk assessment)	Ongoing
Surveillance Index Project	EPA (OPP)	Assists FDA in targeting food monitoring activities	Ongoing funded for FY85; 150 chemicals done so far.
Pesticide Analytical Manual	EPA (OPP)	Assists FDA and USDA in food surveillance activities	Ongoing; funded for FY85
Termiticide Studies	Registrants	Registration - develop appropriate labels	3(c)(2)(B) letters issued; protocols under consideration.
	OPP (through Mississippi State Univ.)	Special Review-whether further restrictions or cancellation is required.	Ongoing; to be completed in FY85
Air Monitoring Studies	EPA (ORD)	Registration, Special Review. Will provide exposure data and models.	In planning stage

Objective 2

Pesticide Monitoring Goals And Objectives

Goal: Provide Information On Exposure And Effects To Assist
In Determining Risks And Benefits From Pesticide Use

OBJECTIVES:

1 Support Regulatory
Decision-Making
For Existing Chemicals

2 **Support Regulatory**
Decision-Making
For New Chemicals/Uses

3 Measure Compliance
With
Regulatory Decisions

4 Determine Trends Of Pesticides In The Environment For
Overall Program Evaluation And Exposure Projects

B. OBJECTIVE II: DETERMINE THE IMPACT OF REGULATORY DECISIONS TO PERMIT NEW CHEMICALS AND/OR NEW USES

Although reexamination of existing pesticide uses for registration is certainly a top priority of EPA at present, the ongoing regular pesticide registration process and other related new chemical/new use approvals are also of vital importance to the Agency. The Office of Pesticide Programs makes about 300 decisions involving new pesticide chemicals, about 75 decisions concerning new biorationals, and 14,500 decisions on new or amended uses of existing pesticides each year. In addition, about 400 experimental use permit reviews and 500 emergency exemption reviews are completed.

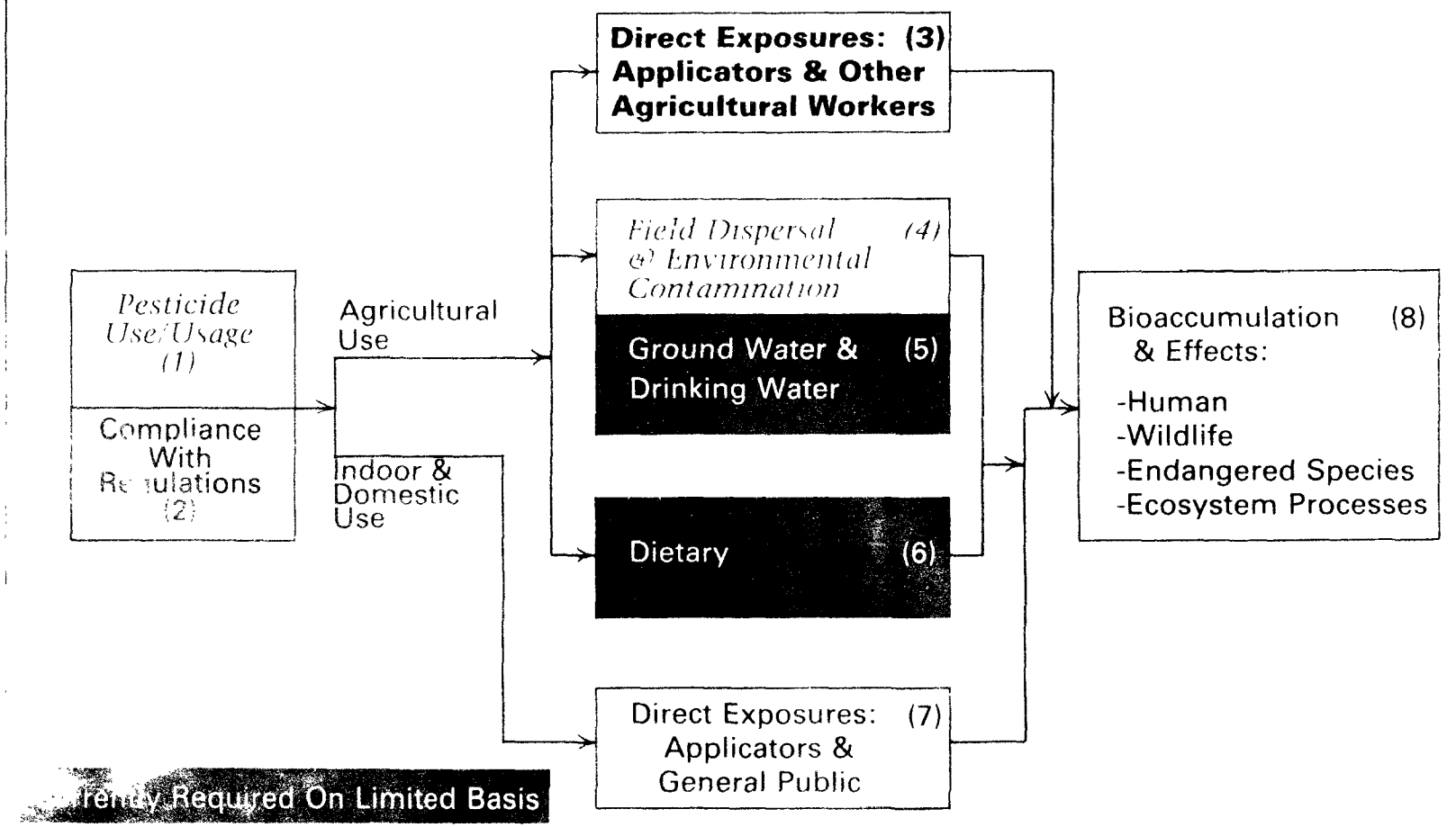
The availability of recently revised registration regulations, data requirements and guidelines helps to ensure that new chemical/ use approvals by EPA are based on complete, up-to-date, scientifically sound data. However, while adequate amounts of good quality toxicity data generally are available to EPA in making pesticide registration decisions, data on exposure -- the other side of the risk assessment equation -- are not always required or available for pre-market pesticide decision making.

Monitoring activities can provide the data on exposure that can assist EPA's decision-making for new chemical/new uses in:

- Development of exposure profiles for chemicals undergoing registration;
- Development of labeling restrictions; and
- Development of permissible residue levels (tolerances).

To fulfill this objective, EPA is pursuing two general subobjectives. The first is to further develop existing guidelines for human exposure monitoring by registrants and to explore other possible monitoring requirements of registrants for new pesticides. The second subobjective is to develop guidelines for registrantrequired monitoring of new pesiticides derived from biotechnology. The Agency may also perform some data gate oring efforts to cross-check results obtained by regist ants and to improve EPA's expertise in this area.

Figure V
Monitoring Needs For Objective 2: Registrant-Required Monitoring For New Chemical/New Use Registration



SUBOBJECTIVE A: REQUIRE MONITORING OF SPECIFIC CHEMICALS ON AN AS-NEEDED BASIS

While toxicology data generally are required and available to support new pesticide/new use registration decisions, a full complement of exposure data is not always available in advance of registration. Historically, EPA has relied on surrogate studies to estimate exposure to applicators, mixers, loaders, and other workers involved in pesticide applications where such information is important to assessing risks. However, actual exposure data are needed to make informed risk assessments for new pesticides and uses, in some cases.

As a data requirement for registration, or as a condition of approving a new pesticide or new use, OPP may require that the registrant conduct certain monitoring studies needed to fully determine the exposure potential, and therefore the risk, of the new pesticide or use. OPP has begun requiring monitoring data in advance of new registrations in some cases (i.e., for pesticide uses that have the potential for contaminating ground water). Through the Pesticide Assessment Guidelines, which inform registrants of acceptable testing methods to use in meeting Agency data requirements, EPA is developing additional guidance on exposure monitoring by registrants. For example, Subdivision K of the Guidelines, concerning field worker reentry, contains exposure monitoring components (i.e., protocols and requirements). For Subdivision U on applicator exposure, OPP is also developing comprehensive monitoring guidelines which will assist registrants in developing useful applicator and other types of worker exposure monitoring data. Aside from directly supporting registrations, monitoring data may also be needed by OPP to support requests for experimental use permits and emergency exemptions.

In addition to human exposure monitoring data, information on new pesticide use and usage would also be useful to OPP. We are considering the possibility of requiring these types of monitoring as part of the terms and conditions of our approval of new pesticide/new use registrations. Such a reporting requirement could help shift the burden of producing use/usage data to pesticide registrants. Figure V indicates those types of monitoring information where registrant-required efforts are currently in effect or being considered.

WHAT DATA SHOULD BE COLLECTED: Data on applicator and other human and environmental exposures presented by the new pesticide or use should be developed. Follow-up use and usage data may also be requested/required.

WHY: These data will permit EPA to better evaluate the potential risk of proposed new pesticide products and uses, and to evaluate our decisions on new products/uses in later years.

REGULATORY UTILITY: Exposure/risk data and use/usage data on new pesticides and new uses can:

- (when requested prior to registration) assist EPA in evaluating registration proposals, experimental use permit requests, and emergency exemption requests;

- (when requested as a condition of approving a proposed new registration) permit EPA later to verify exposure/risk assumptions, and make changes in labeling or registration of a product as needed.

WHO SHOULD COLLECT: Since these data are product-specific and would be used to support or maintain new pesticides and uses, registrants will be primarily responsible for generating and submitting them to EPA as needed. EPA will be responsible for providing guidance in the form of monitoring data requirements, test protocols, guidelines, etc.

ONGOING/PLANNED ACTIVITIES AND PROJECTS: Related activities include the following:

- Pesticide Assessment Guidelines, Subdivision U-Pesticide Applicator Exposure

  OPP is developing guidelines for use by pesticide registrants in conducting applicator exposure monitoring studies for both indoor and outdoor uses. In developing these guidelines EPA will determine when studies are to be required, and will develop protocols for field studies. These guidelines will provide a useful data-gathering mechanism for the Agency and will assist registrants in performing useful studies. The data developed will be used in exposure assessments for pesticide registration and review decisions.

° Pesticide Assessment Guidelines, Subdivision K - Field Worker Reentry

These final guidelines contain a model for calculating reentry intervals and exposure levels. Availability of this model will serve pesticide registrants and Agency reviewers in developing and evaluating worker exposure data submitted in support of registration decisions.

° Other Monitoring Requirements for Specific Pesticides

In several cases, OPP has already imposed monitoring data requirements in connection with the registration of particular new pesticides. For example, the registration of Ridomil was accompanied by a monitoring requirement, related to ground water contamination potential. Similarly, OPP has informed registrants of aldicarb, carbofuran, oxamyl, aldoxycarb, carbosulfan and other pesticides that new registrations will not be issued in the absence of additional monitoring data indicating the leaching potential/environmental fate of these pesticides.

SUBOBJECTIVE B: BIOTECHNOLOGY

A category of potential new pesticides that are of particular concern to EPA are the products of biotechnology, that is, microbial pesticides which have been genetically altered or manipulated by humans. These products potentially offer both risks and benefits to society. By altering microorganisms to overcome limitations such as sensitivity to environmental factors, lack of virulence or potency and limited host range, biotechnology (e.g., RDNA technology) provides the opportunity to develop more efficacious and economically attractive pesticides as an alternative to chemical pesticides. However, these kinds of manipulation may also warrant concerns with respect to safety. Subtle changes in host range or virulence could have deleterious ecological or human health effects. On the other hand, biotechnology may also offer the possibility of developing biologically contained microbial pesticides by incorporating features such as lethal mutants, antibiotic susceptibility or temperature or substrate dependencies that limit their survival.

No engineered pesticide products have been registered by EPA to date and no applications for registration have been received. However, notifications of several planned experimental small scale field programs have recently been received. The Agency does not at this time have reason to believe that significant adverse effects will necessarily occur as a result of small scale field testing of genetically engineered pesticides. However, The Agency is taking a conservative approach and screening each notification received against our adopted interim policy on small scale field testing of these products. Based on information contained in the notifications, we will determine whether experimental use permits (EUP's) are required.

WHAT DATA SHOULD BE COLLECTED: Monitoring Data on the movement, and fate of the microorganism during field testing should be developed.

WHY: These monitoring data will enable EPA to better understand the characteristics and potential risks of engineered microorganisms, and serve in developing the appropriate data requirements for such products.

REGULATORY UTILITY:

- The description of the monitoring program to accompany small scale field testing, which is to be submitted to EPA as part of the initial notification, will help the Agency determine whether an experimental use permit (EUP) is needed.

- Monitoring the microorganism during the field testing program would yield environmental fate and exposure data vital to the Agency's decision on any subsequent application for registration.

- Follow-up monitoring requirements may be developed in the future and attached to any approvals of registrations for genetically engineered products, in order to produce data that would allow the Agency to review and re-evaluate its registration decisions, and make any needed modifications.

WHO SHOULD COLLECT: Potential registrants of engineered pesticides should generate the required monitoring data for their products. EPA should assist in this effort by providing guidance on acceptable test protocols. The Agency also may perform some duplicate field monitoring, at least initially, to cross-check results obtained by potential registrants.

ONGOING/PLANNED ACTIVITIES AND PROJECTS

- Interim Policy on Small Scale Field Testing

  OPP's interim policy published in the Federal Register on October 17, 1984, requires a notification procedure which includes a description of the program for monitoring the microorganism during small scale field tests. As potential registrants contact EPA about performing any small scale field testing, they will be expected to meet this informal requirement. Monitoring descriptions provided will help us to make decisions on proposed small scale field testing.

° OPTS Proposed Policy Regarding Certain Microbial Products

The proposed policy published in the Federal Register on December 31, 1984, reflects OPP's interim policy on EUP notification. Concerning data requirements for registration, the proposed policy notes that additional data beyond those normally required for conventional microbial products may be required for nonindigenous and engineered microbials on a case-by-case basis. These additional data could include environmental fate data, and potentially monitoring studies, to elucidate the fate of engineered pesticides in the environment.

° Special Studies by EPA

Some cross-check monitoring studies on engineered pesticides may be conducted by EPA. These would help validate or invalidate the (potential) registrant's test results and would thus strengthen regulatory decisions on the products of biotechnology.

SUMMARY OF OBJECTIVE II: Determine the Impact of Regulatory Decisions to Permit New Chemicals and/or New Uses

DATA COLLECTION/GENERATION PROJECTS FOR IMPLEMENTATION UNDER THE NATIONAL MONITORING PLAN FOR PESTICIDES

Project Description	Responsible Party	Regulatory Objectives Supported	Current Status
Pesticide Applicator Exposure Guidelines	OPP	Guidelines will permit uniform data development to support registration and Special Reviews	Initiated in FY84; Draft March 1985.
Field Worker Re-entry Guidelines	OPP	Guidelines will permit uniform data to support registration decisions and Special Reviews	completed
Monitoring for Specific New Pesticides and Uses	Pesticide registrants	Data developed help determine environmental fate and exposure from pesticides uses.	Requirements imposed by OPP case-by-case as data are needed.
Biotechnology Interim Policy on Field Testing	Pesticide registrants	Required monitoring protocols will permit OPP to make decisions on proposed field testing.	In effect per 10/17/84 FR Notice
OPTS Proposed Biotechnology Policy	Pesticide registrants	Additional monitoring data may be required case-by-case; will permit registration decisions.	Proposed per 12/31/84 FR Notice
Special Biotechnology Studies	OPP	May undertake to confirm registrant data, increase institutional knowledge.	Anticipated but not yet planned

Objective 3

Pesticide Monitoring Goals And Objectives

Goal: Provide Information On Exposure And Effects To Assist In Determining Risks And Benefits From Pesticide Use

OBJECTIVES:

1 Support Regulatory Decision-Making For Existing Chemicals

2 Support Regulatory Decision-Making For New Chemicals/Uses

3. Measure Compliance With Regulatory Decisions

4. Determine Trends Of Pesticides In The Environment For Overall Program Evaluation And Exposure Problem Alerts

D. OBJECTIVE III: MEASURE USER AND INDUSTRY COMPLIANCE WITH REGULATORY DECISIONS IN THE FIELD

FIFRA is a statute that requires both user and product compliance. Compliance is measured through marketplace, producing establishment, use observation, experimental use permit, emergency exemption, special local need and applicator compliance inspections. Such inspections develop evidence of violations through the collection of samples, labeling and records which can result in civil, administrative and/or criminal enforcement actions.

Currently, enforcement of FIFRA is delegated to participating States through cooperative agreements. The States conduct inspections, take enforcement actions, and certify pesticide applicators under such cooperative agreements. These cooperative agreements resulted in over 76,000 inspections in FY 84 conducted by participating States.

Generally, States do not conduct laboratory inspections/ data audits, import/export, and monitoring of 6(a)(2) adverse effects reporting. Such inspections are usually conducted by EPA because States may not have the legislative authority. Also, States may not be able to receive confidential data submitted by registrants in support of their registrations.

The Office of Compliance Monitoring operates an information collection system authorized under FIFRA Section 7. This section requires manufacturers of pesticides to annually submit reports regarding the amounts of pesticide products produced by their registration number. This data is used by OPP to develop impact and risk/benefit analyses for pesticides.

SUBOBJECTIVE A: DETERMINE EXTENT TO WHICH PESTICIDE USERS ARE IN COMPLIANCE WITH FIFRA REQUIREMENTS AS REFLECTED ON PRODUCT LABELING

Pesticides are in use constantly by private and commercial applicators in a wide variety of settings. By law, all such use must be in accordance with approved product labeling. EPA relies heavily on labeling as a means of communicating vital precautionary information to users, to ensure safe use. Information on user compliance with labeling is important to EPA both from the standpoint of supporting enforcement actions and in reflecting the effectiveness of the labeling itself. States conduct pesticide applicator record inspections to ensure that certified applicators or individuals under their direct supervision are using restricted use pesticides in accordance with their labeling. Also, States conduct inspections at pesticide dealers to ensure that only certified applicators are purchasing restricted use pesticides. For Fiscal Year 1984, States through the cooperative agreements conducted approximately 20,000 applicator recordkeeping and license inspections as well as approximately 16,000 dealer record inspections.

WHAT DATA SHOULD BE COLLECTED: Environmental samples and documentary samples of applicator/dealer records regarding the use and sale of restricted use pesticides.

WHY: To detect and substantiate violations.

REGULATORY UTILITY: These data may provide the basis for:

- FIFRA enforcement actions under section 12 of the law;
- modifications to existing label statements where these are unclear or unenforceable;
- imposition of additional regulatory requirements such as restricted use classification, CRP, closed systems, protective clothing, etc.;
- Modifications to applicator C&T programs;
- special user advisory or guidance pronouncements.

WHO SHOULD COLLECT:

° The States, for EPA.

° FDA, USDA and DOL have MOU's with EPA for exchange of information on pesticide use/misuse.

ONGOING/PLANNED ACTIVITIES AND PROJECTS:

° State FIFRA Programs

The FIFRA Cooperative Enforcement Program has some 49 States participating as well as the District of Columbia, Puerto Rico, the Virgin Islands, Guam, the Mariana Islands and the Pacific Trust Territories as well as a number of Indian Tribes.

The States, through priority setting detailed in the cooperative agreement guidance, establish priorities for specific problem areas within the State. This priority setting process enables States to focus their training, compliance monitoring and enforcement personnel and resources on specific pesticide manufacturing, distribution and use activities which pose a risk to health and the environment. Any adverse data generated from such inspections are referred to OPP for the appropriate regulatory use.

The States may also use such information to further restrict pesticide use, e.g., ground water restrictions in Wisconsin. Such information may also be used to revise Pesticide Applicator Training and Certification materials developed by the U.S. Department of Agriculture, Cooperative Extension Service.

° FDA & USDA Tolerance Compliance Programs

Tolerances for pesticide residues on food and feed commodities are established by EPA, but enforced by FDA for most commodities, except meat, poultry and some egg products, which are inspected by USDA A commodity with residues in excess of established tolerance levels, or for which no tolerance is established, is adulterated and subject to enforcement action, which may include seizure of a shipment. FDA and USDA sampling programs help ensure compliance with tolerances by both domestic and foreign pesticide users, since tolerances apply to all commodities regardless of origin. Information on the annual results of these compliance sampling programs is shared with EPA.

OBJECTIVE 5 - DETERMINE EXTENT TO WHICH PESTICIDE REGISTRANTS, PRODUCERS AND DISTRIBUTORS ARE IN COMPLIANCE WITH PESTICIDE REGULATORY DECISIONS AND POLICIES

The pesticides used in the U.S. and exported to other countries from the U.S. are produced by some 8788 pesticide producing establishments. By law, pesticides made available for use in this country must be registered, as must all pesticide producing establishments. EPA monitors the pesticide producing industry to ensure that their practices and products comply with the requirements of FIFRA.

The States monitor registrant and pesticide producing establishment compliance by conducting establishment and marketplace inspections. Pesticide producing establishment inspections provide EPA with data regarding compliance with the accepted label and verification of the ingredients in the pesticide product. Marketplace inspections discover unregistered products which will either result in the registration of the product or its removal from the retail channels of trade. For Fiscal Year 1984 States through the cooperative agreements conducted 17,456 market place inspections.

States also conduct marketplace inspections to verify registrant/distributor compliance with State annual registration/licensing fee requirements. Registrant noncompliance with State regulations can result in stop sale orders being issued against their products.

WHAT DATA SHOULD BE COLLECTED: Pesticide samples from stocks released for shipment.

WHY: To detect and substantiate violations.

REGULATORY UTILITY: These data may provide the basis for:

- State regulatory actions for non-registration such as stop sale orders issued against products whose registrant/distributor did not pay the State registration/licensing fee.
- FIFRA enforcement actions under sections 12.
- Registration decision-making as described under Objective I of this plan.

WHO SHOULD COLLECT:

° The States, for EPA

ONGOING/PLANNED ACTIVITIES AND PROJECTS:

° State Programs

The States monitor industry compliance with FIFRA through marketplace and pesticide producing establishment inspections. Such inspections result in the collection of samples of pesticide products and their labeling. Labels are compared to the most recent accepted versions to assure that products bear the most up-to-date directions and precautions.

The States also analyze samples to verify that the active ingredients claimed on the label are actually in the product at the percentage stated, and that no other ingredients are contaminating the product. Cross-contamination of a pesticide product can indicate manufacturing or formulation problems that may trigger other regulatory actions by OPP.

Discrepancies between accepted and actual pesticide labeling or active ingredients can result in civil, administrative and/or criminal enforcement actions.

° Federal Programs

EPA conducts the Compliance Monitoring program in Nebraska. This program is essentially the same as the State Cooperative Enforcement discussed previously.

SUBOBJECTIVE C: DETERMINE QUALITY AND VALIDITY OF DATA SUBMITTED IN SUPPORT OF PESTICIDE REGISTRATIONS

EPA's pesticide regulatory decisions are only as good as the data submitted by industry concerning the properties of these chemicals. To insure a sound regulatory program, it is essential that pesticide laboratories follow good practices and produce data of high quality to support pesticide registration.

The States do not conduct Laboratory Inspection/ Data Audits, EPA does. The Office of Compliance Monitoring coordinates with OPP, OTS, and certain other agencies in conducting Laboratory Inspection/Data Audits. For FY 84 EPA conducted approximately 90 Laboratory Inspection/ Data Audits.

WHAT DATA SHOULD BE COLLECTED: Results of Good Laboratory Practice (GLP) inspections and data audits that validate or invalidate studies submitted to the Agency in support of pesticide registrations.

WHY: To determine compliance with the EPA GLP regulations published in the FR on November 29, 1983, and to insure that study reports submitted by labs/ registrants to EPA can be supported by the raw data.

REGULATORY UTILITY: These data may provide the basis for:

- enforcement actions against labs and/or registrants;
- reconsideration by OPP of previous registration/regulatory decisions on particular pesticides, including potentially requests for additional or replacement studies, registration/tolerance reassessment, and imposition of additional use restrictions or cancellation of product registrations/revocation of tolerances.
- validation of studies which will be submitted (ongoing studies are audited/inspected);
- assurance that data which the Agency is requiring to be developed is being developed on schedule.

WHO SHOULD COLLECT: In December 1983, the Office of Pesticides and Toxic Substances (OPTS) established the Office of Compliance Monitoring (OCM) as the management focus for laboratory inspection/data audit activities under both FIFRA and TSCA. Thus, OCM plans annual inspection/audit activities in coordination with OPP (and OTS for chemicals not used as pesticides) and also coordinates with FDA and the National Toxicology Program (NTP) through interagency agreements in order to utilize federal resources effectively.

- OCM conducts laboratory inspections to verify compliance with the Agency's Good Laboratory Practices (GLP) regulations under FIFRA and TSCA.

- OPP and OCM conduct audits of specific studies to determine validity of data submitted to the Agency in support of pesticide registrations.

- FDA also inspects laboratories to determine compliance with their GLP regulations, which are substantially similar to FIFRA GLP requirements. FDA's reports are available to EPA. FDA, on request, reviews actual pesticide studies during inspections.

- NTP is available on an as-needed basis to provide scientific expertise in conducting data audits.

ONGOING/PLANNED ACTIVITIES AND PROGRAMS: Since the reorganization mentioned above, the lab inspection/data audit program for pesticides has significantly increased over previous years. For example, the target of 60 pesticide inspections/audits for FY 84 was an increase over 45 the previous year, and the target was actually exceeded, with over 90 inspections and audits accomplished. For FY 85, 76 pesticide inspections and audits are planned. This is believed to be a realistic figure in terms of resources available. This level of inspections and data audits appears to be adequate to ensure periodic inspection of major testing facilities, and there is leeway in the system to provide for targeting a specific laboratory and/or study on a "for cause" basis if the need arises. The Agency is not planning to revise the current inspection/audit program, but rather to gain experience with the present, relatively new system.

It should be noted that Laboratory Inspections/Data Audits are conducted by EPA personnel at both foreign and domestic laboratories. All data submitted to EPA must adhere to the Agency's Good Laboratory Practice procedures (GLP's). All study data submitted to OPP must have a certification signed by the registrant, the sponsor, and the study director indicating that the study:

1. was conducted according to the GLPs; or

2. was not conducted according to the GLPs and outlines those areas that differ and why they differ; or

3. may or may not have been conducted according to the GLPs because the submitter was not the sponsor of the study (for example, the submitter is a subsequent registrant relying on a study sponsored by a previous registrant).

SUBOBJECTIVE D: DETERMINE EFFECTIVENESS OF THE PESTICIDE APPLICATOR CERTIFICATION AND TRAINING (C&T) PROGRAM IN PROTECTING THE PUBLIC FROM POTENTIAL HAZARDS OF RESTRICTED USE PESTICIDES

Since the 1970's, EPA has been restricting by regulation certain pesticide product uses to certified applicators or persons under their direct supervision, under the authority of FIFRA Section 3. The Agency has also implemented an extensive applicator certification and training program, largely through the States, under FIFRA section 4. More recently, OPP has begun classifying certain pesticide uses for "restricted use" through the registration standards/ reregistration process. Products are being restricted based on chronic as well as acute toxicity hazards. Thus, there is an increasing need to determine the effectiveness of the certification and training program in educating applicators about safe use of the more highly toxic, restricted use pesticides.

WHAT DATA SHOULD BE COLLECTED: Data on the incidence of use versus the misuse of restricted use pesticides.

WHY: To determine the extent to which restricted use pesticides are misused as compared to unrestricted pesticides to determine if the training of pesticide applicators results in fewer pesticide misuse incidents. Such data will assist the States in assessing and possibly revising their current C&T Programs.

REGULATORY UTILITY: This information may provide the basis for:

- modifications in the State certification and training programs;
- modifications in pesticide label language to increase its clarity, effectiveness, enforceability;
- further regulatory actions for some pesticides, if restricted use classification is not effective in protecting users and/or the public.

WHO SHOULD COLLECT:

° EPA through the Regions, States, or a university or private contractor.

ONGOING/PLANNED ACTIVITIES AND PROGRAMS:

° State FIFRA Programs

The FIFRA cooperative agreement program for Pesticide Applicator Certification and Training has essentially the same participants as the enforcement program.

The annual cooperative agreement guidance requires the States to establish priorities for the certification and training program. These priorities could result in the addition of new categories for pesticide applicators as well as new or revised training to address problems relating to the use of restricted use pesticides.

Any changes in the classification of pesticides will require close cooperation and coordination between States and the Agency to assure that pesticides which are chronically or acutely toxic are applied by applicators who have received adequate training under the C & T program.

For FY 85 the Agency, in cooperation with the States, will review the C & T program as it relates to training applicators who have been trained to apply acutely toxic pesticides but now may apply chronically or environmentally toxic pesticides. This review will provide data needed to assess current C & T programs and suggest modifications if necessary.

SUMMARY OF OBJECTIVE III: Measure User and Industry Compliance with Regulatory Decisions in the Field

DATA COLLECTION/GENERATION PROJECTS FOR IMPLEMENTATION UNDER THE NATIONAL MONITORING PLAN FOR PESTICIDES

Project Description	Responsible Party	Regulatory Objectives Supported	Current Status
User Compliance Programs	States	Determine extent of user compliance with product labeling; need for additional regulation.	Ongoing
Food Tolerance Compliance Program	FDA and USDA	Determine compliance with tolerance requirements; need for additional regulation.	Ongoing
Manufacturing/Formulating Compliance Programs	States (EPA for Nebraska)	Ensure producer/distributor compliance with FIFRA regulations	Ongoing
Lab Inspection and Data Audit Program	EPA, FDA, Assistance from NTP	Ensure submission of valid data by registrants	Continued expansion in 1986
Applicator Certification and Training (C&T) Programs	EPA with States	Determine extent of misuse of restricted pesticides for possible modifications of C&T programs, labeling or regulatory status (i.e., continue registration or cancellation).	Ongoing

Objective 4

Pesticide Monitoring Goals And Objectives

Goal: Provide Information On Exposure And Effects To Assist In Determining Risks And Benefits From Pesticide Use

OBJECTIVES:

1 Support Regulatory Decision-Making For Existing Chemicals

2 Support Regulatory Decision-Making For New Chemicals/Uses

3 Measure Compliance With Regulatory Decisions

4. Determine Trends Of Pesticides In The Environment For Overall Program Evaluation And Exposure Problem Alerts

D. OBJECTIVE IV: DETERMINE TRENDS OF PESTICIDES IN THE ENVIRONMENT TO EVALUATE PROGRAM EFFECTIVENESS (ENVIRONMENTAL RESULTS) AND IDENTIFY EMERGING PROBLEMS

Although monitoring activities are often related to specific pesticides, one of the basic objectives served by a multifaceted monitoring program is to provide a broad picture of human and environmental exposure to pesticide chemicals. Monitoring for trends in different environmental media serves two general purposes for regulatory decision making. First, gathering information about pesticide exposure in a variety of human and environmental media can help to identify an emerging, and perhaps unanticipated mode or magnitude of exposure to pesticides, and thus, alert decision makers to the need for action. In addition to "flagging" potential problems, monitoring of a variety of media is important to measuring the actual environmental results of past regulatory decisions. The environmental results of some actions may not be fully played out for years after a decision, and may involve unexpected consequences that could be important to planning future regulatory strategies.

There are several significant limitations on the Agency's ability to pursue a broad approach to monitoring the ambient environment. One obvious constraint is cost. The Agency can not realistically expect resources to be available for every type of monitoring activity that could generate information ideally desirable to have. Therefore, EPA must exercise responsibility to allocate monitoring resources to give the most cost-effective support to regulatory decisions.

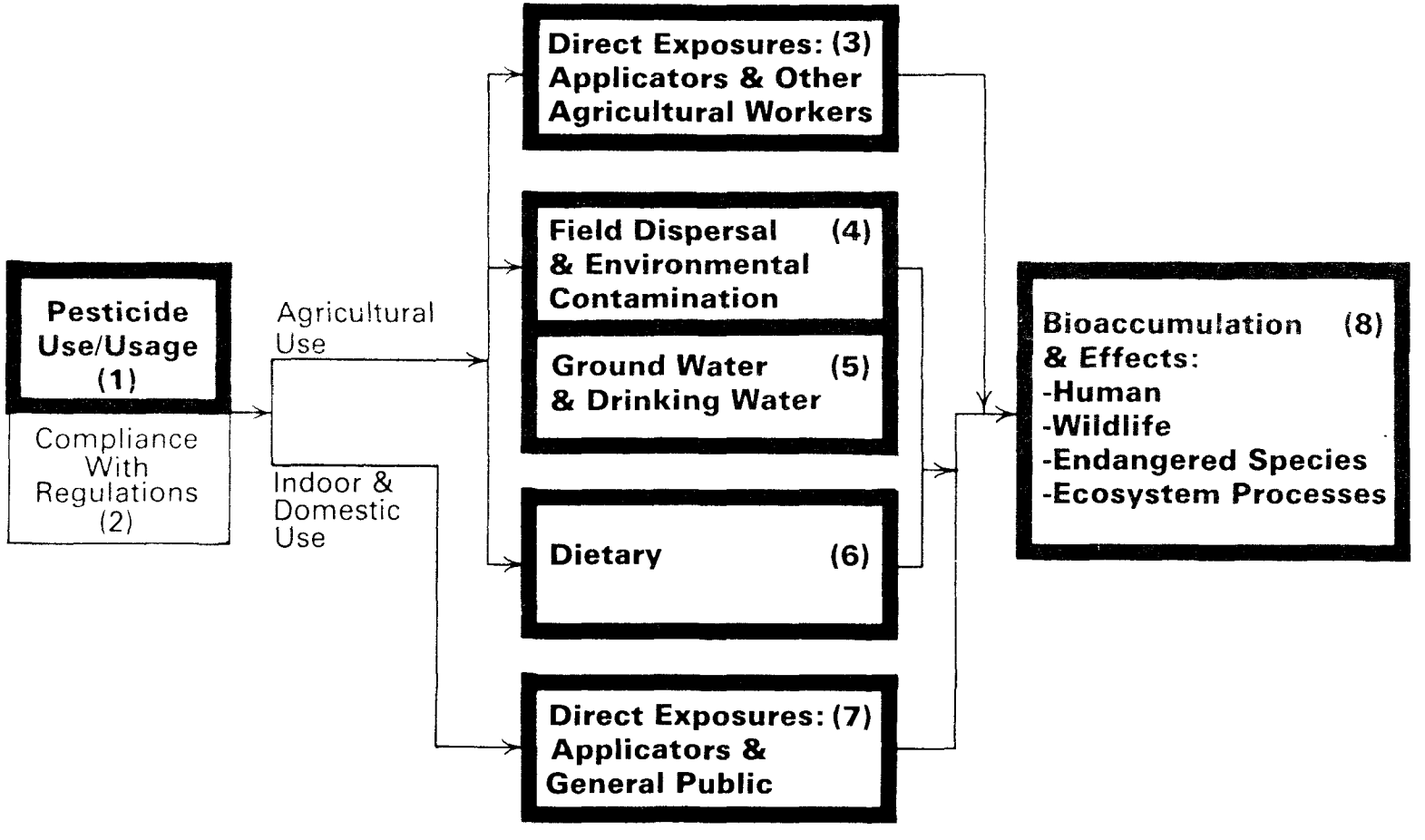
The cost problem is particularly acute for ambient (or general trend) monitoring because the strategy of shifting the burden to the private sector is not always available as an option. As noted throughout this plan, registrants have an obligation under the FIFRA to provide EPA with data adequate to show their products do not pose unreasonable adverse effects. Thus, EPA can use the legal authority of FIFRA to require some chemical-specific monitoring. However, this approach is not always available in relation to ambient monitoring of air, soil, water, or animal and human tissues. For example, the occurence of residues can not always be associated directly with specific uses of pesticide

products, and residues in the ambient environment may include a variety of pesticides simultaneously, including cancelled pesticides for which there is no responsible registrant. Thus, identifying other governmental or private organizations involved in monitoring activities is particularly important to gathering a broad spectrum of ambient monitoring data.

Another fact to recognize about the Agency's monitoring needs in general is that pesticide use has evolved over time, so that new techniques and strategies for monitoring are needed in order to evaluate new generations of pesticide products. Historically, concern about pesticide residues in the environment was directly linked to the extreme persistence of chlorinated hydrocarbon insecticides, such as DDT, aldrin, dieldrin, chlordane, and heptachlor, and monitoring activities were directed at these compounds. These compounds are relatively easy to detect, and trends for the environmental burden of this group of pesticides are generally well understood. However, these chemicals have been largely taken off the market in the past decade, and have been replaced by different classes of chemicals. Today, we need to assess the impact of newer types of chemicals, such as biorationals and synthetic pyrethroids, many of which are not as persistent or simple to detect. A whole new generation of genetically engineered pesticides may also be entering the market in the near future. Thus, in approaching the objective of monitoring for trends in various environmental media, the Agency faces the challenge of developing innovative methods and strategies for choosing what and how to monitor in order to get an accurate picture of the impact of pesticides as currently used.

As indicated by Figure VI, this objective involves nearly all types of monitoring information. These have been organized into four subobjectives: identify trends in the use of chemical or non-chemical approaches to pest control; advance general understanding of worker exposures to pesticides; track trends in general pesticide contamination (including human body burdens); and document pesticide related illness and other incidences of harm.

Figure VI
Monitoring Needs For Objective 4:
Tracking The Status Of Pesticides In The Environment



SUBOBJECTIVE A: ESTABLISH INFORMATION INDICATING TRENDS IN USE OF CHEMICALS OR NON-CHEMICAL APPROACHES

As a result of pesticide regulatory decisions by EPA and other market factors, patterns of pesticide chemical and non-chemical use have changed over a period of years. For example, while chlorinated hydrocarbon pesticides were widely used during the 1950's and 1960's, Federal regulatory actions and the availability of newer organophosphate pesticides and IPM techniques effected a shift in use to those newer compounds and strategies during the 1970's. OPP believes it is valuable to monitor pesticide use and usage in order to determine broad trends in the use of pesticides and other pest controls over time. Such data would be useful in illustrating the social and environmental results of Agency actions, in indicating trends in EPA's regulatory influence, and in predicting the effects of emerging new pest control technology and agricultural practices.

WHAT DATA SHOULD BE COLLECTED: Use and usage data, focusing on individual chemicals, clusters of pesticides by use patterns (for example, fumigants or nematocides), or particular agricultural commodities/crops or other use sites. These data should be collected and evaluated during a five to ten year period.

WHY: These monitoring data may be analyzed to determine trends in the amount and frequency of use of particular pesticides and other pest controls.

REGULATORY UTILITY: These time-related use/usage trends data may be used by OPP to:

- provide a basis for requiring or conducting additional monitoring or health effects studies to determine the consequences of use of substituted pesticides/pest controls;
- evaluate and if necessary adjust previous pesticide regulatory decisions;
- identify situations in which further regulatory action on a previously regulated chemical, or entirely new regulatory action is needed;
- guide future regulatory decisions.

WHO SHOULD COLLECT: EPA, in cooperation with USDA and/or other agencies, through agreements with private groups or through a contractor, should collect these data.

ONGOING/PLANNED ACTIVITIES AND PROJECTS: Although EPA collects pesticide usage data from a variety of sources including other agencies, private subscription data bases, and registrants (as listed in Objective I. A), there is no project at this time to compare and evaluate broad pesticide use/usage patterns over time.

OPP will develop such a project in the near future.

SUBOBJECTIVE B: ADVANCE GENERAL UNDERSTANDING OF AGRICULTURAL AND OTHER WORKER EXPOSURES TO PESTICIDES

There are thousands of individuals who are exposed to pesticides through their work, particularly in agriculture. These include mixers, loaders, farmers, pest control operators, and farmworkers. Some of these invidivuals are exposed when they reenter a field sprayed with pesticides to harvest crops. Determining the risks to those occupationally exposed to pesticides is an important component to regulating existing and new chemicals. Monitoring general trends in worker exposures to pesticides is therefore a critical part of this objective.

WHAT DATA SHOULD BE COLLECTED: Baseline data on exposures to pesticides by applicators and farm workers should be expanded to include a wider variety of field situations, groups at risk, and application technologies.

WHY: Such data will help the Agency identify problem exposure situations and assist in learning of the actual consequences of EPA registration and regulatory decisions.

REGULATORY UTILITY: Based upon the data gathered in this category, the Agency may:

- reexamine existing pesticide registrations and product labeling;
- act to restrict or otherwise modify existing registrations, or to amend product labeling;
- explore broader remedies such as child resistant packaging, closed systems, or protective clothing requirements;
- improve labeling, use restrictions, conditions of use for new products and uses "up front," that is, during the registration process preceeding market entry.

WHO SHOULD COLLECT:

° OPP - has the lead responsibility for collecting and developing data on pesticide applicator and farm worker exposures.

° ORD - as EPA's research lead, it plays a key role in performing needed exposure-related studies, developing needed test methods, etc.

° Department of Labor (DOL) - has worker protection responsibilities which are similar to and sometimes overlap with EPA's user protection responsibilities under FIFRA. DOL shares our concern with health impacts on workers who comes into contact with pesticides.

° Universities - seven are part of the National Pesticide Hazard Assessment Program (NPHAP) which is conducting special exposure/health effects studies under cooperative agreements with EPA; a number of these studies concern worker exposure. The NPHAP is more fully described in Subobjective D: Documenting Pesticide-Induced Illnesses and Other Impacts.

ONGOING/PLANNED ACTIVITIES AND PROJECTS: Several key activities are in progress to monitor trends in agricultural worker exposures to pesticides.

° Exposure for Crops Other Than Tree Fruit

The Agency has developed a model for Subdivision K of the Pesticide Assessment Guidelines (see also Objective II. A) which correlates dislodged residues with field worker exposure based on data obtained during the picking of tree fruit, since this is generally perceived to be the highest exposure situation. The Agency does not currently have a method for setting reentry intervals in less hazardous situations. Data are being developed on other crops/tasks so that worker exposure may be predicted for situations other than the "worst case."

° Youth in Agriculture Project Completion

Final reports from this project, which was conducted under an EPA/DOL interagency agreement, are being reviewed. This review will determine what work must be done to produce a summation of pesticide exposure of juvenile workers during agricultural operations. From the summation, recommendations will be made as to measures that should be taken to protect children in agriculture.

° ULV Application Fieldworker Exposure Study

Use of ultra low volume (ULV) pesticide formulations/applications is increasing. The greater efficacy and longer duration of effective pest control attributed to ULV applications suggest that fieldworker exposure may also be greater than after use of other formulations. Reentry intervals established with other pesticide formulations may not be effective for ULV formulations. OPP is developing a method to quantify dislodgeable pesticide residues after ULV application and will apply that methodology for monitoring fieldworker exposure to residues from ULV application.

SUBOBJECTIVE C: TRACK TRENDS IN GENERAL OR AMBIENT ENVIRONMENTAL CONTAMINATION

The term "ambient monitoring" should be clarified in this context. In general, this term is meant to distinguish between monitoring aimed at evaluating the occurrence of pesticides in a particular medium (e.g., human tissues), as contrasted with monitoring for a particular chemical. In practice, these are not wholly separate types of activities. Monitoring for a specific chemical is generally conducted in a selection of media; for example, EDB residues are monitored in stored grain and ground water, where they are likely to occur, but not in wildlife species where there is virtually no possibility of exposure. Similarly, a project aimed at ambient monitoring in purpose, such as ground water monitoring, must usually select for analysis specific pesticides with some recognizable potential as contaminants, because there is no "all purpose" analytical method for chemical detection. Thus, "ambient monitoring" is not a rigid category, and some of the projects listed under Objective I, pertaining to existing pesticides in ground water, food and feed commodities, and indoor air are ambient monitoring as well as chemical-specific evaluations.

In conducting ambient pesticide monitoring activities and in documenting the occurrence of general pesticide exposure problems, OPP will focus in part on those pesticides for which some regulatory action has already been taken (that is, pesticide uses which have been restricted or cancelled). Specifically, we will record trends in the residue levels of those pesticides in humans and environmental media, and in the incidence of related accidents and illnesses. These trend data will illustrate the environmental results of OPP's past regulatory actions, and may provide the basis for further evaluation of the pesticides in question.

OPP will also initiate appropriate follow-up monitoring activities as decisions to restrict, cancel or continue pesticide uses are reached, through special reviews or other risk/benefit evaluations. Pesticide registrants will be responsible for conducting such monitoring for proprietary chemicals, while EPA and/or cooperating agencies or organizations will conduct needed environmental results monitoring in other cases.

WHAT DATA SHOULD BE COLLECTED: Data on pesticide residues occurring in appropriate environmental media (such as human tissue, soil, water, air, wildlife, etc.)

WHY: These montoring data will enable EPA to chart trends in residue levels and in other health-related parameters, and determine whether intended health and environmental results of regulatory decisions are being achieved. The Agency also needs such data to "flag" unanticipated or emerging health or environmental problems involving pesticide exposure.

REGULATORY UTILITY: These trend data on ambient environmental occurrence of pesticides will provide the basis for:

- regulatory decisions or modifications of previous decisions as necessary to achieve desired risk reduction/health and environmental results (including potentially additional use/label restrictions, tolerance revocations, cancellations suspensions, or enforcement follow-up investigations);

- identification of successful cases where trend data show that desired environmental results, e.g., reduced exposure, are being achieved. This information will be useful in tailoring future regulatory decisions where similar conditions are presented and similar results are desired;

- identification of unanticipated or emerging problems to alert the Agency to the need for closer evaluation of a situation, or regulatory action to deal with a new pesticide exposure situation.

WHO SHOULD COLLECT: EPA, in cooperation with other Federal and State agencies, universities, contractors, etc., will collect most of ambient data for past regulatory decisions. However, as decisions on proprietary chemicals are made in the future, pesticide registrants will be required to conduct follow-up trends/environmental results monitoring activities.

ONGOING/PLANNED ACTIVITIES AND PROJECTS: The following monitoring activities are underway to illustrate environmental results, or could be undertaken/adopted to provide more data on regulated pesticides.

- Develop inventory of all pesticice related monitoring

  The Agency should inventory all potentially [illegible] monitoring activities being pursued in other [illegible] EPA, the States, and other Federal agencies to assist efforts to "piggyback" pesticide monitoring needs onto existing projects through cooperative agreements or other means, and to influence [illegible] being conducted already. This important initial step to establishing coordinated efforts with other programs and agencies should be completed [illegible]

° Residues in Human Adipose Tissue

OPP has participated with OTS's National Human Adipose Tissue Survey (NHATS), which maintains collections of tissue speciments. Over a period of 10 years this project has provided data on residues of a number of pesticides, primarily cancelled chlorinated insecticides. OPP can arrange for analyses of old or new pesticides of concern with OTS to further utilize this data resource on human exposure.

° Blood Sample Network

In FY 1985, OTS is designing a program to collect blood samples from existing sources such as Red Cross blood banks. Samples will be analyzed for various industrial chemicals. OPP will evaluate this approach, to see whether pesticides can be included in the analyses of samples. Blood may be a useful medium to test in addition to adipose tissue, since different pesticides or effects may be detected.

° Hispanic HANES

The Department of Health and Human Services conducts this ongoing Health and Nutrition Evaluation Survey (HANES) of the Hispanic population. OPP is generating pesticide exposure data by analyzing blood serum and urine samples collected in this survey. These data provide general exposure information about the Hispanic population's exposure to pesticides of past and present regulatory interest.

° NHANES III

A National HANES project is scheduled for 1988 by the Department of Health and Human Services. OPP is investigating the utility of this survey to provide additional data on human exposure, through access to human samples which EPA would analyze.

° EDB in Grains -

Special studies by FDA to show EDB food residue levels are being completed this fiscal year.

° Termiticides Studies -

The field monitoring data gathered by OPP and pesticide registrants will help define the current human exposure to selected termiticides and provide information on environmental results of EPA's past decisions on termiticides.

° Selected Residues in Food -

FDA conducts prepared food residue studies developed through the Total Diet/Market Basket Surveys (described more in sub-objective 1-D above). OPP is analyzing these data to chart trends in levels of regulated pesticides in foods, so that environmental results in terms of dietary exposure may be known.

° Residues in Birds and Freshwater Fish -

At OPP's request, USDI (FWS) is providing the results of their on-going studies on residues of pesticides of interest to OPP in migratory and non-migratory birds and freshwater fish. OPP is analyzing these data to determine environmental results of past regulatory decisions on selected pesticides.

° Others -

As OPP piggybacks onto other existing ambient monitoring programs, develops partnerships with other offices and agencies to cooperatively develop trends data, or initiates relevant monitoring activities of its own, analyses for specific pesticides of interest can be included. To cite one example, OPP will be exploring the possibility of utilizing the existing Environmental Radiation Ambient Monitoring System (ERAMS) to collect environmental samples for pesticide analysis.

SUBOBJECTIVE D: DOCUMENT THE OCCURRENCE OF PESTICIDE-INDUCED ILLNESS AND OTHER IMPACTS

Trends in the health status of the U.S. population are an important indicator of the impacts of past regulatory decisions on pesticides. Similarly, trends on other organisms, particularly fish and wildlife, are also important in evaluating the effectiveness of EPA's pesticide regulatory actions. Data documenting the occurrence of pesticide-related illnesses and other impacts can also help EPA identify emerging pesticide use and exposure problems. Thus, monitoring activities to determine the extent of pesticide exposure problems as evidenced by related illness and other harmful effects are an important aspect of the National Monitoring Plan.

WHAT DATA SHOULD BE COLLECTED: Baseline data on accidents and illnesses, health effects, and exposures among the general public and certain segments of the U.S. population (i.e., farm workers or communities with likely high exposures) should be developed. Data on environmental impacts particularly to fish and wildlife also need to be developed.

WHY: These data will permit the Agency to identify trends in pesticide-related health impacts among the U.S. population, impacts on the environment, particularly wildlife, identify problem exposure situations, and in general, clarify the actual health and environmental consequences of EPA's registration and regulatory decisions.

REGULATORY UTILITY: Data on pesticide-related human illness and environmental impacts may provide the basis for:

- reexamination of existing pesticide registrations and product labeling;
- actions to restrict or otherwise modify existing registrations, or to amend product labeling;
- broader remedies such as child resistant packaging, closed systems, or protective clothing requirements;
- improved labeling, use restrictions, conditions of use for new products and uses "up front."

In general, data on illnesses and incidents are of primary use to OPP for developing registration standards and conducting special reviews because they contribute hard evidence to the risk side of the risk/benefit equation. These data may also be of use to other programs and agencies concerned with chemical-related health impacts and trends.

WHO SHOULD COLLECT

- ° OPP has the lead responsibility for collecting and developing data on human illness and impacts relating to pesticides.

- ° Department of Interior has primary responsibility for the protection of fish and wildlife.

- ° National Ocean and Atmospheric Administration has responsibilities for the health of marine fisheries, and certain aquatic endangered species.

- ° Universities - seven are part of the (NPHAP) described below, and are conducting special exposure/health effects studies under cooperative agreements with EPA.

ONGOING/PLANNED ACTIVITIES AND PROJECTS: EPA will continue to collect data on pesticide illness incidents throughout the country as well as conduct more specific studies of localized pesticide health problems. EPA will also be exploring possibilities for tracking harmful effects to wildlife. Specific efforts include:

- ° Pesticide Exposure Incidents - Current Activities -

  OPP's NPHAP project at Texas Tech University includes the National Pesticide Telecommunications Network. This is a twenty-four hour hot-line which provides an emergency response mechanism to address inquiries concerning the diagnosis, management and treatment of pesticide related poisonings.

  OPP headquarters staff includes a Pesticide Incident Response Officer who can be contacted to utilize the medical and laboratory capabilities of the various NPHAP projects and cooperators to provide medical and analytical consultative support in relation to pesticide incidents.

  OPP continues to work with States through AAPCO to promote the collection of pesticide incident information by the States.

- ° Pesticide Exposure Incidents - Future Activities

  Collecting good statistical information on the occurrence of pesticide-related incidents nationally has proven difficult in the past, but continues to be a matter of interest and concern for EPA, Congress and the public. The Agency's former Pesticide Incident Monitoring System (PIMS), which relied primarily on voluntary reporting of incidents was unsatisfactory in many ways. OPP is now evaluating the utility of two existing statistical surveys which are receiving some EPA support now. These are Colorado State University's Hospital Study of Acute Pesticide Poisonings, and the Consum-

Product Safety Commission's (CPSC's) Emergency Room Survey. OPP will determine whether these two surveys should be modified or a new statistical design be developed to satisfy the need for better data on pesticide incidents.

- Health Effects and Special Studies

Operating through the National Pesticide Hazard Assessment Program (NPHAP), with projects located at seven universities throughout the U.S., OPP has the unique capability of planning, conducting and evaluating national and local exposure/health effects studies at minimal cost. Examples of studies that may be funded in FY 85 include Heptachlor in Mother's Milk (Hawaii), Monoclonal Antibodies (Texas), and Immunoassay for Field Exposure to Paraquat (Cal.). The data produced through these special studies will enable OPP to study exposure trends and the impacts of pesticide regulatory decisions and Programs on health and safety, and may provide the basis for regulatory modifications where necessary.

- Study the feasibility of developing a new approach to monitoring for environmental impacts

The Agency needs better information on the effects of current pesticide use, particularly in reference to fish and wildlife effects. Current monitoring data on wildlife is generally limited to reporting trends in residue levels in tissues, which is of very limited utility; residue levels in themselves do not demonstrate the occurrence or absence of adverse effects. There is no regular source of information on actual environmental effects such as changes in populations, survivability or behavior. Such data are clearly relevant to risk/benefit decisions on pesticide uses. The Agency needs to consider possible avenues for obtaining such data. A feasibility study should be undertaken during FY 1986, and if appropriate, a pilot program be undertaken or planned for the following year. This work could lead to the development of protocols for registrant required monitoring of pesticide impact on non-target species.

SUMMARY OF OBJECTIVE IV: Determine Trends of Pesticides in the Environment to Evaluate Regulatory Decisions (Environmental Results) and to Identify Unanticipated or Emerging Problems

DATA COLLECTION/GENERATION PROJECTS

Project Description	Responsible Party	Regulatory Objectives Supported	Current Status
Chemical/Non-chemical Use Trends Study	OPP	To show use/usage trends resulting from regulatory decisions (environmental results).	To be planned in FY85
Fieldworker Exposure Studies	OPP with DOL	To implement and improve re-entry exposure model needed for registration and reregistration decisions.	Projects funded and underway in FY85
EDB in Grains	FDA	To provide trends, environmental results data on EDB.	Funded in FY85
Selected Residues in Food	FDA	To show environmental results of previous decisions.	Funded and underway in FY85
Termiticides Studies	OPP, registrants, Mississippi State University	To show environmental results of previous regulatory decisions.	Funded and underway in FY8
Selected Residues in Birds and Freshwater Fish	USDI (FWS)	To show trends, environmental results of previous regulatory decisions.	Funded and underway in FY85
Selected Residues in Human Adipose Tissue (NHATS)	OPP and OTS	To show trends, environmental results of previous regulatory decisions.	Funded and underway in FY85
Hispanic HANES	HHS	To obtain health trends data for particular pesticides.	Funded in FY85; ongoing
NHANES III	HHS	To obtain additional trends data on regulated pesticides.	To begin in FY87
Human Illness Monitoring	OPP with CPSC and/or Colorado State University	To provide accident/incident trends data; show results of previous decisions.	Being investigated
Health Effects and Special Studies	OPP with NPHAP's (7 universities)	Permit evaluation of exposure trends; show impact of regulatory decisions; support RS/Special Reviews.	Funded for FY85

Implementation

Establish And Maintain Data Systems

Provide Quality Assurance

Provide Federal/State Guidance & Coordination

Provide Registrants With Guidance

Provide Public Access To Information

III. IMPLEMENTATION

In order to implement a comprehensive, effective national pesticide monitoring program, EPA must undertake certain basic activities and provide certain support functions. The areas discussed in this section of the National Monitoring Plan, while not directly supporting particular regulatory objectives, together will serve to ensure that a coordinated Federal pesticide monitoring program is established resulting in the production of high quality data that are readily available to EPA and all other parties who need such information.

A. ESTABLISH AND MAINTAIN DATA SYSTEMS

As the new pesticide monitoring data outlined in this plan are developed by EPA, registrants and others, it is essential that the Agency have in place appropriate mechanisms for managing and using this information and providing access to it. In order to successfully use the exposure information generated to enhance EPA decision making on pesticides, OPP will develop specific mechanisms to receive, store, evaluate, and disseminate the additional information. These will include primarily the adaptation of data systems to effectively handle existing monitoring information and the additional exposure data to be generated. These data systems will make the information gathered readily accessible for risk assessment and regulatory decision making within OPP, and will ensure timely and appropriate dissemination of monitoring and use information to other EPA programs, States and other interested parties outside the Agency.

1. Electronic Bulletin Board

The National Monitoring Plan calls for greater use of externally-generated data in pesticide regulatory decision-making. To do this successfully, OPP must be able to track ongoing pesticide monitoring activities performed externally.

OPP is in the process of establishing an "electronic bulletin board," which will consist of an automated listing of ongoing pesticide monitoring activities sponsored by OPP, other EPA program offices, and other Federal, regional, and State agencies. The listing will

be updated twice yearly to share information about pesticide monitoring activities among the cooperators and encourage data exchange among the various organizations with pesticide regulatory responsibilities. An existing data system will be used to ensure early completion and availability of the bulletin board. This listing will be available as printed material and in electronically-accessible form.

2. Managing Monitoring Data

OPP has begun to thoroughly investigate use of various data management systems to handle monitoring data. OPP hopes to be able to set up several files to store the additional exposure information to be generated under this plan. There is a need for mechanisms that will significantly increase the accessibility to those data not considered proprietary and provide access to graphics and statistical package capabilities. These data systems need to include quality assurance parameters with each record so that all OPP human and environmental exposure information will be of a known quality. EPA's STORET system, as well as microcomputer capabilities are being considered in the light of these needs.

3. Inventory of Registrant-Imposed Studies

In order to track the development and completion of pesticide monitoring studies required by OPP of pesticide registrants, the Program will establish and maintain an automated inventory or file of registrant-imposed studies. This system will be similar to and will complement the electronic bulletin board.

B. PROVIDE QUALITY ASSURANCE

Regulatory decisions in EPA are as good as the data upon which they are based. To assure high quality data, the Agency has instituted a mandatory Quality Assurance program which requires that all data generated by or for the Agency be of known quality and documented. OPP's Quality Assurance program, as part of the Agency-wide program, encompasses a number of activities designed to assure that data collected is of known quality and meets the needs of the data users.

All OPP-sponsored pesticide monitoring activities will be conducted in compliance with the OPP Quality Assurance Plan approved by the Quality Assurance Management Staff of ORD. Each project will have its own quality assurance project plan and, once the project is completed, quality assurance parameters (e.g., confidence levels, conditions of analysis), will become an integral part of the data base. In cases where monitoring projects are conducted cooperatively with other EPA offices and Federal agencies the data quality objectives will be negotiated. The quality assurance requirements of all participants must be included in the overall project quality assurance plan.

It is also important that EPA be able to independently verify the quality of the information being submitted by registrants and other private data sponsors or cooperators. A number of field sampling observations and laboratory audits will be performed annually for a subsample of these externally-sponsored studies. Some short-term monitoring studies may be performed by OPP if any questions arise concerning the results obtained in registrant-sponsored studies. The maintenance of such on-call survey capacity is necessary in order to ensure the quality of the exposure data used in risk assessments by OPP. Additional quality assurance procedures will be prepared by OPP to cover registrant required monitoring. These procedures will be established as registrant monitoring requirements are implemented.

C. PROVIDE FEDERAL/STATE GUIDANCE, COOPERATION

As discussed in the Introduction to this Plan, EPA recognizes its responsibility to assume a leadership role in procuring pesticide exposure monitoring information. The Agency also recognizes that collecting monitoring data is a cooperative effort, shared in part by other Federal and State agencies. To ensure that the pesticide monitoring activities of the EPA and other agencies have maximum utility and are of high quality, EPA will serve as the Federal coordinator and provide guidance as needed.

1. Interagency Coordination

Other Federal agencies have been actively and cooperatively pursuing pesticide monitoring activities that are appropriate within their respective laws and mandates, during the last twenty years. Under this monitoring plan, OPP looks to other Federal agencies to continue and increase their pesticide monitoring activities in close cooperation with EPA. EPA will actively work to develop options for coordinating mechanisms. OPP is investigating with other agencies the establishment of a pesticide monitoring policy board to coordinate multi-media pesticide monitoring activities.

2. Priority List of Chemicals

To ensure that the monitoring activites of EPA and other Federal and State agencies, as well as registrants and others, are focused and will yield the most useful information possible, priorities for pesticide monitoring must be developed. Because OPP's first priority is the protection of human health, the highest priority for pesticide monitoring activities is the assessment of direct human exposure. The second priority is monitoring direct environmental routes of human exposure, and the third priority is monitoring indirect evironmental routes of human exposure.

EPA plans to develop lists of potential problem chemicals for monitoring purposes. These lists will be developed from periodic review of existing exposure, product chemistry, and environmental fate data including additional data generated in the implementation of the monitoring plan. In developing these lists, EPA will also give priority to pesticides with which the Agency has health or environmental concerns (i.e., special review chemicals) and pesticides scheduled for reregistration or registration standards. The list will provide guidance for this and other Federal and State agencies and other organizations in focusing future monitoring activities. New data generated and received by EPA will be reviewed and a revised listing compiled annually.

3. Technical Assistance

To ensure the usefulness and quality of pesticide monitoring information generated by other Federal and State agencies, OPP will continue to provide (and may expand its provision of) technical assistance to these and other outside entities. This assistance in planning, performing and evaluating pesticide monitoring studies is available to other agencies upon request.

D. PROVIDE REGISTRANTS GUIDANCE

While EPA has the lead position in coordinating the development of and procuring pesticide exposure and monitoring information, the Agency believes it is appropriate to place the monitoring data generation burden more squarely on pesticide registrants. For prospective exposure data needs on new pesticide chemicals as well as retrospective data needs for existing pesticides, EPA will require pesticide registrants to generate data on specific products under existing FIFRA authorities. OPP will develop monitoring requirements and associated guidance for registrants to ensure that all monitoring undertaken by registrants is properly performed and produces usable data of verifiable quality.

1. Data Requirements

OPP will develop monitoring data requirements and criteria to ensure that adequate exposure information needed for the pesticide regulatory process is generated routinely by pesticide registrants. OPP's current focus is on developing monitoring requirements for applicator exposure and potential ground water contamination.

2. Protocols, Guidelines, GLP's

To ensure that the monitoring data generated externally is of known and acceptable quality, OPP will develop a series of protocols for registrant-sponsored monitoring studies. The protocols will ensure a degree of uniformity

and specificity by providing guidance for the proper design and execution of monitoring studies so that the resulting data can be used by OPP to refine the risk assessments for specific products and uses. This project includes the development of a number of protocols per year, accomplishment of peer review, and limited field or laboratory validation of the protocols.

OPP will also develop and publish monitoring guidelines, and will prepare extensions of existing GLP requirements to establish an audit function.

3. Technical Assistance

To ensure the usefulness and quality of pesticide monitoring information developed by registrants, OPP will provide increased technical assistance to registrants upon request.

E. PROVIDE PUBLIC ACCESS TO INFORMATION

EPA understands that the pesticide monitoring information developed under this Plan will also be useful to other agencies, groups and individuals, and plans to make this information widely available through a variety of mechanisms.

1. Electronic Bulletin Board

As described in Part A. above, this automated listing of ongoing monitoring activities sponsored by Federal and State agencies will encourage data exchange among cooperating organizations and permit easy sharing of information with outside groups.

2. Annual Report

OPP will complete and distribute an annual summary beginning in 1986, of monitoring information generated by EPA

and its cooperators, including the results of human and environmental residue monitoring studies, as well as information on pesticide use patterns and usage, and pesticide incidents. This annual report will describe how the data developed were or will be used to support the Objectives stated in this Monitoring Plan. The report will also describe monitoring activities that are planned for the coming year.

3. Publication in AOAC Journals

Efforts to publish monitoring data through journals sponsored by the Association of Official Analytical Chemists (AOAC) have been initiated by OPP recently and the utilization of this peer-reviewed publishing outlet will be expanded.

4. Updated Monitoring Plan

As noted in the Introduction, the present document is essentially an overview of current pesticide monitoring activities, rather than a long term plan. OPP is working now to ensure that monitoring needs are regularly considered in the process of planning pesticide program activities. As monitoring considerations are integrated into program planning, the annual program and budget planning process will offer the opportunity to identify and plan for longer term monitoring goals which effectively support OPP's regulatory responsibilities and objectives. Thus, OPP expects to develop more long range monitoring plans over the next several years, and to up-date the National Monitoring Plan to reflect such developments as appropriate, and in no event at greater than five year intervals.

SUMMARY OF PART III: Implementation

DATA COLLECTION/GENERATION PROJECTS FOR IMPLEMENTATION UNDER THE NATIONAL MONITORING PLAN FOR PESTICIDES

Project Description	Responsible Party	Regulatory Objectives Supported	Current Status
Electronic Bulletin Board	OPP	Will permit data sharing among Federal/State agencies; promote partnership and piggyback opportunities.	Planning underway in FY85
Automated Data Management	OPP	Will increase accessibility to monitoring data.	Being explored in FY85.
Inventory of Registrant-Imposed Studies	OPP	Will permit tracking and followup on imposed monitoring data requirements.	Planning underway in FY85
Quality Assurance Program	OPP with other ORD	To ensure that montitoring data collected is of known quality and meets needs of EPA and other users.	Funded and ongoing in FY85
Federal Coordination	OPP with Federal agencies	To ensure coordination, cooperation in pesticide monitoring activities.	Planning underway
Priority List of Chemicals	OPP	To help focus efforts of public and private data developers.	Planning underway in FY85
Technical Assistance	OPP	To ensure quality and usefulness of data developed outside EPA; and to share data and expertise with parties outside OPP.	Funded in FY85
Monitoring Guidelines	OPP	To provide guidance to registrants and other outside parties in developing data of known and acceptable quality.	To begin developing in FY85 or later

APPENDIX - Resource Estimates for Current and Planned Monitoring Activities

Not all of the projects listed under each of the Objectives of this plan can be associated with precise resource estimates. However, estimates can be provided for all the listed projects in the aggregate.

The total estimated costs of the projects supporting the National Pesticide Monitoring Plan, are 33.5 FTE's (Full Time Equivalents, which are Agency staff work time commitments i.e. "man years") and $2.91 million in extramural funds for FY 1985. For FY 1986, the estimates are 42.9 FTE's and $5.097 million.

Listed below are a selection of projects for which significant commitments or estimates have been made in terms of extramural funds.

- Joint OPP/ODW Drinking Water Survey - $400K (FY 85), $1,020K (FY 86).
- Ground water vulnerability assessment - OPP/USGS: $342.2K (FY 85), $300K (FY 86)
- Ground water contamination studies - OPP/USGS: $94.4K (FY 85), $300K (FY 86).
- Survey of Urban and Non-Farm Sites - OPP: $331.1K (FY 85), $400K (FY 86).
- Pest Control Efficacy (Vertebrate Pests) - USDI: $60K (FY 85), $60K (FY 86).
- Use Dilution Test (Disinfectants) - Univ. of North Carolina: $70K (FY 85), $70K (FY 86).
- Field Worker Exposure Studies - OPP through NPHAP: $56K (FY 85), $60K (FY 86).
- Health Effects and Special Studies - OPP through NPHAP: $370K (FY 85), $400K (FY 86).
- Protective Clothing and Devices - ORD with OPP support $275K (FY 85), $275K (FY 86).
- Quality Assurance Program - OPP with ORD: $85K (FY 85), $85K (FY 86).
- The FY 85 funding for cooperative enforcement agreements with states, territories and Indian tribes is $8,705,4[illegible]. The FY 85 funding for cooperative Applicator Certification and Training programs is $1,367,500