PROTECTION FROM INEFFECTIVE PESTICIDES

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EXECUTIVE SUMMARY

A study team from the Program Evaluation Division of the Office of Planning and Evaluation has conducted a detailed review of EPA's role in providing protection from ineffective pesticides. The review examined the policies, procedures and performance of the Agency in keeping ineffective products from being formulated, marketed or used.

Because of their toxic characteristics, most pesticides pose some threat to man or to the environment. The goal of EPA regulation of pesticides is to ensure that the benefits provided by use outweigh the negative effects. For this reason the Agency is concerned with efficacy, the degree to which a pesticide product is capable of providing beneficial results.

Five major activities comprise the existing efficacy assurance program:

- Preregistration testing, the biological evaluation of the pesticidal properties of a product submitted for registration.
- Data review, an analysis of the materials submitted in support of a product registration.
- Producer surveillance, the inspection of the producing establishment, during which product samples may be taken.
- Market surveillance, the inspection of retail establishments, during which product samples may be taken.
- Postregistration testing, the biological evaluation of the pesticidal properties of a registered product.

This report includes a series of recommendations designed to refine the regulatory process. The major thrust of the recommendations is that a lower level of testing would provide adequate protection for most product

groups, but that disinfectants and rodenticides should be reviewed more carefully prior to registration and sampled more frequently thereafter. Development of standard test methods should be emphasized.

A summary of the report's major findings and recommendations follows:

How Ineffective Products Could Reach the Marketplace

- Five of the hypothetical channels to the marketplace account for very few of the ineffective products discovered. These include nonregistration, registration in error, registration under less rigorous requirements, shelf deterioration and developed resistance.

- Minor product changes and poor production procedures account for the largest share of enforcement actions taken against ineffective products.

The Potential Hazards of Using Ineffective Pesticide Products

- The health and environmental effects caused directly by ineffective products are extremely small.

- Severe health problems could result from reliance on ineffective products where the user cannot readily determine the degree of control. The most significant examples of such pesticide groups are rodenticides and disinfectants.

The Ability of the Market to Limit Damage

- Producers of large volumes of pesticides have an incentive to market effective products in order to maintain their sales volumes and avoid any liability for damage.

- Agricutural products, which account for nearly sixty per cent of national pesticide use, are almost always effective as a result of the careful evaluation they receive by both producers and users.

- Consumer garden products are generally reformulations of agricultural products which are well tested.

- Industrial users are capable of protecting themselves with performance contracts and product testing.

- For the majority of pesticides, the user can determine that a product is ineffective in time to switch to an effective substitute.

- No formal study has been conducted by the management of the pesticide program to determine which pesticides or pesticide uses are most likely to be violative. Consequently, there is no assurance that the limited resources available for registration data review, sampling, efficacy evaluation or enforcement have been concentrated on the major problem areas.

- No formal guidelines have been drafted to indicate when an efficacy consideration should initiate a cost/benefit review, the first step in the registration cancellation process.

- OPP has not developed a policy for selecting the specific products to be tested. Consequently, there is no assurance that PED will sample the products likely to be defective.

- No formal follow-up system has been established to assure that the results of efficacy tests conducted by the biological evaluation laboratories are used or even considered by the Registration Division or the Pesticides Enforcement Division.

- A review of the products identified as being defective in three or more samples indicates that even when products are clearly suspect, EPA action frequently has not been sufficient to prevent their continued use.

Program Management Recommendations

- All preregistration biological evaluation activity should be curtailed.

- Efforts to develop standard testing methods should be increased.

- Data review prior to registration should be maintained for all products. Applicants seeking to register products which have suspect active ingredients or which could present serious health problems if ineffective should be required to present corroborative data from an independent testing laboratory.

- The sampling program should include greater emphasis on products with histories of violations.

- The laboratories should communicate to the Regional Offices

the specific products to be sampled. The sampling program should provide the biological evaluation laboratories with samples of requested products.

- Follow-up testing on the product should be conducted immediately if a sample is found to be defective.

- Producers should be notified of all defects suspected in their products.

- Enforcement and registration actions should be taken against all producers marketing products which the laboratories demonstrate to be violative.

- All routine postregistration biological evaluation activity should be curtailed. Only testing for specific registration or enforcement purposes should be continued.

- Program management should conduct a formal study to determine which pesticides or pesticide uses are most likely to be violative. Resources should then be concentrated in these areas.

PROTECTION FROM INEFFECTIVE PESTICIDES

I. INTRODUCTION

In March 1975 the Program Evaluation Division began the second phase of a comprehensive evaluation of EPA's pesticide programs. One element of the evaluation is the preparation of short, operationally relevant papers on issues suggested by the program office. This report is based on a request to examine the Agency's policy for assuring the efficacy of marketed pesticide products.

Because of their toxic characteristics, most pesticides pose some threat to man and to the environment. This inherent risk is normally justified by the benefits that proper use can provide. Occasionally, however, a pesticide does not achieve its intended results. In many cases timing or technique of application is to blame, and the applicator is responsible for the ensuing damage. In other cases the product itself is inherently incapable of effective action.

The goal of EPA regulation of pesticides is to ensure that the benefits of use outweigh the negative effects. Evidence of efficacy, the degree to which a pesticide product is capable of providing beneficial results, is thus inseparable from an evaluation of the usefulness of the product. The Agency requires this information to ensure that the inherent risk is not "unreasonable" as defined in the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA).

In order to assess whether EPA regulations permit ineffective pesticides to adversely affect man or the environment, this paper will answer the following questions:

- How do ineffective products reach the marketplace?
- What are the potential hazards associated with the use of ineffective pesticides?
- Is the normal market mechanism able to limit the damage caused by ineffective products?
- What does EPA do to assure protection from ineffective products?

II. SCOPE OF THE PROBLEM

Unfortunately, it is extremely difficult to be completely successful in keeping ineffective pesticides from being produced, marketed or used. In spite of EPA's regulatory system, several products with potential efficacy problems are identified each year. In the past eighteen months EPA has issued "Notices of Intent to Cancel" the registrations of over twenty-five pesticide products for reasons of inefficacy.[1/]

While there is no doubt that some ineffective products exist, the magnitude of the problems they cause is ill-defined. One of the major reasons contributing to lack of problem definition is that efficacy itself is difficult to determine. The acceptable degree of effectiveness exhibited by a particular product is relative to the control provided by the substitutes. In some cases a product which is able to kill 70 per cent of the target pests is considered effective, since no alternative product offers significantly better control. In other cases 70 percent control is unacceptably low, so the product is considered ineffective even though it kills many pests.

The need for regulation to eliminate ineffective products depends on the potential problems they could cause. These problems must be defined so that decision-makers can determine where resources are best expended. This section describes the scope of the problem, beginning with a general discussion of the various ways that an ineffective product could reach the marketplace and the consumer. A discussion of economic, human health and environmental effects follows. The section concludes with a discussion of the ability of the market to limit the damage which continued use could cause.

1/ For example, the Federal Register, Vol. 39, No. 8 (1/11/74), Page 1665, lists the Notices of Intent to cancel 17 different product registrations for efficacy resons.

HOW INEFFECTIVE PRODUCTS REACH THE MARKETPLACE

Commercial distribution of a pesticide product is not a guarantee of effectiveness, since there are at least seven different ways that an ineffective product may reach the market: as a nonregistered product; as a product registered in error; as a product registered under less rigorous requirements; as a product whose useful life has expired; as a product to which the target pest has developed resistance; as a poorly produced product; or as a product affected by minor changes. This section assesses each of these routes in order to determine the magnitude of the problem and the best control methods.

A. Nonregistered products. Some pesticides are marketed in the United States without first being registered with EPA. These products may be ineffective for a number of reasons, including an inherently ineffective active ingredient, an insufficient amount of active ingredient, incompatible inert ingredients, instability of formulation, dosage rates in labeling directions too low, other inadequate directions for use, etc. Since no objective review of test data has been conducted, there is no assurance that the product is capable of achieving its intended result.

Two factors combine to make nonregistered products a declining problem. First, products previously registered by states for intrastate use only must be federally registered by October 21, 1976. This change was authorized by the Federal Environmental Pesticide Control Act (FEPCA) of 1972, which amended the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). It extends federal data requirements to an estimated 15,000 products. Second, in the past most nonregistered products were not submitted to EPA because the producer was unaware of the registration requirement. This is especially true of products such as dog repellants, which are defined as pesticides under the

Act but which may not normally be considered in that category. In an effort to encourage compliance, EPA emphasized increased surveillance and made prosecution of violative companies marketing nonregistered products a high priority. From 1971 to 1973 over 78 percent (135 to 173) of enforcement actions were based on nonregistration.[2/] This effort was apparently successful, since, in response to the reduced number of violations discovered, the emphasis of EPA enforcement efforts has been shifted.

B. Registration in error. To register a product with EPA, an applicant must show that a pesticide is safe and effective when used as directed. EPA conducts very few preregistration tests. Instead, reviewers in the Registration Division of the Office of Pesticide Programs evaluate the data submitted in support of the application. Approval is given if all the required information is present and if the test results submitted indicate that the product will control the pest. Because of this reliance on summary data provided by the applicant, the possibility exists that an ineffective product could be approved for registration. The recently promulgated regulations for registration should further reduce this already limited possibility.

C. Registration under less rigorous requirements. Efficacy data has been a required part of the registration application only in recent years, partly in response to the increasing awareness of environmental problems. Products initially registered prior to the 1972 amendments were subject to a less comprehensive effectiveness review. Although some ineffective products may have been registered and are still being sold, this problem can be eliminated during the effort to reregister all pesticides by October 1976, if the new, more rigorous requirements are applied during this period of heavy workload.

2/ U. S. Environmental Protection Agency, The First Two Years, February 1973, pages 260-280.

D. Deterioration on the shelf. Some registered products contain one or more ingredients which may lose their effectiveness over time. If sufficient deterioration occurs between production and use, the pesticide might be ineffective even when used according to the label directions. The label dating requirements of the Section 3 regulations should eliminate this problem.

E. Developed resistance. Because of varying susceptibility to toxins, many pest species, especially insect pests, are capable of developing a resistance to the active ingredients in pesticides. Those organisms genetically endowed with the ability to resist the chemical survive to reproduce the entire population, which will be similarly resistant. The consequences of developed resistance are limited by the fact that agricultural associations and pesticide producers often discover and publish information on resistance in time for users to apply alternatives. When EPA is notified that pests have developed resistance to a particular pesticide, registration action is taken to delete that pest from the labeling claims and directions of products containing that active ingredient.

A similar problem impacts the effectiveness of rodenticides. In the case of commensal rat and mouse baits, the pests often "learn" to avoid the pesticide. Thus, even though the active ingredient is inherently effective, the pesticide as formulated may not be.

F. Poor production process. During formulation or manufacture of a product, quality control problems can alter the proportion of ingredients or the physical composition with equally deleterious results on its efficacy. An unpublished study of EPA's enforcement activities indicates that such deficiencies account for the largest proportion of the inefficacious products on the

market. The EPA review at the time of registration attempts to insure consistency of marketed products by examining the manufacturing process and quality control procedures.

G. Minor product changes. Producers occasionally make "minor" changes in product formulation or manufacturing procedures which limit the product's effectiveness. For instance, packaging changes which allow crushing or decomposition, formulating changes which alter particle size, changes in the source of supply of intermediate products which reduce the purity of the finished product, minor changes in the inert ingredient, or implementation of economies in production stages, such as a reduced clean up procedures, may result in reduced effectiveness or increased hazard to man, non-target animals or beneficial plants. Typically, producers correct these problems when they find out about them, so the magnitude of environmental contamination is limited.

THE POTENTIAL HAZARDS OF USING INEFFECTIVE PRODUCTS

Aggregate statistics on the problems caused by pesticides have tended to be unreliable, primarily because of the difficulties associated with measurement technique and attribution of damage. That portion of such impacts due specifically to ineffective products is even more difficult to quantify in any meaningful way. This section therefore describes in general terms the problems which could develop, without attempting to provide quantification of the extent to which they actually occur.

A. Economic considerations. Concern over the economic and consumer protection aspects of pesticide use has had a relatively long history. The Insecticides Act of 1910 was a consumer protection measure designed to assure that a purchased chemical insecticide would effectively

mitigate pest problems. Three of the major issues which motivated passage of the Act are still concerns:

1. Consumer protection. The average consumer is not always able to determine if a pesticide product has adequately controlled the target pest. Furthermore, the purchaser usually assumes that the product, particularly if it displays an EPA registration number, will be effective. Regulation of the industry is necessary to ensure that the consumer is not being defrauded by mislabeled, ineffective, or adulterated products.

2. Crop losses. Some agricultural users might suffer crop losses because of unexpected variations in the strength of purchased chemicals. A user may apply an ineffective pesticide and discover only after it is too late to salvage the crop that the product does not control the target pest. For this reason the use of ineffective pesticides could have severe economic effect on the individual farmer, while at the same time reducing the nation's available food and fiber.

3. Natural control loss. Since pesticides are toxic chemicals, the use of a pesticide which does not have the desired impact on a target pest could upset the ecosystem in the application area. One possible result would be the elimination of natural predators or other biological controls, so that after application the pest was more of a menace than before.

B. Human health considerations. Use of an ineffective pesticide adversely affects human health in two ways:

1. Loss of protection from target pest. The loss of protection could be most serious in cases of ineffective sanitizers, sterilizers or germicides, where the consumer may be unable to determine the effectiveness of control. Continued reliance on such products may result in outbreaks of infection or disease. Similarly, ineffective rodenticides or insecticides could increase

the danger of exposure to diseases transmitted by rodents, ticks or insects.

2. Applicator exposures. While the use of any pesticide exposes applicators to some risks of contact or inhalation, the use of an ineffective pesticide involves risks without sufficient countervailing pest control benefits. This is especially true with some of the more highly toxic pesticides. Moreover, because one application of an ineffective product does not provide control, repeated applications with the same product or an alternative are needed. Each additional application increases the exposure of the applicator to the inherent toxicity of the product.

C. Environmental considerations. As indicated above, the use of an ineffective pesticide upsets the ecosystem in the application area without providing expected benefits. Individual non-target organisms susceptible to the active ingredient will be affected to some degree. Extensive use of such chemicals could cause damage to entire populations or species.

THE ABILITY OF THE MARKET TO LIMIT DAMAGE

The preceding discussion indicates that channels do exist through which ineffective products could reach the marketplace. Even so, government regulation would not be necessary if natural market forces are capable of controlling any problems. This section examines some of the influences which limit production and distribution of ineffective products.

The relative ability of the market to influence producers is enhanced by three factors. First, although there are exceptions, the management and research personnel of nearly all pesticide manufacturers developing data to support registration are responsible individuals with personal reputations to uphold. Second, many of the large pesticide producers are divisions of huge multinational firms and represent comparatively small portions of the

gross assets of the parent firms. Consequently these producers do not wish to generate adverse publicity which might damage the entire firm. Third, the financial consequences of marketing ineffective products are also important. Recalls, adverse publicity, future buyer resistance and other associated penalties could be very costly to a producer.

Because of basic differences in various sectors of the pesticide market, the remainder of this discussion has been divided into three sections corresponding to the major categories of pesticide uses: agricultural, industrial and governmental, and home and garden.

A. Agricultural uses. Agriculture is the largest consumer of pesticides, accounting for nearly 60% of national pesticide use in 1971.[3/] Historically, few problems have developed in this user area, apparently because of three factors which act in combination to assure an overwhelming proportion of effective products. First, the competitive nature of agriculture forces farmers to be good businessmen. They cannot afford to spend large sums annually on products which will not perform, and they must therefore learn about new developments in the agricultural chemicals market. Farmers obtain information about pesticides from a number of sources in addition to manufacturers and suppliers. During the winter, farm organizations such as the American Farm Bureau Federation, the Grange and various farm cooperatives hold public sessions at which many aspects of farming and pesticide use are discussed. They also publish newsletters and educational pamphlets. Similarly, the Agricultural Extension Service through its local or county agents provides information to farmers about product efficacy, application timing and alternative pest controls. Agricultural schools and land grant colleges assist in providing

3/ USDA Economic Research Service, Farmer's Use of Pesticides in 1971, July 1974, p. 5.

the services described above as well as operating programs of their own. Approval or recommendation by these or similar groups is often an informal precondition for large sales volume in agricultural communities. Producers often sponsor numerous field tests throughout the country to demonstrate the value of their products and convince such groups to offer endorsements. This field testing further assures effectiveness.

Second, the effectiveness of an agricultural product is often readily apparent to the trained eye of the farmer. Without evidence of appropriate levels of pest control, farmers are quick to switch to other products to protect their crops.

Finally, because pesticides are economically important to the farmer, legal action against ineffective products can occur as the farmer seeks to recoup his purchase price plus the value of lost production. There are relatively few documented litigations dealing with ineffective agricultural pesticides, since many producers will settle out of court on claims of inefficacy in order to avoid adverse publicity. Whether the court case is won or lost, the producer who forces litigation will lose customers. Therefore, a major guarantee of efficacy of agricultural chemicals is offered by the industry itself, which conducts extensive research to back that assurance.

B. Industrial and governmental use. Industrial and governmental users are often protected from economic loss by signed contracts. The possibility of legal redress can encourage manufacturers to supply a product meeting tighter specifications. Also, most of these users could perform their own quality control checks to guard against improper formulation and conduct some of their own biological tests to make sure that the purchased pesticide is effective against the particular strain of pest. Finally, employees in many industry

and government operations are well enough trained to determine if a product has been effective.

C. Home and garden use. The application of home and garden pesticide products involves less risk of serious problems than use of pesticides in other sectors of the economy. Potential effect on humans are limited because of the reduced strength formulations prepared for use in the home. Potential environmental effects are limited by both the formulations sold and the relatively small volumes released into the environment at any time.

Consumer protection is the major rationale for regulating home and garden pesticides. Since the home and garden market tends to be highly competitive, any price advantage will enable a producer to capture the market. Therefore producers are encouraged to develop products with marginal amounts to active ingredients.

Small consumers often have difficulty determining if the product purchased is controlling the pest. As the least informed group of pesticide users, they know less about the problems they are attempting to control and are probably involved in more misuse than other groups. Even when lack of control is apparent, most consumers will rarely seek legal redress because of the small volume and minor individual cost involved. When complaints are filed, proving that products are inherently ineffective when used as directed is difficult. For these reasons some producers of home and garden products could be tempted to formulate less effective products. Advertising might also be used to convince the consumer to purchase a less effective product instead of the more effective but less publicized alternative. Private and public consumer protection services have not yet been active in evaluating pesticide products.

The magnitude of the problem is limited by the fact that many garden products are essentially agricultural chemicals in smaller packages. Although very few tests have been conducted specifically on these products, some degree of effectiveness is assured by the intensive testing of the active ingredients. The major problem is with fungicides and disinfectants used in the home, since these sensitive compounds can be rendered ineffective with very minor changes anywhere in the production process.

III. EPA's REGULATORY PROGRAM

Based on FIFRA, EPA attempts to ensure that a pesticide product, when used as directed, will satisfy the legitimate expectations of the applicator without causing unreasonable risk to man or to the environment. The first step in the efficacy control process is registration, which includes a review of the efficacy data submitted by the applicant to validate the claims made for the product. The second step of the control process is surveillance at the producing establishment, where product samples are taken. Similar surveillance at the marketplace comprises the third control step. During these inspections, samples of products may be collected and sent to EPA laboratories to be tested chemically in order to determine their composition. Some samples are then sent to other EPA laboratories for biological testing to evaluate pesticidal properties. This section examines EPA's implementation of these control mechanisms designed to keep ineffective pesticides off the market.

REGISTRATION

A. The legal requirement for registration. Section 3(a) of FIFRA, as amended, requires registration with EPA of all pesticides used in the United States. Section 3(c)(5) contains the conditions which must be met before registration is granted, including those that establish EPA's responsibility to insure that pesticide products are effective when registered:

> "The Administrator shall register a pesticide if he determines that ... (A) its composition is such as to warrant the proposed claims for it; ... and (C) it will perform its intended function without unreasonable adverse effects on the environment....."

Further, under Section 3(f)(2), registration is prima facie evidence of compliance with the registration provisions of the Act. Therefore, regardless of how EPA attempts to ensure efficacy, registration itself is an indication to

consumers that the product will perform its intended function.

B. The registration process. The Registration Division is responsible for product registration. Registration applications are first sent to the Product Control Branch where a two part file symbol is assigned. The first part of the symbol identifies the registrant, while the second part designates the specific product. The symbol does not provide any indication as to the type of product (insecticide, fungicide, etc.) or its expected use (agricultural, indoor home use, etc.).

After receiving a file symbol and a "product jacket" (protective folder), the basic data submitted by the applicant is sent to the Reviewability Evaluation Team, which determines if the application is complete. If the application is in order, the basic data is sent to the Chemistry Branch. Scientists review the formula and physical properties of the product to ensure that they are consistent with the known characteristics of the chemicals used. In cases where use of the product could result in residues on food crops, tolerance levels, which specify maximum allowable residues on the food product, are established in conjunction with the Toxicological Branch.

The application and data in support are sent from the Chemistry Branch to one of the fifteen "product manager teams" knowledgeable about a specific chemical group. This group compares the applicant's data with similar products already registered. If no major differences or unusual characteristics are discovered and there is sufficient indication that the product will be safe and effective, it is approved for registration and receives a registration number to replace the file symbol. In cases concerning a new active ingredient or new use, a more exhaustive review is conducted by the Efficacy and Ecological Effects Branch and the Toxicological Branch.

When the review confirms that all essential information has been reported and that the product meets established standards, the product can be granted registration. This rarely happens on the first application. Data is often incomplete or inconclusive, and occasionally is questionable. In these instances the manufacturer is asked to clarify the existing information or to submit additional data.

The average product is submitted and goes through the review process two or three times before the application can be considered acceptable. In most instances a relatively minor label or formulation change is sufficient to correct the problems preventing registration. Few products are ever completely denied registration, although many are not granted registration for all initially requested uses.

C. Success in keeping ineffective products from being registered.

There is no good method of identifying the number of ineffective products that are currently registered. Cancellation actions are not a reasonable measure because even when a problem product is identified the usual procedure is to appropriately modify the label rather than completely take away the registration. Unfortunately a system for recording the number of product and label changes related to efficacy does not exist. An unpublished study of EPA enforcement actions indicates that over ninety percent of registered products are effective.

D. Process recommendations. Several minor changes in the registration process appear warranted:

1. Preregistration testing. In a 1974 report to Congress, Pesticides: Actions Needed to Protect the Consumer from Defective Products, the General Accounting Office recommended establishment of procedures for preregistration

testing of classes of pesticides with high incidence of problems with effectiveness. Although response from EPA was included in the report to indicate that the Agency was preparing a comprehensive policy on efficacy testing, the effort was not completed. Consequently, no definitive criteria have been developed for selecting which pesticides, pesticide chemical groups, or pesticide uses should be emphasized in testing.

Although the Registration Division currently requests the EPA biological laboratories to conduct preregistration tests on some products, the scientists interviewed for this paper were not in unanimous agreement on which products are or should be examined. Developing a specific policy for preregistration testing of selected pesticide groups would help to provide timely review of troublesome products.

2. Criteria for review of registered products. Registered products are occasionally examined to check that the product still conforms to the requirements for registration. The major portion of this effort is a cost/benefit review, performed by the Criteria and Evaluation Division to determine if the benefits provided by the use of a registered pesticide are sufficient to outweigh the risks such use entails. Social, economic and environmental factors are considered in these reviews. The reviews are triggered by evidence of hazard, residue problems, need for standards or protocols and other problems.

Some priority ranking of the products to be reviewed is obviously necessary, since the resources to examine all registrations are not available. The Suspect Chemicals Review Committee has established criteria for hazard evaluation, but thus far there are no specific guidelines for when an efficacy consideration should initiate a cost/benefit review. A formal policy would better guarantee that marginal products

are reviewed and appropriate action taken.

3. Follow-up system on laboratory testing. The EPA biological laboratories evaluate pesticide products to determine efficacy; safety to man, plants and animals; and adverse effects upon the environment. Products are selected for evaluation by the Regions, the Registration Division, Pesticides Enforcement Division (PED) and OPP biological laboratories. The product manager teams in the Registration Division apparently are not automatically provided with test results, although the Product Control Branch of the Division receives all laboratory reports. Consequently, in some cases where the results of efficacy testing have indicated that detailed review or even cancellation is in order, the personnel responsible for initiating such actions have not known about the problem. The situation could be improved by notifying the appropriate product managers of relevant studies, and requiring the product managers in turn to report on actions taken. A follow-up system on laboratory testing would assure that each biological test conducted resulted in appropriate action.

4. Efficacy action information system. In order to obtain a more complete picture of the kinds and frequency of efficacy related registration actions taken, a record keeping system should be established. All product changes, label modifications, or cancellation proceedings resulting from the ineffectiveness of a product would be entered into the system. This would provide OPP officials with a better basis for directing program activities.

SURVEILLANCE AT THE PRODUCING ESTABLISHMENT

A. The legal requirement for surveillance. Section 7(a) of FIFRA, as amended, requires registration with EPA of all establishments producing pesticides for use in the United States. Section 7(c) requires registered

producers to inform the Agency annually of the types and amounts of pesticides produced, sold and distributed. Section 9 authorizes EPA employees to enter producing establishments to inspect and obtain samples of pesticides released for shipment and to examine the collected samples to determine whether they comply with the provisions of the Act. The Pesticides Enforcement Division of the Office of Enforcement, in conjunction with the Regional Offices, is responsible for carrying out these sections of the law.

Inspection of producing establishments is necessary to meet the responsibilities described above. It is also critical to the effort to remove ineffective products from the marketplace since samples collected during these inspections can be evaluated for effectiveness at EPA biological laboratories. A major advantage of surveillance at the producer establishment is that product batches which have not yet been widely distributed can be analyzed for deficiencies.

B. The surveillance process. The Regional Offices have conducted inspections of producing establishments since July 1973. Each Region maintains a staff of approximately five inspectors who periodically visit selected manufacturers and formulators. Although the Pesticides Enforcement Division has suggested that target establishments should be selected on the basis of information about products, the Regions have indicated that criteria relating to the producer is more often used.[4/] Generally, target establishments are selected using some combination of the following criteria:

- Producers known to have marketed violative products.
- Newly registered establishments.
- Establishments which have never been inspected.
- Establishments not inspected in the past two to three years.

4/ All five Regions contacted in a telephone survey so indicated.

- Establishments producing newly registered products.
- Randomly selected registered establishments.

For establishments which produce more than one product, similar criteria are used to select which product to sample. While there is no standard procedure followed by the Regions to determine which product or products to select, most inspection teams use some combination of the following:

- Products which are obviously violative (as when a label does not match that which was registered).
- Products which have never been sampled.
- Products not sampled in the past two or three years.
- Newly registered products.
- Products with a high degree of potential hazard.
- Products produced in large volumes.
- Products with histories of extensive violation (in some Regions all disinfectants are sampled, for example).
- Products sampled according to a random process.

The Pesticides Enforcement Division has in the last two years compiled a guidance package to assist the Regions to establish parameters for the surveillance process. To develop a factual basis for further guidance, PED requested the Regions to sample products chosen on a random basis (in addition to the regular sampling). The results of this study, known as "the Keller Report," will provide better indications of the problems of violative pesticides and the methods of enforcement most likely to minimize these problems.

The inspection teams make a concerted effort to visit the establishments at the times when the products are being formulated. This is

often difficult because pesticide products are manufactured seasonally. For example, an inspection during January through March might result in the sampling of only the agricultural products produced during those months, while products produced at other times would be sampled only on return visits. Unfortunately, such revisits are sometimes not made.

Collected samples are sealed and identified with a sample number and shipped to the Product Analysis Laboratory which services the Region. There are four of these laboratories for the ten Regions. Chemical analyses are then performed to determine if the product conforms to the statement of ingredients on the label. Products found to be adulterated or misbranded are referred back to the Regional office. The Region can initiate enforcement actions to remove the violative product from the market and can also initiate civil or criminal proceedings against the producer or distributor.

Samples found to be properly formulated on the basis of the Product Analysis Laboratory tests can be sent to the Chemical and Biological Investigation Branch (CBIB) of the Technical Services Division, which has laboratories in Corvallis, Oregon and Beltsville, Maryland. Selection of samples to be analyzed for efficacy in these laboratories is the responsibility of the Registration Division, the Regional Office and the TSD laboratory supervisors.

C. Success in inspecting producing establishments.

Discussions with several EPA officials have led to the conclusion that the number of violative products discovered is low relative to the number of establishments inspected. Unfortunately, data necessary to evaluate the success of producer surveillance is not readily available. Neither the Office of Pesticide Programs, the Pesticide Enforcement Division of

the Office of Enforcement nor the Regional Offices regularly compile such information. PED has conducted a study of randomly selected products and is awaiting the final report of the contractor.

D. Process Recommendations.

1. Criteria for selection. PED should continue to develop and effectively communicate to the Regions guidance for a consistent nation-wide producer surveillance program. Such guidance is critical to the efficacy assurance program because the producer surveillance program gathers most of the samples tested in the biological laboratories. OPP laboratories should convey their needs concerning the sampling of specific products to PED for inclusion in the guidance, since without such criteria there is no assurance that the products most likely to be defective will be examined. Some Regional variation in the surveillance program is acceptable because of the seasonal production of pesticides, but this variation should be based on defined criteria. As presently conducted, there is little assurance that all producers will be inspected or that all products will be sampled, even though these are goals of PED. The wide range of criteria used by the Regions suggests either a lack of adequate guidance from or a communication problem with Headquarters.

2. Management system information. OPP and PED should cooperate on reaching a formal determination of the desired objectives of the PED surveillance program, since sample collection is critical to the biological testing program operated by OPP. At the same time, data should be collected on the results of the surveillance, including the number of violative producers and products discovered and the number of corrective actions taken as a percentage of the number of inspections made. This data can be used to determine the major categories of violative products and thereby assist both PED and OPP in developing guidance and establishing priorities.

3. Reinspection. No formal follow-up system exists for inspection visits. When a manufacturing establishment is inspected, those products not available obviously cannot be sampled. The inspection teams usually do not make special trips back to the establishments to take samples because of limited transportion funds. Criteria should be developed for follow-up sampling of such establishments.

4. Availability of labels. Regional inspection teams require copies of approved labels for products to be inspected, in order to compare with package labels and assure compliance. Access to label copies is apparently difficult because of Headquarters filing problems. OPP should revise its filing and storage procedures to correct this.

MARKET SURVEILLANCE

A. The legal authorization for surveillance. Sections 8(b) and 9(a) of FIFRA, as amended, authorize EPA to inspect establishments where pesticides are held for sale and to sample the products found. Market surveillance can discover a number of violations, including unregistered products, improperly labeled products and products which have deteriorated beyond the point where they can be effective. Additional testing performed on samples collected by market surveillance can discover adulterated and biologically ineffective products as well.

B. The market surveillance process. As presently conducted, market surveillance is a minor part of the total surveillance program. While there is Regional variation as to the relative number of market and producer surveillance inspections, the Pesticides Enforcement Division estimates that only about 10% of the annual inspection visits were at retail establishments.

The chemistry and biology laboratories are dependent on the surveillance process for product samples. For this reason, it is critical to the efficacy assurance program that surveillance provide adequate product samples as well as meet the other responsibilities of PED. Like producer surveillance, market surveillance is conducted by the Regional Offices. Explicit criteria have not been developed to assist in the identification of the distributing establishments to inspect, the types of products to sample, the number of samples to take, or the follow-up actions to take when violations are discovered.

C. Process recommendations.

1. Notification of producers. Producers should be notified of all defects found in samples of their products so that they can take corrective actions when possible. Although the Regional Office which collected the tested sample regularly receives copies of the test results, many Regions do not automatically send these to the producer. Such violations should be the basis for enforcement actions. However, even if there is insufficient evidence for use in court, notification should encourage the producer to correct the problem.

2. Management system information. OPP and PED should reach a formal agreement on the objectives of the surveillance program. Data should be collected on the results of the program, so that EPA program managers can determine which products are most likely to be violative. This information is not now aggregated in useful form and in some cases is not available at all. The sampling and testing criteria are therefore not established on the basis of specific information.

3. Criteria for selection. OPP should assist PED in the development of guidance for a consistent nation-wide market surveillance program. Such assistance should include but not be limited to the provision of a list of suspect products to sample. Regional variation

should be based on acceptable, defined criteria. As presently conducted, surveillance appears haphazard, with little assurance that troublesome products are sampled. Also, the lack of selection criteria encourages abuse. Some establishments might be bothered by continuous inspections while others might never be sampled.

POSTREGISTRATION EFFICACY TESTING

A. The testing process. Almost all of the biological testing conducted to evaluate pesticidal properties of selected products ("efficacy testing") is performed on previously registered and marketed products. Testing of product samples collected during manufacturer or market surveillance occurs in laboratories at Beltsville and Corvallis under the supervision of scientists from the Chemical and Biological Investigations Branch (CBIB) of the Technical Services Division.

Postregistration biological testing has two purposes, an evaluation of the effectiveness of a particular product and a check of label claims. Sample selections are usually made by Regional enforcement personnel or CBIB laboratory supervisors, but this does not preclude the Registration Division, the Pesticides Enforcement Division or States from requesting evaluation of product samples.

Although no established criteria have been prepared to assist in selecting the pesticides to be analyzed, the selection has been based on:

- Whether or not there has been a history of trouble with that product or similar products.
- Whether or not the product has been tested previously.
- Whether or not new claims are being made for the product.
- Available laboratory capabilities.

The laboratories also test all samples of vertebrate pesticides collected by the Regions.

Approximately eighty samples per month are tested for efficacy by the CBIB laboratories. Pharmacological testing is conducted on an additional forty five samples each month. Reports on the testing results are sent to the Registration Division and the Regional Office which collected the sample.

B. Test results. According to CBIB records, since July 1, 1972, 2085 different products have been tested for efficacy at EPA biological laboratories (see Table 1). Of these, 396 were found to be biologically defective (inefficacious) in at least one sample. Determining that a single sample is defective is not sufficient to prove that a product is inherently ineffective. The sample analyzed might have been taken from an isolated production batch which was improperly formulated, or the test conditions might not have duplicated use conditions. Therefore, in most cases the product managers in the Registration Division require that more than one sample be found defective before any action is taken.

TABLE 1 [5/]

FINDINGS OF EFFICACY IN PRODUCTS
ANALYZED FROM JULY 1972 TO JUNE 1975

	Number of Products		
A	B	C	D
Analyzed	Found Defective at Least Once	Retests of B	Tested Only Once and Defective
2085	396	110	286

5/ Table I was compiled by the study team from the file of records at the CBIB headquarters at the Beltsville laboratories.

In spite of the need for additional evaluation of some products, less than twenty eight per cent (110 of 396) of the defective products were tested more than once. Automatic follow-up does not occur, and additional testing is dependent on requests from the Regions, the Registration Division or the Technical Services Division.

While biological testing can be a valuable tool for evaluating efficacy, there are several reasons why the biological laboratories cannot always determine product efficacy. The obvious difficulties are:

1. Standard test protocols do not exist for some kinds of products, such as dog and cat repellants. Without commonly agreed-upon methodologies, test results may be subject to various conflicting interpretations.

2. The testing process can be costly and time consuming. This problem is magnified because meaningful conclusions can be drawn only after repeated tests.

3. Crops are seasonal. In some cases, tests can be conducted only during a limited season of the year. If adverse weather conditions, equipment breakdown, or other factors cause delay, an entire year may go by before another test can be attempted.

4. Specialty crops present difficulties. Commodities such as pineapples, sugarcane, rice, raisins, macadamia nuts, wild rice and many, many others are grown in certain limited climatic or geographic areas using unique cultural and harvesting practices. It would require tremendous resources to conduct tests with such crops.

5. Pesticides are applied by many different methods, ranging from aircraft (both fixed wing and helicopters) to mist blowers, to sub-surface injection, to band treatments, to irrigation metering, etc. To be valid, testing must duplicate use conditions. EPA does not initiate cancellation

3. Product 505-1. Notice of Intent to Cancel has been issued.

4. Product 1386-419. Registrant was asked to reformulate the product. In the only test since reformulation, product performed slightly, though not unacceptably, below efficacy standards.

5. Product 3487-19. Producer was requested to submit additional information. Although no response has been received, no follow-up action has been taken.

6. Product 3696-71. No action taken.

7. Product 5602-129. Producer was asked to submit new efficacy data prior to reregistration.

8. Product 6900-63. Registration has been cancelled.

9. Product 13794-2. No action taken.

In cases 1, 3, 7 and 8, Registration Division action has been satisfactory. In cases 2 and 5, at least eight months have passed since the producer was notified. The Product Managers have indicated that Notices of Intent to Cancel should have been issued, but in both cases the folder had been returned to the files and forgotten. In cases 6 and 9 no action was initiated by the Registration Division even though strong evidence existed to indicate that the product was defective in some respects. Finally, although some action was taken in case 4, the product still does not meet standards.

In summary, the CBIB file survey indicates that the current program of postregistration efficacy testing is not providing adequate protection. Proof that a product is ineffective depends on repeated tests with different samples. Such proof is lacking because no automatic retesting occurs. Even when a product is found to be inherently defective, the actions taken by the Registration Division are neither timely nor complete. If these nine products did not receive

prompt, adequate attention, there is little assurance that other products are properly handled.

D. Recommendations.

1. Automatic retesting. When CBIB completes a test and the sample is determined to be defective, the laboratory should automatically request additional samples from different batches of the same product. The Regional surveillance teams should be responsive to such requests. Only by conducting repeat tests on violative products can the laboratories provide timely recommendations to PED and RD.

2. Review policy. The Registration Division has no standard policy for reviewing reports received from CBIB laboratories. From the interviews conducted it appears that no clear guidance has been issued about who has what review and decision-making responsibilities and when they are to be executed. The recent changeover to product manager teams may be responsible for some disorganization. Now is the best time for standardizing the process so that prompt, consistent and necessary registration actions can be completed. For example, every laboratory report received by the ID coordinator should be sent to the appropriate product manager, an expert on the particular chemical family who is responsible for the product's registration file. He should distribute the report for examination and see that all necessary actions are taken.

3. Tickler file. The file study discussed above sufficiently demonstrates the need for better record keeping procedures. A file listing what steps have been taken to obtain more efficacy information or to initiate the cancellation process should be maintained to facilitate timely follow-up action.

4. Research contracts. OPP should contract with State Agricultural Experiment Stations or similar research groups to test agricultural

pesticides for efficacy and phytotoxicity on a local basis. Although such tests might be needed infrequently, the capability should be available on demand. In such testing the product should be identified only by a code number, and the particular use and claim to be tested should be specified.

5. Development of standard test methods. Increased emphasis on the development of standardized procedures for evaluating the efficacy of pesticide products is strongly recommended. Uniform test protocols can reduce EPA's burden in a number of ways. First, producers and researchers could conduct acceptable studies more easily. Second, EPA's reviewers could better review submitted test data. Third, EPA's scientists could more easily duplicate tests in laboratories. Fourth, EPA's enforcement efforts would be hampered less by the problem of comparability of test results based on different procedures.

IV. OPTIONS

Previous sections have described the potential problems that the use of ineffective pesticide products could cause and EPA's regulatory program to limit them. Based on discussions with personnel from each of the divisions of the Office of Pesticide Programs, the Pesticides Enforcement Division, the Regional Offices and a number of knowledgeable groups outside the Agency, this section examines options for each of the five major elements in the control system: preregistration testing, data review, producer surveillance, market surveillance, and postregistration testing. The study team has made recommendations in each area.

PREREGISTRATION EFFICACY TESTING

Preregistration efficacy testing can provide an independent check on the accuracy of the efficacy information submitted with the request for registration. A comprehensive program of preregistration testing would help assure that no ineffective products are registered by mistake. Of course, such testing cannot impact effectiveness problems resulting from unregistered products, shelf-deterioration, developed resistance, quality control, or minor changes. Such testing could be considered a service to producers, since suggestions from the laboratories often result in greatly improved products. Personnel in CBIB have indicated that they believe this is the essence of preregistration evaluation.

Preregistration testing is currently conducted on limited classes of products (e.g. sterilizers). A more comprehensive program might involve either the testing of some new registrations to provide an incentive for the registrant to do thorough tests, the testing of all new registrations to ensure that submitted data is accurate, or the testing of all new active ingredients to develop information against which later product registrations can be compared.

c Recommendation. The primary purpose of preregistration testing is to prevent the registration of ineffective pesticides. However, the study team found that erroneous registration is not a major source of inefficacy. Moreover, even with preregistration testing the possibility of a mistake exists in dealing with products for which standard test protocols have not been developed. Finally, no existing evidence indicates that EPA preregistration tests keep any ineffective products off the market.

The other stated rationale for preregistration testing, to help producers improve products before registration, does not appear to be a proper use of government resources. EPA should not be providing a service, such as product improvement, which is actually a basic responsibility of the manufacturer.

The study team therefore believes that preregistration testing is an unnecessary aspect of the control program. When additional data is needed, EPA should request the producer to provide it. In the rare case where a manufacturer is suspected of data falsification, EPA should not seek to perform the tests but should instead require the producer to obtain a second, independent validation of the effectiveness of his product.

DATA REVIEW

Data review is the evaluation by Registration Division scientists of information supplied by an applicant to support a registration request. This control element has two parameters, extent of review and number of reviews.

1. Extent of review. Three levels of data review are possible. First, a simple check can be made to ensure that all necessary data required have been submitted. This relatively inexpensive option has as a major drawback that no evaluation of data occurs. Consequently,

if an applicant submitted inadequate data in the proper format, it is unlikely he would be caught. As a second option, the data could be compared with data from similar products already registered. Third, a formal and independent evaluation of the data could be made. This most expensive option would provide the best assurance of product efficacy at the time of data review. The benefit of this assurance is questionable, since, as stated earlier, much of the problem of pesticide inefficacy surfaces only on the production line or on the shelf. A more extensive data review would not necessarily solve these problems.

2. Number of applications reviewed. The data review can cover all applications, as is currently the case, or only some selected subset (by class or random determination).

• Recommendation. Data review is and should continue to be the primary method of promoting product efficacy. Assuring that the registrant has carefully documented effectiveness is the most important mechanism for keeping poor products off the market. That so few ineffective pesticides are marketed is attributable to this review and the producers' incentives reinforced by basic market pressures. The data requirements in the Section 3 regulations and guidelines describe the best available methods for testing the efficacy of pesticides. Registration Division review of the submitted data is generally sufficient to determine if a product will or will not perform as intended. Because the review also includes an appraisal of the production process, quality control problems are reduced. Only products with suspect or new active ingredients should be subjected to rigorous examination. However, the routine data review should continue for all products. Further investigation could be done selectively, as required.

PRODUCER ESTABLISHMENT SURVEILLANCE

Samples of products packaged for sale can be collected during visits to producer establishments. Later analysis can determine if they conform to registration requirements. A program of producer surveillance could be instituted at four levels:

1. Comprehensive producer surveillance. A comprehensive producer surveillance program would entail periodic inspection of all establishments, with sampling and chemical testing of all products. Such activity would help ensure that all products were effective when packaged for sale but would not prevent problems caused by mistaken registration, developed resistance, or shelf deterioration. Since available data indicates that most ineffective products result from errors in the production process, a comprehensive program could significantly reduce the number of ineffective pesticides. The cost of a comprehensive program would be large, requiring additional inspection teams and laboratory facilities.

2. Random surveillance. Random surveillance of producing establishments, as currently conducted, provides reasonable assurance that adequate records are kept. Sampling products at the establishments provides a limited control over production of ineffective products.

3. Limited producer surveillance. A program of limited producer surveillance could have a relatively large impact if only products with histories of quality control or batch problems are analyzed. OPP scientists indicate that sporicides and sterilizers often have production problems. Other manufacturers would be inspected only if suspected of violations.

4. No producer surveillance. Inspections could continue until determination is made that most producers were keeping adequate records. No

samples of products would be taken for analysis.

• Recommendation. Producer establishment surveillance is necessary as a deterrent to poor quality control and illegal product changes. Since these are major causes of ineffective products, a strong producer surveillance program is needed. The Office of Pesticide Programs and the Pesticides Enforcement Division should devise a sampling schedule which covers all products but which emphasizes suspect ones (i.e. those with a high probability of efficacy shortcomings and those with violative histories). Indications are that vertebrate pesticides and disinfectants are the most likely violative groups. These products should be emphasized in the sampling program until specific violative groups are formally identified. All samples should be chemically analyzed to verify the registered formulation but should not be routinely evaluated for efficacy. Producer surveillance and chemical testing cannot prevent unregistered pesticides, pesticides registered by mistake, shelf deterioration, or developed resistance problems.

MARKET SURVEILLANCE

Visits to retail establishments, including review of product labels and sampling for chemical testing, can control ineffective pesticides that are unregistered, have deteriorated on the shelf, or have been misformulated by the producer. A program of market surveillance to assure efficacy could be instituted at four levels:

1. Comprehensive market surveillance. A comprehensive market surveillance program would entail periodic inspections of all establishments and sampling of all products. Such activity would reduce the number of ineffective products sold. However, the cost would be very great, requiring expansion of the inspection teams and the laboratories.

2. Random inspection. A randomly chosen sample of retail establishments could be inspected for unregistered products. Other products could be selected and then tested in the laboratories forch emical and biological pr operties. The market surveillance program currently conducted, based on such inspections, provides more assurance that all products are registered than that all products are efficacious.

3. Market surveillance of selected establishments and products. If the major remaining cause of ineffectiveness is shelf deterioration (or improper storage contributing to it), then small volume distributors should be inspected. A program reflecting this consideration would inspect hardware stores and other retail establishments specializing in sales of small packages to individual consumers. Similar selectivity could be applied to the products sampled. If only a few pesticide use groups are likely to be defective, then only these should be sampled.

4. No market surveillance. Inspection could continue until unregistered products are discovered infrequently. Then the program could be reduced. No samples of products would be collected unless violations were suspected. This option should be selected if market surveillance reveals few defective products.

• Recommendation. Although marketplace surveillance can provide protection from ineffectiveness as a result of poor production procedures and minor product changes, it is more efficient to catch these problems at an earlier distribution point through producer establishment surveillance. The unique targets of market surveillance are unregistered products and pesticides which have been on the shelf too long and may have deteriorated. Since the efforts of PED have essentially eliminated most unregistered pesticides and since there are now requirements for label dating, market surveillance activity should be reduced.

POSTREGISTRATION EFFICACY TESTING

Samples collected during producer establishment and market surveillance are first analyzed chemically to verify the presence of the proper amounts of active ingredients. Although analytical tests for percentage of active ingredient are not sufficient for declaring ineffectiveness, such tests can be the basis of stop-sale or removal orders. If the product contains the correct ingredients it may be evaluated for efficacy at EPA's biological laboratories. Postregistration testing is primarily useful in pinpointing deficiencies that cannot be regulated by the four previously discussed controls. Erroneous registration, less rigorous registration, and developed resistance could be discovered through testing. In addition to the analysis of violative products to obtain evidence for cancellation actions and court proceedings, a program of biological testing could be conducted at four levels:

1. Comprehensive testing program. A comprehensive biological testing program would entail the evaluation of all registered products. Sampling could be done at the manufacturer level or the market level or samples could be requested. Laboratory capability would have to be greatly expanded if all products are to be examined on a periodic basis. Additional laboratories would be needed in several geographic locations for the proper analysis of some products, though some testing can be done under contract. A comprehensive program could be a powerful incentive for manufacturers to take diligent steps to insure that their products are effective.

2. Random testing program. A testing program which evaluated the biological effectiveness of a relatively large proportion of pesticide products could have the same benefits as the comprehensive program but at less

cost. If as few as five or ten percent of registered products were periodically examined, a high level of assurance of efficacy would be provided.

3. Selected product testing. EPA's laboratories are too limited to compete with the large producers of agricultural and industrial chemicals, who utilize test facilities in numerous geographical areas. Even when EPA scientists discover an ineffective product, almost certainly the producer will challenge EPA's testing procedures and equipment. Therefore, it might be better for EPA to concentrate its limited testing capability on home and garden products which are not tested extensively by the manufacturer.

4. No postregistration biological testing. EPA laboratories indicate that 19% of the products tested for biological effectiveness might be defective. This figure overstates the percentage of marketed products which are defective since some of the products sampled and tested are those suspected of violation or with histories of inefficacy. Moreover, the value of identifying the small number of ineffective products is further limited because sales continue during the testing period and sometimes during litigation even if EPA tests showed it to be defective. Since most pesticides are produced in batches that can be sold relatively quickly (one year or so), test results usually come too late to prevent any damage that may occur.

- Recommendation. Having a process for verifying that a product is effective as intended is mandatory only if 1) the front-end registration process is not doing an adequate screening job or 2) for some other reasons there is a major market efficacy problem. However, we believe that post-registration testing is generally not required for either reason. The registration process can identify and eliminate most pesticides and product uses that are likely to be ineffective. The Section 3 test protocols and data requirements are sufficient to ensure that producers do not waste time and

money on fundamentally unsound products which do not meet the requirements. Furthermore, the efficacy and safety evaluations completed during the data review period effectively preclude the registration of suspect products.

The study team also believes that inefficacy stemming from pesticide production and sale is not a major threat. Ineffective pesticides may be marketed, but there is no reliable documentation to demonstrate the need for special concern. No data was produced on the number or types of OPP registration actions related to efficacy. In light of this and our conclusion that the limited threat from ineffective pesticides is the result of poor production processes and minor product changes, which could be controlled through a strengthened surveillance program, the study team concludes that routine postregistration efficacy testing is not critical to the Agency, and can be eliminated.

While all routine postregistration biological testing should be curtailed, we wish to emphasize that some testing will remain necessary. All tests conducted should be based on specific requests from PED or the Registration Division. By making these offices responsible for initiating testing and by requiring appropriate responses, this system will assure that effective regulatory actions will take place while testing is kept to a minimum.

This argument for less postregistration efficacy testing does not necessarily mean that the EPA laboratory capabilities should be reduced. We wish to underscore the recommendation on page 31 which focuses on the desirability of developing standard test methodologies. Currently about 50 percent of the CBIB workload involves research on test protocols, accident and safety studies, and special investigation requests from other Federal agencies and States. These responsibilities can be strengthened as the efficacy testing load is decreased.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SUBJECT: Report on "Protection From Ineffective Pesticides" DATE: DEC 8 1975

FROM: Alvin L. Alm, Assistant Administrator
for Planning and Management (PM-208)

Andrew W. Breidenbach, Acting Assistant Administrator
for Water and Hazardous Materials (WH-556)

Stanley Legro, Assistant Administrator
for Enforcement (EN-329)

TO: Russell E. Train, Administrator (A-100)

The Program Evaluation Division has completed a study on protection from ineffective pesticides. The paper has been circulated twice in the Agency for comments, with extensive revisions each time. The final product reflects our best judgment of the direction the program should take.

The report includes a series of policy and program management recommendations. The major thrust of the recommendations is that (1) efficacy testing should be conducted on a systematic basis to meet specific stated needs of the Registration Division, the Criteria and Evaluation Division, the Pesticides Enforcement Division and the Regional Offices; and (2) increased emphasis should be placed on the development of standard test methods for efficacy evaluation.

With your approval we will implement the following:

OFFICE OF PESTICIDE PROGRAMS (DAA)

- Technical Services Divison is developing a suspect products list of pesticides or pesticides uses that are most likely to be defective. Surveillance resources will be concentrated in these areas.

- An efficacy action information system will be established to track biological test results as well as subsequent registration/enforcement actions. This will be used to keep Regions informed of these actions and will also provide input into selection of suspect products for future sampling.

- Contracts or basic ordering agreements for the efficacy testing of agricultural pesticides will be negotiated with State Agricultural Experiment Stations or similar research groups, as required.

TECHNICAL SERVICES DIVISION, OPP

- Preregistration biological evaluation activity will continue at the current very low level on requests critical to Registration Division's decision-making.

- Postregistration (surveillance) biological evaluation activity will be completely aimed at supporting registration/enforcement actions on suspect products. These products will be identified by users in the Registration Division, the Criteria and Evaluation Division, the Pesticides Enforcement Division, and the Regional Offices.

- Whenever a defective sample is found, follow-up samples will automatically be picked up (according to criteria based on contemplated final action) and tested in order to determine if there is an inherent problem with the product necessitating registration/enforcement actions.

- Efforts to develop standard testing methods will be increased.

REGISTRATION DIVISION, OPP

- Preregistration review of efficacy data submitted by the applicant will continue to be the principle method of assuring the efficacy of products.

- An applicant will be required, as appropriate, to present corroborative data from an independent testing laboratory if his product contains suspect active ingredients or could present serious health problems if ineffective.

- Efforts aimed at more rapid registration actions on defective products will continue including specific reporting by product managers on actions taken or not taken.

- A tickler file will be maintained to facilitate timely follow-up action.

. Work on microfilming product labels will continue and will facilitate access to current label information.

PESTICIDES ENFORCEMENT DIVISION, OE

. There will be a continuation of the effort to produce a consistent nation-wide producer surveillance program.

. Guidance will be developed for a consistent, nation-wide market surveillance program.

. The sampling programs will include greater emphasis on products with histories of deficiencies.

. Regions will receive guidance in picking up initial and follow-up samples for biological evaluation.

. Enforcement action will be taken against all producers marketing products which the laboratories demonstrate to be defective.

REGIONAL OFFICES

. Producers will be notified of all defects found in samples of their products.

. Based on guidance from Headquarters, the Regional Offices should implement improved sampling programs.