



R-133192

094231

REPORT TO THE CONGRESS

Pesticides: Actions Needed To Protect The Consumer From Defective Products

B-133192

Environmental Protection Agency

*BY THE COMPTROLLER GENERAL
OF THE UNITED STATES*

~~710678~~
094231

MAY 23, 1974



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

B-133192

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

This is the second in a series of GAO reports issued to alert the Congress to the shortcomings in the Environmental Protection Agency's efforts to protect man and the environment from the effects of harmful pesticides. 24

We made our review pursuant to the Budget and Accounting Act, 1921 (31 U.S.C. 53), and the Accounting and Auditing Act of 1950 (31 U.S.C. 67).

We are sending copies of this report to the Director, Office of Management and Budget; the Secretary of Agriculture; the Secretary of the Treasury; the Administrator of General Services; the Administrator of Veterans Affairs; the Chairman, Council on Environmental Quality; and the Administrator, Environmental Protection Agency.

A handwritten signature in black ink, appearing to read "A. H. Kellen".

Acting

Comptroller General
of the United States

C o n t e n t s

	<u>Page</u>
DIGEST	1
CHAPTER	
1 INTRODUCTION	5
2 IMPROVEMENTS NEEDED IN MARKET SURVEILLANCE PROGRAM	9
Limited coverage of registered pesticides	9
FEPCA's effects on sampling techniques	11
Agency comments	12
Conclusions	12
Recommendation to the Adminis- trator, EPA	13
3 NEED FOR MORE EFFECTIVE CONTROLS OVER IMPORTED PESTICIDES	14
Incomplete reporting hampers EPA's surveillance	14
Inadequate controls over imported pesticides	18
Personnel limitations	19
Conclusion	19
Recommendations to the Secretary of the Treasury and the Administrator of EPA	19
Agency comments	20
4 NEED TO EXPAND SAMPLE ANALYSIS CAPABILITIES	21
Laboratory limitations	21
Effective life of pesticides not established	24
Testing pesticides before registra- tion	25
Conclusions	25
Recommendations to the Administrator, EPA	26
Agency comments	26

CHAPTER

5	NEED TO USE ENFORCEMENT ALTERNATIVES MORE EFFECTIVELY	27
	Canceling the registrations of ineffective pesticides	28
	Recalling ineffective pesticides	33
	Manufacturers not notified of defects	34
	Purchasing defective pesticides	36
	Conclusions	37
	Agency comments	38
	Recommendations to the Adminis- trator, EPA	39
6	OPPORTUNITY TO SUPPLEMENT THE PESTICIDE MARKET SURVEILLANCE PROGRAM WITH STATE ASSISTANCE	40
	State capabilities	40
	Limited use and exchange of data resulted in duplication of effort	41
	EPA should use State resources more	42
	Conclusions	44
	Recommendation to the Adminis- trator, EPA	44
	Agency comments	44
7	SCOPE OF REVIEW	46

APPENDIX

I	Letter dated October 12, 1973, from the Environmental Protection Agency to the General Accounting Office	47
II	Letter dated September 19, 1973, from the Bureau of Customs, Department of the Treasury, to the General Accounting Office	51

APPENDIX

III	Principal officials of the Environmental Protection Agency and the Department of the Treasury responsible for activities discussed in this report	53
-----	---	----

ABBREVIATIONS

EPA	Environmental Protection Agency
FEPCA	Federal Environmental Pesticide Control Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GAO	General Accounting Office
GSA	General Services Administration
VA	Veterans Administration

D I G E S T

WHY THE REVIEW WAS MADE

There has been widespread concern about the effects of pesticides on man and his environment. These pesticides include insecticides, herbicides, rodenticides, fungicides, disinfectants, sanitizers, and plant regulators.

Because of this concern, GAO evaluated the Environmental Protection Agency's (EPA's) policies and practices for determining whether pesticides were being marketed in compliance with the basic pesticide consumer protection law--the Federal Insecticide, Fungicide, and Rodenticide Act.

The act required that all pesticides shipped interstate be safe and effective and be registered with EPA before being sold to the public.

The Federal Environmental Pesticide Control Act of 1972 (FEPCA) amended that law to require that all pesticides--not just those shipped interstate--be registered with EPA. All provisions of this act must be effective by October 21, 1976.

FINDINGS AND CONCLUSIONS

The consumer has not been adequately protected from defective

pesticides because of inadequate EPA efforts to determine whether registered pesticides were marketed in accordance with provisions of the act.

Limited coverage

EPA did not give its inspectors enough guidance for determining which registered pesticides to sample. As a result, inspectors repeatedly sampled some pesticides but never sampled others.

About 32,000 pesticides were registered as of June 30, 1972. Only 7,000 had been sampled during the preceding 4-1/2 years. GAO found that at least 3,300 samples of 253 pesticides had been taken--11 percent of the 29,000 samples taken during that period.

About 64 percent of the manufacturers in the three EPA regions included in GAO's review did not have any of their pesticides sampled by EPA during this period.

According to EPA, the limited number of inspectors and the difficulty in locating samples of many registered pesticides shipped interstate contributed to the limited coverage.

In formulating future sampling plans, EPA should consider many factors, including

--the pesticide's degree of potential hazard,

- history of violations,
- production data and sampling history,
- number of followup samples needed to determine adequacy of corrective action,
- number of samples needed for legal action or registration cancellation,
- safety and effectiveness test needs, and
- coverage provided by State programs. (See pp. 9 to 13.)

The effectiveness of EPA's surveillance over pesticide imports was reduced because the Bureau of Customs did not report the arrival of many pesticide shipments to EPA, and EPA did not adequately sample those that were reported.

Although the Secretary of the Treasury was required to prescribe regulations for implementing the import provisions of FEPCA by January 19, 1973, such regulations had not been promulgated as of March 1974. (See pp. 14 to 19.)

Vital testing not conducted

Because of the lack of space, personnel, and equipment, EPA's biological laboratories could not test most samples for safety and effectiveness.

During the 18-month period preceding June 30, 1972, EPA collected 9,344 samples but tested only 19 percent for safety. Of those tested, 16 percent were found to be defective.

Only 32 percent of the samples were tested for effectiveness. Of those

tested, 28 percent were found to be defective. Thus the number of unsafe and ineffective pesticides being used by consumers could be significant. (See pp. 21 to 24.)

Many pesticides are decomposable, but EPA did not conduct any studies to determine rates of decomposition or the period of time for which pesticides could be expected to be effective. (See pp. 24 and 25.)

In registering new pesticides, EPA relied on manufacturers' test data on the pesticides' safety and effectiveness. Even for those pesticides, such as disinfectants and rodenticides, with histories of violations, EPA made only limited tests before registration. (See p. 25.)

Use of enforcement alternatives

In a 1968 report to the Congress, GAO pointed out that the Federal Government was not prosecuting firms for serious and repeated violations--no manufacturers were referred to the Department of Justice for prosecution during fiscal years 1959-68.

Since then, EPA's prosecution activity has increased steadily; during fiscal year 1973 it referred over 250 cases to Justice for possible prosecution. EPA has not, however, effectively used the enforcement alternatives of canceling registrations and recalling products to prevent marketing of repeatedly ineffective pesticides.

During an 18-month period EPA laboratories found that 25 percent of the disinfectant and 32 percent of the rodenticide samples tested were ineffective. Although EPA repeatedly found some rodenticides and disinfectants ineffective, it did not, with few exceptions, cancel their registrations or require that claims for effectiveness be deleted from the labels. (See pp. 28 to 33.)

Also, EPA requested the recall of only 90 of the 559 disinfectant and rodenticide shipments from which it collected ineffective samples. (See pp. 33 and 34.)

GAO reviewed records for 48 pesticides which EPA found to be defective as a result of safety and effectiveness tests from August 1972 through January 1973. In only 2 of the 48 cases were manufacturers notified of the defects. Other manufacturers were allowed to continue marketing defective pesticides because EPA did not act. (See pp. 34 and 35.)

Although EPA's policy is to notify manufacturers when it discovers an ineffective or chemically deficient pesticide shipment, it did not normally notify the public.

Not only was the consumer exposed to pesticides which EPA found to be frequently ineffective or chemically deficient, but also other Federal agencies purchased quantities of these pesticides and in some cases, in effect, recommended their use to consumers. (See pp. 36 and 37.)

State assistance

Although all States required registration of pesticides sold within their borders and made some market surveillance, EPA made only limited use of the data obtained by the States to supplement its market surveillance programs. (See pp. 40 to 44.)

RECOMMENDATIONS

The Administrator, EPA, should

--devise a more effective sampling program to insure adequate

coverage of pesticides being marketed;

- expand the import market surveillance program and establish procedures to insure that samples of imported pesticides are collected and tested promptly;
- initiate measures to obtain the additional personnel, space, and equipment necessary for conducting a sufficiently broad and thorough testing program;
- take steps to determine the effective life of decomposable pesticides;
- require that expiration dates be included on labels of decomposable pesticides;
- establish procedures for testing, before registration, disinfectants, rodenticides, and any other pesticide categories which EPA has found in its market surveillance program to have a high rate of biological defects;
- request manufacturers to recall production lots from which EPA has collected ineffective samples;
- establish procedures for notifying manufacturers of all deficiencies found in samples of their pesticides; and
- enter into cooperative agreements with the States to better use their resources in carrying out EPA's market surveillance program and to help the States obtain the necessary expertise; particular consideration should be given to having the States (1) collect pesticide samples from the channels of trade, (2) monitor the use of pesticides, and (3) test pesticides for safety and effectiveness.

The Secretary of the Treasury should take prompt action to prescribe the import regulations required by section 17(e) of FEPCA.

AGENCY ACTIONS AND UNRESOLVED ISSUES

EPA generally agreed with GAO's conclusions and recommendations and said it had already taken steps either to implement new programs or to change existing programs in line with suggestions made by the report.

On January 11, 1974, EPA initiated procedures to cancel the registrations of 32 ineffective pesticides. Also, EPA issued guidelines providing for the prompt public release of information on its enforcement activities. (See pp. 12, 20, 26, 38, and 44.)

Customs said import regulations would be published in the Federal Register as a notice of proposed rulemaking in the near future, and, when adopted, should reduce Customs' administrative burden in reporting the arrival of pesticide shipments. (See p. 20.)

MATTERS FOR CONSIDERATION BY
THE CONGRESS

This is the second in a series of GAO reports issued to alert the Congress to the shortcomings in EPA's efforts to protect man and the environment from the effects of harmful pesticides.

GAO's recommendations of actions that should be taken should be useful to the Congress in reviewing EPA's administration of the pesticide consumer protection law.

CHAPTER 1

INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of 1947 (7 U.S.C. 135) provided the basic legal authority for regulating the interstate marketing of pesticides--including insecticides, herbicides, rodenticides, fungicides, disinfectants, sanitizers, and plant regulators. The Administrator of the Environmental Protection Agency (EPA)¹ is responsible for administering the act.

On October 21, 1972, the Federal Environmental Pesticide Control Act (FEPCA) of 1972 (7 U.S.C. 136, supp. II, 1972) amended FIFRA to provide for more effective regulation of the manufacture, distribution, and use of pesticides. All FEPCA provisions must be effective by October 21, 1976.

The major changes are:

1. FEPCA generally requires that all pesticides, except those intended solely for export, be registered with EPA before distribution or sale; FIFRA applied only to those sold interstate.
2. FEPCA provides that all pesticides be classified for general or restricted use on the basis of the degree to which they adversely affect the environment; FIFRA did not require such registration classification.
3. FEPCA requires all pesticide-producing establishments to register and submit production and sales-volume information; FIFRA did not.
4. FEPCA authorizes sampling of pesticides at the manufacturer's plant; FIFRA did not.

¹Under Reorganization Plan No. 3 of 1970, EPA was established on December 2, 1970, and responsibility for administering the act was transferred from the Secretary of Agriculture to the Administrator of EPA.

5. FEPCA authorizes the issuance of an order to prohibit the sale, use, or removal of violative pesticides; FIFRA did not.
6. FEPCA authorizes indemnity payments to any person who owned any quantity of a suspended pesticide at the time it was suspended; FIFRA did not.

The FEPCA provisions which relate to this report are discussed in the applicable chapters.

Because our prior reports¹ indicated weaknesses in EPA's efforts to protect man and his environment from the effects of harmful pesticides and because of the widespread concern about these effects, we reviewed EPA's policies and practices for determining whether pesticides were being marketed in compliance with the requirements of Federal legislation.

Of approximately 32,000 pesticides registered as of June 30, 1972, EPA estimated that about 20,000 were being marketed in interstate commerce at that time. To register a pesticide EPA, under FIFRA, required that (1) evidence be presented showing that the pesticide was safe and effective when used as directed and (2) the safety claims on the label conform to standards based on animal tests and/or use experience. Federal regulations required that warning and cautionary statements be displayed on the labels and that the pesticide's registration number be on the label to indicate that EPA had accepted the pesticide as safe and effective when used as directed.

Registration was valid for 5 years, after which time registrants had to reregister the pesticides or the registrations were canceled. EPA was also required to continuously review registered pesticides to determine if they were still safe and effective in the light of developing scientific data. These requirements were not changed under FEPCA.

¹Reports to the Congress on "Need to Improve Regulatory Enforcement Procedures Involving Pesticides" (B-133192, Sept. 10, 1968) and "Environmental Protection Agency Efforts To Remove Hazardous Pesticides From The Channels of Trade" (B-133192, Apr. 26, 1973).

EPA field inspectors collected pesticide samples from the channels of trade and submitted them to EPA laboratories for testing to determine whether the pesticides, as marketed, conformed to the information provided at the time of registration.

To analyze these samples, EPA had, as of February 1974, 5 chemical laboratories, including 1 used only for methods development, quality control, and special chemical projects; 6 biological laboratories; and 80 professional and technical personnel. After the samples were analyzed in the laboratories, scientists in EPA's Registration Division reviewed the results and submitted them to EPA's Pesticides Enforcement Division. The Enforcement Division was responsible for reviewing all the sample data and for taking appropriate enforcement action where warranted.

FIFRA violations included the interstate marketing of adulterated or misbranded pesticides or pesticides that were not registered by EPA. An adulterated pesticide is one whose strength or purity falls below the standard of quality expressed on its label or which contains an ingredient not included on the approved label. A misbranded pesticide is one whose label is false or misleading or whose packaging or labeling does not comply with standards established by the Administrator for protecting the public.

FEPCA, when fully implemented, will make these violations applicable to all pesticides sold in this country, not just those shipped interstate. Neither FIFRA nor FEPCA makes these violations applicable to pesticides intended solely for export.

In cases of violations of the act, EPA, under FIFRA, could (1) seize the illegal shipment, (2) cancel the pesticide's registration, (3) recommend to the Department of Justice for criminal prosecution the person or persons alleged to be responsible for violating the act, or (4) use a combination of these actions. The act required EPA to notify those against whom criminal proceedings were contemplated (citation).

EPA was not required to issue a citation or prosecute a violator if the violation was minor and if the public interest would be served by a written notice of warning (enforcement correspondence).

EPA used recalls to remove violative pesticides from the channels of trade. Manufacturers were asked to voluntarily recall violative pesticides, but EPA could not enforce its recall requests if manufacturers refused to cooperate because neither FIFRA nor FEPCA provided EPA with recall authority. EPA personnel stated that multiple seizures, or the threat of seizures, were used to supplement the recall program when manufacturers refused to recall a pesticide shipment. They found recall to be more effective and efficient than seizure because seizures required court actions and were limited to the specific quantities and locations of the pesticide identified in the seizure complaints filed by EPA.

Under FEPCA, EPA can issue an order to prohibit the sale, use, or removal of violative pesticides or pesticides whose registrations have been suspended or canceled. FEPCA also has established civil penalties for violations, whereas FIFRA provided only for criminal penalties.

CHAPTER 2

IMPROVEMENTS NEEDED IN MARKET SURVEILLANCE PROGRAM

EPA's market surveillance program consisted of collecting and examining pesticide samples to determine whether they complied with provisions of the act. Because EPA does not normally test pesticides before registering them, it is important that as many pesticides as possible be sampled and tested for chemical composition, safety, and effectiveness. However, EPA did not give its inspectors adequate guidance for determining which pesticides to sample. As a result, inspectors repeatedly sampled some pesticides but never sampled others. Thus, for many pesticides, EPA did not have reasonable assurance that the pesticides were being marketed in accordance with registration requirements designed to protect the consumer.

FEPCA's provisions permitting the collection of pesticide samples at producing establishments should enable EPA to improve its control over which registered pesticides to sample. In formulating future sampling plans, EPA should consider such factors as the pesticide's degree of potential hazard, history of violations, production data, sampling history, number of followup samples necessary to determine adequacy of corrective action taken, number of samples necessary for legal action or registration cancellation, sampling needs for safety and effectiveness testing, coverage provided by State market surveillance programs, and FEPCA's effects on sampling techniques.

LIMITED COVERAGE OF REGISTERED PESTICIDES

Of the approximately 32,000 pesticides registered as of June 30, 1972, only 7,000 had been sampled during the preceding 4-1/2 years, although 29,000 samples were collected. With better control, EPA could have sampled more of the registered pesticides during that time.

EPA divided pesticides into 82 categories based on (1) the type of pesticide, such as rodenticides and herbicides, (2) the active ingredients, and (3) the intended use, such as home and agricultural. On the basis of past violations and the hazards associated with use, EPA headquarters personnel determined the number of samples to be collected in each category. EPA gave its inspectors guidance for determining the number of pesticides to be sampled in each category but not for determining which ones to sample.

According to EPA headquarters personnel, each regional supervisor was responsible for preventing pesticides manufactured in his region from being repeatedly sampled. Inspectors were to sample pesticides only if they were manufactured in their region or if the sample was requested by headquarters or another region. Collecting samples of a pesticide manufactured in another region was to be coordinated with the region having jurisdiction.

There was no indication that regional supervisors were trying to prevent pesticides manufactured in their region from being sampled repeatedly. Also, inspectors repeatedly sampled pesticides manufactured in other regions without obtaining approval of the regional supervisors in those regions.

As a result, some pesticides were repeatedly sampled while others were never sampled.

Repetitive sampling of particular pesticides

Of about 7,000 registered pesticides sampled between January 1968 and June 1972, we found, from a computer printout of sampling history, 253 that EPA had sampled at least 10 times. EPA took at least 3,300 samples of the 253 pesticides--11 percent of the 29,000 samples collected during this 4-1/2-year period. Because two or more samples collected in the same month appear in the printout as only one sample, the actual number collected is understated. For example, the printout indicated that 2 pesticides had been sampled 17 and 16 times in a 34-month period, although our review of supporting records indicated that EPA had sampled them 85 and 59 times.

EPA found no violations for 76 of the 253 pesticides yet collected 958 samples of these 76, apparently because they were readily available in the channels of trade. Over 25,000 other registered pesticides were never sampled.

EPA also collected too many followup samples. Sometimes inspectors collected samples before the manufacturer could correct the deficiencies or after previous samples had shown the deficiencies to be corrected.

Manufacturers not examined for compliance

As shown in the following table, about 64 percent of the registrants in the three regions included in our review (see p. 46) did not have any of their pesticides sampled between January 1968 and June 1972.

<u>Percent of registrants'</u> <u>pesticides sampled</u>	<u>Number of</u> <u>registrants</u>	<u>Percent of</u> <u>registrants</u>
0	781	63.6
1 to 20	106	8.6
21 to 40	105	8.5
41 to 60	83	6.8
61 to 80	34	2.8
81 to 100	119	9.7
	<u>1,228</u>	<u>100.0</u>

EPA officials agreed that their sampling program had not adequately covered most registrants because inspectors were told how many samples to collect from each pesticide category but not which registered pesticides to sample. EPA officials also stated, however, that personnel limitations and the difficulty of locating samples of specific registered pesticides which had been shipped interstate prevented inspectors from more extensively sampling pesticides. They stated, however, that FEPCA should enable EPA to improve its control over which pesticides to sample and thus should improve the coverage of the pesticides being marketed.

FEPCA'S EFFECTS ON SAMPLING TECHNIQUES

Because FIFRA applied only to pesticides shipped interstate and did not permit the use of evidence obtained from a manufacturer or distributor in a criminal prosecution, EPA concentrated on collecting samples at wholesale and retail outlets. Now, FEPCA authorizes EPA to inspect and sample pesticides at the establishments where they are produced or held for shipment or sale.

EPA plans to emphasize inspection of pesticide-producing establishments and collection of samples at the plants.

AGENCY COMMENTS

In commenting on this report, EPA advised us by letter dated October 12, 1973, that it realized a more effective sampling program was needed. (See app. I.) EPA stated that its new sampling program--the random sample selection system--provides for collecting samples by product name--a product list was randomly selected by EPA headquarters--and thus eliminates much of the duplication that occurred under the old program. EPA further stated that the new program would be flexible enough to provide for collecting samples from those firms with known violative histories and for collecting followup samples to measure the effectiveness of corrective actions taken by the firms. A total of 4,500 samples are to be collected under this system in fiscal year 1974.

According to an EPA official, each region, not headquarters, will select the firms to be visited, emphasizing companies that have a history of violations or that have never been sampled. If any manufacturer's products are on the list compiled by EPA headquarters, they will be sampled. Thus the 4,500 randomly selected pesticides will be sampled only if the region selects that particular manufacturer for inspection. There is no requirement that the regions attempt to sample all the products on the randomly selected sample list. EPA officials said that headquarters personnel would review quarterly inspection plans submitted by the regions to insure adequate coverage of the firms included in the random sample. They told us that they would consider the random sample valid if 70 percent of the pesticides on the list were sampled.

We believe that, unless all manufacturers with pesticides on the random selection schedule are inspected, or have an equal chance of being inspected, the sample will be biased.

EPA officials indicated that the random sample selection system was being used to identify possible violators and problem areas for future sampling plans and probably would not be used again for about 3 years. Sampling plans for next year have not been formulated.

CONCLUSIONS

Although the random sample selection system should reduce duplicate sampling and yield some data useful in forming

sampling plans, we believe that a stratified random sample could more effectively cover the pesticide market.

Such a sample should consider many factors, including the pesticide's degree of potential hazard, history of violations, production data, sampling history, number of follow-up samples necessary to determine adequacy of corrective action, number of samples necessary for legal action or registration cancellation, need to test pesticides for safety and effectiveness, coverage provided by State market surveillance programs, and FEPCA's effects on existing State market surveillance programs. (See ch. 6 for discussion of State programs.)

Until such a system is devised, we believe that the deficiencies described in this chapter will not be eliminated.

RECOMMENDATION TO THE ADMINISTRATOR, EPA

We recommend that the Administrator of EPA devise a more effective sampling program to insure adequate coverage of pesticides being marketed by considering the following factors.

- Pesticide's degree of potential hazard.
- History of violations.
- Production data.
- Sampling history.
- Need for followup samples.
- Number of samples necessary for legal action or registration cancellation.
- Safety and effectiveness test needs.
- Market surveillance provided by the States.
- FEPCA's effects on sampling techniques.

CHAPTER 3

NEED FOR MORE EFFECTIVE CONTROLS

OVER IMPORTED PESTICIDES

Imported pesticides are subject to the same FIFRA provisions as are domestically produced pesticides, and EPA is responsible for insuring that pesticides are imported and marketed in accordance with the act. Joint regulations of the Administrator of EPA and the Secretary of the Treasury specify that the Bureau of Customs notify EPA of the arrival of all pesticide shipments and deliver samples of the imported pesticides to EPA upon its request.

Because Customs did not report the arrival of all pesticide shipments, EPA did not have the opportunity to sample them to ascertain whether they complied with the law before being marketed in this country. EPA inspectors, during their normal sampling of marketed pesticides, collected samples of many unreported imported pesticides and found them to be in violation of the act.

The effectiveness of EPA's surveillance over imports was also diminished because EPA did not adequately sample pesticide imports that Customs had reported.

INCOMPLETE REPORTING HAMPERS EPA'S SURVEILLANCE

^A Customs officials at 47 of the 291 ports of entry were regularly reporting pesticide shipments to EPA during fiscal year 1972. They reported 1,026 individual shipments amounting to about 75 million pounds. EPA officials estimate that Customs officials reported only about 60 percent of the fiscal year 1972 imported pesticides.

Customs stated that it was entirely possible that pesticides arrived regularly at only 47 of the 291 ports of entry and questioned EPA's contention that Customs reported only about 60 percent of the fiscal year 1972 imported pesticides. Although an EPA official agreed that pesticides may regularly be imported through only about 47 ports of entry, he stated that Customs officials in New York--where most pesticides enter the country--had reported few imported pesticides during fiscal year 1972. As a result, he maintains, EPA's estimate is conservative.

EPA examined 67 samples from the 1,026 reported shipments and found 26, or 39 percent, to be violative.

EPA's records showed many instances when unreported imported pesticides were also in violation of FIFRA, as illustrated by the following examples.

Example A--A sample of a pesticide imported from a European country was collected from a New York to Hawaii shipment made in July 1971. EPA's examination of this sample revealed that the pesticide label did not contain the following information, as stated in the citation issued to the importer.

"Misbranded in that the label did not bear on the front panel or the part of the label displayed under customary conditions of purchase the warning or caution statement 'Keep out of reach of children' and a signal word such as 'Danger.'

"Misbranded in that the label did not bear a warning or caution statement which is necessary and, if complied with, adequate to prevent injury to living man and other vertebrate animals.

"In that the directions for use for the product differed in substance from the representations made in connection with its registration.

"The product's label failed to bear the signal word 'poison' in red on a contrasting background on the front panel. The product's label failed to bear the precautionary labeling: * * *."

The importer subsequently corrected the labels.

The importer, in a letter dated October 24, 1973, stated that it had always been alert to, and eager to comply with, all developing regulatory and labeling requirements affecting pesticides. The importer further stated that the citation resulted from an unavoidable delay in complying with changing labeling requirements.

However, the citation was issued because the label on the July 1971 shipment differed from the label registered by EPA in May 1967. In a January 1972 letter to EPA, the importer stated that the improper label was inadvertently applied when the supply of registered labels was exhausted. The importer further stated that the defective labeling was

not detected because the shipment passed through the Customs broker and into and out of its warehouse without further inspection.

EPA stated that it is the importer's duty to determine that the pesticides it imports and distributes are properly labeled and in full compliance with FIFRA.

Example B--EPA's examination of another imported pesticide showed that it was unregistered and that its label did not contain the required warning or caution statements to prevent injury to humans and animals. Customs had not reported the shipment, and the pesticide was marketed in this country for about 2 years before EPA collected a sample. The importer told EPA that it was unaware that registration was required. All stocks of the pesticide had been sold, and the importer told us it was no longer being imported.

Example C--In March 1972 a shipment of about 615,000 gallons of creosote oil was imported. Customs officials reported this shipment to EPA which, in turn, requested that Customs detain the shipment because the pesticide was not registered. In April 1972 EPA notified the importer that this pesticide would have to be registered before it could be released. The importer submitted a registration application for the pesticide on April 19, 1972, and EPA registered it on January 4, 1973.

The importer told us that, from November 1971 through October 1972, it imported seven other shipments of creosote oil consisting of approximately 3.8 million gallons. EPA's import records showed that Customs officials had reported only one of these seven shipments to EPA. Customs officials said that they did not report these imports to EPA because they did not realize creosote oil was considered a pesticide.

Problems in identifying chemical imports as pesticides

EPA gave the Bureau of Customs a checklist of the most frequently imported pesticides and their chemical names and asked that Customs personnel report the arrival of all shipments of these pesticides and chemicals. Our comparison of the entry documents at four Customs district offices with the EPA checklist revealed many instances when imported chemicals on the checklist were not reported to EPA. For example, at

the Houston district office we examined all entries for September 1972 and identified 21 shipments of chemicals that were on the EPA checklist. Only two of these shipments had been reported to EPA.

According to Customs officials at the four district offices, not all import shipments were reported to EPA because Customs officials

--failed to recognize the chemicals as pesticides,

--misinterpreted EPA's reporting instructions,

--had previously determined that the chemical was not intended to be used as a pesticide,

--were not aware that pesticides had to be reported to EPA, or

--were not given EPA's checklist (in two of the four district offices).

These reasons indicate a lack of adequate coordination between EPA and Customs personnel. As a result, many imported pesticide shipments were not reported and EPA did not have the opportunity to inspect the pesticides to determine their compliance with the act.

Efforts to improve reporting

During early 1971 EPA met twice with Customs officials in Washington, D.C., to inform them of their reporting responsibilities under the joint regulations and to emphasize that EPA cannot achieve an effective surveillance program unless Customs personnel report all pesticide imports.

According to EPA officials, Customs personnel said that reporting pesticide imports and collecting pesticide samples were burdens on their staff--especially at the larger ports. They also said that it was sometimes difficult to determine whether certain chemical imports were actually pesticides and subject to the FIFRA reporting requirements. Customs personnel were also concerned that reporting pesticide imports to EPA could delay release of the shipment and could result in importers' paying added storage costs.

In March 1971 a Customs official in Baltimore suggested to EPA that some of the reporting problems could be eliminated if the import broker, instead of Customs, completed the documentation (EPA Form 3540-1) required for pesticide imports.

EPA and Customs officials considered this a workable solution and stated that it would be incorporated into the FEPCA import regulations which the Secretary of the Treasury, in consultation with the Administrator, EPA, was required to prescribe by January 19, 1973. However, because of administrative problems, the Secretary of the Treasury had not issued these regulations as of March 1974. EPA officials estimated that, with this new procedure and improved coordination between EPA and Customs personnel, the number of pesticide shipments not reported would be reduced significantly.

Customs advised us by letter dated September 19, 1973 (see app. II), that, although EPA and Customs had temporarily lost contact when EPA assumed administrative responsibility for pesticides, liaison with EPA had been firmly reestablished. In addition, Customs stated that it would forward the pesticide checklist to all Customs field offices.

INADEQUATE CONTROLS OVER IMPORTED PESTICIDES

Customs reported 1,026 pesticide shipments to EPA during fiscal year 1972.

Because EPA delayed collecting and analyzing samples of imported pesticides, some pesticides were partly or completely sold before EPA determined that they did not comply with the law. Of the 67 samples of imported pesticides that EPA collected during fiscal year 1972, 20 were collected after the products had entered the channels of trade; the others were collected at the port of entry.

The 20 pesticide shipments not sampled were in the channels of trade an average 128 days before the samples were collected and 243 days before the Pesticide Enforcement Division completed its reviews. As a result, 3 of the 11 shipments EPA found to be in violation of FIFRA had been completely sold by the time EPA informed the importers that the pesticides had to be brought into compliance with the act. Only the unsold portion of the other shipments could be brought into compliance.

PERSONNEL LIMITATIONS

EPA officials attributed their loose controls over imported pesticides to personnel limitations. They stated that in fiscal year 1972 their 30 field inspectors, who were responsible for monitoring domestic and imported pesticides sold in the United States, investigating pesticide accidents, cooperating with State pesticide regulatory agencies, and many other duties, were insufficient to maintain effective surveillance over pesticides.

The personnel problem was especially serious in the New York region. Not only are the largest number of registered pesticides manufactured in this region but, according to EPA, 60 percent of all pesticide imports enter the country through the New York ports. However, in fiscal year 1972 EPA had only three pesticide inspectors for the region. EPA personnel in New York stated that three inspectors were not enough to satisfactorily cover domestic pesticides, let alone the large number of imported pesticides.

In November 1972 the New York region asked EPA headquarters for six more inspectors to cover pesticide imports in that region. In March 1973 EPA authorized the hiring of three more pesticide inspectors for the New York region, and EPA personnel stated that in fiscal year 1974 the New York region would have 14 or 15 inspectors.

CONCLUSION

Better coordination between EPA and Customs could improve the reporting and sampling of imported pesticides and, as a result, could reduce the number of pesticides imported in violation of the law. EPA needs to expand its import sampling program and to act quickly to reduce the marketing of imported pesticides which are in violation of the act.

RECOMMENDATIONS TO THE SECRETARY OF THE TREASURY AND THE ADMINISTRATOR OF EPA

We recommend that the Secretary of the Treasury promptly prescribe the import regulations required by section 17(e) of FEPCA.

We recommend that the Administrator of EPA expand the import market surveillance program and establish procedures to insure that samples of imported pesticides are collected and tested promptly.

AGENCY COMMENTS

In commenting on our report, EPA advised us that, with the assistance and concurrence of the U.S. Customs Service, its Pesticides Enforcement Division had developed a new import program which should minimize the number of ineffective or unsafe pesticides imported into the United States. EPA stated that proposed regulations to implement section 17(c) of FEPCA would require importers to obtain EPA clearance before importing a pesticide; also EPA would periodically review entry papers to determine unreported pesticides.

EPA said it intended to visit virtually all ports of entry during fiscal year 1974 and stated that:

- The number of import examinations and/or samples collected would increase.
- The regional offices planned to devote over 10 man-years to the import program, a major increase.
- The New York region had hired two full-time import inspectors and would hire another inspector and a full-time case preparation officer if needed.

Customs advised us by letter dated September 19, 1973, that:

- The regulations required to implement the import provisions of FEPCA would soon be published in the Federal Register as a notice of proposed rulemaking.
- The regulations would require importers to obtain EPA clearance before importing pesticides and would thus reduce Customs' administrative burden.
- Its procedures would be streamlined because most samples would either be collected by EPA inspectors or be submitted by the importers.

As mentioned on page 18, these regulations had not been issued as of March 1974 because of administrative problems.

CHAPTER 4

NEED TO EXPAND SAMPLE ANALYSIS CAPABILITIES

EPA's pesticide laboratories conducted both chemical and biological tests on pesticide samples to determine whether they complied with FIFRA's requirements. Chemical tests were made to determine whether the pesticides contained the proper percentages of ingredients as stated on the approved label and whether contaminants were present. Biological tests were used to determine the pesticides' safety and effectiveness. The test results were to be used as a basis for enforcement actions. (See ch. 5.)

An effective market surveillance program depends on a thorough testing program and the use that is made of the test results. However, EPA (1) lacked the staff, facilities, and equipment to biologically test most samples for safety and effectiveness, (2) was not effectively using test results, and (3) did not conduct studies to determine the effective life of any pesticide.

LABORATORY LIMITATIONS

EPA needs to place greater emphasis on the biological tests to protect the consumer from unsafe and ineffective pesticides. As shown by the following table, 16 percent of the samples tested for safety and 28 percent of the samples tested for effectiveness between January 1, 1971, and June 30, 1972, were found to be defective. Despite these high rates, only 19 and 32 percent of the samples collected were tested for safety and effectiveness, respectively. By contrast, the chemical laboratories, whose tests showed that 15 percent of the samples were defective, analyzed 93 percent of the samples collected.

	<u>Biology Laboratories</u>		<u>Chemical laboratories</u>
	<u>Safety</u>	<u>Effectiveness</u>	
Number collected	9,344	9,344	9,344
Number analyzed	1,795	3,008	8,660
Percent analyzed	19	32	93
Number defective	295	840	1,312
Percent defective	16	28	15

An EPA official agreed that more emphasis should be placed on safety and effectiveness testing but indicated that emphasis was placed on chemical analysis because it is quicker.

EPA had five chemical and six biological laboratories for testing pesticide samples. Although the five chemical laboratories had the capability to test most samples, safety and effectiveness testing by the six biological laboratories was limited because of inadequate staffing, facilities, and equipment.

Chemical laboratories

EPA's chemical laboratories tested 8,660 of the 9,344 samples collected between January 1, 1971, and June 30, 1972. The remaining samples were not analyzed because (1) the pesticides were unregistered or the label did not contain an ingredient statement, (2) the laboratory did not have the equipment or an acceptable method to test the pesticides, (3) the product was not subject to FIFRA, (4) the review had to be expedited, (5) the sample was damaged when it arrived at the laboratory, or (6) the pesticides had been recently tested.

The laboratories emphasized testing samples for chemical composition. They also screened about 70 percent of the samples for such pesticide contaminants as chlorinated hydrocarbons (including DDT, aldrin, and dieldrin), and organophosphates (including malathion and parathion). EPA personnel stated that they did not screen for other toxic contaminants because reliable methods for screening were not available or the methods available were time consuming and would thus prevent other pesticides from being tested.

Biological laboratories

Safety testing

The biological laboratories' tests for safety were limited because, according to EPA personnel, the laboratories lacked adequate space, staffing, and equipment. These limitations precluded EPA from making long-term safety tests, such as inhalation studies and studies on the effects of prolonged exposures to pesticides. Emphasis was placed on testing

pesticides for acute (short-term) oral, dermal (skin), and ocular (eye) toxicity to mammals.

Between January 1, 1971, and June 30, 1972, 1,795 of the 9,344 samples collected were tested for acute toxicity to mammals. Another 200 samples were tested for toxicity to fish and plants. The remaining samples were not tested for safety.

Effectiveness testing

Of the 9,344 samples collected, only 3,008 were tested for effectiveness. According to EPA personnel, the remaining 68 percent were not tested for effectiveness because EPA lacked personnel, equipment, and facilities. Registration Division personnel stated that some samples were not tested for effectiveness because other samples of these pesticides had recently been found effective. However, many pesticides were repeatedly tested although they had been found effective in previous tests.

Effectiveness tests were limited to (1) rodenticides on rats and mice, (2) household insecticides on houseflies and cockroaches, (3) crop fungicides on a few fruits, vegetables, and decorative plants, (4) herbicides in turf, crop, and vegetation control, (5) crop insecticides, (6) plant regulators, (7) household fungicides, (8) algacides, and (9) bactericides. The lack of space and personnel limited the scope and duration of these tests.

Testing was also limited because EPA, for the most part, did not have the facilities to test pesticides where they were primarily used. Federal statutes prohibit the movement of certain pests out of an infested area. For example, a herbicide for controlling alligator weed can be tested only in the States in which the weed grows naturally because the weed may not be moved to other localities. EPA's plant biology laboratories in Beltsville, Maryland, and Corvallis, Oregon, lack staff and equipment to make extensive field tests in the areas where the weed grows.

Rodenticide samples were tested only on mice and albino rats raised in captivity on a laboratory diet at the Beltsville laboratory. Because rats in their natural environment adapt to the available food supply, rat baits should be tested in the areas in which they are sold. Also, these rodenticides

should be tested on the different types of rats they are intended to control, but norway and black rats, the most common types, are not raised commercially. EPA is trying to raise norway rats at the Beltsville laboratory by simulating their natural environment, but black rats, especially dangerous because of the diseases they may carry, cannot be brought to Beltsville because they might spread from the Southern States to other parts of the country.

Other rodenticides cannot be tested at all because the rodents (such as moles, gophers, and prairie dogs) cannot be grown in captivity and/or are found only in certain parts of the country.

Because of inadequate facilities or because testing procedures had not been fully developed, the biological laboratories did not test some major pesticide categories for effectiveness. These categories included animal repellents, nematocides (pesticides for controlling round unsegmented worms), viricides (pesticides for controlling viruses), and insecticides for use on livestock, pets, premises, and stored products. Pesticides for use on pets and livestock can no longer be tested because the Department of Agriculture kept the Kerrville, Texas, laboratories, which had been used for such tests, when other pesticide laboratories were transferred to EPA in December 1970. Since then EPA has unsuccessfully attempted to obtain suitable facilities.

EFFECTIVE LIFE OF PESTICIDES NOT ESTABLISHED

The active ingredients in many pesticides can decompose with age. Among these ingredients are sodium hypochlorite, malathion dust, parathion dust, carbon disulfide, hydrogen chloride, carbaryl, and dry DDVP products. According to EPA laboratory personnel, some classes of pesticides become more toxic upon decomposition.

Registered pesticides must meet FIFRA requirements not only when they are manufactured but also at any time before they are sold. Thus, although correctly formulated when manufactured, pesticides do not comply with the act if they are chemically deficient at the time of sale. Also some disinfectants may become ineffective after lengthy storage, even though they are chemically satisfactory.

EPA laboratories, however, have not done any shelf-life studies to find out rates of decomposition and the periods for which pesticides can be expected to be effective. The results of these studies should form the basis for future registration policy for all pesticides with the same decomposable ingredients. The future policy should include using expiration dates on some pesticides to remove them from the market when they can no longer be expected to be effective.

TESTING PESTICIDES BEFORE REGISTRATION

Before registering a pesticide, EPA must determine whether the pesticide will perform its intended function without unreasonable adverse effects on the environment. However, EPA generally relied upon manufacturers' test data in determining whether to register pesticides. The biological laboratories made some limited tests before registration but primarily tested pesticides after they were registered and being marketed.

Of the samples the biological laboratories found to be defective, over 94 percent were tested and found to be chemically satisfactory. Many of these biologically defective pesticides were repeatedly found to be ineffective or underlabeled for toxicity.

Such test results indicate that many pesticides are ineffective or their labels contain inadequate safety precautions when they are registered. The high rate of biologically defective pesticides in certain categories, such as disinfectants and rodenticides, indicates a need for EPA to test pesticides, at least in these categories, before registering them.

CONCLUSIONS

Although 16 percent of the samples tested for safety and 28 percent of the samples tested for effectiveness were defective, EPA did not have the capability to test most of the samples collected. Thus, the number of unsafe and ineffective pesticides being used by consumers could be significant.

Efforts to remove such pesticides from the market depend on EPA's ability to test the pesticides for safety and

effectiveness and on the sampling program's coverage of the pesticide market. To better assure the public of the pesticides' safety and effectiveness, EPA should test more pesticides that are being marketed and should test some pesticides before registration. EPA should also determine the effective life of pesticides.

RECOMMENDATIONS TO THE ADMINISTRATOR, EPA

We recommend that the Administrator of EPA:

- Initiate measures to obtain the additional personnel, space, and equipment necessary for conducting a sufficiently broad and thorough testing program.
- Take steps to determine the effective life of decomposable pesticides.
- Require that expiration dates be included on the labels of decomposable pesticides.
- Establish procedures for testing, before registration, disinfectants and rodenticides and any other pesticide categories which EPA has found in its market surveillance program to have a high rate of biological defects.

AGENCY COMMENTS

EPA advised us that its laboratory capabilities would be expanded as budget and staffing limitations permit and that a total plan for safety and effectiveness evaluation was being formulated to encompass both preregistration and post-registration evaluations and to permit the consideration of shelf lives of decomposable pesticides.

EPA pointed out that it required registrants to submit shelf-life studies on pesticide products which were known to be susceptible to decomposition, such as sodium hypochlorite. EPA advised us that expiration dates would be required for those pesticides which were shown to have significant decomposition potential.

CHAPTER 5

NEED TO USE ENFORCEMENT ALTERNATIVES

MORE EFFECTIVELY

In a report to the Congress¹ we stated that the Federal Government's lack of action in prosecuting manufacturers for serious or repeated violations of FIFRA could indicate that major violations of the law would be treated with minimum consequence. During fiscal years 1959-68 no manufacturers were referred to the Department of Justice for prosecution.

Since then EPA activity in this regard has increased steadily and over 250 cases were referred to the Department of Justice for prosecution during fiscal year 1973. In addition, EPA, in May 1973, began to assess civil penalties under authority granted by FEPCA.

However, EPA did not effectively use other enforcement alternatives--cancellation and recall. It repeatedly found many pesticides to be ineffective but canceled the registrations of only three during fiscal year 1972. In most cases it did not ask manufacturers to recall shipments from which ineffective pesticide samples were collected. Also, after an August 1972 change in sample processing procedures, it did not normally notify manufacturers of biological deficiencies found in their pesticides.

As shown by the following table, EPA found 1,159, or 21 percent, of the 5,568 pesticide samples reviewed for enforcement action during fiscal year 1972 to be in major violation of the act--cases that would warrant such actions as seizure or prosecution. This high violation rate was an increase over the fiscal years 1970 and 1971 violation rates of 16 and 17 percent, respectively.

¹"Need to Improve Regulatory Enforcement Procedures Involving Pesticides" (B-133192, Sept. 10, 1968).

Samples received for enforcement review	5,568
Samples in violation of the law:	
Major violations (citations)	1,159
Minor violations (enforcement correspondence)	<u>650</u>
Total	<u>1,809</u>
Seizures requested	49
Recalls requested	122
Cases referred to the Department of Justice for prosecution	39
Registrations canceled for ineffectiveness	3

CANCELING THE REGISTRATIONS
OF INEFFECTIVE PESTICIDES

As discussed in the preceding chapter, 28 percent of the pesticide samples tested were found to be ineffective for one or more of the purposes claimed on their labels. For example, between January 1, 1971, and June 30, 1972, EPA laboratories tested 1,117 samples of disinfectants and 871 samples of rodenticides for effectiveness and found that 281, or 25 percent, of the disinfectant and 278, or 32 percent, of the rodenticide samples were ineffective.

FIFRA authorized the EPA Administrator to cancel the registration of a pesticide if it did not meet the manufacturer's claims for effectiveness. As illustrated by the examples, EPA did not always cancel pesticides' registrations or require registrants to delete the effectiveness claims from the labels of repeatedly ineffective pesticides.

Example D--On March 5, 1968, EPA registered a disinfectant whose label claimed that it would clean, disinfect, and deodorize floors, walls, bathroom fixtures, and hospital rooms and equipment. The approved labels also stated that using the disinfectant at the recommended dilutions would kill

staphylococcus aureus¹ and salmonella cholereasuis² organisms. Although the label did not contain any effectiveness claims against pseudomonas aeruginosa,³ EPA required that all hospital disinfectants be effective against this organism unless the label prominently displayed a disclaimer to this effect. This label did not have a disclaimer.

EPA tested 16 samples of this disinfectant from February 1968 through August 1972 and found 13 to be ineffective. Its test results for the ineffective samples follow.

<u>Tested</u>	Organism for which disinfectant was found to be ineffective		
	<u>Staphylococcus aureus</u>	<u>Salmonella cholereasuis</u>	<u>Pseudomonas aeruginosa</u>
2-23-68	x	x	
5-24-68	x		
1-26-70	x	x	x
7- 2-70			x
7- 8-70	x		x
12- 9-70	x		
11-27-70	x	x	x
3- 5-71	x		x
4- 1-71	x		
4- 5-71	x		x
1-28-72			x
5- 1-72			x
8-28-72	x		x

¹An organism which causes food poisoning outbreaks. When the organism enters the body through cuts, breaks, operations, or abrasions in the skin, boils, abscesses, carbuncles, and fatal blood poisoning can occur.

²An organism which causes paratyphoid fever, a disease similar to, but milder than, typhoid fever. It is also the cause of a type of food poisoning called salmonellosis.

³An organism that is the primary cause of death in burn patients.

Although the manufacturer was generally notified of the deficiencies and was asked to recall 7 of the 13 shipments from which ineffective samples were collected, EPA did not ask the manufacturer to (1) furnish more test data to support claims for the disinfectant's effectiveness or (2) delete any of the effectiveness claims from the label. After we completed our review, EPA, on January 11, 1974, notified the manufacturer of its intent to cancel the pesticide's registration and, on February 19, 1974, the registration was canceled.

We gave the manufacturer an opportunity to submit written comments on the foregoing test history. As of March 1974, we had not received such comments.

Example E--In July 1968, EPA renewed the registration of a sanitizing agent. The label for this pesticide had directions for using it to sanitize utensils and equipment in eating establishments, food- and milk-processing plants, and barber and beauty shops. The label also claimed that the sanitizer would be effective for the recommended uses in waters up to 550 parts per million (p/m) of hardness. EPA's regulations state that hard waters slow down germicidal activity in some germicides, disinfectants, and sanitizers to the extent that they may not perform satisfactorily in all hard-water areas.

From July 1967 to June 1972, EPA tested 29 samples of the sanitizing agent for effectiveness and found that 25 had a hard-water tolerance of less than 550 p/m, which would make the sanitizer ineffective in such waters.

In March 1969 the Chief of EPA's Disinfectant Evaluation Staff recommended to the Assistant Director for Enforcement that this pesticide's registration be canceled and stated that:

"This is a deficiency of long standing and is considered by Bacteriology to be a very serious one in view of the stature of the manufacturer and common knowledge in the trade that this product as currently distributed possesses this deficiency. For the past 12 months I have been receiving telephone inquiries from public health

officials and competitors calling this problem to our attention and posing the question 'When is the Department going to do something about this situation?'"

Not until September 1970 did EPA ask the manufacturer for more data to support the hard-water tolerance claims. When the manufacturer did not respond to the request, or to an April 1971 followup, EPA, in November 1971, issued a notice of its intent to cancel the registration. In February 1972 the manufacturer submitted a revised label claiming effectiveness in waters up to 400 p/m hardness. EPA did not accept the label because of other questionable safety and effectiveness claims. The manufacturer resubmitted the label in January 1973 and proposed deleting all claims for hard-water tolerance. In March 1973, EPA again rejected the proposed label because other labeling claims were not acceptable. As of January 1, 1974, this manufacturer had not submitted a revised label and could still market the sanitizing agent with a claim for effectiveness in waters of up to 550 p/m hardness.

In commenting on the foregoing information, the manufacturer, by letter dated January 7, 1974, stated that our comments did not reflect its newly approved application for a replacement product. The manufacturer declined to make further written comments, however, because of pending litigation the Federal Government started in August 1973.

An EPA official told us that the manufacturer applied for a new registration for a replacement product in March 1973 but that the registration had not been granted as of January 1974. He indicated that the registration would be accepted with a claim for effectiveness in waters up to 600 p/m hardness on the basis of data submitted by the manufacturer. Because of the problems noted in the existing product, we feel that EPA should test the product in its own laboratory before granting the registration.

Example F--From December 1968 through January 1972, EPA tested eight samples of a rat and mouse killer and found all of them ineffective for the control of rats and/or mice. Each time EPA informed the manufacturer that the rodenticide was ineffective because it did not meet EPA's minimum criteria for bait acceptance and mortality.

EPA also instructed the manufacturer each time to make sure that future batches of the rodenticide complied with all provisions of the act.

In four reports issued between January 1970 and January 1971, laboratory personnel questioned the continued registration of rodenticides claiming to control both rats and mice. In the January 1971 monthly report, laboratory personnel stated that:

"Baits which have tested as satisfactory for rats seldom pass the tests when used for mice. Conversely, many of the poorest rat baits have tested satisfactorily for mouse control. Only a few test satisfactorily for both animals. Based on our recent studies, we believe that most dual registered baits should be registered for only one animal."

Laboratory personnel indicated that they had discussed the problem with registration personnel and understood that registrations would be canceled when their renewal was requested unless the manufacturer submitted more data to prove the effectiveness of the product for both rats and mice.

Even though EPA's laboratory tests showed repeatedly that samples of this rodenticide were ineffective, EPA did not, as would seem to have been warranted, cancel or question its registration. Nor did EPA question its effectiveness when the registration was renewed in March 1971.

We gave the manufacturer an opportunity to comment on the foregoing information. The manufacturer, by letter dated October 29, 1973, stated that it had discontinued the rat and mouse killer because of poor acceptance. The manufacturer stated, however, that it repeatedly tried to improve the product before discontinuing it.

An EPA official told us that several factors prevented EPA from canceling more ineffective pesticides. He said that manufacturers often requested portions of the samples EPA found to be ineffective and that cancellation action was not taken until the manufacturers had completed their tests on the samples and any differences in the test results were resolved. In many cases, additional samples were analyzed to resolve the differences. In addition, the official stated

that cancellation action was not begun if the pesticide was involved in litigation.

We question whether manufacturers should be allowed to continue marketing ineffective pesticides while litigation is pending. To protect the consumer, EPA should revise pesticides' registration status--such as deleting certain claims from the label or canceling the product's registration--whenever it determines that a pesticide is ineffective for the purposes claimed.

RECALLING INEFFECTIVE PESTICIDES

EPA has procedures for the voluntary recall of violative pesticides because it found that the most efficient means of removing ineffective or hazardous pesticides from the market was through the manufacturers' cooperation. EPA's policy on recall states that:

"Recalls will be initiated in all cases where the available information indicates that the product is (a) potentially hazardous when used as directed, or (b) ineffective for the purposes claimed."

However, EPA did not normally ask manufacturers to recall ineffective pesticides, and many remained in the channels of trade.

As mentioned on page 28, EPA's laboratory tests disclosed that 25 percent of the disinfectant samples and 32 percent of the rodenticide samples tested between January 1, 1971, and June 30, 1972, were ineffective. As illustrated below, EPA normally did not ask the manufacturers to recall the production lots from which these samples were drawn.

	<u>Number of ineffective samples</u>	<u>Number of recall requests</u>
Disinfectants	281	80
Rodenticides	<u>278</u>	<u>10</u>
Total	<u>559</u>	<u>90</u>

In many instances the disinfectants were ineffective because they failed to prevent or control organisms, such as staphylococcus aureus, salmonella cholereasuis, and

pseudomonas aeruginosa, on surfaces in hospitals, sickrooms, restaurants, food-processing plants, restrooms, and private homes. EPA's decisions not to request the manufacturers to recall these ineffective pesticides were inconsistent with its recall policy and allowed consumers to unknowingly purchase ineffective pesticides.

For example, during the period January 1968 through December 1972, EPA's test results showed that 64 samples of certain disinfectants produced by one manufacturer were ineffective. EPA requested the manufacturer to recall only 4 of the 64 production lots. Many ineffective disinfectants remained in the channels of trade, and the manufacturer continued marketing ineffective pesticides.

EPA officials informed us that they did not ask manufacturers to recall ineffective pesticides in all cases because the success of their recall program depended on manufacturers' cooperation. They stated that their recall program had been successful in the past because manufacturers found that EPA made recall requests only in serious and extraordinary situations. They stated that, as a result, ineffective pesticides were recalled only if they posed a hazard to the user.

Allowing ineffective pesticides which do not, in EPA's opinion, pose a hazard to the user to remain on the market could indicate to manufacturers that such violations will be treated with minimum consequence. In addition, such actions do not protect the consumer from products that do not perform the job as claimed by the manufacturer.

Although neither FIFRA nor FEPCA gives EPA recall authority, EPA has used seizure orders, or the intent to obtain such orders, to supplement the recall program when manufacturers have refused to voluntarily recall a pesticide shipment. Under FEPCA, EPA also can issue an order to prohibit the sale, use, or removal of violative pesticides. Manufacturers' knowledge that EPA has such authority and will use it should enable EPA to adequately enforce its recall requests.

MANUFACTURERS NOT NOTIFIED OF DEFECTS

Under revised sample processing procedures implemented in August 1972, enforcement action was not to be delayed

pending completion of the biological tests, which sometimes take several months. Registrants were to be notified promptly of any sample deficiencies found as a result of (1) a registration status check, (2) the chemistry laboratory tests, and (3) a comparison of the sample's label with the approved label.

Although EPA had no written procedures for processing biological test results, registration personnel indicated that they were instructed to notify the manufacturer of any defects found in a sample and to ask the manufacturer to inform the Registration Division of any planned corrective action. They also were instructed to send the biological test results to the Enforcement Division only if they felt the pesticide should be recalled. The Enforcement Division was to decide whether to recall a pesticide.

Between July 1, 1972, and January 31, 1973, the biology laboratories reported 260 samples as defective. We reviewed the registration files for 55 to determine what action had been taken. The Enforcement Division issued citations on seven samples because of biological deficiencies found in tests completed before the revised processing procedures were implemented in August 1972 or because of deficiencies found in chemical tests or label reviews. For the 48 samples processed after the effective date of the revised processing procedures, the Registration Division notified the manufacturers of the test results in only 2 cases. Moreover, the Registration Division referred none of the 48 cases to the Enforcement Division for possible enforcement or recall action.

Registration Division personnel told us that action might not have been taken on many of the samples because reviewers questioned the significance of the test results. They agreed, however, that notifying manufacturers of all possible deficiencies, even if the results were inconclusive, could alert the manufacturers to possible defects in their pesticides. An EPA official stated that in many other cases the test results were significant and would be used as a basis for canceling the pesticide's registration.

PURCHASING DEFECTIVE PESTICIDES

The primary objective of an enforcement program should be to protect the consumer. Although EPA's policy is to notify manufacturers when it discovers an ineffective or chemically deficient pesticide shipment, it does not normally notify the public. Not only were consumers exposed to pesticides which EPA found to be frequently in violation of the act but also other Federal agencies purchased quantities of these pesticides and in some cases, in effect, recommended their use to the consumer.

Enforcement actions directed at the manufacturers of defective pesticides may eventually achieve compliance but frequently do not offer the consumer immediate protection.

As shown by the following examples, Federal agencies were purchasing or, in effect, recommending the purchase of ineffective pesticides or pesticides manufactured by firms with records of frequent violations.

Example G--Between May 1968 and February 1972, two of a manufacturer's registered disinfectants were found to be ineffective nine times. Two other samples were found to be chemically deficient. EPA asked the manufacturer to recall 6 of the 11 shipments.

In March 1972 the General Services Administration (GSA) awarded this manufacturer a contract totaling \$102,525 for the purchase of seven registered disinfectants, including the two mentioned above. After the contract was awarded, two more enforcement actions were taken against this manufacturer because the two disinfectants were ineffective or chemically deficient. EPA asked that one shipment be recalled. Another product included in GSA's purchase was cited for ineffectiveness in March and May 1972 and was recalled by the manufacturer at EPA's request on both occasions.

Also a Veterans Administration (VA) hospital official said that VA hospitals generally purchase their own disinfectants and that the two disinfectants mentioned above were among those most frequently purchased.

The manufacturer commented in October 1973 on the foregoing information, and we have considered its comments in preparing this report.

Example H--Enforcement action was taken on 78, or 26 percent, of the 303 samples of another manufacturer's pesticides collected from January 1968 through June 1972--EPA found that 52 of the samples were in major violation of the act. The FIFRA violations included interstate shipment of pesticides that were not registered, were chemically deficient, were contaminated, or were ineffective.

During 1973 GSA had several contracts with this manufacturer to buy a herbicide which EPA found to be in violation in July 1970 and again in November 1972. At least one VA hospital purchased a rodenticide produced by this manufacturer which had been previously found to be ineffective.

The manufacturer commented in October 1973 on the foregoing information, and we have considered its comments in preparing this report.

Both GSA and VA told us that they did not normally test pesticides before purchasing them. These agencies rely on EPA to insure that the pesticides comply with the act.

Example I--In October 1972 the Department of Agriculture published a list of pesticides authorized for use in the Department's poultry, meat, rabbit, and egg product inspection programs. Pesticides were classified as to the uses for which they were authorized. Users could conclude that pesticides on this list have been accepted by the Department as effective. However, EPA tested many of these pesticides and found them to be ineffective.

Consumers, including Government agencies, assume that when a pesticide is registered with EPA it is safe and effective when used as directed. As a result, they do not normally test pesticides before using them, nor do they consult EPA to determine the quality of the manufacturer's products.

CONCLUSIONS

The rate of FIFRA violations increased from 16 percent in fiscal year 1970 to 21 percent in fiscal year 1972. Also, many pesticides which were repeatedly found to be ineffective remained on the market. Thus it is apparent that EPA needs to improve its program for preventing the marketing of defective pesticides.

EPA should cancel the registration of pesticides repeatedly found to be ineffective and should request manufacturers to recall the production lots from which ineffective samples are found. In addition, manufacturers should be notified of all deficiencies found in their pesticides.

Because it is EPA's policy to notify only the manufacturers of the defects in their products, consumers, including Federal agencies, often are unaware that they are purchasing ineffective or chemically deficient pesticides. To protect the public, EPA should promptly release information concerning defective pesticides.

AGENCY COMMENTS

In commenting on our proposal that EPA cancel the registrations or delete certain claims from the labels of those pesticides found to be consistently ineffective, EPA stated by letter dated October 12, 1973, that it would initiate cancellation action when it found a pesticide to be ineffective. EPA stated further that it had approximately 36 such potential cancellation actions in hand. On January 11, 1974, EPA published in the Federal Register a notice of its intent to cancel the registration of 32 pesticides because of their ineffectiveness.

EPA agreed with our view that, in order to protect the public, it should promptly release information concerning enforcement activities. EPA stated that, to establish a prompt and systematic reporting system for all the regions, it would issue guidelines for reporting (1) criminal prosecutions, (2) seizures, (3) civil proceedings, (4) stop sale, use, and removal orders, and (5) voluntary recall actions. These guidelines were issued on October 30, 1973.

EPA said that information would also be made public when a pesticide product was suspended or canceled because of potential hazard or ineffectiveness and that press releases and telephone contacts with the news services would be the primary media through which this information was communicated to the public. EPA also said that it planned to make enforcement histories available to Federal, State, and local agencies upon request and to publish in the Federal Register a notice that such information was available, listing the names and addresses of the persons to be contacted.

We believe that the actions taken and planned by EPA should help assure consumers that the pesticides they purchase are effective.

With respect to the recall of production lots from which ineffective samples were taken, EPA said its policy was to request voluntary recall of unsafe and ineffective pesticides and to back up such requests with seizure and stop-sale actions if recall was not initiated. EPA advised us that the added enforcement tools FEPCA provided expanded its ability to move against violative products and producers and would also make the recall program more effective.

EPA stated that more recall requests could be issued than the inspection staff could supervise; therefore, it screened all potential recall actions, and many less serious cases resulted in informal recalls which did not require field supervision. EPA pointed out that an average 88 informal recall requests were made from fiscal year 1971 through fiscal year 1973 for all types of defects. EPA said that, in deciding to recall pesticides, it considered the potential hazard involved and the scientific opinion regarding the significance of the test results.

The recall information in this report, particularly the table shown on page 33, includes both formal and informal recalls. As can be seen, EPA normally did not ask the manufacturers--formally or informally--to recall the production lots from which ineffective samples were taken. Unsafe or ineffective pesticides should be recalled not only because of the potential health hazard involved but because the consumer is spending money for a product which is not doing the job which a Federal agency--EPA--requires it to do in order to be registered.

RECOMMENDATIONS TO THE ADMINISTRATOR, EPA

We recommend that, to provide the public with additional safeguards against unsafe and ineffective pesticides, the Administrator of EPA

- request manufacturers to recall those production lots from which EPA has collected ineffective samples and
- establish procedures for notifying manufacturers of all deficiencies found in samples of their pesticides.

CHAPTER 6

OPPORTUNITY TO SUPPLEMENT THE

PESTICIDE MARKET SURVEILLANCE PROGRAM

WITH STATE ASSISTANCE

Although all States require the registration of pesticides sold within their borders and most perform some degree of market surveillance over these pesticides, EPA made only limited use of the States' data to supplement its market surveillance program. As a result EPA and the States have duplicated efforts under their market surveillance programs. In light of EPA's added responsibilities under FEPCA and its limited resources, we believe EPA should consider using the States more in carrying out its pesticide programs and should help the States improve their capabilities to test pesticides.

STATE CAPABILITIES

Some States' pesticide registration laws, patterned after FIFRA, require the registration of all pesticides sold within the State. Other State laws, besides requiring registration (1) require commercial pesticide applicators and businesses selling pesticides for agricultural uses to be licensed and (2) restrict the sale, possession, and use of hazardous pesticides.

Many States have pesticide enforcement programs similar to EPA's. State inspectors collect samples of pesticides and send them to State laboratories for analysis. The revenue to conduct these programs generally comes from State pesticide registration fees.

According to EPA statistics, the States had about 493 inspectors collecting pesticide samples in December 1970. These inspectors normally were not full-time pesticide inspectors because they were also responsible for monitoring other State laws. EPA statistics showed that the inspectors spent only about 25 percent of their time on pesticide activities.

Most States had the laboratory capability to analyze the samples for chemical composition. However, according to EPA personnel, these States usually did not test the pesticides for cross-contamination, safety, or effectiveness because they did not have the capability or funds.

LIMITED USE AND EXCHANGE OF DATA
RESULTED IN DUPLICATION OF EFFORT

Because many State-registered pesticides were also federally registered, both Governments monitored the pesticides to insure that they were being marketed in accordance with applicable laws. Because there were limited exchanges of information between EPA and the States and because EPA did not always use the information provided by the States, there was duplication of effort.

For example, 40 percent of the 543 samples analyzed by California from July through December 1971 were registered with EPA, and at least 27 of these pesticides had been sampled and tested by both the State (50 times) and EPA (47 times). In addition, both the State and EPA took enforcement action against three manufacturers for similar violations.

We also identified at least 75 pesticides which both EPA and Texas laboratories analyzed during 1972.

EPA and the States we visited did exchange some information. However, EPA officials said that it could make only limited use of most of the information the States provided because it was not always developed according to EPA's test methods or it was incomplete or untimely. In such cases, we believe, EPA should work with the States to develop test methods and reporting systems acceptable for both State and Federal programs.

EPA officials told us that they had used the information the States provided only as leads to possible violations of the act and that information on which pesticides the States had sampled was not formally considered in EPA's pesticide market surveillance program.

EPA SHOULD USE STATE RESOURCES MORE

As we discussed earlier, EPA's market surveillance program has been hampered by personnel and laboratory limitations. These limited resources will be further taxed under FEPCA because EPA has more responsibilities, such as (1) registering all pesticides, not just those sold interstate, (2) monitoring the use of pesticides, (3) registering all pesticide-producing establishments, (4) prescribing standards for certifying pesticide applicators, and (5) approving State plans for certifying pesticide applicators.

FEPCA authorizes the EPA Administrator to enter into cooperative agreements with States:

"* * * (1) to delegate to any State the authority to cooperate in the enforcement of the Act through the use of its personnel or facilities, to train personnel of the State to cooperate in the enforcement of this Act, and to assist States in implementing cooperative enforcement programs through grants-in-aid; and (2) to assist State agencies in developing and administering State programs for training and certification of applicators consistent with the standards which he prescribes."

This authority to enter into cooperative agreements with the States gives EPA the opportunity to better use the States' resources in carrying out its market surveillance program. EPA should capitalize on the States' expertise--especially on pesticide problems or uses that are unique to individual States. EPA should also (1) help the States obtain adequate test capabilities and (2) work with the States to develop uniform sampling and testing procedures. Such cooperative agreements should improve the effectiveness of both State and Federal programs and should result in benefits such as those discussed below.

Sample collection

EPA estimates that under FEPCA the number of registered pesticides will increase from about 33,000 to about 70,000. This 112 percent increase represents pesticides which were manufactured and sold intrastate and, therefore, were not previously required to comply with Federal regulations. In

addition, EPA will be responsible for registering about 10,000 pesticide-producing establishments.

Under FEPCA, EPA plans to change its sample collection techniques. EPA inspectors will collect most of the samples from the manufacturers' plants rather than from the channels of trade, which should improve EPA's market surveillance program. We believe, however, that there is a need to continue sampling pesticides in the channels of trade to locate unregistered and decomposed pesticides and pesticides whose registrations have been suspended.

EPA should consider giving States the responsibility for collecting pesticide samples from the channels of trade. EPA could limit its role in this area to setting standards, working with the States to identify the number of samples to be collected, and monitoring the States' programs. A coordinated plan of this type would (1) cover the market better, (2) use the States' capabilities and expertise, and (3) reduce duplication of effort.

Surveillance of pesticide use

FEPCA prohibits using any pesticide in a manner inconsistent with its label. Because there are millions of pesticide users, this is an extremely difficult provision for EPA to enforce, particularly with its limited resources. EPA could rely on the States to identify possible misuses of pesticides which EPA could follow up by further investigation; enforcement action; and, if necessary, prosecution.

Laboratory analysis

According to EPA officials, the lack of resources to do field tests is one of the major weaknesses in EPA's effectiveness testing. Pesticides need to be tested at various locations throughout the country because pesticides are not always equally effective in all locations. Also, some pesticides are intended only for pests in certain locations; therefore, the effectiveness of these pesticides should be tested where these pests naturally exist.

Because EPA currently needs field tests to adequately test pesticides for safety and effectiveness, EPA should consider having State land-grant colleges do this testing.

EPA could arrange for it by either cooperative agreements, memorandums of understanding, or grants-in-aid.

EPA pesticide laboratory officials said that having land-grant colleges do the field testing would be a workable solution to EPA's limited capability. They said, however, that using these colleges would involve such administrative problems as (1) obtaining satisfactory agreements with the colleges, (2) getting the colleges to give this testing the proper priority, and (3) obtaining the necessary funds to finance such a program. They also stated that some of these colleges did research for pesticide manufacturers, which could create a conflict of interest problem. However, it seems that such problems could be resolved through proper administrative procedures and practices.

CONCLUSIONS

EPA made only limited use of the States in carrying out its market surveillance activities. If EPA used the States' resources more--especially in the areas of collecting pesticide samples from the channels of trade, monitoring the use of pesticides, and testing pesticides for safety and effectiveness--the Federal program could cover more pesticides.

RECOMMENDATION TO THE ADMINISTRATOR, EPA

We recommend that the Administrator of EPA use his authority to enter into cooperative agreements with the States to better use their resources in carrying out EPA's market surveillance program and to help the States obtain the necessary expertise. Particular consideration should be given to having the States (1) collect pesticide samples from the channels of trade, (2) monitor the use of pesticides, and (3) test pesticides for safety and effectiveness.

AGENCY COMMENTS

EPA said it intends to enter into cooperative agreements with the States to augment and improve its market surveillance capabilities.

EPA commented that in fiscal year 1973 efforts and resources were directed to building the regional FIFRA enforcement programs and decentralizing pesticides enforcement activities. EPA said that regional enforcement programs were

now operational and capable of participating with the States in joint enforcement efforts.

In addition, EPA stated that in fiscal year 1974 the Pesticides Enforcement Division plans to conduct a pilot study with a selected State and an EPA region to develop a cooperative program which would allow the States to collect samples from the market, conduct use and experimental permit surveillance, and analyze pesticide samples.

CHAPTER 7

SCOPE OF REVIEW

We reviewed and evaluated EPA's policies and practices for collecting and examining pesticide samples and initiating enforcement action when the pesticides were marketed in violation of the law. We examined pertinent legislation, documents, reports, and records and interviewed agency personnel at EPA regional offices in Dallas, New York, and San Francisco and at EPA headquarters in Washington, D.C.

We visited and obtained information at EPA's pesticide laboratories at Beltsville, Maryland; Denver; Bay St. Louis, Mississippi; New York; and San Francisco.

We interviewed agency personnel and reviewed pertinent records at Bureau of Customs headquarters in Washington, D.C., and at Customs offices in Houston, New Orleans, New York, and San Francisco.

We also obtained information from agency personnel at GSA and VA headquarters in Washington, D.C., and interviewed State pesticide control officials in Texas, New York, and California.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OCT 12 1973

Mr. Brian P. Crowley
Assistant Director
Resources and Economic Development Division
U. S. General Accounting Office
Washington, D. C. 20548

Dear Mr. Crowley:

The Environmental Protection Agency (EPA) generally concurs with the recommendations and conclusions of your draft report on pesticide enforcement. Steps have already been taken either to implement new programs or change existing programs in line with the suggestions made by the report. Additional enforcement capabilities given to the Agency by the Federal Environmental Pesticides Control Act (FEPCA) will strengthen our means of insuring that unsafe or ineffective pesticides do not reach the marketplace.

The following discussion will outline our present policy in the areas covered by your report, as well as policy and procedures which we intend to implement in the future.

Market Surveillance Program

EPA realized that the coverage of registered pesticides under the Selective Sampling Program was inadequate and that a more effective sampling program was needed. As an interim step, to reduce duplication, regional pesticide inspectors were furnished a computer printout listing the products registered and whether these products had been sampled in the previous three years.

In FY 1972, we began formulating plans for a new sampling scheme to replace the Selective Sampling Program. The new system was designed to provide for the collection of samples by product name thus eliminating much of the duplication of samples occurring under the old system. The system, however, would still be flexible enough to provide for the collection of samples from those firms with known violative histories and for the collection of follow-up samples to measure the effectiveness of corrective actions taken by the firms. By March 1973, we had developed a Random Sample Selection System in which 4,500 products were selected randomly for chemical analysis and 12,000 products (including the 4,500

APPENDIX I

for chemical analysis) for label review. To accomplish this, the pesticides inspectors will visit and inspect the establishments where the products are produced rather than at the wholesale and retail levels as in the past. Approximately 70% of the producers holding Federal registrations will be visited in FY 1974.

This new sampling program will enable EPA to:

- 1) Avoid duplication of sampling.
- 2) Direct sampling efforts to particular products.
- 3) Sample the products before they are distributed in the channels of trade.

To accomplish this sampling and inspection program the regional inspectional staffs were authorized an increase of twenty-four positions in FY 1974.

Controls Over Imported Pesticides

With the assistance and concurrence of the U.S. Customs Service, the Pesticides Enforcement Division has developed a new import program which should minimize the number of ineffective or unsafe pesticides entering the United States from foreign countries. Proposed regulations to implement Section 17(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) will require importers to obtain EPA clearance for a pesticide importation prior to its arrival. This activity will be augmented by periodic EPA review of entry papers to determine if any pesticides are unreported.

During FY 1974 virtually all ports of entry will be visited and the number of import examinations and/or samples collected will increase significantly. Over ten man years will be devoted to the import program by the regional offices, a major increase. Region II has hired two full time import inspectors at the Port of New York. If the workload indicates the need, the Region plans to add an additional inspector and a full time case preparation officer.

Authoritative Enforcement Action

It is the policy of the Agency to request voluntary recall of unsafe and ineffective pesticides and to back up such requests with seizure and stop-sale actions if recall is not initiated. Early in the recall program, it was found that more recall requests could be issued than the inspection staff could supervise. Therefore, all potential recall actions were screened and many less serious cases resulted in informal recalls

which did not require field supervision. An average of eighty-eight informal recall requests were made from FY 1971 through FY 1973 for all types of defects. The potential hazard involved and the scientific opinion regarding the significance of the test results were also considered in making the decision to recall.

We agree that, in order to protect the public, EPA should make a timely release of information concerning enforcement activities. The Office of Public Affairs is issuing guidelines for a prompt and systematic reporting system for all the regions. These guidelines cover the reporting of (1) criminal prosecutions, (2) seizures, (3) civil proceedings, (4) stop-sale, use and removal orders, and (5) voluntary recall actions. Information will also be made public when a pesticide product is suspended or cancelled because of potential hazard or ineffectiveness. Press releases and telephone contacts with the news services will continue to be the primary media through which this information is communicated to the public. The release of this information through the regional offices, rather than through headquarters will guarantee timely communication. We plan to make enforcement histories available to Federal, State, and local agencies upon request, and to publish in the Federal Register a notice that such information is available, listing the name and address of the persons to be contacted.

With the added enforcement tools provided by FEPCA in addition to those previously available under FIFRA, the ability of EPA to move against violative products and producers is greatly expanded. These additional enforcement provisions will also make our recall program more effective since they give us the ability to take more extensive corrective actions if the firm fails to cooperate.

State Assistance to Supplement the Pesticide Market Surveillance Program

The Agency intends to enter into cooperative agreements with the states to augment and improve EPA's market surveillance capabilities.

In FY 1973, efforts and resources were directed toward building the regional FIFRA enforcement programs and decentralizing pesticides enforcement activities. EPA regional enforcement programs are now operational and capable of participating with the states in joint enforcement efforts.

In FY 1974, the Pesticides Enforcement Division plans to conduct a pilot study with a selected state and EPA region to develop a cooperative program which would allow the states to collect samples from the market place, conduct use and experimental permit surveillance and analyze pesticide samples.

APPENDIX I

Samples Analysis Capability

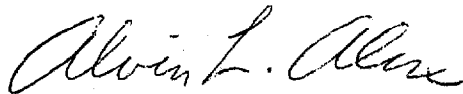
As budget and staffing limitations permit, our laboratory capability will be expanded. A total plan for safety and efficacy evaluation is now being formulated which will encompass both pre- and post-registration evaluations, and permit consideration of shelf-lives of decomposable pesticides.

Presently, we require the registrant to submit shelf-life studies on pesticide products which are known to be susceptible to decomposition, such as sodium hypochlorite. Expiration dates will be required for those pesticides which are shown to have significant decomposition potential.

Your report also recommends cancellation of registration or deletion of certain claims from the labels of those pesticides found to be consistently ineffective. As we find products consistently ineffective, we will take action to require deletion of the specific claims from the label or to cancel the registration. At the present time, we have approximately 36 such potential cancellation actions in hand based on ineffectiveness determinations.

We appreciated the opportunity to review your draft report.

Sincerely yours,



Alvin L. Alm

Assistant Administrator
for Planning and Management



DEPARTMENT OF THE TREASURY
BUREAU OF CUSTOMS

WASHINGTON

SEP 19 1973



Mr. Charles P. McAuley
Assistant Director, General
Government Division
U. S. General Accounting Office
Washington, D. C. 20548

Dear Mr. McAuley:

This is in reply to your letter of August 16, 1973, transmitting copies of your proposed report to Congress entitled "Pesticide Enforcement -- Protecting the Consumer from Defective Products." Chapter 3 of the report concerns the responsibilities of the U. S. Customs Service for reporting importations of pesticides to the Environmental Protection Agency. We will confine our response to that portion of the report.

Under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act, the Secretary of the Treasury is responsible for notifying EPA of the arrival of pesticides and devices and, upon request, deliver thereto samples of such merchandise. Pursuant to an October 21, 1972, amendment of the FIFRA, the Secretary is also responsible, in consultation with EPA, for prescribing regulations for the enforcement of the import provisions of the Act. The above responsibilities of the Secretary have been delegated to the U. S. Customs Service.

The report states that Customs officials at only 47 of the 291 ports of entry were regularly reporting pesticide shipments to EPA during fiscal year 1972. EPA officials have estimated that the 1,026 reported shipments represented about 60 percent of the pesticides imported in that year. We do not question the statement that some importations of this merchandise were not reported. We are of the opinion, however, that EPA's supposition that 40 percent of the pesticide shipments were not reported is unsupported by the facts or the market surveillance program conducted by them. As far as the number of ports reporting to EPA are concerned, it is entirely probable that pesticides regularly arrive at only 47 ports of entry.

REPLY TO: COMMISSIONER OF CUSTOMS, WASHINGTON, D.C. 20226

APPENDIX II

In those instances when pesticides are not reported, the reasons can be traced to the change in the agency having administrative responsibility for the FIFRA, the recent amendment of the Act, and the revisions of the check list of pesticides for use by Customs personnel. We shall discuss each, in turn, below.

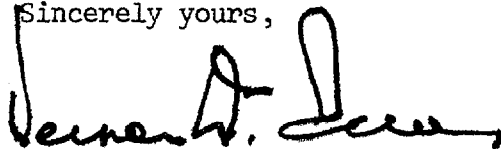
At the time of enactment of the FIFRA, the Customs Service reported shipments of pesticides and devices to the Pesticides Regulation Division, Agricultural Research Service. When EPA assumed administrative responsibility for pesticides, there was a temporary loss of contact between the agencies involved. Since that time, liaison has been firmly reestablished. Such contacts should lessen the percentage of error in the handling of these shipments.

The regulations required to implement the import provisions of the Pesticide Control Act of 1972, will be published in the Federal Register as a notice of proposed rulemaking in the near future. The regulations, when adopted, will require importers of pesticides and devices to obtain clearance from EPA prior to the arrival of the merchandise in the United States. The new procedures will reduce Customs administrative burden in preparing Notices of Importation. Customs procedures will also be streamlined because most samples will either be drawn by EPA inspectors or certified samples will be submitted by importers of the pesticides. Concurrent with the adoption of the above regulations, internal guidelines will be issued to all Customs personnel which will enable them to take appropriate action with respect to these shipments.

When the Department of Agriculture had responsibility for administering the Act, that agency compiled a check list, for the use of Customs officers, of the most frequently imported pesticides. That list has been updated by EPA on at least two occasions. It should be noted that the chemical, creosote, was not reported because it was included on only the latest list prepared by EPA. That list was not sent to all field offices by EPA. We are presently in the process of forwarding the pesticides check list to all Customs field offices, admonishing them to notify EPA of the arrival of any of the substances listed thereon.

With the issuance of updated guidelines and the closer liaison which has been established between EPA and Customs, we feel that the problems enumerated in the report will be resolved.

Sincerely yours,



Commissioner of Customs

PRINCIPAL OFFICIALS OF THE
ENVIRONMENTAL PROTECTION AGENCY
AND THE
DEPARTMENT OF THE TREASURY
RESPONSIBLE FOR ACTIVITIES
DISCUSSED IN THIS REPORT

	Tenure of office	
	From	To
<u>ENVIRONMENTAL PROTECTION AGENCY (note a)</u>		
ADMINISTRATOR:		
Russell E. Train	Sept. 1973	Present
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 ENFORCEMENT AND GENERAL COUNSEL:		
Alan G. Kirk, II	Apr. 1973	Present
John R. Quarles, Jr.	Feb. 1971	Apr. 1973
DEPUTY ASSISTANT ADMINISTRATOR FOR GENERAL ENFORCEMENT:		
Robert L. Baum	Oct. 1973	Present
George V. Allen, Jr.	Apr. 1971	Sept. 1973
ASSISTANT ADMINISTRATOR FOR HAZARDOUS MATERIALS CONTROL (note b):		
Charles L. Elkins (acting)	Oct. 1973	Present
David D. Dominick	June 1971	Sept. 1973
ACTING COMMISSIONER OF PESTICIDES:		
Raymond E. Johnson	Dec. 1970	May 1971

Tenure of office	
<u>From</u>	<u>To</u>

ENVIRONMENTAL PROTECTION AGENCY (continued)DEPUTY ASSISTANT ADMINISTRATOR FOR
PESTICIDES PROGRAMS:

Dr. Henry J. Korp	Dec. 1972	Present
Dr. William M. Upholt	May 1971	Dec. 1972

DEPARTMENT OF THE TREASURY

SECRETARY OF THE TREASURY:

George P. Schultz	June 1972	Present
John B. Connally	Feb. 1971	June 1972
David M. Kennedy	Jan. 1969	Feb. 1971

COMMISSIONER OF CUSTOMS:

Vernon D. Acree	May 1972	Present
Edwin F. Rains (acting)	Feb. 1972	May 1972
Myles J. Ambrose	Aug. 1969	Feb. 1972

^aAll pesticide functions in the Department of Agriculture were transferred under Reorganization Plan No. 3 of 1970 to EPA on December 2, 1970.

^bBefore July 24, 1973, the title of this position was Assistant Administrator for Categorical Programs.

Copies of this report are available at a cost of \$1 from the U.S. General Accounting Office, Room 4522, 441 G Street, N.W., Washington, D.C. 20548. Orders should be accompanied by a check or money order. Please do not send cash.

When ordering a GAO report please use the B-Number, Date and Title, if available, to expedite filling your order.

Copies of GAO reports are provided without charge to Members of Congress, congressional committee staff members, Government officials, news media, college libraries, faculty members and students.

AN EQUAL OPPORTUNITY EMPLOYER

**UNITED STATES
GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548**

**OFFICIAL BUSINESS
PENALTY FOR PRIVATE USE, \$300**

**POSTAGE AND FEES PAID
U. S. GENERAL ACCOUNTING OFFICE**



THIRD CLASS

**U. S. E. ... IVAN
Transportation
Room 5033**