REPORT TO THE CONGRESS

BY THE COMPTROLLER GENERAL OF THE UNITED STATES

Special Pesticide Registration By The Environmental Protection Agency Should Be Improved

Environmental Protection Agency administration of special pesticide registration activities has not always been effective. Agency processing of requests for emergency and experimental uses of pesticides often takes too long. The Agency often approves requests for emergency use of canceled pesticides in non-emergency situations.

Some participating Federal and State agencies have violated their authority by using unregistered, canceled, or suspended pesticides. As a result, the public may not be protected from potentially harmful and dangerous pesticides used under this program.

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

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To the President of the Senate and the
Speaker of the House of Representatives

This report discusses the Environmental Protection Agency's program to regulate pesticides that are used for experimental and emergency purposes or that are registered by the States to meet special local needs. The Agency's administration of the program has not always been effective, and as a result, the American public may not be adequately protected from potentially harmful and dangerous pesticides used under this program.

We made our review pursuant to the Budget and Accounting Act, 1921 (31 U.S.C. 53), the Accounting and Auditing Act of 1950 (31 U.S.C. 67), and the Legislative Reorganization Act of 1970 (31 U.S.C. 1152). Our review was prompted by deficiencies that we noted in other aspects of the Agency's pesticide registration program and increasing congressional interest in controlling pesticide use.

Copies of this report are being sent to the Acting Director, Office of Management and Budget; the Administrator, Environmental Protection Agency; the Secretary of Agriculture; interested congressional committees; Members of Congress; and other interested parties.

Comptroller General
of the United States

COMPTROLLER GENERAL'S
REPORT TO THE CONGRESS

SPECIAL PESTICIDE REGISTRATION BY THE ENVIRONMENTAL PROTECTION AGENCY SHOULD BE IMPROVED

D I G E S T

Each year in the United States over a billion pounds of pesticides are knowingly released into the environment to control insects, rodents, weeds, bacteria, diseases, and other pests that attack man's food and fiber supplies and threaten his health and welfare.

The Environmental Protection Agency regulates these pesticides, registering for use only those that will not cause unreasonable adverse effects on man and the environment. The Agency permits exceptions, allowing limited use of unregistered and previously canceled or suspended pesticides to

--control pest infestations that present health or economic emergencies,

--gather experimental data to register the pesticide, and

--meet a State's special local needs. (See p. 2.)

However, the Agency has not always been effective in administering these special registration activities because:

--Requests for emergency and experimental pesticide uses take too long to process. (See pp. 6 and 22.)

--Program requirements are not always met by the Agency and other Federal and State agencies. (See pp. 25, 28, 30, 46, 49, 57, and 61.)

--States are permitted to register pesticides that the Agency would not register. (See p. 42.)

--Some activities are not coordinated effectively with the Agency's regional offices or responsible State agencies, and many pesticide uses are not monitored adequately. (See pp. 10, 34, and 35.)

Often the Agency has been slow in approving pesticides for both emergency and experimental uses--an average of 40 and 105 days, respectively.

Some requestors, however, have used pesticides illegally to

--protect human health or crops in emergencies or

--avoid losing a growing season in their experimental programs.

One manufacturer, for example, used three products before the experimental permits were approved to avoid missing a season. Thus, the Agency did not assure that man and the environment were protected from inappropriate use of potentially dangerous or harmful pesticides. (See pp. 6 and 22.)

The Environmental Protection Agency and other Federal and State agencies have not complied with regulatory requirements. The Agency has permitted unauthorized agencies to participate in special registration activities and some pesticides to be used inappropriately.

Other Federal and State agencies have violated their pesticide authority. In addition, the Agency has not, as required, issued final regulations governing State registration of pesticides to meet special local needs. (See pp. 25, 28, 30, 46, 49, 57, and 61.)

The Agency has permitted States to register pesticide products on which it has placed registration moratoriums and would not register. In effect, the Agency has given States greater registration authority than it has for such chemicals. (See p. 42.)

The Agency has not always notified its regional offices or State agencies when experimental permits or emergency exemptions were granted. Consequently, these offices and agencies could not monitor program activities. State agencies normally have personnel whose responsibilities include pesticide monitoring

and who could monitor activities if necessary. (See pp. 10, 34, and 35.)

GAO has made over a dozen recommendations to improve the Agency's administration of special registration activities. (See pp. 14, 37, and 51.)

AGENCY COMMENTS

The Agency agrees that its special registration activities should be improved. However, many of its views sharply conflict with GAO's conclusions and recommendations. The Agency's comments are discussed at length in the report. (See pp. 14, 38, and 51.)

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Contents

ABBREVIATIONS

EPA	Environmental Protection Agency
FDA	Food and Drug Administration
GAO	General Accounting Office
HEW	Department of Health, Education, and Welfare
TVA	Tennessee Valley Authority

CHAPTER 1

INTRODUCTION

Pesticides are substances used to control harmful insects, rodents, weeds, bacteria, diseases, and other pests that attack man's food and fiber supplies and threaten his health and welfare. Over 1 billion pounds of pesticides are used domestically each year--55 percent for agriculture; 30 percent for industrial, institutional, and governmental use; and 15 percent for home and garden use. Approximately 34,000 pesticide products--including insecticides, rodenticides, herbicides, fungicides, and disinfectants--made from 1 or more of about 1,800 chemicals were registered with the Environmental Protection Agency (EPA) as of March 1977.

The basic authority for regulating pesticides is (1) the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C 135 et seq. (Supp. V, 1975)) as amended by the Federal Environmental Pesticide Control Act of 1972 (7 U.S.C 136 et seq. (Supp. V, 1975)), referred to in this report as the Pesticide Act, and (2) the Federal Food, Drug and Cosmetic Act, as amended (21 U.S.C. 301 et seq. (Supp. V, 1975)), referred to as the Food and Drug Act. Authority for administering the Pesticide Act was transferred from the Department of Agriculture along with the responsible organization elements to EPA on December 2, 1970, pursuant to Reorganization Plan No. 3 of 1970 which established EPA.

PESTICIDE REGISTRATION AND TOLERANCES

Pesticides are regulated by the Federal Government to insure that quality products are available to the public and that, when properly used, these products will provide effective pest control without unreasonable adverse effects on man or the environment. EPA has the primary responsibility for regulating pesticides.

EPA registers a pesticide under the Pesticide Act when it determines that the pesticide

--meets its proposed claims (product performance),

--complies with labeling and other requirements,

--performs its intended function without unreasonable, adverse effects on the environment (including man safety), and

--will not generally cause unreasonable adverse effects on the environment when used in accordance with widespread and commonly recognized practice.

The act defines unreasonable adverse effects as 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 or feed, the Food and Drug Act requires that a tolerance--the maximum pesticide residue allowed in food--be established. EPA's Office of Pesticide Programs establishes all tolerances for pesticide residues remaining in or on raw agricultural commodities and for pesticide food additives.

Before EPA's existence, tolerances were established by the Food and Drug Administration (FDA) of the Department of Health, Education, and Welfare. FDA is still responsible for enforcing established tolerances. FDA tests samples of food to determine if any residues exceeding tolerance levels remain on the food, rendering the food adulterated. Adulterated foods may not be sold in interstate commerce.

SPECIAL REGISTRATION ACTIVITIES

While a pesticide generally must be registered by EPA before it can be used in the United States, the Pesticide Act and its implementing regulations allow certain exceptions for using unregistered and previously canceled or suspended pesticides under specified conditions. These exceptions include:

--Experimental Use Permits--permits to use pesticides for accumulating information necessary to (1) register a product not previously registered with EPA or (2) modify the use, application, crop, amount, or pest involved with a currently registered product. Permits are normally granted for 1-year periods.

--Emergency Exemptions--exemptions granted to Federal or State agencies to use suspended, canceled, or unregistered pesticides in emergency situations where (1) pest outbreaks have or are about to occur and effective registered pesticides are not available, (2) significant economic or health problems will occur without the use of pesticides, and (3) there is insufficient time available from discovery of a pest outbreak to register pesticides to control the pest.

--State Registrations--pesticide registrations by States, certified by EPA as capable of registering pesticides, for use and distribution only within the registering State to meet special local needs.

The special registration activities are administered by the special registration section at EPA headquarters in Washington, D.C. EPA regional office staffs monitor the various special registrations within their jurisdictions.

SCOPE OF REVIEW

We reviewed EPA's policies and practices and examined pertinent legislation, documents, reports, and records on special registration activities.

We interviewed responsible agency officials at EPA headquarters in Washington, D.C., and at EPA regional offices in Atlanta, Chicago, Dallas, Denver, and Kansas City. We also obtained information from a number of State officials and major pesticide manufacturers on their special registration activities and on their views on EPA's handling of special registration activities.

CHAPTER 2

EXPERIMENTAL USE PERMIT PROGRAM IS NOT EFFECTIVE

EPA's experimental use permit program has not been fully effective because (1) the types of data that must be submitted with a permit application have not been clearly defined, (2) permits were not processed in a timely manner, (3) headquarters did not notify regions of approved permits in a timely manner or notifications were not made at all, and (4) pesticide applications under permits were not adequately monitored. Delays in approving such permits cause corresponding delays in marketing new pesticides, resulting in increased costs to the manufacturer. Ultimately, the consumer must pay higher prices for pesticides.

Under Section 5 of the Pesticide Act, EPA issues experimental use permits to enable manufacturers to develop certain data--primarily efficacy data and environmental chemistry data--needed for product registration. The permits are issued subject to a number of conditions which generally specify (1) who may apply the pesticide, (2) the location, total acreage, and crops that may be treated, and (3) any reporting requirements. As part of its program, EPA requires monitoring to assure that permit requirements are followed and to identify the extent of adverse effects as they become known.

The permit program provides an important link between the "birth" of a pesticide and its registration and subsequent introduction into commerce. During this phase a pesticide is tested to determine whether it is effective and whether it will adversely affect man or the environment. Of necessity, the experimental use program must be efficient and effective to encourage the development of new pesticides.

Pesticide product development has declined in recent years. A 1975 National Agricultrual Chemicals Association report pointed out that while pesticide sales have increased, research and development expenditures have decreased each year since 1972--from 8.5 percent in 1972 to 6.5 percent in 1975--in terms of total domestic sales. A followup 1976 report said that research and development expenditures increased to about 7.9 percent of domestic sales but that the total number of new products screened for development was about 6,000 less in 1976 than 1975. This deemphasis in developing pesticides will not be felt for several years because of the long lead time required to register pesticides--products registered by EPA in 1974 and 1975 were actually discovered an average of 8 years previously.

The reasons for industry's growing reluctance to develop new pesticides were discussed in an August 1975 report of the Entomological Society of America which stated that:

> "The pesticide industry has substantially reduced its efforts in this field * * * [because of] shrinking profits, increased costs of discovering effective compounds and obtaining the data required to establish tolerances and obtain registration, the relatively short effective life of many compounds and the widespread antipathy of society at large to the use of pesticides * * *."

Another report (William Blair & Company, July 1975) stated that the number of active researchers and funds available for research and development of innovative approaches to pest management has been reduced, creating a tendency to concentrate research efforts on developing variations on existing chemical controls. We did not attempt to determine what economic, social, political or other factors, such as pesticide registration requirements, have caused the decline in pesticide product development. Although EPA's experimental permit is only one of many factors that may affect pesticide development, this program must be as effective and efficient as possible to encourage development of innovative products that will be less hazardous to man and the environment. This chapter discusses our recommendations for improving EPA's experimental program.

GUIDELINES NEEDED

EPA has not issued guidelines setting out the (1) minimum data required for permit approvals and (2) type of data required to be developed while the pesticide is being used experimentally. As a result, EPA is using registration data requirements and the manufacturer may be required to begin all tests, including laboratory animal feeding studies which are required for full EPA registration but are not necessary to determine environmental safety and efficacy. For example, a permit requestor may be required to begin expensive laboratory tests, such as 2-year chronic feeding studies costing $250,000, before it is known whether the experimental pesticide is sufficiently safe and effective in the environment to warrant EPA registration.

EPA's regulations for experimental use permits require among other things available data on the

--rate of decline of residues on the treated crop or environmental site or other information regarding entry of persons into treated areas and

--results of toxicity tests and other data concerning products' potential for causing injury to users or other exposed persons, including any available epidemiological information.

These requirements are not specific and EPA has not issued appropriate guidelines to implement them. Both EPA reviewers and permit applicants told us that they are not sure what data is required for permit approval or what data must be obtained during the experimental use period.

Representatives of eight major pesticide manufacturers we visited said that lack of guidelines was a common problem. They also said that some EPA reviewers are more stringent and require more data than other reviewers for similar products. EPA officials agreed with these comments and added that it was primarily a problem of not having guidelines on which to base data requirements.

Another problem is that data required by EPA reviewers may be inconsistent with the purpose of an experimental use permit. For example, EPA denied one permit application because the EPA reviewer said he was unable to determine if the product would be effective. This does not appear to be appropriate because the primary intent of the experimental permit program is to determine the pesticide's effectiveness.

Development of guidelines implementing EPA regulations should reduce delays in permit processing because requestors can conform applications to specific requirements and various EPA reviewers can act on applications more consistently than was done in the past. In developing specific guidelines for granting experimental permits before toxicity tests are completed, EPA should include a standard condition that treated crops with detectable residues of the experimental pesticide could not be marketed without EPA waiver. The guidelines should be sufficiently flexible to allow different requirements for new uses of registered pesticides and new pesticides which have not been previously registered.

PROCESSING TIMES ARE EXCESSIVE

EPA's processing of original permits, extensions, and renewals has not been timely. EPA regulations state only

that EPA will act on permit applications as quickly as possible. In its proposed permit regulations, EPA set its processing time at 90 days; however, public and industry comments on the proposed regulations advocated 30- or 60-day processing periods as more reasonable. As a result, EPA's regulations do not specify processing periods for applications. EPA records show that an average of 105 days--ranging from 3 to 547--elapsed between the dates of application and approval. The following table shows the processing times, where available, for permits issued between July 1974 and March 1976.

	Number	Average number of days from application to approval
New permits	196	114
Extensions	77	86
Renewals	7	58
Total	280	105

EPA delays in acting on permit applications have had detrimental effects on some manufacturers' pesticide development programs because frequently the permits are approved too late in the season for the pesticide to be used effectively. Also, there have been instances where manufacturers illegally applied pesticides before EPA acted rather than lose an entire year. These points are illustrated in the following examples.

Example 1

On August 5, 1975, a manufacturer requested an experimental permit for testing an herbicide on peanuts and soybeans that were to be destroyed after testing. EPA issued the permit 210 days later on March 2, 1976--2 months after the manufacturer was to begin his experimental program. As a result, the manufacturer may have found it difficult to find farmers willing to test the pesticide because the crops were already planted or were being planted and the farmers would likely already have purchased other pesticides to alleviate potential pest problems. This example is especially significant because EPA received the request during a "slack period" when permit submissions were relatively light.

Example 2

On May 20 and 27, and July 29, 1975, EPA issued three experimental use permits to one manufacturer. These permits were requested on January 28 and February 25, 1975, and November 30, 1974, respectively. On July 22 and August 6, 1975, an EPA investigator visited two of the manufacturer's

test sites and found that one of the products had been used in May 1975 before the permit was approved. Further, in October 1975 an EPA inspector in the Kansas City region found that all three products were used at different sites before the permits were approved. A company representative told EPA that he had been instructed by his headquarters office to proceed with testing the three products even though the permits had not been approved.

The Pesticide Act provides for civil or criminal penalties for such illegal use after the Agency's final regulations have been in effect for 60 days. EPA's experimental use permit regulations were not published in the Federal Register until April 30, 1975; consequently, EPA could not take punitive actions until after June 30, 1975. Because these violations occurred in May 1975, EPA was unable to act. However, EPA did include the company on a list of "potential violators" so that the company's pesticide activities could be closely monitored in the future.

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Before the House Subcommittee on HUD--Independent Agencies, Committee on Appropriations, one pesticide industry official testified:

> "The main difficulties that both the industry groups and the regulatory agencies are not aware of is the fact that there are certain fields of pesticides where a year cannot be divided into 12 months.
>
> "The year consists of 4 months because insects and plants mature and grow during very limited amounts of time. The EPA also has to approve large scale field research that can only be done in the summer. If you apply in February for experimental permits and ask for them to be granted in May and the agency gives it to you in June, you have lost an entire year."

Other pesticide manufacturers told us that many pesticide products must be applied at certain stages of plant growth or during a specific phase of pest infestation to be effective. Therefore, permits must be approved before that time or the experimental program is delayed until the required test conditions recur, often 6 months or a year later.

The untimely approval of experimental use permits, in addition to causing delays for as much as a year, also affects other aspects of an experimental program. For example, a pesticide product legally cannot be used until an EPA-approved

label is available; however, printing labels and shipping products may require 3 or 4 weeks after permit approval. If permits are not approved until just before the testing season, the manufacturer may have trouble starting his experimental program on time.

Manufacturers told us that the interest and commitment of farmers who are willing to test the product also may be adversely affected without some assurance of timely EPA approval. Prospective farmers participating in the experimental program must have sufficient lead time to obtain other products to alleviate pest problems in the event a permit is not approved when needed.

Longer experimental periods needed

EPA normally issues experimental use permits for 1-year periods; however, many permits must be extended or renewed beyond that period to develop data necessary to support registration. A total of 84 of the 286--or 30 percent--approved permit actions during the period July 1974 through March 1976 were extensions or renewals. In addition, 47 permits originally issued during this period were later extended, and 9 permits previously extended were reextended. The burden of processing extensions and renewals contributes, at least in part, to the excessive time required to approve permits.

We could not readily determine from EPA records how many extensions were requested by manufacturers because (1) additional data was needed or (2) the original permit was approved too late. However, EPA officials and industry representatives told us most extensions were requested to develop additional data. During our review we met with 13 pesticide manufacturers who had received 112 permits for which 35 extensions or renewals were granted. Thirty of these extensions or renewals were requested to develop additional data. If the original permits had been issued for sufficient periods to allow manufacturers to complete their experimental program, EPA's processing workload would have been reduced by about 30 percent.

Approximately 45 percent of EPA's permit workload is received between December and March. Manufacturers normally evaluate experimental test results at the end of a growing season, completing this work about the end of the calendar year. Extensions or renewals are usually requested immediately thereafter, resulting in a flood of applications that EPA cannot handle promptly. Apparently, alternatives to

alleviate this seasonal surge do not exist, but as much as 30 percent of the workload could be eliminated if EPA made permits effective for 2 years rather than 1. Manufacturers we visited said that they generally need at least 2 years to develop the data needed to register pesticide products.

Manufacturing officials told us that they had submitted permit applications during the "off season" to miss the seasonal surge. These officals said, however, that their experiences show that EPA does not act on extension applications until about 30 days before they are needed. For example, one official said that although it was known in July 1976 that an extension was needed in April 1977, the company would not apply for the extension until shortly before April because EPA would not act on it before that time.

An EPA official explained that permits are not approved in advance because EPA wants to review all pertinent data before a decision is made. He said it is harder to cancel an issued permit than not to issue one in the first place.

We see no compelling reasons why permits should not be processed and either approved or disapproved as they are received. We believe this would benefit both EPA and the manufacturer. Manufacturers would be able to plan their programs and line up farmers who are willing to test their product. This would also help spread EPA's workload throughout the year, allowing it to review applications more thoroughly and in shorter turnaround time.

EPA DOES NOT ADEQUATELY MONITOR EXPERIMENTAL PRODUCTS

In the five EPA regions we visited, 116 of the 201 (58 percent) experimental use permits applicable to those regions were identified by EPA as having been monitored. However, EPA visited the application sites of only 41 permits and most of these visits were made after the pesticides had been used; thus, EPA inspectors could not readily determine if permit conditions were met. At least seven permits were monitored by telephone contacts only. We could not determine how or the extent to which the remaining 68 were monitored because EPA's records were inadequate. The remaining 85 permits were not monitored because the regions either were unaware that they existed or did not believe that monitoring was warranted.

Each EPA region is responsible for monitoring selected experimental pesticide uses within its region. This responsibility includes developing monitoring schedules and assigning personnel to visit sites and determine whether

--the product was effective;

--the product was applied in accordance with label directions and the terms of the permit;

--the permittee supervised testing activities, evaluated results, and reported adverse effects to EPA;

--food or feed not covered by tolerances were disposed of properly;

--unused pesticides were disposed of in accordance with permit instructions; and

--there were adverse reactions or side effects, such as accidents and undesirable effects, on beneficial plants and animals.

The following table shows EPA's monitoring efforts in each of the five regions included in our review.

EPA region	Number of permits (note a) Applicable to each region	Region was aware of Number	Region was aware of Percent	Considered as monitored	Number of site visits
Atlanta	168	135	81	81	(b)
Chicago	143	129	90	33	26
Dallas	162	143	88	4	4
Kansas City	122	110	90	16	16
Denver	113	74	65	21	(b)

a/A permit may be issued for use in one or more regions; thus each permit may be listed as many as five times, once for each region.

b/The quality of the monitoring reports was such that we could not determine whether site visits were made. However, it appears that 70 to 80 percent of the monitoring actions were telephone contacts.

The objectives of EPA's monitoring activities are to determine whether experimental products are used in accordance with permit conditions and whether significant adverse effects occur. These objectives generally were not achieved

because (1) monitoring visits were made after experimental products were applied and (2) monitoring was done by telephone.

EPA monitoring consisted of 46 site visits on 41 permits in the Chicago, Dallas, and Kansas City regions. Although some regions monitored considerably more than others, most monitoring was done after the product was applied. It is important to visit testing sites when the pesticide is applied to assure that EPA restrictions are met and that significant adverse effects do not occur. Only through first-hand observation can EPA investigators make these determinations; to do so after the fact requires reliance on written records or the memory of participants. This procedure is not the most effective way to achieve EPA's mission. Telephone monitoring is not the most effective form of monitoring and should be used only to monitor permits that (1) would not be monitored otherwise because sufficient staff is not available or (2) do not warrant onsite monitoring.

In EPA's Denver and Atlanta regions we could not determine the quality of monitoring because the records were inadequate. Although Atlanta regional officials told us that their monitoring consisted of site visits rather than telephone contacts, we were unable to verify or confirm this information. A Denver regional official said that telephone calls were treated the same as site visits. The type of monitoring performed and any deviations from procedures prescribed in the experimental use permit should be adequately documented.

Factors contributing to inadequate monitoring included headquarters failure to (1) notify regional offices or to notify them in a timely manner about permit approvals and (2) place monitoring on a high priority. For example, the Dallas region was aware of only 88 percent of the permits issued for use in the region; notification of the issuance of 105 experimental permits came an average of 41 days after approval.

A region usually learns of experimental permits when EPA headquarters forwards a package containing the (1) original permit or applicable extension or renewal letters, (2) product label, and (3) manufacturer's experimental program. As shown in the table on page 11, the regions were not aware of all permits issued for use within the region.

EPA regional officials said that monitoring plans could be affected if the region was not aware of all experimental permits especially if the permit was (1) issued to a manufacturer who was being monitored closely because of past violations or (2) for a new chemical. However, a Dallas regional official said that it did not matter whether EPA was aware of all permits because it did not have the resources to monitor them anyway, and permit monitoring was given low priority.

An EPA official told us that monitoring is limited because regions have very limited staff resources and travel funds available for pesticide investigations. For example, EPA's Denver region had only three inspectors to cover the entire region--six States. As a result, regional officials apply these limited resources to those areas where they have found the most violations--establishment inspections and pesticide misuse investigations rather than monitoring experimental products.

CONCLUSIONS

The experimental use permit program has not been fully effective because EPA has not promulgated guidelines to implement its rather general regulations particularly concerning the specific data which should be (1) required as a basis for permit approvals and (2) developed while the pesticide is being used experimentally. Such guidelines should reduce delays in processing because requestors will be able to conform applications to specific requirements and various EPA reviewers will be able to act on applications more consistently than was done in the past.

Permits should be processed and either approved or disapproved within a reasonable time after being received. This would enable manufacturers to better plan their programs and line up farmers willing to test experimental products. By processing the applications as received rather than creating a backlog to be processed shortly before the growing season, EPA would benefit by spreading its workload more evenly throughout the year, permitting it to review applications more thoroughly, and in shorter turnaround time.

Monitoring of unregistered pesticide products, the safety of which has not been established, should be given high priority as a basis for insuring that permit restrictions are followed and that the public is not unnecessarily exposed to harmful pesticides. EPA has not adequately monitored permits to assure that terms and conditions are met. Of the 201

experimental use permits applicable to the five EPA regions we visited, only 58 percent were identified as being monitored by EPA and only 20 percent were monitored onsite. Most of the site visits were made after the pesticides were used; thus, EPA inspectors could not readily determine if permit conditions were met.

In addition, EPA headquarters' communication with regions has not been good--notifications of permit approvals either have been untimely (after pesticide applications were made) or have not been made at all.

RECOMMENDATIONS

We recommend that the Administrator, EPA:

--Promulgate guidelines specifying data requirements that are necessary for permit approvals and the type and extent of data to be developed under permits.

--Require reviewers to act on--approve or disapprove--properly prepared permits within a specified period.

--Furnish prompt information on permit approvals to applicable regions so that site visits can be programed when experimental pesticides are applied.

--Set priorities for the permit-monitoring program to assure proper control of experimental products the safety of which has not been established.

--Authorize experimental use permits for the reasonable duration of an experimental program rather than limiting them to 1 year as is now done.

AGENCY COMMENTS AND OUR EVALUATION

In commenting on our proposed report EPA said that we concluded that the experimental use permit program was having a direct adverse impact on research and development in the pesticide industry. In rebuttal EPA cites

--a report by William Blair and Company in which the pesticide industry is characterized as one of "extraordinary profitability;"

--an EPA report titled "FIFRA: Impact on the Industry"1/ which points out that (1) in recent years about an equal number of firms have entered and left the pesticide research field, (2) high profits and profit potentials have kept the industry interested, and (3) although pesticide innovations may be fewer than in the past, the industry has and will continue to build on its existing research and development base; and

--a purported 300-percent increase in experimental permits since FIFRA was amended in 1972.

We concluded that EPA's experimental use permit program is not fully effective, not that the program is having a direct adverse impact on research efforts in the pesticide industry. There is solid evidence that pesticide product development as a percentage of sales has declined in recent years. In line with congressional intent when it amended the Pesticide Act, we believe that the experimental permit program, only one of many factors affecting pesticide development, should be as effective and efficient as possible to encourage development of innovative pesticide products.

Several clarifications must be made regarding EPA's specific comments. First, EPA's statements on the Blair report were taken out of context without appropriate qualifiers. Blair's conclusion that the industry was "extremely profitable" is based on hard evidence for only one company which Blair cites as being "somewhat atypical." The report further says that profits from pesticide operations are not reported separately by virtually all major manufacturers, "thus obscuring the facts." Other statements concerning profits from pesticide operations are estimates which the report says "seem likely." More importantly, other pertinent conclusions of the report are not addressed, including:

--A number of manufacturers were driven out of the industry or their efforts were greatly reduced because of (1) uncertainty before and after the Pesticide Act and (2) the law's general result to boost research and development expenditures substantially on both existing and new products. It is an "ironic consequence" that the law's objective of encouraging innovative pesticide approaches instead reduced the

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1/FIFRA--Federal Insecticide, Fungicide and Rodenticide Act.

number of active researchers and the funds available for new research and concentrated research and development efforts on developing variations of existing "safe" chemical approaches.

--Research and development efforts generally are (1) concentrated toward developing existing pesticide products and (2) directed primarily to the highest volume potential market with the exclusion of smaller, more specialized markets, i.e., concentration on a few major pests and crops, while many others are neglected.

--Expeditious processing of experimental permit applications is essential for the timely development of a product, since a minor delay often pushes testing back a full year until the next growing season. Further, EPA's process is especially slow for radical products that may provide major advances in pesticide safety and has contributed to delays of as long as 8 years in the registration of some chemicals.

We find the foregoing arguments supportive of the conclusions and recommendations we made on EPA's experimental permit program.

The statements to which EPA refers in its report entitled "FIFRA: Impact on the Industry" were taken from the Blair report just discussed. Consequently, no further discussion of these statements is necessary.

We found EPA's statement that experimental permits have increased 300 percent since amendment of the Pesticide Act to be erroneous. For a 21-month period preceding enactment of the 1972 amendments, EPA issued 174 permits as compared to 286 permits for a similar 21-month period ended March 1976 (the period of our sample). This is a 65-percent increase, not a 300-percent increase as EPA states. Also, a review of the permits in our sample shows that 52 percent of the increase was not due to added interest in research and development on the part of the pesticide manufacturers, rather to changes in the regulations requiring permits for testing which were not previously required. Under EPA's new regulations (1) pesticide manufacturers are now required to obtain permits to conduct additional testing of previously registered pesticides, for example, extending use of the pesticide to other pests, or changing the dosage rate or the method of application and (2) Federal and State agencies previously

authorized to experiment without permits are now required to obtain permits.

EPA agreed with our recommendation that guidelines specifying data requirements for experimental permit approvals are needed, but felt that defining data to be developed under an experimental permit would be repetitious of its general registration guidelines. EPA also said that it does not plan to develop permit guidelines until after its general registration guidelines are finalized.

While EPA may be correct in stating that defining data to be developed under an experimental permit would be repetitious, it does not address the very real problem that neither pesticide manufacturers nor EPA permit reviewers really know what should be included in the experimental permit application or what data is required to be developed under the approved permit. (See p. 6.) Such guidelines should eliminate these uncertainties, thereby facilitating the applicants' preparation of acceptable packages as well as EPA's review and approval process. Also, it appears that it would be advantageous to EPA to develop permit guidelines now, in view of the time-consuming process needed to obtain approval. For example, EPA published proposed registration guidelines in the Federal Register in June 1975; they have as yet not been finalized and are now scheduled to be reproposed in the Federal Register in various sections from November 1977 through May 1978. To delay the permit guidelines until the registration guidelines are finalized could delay them for up to 2 years or longer which we believe is unacceptable.

EPA also disagreed with our argument that manufacturers should not be required to start chronic feeding studies as a condition of permit approval. EPA said that long-term feeding studies are an important part of the safety data required for registration and when the manufacturer enters the final stages of testing under a permit, it is in his best economic interest to conduct such studies concurrently to be fully prepared for registration when the experimental program is finished.

Generally this is true; however, there are exceptions where the manufacturer may not yet have determined that the chemical is sufficiently effective under actual use conditions to be worth pursuing. To require that manufacturers commit themselves to studies in excess of one quarter of a million dollars at such time may result in no-go decisions for beneficial pesticides. We see no problem in approving

such permits provided (1) the manufacturer is aware that registration will not proceed until all appropriate test data is provided and (2) appropriate safeguards are established for the experimental uses.

EPA agreed that permits should be submitted, processed, and either approved or disapproved as they are received. However, EPA said that applicants, not EPA, control the submission of permit applications and that they are not submitted far enough in advance of the testing date to be processed. Concerning processing applications more effectively, EPA concluded that the report contained conflicting statements regarding (1) the processing of applications as received to spread EPA's workload throughout the year and (2) that there do not appear to be alternatives in alleviating seasonal surge of applications.

Office of Pesticide Program officials may believe that permits are processed and either approved or disapproved as they are received; however, permit reviewers tell a different story. One reviewer told us that permits are not approved in advance because EPA wants to insure that all pertinent data is reviewed before a permit is approved and that, as a result, permit applications are set aside until just before they are needed. This is consistent with information obtained from pesticide manufacturers presented on page 10.

Had EPA considered this in its comments, it would have found no conflict in our statements because permits submitted during slack periods were being held until shortly before they were needed, thereby creating a backlog that was affecting the seasonal surge that we had characterized as being unavoidable. Thus, contrary to its statement, EPA was exercising a great deal of control on permit submissions. If EPA implements our recommendation, which it states is its policy, we believe that permit-processing time can be improved substantially.

Furthermore, if EPA implements our recommendation that experimental permits be issued for the duration of an experimental program rather than limiting it to 1 year as is done now, it appears that up to 30 percent--the percentage of permit extensions and renewals in our sample--of experimental applications could be eliminated, allowing EPA to concentrate on new applications.

EPA agreed with this recommendation but did not believe it necessary because EPA's experimental use permit regulations already have such a policy which was reaffirmed March 28 and

29, 1977, when EPA met with the American Association of Pesticide Control Officials. This meeting occurred almost 2 months after we first discussed this recommendation with EPA officials on February 1, 1977. We believed it necessary to document the recommendation because, as EPA pointed out, experimental programs of longer than 1 year were permitted by EPA's regulations. However, EPA reviewers told us that 1-year permits were the in-house rule and, in fact, none of the 286 permits in our sample were for more than 1-year programs.

In commenting on the timing of its approval of experimental permits, EPA stated that for fiscal year 1977 it projected that its resources would allow experimental permits to be processed in the following time frames:

20 percent within 90 days,
50 percent within 120 days, and
30 percent within 180 days.

We believe that such time frames do not reflect EPA's stated policy of processing permits as expeditiously as possible and that this could delay development of new products unnecessarily. The House Subcommittee on Department Investigations, Oversight, and Research, Committee on Agriculture, also does not agree with such lengthy time frames and as of December 1977 had proposed an amendment to the Pesticide Act to require EPA to approve or disapprove all permits within 90 days as compared to EPA's 120- to 180-day time frame for up to 80 percent of permit applications.

In commenting on our recommendations concerning the notification of EPA regional offices of experimental permit approvals and monitoring of experimental uses, EPA's Office of Enforcement stated that the following corrective actions had been taken:

--A procedure was established to insure that regions are promptly notified when permits are issued.

--Procedures setting priorities for permit monitoring were being developed.

--To insure that priority permits are being monitored and to adequately cover those permits a comprehensive review of regional policies and procedures concerning experimental permit monitoring, inspecting, reporting, and recordkeeping was being initiated. The results of the review will be used to assist the regions in

planning, conducting, and reporting permit monitoring and in revising EPA guidance and manuals.

We believe that these actions, if properly followed through, will substantially correct the problems noted.

The Office of Pesticide Programs, on the other hand, agreed that prompt regional notification of experimental permits was necessary but did not agree that monitoring had been inadequate. However, the Office of Pesticide Programs is only indirectly involved in the monitoring process.

CHAPTER 3

INEFFICIENCIES IN ADMINISTERING EMERGENCY EXEMPTIONS

Certain State and Federal agencies have misused emergency exemptions by (1) illegally taking crisis exemptions on suspended or canceled pesticides, (2) taking crisis exemptions when a crisis did not exist, and (3) not always complying with EPA restrictions and requirements under the exemption.

EPA's administration of the emergency exemption program has been hampered by a number of problems, including

--untimely action on requested emergency exemptions;

--granting exemptions to unauthorized organizations;

--granting exemptions repeatedly to certain requestors for pest problems not meeting EPA criteria for emergencies;

--poor communication between EPA's headquarters and regional offices in evaluating, approving, and reporting exemption actions; and

--monitoring emergency exemptions inadequately.

Predictably, these problems have adversely affected EPA's relations with some States.

Section 18 of the Pesticide Act permits EPA to grant Federal and State agencies exemptions to use suspended, canceled, or unregistered pesticides in emergency situations. By EPA definition, an emergency exists when (1) a pest outbreak has or is about to occur and no registered pesticide is available, (2) significant health or economic problems will occur without the use of a pesticide, and (3) there is insufficient time to register a pesticide to control the pest outbreak.

In December 1973 EPA established regulations for three types of emergency exemptions: quarantine-public health, specific, and crisis. Quarantine-public health exemptions are granted to prevent the spread of a foreign pest into or throughout the United States. Such exemptions may be requested by Governors or their designees, usually State lead pesticide agencies, and by Federal agencies.

Specific exemptions are granted to control pest outbreaks for which registered pesticides are not readily available and significant economic or health problems will occur unless the pest is controlled. These exemptions are also requested by State Governors or their designees and by Federal agencies.

Crisis exemptions may be taken for unpredictable pest outbreaks in the United States where registered pesticides are not readily available and the time element is too critical to request a specific exemption. In contrast to specific and quarantine-public health exemptions, State or Federal agencies, upon determining that a crisis exists, may apply the pesticide before notifying EPA. EPA can, if deemed necessary, stop further applications of the pesticide. Pesticides that EPA has suspended or canceled cannot be used legally under crisis exemptions.

A total of 128 emergency exemptions were requested or taken during the period December 3, 1973, to June 30, 1976. The disposition of these exemptions is shown in the following table.

Disposition of Exemption Actions

Specific exemptions granted	58
Quarantine-public health exemptions granted	1
Crisis exemptions taken	19
Specific exemption requests denied	36
Specific exemption requests withdrawn	14
Total	128

PROCESSING TIMES ARE EXCESSIVE

Emergency exemptions provide Federal and State agencies a means to control unexpected pest outbreaks when registered pesticides are not available. Such "emergencies" may require the use of registered pesticides for unregistered uses or the use of unregistered, suspended, or canceled pesticides.

Federal or State agency requests for specific exemptions must be reviewed and acted on quickly to prevent the destruction of important commercial crops or to protect the public from harmful pests. The following table shows processing times for emergency exemptions requested between December 3, 1973, and June 30, 1976.

Type of exemption	Number of exemptions	Processing time	
		Average	Range
		(days)	
Specific	108	88	1 to 395
Quarantine-Public Health	1	129	

Between July 1, 1975, and June 30, 1976, EPA's average processing time dropped from 155 days for the preceding year to 40 days. Following is a table showing the range of days for processing exemptions during this period.

Days	Number of exemptions
1 to 10	18
11 to 20	8
21 to 30	12
31 to 50	2
51 to 100	4
101 to 200	1
201 to 335	3
Total	48

EPA's processing of emergency exemptions is obviously too long to be effective. If emergencies existed, an average 40-day delay before EPA acted on the request could be catastrophic. At any rate, the emergency would generally have run its course and any probable harm to people or the environment would already have resulted. The following examples illustrate the potential for harm resulting from delays in EPA's actions on exemption requests.

Example 1

On March 7, 1975, Wyoming requested a specific exemption to use strychnine-treated eggs against rabid skunks because five rabid skunks and a rabid cow were found in Campbell and Crook Counties between January 6 and February 20, 1975. This request was similar to a February 17, 1974, request EPA approved on March 14, 1974, and extended on three separate occasions--May 30, 1974; August 23, 1974; and October 5, 1974--and to five requests previously approved for Montana and Texas.

Two weeks later, on March 21, 1975, a skunk attacked children playing on the school grounds in Campbell County. The skunk was shot and, when tested, was found to be rabid.

Because EPA had not acted on the request, State officials on March 24, 1975, declared the situation to be a crisis and decided to use strychnine to eradicate the skunks. Wyoming placed 26 strychnine-treated eggs in abandoned buildings within one-quarter mile of the school. By April 7, 1975, three dead skunks were recovered and diagnosed as being rabid.

The use of strychnine under a crisis exemption is illegal; but, because the time element was critical, Wyoming could not wait for EPA to act on its specific exemption request. EPA later approved the request on June 17, 1975--more than 3 months after the original request and more than 2 months after Wyoming illegally used the strychnine. An EPA official said the lengthy approval process for this particular request resulted because Wyoming did not provide sufficient information for EPA to make a decision. Wyoming provided this information to EPA on April 3, 1975.

Example 2

On April 29, 1976, the Government of Guam requested a specific exemption to use compound 1080--a pesticide canceled by EPA in 1972--to control a large population of wild and stray dogs threatening public health and safety. Guam used compound 1080 initially between 1967 and 1969 to control rabies epidemics and had used it since to control the expanding dog population. Guam officials said the dogs presented a rabies threat as well as a serious nuisance, attacking humans and livestock and destroying property. In 1975 the Government of Guam recorded over 750 unprovoked attacks on humans by dogs.

A decision was finally issued on the request on March 9, 1977--over 10 months later. An EPA official said it took so long to make a decision on the request because the San Francisco Regional Office had to determine if an emergency existed. He said that EPA ultimately decided the request was not an emergency because the incidence of dogs attacking humans in Guam was no greater than in the continental United States.

EPA officials said that EPA generally requires lengthy time frames for approving exemption requests because (1) the requestor may not provide sufficient information for EPA to make a decision, (2) there is a lack of manpower (only one person is available to review emergency exemption requests), and (3) red tape slows down the review process. The Deputy Assistant Administrator or Administrator signs

approvals or denials of specific exemptions depending on the scope of the problem. This process may take from 1 day to 2 weeks. EPA officials said that some delays in acting on requests resulted because some were denied, but formal denial letters were not issued until later because of higher priority work.

It is obvious that EPA's 40-day average for processing emergency exemption requests is too long to best serve the public. In one of the examples cited, Wyoming illegally used a canceled pesticide to protect its citizens. Exemption requestors should not have to make decisions such as to illegally use a pesticide; rather they should be able to rely on EPA making a reasoned, judicious decision on their requests. EPA should take steps to insure each response, whether it is by making its information-gathering process more effective, providing additional staff, or streamlining its red tape review/approval process, or all three.

SPECIFIC EXEMPTIONS GRANTED TO ORGANIZATIONS NOT AUTHORIZED TO RECEIVE THEM

EPA's regulations state that specific exemptions may be granted only to Governors or their designees, usually the lead agency for coordinating pesticide use within the State, and to Federal agencies. However, EPA granted seven emergency exemptions to unauthorized organizations without notifying responsible State officials. Consequently, the State was unable to monitor the applications, some pesticide applications were apparently improperly made, and EPA-State relations were adversely affected.

EPA requires that specific exemptions be requested in writing by the head of the Federal agency or the Governor of the State involved or other official designee. EPA regional personnel are to be notified of requests immediately to provide them the opportunity to contact relevant State agencies and to evaluate the need for the exemptions. When specific exemptions are granted, EPA (1) may restrict the quantity and conditions under which the pesticide is used and (2) require monitoring of the application.

During 1974 and 1975 EPA granted seven specific exemptions for the use of toxaphene on sunflowers and rangeland to three universities which were not authorized to request exemptions. Toxaphene is a chlorinated hydrocarbon which may persist in the soil for more than 10 years and in lakes and ponds for up to 9 years.

The seven toxaphene exemptions are shown in the following table.

Date of Exemption	Granted to	Applied to	Pest
May 1974	South Dakota State University	Rangeland	Sod webworm
June 1974	North Dakota State University	Sunflowers	Sunflower beetles
June 1974	South Dakota State University	Sunflowers	Cutworms and thistle caterpillars
June 1975	University of Minnesota	Sunflowers	Army cutworms and sunflower beetles
June 1975	South Dakota State University	Sunflowers	Cutworms
July 1975	North Dakota State University	Sunflowers	Army cutworms and sunflower beetles
July 1975	South Dakota State University	Sunflowers	Grasshoppers

The South Dakota Department of Agriculture, the North Dakota Department of Labs and Agriculture, and the Minnesota Department of Agriculture were the only designated agencies authorized to request exemptions in their respective States.

Because of EPA's limited review and monitoring of exemptions (see p. 34), it is important to have State lead agency involvement in approving and monitoring. In our review of the files at EPA headquarters and the Denver region, we found that only one of the exemptions had been reviewed/monitored by EPA. EPA's National Enforcement Investigations Center, which assists the regions and headquarters through compliance inspections, reviewed this exemption at the request of the Denver region. This investigation included determining the effects and efficacy of using toxaphene but did not determine the extent to which the requestor adhered to all toxaphene use restrictions. There is no assurance that the grantees adhered to exemption restrictions. For example, the Center

did not determine if sunflower seeds harvested from treated areas were used for oil only, as specified in the exemption.

As a result of the Center's review, EPA stated in an October 10, 1975, letter to a South Dakota State University extension entomologist that the University had "* * *failed to adequately implement significant portions of the restrictions specified in the (1975) specific exemption * * *" to insure adequate protection of public health and to minimize any adverse environmental effects resulting from the toxaphene. Recognized problems included

--failure to notify EPA regional personnel of the times and places of toxaphene use,

--failure to properly supervise aerial use of toxaphene, and

--publishing in a newsletter that toxaphene use had been approved without adequately describing the use restrictions.

We also noted unresolved discrepancies between the information submitted by the University to EPA on the exemption spraying and that contained in the Center's report. For example, the University's report stated that 2,500 acres of sunflowers were sprayed in one county, whereas the Center's report indicated that less than 500 acres were planted in sunflowers. This could indicate that crops not included in the permit were sprayed or that fields were sprayed a number of times, thereby resulting in excessive toxaphene residues in certain crops. An EPA official said that obviously there is a discrepancy; however, available documentation is not sufficient to resolve the discrepancy.

The South Dakota Department of Agriculture, the State lead agency, was not advised of the 1975 exemption until after it had been approved. The Department was not aware of a cutworm problem, and an emergency condition may not have existed. EPA regional officials told us that failure to coordinate this exemption had detrimentally affected EPA's working relations with the Department of Agriculture.

A similar deterioration in cooperation resulted when EPA failed to coordinate a 1975 toxaphene exemption with the Minnesota Department of Agriculture. In a July 1975 letter to EPA, the Department of Agriculture stated:

"We also suggest that it is gross neglect on the part of your agency and staff not to also notify

the State regulatory agency with regard to this particular situation."

* * * * *

"* * * the actions of your agency again indicate to the Department of Agriculture in Minnesota your intent to completely disregard the State regulatory agency in the implementation of any types of programs. Had you had any intent of cooperation, you would have been in contact with the State regulatory agency to determine whether or not it could provide assistance in implementing this program. Instead, you have chosen to completely ignore us, therefore, we see no reason for spending any effort in providing you with assistance in implementing the program."

The practice of granting specific exemptions to unauthorized organizations may result in the misuse of potentially hazardous pesticides and may adversely affect man and the environment. Although we did not note any instances where specific exemptions were granted to unauthorized organizations in 1976, this situation could recur because EPA's procedures have not been changed. Also, the exclusion of responsible State agencies from participation in the decisionmaking and monitoring of exemptions is not consistent with EPA's policy of obtaining greater State participation in its pesticide programs. Alienation of State agencies, as occurred in South Dakota and Minnesota, could adversely affect EPA State cooperation in all pesticide regulatory activities.

NONCOMPLIANCE WITH EXEMPTION PROGRAM REQUIREMENTS

A common problem in EPA's emergency exemption program is that Federal and State agencies often do not comply with EPA's regulations and with specific exemption requirements. EPA may approve emergency exemptions with restrictions on (1) the quantity of pesticide used, (2) who may apply the pesticide, and (3) the conditions under which the pesticide may be applied. The exemption may also require certain monitoring activities. Restrictions and monitoring reduce potential adverse effects created by use of the pesticide.

The following two examples illustrate cases where requirements were not met.

Example 1

The DDT emergency exemption to control the Douglas-fir tussock moth in the Pacific Northwest is probably the most controversial exemption ever granted as well as the best monitored. Yet, despite (1) elaborate precautions taken to control DDT use and minimize its adverse effects on man or the environment and (2) constant onsite monitoring by EPA personnel, major restrictions imposed when the exemption was granted were not met. While evaluating various reports on the exemption, we noted the following problem areas.

--DDT apparently was used unnecessarily on 332,000 of the 421,000 acres sprayed because moth populations were near or below the U.S. Forest Service's action level at the time of spraying or within 4 days of spraying.

--Data sufficient to register DDT alternatives were not developed because the moth population was collapsing and testing had not progressed to the stage where reliable evaluations could be made.

--The U.S. Forest Service overestimated benefits derived from using DDT.

--Approximately 18,000 cattle and 900 sheep were contaminated with excessive DDT residues in their tissues from the spraying. Consequently, about 6,500 cattle scheduled for sale could not be marketed as scheduled, resulting in economic losses to the owners.

Appendix I is a case history of the DDT emergency exemption which details some of EPA's problems in administering emergency exemptions.

Example 2

The Department of Agriculture's Animal and Plant Health Inspection Service requested a specific exemption to use carbaryl and dieldrin on citrus fruit to combat the West Indian sugar cane root borer. EPA denied this request in February 1975 because the insect had been a continual problem since 1968 and data could have been developed and used to register the pesticides requested. EPA offered to grant the

Service an experimental use permit to test carbaryl on a fairly large scale, provided the Service could assure EPA that illegal residues would not result. However, in March 1975 the Service declared a crisis exemption and used the pesticides on 250 acres. In April 1975 the Service again requested a specific exemption for carbaryl but withdrew the application when EPA reiterated its previous objection.

In June 1975 the Service again bypassed EPA and declared a crisis exemption for carbaryl to control the West Indian sugar cane root borer. In July 1975 the Service requested for the third time a specific exemption for carbaryl; it too was withdrawn when EPA objected.

The exemptions just discussed indicate that EPA is not effectively administering emergency exemptions and that the American public may be unnecessarily exposed to pesticides known to be harmful.

The regulations provide that an agency's right to take crisis exemptions can be revoked if EPA determines the agency is not complying with exemption requirements. However, EPA has not been enforcing this provision. EPA should actively enforce this provision to prevent violations similar to those discussed and revoke an agency's crisis exemption authority for appropriate periods--probably 1 year.

EMERGENCY EXEMPTIONS REPEATEDLY GRANTED FOR SIMILAR USE

EPA repeatedly has granted Federal and State agencies emergency exemptions to control continuing, predictable pest outbreaks. Essentially, repeated pesticide exemptions for the same use have the same effect as pesticide registrations, indicating that the pesticide or a substitute should be registered for the use and that exemptions were granted for nonemergency situations. The following table lists repeated exemptions granted by EPA between May 1973 and June 30, 1976.

Pesticide	Pest	Number of exemptions
Strychnine	Control rabid skunks	a/12
2,4-D	Water hyacinth	3
	Eurasian watermilfoil	a/ 3
	Alligator weed	3
DDT	Rabid bats	5
Toxaphene	Army cutworm (in sunflowers)	4
	Sunflower beetle (in sunflowers)	4

a/One 2,4-D and two strychnine exemptions were granted before EPA issued final emergency exemption regulations in December 1973.

Several of these exemptions were granted repeatedly to the same agency. If valid emergencies exist and are likely to recure periodically, EPA should register a pesticide to control such emergencies. On the other hand, it appears that some of these situations were not true emergencies and EPA should not have granted exemptions in these instances. The following examples illustrate these points.

Example 1

All strychnine registrations for animal control were canceled and suspended on March 9, 1972. However, substitutes have not been registered to control animals, particularly rabid animals, that present a real danger to people. Consequently, EPA has granted certain States specific exemptions to use strychnine for controlling rabid skunks almost continuously since June 1973. Following is a chronology of actions relating to Montana's efforts to control rabid skunks.

Date	Action
June 1973	EPA granted specific exemption effective June 6, 1973, through October 31, 1973.
December 1973	EPA granted exemption effective December 20, 1973, through May 31, 1974.
June 1974	Above exemption extended through October 1, 1974
December 1974	Montana registers strychnine for intrastate control of rabid skunks. Registration effective January 1, 1975, through December 31, 1975.
March 1975	Montana requests Federal registration of strychnine.
August 1975	Montana submits application for Federal registration of two strychnine products to be used intrastate.
September 1975	EPA informs Montana that Federal registration is not possible.
October 1975	Montana informs EPA that State registration was canceled effective October 4 1975.
November 1975	EPA grants specific exemption effective November 17, 1975, through March 31, 1976.
April 1976	Above exemption extended through November 16, 1976.

A total of nine exemptions was also granted to Wyoming and Texas for almost continuous use of strychnine to control rabid skunks.

Requests similar to Montana's were made during the same period by HEW's Center for Disease Control and other States to register strychnine for rabid skunk control. In September 1975 EPA denied such registrations because the cancellation and suspension order would have to be reconsidered and public hearings held before it could register strychnine.

It is readily apparent from the number and nature of strychnine exemptions granted that there is a definite need to register either strychnine or another pesticide to control rabid skunks.

EPA has a precedent for registering a canceled pesticide for health-related use. In May 1976, at the request of the Center for Disease Control, EPA registered a DDT product for controlling rabid bats. EPA delegated authority to the Center to approve use of the product in situations the Center determined to be bona fide health emergencies.

EPA should establish a rational policy for controlling recurring infestations of rabid animals which are a threat to people. If it determines that strychnine is the only available pesticide for such control, it should register such products for use by an agency such as the Center for Disease Control in bona fide emergencies, as it did in registering DDT to control rabid bats.

Example 2

Since 1958 the Tennessee Valley Authority (TVA) has used 2,4-D extensively to control Eurasian watermilfoil (aquatic plants) in eight TVA reservoirs on the Tennessee River and its tributaries. Between calendar years 1973 and 1976, EPA granted TVA four emergency exemptions for unregistered use of 2,4-D. In granting the exemption, EPA recognized that the use did not constitute an emergency. For example, in its 1975 letter to TVA approving the exemption, EPA stated:

> "It should be emphasized that additional specific exemption requests by the TVA for the use of 2,4-D in moving water beyond calendar year 1975 will not be granted since, in our estimation, there will have been adequate time to gather the necessary data to register 2,4-D for this use by then."

Despite this and similar warnings in previous years, EPA did grant TVA an additional exemption in 1976.

In commenting on this example, TVA said

> "In a very real sense the emergency with Eurasian watermilfoil which confronted TVA and that required the unregistered use of 2,4-D, was the result, not of the pest outbreak itself, but of EPA's failure to act in a timely fashion on TVA's April 1973 petition to establish tolerances for 2,4-D residues in fish and potable water. EPA did not establish these tolerances until June 10, 1976--more than three years after the petition was submitted. (This tardy action is continuing to cost the taxpayers money; only one manufacturer of 2,4-D was able to obtain an appropriate label from EPA in the short time between the establishment of tolerances and TVA's request for bids for our 1977 supply of 2,4-D, forcing us to pay a substantial premium.)"

Granting of exemptions in recurring, predictable situations does not conform to EPA's policy and has not been consistently applied to exemption requestors. For example, in March 1974, the Department of Agriculture's Animal and Plant Health Inspection Service requested a specific exemption to use carbaryl and dieldrin on citrus fruit to combat the West Indian sugar cane root borer. EPA denied this request in February 1975 because the insect had been a continual problem since 1968 and data could have been developed and used to register the pesticides requested. EPA should discontinue the practice of granting exemptions for non-emergency uses. This would result in more consistent application of its emergency exemption procedures.

COORDINATION OF EXEMPTION ACTIONS AND MONITORING IS NOT GOOD

EPA headquarters has not done a good job of keeping its regional offices advised of exemption requests and, consequently, the regional offices could not fulfill requirements for obtaining data needed to make informed decisions on requests and monitoring. Even when regional offices were notified of requests, the time provided was often too short or regional offices' efforts were too limited to have significant impact on decisions.

This lack of communication hampers EPA's ability to insure that highly toxic pesticides, some of which have been banned because of their persistence in the environment or their ability to produce cancers, are used in accordance with exemption restrictions.

A December 3, 1974, memo directed regional pesticide branch chiefs to determine for specific and quarantine-public health exemption requests

--whether an emergency exists,

--the economic benefits and losses that could be anticipated with and without the exemption,

--alternatives to the requested pesticide, and

--whether the proposed use will adversely affect man and/or the environment.

EPA headquarters recognized that all relevant facts must be considered before making decisions on exemption requests and that regional personnel, being closer to the

scene of proposed application, were in a better position to assess exemption requests. Regional staffs were to contact all relevant State agencies which could be affected by or which had expertise in pesticide use. The information obtained was to be submitted to EPA headquarters by phone as soon as possible and was to be followed by a written report.

Despite the obvious benefits that could be derived from proper implementation of this memo, the exchange of information between EPA headquarters and regional staffs during the decisionmaking process has continued to be extremely limited. For example, in the five regions we visited, 46 exemptions were requested after the memo was issued. However, the regions (1) were aware of only 24 requests, (2) provided oral comments on only 20, and (3) provided no written comments.

EPA regional officials told us that their efforts were generally limited to commenting on whether emergencies actually existed and whether data provided in the request was accurate. They stated that the regions did not have the expertise or access to sufficient information to render opinions on anticipated economic benefits and losses likely to result from the approval or denial of the request. The officials said that written reports were not provided to headquarters because they had not had significant adverse comments warranting written documentation.

The absence of adequate communication between EPA headquarters, the regions, and State agencies also affected the extent of monitoring performed as evidenced by the number of inadequately monitored exemptions. Regional staffs were aware of only 40 and monitored only 8 emergency exemptions approved for the five EPA regions we visited. Regional monitoring was done after the pesticide was applied rather than at the time of application for six of the eight exemptions monitored. Therefore, EPA could not insure that exemption requirements were followed. There were benefits to EPA's monitoring--the assurance that no obvious, lasting detrimental environmental effects occurred and that the soil did not contain excessive pesticide residues where products were applied.

Some State lead agencies were also unaware that certain exemptions had been granted, and therefore, could not monitor these emergency exemptions. (See discussion of toxaphene exemptions on pp. 25 to 28.) A State lead agency is responsible for knowing what pesticides are being used in the State and assuring that they are properly applied. Normally it has

personnel whose responsibilities include pesticide monitoring who could monitor emergency exemptions if deemed appropriate.

EPA headquarters should communicate in a timely manner with regional staffs to enable them to assess exemption requests through contacts with appropriate agencies in the States. We believe that the objectives of the 1974 memo are laudable and that every encouragement should be provided to the regional staffs to comply with its requirements. EPA should also field monitor as many emergency exemption pesticide applications as possible, particularly those involving suspended or canceled pesticides. We believe that the presence of EPA personnel during applications would greatly reduce the possibility of exemption restrictions being violated. EPA should also keep State lead agencies appropriately advised of approved exemptions and encourage them to monitor applications which EPA personnel cannot.

CONCLUSIONS

EPA's 40-day average for processing exemption requests is obviously too long to best serve the public when true emergencies exist. Exemption requestors should not have to illegally use pesticides in such cases, rather they should be able to rely on EPA making timely decisions to meet the emergency. EPA could insure more timely responses by making its information-gathering process more effective, providing additional staff, and streamlining its review and approval process.

EPA's practice of granting specific exemptions to unauthorized organizations may result in misuse of potentially hazardous pesticides and adversely affect man and the environment. This has resulted in excluding responsible State agencies from participation in decisionmaking and monitoring of such exemptions and has adversely affected EPA's relationship with some States.

EPA has repeatedly granted Federal and State agencies emergency exemptions to control continuing, predictable pest outbreaks of which many are not emergencies under EPA criteria. Exemptions should not be granted in nonemergency situations. In controlling recurring infestations that are true emergencies, such as rabid animals that are a threat to man, EPA should register a suitable pesticide which can be used by appropriate State or Federal agencies without going through the exemption process; or, if sufficient data is not available, EPA should require that the user collect data needed for registration as a condition of the exemption.

If the only available alternative is to use a suspended or canceled pesticide, such as strychnine for control of rabid skunks, EPA should consider registering the pesticide for restricted use under supervision of a responsible agency such as the Center for Disease Control; this has already been done for DDT use to control rabid bats.

EPA headquarters has not done a good job of informing its regional offices or State lead agencies about requests for or approval of exemptions. Consequently, the regions could not fulfill requirements for obtaining data needed to make informed decisions on the need for exemptions and neither regional nor State lead agencies monitored many exemptions to assure that man and the environment were not adversely affected. To compound the problem, when EPA's regional offices did monitor exemptions, it was usually after the pesticide was applied and EPA could not assure that exemption requirements were followed.

RECOMMENDATIONS

To strengthen controls over emergency exemptions and avoid unnecessary use and exposure of the environment to known harmful pesticides, we recommend that the Administrator, EPA, take action to see that:

--Specific exemptions are granted only to authorized State and Federal agencies.

--State and Federal agencies are prevented from taking illegal crisis exemptions for suspended or canceled pesticides.

--Applications under specific and crisis exemptions are monitored, particularly those involving canceled or suspended pesticides.

--Flagrant or repeated violators of exemption requirements are prosecuted or their authority to request specific exemptions or to take crisis exemptions is suspended.

In addition, we recommend that priority be given to improving program operations to make sure that

--timely review and action is taken on emergency requests,

--pesticides necessary to control continuing, predictable pest outbreaks are registered, and

--communications between headquarters and regions on exemption requests are improved and regional input into the decisionmaking process is obtained.

AGENCY COMMENTS AND OUR EVALUATION

In commenting on the draft report, EPA said that there are overriding philosophical inconsistencies and a basic misunderstanding of the intent of the emergency exemption program. EPA pointed out that we had consistently criticized it for actions of States or other agencies in taking exemptions illegally when EPA had not approved or had actually disapproved them.

As with other EPA comments, we discussed this matter repeatedly with EPA officials. We pointed out that, with the exception of those instances where States were forced to act illegally because of EPA's failure to take timely action, the examples cited were not a criticism of EPA that States or other agencies took illegal exemptions, but rather a criticism of EPA's failure to take corrective action so that such illegal actions would not recur.

In this regard, EPA said it considered our recommendation to revoke emergency exemption authority of flagrant or repeated violations to be rather ill-considered in light of our emphasis on good Federal/State/regional relations, especially when it has found only a very few organizations that have a pattern of repeated violations.

It seems obvious to us that our recommendation to revoke exemption authority would apply only to the very few organizations which had a pattern of repeated violations, thereby conforming to our terminology of "flagrant or repeated violators." Organizations which "react favorably to EPA's constructive criticism" in our opinion could not be characterized as flagrant or repeated violators and therefore would not be subject to revocation sanctions. On the other hand, violators who take exemptions disapproved by EPA or who show a pattern of repeated violations do fall into this characterization and should, in our opinion, be penalized. Further, we do not believe that revoking the crisis exemption authority of an agency that has repeatedly ignored EPA's decisions and circumvented them through apparently illegal means could damage EPA's relations with that agency, and remedial actions against such violators would tend to deter other agencies from acting similarly.

In commenting on our recommendations to improve the timeliness of actions to approve emergency exemptions, EPA did not comment on the adequacy of its average time to process emergency exemptions, rather it focused on its improvement in average processing time to 40 days for the period July 1, 1975, to June 30, 1976. Although this is a laudable improvement, much still remains to be done as 22 of the total 48 emergency exemptions required from 21 to 335 days to process.

We believe that the nature of an emergency exemption request makes it imperative that more timely actions be taken. As we have shown in the rabid skunk example on page 23, the State had to act illegally to protect the public because EPA did not respond promptly to its request. Further, although we agree with EPA that only reasoned judgments should be made, we do not concur that the Guam example on page 24 represents effective EPA action in disapproving a requested exemption. We see no valid reason why EPA took 10 months to ascertain that an emergency did not exist. In emergency situations time is of the essence, and we believe that EPA must act quickly on exemption requests--whether the decision is to approve or deny--in order for the program to be effective.

In commenting on our recommendation that exemptions are granted only to authorized State and Federal agencies, EPA said that it has taken measures to insure that the State lead agency and the EPA regional office are always involved in exemption requests. EPA also said that its policy has been to work with the State agency responsible for the area in which the emergency exists, not to solicit single designations of authorized agencies within each State. EPA asked for our guidance on the desirability of requesting that Governors designate a single authorized agency or organization to request emergency exemptions. We do not object to EPA's working with the State agency responsible for abating an emergency or to the concept of State Governors appointing multiple designees to request exemptions. We do suggest that if multiple designees are named, all exemption actions for the State be coordinated with each of the designees. Coordination of all actions should preclude the type of adverse relations that occurred with certain States.

In commenting on our recommendation that EPA register effective pesticides to control continuing, predictable pest outbreaks, EPA agreed that such registrations are needed, but disagreed that it had approved exemptions that

were not emergencies within the terms of its regulations. EPA attributed the need to grant exemptions in these situations to problems in implementing its 1975 registration requirements. We do not concur that the examples cited on pages 31 to 33 met EPA's criteria for emergencies because the pest outbreaks were predictable. EPA's criteria provides that an "emergency" is not predictable. We do not believe that EPA should use its emergency exemption authority as a substitute for registration of safe, effective pesticides which the Congress intended when it passed the Pesticide Act.

EPA told us that currently it receives regional input on every emergency exemption requested, informs the regions and State agencies of all exemption approvals, and makes monitoring requirements a part of those exemptions deemed hazardous enough to warrant monitoring. We believe the foregoing procedures, if followed, generally will correct the problems we noted during our review of the program. However, it is not apparent that it would correct the low priority placed on monitoring in the past. We strongly urge that EPA adequately consider the monitoring of pesticides under its emergency exemptions, particularly those pesticides which have been canceled or suspended.

CHAPTER 4

NEED TO IMPROVE STATE PESTICIDE REGISTRATION PROGRAM

States have misused their registration authority by registering pesticide ingredients EPA had

--previously suspended or canceled and

--ordered the State not to register because of unreasonable environmental effects or lack of safety/efficacy data.

In addition, States were permitted to register pesticide products that EPA had placed under registration moratoriums.

EPA has given low priority to promulgating the regulations for State registrations that were mandated by the 1972 Pesticide Act amendments. EPA does not expect final regulations to be printed in the Federal Register for some time. The timing is not known because of uncertainty about congressional action on proposed amendments to the Pesticide Act. Delays in implementing these regulations and requiring States to be certified as capable of registering pesticides under EPA's interim regulations caused relations between EPA and some States to deteriorate.

State-registered pesticides are limited to distribution and use within the State of registration for special local needs, particularly on minor pests or speciality crops for which effective EPA-registered pesticides are not available. Upon approval, State registrations have the same force and effect as EPA registrations.

Senate Report No. 92-838, dated June 7, 1972, stated that the purpose of State registration is

> "* * *to give a State the opportunity to meet expeditiously and with less cost and administrative burden on the registrant the problem of registering for local use a pesticide needed to treat a pest infestation which is a problem in such State but is not sufficiently widespread to warrant the expense and difficulties of Federal registration."

Clearly then, State pesticide registrations were intended to deal with localized problems that arise because of gaps in EPA registrations.

As of April 11, 1977, 45 States and 1 territory had been approved to register pesticides and had registered 646 products containing 142 active ingredients for special local needs. Of the 646 State registrations, EPA approved 592 and disapproved 44, and the States withdrew 10.

STATES REGISTER PESTICIDES THAT EPA WOULD NOT REGISTER

Under Section 24(c) of the Pesticide Act, States have registered pesticide products that EPA would not register. Of the 646 State pesticide registrations, 131 contained active pesticide ingredients that EPA would not register at the time because EPA had determined that these ingredients may have an unreasonable adverse effect on man or the environment.

EPA's pesticide registration policy concerning data requirements, which was published in the Federal Register on May 27, 1976, states that pesticide chemicals meeting or exceeding the criteria for risk would not be registered or reregistered until safety and environmental studies had been reevaluated, or until appropriate studies not currently available were done. This means that these pesticides and others with potentially dangerous characteristics are subject to intensive scientific review and public comment before a decision is made on whether to allow continued use or begin the process of removing them from commerce. This process is called "rebuttable presumption against registration." As of April 11, 1977, the States had registered 131 products (20 percent of total State registrations) containing 20 of these pesticide ingredients, 8 of which were potential carcinogens. Following is a table listing pesticide ingredients that were registered by the States but which EPA would not currently register.

Pesticide	Reason on list	Suspected carcinogen	Number of State registrations
BHC	a/potential oncogen	yes	1
Lindane	a/potential oncogen	no	30
Arsenic compounds	a/potential oncogen	yes	1
Carbaryl	b/potential teratogen a/potential oncogen	no	17
Benomyl	population reduction in nontarget species	no	13
EBDC compounds	carcinogen, causes thyroid cancer	yes	3
Strychnine	lack of emergency treatment; population reduction in nontarget species	no	c/14
DDVP	d/potential mutagen	no	2
Paraquat	lack of emergency treatment; population reduction in nontarget species	no	6
Dimethoate	a/potential oncogen	yes	4
Monuron	a/potential oncogen	yes	1
Ethylene Dibromide	a/potential oncogen	yes	e/4
Ethylene Oxide	b/potential oncogen	no	1
2, 4, 5-T	potential teratogen, contains dioxin contaminent	no	10
Trichlorfon	a/potential oncogen	yes	5

Pesticide	Reason on list	Suspected carcinogen	Number of State registrations
1080	lack of emergency treatment; population reduction in nontarget species	no	c/10
PCNB	a/potential oncogen	no	1
Rotenone	a/potential oncogen	no	2
Pronomide	a/potential oncogen	yes	2
Piperonyl butoxide	a/potential oncogen	no	4
Total			131

a/Potential to cause tumors, both benign and malignant.

b/Potential to cause birth defects.

c/Registrations disapproved by EPA.

d/Potential to cause permanent genetic changes.

e/Two registrations disapproved by EPA.

Following are two examples in which a State registered pesticides after EPA determined that they exceeded risk criteria and may cause unreasonable adverse health effects.

Example 1

EBDC compounds--EBDC (ethylene bisdiothiocarbamate) pesticides have been used extensively as agricultural fungicides for the past 30 years. At present there are six EBDC pesticide compounds having registered uses for approximately 80 crops. Ethylene thiourea (ETU), a potential carcinogen, is a degradation product of the EBDC compounds and may be a residue on certain food crops, such as spinach or lettuce. Repeated dietary exposures to EBDC's or ETU causes changes in the thyroid gland, including cancer, and depression of blood cholinesterase in warm-blooded animals.

Example 2

PCNB--PCNB (pentachloronitrobenzene) is registered primarily for use as a soil fungicide and as a seed treatment. In December 1969 the Mrak Commission 1/ recommended that human exposure to PCNB be minimized because laboratory tests showed it to be both a carcinogen and a teratogen. Also, an April 1976 EPA scientific review reported that PCNB could cause birth defects and tumors in test animals.

It is obvious that pesticides with such serious unresolved health questions should not be more widely dispersed into the environment until the questions of safety are resolved.

We gave an EPA official a list of these pesticides and asked why EPA was allowing States to register products containing pesticides that EPA would not register under its policy. This official said that EPA does not approve State registrations and only acknowledges receipt of the registration from the State. EPA officials also stated that pesticides identified by EPA as meeting or exceeding the risk criteria were not considered when evaluating State registrations and that EPA did not believe it could restrict the States from registering these pesticides. In addition, EPA does not plan to deal with such pesticides in the regulations for State registrations.

1/A commission established in 1969 by the Secretary of HEW to study pesticides and their relationship to environmental health.

We totally disagree with this reasoning because under the Pesticide Act EPA has 90 days in which to disapprove State pesticide registrations and has done so in 44 instances. Perhaps even more significant, the Pesticide Act gives State registrations the same status as EPA registrations if not disapproved within 90 days. Thus, by not disapproving State registrations, EPA is approving them (contrary to its statement) by allowing them to become Federal registrations at the end of the 90-day period. This means that State registrations would then be subject to the complex suspension and cancellation provisions should EPA later find it necessary to cancel such registrations. Such actions by EPA have taken 2 or more years for cancellation of such pesticides as DDT, aldrin/dieldrin, and chlordane/heptachlor.

Further, it does not seem logical that the Congress intended the States to register pesticides on which EPA had placed registration moratoriums. We believe that EPA should immediately notify the States that such pesticides may not be registered until they have been cleared. Such a provision should be included in EPA's State registration regulations.

STATE REGISTRATION AUTHORITY MISUSED

EPA disapproved 44 of 646 State registrations because the registrations violated provisions of the Pesticide Act and the implementing interim regulations. The following table shows the reasons registrations were disapproved.

State Registrations Disapproved

Numbers	Reasons
24 (note a)	Contained a suspended or canceled pesticide
13	Lacked tolerances
5	Product not previously registered by EPA
2	Use not efficacious
44	

a/These registrations appear to be only technical violations of the Pesticide Act. The use for which State registrations were made was not considered in the cancellation action, and it was believed that these registrations would not be affected by that action.

States with registration authority have been certified by EPA as capable of exercising adequate controls to assure that State registrations comply with the provisions of the Pesticide Act and EPA's regulations. It appears that those States that violated provisions of the law or regulations either do not have this capability or have done so intentially. EPA should take remedial action to insure that States are aware of their registration authority limitations. If States then fail to comply, EPA should take stronger action, such as rescinding States' authority to register pesticides.

The following example illustrates a situation that we believe warranted stronger EPA action. Tennessee registered two products--one containing fenthion and one containing methyl parathion--to control infestations of an estimated 5 million blackbirds in a State park. Before registering either product, the State asked EPA to recommend pesticides to control the bird infestation. EPA documents state that the State was advised to use TEPP or Tergitol. EPA also advised the State not to register (1) fenthion because it was not efficacious for this use and would create unreasonable adverse effects and (2) methyl parathion because its efficacy had not been determined.

In defending the registration of fenthion and methyl parathion, a Tennessee official wrote us that:

> "At that time, litigation pending with reference to a proposed use of Tergitol in a military installation located partly in Tennessee and partly in Kentucky prevented us from securing this material. We had reservations about the use of TEPP because of its very high toxicity, and we were not at all sure that we could use the material safely. We did, however, get in touch with the manufacturers of this compound to determine what data, if any, the manufacturers had as to the efficacy of the material for killing birds. We were told by the company that they had no data of a positive nature, and, as a matter of fact, the only data that they had was negative in that when securing a registration for the material in control of insects affecting hops, birds were caged in the hop fields prior to spraying with the material, and none of the caged birds were injured."

EPA officials told us that TEPP is an efficacious product for controlling birds. We also found that methyl parathion was neither registered or used by Tennessee until February 8 and 9, 1976, respectively--5 days after the President signed a bill into law authorizing the emergency use of Tergitol in both Kentucky and Tennessee.

Kentucky, which was also affected by the litigation, sprayed Tergitol on February 5, 1976--4 days before Tennessee sprayed methyl parathion. Tennessee officials also said that they were not able to obtain Tergitol for spraying; however, EPA and Department of the Interior officials said that stocks were available and could have been obtained.

During the course of these events, EPA on several occasions recommended that Tennessee obtain an experimental permit or an emergency exemption rather than register unproven products under State authority. EPA also contacted Tennessee State employees several times to determine what Tennessee was doing about the bird problem. According to EPA documents, these inquiries were ignored or evaded; after Tennessee began spraying, only one individual was available to EPA and he stated he was "not allowed" to discuss the spraying. The documents also say that after Tennessee's registration and use of fenthion, a Tennessee Department of Agriculture employee admitted that if EPA had been aware of the State's intent to register fenthion, EPA would have disapproved the registration.

Subsequent surveys of the sprayed area by an EPA inspector and a Tennessee State employee showed that the fenthion killed only 88 birds in an estimated 10,800-square-foot area where bird mortality should have been heaviest. Methyl parathion was similarly ineffective, and the State canceled both registrations.

Tennessee actions during this situation appear to be violations of its State registration authority, warranting action stronger than EPA's warning the State that similar violations would result in suspension of its registration authority.

The foregoing example demonstrates shortcomings in pesticide registrations of certain States. EPA should take action to insure that States do not register pesticides prohibited by the act or take action to limit or remove the States' registration authority for intentional violations.

REGULATIONS FOR CERTIFYING STATES NOT FINALIZED

The 1972 amendments to the Pesticide Act provided limited State registration authority under Section 24(c) for pesticides to meet special local needs that were not sufficient to justify Federal registrations. Regulations were to be finalized by October 21, 1974; however, EPA's interim regulations did not appear in the Federal Register for public comment until September 3, 1975--about 11 months after the mandated deadline for completing them. EPA is required to solicit public comment on the interim regulations before they are finalized because such regulations have the same legal effect as laws.

As of December 1977 EPA was still reviewing and evaluating public comments. An EPA official said that final regulations are being held in abeyance until the Congress acts on EPA's proposed amendments to the Pesticide Act. The official added that if the amendments are passed, issuance of final section 24(c) regulations would be delayed until new section 3 regulations are issued in accordance with the amendments. According to the official, the additional delay would be necessary to assure compatability between both sets of regulations. The regulations could be delayed as long as 2 or 3 years.

An EPA official said that the interim regulations were not completed in time to meet the legislative deadline because EPA gave low priority to these regulations while concentrating on Federal regulations for registering, reregistering, and classifying pesticides in accordance with section 3 of the act. This created no problems before the effective date of the new section 3 regulations on August 4, 1975. However, after that date, the States could no longer register pesticides except under the limited section 24(c) authority. Consequently, the need for section 24(c) regulations became critical for States with special local needs which were not being met under Federal registrations.

Because of delays in finalizing section 3 regulations, EPA elected to certify each State under the interim 24(c) regulations published in the September 3, 1975, Federal Register. An EPA official said that EPA would thus gain experience under the interim regulations to determine what changes were needed.

Delays in implementing the State registration regulations have further deteriorated relations between EPA and

certain States. Officials in one State we visited said that the State would not seek certification until after the final regulations were issued because requirements in the interim regulations may be substantially changed in the final regulations. Consequently, they said that the State did not want to expend funds, possibly needlessly, until the final requirements were firmed up. These officials explained that their reservations stemmed from previous experiences in which EPA had assured them that final regulations would be similar to interim regulations but, when finalized, the regulations were substantially different, resulting in wasted efforts and funds. Officials in two other States expressed similar sentiments, but told us that their States had elected to seek certification anyway.

CONCLUSIONS

States have obviously misused their registration authority granted under section 24(c) of the Pesticide Act by registering pesticides that:

--EPA had previously suspended or canceled.

--Required food tolerances but for which EPA had not set tolerances.

--EPA had directed the State not to register because the use caused unreasonable adverse environmental effects or was not efficacious for the intended use.

Because the foregoing are violations of the Pesticide Act, it appears that (1) certain States either intentionally violated their registration authority or (2) EPA has certified States that are incapable of assuring that registrations are in accord with the purposes of the Pesticide Act. In any case, EPA should take appropriate action against those States which have had intentional or repeated violations of the type noted. It is also apparent that EPA has permitted some States to continue using pesticides (for 90 days starting from the date of State registration) after EPA disapproved the State registrations. Use of pesticides that violate provisions of the act should be discontinued immediately.

EPA has allowed States to register pesticides that EPA has determined exceed established risk criteria and which must undergo additional scientific review before EPA may register any additional pesticides containing such chemicals. Thus, in effect, EPA has given the States greater registration authority than EPA has for such chemicals.

This gives us great concern because State registrations have the same legal status as Federal registrations if EPA does not disapprove them within 90 days of State approval. If EPA decides to cancel or suspend such State registrations after that date, they are subject to the same lengthy suspension and cancellation proceedings accorded Federal registrations--some Federal proceedings have taken well over 2 years to complete. We believe that State registrations of such chemicals should be subject to the same constraints as are EPA registrations and that such constraints should be spelled out in EPA's State registration regulations.

EPA has not promulgated State registration regulations in a timely manner and does not intend to do so in the near future. The importance of State registrations and EPA's delay in finalizing its regulations for such registrations have caused friction between EPA and some States. We believe that EPA's experience--in operating under its interim regulations and in certifying 45 States and 1 territory as capable of performing State registrations--provides sufficient expertise for EPA to finalize the mandated regulations. We believe such effort should be given priority attention and should incorporate the matters discussed in the preceding paragraphs.

RECOMMENDATIONS

We recommend that the Administrator, EPA, promulgate final regulations for State registrations and incorporate the following:

--States that intentionally or repeatedly violate their authority should be penalized immediately either by fines or suspension of their registration authority.

--States should not be permitted to register pesticides that EPA will not register.

AGENCY COMMENTS AND OUR EVALUATION

In commenting on our recommendation that States should not be permitted to register pesticides that EPA will not register, EPA agreed that there is some inconsistency between actions taken under section 24(c) and the lack of action taken under section 3 regulations regarding registration of rebuttable presumption against registration candidate chemicals or compounds under such review (registration moratoriums). EPA said that it is working to clarify this issue and that it

has proposed amendments to the Pesticide Act, which are being considered by the Congress, to resolve the issue. EPA said that the amendments include a concept designed to allow "conditional registration" of candidate chemicals for old uses or new uses where significant additional exposure is not anticipated. The primary criteria for such registrations would be clear evidence that it would not cause incremental, unreasonable adverse effects. We do not feel that pesticides under the rebuttable presumption against registration process should be registered by either States or EPA if other safe, effective pesticides are already registered.

In this regard, EPA also said that the Congress never intended that EPA devote extensive resources to reviewing State registrations and that EPA intends its review to serve solely as an audit function. We would like to emphasize that the Congress also made it illegal for States to take certain registration actions--such as registering canceled pesticides--however, as noted on page 46, several such State registrations did occur. We believe that EPA's audit role must be sufficient to preclude such illegal or irresponsible actions and that the Congress intended this by providing the 90-day period for EPA disapproval.

Concerning our recommendation that States which intentionally or repeatedly violate their registration authority be penalized, EPA did not believe that curtailing or suspending State authority under section 24(c) as a penalty for infractions of this authority is warranted, because deliberate misuse of this authority is not a prevalent or pervasive problem. While the problem may be neither prevalent nor pervasive at present, we believe that the examples noted indicate that certain States either violated their authority or are not capable of insuring that their registrations are in accordance with the intent of the Pesticide Act. Effective EPA sanctions on a case-by-case basis would aid in insuring compliance with the provisions of the Pesticide Act.

Finally, EPA commented on our observations that it had not promulgated State registration regulations in a timely manner with negative impact on some State/EPA relations by stating that although finalization of the regulations was important, operations under the interim regulations had (1) been effective, (2) been valuable in providing information to modify the proposed regulations and make them more workable, and (3) not caused a deterioration in its relations with the States. However, as pointed out in the report,

some State officials told us that they were unhappy that regulations had not been finalized and that they believed State/EPA relations had suffered as a result. We believe that these assertions cannot be ignored and that it is in the best interest of all concerned for EPA to begin finalizing the regulations at once.

APPENDIX I

THE DDT EMERGENCY EXEMPTION FOR DOUGLAS-FIR TUSSOCK MOTH CONTROL: A CASE HISTORY

The DDT emergency exemption to control the Douglas-fir tussock moth in the Pacific Northwest was perhaps the most controversial exemption EPA has ever granted. For this reason and because of many reports that the exemption was not warranted, we evaluated it to determine whether (1) DDT use was in fact necessary and (2) EPA requirements were met. We noted the following problem areas.

--DDT was used unnecessarily on 52,000 acres because the moth populations were near or below the U.S. Forest Service's action level. Also, moth populations within 4 days of spraying were at or below the action level on an additional 280,000 acres, raising the total to 332,000 acres where spraying apparently was not necessary.

--Data sufficient to register DDT alternatives was not developed during the 1974 program because the moth population was collapsing and testing had not progressed to the stage where reliable evaluations could be made.

--The U.S. Forest Service overestimated benefits derived from DDT use.

--Approximately 18,000 cattle and 900 sheep were contaminated with excessive DDT residues in their tissues from the spraying. Consequently, about 6,500 cattle scheduled for sale could not be marketed as scheduled, resulting in economic losses to the owners.

BACKGROUND

DDT (Dichloro-diphenyl-trichloroethane), a chlorinated hydrocarbon, is a broad spectrum insecticide acutely toxic to many invertebrates. Before 1972 DDT was the most widely used pesticide in the United States because of its effectiveness in controlling a large number of pests, its low cost, and its persistence. A 1975 EPA review of DDT literature identified several studies that showed that DDT could persist in the environment for decades.

During the 30 years before its cancellation, approximately 1,350 million pounds of DDT were used domestically.

When it was canceled, major uses included cotton (86 percent), soybeans (5 percent), peanuts (8 percent), and miscellaneous crops (1 percent). On June 14, 1972, EPA canceled DDT use in the United States effective December 31, 1972. The cancellation was based on DDT's persistence, transport, biomagnification, toxicological effects, and absence of benefits in relation to availability of effective and less environmentally harmful substitutes.

Tussock moth larvae defoliate true firs and Douglas-firs in forest lands of the western United States. Many trees are partially or completely killed either directly by the defoliation or because they are vulnerable to attack by other insects in their weakened state.

Usually the moth is present in the environment at relatively low concentrations; however, at periodic intervals (usually 8 to 10 years), the population increases to epidemic proportions. Major buildups and outbreaks occur in 3-year cycles. Epidemic-level moth outbreaks are usually not discovered until the second year of the cycle when defoliation is noticeable. For example, in parts of the Blue Mountains, Oregon, the moth population increased rapidly in 1971; defoliation became noticeable in 1972; and the outbreak in those areas collasped in 1973. A natural virus appears to have been the major factor in the collapse of moth populations in the past.

1973 EXEMPTION REQUEST

On March 20, 1973, the U.S. Forest Service requested a specific exemption to use DDT on 449,000 acres in the Blue Mountain area (Pacific Northwest) to control the moth. Additional requests for DDT exemptions were also received from several municipalities in Washington and Oregon in April 1973 and the Boise Cascade Corporation of Idaho in May and June 1973.

EPA inspection teams made onsite surveys to assess the situation in March and May 1973. The teams found that moth larvae in the area were infected by the natural virus. The EPA teams believed that the moth population would collapse in 1973, following its normal 3-year cycle. The U.S. Forest Service and Washington and Oregon State officials agreed that the populations would collapse in those areas noticeably defoliated during 1972.

On the basis of inspection team reports and other information available, EPA denied the exemption request because benefits derived from protecting immediate and future forest resources and recreational areas from moth damage were outweighed by such risks as reduced bird and fish populations, accumulated DDT residues in cattle and sheep grazing in sprayed areas, contaminated water supplies, and unknown effects on human health and the environment.

The moth population collapsed as expected in the Blue Mountain area in 1973; however, Forest Service officials said significant damage had already occurred as they forecasted before the collapse.

1974 EXEMPTION

On January 3, 1974, the U.S. Forest Service again requested an emergency exemption to use DDT to control several distinct outbreaks of the moth in the Pacific Northwest.

On February 28, 1974, EPA granted the emergency exemption authorizing application on 650,000 acres of Federal, State, and private land in Oregon, Idaho, and Washington at a rate of 3/4 pounds per acre (total of 490,000 pounds). The exemption was granted subject to certain spray restrictions and research and monitoring requirements. One of the major conditions in allowing the exemption was to develop alternatives to DDT that could be registered.

EPA approved the exemption request on the basis of the following findings.

--A moth outbreak had or was about to occur and there were no alternative pesticides or methods to control the pest.

--Significant economic problems would occur without DDT use.

--There was insufficient time for a pesticide to be registered.

--The benefits of DDT use outweighed the risks involved.

In the order announcing the decision, the EPA Administrator stated that EPA lacked considerable data which, ideally, should be assessed before a decision was made. In this case, however, EPA did not believe it had this option. EPA was uncertain about the (1) relationship between the

intensity of larval populations and tree damage, (2) economic and social impact of a decision not to control the infestation, and (3) virus concentration in moth larvae and its potential to cause a collapse of some or all the infestations.

Exemption restrictions

Although EPA granted the exemption, it cautioned the U.S. Forest Service that the exemption was not a directive from EPA to use DDT against the moth. EPA directed the U.S. Forest Service to survey and assess the viability of the moth egg masses and the virus concentration as a basis to insure that unnecessary DDT applications were not made.

Specifically, EPA stipulated that the U.S. Forest Service not spray acreage where larval incidence was too low to justify DDT use or where viral incidence would control the outbreak without DDT use. Lab hatches of egg masses were to be done and verified by field surveys at the time of natural hatch.

EPA also required that livestock and other domestic animals be removed from the treatment area to the extent possible and that hunters be informed that DDT residues may be present in game animals taken from the sprayed area.

Under the exemption, the U.S. Forest Service was to perform sufficient research to register other pesticides as alternatives to DDT control of the moth. EPA required the U.S. Forest Service to test resmethrin, bioethanomethrin, carbaryl, and trichlorfon as a followup to a 1973 test when these chemicals were used in attempts to develop DDT alternatives. In addition, the U.S. Forest Service was instructed to conduct statistical evaluations of DDT efficacy in preventing tree damage and mortality and to determine if DDT was efficacious at lower application rates. A final requirement was to better define the correlation between egg masses and larval populations, virus incidence, and tree damage and/or mortality. This research was to be completed and submitted to EPA by December 1, 1974.

DDT APPLIED UNNECESSARILY

The U.S. Forest Service did not comply with EPA's directive that unnecessary DDT applications not be made. In fact, up to 52,000 acres may have been sprayed unnecessarily, based on the U.S. Forest Service's own criteria.

In setting up parameters for its DDT spraying program, the U.S. Forest Service determined that areas should be sprayed only if larvae infestations exceeded 20 larvae in a 1,000-square-inch area. The following table shows moth populations for various areas before spraying and at 4- and 21-day intervals after spraying.

Moth Populations by Test Area and Sampling Periods

Test Area	Acreage	Prespray level (note a)	Postspray levels 4 days (note a)	Postspray levels 21 days (note a)
Colville, Wash.:				
treated	167,200	55.3- 78.9	0.6- 1.4	0.1- 0.3
untreated	872	17.8- 49.6	8.7-18	6.8-11.9
Pomeroy, Wash.:				
treated	17,200	17.7- 25.5	0.04-0.3	0.03-0.1
untreated	32,826	3.8- 8.3	1.3- 3.1	0.7- 1.3
Halfway, Oreg.:				
treated	33,700	15.6- 24.8	0.2- 0.5	0.1- 0.5
untreated	6,985	10.3- 18.8	7.3- 14.9	3.1- 6.4
LaGrande, Oreg.:				
treated	38,100	22.0- 29.2	0.2- 0.4	0.01-0.02
untreated	54,623	16.0- 33.2	6.2- 12.8	0.6- 2.2
Wallowa, Oreg.:				
treated	88,400	31.5- 48.2	0.3- 1.0	0.03-0.2
untreated	19,083	58.3-100.3	24.3- 39.2	10.5-23.2
St. Joe, Idaho:				
treated	75,300	23.0- 33.4	0.04- 1.1	0.1- 1.2
untreated	7,928	9.0- 12.4	7.8- 11.0	3.6- 6.6
Sawtooth, Idaho:				
treated	1,100	8.0- 12.2	0.3- 0.6	0.3- 0.6
untreated	100	5.1- 10.8	2.2- 4.8	2.4- 5.8

a/Number of larvae per 1,000 square inches.

The table shows that DDT was effective in reducing moth populations. However, it also shows that the populations were declining significantly in untreated areas, probably due to a naturally occurring virus and such other factors as egg infertility, overwintering stress, and egg predation. For example, moth population in the unsprayed LaGrande, Oregon, and Colville, Washington, areas, within 4 days of the spraying of the remaining acreage, had declined to about one-third of their prespray levels--both below the U.S. Forest Service's action level.

The table also shows that three sprayed areas totaling 52,000 acres were below or very near the action levels. The spraying was questionable in view of the declining moth populations. The questionable areas included Sawtooth, Idaho, (1,100 acres); Pomeroy, Washington, (17,200 acres); and Halfway, Oregon, (33,700 acres). Also, moth populations within 4 days of spraying were at or below the action level on an additional 280,000 acres, raising the total to 332,000 acres where spraying apparently was not necessary.

Agency comments and our evaluation

In commenting on our draft report the U.S. Forest Service disagreed with our conclusion that DDT was used unnecessarily. The Service said that:

--The need for treatment was determined by its 1973 fall egg mass survey and subsequent virus level determinations as indicated in its environmental impact statement.

--Prespray moth population data could not be used as indications of actual population levels, and there was not sufficient time to measure precise population levels before treatment in the spring of 1974.

--Serious damage would have occurred had DDT not been used.

In analyzing the data on egg mass density and viral incidence presented in the Forest Service's environmental impact statement, we found that the data was not sufficient to support the Service's claim that DDT was not sprayed unnecessarily. An analysis of the data follows.

Unit	DDT-treated acreage	Total acreage meeting treatment criteria A (note a)	B (note b)	Total	withheld (note c)	available	DDT-treated acreage not meeting criteria
Colville	167,200	83,840	2,560	[illegible]	500	85,900	81,300
Pomeroy	17,200	39,680	3,200	42,880	500	42,380	-
Wallowa	88,400	71,680	640	72,320	9,200	63,120	25,280
LaGrande	38,100	48,000	-	48,000	1,100	46,900	-
Halfway	33,700	40,960	2,560	43,520	16,200	27,320	6,380
Total	344,600	284,160	8,960	293,120	27,500	265,620	112,960

a/Recommended for control.
b/Treatment optional pending further evaluations, such as aerial surveys.
c/Acreage set aside as control plots and for research and testing of other chemicals.

About 284,160 acres were recommended for control on the basis of the 1973 fall egg mass survey and subsequent virus level determinations, and treatment was optional on an additional 8,960 acres (a total of about 293,120 acres). Some 27,500 of these acres were set aside for research and testing of other chemicals. Thus, only about 265,620 acres met the treatment criteria and should have been treated with DDT; about 112,690 of the 344,600 acres treated did not meet treatment criteria. A prime example of unnecessary spraying occurred in the Colville unit. The fall egg mass survey and subsequent virus level determinations showed that a section of land totaling about 23,040 acres should not be treated, and the U.S. Forest Service indicated it its environmental impact statement that this area was not to be treated. However, at least 16,640 of these acres were treated with DDT during the program.

We could not make reliable evaluations for the St. Joe and Sawtooth units because of incomplete information. The U.S. Forest Service said in its 1974 environmental impact statement that about 46,100 acres needed treatment and treatment was optional on another 97,500 acres; however, an analysis of the 1973 fall egg mass survey and egg viability data included in the statement indicates that only 12,160 acres may have needed treatment. Specific data pertaining to the Sawtooth unit was not included and we could not determine whether the unit was included in the 1973 fall egg mass survey.

While the prespray population data may not accurately reflect the true moth population, it was certainly an indication that populations were not as heavy as originally believed. More importantly, the 4-day and 21-day postspray data collected by the Forest Service showed clearly that the moth was declining at an extraordinary rate and that only a small portion of the moth populations would reach the fifth to seventh instars, the stages of development that the Forest Service states causes significant defoliation. At 21 days

postspray, the bulk of the moth population was only in the third or fourth instar--still too early to do significant damage.

A U.S. Forest Service researcher involved in the spraying told us that in retrospect it was a "given" that the spraying was unnecessary. Another U.S. Forest Service official stated that the population trends should have raised a "red flag" and spraying should have been discontinued until true populations were determined in the unsprayed areas. This position is further supported in an article published by a U.S. Forest Service researcher in September 1976 issue of the "Annals of the Entomological Society of America" which indicates that moth populations may not have been sufficient to justify treatment. The researcher found:

> "Egg masses for the 1973-74 generation were difficult to find on most plots and none was collected from heavy areas. Nevertheless, samples were available to estimate egg mortality independently for the other classes * * *. Expected egg densities were low on heavy and moderate plots but relatively high on light and very light plots. However, 90 percent or more of the eggs in all class samples failed to hatch. This mortality was fairly equally divided among three natural causes: hymenopterous parasites, infertility, and losses presumably due to overwintering stress and egg predation." (Underscoring added.)

The researcher also said that moth populations, after hatch, declined sharply. For example, moth populations in the first stage of development dropped by 92 percent (from 14 to 1.1 larvae per 100 square inches) because of virus, predators, parasites, and dispersion. One-half of the surviving population died for the same reasons within 21 days.

Based on the foregoing, we conclude that the U.S. Forest Service's argument is not convincing that all spraying was necessary and that significant damage would have occurred without the spraying.

U.S. FOREST SERVICE DID NOT IDENTIFY EFFICACIOUS DDT ALTERNATIVES

A major condition of the exemption was to develop registerable DDT alternatives for controlling the tussock moth. Field experiments were carried out, but some were scaled back or canceled because of low insect population in study areas. For example, proposed testing in Idaho of two of the most

promising pesticides, bacillus thuringiensis and the nuclear polyhedrosis virus, was canceled because of inadequate moth populations to provide satisfactory tests. Because of low populations in the test areas, no alternative pesticides were registered as a result of the exemption testing. The results of some of the alternative testing is discussed in the following sections.

In a November 1974 draft interim report on the program, the U.S. Forest Service said that in a field experiment using Sevin-4-Oil and Dylox, moth populations were the lowest of any used for testing in 1974. Because of the low insect populations, an additional test of Dylox was conducted in Wallowa, Oregon, and Seven-4-Oil in St. Joe, Idaho (high insect population areas). The additional test of Dylox on two 300-acre plots resulted in moth population reductions of 68 and 79 percent 4 days after spraying. The U.S. Forest Service draft stated that

> "Although some larvae were killed, the density of the surviving larvae was still at a level high enough to cause serious defoliation. Sometime between the 4-day and 21-day sampling periods a virus caused the moth population to collapse before the evaluation was completed."

The same situation occurred during the Sevin-4-Oil test. Population reductions on two 600-acre plots were 83 and 88 percent after 7 days and 97 and 96 percent after 14 days. Again, prespray larval populations were high, but a 60-percent reduction due to natural factors (virus) occurred in an untreated check plot after 14 days. Because the moth population collapsed before the tests could be completely evaluated, no analysis was made to determine the effectiveness of these pesticides.

Several EPA and U.S. Forest Service memos state that alternative pesticides could not be tested because of a natural decline in moth populations due to a combination of factors including virus and other natural predators. Two researchers who studied the project told us that the moth population was declining naturally in the entire area. One of these officials said that by 1975 moth populations had collapsed entirely and, consequently, additional studies of alternative pesticides could not be made.

U.S. Forest Service officials said that DDT alternatives were not developed because the tests had not progressed sufficiently to make a reliable evaluation when the population

collapsed. One official said DDT alternatives could not be tested in DDT-treated areas because treatment had already begun, and therefore, it was too late to switch.

Agency comments and our evaluation

With regard to development of DDT alternatives, the U.S. Forest Service said:

> "The reasons for not being able to register alternative pesticides are many, the least of which was the declining moth population in some areas * * *. One season's testing under the best of circumstances would usually not be sufficient to generate enough data to satisfy registration needs."
>
> * * * * *
>
> "It is true that the populations collapsed on some of the DDT alternative test areas before an effective test could be carried out. Because of the detailed planning and preparation work required to set up an adequate study area, it was not possible to move some of these tests to high insect population areas at the last minute. Although unfortunate from an experimental standpoint, it is completely erroneous to conclude that the insect population declines experienced in some of these areas were general in nature. It should be noted that some of these tests were quite successful, e.g., Acephate, Dimilin, and Sevin-4 Oil."

We agree that one season's testing may not be sufficient to generate enough data to satisfy registration needs; however, most of the chemicals tested by the Forest Service were also tested in 1973. Collection of data from 2 years of spraying is generally more than adequate to establish efficacy, which EPA believed appropriate in this instance because it made the registration of viable DDT alternatives a major condition in approving the spraying exemption. Also important is the fact that the Forest Service accepted this condition as reasonable when it agreed to the EPA conditions of the exemption.

To the Forest Service's credit, the follow-on program which was conducted in New Mexico, Colorado, and Canada beginning in December 1974 has resulted in the registration of two biological pesticides--bacillus thuringiensis and the polyhedrosis virus--and development of data to support the registration of three other chemical pesticides--orthene,

dimilin, and Sevin-4-Oil. However, the major portion of the data used to support the registration actions appears to have been developed since 1975, not during 1974 (the year of the DDT programs). Some data on the pesticides was collected in 1974 as well as 1973, but the tests merely indicated that the pesticides were promising alternatives and that additional testing would be needed, the same conclusions reached after the 1973 sprayings. Data used to support the registration of Sevin-4-Oil was developed in 1974 in Montana, an area not included in the DDT spraying area approved by EPA. Some Sevin-4-Oil tests were conducted in Idaho in 1974, but again the data developed was not adequate to make reliable determinations of its effectiveness.

Consequently, we must conclude that the 1974 DDT exemption had little or no effect on the registration of viable alternative pesticides to control the tussock moth and that this important condition of the DDT exemption was not complied with.

U.S. FOREST SERVICE OVERESTIMATED BENEFITS OF DDT USE

The U.S. Forest Service began using DDT on June 9, 1974, in the Colville unit in Washington and concluded the program on July 25, 1974, on the LaGrande unit in Oregon. A total of 420,944 acres were treated with 315,708 pounds of DDT (three-quarter pounds per acre). An additional 5,615 acres were sprayed at rates of one quarter and one-half pounds of DDT an acre. Only 6,060 acres were sprayed with DDT substitute pesticides.

The U.S. Forest Service stated in its report on the project that the program was highly successful in accomplishing its objectives of reducing moth populations and reducing timber losses. The Service reported that the effect of DDT on the moth population was immediate and dramatic, resulting in 98.8-percent reductions in the populations. The U.S. Forest Service estimated that treating the 420,944 acres prevented an additional loss of 411 million board feet of timber with a value of $11.6 million and prevented a loss of $23.8 million in damage to immature trees, growth losses, reforestation expenses, recreation losses, and increased fire protection costs. These estimates assume treatments prevented about 90 percent of the 1974 damage that otherwise would have occurred had the areas not been treated.

The U.S. Forest Service's benefit estimates did not consider the effects of the natural virus and other predators

on moth population declines. The Service recognized that significant natural declines in populations were occurring and in fact used these declines to justify terminating efficacy studies of DDT alternatives during the 1974 program. For example, the Service canceled proposed tests of bacillus thuringiensis and the nuclear polyhedrosis virus because adequate moth populations were not available to provide satisfactory tests. Using the U.S. Forest Service's rationale, all but one of the DDT-treated areas likewise would be unsuitable for determining the efficacy, and hence the resulting benefits, of the DDT applications because of similar declines in moth populations in adjoining untreated areas.

The extent of moth population declines in treated and untreated areas is shown in the following table.

Test area	Acreage	Percentage of prespray population reductions after 4 days	21 days
Colville, Wash.:			
treated	167,200	98.2	99.6
untreated	872	63.7	76.0
Pomeroy, Wash.:			
treated	17,200	98.8	99.6
untreated	32,826	62.6	84.3
Halfway, Oreg.:			
treated	33,700	98.0	98.0
untreated	6,985	20.7	66.0
LaGrande, Oreg.:			
treated	38,100	98.6	99.9
untreated	54,623	61.4	93.4
Wallowa, Oreg.:			
treated	88,400	97.9	99.6
untreated	19,083	60.9	76.9
St. Joe, Idaho:			
treated	75,300	96.7	96.4
untreated	7,928	11.3	46.7
Sawtooth, Idaho:			
treated	1,100	95.1	95.1
untreated	100	55.6	46.3

In five of seven test areas, moth populations in the untreated areas declined by 55 percent or more because of natural causes within 7 days (or 4 days after treated areas were sprayed). After 21 days populations in all untreated areas had declined to a minimum of 54 percent of the pre-treatment populations; 5 untreated areas adjacent to sprayed areas totaling 344,600 acres experienced declines ranging from 66 to 93 percent.

The foregoing is supported in EPA's August 20, 1974, monitoring report. In the report EPA stated:

> "The Forest Service sampled and collected egg masses in fall 1973; they also determined the viral incidence of larvae hatched from these eggs. These data were used to estimate the 1974 larval populations and to decide what areas required treatment. The inaccuracy of these estimates is clearly illustrated by the fact that 106,000 acres, of approximately 460,000 acres scheduled for treatment on the basis of egg surveys, had insufficient larvae to warrant spraying. Also, approximately 45 percent of the 79,161 acres sprayed due to visible defoliation had been included in the fall egg mass surveys and judged not to require treatment. More reliable measurements of larval populations are possible from direct field larval counts. The Forest Service did some prespray larval sampling in its "cluster plot" analysis. However, this analysis was primarily intended to evaluate DDT efficacy over the entire project. This prespray larval survey did not adequately ensure an accurate count of larvae in each spray block because:
>
> 1) an insufficient number of samples was included.
>
> 2) all spray blocks were not sampled.
>
> 3) sampling occurred before an established first instar larval population was present. Thus, a varying proportion of the eggs had not yet hatched and adequate larval dispersion had not yet occurred.
>
> 4) established and declining tussock moth populations were inappropriately sampled using methods and assumtions designed to measure incipient populations.

"In addition to the inadequacies of the survey, the Forest Service workplan did not guarantee that if the larval populations fell below the threshold density of 20 larvae/1000 $in.^2$, a spray block would be re-evaluated or eliminated from treatment. This and the inadequacies of the larval survey could lead to the unnecessary spraying of areas which did not have tussock moth populations large enough to warrant treatment."

In disagreeing with EPA's report, the Forest Service said:

--The report ignores the fact that EPA was told a complete prespray larval survey was not possible due to the short interval between moth egg hatch and the need to treat.

--Item 4 above is completely in error because a predetermined number of plots were surveyed, much of which were in the incipient stage--before visible defoliation had occurred.

--It was not feasible to carry out more than one type of survey because of the intermingled nature of the different outbreaks.

Notwithstanding the Forest Service's comments that it had insufficient time to carry out the type of indepth sampling EPA believed necessary, apparently EPA expected the Service to do this sampling, without which it would not be possible to insure that only necessary spraying was done and that DDT benefits were accurately measured.

On the basis of the foregoing, it appears that at best U.S. Forest Service estimates of benefits were very optimistic and at worst that benefits were nonexistent. It is true that moth populations experienced large declines in the DDT-treated areas; however, it is not apparent whether these declines resulted because the larvae were in a weakened state because of the natural virus and other factors or whether the DDT was truly efficacious. The Service, on the other hand, did not estimate the cost of detrimental environmental and economic effects resulting from the DDT applications. For example, an estimated 18,000 cattle and 900 sheep, found to have excessive DDT residues in their tissues from the spraying, were restricted from being marketed for up to 1 year. Consequently, about 6,500 cattle scheduled for sale during that year could not be marketed, resulting in economic losses to the owners.

Agency comments and our evaluation

In commenting on our proposed report on the benefits of DDT use, the U.S. Forest Service said

> "If any error was made in estimating benefits from using DDT, we believe, it was an underestimation. Because there was no existing data based on how much subsequent loss to bark beetles could be expected if tussock moth damage was not prevented, an estimate of this benefit was not included in the calculations. Salvage logging is now being conducted on an emergency basis in most of the untreated areas in an attempt to recover trees first defoliated by the tussock moth and subsequently killed by Douglas-fir bark beetles. In many cases this is the second logging entry, as the first efforts were limited in most cases to picking up only trees killed or severely damaged by the tussock moth alone. The difference between treated and untreated areas in this regard is striking and plainly visible at this time, particularly from low-flying aircraft."

We do not believe the U.S. Forest Service-claimed benefits from DDT use is warranted because Service estimates do not make allowance for the decline in moth populations resulting from natural causes. For example, the U.S. Forest Service assumes that about 90 percent of the 1974 damage that would have occurred was prevented by using DDT. As stated previously in a published report by the Forest Service researcher, moth populations failed to hatch as anticipated and those that hatched declined so rapidly that spraying was questionable. This coupled with the Forest Service's failure to recognize the adverse effects to grazing animals and to the environment, in our opinion, results in a significant overestimation of spraying benefits.

CONCLUSIONS

Contrary to U.S. Forest Service assessments, the DDT exemption for controlling the moth was, at best, of limited success. In fact, it appears that DDT treatment of over 330,000 of the 420,944 acres sprayed was questionable because (1) populations were at or below levels the U.S. Forest Service deemed harmful or (2) populations were declining so rapidly that spraying was not necessary. Consequently, the Service did not comply with EPA's directive that only

necessary DDT applications be made, and over 315,000 pounds of DDT were applied in the Pacific Northwest, much of it unnecessarily. This is environmentally significant because DDT will not degrade significantly for decades and, in the absence of offsetting benefits, was not justified.

Because of declines in moth populations, the U.S. Forest Service was unable to fulfill a major consideration--to identify efficacious, registerable pesticides to use in place of DDT in future moth infestations--in EPA's approval of the exemption. We believe that the U.S. Forest Service should have terminated all DDT applications when it found that moth populations were in substantial decline and that it could not test the efficacy of DDT alternatives.

We also believe that had sufficient monitoring been conducted, EPA early on would have detected that moth populations were declining and that additional DDT should be applied only after additional counts of moth populations and virus incidence had been made. Areas where the moths were declining rapidly or where the virus incidence was high should not have been treated.

APPENDIX II

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

SEP 26, 1977

OFFICE OF
PLANNING AND MANAGEMENT

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

Dear Mr. Eschwege:

Enclosed are EPA's comments from the Offices of Pesticide Programs and Pesticide Enforcement on your draft report entitled "Opportunities for Improving EPA's Special Pesticide Registration Activities". I am sorry for the delay in relaying these comments.

Preparation of this report has been a difficult exercise for both your audit group and EPA staff. Strong and differing views are held by both parties on the state and health of the special pesticide review activity. The result in this case is a set of straightforward and frank comments.

Be assured that they were not prepared and are not intended to reflect a hostile attitude on the part of EPA. They are intended, however, to forcefully and factually state the Agency's position on both the special registration activity and your draft report. I hope these comments will further a constructive dialogue between us that will improve both the special registration activity and the GAO report on it.

Sincerely yours,

Bill Drayton

William Drayton, Jr.
Assistant Administrator
for Planning and Management

Enclosure

APPENDIX II

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

Comments on the GAO Report, "Opportunities for Improving EPA's Special Registration Activities"

SUMMARY

The GAO began examining the work of the Office of Pesticide Program's special registration early in February 1976, looking specifically at the Agency's handling of experimental use permits, emergency exemptions, and State registrations under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Agency staff cooperated fully with the GAO investigators, and all files were made available for inspection.

An original draft report was completed by GAO late May 1977 on which the Agency informally commented, with the present draft following in August. The Agency's comments on the latest draft are attached.

Overall, EPA is disappointed in GAO's seemingly contradictory recommendations and regulatory philosophy. Major flaws are that isolated instances are interpreted as trends, conclusions are not supported by the facts cited, and advice in specific areas would work to the detriment of program objectives in others; the GAO also seems intent on not giving credit where it is due, and ignores the positive aspects of the special registration reviews and improvements.

Agency comments on each of the three major parts of the report, i.e., Experimental Use Permits, Emergency Exemptions, and State Special Local Need Registrations, follow in order.

Edwin L. Johnson
Deputy Assistant Administrator
for Pesticide Programs

I. EXPERIMENTAL USE PERMITS

GAO concludes that EPA's experimental use permit program is not fully effective, and, as a result, new pesticide product development has declined in recent years.

In support of GAO's conclusion that EPA's experimental use permit program is having a direct, adverse impact on research and development efforts in the pesticides industry, the report cites a 1975 report by the National Agricultural Chemicals Association (NACA). EPA has addressed such concerns in a paper presented to the Senate Committee on Agriculture, Nutrition, and Forestry during recent deliberations on the amendment of FIFRA. This paper was included in the Committee report published on July 6, 1977. We provided GAO a copy of the Committee report and called attention to the study conducted by William Blair and Company in which the pesticide industry is characterized as one with "extraordinary profitability" (p. 63). According to a NACA survey, the categories of research and development most heavily impacted by EPA requirements amount to only about one third of total research and development expenditures.

EPA also directed GAO to our recent study, "FIFRA: Impact on the Industry", also included in the Senate Committee Report. This impact paper points out that in recent years about an equal number of firms have entered and left the pesticide research field. High profits and profit potentials have kept the industry interested. Although more stringent and extensive registration data requirements may result in innovations in the pesticide industry being fewer in number than in the past, the industry has and will continue to build on its existing research and development base with changes in use patterns and formulations of previously-registered products, and new chemicals within already successful classes of compounds. Partial evidence of this trend is the fact that issuance of experimental use permits has increased by 300% since FIFRA was amended in 1972. While this increase in the issuance of EUP's is due in part to the fact that Federal and State Agencies previously authorized to experiment without permits now are required to obtain EUP's, the majority of this increase, however, represents permits issued to industry.

In light of this radical increase in the number of permit applications and EUP's issued, and the continued high profit realization by pesticide industries, we feel that GAO's initial contention that the EUP program has led to a decline in research and development was unsubstantiated. The report has, however been revised to reflect that the Experimental Use Permit program is only one of several factors impacting on research and development activities. Since the Agency has not seen any information to substantiate the contention that EPA is driving firms from the pesticide field, we must take issue with the GAO's conclusions on this point.

There are several areas investigated by GAO discussed in the present draft report and an earlier version which bear close attention:

A. Guidelines

GAO RECOMMENDATION: promulgate guidelines specifying data requirements that are necessary for permit approvals and the type and extent of data to be developed under permits.

AGENCY COMMENT: The Agency does intend to promulgate general data requirements for the approval of experimental use permits. These requirements will be included as a section in the general registration Guidelines. Until, however, the Guidelines for full registration are finalized, the formulation of the EUP Guidelines would be ineffective. As the data requirements for full registration change, so do the requirements for EUP approval. It is necessary to first establish the full registration Guidelines before codifying the general data requirements for EUP approval.

The Agency is at a loss to understand GAO's implication that manufacturers should not be required to begin Section 3 registration data development, in particular long term animal feeding studies prior to the application for an EUP. The intent of the EUP program is to allow the development of efficacy data as well as field, fish, and wildlife, and environmental safety data necessary for full registration. Long term feeding studies are an important part of the safety data required, from EPA's standpoint. And surely, when the manufacturer enters the final stages of testing under the EUP, it is in his best economic interest to run such time consuming studies concurrently, to expedite compliance with full registration requirements and thus be fully prepared to apply for registration when the EUP is concluded.

The definition of data to be developed specifically under an EUP (as opposed to data to obtain an EUP) would be repetitious of the Section 3 registration guidelines. It would create additional time-consuming administrative problems to repeat this information in EUP guidelines.

B. Excessive Processing Times

GAO RECOMMMENDATION: Require reviewers to act on--approve or disapprove--properly prepared permits within a specified period.

AGENCY COMMENT: GAO sees no compelling reasons why permits should not be submitted, processed and either approved or disapproved as they are received. We fully concur with this observation. Unfortunately, however, EPA does not control the submission of permit applications. Applicants do not, in fact, submit their applications far enough in advance of the date they wish to begin testing.

[See GAO note 1, p. 85.]

The preamble to our Section 5 regulations states that EPA will generally require at least 90 days (not 60 days) to complete our review and issue the permit. The regulations themselves state that:

"An application or request for amendment to an existing permit shall be submitted...as far as possible in advance of the intended date of shipment or use. Applications will be processed as expeditiously as possible." (40FR 18783)

[See GAO note 1, p. 85.]

For Fiscal Year 1977 we projected that our resources and manpower would allow experimental use permit processing within the following time frames, depending on the chemical and testing situation involved:

20% within 90 days
50% within 120 days
30% within 180 days.

The report contains a number of conflicting statements on how to accomplish processing more efficiently. On the one hand, the report recommends that applications be processed "as they are received" and says that this will help to "spread EPA's workload throughout the year." On the other hand the report states that "there do not appear to be alternatives in alleviating this seasonal surge [of applications]." We fail to see how processing a "flood

of applications", as they are received will spread the workload throughout the year. We agree that all applications should be processed as they are received and in fact, we currently process and have in the past processed applications "as received." When possible, we attempt to prioritize submissions by the date needed. However, this is not always possible during the peak workload period With severely limited manpower, the final action on "seasonal surge" applications may not always be timely. The only ones who can spread the workload over the year while maintaining timely processing are the applicants. They can do this by submitting their permit applications as far in advance as possible.

C. Notification & Monitoring

GAO RECOMMENDATIONS: Furnish prompt information on permit approvals to applicable regions so that site visits can be programed when the experimental pesticides are being applied. Prioritize the permit monitoring program to assure proper control of experimental products whose safety has not been established.

AGENCY COMMENTS: The establishment of a good monitoring program is wholly dependent on knowing the basic properties of the chemical in question and its likely potential problems in the environment. EPA attempts to ensure that the "American public is not unncessarily exposed to harmful pesticides" (p. 18) before we issue an experimental use permit. There seems to be a discrepancy in the GAO findings in that on one hand, it implies that the Agency is requiring too much data to support an experimental use permit, and. on the other, the Agency is not adequately monitoring experimental products "whose safety has not been established

[See GAO note 2, p. 85.]

Regardless of this philosophical discrepancy, we do not agree that the 58% rate of experimental use permit monitoring is not adequate. We do not feel that extensive monitoring is necessary in many cases. The majority of EUP's are issued for "old" chemicals for which changes in use patterns, e.g , changed dosage, mode of application, or a different pest are sought. Acreage is often small and exposure to man and the environment is minimal Within the experimental use permit category, Regions prioritize monitoring so that the more dangerous chemicals, or those about which little is known, are monitored. In short, we feel that 58% is entirely adequate and appropriate for Agency monitoring of EUP's.

We agree with GAO that prompt notification of Regions on approval of experimental use permits is necessary, but we do not agree that the lack of notification of permit approvals causes "inadequate" monitoring. GAO would instruct EPA to "furnish prompt information on permit approvals to applicable regions so that site visits can be programmed when the experimental pesticides are being applied." It does not necessarily follow that an inspector must be on site at the time of pesticide application to determine if permit conditions have been met. While communications may not always have been optimal,

we try to furnish information on permit approval to Regions on a timely basis. As of June 1 1977, we were current on all permit approval notifications.

D. Extension of Permit Period

GAO RECOMMENDATION: Authorize experimental use permits for the reasonable duration of an experimental program rather than limiting them to 1 year as is now done.

AGENCY COMMENT: We agree with this recommendation, but not with the necessity for making the recommendation. We presently do consider the issuance of permits for more than one year on a case-by-case basis. The Section 5 regulations, when finalized, included such a policy, which was reaffirmed March 28 & 29, 1977, meeting of American Association of Pesticide Control Officials (AAPCO). We must, of course, require a two year program for a two year permit.

II. EMERGENCY EXEMPTIONS

As is the case with GAO's comments on the Experimental Use Permit Program EPA feels that there are overriding philosophical inconsistencies and basic misunderstanding of the intent of the Emergency Exemption Program, which must be addressed before considering the specific allegations made by GAO. GAO consistently cites examples of States or other agencies taking crisis exemptions illegally in the face of EPA lack of approval or actual disapproval of exemption requests. It does not seem to follow logically that, in the case of Agency failure to approve a request, or when the Agency rejects a request, the Agency can then be held liable for illegal use of the product in question. No one is compelled or has to use a pesticide illegally. The Agency cannot see the logic in criticizing the decision making because some Agencies are circumventing unfavorable decisions.

There are several aspects of emergency exemption processing singled out by GAO for particular discussion:

A. Untimely Action

GAO RECOMMENDATION: Timely review and action should be taken on emergency requests.

AGENCY COMMENTS: GAO originally used figures in support of its contention that emergency exemption processing takes too long which were biased by the statistical method employed. In response to Agency concerns on this biased methodology, we understand that GAO has performed a median analysis. This analysis shows a median processing time of 18 days, as opposed to an average processing time of 88 days. In the final draft of their report GAO revised the processing time figure on the basis of averaged processing times for 48 exemptions issued between July 1, 1977, and June 30, 1976. The average processing time for exemptions issued during this period was 40 days, less than half the time indicated by the original statistical methodology.

The meaningful consideration in issuing emergency exemptions is not the number of days it takes to process a request, but how close the Agency comes to meeting the date of anticipated need. The purpose of the emergency exemption program has been served if the exemption is granted in time to allow effective resolution of the emergency situation. We believe that this program is effective.

[See GAO note 1, p. 85.]

We believe that the Guam example supports the notion that the Agency should indeed take sufficient time to ensure a fully informed decision, which avoids unjustified exemptions. After the "delay" period necessary to acquire all pertinent information, EPA, in conjunction with the Center for Disease Control, could not determine that an emergency existed within the terms of the regulations. Therefore, the Agency did not grant an unnecessary exemption, and did not allow the proliferation of 1080, a compound with potential for causing secondary poisoning and other adverse effects.

B. Unauthorized Agencies

GAO RECOMMENDATION: Specific exemptions should be granted only to authorized State and Federal agencies.

AGENCY COMMENTS: While the regulations governing the issuance of emergency exemptions specify that these exemptions are to be requested by the Governor or his designee, we have never solicited single designations of authorized agencies. While we generally assume that the State lead agency is a Governor's designee, the lead agency may not necessarily be the sole designee. In cases where an emergency actually existed, we have not quibbled over jurisdictions, but have worked with responsible State agencies to remedy the emergency situation. We feel that this policy has been effective and, in fact, in some circumstances works better than insisting on a single Governor s designee. For example, should the lead agency be the State Department of Agriculture or Pesticides Agency, and the emergency be a threat to public health, certain public health organizations would possess the expertise necessary to properly identify and judge the extent of the emergency condition. We are open to suggestions on this point and solicit GAO's guidance on the desirability of requesting that Governors designate a single agency or organization as authorized to request emergency exemptions.

We agree that, in the case of the toxaphene exemptions, the recipients may not have been "authorized" organizations. It was assumed at the time of issuance that these State organizations were authorized to receive exemptions. Since the time of those exemptions, measures have been taken to ensure that the State lead agency and the Regional office are always involved in applications for exemptions.

[See GAO note 1, p. 85.]

[See GAO note 1, p. 85.]

C. Noncompliance

GAO RECOMMENDATION: State and Federal agencies should be prevented from taking illegal crisis exemptions for suspended or canceled pesticides.

AGENCY COMMENT: Again, it does not seem sensible that EPA should be criticized for illegal use of pesticides under crisis exemptions taken by other agencies, as in the APHIS/carbaryl example. It is not immediately apparent exactly how this example illustrates GAO's allegation that EPA is not effectively administering emergency exemptions and that the American public may be unnecessarily exposed to pesticides known to be harmful. EPA denied the exemption in question. We agree with GAO that agencies taking illegal crisis exemptions should be censured, but question the remedial measures GAO has suggested. Revocation of crisis exemption authority would place in serious jeopardy the Federal/State relations that we and GAO are most concerned about.

D. Repeated Exemptions

GAO RECOMMENDATIONS: Pesticides necessary to control continuing predictable pest outbreaks should be registered.

AGENCY COMMENT: EPA has not "repeatedly" granted Federal and State agencies emergency exemptions to control continuing, predictable pest outbreaks unless those outbreaks constitute emergency situations within the terms of the regulations, and subject to the availability of and the opportunity to make available registered alternatives. Determination of the necessity for issuing an emergency exemption pursuant to Section 18 is based on the question of whether or not emergency conditions within the terms of the regulations exist. Such a determination is not predicated upon previous issuance of Section 18's in the same or similar circumstances, although that factor may be taken into account. If there has been the opportunity to register an alternative for the use for which an emergency exemption is requested, the exemption request will probably be denied. It must be recognized, however, that the opportunity to register alternative pesticides has been limited for some time due to problems being encountered in implementation of the 1975 Section 3 registration requirements. These difficulties have resulted in an escalation in the number of Section 18's being granted, a trend not likely to halt in the near future.

GAO recommends that pesticides necessary to control continuing predictable pest outbreaks be registered. We agree, and the registration to CDC for DDT for control of rabid bats is evidence that we are moving in that direction. We are willing to consider applications for pesticide use in similar situations.

E. Monitoring and Communications

GAO RECOMMENDATION: Applications under specific and crisis exemptions should be monitored, particularly those involving canceled or suspended pesticides; and communications between headquarters and Regions on exemption requests should be improved and regional input into the decision-making process should be obtained.

AGENCY COMMENTS: In situations where the emergency exemption application is deemed hazardous enough to warrant monitoring. monitoring is included as part of the emergency exemption order and assigned to a responsible State agency or other organization.

"Absence of adequate communication" has not affected the extent of monitoring. The number of permits monitored is a function of staffing, resources, and the need to monitor, not communication. Several Regions have commented on this point to the effect that they monitored what they originally intended to monitor; additional monitoring was not possible given resource constraints.

At this point in time, headquarters receives Regional input on every emergency exemption requested and informs the Regions and State agencies of all emergency exemption approvals. Although this intercourse may not be as well documented as GAO would like, the essential information exchange has and does take place. Undoubtedly, filing and documentation problems do exist, and could conceivably be perceived as lack of communication. We do have significant verbal, one-to-one communication; however, we recognize the need for better documentation of exchanges between headquarters and Regional offices.

F. Discipline

GAO RECOMMENDATION: Flagrant or repeated violators of exemption requirements should be prosecuted or their authority to request specific exemptions or to take crisis exemptions revoked.

AGENCY COMMENTS: GAO's recommendation to revoke certain agencies' authority to take crisis exemptions seems rather ill-considered in light of their emphasis on good Federal/State/Regional relations. First of all, revocation of crisis exemption authority is an extremely strong measure and could irreparably damage those relations.

We consider a better solution to be actions designed to inform the State of their obligations under law and regulations. EPA has no desire to penalize entire States due to poor judgment on the part of one of its agencies. We have found in the past that States and other agencies react favorably to constructive criticism and we do not see the pattern of repeated violations, except in the case of a very few organizations.

III. SECTION 24(c)

The purpose of a State registration is to allow registrations to meet a "special local need"; this may or may not involve a minor or specialty crop. Frequently the special local need is for a pesticide dosage rate change, a change in dilution rate, use of different application equipment or techniques, change in timing of applications, or many other minor changes necessitated by local conditions. These changes preclude using an EPA registered product as currently labeled.

A. Pesticides Which EPA Would Not Register

GAO RECOMMENDATION: States should not be permitted to register pesticides that EPA will not register.

AGENCY COMMENTS:

[See GAO note 1, p. 85.]

There is, as GAO points out, some inconsistency between actions taken under Section 24(c) and the lack of action taken under Section 3 in the case of applications involving rebuttable presumption against registration (RPAR) candidate chemicals or compounds under RPAR review (registration "moratoriums"). We are actively working to clarify the issue of registration of chemicals which are candidates

for, or are under, RPAR review. The concept of "conditional registration" included in the most recent proposed amendments to FIFRA is designed to deal with registration inconsistencies arising from failure to register products containing RPAR candidate chemicals, while previously registered products containing RPAR candidate chemicals may continue to be sold and used. Chemicals which are candidates for RPAR action would be eligible for conditional registration on an old chemical, new use basis if the new use is minor, a new pest for an old site for example, or a specialty crop use, and if significant additional exposure is not anticipated. The primary criterion for conditional registration would be clear evidence that such use would not result in incremental unreasonable adverse effects. Under such a conditional registration scheme, States would likewise be able to register RPAR candidates upon demonstrating that no incremental hazard would result. Section 3(c)(7)(C) of the proposed amendments to the FIFRA, recently passed by the Senate, reflect such a conditional registration scheme. Similar measures are to be considered by the House when Congress reconvenes.

B. Registration Authority Misused

GAO RECOMMENDATION: Upon EPA disapproval, use of State-registered pesticides violating provisions of the Pesticide Act should be discontinued immediately.

AGENCY COMMENTS:

[See GAO note 1, p. 85.]

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It should be noted that there was never any intention to devote extensive resources to reviewing individual State registrations, and, in fact, such review would seem to go against the Congressional intent of the 24(c) provisions. Once a State has submitted and has had approved a State Plan for making 24(c) registrations, that State is regarded as being capable, within the terms of the approved plan, of making such registrations. EPA intends, within the next few months, to review the State plans and identify areas where the State review process may need upgrading. Once this increased review capability is established, our review of State registrations will serve solely an audit function.

C. Federal-State Relations

GAO RECOMMENDATION: States that intentionally or repeatedly violate their authority should be immediately penalized either by fines or suspension of their registration authority.

AGENCY COMMENTS: GAO asserts that the 24(c) regulations governing the issuance of special local needs registrations should be finalized, and that States which violate their 24(c) authority should be severely penalized. We agree that the finalization of 24(c) regulations is important. However, GAO's assertion that the lack of these regulations has resulted in a deterioration of Federal State relations is not, in our opinion, a sound one. States are naturally unhappy about being regulated by EPA at all. We feel that the interim certification program has been effective not only in permitting the States to register products in the absence of finalized regulations, but also in providing valuable information in modifying the proposed regulations to make them more workable.

On the one hand GAO recommends that we improve Federal/State relations; at the same time they sanction the severe measure of curtailing or suspending State authority under Section 24(c) as a penalty for infractions of that authority. We do not perceive deliberate State misuse of 24(c) to be a prevalent or pervasive problem. The sole precedent of this type of behavior available for scrutiny, the situation involving Tennessee, clearly indicates that such severe penalties are not advisable. Suspension of Tennessee's Section 24(c) authority was contemplated. The decision not to take such action has been vindicated by the subsequent exceptional operation of the Tennessee State program.

APPENDIX II

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

11 JUN 1977

OFFICE OF ENFORCEMENT

To: Malcolm S. Stringer
Director, Office of Audit PM-209

Subject: GAO Draft Report - "Opportunities for Improving EPA's Special Pesticide Registration Activities - EPA DOES NOT ADEQUATELY MONITOR EXPERIMENTAL PRODUCTS" (Page 14)

The principal findings in the report concerning pesticides enforcement are, (1) regions are not aware of all permits issued for experimental use within the region, (2) regions are not notified of the issuance of permits in time to inspect the use of the experimental pesticide, (3) priority for monitoring and inspection of experimental pesticides is not established, (4) regions do not have adequate plans for monitoring permits issued for use in several regions, and (5) regions do not maintain adequate records of experimental permit monitoring and inspection activities.

The Special Registration Section, Registration Division, Office of Pesticide Programs, is responsible for notifying regions of the issuance of permits and for establishing priorities for inspection of experimental pesticides where safety has not been established. The Office of Enforcement's Pesticides and Toxic Substances Enforcement Division personnel have met with personnel of the Special Registration Section and established a review procedure that should ensure that regions are promptly notified by them when permits are issued. The Pesticides and Toxic Substances Enforcement Division is working with the Special Registration Section in the development of procedures for setting priorities for permit monitoring.

Section 5 of the Pesticides Inspection Manual provides instructions for the regional offices to follow in deciding which permits to monitor when the experimental pesticide is being used in several regions. It also provides guidance on conducting inspections and submitting reports to the regional offices when permits are monitored. All records concerning experimental permit monitoring should be maintained in the regional offices.

Information received by the Office of Enforcement through the Agency formal reporting system did not reveal the deficiencies noted in the draft GAO report. Therefore, in order to ensure that priority permits are being monitored and that adequate coverage is given those permits we are initiating a comprehensive review of regional policies and procedures for experimental use monitoring, inspection, reporting and record keeping. Results of the review will be used to (1) assist the regions in planning, conducting and reporting permit monitoring and (2) in revising Agency guidance and manuals.

Stanley W. Legro

GAO note:

1. Deleted material pertained to a matter contained in the draft report which has been changed or is not included in this report.

2. Page references in this appendix refer to our draft report and do not necessarily agree with this final report.

APPENDIX III

UNITED STATES DEPARTMENT OF AGRICULTURE
FOREST SERVICE
P.O. Box 2417
Washington, DC 20013

5200
Sep 15, 1977

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

Dear Mr. Eschwege:

We have reviewed your proposed report, "Opportunities for Improving EPA's Special Pesticide Registration Activities," including the review draft of Appendix I enclosed with Robert G. Chambers' August 12 letter to James L. Stewart. Comments prepared by the Animal and Plant Health Inspection Service were forwarded to you on July 14. Because they covered most of the important concerns in the main body of the report, we will confine our remarks to Chapter 3, the section on "Noncompliance with Exemption Program Requirement," and Appendix I.

Although the review draft of Appendix I does not reflect all the facts we have been attempting to point out to you in earlier discussions, we are glad to see the material on pages 61A and 64A. [See GAO note 1, p. 90.]
We are concerned about the "problem areas" (page 54) and the "Conclusions" (page 66). We believe your comments are due primarily to misunderstandings of how Douglas-fir tussock moth outbreaks occur and the rapidity of damage suffered when moth levels reach epidemic levels.

In our opinion, the report is wrong in implying or concluding that:

1. DDT was used unnecessarily.

2. Survey methods used to measure Douglas-fir tussock moth populations were inadequate.

3. Serious damage would not have occurred if the DDT treatments had not been applied because 1974 insect populations were declining at an unusually rapid rate.

4. It is possible to draw some inference about the insect population level in the total treatment area from the prespray efficacy plot data.

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5. It was possible in some way to remeasure the precise insect population levels in the spring of 1974, just prior to treatment (within 3 days of treatment).

6. The 1974 effort towards development of DDT alternatives was inadequate.

Consequently, we believe the following information should be recognized in preparing the final report.

Individual outbreaks normally go through a 3-year cycle starting with a release phase the first year in which populations build up to epidemic proportions. Considerable damage is caused the second year when defoliation first becomes noticeable. Severe tree mortality is caused the third year just before the populations collapse from natural causes. Occasionally this collapse occurs in the second year. During 1973 and 1974, we had outbreaks in all three stages of development. The most ideal time to treat an outbreak with insecticides is early in the second year prior to heavy defoliation. Most of the area treated during 1974 was treated at the most opportune time. Only about 127,000 acres of the 482,000 acres treated had been defoliated to any noticeable degree in 1973. All areas were treated early enough in 1974 to prevent serious defoliation. Serious defoliation would have occurred if DDT had not been sprayed.

We do not concur that DDT was used unnecessarily. The implication that some areas were treated with DDT unnecessarily occurs on page 54, first "problem area" and the first paragraph under "Conclusions" on page 66. This same implication appears to be the basis for a number of other incorrect or misleading statements (third "problem area" on page 54, the entire section, "DDT Applied Unnecessarily," starting on page 58, the last paragraph on page 62, all of the material on page 63, the first three lines on page 64, and the first sentence on page 65). The objective of the control program was to protect the timber resource. Again, we believe that had DDT not been sprayed, serious damage would have occurred prior to natural collapse of the tussock moth population.

[See GAO note 2, p. 90.]

[See GAO note 2, p. 90.]

The last paragraph on page 59 also relates to the timing of insect population collapse. Although conclusions are not made in this paragraph, it could be inferred that a decline "to about 1/3 of their prespray levels--both below the U.S. Forest Service's action level" is significant. This type of decline is quite normal and was fully anticipated. The point again here is that in order to prevent serious damage, even during this short period of time, it was necessary to treat the areas with DDT.

Everyone predicted that the insect population would collapse on the areas to be treated in 1974. This usually occurs and it happened in the earlier outbreak areas during 1972 and 1973. Studies of earlier outbreaks also verified this prediction--at least in areas where visible damage has occurred during 1973 and in previous years. However, the timing of the collapse is the important element of concern. An insect population collapse does little good if most of the affected trees end up as severely damaged as they would have been without a collapse. Tussock moths can completely defoliate and kill trees in a few weeks' time. Population collapse usually occurs in the late larval development stages after this kind of damage has been done. Laboratory studies on egg viability and virus incidence indicated the collapse would not occur soon enough to prevent serious tree damage on a large number of areas recommended for control. This is why treatment was applied early in the year (when 70 percent of the egg masses had hatched).

We do not concur that our efforts in determining population levels were inadequate. The basis for most of the statements on population levels and decline are taken from Table 5 (page 24) of the "1974 Cooperative Douglas-Fir Tussock Moth Control Project" report.

We believe the authors of the proposed report should review the Entomological Evaluation, Section B, in the Appendix (page B-1 to B-200) of the USDA Forest Service 1974 Environmental Statement Cooperative Douglas-fir Tussock Moth Pest Management Plan. This document which was provided to you earlier explains in detail how decisions to treat individual areas were made. During the summer of 1973, Douglas-fir tussock moth damage was detected on 799,000 acres. An egg mass survey was made in the fall of 1973 to predict tussock moth population levels in 1974 and the need for treatment. This survey showed that tussock moth populations would be high enough in 1974 to cause additional serious damage on about 649,000 acres. Continuing evaluations during the winter and early spring months including a laboratory examination of insect egg viability and the presence of a natural virus disease reduced the area needing control to about 455,000 acres. Some 77,000 acres of this

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were set aside for determining efficacy of the proposed treatments, research, and testing of other chemicals. During the on-the-ground insect population evaluations in early 1974, it was possible to delete another 106,000 acres from the recommended treatment program because of apparent low insect populations. However, it was necessary to treat an additional 155,000 acres because of new insect populations and defoliation that were discovered just prior to and during spray operations. The total area that was finally treated with DDT was just slightly more than the Environmental Statement estimate (408,000 acres).

At best, any attempt to use the prespray population data as an indication of actual population levels throughout the entire unit must take into account that these data were collected at the time of only 70 percent egg hatch.

[See GAO note 2, p. 90.]

We do not concur that benefits of using DDT were overestimated. The last outbreak collapsed at the end of the 1974 growing season. Most areas treated with DDT remained green and relatively undamaged as compared to affected areas that were not treated. If any error was made in estimating benefits from using DDT, we believe it was an underestimation. Because there was no existing data base on how much subsequent loss to bark beetles could be expected if tussock moth damage was not prevented, an estimate of this benefit was not included in the calculations. Salvage logging is now being conducted on an emergency basis in most of the untreated areas in an attempt to recover trees first defoliated by the tussock moth and subsequently killed by Douglas-fir bark beetles. In many cases this is the second logging entry, as the first efforts were limited in most cases to salvaging only trees killed or severely damaged by the tussock moth alone. The difference between treated and untreated areas in this regard is striking and plainly visible at this time,

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particularly from low-flying aircraft. This was the first time in the history of treating tussock moth outbreaks that comparable untreated "check" areas were established to answer the question, "What will happen if the areas are not treated?" The massive damage in these areas exceeded all expectations.

Congress provided EPA with $250,000 to determine the impact of not being able to use DDT to control Douglas-fir tussock moth. We are currently engaged in a cooperative effort with them to make this determination. We tentatively plan to do this under contract with an organization that has the capability of pulling together all existing information into a composite package. The target date for completion is early 1979.

We do not concur that our effort to find alternatives to DDT were inadequate. The reasons for not being able to register alternative pesticides are many, the least of which was the declining moth population in some areas as stated in the second paragraph on page 60. One season's testing under the best circumstances would usually not be sufficient to generate enough data to satisfy registration needs. We suggest changing the sentence to read: "Because of declines in moth populations and the usual requirement of more than one year's data for registration, the U.S. Forest Service . . . ."

It is true that the population collapsed on some of the DDT alternative test areas before an effective test could be carried out. Because of the detailed planning and preparation work required to set up an adequate study area, it was not possible to move some of these tests to high insect population areas at the last minute. Although unfortunate from an experimental standpoint, it is completely erroneous to conclude that the insect population declines experienced in some of these areas were general in nature. It should be noted that some of these tests were quite successful; e.g., Acephate, Dimilin, and Sevin 4 Oil. A copy of a December 1976 article reprint from the Journal of Economic Entomology, "Field Evaluations of Acephate and Dimilin Against the Douglas-fir Tussock Moth" is enclosed. The high insect population levels present at the time in this area should be acknowledged. A copy of the Sevin 4 Oil test report, as it appeared in the April 1976 issue of the Journal of Economic Entomology, was sent to you earlier.

[See GAO note 2.]

Sincerely,

for JOHN R. MCGUIRE
Chief

Enclosure [See GAO note 3.]

GAO note:

1. Page references in this appendix refer to our draft report and do not necessarily agree with this final report.

2. Deleted material pertained to a matter contained in the draft report which has been changed or is not included in this report.

3. The enclosure of this letter was considered in the preparation of our final report but has not been included.

APPENDIX IV

State of Tennessee
DEPARTMENT OF AGRICULTURE

ELLINGTON AGRICULTURAL CENTER
Box 40627, Melrose Station
Nashville, Tenn. 37204

Ray Blanton, *Governor*
Edward S. Porter, *Commissioner*

June 8, 1977

Mr. Henry Eschwege, Director
Community & Economic Development Division
U. S. General Accounting Office
Room 2434, Waterside Mall
401 M Street, S. W.
Washington, D. C. 20460

Dear Mr. Eschwege:

This letter is in response to your letter to Governor Ray Blanton as per his request.

We have the following comments on your draft, which was furnished us on May 20, of a proposed report to the Congress entitled "Opportunities for Improving EPA Special Pesticide Registration Activities." We note your comment that the parts of this draft which effect Tennessee are on pages 47-49 of this draft.

[See GAO note 1, p. 93.]

The following comments relate to Example 2, on page 48, where you are discussing a state, obviously Tennessee. EPA did not advise this State not to register Methyl Parathion for use in bird control, quite possibly for the reason that the possibility for registering this material was never discussed with EPA. When we appealed to EPA for help in an emergency situation that was causing a great deal of concern in this State, they did suggest the use of Tepp as well as Tergitol. At that time, litigation pending with reference to a proposed use of Tergitol in a military installation located partly in Tennessee and partly in Kentucky prevented us from securing this material. We had reservations about the use of Tepp because of its very high toxicity, and we were not at all sure that we could use the material safely. We did however, get in touch with the manufacturers of this compound to determine what data, if any, the manufacturers had as to the efficacy of the material for killing birds. We were told by the company that they had no data of a positive nature, and, as a matter of fact, the only data that they had was negative in that when securing a registration for the material in control of insects affecting hops, birds were caged in the hop fields prior to spraying with the material, and none of the cated birds were injured. This was hardly encouraging, and we decided to pursue other means.

Fenthion is used for bird control in some sections of the world, notably in Africa, and this Department had, together with the Fish and Wildlife Service of the Interior Department and the University of Tennessee, been a party to an experimental use

of Fenthion some ten years or so ago, in which the material showed some promise. It therefore was registered in conformity with the established laws and regulations but failed to perform, and the registration was cancelled. In this connection we strongly object to the use of the word "ultimately" in the sentence at the top of Page 49, of the draft, "the State Ultimately cancelled the registrations." The State registered Fenthion on January 28, and cancelled this registration on February 18. The registration for the product containing parathion was registered on February 9, and cancelled on February 23. In both cases the State cancelled the registrations, just as soon as the applications could be evaluated. We believe that this does not represent "ultimate" cancellation, but it does indicate about as prompt action as could reasonably be taken with any evaluation made of the treatment.

With reference to evaluation, we notice reference in the final paragraph on page 48, of the draft in which "subsequent surveys" are quoted to the effect that only 88 birds were killed in an "estimated" 10,800 square foot area. No information is furnished as to who may have made these surveys, whether or not it was an agency which was capable of making an evaluation, and certainly it does not represent an official evaluation of any of the agencys that were concerned in this application.

[See GAO note 2, p. 93.]

Further along on the same page, you comment that it is your belief that EPA's action in this case was insufficient for "what appears to be deliberate violations of state registration authority." I think that if you will consult EPA's legal staff they will also assure you that they tried very hard to find a violation under which they could proceed against this State, and they could find none. In other words, the actions of the agencies of this State were in accordance with the Law.

I would like to comment on one further factor with reference to 24-C. At the present time, the chemical manufacturers and formulators are finding that an application for a change in registration in addition of a use, or a site, or a crop requires so much time that they

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are putting intense pressure for the use of 24-C to satisfy very real needs involving in most instances several contiguous states. It was never intended that 24-C should serve as a vehicle for registrations of this nature and the states would not receive these requests if such requests were handled promptly by the Environmental Protection Agency. As it is, the companies and groups involved are turning to requests of this nature in desperation to get some kind of action.

Yours very truly,

Edward S. Porter

ESP:ma

GAO notes:

1. Page references in this appendix refer to our draft report and do not necessarily agree with this final report.

2. Deleted material pertained to a matter contained in the draft report which has been changed or is not included in this report.

APPENDIX V

PRINCIPAL ENVIRONMENTAL PROTECTION AGENCY

OFFICIALS RESPONSIBLE FOR ACTIVITIES

DISCUSSED IN THIS REPORT

	Tenure of office	
	From	To
ADMINISTRATOR:		
Douglas M. Costle	Mar. 1977	Present
John R. Quarles, Jr. (acting)	Jan. 1977	Mar. 1977
Russell E. Train	Sept. 1973	Jan. 1977
John R. Quarles, Jr. (acting)	Aug. 1973	Sept. 1973
Robert W. Fri (acting)	Apr. 1973	Aug. 1973
William D. Ruckelshaus	Dec. 1970	Apr. 1973
ASSISTANT ADMINISTRATOR FOR WATER AND HAZARDOUS MATERIALS:		
Thomas C. Jorling	June 1977	Present
Andrew Briedenbach	Dec. 1975	June 1977
Andrew Briedenbach	Sept. 1975	Dec. 1975
James L. Agee	Aug. 1974	Sept. 1975
James L. Agee (acting)	Apr. 1974	Aug. 1974
ASSISTANT ADMINISTRATOR FOR HAZARDOUS MATERIALS CONTROL (note a):		
Charles L. Elkins (acting)	Oct. 1973	Apr. 1974
David D. Dominick	June 1971	Sept. 1973
DEPUTY ASSISTANT ADMINISTRATOR FOR PESTICIDES PROGRAMS:		
Edwin L. Johnson	Mar. 1975	Present
Edwin L. Johnson (acting)	Dec. 1974	Mar. 1975
Henry J. Korp (acting)	Oct. 1974	Dec. 1974
Henry J. Korp	Dec. 1972	Oct. 1974

a/Before July 24, 1973, the title of this position was Assistant Administrator for Categorical Programs.

(087800)