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Report to the Chairman, Environment,
Energy, and Natural Resources
Subcommittee, Committee on Government
Operations, House of Representatives

April 1989

PESTICIDES

Export of Unregistered Pesticides Is Not Adequately Monitored by EPA





United States
General Accounting Office
Washington, D.C. 20548

**Resources, Community, and
Economic Development Division**

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The Honorable Mike Synar
Chairman, Environment,
Energy, and Natural
Resources Subcommittee
Committee on Government Operations
House of Representatives

Dear Mr. Chairman:

This report responds to your February 11, 1988, request and subsequent discussions with your office. You asked us to review the implementation of Section 17 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) concerning the export of pesticides. As requested, we focused particularly on the notification requirements concerning the export of pesticides that are not allowed to be sold in the United States.

As arranged with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this letter. At that time, we will send copies to the Administrator, Environmental Protection Agency, and to other interested parties and make copies available to others upon request.

This report was prepared under the direction of Richard L. Hembra, Director, Environmental Protection Issues. Major contributors are listed in appendix III.

Sincerely yours,

A handwritten signature in cursive script, appearing to read 'J. Dexter Peach'.

J. Dexter Peach
Assistant Comptroller General

Executive Summary

Purpose

Pesticides are used globally to kill and control an enormous variety of unwanted plants or pests. Over the past 30 years, the types and amount of pesticides have dramatically increased. Although the United States is not the leading exporter of pesticides, U.S. pesticide export sales are estimated to represent approximately one-quarter of the world pesticide market. Some of these exports have been banned for use in the United States. Furthermore, countries receiving U.S. pesticides may, in turn, export food that has been treated with these pesticides to the United States and to other countries. While pesticides are recognized as important components in meeting the increasing demands for food and in the fight against insect-borne diseases, they also have the potential to create serious problems affecting human health and the environment. From poisonings or potential risks from cancer to environmental concerns over endangered species, pesticide misuse problems have raised international concern.

Concerned about the U.S. role in adequately notifying foreign governments of the export of pesticides that are not allowed to be sold here, the Chairman, Environment, Energy, and Natural Resources Subcommittee, House Committee on Government Operations, requested that GAO review the implementation of the notification requirements under Section 17 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Background

In 1978 the Congress amended FIFRA to include export notification provisions for pesticides intended solely for export. The Environmental Protection Agency (EPA) is responsible for export notices to importing countries of unregistered pesticides and worldwide notices of regulatory action on U.S. pesticides. Section 17(a) establishes notification requirements for the export of pesticides that are not registered for domestic use in the United States. The exporter/manufacturer is responsible for forwarding these notices to EPA, which then forwards them to the importing country. Section 17(b) requires notification by EPA whenever a pesticide registration is canceled or suspended. These two types of notices provide foreign governments with crucial information on unregistered products.

GAO has reported in the past that EPA could improve its implementation of both sections of FIFRA. Ten years ago, GAO concluded that EPA does not monitor pesticide exports, and its recommendations were aimed at improving EPA's ability to monitor compliance by pesticide manufacturers with FIFRA export notice requirements. GAO also recommended that

EPA implement procedures to ensure that foreign countries be notified of all significant changes in pesticide registration.

Results in Brief

GAO found that EPA has yet to establish an effective program to determine whether pesticide manufacturers are complying with the export notification requirements. EPA does not know whether export notices are being submitted, as required under FIFRA.

In addition, EPA's enforcement policy concerning certain unregistered pesticides under section 17 greatly hinders any effort it might make to monitor compliance. EPA's policy, in effect, exempts the majority of unregistered pesticide exports from the notice requirement.

EPA does not have internal procedures for preparing and issuing notices to foreign countries and international organizations when it has taken significant action on a pesticide because of a serious health or environmental concern. GAO found that notices were not sent for three pesticides (out of four) that were voluntarily canceled because of concern about toxic effects. As a result, foreign governments may not be alerted to unreasonable hazards associated with using particular pesticides.

Principal Findings

EPA Not Effectively Monitoring Compliance With Section 17(a)

EPA does not have a program to monitor compliance with pesticide export notification requirements under Section 17 of FIFRA. To determine compliance, EPA would have to match the information on the export notices with information it receives from manufacturers on unregistered pesticide exports. Any compliance-monitoring effort would be hampered by the inadequate quality and type of information contained in the notices of export. GAO found that the notices lack clarity and may not contain enough meaningful information to be useful to foreign governments in properly identifying products.

EPA's ability to monitor compliance is also hindered by its policy governing section 17(a). EPA established an enforcement policy that the requirement in section 17(a) concerning an export notice is not applicable to unregistered pesticides that are similar in composition and use to registered products in the United States, thereby exempting the majority

of unregistered pesticide exports. GAO's review of 16 companies exporting about 80 percent of the unregistered pesticide products determined that EPA received notices on only about 26 percent of the products. All exporting companies cited EPA's "similar in composition and use" policy as reasons for not obtaining section 17(a) notices. EPA's policy, in effect, hampers any effort EPA might make to monitor compliance since it would have to determine whether a particular exported unregistered pesticide is or is not similar to any 1 of approximately 45,000 registered pesticide products—a difficult and time-consuming task. GAO believes that EPA needs to change its enforcement policy concerning unregistered pesticides. EPA's policy, in effect, exempts a large number of pesticides claimed to be similar to registered pesticides.

Foreign Countries Not Adequately Notified on Pesticides of U.S. Concern

GAO's review substantiates its earlier conclusions that EPA does not have adequate procedures for preparing and issuing section 17(b) notices. As a result, EPA does not know if it sent notices to foreign governments for all pesticides where significant action has been taken because of a health or environmental concern about a pesticide. GAO's review identified three out of four pesticides whose uses were voluntarily canceled by the manufacturer because of probable carcinogenic and other toxic effects, for which no notices were issued.

An EPA booklet summarizing and clarifying the agency's actions on suspended, canceled, and restricted pesticides is outdated. If updated annually, foreign governments and others could use it as a reference guide. The 17(b) notices issued after the booklet's annual update would serve as supplemental information to give foreign governments a current description of U.S. regulatory actions.

Recommendations

GAO makes recommendations to the Administrator, EPA, on actions to strengthen EPA's oversight of pesticide exports, including (1) monitoring compliance with export notification requirements, (2) changing its enforcement policy concerning unregistered pesticides under section 17(a) (see chap. 2), and (3) developing criteria and procedures to improve preparation and issuance of section 17(b) notices, including specifying what constitutes a significant action on a pesticide. (See chap. 3.)

Agency Comments

GAO discussed the factual information contained in a draft of this report with responsible EPA officials. These officials agreed with the facts presented, and their views have been incorporated into the report where appropriate. As requested, GAO did not obtain official agency comments on the report.

Contents

Executive Summary		2
Chapter 1		8
Introduction	Federal Pesticide Regulation	8
	FIFRA Section 17 Requirements for Unregistered Pesticide Exports	10
	Prior GAO Reports	13
	Objectives, Scope, and Methodology	14
Chapter 2		18
EPA Not Effectively Monitoring Compliance With Export Notification Requirements	Obtaining Section 17(a) Export Notices: Purchaser Acknowledgment Statements	18
	Improved Reporting Requirements Are Needed	20
	EPA's Enforcement Policy for FIFRA Section 17(a) Hampers Efforts to Monitor Compliance	23
	Conclusions	25
	Recommendations to the Administrator, EPA	26
Chapter 3		27
Foreign Countries Not Adequately Notified of U.S. Concerns on Specific Pesticides	Importance of Section 17(b) Notices	27
	EPA Does Not Have Internal Guidance for Preparing and Issuing Notices	28
	Guidance for Transmission of Notices by the Department of State and U.S. Embassies Is Not Current	30
	Voluntarily Canceled Pesticides for Which 17(b) Notices Were Not Issued	32
	Suspended and Canceled Pesticide Booklet Is Outdated	34
	Conclusions	35
	Recommendations to the Administrator, EPA	36
Appendixes		
	Appendix I: EPA's Office of Pesticide Programs October 25, 1988, Revised List of Canceled and/or Suspended Chemicals	38
	Appendix II: EPA's Office of Pesticide Programs October 25, 1988, Revised List of Voluntarily Canceled Chemicals of Significance	39
	Appendix III: Major Contributors to This Report	40

Tables	Table 1.1: U.S. Pesticide Exports (Rounded Figures)	12
	Table 2.1: Section 17(a) Export Notices Received by EPA, 1985-87	19
	Table 3.1: EPA's Notices of Regulatory Action for 1985 Through 1988	30

Abbreviations

EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GAO	General Accounting Office
OCM	Office of Compliance Monitoring
OLA	Office of International Activities
OPP	Office of Pesticide Programs
OPTS	Office of Pesticides and Toxic Substances
TSCA	Toxic Substances Control Act

Introduction

Pesticides are chemicals or biological substances designed to destroy or control any unwanted species of plant or animal. Pesticides are applied in countless ways, not only on food crops. They are used on our forests, lakes, city parks, lawns, playing fields, pets, and livestock; and in our hospitals, schools, offices, and homes. They are contained in a wide variety of products ranging from weed killers and bug spray to shelf paper and mattresses. These chemicals make apples crisper, prevent mold on bathroom walls, or kill bacteria on medical equipment. Pesticides also play a dramatic role in the fight against insect-borne diseases, such as malaria and yellow fever.

While pesticides are recognized as important components of agricultural production and public health programs, they also have the potential to create problems affecting health and the environment. Because pesticides are designed to kill and control living organisms, unacceptable levels of exposure to them can be hazardous. Some pesticides have been shown to cause chronic health effects such as cancer or birth defects. Some pesticides can produce changes in the genetic material, or genetic mutations, that can be passed to the next generation. Other pesticides can cause sterility or impaired fertility. Some pesticides persist in the environment over long periods of time and accumulate in the tissues of people, animals, and plants.

Pesticides can also have detrimental effects on the environment. The widespread use of chlorinated insecticides, such as the familiar canceled chemical DDT and its chemical cousins, led to public outcry in the early 1970s over residues in fish and their threat to bird reproduction, in particular, bald eagles, ospreys, peregrine falcons, and brown pelicans.

Federal Pesticide Regulation

Responsibility for protecting public health and the environment from unsafe pesticide residues is shared primarily by the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA). Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136 et seq.), EPA has the authority to regulate the sale and use of pesticides in the United States. FIFRA was originally enacted in 1947 but was significantly amended in 1972 when the emphasis in pesticide regulation changed from ensuring product performance to protecting the public health and environment. FIFRA requires that all pesticides sold in the United States be licensed, or registered, for use by EPA. Under FIFRA, EPA is required to evaluate the risks and benefits of a proposed pesticide use. EPA is also authorized to register pesticide products,

specify the terms and conditions of their use prior to being marketed, and remove unreasonably hazardous pesticides from the marketplace.

EPA is responsible for registering specified uses of pesticide products on the basis of both safety and benefits. A registration must be obtained for each use of a particular pesticide. In other words, a chemical that has been registered for use on wheat must be registered again for use on lettuce and once again for use on apples. Each company that manufactures a particular pesticide must register it with EPA. To register a pesticide, EPA must determine that the pesticide will not cause any "unreasonable adverse effects on the environment" or humans. In other words, the benefits arising from the pesticide's use must outweigh the risks. EPA relies almost exclusively on health and safety tests conducted by the pesticide manufacturer when deciding whether to register a pesticide. EPA then reviews these tests and can require more information or testing if not satisfied with the information submitted by pesticide registrants.

Over the years, EPA has canceled, suspended, or significantly restricted the registrations of a number of pesticides (or pesticide product ingredients) because of the unreasonable hazards they posed to humans or the environment. DDT and dieldrin, for example, were banned from use in the United States in 1972 and 1974, respectively, because of their carcinogenicity and environmental persistence.

Under the 1972 amendments to FIFRA, the Congress mandated that EPA reassess the safety of all pesticide products that had been previously registered. Most pesticides used today were initially registered before contemporary regulatory and scientific requirements were imposed; therefore, most of the approximately 45,000 pesticide products licensed for sale have not been assessed to determine their long-term effects. The Congress, through the 1988 amendments to FIFRA, has refocused EPA's reassessment program by providing additional funding for conducting assessments and about 9 years for completing the task. (These 1988 amendments did not change the section 17 requirements.) As EPA completes its work, the number of pesticides marketed today may not be the number allowed to be marketed tomorrow. As a result, some previously registered products may be added to EPA's list of canceled and suspended pesticides.

EPA also uses label requirements as a primary mechanism for regulating the use and misuse of pesticides. Labels must specify the composition

and packaging of a product and provide directions, warnings, precautionary statements, and other needed restrictions to ensure that proper use of the pesticide product poses no unreasonable risk.

If the pesticide is to be used in the production of a food crop or animal feed, the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 et seq.), requires that, in addition to being registered, the pesticide must have a "tolerance" (maximum allowable limit for pesticide residues), or an exemption from a tolerance. Tolerances are set by EPA for each individual crop or food type, including vegetables, fruits, eggs, and meat on which the pesticide will be used. FDA enforces the tolerances by conducting nationwide monitoring and testing of food for levels of pesticide residues.¹

FIFRA Section 17 Requirements for Unregistered Pesticide Exports

On September 30, 1978, the Congress amended FIFRA to include export notification provisions for pesticides intended solely for export. Section 17(a) establishes notification requirements for the export of pesticides that are not registered for domestic use in the United States. In addition, section 17(b), originally enacted in 1972, requires worldwide notification whenever a pesticide registration is canceled or suspended. (Chapter 2 addresses section 17(a) and chapter 3 deals with section 17(b).)

FIFRA does not provide EPA with the authority to prohibit the export of unregistered pesticides. It does, however, require that EPA establish labeling requirements for exported products and requires exporters to label unregistered pesticides as such. FIFRA also requires all pesticide-producing establishments to file annual production reports to EPA, including the amounts sold or distributed for export.

Products Subject to Section 17 Requirements

Over the past 30 years, the types and amount of pesticides used worldwide have dramatically increased. Hundreds of pesticides are exported from the United States and other countries each year. Some of these exported pesticides have been banned or, alternatively, never registered in developed nations.

Worldwide pesticide sales have dramatically increased. From 1977 to 1987, the worldwide agricultural chemical market doubled in size to more than a \$17 billion industry. Although reliable statistics are not

¹The U.S. Department of Agriculture monitors meat, poultry, and eggs, and FDA monitors other foods to ensure that consumers are not exposed to unsafe levels of pesticide residues in food.

available, U.S. pesticide export sales currently represent approximately one-quarter of the world pesticide market, according to estimates from EPA's Office of Pesticide Programs (OPP), Economic Analysis Branch. Although a major contributor, the United States is not the leading exporter of pesticides. West Germany is the largest pesticide exporter.

Key markets in Western Europe now represent 25 percent of the world market, and the Far East, where pesticide application rates are the highest, accounts for about 23 percent of the worldwide use. The fastest growing markets today are India, Brazil, China, and Spain. Other OPP estimates state that "the United States supplies approximately half, and sometimes less than half, of the pesticides imported in most Latin American countries," where a substantial amount of the fresh fruits and vegetables we eat in the winter months are grown.

The use of pesticides on food in other countries is not governed by U.S. regulations, but instead by the laws of the nation in which the pesticide is used. Exported food to the United States, however, must not contain pesticide residues in excess of EPA-established tolerances. Although laws and regulations designed to minimize pesticides' risks have been adopted in many countries, pesticide misuse is recognized as more acute in developing countries, where more persistent and hazardous pesticides are commonly used, sometimes with little monitoring and regulatory control. Farmers may be untrained in safe and proper agrichemical uses. In addition, implementing effective regulation can be a problem because of a lack of appropriate infrastructure, scientific resources, and technical expertise.

Although U.S. export statistics vary, the best estimates conclude that about 400-600 million pounds of U.S.-manufactured pesticides are exported each year to foreign countries.² Table 1.1 shows U.S. pesticide exports for calendar years 1985, 1986, and 1987, and the percentage of unregistered products. About a quarter of these pesticides are products that are not registered for use in the United States.

²About 1 billion pounds of active ingredient of conventional pesticides were used in the United States during 1987, according to EPA estimates.

Chapter 1
Introduction

Table 1.1: U.S. Pesticide Exports (Rounded Figures)

Figures in millions

	1985		1986		1987	
	Dry or solid chemical product (lbs.)	Liquid chemical product (gal.)	Dry or solid chemical product (lbs.)	Liquid chemical product (gal.)	Dry or solid chemical product (lbs.)	Liquid chemical product (gal.)
Total pesticide exports (registered and unregistered products)	708	10	341	18	372	16
Unregistered products	118	3	98	5	116	3
Percent of products unregistered	16.7	30.0	28.7	27.8	31.2	18.8

Source: EPA Annual Production Report data (FIFRA Sec. 7), FIFRA, and TSCA Enforcement System.

Some of these unregistered exports are pesticides that have been canceled or suspended for U.S. use because they may cause cancer or otherwise endanger humans, wildlife, or the environment. Other exported products have been voluntarily taken off the market by the producer because of economic considerations or concern over potential adverse health or environmental effects. Appendixes I and II contain a list of these canceled, suspended, or voluntarily canceled pesticides.

In addition, many pesticide exports consist of products that may never have been registered with EPA. Some involve products whose chemical contents are unknown (either because registration has not been sought or has not yet been granted) and/or whose human and environmental hazards have not been conclusively evaluated. Other unregistered pesticide products may consist of active ingredients contained in registered products that differ from registered products in their formulations.

Export Notices: Section 17(a) Notices

Section 17(a) of FIFRA requires that, before an unregistered pesticide is exported, the foreign purchaser has signed a statement acknowledging an awareness that the pesticide is not registered and cannot be sold for use in the United States. EPA requires that the exporter/manufacturer then transmit the foreign purchaser acknowledgment statement to EPA and certify to EPA that shipment did not occur prior to receiving the foreign purchaser statement. EPA sends copies of these statements to U.S. embassies in the importing countries, which then forward the statements to the appropriate government official in the importing country. EPA requires these statements for the first shipment of each unregistered product to a particular purchaser for each importing country, annually. Shipment of the unregistered pesticide may proceed before the foreign

government has received the notice, since its purpose is only informational.

Notices of Regulatory
Action: Section 17(b)
Notices

Section 17(b) of FIFRA requires that EPA notify foreign governments and appropriate international agencies “Whenever a registration, or a cancellation or suspension of the registration of a pesticide becomes effective, or ceases to be effective” EPA did not, however, develop a regulation to interpret section 17(b). Instead, EPA issues notices to foreign governments and international organizations on those cancellations and suspensions of U.S. pesticide registrations it deems of “national or international significance.” EPA prepares these notices of control action and sends them to the Department of State, which forwards the information to all U.S. embassies for transmittal to their host governments. These notices explain the action, and the health and safety concerns that prompted it, and offers additional information upon request.

Prior GAO Reports

In April 1978, we reported several deficiencies in EPA’s implementation of section 17(b)’s notification provision.³ We concluded that EPA often does not make notifications on regulatory actions and was, therefore, not complying adequately with the law. We recommended that EPA compile information on all pesticide suspensions and cancellations—both agency and registrant-initiated—in a concise publication for distribution to appropriate foreign nations. We also recommended that EPA develop an appropriate system with the Department of State for timely and efficient dissemination of this and similar data to foreign officials. We could find no record of EPA corrective actions.

In July 1978, we testified before the Commerce, Consumer, and Monetary Affairs Subcommittee, House Committee on Government Operations, on federal efforts to notify foreign nations regarding pesticide suspensions and cancellations. We concluded that foreign nations are not receiving all EPA notifications and that, when notifications are received, they may be illegible or unclear in meaning.

³Need to Notify Foreign Nations of U.S. Pesticide Suspension and Cancellation Actions (CED-78-103, Apr. 20, 1978).

In June 1979, we again reported that EPA does not, as required by law, notify foreign countries of all significant registration actions.⁴ We concluded that EPA's criteria for limiting notifications appears questionable, and we recommended that EPA, through appropriate Department of State channels, implement procedures to ensure that foreign countries be notified of all suspensions, cancellations, restrictions, and significant changes in registration.

Our June 1979 report also concluded that neither EPA nor any other federal agency monitors pesticide exports, and we made recommendations aimed at improving EPA's ability to monitor compliance by pesticide manufacturers with FIFRA Section 17(a) requirements. We concluded that EPA's ability to effectively monitor is hampered by a problem with available information. We could find no record of EPA corrective actions.

In the decade since we issued these reports, these problems have not been resolved, although EPA has told us that it has made attempts to address them. During the course of our review, EPA officials have been extremely candid and fully cooperative. Although publicly acknowledging the need for improvements, the pull of conflicting priorities has generally made it difficult for EPA to effect these needed changes, according to officials responsible for the notification program.

Objectives; Scope, and Methodology

In a February 11, 1988, letter and subsequent meetings, the Chairman, Environment, Energy, and Natural Resources Subcommittee, House Committee on Government Operations, asked us to review the implementation of Section 17 of FIFRA concerning the export of pesticides, focusing particularly on the notification requirements concerning the export of pesticides that are not allowed to be sold in the United States. The objectives of our review were to determine

- how the notification of exported unregistered pesticides (FIFRA sec. 17(a) requirements) is being carried out and
- whether the United States is adequately transmitting to foreign governments vital information (FIFRA sec. 17(b) requirements) about pesticides that are no longer registered.

Chapter 2 addresses our first objective dealing with section 17(a) requirements, and chapter 3 addresses section 17(b) requirements.

⁴Better Regulation of Pesticide Exports and Pesticide Residues in Imported Food Is Essential (CED-79-43, June 22, 1979).

We performed our work at EPA and the Department of State's Washington, D.C., headquarters. We also interviewed U.S. embassy staff responsible for transmitting both the 17(a) and 17(b) notices in the following five Latin American countries: Chile, Costa Rica, the Dominican Republic, Guatemala, and Mexico. The countries were selected for a separate ongoing GAO review addressing U.S. government agencies' and international organizations' efforts to assist foreign governments in meeting U.S. safety requirements. These countries were selected on the basis of large exports of fruits and vegetables to the United States. (A separate GAO report addressing these efforts is expected within a few months.)

To determine how the notification of exported unregistered pesticides (FIFRA sec. 17(a) requirements) is being carried out, we reviewed pertinent legislation, and EPA's policies and procedures as well as documents and reports relating to the export notices. We interviewed EPA officials in the three offices responsible for export notices: the Office of Compliance Monitoring (OCM), the Office of International Activities (OIA), and the Office of Pesticide Programs (OPP). We also discussed section 17(a) requirements with EPA's Office of General Counsel.

We gathered data involving several sets of EPA- and industry-generated information to document the export notification process and to determine the extent of unregistered pesticides exported annually. Each set of data contains some data elements contained in one or more of the other sets; however, no one set contains complete information on the specific chemical name, manufacturer, quantity, and country destination. We matched these data to understand the extent of unregistered pesticide exports—a fact currently unknown by EPA.

We also attempted to determine if manufacturers are complying with the section 17(a) notification requirements. We first matched the 17(a) notices received by EPA during 1987 with the 1987 confidential EPA production data required by FIFRA Section 7. At our request, EPA supplied computer-generated records of OCM's FIFRA and Toxic Substances Control Act (TSCA) Enforcement System data base. These data contained information on all pesticides produced, sold, and exported by company for the years 1985, 1986, and 1987. Although we did not test the reliability of the data used or the system which captures the data, we did verify totals to EPA-produced documents.

Second, we contacted 16 out of the 42 companies exporting unregistered pesticide products during 1987 (on the basis of EPA data available as of late July 1988). These 16 companies exported about 80 percent (209 out

of 262) of the total number of unregistered exported products during this period. We solicited manufacturer interpretations of the FIFRA Section 17(a) notification requirements and asked them for explanations of why section 17(a) notices were not obtained for all unregistered pesticide products exported by their company.

To determine whether the United States is transmitting these export notices to foreign governments, we interviewed U.S. embassy staff responsible for transmitting these export notices in the five countries mentioned earlier; however, we encountered difficulty in tracing the notices through U.S. embassies to foreign governments because of a lack of formal transmittal procedures and record-keeping requirements. In addition, there was a high rate of personnel turnover at each embassy and in some governments, which contributed to a lack of institutional memory about the notices. Because of these difficulties, our review did not determine whether foreign governments or users of unregistered U.S. pesticides in these countries are receiving the information contained in all of the notices.

To determine whether the United States is transmitting to foreign governments vital information required under section 17(b) about pesticides that are no longer registered, we reviewed pertinent legislation; EPA's policies, procedures, notices of control action, and other documents; and State Department cables on pesticides to and from U.S. embassies. We interviewed EPA's officials in OIA, OPP, and OCM about policies and procedures and coordination efforts in initiating and preparing 17(b) notices and publishing a booklet on canceled, suspended, and restricted pesticides. We also interviewed a State Department official about State's role in the process for transmitting the notices to the embassies. We interviewed U.S. embassy staff in the five countries about guidance received from EPA on processing 17(b) notices and obtained information on the notices each embassy received from 1985 through 1988.

Regarding the adequacy of EPA section 17(b) notification actions, we requested from OPP a current list of canceled, suspended, or voluntarily canceled pesticides. We used this list along with EPA's "Fiscal Year 1987 Report on the Status of Chemicals in the Special Review Program, Registration Standards Program, Data Call-in Program, and other Registration Activities," Federal Register notices, 17(b) notices issued from 1983 through 1988, and interviews with OPP officials to identify pesticides that EPA suspected were potentially hazardous but, for which, EPA did not issue notices of regulatory action.

To obtain input from the pesticide industry, we interviewed officials of the National Agricultural Chemicals Association, a major pesticide trade association. To obtain input from environmental groups, we interviewed representatives from Greenpeace International and the National Coalition Against the Misuse of Pesticides. To obtain information from the international community, we contacted officials at the U.S. Agency for International Development and the Food and Agriculture Organization of the United Nations.

We reviewed the EPA Administrator's fiscal years 1983 through 1988 Federal Managers' Financial Integrity Act reports for previously reported internal control weaknesses in the Office of Pesticides and Toxic Substances. In addition, we reviewed the individual annual reports on internal controls submitted by the Office of Pesticides and Toxic Substances and looked at those weaknesses in connection with the adequacy of section 17 requirements.

Our work was performed between February 1988 and March 1989 in accordance with generally accepted government auditing standards. We discussed the factual information contained in a draft of this report with responsible officials at EPA and the Department of State. These officials agreed with the facts presented, and their views have been incorporated into the report where appropriate. As requested, we did not obtain official agency comments on the report.

EPA Not Effectively Monitoring Compliance With Export Notification Requirements

We reported in 1979 that neither EPA nor any other federal agency monitored the content, quantity, and destination of unregistered exported pesticides. In 1988, we again found that EPA did not have a program to determine whether pesticide manufacturers are complying with the export notification requirements under FIFRA Section 17(a) for unregistered pesticide exports. Compliance monitoring is inhibited by the lack of available information. Even if EPA routinely monitored compliance with section 17(a), its efforts would be hampered by the inadequate quality and type of information contained in the notices of export, which makes it difficult to properly identify products. As a result, EPA has no assurance that importing countries are adequately notified of unregistered pesticides entering their borders.

We also question EPA's policy that the requirement in section 17(a) concerning an export notice from a foreign purchaser is not applicable to unregistered pesticides that are similar in composition and use to registered products in the United States. As a result, EPA's policy, in effect, exempts the majority of unregistered pesticide exports from the notice requirement as well as from the requirement that the label must be clearly marked "Not Registered for Use in the United States of America."

Foreign governments need to receive information on unregistered pesticide exports so they may properly evaluate the risk of continued use of the pesticide. In addition, hazardous unregistered pesticides could pose a threat to people in other nations as well. Countries receiving U.S. pesticides may, in turn, export food that has been treated with these pesticides to the United States and other countries.

Obtaining Section 17(a) Export Notices: Purchaser Acknowledgment Statements

The export notification process under FIFRA Section 17(a) involves a number of steps. First, prior to export, the U.S. exporter (or manufacturer) must obtain a statement from the foreign purchaser acknowledging an awareness that the pesticide is not registered and cannot be sold for use in the United States. The exporter then transmits the foreign purchaser acknowledgment statement to EPA and certifies to EPA that shipment did not occur prior to receiving the foreign purchaser statement. EPA then sends copies of these statements to U.S. embassies in the importing country. Finally, U.S. embassies forward the statements to the appropriate official in the government of the importing country. EPA requires these statements for the first shipment of each unregistered product to a particular purchaser for each importing country, annually. Statements must be transmitted to EPA within 7 days of receipt by the

**Chapter 2
EPA Not Effectively Monitoring Compliance
With Export Notification Requirements**

exporter. Table 2.1 shows the number of section 17(a) notices received by EPA during 1985, 1986, and 1987, and the number of companies sending these notices.

Table 2.1: Section 17(a) Export Notices Received by EPA, 1985-87

	1985	1986	1987
Number of notices	186	159	191
Number of companies sending notices	19	17	14

Source: Export notices contained in OIA files.

Each statement must include the following information:

- The name and address of the exporter.
- The name and address of the foreign purchaser.
- The name of the product and the active ingredient and an indication that the purchaser understands that the product is not registered for use in the United States.
- The destination of the export shipment, if different from the purchaser's address.
- The date and signature of the foreign purchaser.

The purpose of the export notices is to advise foreign governments that pesticides that have been judged by the United States to be hazardous to human health or to the environment, or pesticides for which no hazard assessment has been made, are being exported by U.S. producers to their country. Foreign governments may then, in turn, use the information in whatever way they may so choose, including evaluating the risk of continued use of the pesticide in that country versus the pesticide's benefits.

**Needed Improvements
Acknowledged by EPA**

EPA has acknowledged in the past the need for improvements in its FIFRA export notification system. During March 1986 testimony before the Subcommittee on Department Operations, Research, and Foreign Agriculture, House Committee on Agriculture, the Assistant Administrator for Pesticides and Toxic Substances called for administrative improvements of its export notification system and particularly agreed that "in order for the notices to be more meaningful, more information should be transmitted."

In addition, a July 1987 paper reporting on a joint EPA and Organization of American States project on pesticide export information exchange made the following recommendations:

- The U.S. notification system should be revised, in order to improve its efficiency and effectiveness. The United States should change the process for transmitting the notifications. (The paper contained no specifics or explanation.)
- The content of the export notices may not contain enough meaningful information to be useful to the recipient and, therefore, the content should be expanded, in order to communicate more comprehensive information. (Again, the paper did not contain specifics; however, complete chemical descriptions containing all generic or chemical names, common names, or other trade names would be helpful in order to fully identify products.)

Although publicly acknowledging the need for improvements, the pull of conflicting priorities has generally made it difficult for EPA to effect these needed changes, according to officials responsible for the notification program. In June 1987, EPA's OIA, however, instituted one important change that has streamlined the 17(a) notice transmittal process. Prior to that time, EPA would send a copy of the purchaser acknowledgment statement to the Department of State, which would then log, copy, and specify the registration status of the pesticide before sending a copy to the U.S. embassy for transmittal to the appropriate official in the importing country. The Department of State and EPA both felt that this process was duplicative and sometimes resulted in unnecessary delays. Now, EPA sends the notices directly to the U.S. embassies in the importing countries. EPA has stated that this change has considerably improved the timeliness of the notices; the process from OIA to the U.S. embassies now generally takes less than 5 days, according to the OIA official responsible for the export notices.

Improved Reporting Requirements Are Needed

The key elements for effective notices are the content and format of the notices, and how they are transmitted. During the course of our review, we were frequently told by U.S. embassies, the pesticide industry, EPA, and other groups that the section 17(a) export notices lack the kind of detailed information that would permit unregistered pesticide products to be properly identified and controlled.

Although most of the notices contain the name of the product and the active ingredient, the information is sometimes illegible or incomplete.

For example, some copies of notices in EPA files were of poor quality, therefore, making it impossible to identify the product. Some copies contain only a trade name without the required active ingredient's name. A trade name without its common or chemical name is inadequate to properly identify the product. Full chemical descriptions containing all generic or chemical names, common names, or other trade names are helpful in order to fully identify products.

EPA agrees that the contents of these notices lack clarity and that the notices may not contain enough meaningful information to be useful to the recipient. There was also general agreement among those we interviewed that improvements should be made in what information is provided to foreign governments.

Our review of the notices from the embassies' files indicated that most of them had received at least some of the notices since 1985. For example, 1 embassy's files contained 4 out of 5 notices sent from EPA during 1987 and another contained 8 out of 13 notices sent from EPA during 1985 through 1987. However, most of the embassies had destroyed their 1985 files, and staff at every embassy indicated that they sometimes do not retain copies before transmitting them to the foreign governments. Embassy staff did recall receiving and sending export notices.

Although EPA has streamlined the transmittal process for export notices to the U.S. embassies, no formal procedures govern the processing and transmittal of FIFRA notices once they arrive at the U.S. embassies. We address the issue of transmittal procedures for both section 17(a) and 17(b) notices, and offer a recommendation toward improvement in chapter 3.

EPA's data base containing annual production data also lacks the detailed information needed to properly identify unregistered pesticide exports. By March 1st of each year, each pesticide manufacturer must report (under FIFRA sec. 7) the types and amounts of pesticides being produced, sold, and distributed, including those exported, in the previous year. This confidential information is sent to 1 of EPA's 10 regions, where information is entered into an OCM national data base. Each separate reporting form (EPA Form 3540-16) contains specific chemical ingredient information for each unregistered product, including a list of the chemical names for each ingredient and the percentage of each ingredient. Although the individual forms contain this descriptive information, OCM's data base does not contain active ingredient information. The data base only lists the trade name and manufacturer (and address), and

some general use, type, and quantity information. Not having complete information makes it difficult for EPA to clearly identify individual unregistered pesticide exports. EPA agrees that active ingredient information would be helpful and might be included in its data base information.

To determine manufacturer compliance with the section 17(a) requirements, EPA would have to match the information on the export notices received with information contained in the annual production data on unregistered pesticide exports. This exercise would enable EPA to determine the unregistered pesticide exports for which notices were not transmitted.

We performed this comparison and found it very difficult, and sometimes impossible, to properly identify products because of incomplete information. The export notices contain the trade name and active ingredient, but the information is sometimes incomplete. The annual production data contain only the trade name without any additional information to correctly identify the individual product. Full chemical descriptions should contain all generic or chemical names, common names, or other trade names in order to fully identify products.

Pesticide Export Information Would Help FDA Monitor Imported Foods

Detailed information on unregistered pesticide exports would not only assist EPA's compliance efforts, it would also help FDA in its monitoring of pesticide residues on imported food. During recent years, the rise in agricultural imports (especially fruit and vegetable imports) has been significant. In our 1979 report, we recommended that EPA provide information on the destination of exports to FDA and, in 1986, we again reported that FDA lacked information on pesticides used in foreign food production.¹ According to OCM's Director of the Compliance Division, EPA does not have a system for transferring information to FDA on pesticide export notices or information on production data for unregistered products that are intended for export. EPA has information on the content, quantity, and destination of unregistered exported pesticides, although it is not conveniently located in one source. Better information about pesticides used in the production of foods imported into the United States would assist FDA, along with other information available from other sources, in determining which pesticides to test for on food imported into the United States by these countries.

¹Pesticides: Better Sampling and Enforcement Needed on Imported Food (GAO/RCED-86-219, Sept. 26, 1986).

EPA's Enforcement Policy for FIFRA Section 17(a) Hampers Efforts to Monitor Compliance

No exceptions are expressly provided under Section 17(a) of FIFRA concerning notification requirements for unregistered pesticides, nor does the legislative history suggest that any are intended. However, in a July 1980 Federal Register notice, EPA established a policy that this requirement is not applicable to unregistered pesticides that are minor variations on formulations registered in the United States and contain only active ingredients that are registered in the United States.² Under this policy, EPA treats similar unregistered pesticides differently from the way they are treated throughout the rest of the pesticide program. In the notice, EPA stated that section 17(a)(2) applies to (1) all pesticide products that contain an active ingredient not found in a federally registered product, (2) all pesticide products in which an adverse decision concerning the use of the pesticide in the United States has been made (e.g., denial or cancellation of registration), or (3) all pesticides that are not similar in composition or that are being exported for a use that is substantially different from any currently registered use of that pesticide. (EPA's policy statement uses both "minor variations on formulations" and "similar in composition and use" language.)

In the notice, EPA stated its belief that the Congress did not intend that exported products with minor variations from EPA-registered pesticides be subject to the acknowledgment requirement. EPA did not explain the legal basis for its policy or statement concerning Congress' intent.

We sought EPA's views on the legal basis for its policy in a January 30, 1989, letter to its Associate General Counsel for Pesticides and Toxic Substances. EPA responded that, after reviewing the notice in light of the statute and its legislative history, EPA believes the policy is best characterized as a statement of enforcement policy indicating how the agency intends to exercise its prosecutorial discretion. EPA explained that the policy's apparent focus on situations that are likely to present the greatest potential for risk avoidance would seem consistent with the statute and thus well within the agency's discretion. In stating its reliance on the rationale of prosecutorial discretion to support its policy, EPA referred to the legal principle that federal agencies have discretion to decline to take enforcement action against particular violations of the laws unless the Congress has manifested an intent to restrict an agency's exercise of enforcement discretion.³ EPA also stated that it found no evidence that the Congress meant to impose restrictions on the enforcement

²45 Fed. Reg. 50274 (1980).

³Heckler v. Chaney, 470 U.S. 821 (1985).

discretion that is available to it under FIFRA. To the extent that EPA's policy reflects its decision not to take enforcement action where unregistered pesticides are similar, we believe this would constitute a valid exercise of EPA's enforcement discretion.⁴

Although we could find no support for its position that the Congress did not intend for notices to be provided for similar pesticides, EPA has the authority to use its enforcement discretion. Nevertheless, EPA's policy, in effect, exempts the majority of pesticide exports from the notice requirement. We matched the notices received by EPA with FIFRA Section 7 production data and used various other sources to identify the pesticide products. As best we could with the data provided, we obtained a list of those products exported by companies during 1987 (on the basis of EPA data available as of late July 1988) that were coded on EPA's data base as being unregistered products and that did not have a notice. We contacted by letter 16 out of the 42 companies exporting unregistered pesticide products during the 1987 period. These 16 companies exported about 80 percent (209 out of 262) of the total number of unregistered exported products during this period. We asked them to explain why section 17(a) notices were not obtained for all unregistered pesticide products exported by their company and asked them how they decide which products require notices.

Manufacturers generally were familiar with the notice requirement. As best as we could determine, only 54 products out of the 209 unregistered exported products were covered by export notices. Thus, EPA received notices on 54 pesticide products rather than for the 209 unregistered pesticides that these manufacturers exported during that period (or about 26 percent). (As best we could determine with the data provided, these 54 products account for about 10 percent of the total amount, in gallons and pounds, of unregistered pesticides exported in 1987.) All exporting companies cited EPA's "similar in composition and use" exemption as reasons for not obtaining foreign purchaser acknowledgment statements.

EPA's nonenforcement policy also applies to the labeling requirements for exported pesticides. Unregistered pesticides must bear the statement "Not Registered for Use in the United States of America." EPA's policy, however, in effect exempts similar products from the labeling requirements. We believe that EPA, therefore, does not monitor for compliance

⁴This explanation for EPA's policy has thus far been communicated only in the form of a letter responding to our request, not as a revision of its 1980 Federal Register notice.

with the labeling requirements. For EPA to determine compliance with section 17(a) and the labeling requirements, it would have to make a determination that a particular exported pesticide is similar in composition and use to 1 of the 45,000 registered products.

Conclusions

EPA does not have an effective program to monitor the content, quantity, and destination of exported unregistered pesticides to ensure that exported pesticides comply with the law. Foreign governments rely on the United States for information on pesticides that the United States has judged to be hazardous to human health or to the environment, or pesticides for which no hazard assessment has been made. In addition, improvements in U.S. notification requirements could protect U.S.-imported products when foreign governments receive full information on hazardous unregistered pesticides previously used on foods produced in their countries intended for U.S. markets.

We have previously noted EPA's limited ability to perform its enforcement responsibility in monitoring compliance with export notification requirements. However, EPA still does not know whether section 17(a) notices are being submitted, as required.

To enable EPA to better monitor compliance, we believe that improvements need to be made in the reporting requirements to assist EPA in the monitoring of unregistered pesticides. These improvements will also help assist foreign governments in clearly identifying unregistered pesticide products. EPA's ability to effectively monitor compliance is hampered by a problem with available information. We believe that the content and quality of both the notices and the section 7 production data base information need to be improved in order for EPA to monitor compliance. In addition, we believe that EPA should routinely provide pesticide export information to FDA to assist FDA in its monitoring of pesticide residues on imported food because countries receiving unregistered U.S. pesticides may, in turn, export food that has been treated with these pesticides to the United States.

We believe that EPA, through its enforcement policy, has treated unregistered pesticides for purposes of section 17(a) requirements differently from the way they are treated throughout the rest of the pesticide program. EPA's enforcement policy, in effect, exempts the majority of pesticide exports from the notice and labeling requirement. This policy

makes it extremely difficult and time-consuming, possibly even impossible, for EPA to monitor compliance with section 17(a) or the labeling requirements for unregistered pesticides.

Recommendations to the Administrator, EPA

We recommend that the Administrator, EPA, take appropriate actions to strengthen EPA's oversight of pesticide exports. Such actions should include

- monitoring compliance with the notification requirements by matching export notice information with export production data;
- requiring manufacturers to improve the quality and type of information contained in the export notices, such as reporting full chemical descriptions; and
- changing EPA's enforcement policy concerning an unregistered pesticide currently used for section 17(a) notices, which in effect exempts a large number of pesticides claimed to be similar to registered pesticides. Such a change would then be consistent with the way EPA treats an unregistered pesticide used throughout the rest of the pesticide program.

We also recommend that the EPA Administrator regularly provide this information to FDA to assist FDA in its monitoring of pesticide residues on imported food.

Foreign Countries Not Adequately Notified of U.S. Concerns on Specific Pesticides

EPA does not have adequate procedures for preparing and issuing notices to foreign countries and international organizations when it has taken significant action on a pesticide because of a serious health or environmental concern. Consequently, EPA has not issued notices to foreign governments for all pesticides where significant action has been taken. We identified four pesticides that were voluntarily canceled by the manufacturer after EPA began special reviews because of concerns about birth defects; and carcinogenic, oncogenic, and neurotoxic effects.¹ EPA issued a notice on only one of these pesticides.

In addition to such notices, EPA periodically publishes a booklet that summarizes and clarifies the agency's actions on canceled, suspended, and restricted pesticides. Unfortunately, this booklet was last published in 1985. Such a booklet should be updated annually and could be used by foreign governments and others as a reference guide to U.S. regulatory actions on pesticides. Foreign governments agree that such information would be very helpful.

Importance of Section 17(b) Notices

Section 17(b) of FIFRA requires EPA to notify foreign governments and appropriate international agencies "Whenever a registration, or a cancellation or suspension of the registration of a pesticide becomes effective, or ceases to be effective . . ." EPA does not have any regulation or formal policy statement on when to issue a notice; however, the Deputy Chief, Policy and Special Projects, OPP, told us it issues notices on those cancellations and suspensions it deems of national or international significance. However, it does not have any criteria for what constitutes national or international significance.

The notification to foreign governments of U.S. suspension and cancellation of pesticide registrations benefits both the United States and the foreign governments. Foreign governments benefit because they are alerted to unreasonable hazards associated with using particular pesticides and can act to lessen exposure of their workers and citizens. The United States can benefit when a foreign government restricts using these harmful pesticides on crops that are subsequently imported into the United States.

¹ Carcinogenic effects produce or incite cancer in living tissue. Oncogenic effects produce or incite tumor formations in living tissue. Neurotoxic effects include diseases of the brain and peripheral nerves, psychiatric conditions, sexual dysfunction, and impairment of memory, reaction time, coordination, and sensory function.

The 17(b) notices generally contain information on when EPA took the action, background on what precipitated the action, an explanation of the regulatory action, and the basis EPA had for taking the action. The notices also give EPA contacts that provide additional information on the affected pesticide and registered products that could be used in lieu of the pesticide to the foreign governments upon request.

EPA Does Not Have Internal Guidance for Preparing and Issuing Notices

EPA has not developed any criteria for determining when a notice should be prepared, according to the Deputy Chief, Policy and Special Projects, OPP. Notices are prepared on an ad-hoc, case-by-case basis. As a result, EPA does not know whether it has sent notices in all cases where notices should have been sent to protect human health and the environment.

The responsibility for preparing 17(b) notices is formally delegated to OPP; however, in practice, it is shared by OPP and OIA. If someone in OPP or OIA believes that a 17(b) notice on a pesticide is necessary, he or she can initiate action. OIA usually prepares the notice that, after review by OPP and if necessary by EPA's Office of General Counsel, it sends in cable format to the Department of State. State reviews the notice and cables it to U.S. embassies and other international organizations. After the initial English-version cable is sent, State translates the notice into Spanish and French and then transmits this version to the designated embassies. State sends a copy of each notice it transmits back to OIA for its files. OIA was discarding this copy until we brought it to OIA's attention that for proper internal control purposes, it was important to keep copies. We believe this copy is needed to determine if a notice was actually transmitted to the U.S. embassies. As a result, in December 1988, OIA began keeping State's official transmitted copies of 17(b) notices.

We requested notices prepared by EPA from 1985 through 1988; however, EPA did not have a complete file of all its notices for this time period. The Environmental Protection Specialist, OIA, provided us with six notices issued before 1985, none for 1985, and eight issued in 1986 through 1988. Since EPA was not keeping the official State Department-transmitted copy of the notices, EPA provided us with seven of its internal copies, which officials said were reviewed by EPA and transmitted to State.

The eighth notice provided by EPA and dated July 1988, for the cancellation of four inorganic arsenicals, was typed in cable format but did not have a record of EPA's review or approval included. As a result of our inquiry about this notice to both EPA and the State Department, State

Chapter 3
Foreign Countries Not Adequately Notified of
U.S. Concerns on Specific Pesticides

performed a computer search of its cable files and could not find any indication that this notice was transmitted to the embassies. EPA also could not find any support that the notice was sent to State for transmission. In December 1988, almost 6 months after the original notice was prepared, EPA prepared a new notice that was transmitted to the embassies for distribution to the foreign governments. The notice states that "It has recently come to the attention of EPA and the [State] Department that there is no record of the original transmission. Appreciate post's assistance in transmitting information to appropriate host officials ASAP." This action was based on evidence that inorganic arsenical pesticides posed cancer risks to people working with the pesticide and caused a number of documented cases of accidental poisonings of children because of its acute toxicity.

EPA was unable to provide us with any notices issued in 1985. However, during our review of the State Department's files, we found correspondence between the U.S. embassies and State indicating that a notice was issued in January 1985 canceling the uses of dibromochloropropane (DBCP). We have added DBCP as one of the nine notices issued between 1985 and 1988. Table 3.1 summarizes the eight notices provided to us by EPA and one we obtained from State Department files.

**Chapter 3
Foreign Countries Not Adequately Notified of
U.S. Concerns on Specific Pesticides**

Table 3.1: EPA's Notices of Regulatory Action for 1985 Through 1988

Pesticide	Date of notice	Action
Inorganic arsenicals ^a	Dec. 1988 ^c	Canceled registrations of most nonwood preservative minor uses.
Cyhexatin	Sept. 1987	Voluntary cancellation of registration
Cyhexatin	Aug. 1987	Significant voluntary restriction
Aldrin/dieldrin ^b	Aug. 1987	Intent to cancel remaining registrations
Chlordane/heptachlor		Significant restrictions on sale and use in United States
2,4,5-T[P] (Silvex)	Apr. 1987	Canceled all registrations
Dinoseb	Oct. 1986	Emergency suspension of all uses
Dicofol	Oct. 1986	Product registrations canceled and requested manufacturers to recall all canceled stocks
Diazinon	Oct. 1986	Special review and preliminary determination to cancel registrations for products used on golf courses and sod farms
DBCP	Jan. 1985 ^d	Intent to cancel registrations

^aIncluding lead arsenate, calcium arsenate, sodium arsenate, sodium arsenite, and arsenic trioxide.

^bEPA notified foreign governments of its actions on aldrin/dieldrin and chlordane/heptachlor on the same notice.

^cNotice should have been transmitted in July 1988; however, original was misplaced, and a new notice was developed and transmitted when we brought it to EPA's and the Department of State's attention.

^dDate U.S. embassies received and sent out notices to foreign governments.

We spoke to U.S. embassy staff in Chile, Costa Rica, the Dominican Republic, Guatemala, and Mexico about their receipt of notices since 1985. Most embassy staff were fairly new to their positions; however, they generally recalled receiving notices on pesticides from EPA. Our review of the notices from the embassies' files showed that most of them had at least some of the notices listed in table 3.1 in their files. We spoke to staff from these embassies after EPA sent out its last notice in December 1988 on inorganic arsenicals and found that all of them had received the notice.

**Guidance for
Transmission of
Notices by the
Department of State
and U.S. Embassies Is
Not Current**

EPA, in consultation with the State Department, developed and issued transmittal guidance on 17(b) notifications for use by the U.S. embassies in December 1984. As a result of this guidance, EPA officials said they received substantial communication from the embassies on two notices sent out soon afterward. However, over the last couple of years, EPA received little or no communication from the embassies. Also, the staff in five embassies we contacted were not aware of this guidance; however, they indicated that it would be helpful to have written guidance. Without this guidance, embassy staff may not know what to do with the

Chapter 3
Foreign Countries Not Adequately Notified of
U.S. Concerns on Specific Pesticides

notice unless a former embassy staff member verbally explained the process.

The 1984 guidance explained EPA's program and legislation, the purpose of the notice, and the types of action that are subject to a notice. The guidance also suggested the appropriate host government officials who would be interested in the notices. It also advised the embassies to request or confirm the host government's designation of appropriate officials to receive the notices. The embassies were instructed to keep a record of the designated officials and maintain a file of all notices, instructions, and host government responses for future reference of new embassy personnel. It requested the embassies to send a copy of the guidance to the host governments and to ask the governments to inform the embassies if they planned to take a regulatory action on a pesticide covered in a particular notice. The embassies were also requested to report any significant action to EPA via the State Department.

After the two notices were sent in December 1984, most embassies cabled EPA with information on the foreign governments' preference for Spanish or French translations, and the name of the person(s) and office(s) in the foreign governments that were designated to receive the notices. Other cables included information on (1) one embassy's procedures for handling the notices, (2) the acknowledgment of one foreign government's receipt of the notices, (3) suggestions on improving the notification system, (4) the reaction of the foreign governments to the notices, and (5) requests for more information by the foreign governments. However, we did not find reports to EPA on any significant actions that might have been taken by foreign governments on the pesticides.

U.S. embassy staff in Chile, Costa Rica, the Dominican Republic, Guatemala, and Mexico stated that they were not aware of the 1984 guidance. However, the staff added that they usually keep files for only about 2 to 3 years. If the guidance was discarded as a result of this practice, this may account for the fact that current embassy staff were not aware of it since EPA issued it over 4 years ago.

An Environmental Affairs Officer from the Office of Environmental Protection, State Department, told us that little feedback was received on notices sent out over the last couple of years and added that it might be beneficial for EPA to update and reissue this guidance. The Deputy Chief, Policy and Special Projects, OPP; and an Environmental Protection

Specialist, OIA, suggested that EPA could reissue the guidance annually and cable it to the embassies with the first 17(b) notice for the new year.

Our review did not conclusively determine whether foreign governments or users of unregistered U.S. pesticides in these countries are receiving the information contained in all of the notices. We encountered difficulty in tracing the notices from U.S. embassies to foreign governments because of the lack of formal transmittal procedures and record-keeping requirements at the embassies. In addition, most embassy staff were fairly new to their positions, which may contribute to a lack of institutional memory about the notices. This high turnover rate makes it even more important to provide guidance to the embassies and for the embassies to keep records of the notices received.

Without current section 17(a) guidance, embassy staff may not know what to do with the 17(a) notice unless a former embassy staff member verbally explained the process. The December 1984 guidance explains that the 17(b) notices are supplemented by a country-specific notice of export (17(a) notice) from the United States to the government of the importing country the first time each year that an unregistered pesticide is exported to that country. In the guidance, EPA said that instructions were being prepared for the use of embassy personnel in the processing of 17(a) export notices. These instructions were to have been sent in a separate telegram. As of April 5, 1989, however, EPA had still not prepared these instructions.

Voluntarily Canceled Pesticides for Which 17(b) Notices Were Not Issued

Our review identified four pesticides whose registrations were voluntarily canceled by the manufacturers. EPA issued notices on only one of these pesticides. The three pesticides for which no notices were sent have been shown to cause significant risks to the health of humans or animals and were under special review by EPA.² Before EPA took final action on the pesticides, the registrants voluntarily canceled EPN,³ carbon tetrachloride, and captafol registrations. EPA's decisions to take action were based on data it acquired showing that the pesticides caused oncogenic, neurotoxic, and probable carcinogenic effects to the health of humans or animals.

²During the special review process, EPA determines whether or not a pesticide poses an unreasonable risk on the basis of both the toxic effects associated with the pesticide and the actual or projected exposure of humans and nontarget organisms to the pesticide.

³The generic name for EPN is O-ethyl O-p-nitrophenyl phenylphosphonothioate.

The fourth pesticide, cyhexatin, for which EPA issued two notices—a warning and a voluntary cancellation notice—was voluntarily canceled by its manufacturers in late 1987 because interim results of a study showed it caused birth defects in laboratory animals. EPA sent out its first notice on the pesticide to foreign governments in August 1987, warning them that there may be a risk of birth defects when pregnant women are exposed to the pesticide during application or while working in the fields where it was applied. The second notice, issued about a month later, was a notice of cyhexatin's voluntary cancellation by the manufacturers. These actions resulted from a registration standard review which EPA began in 1985. Cyhexatin was used on a variety of fruits and vegetables including apples, citrus fruits, strawberries, and seed carrots.

On March 26, 1987, EPA sent a written notice to the registrants of EPN which informed them that EPA was planning to initiate a special review on the basis of data submitted by the manufacturers showing that EPN causes delayed neurotoxic effects in laboratory animals. As a result of this notice, all registrants, except one, voluntarily canceled their registrations. The one remaining registration for EPN was suspended by EPA on July 8, 1987, because the registrant failed to comply with its request for data on the pesticide. Before its cancellation, EPN was used primarily on cotton, field corn, sweet corn, and soybeans. It was also used for ground and aerial application as a mosquito larvicide.

On October 15, 1980, EPA initiated a special review on carbon tetrachloride because human exposure to it may cause damage to the liver, lungs, kidneys, and central nervous system primarily as a result of high oral or inhalation exposures. Carbon tetrachloride is also regarded as a probable human carcinogen on the basis of studies by the National Cancer Institute and others. In addition, significant concentrations of carbon tetrachloride are present in the atmosphere, in part owing to the use of the chemical as a pesticide, and may contribute to the breakdown of the atmosphere's ozone layer. Since the initiation of the special review, all grain uses of carbon tetrachloride have been voluntarily canceled or suspended. On November 12, 1986, EPA formally announced its intent to cancel all products containing the pesticide. In the announcement, EPA permitted a single product registration to remain for carbon tetrachloride's use on encased museum specimens not for public display.

On January 9, 1985, EPA initiated a special review of captafol on the basis of studies that showed it caused oncogenic effects in laboratory animals and was very highly toxic to fish. EPA determined that captafol

met or exceeded the risk criterion stated in federal regulations. Since the initiation of the special review, the registrants voluntarily requested cancellation of all product registrations. These cancellations were effective May 15, 1987, and, therefore, EPA terminated its special review of the pesticide. Before its cancellation, captafol was used for controlling foliar and fruit diseases of certain fruits, vegetables, and peanuts. It was also applied to seeds of corn, cotton, peanuts, rice and sorghum; to pineapple plant stock as a preplant treatment; and to wood as a preservative treatment.

The Deputy Chief, Policy and Special Projects, OPP; and an Environmental Protection Specialist, OIA, stated that 17(b) notices were not issued on these pesticides. The Deputy Chief added that EPA does not routinely prepare notices on pesticides that are voluntarily canceled by the registrants; however, if EPA feels they are of a health concern, then it prepares a 17(b) notice, as in the case of the notice on cyhexatin.

Suspended and Canceled Pesticide Booklet Is Outdated

EPA last published its booklet entitled Suspended, Canceled, and Restricted Pesticides in 1985. Although the booklet was designed as a quick reference guide to be used by regional EPA inspectors, it could also serve as a general reference for anyone involved or interested in pesticide regulatory work. Foreign governments use this booklet to summarize and clarify U.S. actions on over 40 pesticides that have been suspended, canceled, or otherwise restricted. The type of information in the booklet is sufficient to alert countries using affected pesticides to initiate actions or request additional data as a basis for making their own risk-benefit analysis concerning continued use. We believe this booklet is important to anyone working with pesticides, especially as a reference document on past U.S. actions, and should be updated annually; however, the booklet is not a substitute for the 17(b) notices. The notices issued after the booklet's annual update would supplement it to give the foreign governments a complete up-to-date picture of U.S. regulatory action.

In our 1978 report,⁴ we recommended that EPA compile information on suspensions and cancellations for distribution to appropriate foreign governments. At that time, we found that foreign government officials were particularly interested in EPA's booklet on suspended and canceled pesticides.

⁴Need to Notify Foreign Nations of U.S. Pesticide Suspension and Cancellation Actions (CED-78-103, Apr. 20, 1978).

Currently, various agencies of the United Nations are concerned about the dissemination of information on pesticides that are harmful to health and environment. These agencies support the annual update of a list of pesticides whose sale has been banned, withdrawn, or severely restricted. Additionally, embassy staff in Chile, Costa Rica, the Dominican Republic, Guatemala, and Mexico stated they felt that a frequently updated booklet, such as EPA's, would be useful to them and the foreign governments because it would give the current status of pesticides whose registration was suspended or canceled, or whose uses were restricted.

The Director of the Compliance Division, OPTS, stated that his office was in the process of updating the booklet; however, other priorities and a lack of resources put the updating on hold. He did not know when resources would permit the work on the booklet to resume. The Director also said that the booklet, in its current form, was not intended to be used as a reference guide by foreign governments. However, he said that such a list would be useful for foreign governments and agreed that EPA should prepare current listings for use by foreign governments.

EPA has not updated its booklet since 1985. Because it has been 4 years since the last update, the first annual update might take time and effort. We believe, however, future annual updates should be relatively easy, since EPA would just have to add the previous years' canceled and suspended pesticides which could be extracted from the 17(b) notices issued during that year.

Conclusions

EPA does not have internal procedures for determining when to prepare and issue a notice to foreign governments and international organizations when it has taken significant action on a pesticide because of a health or environmental concern. EPA also does not have any criteria for what constitutes national or international significance, or what constitutes a significant action on a pesticide. As a result, EPA does not know if it sent notices in all cases where notices should have been sent.

EPA does not routinely issue notices to foreign governments on voluntarily canceled pesticides, unless it believes a health concern exists. This could result in notices not being issued. On the three pesticides we described that were voluntarily canceled by the manufacturers, EPA was concerned that they caused oncogenic, neurotoxic, and probable carcinogenic effects to the health of humans or animals; however, it did not send out notices to the foreign governments. Not having notices issued

could result in continued use in foreign countries of a pesticide that may jeopardize the health of its citizens or damage its environment. Additionally, the crops treated with the pesticide could be imported into the United States to the detriment of the health of U.S. citizens and the environment.

EPA has not developed any guidance on section 17(a) export notices and has not updated its 1984 guidance on 17(b) notices for the U.S. embassies. As a result, embassy staff do not have guidance on how to handle the notices other than verbal instructions from previous embassy staff. We believe that EPA needs to update its 1984 guidance and develop 17(a) guidance.

EPA last issued its booklet on suspended, canceled, and restricted pesticides in 1985. Various organizations of the United Nations and U.S. embassy staff from five embassies all support a more frequent or annual update of the booklet. This booklet should be updated annually, making it a useful document for all parties concerned including foreign governments, which could use it as a reference guide of all currently suspended, canceled, and restricted pesticides in the United States. The 17(b) notices issued after the booklet's annual update would supplement it to give the foreign governments a complete up-to-date picture of U.S. regulatory actions.

Recommendations to the Administrator, EPA

We recommend that the Administrator, EPA, take the following actions to improve its notification program:

- Develop internal criteria and procedures for determining whether and when to prepare and issue a notice of regulatory action (sec. 17(b) notices), including specifying what constitutes a significant action on a pesticide.
- Annually update and issue to all parties concerned, including foreign governments, its booklet on suspended, canceled, and restricted pesticides.
- Establish guidance on section 17(a) transmittal procedures for sending notices to foreign governments. In addition, in cooperation with the Department of State, annually update and send both section 17(a) and 17(b) guidance to U.S. embassies.

EPA's Office of Pesticide Programs October 25, 1988, Revised List of Canceled and/or Suspended Chemicals

Aldrin
Aspon
Brominated salicylanilide
Carbophenothion
Chlordane/Heptachlor
Cycloheximide
DBCP (dibromochloropropane)
DDD (TDE) (1,1- dichloro - 2,2- bis [p-chlorophenyl] ethane)
DDT (dichloro diphenyl trichloroethane)
Demeton
Dialifor
Dieldrin
Dinitramine
Dinoseb
EDB (ethylene dibromide)
Fenamiosulf
Fluchloralin
Kepone (Chlordecone)
Mirex
Monuron TCA (trichloroacetic acid)
Perfluidone
Potassium permanganate
Silvex
2,4,5-T (2,4,5- trichlorophenoxy-acetic acid)
Thiophanate
Toxaphene

EPA's Office of Pesticide Programs October 25, 1988, Revised List of Voluntarily Canceled Chemicals of Significance

Acrylonitrile
Arsenic trioxide
Benzene (all products)
BHC (benzene hexachloride)
Captafol
Carbon tetrachloride
Chloranil
Copper acetoarsenite
Copper arsenate (basic)
Cyhexatin
Endrin
EPN (O-ethyl O-p-nitrophenyl phenylphosphonothioate)
Erbon
Hexachlorobenzene
Lead arsenate
Monuron
Nitrofen (TOK^a)
OMPA (Octamethylpyrophosphoramidate)
Pentachlorophenol—some nonwood uses continue
Perthane
Phenarsazine chloride
Ronnal
Safrole
Sodium arsenite
Strobane
Trysben

^atrade name

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