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REPORT BY THE

Comptroller General

OF THE UNITED STATES

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RELEASED

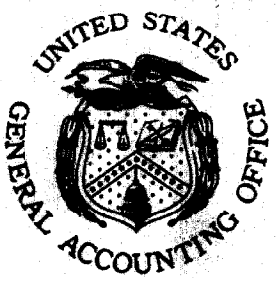
Delays and Unresolved Issues Plague New Pesticide Protection Programs

The Environmental Protection Agency has several new programs to better regulate pesticides--chemicals which provide great benefits but which can threaten man and the environment. The most recent is a 10 to 15-year program to reassess the safety of 35,000 federally registered pesticide products. However, the program, which started in October 1978, is already behind schedule and has many unresolved policy and procedural issues which jeopardize its success.

Another program, begun in 1975, evaluates the risks and benefits of known, potentially hazardous pesticides. While EPA has restricted or canceled uses of some of these pesticides, many remain unevaluated, leaving the public largely unprotected.

Under a third program, EPA and the Food and Drug Administration inspect private safety testing laboratories. EPA needs more legal authority to suspend pesticides not supported by valid safety tests.

GAO is recommending actions to speed up and improve these programs.



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FEBRUARY 15, 1980

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-196815

The Honorable Edward M. Kennedy
Chairman, Committee on the Judiciary SEN02500
and the Subcommittee on Health SEN07102
and Scientific Research
Committee on Labor and Human Resources
United States Senate

Dear Mr. Chairman:

As requested in your September 28, 1978, letter, this report discusses some of the progress and problems with several fairly recent Environmental Protection Agency pesticide regulatory programs.

The report shows that while the two main programs we reviewed--registration standards and rebuttable presumption against registration--have the potential for serving as effective regulatory tools for protecting the public from dangerous pesticides, the programs are hindered by various management deficiencies. Also the Agency needs more legal authority to take action against firms whose pesticides are not supported by valid safety tests.

As agreed with your office, unless you publicly announce its contents earlier, we will not distribute the report to the agencies involved and other interested parties until 30 days after the date of the report.

Sincerely yours,

Comptroller General
of the United States

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COMPTROLLER GENERAL'S REPORT TO THE COMMITTEE ON THE JUDICIARY AND THE SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH, COMMITTEE ON LABOR AND HUMAN RESOURCES UNITED STATES SENATE

DELAYS AND UNRESOLVED ISSUES PLAGUE NEW PESTICIDE PROTECTION PROGRAMS

D I G E S T

The Environmental Protection Agency (EPA) has established several major new programs to better protect the public from hazardous pesticides. GAO reviewed three of these programs--registration standards, rebuttable presumption against registration (evaluating risks and benefits of particular pesticides), and laboratory inspection--and found that improvements are needed if EPA is to assure the public that

--registered pesticides and their associated tolerances (maximum legal amounts of pesticides allowed to remain on food) are reasonably safe and

--hazardous pesticides are promptly identified and evaluated and, if necessary, restricted or banned from public use.

POOR PLANNING JEOPARDIZES EFFECTIVENESS OF REGISTRATION STANDARDS PROGRAM

Registration standards, the most recent and ambitious program, is designed to reassess the safety of the 35,000 pesticide products which the Government has registered over the past three decades. It is a comprehensive and costly effort which could last 15 years.

The program began in October 1978 and is progressing slowly. Also, EPA has not resolved many basic policy and procedural issues which, if not done soon, will jeopardize the program's chance of success. For example, EPA has not (1) developed

operating procedures, (2) set priorities on which pesticides to examine first, and (3) developed sound administrative controls for budgeting and program monitoring.

In addition to serving as the basis for pesticide reregistrations, the registration standards program will be EPA's primary means of reassessing the safety of each of the 6,000 pesticide tolerances the Government has approved during the past 30 years. GAO found, however, that EPA has not determined how it will perform these important reassessments. Additionally, EPA has not yet completed a comprehensive review of its overall tolerance-setting procedures--something it promised to do 4 years ago. Because of these problems, GAO concluded that EPA has a long way to go before it can assure the public that federally approved tolerance levels are reasonably safe. GAO's recommendations on registration standards problems appear in chapter 2. (See p. 23.)

DECISIONS ON HAZARDOUS PESTICIDES ARE NOT TIMELY

While the registration standards program will cover all previously registered pesticides, the rebuttable presumption against registration program concentrates on evaluating the risks and benefits of those pesticides which are suspected of causing serious health or environmental problems. EPA performs this review on a pesticide when tests show it may cause such problems as cancer, mutations, or birth defects.

Since its inception in 1975, the rebuttable presumption program has led to the cancellation of some or all uses of about 20 dangerous pesticides. For example, EPA canceled 19 vegetable crop and 22 home garden uses of DBCP--a pesticide which causes cancer in lab animals and reduced sperm counts in humans.

However, the program is progressing too slowly, and the public may be exposed to hazardous pesticides longer than necessary. For example, the 23 pesticides under review

as of June 1979 were in process an average of 88 weeks--twice as long as EPA predicted. Also, 30 pesticides referred to EPA for possible rebuttable presumption review remained unprocessed from 8 months to over 3 years.

In addition to improving timeliness, EPA can improve program effectiveness by:

--Better analyzing pesticides designated for possible rebuttable presumption review.

--Developing a priority system to review first pesticides suspected of being the most dangerous.

--Developing more accurate information on human exposure to pesticides, including working with the Department of Health, Education, and Welfare's Food and Drug Administration and the Department of Agriculture to better detect pesticide levels in food.

--Explaining fully in its rebuttable presumption reports how EPA determines the economic benefits of continuing a pesticide's use.

GAO's recommendations on these issues are in chapter 3. (See p. 49.)

MORE AUTHORITY NEEDED TO BETTER USE LAB INSPECTION RESULTS

Regulatory decisions under the registration standards and rebuttable presumption programs depend on valid test information concerning a pesticide's safety. In 1977, EPA together with the Food and Drug Administration, started inspecting private labs performing federally required safety tests on pesticides, food additives, and drugs. The agencies determine whether labs follow acceptable procedures so that test results are accurate and reliable.

The inspection program is a positive step toward improving the quality of pesticide safety testing. To make the program more

effective and to better protect the public from potentially dangerous pesticides, EPA should ask the Congress to give it authority to restrict or suspend pesticides not supported by valid safety tests. GAO's recommendations on lab inspections are in chapter 4. (See p. 57.)

AGENCY COMMENTS

EPA agreed with most of GAO's recommendations. Often, EPA said it was making the recommended change or planned to do so soon. It disagreed with GAO's recommendation to have an independent office, responsible to EPA's Administrator, monitor EPA's overall progress in reregistering pesticides and reexamining tolerances. EPA also expressed reservation on GAO's recommendations to issue formal operating procedures describing all phases of its rebuttable presumption against registration program and to require registrants to submit certain safety testing data during rebuttable presumption reviews. Finally, EPA disagreed with GAO's recommendations that it ask the Congress for authority to take appropriate regulatory action on pesticides not supported by valid safety tests. (See app. II.)

GAO continues to believe its recommendations are necessary to improve the effectiveness of pesticide regulation.

The Departments of Health, Education, and Welfare and Agriculture agreed with GAO's recommendations directly affecting them. (See apps. III and IV.)

Contents

ABBREVIATIONS

EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GAO	General Accounting Office
OPP	Office of Pesticide Programs
RPAR	rebuttable presumption against registration
USDA	Department of Agriculture

CHAPTER 1

INTRODUCTION

The United States uses about 1 billion pounds of pesticides annually to control insects, diseases, rodents, weeds, bacteria, and other pests that attack our food and fiber supplies and threaten our health and welfare. Although pesticides are beneficial to agricultural production, public health and sanitation, and protection of natural resources, they are a mixed blessing. If used improperly or without sufficient knowledge of their side effects, pesticides, like other chemicals, can poison; cause cancer, birth defects, and other crippling afflictions; and can harm wildlife and our environment.

PESTICIDE REGULATION

The Environmental Protection Agency (EPA) is the primary regulator of pesticides. Its authority is contained in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 et seq.), as amended and the Federal Food, Drug, and Cosmetic Act (FFDCA) of 1938 (21 U.S.C. 301 et seq.), as amended. Under FIFRA, a pesticide can generally not be sold, shipped, or delivered unless EPA has registered it. FIFRA further provides that EPA can only unconditionally register a pesticide if it determines, among other things, that the pesticide will perform its intended function without, causing "* * *any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."

If a pesticide remains in or on food, FFDCA requires that pesticide manufacturers, or other petitioners, apply to EPA for a tolerance--the maximum residue allowed in or on food for that pesticide. EPA sets tolerances on the basis of data the petitioner submits on the nature, level, and toxicity of a pesticide's residues. This data, which includes the results of tests of the pesticide's effect on laboratory animals such as mice, is similar to the types of data pesticide manufacturers must submit to EPA to register a pesticide.

The task of enforcing tolerances--generally by sampling food--belongs to the Food and Drug Administration (FDA), Department of Health, Education, and Welfare and the Department of Agriculture (USDA). FDA enforces tolerances on general food commodities and USDA handles meat and poultry. Prior to EPA's creation in December 1970, USDA regulated pesticides and FDA granted tolerances.

EPA's Office of Pesticide Programs (OPP) carries out most of the EPA's pesticide regulatory responsibilities. During fiscal year 1979, OPP had a staff of about 620 and a budget of about $40 million.

WHY AND HOW WE PERFORMED THE REVIEW

On September 28, 1978, the Chairman, Subcommittee on Health and Scientific Research, Senate Committee on Labor and Human Resources, asked us to review several pesticide regulatory programs. The review was made because of his interest in the status of EPA's efforts to protect the public from potentially hazardous pesticides. The Chairman was concerned because our 1975 report on Federal pesticide registration (see app. I) and a report of the Subcommittee on Administrative Practice and Procedure, Senate Committee on the Judiciary, disclosed that EPA needed to significantly upgrade its pesticide programs before they could be relied on to protect the public and the environment from exposure to hazardous pesticides.

As agreed with the Chairman's office, our review concentrated on two fairly new pesticide programs--registration standards 1/ and rebuttable presumption against registration (RPAR). The former was designed to thoroughly reevaluate the safety of the estimated 35,000 pesticide products which the Government had registered during the last three decades. The latter, EPA designed to identify certain high-risk pesticides and, after public and industry input, to undertake risk/benefit analyses to determine whether the pesticides identified should be canceled, placed under restricted use, or left alone.

On the registration standards program, we reviewed EPA's planning and its management and administrative controls. We did not review the quality of standards because EPA has not yet completed any.

On the RPAR program, in addition to reviewing planning and management, we concentrated on two pesticides--toxaphene and DBCP--the former because it is widely used and the latter because when we began our review it was the only pesticide for which EPA had completed an RPAR.

1/Until recently the "registration" standards program was called the "generic" standards program. For consistency, we refer to it as the registration standards program.

We also agreed to (1) determine the status of EPA's review of its procedures for approving tolerances, (2) evaluate EPA's efforts to reassess, under the registration standards program, the safety of the estimated 6,000 federally approved tolerances, and (3) examine some broad policy issues associated with EPA's laboratory audit program.

We conducted our review at EPA headquarters in Washington, D.C., where we interviewed numerous officials and examined pertinent legislation and documents. We also talked with officials of the National Institute for Occupational Safety and Health, National Cancer Institute, USDA, FDA, industry, and a public interest group.

CHAPTER 2

LIMITED PROGRESS IN DEVELOPING AN EFFECTIVE REGISTRATION STANDARDS PROGRAM

After several false starts, dating back to 1975, EPA finally began in 1978, a registration standards program to reassess the safety of the 35,000 pesticide products and their accompanying tolerances which the Government had registered (or approved) over the past three decades. The task is not easy. Registration standards will be a long and costly program spanning up to 15 years, involving hundreds of EPA and contractor personnel, and costing as much as $200 million. Although it is too early to predict the program's chances of success, the program is already 5 months behind EPA's schedule and has many other problems which must be corrected if it is to be effective in assuring that only reasonably safe pesticides are used in this country.

EPA is behind schedule primarily because it did not (1) provide its largest contractor with computer programs vital for the timely completion of standards work and (2) develop useful prototype (model) standards before starting full-scale production. While these two factors no longer appear to affect the program's progress, to avoid further delays and to help insure the program's future success, EPA should:

--Develop registration standards operating procedures, including procedures for reassessing tolerances and for dealing with high-risk pesticides, and develop a formal training program to train personnel who will work on developing standards.

--Select the potentially most dangerous pesticides to be reviewed first.

--Finalize legally required registration guidelines.

--Obtain, from the pesticide industry, the results of certain key safety tests required by EPA regulations and become aware of and ultimately have access to, other relevant health and safety test data possessed by industry.

--Obtain public comment on pesticides undergoing standards development.

--Improve its accounting and budgeting for resources and its tracking of pesticides through the complex registration standards program.

--Monitor overall program progress.

In a related matter, EPA has not finished examining the adequacy of its tolerance-setting procedures--something it first promised back in 1975. Until it thoroughly completes this task and tolerance reevaluations under registration standards, EPA cannot assure the public that tolerance levels are reasonably safe.

REGISTRATION STANDARDS--THEIR HISTORY, WHAT THEY ARE, AND HOW THEY WORK

The registration standards program evolved from EPA's early failure to conduct an effective pesticide reregistration program. Under the 1972 FIFRA amendments, EPA was required to reregister, by October 21, 1976, the 35,000 pesticides previously registered by the Department of Agriculture (prior to December 1970) and EPA. Amendments in 1978 reaffirmed the need for the expeditious reregistration of pesticides but deleted the deadline requirement.

During 1975, two EPA officials started reviewing Agency files to determine whether required safety data was present. 1/ In May 1976, EPA formally established a task force to continue this reregistration effort. However, EPA officials mistakenly assumed that most of the data was scientifically valid. Accordingly, reviewers skimmed through the files to determine whether data existed but generally did not review the data's quality.

An EPA official told us that this early attempt was a "rubber stamp" approach to reregistration. He also told us that EPA took this approach because of statutory time constraints and because EPA did not have sufficient resources to conduct a thorough reregistration program.

In August 1976, EPA, because of the criticism it was generating, halted its reregistration program without reregistering any pesticides. A summary of this criticism appeared in a March 1977 EPA report entitled, "FIFRA: Impact on the Industry"

1/Data submitted by pesticide firms during the last three decades to support product registrations.

" * * * Senate hearings, discussions with GAO and FDA concerning the reliability of certain data submitted to FDA, and a subsequent preliminary report of an independent toxicologist on a sample of pesticide data raised serious doubts about (1) the adequacy of the testing [data] in EPA files, and (2) the completeness of the Agency's own review and follow-up. Since then, in December 1976, the staff of the Senate Subcommittee on Administrative Practice and Procedure has issued a report stating that the Agency has, in fact, been negligent in its public duty by not reviewing all data in depth prior to reregistration."

EPA officials met several times in August 1976 to discuss the need for a more comprehensive reregistration program to overcome the deficiencies of the one just terminated. In September 1976, several officials proposed a plan to establish such a program and suggested that a permanent staff of about 60 scientists and program managers have responsibility for it. EPA management endorsed the program but failed to provide the staff to operate it.

In February 1977, pesticide officials presented another reregistration plan to EPA management to be carried out by a staff of about 90 people. This plan was also not implemented, and the reregistration task force operated with a small staff until its demise in July 1978.

EPA began planning for what is now known as the registration standards program in 1977. EPA realized it needed to change its narrowly focused strategy toward reregistration and decided to (1) thoroughly reevaluate all health and safety data in its files and all published literature relating to a pesticide's uses, (2) restructure its reregistration program to concentrate on the estimated 514 active chemical ingredients in pesticides, instead of considering the merits of each of the 35,000 pesticide products separately, and (3) reassess the safety of the estimated 6,000 tolerances on food and feed products which the Government had approved over the last 30 years.

For the remainder of 1977 and until October 1978, when the registration standards program formally began, EPA worked on defining the concept of a registration standard and preparing for the program's start.

Under registration standards, EPA will develop comprehensive regulatory statements, or standards, for each of the 514 active chemical ingredients used in

domestically sold pesticides. Pesticide products generally consist of one or more active ingredients mixed with a number of inert ingredients (such as water or salt). Each standard will state whether the pesticide should be reregistered and the rationale for the decision. For regulatory purposes, standards will group together products containing common active ingredients.

EPA has not decided on the precise legal status of a standard--whether it will be a regulation or something less binding, such as a guideline--or on its format. However, based on draft EPA documents, each standard will likely consist of two major sections--one addressing the pesticide's active ingredient and another addressing the pesticide's formulated products--the products which are sold to the public and which EPA must register.

In the two sections, EPA will indicate:

--Which of the pesticide's uses do not cause unreasonable adverse effects to man and the environment.

--Why EPA decided to reregister the product, with or without restrictions, or ban its use.

--Whether the safety data supporting the pesticide is valid and complete and whether data gaps exist which must be filled by pesticide firms before EPA will unconditionally reregister a product.

--Whether existing tolerances for the pesticide's uses on food or feed crops are justifiable or should be changed.

--What labels should appear on the pesticide.

EPA's Office of Pesticide Programs is responsible for developing the standards. OPP plans to use substantial contractor assistance to augment its own staff. The program is expected to last 10 to 15 years and may cost up to $200 million. 1/

1/EPA has not estimated formally the total cost of developing 514 standards. However, we made our $200 million estimate on the basis of available information.

According to EPA plans, each standard will be developed in five phases and will take an average of 14 months to complete. The phases are:

--Phase 1: data gathering and preparation--EPA will gather data relating to the registrability of the pesticide from its own files, published literature and other sources, and sort the data by scientific discipline, including toxicology, residue and product chemistry, environmental fate, and ecological effects.

--Phase 2: disciplinary review--EPA will review and validate each study gathered during phase 1, consolidate the results of individual reviews, and prepare a comprehensive assessment of the pesticide's characteristics.

--Phase 3: identifying options--EPA will determine whether the currently registered uses of an existing pesticide or the proposed uses of a new one meet the legal standard of no unreasonable adverse effect.

--Phase 4: drafting standard--For each pesticide product, EPA will select preliminary regulatory options, such as allowing unrestricted use, restricting or banning use, or changing labels and publish a draft standard in the Federal Register for public comment.

--Phase 5: final standard--EPA will evaluate public comment, make the necessary changes, and issue a final standard.

According to EPA officials, important health and safety studies for many of the registration standards pesticides are missing, precluding EPA from developing final registration standards and from unconditionally reregistering all pesticides. Therefore, EPA plans to issue interim registration standards on many pesticides and plans to direct the applicable pesticide firms to fill data gaps by locating or performing required studies and submitting them to EPA for review.

The 1978 FIFRA amendments allow EPA, under certain circumstances, to conditionally amend the registration of previously registered products and to conditionally register new pesticide products. In May 1979, EPA issued an interim final regulation in the Federal Register permitting certain types of conditional registration if pesticide firms prove

that their products will not significantly increase risks to man or the environment. The regulation stated that conditional registration will apply at least until a final registration standard for a particular pesticide is published.

The registration standards program is related to but conceptually different from another EPA regulatory process--rebuttable presumption against registration (RPAR). During RPAR, EPA examines the risks and benefits from the use of high-risk pesticides. (See ch. 3.) These pesticides are presumed to pose risks to man or the environment because health and safety tests show that the pesticides meet or exceed risk criteria listed in EPA regulations.

Registration standards, on the other hand, presume the products containing a particular pesticide chemical are reregistrable. Also, under registration standards EPA will review all uses and associated risks of a chemical not just those which meet the RPAR criteria. Further, unlike RPAR, under registration standards EPA (1) will look at uses not posing special risk to determine appropriate incremental risk reduction measures, such as labeling changes, use restrictions, or special packaging and (2) will not thoroughly review the benefits of a pesticide's uses.

STANDARDS DEVELOPMENT IS ALREADY BEHIND SCHEDULE

As of September 1979, EPA was already 5 months behind schedule in developing the first group of registration standards. Delays cost money and prevent EPA from reaching timely conclusions on the safety of previously registered pesticides. As a result, the public may be exposed to hazardous pesticides longer than necessary.

On October 1, 1978, EPA began working on four registration standards a month. At this rate, and with the average standard expected to take 14 months to complete, EPA estimated in its fiscal year 1980 budget request to the Congress that it would complete 47 standards during fiscal year 1980. Recently, however, EPA told us that, because of startup problems, EPA will only complete 7 to 14 standards during fiscal year 1980--a significant decline over the earlier estimate.

EPA has not formally analyzed the causes for the current delays. We believe that aside from normal startup problems, the delays resulted primarily because EPA did not (1) provide its largest registration standards contractor

with computer programs vital for the timely completion of phase 1 work and (2) develop realistic prototype registration standards before starting full-scale production.

Perfected computer programs are not available

The first phase of registration standards--data gathering and indexing and cataloging--began on October 1, 1978. Work on the remaining phases generally cannot begin until this phase is completed. Two contractors are performing most of the phase 1 work: Raven Systems and Research, Inc., Washington, D.C., and Franklin Institute, Philadelphia, Pennsylvania. Raven has the largest standards contract--$8.2 million over 2 years--and is responsible for delivering to EPA, within 90 days of the start of work on a particular standard, indexed copies of all test data. 1/ The data includes all health and safety studies collected by Raven from EPA registration files and pertinent published literature collected by Franklin Institute from worldwide sources.

According to its contract with Raven, EPA was to develop a series of computer programs for Raven to use to expedite the indexing and cataloging of data collected by Raven and Franklin Insititute. However, EPA did not complete the computer programs until the summer of 1979, leaving Raven to index and catalog data manually. This, in part, resulted in Raven only completing 10 of the 32 data packages scheduled for completion by August 31, 1979.

EPA and Raven officials agreed that not having the computer programs was a primary reason for the delays. Other reasons cited included normal startup problems, inadequate EPA guidance to Raven, and delays in awarding the Franklin Institute contract. An EPA official stated that because Raven's contract is a cost plus fee type, the delays caused EPA to waste an undeterminable amount of money.

Inadequate prototype used

Another major cause for the delays was EPA's inadequate use of prototype (or model) standards. EPA could have perfected computer programs and gained valuable experience developing registration standards if it had developed prototypes before full-scale production began.

1/The contract also requires Raven to perform some services not directly related to the registration standards program.

In December 1977, EPA began work on a prototype registration standard for the chemical metolachlor--a relatively new and limited-use herbicide. However, the procedures EPA used on metolachlor were different than those for chemicals undergoing typical registration standards development. For example, unlike the standards to be developed after October 1978, EPA personnel performed most of the work on metolachlor, including manually indexing and cataloging the data. EPA officials stated it was poor planning to start full-scale registration standards development without several meaningful prototypes and without perfected computer programs.

A better approach would have been for EPA to work on several prototypes using contractor assistance and computer programs. This would have given EPA experience working with a contractor and a chance to refine and perfect its computer programs as well as its overall registration standards operating procedures.

NEED TO STRENGTHEN OVERALL PROGRAM MANAGEMENT AND RESOLVE POLICY AND PROCEDURAL ISSUES

To avoid additional setbacks and to improve the program's chance of success, EPA needs to strengthen its overall management of the program by establishing uniform operating procedures, resolving a number of policy and procedural issues, and improving administrative controls. Without such improvements, EPA will jeopardize its chance to develop registration standards on all 514 active ingredients efficiently and effectively.

Need to establish operating procedures and integrate with RPAR

Registration standards will be a long, complex, and costly program. To assure that it operates efficiently and that standards are developed consistently, EPA should have a formal operating manual covering all phases of work, including how standards will interface with the Agency's RPAR program--EPA's main program for regulating pesticides identified as being hazardous. (See ch. 3.) Currently, there is no operating manual for the registration standards program.

OPP has about 15 branches which work on registration standards. Although a few branches have documents which partially explain what they do in the early phases of the program, there is no overall operating manual which

describes, from start to finish, how a standard will be developed.

The need for operating procedures is illustrated by a statement an OPP official made. He told us his branch received a considerable amount of information--data packages--from contractors but his branch did not know what to do with it.

To prepare a registration standards operating manual, EPA needs to clarify the relationship between registration standards and the RPAR process. Registration standards reviewers will likely find that some of the risks associated with the 514 standards pesticides meet or exceed the risk criteria for starting RPAR reviews.

During March 1979, we discussed with EPA pesticide officials the need for a formal registration standards operating manual, including integration of the RPAR and registration standards programs and the need to resolve some of the other issues described in this chapter. Also, on April 17, 1979, we sent a letter to EPA's Assistant Administrator for Pesticides and Toxic Substances outlining many of our concerns.

In a May 2, 1979, letter of response, the Assistant Administrator agreed that,

> "* * *an operating plan and procedures spelling out the roles of the various divisions within the Office of Pesticide Programs (OPP) and clearly identifying lines of authority are essential to the construction of a sound program."

He said that, in April 1979, OPP established a special registration standards task force to, among other things, develop an operations manual for the registration standards program and to define the precise relationship between the development of registration standards and the RPAR process.

In September 1979, the head of the task force told us that an overall operating manual still did not exist. He added that his staff was developing procedures for phase 2 of the registration standards program and that once these are completed the staff will work on procedures for the other phases. He also commented that the task force has not made much progress coordinating the standards program with the RPAR process. In its December 1979, comments to our draft report, EPA told us that a complete operating manual will not be available for another 6 to 8 months. (EPA's comments on registration standards are in part I of App. II.)

Going hand in hand with a need for operating procedures is a need for training. Our talks with various officials in OPP pesticide branches involved with registration standards indicated that often they were unfamiliar with the program's objectives and procedures. They told us that they had received little or no formal training on registration standards.

In our April 1979 letter, we told the Assistant Administrator of the need for a formal registration standards training program. He replied that some EPA pesticide staff members had received informal training on the history and status of the registration standards program and on some of the procedures to be followed during the program's early phases. He added that the recently established registration standards task force will schedule additional training as necessary.

In September 1979, a task force member told us that EPA still did not have a registration standards training program. Another pesticide official told us that training was desperately needed. He suggested that as soon as EPA develops operating procedures for the program it should hold training sessions to insure that the staff understands and follows the procedures.

Need to prioritize pesticides

Over the next 10 to 15 years, EPA will select about 48 chemicals annually for registration standards development. To minimize public risk, EPA should rank pesticides in order of their potential risk, taking into account such factors as a chemical's toxicity and public and environmental exposure. However, EPA does not have a system for selecting future chemicals for registration standards review.

During the summer of 1978, EPA officials selected the first 42 pesticides to be reviewed in the registration standards program. These pesticides, along with several others, represented EPA's fiscal year 1979 workload.

In selecting the pesticides, the officials scanned all 514 pesticide active ingredients and intentionally excluded most widely used pesticides and all pesticides RPAR identified as posing high risks to man or the environment. According to one of the officials, EPA then tried to select a variety of pesticides based on such factors as extent of the pesticide's use, type of pesticide, and the pesticide's manu-

facturer. Another official told us that these 42 chemicals were chosen because developing registration standards for them would be relatively easy.

EPA has not yet decided which pesticides to review over the next few years. To help make the selections, OPP plans to develop a registration standards priority system. In December 1979, EPA said that it plans to complete the system in 1980.

Need to finalize registration guidelines

During registration standards reviews, EPA will use published registration guidelines as the criteria for determining whether testing data supports reregistration of a pesticide. However, because these guidelines have not been issued in final, EPA is not assured of having uniform criteria to evaluate the data applicable to each of the 514 registration standards pesticides.

In July 1975, EPA published regulations in the Federal Register establishing basic pesticide product registration requirements. In June 1975, EPA also published proposed registration guidelines. 1/ The guidelines, which have been under development since 1969, are intended to further describe the kinds of data which pesticide firms must submit to register a product. The guidelines include sections on human and domestic animal hazard evaluation, chemistry, and product performance and labels. The 1972 FIFRA amendments require both the regulations and the guidelines.

Responding to public and internal comments, EPA decided to revise the proposed guidelines so that they could better explain how pesticide firms are to comply with the 1975 regulations. EPA reproposed various sections in July and August 1978 and in September 1979 and plans to repropose others soon.

An EPA scientist told us that the proposed guidelines could pose a serious problem because it is difficult to use changing criteria to evaluate large amounts of data. Another official stated that EPA should place a high priority on finalizing the guidelines so that EPA can have uniform evaluation criteria for registration standards reviews.

1/One section of the guidelines was issued in final during 1975 but, according to EPA officials, is now obsolete and must be revised.

Need to call in key safety data

Under registration standards, EPA plans to review a variety of safety testing data to determine whether a pesticide poses unreasonable risks. However, according to EPA officials, key tests required under current EPA regulations have not been performed for many of the 514 registration standards pesticides. Included are long-term (up to 3 years) animal feeding studies which show whether a pesticide causes chronic effects, such as cancer or birth defects, in animals. An official told us that EPA needs the results of these tests to make even preliminary decisions concerning a pesticide's safety and whether it should be reregistered.

The need for a program requiring registrants to perform missing safety tests and submit results to EPA is not new. Our 1975 report concluded that safety testing is missing for many pesticides to which people are exposed. We recommended that EPA identify and notify registrants of the pesticides and cancel registrations when the data is not submitted within a reasonable time.

EPA agreed. As part of its unsuccessful early attempt to reregister pesticides, EPA issued in February 1976 a call-in notice in the Federal Register categorizing active ingredients according to adequacy of existing data and listing a schedule for new data submission. However, that reregistration effort was halted in August 1976 because of widespread criticism by us, the Congress, and others concerning the thoroughness of EPA's review of safety data.

In our April 17, 1979, letter to the Assistant Administrator, we pointed out that a program requiring registrants to perform key safety tests and submit the results to EPA would help the Agency make more timely final decisions concerning the registrability of a pesticide. In his May 2, 1979, reply, the Assistant Administrator stated he agreed that such a program was essential. He stated that late in 1978 he decided to develop such a program and, since then, EPA has explored options for implementation. In December 1979, EPA told us that the program has not yet been implemented.

Need to identify and have access to all safety- and health-related data

To assure that registration standards reviews are thorough and comprehensive, EPA should be aware of, and ultimately have access to, all health and safety studies --published and unpublished--for a particular pesticide.

This includes studies required by Federal regulations and those performed for other reasons. However, EPA has not asked registrants to submit a list of all health and safety studies in their possession so that EPA could review the lists and identify and request copies of studies not in its files but considered desirable to determine if a pesticide should be reregistered.

During the first phase of the standards process, EPA collects all the data in its files relating to the health and safety of a pesticide. EPA file data includes unpublished tests submitted to the Government over the years to support either original or amended pesticide registrations (including tolerance approvals). EPA officials believe, however, that pesticide manufacturers may have health- and safety-related studies which EPA is not aware of but which would help it to decide whether to reregister a pesticide under registration standards.

We did not question pesticide manufacturers to determine whether more data exists. However, an official of a large pesticide firm told us that to meet the regulatory requirements of a foreign nation, his firm performed a study on the chronic effects of one of its domestically sold products. The test was not submitted to EPA. The official stated that EPA does not require the test to register the pesticide. He stated that the study corroborated the conclusions of health studies already submitted to EPA which showed that the pesticide does not pose any adverse effects to man or the environment. Also, his firm does not plan to submit the test results to EPA.

EPA scientists told us that scientists do not always agree on the significance of certain health and safety tests. Because of this disagreement and because they wanted to perform thorough registration standards reviews, they stated EPA should be aware of all health- and safety-related tests and be able to obtain from pesticide firms copies of tests which EPA does not have but which are relevant to pesticide reregistration decisions. The scientists also said that having too many tests to review during the standards process was not a problem.

In commenting on our draft report in December 1979, EPA said that from a scientific standpoint it agreed that it should know about all studies on a pesticide in a registrant's possession, whether or not the studies are required under EPA registration guidelines. However, from a legal standpoint EPA questioned whether FIFRA gives EPA authority to require registrants to submit all health and safety studies for the registration standards process.

Need to obtain public comment

In a December 11, 1978, speech before a conference on pesticides and human health, the Assistant Administrator for Pesticides and Toxic Substances stated that one of the benefits of the registration standards program is that it will allow "full public participation by inviting public comment and information prior to the development of a generic [registration] standard."

In our draft report we suggested that EPA publish a Federal Register notice inviting public comment on the program's objectives and procedures. On December 25, 1979, over a year after the program began, EPA published an advance notice of proposed rulemaking on the registration standards program. The notice described the program's objectives, the proposed organization of a standard, and how standards will be developed. While the notice invited public comment on various important but unresolved program issues, it did not invite the public to comment on and submit health and safety data for the many pesticides that have entered or will soon enter the registration standards program. In January 1980, an OPP official said EPA plans to issue a notice inviting comment on individual pesticides.

Need to better budget and account for program costs

To determine whether major Government programs are operating efficiently, program managers, the Congress, and the public need to know what resources are budgeted and actually spent. This is crucial for a program like registration standards, which affects public health and which has a multimillion dollar price tag. However, EPA does not accurately budget and account for the resources--in dollars or staff-years--directly associated with the development of an individual registration standard or the overall standards program.

Part of the problem is that pesticide project managers were not required to, and did not, prepare budgets projecting resources required to prepare a standard. Also, EPA's payroll system did not require employees to allocate their time by program area or by parts of a program, such as an individual registration standard. As a result, EPA officials could not tell us how much money and staff time it spent on individual registration standards or on the overall registration standards program.

In our April 1979 letter to the Assistant Administrator, we pointed out that OPP did not keep track of the time EPA

personnel spend working on registration standards. In October 1979, in what we believe is a step toward improving its accounting for program costs, OPP began requiring its employees to record the time they spend on individual tasks, such as developing a registration standard.

We also, however, found problems with EPA's budgeting for the overall registration standards program. For example, OPP's budget for the first half of fiscal year 1979 showed that one technical support division would spend about $2.6 million out of the program's total 6-month budget of $9.2 million. The division performs various technical support services, such as economic benefit analyses, for several pesticide programs. However, a registration standards official told us that this division's role in developing individual standards is minor. Therefore, we asked a top EPA pesticide official why so much of the program's budget--28 percent--was allocated to that support division. He did not know, but stated that much of the $2.6 million might have been spent on another pesticide program--RPAR. He and other pesticide officials stated that EPA should improve its budgeting for the registration standards program.

Need to establish a tracking system

Because the registration standards program is very complex, EPA needs a uniform tracking system capable of (1) quickly pinpointing the location of a pesticide within the program and (2) determining whether work is progressing on time. EPA does not have such a system. The need for a good tracking system will become even more apparent as additional chemicals enter the different phases of the registration standards process.

While EPA does maintain records of some registration standards' milestones, it does not have a uniform system which shows whether critical registration standards' tasks are being performed on time by either EPA staff or contractors. For example, as of May 1, 1979, 28 chemicals had started the standards process. For each chemical the primary phase 1 contractor--Raven Research, Inc.--was to have provided EPA with various sets of data, with deliveries to be staggered over 90-day periods. We asked EPA and Raven for a list showing scheduled and actual delivery dates of the sets of data for each of the 28 chemicals. An EPA and a Raven official stated that this information was not readily available. The officials added that EPA had not required Raven to report this information. More recently, the Raven official said that EPA had asked his company to develop better status reporting procedures and that Raven was developing them.

In December 1979, EPA told us that it clearly needed a registration standards tracking system and was developing one.

EPA IS NOT PREPARED TO REASSESS TOLERANCES UNDER REGISTRATION STANDARDS

In addition to serving as the basis for the reregistration of pesticides, the registration standards program will be the primary vehicle to reassess the safety of about 6,000 existing tolerances on food and feed products. While the standards program is over a year old, no formal procedures for reassessing individual tolerances exist. In addition, a comprehensive review of EPA tolerance-setting procedures, started by EPA in 1977, is still incomplete. As a result of these problems, EPA is not adequately prepared to reevaluate existing tolerances under registration standards.

Our 1975 report to the Congress stated that the public is exposed daily to many pesticides which are not supported by animal and environmental safety studies. The situation has not improved. During our current review, an EPA pesticide official told us that the basis for many tolerances granted by the Food and Drug Administration is still obscure. According to the official, little, if any, documentation exists explaining how or why these tolerances were granted. Additionally, the Assistant Administrator for Pesticides and Toxic Substances stated that not much difference exists between the present condition of EPA's test data files and those that existed at the time of our 1975 report.

In our April 17, 1979, letter to the Assistant Administrator, we stressed the need for EPA to develop a formal plan and procedures which outline, step by step, how tolerance reassessments will be performed under the registration standards program. In his May 2, 1979, reply, the Assistant Administrator agreed that tolerance reassessment procedures must be completed. He also stated that EPA had asked its Science Advisory Board 1/ to study the scientific foundation of the tolerance-setting program. He added that the Board's review, which was requested in April 1977 and is expected to be completed in early 1980, is a "preliminary and fundamental step in the reassessment of existing, individual tolerances."

1/The Board is an advisory body within EPA that provides independent scientific and technical advice to the Administrator.

The Board's tolerance program review, which may have an important effect on individual tolerance reevaluation, should have been completed sooner. As early as September 1975, EPA told us that it would conduct a comprehensive scientific review of the tolerance-setting procedures. However, EPA did not formally start the review until 19 months later, when it requested the Board's assistance. EPA originally intended that its pesticide office review the tolerance-setting procedures. Although EPA pesticide officials began to examine certain issues in 1975, no group was formally organized for this purpose. This informal effort resulted in a document which described how the tolerance system operated but did not evaluate it.

In its 1977 request to the Board, EPA asked for a scientific review of all the tolerance-setting procedures and specified some areas of particular interest. However, this request did not mention suggested reporting timeframes, nor did EPA subsequently develop formal reporting agreements concerning the review's scope or target completion dates. Almost 1 year after requesting the Board's assistance, EPA was unable to tell a House subcommittee when the tolerance review would be completed. For a review as important and as complicated as this, formal reporting agreements could have helped assure that the Board's examination was appropriately directed and was proceeding as rapidly as possible.

Although the Board's final report is expected soon, EPA will still not have completed a comprehensive review of the tolerance-setting program. After reviewing the report, EPA will need time to examine the recommendations and determine whether or not to implement them. One EPA pesticide official stated that it could take over 2 years before the Board's recommendations, if accepted, will actually change existing procedures.

EPA should also examine issues not included in the Board's evaluation in order to complete a thorough review of tolerance-setting procedures. Although the Board's review covered many important aspects of the tolerance program, it did not examine all issues--particularly those dealing with policy or legal matters. For example, the Board did not fully evaluate and take clear positions on such issues as:

--How to regulate tolerances for pesticides suspected of causing cancer or mutations.

--Whether financial benefits, as well as health implications, should be explicitly considered when reviewing a tolerance application.

--The need for emergency tolerance revocation procedures similar to FIFRA's registration suspension authority.

EPA SHOULD MONITOR THE OVERALL PROGRESS OF THE REGISTRATION STANDARDS PROGRAM

The public has much at stake in the registration standards program's success. Aside from the large resource investment needed to complete 514 standards, EPA plans to combine the current RPAR process with registration standards and give the latter responsibility for eliminating unreasonably hazardous pesticides. Because of this and the problems we noted in EPA's earlier reregistration efforts and its current registration standards development, EPA should have an independent office monitor the program's progress and, when necessary, recommend changes and improvements. EPA's recently established Office of Inspector General, an independent office responsible to the Administrator, could perform this function.

We found that, even within OPP, no group or individual monitored the program's overall progress and identified early many of the problems we uncovered. For example, as mentioned earlier, EPA pesticide officials had not investigated the cause of the 5-month delay in the first group of registration standards pesticides.

Aside from monitoring the program's overall progress, the assigned office should reassess EPA's heavy reliance on contractor assistance. According to OPP officials, contractors will perform about one-half of the work needed to develop the 514 standards. They also stated that using contractors generally costs much more than using EPA staff.

OPP officials said that contractors are being used on registration standards because EPA does not have sufficient staff to perform all the work internally. The officials added however, that they did not analyze the costs and benefits of using contractor staff vis-a-vis EPA staff.

CONCLUSIONS

The public is exposed daily to many of the 35,000 federally registered pesticides. They are in our food, air, and drinking water. While pesticides provide great benefits, they present potential risks to man and the environment. With registration standards, EPA can, for the first time, comprehensively evaluate the safety of all previously registered pesticides and all previously granted tolerances. However, the program is already behind schedule. More importantly,

there are many other problems which, if not corrected soon, may cause additional delays and will jeopardize the program's efficiency and effectiveness.

While the primary causes of the program's 5-month delay--inadequate computer programs and prototype standards--apparently no longer present problems, EPA does not have a tracking system to help minimize or avoid future setbacks. A tracking system would help EPA monitor planned and actual progress of pesticides passing through the complex registration standards program and help EPA identify delays so management could take prompt corrective action.

Next, formal operating procedures on how to prepare a standard from start to finish are needed. Without a comprehensive procedures manual, EPA may not be able to develop uniformally sound standards within reasonable times. Because EPA is combining the RPAR program with the registration standards program, the procedures manual should also indicate how registration standards reviewers should handle high-risk pesticides. Also, because of the program's size and complexity, EPA needs to develop a registration standards training program.

EPA also has not prioritized the 514 registration standards pesticides so that those which may pose the greatest risk to man and the environment are reviewed first. EPA needs such a system because it can not work concurrently on all 514 pesticides.

Another problem concerns the registration guidelines which EPA is using as criteria to evaluate the validity of health and safety data. The guidelines are only proposed and are subject to change. The sooner EPA finalizes them, the sooner it will have uniform criteria to compare the mass of testing data which it must evaluate during the next 10 to 15 years.

Further, EPA may have difficulty making even preliminary decisions concerning whether to reregister certain pesticides because key long-term health and safety tests have not been performed for many of the 514 pesticides. Although EPA agrees that it should require registrants to develop and submit key data, it has not yet done this.

To do thorough registration standards reviews, EPA scientists should be aware of, and have access to, all health and safety tests in industry possession, even those not required under current EPA regulations. By requiring registrants to submit a list of all the health and safety studies they have for registration standards pesticide, EPA could

identify tests it does not have but which it feels it needs to determine whether to reregister a pesticide. EPA has also been remiss in not soliciting public comment on pesticides that are under standards development.

Next, EPA's budgeting and accounting procedures do not adequately show what resources are budgeted for, and actually spent on, the registration standards program. This is crucial for a program as big and important as registration standards.

Also, EPA is unprepared under the registration standards program to reassess the safety of the estimated 6,000 federally approved tolerances. Although EPA acknowledged the importance of these reassessments, it has not yet developed procedures to do them. Additionally, EPA has not completed another important prerequisite for tolerance reassessments--a thorough review of its tolerance-setting procedures. While the Science Advisory Board has reviewed certain aspects of tolerance setting, important program issues have not been thoroughly reviewed. Until EPA completes a thorough review of its tolerance procedures and develops and implements procedures for reassessing individual tolerances, it cannot assure the public that federally approved tolerance levels are reasonably safe.

Finally, EPA has not adequately monitored the overall progress of the registration standards program. If it did it could have anticipated many of the above problems and could have made better progress at resolving them. Because of problems with past and present EPA reregistration efforts, another office, outside of the Assistant Administrator for Pesticides and Toxic Substances, should do the monitoring.

As part of this overall monitoring, EPA should reevaluate its de facto decision to rely heavily on contractors for the registration standards program. By examining the costs and benefits of using contractors, EPA would be in a better position to determine whether its current approach is the most effective and efficient.

RECOMMENDATIONS

To help insure that the registration standards program is successful, we recommend that the Administrator, EPA:

--Establish written operating procedures for all phases of registration standards development. The procedures should also (1) state how to handle RPAR pesticides, (2) state how to reassess the safety of existing tolerances,

(3) require registration standards program managers to prepare budgets projecting the resources, in dollars and staff-years, needed to complete a standard and to periodically determine the reason for significant differences between resources budgeted and spent, and (4) require the Office of Pesticide Programs to more accurately budget and account for the resources spent on the overall registration standards program. After developing formal operating procedures, a training program for all staff working on standards' development should also be developed.

--Rank the 514 registration standards pesticides in order of their potential risk to man and the environment and concentrate on developing standards first for those pesticides ranking highest.

--Promptly finalize the proposed reregistration guidelines.

--Identify key health and safety tests which are required by EPA regulation and which are necessary to make even preliminary registration decisions, require registrants to submit missing tests within reasonable time, and cancel registrations of firms not complying.

--Require that each registrant submit a list of all (published and unpublished) health and safety tests it has for each registration standard pesticide, and have EPA scientists review the lists to identify and request that registrants submit copies of those tests which EPA needs to complete a standard. If EPA believes it needs additional legal authority to do this, it should submit a FIFRA amendment to the Congress.

--Publish a Federal Register notice inviting public comment on pesticides undergoing standards development.

--Develop a tracking system to monitor the status of a pesticide as it goes through the registration standards system and institute procedures to identify and alleviate obstacles which seriously impede progress.

--Have an independent office, responsible to the Administrator, monitor EPA's overall progress in

reregistering pesticides and reexamining tolerances and, when necessary, recommend improvements. The office should also examine the costs and benefits of using contractors for standards work.

To help insure that EPA only approves tolerances that are reasonably safe, we recommend that the Administrator, EPA, promptly:

--Review the Science Advisory Board's recommendations on the adequacy of EPA's tolerance-setting procedures and implement accepted recommendations.

--Reevaluate those tolerance-setting issues and procedures not reevaluated by the Board.

AGENCY COMMENTS AND OUR EVALUATION

We sent a draft of this report for comment to EPA, the Departments of Health, Education, and Welfare and Agriculture. (See apps. II, III, and IV.) This chapter's recommendations are addressed to EPA only. EPA agreed with most of our recommendations. It stated that in many cases it is in the process of making the recommended change or planned to do so soon.

EPA disagreed with our conclusion that it does not accurately budget and account for resources associated with individual registration standards and the overall standards program. EPA stated that because it had not completed any standards, it formulated estimated budgeted costs from a detailed, systematic budgeting process and historical budgeting experiences in other pesticide programs.

We recognize that it is difficult for an agency to estimate the future costs of a new program. However, our concern lies deeper than that. EPA officials did not know how much money and staff time it was spending on individual standards, some of which were in process for over 6 months, or on the entire program. Without such data, EPA and others will not know whether the program has been run efficiently.

EPA commented that we did not sufficiently recognize its "time accounting information system" which according to EPA, "* * *was developed largely to capture accurate data on the costs of the registration standards program for budgeting and planning purposes." As stated earlier in the

chapter, the system should enable EPA to improve its accounting for program costs. However, it began in October 1979--too late for us to review in detail.

EPA disagreed with our recommendation that an independent office, responsible to the Administrator, monitor the registration standards program's progress. EPA believes that there is already ample means--through existing organizational review levels--for the Administrator to assess the progress of the registration standards program.

We continue to believe, however, that an independent office can perform this function better. EPA's recently established Office of Inspector General could provide the Administrator with a more impartial assessment of progress and problems with EPA's reregistration efforts and when necessary, recommend changes and improvements.

EPA also disagreed with our recommendation that it examine the costs and benefits of using contractors on registration standards work. EPA commented that its "current mix of contractor and in-house resources can only be finally evaluated after several years of experience, although current performance is quite promising." We continue to believe that EPA should examine the costs and benefits of relying on contractors to perform standards work. We are mindful of the fact that the program is of long duration--10 to 15 years--and will require significant Federal expenditures--as much as $200 million. We believe that until EPA performs such a study it will not be in a position to determine whether its present strategy is the most efficient and effective.

Finally, EPA shared our concern for the prompt completion of the Science Advisory Board's review of tolerance procedures. EPA said that in anticipation of the Board's final report, which should be ready soon, EPA is preparing a plan for implementing the Board's recommendations and determining how individual tolerance reassessments will fit in the registration standards program.

EPA did not, however, fully respond to our recommendation that it reevaluate tolerance issues and procedures not evaluated by the Board. Instead, EPA summarized its position on each of the three examples of tolerance policy issues which the Board did not thoroughly review and resolve. EPA's comments did not indicate whether these positions were reached as part of a comprehensive evaluation of the tolerance-setting program or on an ad hoc basis. Therefore, we continue to believe that upon completion of the Board's review, EPA should determine which science, policy, or

legal issues on tolerances have not been thoroughly evaluated. Outstanding issues should be reviewed, preferably by an independent group of experts.

CHAPTER 3

RPAR--A GOOD CONCEPT WHICH CAN BE MADE MORE EFFECTIVE

EPA's rebuttable presumption against registration program is designed to quickly and comprehensively weigh the risks and benefits of potentially hazardous pesticides to determine if regulatory action is necessary to protect the public and the environment. While RPAR is a complex process, it can be an effective method for making difficult pesticide regulatory decisions. Since its inception in late 1975, RPAR has allowed EPA to cancel some or all uses of about 20 dangerous pesticides. EPA, however, has not completed RPAR reviews of individual pesticides on time.

While timeliness is a major problem, we identified these four other deficiencies which hinder program effectiveness:

--EPA does not quickly and thoroughly review pesticides referred to the RPAR program.

--EPA does not determine which pesticides undergoing RPAR review are the most hazardous and should be reviewed first.

--EPA does not always have enough accurate, actual test and monitoring data on an important component of RPAR risk assessments--exposure analyses.

--EPA benefits estimates may mislead Agency decisionmakers and the public because the estimates are not as precise as they appear to be.

RPAR--ITS EVOLUTION, HOW IT WORKS, AND ITS ACCOMPLISHMENTS

The 1972 amendments to FIFRA require EPA to insure stricter human health and environmental protection from pesticides, including the reregistration of all pesticides to insure they meet new safety requirements. Because EPA's reregistration program--registration standards--only began recently, its pesticide review has centered on another program--rebuttable presumption against registration. During RPAR, EPA weighs the risks and benefits of pesticides (active ingredients) suspected of posing danger to the public or environment and decides whether to take regulatory action.

The RPAR program resulted from growing public concern over pesticides safety. RPAR began in December 1975 when EPA's Administrator established a separate office (now a division) within the Office of Pesticide Programs to implement the new procedure. The new office developed a list of 45 RPAR pesticides. The list combined recommendations from several sources, including the Mrak Commission on Pesticides (Department of Health, Education, and Welfare, 1969) 1/ and a special EPA group which reviewed suspected hazardous pesticides.

A pesticide must meet certain "risk criteria" before it enters the RPAR process. These criteria (40 CFR 162.11) include short- and long-term risk levels (whether a pesticide causes cancer, mutations, birth defects, etc.) and whether an emergency treatment exists for those exposed to the pesticide. If EPA determines that a pesticide meets at least one of these criteria, it publishes a Federal Register RPAR notice. Registrants who wish to maintain registration of an existing pesticide or applicants who wish to register the pesticide can then submit evidence rebutting the presumption. Rebuttals can be based on proof that actual exposure to the pesticide does not cause the effects described, or that the study (or studies) supporting the presumption is not valid.

If the risk presumption is rebutted, EPA terminates the process and does not take regulatory action against the pesticide in question. If the presumption is not rebutted, EPA develops and gathers risk and benefit evidence for the RPAR pesticide. EPA uses this information for risk and benefit analyses. From these analyses, EPA develops various methods (regulatory options) to reduce the pesticide's risk and then analyzes their costs. One, or several, of the options becomes the RPAR decision, when approved by EPA's Administrator. The decision can be cancellation, restricted use or unrestricted use. Affected parties may appeal the decision through EPA's administrative hearing process, and then, if not satisfied, through the Federal court system.

Each of OPP's six divisions is involved in some part of the RPAR process. OPP assigns a project manager and a a team of scientists and economists from these divisions

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1/The Mrak Commission, officially the "Secretary's Commission on Pesticides and Their Relationship to Environmental Health," conducted a comprehensive literature review and an assessment of the environmental and human health implications of a number of pesticides.

to each RPAR review. Other participants include the Departments of Agriculture and the Interior, the Food and Drug Adminstration, EPA's Science Advisory Panel and Cancer Assessment Group, the pesticide industry, environmental groups, and the public.

The RPAR program has made progress toward removing some hazardous pesticides from the environment. As of December 5, 1979, EPA completed full RPAR reviews on six pesticides. 1/ The resulting regulatory decisions, if upheld in EPA hearings and the Federal courts, will remove or restrict the uses of these pesticides where EPA judged risks outweighed benefits. For example, EPA decided to cancel:

--Nineteen vegetable crop and 22 home garden uses of the pesticide DBCP, which causes cancer in laboratory animals and reduced sperm counts in humans.

--All uses of the pesticide chlorobenzilate, except on citrus fruits, where protective measures were required. Chlorobenzilate also causes cancer in lab animals.

Also, registrants voluntarily canceled some or all uses of 17 other pesticides after learning that EPA was considering evaluating them under the RPAR process.

EPA has also considerably expanded its original list of 45 RPAR pesticides. As of June 30, 1979, EPA had identified, or received referrals on, 233 pesticides. The December 5, 1979, status of the 233 pesticides is summarized below:

1/Chlorobenzilate, DBCP, amitraz, endrin, pronamide, and 2-4-5-T/silvex.

	Pesticides
RPAR completed	6
RPAR notice issued--work ongoing	a/24
Voluntarily canceled	17
Accepted--awaiting RPAR review	b/59
Rejected	b/89
Referred--RPAR acceptance pending	b/30
Transferred to FDA	1
Combined	2
Other actions (note c)	5
Total	233

a/The RPARs for two pesticides were combined after individual RPAR notices were issued.

b/These figures are as of June 30, 1979.

c/Includes label changes, voluntary cancellation requests, restricted use recommendations, etc.

EPA plans to complete work on the original 45 RPAR candidates and several others by fiscal year 1981. The RPAR program will then be merged with the larger registration standards program. If EPA determines, during registration standards work, that a pesticide meets at least one RPAR risk criterion, it will perform an RPAR risk-benefit analysis and make a regulatory decision.

RPAR TIMELINESS: IMPROVING, BUT STILL NOT ADEQUATE

The RPAR program's timeliness has improved recently but is still not meeting the expectations of EPA officials, the pesticide industry, or environmental groups. As a result, EPA is not protecting the public and the environment from potentially hazardous pesticides as quickly as possible.

EPA published its first RPAR notice in March 1976. By December 5, 1979, EPA had published RPAR notices on 29 more pesticides, 6 in 1976, 14 in 1977, 8 in 1978, and 1 in 1979. Their status, as of December 5, 1979, was:

Completed	6
In process	23
Combined with another pesticide	1
Total	a/30

a/Of these, 28 were included in EPA's original list of 45 RPAR pesticides.

EPA estimates allow about 43 weeks between RPAR notice of issuance and the final regulatory decision. Actual performance has not met this standard. As of June 30, 1979, the average RPAR completion time (RPAR notice to regulatory decision) was 74 weeks (incomplete RPARs were in process an average of about 89 weeks), almost twice as long as expected.

We believe that RPARs are taking longer to complete than expected because EPA has

--emphasized starting, but not completing, RPARs;

--planned poorly;

--not resolved several important policy and procedural issues;

--failed to develop formal RPAR operating procedures;

--relied on an inaccurate status reporting system; and

--not received timely assistance from its Cancer Assessment Group.

EPA started, but did not complete, RPARs

During RPAR's first 2 years, EPA emphasized only the initial RPAR phase--the portion of the RPAR process which leads to publication of an RPAR notice. As a result, 21 RPAR notices were issued in 1976 and 1977 but, in that time, EPA had not completed any RPARs.

In late 1977, EPA began to emphasize completing unfinished RPAR reviews. This decision resulted from pressure for decisions from within EPA and from USDA, the industry, and environmentalists.

Better planning guidance needed

EPA has prepared several overly optimistic completion plans and schedules. A July 1976 schedule shows that EPA planned to complete its original group of 45 RPAR pesticides by September 1977. None of this plan's milestones were met, and subsequent schedules met the same fate. More recently, in June 1978, EPA stated that it would complete two RPARs per month. Eighteen months later, only six were complete. We believe that better planning would help EPA complete RPARs faster.

EPA attempted to meet its two per month goal by requiring all project managers to develop work plans for

completing RPAR reviews. OPP provided each manager with a completion date, based on its goal of finishing two RPARs per month.

OPP's only formal planning guidance to each project manager was the required completion date and a few intermediate milestone dates. OPP did not require managers to adhere to a standard format or provide them with specific tasks to be included or a basis to estimate how long it would take to complete specific RPAR tasks.

Because OPP did not provide planning guidance, the RPAR plans varied considerably in detail and format. We reviewed five plans and found that

--the number of tasks included in them ranged from 8 to over 100;

--one plan did not estimate the resources needed for its completion;

--two plans did not include milestones for the final phase of the RPAR process;

--one plan stated that because deadlines were based on an imposed completion date, its milestone were too short for proper supervisory review; and

--one plan imposed 20 conditions for meeting its milestones.

A top EPA pesticide official stated that the June 1978 completion plans were inadequate and that future plans would be uniform and more realistic.

RPAR policy and procedural questions need to be resolved

Several important, but unresolved, policy and procedural questions which delay RPAR reviews are:

--How to select which uses of a pesticide to analyze.

--How to select the RPAR pesticide alternatives to review.

--What is the project manager's extent of authority, and what are the responsibilities of each RPAR team member.

--What criteria to use to make difficult risk-benefit decisions.

Selecting uses to analyze

Each RPAR review assesses the risks and benefits of a pesticide's uses. Because pesticides are used extensively, they often have an extremely large number of uses. OPP, however, has time and resource constraints and cannot always analyze each use of an RPAR pesticide. For example, one RPAR pesticide, toxaphene, 1/ has more than 300 uses; analyzing each is not practical. In cases like this, the RPAR teams must identify the most important uses for risk-benefit analyses.

OPP does not have criteria to guide EPA's RPAR teams to decide what uses should be reviewed. This delays RPAR completions. In the toxaphene RPAR, for example, the RPAR team took 4 months to determine which uses to analyze. This is an excessive amount of time, in light of EPA's estimate that RPAR issuance to regulatory decision should take about 10 months. As of June 30, 1979, the toxaphene RPAR was about 1 year behind schedule.

Selecting alternatives to review

How to select and analyze possible RPAR pesticide alternatives is another unresolved policy question. During each RPAR, EPA considers the risks and benefits of the RPAR pesticide as well as alternative pesticides. An alternative is any pesticide which can be used as a substitute for the RPAR pesticide to control the same pest(s). For example, farmers who use toxaphene to control insects on peanut crops could use several other pesticides--among them methyl parathion, azodrin, or EPN--if toxaphene was canceled. EPA evaluates alternatives like these to see if canceling the RPAR pesticide will result in increased use of alternatives which may be equally or more dangerous than the RPAR pesticide. While RPAR teams are required to identify alternatives which are potentially hazardous, OPP has not specified how the alternatives should be selected or analyzed.

Delay caused by this problem can also be illustrated by the toxaphene review. The RPAR team first discussed alternatives in March 1977 but did not completely select them until October 1978 due to confusion over what criteria

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1/Toxaphene--which causes cancer in laboratory animals--is the highest-volume insecticide in the United States.

to use. Because OPP did not provide the team with formal guidance, EPA's top pesticide official had to make the decision.

OPP tried to set a policy on selecting and analyzing RPAR alternatives in a September 1978 memorandum. The memorandum discussed, in general, a procedure for reviewing alternatives but did not address how specific alternatives should be selected or the extent to which they should be analyzed. The memorandum did, however, instruct project managers not to analyze alternatives which are themselves RPAR pesticides.

Defining RPAR team members' responsibilities

RPARs have also been delayed because, until recently, EPA had not defined the authority of the project manager and the responsibilities of other RPAR team members. Defining roles is important because each RPAR is complex, involving many interdependent staffs and events. For example, one ongoing RPAR requires completing 50 individual tasks by a total of 15 EPA, contractor, and USDA personnel.

Because OPP had not formally defined the project manager's authority or team members' responsibilities, project managers had problems coordinating RPAR work and enforcing deadlines. For example:

--One project manager proposed a revised RPAR completion schedule, but work was delayed because his project team members refused to concur with it.

--One RPAR review was delayed 2 weeks because of a dispute over whose responsibility it was to photocopy a series of papers.

--A top official in OPP's division for directing RPAR work stated that his division lacks authority to take action when another division delays the RPAR process.

In its December 1979, comments to our draft report, EPA said the roles and authorities of the project manager and team members have been clarified and agreed to by OPP divisions. EPA did not indicate whether these agreements will be included in a revised RPAR operating manual. (EPA's comments on the RPAR program are in part II of app. II.)

Criteria for proposed regulatory decisions

Finally, project managers do not have criteria to weigh the risks and benefits of RPAR pesticides to develop regulatory decision proposals. Several project managers stated that the lack of criteria delayed their work because they did not have any "benchmarks" against which to compare their risk-benefit judgments.

A high-level EPA pesticide official stated, in June 1979, that pesticide risk-benefit regulatory decisions are subjective ones, and decisionmakers must balance the relative values they assign to human health, environmental, economic, and social factors. For example, one recent RPAR required a risk-benefit decision between risks of birth defects and short-term poisoning and benefits of about $15 million (the economic loss to the user of canceling the pesticide). The project team recommended canceling some uses and placing restrictions on others, thus substantially reducing risks and only marginally reducing benefits.

We agree that most if not all RPAR decisions are, to some degree, subjective. However, we believe formal criteria would help alleviate delays and help assure that RPAR decisions are consistent.

Procedures should be formalized and updated

EPA's failure to develop formal up-to-date RPAR operating procedures has delayed RPAR reviews. Although the RPAR process began in late 1975, there are no formal procedures describing each RPAR task and how it should be performed. Interim procedures were issued in 1976, but they concentrated only on the initial phases of the RPAR process. Expanded procedures were drafted in December 1978, but have not been finalized. As of June 30, 1979, OPP considered these procedures obsolete and planned to revise and include them in its registration standards program. A high-level RPAR official agreed with us that OPP needs to formally update its procedures to help insure timely RPAR completions.

In December 1979, EPA told us it was revising its RPAR operating manual but that the manual may not include all pertinent RPAR activities.

RPAR reporting system is not providing accurate information

RPAR status reports can be a useful management tool for OPP officials to take action to prevent serious RPAR delays. The reports, however, are often inaccurate and out-of-date.

OPP began its current RPAR status reporting system in the summer of 1978. Weekly reports summarize the status of each ongoing RPAR review. The reports list, by task, original due date, estimated actual completion date, individual responsible, and number of days behind schedule. Although establishing the reporting system is a positive step to track RPAR progress, the reports are often outdated and inaccurate, and managers are hindered from taking prompt remedial action to overcome delays.

For example, we identified the following inaccuracies in the reporting of 8 of the 13 RPAR's listed in a July 1979 status report of ongoing RPARs:

--Dates for completing RPAR tasks were obsolete. For example, the completion date for one task was listed as March 1979, when actually the task was still incomplete in July--4 months later.

--Delays in completing unfinished tasks were underestimated. For example, one task was listed as 108 days overdue when it was actually 252 days late. One listed RPAR had 14 underestimated delays.

In December 1979, EPA said it is setting up a better system to monitor the status of RPAR pesticides.

Cancer-risk assessment delays are not corrected

EPA's Cancer Assessment Group has an important RPAR role, but has not been able to complete its work on schedule. The Group, which does cancer work for many EPA offices, is responsible for almost all RPAR tasks involving cancer, including cancer-risk assessment. These risk assessments, in part, estimate the number of deaths that will result from continued use of cancer-causing RPAR pesticides.

According to a June 30, 1979, RPAR status report, the Group was behind schedule on each of its completed, or ongoing, cancer-risk assessments. Delays ranged from 3 weeks to 9 months.

EPA officials stated that the Group does not have the resources to meet all its RPAR responsibilities. EPA was considering a plan to accelerate completion of cancer-risk analyses by having OPP perform them, internally or by contract. This plan was discussed in the fall of 1978. In December 1979, EPA told us that it was still working to resolve this problem.

EPA IS NOT PROCESSING RPAR REFERRALS QUICKLY OR CONSIDERING ALL READILY AVAILABLE INFORMATION

In addition to not completing RPAR reviews on schedule, EPA is also not quickly or thoroughly reviewing information on additional pesticides referred to it for possible RPAR action. Anyone with documented concerns about a pesticide's safety can refer them to EPA for possible RPAR review. OPP then preliminarily reviews the risk evidence and decides whether the referred pesticide will be accepted or rejected for RPAR. However, EPA has not made this decision in a timely manner and, in several cases, did not consider some important and readily available risk information on referred pesticides.

From the RPAR program's inception (December 1975) to June 30, 1979, EPA received 163 referrals. It accepted 39, rejected 88, and 30 were pending. 1/ Our analysis of the 39 acceptances 2/ shows that EPA took an average of 6 months to decide to conduct RPAR reviews on them. The 30 pending referrals, however, remained unprocessed from 8 months to more than 3 years:

Years pending as of June 30, 1979	Number of referred pesticides
less than 1	2
1 to 2	18
2 to 3	6
more than 3	4
Total	30

1/One was voluntarily canceled by the registrant, and EPA took action such as requiring label restrictions for five others.

2/Excluding two for which dates were unavailable.

OPP officials stated that pesticides which originate as referrals will not be included in the current RPAR program, but will be analyzed as registration standards. As a result, OPP places a low priority on processing them. At the time we completed our review, only one EPA employee was assigned, part time, to processing referrals.

We did not review the potential risk of each pending or rejected referral. We did, however, obtain published, readily available information from the National Institute for Occupational Safety and Health. Institute laboratory tests show that four referred pesticides cause adverse effects.

Pesticide	Adverse effect	Month referred for RPAR	Referral decision status as of June 30, 1979
2-Nitropropane	Cancer	Aug. 1977	Rejected (Dec. 1978)
Carbophenothion	Irreversible nerve damage	Apr. 1977	Pending
Dicrotophos	Mutations	June 1977	Pending
Monocrotophos	Mutations	July 1977	Pending

OPP rejected 2-nitropropane because it decided that the risk information submitted, which did not include the Institute's test results, was insufficient to warrant RPAR review. The OPP official responsible for processing referrals stated that he was unaware of the Institute's test on 2-nitropropane or the three other pending referrals. He said that OPP bases the referral decision only on the risk information submitted to it and that it does not obtain other pertinent, readily available data, such as the Institute's test results.

In December 1979, EPA said it plans to start a project in fiscal year 1980 which will determine the appropriate mechanisms for reviewing referred pesticides.

RPAR PESTICIDES POSING THE HIGHEST RISK NEED TO BE IDENTIFIED AND REVIEWED FIRST

EPA does not have a system to identify those pesticides which appear to pose the highest risk to man and the environment so that it can review them before it reviews others

posing less risk. The order in which RPAR pesticides are reviewed is important because of the slow progress being made and the heavy backlog of pesticides awaiting review.

In 1976, EPA developed a priority system which, among other things, attempted to quantify each RPAR pesticide's relative risk. EPA used the system to rank each of the 45 original RPAR pesticides based on general criteria such as volume produced annually, persistence in the environment, and type of hazardous effect it causes. Each pesticide received a point score. EPA did not use the system to allocate its resources because all 45 RPAR pesticides were being reviewed concurrently.

In 1978, EPA became concerned about the program's slow progress. To correct this, OPP selected 16 of the 45 RPAR pesticides and began devoting most RPAR resources to completing them. The 16 priority pesticides were selected because they were in the process for the longest time or they were closest to completion. OPP did not attempt to identify the most hazardous pesticides when it selected these priority pesticides.

We compared the 1976 rankings with the 1978 priority selections to determine whether the priority pesticides were among the most hazardous of the original 45 RPAR pesticides. Some of the priority selections were ranked low in 1976 and some pesticides ranked high in 1976 were not included in the priority list. Some examples are shown below:

Pesticide	Original priority ranking (note a)	Included in 1978 priority list
Creosote	4	No
Cadmium	10	No
Triallate	15	No
1080	21	Yes
Strychnine	27	Yes
Pronamide	40	Yes

a/Lower numbers indicate higher priority.

EPA stated that a priority system will be developed as part of the registration standards program. As of December 1979, the system had not been developed.

MORE AND BETTER TEST DATA NEEDED FOR RPAR EXPOSURE ANALYSES

To reach sound regulatory decisions on RPAR pesticides, EPA needs accurate and complete data to assess each pesticide's risks and benefits. However, EPA often does not have such data on a major ingredient of risk assessment--exposure analyses.

A pesticide's risk results from two factors, the harmful effect it causes and the amount of human and environmental exposure to it. Exposure is important because (1) a hazardous pesticide used widely is more dangerous than an equally hazardous pesticide with limited use and (2) RPAR decisions aimed at reducing risk often involve reducing pesticide exposure.

RPAR exposure analyses identify and quantify the pesticide dose which humans and the environment receive. OPP prepares two types of human exposure analyses: nondietary and dietary. Nondietary exposure results primarily from inhalation and skin absorption. Dietary exposure is the amount of a pesticide remaining in, or on, food. This amount is called a residue. As we discussed in chapter 1, EPA establishes, by law, a maximum safe residue level (called a tolerance) for each food treated with a pesticide. During each RPAR, EPA combines the exposure analyses with an analysis of the pesticide's harmful effect; the result is the RPAR risk analysis.

Our review showed that, often

--nondietary exposure analyses are based on assumptions instead of actual exposure data and

--dietary exposure analyses are based on questionable residue data or tolerance levels which generally overstate dietary exposure.

More test data needed for nondietary exposure analyses

EPA's nondietary exposure analyses often rely on assumptions about a pesticide's movement and destination in the environment because it does not have actual test

data. EPA recognizes that the lack of exposure data is a serious RPAR problem.

We did not evaluate the validity of EPA's exposure assumptions. OPP officials stated, however, that using assumptions could result in different exposure estimates than if actual data was used. Overestimated exposure leads to overestimated risk, which could cause the risk-benefit scale to tip in favor of cancellation or restriction. Underestimated exposure leads to underestimated risk and could cause EPA to permit hazardous pesticides to remain in unrestricted use.

EPA has authority, under FIFRA, section 3(c)(2)(B), to require registrants to submit, "* * *additional data* * * to maintain in effect an existing registration of a pesticide* * *." As of June 30, 1979, EPA had not used this authority to obtain human exposure data during any RPAR. OPP officials argued that requiring registrants to develop and submit exposure data for RPARs would be expensive and time consuming. EPA has, however, continually urged the pesticide industry to voluntarily submit exposure data for RPARs. An OPP official stated that the industry has exerted "almost no effort in the exposure data area."

However, in one case, chlorobenzilate, EPA required registrants to submit exposure data after the RPAR was completed. EPA concluded that it needed the additional data to reevaluate certain chlorobenzilate uses the RPAR decision did not cancel. In February 1979, EPA directed the registrants to submit this data within 18 months.

More accurate residue data needed for dietary exposure analyses

EPA uses pesticide residue data to prepare RPAR dietary exposure analyses. The Food and Drug Administration's tolerance enforcement program is a primary source of this data, although USDA informed us that it also tests for pesticide residues. FDA periodically examines pesticide residue levels in food samples to determine if the levels exceed tolerances. We have, in the past, pointed out deficiencies in FDA's residue testing program. For example, we testified before the House Subcommittee on Oversight and Investigations, Committee on Interstate and Foreign Commerce, in February 1978, that FDA's testing program does not detect many pesticides which have tolerances. The program identified only 107 of the 268 pesticides having tolerances. Many of the RPAR pesticides are not detectable. In these cases, OPP has used tolerance residue levels, which are generally much

higher than actual residue levels. We also identified deficiencies in FDA's "total diet" residue sampling program which could result in residues escaping detection.

The following two examples illustrate EPA's need for more and better RPAR pesticide residue data. First, in the dimethoate 1/ RPAR, FDA did not provide EPA with any residue data because FDA's testing methods did not, at the time the RPAR was conducted, detect dimethoate. As a result, the dimethoate dietary exposure analyses were based on tolerance levels. The dimethoate RPAR project manager stated that using tolerances overstates risk, because pesticide residues rarely appear at, or near, tolerance levels. To compensate, the project manager planned to emphasize, in the risk-benefit analysis, that risk is overstated.

Second, in the toxaphene RPAR, EPA used FDA residue and tolerance data. The residue data was from FDA's total diet surveys. These surveys are a part of FDA's tolerance enforcement program in which FDA periodically selects, in several cities, a food commodity sample representing the typical diet of a 16 to 19 year-old male. The foods are blended together and then analyzed for pesticide residues. In February 1978, we testified that the total diet program is not an adequate surveillance tool because:

--Foods are blended together and individual pesticide residues could escape detection.

--The program is not statistically valid or representative of the typical diets of the population.

Despite the inaccuracies of using tolerances and the deficiencies of the total diet program, the toxaphene project manager stated that these were the only two sources available.

FDA does, however, have methodologies which can, and should be, used to more accurately provide pesticide residue data. Most of these methods detect only one pesticide at a time and are costly. Public exposure to pesticides like dimethoate, which are detectable only by single residue methods, is largely unknown because FDA rarely uses these methods. FDA has conducted special residue surveys for

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1/Dimethoate is a insecticide which causes mutations and reproductive effects in laboratory animals.

RPARs but does not conduct them for all RPARs. In one case, an EPA official stated that FDA conducted a special residue survey because of high-level coordination between the two agencies.

In addition, USDA, in its comments on our draft report, informed us that it tests for pesticide residues and has "expertise and experience in this area which could assist EPA* * *."

BENEFITS ESTIMATES MAY MISLEAD EPA DECISIONMAKERS AND THE PUBLIC

A crucial phase of the RPAR process is EPA/USDA's estimate of each pesticide's benefits. During each RPAR, EPA's RPAR team compares the pesticide's benefits against its risks and attempts to develop a regulatory proposal which minimizes risks without eliminating benefits. Our review of the benefits analyses for two RPAR pesticides, toxaphene and DBCP, showed that benefit estimates rely on imprecise data and assumptions which are subjective and not fully explained.

RPAR benefits analyses, however, present these estimates as precise dollar amounts and do not

--reflect that the estimates are sensitive to data and assumption changes or

--present estimates in ranges of dollar amounts.

As a result, these estimates may mislead RPAR decisionmakers and the public--including the pesticide industry and environmental groups--because they appear to be more precise than they actually are.

EPA and USDA cooperatively estimate the benefits expected from continued use of each RPAR pesticide. At the beginning of each RPAR, EPA and USDA form a benefits assessment team consisting of economists and scientists from both agencies plus scientists from outside the Government. According to USDA, team members are recognized experts in their areas of study. The team assembles and analyzes information on usage, effectiveness, and application costs of the RPAR pesticide and its alternatives and prepares an analysis of its judgments of the RPAR pesticide's benefits. The analysis is submitted to the RPAR project manager who uses it for the risk-benefit assessment.

EPA and USDA define benefits as the dollar value, to the farmer or other user, of continued use of the RPAR

pesticide. In other words, benefits are the user's potential losses if EPA bans the pesticide. Benefits are estimated for:

--Control costs: the cost difference between the RPAR pesticide and alternative pesticides.

--Revenues or productivity: the yield (and revenue) difference between using the RPAR pesticide and alternatives or, no pesticide at all.

Data uncertainties not reflected

Although RPAR benefits analyses rely heavily on data such as volume used, crop yield effects, and application costs, this data is often imprecise. To compensate, the assessment team selects from several available estimates or develops its own. Despite these uncertainties, EPA presents benefits estimates as precise dollar amounts.

In the toxaphene RPAR, for example, EPA/USDA identified several estimates of the pesticide's usage volume (number of pounds applied). Estimates of toxaphene's total volume ranged from 59 million to 116 million pounds for 1975, the latest year this data was available. The uncertainty about toxaphene's actual volume particularly affected the estimates of toxaphene's control benefit for cotton use. Toxaphene's largest single use is on cotton crops.

The USDA/EPA assessment team estimated that toxaphene's control benefit for cotton use is about $30 million annually. This amount is based on a USDA estimate that 26 million pounds of toxaphene was applied to cotton in 1976. EPA economists, however, later independently reduced the cotton benefit estimate to $11.5 million and revised the toxaphene benefit analysis. One of the reasons for the difference between the two estimates was EPA's decision to use the lowest estimate of toxaphene's cotton volume, 22 million pounds.

Another data uncertainty affected the calculation of toxaphene's cotton revenue benefit. The assessment team determined that the revenue benefit for cotton is about $84 million annually. The team based the estimate on a USDA mail survey of State scientists. USDA asked the scientists to estimate, among other things, the extent to which toxaphene increases cotton yields, compared to its alternatives. EPA economists, however, conducted an independent review and concluded that toxaphene did not produce increased yields. As a result, EPA listed toxaphene's cotton revenue benefit as zero in its most recent draft benefits analysis.

Despite the data uncertainties underlying both benefits estimates for toxaphene's use on cotton, the most recent draft benefits analysis does not

--state that the estimates used were significantly different from the assessment team's original estimates or

--explain why the original estimates were changed.

Both estimates are presented as precise dollar amounts. If EPA includes the assessment team's original estimates in the final toxaphene benefits analysis, toxaphene's estimated benefits to cotton producers could present, as ranges of dollar values, a more realistic approach.

Sensitivity to assumption not reflected

RPAR estimates of revenue and control benefits are often based largely on subjective assumptions. For example, EPA/USDA used assumptions to estimate both the revenue and control benefits of DBCP use on tomatoes--a major use. Although we did not evaluate the assumptions' validities, we did determine that changing the assumptions materially changes benefits estimates.

The assessment team's estimate of the revenue (increased yield) benefits of DBCP's use on tomatoes was based on several assumptions. Two major assumptions were:

--Five percent of tomato acreage would remain untreated by alternative pesticides if DBCP's use was canceled.

--Seventy percent of tomato production would be lost on the untreated acreage.

Neither of these assumptions are well documented in the benefit reports. The first assumption apparently reflects the assessment team's conclusion that some farmers would not use alternatives because of product unfamiliarity or higher treatment costs. According to a USDA official, the second assumption represents a compromise between two conflicting judgments of DBCP's effectiveness on tomatoes. Using these assumptions, the EPA/USDA team calculated that DBCP's use on tomatoes caused increased yields worth $5.6 million annually.

To determine the effect changing these assumptions would have on revenue benefits, we performed the same calculation but used alternative assumptions of 3 percent untreated

acreage and 50 percent production loss. This produced a $2.4-million a year benefit estimate, less than one-half the assessment team's estimate.

EPA/USDA also used several assumptions to calculate DBCP's control benefits to vegetable producers. The assessment team identified four alternative pesticides and their costs and then estimated the percentage of total vegetable crop acres on which each would be used if DBCP was canceled. For example, the assessment team developed the following use percentages for one crop--tomatoes:

Alternative	Cost per acre	Percent of use
EDB	$ 9.17	20
D-D	30.80	20
Vorlex	48.00	35
Telone II	32.80	20
No treatment	-	5
Total		100

The assessment team's basis for assuming that each of the DBCP alternatives would be used in the estimated percentages is not explicity stated in the DBCP benefits analysis or supporting documentation. The analysis stated that each set of percentages is based on factors such as pesticide effectiveness and treatment cost per acre. The analysis does not state, however, how these factors were considered. Using its estimated percentages, the team calculated DBCP's vegetable control benefits to be $7.7 million annually.

Again, we performed the same calculation, but hypothetically assumed that all producers would switch to EDB, the cheapest pesticide alternative. Using this assumption, our estimate of DBCP's yearly vegetable control benefit is only $2.2 million, less than one-third of the EPA/USDA estimate.

The DBCP final benefits analysis does not reflect that benefits estimates are sensitive to changes in assumptions nor does it show the range in estimates which different assumptions would produce. In addition, although the analysis lists the assumptions used, it does not fully explain their bases.

CONCLUSIONS

RPAR can be an effective means for making difficult decisions to regulate pesticides but, from a practical standpoint, EPA's 4 year RPAR record shows limited progress. While EPA has used the RPAR process to remove some dangerous pesticides from the environment and has identified others which it may regulate, the process is still not meeting its goal--to quickly and thoroughly make regulatory decisions on potentially hazardous pesticides.

EPA is aware that it needs to accelerate the RPAR process. However, we noted a number of problems which prevent EPA from meeting its completion goals and insuring that the public and the environment are not exposed to dangerous pesticides any longer than necessary.

First, EPA has not provided formal planning guidance to RPAR project managers. EPA did not standardize planning format or level of detail, identify tasks to be included, or provide a basis to estimate how long RPAR tasks should take to complete. As a result, imposed completion dates included in RPAR plans were not met.

Second, EPA has not resolved important RPAR policy questions. EPA has not developed criteria for RPAR teams to determine which RPAR uses and alternatives to review and it has not developed criteria to help RPAR teams make difficult risk-benefit decisions. Also, until recently EPA had not defined the extent of the project manager's authority or the responsibilities of each team member. As a result, RPAR teams spent too much time deciding these issues.

Third, the absence of formal day-to-day operating procedures for the complex RPAR process has delayed progress. A system as complex as RPAR cannot operate in a timely or consistent manner without such procedures. While EPA recognizes this problem it has not yet corrected it.

Fourth, EPA's RPAR status reporting system is not providing management with accurate and up-to-date information. Without such information, management is not fully informed of RPAR delays and cannot take remedial action to overcome them.

Fifth, delays in completing cancer-risk assessments have delayed the RPAR program. While EPA believes its Cancer Assessment Group does not have sufficient resources to complete all RPAR cancer work, it has not completed action to reduce delays.

In addition to these problems which delay completing RPARs, several other deficiencies inhibit the program's effectiveness. Potentially hazardous pesticides referred to EPA as new RPAR candidates are not assessed in a timely or thorough manner. A priority system has not been established to analyze the highest risk pesticides first. The RPAR exposure analyses are not always based on accurate or actual test data. Finally, benefits estimates may mislead EPA decisonmakers and the public because the estimates are not as precise as they appear to be.

RECOMMENDATIONS

EPA needs to complete RPARs faster so that the public is not exposed to dangerous pesticides any longer than necessary. We recommend that the Administrator, EPA, issue and require the Agency to follow a formal RPAR operating manual describing all phases of the process. The manual should include:

--Guidance on planning format, level of detail, specific tasks to be included, and a basis to determine how long each task should take.

--Procedures for selecting and reviewing pesticide uses and alternatives.

--Definitions of the project manager's extent of authority and team members' responsibilities.

--Criteria for risk-benefit decisions.

--Procedures to insure that cancer-risk assessments are completed promptly.

--Procedures to insure that status reports are accurate and up-to-date.

--Procedures to identify the most hazardous RPAR pesticides and complete them first.

To improve the timeliness and quality of RPAR referral decisions, we recommend that the Administrator, EPA:

--Decide if pending referrals should be accepted or rejected, and implement procedures to quickly evaluate future referrals and identify and consider readily available risk data from sources such as the National Institute for Occupational Safety and Health.

To improve the quality and usefulness of RPAR exposure analyses, we recommend that the Administrator, EPA:

--Require registrants to submit nondietary exposure test data during RPARs.

--With the Commissioner, FDA, conduct pesticide food residue tests on individual RPAR pesticides.

--Consult USDA to determine what residue testing assistance it can provide.

Finally, to improve the usefulness of RPAR benefit information provided to EPA decisionmakers and the public, we recommend that the Administrator, EPA, require that benefits analyses:

--Fully explain the bases for important assumptions used to calculate benefits estimates.

--Show the range in benefits estimates which alternative underlying data and assumptions would produce.

AGENCY COMMENTS AND OUR EVALUATION

EPA, the Department of Health, Education, and Welfare, and USDA, in their comments on our draft report, generally agreed with our RPAR recommendations. EPA, however, expressed reservations about fully implementing our recommendations to issue a formal RPAR operating procedure describing all phases of the process and to require registrants to submit nondietary exposure test data during RPARs. (See part II of app. II and apps. III and IV.)

Concerning the RPAR operating manual, EPA stated it is either incorporating existing guidance or developing new guidance for some issues our report addressed for inclusion in a revised RPAR operating manual. EPA stated that it is dealing satisfactorily with the other items we specified for inclusion in a formal RPAR manual, and that not all may actually be included in the manual. We agree that EPA's ongoing or proposed actions in these areas when completed will enable EPA to complete RPARs faster. We still maintain, however, that EPA's revised operating manual should describe all RPAR procedures to insure that all RPAR participants are aware of, and follow, these procedures.

In response to our recommendation that EPA require registrants to submit nondietary exposure data during RPARs, EPA stated that our description of the difficulties in exposure assessment is perceptive and, for the most part, accurate. EPA also stated, however, that exposure assessments are based to a larger extent on actual field data than our report suggests. EPA said it, USDA, and State agencies are now funding exposure studies. EPA commented that it is in the best interests of the pesticide industry to provide as much exposure data as possible because, in the absence of such data, EPA will take a "worst case" approach. EPA concluded that it will develop protocols for obtaining real-life exposure data.

Although we agree that the development of exposure data protocols is a positive step, we still maintain that EPA should require registrants to submit exposure test data. In view of EPA's statement that there are use patterns for which no exposure data is available and its agreement that it has a long way to go in obtaining exposure data, we believe the data should be generated to minimize EPA's reliance on exposure assumptions. We do not feel that EPA should rely on the pesticide industry to voluntarily submit such data based on the industry's perception of its "best interests." Nor do we believe that EPA, USDA, or State agencies should carry the financial burden of funding exposure studies on potentially hazardous pesticides.

CHAPTER 4

EPA NEEDS MORE AUTHORITY TO EFFECTIVELY USE THE RESULTS OF LABORATORY INSPECTIONS

The joint EPA/FDA program to inspect testing laboratories is designed to insure that tests conducted to determine the safety of chemical compounds are accurate and reliable. FDA and EPA officials believe that the inspection program has improved conditions in labs and, as a result, test data quality has improved. Although we did not verify this, we believe that the inspection program is a positive step toward improving pesticide testing.

EPA lacks legal authority to restrict or suspend a pesticide's use when EPA later determines that the pesticide was not supported by valid safety tests when registered. Because of this, EPA's ability to protect the public and the environment from dangerous pesticides is hindered.

Also, EPA's lab inspection program could be improved if EPA received information from the USDA's lab inspection program.

WHY THE LAB INSPECTION PROGRAM BEGAN AND HOW IT WORKS

Laws permit EPA and FDA to only register or approve food additives, drugs, and pesticides which do not pose unreasonable adverse effects. This safety determination is based on required tests conducted at testing labs. FDA and EPA require that compounds be tested on animals before they are registered or approved. Test results indicate whether compounds may adversely affect humans (cause cancer, birth defects, mutations, etc.) or the environment. Tests submitted to EPA support pesticide registrations and food tolerance decisions, as required by FIFRA and the Federal Food, Drug, and Cosmetic Act, respectively. Tests submitted to FDA support food additive and drug approvals as required by FFDCA. Both agencies require the same types of tests and receive test data from many of the same labs.

A registrant who seeks EPA or FDA's approval to sell a product conducts the required tests at its own lab or has the product tested by an independent lab. In the latter case, the lab submits the tests' results to the registrant and the registrant submits them to EPA or FDA.

The need for a comprehensive lab inspection program became apparent in 1975 when FDA personnel visited several independent labs and identified serious testing deficiencies at each. In January 1976, EPA's Deputy Administrator testified before the Senate Subcommittee on Health, Committee on Labor and Public Welfare, that an EPA review of several tests indicated serious pesticide testing deficiencies.

Also in January 1976, we issued a report on EPA's basis for determining whether safety data submitted by pesticide registrants is complete, accurate, and reliable. We recommended that EPA determine whether a lab inspection program was necessary and suggested that a joint EPA-FDA inspection program would avoid duplication. In December 1976, FDA and EPA established a limited "pilot" inspection program with FDA as the lead agency because of its experience with inspections. In March 1977, EPA stated that its portion of the inspection program was "fully operational."

As the lead agency, FDA generally inspects each lab and sends a report to EPA. The inspections have two phases: first, a general inspection of the lab's physical plant and operating procedures and the second, a "data audit" of one or more tests which support EPA or FDA registrations. During the second phase, the inspector examines supporting documentation to determine whether the test conclusions are valid. Occasionally, when either agency needs to review a certain test, it will conduct a data audit without a general inspection.

FDA bases its laboratory evaluations on a set of general procedural standards, known as "Good Laboratory Practice." FDA issued the standards as a final regulation in December 1978. EPA officials said that EPA plans to soon issue its own standards, which will be similar to FDA's.

If FDA finds serious problems at a lab, it instructs the lab to correct them and subsequently conducts a followup inspection. If the lab does not correct the problems, FDA, under certain circumstances, can refuse to accept subsequent test data from the lab. EPA plans to consider adopting a similar policy.

In fiscal year 1979, EPA allocated about $282,000 and 6.3 staff-years for its portion of the inspection program. As of June 30, 1979, FDA inspected 65 labs which conduct pesticide tests. Because FDA actually conducts the program, EPA's responsibilities are limited. They include

--helping FDA plan inspection schedules,

--selecting pesticide tests to audit,

--reviewing FDA inspection reports,

--conducting some data audits and followup inspections, and

--helping provide documentation and evidence to support an enforcement case against a lab or registrant, if appropriate.

EPA CANNOT TAKE REGULATORY ACTION BASED SOLELY ON INVALID PESTICIDE TEST DATA

EPA does not have statutory authority to suspend or cancel registered pesticides when inspections show that the safety tests supporting the registration are not valid. EPA can require that registrants repeat a test but, in the interim, cannot take other regulatory action, such as suspending use. Some tests take up to 3 years to complete. During this time, the public and the environment can be exposed to potentially dangerous pesticides not supported by valid safety data.

FIFRA does not allow EPA to withdraw a pesticide from the market solely because fraudulent or poor quality data was used to support its initial registration. According to FIFRA, section 6, EPA can suspend a pesticide's use only if EPA determines that it poses an "imminent hazard," defined as

> "* * *a situation which exists when the continued use of a pesticide during the time required for cancellation proceeding would be likely to result in unreasonable adverse effects on the environment."

Section 6 allows EPA to cancel a pesticide's use, if

--the initial registration failed to comply with FIFRA's provisions or

--evidence exists that the pesticide causes unreasonable adverse effects on the environment.

While providing faulty data can be argued as failure to comply with FIFRA, we are unaware that the provision has ever been interpreted in this manner.

FIFRA does provide, however, that if EPA determines that additional data is required to continue an existing pesticide registration, EPA can require the registrant to submit it. If the registrant refuses, EPA can suspend the pesticide and ultimately cancel it. The cancellation would be based on failure to provide additional data, not the submission of unreliable or faulty data.

Even if EPA required the registrant to submit new test data, and the registrant agreed, completing the new tests could take as long as 3 years. For example, EPA-required long-term tests, designed to show whether a pesticide causes cancer in animals, can take up to 24 months to perform. After this, the lab analyzes and submits the results and its safety conclusions to the registrant, which then submits the data to EPA. EPA then reviews this information to determine whether the conclusions are valid. EPA officials stated that test completion and analysis could take up to 3 years. In the interim, EPA could not assure the public that the pesticide being marketed is safe.

This situation has occurred with data from tests conducted at a lab which was, at one time, the Nation's largest lab conducting chemical compound safety testing. From 1976 to 1978, FDA, with and without EPA, inspected three of the lab's facilities and discovered serious deficiencies. Some were so serious that EPA referred the information to the Department of Justice for possible legal action.

Because of these, and other findings, EPA decided that it needed to determine whether this lab's studies could still support pesticide regulatory decisions. To do this, EPA developed a special test validation program. Of the more than 4,000 tests from that lab in EPA files, the Agency selected 640 for validation. These tests support over 100 pesticide food tolerances and are the lab's most important tests. Each registrant for whom one of these tests was performed must determine the validity of the tests using EPA validation guidelines. Registrants then send a validation report to EPA, which makes the final decision on a test's validity. If EPA finds a test invalid, it may require the registrant to repeat it. Many registrants are voluntarily repeating tests.

EPA anticipates that the validations will be completed during fiscal year 1980. EPA officials believe many of the tests will have to be repeated because of their poor quality. This process could continue several years after validations are completed because of the time it takes to

complete long-term tests. In the interim, EPA cannot restrict the use of pesticides supported by invalid tests from this lab unless EPA becomes aware of other risk information, which it can use to meet FIFRA suspension or cancellation requirements. As a result, the public and the environment are being exposed to pesticides which may not be supported by valid safety tests.

Unlike EPA, FDA has the authority to prohibit the use of approved chemical compounds when it determines, through lab inspections or other means, that safety test data is invalid. Section 505, FFDCA, allows FDA to withdraw approval of a drug when FDA determines that the original drug approval application "* * *contains any untrue statement of a material fact." Under this provision, FDA could withdraw a drug from use if its original approval was based on test data which subsequently proved to be invalid. FIFRA does not allow EPA to take similar action for pesticides.

EPA DOES NOT RECEIVE USDA LAB INSPECTION RESULTS

The Department of Agriculture also inspects test labs. Under provisions of the Animal Welfare Act, USDA inspects, at least three times a year, all labs which use test animals. Most of these labs conduct tests submitted to EPA and FDA. Although USDA's inspections are restricted to animal welfare, it evaluates lab procedures relating to animal handling, cleanliness, medical care, and space requirements. While EPA could not take regulatory action based on USDA findings, EPA officials stated that this information would be useful because:

--It would provide relatively current information on lab conditions.

--EPA could use the information as a basis for determining which labs and tests to inspect and audit.

An official added that while in the past EPA had not asked USDA for its inspection results, EPA will consider doing this in the future.

CONCLUSIONS

EPA's inability to restrict use of pesticides unsupported by valid safety tests could result in public exposure to dangerous pesticides for as long as 3 years. During this period, EPA would not be fulfilling its mission to protect the public and the environment from hazardous pesticides. Even if EPA

requires registrants to repeat invalid tests, the pesticides would remain on the market despite their unverified safety.

In contrast, FDA has the authority to take regulatory action against drug approvals unsupported by valid safety tests. As a result, drug applicants have a greater incentive than pesticide registrants to submit accurate data, and FDA can be more effective than EPA to protect the public from potentially hazardous chemical compounds.

Because EPA does not generally inspect pesticide labs it should have readily available inspection information from other sources. EPA is not, however, obtaining information from USDA's inspection program. This information would help EPA better insure that lab conditions are adequate to produce accurate and reliable safety test data.

RECOMMENDATIONS

To protect the public from potentially dangerous pesticides, we recommend that the Administrator, EPA, submit a FIFRA amendment to the Congress to authorize EPA to take appropriate regulatory action, including suspension, on pesticides which it later determines were not supported by valid safety tests when registered.

To obtain available inspection information on labs which perform pesticide safety tests, we recommend that the Administrator, EPA, arrange with USDA to receive results of its lab inspection program.

AGENCY COMMENTS AND OUR EVALUATION

In commenting on our draft report, EPA disagreed with our recommendation that it seek authority to take appropriate regulatory action, including suspension, on pesticides which EPA determines were not supported by valid safety tests when registered. (See part III of app. II.) EPA stated that it does have authority to take less restrictive actions than suspending a pesticide and that suspension is an abrupt action which may be more extreme than necessary in many cases. We are not suggesting that EPA use suspension authority lightly. Instead, we perceive this authority as a necessary regulatory option which EPA should use judiciously, in extreme cases of inaccurate or unreliable data on a pesticide which, because of its widespread use, may threaten a large segment of the population.

EPA agreed to implement our recommendation concerning USDA's lab inspection program.

GAO REPORTS ON PESTICIDES

1. "Better Regulation of Pesticide Exports and Pesticide Residues in Imported Food Is Essential" (CED-79-43, June 22, 1979).

2. "Problems in Preventing the Marketing of Raw Meat and Poultry Containing Potentially Harmful Residues" (HRD-79-10, Apr. 17, 1979).

3. "Need for EPA to Improve Foreign Nation Notifications" (CED-78-103, Apr. 20, 1978).

4. "Special Pesticide Registration by the Environmental Protection Agency Should be Improved" (CED-78-9, Jan. 9, 1978).

5. "Adequacy of Safety and Efficacy Data Provided to EPA by Nongovernmental Laboratories" (RED-76-63, Jan. 26, 1976).

6. "Federal Pesticide Registration Program: Is It Protecting the Public and the Environment Adequately from Pesticide Hazards?" (RED-76-42, Dec. 4, 1975).

7. "Questions on the Safety of the Pesticide Maleic Hydrazide Used on Potatoes and Other Crops Have Not Been Answered" (B-133192, Oct. 23, 1974).

8. "Pesticides: Actions Needed to Protect the Consumer from Defective Products" (B-133192, May 23, 1974).

9. "Environmental Protection Agency Efforts to Remove Hazardous Pesticides from the Channels of Trade" (B-133192, Apr. 26, 1973).

APPENDIX II

ENVIRONMENTAL PROTECTION AGENCY COMMENTS

This appendix contains EPA's comments on our draft report. EPA noted that the draft report focused on real problems in Federal pesticide regulatory programs and provided constructive recommendations. However, EPA also stated that our report "* * *seems to diminish or ignore the progress that has been made during the last six months* * *" and that we overemphasize procedures. EPA stated there "* * *is no substitute for taking action, making proper staff judgments on issues and developing a trained staff through doing." (See p. 61.)

We have addressed these comments in the body of the report or, in some cases, in brackets immediately under the paragraphs in which a point is raised. In those instances where EPA's contentions were germane, appropriate changes were made in the report. However, EPA frequently raised points which are not at issue in our report. We restricted our responses to those issues relating directly to the report.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

27 DEC 1979

OFFICE OF
PLANNING AND MANAGEMENT

Honorable Henry Eschwege
Director
Community & Economic Development Division
United States General Accounting Office
Washington, D.C. 20548

Dear Mr. Eschwege:

The Environmental Protection Agency (EPA) has reviewed the General Accounting Office (GAO) draft report entitled "Protecting The Public From Dangerous Pesticides - New Programs For Old Problems" and appreciate the opportunity to comment on the reports findings.

The Agency's response as prepared by the staff of the Assistant Administrator for Toxic Substances is enclosed.

While we found your draft thoughtful and provocative, we must take issue with significant portions of the analysis and resulting recommendations presented in it. I wish to note especially the discussion, to be found on page 3 of the attached response, of the factors that we believe should be considered in establishing priorities for the development of generic standards.

Sincerely yours,

C. W. Craft

for William Drayton, Jr.
Assistant Administrator for
Planning and Management

Enclosure

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DEC 17 1979

OFFICE OF TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Comments on the Draft GAO Report "Protecting the Public from Dangerous Pesticides -- New Programs for Old Problems"

TO: William Drayton, Jr.
Assistant Administrator
for Planning and Management (PM-208)

FROM: Steven D. Jellinek
Assistant Administrator
for Pesticides and Toxic Substances (TS-788)

We would like to compliment GAO for focusing on real problems in the Federal program for regulation of pesticides and for providing recommendations in a constructive tone. Too often in the past in examining EPA's regulatory programs, GAO has concentrated on insignificant issues or has recommended overly simple, impractical solutions to extraordinarily complex problems. The current report, while critical of the Agency, nevertheless displays a better understanding of the management complexities and competing social values in our major programs. We have three general criticisms to make. The report seems to diminish or ignore the progress that has been made during the last six months while this report was being prepared. It overemphasizes procedures. Procedures cannot ensure timely, quality work. There is no substitute for taking action, making proper staff judgments on issues and developing a trained staff through doing. And, the section on laboratory audits seems to us to be quite superficial.

Our specific responses to GAO's recommendations follow. We have also attached a list of briefer comments on specific inaccuracies noted in the body of the report.

Attachments

GAO note: EPA's list of "briefer comments" has not been included in this appendix.

APPENDIX II

I. GENERIC STANDARDS

1) GAO Recommendation: Establish formal written operating procedures for registration standards development including procedures: 1)for dealing with high risk pesticides, 2) for reassessing tolerances, and 3) for budgeting and periodically accounting for resources spent. Develop a formal training program for appropriate personnel.

EPA Response: We agree that written operating procedures for registration standards development would be useful. The Office of Pesticide Programs has drafted such procedures for Phase I (data gathering) of the registration standards process which are now awaiting management approval. Procedures for Phase II (data review) are almost complete. OPP personnel are following these procedures for Phase I and II now. We plan to complete procedures for Phases III, IV, and V (preparation of a regulatory position and publication of proposed standard, consideration of public comment, publication of standard) during the next six to eight months. These operating procedures will include procedures for dealing with high risk pesticides (prioritization and RPAR) and for tolerance reassessment as well. [As these operating procedures are completed and approved, we will make them available to GAO.]

We disagree with GAO's conclusions regarding our accounting procedures for registration standards(pp. 17-18). GAO alleges that our budgeting of resources is based on poor information and that our accounting procedures yield inaccurate information.

Since, to date, no registration standards have been completed, it is difficult to understand the basis for GAO's allegation that registration standard budgeting was "inaccurate." While the budgeted costs were theoretical in that they were not based upon historical experience with the development of registration standards, they were not wild guesses. Rather, the Agency derived them from a detailed, systematic zero-based budgeting process involving all levels of management and all appropriate areas of scientific expertise. Moreover, although the Agency did not have direct experience with registration standards to guide it in estimating unit costs, many of the registration standards activities are similar to other Pesticide Program activities for which historical budgeting experience is available. Examples are the registration and RPAR processes. Experience in these areas provided a reasonably sound data base and underlies many of the unit costs employed in the Agency's carefully designed zero-based budgeting process. In short, the unit cost estimates used were refined as much as possible in the absence of actual experience; only time will tell how "inaccurate" the estimates were. It is certainly too early to make such a determination now.

GAO note: Page numbers have been changed to correspond to the final report.

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In addition, GAO has not given sufficient recognition to Pesticide Programs' Time Accounting Information System (TAIS). TAIS was developed largely to capture accurate data on the costs of the registration standards program for budgeting and planning purposes. The system is unique to EPA, a major management initiative, and developed in time to capture all but a very small fraction of registration standard cost experience.

It's basic objectives are to:

- Provide valid unit cost data to support OPP's external budget requests and to assist in the development of divisional budgets

- Assist in identifying workloads and the impact of special projects on schedules and personnel resources

- Provide a historical data base for developing, monitoring and forecasting long range plans and personnel needs

- Monitor human resource expenditures for possible reallocation

- Assign personnel to specific projects and tasks

TAIS deserves more than the passing mention given it by GAO.

The Agency has not developed a comparable time accounting system to capture contractor costs, but will consider the possibility of developing one to improve further our budgeting practices.

Pesticide Programs has recently embarked upon another major management improvement, the Planning and Management System (PMS). While the principal purposes of PMS are to foster integrated, comprehensive planning and workload balancing, (among other things, addressing difficulties in the RPAR program reported by GAO on p. 48), it will likely lead, ultimately, to improved budget estimating through more accurate unit costs. Such improved information can only help to improve program efficiency by permitting better-informed decisions on allocation of resources. Information on PMS is attached.

Finally, we believe that GAO has chosen a misleading example(p. 18)to illustrate the existence of inaccuracies in our accounting system. GAO notes that the Benefits and Field Studies Division in the Office of Pesticide Programs, which has a "minor" role in registration standards development, received 28% of the FY79 registration standards resources. That allocation, however, included a large sum for epidemiologic studies contracts. In 1979 responsibility for these contracts was transferred

to the Hazard Evaluation Division. The 1980 allocation to Benefits and Field Studies for registration standards will reflect this transfer of responsibility and be commensurate with its role in the development of registration standards.

/GAO COMMENT: We do not agree that our example is misleading. As we stated on page 18, a top pesticide official told us that much of the $2.6 million budgeted for the Benefits and Field Studies Division's registration standards work might have actually been spent on the RPAR program. He and other EPA officials could not adequately explain to us why the money was allocated for the registration standards program. Our response to EPA's other comments on its budgeting and accounting procedures appears on page 25./

2) GAO Recommendation: Rank generic standards pesticides in order of potential risk and develop standards for highest risk pesticides first.

EPA Response: A ranking system which gives priority to major risk pesticides in ordering the development of registration standards is important. However, the Agency also needs to preserve a certain flexibility in the sequence of development for registration standards to accommodate the review and development of standards for pesticides which were not selected for early attention, but for which new evidence or strong public interest shows a need to begin development of standards. EPA is legally required to weigh factors in addition to high risk as well.

In section 3(g) of the FIFRA, Congress itself has provided some guidance on the order in which particular pesticides should be considered for reregistration. That section states: "The Administrator shall accomplish the reregistration of all pesticides in the most expeditious manner practicable: provided, that, to the extent appropriate, any pesticide that results in a postharvest residue in or on food or feed crops shall be given priority in the reregistration process." We interpret section 3(g) as establishing two different, but simultaneous goals - to review pesticides to which people are exposed through their food supply as early as possible during the reregistration process and to reregister all pesticide products expeditiously. People are also exposed from home uses, perhaps more significantly than from food. This risk must be considered as well.

The Agency does not believe it is in the public interest to delay beginning the development of registration standards for the sake of developing highly sophisticated ranking criteria based on the risks associated with use of a particular pesticide. Moreover to apply such criteria the Agency would need to perform data reviews and assessments virtually equivalent to standards development itself. Therefore, the Agency selected pesticide chemicals for the first and second years of registration standards development on a less stringent basis, keeping in mind both the involuntary and potentially widespread human exposure to food use chemicals, and exposure to pesticides used directly on the human body or with similar exposure potential. Of the 58 pesticides selected for review so far, 36 are pesticides with food uses and 3 are pesticides with direct human exposure. In selecting these first chemicals, the Agency has thus considered both the extent and type of human exposure associated with their use.

Additionally, the size and quality of the data base for any particular pesticide can directly influence the time it takes to complete a standard. Selecting only two or three major chemicals, particularly while we are still setting up the program, may completely tie up our resources. Such a selection may also result in inefficient use of our resources, because of potentially lengthy periods spent waiting for completed reviews of the large number of studies supporting these chemicals. Thus the Agency has chosen a mixture of chemicals to test our system, allowing for completion of standards as policy issues are resolved, without being caught up in the sheer volume of data as well. The development of registration standards for these initial pesticides should help establish better protocols and procedures for subsequent standards, based on experience rather than conjecture.

Finally, we also believe that beginning work at the same time on several different standards for products with the same or similar uses (use clusters) can both improve the quality of our decisions and increase the efficiency with which data are reviewed and standards are developed. Although this use cluster approach cannot by its very nature address only or all high risk pesticides first, comparative assessments of pesticides within a use cluster will enable the Agency to take into account risks and benefits of pesticides which may be used as alternatives to pesticides with uses found to be unacceptable.

The Office of Pesticide Programs has drafted a proposed system to rank pesticides and is now testing it with a small number of chemicals. We expect to complete our priority ranking system after reviewing public comments received on our Advanced Notice of Proposed Rulemaking (ANPRM) for Registration Standards early in 1980 and to use our final ranking system to select new chemicals for standards development in the second half of FY80. When the ranking system is complete, we will also be publishing it in the Federal Register.

/GAO COMMENT: By recommending that EPA rank pesticides in order of their potential risk and concentrate on them first, we are not suggesting that EPA delay the development of any registration standards./

3) GAO Recommendation: Finalize proposed registration guidelines promptly.

EPA Response: Obviously, we agree that the Guidelines need to be published in final form as soon as possible. We are less than six months away, we hope, from publishing final Guidelines on Human Hazard (the acute hazards portion), Product Chemistry, Environmental Fate, and Fish and Wildlife. Progress is being made on all fronts. However, because of the large scope of Guidelines; the need to ensure they reflect the state-of-the-art in their respective scientific disciplines, without being excessively burdensome on industry; the need for interoffice, interagency, and international consistency of test protocols; and the statutory requirements for review by the U.S. Department of Agriculture and the Scientific Advisory Panel, it simply is not a process which is easily or quickly completed.

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We also emphasize here that issuing final Guidelines is not really as important as making good guidelines available for the public and the Agency, whether they be proposed or final. We know that scientific knowledge and technological procedures are always evolving, and we anticipate that the Guidelines will be continually revised over the years. In other words, the Guidelines will never really be "final" because scientific knowledge about testing techniques for most portions of the Guidelines keeps advancing. We are in a phase right now between proposed and final rulemaking. However, it is not entirely true that because the Guidelines have not been issued as final, "EPA is not assured of having uniform criteria to evaluate the data" (p. 14). The quality of the Guidelines is dependent on the quality of their standards and requirements; finality or lack of finality doesn't impose or prevent uniform criteria. Agency reviewers are already using the proposed Guidelines as appropriate to completed studies and as new studies are begun to support pesticide registrations. This is a great improvement over the case-by-case approach taken before the Guidelines existed at all and that improvement in quality is, after all, the real purpose of the Guidelines.

The Guidelines are expected to have their greatest impact when applied prospectively. Much of the data which will be evaluated in making registration standards are data submitted at the time of original registration. We do not intend to discard this data in every case and require new testing. Uniformity is not a preeminent goal. If the studies are not consistent with Guidelines, then data reviewers are expected to use judgment, describe study limitations and their effect on confidence in evaluations of risk. Where test design or execution flaws erode confidence in study results sufficiently and there isn't sufficient redundancy in tests submitted to restore confidence, additional testing will be required. But since some pesticides have never been tested for some effects, we believe the marginal regulatory value of requiring a new test as a replacement for an existing test which almost meets Guidelines standards, would not be the best use of testing resources. Where testing is required for future submission, adherence to the Guidelines should enhance the quality of the results and the confidence that can be placed in evaluations based on them.

In short, we agree that the Guidelines must be made final as soon as possible and we are working hard toward that goal. But we want to emphasize also that the proposed Guidelines are being used until final ones are published, that the Guidelines are never truly "final", and that rulemaking status is not as important as the quality of the requirements.

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4) GAO Recommendation: Identify key health and safety tests which are necessary to make even preliminary decisions, require registrants to submit missing tests within a reasonable time, and cancel registrations of firms not complying.

EPA Response: This recommendation sounds very much like the Data Call-In Program which we are now putting into final form. This Program is generally described in the ANPRM for Registration Standards, now awaiting signature by the Administrator. A copy of the ANPRM is a attached for GAO's information. The Data Call-In Program is the first major stage in the construction of pesticide registration standards scheduled for development several years from now. It will assure that much of the necessary testing of already registered pesticides, which may be lacking now or which is plainly inadequate, will be done or in progress by the time the Agency actually starts work on the registration standards covering these pesticides. (Obviously, because many tests covered by the Data Call-In Program take three years or longer to perform, the Program will not produce data quickly enough to affect the completeness of registration standards which are now being developed or scheduled in the next two years.)

The Data Call-In Program will be primarily concerned with development of studies taking more than six months to perform, since we can require any needed short-term testing soon after the start of work on a standard and still receive the data in time to use it. As part of the Data Call-In Program, the Agency intends for each pesticide chemical: 1) to determine, based on use patterns of products containing the pesticide, what types of long term hazard effects data will be required; 2) to screen EPA files quickly to disclose positive data "gaps" (complete absence of data); and 3) to develop "rejection criteria" which registrants must use to judge whether data on hand are totally inadequate for modern decision making. For each group of pesticide products in the Data Call-In Program, EPA plans to inform the registrants of the data requirements and the data gaps which need to be filled to support the continued registration of their products. EPA will also require registrants to review existing studies and identify those which did not satisfy the rejection criteria. Registrants may rely only on those data which are not rejected by these criteria.[1] Registrants will then have to provide the required missing data and will also be required to submit proposed protocols and periodic progress reports.

[1]Since detailed review of "validation" of data must be done systematically through the standards process, data which "pass" the rejection criteria now, may be determined later during standard development to have some flaw or combination of problems such that repetition of the study will be required.

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While we are completing our planning for Data Call-In, we are also going ahead with a pilot Data Call-In Program for 16 urea herbicides. These urea herbicides were chosen because: 1) the group is a manageable size and 2) they have a good mix of food and non-food uses. We will be informing registrants of products containing any of these herbicides of the requirement to fill identified data gaps and to apply rejection criteria to existing data.

We also point out that in the past year, tolerance setting has, in many cases, served as a "Data Call-in" to some extent. In tolerance petition reviews, we have identified a number of chemicals which, for example, lack data from a second oncogenicity tests as now required by the proposed Guidelines. Though in many cases we feel that we have enough information to recommend for a tolerance, we have at the same time imposed a requirement that a second oncogenicity study be conducted. This procedure cannot, of course, serve as a systematic way to call in missing data, and we are not suggesting it could satisfy GAO's concerns. We mention it, however, as an indication that we too have been concerned about imposing defensive data requirements, and have already required, on a case-by-case basis, many registrants to start testing.

5) GAO Recommendation: Require that each registrant submit a list of all (published and unpublished) health and safety tests it has for each generic standard pesticide.

EPA Response: From a purely scientific standpoint we must agree that it is a good idea to know about all studies on a pesticide which a registrant has in his possession, whether or not the studies are specifically required in the Guidelines for registration under FIFRA. However, from a legal standpoint the Agency is authorized by FIFRA to require submission by a firm of all health and safety data only when the firm is applying for registration, amended registration, or reregistration. FIFRA section 6(a)(2) requires submission of some of this data; see the statement published at 44 FR 40716 (July 12, 1979).

6) GAO Recommendation: Publish a Federal Register Notice inviting public comment on the program's objectives and procedures and on pesticides undergoing standards development.

EPA Response: One of the features of the new registration standards process is that it will be a very public decision-making procedure. Opportunity for public comment is an essential element to the effective functioning of a regulatory body serving the public health and environment. An ANPRM for the registration standards system is now awaiting the Administrator's approval as I indicated earlier. We expect to publish it in the Federal Register this month. This ANPRM discusses the organization of a typical registration standard: the steps in the preparation of a standard (including the Data Call-In Program, data gathering, data review, preparation of a regulatory position and publication of a proposed standard, and consideration of public comment

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and the publication of a final standard); maintenance of a standard; registration and reregistration under standards, legal status of a standard; and the order of development of standards. We also note that, as described in the ANPRM, we will also be issuing additional Federal Register notices whenever we actually begin collecting and organizing data on a particular active ingredient. These notices will signal start of work and will solicit submission of pertinent information.

We have been working on this ANPRM for at least a year. While this is a long time, the ANPRM in itself is a major accomplishment. In drafting this document the Agency has been able to identify, analyze, and, in many cases, resolve major policy issues raised by the registration standards program. Thus the ANPRM has already served an important internal function in helping us to clarify issues and problems. When published, we hope it will provide the public with a thorough and substantive discussion of the program and will explain a number of very specific issues on which we desire public comment.

Even though the ANPRM is not yet published, some of the Pesticide Program's managers have already discussed the registration standards system in detail at many public meetings this fall. Finally, I note that this month we are completing a videotape and detailed brochure describing the system. This brochure will be available to all members of the public.

7) GAO Recommendation: Develop a tracking system to monitor the status of a pesticide as it travels through the standards system and institute procedures to identify and alleviate obstacles.

EPA Response: GAO recommends that EPA establish a tracking system for registration standards as a way to prevent the sort of delays which are discussed on pages 9-10 of the report. This discussion focuses on two points: first, the need for scheduling and tracking of overall registration standard development and second, problems in scheduling and tracking within Phase I of the development process.

The need for a registration standards tracking system is clear and we are developing such a system. It is complete for Phases I, II, and III of the Standards Program and work on the tracking system is in progress for Phases IV and V. The development of a tracking system is proceeding a pace with standards development and has not been a notable omission to date.

With regard to Phase I data gathering activities GAO is correct that we are behind schedule. The Agency was too optimistic in planning Phase I, considering: (1) the unprecedented complexity of the tasks involved in data gathering, (2) the need to coordinate two contractors'

efforts to produce a Phase I data package, (3) the amount of Pesticides Program contractor interchange necessary to produce a Phase I package (and the time required to smooth out these interchanges), and (4) the fact that the principal contractor, RAVEN, did not have an information management and indexing capability prior to award of the contract. In retrospect, these complications made the goal of producing a data package each week during the first year unrealistic. Even if EPA had completed the development of a tracking system prior to award of the contracts, production of one Phase I package per week would not have been possible until long after the original FY 1979 schedule called for such a frequency due to the unforecasted complexity of the task as described above.

A current schedule showing planned and actual Phase I data package deliveries is attached for GAO's information.

We have also been considering the need for status reporting by the contractor for Phase I. Basically, however, our approach has been not to develop a detailed tracking system for individual steps to be accomplished within the overall Phase I goal of data gathering, until the need for such a system is indicated. Since actual deliveries are reaching a level of 1 per week (13 deliveries in August, September, and October) we do not believe such a detailed system is now necessary. The reasons for the Phase I delays were largely "start-up" problems and not failure to track progress.

In planning these contracts EPA selected an award fee contract to mitigate the need for a detailed Phase I tracking system. The variable fee awarded on the basis of contractor performance lessens the need for interim tracking and allows us to concentrate more on the timeliness and quality of final products since the contractor has a strong incentive to monitor the details of their own performance.

8) GAO Recommendation: An independent office, responsible to the Administrator, should periodically monitor progress in reregistering pesticides and reassessing tolerances and should examine costs and benefits of using contractors for standards work.

EPA Response: In addition to the direct line of management control from the Administrator to the Assistant Administrator for Pesticides and Toxic Substances and to the Deputy Assistant Administrator for Pesticide Programs, the Administrator and his immediate staff obtain "independent" advice on problems and progress from EPA's Office of Planning and Management. Other entities within the Agency (Working Groups, Red Border Review, Steering Committee) also actively pursue the execution of EPA collegial policy to assist in the discharge of EPA's pesticide regulatory responsibilties. Close Congressional oversight (of which GAO's report is a manifestation) is also a useful tool in identifying and correcting problems.

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The Office of Pesticide Program is also conducting a number of monitoring and evaluative projects itself. Specifically, the tracking system just discussed will enhance significantly its ability to monitor progress. In addition, Pesticide Programs has begun a detailed program planning process which both plans and monitors the progress of all OPP programs (the PMS discussed earlier). The Director of the Special Pesticide Registration Division, which manages standards development, has established an evaluation section which will perform a monitoring function such as GAO suggests. For instance, with the completion of 20 Phase I data packages and the beginning of Phase II for these chemicals, OPP has just completed a program evaluation. This evaluation highlights a number of areas where additional procedural work and training are needed. This evaluation section will also evaluate on a continuing basis our use of contractors. (One such evaluation is in progress now.)

Although GAO criticizes our reliance on contractors, there are several reasons why we have relied and will continue to rely heavily on contractor resources in the registration standards program. First, some professionals such as toxicologists, simply cannot be hired by the Federal Government in the numbers and at the skill levels required to accomplish registration as quickly as EPA plans. The only source available for significant numbers of some skills is the private sector. Second, the emphasis of Federal budgeting "guidelines" in the past several years has been on the use of contractor resources, rather than on hiring more staff in EPA. It is very unlikely, for example, that the Administrator would have authorized hiring of new personnel equivalent to the support provided by the Raven contract alone (160 work years) not to mention other contracts at least partly related to standards development (60-100 work years). Third, while contractor costs do, generally, exceed the direct costs of "in-house" resources, the difference is reduced by full consideration of indirect costs, for example, pensions, health benefits, overhead. In addition, because of the Civil Service requirements which the Federal Government follows in dealing with its personnel, the usually greater management flexibility in the private sector may well more than compensate for the differnce in direct costs--particularly if the motivation, such as award fee, is present to make changes. The current mix of contractual and in-house resources can only be finally evaluated after several years of experience, although current performance is quite promising.

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9) GAO Recommendations: Review the Scientific Advisory Board's recommendations on the adequacy of EPA's tolerance setting procedures and implement accepted recommendations. Reevaluate those tolerance setting issues and procedures not reevaluated by the Board.

The GAO report correctly notes that we do not yet have the final report of the Science Advisory Board (SAB) on the Agency's tolerance setting procedures. We hope to receive this report by the end of 1979. As we have stated to Congressional Committees, we do not believe it would be an intelligent use of resources to embark on a tolerance reassessment program until the underlying scientific principles of tolerance setting have been examined and recommendations provided by the SAB.

In anticipation of the SAB's final report, however, the Agency is preparing a plan for implementing the SAB recommendations. We plan to prepare a thorough response on the SAB final report and articulate the changes we will be making in the tolerance program (and those we won't) and how tolerance reassessment will fit in with registration standards. (The ANPRM for Registration Standards also addresses integrating tolerance reassessment into the registration standards system.) However, the SAB report in its draft forms has not found radical problems in the tolerance setting process, and its recommendations are likely to be addressed to "fine tuning" rather than wholesale restructing of the current procedures.

While the report criticizes the Agency for not pushing the SAB to deliver its report, GAO should also realize that the SAB is not a committee under the direct control of the Agency. It is an independent advisory board composed of scientists who provide scientific and technical guidance to the Administrator. While we can request certain recommendations by certain times, we cannot impose a schedule on the SAB. Nonetheless, because we share GAO's concern to have a completed SAB report, some time ago we requested the SAB to move as quickly as possible consistent with the complexity of the issues under consideration.

Finally, we would like to summarize the Agency position on each of the three policy issues GAO suggests remain unresolved (p. 20).

First, we believe that section 408 of the FFDCA permits the establishment of tolerances for carcinogens or mutagens. Briefly, as evidenced for example in our regulatory decisions for pronamide and BAAM the Agency has decided to establish or continue tolerances for these pesticides, even though they are carcinogens. Using a risk assessment calculation developed by our Carcinogen Assessment Group, the Agency estimated the incremental increase in cancer risks

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in human populations consuming products containing residues of these substances. The Agency also assessed the benefits of continued or proposed new use.. The risk and the benefit assessments were weighed against one another and for certain uses and tolerances of pronamide and BAAM the Agency found the benefits to outweigh the risks. In other words, we have adopted a risk/benefit approach to tolerance setting for carcinogens and mutagens.

Second, our Office of General Counsel in a memorandum of September 13, 1977, has concluded that EPA can consider risks and benefits when issuing tolerances.

Third, we agree that parallel authorities under the FIFRA and the FFDCA would be logical so that if the Agency took action to suspend product registrations under the FIFRA for instance, it could also take action to suspend tolerances under the FFDCA if it were needed to protect public health. However, suspending tolerances would also create economic difficulties for growers and packers, and we think that actual need to suspend tolerances would be very unlikely. In most cases, suspending product registrations will most effectively protect the public health by suspending pesticide use. We also should point out that the Agency will in the future revoke tolerances as appropriate in coordination with cancellation of product registrations.

II. RPAR

1) GAO Recommendation: Issue a formal RPAR operating manual describing all phases of the process. It should include: 1) guidance on planning format, detail, specific tasks, and basis for determining length of time tasks should take; 2) procedures for selection and review of pesticide uses and alternatives; 3) definition of project manager's authority and team members' responsibility; 4) criteria for risk/benefit decisions; 5) procedures for prompt completion of cancer risk assessment; 6) procedures for accurate, up-to-date status reports; and 7) procedures to identify the most hazardous of the pesticides in the RPAR process, whose reviews should be completed first.

EPA Response: There is an RPAR operating manual which the Office of Pesticide Programs is revising now. Its format when revised will be the same as that of the registration standards manual in anticipation of the RPAR program becoming a part of the standards program in FY82. The procedures in the revised manual will reflect the new team approach we are using to manage pesticide reviews. There is also existing guidance available on planning formats, procedures and time which will be incorporated into the revised RPAR manual. The Office of

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Pesticide Programs has also developed new flow charts which clarify the relationship of specific tasks in the RPAR process. As sections of the manual are revised, they become available for use. The revised sections of the RPAR manual and the pre- and post-RPAR flow charts are attached.

With regard to procedures for selecting and reviewing pesticide uses and alternatives, we do not believe useful, detailed guidance can be developed. The process of selecting and reviewing uses and alternatives is very dependent upon the characteristics of the particular chemical under review and must ultimately be a subjectively determined selection among several possible choices. In any given instance, the quality of the decision will depend on the judgement and experience of the decision maker and the completeness and validity of underlying data. The elements of judgment and experience cannot be learned by reading detailed operating procedures. It can only come from working through some actual cases. However, general guidance on the types of questions which should be asked and answered in selecting and reviewing pesticide uses and alternatives is available and will also be included in the revised RPAR manual.

The roles and authorities of the Project Manager and team members have been clarified and agreed to by Division representatives in the Office of Pesticide Programs.

As for specific criteria for risk/benefit decisions, we believe again that this process is not amenable to standarized, detailed "recipes". However, EPA has planned a project for FY80 which will provide guidance, instruction and assistance on how to conduct a risk-benefit analysis for RPAR chemicals and their alternatives. The project calls for development of an instruction document which can be used by Project Managers on the conduct of risk-benefit analysis for an RPAR chemical and subsequent training and assistance. This new work will focus on quantifying decisions based on qualitative data, the use of sensitivity analyses, and the use of confidence intervals or ranges rather than point estimates.

Concerning cancer risk assessment, GAO should be aware that the Hazard Evaluation Division in the Office of Pesticide Programs is taking the lead now in doing these assessments with oversight by the Carcinogen Assessment Group. We are now working on a policy memorandum to expressly discuss the roles of the Hazard Evaluation Division and the Carcinogen Assessment Group in all continuing and new assessments. We will be glad to share this policy statement with GAO as soon as we have worked it out.

To insure an accurate and up-to-date status report, a tracking system is being set up to monitor on a bi-weekly basis the chemicals under review. A list of approximately 150 key tasks has been developed

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and all projects are being scheduled and tracked against these same tasks. Tracking is tied to management level. The most detailed tracking is performed at the Division level with tracking of major tasks to be accomplished at the Deputy Assistant Administrator/ Assistant Administrator level.

Finally, with regard to ranking chemicals in RPAR review, GAO should know that a risk priority system was used to determine the existing RPAR actions. We do not necessarily complete RPAR review of chemicals in the same order as we issue RPAR notices; we have finished reviewing some less risky chemicals before more difficult, riskier chemicals. Final decisions on beginning new RPAR's are dependent on the registration standards prioritization process since the Agency is committed to integrating the two processes as quickly as possible.

In sum, I believe we are already dealing satisfactorily with the seven items GAO specifies for inclusion in a formal RPAR manual, though not all of our pertinent activities may actually become formalized in the RPAR operations manual.

2) GAO Recommendations: Decide if pending RPAR referrals should be accepted, implement a prompt referral review procedure, and identify and consider risk data readily available from sources such as the National Institute of Occupational Health.

EPA Response: OPP is currently identifying the appropriate action for pending referral chemicals. In addition, OPP has planned a project for FY80 which will determine the appropriate review mechanism for referral chemicals. Such issues as those mentioned in the report will be addressed in the issue paper developed as part of the RPAR referral project. When this project is complete, we will notify GAO of our decisions regarding RPAR referral chemicals.

3) GAO Recommendation: Require registrants to submit nondietary exposure test data during RPARs.

EPA Response: GAO's description of the difficulties in exposure assessment is perceptive and for the most part accurate. Their general conclusion is that EPA lacks reliable data on actual human exposure to pesticides under RPAR review. While this conclusion is still true to a large extent, we now encourage data development by: 1) drawing worst case assumptions about exposure in the absence of reliable data and 2) telling the registrants we will cancel registrations unless they rebut the presumption, which they can do by generating real data showing we were wrong in our assumption that exposure was high. In addition, EPA, USDA, and State agencies are now funding such studies. Although assumptions about breathing rates, absorption efficiencies, duration of exposure and number of people exposed must still be made even when specific exposure data are available, exposure assessments are currently based to a larger extent on actual field data than the GAO report suggests.

Risk/benefit decisions do depend heavily on exposure assessments (we don't know who would have implied that because exposure data are so sketchy they do not have much of a bearing on RPAR decisions (p.37)). There certainly are use patterns for which no exposure data at all are available; but even for these uses, risk assessment requires some estimate of exposure, except for the rare cases in which a direct epidemiological link between use and health effects can be established.

/GAO COMMENT: The paragraph in question (para. 6, p. 41) no longer contains the aforementioned implication./

The statement (p.38) that industry has exerted "...almost no effort in the exposure data area" is no longer correct. We believe that industry knows that in the absence of exposure data, EPA will overestimate (take a "worst case" approach) rather than underestimate exposure, and it is therefore in their best interest to provide as much data as possible.

We do agree that we have a long way to go in obtaining real life exposure data, and have asked our Office of Research and Development for protocols for developing such data. These protocols will be used in developing worker exposure guidelines.

4) GAO Recommendation: Conduct, with FDA, food residue tests on individual RPAR pesticides.

EPA Response: EPA agrees that more information from FDA's residue sampling program would be very helpful. FDA has recently prepared a report ("FDA Monitoring Programs for Pesticides and Industrial Chemical Residues in Food," June 1979) recommending the development of a surveillance index to set priorities for their surveillance and market basket monitoring. In September 1979 we entered into an agreement with FDA to cooperate on the development of this index. We will identify and submit to FDA a list of the "important" chemicals for monitoring rather than simply those for which methodology is most convenient. Special surveillance programs for RPAR chemicals -- such as the surveillance programs initiated for DBCP and EDB -- will be a part of the new approach to monitoring.

These new efforts aside, we think it is important to note that assuming that pesticide residues are occurring at the tolerance level tends to overestimate dietary exposure; this means that, in the absence of sampling data from FDA, we are taking a conservative approach as far as public health is concerned. Thus, while reliance on tolerance levels alone is not the most accurate way to estimate dietary exposure, it is the most protective.

5) GAO Recommendation: EPA should fully explain the bases for important assumptions used to calculate benefit estimates and show the range in benefit estimates which use of alternative data and/or different assumptions would indicate.

EPA Responses: We agree with GAO that it is necessary to explicitly document the bases for benefit estimates and to identify uncertainties

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in the data base. Sensitivity analyses are important for both benefit and risk assessments. We are pursuing this as discussed earlier in response to GAO's first RPAR recommendation. In addition, the Office of Pesticide Programs has planned a thorough review of the benefit analysis aspect of the RPAR process. A project is planned for FY80 which will improve the presentation of both RPAR and registration standards chemicals information by describing the level of uncertainty inherent in the data base and hence, in the recommendations for action. The project will address both risk and benefit analyses.

III. LABORATORY AUDITS PROGRAM

1&2) GAO Recommendation: The Administrator should submit to Congress amendments to FIFRA expressly authorizing EPA to inspect laboratories and reject tests from labs refusing to allow inspections and to take regulatory action, including suspension, with regard to registered pesticides for which the Agency later determines the supporting data are invalid.

EPA Response: The GAO is correct that FIFRA does not expressly authorize EPA to conduct laboratory inspections. However, results do not suggest that lack of express authority has hampered the audit program to date or is likely to do so in the future.

Audits (review of raw data) and actual inspections of laboratories are not the same things. The Act rather explicitly authorizes the Agency to request for review full data (in effect, an audit) when necessary to make a registration decision. Specifically, FIFRA, section 3(c)(1)(D), does authorize the Agency to request a registrant to support his registration with, "a full description of the tests made and the results thereof" pertaining to his product. While the Agency does not normally request a "full description," the Act clearly gives us the power to do so. Moreover, in the event the Agency requests to conduct a laboratory audit in order to obtain that "full description" of a test which may be invalid, and the laboratory refuses to allow the audit, the Agency will notify the registrant that the data in question will be considered insufficient to support his product registration. The registrant then has the option either to redo his data elsewhere in a laboratory which does permit inspection or to persuade the laboratory to permit the requested inspection. The expense and inconvenience to the registrant which may result if a laboratory which he operates or employs refuses the audit can be significant and strong inducement to comply with the inspection request. The Act does not, of course, authorize the sort of immediate "suspension" action GAO recommends; i.e., suspension because that data have been found to be invalid. However, section 3(c)(2)(B) does

authorize the Agency to issue a notice of intent to suspend a product registration if the registrant has failed to take appropriate steps to secure data required to support continued registration of his product. The sort of abrupt action GAO has in mind is more extreme than may be necessary in many cases. Even if some data are found invalid after registration, it does not always logically follow that the product is actually posing an "imminent hazard" to human health, the statutory trigger for suspension action. The risk stays the same regardless of the validity of data. If data previously accepted are now found to be invalid, what changes is the Agency's level of knowledge and certainty. If the Agency considered use of the pesticide acceptable before the data were found invalid, despite the increase in the Agency's level of uncertainty about the effects of that pesticide, its use may still be acceptable during the time it takes to develop and review valid data.

And if the Agency's level of uncertainty was too great, the Agency could assume the risk was high and suspend if the hypothesized risk exceeded the benefits of use for the period of time necessary to complete cancellation proceedings. If a lesser hazard exists which is still found to be unreasonable, then cancellation or similar action is available. But without evidence of imminent hazard or unreasonable risk, it is more appropriate to permit registrants reasonable time to replace that data than to suspend or cancel registrations, although registered products for which certain data are invalid may pose a degree of risk which cannot be completely characterized until new data are developed.

/GAO COMMENT: In a draft of this report we had proposed that EPA submit to the Congress a FIFRA amendment authorizing EPA to inspect laboratories and to reject tests from labs refusing to allow inspections. We deleted our proposal on the basis of EPA's comments and subsequent discussions with EPA officials in which it was pointed out that EPA relies on FDA to perform general inspections of labs and that EPA has authority to review pesticide testing data./

3) GAO Recommendation: EPA should arrange with USDA to receive results of that Department's laboratory inspection program.

EPA Response: EPA will request to be notified of USDA inspection results in the future and will review them for information which will aid EPA's laboratory inspection program.

4) GAO Recommendation: EPA and FDA should routinely conduct more unannounced inspections:

EPA Response: EPA does notify registrants in advance of test audits but normally does not give more than one day's notice. This advance notice is considered necessary because prior to the audit the lab must obtain a release from the sponsor of the data. In addition, as recognized by GAO, unannounced audits have presented problems because key personnel were sometimes not available, important documents were not readily accessible and labs could not prepare for work disruptions caused by the audits. EPA's audit concentrates on completed studies. 24-hour notice of an audit would not allow a major cover-up of data generated possibly years ago by a lab.

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The report recommends that EPA and FDA routinely conduct more unannounced inspections. At this time EPA and FDA do conduct unannounced audits or inspections if there is any suspicion of bad practices. EPA will consider doing more unannounced audits; however, we believe that the advantages of 1-day advance notice outweigh the problems caused by unannounced audits. EPA will continue to conduct unannounced audits if there is any suspicion of bad practices.

/GAO COMMENT: In a draft of this report, we had proposed that EPA and the Department of Health, Education, and Welfare routinely conduct more unannounced inspections of labs. After considering EPA's and the Department's comments (see app. III), we deleted our proposal./

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

REFER TO:

OFFICE OF THE INSPECTOR GENERAL

DEC 13 1979

Mr. Gregory J. Ahart
Director, Human Resources
Division
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Ahart:

The Secretary asked that I respond to your request for our comments on your draft report entitled, "Protecting the Public From Dangerous Pesticides--New Programs For Old Problems." The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

Richard B. Lowe III
Acting Inspector General

Enclosure

APPENDIX III

COMMENTS OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE ON THE GENERAL ACCOUNTING OFFICE'S DRAFT REPORT ENTITLED "PROTECTING THE PUBLIC FROM DANGEROUS PESTICIDES -- NEW PROGRAMS FOR OLD PROBLEMS"

General Comments

This report primarily addresses the Environmental Protection Agency (EPA) pesticide program, and we defer to that Agency for response to issues unrelated to HEW's activities. We would like to point out, however, that in general the report focuses upon the managerial and administrative aspects of the review of pesticide safety and only briefly mentions some of the very real scientific and technological issues that have created many of the problems cited by the report. Examples of the issues that have not been satisfactorily resolved within the scientific community include questions such as what is a carcinogen, what constitutes adequate evidence in support of safety, and what procedures are proper for determining risks and benefits quantitatively. These are societal issues that have no simple solutions, but until such solutions are found, regulatory agencies will not be able to function with the consistency, efficiency, and specificity that is desirable.

GAO Recommendation

To ensure that exposure analyses are based on actual and accurate test and monitoring data, we recommend that the Administrator, EPA, with the Commissioner, FDA, conduct pesticide food residue tests on individual RPAR pesticides.

Department Comment

We concur. The Food and Drug Administration (FDA) has, in fact, honored EPA's requests to conduct special food surveys for pesticide residues where data on such residues have not been generated by the routine FDA monitoring programs and EPA needs such data for assessing dietary exposures to a particular pesticide. In some instances, we have initiated these special surveys. Examples of Rebuttable Presumption Against Registration (RPAR) pesticides where special surveys have or are being conducted by FDA are: dibromochloropropane, ethylene dibromide, maleic hydrazide, benomyl, ethylenebisdithiocarbamates and their degradation product ethylene thiourea, pronamide, Kepone, and mirex. Additionally, FDA's Total Diet Study and surveillance programs cover 24 pesticides currently on EPA's RPAR list. Residue data generated by the FDA sampling programs on these pesticides, as well as many other pesticide chemicals, are made available to EPA. Additionally, FDA data provided to EPA on residues in food of aldrin, dieldrin, heptachlor, and chlordane were instrumental in effecting the cancellations of their registrations.

We recognize however, that the FDA monitoring programs can be improved to provide residue data on a greater number of pesticides, as well as data that may be more meaningful in assessing dietary exposures to pesticide residues. In June 1979, an FDA study group prepared a report that, among other things, addressed the need for such improvements. The recommendations of the study group were approved by the Commissioner of Food and Drugs and their implementation is proceeding.

GAO Recommendation

To further enable inspectors to obtain the most accurate information on test laboratory conditions, we recommend that the Administrator, EPA, together with the Secretary, HEW, through the Commissioner, FDA, routinely conduct more unannounced inspections. These inspections could be conducted on a random basis, or based on criteria such as past laboratory performance.

Department Comment

We do not concur. FDA has conducted two evaluations of the toxicology laboratory industry to assess compliance with the Good Laboratory Practices (GLP) regulations. The first study examined conditions and practices in 1977 well before publication of the final GLP regulations (December 1978). The second examined findings at 28 laboratories inspected during the second quarter of FY 1979. In both studies, firms were randomly selected, and almost all were not notified prior to inspections.

These studies were designed primarily to measure the state-of-compliance and changes in industry compliance over time, but they also provide evidence to refute the assumption that non-compliant laboratories could correct outstanding deficiencies between the time of notification and the time of inspection. The more chronic and serious problems experienced by toxicological laboratories are not deficiencies that can be corrected by hasty action a few days before an inspection; rather they are procedural errors that cannot easily be disguised. The absence of operational quality assurance units, maintenance of records on equipment calibration, adequacy of standard operating procedures, records of periodic feed analysis, and design of adequate study protocols are the most frequent areas of deficiencies. We do not believe that a toxicology laboratory could convincingly disguise the more serious deficiencies on short notice. The availability of resources and regulatory requirements together make inspections somewhat predictable, even in the absence of prenotification. Regulations require that toxicology laboratories be inspected at least once every two years; available resources do not permit more frequent surveillance inspections. Consequently, a laboratory can guage the timing of an FDA inspection simply by the calendar.

For these reasons, we believe that a laboratory gains very little advantage from announcement of an inspection. On the other hand, there is considerable gain in operational efficiency for FDA to announce its inspection. Laboratories are usually inspected in conjunction with an audit of a specific study

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that has been submitted to either FDA or EPA in support of a petition for approval or registration of a product. The studies are, therefore, always completed studies whose records may be stored off the laboratory premises. Because the GLP regulations regarding data storage are new, many of the laboratories now being inspected must retrieve records of a particular study. Of equal importance in conducting a study audit is the availability of the study director to "reconstruct" the study from available records. Our experience during the pilot phase was that, because the studies and audit were completed, the study director was not always available when FDA investigators arrived unannounced. This often entailed lengthy delays with FDA investigators being required to return later to complete the inspection, particularly if the study director were on vacation or otherwise out of touch with the laboratory. Finally, and perhaps most significantly, when studies are done under contract for a product sponsor, the data generated by the study do not belong to the laboratory, but to the product sponsor; and laboratories generally will not release it to FDA investigators without prior authorization by the sponsor. This means that an unannounced inspection involving a study audit can be delayed several days while authorization for release of data is secured from the sponsors. For these reasons, FDA and EPA concluded that inspections of laboratories should be announced prior to the investigators' arrival. As stated above, we do not believe this approach significantly affects the validity of the inspection. However, the authority to inspect without prior announcement (except as provided in number 6 below) remains and is used when seen appropriate by FDA. In fact, almost all inspections of establishments other than laboratories are unannounced.

/GAO COMMENT: In a draft of this report, we had proposed that EPA and the Department of Health, Education, and Welfare routinely conduct more unannounced inspections of labs. After considering the Department's and EPA's (see app. II) comments, we deleted our proposal./

Technical Comments

1. Throughout chapter 4, the report inaccurately refers to FDA's approval of food additives and new drug applications as "registration." Under the Federal Food, Drug, and Cosmetic Act (FFDCA), these products are not "registered", but "approved" prior to their introduction into interstate commerce. "Approval" under the FFDCA, like "registration" under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), involves the submission and evaluation of safety data, whereas "registration" in the FFDCA involves little more than submission of a mailing address. Thus wherever the words "register" or "registration," appear in relation to the FFDCA they should be changed to read either "approval" or "petitions."

2. Page 43, paragraph 2

The statement that FDA's Total Diet testing methods do not detect dimethoate was correct until recently. However, these methods have been added to the FY 80 Total Diet Study. Moreover, FDA surveillance programs have included, at least in the past several years, analytical methods that can quantitatively detect dimethoate and its oxygen analogue. The surveillance program instructs the District Offices to test a portion of

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fruit and vegetable commodities collected using these methods. Therefore, FDA does have data on the levels and incidence of dimethoate on a variety of crops. This data could be used to calculate dietary exposures from individual foods.

3. Page 43, paragraphs 3 and 4

This discussion of FDA's Total Diet Study is apparently based upon previous GAO reports. It should be noted that the FDA did not agree with these reports. However, the reasons GAO states in this report for the inadequacies of the Total Diet Study do not in any way negate the usefulness of the data in calculating dietary exposure to toxaphene. The extensive data on toxaphene derived from the Total Diet Study over the past 15 years are sufficiently valid for calculating dietary exposures to pesticides in food. Also, because toxaphene has been extensively covered by the surveillance program, there are thousands of sample results on toxaphene residues for a wide variety of foods. These paragraphs should be modified to reflect that FDA has extensive data on toxaphene.

4. Page 43, paragraph 5

The statement that FDA conducted one special residue survey for an RPAR is incorrect. As stated in response to GAO's recommendation that FDA conduct residue tests on individual RPAR pesticides, FDA has conducted several special surveys for RPAR pesticides. Additionally, the FDA Total Diet Study and surveillance programs cover 24 pesticides currently on EPA's RPAR list. These paragraphs should be revised to accurately reflect that the data on toxaphene, as well as all the other pesticides covered by these programs, are valid and of a high caliber.

5. Page 53, paragraph 5

This paragraph requires some clarification. GAO is apparently referring to disqualification of laboratories for conducting tests in support of petitions to FDA. FDA's GLP regulations contain provisions for disqualifying laboratories with serious problems which are not corrected. These provisions can only be implemented if three conditions are met, (a) there must have been serious deviations from the GLP regulations; (b) these deviations must have had an adverse impact on the validity of the studies; and (c) lesser corrective actions by FDA have not or would not be effective in achieving compliance. All disqualification actions must afford the laboratory an opportunity for a hearing before the Commissioner of Food and Drugs.

Two of the less severe regulatory options available to FDA are rejection of an individual study and withdrawal of a marketing approval for investigational new drug exemptions (if that approval was based on the rejected study.)

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6. Page 49, paragraph 3

This paragraph is incorrect. Under section 704(a) of the FFDCA, FDA may inspect laboratories which are an organizational part of a firm over which FDA has inspection authority e.g., drug firms, food manufacturers. A significant number of independent laboratories, however, perform toxicological tests under contract. FDA can exercise its inspection authority over these laboratories while they are actually performing the tests called for in the contract because the contract makes the laboratory a legal extension of the firm over which FDA has inspection authority. Once the contracted tests have been completed and a report has been submitted to the client, the legal relationship ceases. Whether FDA can compel an inspection of that independent laboratory is unclear.

The fact remains, however, that in making inspections of over 300 laboratories, only seven initially refused to permit an inspection and of these, three subsequently asked to be inspected. Consequently, lack of explicit inspectional authority has not hampered the effectiveness of the program.

We suggest that this paragraph be revised to read:

> "FDA, however, does have some authority to conduct inspections and under its Good Laboratory Practice Regulations can reject tests conducted in independent laboratories that have refused to allow inspections."

/GAO COMMENT: FDA's comment refers to a paragraph in our draft report which has been deleted. The paragraph concerned EPA's legal authority to inspect labs. (See GAO Comment on p. 78.)/

APPENDIX IV

DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

DEC 19 1979

Mr. Henry Eschwege
U. S. General Accounting Office
Community and Economic
Development Division
Washington, D.C. 20548

Dear Mr. Eschwege:

The U.S. Department of Agriculture is pleased to have the opportunity to comment on the draft report entitled "Protecting the Public From Dangerous Pesticides -- New Programs for Old Problems. We are of course vitally interested in this important matter and have developed in cooperation with the Environmental Protection Agency several Memorandums of Understanding on many of the issues you raise in your report. We are enclosing copies of these documents.

There are many points throughout where the Department supports the comments made in your report; and overall we believe it is well prepared. We plan to work closely with EPA to resolve many of the problems that you have identified which are delaying the RPAR process. We fully support the admonitions contained in the report to avoid duplication of effort among Federal agencies. In addition, we believe that existing staff in the EPA, FDA or USDA, and the USDA/State University system may be more capable of handling some of the analysis with less reliance on contractor inputs, thus avoiding technical over-lap.

We believe it would be helpful to the members of Congress and other concerned individuals reading this report to explain in greater detail, in either chapter one or chapter three, the genesis of the Rebuttable Presumption Against Registration (RPAR) program and the process of review. It might also be worthwhile to make a statement of Congressional intent as it relates to the RPAR and Generic Standards role in registration.

We will comment only upon those areas of the report where the Department is directly involved in carrying out the programs discussed. A number of these specific comments are attached for your use.

Sincerely,

Jim Williams

Jim Williams
Acting Secretary

APPENDIX IV

SPECIFIC USDA COMMENTS ON THE U.S. GENERAL ACCOUNTING OFFICE DRAFT OF A PROPOSED REPORT ON PROTECTING THE PUBLIC FROM DANGEROUS PESTICIDES -- NEW PROGRAMS FOR OLD PROBLEMS

Page ii, para. 4 - You may wish to use another chemical to make the point indicated. While it is true that most of the uses of chlorobenzilate were cancelled, the use on citrus which accounts for 97% of the volume of the product was maintained.

Page iii, third recommendation - The EPA should also work with the USDA in this regard since the Department also tests for pesticide residues in the environment and in foods, particularly meat and poultry, and has expertise and experience in this area which could assist EPA in developing better testing of exposure to humans and the environment. We suggest USDA be added to the recommendation.

Page iii, fourth recommendation - It would be helpful for the agency to also include an explanation on how the weighing process works for determining risks of continuing pesticide use.

Page 1, para. 4 - The USDA in addition to the FDA enforces tolerance levels in foods, specifically meat and poultry. We suggest the paragraph be expanded to reflect the USDA responsibility in this area.

Page 5, para. 1 - The task of examining the adequacy of the tolerance setting procedures might be better conducted by the National Academy of Sciences. This would relieve agency personnel of the burden and would provide for an independent review. USDA would be willing to assist as necessary. We suggest the report would benefit by exploring this possibility.

Page 11, para. 4 - We fully support the need for establishing written operation procedures since all users , registrants, advisors, the public, as well as other involved federal agencies need to know the rules. Again, the USDA would welcome the opportunity to provide input and assistance to EPA in this regard.

Page 21, para. 3 & 4 - Depending upon the work loads required GAO may wish to recommend to the agency that it might be advantageous to overall economy to ascertain if other federal agencies have the information needed or could gather it in a more efficient manner. In many instances, contractors gather their information by going to another governmental agency to get their inputs. Precise needs would have to be spelled out by EPA in either case. As stated before, USDA would be willing to assist where it can.

Page 21, para. 5- Nothing in the pesticide or environmental area is "once and for all". New techniques and an ever developing state of the art always leaves open the possibility of discovering other heretofore unknown hazards or other interpretations on present information. GAO may wish to modify this paragraph to reflect accomplishment for a chemical at a point in time.

Page 32 - We agree that better planning is needed and would suggest that the paragraph include a comment recommending that planning should involve all the actors in the program including other federal departments or groups such as USDA, FDA, DOI, CAG etc.

Page 34, first 2 para. - We agree that it is difficult or impossible to analyze each use of a pesticide with present resource contraints. USDA also finds it difficult to adequately cover the benefits aspect on all uses with the joint USDA/ States/EPA assessment team. It must be pointed out however, and care must be taken that should all uses not be analyzed, they should not be automatically cancelled either. This would be tragic to the minor or specialty crop growers and users of those crops.

Page 34, last para. & page 44, para. 2 - There are several places in the report where the term "RPAR Team" is used. It is unclear at times if GAO is referring to the joint USDA/States/ EPA assessment team or some other team within the EPA. Clarification is suggested by adding more descriptive language.

Page 34, para. 3 - We agree that RPAR'd pesticides or even RPAR candidates should not be considered as viable alternatives. This is USDA's first indication that this is also an EPA policy.

Page 44, para. 3 - The paragraph points out that benefit estimates rely on imprecise data. We believe that GAO should also point out that the risk data in these and other cases is also imprecise.

Page 46, mid page - It is recognized by most that changing the assumptions will change the benefits estimates. The judgements and assumptions made by the joint USDA/States/EPA assessment teams are made by a group of recognized experts in the area of study and reflect the best knowledgeable judgements available. We believe that recognition of this fact should be made in this report.

Page 47, mid page - The assessment team composed of experts as described above used their expertise in rendering an opinion. In this specific case EDB is an RPAR'd pesticide and as indicated above, should not be used as an alternative pesticide in the analysis.

Page 49 - We concur, this operating manual should also be made public and EPA should obtain input, prior to finalization,

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by those outside the agency involved in the program. This input should especially involve consideration of time frames and data requirements. The GAO may wish to make such a recommendation to the agency.

Page 49, BOTTOM - Other sources of data should also be used such as National Cancer Institute, Food and Drug, other HEW Agencies, and the USDA. USDA in many cases does assist in exposure information, and has federal and state projects underway on exposure, pesticide degredation, and other areas as well. We would also be willing to assist the agency on the topic and GAO might make such a recommendation here also.

Page 50, TOP - EPA should also cooperate more fully with USDA in identification of their short and long term research needs, including exposure information and residue analysis.

(089050)

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