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# REPORT TO THE CONGRESS

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Environmental Protection Agency  
Efforts To Remove  
Hazardous Pesticides From  
The Channels Of Trade B-133192

*BY THE COMPTROLLER GENERAL  
OF THE UNITED STATES*

APRIL 26, 1973

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

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

This is our report on Environmental Protection Agency efforts to remove hazardous pesticides from the channels of trade.

Our review was made 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).

Copies of this report are being sent to the Director, Office of Management and Budget; the Secretary of Agriculture; the Chairman, Council on Environmental Quality; and the Administrator of the Environmental Protection Agency.

A handwritten signature in black ink, reading "James B. Stacks".

Comptroller General  
of the United States

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ABBREVIATIONS

EPA	Environmental Protection Agency
FEPCA	Federal Environmental Pesticide Control Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GAO	General Accounting Office
p.p.m.	parts per million

## Glossary<sup>1</sup>

Administrative review process	An appeal process afforded to a registrant or an applicant who has been notified by the Environmental Protection Agency (EPA) that it is either refusing to register a pesticide or suspending or canceling a registration. After being notified, the registrant or applicant may, within 30 days, file a petition requesting that the matter be referred to an advisory committee or file objections and request a public hearing. If the advisory committee rules against the registrant or applicant, he may then request a public hearing. If a registrant who has received a cancellation notice does not avail himself of this review process, cancellation of his registration will become effective 30 days after he receives the notice. If he avails himself of the administrative review process, the registration remains in effect during the proceedings.
Aldrin	A chlorinated hydrocarbon insecticide for controlling (1) a wide range of soil-inhabiting insects, (2) certain insects attacking field, vegetable, and fruit crops, and (3) termites.
Cancellation	The Administrator of EPA may issue a notice of intent to cancel a pesticide's registration if he determines that there is a substantial question as to the pesticide's safety.

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<sup>1</sup>Terms used by EPA prior to the passage of the Federal Environmental Pesticide Control Act of 1972--enacted on October 21, 1972.

If a registrant appeals the notice of cancellation, the pesticide may continue to be marketed pending the completion of the administrative review process. If the notice is not appealed, the cancellation becomes effective at the end of 30 days from notification.

DDT                   A broad-spectrum, chlorinated (diphenyl aliphatic) hydrocarbon insecticide for controlling (1) household and livestock insects and (2) certain insects attacking field, forage, vegetable, and fruit crops.

DDVP                   An aliphatic phosphorus compound derivative insecticide used in vaporizing devices for controlling household and livestock insects.

Dieldrin               A broad-spectrum chlorinated hydrocarbon insecticide for controlling (1) soil insects, (2) certain insects attacking field, vegetable, and fruit crops, and (3) household insects.

Imminent hazard       An imminent hazard exists if the real or potential risk of the continued use of a pesticide is so hazardous as to require that its use be stopped immediately to prevent injury to man and his environment.

Judicial review       If a registrant or an applicant objects to an order issued by the Administrator of EPA following an advisory committee review or a public hearing, he can obtain judicial review by filing an appeal in an appropriate Federal court.

Mercury                A chemical element widely used in manufacturing. All of its pesticide uses have been suspended or canceled.

Registrant	Any manufacturer, formulator, or individual who has registered any pesticide pursuant to law.
Substantial question of safety	A situation where information not previously available clearly demonstrates that one or several pesticide uses or frequent misuses did, can, or may result in unintended significant damage to humans, other living organisms, or other indispensable segments of the environment and for which the potential risk of damage did, can, or may outweigh the benefits of continued use.
Suspension	The Administrator of EPA may immediately suspend the registration of a pesticide if he determines that the action is necessary to prevent an imminent hazard to the public. The registrant may appeal the suspension order; however, shipments of pesticides affected by the suspension are prohibited as of the date of the suspension notice. Suspension is stronger than cancellation.
TDE	A DDT derivative for controlling (1) household and livestock insects and (2) certain insects attacking field, forage, vegetable, and fruit crops.
Thallium sulphate	A highly poisonous, white, prismatic compound used as a chemical reagent. All of its pesticide uses (rat and mouse poison and ant and roach bait poison) have been canceled.
2,4,5-T	A phenoxy herbicide used primarily for controlling woody plants. Present registrations allow its application to pastures, rangelands, and noncrop areas, including industrial sites, fence rows, and such rights-of-way as under power lines and along highways and railroads.

D I G E S T

WHY THE REVIEW WAS MADE

Prior reviews of the General Accounting Office (GAO) have indicated weaknesses in the Federal Government's policies and practices for removing hazardous pesticides from the channels of trade.

GAO reviewed the Environmental Protection Agency's (EPA's) administration of its responsibilities in this area because of widespread concern about the effect of pesticides on man and his environment.

Background

The Federal Insecticide, Fungicide, and Rodenticide Act of 1947--the basic consumer protection law in the area of pesticides--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 amended the basic law to require that all pesticides, not just those shipped interstate, be registered with EPA before they are distributed or sold.

As of June 30, 1972, approximately 32,000 pesticides were registered with EPA.

During fiscal years 1970 and 1971, EPA suspended or canceled registrations of about 3,200 pesticides con-

taining DDT, TDE, aldrin, dieldrin, mercury, thallium sulphate, or 2,4,5,-T because their use presented an imminent hazard or substantial question of safety to the public. (See glossary.)

The Administrator can suspend a pesticide's registration to prevent an imminent hazard to the public. Although a registrant can appeal, shipment of the pesticide is prohibited as of the date of the suspension. Suspension is stronger than cancellation.

The Administrator of EPA can cancel a pesticide's registration if the continued use of the pesticide presents a substantial question of safety to the public. If a manufacturer who is a registrant appeals the cancellation, the pesticide can be marketed pending the completion of the appeal process.

FINDINGS AND CONCLUSIONS

EPA suspended or canceled registrations of certain pesticides containing 2,4,5-T, mercury, and thallium sulphate because they presented an imminent hazard or substantial question of safety to the public.

The effectiveness of EPA's actions was diminished, however, because EPA allowed other pesticides containing the same ingredients and registered for the same uses to remain on the market.

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Although EPA continued to suspend certain 2,4,5-T registrations because of the hazards of 2,3,7,8 tetrachlorodibenzo-p-dioxin (dioxin), a highly poisonous or toxic contaminant of 2,4,5-T, it did not suspend or cancel the registrations of other pesticides containing dioxin. (See pp. 9 to 17.)

EPA canceled registrations of all pesticides containing DDT, TDE, aldrin, and dieldrin because there was a substantial question as to their safety.

Registrants appealed these cancellation decisions because they wanted the pesticides for specific uses, such as those which the Department of Agriculture considered essential because no safe and effective substitutes were available.

GAO believes that the challenged pesticides should be marketed only for the uses stated by the registrants to be the basis for their appeals. However, labels on challenged pesticides were not altered to delete those uses which registrants did not appeal.

Therefore, pesticides involving a substantial question of safety to man and his environment continued to be marketed for all label uses during the appeal process. (See pp. 18 to 20.)

EPA does not have statutory authority to recall pesticides whose registrations have been suspended. Although its policy is to request manufacturers to voluntarily recall those pesticides that are potentially hazardous to the public or ineffective for the purposes claimed, EPA did not always do this, with the result that hazardous pesticides

sometimes remained in the channels of trade.

EPA should make every effort to have all pesticides found to be imminently hazardous to the public removed immediately from the channels of trade. (See pp. 28 to 31.)

As of October 1972, appeals following the suspension or cancellation of pesticide registrations had been in process for as long as 2-1/2 years. Revised procedures to be put into effect under the 1972 act should speed the appeal process. However, many delays were encountered in selecting the advisory committees and in preparing for the public hearings rather than in the appeal review process itself. Advisory committee members should be selected and public hearings should be conducted promptly.

An informal meeting held before issuance of a suspension or cancellation order might help EPA determine the issues requiring further scientific review and the manufacturer's intention of requesting a public hearing. Such an informal meeting might reduce delays. (See pp. 34 to 38.)

#### RECOMMENDATIONS OR SUGGESTIONS

The Administrator, EPA, should

- establish procedures requiring the suspension of registrations of all pesticides containing the same hazardous ingredients in excess of established limits and registered for the same general uses;
- establish a safe level for dioxin contamination and prohibit the use of all pesticides containing dioxin

in excess of the established standard;

- require that, when EPA cancels a pesticide registration and the manufacturer appeals certain uses of the pesticide, the label be amended to delete the uses not appealed;
- request manufacturers to recall all hazardous pesticides whose registrations have been suspended by EPA because of the imminent hazard to the public; and
- develop procedures to provide for an informal meeting before suspending or canceling a pesticide registration.

AGENCY ACTIONS AND UNRESOLVED ISSUES

EPA stated that:

- Suspension must be based on a finding of imminent hazard and the factors affecting suspension are much too complex to permit uniform criteria for all cases.  
  
This may be true; however, once EPA has suspended a pesticide, it should not allow other pesticides containing the same hazardous ingredients in excess of established limits and registered for the same general uses as the suspended product to be marketed.
- The question of dioxin safety was being researched; such efforts were expected to clarify the safety question.
- It agreed that labels should be amended to delete the uses not appealed and that its General Counsel was deciding on the legality of requiring such a change.

EPA subsequently advised GAO that it does have the authority to require the deletion of unappealed uses and contemplated establishing procedures to implement this authority.

- It disagreed with GAO's proposal that manufacturers should recall all hazardous pesticides whose registrations have been suspended, because recalling some pesticides would be more hazardous than using the products according to label directions.

On the question of recall hazards, pesticide manufacturers, scientists, State agencies, and environmental groups generally agreed that the process of returning stocks to the manufacturers, if properly handled, would not create any hazards other than those encountered in distributing the pesticides.

They also pointed out that recall insures proper disposal, which may not be possible if the hazardous pesticides are left on the market. If adequate disposal methods are not available, recalling and storing the pesticides eliminates the possibility of the pesticides causing irreversible damage through use or misuse.

Since EPA's decisions to suspend pesticide registrations are made on the basis that the pesticides present an imminent hazard to the public, EPA should follow its recall policy and request manufacturers to recall all pesticides whose registrations have been suspended.

- It would develop procedures to provide for an informal hearing consistent with the legislation

before suspending or canceling a pesticide registration.

However, the informal contact we mentioned does not require legislative authority, and EPA should meet with the registrants before taking any suspension or cancellation action.

MATTERS FOR CONSIDERATION  
BY THE CONGRESS

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

## 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. The Administrator of the Environmental Protection Agency (EPA)<sup>1</sup> is responsible for administering the act.

On October 21, 1972, after our review had been completed, FIFRA was amended by the Federal Environmental Pesticide Control Act (FEPCA) of 1972 (Public Law 92-516) to provide for more effective regulation of the manufacture, distribution, and use of pesticides. All FEPCA provisions are required to be effective by October 21, 1976.

The major changes are:

1. FEPCA generally requires that all pesticides 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 registration classification.
3. FEPCA requires the registration of all pesticide-producing establishments and their submission of production and sales-volume information; FIFRA did not.
4. FEPCA authorizes sampling of pesticides at the manufacturer's plant; FIFRA did not.
5. FEPCA authorizes the issuance of an order to prohibit the sale, use, or removal of violative pesticides; FIFRA did not.

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<sup>1</sup>Under 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.

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.

As of June 30, 1972, approximately 32,000 pesticides were registered with EPA. Because prior reviews<sup>1</sup> by our office indicated that there were weaknesses in the Department of Agriculture's policies and practices for removing hazardous pesticides from the channels of trade, we reviewed EPA's administration of such activities.

#### FIFRA PROCEDURES FOR REGISTRATION, SUSPENSION, AND CANCELLATION

FIFRA generally required that every commercial pesticide be registered with EPA before it was shipped interstate. To register a pesticide EPA required that (1) evidence be presented to EPA showing that the pesticide was safe and effective when used as directed and (2) the safety claim on the pesticide label conform to proven facts. Federal regulations required that warning and cautionary statements be displayed on the labels and that the pesticide's registration number be on the labels to indicate that EPA had accepted the pesticide as safe and effective when used as directed. FEPCA's requirements are basically the same.

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 light of developing scientific data. These requirements were not changed under FEPCA.

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<sup>1</sup>Reports to the Congress on "Need to Improve Regulatory Enforcement Procedures Involving Pesticides" (B-133192, Sept. 10, 1968) and "Need to Resolve Questions of Safety Involving Certain Registered Uses of Lindane Pesticide Pellets" (B-133192, Feb. 20, 1969).

FIFRA provided that the Administrator of EPA could issue a cancellation notice whenever it appeared that a registered pesticide no longer met the safety and effectiveness standards. The cancellation was effective 30 days from the time the registrant received the notice unless, within such time, the registrant (1) made the necessary corrections, (2) filed a petition requesting that the matter be referred to an advisory committee selected by EPA from persons nominated by the National Academy of Sciences,<sup>1</sup> or (3) filed objections and requested a public hearing.

The advisory committee evaluated scientific evidence concerning the registration of the pesticide in question and presented its report and recommendations to the Administrator of EPA. The Administrator then decided whether to affirm the cancellation notice.

If the registrant received an adverse ruling, he could request a public hearing so that relevant and material evidence concerning the pesticide's continued registration could be presented. FIFRA required that, within 90 days after the hearing, the Administrator of EPA issue an order as to whether the cancellation notice should be affirmed. This order was to be based on evidence recorded at the public hearing and any report and recommendation of the advisory committee. Pending the issuance of a final cancellation order at the end of the administrative review, the pesticides could be shipped interstate. At the end of the administrative review proceedings, judicial review was available to the registrant.

FIFRA also provided that the Administrator could immediately suspend a pesticide's registration to prevent an imminent hazard to the public. Suspension prohibited further interstate shipments of pesticides so dangerous that their continued use could not be tolerated during the administrative review process discussed above.

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<sup>1</sup>The National Academy of Sciences is a nonprofit, quasi-official, Federal agency consisting of scientists and engineers who, when called upon by a Government agency, investigate, examine, experiment, and report on any subject of science or art.

FEPCA did not change the basis for suspension or cancellation. Changes in the appeal procedures are discussed in chapter 4.

EPA had two methods--seizure and recall--for removing pesticides that remained in the channels of trade after suspension or cancellation. EPA also used these methods for removing from the market pesticides suspected or known to violate FIFRA when the violations were not serious or extensive enough to warrant canceling or suspending the pesticides' registrations. Seizures were authorized under FIFRA but required court actions and were limited to the specific quantities and locations of the pesticides identified in the seizure complaints filed by EPA.

Pesticide recalls were voluntary actions of the manufacturer because EPA had no recall authority. EPA could not enforce its recall requests if the manufacturers refused to cooperate. FEPCA did not provide EPA with recall authority.

BEST DOCUMENT AVAILABLE

## CHAPTER 2

### NEED TO IMPROVE POLICIES AND PROCEDURES

#### FOR SUSPENDING AND CANCELING PESTICIDE REGISTRATIONS

During fiscal years 1970 and 1971, EPA suspended or canceled the registrations of certain pesticides containing 2,4,5-T, mercury, and thallium sulphate because they presented an imminent hazard or substantial question of safety to the public. However, it allowed other registered pesticides containing the same hazardous ingredients and registered for the same uses to remain on the market.

Also during fiscal years 1970 and 1971, EPA canceled the registrations of all pesticides containing DDT, TDE, aldrin, and dieldrin, and the registrants appealed. The effectiveness of EPA's cancellations was diminished because under FIFRA, registrants who appealed EPA's decisions could continue to market their pesticides interstate for all uses stated on the pesticides' labels until a final cancellation order was issued. The registrants generally appealed to retain registration of pesticides only for specific uses.

Many of the manufacturers, scientists, and State officials we contacted questioned EPA's decisions to cancel all registered pesticides containing DDT, TDE, aldrin, and dieldrin. They suggested that these pesticides be restricted to essential uses (no safe and effective substitutes were available) and that the nonessential uses be canceled. However, environmentalists and some scientists pointed out that these pesticides did not readily break down and that there were possible hazards from their continued buildup in the environment. They agreed with EPA's suspension or cancellation of the registrations of these pesticides.

#### DELAYS IN SUSPENDING OR CANCELING REGISTRATIONS OF OTHER PESTICIDES CONTAINING THE SAME HAZARDOUS INGREDIENTS

EPA permitted the continued registration of certain pesticides containing the same hazardous ingredients and in some cases registered for the same uses as other pesticides whose registrations were suspended or canceled because they posed a danger to public health and safety. This



diminished the effectiveness of EPA's suspension actions, as can be seen in the following examples.

### Thallium sulphate

As of June 1, 1971, 11 thallium sulphate pesticides were registered, six of which were technical-grade pesticides containing at least 99 percent thallium sulphate. The sale and use of technical-grade thallium sulphate was restricted to Government agencies and manufacturers of pesticides containing thallium sulphate (formulated thallium sulphate pesticides). The other five pesticides were formulated and contained a maximum 1.5 percent thallium sulphate.

On June 2, 1971, EPA suspended two of the technical-grade thallium sulphate registrations because of the discovery of 48 dead eagles in Wyoming, 21 of which were found to contain lethal doses of thallium sulphate. EPA cited the pesticides' toxic properties and stated that:

Although the labeling \* \* \* bears extensive precautionary statements \* \* \* such labeling has not prevented shipment to, and use by ranchers as an economic poison for predator control \* \* \* and use of these products in this manner would constitute an imminent hazard to the public.

An EPA survey revealed that a manufacturer had shipped 65 pounds of technical-grade thallium sulphate pesticides to six ranchers in Wyoming during 1970 and 1971. At the time this manufacturer's registration was suspended, four other manufacturers held registrations for the technical-grade pesticides. The labels on their pesticides did not contain warnings in addition to those on the pesticides whose registrations were suspended. One of these labels did not restrict use of the pesticide to manufacturers of formulated thallium sulphate pesticides and contained instructions for formulating the technical-grade thallium sulphate for use in bait. Such labeling might result in misuse of this pesticide.

In June 1971, EPA knew that one of the four registered manufacturers had sold about 870 pounds of a technical-grade pesticide to three ranchers in Hawaii. EPA inspectors collected a sample of the pesticide from a July 1971 shipment

to one of the ranchers. Other than the symbolic skull and crossbones, the label did not contain any warnings or the required registration number. The manufacturer explained to EPA that it had accidentally mislabeled the pesticide, and it applied corrected labels. In August 1971 the Director of EPA's Enforcement Division recommended that EPA's Pesticide Regulation Division consider suspending the pesticide's registration for the same reasons that the other technical-grade thallium sulphate pesticide registrations were suspended.

EPA officials informed us that, after checking with State officials and certain grower organizations in Hawaii, they concluded that the situation was not comparable to the Wyoming shipments since there was no evidence of injury. As a result, EPA did not suspend the registration.

One EPA official, in commenting on the action taken against only one of the five manufacturers, stated in a memo that:

If, in subsequent events, a hazard to beneficial wildlife based on unintended use of registered products is uncovered, and the suspension cancellation authority of the Act is used, it should be a broad action against all similarly labeled products and not a punitive action against the registration of only one of those products. An attempt to use the suspension cancellation authority of the Act to punish a single registrant under these conditions and allow similarly labeled products to remain registered may place an additional strain on the exercise of that authority.

On March 9, 1972, about 9 months after the initial suspension, the Administrator suspended all remaining thallium sulphate pesticide registrations, again citing the misuse of thallium sulphate resulting in the Wyoming eagle kills.

### Mercury

On February 18, 1970, the Department of Agriculture suspended registrations for 21 pesticides containing cyano (methylmercuri) guanidine, an alkyl mercury compound used for treating seeds. This action was taken following the

hospitalization of three New Mexico children who ate meat from a hog which had been fed seed grain treated with a fungicide containing cyano (methylmercuri) guanidine. In suspending the registrations, the Department stated that:

The directions for use and warning and caution statements on labels of the pesticide were inadequate to prevent the treated seed screenings and sweepings from being fed to the hogs.

At the time of the suspension, 25 other alkyl mercury pesticides were registered for treating seeds. In a letter dated March 6, 1970, the Acting Administrator of the Agricultural Research Service recognized that the 25 pesticides which were still registered presented the same hazards to the public as the suspended pesticides and stated that:

We recommend that the registration of all alkyl mercury compounds, with directions for use as seed treatments, be suspended immediately because of identical imminent health hazards as are associated with \* \* \* [cyano (methylmercuri) guanidine] that has been suspended. Since there are identical hazards associated with the alkyls not suspended, the Department can be accused of arbitrary and capricious action in the case of \* \* \* [cyano (methylmercuri) guanidine] unless we take immediate action against equally hazardous compounds.

On March 9, 1970, about 3 weeks after the suspension of cyano (methylmercuri) guanidine, the 25 remaining alkyl mercury pesticides were suspended. This suspension did not affect 37 more alkyl mercury pesticides registered for uses other than treating seeds.

A November 1970 report of the Department of Health, Education, and Welfare on the hazards of mercury recommended that the use of all alkyl mercury pesticides be terminated. The scientific advisory committee reviewing the cancellation of algicides containing mercury cited this recommendation in its July 6, 1971, report.

On July 23, 1971, a Special Pesticides Review Group, established by EPA's Office of Pesticides Programs to review registered uses of mercury pesticides, recommended that

EPA suspend the registrations of all remaining alkyl mercury pesticides. The report stated in part that:

It is the opinion of this Special Group that pesticides containing alkylmercury compounds can not be labeled adequately to protect the safety of the public.

Despite the recommendations of the review groups and the hazards cited in the previous mercury suspensions, EPA delayed action primarily because it undertook yet another review of mercury pesticides. It was not until March 24, 1972, shortly after EPA completed this latest review and 8 months after EPA's Special Pesticides Review Group had recommended suspension, that EPA suspended the remaining alkyl mercury pesticides.

#### 2,4,5-T

In continuing the suspension and cancellation of certain 2,4,5-T registrations, EPA cited the hazards of 2,3,7,8 tetrachlorodibenzo-p-dioxin (dioxin), a highly toxic contaminant of 2,4,5-T. However, EPA did not suspend or cancel the registrations of other pesticides containing dioxin or limit the dioxin content of these pesticides.

In October 1969 the National Cancer Institute released a study of the teratogenic (causing birth defects) effects of a number of pesticides, which revealed that rats and mice, when administered large doses of 2,4,5-T during early pregnancy, gave birth to defective offspring. More animal experiments conducted in early 1970 by the National Institute of Environmental Health Sciences confirmed this finding; therefore, in April and May 1970, EPA, acting in counsel with the Departments of Health, Education, and Welfare and the Interior, suspended and/or canceled the registrations of 2,4,5-T pesticides for uses around the home, recreational areas, lakes, ponds, and ditch banks and on food crops intended for human consumption.

Subsequent studies attributed the primary hazards of using 2,4,5-T to dioxin, which exists in varying amounts in all commercially produced 2,4,5-T. Dioxin is formed in the production of trichlorophenol, an intermediate in the production of 2,4,5-T. The toxicity of dioxin was identified

as the cause of a severe skin disease, chloracne, in Germany in 1899. Major outbreaks of chloracne were reported in Germany in the 1950s and at one U.S. plant in 1964.

In September 1970 pesticide manufacturers and distributors were notified that 2,4,5-T, silvex, and other pesticides could no longer contain dioxin. The notification stated that:

The United States Department of Agriculture has determined that certain toxic chlorodioxins (such as 2,3,7,8-tetrachlorodibenzo-para-dioxin) may be present as contaminants in the basic materials used in formulating 2,4,5-T and silvex. The presence of such chlorodioxins in economic poisons constitutes a possible hazard to man because these chlorodioxins have been found to be extremely toxic to laboratory animals. Therefore, products containing such contaminants are considered to be in violation of the Federal Insecticide, Fungicide, and Rodenticide Act. Appropriate regulatory action will be taken under the provisions of the Act if these chlorodioxins are found in any economic poison.

EPA officials said, however, that they could not enforce the ban because they could not detect the dioxin content in formulated pesticides if it was below five parts per million (p.p.m.) and in technical material if it was below 0.5 p.p.m. EPA personnel stated that, because of their limited capability and the hazards involved in testing for dioxin, they had not set up procedures to test pesticides for dioxin content.

Four manufacturers appealed the April and May suspension or cancellation of the registrations of eight pesticides containing 2,4,5-T. Two of the manufacturers requested that a scientific advisory committee review the scientific data available on 2,4,5-T. The other two manufacturers requested a public hearing. As of October 1972, a court order obtained by one of the manufacturers was delaying the start of the public hearing.

Recommendations of the  
advisory committee

On May 7, 1971, a nine-member advisory committee recommended that the registrations be restored on the condition that a permissible residue level be set and that the dioxin level of 2,4,5-T be restricted. The committee recommended that:

- b. A limit of 0.5 ppm of contamination with 2,3,7,8-tetrachlorodibenzo-p-dioxin be set for existing inventories of 2,4,5-T except as specified in item c. below, and a limit of 0.1 ppm of contamination with this dioxin be established in all future production of 2,4,5-T. Surveillance should be maintained by requiring that a manufacturer submit a reference sample and a certified analysis of each future production lot to the Environmental Protection Agency.
- c. All formulations to be used around the home and in recreational areas as of present date should be limited to 0.1 ppm of the dioxin, TCDD \* \* \*.

The 2,4,5-T manufacturers reported to the advisory committee that, with good manufacturing practices, they could limit the dioxin content of 2,4,5-T to 0.1 p.p.m. or less. In contrast, the level of dioxin in the sample used in the initial study for the National Cancer Institute, which resulted in the suspension and/or cancellation of certain pesticides containing 2,4,5-T, was between 19 and 35 p.p.m.

In a report dissenting on the findings of the advisory committee, one committee member stated that the suspensions and cancellations should remain in effect but that use of 2,4,5-T for forestation and rights-of-way should be permitted under certain conditions. Two of these conditions were that a limit of 0.1 p.p.m. of dioxin contamination be set on all future production of 2,4,5-T and that existing stocks be used only if the dioxin content did not exceed 0.5 p.p.m. The committee member advised us that his objections were based primarily on the inadequacy of current methods of making toxicological studies. He stated that current studies had not established a "no hazard" dose of either 2,4,5-T or dioxin.

Administrator's order on 2,4,5-T

On August 6, 1971, the Administrator decided to continue the suspension and cancellation of registrations pending the evaluation of additional evidence at a public hearing. The Administrator cited the hazards of dioxin and the problems associated with monitoring the production of 2,4,5-T to control the level of dioxin. The Administrator also cited the need for additional information on the benefits of 2,4,5-T versus the risks involved in its use.

In orders issued November 4, 1971, and April 13, 1972, the Administrator stated that:

A contaminant of 2,4,5-T--tetracholorodibenzoparadioxin (TCDD, or dioxin)--is one of the most teratogenic chemicals known. The registrants have not established that 1 part per million of this contaminant--or even 0.1 ppm--in 2,4,5-T does not pose a danger to the public health and safety.

\* \* \* \* \*

The dose response curves for 2,4,5-T and dioxin have not been determined, and the possibility of "no effect" levels for these chemicals is only a matter of conjecture at this time.

As with another well-known teratogen, thalidomide, the possibility exists that dioxin may be many times more potent in humans than in test animals \* \* \*.

Despite these hazards, EPA did not follow the advisory committee's recommendations to (1) set limits on the dioxin content of existing and future lots of 2,4,5-T and (2) require manufacturers to submit to EPA a reference sample and a certified analysis of each production lot of 2,4,5-T.

Dioxin in products other  
than 2,4,5-T

Because dioxin is formed in the production of trichlorophenol rather than in the final production of 2,4,5-T, the same dioxin content would be found in other pesticides formed through a reaction with trichlorophenol.

Both manufacturers requesting the convening of an advisory committee stated that no additional dioxin is produced after the production of trichlorophenol.

One manufacturer told us that he could not understand why EPA had not suspended or canceled silvex and other pesticides formed through reactions with trichlorophenol. Other pesticides formed through reactions with trichlorophenol and thus having the same dioxin content as 2,4,5-T include silvex, ronnel, erbon, and hexachlorophene. The Army Corps of Engineers substituted silvex for 2,4,5-T in its operations, and we found that pesticides containing silvex were available at many hardware and department stores in the Washington, D.C., area.

Although EPA officials stated that these other pesticides could have the same dioxin content as currently produced 2,4,5-T, they said that EPA had not suspended or canceled these other registrations because tests on 56 samples of 2,4,5-T, silvex, ronnel, erbon, and hexachlorophene in late 1970 by the Agricultural Research Service of the Department of Agriculture had revealed that only 20 of 42 samples of 2,4,5-T and one of the seven silvex samples tested contained dioxin in excess of 0.5 p.p.m.--the limit recommended by the advisory committee. Of the 20 samples of 2,4,5-T containing dioxin in excess of 0.5 p.p.m., 19 were produced by one manufacturer who has since stopped producing 2,4,5-T. The officials further stated that, although current manufacturing processes can limit the dioxin content of 2,4,5-T and other pesticides to 0.1 p.p.m. or less, the suspension of 2,4,5-T was continued because there was a question as to whether pure 2,4,5-T was also teratogenic.

In continuing the suspension of 2,4,5-T, the Administration of EPA stressed the toxicity of dioxin and the fact that a safe level of dioxin had not been determined. (See p. 16.) Because silvex, ronnel, erbon, and hexachlorophene can contain the same level of dioxin as 2,4,5-T and because a safe level of dioxin has not been determined, we believe EPA should establish a standard for dioxin content and prohibit the use of all pesticides containing dioxin in excess of the established standard.



CONTINUED MARKETING OF PESTICIDES  
FOR ALL LABELED USES PENDING THE  
OUTCOME OF LENGTHY APPEALS

Registrants appealed EPA's decisions to cancel the registrations of all pesticides containing DDT, TDE, aldrin, and dieldrin. Generally, they appealed to retain registration of the pesticides for those uses deemed essential (no safe and effective substitutes available) by the Department of Agriculture.

The sole manufacturer of aldrin and dieldrin notified EPA that it did not plan to appeal the following uses of aldrin and dieldrin.

Aldrin

Aquatic areas  
Cranberries (foliar, soil)  
Foliar uses (except as  
applied by ground rig)  
Grapes (bait and foliar)  
Home lawns (except as  
applied by professionals)  
Mangoes (foliar)  
Rice (seed treatment)  
Vertebrate animal control

Dieldrin

Aquatic areas  
Barns (all uses)  
Blueberry, huckleberry (foliar)  
Citrus (soil)  
Cranberries (foliar, soil)  
Grapes  
Home lawns (except as applied  
by professionals)  
Households (except as applied  
by pest control operators or  
from aerosol cans)  
Mothproofing of wool  
Noncrop, nongrazing areas  
(all homeowner uses)  
Orchards (stinkbug uses)  
Paint combinations  
Poultry operations  
Tobacco (foliar, soil)  
Vertebrate animal control

The Aldrin/Dieldrin Advisory Committee, established pursuant to the manufacturer's request to review the scientific data on aldrin and dieldrin, considered most of these uses non-essential (safe and effective substitutes were available). In its March 28, 1972, report, the advisory committee recommended that the nonessential uses be disallowed.

On June 26, 1972, the Administrator stated that EPA was considering suspending those uses of aldrin and dieldrin

presenting an imminent hazard to the public, i.e., those uses involving aerial and ground methods of spraying and dusting and those involving use in and around the home and other buildings. The aldrin and dieldrin registrants did not appeal the aerial application and certain household uses.

A group of 27 DDT registrants requested a public hearing and filed a joint appeal stating that they would appeal only those uses listed as essential by the Department of Agriculture, which supported the continued registration of the pesticides for those uses. The appeal involved 327 registered pesticides whose labels contained directions for 16 of the 34 essential uses identified by the Department of Agriculture. Our review of 262 labels showed that 224 contained directions for unappealed uses.

Under FIFRA these registrants were permitted to market the pesticides during the appeals process, with the result that the pesticides continued to be marketed for all label uses pending the outcome of lengthy appeals. The pesticide labels were not amended to delete the unappealed uses. EPA officials told us that they canceled the pesticides' registrations, not their specific uses.

Because the registrants generally appealed for the purpose of retaining registrations of pesticides only for certain uses, we believe that, during the appeal process, the pesticides should be marketed only for those uses identified by the registrants as the basis for their appeals. We believe EPA should consider requiring that the labels of canceled pesticides be amended to include only those uses appealed by the registrants.

Although EPA officials agreed that it would be desirable to require registrants to amend their pesticide labels during the appeal process, they expressed concern about the specific procedures to carry out such a requirement. They stated that it would be necessary to review the labels of every pesticide whose registration had been canceled and appealed, to identify those uses the registrants wished to retain. In mass cancellations, such as DDT or aldrin and dieldrin, such pesticides could number in the hundreds. The officials told us, however, that they would undertake a study to determine the feasibility and

practicability of requiring registrants to delete from their pesticide labels those uses which they were not interested in retaining.

RESTRICTING REGISTERED USES  
VERSUS CANCELING ALL USES

Those having an interest in the manufacture, sale, and registration of pesticides differed as to the soundness of EPA's policies and practices for suspending and canceling pesticide registrations.

Many of the manufacturers, scientists, State officials, and farm group representatives we contacted suggested that restricting uses of pesticides such as DDT, TDE, aldrin, and dieldrin would be more appropriate than canceling all uses. Their comments generally reflected the belief that the benefits of certain essential uses of these pesticides-- where no safe and effective substitutes were available-- outweighed any possible risks from their continued use. On the other hand, the environmentalists and some scientists we contacted supported the cancellation of all uses of these pesticides. They pointed out that these pesticides do not readily break down and that there are possible hazards from their continued buildup in the environment.

State officials' views

Officials of several States stated that EPA should restrict the use of, rather than suspend or cancel, certain hazardous pesticides. Some of their comments follow.

If at all possible, restriction and good enforcement of same seems more reasonable than cancellation (which is rather final) \* \* \*.

\* \* \* \* \*

Action against DDT, Aldrin, Dieldrin, and 2,4,5-T canceled some uses which are still considered essential in our state.

\* \* \* \* \*

Each of these pesticides are generally classed as villain by the public due to action by the government. We feel these chemicals to have definite beneficial uses and suggest restrictions over suspension or cancellation.

A May 1971 Minnesota Department of Agriculture survey report on State actions to ban or restrict the use of pesticides revealed that only five States had banned all uses of a pesticide. In contrast, 29 States had restricted pesticide use.

#### Manufacturers' views

Although the 35 manufacturers we contacted generally disagreed with one or more of EPA's suspensions or cancellations involving DDT, TDE, aldrin, dieldrin, 2,4,5-T, mercury, and thallium sulphate, many supported restricted use as an alternative to mass cancellations. Some of their comments follow.

Each of these compounds have a place in promoting the general economy. These compounds, without exception, can do a great deal of good in helping man's enviroment [sic] if proper controls are observed. We feel controls, not cancellation would prove to be a better approach.

\* \* \* \* \*

We are in agreement to cancel Mercury and Thallium Sulfate. The other chemicals are still very much needed by farmers. There should be some regulations to prevent misuse, but used correctly they are still indispensable [sic] tools for the farmer to use on certain crops.

\* \* \* \* \*

I believe all these chemical [sic] used by registered P.C.O.'s [pest control operators] will do more good than harm.

#### Scientists' views

Of 24 scientists contacted, 19 said that they agreed with EPA's actions to suspend or cancel the registrations

of the pesticides discussed in this report. Five scientists who disagreed stated that certain uses of the pesticides may be essential, and they advocated restricted use rather than cancellation of all uses.

Comments on the desirability of restricting rather than canceling the use of certain pesticides included:

I feel that announcing the cancellations was a good indication that a review was needed and I agree with this review. However, as far as following through with complete suspension of all these materials, I do not feel that this is justified. I feel, particularly in the case of the insecticides, that there are specific restricted use areas where they should be retained. I understand that the same may be true for the fungicides and herbicides. I do feel that Aldrin and Dieldrin in termitite [sic] control are still without replacement and therefore this should be retained. In many areas of the United States DDT in small quantities and for very restricted uses would make a major economic difference in production or maintenance of quality products \* \* \*.

\* \* \* \* \*

In general, pesticides should be regulated according to specific uses rather than by a ban on a compound in all of its uses.

\* \* \* \* \*

I believe the use of such materials should be allowed, but only under supervision of licensed and professional people. These professionals should then be held liable for any misuse of such products.

\* \* \* \* \*

The negative response does not indicate disagreement in suspension and cancellation actions for all products, but rather in part of it. There would appear to be scientific

justification for more stringently restricting the use of mercury and thallium sulfate. Selective restrictions on the use of aldrin and dieldrin are probably justified, but not a complete prohibition of their use. A similar situations [sic] exists with respect to DDT. It is necessary to emphasize that continued use of this product for limited purposes is essential \* \* \*.

#### Environmental groups' views

The nine environmental groups we contacted favored canceling all uses of these pesticides because they do not decompose and because of the possible hazards of their continued buildup in the environment. Many environmentalists advocated suspending the pesticides pending the outcome of appeals. Many also were concerned about pesticide use contrary to label directions. They stated that removing a use or method of application from the label does not prevent someone from using the pesticide for a suspended or canceled use.

#### Canceling registrations for uses deemed essential

Although EPA canceled all registrations of pesticides containing DDT, TDE, aldrin, and dieldrin,<sup>1</sup> the Department of Agriculture, State agencies, and special review groups recommended the continued registration of these pesticides for certain essential uses. For example, a special review group established by EPA concluded that there was no known safe, effective substitute for DDT for certain uses, including the control of a variety of insects on cotton. The review group stated that:

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<sup>1</sup>After the administrative review process for DDT and TDE was completed on June 2, 1972, EPA allowed DDT to be used for corn borers on green peppers, weevils on stored sweet potatoes, and cutworms on onions. As of October 1972 the administrative review process for aldrin and dieldrin had not been completed.

The documentation supporting the continued registration of DDT on cotton is overwhelming \* \* \*. No other insecticide is effective for the control of so many important insect pests on cotton. Deletion of the DDT registration on cotton would be disastrous to the industry. We recommend that the registration on cotton be continued until satisfactory substitutes are found.

As a result of a study conducted in late 1970, the Department of Agriculture proposed retaining DDT for certain uses, including the control of such cotton pests as budworms, boll weevils, cutworms, fall armyworms, cotton bollworms, and cotton fleahoppers. Several States and the National Cotton Council also recommended using DDT to control these and other insects on cotton.

EPA established a review group to study the necessity for aldrin and dieldrin. According to EPA, the recommendations of the review group were to serve as a basis for any future changes in the registration for aldrin and dieldrin.

In its report issued October 21, 1970, the review group recommended that:

\* \* \* the use of aldrin and dieldrin for termite control under its present registration be continued as is. This recommendation is based on studies made of experimental plots where these chemicals were applied 18 to 20 years ago and very little or no movement of the pesticides has taken place in that length of time.

The retention of aldrin and/or dieldrin for the control of termites was also requested by 22 States. However, EPA canceled the registrations of all aldrin and dieldrin pesticides.

#### FEPCA provisions

FEPCA provides that all pesticides be classified for general or restricted use. Restricted-use pesticides are to be used only by, or under the supervision of, certified applicators or under other restrictions determined by the

Administrator of EPA. The restrictions are to be suited to the degree of hazard and the adverse environmental effects that could be caused by the misuse of the pesticides.

These provisions will enable EPA to (1) restrict the use of pesticides to protect persons and the environment and (2) permit the use of pesticides for agricultural purposes when their use is deemed essential.

### CONCLUSIONS

The effectiveness of EPA's policies and procedures for suspending and canceling the registration of hazardous pesticides could be strengthened if EPA made such actions applicable to all pesticides containing the same hazardous ingredients and used for the same purposes as the pesticides whose registrations are suspended or canceled.

In view of the hazards associated with dioxin in pesticides, EPA should establish a standard for dioxin content and should prohibit the use of all pesticides containing dioxin in excess of the established standard.

The effectiveness of EPA's cancellations could also be strengthened if the labels of canceled pesticides were amended to delete those uses not appealed by the registrants.

### AGENCY COMMENTS

EPA advised us by letter dated October 30, 1972, that the factors affecting suspension are much too complex to permit uniform criteria for all cases. (See app. I.) We agree, but once EPA has suspended a pesticide, it should not allow other pesticides containing the same hazardous ingredients in excess of established limits and registered for the same general uses as the suspended pesticide to be marketed. Such a practice results in unfair competition--some manufacturers can market their pesticides while other manufacturers are prohibited from doing so--and permits hazardous pesticides to remain on the market.

EPA told us also that the question of dioxin safety was being researched and that such efforts were expected to clarify the safety question.



With respect to the deletion of uses not appealed, EPA stated that while the term "registered uses" is commonly employed, uses are never registered or canceled; therefore, when the appeal procedure is invoked, it is an appeal pursuant to their action to cancel the pesticide, regardless of the fact that an appellant may present evidence supporting only specific uses of that pesticide. EPA stated also that it agreed with the intent of our views and that its General Counsel was deciding on the legality of requiring labeling changes when an appeal deals only with some of the uses on the label. However, EPA did require registrants to delete unappealed, canceled uses from their labels. (See p. 31.)

EPA advised us in January 1973 that it does have the authority to require labeling changes and that it contemplated establishing procedures to implement this authority.

#### RECOMMENDATIONS

We recommend that the Administrator of EPA

- establish procedures requiring the suspension of registrations of all pesticides containing the same hazardous ingredients in excess of established limits and registered for the same general uses;
- establish a safe level for dioxin contamination and prohibit the use of all pesticides containing dioxin in excess of the established standard; and
- require that, when EPA cancels a pesticide registration and the manufacturer appeals certain uses of the pesticide, the label be amended to delete the uses not appealed.

## CHAPTER 3

### NEED TO RECALL HAZARDOUS PRODUCTS

FIFRA authorized the seizure of pesticides found to violate the act; FEPCA did not modify that authority. EPA experience showed that seizure was sometimes ineffective because of the efforts required to (1) locate the outstanding stock of the violative pesticides, (2) obtain and analyze samples, (3) process the necessary court papers, and (4) actually seize the pesticides. EPA officials therefore initiated procedures for the voluntary recall of violative pesticides because they found that manufacturers' cooperation was the most efficient means of removing ineffective or hazardous pesticides from the market. EPA's policy on recall follows.

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. A product will be considered in the potentially hazardous category when, among other things, its use as directed is likely to result in:

1. Injury to the user or handler of the product;
2. Injury to animals where direct application is made;
3. Injury to plants;
4. Injury to consumers due to residues;
5. Economic injury to growers due to actionable (harmful) residues;
6. Injury to fish or wildlife; or
7. Identifiable adverse effects on the environment.

However, EPA did not always request manufacturers to recall hazardous pesticides whose registrations had been suspended, with the result that hazardous pesticides sometimes remained in the channels of trade.

SUSPENDED PRODUCTS REMAIN ON THE MARKET  
DESPITE THEIR HAZARDS

EPA has not established specific procedures for large-scale registration suspensions and cancellations such as those experienced with DDT, aldrin, dieldrin, mercury, and 2,4,5-T. The decision to recall pesticides of this nature is complex and requires careful consideration of (1) the degree of hazard to the public, (2) the hazards associated with improper disposal or collection and shipment of the pesticides, and (3) the quantity of hazardous pesticides in the channels of trade.

The following examples show hazardous pesticides which were not recalled after their registrations had been suspended.

Example 1

During February and March 1970, EPA suspended the registrations of 46 seed treatment pesticides containing alkyl mercury because their continued use constituted an imminent hazard to the public. EPA based its decision on an extensive history of accidents involving both occupational and incidental exposures. The alkyl mercury compounds have been shown to be easily absorbed through biological tissues and to irreversibly damage the central nervous system. EPA also determined that no label would prevent the misuse of these highly toxic pesticides.

Despite these hazards, EPA did not request manufacturers to recall existing stock from the channels of trade, because, in its opinion, collecting, shipping, storing, and/or disposing of recalled pesticides would be more hazardous than using existing stocks according to label directions. For example, EPA officials stated that recall would involve a potential danger from handling and storing open or leaking containers. EPA used this reasoning despite its contention that no label would prevent misuse. Further, EPA recommended that manufacturers dispose of their warehouse stocks by selling the pesticides intrastate as presently labeled since the suspension of these registrations prohibited further interstate shipments.

Considering the hazards of these pesticides, it would seem that the public's exposure to them should have been minimized to the greatest extent possible. EPA's recommendation that existing stocks be sold intrastate did not, in our opinion, adequately protect the public from these hazardous pesticides.

EPA did not suspend other registered alkyl mercury pesticides until March 24, 1972--a total of 25 months after the initial alkyl mercury suspension. (See p. 11.) Had EPA initially suspended all the registered alkyl mercury pesticides and at that time recalled existing stocks, it could have stopped their sale and use 25 months earlier.

### Example 2

On October 7, 1971, EPA suspended the registrations of three phenylmercuric acetate pesticides used primarily to control algae in swimming pools and water-cooling towers. In suspending these registrations, EPA stated that:

Bacteria in bottom sediments convert phenylmercuric acetate into various methylmercury compounds.

\* \* \* \* \*

Methylmercury has a propensity for the human nervous system and about 10 percent of the total body burden lodges in the head and, more specifically, presumably in the brain.

\* \* \* \* \*

Phenylmercuric acetate is stored in the human body, especially in the kidneys and liver, and contributes to the total body burden of heavy metals. Over extended periods of exposure, as little as 0.5 parts per million in the diet of female rats have caused renal lesions. Any chronic effects may be aggravated in persons suffering from kidney disease.

High residues of mercury in the hair of elementary school children (reflecting internal exposure) have been traced to the use by the

children of an institutional pool treated with phenylmercuric acetate as an algicide.

\* \* \* \* \*

\* \* \* there are cultural and chemical alternative methods for the control of algae in swimming pools and water cooling towers which are safer than and equally as effective as the subject products.

EPA inspectors determined that approximately 45,000 gallons of these pesticides were shipped to consignees from January 1 to October 1, 1971. They estimated that about 5.5 percent of this amount was on the market at the time of the suspension and that consumers had an undisclosed amount. EPA decided not to recall this stock because, according to an October 11, 1971, EPA news release:

\* \* \* environmental contamination through the continued use of the small quantities of products presently in channels of trade are considered minimal when compared to the hazards associated with improper disposal or collection and reshipment of the products to a central point for further reprocessing. Therefore, no recall of the products is being requested.

This release indicated that the hazards applied to the environment. However, the suspension order indicated that the imminent hazards applied to both man and the environment. We believe that the potential hazards to man justified recalling all existing stocks so that human exposure to these pesticides would be minimized. Further, a recall under EPA's supervision should insure that the pesticides are properly collected, shipped, and reprocessed.

### Example 3

As discussed in chapter 2, the 2,4,5-T Scientific Advisory Committee concluded that the toxicity of 2,4,5-T appeared to have been caused by dioxin. The committee recommended that the 2,4,5-T registrations be restored to their status prior to the suspension and cancellation actions but that a 0.5-p.p.m. limit be placed on the dioxin content of existing 2,4,5-T stocks, with the exception of

pesticides intended for home use, which should have a 0.1-p.p.m. limit. The committee also recommended that all future pesticides be limited to 0.1-p.p.m. of dioxin.

After the advisory committee issued its report in May 1971, EPA decided not to reinstate the 2,4,5-T registrations which had been suspended or canceled and ordered a full public hearing. EPA based its decision on the hazards of dioxin and the problems of monitoring the dioxin content in 2,4,5-T.

At the time of the suspensions and cancellations, approximately 5 million pounds of 2,4,5-T were in the channels of trade. All of this material contained dioxin. However, despite the advisory committee's recommendations on the dioxin content of existing stocks of 2,4,5-T and EPA's recognition of the dioxin hazards, no action was taken to determine the dioxin content of 2,4,5-T pesticides on the market. With the exception of 56,000 pounds recalled from the channels of trade, EPA either (1) required the manufacturers to eliminate from their labels directions for the suspended and canceled uses that were not appealed or (2) permitted shipment under the existing label for those uses that were not suspended or canceled.

EPA personnel stated that, because of their limited capability (see p. 14) and the hazards involved in testing for dioxin, they had not set up procedures to test pesticides for dioxin content.

Considering the recognized hazards of dioxin, we believe that EPA should have (1) contacted the manufacturers of 2,4,5-T to determine if they could identify the dioxin content of 2,4,5-T pesticides, (2) requested manufacturers to recall all 2,4,5-T pesticides that they could identify as exceeding the limits recommended by the advisory committee, and (3) requested manufacturers to recall all other 2,4,5-T pesticides whose dioxin content could not be determined. In addition, EPA should have followed the advisory committee's recommendation on requiring manufacturers to submit data on the dioxin content of all subsequent production lots of 2,4,5-T that were not affected by the suspension and cancellation.

## CONCLUSIONS

Recall is a valuable tool for removing hazardous or ineffective pesticides from the market. In view of the potential danger to man and the environment from hazardous pesticides, existing stocks should be recalled to minimize the public's exposure.

## AGENCY COMMENTS

In response to our proposal that the Administrator of EPA request manufacturers to recall all hazardous pesticides whose registrations have been suspended, EPA advised us that it could not concur with a blanket policy to recall all stocks in every suspension case. EPA stated that the extent of the recall, the pesticide involved, and the technology available for disposal all have an impact in the decisionmaking process. EPA also stated that there were instances where recall would be more hazardous than using the pesticide according to label directions.

We solicited the opinions of pesticide manufacturers, scientists, State agencies, and environmental groups on the hazards associated with the collection, shipment, storage, and disposal of recalled pesticides. They generally agreed that the process of returning stocks to the manufacturers, if properly handled, would not create any hazards other than those encountered in distributing the pesticides. They pointed out that recall insures proper disposal, which may not be possible if the hazardous pesticides are left on the market, and that, when adequate disposal methods are not available, the recall and proper storage of the pesticides eliminates the possibility that the pesticides might cause irreversible damage through their use or misuse.

Since EPA's decisions to suspend pesticide registrations are made on the basis that the pesticides present an imminent hazard to the public, we believe that EPA should request manufacturers to recall all pesticides whose registrations have been suspended.

RECOMMENDATION

We recommend that the Administrator of EPA request manufacturers to recall all pesticides whose registrations have been suspended by EPA because of the imminent hazard to the public.



## CHAPTER 4

### DELAYS IN RESOLVING APPEALS

FIFRA provided extensive administrative procedures for registrants who appealed EPA's decisions to suspend or cancel registrations. The appeals should be resolved expeditiously to minimize:

1. Continued marketing, during cancellation proceedings, of pesticides involving a substantial question of safety to man and the environment.
2. Manufacturers' and users' uncertainty about the continued registration of the pesticides.

### EXCESSIVE DELAYS IN RESOLVING APPEALS

During fiscal years 1970 and 1971, EPA acted to suspend and/or cancel the registration of about 3,200 pesticides containing DDT, TDE, aldrin, dieldrin, mercury, thallium sulphate, or 2,4,5-T because their use presented an imminent hazard or a substantial question of safety to the public. The registrants appealed the suspension or cancellation of 743 of the 3,200 pesticides. As of October 1972, appeals involving only three of the pesticides had been fully resolved. The administrative review process had been completed for 332 of the remaining 740 pesticide registrations appealed, but the judicial process had not been completed. As shown by the following table, the appeals had been in process for periods up to 30 months.

<u>Pesticide</u>	<u>Number of pesticide registrations</u>	<u>Suspension or cancellation</u>	<u>Advisory committee report</u>	<u>Completed public hearings</u>	<u>Elapsed months as of October 31, 1972 (note a)</u>	<u>Status as of October 31, 1972</u>
DDT	1	8-18-70	9-9-71	Pending	26	Unresolved
DDT	3	1-15-71	9-9-71	Pending	22	Unresolved
DDT	316	1-15-71	(b)	3-16-72	22	Judicial review
TDE	16	3-18-71	(b)	3-16-72	19	Judicial review
Mercury	2	7-22-69	7-6-71	(c)	d29	Resolved 12-71
Mercury	1	8- 7-70	7-6-71	(c)	d16	Resolved 12-71
Aldrin and dieldrin	396	3-18-71	3-28-72	Pending	19	Unresolved
2,4,5-T	8	5- 1-70	5- 7-71	Pending	30	Unresolved
Total	<u>743</u>					

<sup>a</sup>Elapsed months from the date of suspension or cancellation to October 31, 1972.

<sup>b</sup>There was no advisory committee.

<sup>c</sup>A public hearing was not held.

<sup>d</sup>Elapsed months as of December 15, 1971.

Note: This table does not include statistics on lindane pesticide pellets used in vaporizers, the subject of a previous GAO report to the Congress (B-133192, Feb. 20, 1969). Three manufacturers appealed the April 1969 cancellation of these pesticides; however, the first appeal was not completed until May 11, 1972. The other two appeals were completed on December 6, 1972--after 44 months.

The appeals were prolonged, in part, by delays in (1) selecting scientists to serve on the advisory committees, (2) gathering scientific information to be reviewed by the advisory committees, and (3) obtaining a hearing examiner for the public hearings. In addition, many of the registrants we contacted indicated that the lack of adequate communication between EPA and the registrants before a suspension or cancellation caused delays in resolving the appeals.

Delays in selecting the advisory committees and initiating public hearings

As shown by the preceding table, appeals take a long time. Under FIFRA, the advisory committee had 60 days, which could be extended another 60 days, to deliberate and submit its report; the Administrator had 90 days to issue an order on the basis of the advisory committee report; and the registrant had 60 days to file objections to the Administrator's order and request a public hearing.

FEPCA has made the advisory committee review a part of the public hearing process. The advisory committee will convene only if requested during the public hearing. The committee will be required to report, in writing, to the hearing examiner within 60 days after questions of scientific fact are referred to it. Because the recommendations of the advisory committee will become part of the hearing, the appeal process will be limited to a public hearing rather than to FIFRA's two-step appeal procedure of an advisory committee review and a public hearing. The revised procedures should speed the administrative review process.

Many of the delays under FIFRA's procedures were encountered in selecting members for the advisory committees and in preparing for the public hearings rather than in the review process. There remains the need to select advisory committees and initiate public hearings promptly.

Neither FIFRA nor FEPCA contain a time frame for selecting advisory committees. The selection time ranged from 5 months for the 2,4,5-T advisory committee to 17 months for the mercury advisory committee.

In the mercury case, the registrant requested an advisory committee on August 18, 1969, after the cancellation of two mercury algicides. An advisory committee was not established at that time, and the registrant again requested an advisory committee after a third mercury pesticide was canceled in August 1970. EPA established an advisory committee in January 1971--17 months after the initial request. The advisory committee recommended that the cancellation be sustained, and the Administrator suspended the pesticides as imminent hazards on October 7, 1971. Had EPA appointed an advisory committee promptly, the marketing of these hazardous pesticides might have been stopped earlier.

According to EPA officials the delay in appointing this advisory committee was caused by difficulty in obtaining qualified scientists to serve on the advisory committee and by a shortage of EPA staff that was needed to review the qualifications of the advisory committee nominees and to gather scientific information for the committee to review.

Public hearings normally were postponed until after the advisory committee issued its report. Manufacturers who requested public hearings also faced long delays in their appeals. For example, as of October 1972, the two manufacturers who requested a public hearing on the 2,4,5-T cancellation had been waiting about 2-1/2 years for the start of the hearing. (See p. 14.) According to an EPA official, this delay was caused in part by the difficulty in obtaining a hearing examiner from another Federal agency since EPA did not have its own hearing examiners. As of October 1972 the start of the hearing was being delayed by a court order obtained by one of the manufacturers.

Although EPA canceled the registration of all DDT pesticides on January 15, 1971, the DDT hearing did not begin until August 1971. The hearing, which lasted 7 months, was preceded by 6 months of preparation and prehearing conferences. As a result, the hearings were not completed until March 16, 1972.

#### Usefulness of an informal meeting

Many registrants we contacted stated that the appeal proceedings could be shortened, and in some cases eliminated, if EPA would contact the registrants before suspending or

canceling pesticides. Some of these registrants stated that they had considerable expertise with regard to the pesticides and should be given the opportunity to examine and comment on the scientific evidence supporting the proposed suspension or cancellation. They also said that an interchange of information before EPA made a decision could eliminate many of the misunderstandings and could result in better EPA decisions. According to the registrants, this interchange would limit the appeals to areas of complete disagreement and would identify the areas that should be resolved by an advisory committee or a public hearing.

We believe that an informal meeting before a suspension or cancellation would benefit both EPA and the registrants. We discussed this concept with environmental groups and pesticide manufacturers and most approved.

If, after an informal meeting, a manufacturer said it wanted to have questions of safety and efficacy referred to an advisory committee, EPA could begin to establish the committee in anticipation of the appeals. Similarly, the informal meeting might effectively limit the issues to be referred to the advisory committee or discussed at the public hearing.

### CONCLUSIONS

Lengthy appeals following cancellations of pesticide registrations have permitted the continued marketing of pesticides involving a substantial question of safety to man and his environment. The question of safety and continued use of the pesticide should be resolved as quickly as possible for the benefit of both the consumer and the manufacturers.

Although the FEPCA provisions which include the scientific review as part of the public hearing should shorten the administrative review process, we believe that appeals could be resolved more rapidly if advisory committees were selected and public hearings initiated promptly. Holding an informal meeting before issuing a cancellation order might help EPA to determine the issues requiring further scientific review and the manufacturers' intentions of requesting a public hearing. Such an informal meeting might also reduce delays in preparing for the public hearings

and enable EPA to begin selecting a scientific advisory committee earlier.

#### AGENCY COMMENTS

EPA advised us that FEPCA contains provisions permitting the Administrator to hold hearings to determine whether registrations should be suspended or canceled and that it will develop procedures for such hearings.

However, the informal contact we mentioned does not require legislative authority, and it is our opinion that EPA should meet with registrants before taking any suspension or cancellation action.

#### RECOMMENDATION

We recommend that the Administrator of EPA develop procedures to provide for an informal meeting before suspending or canceling a pesticide registration.

## CHAPTER 5

### SCOPE OF REVIEW

We reviewed and evaluated EPA's policies and practices for suspending and/or canceling the registrations of hazardous pesticides and for removing these pesticides from the channels of trade. We reviewed pertinent legislation, documents, reports, and records and interviewed agency personnel at EPA headquarters.

Through interviews and questionnaires, we solicited the views of State pesticide regulatory agencies, pesticide manufacturers, scientists, and environmental groups as to EPA's decision to suspend or cancel the registrations of pesticides containing DDT, TDE, aldrin, dieldrin, mercury, 2,4,5-T, and thallium sulphate.

We mailed questionnaires to 50 pesticide manufacturers affected by the suspensions and cancellations discussed in this report; 26 responded. We also interviewed nine manufacturers whose pesticide registrations were either suspended or canceled.

We also mailed questionnaires to 50 scientists; 24 responded. We selected these scientists primarily from among the nominees to the DDT, aldrin-dieldrin, mercury, and 2,4,5-T advisory committees. Of those responding to our questionnaires, 17 had served on advisory committees. We also interviewed seven scientists.

We interviewed State pesticide control officers from two States and solicited officials' opinions in the other 48 States. Officials of 27 States responded to our questionnaire. We also contacted nine environmental groups in the Washington, D.C., area.

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

30 OCT 1972

Mr. Edward A. Densmore  
Assistant Director  
Resources & Economic Development Division  
General Accounting Office  
Room 1689, Parklawn Building  
Rockville, Maryland 20852

Dear Mr. Densmore:

We have reviewed your draft report to the Congress, "Assessment of Efforts to Remove Hazardous Pesticides from the Channels of Trade," and we have the following comments to offer:

Recommendation #1

"....establish procedures requiring that EPA suspension actions be consistently applied to all pesticides products that contain the same hazardous ingredients and are registered for the same general uses."

Comment

A suspension action must be based on a finding of an imminent hazard and the factors affecting suspension are much too complex to permit uniform criteria for all cases. This was discussed in the Agency's March 18, 1971 statement "Reasons Underlying the Registration Decisions Concerning Products Containing DDT, 2,4,5-T, Aldrin and Dieldrin" in Chapter II, Formulation of Standards.

Recommendation #2

"....establish a standard for dioxin content and prohibit the use of all products that contain dioxin in excess of the established standard."

Comment

The question of dioxin safety is presently being researched in laboratories connected with a number of Federal agencies. Further research on detection of low concentrations of dioxin is being carried out under a grant from the National Institute of Environmental Health Sciences at Harvard University. We expect these research efforts will help to clarify the question of dioxin safety.

Recommendation #3

". . . require that, when EPA cancels or suspends a product registration and the manufacturer appeals certain uses of the product, the product label be amended to delete the uses not appealed."

Comment

While the term "registered uses" is commonly employed, "uses" are never registered or cancelled. The FIFRA provides only for the registration and cancellation of economic poisons which may bear certain directions for use accepted in connection with the registration. Therefore, when the appeal procedure is invoked it is an appeal pursuant to our action to cancel the product, regardless of the fact that the appellant may present evidence supporting only specific uses of that product. Since suspension stops shipment immediately, removal of "uses" from the label is a moot point. We agree with the spirit of the recommendation and are obtaining an opinion on the legality of requiring a change in labeling of a product under appeal if the substance of the appeal deals only with a portion of the uses on the label.

Recommendation #4

". . . request manufacturers to recall all hazardous products whose registrations have been suspended."

Comment

The extent of the recall, the product involved, and the technology available for disposal all have an impact in the decision-making process. We cannot concur with a blanket policy to initiate full recall (return) of all stocks in every suspension case. There are instances where the process of recall would present a greater hazard than the use of the product in accordance with label directions and precautions.

Recommendation #5

". . . develop procedures to provide for an informal hearing prior to a cancellation or suspension of a pesticide registration, . . ."

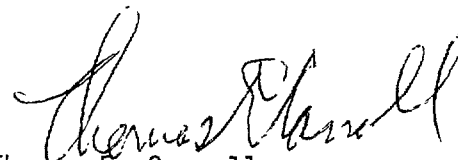
Comment

The new legislation (PL 92-516, The Federal Environmental Pesticide Control Act of 1972) contains provisions permitting the Administrator to hold hearings to determine if registrations should be cancelled or suspended. We will develop procedures for such hearings that are consistent with the legislation.



[See GAO note.]

We appreciated the opportunity to review your draft.

A handwritten signature in cursive script, appearing to read "Thomas E. Carroll".

Thomas E. Carroll  
Assistant Administrator  
for Planning and Management

GAO note: The deleted comments pertain to matters discussed in the draft report but omitted from the final report.

APPENDIX II

PRINCIPAL OFFICIALS OF THE  
 ENVIRONMENTAL PROTECTION AGENCY  
 RESPONSIBLE FOR ADMINISTRATION OF ACTIVITIES  
 DISCUSSED IN THIS REPORT

	Tenure of office (note a)	
	<u>From</u>	<u>To</u>
ADMINISTRATOR: William D. Ruckelshaus	Dec. 1970	Present
ASSISTANT ADMINISTRATOR FOR CATEGORICAL PROGRAMS: David D. Dominick	June 1971	Present
ACTING COMMISSIONER OF PESTICIDES: Raymond E. Johnson	Dec. 1970	May 1971
DEPUTY ASSISTANT ADMINISTRATOR FOR PESTICIDES PROGRAMS: Dr. William Upholt	May 1971	Dec. 1972
Dr. J. Henry Korp	Dec. 1972	Present

<sup>a</sup>All pesticide functions in the Department of Agriculture were transferred on December 2, 1970, to EPA in accordance with Reorganization Plan No. 3 of 1970.

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