BY THE COMPTROLLER GENERAL

Report To The Congress

OF THE UNITED STATES

10,572

Better Regulation Of Pesticide Exports And Pesticide Residues In Imported Food Is Essential

Pesticides suspended, canceled, or never registered for use in the United States because of hazards associated with their use are exported routinely. Serious injuries have occurred from the use of these pesticides in other countries. The Environmental Protection Agency in many cases has neither informed other governments of pesticide suspensions, cancellations, and restrictions in the United States nor revoked tolerances for residues of these pesticides on imported food.

A-C00024

The Food and Drug Administration does not analyze imported food for many potential residues. It allows food to be marketed before testing it for illegal residues. Importers are not penalized if their imports later are determined to contain illegal residues. The safety and appropriateness of some residues allowed on imported food has not been determined.

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

This report discusses Federal efforts to regulate the export of pesticides from the United States and to ensure that imported foods do not contain residues of pesticides at levels which may be harmful to American consumers. The Environmental Protection Agency and the Food and Drug Administration, Department of Health, Education, and Welfare. are primarily responsible for administering the activities discussed in this report.

We are sending copies of this report to the Administrator, Environmental Protection Agency; the Secretary of Health, Education, and Welfare; the Secretary of State; and the Director, Office of Management and Budget.

Comptroller General
of the United States

COMPTROLLER GENERAL'S REPORT TO THE CONGRESS

BETTER REGULATION OF PESTICIDE EXPORTS AND PESTICIDE RESIDUES IN IMPORTED FOOD IS ESSENTIAL

D I G E S T

World demand for pesticides is growing. Developing countries are expected to become more and more dependent on pesticides as they improve food and fiber production. For example, the dollar value of Africa's pesticide demand is expected to increase more than fivefold during the decade ending in 1984. (See pp. 1 and 2.)

Although pesticides are beneficial to the world's health and well-being, they are not problem free. They can be poisonous to people and animals and damaging to the environment. Some pose long-term dangers by building up in the environment where they remain active for several years. (See p. 2.)

American agricultural imports in fiscal year 1977 totaled over $13 billion, making other countries' pesticide practices increasingly important because pesticide residues may be on these imports. The Food and Drug Administration--~~whose job is~~ to ~~assure that~~ marketed ~~food is safe, pure~~, and wholesome--has identified neither the pesticide practices of nor all pesticides used in other countries. Such knowledge is essential if the agency is to make sure that food imports do not contain harmful residues of pesticides that have been suspended, canceled, or never registered in the United States. (See pp. 7 and 8.)

INADEQUATE ANALYSIS OF FOOD FOR PESTICIDE RESIDUES

The methods that the Food and Drug Administration uses to analyze pesticide residues on imported food does not detect residues of many pesticides used in foreign countries. Further, the agency neither determines the source or identity of all contaminants found in imported food nor ascertains whether the contaminants are

harmful to consumers. GAO recommends that the Secretary, Department of Health, Education, and Welfare direct the Food and Drug Administration to

--determine what pesticides are used on imported food,

--test for all potential residues periodically, and

--identify the nature and source of contaminants found. (See pp. 10 to 12, 20, and 21.)

INAPPROPRIATE TOLERANCES AND ACTION LEVELS

The Environmental Protection Agency has not canceled over 297 tolerances for pesticides whose uses have been suspended and canceled up to 6 years ago due to adverse human or environmental harm. Often these pesticides persist for years in nature and unavoidably contaminate food.

When the Environmental Protection Agency revokes tolerances the Food and Drug Administration may establish "action levels" --the maximum residues of pesticides without tolerances that cannot be avoided. However, the Food and Drug Administration has established action levels without (1) determining if residues are in fact unavoidable and (2) an Environmental Protection Agency evaluation to determine if residues can be safely consumed. (See pp. 28 and 31 to 33.)

Continuing tolerances and/or action levels without adequate determinations as to safety and unavoidability mislead and condone other countries' use of hazardous pesticides. This may result in illegal and unsafe residues on U.S. food imports.

The Environmental Protection Agency should revoke all tolerances for suspended and canceled pesticide uses and review, with the Food and Drug Administration, the safety and appropriateness of all existing and proposed action levels. Action levels

should be established only as necessary for environmental contaminants that cannot be avoided. (See pp. 29 to 31 and 34.)

ADULTERATED FOOD MARKETED

Half of the imported food that the Food and Drug Administration found to be adulterated during a 15-month period was marketed without penalty to importers and consumed by an unsuspecting American public. This occurred because the Food and Drug Administration's policy permits perishable products to enter commercial channels before residue analyses are complete. (See pp. 39 to 41.)

Action can be taken to reduce the frequency that such products are allowed to enter the marketplace. Accordingly, a number of steps can and should be taken to improve the Food and Drug Administration's testing and inspection and to discourage adulterated products from being imported. (See p. 46.)

NEED TO MONITOR PESTICIDE EXPORTS

Neither the Environmental Protection Agency nor any other Federal agency monitors the millions of pounds of unregistered pesticides that are routinely exported from the United States each year. Some of these exports are pesticides that have been suspended or canceled for various food crop uses in this country. The majority of these unregistered and exported pesticides are products whose chemical contents are not known and have not been evaluated in terms of their human and environmental hazards. (See pp. 50 to 52.)

The Environmental Protection Agency needs to monitor these exported pesticides more vigorously not only to alert other governments about the dangers of specific products but also to provide information to the Food and Drug Administration that would be useful in its imported food monitoring program. (See pp. 51 and 52.)

FOREIGN NATIONS NOT NOTIFIED ABOUT PESTICIDE CANCELLATIONS

The law requires that the Environmental Protection Agency notify other nations and international organizations of all pesticide registration actions. However, the Agency limits its notifications to registration cancellations. (See p. 50.)

Other Agency regulatory actions are also of interest to foreign governments. Notifications should be furnished to other countries when a pesticide

--registration is suspended,

--is under scientific review in the Agency's Rebuttable Presumption Against Registration program,

--registration is withdrawn at producer requests, and

--may be applied only by specially trained and certified applicators. (See pp. 64 to 67.)

AGENCY COMMENTS

The Department of Health, Education, and Welfare agreed that its monitoring of imported food should be improved. However, it did not concur with GAO's recommendations that it

--require shippers/importers to provide certificates identifying pesticides used on food imports and that residues comply with U.S. tolerances,

--determine the source and identity of all unknown residues detected in food, and

--investigate pesticide use conditions when high residues of pesticides subject to action levels are found.

GAO continues to believe that these recommendations are necessary for the Department to fulfill its mandate under the Federal Food, Drug, and Cosmetic Act. The Department's comments, included as appendix I, are discussed at length in the report. (See pp. 21, 35, and 46.)

The Department of State advised GAO it was working with the Environmental Protection Agency to develop a suitable mechanism for notifying other governments regarding U.S. pesticide actions. The Department's comments, included as appendix II, are discussed on page 67.

GAO forwarded a draft of this report to the Environmental Protection Agency in mid-January 1979, but its comments were received too late (May 31, 1979) to be considered in this report. Report matters were discussed, however, with Agency officials during GAO's review and their comments are included in the body of the report as appropriate.

Contents

ABBREVIATIONS

ACC	Associate Commissioner for Compliance
CCPR	Codex Committee on Pesticide Residues
DBCP	dibromochloropropane
DDD	1,1-dichloro-2,2-bis(p-chorophenylethane)
DDT	dichloro diphenyl trichloroethane
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
HEW	Department of Health, Education, and Welfare
RPAR	Rebuttable Presumption Against Registration
OMPA	octamethylprophosphoramide
USDA	U.S. Department of Agriculture

CHAPTER 1

INTRODUCTION

In recent years, the domestic and international market and demand for pesticides has grown dramatically. In a world confronted with a rapidly rising population--estimated at 7 billion by the end of the century--pesticide use is vitally important in efforts to protect human health and to increase world food and fiber production. Pesticides might be the major factor in the ability to provide adequate food for the additional world population expected by the year 2000.

The magnitude of pesticide use, and its increasing importance in world food production, is evidenced by the following:

--The International Trade Commission has reported that production of pesticides almost doubled--to 1.6 billion pounds--during a 4-year period ended in 1975.

--Pesticide requirements for developing countries are expected to increase fivefold in dollar value by 1985, if their required food production is to be achieved. Pesticide use in Central and South American countries, major exporters of food to the United States, is expected to increase from $410 million in 1974 to $825 million by 1980.

--World demand for pesticides is expected to approach $8 billion by 1980 and $10 billion by 1984. As shown, in some areas--Asia, Central and South America, and Africa--this will represent more than a 100-percent increase in the value of pesticides used.

Area	Pesticide demand 1974 (millions)	Pesticide demand 1984 (millions)	Projected increase 1974-84 (percent)
Europe and U.S.S.R.	$1,828	$2,867	57
Asia	883	2,118	140
Central and South America	410	1,092	166
North America	1,977	3,291	66
Africa	92	593	544
Total	$5,190	$9,961	92

Although beneficial to agricultural production, public health and sanitation, and protection of natural resources, pesticides are not problem free. If used improperly or without sufficient knowledge of their side effects, pesticides can poison people and animals. They can contaminate water, food, air, and soil and can accumulate in man, animals, and the environment. Persistent pesticides can create future dangers to man and wildlife because residues may remain active in the environment for several years. The World Health Organization, an affiliate of the United Nations, has estimated that there are 500,000 pesticide poisoning cases worldwide each year from direct exposure to pesticides and that about 5,000 are fatal. Because of these dangers, it is generally recognized that the manufacture, sale, and distribution of pesticide products must be regulated.

PESTICIDE REGULATION IN THE UNITED STATES

Pesticides are regulated by the Federal Government to ensure that quality products are available to the public and that, when properly used, these products will provide consumers with effective pest control without unreasonable adverse effects to man or the environment. The legal authorities for pesticide regulation within the United States are the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of 1947 (7 U.S.C. 135), as amended, and the Federal Food, Drug and Cosmetic Act (FFDCA) of 1938 (21 U.S.C. 301) as amended.

FIFRA

FIFRA as amended requires that the Environmental Protection Agency (EPA) register all pesticides before distribution, sale, or use in the United States. EPA registers a pesticide when it determines that the product, when used according to commonly recognized practice, can safely and effectively perform its intended function without unreasonable risks to man or the environment.

A pesticide produced solely for export is not required to be registered with EPA and may be exported regardless of its U.S. regulatory status or the appropriateness of its intended use. However, FIFRA requires that pesticide exports be prepared and packed as directed and specified by the foreign purchaser and that domestic producers maintain records of shipments and purchasers' specifications. In addition, September 1978 amendments to FIFRA require that unregistered pesticides produced for export be labeled "Not Registered for Use in the United States of America" and that foreign purchasers of unregistered pesticides sign

statements acknowledging their understanding that such pesticides are not allowed for U.S. use. Copies of foreign purchaser acknowledgements are to be transmitted to government officials of the importing countries.

In 1976 domestic producers exported over 552 million pounds of pesticides of which approximately 140 million pounds, or 25 percent, were unregistered. Twenty-eight percent of these exports were for Latin American countries from which we obtain 38 percent of all imported agricultural commodities.

FFDCA

FFDCA requires that, if a pesticide remains in or on food, that a tolerance (the maximum residue allowed in food) be established for that pesticide. Under the act, any food product containing residues of a pesticide for which a tolerance has not been established or containing residues in excess of established tolerances is adulterated. The tolerance setting and enforcement procedures involve two agencies--EPA and the Food and Drug Administration (FDA), Department of Health, Education, and Welfare (HEW).

EPA establishes tolerances on the bases of the nature, amount, and toxicity of the pesticides' residues. EPA also considers all the foods on which the pesticide is allowed and what the total possible dietary intake would be.

FDA is responsible for assuring that all food marketed in the United States--including food imported from other nations--meets FFDCA residue requirements. The monitoring of imported food is a significant FDA responsibility. In fiscal year 1977, the United States imported $13.4 billion of agricultural products of which approximately 71 percent was from developing countries whose pesticide control mechanisms are less effective than those of the United States. U.S. agricultural imports from Central and South American countries where pesticide use is increasing rapidly, amounted to $4.1 billion in fiscal year 1977.

FDA monitors imported food for conformance with residue tolerances by chemically analyzing samples collected from individual shipments received at various U.S. entry points. Food found to be adulterated is required to be denied entry and reexported or destroyed.

FFDCA requires the U.S. Customs Service to deliver to FDA, upon request, samples of imported products that are subject to FDA regulation. In practice, however, FDA

inspectors generally collect samples. To assist FDA, Customs (1) notifies FDA of products being imported and (2) requires brokers, agents, or shippers (referred to as importers) to post a bond on imported products distributed to owners or consignees pending FDA approval for release into U.S. commerce.

In selecting samples for testing, FDA considers the following factors:

--Volume of products entering the port.

--A weekly listing of all violative products detained by FDA nationwide.

--Alerts issued on potentially violative products having national significance.

--Previous violative history of importers and of products being imported.

--Other leads to potentially violative products from news items, trade journals, complaints by consumers and competitors, and general knowledge of the cultivation and/or processing of the product in foreign countries.

SCOPE OF REVIEW

We undertook this review of Federal efforts to regulate the export of pesticides and the import of food containing pesticide residues because (1) our earlier reports indicated significant weaknesses in EPA's and FDA's efforts to protect man and the environment from the effects of harmful pesticides and environmental contaminants, (2) of the widespread concern about these effects, and (3) the significance of some U.S. food imports, coupled with increasing pesticide use in foreign nations. Appendix VII lists our earlier reports.

We reviewed pertinent legislation, documents, reports and records, and EPA's and FDA's policies and practices on (1) controlling pesticide residues on imported food, (2) monitoring exported pesticides, and (3) informing foreign countries of U.S. pesticide regulations.

We interviewed agency officials at EPA, FDA, State Department, the Department of Agriculture, and the U.S. Customs Service in Washington, D.C. We also interviewed and obtained information from agency officials in 12 EPA

and FDA field offices and from commercial and Government officials knowledgeable about pesticide use and regulation in 20 foreign countries.

CHAPTER 2

IMPORTED FOOD IS NOT TESTED FOR MANY POTENTIALLY UNSAFE PESTICIDE RESIDUES

U.S. food imports may contain unsafe pesticide residues because:

--Foreign nations permit use of pesticides which EPA either does not permit or has not evaluated for consumer safety.

--FDA's generally used multiresidue analysis tests detect neither the bulk of pesticides with U.S. tolerances nor other pesticides never registered by the United States which foreign nations use on food crops.

--FDA does not always identify unknown residues it detects on imported food.

--FDA does not sample all significant food commodity imports for pesticide residues.

To effectively use residue analyses for monitoring food imports for pesticide residues, FDA needs information on pesticide use from importing countries. FDA does not, however, receive such data and, therefore, generally restricts its monitoring to two multiresidue analyses that provide the greatest coverage for its efforts. The two multiresidue methods cover only about 90 of 268 pesticides that have U.S. tolerances and only a few other pesticides which foreign countries allow on food. Other single residue analyses could be used productively only if FDA knew the pesticides used on crops being imported. Even then FDA's program would be adversely affected because of the time required to set up equipment to run different residue analyses.

IMPORTED FOOD MAY CONTAIN UNSAFE PESTICIDES

Under U.S. law any pesticide residue on food is ordinarily deemed unsafe unless a tolerance--or an exemption from the requirement of a tolerance--has been established and the amount of residue remaining is within the limits of that tolerance. Pesticide use patterns in foreign countries clearly indicate that a large portion of food imported into the United States may in fact contain unsafe pesticide residues. Many large quantity U.S. food imports are from countries whose laws allow food to be treated with pesticides for which U.S.

tolerances have not been established. In some foreign countries pesticides known or suspected of causing cancer, birth defects, and gene mutations are carelessly or excessively used. Examples of such use are detailed on pages 8, 17, 52, and 53. Adverse health effects associated with pesticides used in other countries are shown in appendix V.

Approximately 34 percent of the value of all agricultural commodities imported into the United States in fiscal year 1977 consisted of 10 commodities imported from 11 foreign countries whose laws allow those commodities to be treated with pesticides lacking U.S. tolerances. As shown in table 2 on page 11, most of the pesticides which foreign countries allow, recommend, or use on these commodities lack U.S. tolerances. For example, in the two countries from which the U.S. imports 39 percent of all tea, 20 of the 24 pesticides allowed on tea have no residue tolerances. Similarly, 76 of 94 different pesticides allowed on coffee in six countries have no U.S. residue tolerances.

Consumption of food containing pesticide residues for which no tolerances are established may pose either unknown or unacceptable hazards to humans. Before establishing tolerances EPA must determine what levels of a pesticide residue will not pose unreasonable risks to consumers. Some hazards that EPA evaluates include the pesticides' potential to cause cancers, gene mutations, and birth defects. EPA generally establishes tolerances when pesticides are registered for food use. However, many pesticides used in foreign countries are not registered for food use in the United States and in the general absence of strong tolerance-setting programs in other countries, the hazards these pesticides pose to consumers have not been fully evaluated.

In addition, some pesticides which foreign countries permit on U.S. imports are known to pose serious hazards to humans. U.S. registrations of aldrin, dieldrin, kepone, heptachlor, and chlordane, for example, were canceled because of the pesticides' cancer-causing potential. DDT was canceled because its residues build up in the food chain and cause widespread environmental contamination. As shown in table 1 on the following page at least four foreign countries allow these pesticides to be used on foods which the U.S. imports.

Other countries also permit using suspended and canceled pesticides on food. We did not investigate pesticide regulations of all countries from which the U.S. imports food and pesticide use data was not available, however, we did gather limited data indicating pesticides which foreign countries have banned or restricted and those that the countries allow to be used. (See app. V.) Foreign country use is often at variance with U.S. use.

TABLE 1

Food on Which Foreign Countries Allow Use of Suspended and Canceled Pesticides

Pesticide	Country			
	Ecuador	Guatemala	Costa Rica	India
Aldrin	cacao coffee	coffee sugar	coffee	sugar tea
Dieldrin	coffee	bananas sugar coffee	bananas coffee cacao	
Heptachlor		sugar	sugar cacao	sugar
Chlordane	cacao		coffee	
DDT		bananas		
Kepone		bananas		

Appendix III shows that large quantities of these pesticides were exported during calendar year 1976 (latest data available), indicating that other nations do not always follow the U.S. lead in banning pesticide use. This can present an increasingly serious situation because, unlike the chlorinated pesticides listed in the table above, many pesticides EPA is reviewing for cancellation or suspension actions are not detectable with FDA's two most frequently used multiresidue detection methods.

In some countries, hazardous pesticides are used extensively.

--Brazil, Ecuador, and other major Central American banana-producing countries apply benomyl--a pesticide suspected of causing cancer, birth defects, and gene mutations--to bananas 12 to 20 times annually.

--An estimated one-fifth of the world's parathion is applied in the small nation of El Salvador--sixth largest source of U.S. coffee imports.

--In Nicaragua, Honduras, Guatemala, and El Salvador use of DDT, dieldrin, toxaphene, endrin, and methyl and ethyl parathion on cotton has contaminated food, feed, water, and wildlife. For example, Guatemalan milk was found to be contaminated with DDT residues

at levels 90 times the U.S. tolerance. Over seven percent of all U.S. agricultural imports originate in these four countries.

Of these hazardous pesticides which are extensively used, only benomyl is not detected by FDA's two most frequently used multiresidue methods.

FDA IS NOT GENERALLY AWARE OF FOREIGN PESTICIDE USE

FDA does not know what pesticides are used on U.S. food imports or whether the residues that remain are safe for human consumption. Neither FDA nor the Department of State gathers data on foreign pesticide use to identify residues likely to be on imported food.

FDA efforts to obtain data on foreign pesticide use have been limited to identifying those pesticides (1) the Canadian and Mexican Governments have approved for use and (2) for which the United Nations has proposed international residue tolerances. According to FDA's Associate Commissioner for Compliance (ACC),

> "FDA does not have direct access to reliable information on what pesticides are actually being used in the U.S. * * * Therefore, to ask foreign governments for information which, as a practical matter, FDA is unable to obtain in the U.S., appears to be an unreasonable request and one that ACC is unwilling to formally pursue."

The Department of State's "Foreign Affairs Manual" which is distributed to foreign service officers overseas, calls for alert reporting on pesticide chemicals used on raw agricultural commodities of export significance. State Department officials in Washington, D.C., told us, however, that no overseas embassy could possible carry out all the reporting requirements specified in the manual and that pesticide reporting is a low priority. Consequently, little pesticide reporting is done.

The United States imports approximately 600 different food commodities from over 150 countries. There are hundreds of pesticides and almost an equal number of residue tests which would have to be used on these commodities to identify and quantify the residues. Information about pesticide use is, therefore, necessary for determining commodities to sample--those likely to be adulterated--and pesticide tests to conduct. Without such information some food may never be tested even though it is potentially adulterated.

IMPORTED FOOD IS NOT TESTED FOR LIKELY RESIDUES

FDA cannot assure that imported food is free from pesticide residues in excess of tolerances. Because of time and funding, FDA uses only one of six multiresidue tests for each food sample analyzed. Therefore, each sample is analyzed for a maximum of 73 of the 268 pesticides having U.S. tolerances and only a few of many others which foreign countries allow on food. Although many single residue tests are available, FDA cannot effectively use these tests without reliable data regarding pesticide use in the exporting country.

Multiresidue tests are capable of simultaneously identifying and measuring residues of several chemicals in a single analysis. FDA officials have repeatedly told the Congress that six multiresidue methods are available for monitoring pesticide residues in imported food. They told us, however, that only two of these are used because the other tests are not as accurate and do not detect as many pesticides. In addition, FDA has emphasized that selecting available multiresidue methods requires knowing which residues are on the foods. FDA does not have this data.

For all practical purposes FDA uses only two of the six multiresidue methods which, collectively, can detect residues of only 90 of the 268 pesticides which have U.S. tolerances. These tests also cannot assure that imported food does not contain pesticides which do not have tolerances. We identified 130 different pesticides allowed, recommended, or used on 10 imported commodities which cannot be detected with FDA's two most commonly used tests. (See table 2 on the following page and app. VI.)

TABLE 2

Pesticides Used in Foreign Countries
on Food Exported to the United States

Commodity	Countries surveyed	Number of pesticides: Allowed, recommended, or used	Having no U.S. tolerance	Not detectable with FDA tests
Bananas	Colombia, Costa Rica, Ecuador, Guatemala, Mexico	45	25	37
Coffee	Brazil, Colombia, Costa Rica, Ecuador, Guatemala, Mexico	94	76	64
Sugar	Brazil, Colombia, Costa Rica, Ecuador, Guatemala, India, Thailand	61	34	33
Tomatoes	Mexico, Spain	53	21	28
Tea	India, Sri Lanka	24	20	11
Cacao	Costa Rica, Ecuador	14	7	7
Tapioca	Thailand	4	4	1
Straw-berries	Mexico	13	-	5
Peppers	Mexico	12	-	4
Olives	Italy, Spain	20	14	8

FDA could use several additional single residue tests for imported food monitoring if it knew which pesticides were being used. Pesticide manufacturers are required to submit tests capable of detecting each pesticide having a tolerance. Most of the methods submitted, however, are single residue methods which detect only one pesticide per analysis. Since FDA does not generally know the spray history of imported commodities, its chemists do not know which methods to apply. FDA maintains that it would be economically and physically impractical to use single residue methods to test food samples for all significant chemical residues that may be present.

FDA's efforts to protect the American consumer from potentially harmful pesticide residues and other chemical contaminants in imported food are clearly inadequate as evidenced by:

--its lack of knowledge regarding foreign pesticide use and

--the inability of its commonly used multiresidue analyses to detect 178 pesticides having U.S. tolerances and over 90 others permitted to be used in foreign countries which could not be identified as having U.S. tolerances.

Obviously, other measures are necessary for FDA to fulfill its legislative mandate under FFDCA.

IMPORTED FOOD RESIDUE TESTING IS LIMITED

The amount of residue testing FDA does to ensure that imported food does not contain violative levels of pesticides is limited--less than 2,000 samples tested for fiscal year 1977 out of hundreds of thousands of shipments. Total residue testing was as follows:

Comparison of Pesticide Residue Findings in Produce of Different Countries of Origin

	Mexico	Other foreign countries	United States
Fiscal year 1977			
Samples tested (note a)	1,258	708	2,892
Violative samples:			
Above EPA tolerance	21 (1.7%)	9 (1.3%)	9 (0.3%)
No tolerance	69 (5.5%)	45 (6.3%)	14 (0.5%)
Total	90 (7.2%)	54 (7.6%)	23 (0.8%)
Detentions or seizures	40	123	0
Fiscal year 1978 (to May 1978)			
Samples tested (note a)	531	295	1,425
Violative samples:			
Above EPA tolerance	3 (0.6%)	6 (2.0%)	4 (0.3%)
No tolerance	14 (2.6%)	7 (2.4%)	10 (0.7%)
Total	17 (3.2%)	13 (4.4%)	14 (1.0%)
Detentions or seizures	27	16	0

a/ Includes both objective (random) and subjective (nonrandom resulting from identified problems) samples.

To further place this in perspective, 1977 data on residue samples of Mexican crops shows that FDA took numerous testing samples of some commodities while many others were not tested at all.

Commodity	Mexican imports (pounds) (notes a and b)	FDA Coverage: Number of samples (notes c and d)	FDA Coverage: Shipments denied entry (note b)
	(000 omitted)		
Asparagus	9,406	1	
Bananas	40,206	1	
Beans	16,928	52	6
Brussel sprouts	3,998	0	
Cabbage	24,668	17	
Carrots	18,533	3	
Citrus fruits	78,724	0	
Cucumbers	235,154	67	
Eggplant	31,871	31	
Garlic	13,227	0	
Grapefruit	9,494	0	
Grapes	14,732	0	
Juices (gallons)	15,165	1	
Limes	17,357	0	
Mangos	19,988	9	
Melons	378,587	39	
Okra	16,170	6	
Onions	97,450	0	
Peas	6,788	20	
Peppers	112,873	606	28
Pineapple	111,235	6	
Radishes	2,858	1	
Squash	66,863	92	
Strawberries	108,750	122	6
Tomatoes	810,396	160	
Total		1,234	40

a/ Calendar year
b/ Extracted from "Mexico, United States Imports, Fruits and Vegetables," Mar. 1978.
c/ Fiscal year.
d/ Unexplained difference in samples taken in this schedule and preceding one probably relates to commodities which were sampled but not listed in the imports column.

Although the import data does not correlate exactly with samples taken due to a difference in reporting periods, it is indicative of the coverage provided by FDA.

FDA officials believe that FDA's program provides assurance that imported food generally complies with U.S. law. They stated that the following factors contributed to FDA's selection of pesticides to test for in Mexican produce.

--Evaluation of pesticide residue data and problems from current and past surveillance activities.

--Available information on what pesticides may be used on commodities sampled.

--Capability of available multiresidue tests to detect pesticides likely to be used.

--Information received from other Government agencies and industry.

They further stated that FDA's surveillance program is sufficiently flexible to redirect or modify selection of the pesticides to be covered if new information becomes available to warrant such a change. If illegal pesticide residues are found or suspected in samples of one FDA office, FDA will selectively intensify sampling of that specific pesticide/commodity combination by advising its other offices to test for these pesticides.

It appears that FDA's sampling program could be improved significantly. For example, seven commodities totaling 234.9 million pounds (see table on preceding page) imported during calendar year 1977 from Mexico would not have been sampled under FDA's fiscal year 1977 sampling program. There are many other unexplained anomolies in FDA's sampling. For example:

--Sampling of peppers was 100 times greater than pineapples (606 versus 6) even though total imports were about the same (112.8 versus 111.2 million pounds).

--No grape samples were taken compared to 52 samples of beans. Grape and bean imports were not significantly different (14.7 versus 16.9 million pounds).

--Onion imports totaling 97.4 million pounds were not sampled whereas squash imports totaling only 66.8 million pounds were sampled 92 times.

Such anomolies do not inspire confidence in the validity of FDA's sampling program.

The number of violative samples FDA has detected do not warrant the sampling concentration afforded selected commodities to the exclusion of samples for other commodities. FDA statistics show that only 40 food shipments from Mexico were detained during fiscal year 1977. There were no detentions of tomatoes or 5 other commodities although 160 and 249 shipments, respectively, were sampled; collectively this sampling is over 30 percent of fiscal year 1977 sampling. It is not reasonable that 30 percent of the sampling was directed at commodities that resulted in no detentions, while FDA did not sample seven commodities that aggregated 234.9 million pounds of Mexican imports.

Directing a portion of this sampling at commodities which were not sampled might not have resulted in more produce detentions, but it would have provided a higher degree of assurance that the unsampled commodities did not contain violative levels of pesticides which might harm consumers.

OPPORTUNITIES ARE AVAILABLE FOR IDENTIFYING FOREIGN PESTICIDE USE

To effectively monitor imported food, FDA must have information on pesticide use within exporting countries. This information can be obtained effectively through the full, voluntary exchange of data between FDA and foreign nations/exporters regarding (1) pesticide use within the country and (2) certificates of compliance with U.S. tolerance requirements. Ideally the information exchanged should include pesticide crop usage application rates and the types of application (i.e., ground, aircraft, or water applications). Such data would enable FDA, in consultation with EPA to identify usage patterns which could result in harmful residues on U.S. imported food.

Because a pesticide may not be used on all crops for which it is authorized, FDA could also require import certificates which certify that the import shipment is in compliance with U.S. tolerance requirements and which identify all pesticides actually used on the imported crop. We found that some foreign countries attempt to overcome residue problems by requiring certificates from the country of origin. For example, white rice exported from Thailand to China was accompanied by a certificate that indicated the results of analyses for arsenic, mercury, phosphides, cyanide, and malathion. It appears that desire to consumate sales provides a strong impetus for exporting countries to comply with requirements of importing countries.

In our July 5, 1977, report to the Congress (HRD-77-72) we recommended that FDA require importers to certify that imported products meet the requirements of U.S. law. We noted that such a requirement should help improve FDA's import coverage and reduce attempted importation of violative products. Certificates would be especially useful if FDA also required importers to identify all pesticides that have been used on the imported food. FDA could then select appropriate residue tests to determine if pesticide residues were within tolerances.

HEW, however, did not believe that importer certifications of compliance would be beneficial or achieve the intended result. HEW said that an importer's certificate would not give FDA greater assurance that the product was in compliance with the requirements of FFDCA. Consequently, HEW said FDA would still have to examine such products and there would be no savings of FDA resources. Importers might view such a requirement as something more than a paperwork requirement and actually test their imports, but this would be of marginal value according to HEW, unless FDA could continually confirm the validity of such tests.

We agree that an importer certificate of compliance with law should not be used as a substitute for chemical testing. Rather it should be an adjunct to assist in (1) focusing FDA's testing on likely residues and (2) identifying previously unknown residues. It would also be highly desirable for FDA to couple a certificate requirement with an enforcement mechanism, i.e., forfeiture of a security bond, that would make it highly unprofitable for importers to violate tolerance requirements. As noted on page 44, importer security bonds are currently required but are ineffective because they are forfeited only if the importer does not try to recover adulterated food from the channels of trade. Because much imported food is highly perishable, it has usually been consumed before FDA completes residue analysis and, therefore, the importer has little to do to avoid forfeiting its bond. However, security bonds would be an effective deterrent if forfeiture were tied to compliance with the importers' certification.

UNKNOWN RESIDUES FOUND IN IMPORTED FOOD ARE NOT ALWAYS IDENTIFIED

In addition to not being able to detect many pesticides, FDA does not even determine the identity of all chemical residues it detects on imported food. Using routine tests FDA chemists have detected "unknown" substances in imported food. What these substances are and how frequently they

occur, however, is not generally known because FDA does not require centralized reporting of unknown substances.

Under present procedures, FDA field laboratories are not required to report findings of unknown substances to FDA headquarters. Voluntary reportings have been requested; however, no criteria exist for what should be reported. FDA chemists have urged that headquarters develop a comprehensive definition of an unidentified residue, but efforts to do so are only just beginning. The absence of criteria results in spotty reporting of unknown chemicals to FDA headquarters. For example, during fiscal year 1977 and the first two quarters of fiscal year 1978, a total of 202 unidentified residues were reported in 79 imported food samples. All but two of these samples were reported by one FDA district laboratory.

In addition, FDA does not investigate all unknown residues that are found. FDA officials told us that

> "Identification of each response [unknown residue] would be an unending and virtually impossible task. * * * These compounds may be attributable to any one of several sources. * * * It is impossible to identify the source of these compounds until their chemical structure has been elucidated."

FDA research of unknown residues, although limited, has shown that they include pesticides and other chemicals that were not previously observed in food. In researching one unknown residue, FDA found it to be a pesticide registered for use on rice paddies in Japan but not for use in the United States. Apparently the pesticide contaminated streams adjacent to rice paddies because FDA found residues in samples of imported trout. Some subsequent trout shipments were also found to contain the pesticide and were prohibited from import because EPA had not established residue tolerances. Our review of the scientific literature indicated that this pesticide had not been adequately evaluated in the United States. Studies performed overseas showed that although the pesticide had a low toxicity it could cause frameshift mutations in Salmonella; the implications of such mutations in humans has not been determined through appropriate testing in mammals.

The absence of a strong FDA effort to identify chemical residues in imported food that may be harmful to consumers and the failure to disseminate this information to all FDA district laboratories to alert them to the potential for such residues is inconsistent with FDA's legislative mandate to remove adulterated food from the channels of trade. It also points up the need to improve the detection tools

available to the FDA laboratories to enable them to adequately carry out their responsibilities.

GREATER EFFORT NEEDED IN DEVELOPING DETECTION METHODS

The six multiresidue methods available to FDA can collectively detect about 200 different pesticide and their metabolites or degradation products, including 107 of the 268 having U.S. tolerances. However, all these methods are not used on each food sample. Moreover, even if they were, the methods fall short in detecting many pesticide chemicals that have EPA tolerances.

The exact number of other nondetectable pesticide chemicals that may have agricultural usage in foreign nations, but are either not registered for such usage in the United States or not subject to EPA tolerance, is not known. We identified 130 (see app. VI) that are not detected by FDA's two most widely used multiresidue methods.

FDA's multiresidue methods are generally limited to quantitatively measuring the amount of pesticide residue present in food with an accuracy of plus or minus 15 percent. However, depending on the pesticide and the commodity being tested, measurement capabilities may be considerably less. For several pesticides, FDA's methods may recover only a part of the total amount of residue that is present in the sample which is not acceptable for enforcement purposes and necessitates additional analyses using a single residue method.

In fiscal year 1977, FDA spent $2.4 million on research to develop methods for detecting pesticide, metal, and industrial chemical contaminants in food. Although this represents 30 percent of the resources FDA devoted to ensuring food safety in fiscal year 1977, less than half of this amount was devoted to the development of methods for detecting pesticides.

A working group at FDA's 1976 Industrial Chemical Workshop recommended that "due to the unknown and varied pesticide usage of foreign lands, broader spectra residue methods must be encouraged to increase coverage in the program." The head of FDA's methods development group described their methods development efforts as "woefully inadequate" and acknowledged that FDA has been slow in developing pesticide detection techniques. He said that FDA has no strategy to guide methods development work. Both EPA and FDA scientists told us that when EPA was formed in 1970 efforts to to develop pesticide detection methods lost emphasis and were even suspended.

Before the formation of EPA, approximately 30 FDA scientists were involved in methods development. Currently only seven FDA scientists are assigned to research pesticide detection methods. The small number of scientists committed to this important aspect of FDA's program clearly is inconsistent with the magnitude of the problems associated with detecting most pesticides used on food which effectively cannot be detected by current state-of-the-art, multiresidue detection analyses. We believe that FDA should accord multiresidue detection methods development a very high priority within its efforts to assure the safety of the Nation's food supply.

CONCLUSIONS

Imported food may be contaminated with pesticides not allowed in the United States or with pesticide residues in excess of legally established U.S. limits. Many pesticides permitted in foreign countries have no U.S. tolerances.

FDA does not know what pesticide residues may be present in imported food because neither FDA nor Department of State officials gather data on overseas pesticide use. Lacking knowledge of likely residues, FDA is unable to effectively determine which tests should be conducted on imported food to ensure its safety and purity.

The tests FDA uses for monitoring residues in imported food detect less than half of the pesticides having U.S. tolerances and few of others that foreign countries allow on food. When unknown residues are detected, FDA does not always research their identity, which it is mandated to do under FFDCA.

The effectiveness of FDA's sampling program is further impaired because some import commodities are sampled extensively, even though no violations were detected, while other significant commodity imports are not sampled at all. All significant commodity imports should be sampled each year, despite the lack of violations in prior years, because pest problems and pesticide use can vary significantly from year to year. It appears that such sampling can be done without seriously impairing FDA's current program by requiring a minimum number of samples of each major commodity imported; when a commodity sample is found to be adulterated, FDA can selectively increase sampling to ensure that the consumer is adequately protected.

To effectively fulfill its mandate to protect the American consumer from harmful pesticide residues in food,

we believe that FDA should develop a multipronged approach that would include:

--Obtaining information from foreign nations regarding pesticide usage by crops.

--Requiring importers to provide certificates indicating which pesticides were used on the import and certifying that residues do not exceed U.S. tolerances.

--Developing multiresidue detection methods which could effectively identify most pesticide residues used on food.

Such a program would provide reasonable assurance from a number of sources that food imports do not contain harmful levels of pesticide residues, as contrasted to the hit or miss program now used. We believe that the program could be strengthened further if importers were required to forfeit security bonds when FDA later learns through residue testing that either the importer has not identified all pesticides used on the crop and/or that the import contained residues in excess of tolerances. Such a requirement would provide a strong stimulus for compliance by making it highly unprofitable for non-complying importers. This is discussed in more detail on page 44.

FDA should reconsider the relatively low priority accorded multiresidue detection methodology development because the ultimate reliability of its program lies in such methodology. It is not enough to know what pesticides are used on a crop. FDA must have an available multiresidue method capable of identifying most pesticide residues on a particular import without adversely affecting--because of time losses in setting up and calibrating equipment--its ability to test for other residues on other imports. This means that ideally FDA should have relatively few, broad-spectra multiresidue analyses which will detect most pesticide residues. FDA has far to go to achieve this.

RECOMMENDATIONS

To ensure that imported food is adequately monitored for pesticide residues, we recommend that the Secretary, Department of Health, Education, and Welfare, require the Commissioner, Food and Drug Administration, to

--obtain data about foreign pesticide usage as a basis for determining what pesticide residue analyses to perform,

--require importers to provide certificates which identify pesticides that have been used on imported food and certify that residues comply with U.S. tolerances,

--determine the source and identity of all unknown residues detected in imported food,

--commit resources necessary to develop analytic methods which detect most pesticide residues likely to be present in imported food, and

--revise the residue sampling program to ensure that all significant imported food commodities are sampled each year for pesticide residues.

AGENCY COMMENTS AND OUR EVALUATION

In commenting on the report, HEW said that it believed that the draft report neither accurately nor fairly reflects either the degree to which pesticide residues pose a risk to the U.S. consumer or the FDA's program for identifying and detaining violative imported products. HEW stated that many of our criticisms of FDA's programs and professional competence are based upon unsubstantiated conclusions and hypothetical situations, thereby creating unfounded apprehensions about the food supply and those charged with assuring its safety. To illustrate its concern HEW cited FDA's Total Diet Study that has been conducted annually since 1964, and that has consistently shown that the American consumer's dietary exposure to pesticide residues is substantially below the acceptable daily intake (the daily intake which, during an entire lifetime appears to be without appreciable risk)--some less than one ten-thousandth of the acceptable daily intake.

In each case that we concluded improvements were needed in FDA's program, we provided concrete examples demonstrating the utility of the improvement. However, we did not consider such programs as FDA's Total Diet Study as pertinent because we had previously reported that no statistically reliable judgments can be made from this study and because the December 1978 report "Cancer-Causing Chemicals in Food" of the Subcommittee on Oversight and Investigations, Committee on Interstate and Foreign Affairs, concluded that the study is "riddled with weaknesses," based in part on statements made by the Commissioner, FDA. HEW's comments on each of our recommendations are discussed at length below and on pages 35 to 38 and 46 to 49.

HEW also said it recognized the need for improvements in FDA's coverage of imported food for pesticide residues, and that several actions are well underway to accomplish these

improvements. FDA had made changes to its programs after the investigative part of our work was completed. We have appropriately acknowledged these improvements in discussing HEW's comments on our recommendations.

Foreign data on pesticide use

HEW agreed that FDA should have data on pesticides approved for use in the production of food in foreign countries. According to HEW, FDA in seeking this information on a voluntary basis has received official listings of pesticides used in several countries and has instructed its field offices to use the data received from Mexico in analyzing imported Mexican produce. HEW said it had reservations, however, that FDA should obtain information such as application rates and types of application--ground, aircraft, and water applications--because this information is not totally relevant to enforcing tolerances and illegal residues may occur regardless of the route and frequency of administration. HEW further stated that there are limitations to anticipating what pesticide residues might be present in imported food commodities because:

--FDA's experience indicates that pesticide usage, including usage in the United States, is not confined to approved uses.

--Food and feed may become pesticide contaminated because of movement and persistence of pesticides in the environment.

--FDA does not have statutory authority to require foreign countries to submit pesticide use data.

We applaud FDA's efforts to focus its Mexican sampling program on pesticides actually used in Mexico. Although this occurred after our audit work was completed, this approach was discussed with FDA on several occasions during our audit. If broadly adopted it would result in improvement in FDA's pesticide residue analysis program. We reserve judgment about how effectively FDA's field offices use this data until after the program is evaluated and evidence is available that analytical methods other than the two commonly used multiresidue methods were employed in an effort to detect pesticides not previously analyzed for. Complete reliance by the field offices on the two multiresidue methods would not result in the identification of any more pesticides than detected previously.

HEW's reservations concerning the limitations of obtaining and relying on a country's pesticide usage data

in its program apparently presumes that FDA would use this data in a vacuum rather than as a supplement to its current program. Clearly, our intent was that the information was to supplement rather than to supplant FDA's existing program. (See pp. 9 to 11 and 19 to 20.)

Further, we too realize that FDA cannot "require" foreign countries to provide pesticide usage and application data. However, FDA officials told us that other nations, such as Mexico willingly provided them requested pesticide data. Our experience in dealing with foreign nations on this study was that other nations would likewise be cooperative. Finally, EPA has recently reported that (1) significant differences in pesticide residues result on crops from applying dilute and concentrated pesticide sprays (even though the same amount of active ingredient was applied) and (2) significant drift occurs from aircraft applications. An FDA official said that knowing a pesticide is applied by aircraft might be useful because of airborne drift to other crops associated with the application. We continue to believe that mode of application as well as application rates could contrast pesticide practices used in foreign nations with U.S. practices, thereby identifying pesticides which are most likely to be violative.

HEW also said that GAO failed to recognize the importance of U.S. involvement in the international Codex Committee on Pesticide Residues (CCPR) of the Food and Agriculture Organization and the World Health Organization, and the CCPR's efforts to develop international tolerances for pesticides in food. HEW concluded that its resources would be more appropriately spent in conjunction with the CCPR's work rather than obtaining pesticide usage data from other nations.

We support the work of CCPR and its efforts to harmonize pesticide tolerances on a worldwide basis. However, we found CCPR's efforts to be of little or no value in focusing attention on pesticide residues likely to occur in imported food of specific countries because:

--Since its inception in 1962, CCPR has reviewed 150 pesticides and recommended tolerances on only about 75. This latter figure is less than 30 percent of the pesticides for which tolerances have been established in the United States alone.

--Acceptance of CCPR recommended tolerances is voluntary for member nations and is frequently very difficult to obtain because the recommendations may be

incompatible with member countries' desires, agricultural practices, climatic conditions, and residue tolerance laws.

--Pesticides for which CCPR has recommended tolerances are not used in all countries and to analyze for such residues would not be productive.

As can readily be seen, devoting FDA's resources to CCPR is not an effective method of dealing with the problems addressed in this report. Developing data on pesticides used in foreign countries is essential to complement FDA's multiresidue testing because it will permit selective testing for likely residues which are not picked up by multiresidue analysis.

Certification that pesticides used on food imports comply with U.S. tolerances

HEW did not concur with our recommendation that it require importers to provide certificates identifying pesticides that have been used on imported food and certify that residues comply with U.S. tolerances. HEW said that it had considered imposing importer certification as a condition for permitting entry of imported food, but had detemined that it would not improve the regulation of imported food. HEW further stated that when the border has been closed to certain shippers or commodities because of repeated instances of an imported food containing illegal pesticide residues, FDA does request that a foreign government or another responsible party certify shipments before entry; FDA monitors and audits these certificates to ensure their validity.

HEW's response is inconsistent--on the one hand it finds that importer/shipper certifications would not improve the regulation of imported food which it does not suspect of being adulterated while on the other hand it finds such certificates are sufficient to permit entry of food commodities which have repeatedly been found violative. In the latter case food commodities that have been found violative repeatedly enter the country and are consumed before FDA analyzes the commodity. Thus a great deal of reliance is placed on these certificates. HEW offers no rationale as to why such certifications would not aid it in the regulation of other food imports.

We continue to believe that importer certifications regarding the identity of pesticides used on the commodity offers another valuable source of information which FDA can use to tailor its residue analysis program to look for pesticide residues likely to be found on the commodity.

Again, as with our previous recommendation, certificates should not be considered a substitute for FDA's multiresidue testing, but a supplemental program to focus residue testing on pesticides which the importer/shipper acknowledges were used on the import.

Identify unknown residues detected

HEW did not concur with our recommendation to determine the source and identity of all unknown residues in imported food. HEW said that analytical technology has advanced to the point that minute quantities of compounds are being revealed as unidentified responses, even those that may be intrinsic components of the food or natural constituents derived from soil or water during growth. HEW said that it recognized the need for caution in dismissing unidentified responses as posing no risk to the consumer and that FDA's Residue Task Force is developing criteria to assist analysts in determining when unidentified responses should be pursued, thereby providing a significant degree of consumer protection within present and projected resource constraints.

Over the years FDA has analyzed many thousands of samples of a commodity such as tomatoes, carrots, and peppers. During this time analytical profiles or fingerprints for each commodity have been developed for each of its residue analysis methods. Obviously, only significant deviations from a given profile would qualify as unknowns, subject to identification efforts. We believe that it is fully appropriate and necessary that FDA determine the source and identity of these residues to ensure that they do not pose risks to consumers, as intended by FFDCA.

We are unable to comment on the adequacy of the criteria FDA is developing for pursuing unidentified residues in that FDA said that it was inappropriate to release the criteria to to us in the draft stage.

Commit resources to develop analytical methodologies

HEW concurred with our recommendation to commit resources necessary to develop methods which detect pesticide residues likely to be present in imported food. HEW said that it had reevaluated this program over the past several years and had assigned additional personnel to develop multiresidue methods that can be used for simultaneously detecting residues of many different pesticides.

HEW cautioned that the complexity and scientific limitations involved in developing additional multiresidue methods should be recognized and that further major advances in analytical technology must occur before most remaining pesticides can be included in multiresidue methods.

In discussing these comments, FDA officials told us that 11 chemists are now assigned to methods development--an increase of 4 since we completed our work. Although this is a significant increase, it still falls far short of the 30 chemists which were involved in this work in 1970. It is not possible to assess what impact the increased staff might have on FDA's methods development program.

Revise the residue sampling program

Regarding our recommendation that FDA revise its residue sampling program to ensure that all significant imported food commodities are sampled each year for pesticide residues, HEW said that FDA had taken specific steps to improve sampling after we had completed the investigative phase of our study. HEW said that on October 1, 1978, it initiated a pilot program for Mexican imports that provides more specific instructions and information about factors such as (1) volume of import commodities, (2) previous pesticide problems, (3) likelihood of residues, and (4) other relevant information. HEW said that if successful this program approach will be expanded to include commodities from other countries.

Although HEW states that FDA's pilot effort to improve its Mexican sampling program was initiated in October 1978, FDA's program guidance manual was dated December 15, 1978, and it appears that fine tuning of the Mexican sampling program did not get underway until mid-January 1979. As a consequence, the overall success of FDA's pilot effort to improve its sampling program cannot be adequately evaluated at this time. Notwithstanding, early actions reported as being taken are encouraging:

--FDA's sampling of Mexican produce has been broadened to include many additional commodities such as broccoli, brussel sprouts, cauliflower, limes, onions, and sesame seeds--of those that we had noted previously that no samples were taken, only garlic, grapes, and juices had not been sampled.

--FDA directed district offices to expand sampling of tomatoes and initiate sampling of onions on the basis of USDA import statistics. Onions were a major import for which no samples were taken during fiscal year.

--FDA closed the border to six Mexican shippers after finding repeated violations for pesticides without tolerances, one for acephate in carrots; one for profenofos on tomatoes; and three for daconil (Bravo) on English peas and Chinese peas.

--FDA intelligence disclosed that methomyl is being used on Mexican strawberries and that carrots grown in fields previously used for potatoes may contain residues of pentachloronitrobenzene (PCNB). There are no residue tolerances for these pesticides in these crops.

--Two of the chemicals noted above, methomyl and daconil, are not detected by FDA's two most commonly used multiresidue methods indicating that additional methods are being used, with some success.

We encourage FDA to continue and broaden its efforts by including food imports of other nations that have provided FDA intelligence on their pesticide usage.

CHAPTER 3

INAPPROPRIATE USE OF TOLERANCES AND ACTION LEVELS

Over the years, EPA has suspended, canceled, or significantly restricted the registrations of 14 pesticides (or pesticide product ingredients) because of the unreasonable hazards they posed to man or the environment. However, the residue tolerances associated with the use of these pesticides on food crops were not revoked and remain in effect up to 6 years after regulatory action. As a result, food containing residues of these pesticides, particularly imported food, may legally enter the U.S. channels of trade at the levels allowed before EPA's regulatory action.

EPA maintains that tolerances of canceled pesticides have been retained because many of the pesticides are persistent and will continue to be found in foods for several years. While this is true, it does not justify the continuation of tolerances at levels set when the pesticide was applied directly to the crop. In fact, inadvertent residues resulting from residual levels of the pesticide in the environment are generally only a fraction of established tolerances.

An alternative to continuing tolerances of canceled pesticides is using "action levels"--residue levels which are determined to be safe and unavoidable, resulting from environmental contamination rather than purposeful application of the pesticide to a crop. FDA has extensively used action levels in the past; however, in many cases FDA and EPA have not determined that FDA's criteria for action levels have been met--that the residues at established action levels can be consumed safely and that residues are unavoidable and do not result from purposeful pesticide uses on a crop.

Continuing tolerances of canceled pesticides and/or setting action levels without determining if appropriate safety and unavoidability criteria are met could condone foreign use of these pesticides by giving the appearance that the United States approves of their use. To the extent that such pesticides are used and remain on imported food, Federal efforts to protect the consumer from pesticides EPA has determined pose unreasonable adverse effects are thwarted.

TOLERANCES FOR SUSPENDED AND CANCELED PESTICIDES SHOULD BE REVOKED

Before registering pesticides for use in or on food crops or for uses that may result, directly or indirectly, in food residues, EPA establishes residue tolerances under FFDCA. EPA establishes residue tolerances when registering pesticides for use in the United States. EPA generally has not revoked tolerances when it canceled U.S. pesticide registrations.

EPA has suspended, canceled, or significantly restricted registrations of such pesticides as aldrin, dieldrin, DDT, heptachlor, OMPA, mirex, and strobane due to adverse human or environmental effects resulting from their use. DDT, for example, was canceled because of its persistence. Persistent pesticides can create potential hazards to man and wildlife because residues may build up in the environment and in turn in man's food chain. Aldrin was suspended and eventually canceled because it causes cancers in animals. Although suspended and canceled pesticides are not allowed for use on food crops except in unusual situations, over 297 tolerances originally established in conjunction with the domestic use of these pesticides on food crops remain in effect up to 6 years after regulatory action was taken.

EPA's continuation of tolerances for suspended and canceled pesticides condones the use of these pesticides on food in foreign countries. American farmers, however, are precluded from using suspended and canceled pesticides, and have alleged that the use by foreign farmers of such pesticides which are cheaper and longer lasting places them at a competitive disadvantage.

Foreign officials referring to the U.S. Code of Federal Regulations, which lists all pesticide residue tolerances, can be misled to believe that U.S. regulations permit food to be treated with pesticides which have been canceled. The code clearly indicates that suspended and canceled pesticides may be used on food crops. For example, tolerances for residues of the canceled pesticide heptachlor are listed as follows:

> "Tolerances for total residues of the insecticide heptachlor * * * and its oxidation product heptachlor epoxide * * * from application of heptachlor in or on raw agricultural commodities are established as follows * * *" [Underscoring supplied.]

In spite of the obvious problems, EPA believes retention of tolerances for canceled and suspended pesticides is

necessary. EPA's Deputy Assistant Administrator for Pesticide Programs testified before the Senate Subcommittee on Foreign Agricultural Policy, Committee on Agriculture and Forestry, on May 25, 1978, that:

> "It is important to retain the tolerances because of the persistent nature of the canceled pesticides which may remain in the soil or immediate environment of crops for years even after actual use of the pesticide has been discontinued.* * * If legal limits for residues of canceled products are not retained, domestic producers would be unable to produce crops without such unavoidable residues being present, and their crops would be in jeopardy of being declared 'adulterated' through no fault of their own."

However, as previously noted, Federal regulations provide for setting action levels to permit the marketing of food containing canceled pesticides resulting from inadvertent environmental contamination.

Responding to the subcommittee's questions, EPA stated that:

> "Ideally, tolerances would be gradually lowered over the years as residue levels decrease to reflect the occurrence of such 'secondary' residues. * * * Thus far, tolerances for only one canceled pesticide, DDT, have been revised. Use of other pesticides subject to formal cancellation actions has ceased too recently for residue levels to have declined sufficiently to merit tolerance revision."

Contrary to EPA's statements, canceled pesticide residues detected by FDA in food have, in fact, declined to levels well below established tolerances--in many cases to only trace levels. In fiscal year 1976, for example, 75 percent of all domestic food samples analyzed by FDA contained no detectable residues of the canceled pesticide dieldrin. Sixty-seven percent contained no detectable levels of DDE, a major metabolite of DDT. Even in foreign countries which may still permit the use of these pesticides, residues may be relatively insignificant. For example, an FDA compliance program evaluation of pesticide residues in coffee disclosed the following:

PESTICIDE RESIDUES IN IMPORTED COFFEE BEANS (August 1977 - October 1977)

Country of Origin	Number Samples Examined	No Residues Found	Residues Detected	Residues found in individual samples (ppm) DDT	DDE	BHC	Lindane	Dieldrin	Heptachlor	Diazinon	Malathion
Brazil	1	0	1			Trace					
Colombia	16	11	5	Trace Trace 0.02	Trace			Trace		0.13	0.20
Costa Rica	1	1	0								
Dominican Republic	1	1	0								
Ecuador	8	3	5	Trace Trace Trace 0.03 0.03	Trace Trace Trace	Trace	Trace		Trace		
Guatemala	4	3	1	Trace		Trace					
Haiti	1	0	1	0.08							
Honduras	2	1	1	Trace							
India	2	0	2			Trace 0.03	0.01				
Indonesia	1	0	1			Trace				0.01	
Ivory Coast	1	1	0								
Kenya	1	1	0								
Mexico	5	1	4	Trace 0.03 0.08 0.03	Trace Trace 0.01	Trace Trace					
New Guinea	1	1	0								
Nicaragua	1	1	0								
Panama	1	1	0								
Peru	5	3	2	Trace	Trace	Trace Trace	0.02				
Uganda	1	0	1	0.02							
Venezuela	2	1	1	Trace		Trace					
Total	55	30	25	18	8	11	3	1	1	2	1

These results, along with the results of U.S. food monitoring, negate the argument that tolerances for persistent pesticides need to be retained for extended periods. For example, tolerances for DDT range from 1 to 20 parts per million for about 40 crops. Continuing these tolerances permits foreign farmers to export food to the United States which contain higher residues, probably due to purposeful pesticide use, than found in U.S. food.

EPA officials said that since we "surfaced the issue" they have considered the international aspects of U.S. tolerances for suspended and canceled pesticides and agree with our concerns. They told us that they plan to consider revoking tolerances for suspended and canceled pesticides and have informed FDA that action levels may be necessary. We believe that such revocations should be an integral part of EPA's pesticide cancellation process.

ACTION LEVELS SHOULD BE SAFE AND RESIDUES UNAVOIDABLE

Residues of pesticides for which there are no tolerances or which have exemptions from tolerances and residues of unregistered pesticides--including those whose use has been

suspended or canceled--may be allowed on food at or below specified action levels. Federal regulations specify that action levels may be established for residues which cannot be avoided by good practice provided the action levels are

> "sufficient for the protection of the public health, taking into account the extent to which the presence of the substance cannot be avoided and the other ways in which the consumer may be affected by the same or related poisonous or deleterious substances."

Action levels are established and enforced by FDA. Federal regulations require, however, that EPA recommend the appropriate levels on the basis of toxicological evidence. As of May 1978, FDA had established approximately 311 action levels for residues of 18 different chemicals on a variety of food commodities. However, all were established before the formalization in September 1977 of Federal regulations requiring EPA recommendations--based on a toxicological evaluation of the pesticide.

Safety of action levels not evaluated

The safety of some existing action levels is clearly not supported by scientific evidence. Although EPA states that the toxicology evaluation procedures are the same as followed in establishing tolerances, FDA is nevertheless utilizing action levels which do not meet the safety criteria EPA applies to tolerances. For example,

--FDA established action levels for residues of the pesticide leptophos (phosvel) in peppers and green beans. On November 22, 1976, EPA revoked all tolerances for such residues based on a lack of evidence to support their safety. The scientific advisory committee which performed the review of leptophos tolerances stated that:

> "No scientifically supportable 'no effect' dose or tolerance limits can be established at the present time because of insufficient data. * * * The existence of tolerances implies that the specified limits are safe. This cannot be proven at the present time."

When questioned by the Senate Foreign Agricultural Policy Subcommittee regarding leptophos action levels, EPA stated that:

> "FDA did not request EPA recommend an action level for leptophos, and this Agency did not make such a recommendation."

--FDA established action levels for residues of the pesticide endrin--a suspected carcinogen having no food residue tolerances--in approximately 56 food commodities. Applying to these action levels the same calculations EPA used in establishing tolerances, we found that human exposure to endrin residues allowed by these action levels exceeds by approximately 147 percent the acceptable daily intake--the theoretical amount that could be eaten daily by an individual over his lifetime without harm. Normally, EPA does not establish pesticide tolerances if the total residues theoretically present in man's daily diet from existing tolerances exceed an acceptable daily intake.

When evaluating the safety of proposed tolerances, EPA considers the possible dietary intake of pesticide residues from already existing tolerances. EPA does not, however, follow this procedure when recommending action levels to FDA. EPA officials believe that certain assumptions inherent in tolerance evaluations are not valid in the case of action levels.

For example, EPA safety evaluations of tolerances assume a lifetime of exposure to residues at proposed levels. In addition, tolerance evaluations assume that (1) all food commodities at the time of consumption contain residue levels equal to the tolerance and (2) all food commodities are treated with each pesticide for which tolerances exist. EPA officials believe, however, that all commodities are not treated with all pesticides for which tolerances exist and that even when treated most raw agricultural commodities at the time of harvest have residues lower than tolerances. EPA officials stated that action levels are generally established to deal with unexpected pesticide residues that are "* * * situations often temporary in nature * * * and not due to normal use patterns for the pesticide."

However, we believe consideration of daily dietary intake is appropriate when evaluating action levels because neither action levels nor the occurrence of residues they allow have been temporary in nature. Most existing action levels were established 6 years ago (1972)--some as early as 1964; yet, during the 15-month period ended September 1977, 32 percent of all imported food samples analyzed by FDA contained one or more residues of chemicals subject to action levels. FDA, for example, established action levels for monitor and azodrin in 1973 and 1974, respectively, upon finding residues of these pesticides in imported Mexican produce. Approximately 7 percent of all samples of imported Mexican

produce analyzed by FDA from July 1, 1976, to September 30, 1977, contained residues of monitor and azodrin at or above established action levels.

Avoidability of residues not determined

Action levels are applicable only when there is reason to conclude that residues are due to unavoidable sources of contamination. Although FDA officials state that all action levels are set at levels lower than would result from purposeful pesticide use, neither FDA nor EPA officials have sufficient information about pesticide use conditions in other countries to determine the lowest levels at which residues from purposeful use might result. If foreign countries intentionally use pesticides that result in residue levels lower than action levels, then FDA is in effect condoning the use of these pesticides on imported food even though their use is not allowed in the United States.

CONCLUSIONS

Tolerances established for uses of pesticides which have been suspended or canceled are no longer needed. Residues of suspended and canceled pesticides that may be unavoidably present in food can be allowed, if safe, by establishing appropriate action levels. EPA's continuation of tolerances for residues of suspended and canceled pesticides serves only to mislead and condone foreign country use of hazardous pesticides that these nations believe EPA allows and approves.

Residues of pesticides for which there are neither tolerances nor exemptions from tolerances could be allowed to remain in food under action levels, provided the residues are determined to be safe and unavoidable. Pesticide residues allowed by some current action levels, however, may be unsafe and may have resulted from the direct, purposeful use of pesticides on food. The use of action levels without adequate determination of the safety and unavoidability of residues to a large extent defeats the purpose of EPA's pesticide registration program--to eliminate consumer exposure to pesticides posing unreasonable, adverse effects.

RECOMMENDATIONS

We recommend that the Administrator, EPA:

--Immediately revoke tolerances for residues of pesticides that have already been suspended and canceled for food uses.

--Make tolerance revocation an integral part of EPA's pesticide cancellation process.

We recommend that the Administrator, EPA, together with the Secretary of HEW, through the Commissioner, FDA:

--Determine whether existing and proposed action levels are safe and appropriate.

--Establish action levels for residues of suspended and canceled pesticides that may be unavoidably present in food, but only after determining such residues are safe.

--Investigate pesticide use conditions in foreign countries when significant residues of a pesticide are detected in an import to ensure that action levels are, in fact, lower than residue levels which may result from the direct, purposeful application of pesticides to food.

AGENCY COMMENTS AND OUR EVALUATION

Determine safety of action levels

HEW said that FDA and EPA initiated a joint effort in September 1978 to reevaluate existing action levels and assure that they are safe and appropriate. HEW said the effort is being conducted in conjunction with EPA's plan to revoke existing tolerances for canceled pesticides. HEW further said that action levels are established after a determination is made about the safety of a residue and that the validity of action levels will be reassessed periodically.

As indicated on page 31, EPA's efforts to review existing tolerances for canceled pesticides and action levels was begun after we brought this matter to its attention. Unfortunately, no reviews on action levels have been completed in the 7-month period since the program was initiated.

Although HEW states that action levels are established only after appropriate determinations, it did not address our concerns described on pages 32 and 33, regarding

--the exclusion of action levels from EPA's calculations of total dietary intake of pesticides and

--whether residues result from purposeful use or from unavoidable environmental contamination.

Both determinations must be made to ensure that action levels are in fact safe and appropriate. In doing less, FDA is not complying with its mandate under FFDCA.

Acton levels for suspended and canceled pesticides

HEW said that although it did not disagree, some clarification is needed regarding our recommendation that FDA in the future establish action levels for unavoidable residues of suspended and canceled pesticides only after determining such residues are safe. HEW said FDA has established action levels for pesticides on the basis of safety, unavoidability, and information available at the time the action levels were established. HEW said that action levels for leptophos, monitor, and azodrin are unwarranted and FDA has not established action levels for these pesticides. HEW further stated that FDA's policy is that residues of these chemicals found in imported food are the result of purposeful use, and that any detectable, measurable, and confirmable amount would be considered actionable.

FDA officials told us the documents (see app. VIII) detailing FDA action levels supplied to GAO during its review were in error--that monitor, leptophos, and azodrin should not have been listed as having action levels of 0.1 part per million. FDA explained that these were in fact the limits of reliability of their residue detection methods rather than action levels. While it is not productive to argue whether FDA erred in listing certain pesticides as having action levels, FDA's field offices have operated under the premise that action levels do exist and have treated imports accordingly.

HEW states that it is FDA's policy that residues of monitor, leptophos, and azodrin result from purposeful use and, therefore, are violative. However, FDA uses residue methodology that is sensitive only to 0.1 part per million thereby permitting entry of many import shipments where residues were detected at levels below 0.1 part per million. For example, monitor was detected in 307 shipments from October 1, 1978, through February 28, 1979; however, only 6 (2 percent) were deemed violative. This is very disconcerting in light of (1) FDA's policy that these residues result from purposeful use and, therefore, are violative, (2) a history of repeated violations, and (3) the existence of other single residue methods with greater sensitivity according to data submitted by the registrant: monitor--0.05 part per million on peppers, azodrin--0.03 part per million on

tomatoes, and leptophos--0.03 part per million on tomatoes. An EPA chemist told us that these methods had not been validated by EPA, however, EPA had validated the registrants' methods for other commodities and the stated sensitivity of methods could often be improved further by changes in the cleanup processes.

Further, HEW's comments do not address our concern that EPA's safety evaluations do not include consideration of the potential human exposure allowed by action levels as is done when tolerances are established. (See endrin example on page 33.) We strongly believe that it is necessary to make such judgments on the safety of action levels.

We believe that the foregoing clearly demonstrates that improvements are needed to ensure not only that residues at action levels can be safely consumed but that such residues are unavoidable.

Investigate pesticide use conditions when high residues of pesticides subject to action levels are found

HEW did not concur with our recommendation that FDA investigate pesticide use conditions in foreign countries when significant residues of a pesticide are detected in an import to ensure that action levels are, in fact, lower than residue levels which may result from the direct, purposeful application of pesticides to food. HEW said that FDA does not have the authority to investigate pesticide use conditions in foreign countries and that resources should not be committed in the absence of evidence that residues lower than action levels are occurring as a result of direct, purposeful application of pesticides.

HEW's response regarding FDA's lack of investigative authority is inconsistent with actions already taken by FDA in its pilot program for Mexican food imports. The following excerpts from the program's March 20, 1979, status report describe investigative efforts by FDA:

--"FDA intelligence gathering indicates methomyl being used by Mexican growers on strawberries. The use of methomyl on strawberries is not permitted. * * * If methomyl residues are confirmed the necessary steps will be taken to 'gear up' Dallas and Los Angeles Districts to enable them to perform the analyses in their respective areas."

--"The * * * Mexican Liaison Representative reports that Mexican Agricultural Officials have collected

several samples of carrots for analysis from the area which for the past 4 - 7 years has been used to grow potatoes. Carrots from this area have been analyzed by FDA and were found to contain PCNB. PCNB is permitted in potatoes but not permitted in carrots. The PCNB residue found in carrots is apparently coming from the soil which results from its prior use on potatoes. This situation is being monitored very closely by FDA."

We believe this investigative activity is well within FDA's authority and should be encouraged.

As regards residues occurring from direct, purposeful pesticide use resulting in residues lower than action levels, HEW and FDA are well aware that a wide range of residues--from negligible to several parts per million--will result in food from purposeful pesticide use depending on

--persistence of the pesticide,

--concentration of mixture applied,

--method and rate of application,

--soil and climatic conditions, and

--length of time between application and harvest.

An excellent example of this is contained in FDA's own data. FDA policy is that residues of monitor on imported Mexican produce is the result of purposeful use. Yet only 6 of 307 samples in which the pesticide was detected contained residues large enough to be within levels which FDA could accurately quantify and take regulatory action.

In light of the foregoing, we strongly believe that this recommendation should be implemented.

CHAPTER 4

ADULTERATED FOOD IS MARKETED WITHOUT PENALTY

Even when the pesticide residues on imported food are identified as being violative, the food will probably be marketed and consumed rather than detained or destroyed. Both existing law and FDA procedures permit imported products--primarily perishable foods--to be distributed before completion of residue analyses. If the analysis subsequently finds the product to be violative, it often has already been marketed and consumed.

Importers are not penalized for marketing adulterated foods provided a reasonable attempt was made to recall the food. However, even importers with histories of repeated violations are not penalized and their imports are seldom detained pending analysis. FDA import inspectors allow food imports to be distributed before analysis because (1) they are unaware of previous importer violations and (2) results of laboratory analyses will not be reported before perishable food spoils.

ESTABLISHED POLICIES REGARDING IMPORTED PERISHABLE FOOD

Section 801(b) of FFDCA provides that imported products may be delivered to owners or consignees prior to FDA admissibility decisions when necessary to avoid unusual loss, inconvenience to importers, or port congestion. The act further provides that, when this occurs, importers must file good and sufficient bonds to pay for damages associated with not returning adulterated products for required regulatory actions. FDA's implementing procedures provide that imports of perishable produce, fresh fish, and seafood--from which samples have been taken--be held "intact" pending the results of sample examinations unless

- --there is no reason to suspect the product is adulterated,
- --the projected time lapse between sample collection and the importer being notified about shipment admissibility is such that the product would deteriorate or spoil, and
- --the importer has signed an agreement with FDA that an an attempt will be made to recall any distributed merchandise if the sample is later found to be adulterated.

Perishable food which FDA does not require to be held intact pending analyses may be distributed immediately upon import. Under the agreements importers sign with FDA, they are not penalized for marketing adulterated food which cannot be reclaimed provided recalls are attempted. FDA officials told us that most perishable produce released for immediate distribution cannot be recalled because it is consumed prior to completion of laboratory analysis.

FDA policy does, however, stipulate that the perishable products of importers with histories of repeated violations as well as imports suspected of being adulterated will not be released until the results of laboratory analyses are known. If one sample of an importer's produce is found adulterated, the policy requires that all subsequently sampled shipments be held until there is assurance that problems have been resolved.

FDA DOES NOT DETAIN SHIPMENTS OF IMPORTERS WITH HISTORIES OF VIOLATIONS

FDA is not effectively implementing its own policy that perishable food be held intact until analyses are complete for imports with histories of violations or for food suspected of being adulterated. In some cases, even obviously suspect food is not detained. For example, Department of Agriculture personnel in the Dallas, Texas, district complained of a pronounced "insecticide-like smell" associated with an imported shipment of cabbage. Despite this complaint, the cabbage was allowed to enter commercial channels. The importer had a history of shipping adulterated products. Subsequent analysis confirmed the presence of violative residues of the pesticide BHC, a pesticide whose registration was canceled at the request of registrants in October 1976 because it may cause cancers. FDA officials agreed that the cabbage should have been held pending analysis on the basis of the USDA report of pesticide smell. FDA officials said that the cabbage shipment was released because FDA had not previously detected adulterated cabbage shipments from the importer. They explained that they hold suspect products on the basis of violation histories of identical products from the same shipper; other perishable produce of the importer is not held until a similar violation history develops.

The violation history of the cabbage importer is not uncommon. Other examples follow.

--Four importers of Mexican peppers had a history of adulterated shipments during the 15-month period ended September 1977.

Importer	Violative shipments		
	Total	Released	Denied Entry
1	8	6	2
2	19	9	10
3	14	9	5
4	6	5	1
Total	47	29	18

As shown FDA denied entry to only 18 of these shipments; the other 29 were released immediately. In one instance an imported pepper taken from a released shipment was found to contain pesticide residues 29 times the allowable limit. Although 66 of the 606 Mexican shipments of peppers sampled by FDA in the 15-month period ended September 30, 1977, were adulterated, only one-third were denied entry. Most peppers were imported from November 1976 through May 1977; however, few shipments were held pending analysis until March, when FDA closed the border to the four pepper importers and began holding all pepper shipments pending analysis.

--A sampled shipment of poblano peppers was allowed immediate entry into the United States even though the shipper had previously shipped adulterated serrano peppers. During analysis the poblano peppers were found to be adulterated with the same chemical as were the serrano peppers. The distinction between varieties of peppers is inconsequential--emphasis should have been on the importer's violative history rather than the specific pepper variety involved.

OPPORTUNITIES FOR FDA TO IMPROVE ITS RESIDUE MONITORING

FDA import inspectors are currently handicapped in detecting and removing from trade adulterated food imports because (1) they are not aware of previous importer violations and (2) laboratory analyses take a long time to complete.

FDA inspectors often do not know that importers have previously delivered adulterated food for import so they allow adulterated food to enter the domestic market. Currently, FDA headquarters compiles weekly and monthly lists of all importers whose food was found to be adulterated and was denied entry into U.S. commerce by FDA. However, these lists are inadequate because they do not identify all importers and products sampled and found to be adulterated

after the shipment entered U.S. commerce. A more effective monitoring program could be carried out if FDA headquarters provided its inspectors with the results of all laboratory analyses that found adulterated food. This would alert FDA inspectors to importers and products that are repeatedly in violation and allow inspectors to prevent these products from entering the U.S. market until appropriate analyses are completed.

Analyses take too long to make

FDA must also address the lack of timeliness in completing analysis testing. Too often the results of laboratory analyses are not reported in time to prevent the marketing of adulterated food. For example, officials told us that FDA allowed import of a shipment of serrano peppers later identified as containing illegal residues because

> "* * * the inspector was not informed of * * * previous violations in time. The previous samples were collected on 1/17/77 and 1/31/77 but results of analysis were not reported till 2/17/77 and 3/3/77."

In another instance FDA sampled dried eggs for both salmonella and pesticides. FDA's Dallas laboratory received and analyzed the sample for salmonella before the New Orleans, Louisiana, laboratory completed the chemical analysis. Based on negative results of the salmonella examination, FDA released the shipment. A week later, however, the New Orleans laboratory completed chemical analysis and found violative levels of PCB, a highly toxic industrial contaminant. FDA did not request a recall of the eggs because of the time that had transpired since release of the shipment.

We reviewed FDA records of 108 food samples found to contain violative pesticide residues collected from import offerings at 10 ports of entry. The elapsed time from filing of entry papers to FDA decisions took from 4 to over 50 days; the average time for laboratories to report initial analyses was 11 days. Sample analyses can, however, be reported in 1 or 2 days as were 17 of the 108 we examined.

Delays in reporting analyses generally occur because FDA laboratories cannot begin analyses when import samples are received. For example, during the period November through March when most Mexican produce is imported, the workload is such that many imported food samples do not receive prompt attention. At other times, chemists normally assigned to routine import surveillance are detailed to assist in special

surveys such as one associated with the concern over PCB and PBB contamination of milk supplies in Indiana and Michigan, respectively.

Regulatory analyses of imported food should neither be delayed during heavy import periods nor sacrificed in favor of special surveys. We recognize the importance of special surveys such as the one for PCB/PBB in milk, however, if such work will impair FDA's surveillance program, FDA should consider hiring additional residue analysts or contracting for the special survey work.

In addition some samples were analyzed twice before FDA initiated regulatory actions. A check analysis may be necessary; however, these imports should not be released once they are identified as potentially adulterated. Further, if not done in a timely manner check analyses are pointless when performed on perishable commodities likely to spoil or to be consumed before the analysis is completed.

Canadian white bass not adequately monitored for mercury contamination

FDA's monitoring standard in at least one instance appeared to be arbitrarily established and was not reevaluated when circumstances changed. Until September 1976, FDA's Detroit, Michigan, district analyzed white bass imported from Canada for mercury contamination. In September 1976, however, analyses were discontinued because both FDA and Canadian studies disclosed that there was a correlation between the size of the fish and the levels of mercury residue likely to be present. Specifically, the studies showed that white bass 11.5 inches or smaller contained mercury residues less than FDA's established action level of 0.5 part per million.

In light of these studies, FDA and Canadian officials agreed that imported shipments would not be accepted if

--10 percent of the white bass in any shipment exceeded 12.5 inches and

--any shipment contained fish over 15 inches.

FDA began (1) monitoring white bass on the basis of length rather than mercury analysis and (2) detaining only shipments with fish that exceeded 12.5 inches. FDA's substitution of the length criteria for chemical testing does not appear to be justified. During the summer of 1976--just months before establishing the size monitoring criteria--the Detroit office found 7 of 16 shipments contained mercury in excess of the action levels and 2 of the 7 adulterated

shipments did not contain fish over 12.5 inches. This suggests that fish length was not a good indicator of fish with violative mercury levels. FDA allowed all 16 shipments to be marketed before analyzing samples apparently because it knew that a lengthy period would elapse before the laboratory analysis would be performed due to other priority testing requirements.

In April 1977 Canadian officials requested that FDA further raise its monitoring level to bass exceeding 13.5 inches because recent tests showed that, smaller fish contained mercury residues under the FDA-established action level. Despite the fact that its most recent sampling experience showed that white bass had excessive mercury levels, FDA raised the monitoring criteria without performing additional independent checks to show that the fish were, in fact, safe.

FDA's decision to monitor white bass on the basis of length appears to be an arbitrary and inadequate way to check for harmful mercury residues.

COMPLIANCE BONDS NOT USED AS ENFORCEMENT TOOL

FDA requires importers to provide bonds for food released into the channels of trade before FDA determines if the imports comply with all residue requirements. This serves as a basis for ensuring that importers will attempt to recall adulterated shipments. We found no cases where FDA required importers to forfeit compliance bonds for perishable imports. Apparently compliance bonds as currently used are totally ineffective.

During the 15-month period ended September 30, 1977, FDA detected illegal pesticide residues in 160 shipments of imported food. Almost half of these shipments--79 shipments --were released and marketed before FDA completed residue analyses. This occurred because FDA did not suspect the food was adulterated and, being mostly perishable products, it may have spoiled if detained pending the results of laboratory analyses. FDA officials told us that importers were not penalized because these shipments had already been marketed and consumed, and therefore, were beyond the importers' recall.

FDA officials told us that under terms of the agreements signed with FDA, importers do not forfeit compliance bonds for food imports subsequently found to be adulterated so long as recalls are attempted. FDA's import manager told us that bond forfeitures would not be appropriate when importers have acted in good faith to recall them.

We do not concur with FDA's view that it would be inappropriate to forfeit bonds in these circumstances, provided FDA writes such a provision into the agreement. We suggested this to FDA's Associate Commissioner for Compliance. He told us that a study group was examining regulatory alternatives and may consider this.

CONCLUSIONS

Under current FDA policies and procedures for monitoring pesticide residues, food identified as adulterated often enters the U.S. channels of trade. This generally occurs because perishable food cannot be detained at the port of entry while FDA completes residue analyses. Residue analyses often take several days or even weeks to complete due to sample backlogs or higher priority work. This delay is compounded because FDA often does not take action until a check analysis is completed to provide an adequate basis for regulatory action against the importer. Such analyses appear superfluous when not completed in time to prevent adulterated food from entering the market.

Adulterated food imports may also enter the market because FDA headquarters does not notify its inspectors of all violations detected at other ports of entry. Currently, FDA headquarters only provides periodic listings of adulterated shipments that are detained at ports--other adulterated shipments that were not detained are not listed. As a result, inspectors at many entry ports are not aware of the violation and do not have a basis to consider detaining a shipment until residue testing is completed. We believe that data on all adulterated shipments, including the importer's name, should be included in FDA's periodic listing of violations.

Other adulterated food may enter without sampling because FDA has adopted inappropriate sampling criteria, such as the size limitations on residue sampling of imported white bass. Fish length may be an appropriate consideration in determining the extent of sampling, however, data indicating that violative samples of smaller fish do occur argues that selective sampling of shipments of fish of all sizes should be done.

Lastly, the importer agreements FDA currently uses do not deter adulterated food shipments, even though security bonds are required, because there is no penalty for adulterated imports, provided importers attempt to reclaim adulterated shipments. Given the time lag between entry of the shipment and determinations that violations exist, most imported food is consumed and the importer has little to do to

avoid forfeiting its bond. We believe that automatic forfeiture of security bonds would be an effective deterrent because importers would be economically affected by such forfeitures. Repeated violations and forfeitures would affect their ability to obtain bonds and continue in the import business.

RECOMMENDATIONS

We recommend that the Secretary, HEW, through the Commissioner, FDA:

- --Provide for the timely completion and reporting of laboratory analyses so that actions can be taken to prevent the marketing of adulterated food, particularly food suspected of being adulterated.

- --Take appropriate actions to deny entry of suspected adulterated shipments into U.S. commerce until check analyses are completed.

- --Consider including provisions for penalties--such as automatic forfeiture of security bonds--in importer agreements to penalize importers of adulterated food which has already been marketed.

AGENCY COMMENTS AND OUR EVALUATION

Timely completion and reporting of residue analyses

In response to our recommendation that FDA provide for the timely completion and reporting of laboratory analyses so that actions can be taken to prevent the marketing of adulterated food, HEW said that FDA has always tried to do this. HEW said that analyses may be delayed because of unusually heavy demands on FDA's analytical capability, but that this was not considered a serious problem because suspect food is held pending completion of analysis.

Contrary to HEW, we believe this could be a serious problem because much food, particularly produce, is perishable and could not be held at the border an average of 11 days--the average time FDA took to determine shipments were violative, during the period we sampled. (See page 42.) If analyses could not be completed more quickly, FDA would have to release shipments for U.S. entry before analysis is complete, let the shipment spoil, or return the shipment to the country of origin. These options are all much less desirable than timely decisions on entry or denial of entry based on residue analyses.

In questioning FDA officials we were told that the elapsed time for completing analyses currently was not available. In the absence of such data, it is not possible to assess HEW's statement regarding improvement. We believe that a complete review of the timeliness of analyses should be made by FDA when it evaluates the effectiveness of its pilot program for Mexican imports.

Report all violative laboratory analyses

In commenting on our recommendation that FDA provide its inspectors with results of all violative laboratory analyses so that importers and products found repeatedly violative can be prevented from entering the U.S. market before analyses, HEW said that FDA had initiated in April 1977 a procedure to provide each district a listing of all products found violative. HEW said that the listing includes the commodity, the shipper, the importer, and the cause of violation.

Although HEW's comments indicate that this action was initiated in April 1977, it had not been implemented as of September 1977 when we first discussed with FDA officials why only violative samples actually being denied entry into the United States were being listed. It appears that the new procedure was initiated in April 1978 and will adequately address this recommendation. To be effective these lists should be made available to FDA inspectors in a timely manner.

Deny entry of suspect shipments until check analyses are complete

HEW said that FDA does take action to deny entry of suspected violative shipments into U.S. commerce before check analyses are completed. HEW said this had been FDA's policy and long standing practice to deny entry to such shipments and that check analyses had no bearing on this practice because shipments are not released until check analyses are complete.

Our review of FDA records disclosed many instances where violative shipments, which underwent check analyses, entered the U.S. market. However, these records do not show whether the shipment was released before or after completion of the original analysis which indicated the shipment was violative. In view of the foregoing, we must conclude that FDA is not holding at the border shipments of commodities that have

been found repeatedly violative (see example of four importers on pp. 40 and 41) and is making check analyses on produce shipments that have already been released into commerce and consumed. This makes no sense because such shipemtns cannot be recovered and, barring a change in its policy, FDA does not assess penalties against shippers. It would be more productive for FDA to concentrate its limited analytical resources on shipments that are being held at the port pending analysis.

Sample imported fish regardless of length

In commenting on our recommendation that FDA reinstitute the sampling of all imported fish regardless of length, HEW said that it has always taken samples of fish for chemical contaminants without regard to size. HEW said that it had suspended testing for mercury in white bass for a period of time based on Canadian testing for mercury and evidence that violative mercury levels (0.5 part per million) were not found in samples below a certain length. HEW further said that based on reevaluation of toxicology data, the action level for mercury in white bass was doubled to 1 part per million, and FDA has resumed routine mercury sampling of white bass.

The intent of this recommendation will have been fulfilled by resumption of FDA mercury sampling of white bass, however, we remain concerned about FDA's decision to substitute fish length for residue testing, especially in view of FDA's most recent experience showing that two of seven samples (29 percent) within the length criteria were violative. FDA should not have replaced its mercury sampling program with a program as imprecise as fish length. We believe that FDA could have reduced--but not eliminated--its overall mercury sampling based on monitoring the length of white bass.

Provision for penalties in importer agreements

HEW said that it would give further consideration to our recommendation that FDA include provisions for penalties --such as automatic forfeiture of security bonds--in importer agreements to penalize importers of violative food which has already been marketed. HEW said that under current procedures it takes action against shippers, against specific commodities, or against a country until identified problems have been resolved. HEW believes that this approach more appropriately addressed the responsible party for violative

products rather than just the importer, a/ who has no control over pesticide use in foreign produce.

We do not disagree with FDA's current approach for preventing entry of violative food commodities into the United States. Our recommendaton is intended to supplement the current procedures in cases where good faith efforts were not made to recall violative shipments allowed entry and which, therefore, warrant sanctions against importers. Such penalty provisions could also be effectively used in connection with our recommendation on page 20 that FDA require certificates regarding pesticides used on the import commodity; importers who fail to list pesticides could be penalized if deemed appropriate by FDA.

As now constituted, the bonding provision benefits no one, save the bonding agent. If FDA chooses not to write penalty provisions in its agreements tied to bond forfeiture, we see no valid rationale for continuing bonding requirements.

a/ On page 4, we defined brokers, agents, or shippers as importers for sake of brevity. This definition is intended to apply in this case.

CHAPTER 5

NEED TO MONITOR PESTICIDE EXPORTS

Each year the United States exports millions of pounds of pesticides to foreign countries. A large portion of these exports are pesticides that have been suspended or canceled for U.S. use because they may cause cancer or otherwise endanger humans, wildlife, or the environment. The majority of unregistered pesticides exported, however, involve products whose chemical contents are unknown and/or whose human and environmental hazards have not been adequately evaluated.

The production and distribution of pesticides produced solely for export are largely uncontrolled. Neither EPA nor any other Federal agency monitors the content, destination, and intended uses of such pesticides. Some exported pesticides have caused serious deaths and injuries in foreign countries. In addition, exported pesticides that are used on food crops in foreign countries, may be present as residues on U.S. food imports. The extent to which imported food contains residues of harmful pesticides or pesticides whose hazards have not been adequately evaluated is unknown.

MAGNITUDE OF PESTICIDE EXPORTS

The Bureau of the Census reported that in calendar year 1976 over 552 million pounds of pesticides were exported from the United States. (See app. III.) Available data shows that over 161 million pounds, or 29 percent, represented pesticides not registered for U.S. use. About 20 percent of these unregistered pesticides--some 31 million pounds--involve pesticides that EPA had suspended or canceled because their uses posed unreasonable hazards to human life, wildlife, or the environment. A more significant portion of pesticide exports--some 130 million pounds--consists of products that may never have been registered with EPA. Some unregistered pesticide exports consist of chemicals whose properties have not been studied or, if studied, are considered too hazardous for U.S. use. Other unregistered pesticide products may consist of "active ingredients" contained in registered products, that differ from registered products only in their formulations; that is the combinations and relative amounts of active ingredients.

Nonetheless, EPA knows little about most of these products and some undoubtedly contain chemicals that EPA has not evaluated adequately for potential adverse effects.

REGULATORY STATUS OF EXPORTED PESTICIDES

Pesticides produced solely for export are not required under law to be registered with EPA. Basically, any pesticide may be exported regardless of its domestic regulatory status or the appropriateness of its intended use. Section 17(a) of the Federal Insecticide, Fungicide, and Rodenticide Act provides that

> "* * * no pesticide or device shall be deemed in violation of this Act when intended solely for export to any foreign country * * *"

Pesticide manufactures are, however, required to keep records of the chemical content, quantities, purchasers, and dates of shipment and receipt of all exports. EPA is responsible for assuring that these records are maintained and, furthermore, is authorized to inspect products ready for distribution. Further, the amendments to FIFRA passed in September 1978 also require exporters to label unregistered pesticides as such and to obtain statements from importing countries that they understand the product cannot be used in the United States.

Knowledge of the production and distribution of exported pesticides is both useful and necessary.

--EPA must inspect export products and export records to assure that unregistered pesticides (considered too dangerous or too little studied for U.S. use) are actually exported and not sold or distributed in the United States.

--As explained in chapter 2, FDA needs to know what pesticides are used on food in foreign countries to adequately monitor for potential residues in imported food; knowledge of the destination and use of large volume U.S. pesticide exports could assist FDA in its monitoring. Information on the use of suspended and canceled pesticides is particularly important since these pesticides are known to be harmful.

No Federal agency monitors pesticide exports for content, quantity, destination, and use. In fact, no single, authoritative, comprehensive source of data exists on U.S. pesticide exports. Some Federal agencies, including EPA, keep statistics on the production and movement of certain pesticides; in most cases export data is reported by pesticide groups but not by individual product. The importance of such data is shown by information provided the Subcommittee on Foreign Agricultural Policy, Senate Committee on Agriculture,

Nutrition, and Forestry, by the Secretary-Manager, West Mexico Vegetable Association:

> "Incidentally, the pesticides used in Mexico are all manufactured in the United States. Mexican growers use American-made pesticides and follow rules and regulations drawn up in the United States, unless of course the Mexican regulations are more restrictive."

Monitoring of pesticide export data could provide FDA with an additional source of information on which to base its residue monitoring program.

Despite its responsibility for monitoring unregistered products, EPA does not inspect exports or even check to see that required records are maintained. An EPA regional official told us that EPA would inspect export records if a violation was suspected; however, he said he could not imagine how one would suspect an export violation. Another said, "To be honest with you, we don't do anything with exports."

GROWING CONCERN OVER PESTICIDE EXPORTS

In recent years, pesticide exporting has become a matter of national and international concern. This concern stems from reported incidents of widespread poisoning, death, and severe environmental harm in foreign countries. The World Health Organization has estimated that there are 500,000 pesticide poisoning cases worldwide each year from direct pesticide exposure and that about 5,000 are fatal. In our visits to foreign countries and review of available literature we compiled the following data:

Country	Year	Poisoning	Deaths
Sri Lanka	1975	-	864
New Zealand	1976	226	6
Nicaragua	1962-72	3,000	400
Netherlands	1976	716	-
Guatemala	1976	1,039	-
El Salvador	1974	1,280	6
Pakistan	1976	2,900	5
Italy	1976	159	9
Australia	1975	365	7
France	1975	270	-

As shown above, the data we were able to gather from foreign nations on pesticide incidents was meager. The total extent of human suffering and environmental harm

resulting from trade in pesticides is as difficult to document as are the benefits resulting from improved health, sanitation, and food production. Foreign countries' systems for identifying and recording pesticide-related poisonings and deaths vary from elaborate to nonexistent. Foreign officials could not provide us specifics relating to human poisonings and/or deaths in their countries. We did note, however, that a study funded by the U.S. National Academy of Sciences found that extensive use of DDT on cotton has resulted in widespread contamination of food supplies in four Central American countries, including El Salvador. In 1976 the U.S. Department of Agriculture refused entry to about half a million pounds of DDT-contaminated beef from El Salvador. Some of the beef contained residues about 19 times the U.S. tolerance.

In addition, we found a number of unofficial newspaper reports detailing pesticide incidents. Among the incidents reported are those involving pesticides which had been suspended or canceled in this country but which were, nevertheless, still exported overseas. Other reports have involved pesticides significantly restricted or never registered in the United States. For example:

--Aldrin was the suspected cause of 13 deaths in Brazil in 1975. It was suspended for use on food crops in the United States in 1974.

--2,4,5-T was the suspected cause of 70 miscarriages in Colombia in 1975. It is not registered for use on food crops in the United States; current uses are limited to rights-of-way, forests, and range lands. Even these uses are being questioned currently by EPA.

--Improper use of malathion, during the summer of 1976, caused at least 5 deaths and an estimated 2,900 illnesses in Pakistan.

--Phosvel (leptophos), a pesticide never registered in the United States, resulted in the death and illness of a number of farmers in rural communities in Egypt during 1971; in addition, over 1,000 Egyptian water buffalo died from phosvel poisoning. The United States was the only producer, exporting 13.9 million pounds of phosvel to 50 countries, including Egypt from 1971 to 1976.

In addition to the potential harm some pesticides pose to the workers and residents of other nations, there are also ramifications for the American consumer. Exported pesticides may return to the United States on imported food in the form

of excessive and illegal residues or by air or water as environmental pollutants, thereby posing harm to U.S. citizens. As reported in chapter 2, FDA does not know what pesticides are used overseas on food and at present can not fully monitor imported food for such residues.

Federal concern over export of hazardous pesticides

Considerable Federal attention has been focused on the export of hazardous pesticides in recent months. This attention has been focused not only on the harmful effects of pesticides on residents of foreign importing nations but also on the potential adverse economic impact on U.S. farmers who can not use some of these exported products because they are not registered for use on the same crop in the United States.

House Committee on Government Operations

The October 4, 1978, "Report on Export of Products Banned By U.S. Regulatory Agencies" of the House Committee on Government Operations, while recognizing that the risk assessment of a particular product will vary depending on the nature of the hazard, health, or safety conditions in the importing country, and the availability of alternatives to the product, nevertheless concluded that:

> "It is critical that U.S. agency officials have accurate data on the amount and destination of potentially hazardous pesticides exported from the United States because of the human and environmental dangers which those pesticides represent to foreign users."

To correct what were perceived as shortcomings in the gathering of data regarding pesticide exports the report recommended that:

--An export permit procedure similar to the one proposed in section 134 of the Drug Regulation Reform Act should be incorporated in agency statutes to govern situations where export is allowed. Section 134 as applied to pesticides would require an exporter of an unapproved or noncompliant pesticide to notify the importing government of the legal status of that pesticide in this country.

--No product which is banned from the domestic market should be allowed to be exported without an EPA determination that export can be justified for any of the following reasons:

1. Circumstances would render the product safe for use in foreign countries as determined by the U.S. regulatory agency.

2. A company has requested permission to export the product and has met the criteria established by statute or regulation of the U.S. regulatory agency for such exports.

3. A foreign country has requested that export be allowed.

--FIFRA be amended to require (a) foreign governments to certify that notification has been received and (b) manufacturers to inform EPA of the intended country of destination of exported, canceled, or suspended pesticides.

Committee on Agriculture, Nutrition and Forestry

Extensive hearings before the Subcommittee on Foreign Agricultural Policy, Committee on Agriculture, Nutrition, and Forestry, were held to consider the adverse impact of substantial increases in Mexican imports on the Florida winter vegetable industry. Among other things, representatives of the Florida growers charged that Mexican growers could use pesticides on vegetable crops that were not allowed in the United States.

Much of the testimony on pesticides dealt with Mexican use of the pesticide monitor which is manufactured by a U.S. firm. It is U.S. registered for use on broccoli, cabbage, and cauliflower; residue tolerances have been set at 1.0 part per million for each of the three vegetables. In addition tolerances have also been established for cucumbers, eggplants, peppers, tomatoes, and lettuce at 1.0 part per million and for melons at 0.5 part per million. The latter tolerances applied only to imports as monitor was not registered for U.S. use on these six crops.

A representative of the Florida growers testified that apparently a tremendous amount of political pressure must have been applied, because FDA arbitrarily established a tolerance of one part per million of Monitor-4 on peppers, and notified all States to accept these peppers. The representative believed that FDA's action allowed Mexican produce treated with monitor to enter the United States while at the same time Florida producers were denied use. To illustrate his case, he explained that:

"Florida tomato growers were plagued last season by a pest called leafminer, which defoliates the plant, and seriously affects total yields. Although several new chemicals that controlled leafminers were available, they could not be used in Florida because the EPA had not approved labels for them. A specific exemption to use Vydate L in Florida was flatly refused by the EPA although it was being used extensively in Mexico. Monitor, which also controls leafminer, was another product used widely in Mexico last year, but not approved for use in Florida."

On the other hand, representatives of the Mexican growers and distributors testified that, although Mexican farmers are not required by Mexican law to use pesticides registered in the United States, nevertheless, they voluntarily do because they do not want to be subjected unnecessarily to unwarranted criticisms about safety and purity, etc. Further, they testified that:

--Their National Farmers Union has a complete compendium of pesticides compiled by EPA which is updated every month, and polices the use of acceptable pesticides by Mexican farmers.

--FDA and the Department of Agriculture conduct inspections both in the field and at the border crossing to assure that dangerous and/or injurious pesticides are not used on vegetables sold in the United States, and that State inspectors may also inspect the produce loads.

FDA officials took exception to the Florida growers statements because tolerances (1) were established by EPA, not FDA, and (2) underwent the same procedures as other requests for tolerance action. In a similar vein, FDA has found residues of pesticides on imports authorized by neither EPA nor Mexico, contrary to statements of Mexican grower representatives. Nevertheless, the divergent viewpoints of the groups are indicative of growing concern and friction in this area.

President's ad hoc interagency working group

Still another effort to address exports of hazardous products, including banned pesticides, was undertaken by an ad hoc interagency working group, chaired by the Special Assistant to the President for Consumer Affairs. The President's special assistant testified before a congressional subcommittee that almost every foreign delegation that has

met with the working group has expressed growing concern about the potential hazards of products exported from the United States and other countries. The special assistant explained that the purpose of the interagency working group is to assess the current state of the law with respect to these exports, determine whether a new policy to deal with the issue more uniformly and consistently is needed, and develop such a policy if a need is found to exist.

She said that the working group had completed defining the state of U.S. laws with respect to the export of banned products--the laws ranged from permissive allowing export of U.S.-banned products to restrictive prohibiting such exports. As a result members of the working group had unaminously agreed that a uniform policy governing the exportation of U.S.-banned products is needed and was in the process of developing the policy. In articulating the policy, a variety of complex factors were being considered:

--Moral responsibility to limit the exportation of hazardous products must be balanced with the right and willingness of a foreign government to protect the health and safety of its citizens.

--Protecting the health and safety of U.S. citizens by assuring that exported hazardous products, such as pesticides banned in this country, are not reimported on food imports.

--Differing economic, social, and cultural conditions in a foreign country that suggest a product whose use is banned or severely restricted in the United States may be justifiable for use in that country.

--Taking into account economic burdens that the policy may impose, such as the U.S. balance-of-trade deficit.

--Recognizing the need to coordinate and cooperate with the relevant international agencies, organizations, and governments in data analysis, information sharing, and the development of consistent, uniform policy approaches.

--Taking into account the feasibility and practicability of administering and enforcing the policy.

The special assistant testified that the working group had a September 1978 timetable for recommending to the President a comprehensive policy on exporting banned products. As of May 31, 1979, the policy was still in the formulation stage.

International concern over use of hazardous pesticides

In addition to Federal concern, there has also been a great deal of international concern over the worldwide use of pesticides. Efforts to mitigate these concerns are typified by the international conferences described in the following sections. The benefits of such international activities are obvious and should be given every encouragement.

Ad hoc government consultation on international standardization of pesticide registration requirements

This conference, sponsored by the Food and Agriculture Organization of the United Nations, convened in Rome, Italy, October 24 to 28, 1977, with delegations from 41 countries and 11 chemical industry groups and international organizations. The report of the conference noted that:

> "* * * pest control ranks high on the list of inputs required to achieve the goals of higher food production and freedom from vector-borne diseases. In requesting delegates to guide national authorities in the establishment and administration of appropriate legislation controlling the sale of pesticides, * * * [it was] pointed out that the consultation provided a unique opportunity for governments and the chemical industry to discuss the basis of pesticide registration requirements leading to the production of acceptable guidelines and technical methods. Delegates were encouraged to take action on aspects where agreement was already possible and to make proposals for future action and follow up which would lead to a great degree of international harmonization. The importance of involving all bodies engaged or interested in this work was stressed. FAO [Food and Agriculture Organization] could serve to catalyze and coordinate the efforts and to provide a means whereby national governments could agree to the adoption of uniform requirements and standardization methods."

Overall objectives of the conference were to:

--analyze and discuss the basis for harmonizing the requirements for pesticide registration in different countries;

--provide opportunity for governments and industry to discuss the basis for pesticide registration requirements with a view to producing generally acceptable guidelines;

--ascertain what action is being taken to develop or harmonize any aspects of the many diverse requirements for pesticide registration;

--guide developing countries in establishing and administering legislation for controlling the sale and marketing of pesticides;

--stimulate action for developing and adopting guidelines or standards or technical methods (chemical, analytical, biological, toxicological) for the evaluation of pesticides;

--consider the implication of registration requirements on the development of "target-specific insecticides" needed for the integrated pest management programs.

The work of the conference was divided among six committees which produced reports elucidating general guidelines for evaluating and/or describing pesticides' (1) chemical and physical properties, (2) biological activity, efficacy and crop safety, (3) toxicology (effects of human and animal exposure), (4) residues in agricultural produce, (5) environmental impact potential, and (6) labeling, packaging, storage, and disposal. Each of the reports was accepted and the conference recommended that registration authorities consider and fully use data generated in other countries in their registration of pesticides. In effect this recommendation would increase the transportability of data and would require new ways of reconciling the public and industrial interests in data in both developed and developing countries, while protecting the developer of data from use by competing manufacturers. The success of such efforts would greatly enhance the use of environmentally sound pesticides throughout the world, particularly in those countries without resources to adequately perform needed tests.

Conference on United States policy options for reducing impact of pesticides on the global environment

This conference, sponsored by the U.S. Department of State in cooperation with the U.S. National Committee for Man and the Biosphere, is scheduled for June 7 to 8, 1979, in Washington, D.C. Conception of the conference was based on the following:

"The United States, in an effort to help alleviate global food shortages and, at the same time maintain its commitment to environmental protection, has been caught on the horns of a dilemma. This nation currently manufactures close to two billion pounds of pesticides each year (almost 80% more than just ten years ago); nearly 40% of the total is exported overseas. Recently, there have been increasing calls in the U.S. for stricter pesticide control regulations, restrictions on pesticides shipped abroad, and acceleration of integrated pest management (IPM) research programs. * * * [The State Department will] sponsor an international conference to address these critical issues in order to generate policy options for reducing the impact of pesticides in the global environment. The need for this type of project and its potential for achieving significant outputs is clear."

Critical issues to be addressed in the conference include:

--Magnitude of global health and environmental impacts created by U.S. pesticide policies and the constraints (political, legal, institutional, and economic) to mitigate these impacts.

--Adequacy of U.S. procedures for (a) informing less developed countries of pesticide registrations, suspensions, and cancellations, (b) providing instructions on labeling, packaging, using, storing, and disposing of pesticides in these countries, and (c) providing risk/benefit information to those importing U.S. pesticides.

--Financial impacts on U.S. manufacturers of regulations which limit international trade in pesticides and how these impacts, along with potential environmental benefits, should be balanced in designing a regulatory framework.

--Problems associated with complex pesticide regulation in less developed countries.

--Adequacy of the U.S. Agency for International Development funded pesticide programs in addressing environmental impacts of pesticide use in less developed countries.

--Role, methods, and constraints to wide dissemination of integrated pest management techniques, particularly

in less developed countries as a means of limiting global use of pesticides.

CONCLUSIONS

The uncontrolled export of hazardous pesticides poses dangers to U.S. citizens, as well as to people in other nations. The extent of danger, however, is not known, because the content, destination, and use of most exports are not monitored. Presently, Federal law does not provide the means for tracking exports and minimizing hazards.

There is a growing concern both in the United States and abroad about the uncontrolled export of hazardous products, particularly products which cannot be used domestically. These concerns include (1) the ethics or morality of exporting products that are banned domestically, (2) the possible harm to residents of importing nations resulting from the use of these products, and (3) the potential adverse effects on U.S. citizens when food products are imported that contain residues of these hazardous, exported pesticide products.

We believe that such concerns can only be adequately addressed if responsible Federal agencies have sufficient information to make reasoned judgments on export policy. Ideally, such information would include quantity, chemical content, destination, and intended use of exported pesticides, particularly pesticides containing suspended or canceled pesticide chemicals.

RECOMMENDATIONS

We recommend that the Administrator, EPA:

--Ensure that pesticide manufacturers maintain export records as required by FIFRA.

--Monitor the chemical content, destination, and, if possible, intended use of pesticide exports.

--Provide information on the destination and intended use of exports to FDA to assist in monitoring imported food for pesticide residues.

--When large shipments of unregistered pesticides are exported, inform foreign countries that either the hazards of their use are unknown or, if known, the nature of these hazards and U.S. restrictions on their use.

CHAPTER 6

NEED TO NOTIFY FOREIGN NATIONS OF U.S. PESTICIDE ACTIONS

Federal law requires that EPA notify foreign nations and international organizations of all pesticide registration actions. Despite this comprehensive congressional mandate, EPA has limited its notification actions to only those pesticides whose registrations are canceled. It does not advise foreign nations when pesticides are (1) suspended, (2) undergoing Rebuttable Presumptions Against Registration (RPAR) actions, (3) voluntarily withdrawn from use by the producers, or (4) restricted to use by specially trained and certified applicators.

We informed EPA on April 20, 1978, that its notification procedure did not comply adequately with the law. EPA, however, disagreed and indicated that they would continue to limit their notifications to those it deemed of significance. EPA's continued practice neither complies with the intent of the legislation nor adequately recognizes foreign nations' desires to be more fully informed about U.S. regulatory actions.

EPA HAS NOT COMPLIED WITH THE LAW

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." Appropriate notifications should be forwarded to the Department of State for transmittal to foreign nations.

EPA does not notify foreign nations of all significant pesticide registration actions. In our April 20, 1978, report to the Administrator, EPA, (see app. IX) we noted that since the act was amended in 1972 to require notifications, the registrations of 14 pesticides (or pesticide product ingredients) have been suspended, canceled, or significantly restricted because of their unreasonable hazards to man or the environment. However, EPA had notified foreign nations of actions on only five of these chemicals. EPA had not notified foreign nations on the other nine actions involving quarternary ammonium compounds, chlordane, heptachlor, kepone, OMPA, strobane, aramite, chloranil, and safrole. Since April 1978, EPA notified foreign nations of cancelling three of these chemicals--kepone, chlordane, and heptachlor--and one more--DBCP, which was canceled in 1978. Six pesticide actions still require notifications.

In addition, EPA has not been timely about notifying foreign nations of registration cancellations. Registrations of kepone, for example, were canceled in 1976, but EPA did not notify foreign nations of this action until 1978. In fact, although the FIFRA amendments requiring foreign country notifications were passed in 1972, EPA did not make any notifications until 1975.

EPA's lack of timeliness appears unjustified since the notification process is simple. Notification consists of forwarding copies of the Federal Register notice and a two- or three-paragraph summary of the regulatory action through the State Department to the intended recipients. There appears to be no valid reason why notification should take 2 years, as in the kepone case.

EPA's criteria limiting notifications appears questionable

EPA notifies foreign nations of only those pesticide actions it deems of "national or international significance." EPA narrowly defines significant actions as agency-initiated cancellations involving all registered uses of a basic pesticide ingredient. Under this definition, foreign nations are not advised of:

--Suspensions of pesticides initiated by EPA.

--Cancellations and suspensions not involving all or most uses of a basic pesticide ingredient.

--Pesticides that are being reexamined under the RPAR process.

--Restricted-use pesticides.

EPA's criteria for notifications are too restrictive. Regulatory actions of the type previously enumerated could have national and international implications, warranting notification be made.

Suspended pesticides not included under the notification process

EPA does not consider a suspended pesticide registration a final regulatory action and, therefore, does not provide for notifying foreign governments when a suspension occurs. Under this policy, EPA notified foreign nations of the heptachlor and chlordane cancellations in 1978, but not of their suspensions 2 years earlier in 1976. The registrations of chlordane and heptachlor were suspended and ultimately

canceled because of their suspected potential to cause tumors in animals and in humans. These pesticides were two of the most widely used in the world. FIFRA specifically requires notifications be sent on both suspensions and cancellations; current EPA policy regarding suspensions is not in conformance with the law.

In responding to our April 20, 1978, report (see app. IX), however, EPA indicated that it will continue limiting notifications to those it deems of significance and will consider notifications of cancellation actions but not suspensions. EPA responded that:

> "* * *in the future, each cancellation action taken for risk/benefit reasons will be reviewed in the Office of Pesticide Programs to determine if it meets the criteria of having 'national or international significance' * * *." [Underscoring supplied.]

We believe that EPA cannot readily determine the international significance of pesticide regulatory restrictions. Relatively minor pesticide uses in the United States may be significant uses in one or more foreign nations because of differences in climates, crops, and pests. EPA should, as FIFRA requires, notify foreign nations of all suspensions and cancellation actions.

Foreign nations not advised of pesticide uses withdrawn at request of registrants

Frequently, manufacturers or formulators of pesticides voluntarily request EPA to withdraw pesticide registrations from domestic use. In some cases, the voluntary withdrawal may be predicated on the fact that the pesticide has become suspect since its original registration of being potentially hazardous to human health and well-being. Such pesticides can, under the law, be exported without foreign governments being specifically aware of the suspected dangers inherent in their use. Notice is not even made where the pesticide was formally approved for numerous uses that could have international implications, such as in the cases of aramite, strobane, OMPA, and chlordimeform.

Aramite, for example, was once registered for U.S. use on 39 food crops. Tests showing that it causes cancer in rats and dogs resulted in requests for cancellation by pesticide registrants. Similarly, 34 product registrations of strobane were canceled because of its suspected cancer potential. OMPA was contained in only three products, but registrants voluntarily requested its cancellation because

the compound's high toxicity made products containing it unsafe for use.

Chlordimeform is an example of a registrant-initiated action warranting foreign country notification. EPA had registered chlordimeform for use on fruit trees and vegetables. In September 1976, however, U.S. chlordimeform manufacturers voluntarily ceased production and initiated a recall of all products because the pesticide was found to cause tumors in mice. In March 1978 registrants requested and received amended registrations limiting approved chlordimeform use to cotton. Since EPA has not revoked the 33 residue tolerances originally established for food uses of chlordimeform, foreign countries may mistakenly believe that U.S. regulations still permit the pesticide's use on food. Presence of chlordimeform residues on imported food would not be detectable with tests that FDA routinely uses to monitor imported food.

Foreign countries want to be and should be notified of registrant-initiated actions--including production and registration limitations--when such actions appear to be based on human health concerns. Our work overseas showed that at least two countries suspended use of chlordimeform when a U.S. manufacturer informed the government of cessation of U.S. production due to the pesticide's tumor-inducing properties.

Need to consider advising foreign governments on restricted-use pesticides and pesticides undergoing RPAR

EPA has taken significant pesticide regulatory actions other than the suspension or cancellation of registrations. Usually, such actions involve restricting a pesticide's use. Foreign governments are not, however, informed when such restrictions occur.

For example, EPA has limited the use of 23 pesticides to trained and certified applicators or persons under the supervision of certified applicators. Restricted-use pesticides are highly toxic and have histories of accidents during use. Persons who want to use these pesticides must demonstrate competence in the safe use and handling of pesticides through among other things, written or oral examinations. Applicators must be aware of the hazards of pesticides, precautions necessary to guard against injury, and first aid and other procedures to be followed in case of accident.

EPA has also issued Rebuttable Presumptions Against (the continued) Registration of 24 pesticides. An RPAR means that a pesticide has potentially dangerous characteristics and EPA is subjecting it to intensive scientific review to determine whether to allow continued use. Many RPAR chemicals are suspected of causing human cancers. Others may cause birth defects and genetic mutations.

RPAR pesticides and restricted-use pesticides are highly toxic, have histories of accidents during use and are suspected of causing serious human injury. Sodium cyanide, a restricted-use pesticide, is one of the most toxic chemicals known to man. It acts through either ingestion or inhalation of very low doses and there is no true effective antidote. Dimethoate, an RPAR chemical, is suspected not only of causing cancer but also genetic mutations and birth defects.

Although not required by law, EPA should notify foreign nations of restricted-use pesticides and of pesticides for which EPA has issued an RPAR. Notifications of known and suspected dangers of pesticides will be beneficial to both the United States and foreign nations. The latter benefit because they are alerted to some pesticides' unreasonable hazards and often follow the U.S. lead, which lessens exposure of their workers and citizens. The United States benefits when a nation restricts using these pesticides on U.S. food and fiber imports. Both can start the search for adequate substitutes as soon as potentially dangerous pesticides are recognized.

Foreign nations want timely pesticide data

Foreign officials in 14 countries expressly told us that they wanted to receive timely notifications on U.S. pesticide regulatory actions; none said that they did not want notifications. Officials of 27 nations informed State Department officials that their governments desired to receive notifications. Representatives from less developed nations told us that they were particularly anxious to receive timely data because they did not have funds or the expertise to perform the types of hazard evaluations EPA does. They rely heavily on U.S. registration as a guide for allowing use in their country. Guatemala, for example, canceled leptophos use based on information EPA provided. Costa Rican officials expressed keen interest in receiving all types of data on pesticide regulations because their country is patterning its regulatory system on that of the United States.

CONCLUSIONS

Although FIFRA requires EPA to notify foreign countries of both the suspension and cancellation of pesticide registrations, EPA has limited notifications to "significant" cancellation actions. In its attempts to identify significant actions, EPA has overlooked the need to notify foreign nations of several pesticide cancellations of importance that affect human health. We believe that EPA, as required by law, should notify foreign nations of all pesticide suspensions and cancellations in order that the nations are alerted to the unreasonable hazards of using these pesticides.

Other pesticide actions not involving the suspension or cancellation of registrations--such as restricted-use actions and RPARs--also have serious implications for human health. We believe that EPA, although not specifically required by law, should notify foreign nations of these actions because they desire and would benefit from the receipt of such data.

RECOMMENDATIONS

We recommend that the Administrator, EPA, through appropriate Department of State channels:

--Implement procedures to ensure that foreign countries are notified of all suspensions and cancellations and significant changes in registrations whether initiated by registrants or EPA.

--Notify foreign nations of all chemicals restricted in use and subject to Rebuttable Presumption Against Registration.

AGENCY COMMENTS AND OUR EVALUATION

In commenting on our recommendation that EPA and the Department of State implement procedures to ensure that foreign countries are notified of all significant pesticide registration-related actions, the Department said that it was working with EPA to develop a suitable mechanism for notifications. The Department said the following elements are being considered:

--A one-page EPA synopsis, in layman's language, of the action.

--EPA transmittal to the Department of sufficient quantities of Federal Register notices to be distributed to posts and missions.

--Department translation of one-page synopses into Spanish and French.

--Delivery of synopses and "Federal Register" notices by post and mission personnel.

--Report to EPA on the date and the foreign officials to whom notifications were made.

The Department said it also is developing procedures for expanding the process to include notifications regarding the U.S. export of unregistered pesticide products.

The procedures described by the Department of State appear adequate to ensure that notifications requested by EPA are made. However, the major weakness in the system remains whether EPA elects to make notifications required of it by law. EPA has not committed itself to make notifications regarding (1) all pesticide cancellations, particularly cancellations initiated at the registrant's request, (2) any suspension action, and (3) pesticides restricted in use or subject to Rebuttable Presumption Against Registration action. Without full EPA cooperation in initiating these notifications, the notification mechanism will remain relatively ineffective.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

APR 20 1979

Mr. Gregory J. Ahart
Director, Human Resources
Division
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Ahart:

The Secretary asked that I respond to your request for our comments on your draft report entitled, "Need For Better Regulation of Pesticide Exports and Pesticide Residues in Imported Food." The enclosed comments represent the tentative position of the Department and are subject to re-evaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

Thomas D. Morris
Inspector General

Enclosure

COMMENTS OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
ON THE GENERAL ACCOUNTING OFFICE'S DRAFT REPORT ENTITLED
NEED FOR BETTER REGULATION OF
PESTICIDE EXPORTS AND PESTICIDE RESIDUES IN IMPORTED FOOD

General Comments

We believe this draft report neither accurately nor fairly reflects either the degree to which pesticide residues pose a risk to the U.S. consumer or the Food and Drug Administration's (FDA) program for identifying and detaining violative imported products. We recognize the need for improvements in FDA's coverage of imported food for pesticide residues, and several actions are well underway to accomplish these improvements. However, many of the criticisms of FDA programs and professional competence are based upon unsubstantiated conclusions. GAO has posed hypothetical situations without citing sufficient evidence to substantiate their occurrence and thereby may create unfounded apprehensions about the food supply and those charged with assuring its safety. For example:

- There is no documentation to support GAO's contention that some foreign countries carelessly or excessively use pesticides known or suspected of causing cancer, birth defects and gene mutations. (See page 7 of the draft report.)

- GAO has offered no documentation to substantiate the claim that pesticide residues allowed by some current action levels may have resulted from the direct purposeful use of pesticides on food. (See pages 21 and 27 of the draft report.)

- GAO expressed concern about certain pesticides that are banned in the U.S. (e.g. DDT, dieldrin, heptachlor, chlordane) being used in foreign countries. GAO did not mention, however, that FDA routinely examines imported foods for residues of these pesticides.

- GAO has misinterpreted the Federal Food, Drug, and Cosmetic Act (FFDCA) as requiring that FDA research the identity of all unknown residues in food (See page 18 of the draft report and page 6 of the comments for further discussion of unknown residues.)

GAO has not provided sufficient background information for the reader to readily grasp the significance of pesticide residues found in imported foods or the magnitude of the problems that would have to be overcome to implement the recommendations they propose. The report takes imported foods (and pesticide residues in particular) out of context of total food consumption, leaving the reader unable to determine the relative intake of imported foods versus domestically produced foods, which creates the impression that the problem is much greater than it, in fact, is. It also fails to point out that even according to its own figures over 96% of the imported produce tested for pesticide residues meets U.S. tolerances established by the Environmental Protection Agency

(EPA). This is particularly significant when coupled with the fact that the report does not show that any of the cited yearly pesticide poisonings are the result of pesticide residues in food. The report states that on a world-wide basis there are 500,000 pesticide poisonings annually. It should be pointed out that these poisonings are primarily due to direct, accidental ingestion of or exposure to pesticide chemical products. This is quite different from GAO's implication that pesticide residues in commercially marketed food have caused this number of poisonings.

The FDA's Total Diet Study, which has been conducted annually since 1964, has consistently shown that the American consumer's dietary exposure to pesticide residues is substantially below the Acceptable Daily Intake (ADI)* recommended by the United Nations Food and Agriculture Organization/World Health Organization (FAO/WHO). For many pesticides the U.S. consumption level was less than one ten thousandth of the FAO/WHO ADI, and in no case was the intake as high as the ADI.

The report suggests that food importers should routinely be required to certify that all the food products they are importing meet EPA pesticide tolerances. Yet it does not address the complexities of the world trade situation or the effect such a requirement would have. A cursory examination of the world wide distribution system for food would reveal that the identity of a specific grower (the only person to know with any certainty what pesticides may have been used on a particular crop) is soon lost. Most food is imported in bulk shipments, not in small amounts. Products from many growers and geographic areas are commingled in such a way that identification of the specific origin of any one item is not always possible. It is often not practical for the importer to know what pesticides have been used. For this reason it would be unrealistic and unreasonable to ask the importer to certify his products. Moreover, the frequency with which imported food is found to contain pesticide residues in violation of U.S. regulations does not warrant such a request as a general matter. There are, however, situations where we believe certifications are necessary and appropriate. These situations will be discussed in more detail in the comments addressing specific recommendations.

The actual incidence of illegal pesticide residues on imported food is very low, the American consumer's dietary intake of pesticides from all food is very low, and the difficulty of tracing food samples, particularly imports, to their origin is enormous, if not impossible. The cost of implementing many of GAO's recommendations would far exceed the benefits to be derived therefrom. For example, the report omits any analysis of the sources of food imported into the U.S. which would have shown the

* The ADI of a chemical is the daily intake which, during an entire lifetime, appears to be without appreciable risk on the basis of all known facts at the time.

APPENDIX I

magnitude of the problem of identifying pesticide residues. During 1977 the U.S. imported food in 43 commodity codes (Commodity codes are aggregations of separate food items for statistical purposes. All fresh vegetables are included in only one commodity code, and all fresh fruits comprise another) from some 141 countries, thus making some 1,737 country-commodity code combinations. Yet, many of these combinations represent only minuscule percentages of the total amount of imported food. To fully appreciate the complexity of the problems of identifying pesticide residues on food, each country-commodity code combination would have to be further broken down into its specific products and cross-referenced with all the pesticides used world wide.

We are also concerned that GAO based this report on outdated information that does not reflect actions taken by FDA during the last several years to strengthen the program for preventing imported foods having illegal residues of pesticides from entering the U.S. Actions taken by FDA include:

1. Reprogramming resources into analytical methodology development.

2. Initiating an improved sampling program for food imported from Mexico and developing a plan to extend this approach to imported foods from other countries, also.

3. Initiating a computerized reporting system that will assure that complete and up-to-date information is being provided to headquarters and disseminated to relevant districts.

4. Initiating a reevaluation of existing action levels with EPA.

5. Establishing a Residue Task Force to analyze and improve residue-related regulatory efforts, including pesticide residues.

6. Developing and implementing a major revision of the regulatory guidelines used by our field offices for initiating action against violative pesticide residues in imported food.

Again, by not considering these actions, GAO has mischaracterized the program. There are also several recommendations for actions that the agency has already taken. Consequently, in addressing the individual recommendations, we suggest that GAO reflect changes in FDA's program.

GAO Recommendation - 1

To ensure that imported food is adequately monitored for pesticide residues, we recommend that the Secretary, Department of Health, Education, and Welfare, require the Commissioner, Food and Drug Administration to:

--obtain data about foreign pesticide usage as a basis for determining what pesticide residue analyses to perform.

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Department Comment

We agree that FDA should have data on pesticides approved for use in the production of food in foreign countries. In fact, FDA is seeking such information on a voluntary basis from countries that export food products to the U.S. Several foreign countries have supplied FDA with official listings of the pesticides that they have approved for agricultural use. Moreover, while not mentioned in the GAO report, based on the listing received from the Mexican Government, FDA field offices have been instructed to analyze imported Mexican produce for those pesticides approved for use in that country. We have reservations, however, that FDA should obtain all information along the lines suggested by GAO's definition of an "ideal" exchange of information, that is, "ideally the information exchanges should include...pesticide crop usage application rates and the types of application, (i.e. ground, aircraft, or water application)". Information about method of application, etc. is not totally relevant for enforcing tolerances. The most important question is whether the pesticide residue exceeds the established tolerance or not. Illegal residues may occur regardless of the route and frequency of administration.

It should also be recognized that there are limitations to anticipating what pesticide residues might be present in imported food commodities. For example:

1. FDA's experience has indicated that the use of pesticides in a country, including the U.S., will not always be confined to uses that are approved. FDA frequently finds pesticide residues in Mexican produce even though a particular pesticide is not approved for use on a particular food in Mexico. Therefore, FDA's coverage of imported food must also give attention to pesticide residues in food that could occur because of pesticide misuse by foreign producers.

2. Food and feed commodities may also become contaminated with a pesticide because of the movement and persistence of the pesticide in the environment. Therefore, analysis of imported food must give attention to possible residues from environmental sources.

3. FDA does not have statutory authority to require foreign countries to submit data to the Agency. To obtain data on foreign pesticide usage is, therefore, totally dependent upon the willingness of foreign countries to make the dat. available.

4. The GAO recommendation, as well as the report itself, fails to fully recognize the importance of U.S. involvement in the Codex Committee on Pesticide Residues (CCPR) and the relationship the CCPR has to the problem of pesticide residues in imported food. The CCPR is an international organization sponsored by the World Health Organization and the Food and Agriculture Organization for the purpose of developing international tolerances for pesticide residues in food

for acceptance by member countries. To obtain international harmony in this area would represent a major step toward resolving existing differences in pesticide usage by foreign countries. It would also provide a more meaningful basis for determining what pesticide residues should be included in FDA's analysis of imported food.

Therefore, for the long term, we believe that the time and resources required to implement the GAO recommendation would be more appropriately spent in conjunction with the work of the CCPR. FDA, EPA, and the United States Department of Agriculture have been and will continue to do precisely this.

GAO Recommendation - 2

--require importers to provide certificates which indentify pesticides that have been used on imported food and certify that residues comply with U.S. tolerances.

Department Comment

We do not concur. The report contains no analysis to show that importer certification would achieve the intended result, nor that the importers could or would take the responsibility for identifying pesticides that have been used on food they import and certifying that residues comply with U.S. tolerances. The Department has considered the feasibility of imposing importer certification as a condition for permitting the entry of foreign food and has determined that it would not improve the regulation of imported foods. FDA does, however, have a policy of requesting that a foreign government or another responsible party certify shipments of produce under certain circumstances. Whenever FDA finds repeated shipments of an imported food that contain illegal pesticide residues, the points of entry are closed to that specific commodity and/or shipper. It is FDA's policy in such cases to deny entry unless the government of the exporting country certifies that the commodity complies with U.S. tolerances or the shipment is accompanied by a certificate of analysis by a reputable analytical laboratory. FDA then monitors and audits such certificates to ensure their validity.

GAO Recommendation - 3

--determine the source and identity of all unknown residues detected in imported foods.

Department Comment

We do not concur. Analytical technology has advanced to the point that minute quantities of compounds, hitherto undetected, are being revealed as "unidentified responses" on the analytical equipment. These unidentified compounds may pose no risk to the consumer; and, in fact, are often intrinsic components of the food or natural constituents derived from soil or water during growth. Therefore, not all "unknown residues" are pesticide residues. While it would be desirable, given unlimited resources,

to determine the exact composition of all food and to pursue the identity of all "unidentified responses", this course of action is not possible with the resources available to FDA, nor is it likely to become practical in the foreseeable future. To positively identify even one such analytical response can require many months of effort and tie up analytical resources that could be more profitably used otherwise.

We recognize the need for caution in dismissing "unidentified responses" as posing no risk to the consumer, however, and FDA is developing criteria to assist analysts in determining when the "unidentified responses" should be pursued. The criteria will apply equally to domestic and imported foods. While this approach will not result in identification of all unknown responses, we believe that it will permit the agency to provide a significant degree of consumer protection within present and projected resource constraints.

GAO Recommendation - 4

--commit resources necessary to develop analytical methodologies which detect most pesticide residues likely to be present in imported food.

Department Comment

We concur. The agency has reevaluated this program over the past several years and has assigned additional personnel to the task of developing analytical methodologies for detecting chemical residues likely to occur in food. We also sought additional positions.

In addition to requesting resources for the task of developing analytical methods, present resources will be used more effectively. FDA is working to develop multiresidue methods that can be used for simultaneously detecting residues of many different pesticides. As GAO pointed out, six of these methods are already in use. Other methods are being developed on a priority basis.

The complexity and scientific limitations involved in developing additional multiresidue analytical methods should be recognized, however. Many pesticides do not lend themselves to detection by the multiresidue technology of today, and still must be detected using a single residue analytical method. Multiresidue analytical methods have already been developed for about half the pesticides that are used in the U.S. and other countries. Further major advances in analytical technology must occur before most of the remaining pesticides can be included in multiresidue methods.

It should also be noted that development of new methodology is a continuous process; and, as new knowledge of the toxicity of pesticides is developed, so will the need for new and better analytical methods.

GAO Recommendation - 5

--revise the residue sampling program to ensure that all significant imported food commodities are sampled each year for pesticide residues.

Department Comment

As discussed in the General Comments above, FDA has taken specific actions to improve the sampling program for imported foods subsequent to the conclusion of the investigative phase of GAO's study. The agency has restructured the program for Mexican produce to provide more specific instructions and information about factors such as volume of the commodity imported nationwide, records of previous pesticide residue problems, the likelihood of a residue remaining, given the chemical and physical properties of the pesticide, and other relevant information. These procedures were initiated on October 1, 1978 on a pilot basis for Mexican imports, which comprise the majority of all fresh produce entering the U.S. If this program approach proves successful, it will be expanded to include other commodities from other countries.

GAO Recommendation - 6

We recommend that the Administrator, EPA, together with the Secretary of HEW, through the Commissioner, FDA:

--Determine whether existing and proposed action levels are safe and appropriate.

Department Comment

FDA and EPA have taken steps that will assure that existing action levels are safe and appropriate. A joint effort by FDA and EPA to reevaluate existing action levels was initiated in September, 1978. Initial attention is being focused upon those action levels for pesticides that have been cancelled by EPA. This program is being conducted in conjunction with EPA's plan to revoke existing tolerances for previously cancelled pesticides. Steps to reduce or rescind present action levels will be taken as appropriate.

Action levels are established after a determination is made about the safety of a residue and about analytical capabilities for detecting the residues. We believe this approach is consistent with the agency mandate to protect the public, therefore, no change in policy is anticipated. The validity of action levels will be reassessed periodically as better detection methodology is developed and as more information about pesticides becomes available.

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GAO Recommendation - 7

--In the future establish action levels for residues of suspended and cancelled pesticides that may be unavoidably present in food, only after determining such residues are safe.

Department Comment

Although we cannot disagree with this recommendation, some clarification of GAO's discussion about action levels is needed to give FDA's position the proper perspective. FDA has established action levels for pesticides on the basis of safety, unavoidability, and information available at the time the action levels were established. GAO has offered no evidence to the contrary. They have gone to some lengths to show that action levels for leptophos, Monitor, and Azodrin are unwarranted, and we agree. FDA has not established action levels for leptophos, Monitor, and Azodrin. The agency's policy is: that residues of these chemicals found in imported food are the result of purposeful use; there is no tolerance and therefore, such residues are violative. Any amount of a residue that is detectable, measurable, and confirmable would be considered actionable.

Although the present action level for endrin was established with due consideration of safety based upon knowledge available at the time, FDA has some questions about the validity of the action level, given information presently available. The endrin action level will be reviewed as a part of the effort EPA and FDA initiated in September, 1978.

Note should be made of the advances made in scientific knowledge during the last decade. Decisions that were made on the best available information a decade ago may be invalid based upon the more complete information available today. It is for this reason that FDA, together with EPA, will be reevaluating the appropriateness of action levels and tolerances that have already been established. We anticipate that periodic reevaluation of pesticide action levels and tolerances will be a continuing need so long as scientific advances reveal new information that calls into question decisions made in good faith and on the best available information at earlier times.

GAO Recommendation - 8

--Investigate pesticide use conditions in foreign countries when significant residues of a pesticide are detected in an import to ensure that action levels are, in fact, lower than residue levels which may result from the direct, purposeful application of pesticides to food.

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Department Comment

We do not concur. FDA does not have the authority to investigate pesticide use conditions in foreign countries, and the absence of such investigations is not sufficient cause to justify this recommended course of action. Rather, the justification must be based on evidence that residues lower than action levels are occurring as a result of direct purposeful application of pesticides. If there is such evidence, the final report should include it so that it may be properly evaluated. Absent such evidence, the agency should not commit resources to investigate wholly speculative situations.

GAO Recommendation - 9

We recommend that the Secretary, HEW, through the Commissioner of FDA:

--Provide for the timely completion and reporting of laboratory analyses so that actions can be taken to prevent the marketing of adulterated food, particularly food suspected of being adulterated.

Department Comment

FDA has always tried to assure that the laboratory analyses for food suspected of being adulterated are completed in a timely manner and that the food is not released for distribution until the analysis is done. In some instances, however, the analyses for pesticides (or for other contaminants) may be delayed because of unusually heavy demands on the agency's analytical capabilities. We do not believe this is a serious problem because imported foods suspected of being contaminated, whether with pesticides or other chemicals, are held pending completion of analysis.

FDA has also implemented a computerized system for reporting the results of pesticide analyses which assures that the reports are received and made available to the districts. The system is being fully utilized with regard to produce from Mexico and has the capability of further expansion. We believe these improvements have significantly reduced the average amount of time taken to complete analyses and are providing up-to-date information to the districts to assist them with their regulatory activities.

GAO Recommendation - 10

--Provide inspectors with results of all violative laboratory analyses so that importers and products found repeatedly violative are identified and prevented from entering the U.S. market before analyses are completed.

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Department Comment

In April, 1977, FDA initiated a procedure to ensure that each district is provided a current list of products that have been found violative. The listing includes the commodity, the shipper, and the importer as well as the identified cause of the violation. FDA's procedures now assure that all violative shipments are shown on the listing, including those that have been found violative after they were admitted into commerce prior to completion of the analysis - a practice followed only if the commodity is fresh produce, fish, or shellfish and there is no reason to suspect that the commodity is violative.

When a sample from a shipment that was admitted prior to completion of the analysis is found to contain illegal residues, the importer is issued a notice of detention. FDA then compiles the notices of detention as described above and issues the compilation to the district offices, on a weekly and monthly basis.

Shipments of perishable food for which there is reason to suspect contamination and all non-perishables are not admitted for distribution until sample analyses are completed. When the shipment is violative, these importers are also issued notices of detention, which are included on the detention list described above.

GAO Recommendation - 11

--Take appropriate actions to deny entry of suspected violative shipments into the U.S. commerce before check analyses are completed.

Department Comment

We do. As the statute requires (21 U.S.C. 801 (a)), it has been FDA's policy and long standing practice to hold suspect shipments at the point of entry until the laboratory analysis is complete. If illegal residues are detected, the shipment is denied entry. The additional time taken for check analysis has no bearing upon this procedure because the shipment is not released until the check analysis is completed. The check analysis is done for the purpose of verifying violations.

GAO Recommendation - 12

--Reinstitute the sampling of all imported fish regardless of length.

Department Comment

FDA has always taken samples of fish for chemical contaminant analyses without regard to size. Mercury, an industrial pollution chemical and not a pesticide, has contaminated much of the fishing grounds in the Great Lakes region as well as other parts of the world. This was a problem of concern to both the United States and Canada. The Food and Drug Administration worked closely with Canada to monitor mercury levels in all fish.

In 1970, FDA established an action level for mercury in fish at 0.5 parts per million (ppm). Although, the action level applied to all fish, and there was a sampling program for imported fish as well as domestic, the practice of screening imported fish for mercury on the basis of size applied to only one variety of fish, white bass, in only one FDA district, Detroit. This practice was the outgrowth of the Great Lakes Environmental Contaminants Study, which was done jointly by the Michigan Department of Agriculture, the Michigan Department of Public Health, the Michigan Department of Natural Resources, the U.S. Department of Interior, and the U.S. Food and Drug Administration. The study showed that there is a correlation between the size of the white bass and the degree of mercury contamination. This finding was confirmed by the Canadian Government, which initiated the practice of analyzing samples of white bass caught in the Great Lakes that were intended for export to the U.S. Due to the correlation between fish size and contamination, the Canadian Government adopted the practice of prohibiting export to the U.S.of white bass over a specified length.

As the levels of mercury contamination decreased, the Canadian Government increased the size of the white bass allowed to be shipped to the U.S. After consultation with FDA headquarters, the Detriot district made the decision to accept the sample analyses done by Canada. (Effectively the Canadian Government certified that the fish offered for import into the U.S. did not have mercury residues that exceeded the 0.5 ppm action level established by FDA.) No white bass over the specified length were offered for import during that time.

Subsequently, in 1978 the agency received additional data on the consumption of fish in the U.S. which led us to conclude that the probability of systematic exposure to substantial intake of methylmercury by the average consumer may be lower than FDA had originally estimated when it set the 0.5 ppm action level. The new data made it possible to estimate probable methylmercury intakes based on mercury levels in individual species of fish and other aquatic animals. It was considered that a 1.0 ppm regulatory level for mercury residues in fish would provide adequate protection to consumers. This action level has been judicially approved. Anderson Seafoods, Inc. at al v. Joseph Califano, Jr., Secretary of DHEW, et al, 447 F. Supp. 1151 (N.D. Fla. 1978).

Therefore, the agency adopted the 1.0 ppm action level for regulatory purposes. It was no longer necessary to detain the larger white fish because most mercury residues were lower than the action level. The Canadian Government has stopped testing the white bass before allowing them to be exported, and the Detroit district has resumed sampling white bass.

We believe the approach adopted by the Detroit district and the Canadian Government was based upon sound scientific evidence and was an appropriate utilization of limited FDA resources, particularly in light of the heavy

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demands being made upon that district for analyses of food and feed implicated in the Michigan polybrominated biphenyls contamination incident.

GAO Recommendation - 13

--Consider including provisions for penalties--such as automatic forfeiture of security bonds--in importer agreements to penalize importers of violative food which has already been marketed.

Department Comment

We will give further consideration to including provisions for penalties in importer agreements. We believe, however, that there are other courses of action open to the Food and Drug Administration that will be more effective in obtaining compliance with pesticide tolerances and action levels. For example, if repeated violations by one shipper, in one commodity, or from one locale are detected, FDA issues instructions to detain all similar products offered for import until the exporting government certifies that the product meets U.S. standards or a reputable independent laboratory has analyzed the shipment and certified that it meets U.S. standards. This action can be taken against a shipper (prohibiting all products shipped by that firm); against a specific commodity (prohibiting all shipments of that specific commodity), or against a country (prohibiting entry of all products from that country) until the problems have been resolved. We believe this approach appropriately addresses the party responsible for the over-tolerance residues rather than the importer, who has no control over the use of pesticides on foreign produce.

DEPARTMENT OF STATE

Washington, D C. 20520

March 8, 1979

Mr. J. K. Fasick
Director
International Division
U. S. General Accounting Office
Washington, D. C.

Dear Mr. Fasick:

I am replying to your letter of January 16, 1979, which forwarded copies of the draft report: "Need for Better Regulation of Pesticide Exports and Pesticide Residues in Imported Food."

The enclosed comments on this report were prepared by the Assistant Secretary for the Bureau of Oceans and International Environmental and Scientific Affairs.

We appreciate having had the opportunity to review and comment on the draft report. If I may be of further assistance, I trust you will let me know.

Sincerely,

Roger B. Feldman

Roger B. Feldman
Deputy Assistant Secretary
for Budget and Finance

Enclosure:
As stated

GAO DRAFT REPORT: NEED FOR BETTER REGULATION OF PESTICIDE EXPORTS AND PESTICIDE RESIDUES IN IMPORTED FOOD

The Department appreciates the opportunity to comment on the Draft Report, and is pleased to offer comments pertinent to Chapter 6, entitled "Need to Notify Foreign Nations of US Pesticide Actions". We apologize for the delay in our response.

Over the past several months, the Department has met with representatives of the Environmental Protection Agency (EPA) in order to develop a suitable mechanism for the notification of foreign governments specified under Section 17(b) of the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), as amended on September 30, 1978 (P.L. 95-396). In this regard, we notified Congressman Rosenthal of our efforts on January 3, of this year.

Briefly, we are in the process of completing an agreement with EPA, in which the following elements are under consideration: (1) Preparation by EPA of a one-page synopsis, in layman's language, of the FIFRA action, 2) transmittal by EPA to the Department, of sufficient quantities of Federal Register (FR) notices to be distributed in duplicate to our posts and missions, 3) preparation by the Department of Spanish and French translations of the one-page synopses, 4) instructions by the Department to post and mission personnel, to deliver the synopses and FR notice to appropriate host government officials, and to report the name of the individual and the date of the transaction, and finally 5) a report by the Department to EPA of the actions taken under item 4.

Since we sent our letter to Congressman Rosenthal, we have had additional discussions with EPA. We wanted to ascertain whether the procedures we had developed for Section 17(b) of FIFRA, would also be applicable to Section 17(a), involving the notification of the exports of pesticides not registered under Section 3, or sold under Section 6(a)(1) of FIFRA. We believe they are, and are working with EPA to develop internal administrative procedures for the expansion of the FIFRA notification process.

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We believe that such procedures would directly answer those questions raised in your draft report pertaining to the notification of foreign governments. These should, in our opinion, satisfy both the letter and intent of Sections 17(a) & (b) FIFRA.

Thomas R. Pickering
Assistant Secretary
Bureau of Oceans and International
Environmental and Scientific Affairs

U.S. PESTICIDE EXPORTS CALANDAR YEAR 1976

SIC-based export product code	Commodity	Net quantity (pounds)	Value (dollars)
286940 10	Fungicides	10,605,427	14,543,238
286940 20	Herbicides--2, 4-D, and 2, 4, 5-T, including salts and esters thereof as parent acid	10,732,596	8,842,727
286940 30	Herbicides, NEC	51,899,687	72,948,384
286940 40	Dichlorodiphenyl - trichloroethane (DDT)	13,569,546	5,057,190
286940 45	Parathion and methyl parathion	4,966,164	5,216,093
286940 55	Organic phosphate insecticides, NEC	42,062,539	60,126,550
286940 65	Aldrin-Toxaphene group of insecticides	21,271,615	16,140,643
286940 97	Insecticides NEC, disinfectants, deodorants, fumigants, germicides, and agricultural chemicals NEC	95,713,561	90,511,228
28793A 10	DDT preparations--primarily for agricultural use	11,863,317	5,737,951
28793A 20	Chlorinated Hydrocarbon pesticidal preparations --primarily for agricultural use, not containing DDT, excluding aerosols	18,784,240	12,242,363

SIC-based export product code	Commodity	Net quantity (pounds)	Value (dollars)
28793A 30	Organic phosphate containing preparations--primarily for agricultural use, excluding fly sprays and aerosols	21,667,313	27,813,445
28793A 40	Other insecticidal and fungicidal preparations --primarily for agricultural use	74,248,100	90,305,823
28793A 50	Herbicidal preparations	133,787,918	163,650,405
287940 00	Insecticides, repellants, fumigants, and rodenticides household and industrial	20,060,876	17,514,182
28793A 60	Agricultural chemical preparations NEC* including plant growth, plant growth regulation, similar type growth	21,517,025	23,597,942

* Not elsewhere classified

Source: U.S. Exports; Domestic Merchandise SIC-Based Products by World Areas; FT 610 Annual 1976; issued January 1978; U.S. Department of Commerce: Bureau of the Census.

U.S. PESTICIDE EXPORTS BY DESTINATION - 1976

Area	Quantity	
Western Hemishpere		
Canada	116,986,798	
20 Latin American Republics	154,627,138	
Other Western Hemishpere	6,193,947	
Subtotal		277,807,883
Western Europe	133,379,347	
Communist Areas in Europe	10,102,236	
Asia	99,092,086	
Australia and Oceania	13,129,565	
Africa	30,238,807	
Subtotal		274,942,041
Total		552,749,924

Source: U.S. Exports; Domestic Merchandis SIC-Based Products by World Areas; FT 610 Annual 1976; issued January 1978; U.S. Department of Commerce: Bureau of the Census.

APPENDIX VI

PESTICIDES ALLOWED/RECOMMENDED/USED IN FOREIGN COUNTRIES THAT ARE NOT DETECTED BY FDA'S TWO MOST USED MULTIRESIDUE TESTS

Having U.S. Tolerance	Without U.S. Tolerance [a]	Identity Unknown
aminotriazole	agallol [b]	AZ
asulam (asulox)	alachlor	benozan
azinphos ethyl (gusathion)	alfacron [b]	bromopropilato
carbaryl [h]	ametryne (gesapax)	caloxin
carboxin	antracol (propineb)	carbendazin
copper compounds (exempt)	arseniato de plomo	cetrol
dimecron (phosphamidon)	banvel (dicamba)	chlorfenvinphos
dipterex (trichlorophon) [e]	baythion (phoxim, valexon) [b]	cianazina
dithane (maneb) [f]	bayrusil (quinalphos, fluchloralin)	citrolina
dowpon (dalapon)	benlate (benomyl) [d]	clorahep
endosulfan (thiodan)	bidrin	corogard
ethylene dibromide [f]	bifenox	cortison (coleroga)
folimat	cylan (phosfolan) [b]	crisquat
furadan	cytrolane [b]	cylane
gardona [f]	daconate (MSMA)	dinatranina
isopropalin	dazomet [b]	dinorsol
metiram (polyram-combi)	dichloropropane [b]	Easton Mono M
methyl bromide	dicofol	fastoxin
nemagon (DBCP, fumazon) [f]	diquat	fencapton
	DSMA	ferban
	elocron (dioxacarb) [b]	fingicafe
		formotion
		fungite
		fungitex B-100
		gesator
		khizoctal

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[a] Without U.S. tolerance on one or more of the following imported crops: sugar, bananas, olives, coffee tomatoes, strawberries, tea, cacoa, tapioca, and peppers.

[b] Pesticide has no U.S. tolerances.

Suspected toxic effects include:

[c] birth defects, reduced fertility, and respiratory effects.

[d] mutations and birth defects.

[e] cancer, birth defects, mutations, and bone marrow effects.

[f] cancer.

[g] blood effects.

[h] cancer and birth defects.

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Having U.S. Tolerance	Without U.S. Tolerance	Identity Unknown
norea (herban)	fensulfothion (terracur)	luxan
pebulato	fluometuron (cotorran)	methyl isocyanate
phostoxin	fluorodifen	metilsotiocianato
propargite	glyphosate (roundup)	metomilo
randox (allidochlor)	herbicide 273 (endothal)	MV-4
sencor (metribuzan)	karmex (diuron)	nemafen
thiabendazole (mertic)	lannate (methomyl)	oxidemeton methyl
thiram (vancide) h/	malathion	oxidorm
topsin	metasystox	penoxin
	metox (chlorbenside)	pentanchloro
	monuron (telvar)	plazinon
	morestan	pormasol
	napropamida (devrinol)	profos
	nemacur	quick amine
	nickel chloride b/	sulfamine
	nuvan (DDVP, dichlorvos) g/	terrazan
	parahep (parathion and heptachlor) f/	tiram
	paraquat (gramoxone) c/	tordoxi
	PCNB h/	turcide
	PCP b/	UF-63
	sicarol (pyracarbolid) b/	
	streptomycin	
	sumitol (secbumeton)	
	systox (demeton)	
	TCA	
	temik (aldicarb)	
	thanite	
	thiometon	
	tordon (picloram)	
	trifluralin b/	
	urbacide (monget, tuzet) b/	
	velpar b/	
	weedone (formula 40; 2,4,D)	
	weedone (2,4,5-T) f/	
	zineb h/	

GAO REPORTS DEALING WITH PESTICIDES, ENVIRONMENTAL CONTAMINANTS, AND ANIMAL DRUGS

PESTICIDES

1. "Problems in Preventing the Marketing of Raw Meat and Poultry Containing Potentially Harmful Residues" (report to the Congress, HRD-79-10, Apr. 10, 1979).

2. "Need for EPA to Improve Foreign Nation Notifications" (report to the Administrator, EPA, Apr. 20, 1978).

3. "Adequacy of Safety and Efficacy Data Provided to EPA by Nongovernmental Laboratories" (report to the the Administrator, EPA, Jan. 26, 1978).

4. "Special Pesticide Registration by the Environmental Protection Agency Should be Improved" (report to the Congress, CED-78-9, Jan. 9, 1978).

5. "Federal Pesticide Registration Program: Is it Protecting the Public and the Environment Adequately from Pesticide Hazards?" (report to the Congress, RED-76-42, Dec. 4, 1975).

6. "Questions on the Safety of the Pesticide Maleic Hydrazide Used on Potatoes and Other Crops Have Not Been Answered" (report to Congresswoman Julia B. Hansen, B-133192, Oct. 23, 1974).

7. "Pesticides: Actions Needed to Protect the Consumer from Defective Products" (report to the Congress, B-133192, May 23, 1974).

8. "Environmental Protection Agency Efforts to Remove Hazardous Pesticides from the Channels of Trade" (report to the Congress, B-133192, Apr. 26, 1973).

ENVIRONMENTAL CONTAMINANTS

1. "Federal Efforts to Protect Consumers from Polybrominated Biphenyl Contaminated Food Products" (report to the Chairman, Subcommittee on Science, Technology, and Space, Senate Committee on Commerce, Science, and Transportation, and Senator Donald W. Riegle, Jr., HRD-77-96, June 8, 1977).

2. "Sewage Sludge Disposal on Agricultural Land" (report to the Administrator, EPA, CED-77-78, May 23, 1977.)

3. "An Incident of Contamination of Livestock Feed and Certain Consumer Products" (report to the Chairman, Senate Committee on Agriculture and Forestry, B-164031(2), Dec. 1, 1972.

ANIMAL DRUGS

1. "Need to Establish Safety and Effectiveness of Anti-Biotics Used in Animal Feeds" (report to the Chairman, Subcommittee on Oversight and Investigations, House Committee on Interstate and Foreign Commerce, HRD-77-81, June 27, 1977).

2. "Use of Cancer-Causing Drugs in Food-Producing Animals May Pose Public Health Hazard: The Case of Nitrofurans" (report to the Chairman, Subcommittee on Oversight and Investigations, House Committee on Interstate and Foreign Commerce, MWD-76-85, Feb. 25, 1976).

APPENDIX VIII

Associate Commissioner for Compliance
THROUGH: Acting Director, Bureau of Foods /s/ Howard R. Roberts

Associate Director for Compliance
Bureau of Foods (HFF-300)

List of Poisonous and Deleterious Substances Action Levels

The attached list has been complied by the Bureau of Foods to be placed on file with the Hearing Clerk in conjunction with the regulation concerning poisonous or deleterious substances (Docket No. 77N-0166 which we understand will be published on September 30, 1977.

Taylor M. Quinn

Enclosure

cc: HF-1
HF-2
HFC-1
GCF-1
HFF-1
HFF-300
HFF-312
HFC-1 r/f
HFF-1 r/f
HFF-300 r/f

HMPippin:bjw:9/29/77

APPENDIX VIII

ACTION LEVELS FOR POISONOUS OR DELETERIOUS SUBSTANCES IN HUMAN FOOD AND ANIMAL FEED

The following is a list of current action levels established by the Food and Drug Administration for poisonous or deleterious substances in human food and animal feed. Action levels are established by the Commissioner of FDA to control levels of contaminants in food and feeds. An action level for a poisonous or deleterions substance may be established in accordance with criteria set forth in 21 CFR 109.4 and 509.4 and shall be revoked when a tolerance for the same substance and use becomes effective. When a new action level is established or existing action levels are revised or revoked, a notice shall be published in the FEDERAL REGISTER as soon as practicable and this list will be amended to reflect those changes.

The levels represent the limit at or above which FDA will take legal action against the product to remove it from the market. Where no established tolerance or action level exists the FDA will take legal action against the product at the minimum detectable level.

The mixing of a food containing any amount of a substance or above the action level with another lot of the same or another food is not permitted and renders the final food unlawful regardless of the level of the substance in the finished food.

It is realized that new action levels may have been established, or changes made in existing action levels, since this list was published. It is the responsibility of the user of this list to determine whether these conditions exist. The following FDA Headquarters unit will be able to assist you.

Food and Drug Administration
Guidelines and Compliance Research Branch
Bureau of Foods, (HFF-312)
200 C Street, S.W.
Washington, D.C. 20204
Telephone (202) 245-3092

Additional copies of this listing of food ~~defect~~ action levels are available from:

Food and Drug Administration
Industry Guidance Branch
Bureau of Foods (HFF-342)
200 C Street, S.W.
Washington, D.C. 20204
Telephone (202) 245-1523

APPENDIX VIII

LIST OF FDA ACTION LEVELS

SUBSTANCE	COMMODITY	ACTION LEVEL	REFERENCE[1]
Azodrin	Peppers	0.1 ppm	TWXRUEVEHQ0002
	Squash	0.1 ppm	Memo, 2-25-74
	Strawberries	0.1 ppm	from Sam D. Fine Assoc. Commissioner for Compliance

APPENDIX VIII

LIST OF FDA ACTION LEVELS

SUBSTANCE	COMMODITY	ACTION LEVEL	REFERENCE[1]
Endrin	Animal Feed, processed	0.03 ppm	7426.04 - F
	Apples	0.05 ppm	7420.09 - G
	Apricots	0.05 ppm	" " "
	Artichokes	0.05 ppm	" " "
	Asparagus	0.05 ppm	" " "
	Beans	0.05 ppm	" " "
	Beets	0.05 ppm	7420.09 - G
	Blackberries	0.05 ppm	" " "
	Blueberries	0.05 ppm	" " "
	Boysenberries	0.05 ppm	" " "
	Butter (fat basis)	0.3 ppm	7420.08 - E
	Carrots	0.05 ppm	7420.09 - G
	Cherries	0.05 ppm	" " "
	Citrus Fruit	0.05 ppm	" " "
	Collards	0.05 ppm	" " "
	Corn, fresh sweet	0.05 ppm	" " "
	Cranberries	0.05 ppm	" " "
	Currants	0.05 ppm	" " "
	Dairy Products (fat basis), manufactured, excluding low fat dairy products	0.3 ppm	7420.08 - E
	Dewberries	0.05 ppm	7420.09 - G
	Eggs	0.03 ppm	" " "
	Elderberries	0.05 ppm	" " "
	Endive	0.05 ppm	" " "
	Figs	0.05 ppm	" " "
	Fish Meal, Fish Solubles, Fish Oil (animal feed)	0.3 ppm	7426.04 - F
	Fish, raw edible portion	0.3 ppm	7420.09 - G
	Fish, smoked, frozen, canned	0.3 ppm	7420.08 - E
	Gooseberries	0.05 ppm	7420.09 - G
	Grapes	0.05 ppm	" " "
	Guavas	0.05 ppm	" " "
	Huckleberries	0.05 ppm	" " "
	Kale	0.05 ppm	" " "
	Kohlrobi	0.05 ppm	" " "
	Milk (fat basis), raw unpasteurized	0.3 ppm	" " "
	Lettuce	0.05 ppm	" " "
	Loganberries	0.05 ppm	" " "
	Mangoes	0.05 ppm	" " "
	Melons	0.05 ppm	" " "
	Mustard Greens	0.05 ppm	" " "
	Nectarines	0.05 ppm	" " "
	Oilseed Meal, peanut, soybean, cottonseed, etc. (animal feed)	0.03 ppm	7426.07 - F
	Okra	0.05 ppm	7420.09 - G
	Onions	0.05 ppm	" " "

APPENDIX VIII

LIST OF FDA ACTION LEVELS

SUBSTANCE	COMMODITY	ACTION LEVEL	REFERENCE[1]
Endrin	Peaches	0.05 ppm	7420.09 - G
	Pears	0.05 ppm	" " "
	Peas	0.05 ppm	" " "
	Pimentoes	0.05 ppm	" " "
	Pineapples	0.05 ppm	" " "
	Plums	0.05 ppm	" " "
	Pumpkins	0.05 ppm	" " "
	Quinces	0.05 ppm	" " "
	Radishes	0.05 ppm	" " "
	Raspberries	0.05 ppm	" " "
	Rutabagas	0.05 ppm	" " "
	Shellfish, raw edible portions	0.3 ppm	" " "
	Shellfish, smoked, frozen, canned	0.3 ppm	7420.08 - E
	Spinach	0.05 ppm	7420.09 - G
	Strawberries	0.05 ppm	" " "
	Sweet Potatoes	0.05 ppm	" " "
	Turnips	0.05 ppm	" " "
	Turnip Green	0.05 ppm	" " "
	Vegetable Oils & Fats, including soapstock (animal feed)	0.3 ppm	7426.04 - F

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LIST OF FDA ACTION LEVELS

SUBSTANCE	COMMODITY	ACTION LEVEL	REFERENCE
Monitor	Produces (except those for which tolerances are established)	0.1 ppm	Memo 3-21-73 John R. Wessel Memo 3-19-73 Douglas D. Carl EPA

APPENDIX VIII

LIST OF FDA ACTION LEVELS

SUBSTANCE	COMMODITY	ACTION LEVEL	REFERENCE
Phosvel	Peppers	0.1 ppm	Memo, 2-25-74 from Sam D. Fine Assoc. Commissioner for Compliance
	Green Beans	0.1 ppm	

APPENDIX IX

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

COMMUNITY AND ECONOMIC
DEVELOPMENT DIVISION

B-133192

April 20, 1978

The Honorable Douglas M. Costle
Administrator, Environmental
Protection Agency

Dear Mr. Costle:

In our ongoing review of Federal programs for regulating pesticide imports and exports, we examined EPA's compliance with Section 17(b) of the Federal Insecticide, Fungicide, and Rodenticide Act which 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." Appropriate notifications should be forwarded to the Department of State for transmittal to foreign nations. During the review, we noted deficiencies which we believe warrant your immediate attention.

Notification of United States suspension and cancellation actions are beneficial to both the United States and foreign nations. The latter benefit because they are alerted to some pesticides' unreasonable hazards and often follow the U.S. lead, which lessens exposure of their workers and citizens. The U.S. benefits when a nation restricts using these pesticides on U.S. food and fiber imports.

We reviewed EPA's and the Department of State's policies, practices, and pertinent legislation as well as documents, reports, and records on foreign country notifications of EPA's pesticide suspensions and cancellations. Regarding the adequacy of EPA notification actions, we also interviewed responsible officials of EPA, the Department of State, and the following countries: Costa Rica, West Germany, Guatemala, Indonesia, Mexico, New Zealand, the Philippines, Sri Lanka, Surinam, and Thailand.

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(08700)

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Since 1972, when the act was amended to require foreign nation notifications, EPA has canceled, suspended, or significantly restricted using 14 pesticides (or pesticide product ingredients). EPA and Department of State records indicate that EPA requested State to notify foreign nations about five pesticide regulatory actions taken. In each of these cases, State notified U.S. Embassies; agricultural and scientific attaches or other Embassy personnel were responsible for assuring that foreign government officials received notification. However, in talking with cognizant foreign officials, we found that few had actually received the notifications. It appears that notifications were not distributed to cognizant officials because neither EPA nor State had procedures for assuring that notifications reach their proper destination.

EPA did not request State to notify foreign nations about the following nine pesticides because it believed it was not necessary.

Pesticide	Year of EPA regulatory action
quaternary ammonium compounds	1973
chlordane	1976
heptachlor	1976
kepone	1976
OMPA	1976
strobane	1976
aramite	1977
chloranil	1977
safrole	1977

EPA's criteria for reporting suspension and cancellation actions limit foreign government notifications to those actions "* * * determined to have national or international significance." EPA officials said that only EPA initiated cancellations and suspensions of basic pesticide active ingredients registered for use in several products are considered actions of national or international significance; actions on individual pesticide products are not. EPA officials stated that EPA decided notification on the substances listed above were not required either because registrants initiated the cancellations or because all product uses were not canceled.

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However, we believe these actions have both national and international implications, and notifications should have been made. For example, registrations of chlordane and heptachlor were suspended, and strobane was canceled for most uses because of their suspected potential for causing tumors in animals. Chlordane and heptachlor were two of the most widely used pesticides in the world. The strobane action canceled 34 product registrations.

EPA, or its predecessor, had also canceled six other pesticides prior to the act's 1972 amendment. The pesticides were bithionol, endrin, lindane, polychlorinated biphenyls, polychlorinated terphenyls, and thallium sulfate. Although the admendment did not require notification of these cancellations, such information is of great interest to nations which do not have resources to extensively evaluate pesticides before use.

In talking with cognizant foreign officials, we found their countries have received very little, if any, information through official channels regarding the U.S. regulatory status of pesticides. Those countries that had information obtained it largely through personal contacts in the United States and from industry publications. Most wanted to receive regular and timely EPA data. Representatives from less developed nations were particularly anxious to receive such timely data because they did not have funds or qualified people to perform hazard evaluations equivalent to EPA's; therefore, they rely heavily on U.S. registration as a guide for allowing use in their country. These officials were particularly interested in the EPA booklet "Suspended and Cancelled Pesticides," which summarizes EPA actions on pesticide suspensions, cancellations, and other restrictions. During the review, several copies were distributed to interested foreign officials. This type of information is sufficient to alert countries using affected pesticides to initiate actions or request additional data as a basis for making their own risk-benefit analyses concerning continued use.

Based on the foregoing, EPA and State could improve their joint implementation of the pesticide law's notification provision. Therefore, we recommend that EPA:

--Review all pesticide suspensions and cancellations--both Agency- and registrant-initiated--to identify those of "national and international" significance.

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--Compile information on these actions in a concise publication for distribution to appropriate foreign nations.

--Develop an appropriate system with State for timely and efficient dissemination of this and similar data to foreign officials.

Regarding the last recommendation, it may be most effectively implemented if EPA can provide direct notifications to appropriate foreign officials.

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As you know, section 236 of the Legislative Reorganization Act of 1970 requires the head of a Federal agency to submit a written statement on actions taken on our recommendations to the Senate Committee on Governmental Affairs and the House Committee on Government Operations not later than 60 days after the date of the report and to the House and Senate Committees on Appropriations with the agency's first request for appropriations made more than 60 days after the date of the report.

Copies of this report are being sent to the Department of State; the Director, Office of Management and Budget; and cognizant House and Senate committees.

Our overall review of pesticide imports and exports is continuing. We appreciate the courtesies and cooperation extended to our representatives, and we will continue to keep you informed of our progress.

Sincerely yours,

Henry Eschwege

Henry Eschwege
Director

(08700)

*U.S. GOVERNMENT PRINTING OFFICE: 1979 620-167/215 1-3