United States General Accounting Office

GAO

Report to the Chairman, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

September 1992

PESTICIDES

Adulterated Imported Foods Are Reaching U.S. Grocery Shelves

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GAO

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Resources, Community, and
Economic Development Division

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September 24, 1992

The Honorable John D. Dingell
Chairman, Subcommittee on Oversight
and Investigations
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

This report responds to your request for information on the progress of the Food and Drug Administration's (FDA) pesticide monitoring program in preventing imported foods adulterated with illegal pesticide residues from reaching U.S. grocery shelves. The report contains matters for consideration by the Congress and recommendations aimed at deterring importers from distributing such foods and making more effective use of FDA's resources in detecting pesticide violations.

As arranged with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this letter. At that time, we will send copies to the Administrator, Environmental Protection Agency; the Secretary of Commerce; and the Secretary of Health and Human Services. We will make copies available to others on request.

The report was prepared under the direction of Richard L. Hembra, Director, Environmental Protection Issues, who can be reached at (202) 275-6111 if you or your staff have any questions. Major contributors to the report are listed in appendix I.

Sincerely yours,

J. Dexter Peach
Assistant Comptroller General

Executive Summary

Purpose

Food imports have tripled in the past 15 years; almost half of the fruits and vegetables consumed in the United States during the winter are now imported. Consumers rely on the Food and Drug Administration (FDA) to test imported and domestic crops to ensure that they are free of prohibited pesticides. The Chairman, Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, requested that GAO evaluate whether (1) federal deterrents are adequate to prevent adulterated foods from reaching U.S. grocery shelves and (2) FDA is using its resources to maximize the detection of unsafe foods.

Background

Pesticides—toxic chemicals that kill or control insects, weeds, fungi, and other pests—are extensively used in food production worldwide. There is evidence that some pesticides cause cancer, birth defects, and other health problems. To ensure that U.S. consumers are not exposed to unsafe pesticides, the Environmental Protection Agency (EPA) restricts the amounts and types of pesticide residues that may be present in food. FDA tests foods for pesticide residues and samples about 1 percent of the 1.2 million food shipments—mainly fruits and vegetables—valued at about $16 billion that enter the United States each year. The U.S. Customs Service, which controls the points where food shipments enter the United States, ensures that adulterated foods are either exported from the United States or destroyed. Importers are required to hold shipments that are being sampled pending test results and must return pesticide-adulterated shipments to Customs. If an importer distributes an adulterated shipment, FDA can criminally prosecute the importer and Customs may assess damages.

Results in Brief

About 4 percent of the imported food shipments FDA tested during 1988-90 contained prohibited pesticides. Although FDA instructed importers to return these adulterated shipments to Customs for supervised export or destruction, about a third of the shipments were not returned in the four FDA districts GAO reviewed. Customs and FDA records show a long-term problem of importers distributing these foods. Importers may distribute adulterated foods because the consequences for doing so are inadequate to deter such actions. FDA rarely prosecutes such cases because of the practical difficulties of pursuing criminal prosecution. Furthermore, the damages that Customs may require importers to pay are low enough so that the importers can still profit from distributing the adulterated foods.

FDA could make two improvements in its monitoring program in order to detect more adulterated shipments with the same resources. When sampling a food shipment, FDA could prevent companion shipments—that is, shipments of the same crop from the same grower arriving at about the same time—from reaching consumers until FDA determines whether the sampled shipment is adulterated. If the sampled shipment is found to be adulterated, these companion shipments may be similarly adulterated, but FDA has no way of recovering them. In addition, FDA could grant its district offices more authority to impose "automatic detention" status on foods from a grower who has violated pesticide restrictions. Under automatic detention status, the importer must prove that subsequent shipments are free of prohibited pesticide residues before they are admitted into the United States. Currently, district offices must await headquarters' approval to impose this status. Meanwhile, FDA procedures require the district offices to continue sampling all of the shipments from the same source, tying up resources that could be used for sampling other imported food.

Principal Findings

Deterrents Against Improper Distributions Are Not Effective

Existing FDA and Customs deterrents have not ensured that importers export or destroy food shipments that contain prohibited pesticides. At four FDA districts during 1988-90, about one-third of the imported food shipments that FDA found to be adulterated with illegal pesticide residues were not returned to Customs for supervised destruction or export. GAO reported on similar conditions in 1979 and again in 1986.[1] Taken together, this information shows a long-term trend of importers' disregarding U.S. laws prohibiting the distribution of adulterated foods.

While most importers comply with FDA's instructions, a few repeatedly fail to do so. Some importers choose to pay the relatively low damages assessed by Customs rather than destroying or exporting the food. In GAO's sample of 989 pesticide-adulterated shipments, over 64 percent of the 336 shipments that were illegally distributed came from 10 importers.

Although FDA could criminally prosecute such offenders, these cases have low priority for Department of Justice prosecution. In addition, Customs damages are based on bond amounts that are set for purposes other than

[1]Better Regulation of Pesticide Exports and Pesticide Residues in Imported Food Is Essential (CED-79-43, June 22, 1979) and Pesticides: Better Sampling and Enforcement Needed on Imported Food (GAO-RCED-86-219, Sept. 26, 1986).

enforcement of pesticide regulations. The Congress could provide a more effective means of stopping the distribution of pesticide-adulterated food if it gave FDA the authority to impose on importers penalties commensurate with the potential danger posed to public health and sizable enough to effectively deter violations.

Another means of controlling improper distribution is to take physical possession of food shipments—until they have been tested—from the relatively few importers who repeatedly disregard FDA's requirements and distribute pesticide-adulterated foods. The U.S. Department of Agriculture (USDA), for example, which controls the distribution of imported meat, stores each sampled meat shipment at a repeat offender's expense until test results are known. FDA could use Customs' public bonded warehouses, requiring the importers to pay the storage costs, for this purpose.

FDA Could Detect More Violations With the Same Resources

While FDA has limited resources to test for pesticides, GAO found opportunities for FDA to use these resources more effectively. When a shipment is adulterated, the chances increase that companion shipments of the same food from the same grower will also be adulterated. However, FDA does not track a grower's companion shipments. For example, if 12 truckloads of a grower's strawberries cross the border in a week, FDA might sample 1 truckload and release the other 11. If the sampled shipment is found to be adulterated, FDA will order it exported or destroyed but will seldom try to stop the remaining 11 truckloads from reaching consumers.

When a food and a grower are placed on automatic detention status, the importer—not FDA—must provide a laboratory certification that each new shipment of imported food is not adulterated. The independent analysis must show that any subsequent imports comply with pesticide residue tolerances set by EPA. However, automatic detention is often not implemented until as long as a month after a violation is detected. During the first 6 months of fiscal year 1992, over 80 percent of automatic detention cases required headquarters' approval, although FDA officials reported that headquarters rarely turns down a recommendation for automatic detention. These cases took an average of 27 days from sampling to the initiation of automatic detention. In the remaining cases, in which districts had the authority to implement automatic detention, the process took an average of 12 days.

Until automatic detention is implemented, the district that detected the violation must continue to test all food subsequently imported from the source of the violation. In two districts GAO visited, 30 percent of the sampling work load consisted of shipments from growers for whom the district had requested automatic detention status from headquarters. If automatic detention could be initiated more promptly, FDA could redirect limited resources to additional sampling of untested products.

Recommendations

To make more effective use of FDA's resources in detecting pesticide violations, GAO recommends that the Secretary of Health and Human Services direct the Administrator, FDA, to (1) ensure that shipments of the same food from the same grower arriving simultaneously with or soon after sampled shipments are not distributed until the sample is determined to be free of prohibited pesticides, with a reasonable deadline for the test results to be communicated to Customs and the importer, and (2) delegate to the district offices greater responsibility to initiate automatic detention.

Matters for Congressional Consideration

To effectively deter importers from distributing pesticide-adulterated food and to penalize them appropriately when they do so, the Congress may wish to consider authorizing the Secretary of Health and Human Services

- to impose on importers who illegally distribute food shipments civil administrative penalties commensurate with the potential danger posed to public health and sufficient to remove an importer's economic incentive for distributing adulterated foods and
- to order importers who have repeatedly distributed shipments before FDA releases them to pay for the storage of sampled shipments in Customs-controlled warehouses until they are released.

Agency Comments

As requested, GAO did not obtain written agency comments on this report. However, GAO discussed the facts contained in the report with responsible division heads in FDA, Customs, and USDA. They generally agreed with the information presented.

Contents

Abbreviations

CFSAN	Center for Food Safety and Applied Nutrition
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
GAO	General Accounting Office
USDA	United States Department of Agriculture

Introduction

Pesticides are extensively used in food production worldwide to destroy or control weeds, insects, fungi, and other pests. While pesticides enhance agricultural productivity, human exposure to pesticide residue levels above certain amounts can cause adverse health effects. Some pesticides have been shown to cause cancer or birth defects and may persist in the environment for long periods of time, accumulating in the tissues of plants, animals, and humans. Many pesticides used in food production remain on food and are ingested along with the food.

The United States imports increasing quantities of food from many countries around the world. Responsibility for monitoring the acceptability of crops entering the United States rests with the Food and Drug Administration (FDA). The U.S. Department of Agriculture (USDA) fulfills similar responsibilities for meat and poultry imports. Both agencies monitor imports and reject shipments of products containing unacceptable pesticide residues.

FDA sampled about 1 percent of the imported food shipments entering the United States during 1990 for pesticide residues. Much of this imported food comes from countries where the rules governing the use of pesticides are less strict than those set by the Environmental Protection Agency (EPA). Growers in these countries may treat crops with pesticides that EPA does not permit for those crops or may leave pesticide residues on their crops that exceed tolerance levels set by EPA. However, the Federal Food, Drug, and Cosmetic Act prohibits marketing such crops in the United States. FDA-regulated imported food shipments have increased from half a million in 1973 to 1.2 million in 1990. The import value of the 1990 shipments, excluding fish, was about $16 billion.

The Removal of Unsafe Imports Is a Shared Responsibility

Keeping imported food free of prohibited pesticide residues is a responsibility shared by FDA, the U.S. Customs Service, and the importer of the food shipment. FDA samples and tests shipments to identify prohibited residues. When its tests are complete, FDA must notify Customs and the food importer that the shipment is either acceptable or unacceptable. The importer is required to retain control over each shipment being tested until FDA releases it or gives notice that it is adulterated.

Sampling and testing are performed by FDA field organizations. FDA has 6 regions, 21 districts, and 18 laboratories throughout the country. Each district is responsible for sampling a certain number of food items arriving through ports in its district, selecting a sample from a small proportion of

those shipments, and sending the sample to FDA's laboratories to be tested for illegal pesticide residues.

If FDA finds pesticide adulteration in the sample, importers are expected to return the shipment from which the sample was taken to Customs, where the shipment will be either destroyed or exported under Customs supervision. To ensure that importers carry out their responsibilities, Customs requires the posting of a bond based on the import value of the goods. If an importer fails to return the adulterated food, Customs may claim damages for the importer's failure to honor the agreement.

When an FDA district office detects pesticide-adulterated food, in most cases it notifies FDA headquarters. Headquarters reviews the case and decides if all future shipments of the same food from the same grower should be put on a status called automatic detention. Under automatic detention, the importer must obtain an independent laboratory analysis for all subsequent shipments showing that the food is free of prohibited pesticides before the shipment can be admitted into the country. Automatic detention is based on the principle that shipments from the same source have an increased probability of containing unacceptable pesticide residues.

Objectives, Scope, and Methodology

We reported in 1979 and again in 1986 that numerous shipments of food that FDA identified as adulterated were nevertheless reaching U.S. consumers.[1] In an October 5, 1990, letter, the Chairman of the Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, asked us to assess the progress of FDA's pesticide monitoring program in excluding imported food adulterated with illegal pesticide residues. In this review, our objectives were to evaluate whether federal deterrents are adequate to prevent adulterated food from reaching U.S. grocery shelves and whether FDA is using its resources to maximize the detection of adulterated shipments.

To meet these objectives, we performed work at FDA and Customs Service headquarters in Washington, D.C. We also performed work at FDA and Customs field offices in California, Florida, Pennsylvania, and Texas. These locations were chosen because they account for approximately 40 percent of all FDA-regulated imported food; include all transportation

[1]Better Regulation of Pesticide Exports and Pesticide Residues in Imported Food Is Essential (CED-79-43, June 22, 1979) and Pesticides: Better Sampling and Enforcement Needed on Imported Food (GAO-RCED-86-219, Sept. 26, 1986).

modes, i.e., air, sea, and land; and provide coverage of four of FDA's six regions and four of Customs' seven regions.

To assess the two agencies' deterrents for keeping adulterated food off U.S. grocery shelves, we reviewed all the identifiable shipments that were denied entry at border and seaports in Texas and seaports and airports in Miami, Philadelphia, and San Francisco during fiscal years 1988-90. We relied primarily on two FDA systems to identify adulterated shipments: FDA's Laboratory Management System and FDA's Shipment Disposition System. To obtain the most complete data possible for each location, we supplemented FDA's data with documents from Customs' files. Records were generally sufficient at each location, except Philadelphia, to reach a conclusion about the disposition of shipments. Customs records in Philadelphia show that 125 shipments of adulterated food were approved for export, generally to Canada, but the records do not show whether the shipments were ever made. We verified 55 Customs export records in Buffalo and Champlain, New York, and confirmed the export of 43 shipments. Our review in the four locations included 989 instances in which shipments were denied entry.

At the agencies' headquarters, we interviewed FDA and the Customs officials and examined procedures, laws, and regulations governing the handling of shipments when FDA finds or suspects adulteration with pesticides. At the field offices, we interviewed FDA and Customs officials to obtain information on current practices.

To identify approaches that might make FDA's program more effective, we compared FDA's program with USDA's parallel residue monitoring program for imported meat and poultry products. We obtained program material describing how shipments of imported meat and poultry products denied entry were controlled and disposed of. We also visited one USDA import facility and observed and verified the control procedures.

We conducted our review between April 1991 and August 1992 in accordance with generally accepted government auditing standards. As agreed, we did not obtain written agency comments on a draft of this report. However, Customs, USDA, and FDA officials, including responsible division heads, reviewed and commented on the factual material in the report and generally agreed with the facts as presented. The officials' comments have been incorporated where appropriate.

Current Deterrents Do Not Keep Importers From Distributing Adulterated Imported Food

FDA's program of testing imported foods for the presence of illegal pesticides has had marked success. More foods are tested today than were tested 13 years ago, and pesticide violation rates have decreased. However, one disturbing trend continues unabated—shipments of imported food that FDA identifies as adulterated with pesticides still make their way to U.S. grocery shelves. Even though importers are required to return adulterated foods to Customs for supervised disposal, in the four FDA districts included in our review, one-third of the adulterated shipments were not returned and were presumably sold in commerce. In addition, 8 percent of the importers accounted for 64 percent of the adulterated shipments that were distributed to grocery shelves. Without maintaining tighter controls over the sampled shipments of repeat offenders, FDA is not effectively reducing the influx of adulterated food.

Although the distribution of adulterated food is subject to criminal penalties under the Federal Food, Drug, and Cosmetic Act, the strict burden of proof requirements and the low priority given to these cases by the Department of Justice have resulted in few prosecution attempts. Furthermore, according to FDA and Customs officials, the damages imposed by Customs are an ineffective deterrent to violators. A system of administrative penalties, to be assessed by FDA, could provide a means of punishment commensurate with the danger posed to public health as well as an effective deterrent to violations.

FDA's Program Has Identified Adulterated Shipments

While the number of FDA-regulated food shipments increased from half a million to 1.2 million between 1973 and 1990 (a 140-percent increase), FDA staff devoted to monitoring shipments went from 355 in 1973 to 363 in 1990 (only a 2-percent increase). This growing disparity between the volume of food imports and the size of the FDA monitoring staff has resulted in a 50-percent decrease in the percentage of shipments that FDA inspects for unsanitary conditions, such as the presence of mold or insects. At the same time, however, FDA has managed to increase its testing for pesticide residues. In 1977, FDA tested about 2,000 shipments out of just under 1 million; 7.3 percent of the imported foods tested contained illegal pesticide residues. In 1990, in testing about 10,000 shipments out of about 1.2 million, FDA found illegal pesticide residues on 4.3 percent of the foods.

Examples of adulterated foods that FDA detected at U.S. ports of entry during 1990 include

- spinach containing residues of chlorothalonil, a fungicide approved by EPA for use on other crops but not on spinach;
- snow peas containing residues of EDBCs, fungicides approved by EPA for use on other crops but not on snow peas; and
- squash containing residues of BHC and DDT, insecticides for which EPA has cancelled all use in the United States.

Pesticide-Adulterated Food Is Being Distributed

Even though FDA's pesticide testing program has had success in detecting adulterated food, shipments refused by FDA still find their way through the Customs net into U.S. markets. During fiscal years 1988-90, in the four locations we reviewed, importers did not properly dispose of 336 of the 989 imported shipments that FDA found to be adulterated with pesticides. The statistics shown in table 2.1, which are consistent with information in our 1979 and 1988 reports, show a large amount of adulterated food is reaching U.S. consumers. These reports showed the distribution of about 50 percent and 45 percent of adulterated shipments, respectively. Taken together, the information shows a long-term trend of illegal distribution of adulterated imported foods, although at a reduced rate.

Table 2.1: Distribution of Adulterated Shipments by FDA District, Fiscal Years 1988-90

Location	Number of adulterated shipments	Number distributed into U.S. markets	Percent distributed into U.S. markets
Dallas	372[a]	104	28
Miami	343	177	52
Philadelphia	192[a]	19	10
San Francisco	82	36	44
Total	**989**	**336[b]**	**34**

[a]Excluding 21 shipments in Dallas and 48 shipments in Philadelphia, for which the disposition could not be determined because of incomplete files.

[b]Included in the total are 36 shipments in which only part of the shipment was distributed.

While we could not document that the 336 adulterated shipments actually reached U.S. consumers, both Customs and FDA records confirm that importers are selling adulterated food into U.S. food distribution channels. Of the 336 adulterated shipments, we found that 62 were distributed as a result of errors by FDA or Customs. According to the records, the rest were illegally distributed without an FDA release. In 51 cases, importers claimed to have exported or destroyed the shipment but could not provide the required Customs verification of disposal.

Distribution of adulterated food shipments is possible because importers retain possession of shipments while FDA conducts pesticide residue testing. Importers take possession of shipments immediately upon their arrival, and FDA notifies the importers if it intends to sample the shipment. Unless the sampled shipment is considered perishable,[1] importers are required to hold it at the port until the results of FDA's tests are known. Perishable shipments may be shipped to their destination, but must remain under the importer's control until 5 p.m. the day after sampling, to give FDA time to conduct tests and inform importers of the results.

Despite various FDA regulations to prevent adulterated food from entering U.S. markets, importers released sampled food shipments containing illegal pesticides, regardless of whether the shipments were to be held at ports of entry (nonperishable food), be under importers' control (perishable food), or be tested before entry (under automatic detention). Table 2.2 shows that 60 percent of the perishable foods and 38 percent of the nonperishable foods in our review were not returned to Customs by the importers as required by FDA regulations. The table also shows that for 156 of the 336 improper distributions (or 46 percent), these foods were on automatic detention status, indicating that the same food imported from the same source had a history of pesticide adulteration. In these cases, distributions occurred even though the importers were required to provide FDA with private laboratory certifications showing that their imported foods were free of illegal pesticides and to obtain FDA's approval before moving the shipments.

Table 2.2: Distribution of Adulterated Shipments, Fiscal Years 1988-90

	Perishable	Nonperishable	Automatic detention	Total
Identified	57	386	546	989
Distributed	34	146	156	336
Percent distributed	60	38	29	34

FDA Lacks Sufficient Authority to Deter Illegal Distributions of Adulterated Food

FDA lacks the authority to fine importers who distribute adulterated food shipments. Currently, even when importers are caught distributing adulterated shipments, they are paying penalties below the U.S. wholesale value of their shipments. In the meantime, the importers have avoided the cost of storage, reduced the possibility of spoilage, and increased the opportunity for revenue.

[1]A shipment is considered highly perishable if it will deteriorate in 7 days or less with proper storage.

Damages Are Based on a Bond Agreement

The principal enforcement tool for deterring importers from endangering public health is a bond agreement between the importers and Customs. Under this agreement, the importer promises (1) to pay all duties, taxes, and charges; (2) retain control over the shipment until its acceptability is determined; and (3) properly dispose of the shipment if it is found to be unacceptable. To ensure compliance with this agreement, the importer posts a bond. If the importer does not comply, Customs may assess liquidated damages under the bond. The payment of liquidated damages is a simple contractual matter: a pre-agreed payment when one party, the importer, fails to perform as stated in the contract. Thus, liquidated damages are the bond or portion thereof that the importer forfeits because of failure to perform as agreed.

Liquidated damages, however, have not acted as an adequate deterrent to the distribution of adulterated shipments for two reasons. First, the damages are not high enough to prevent an importer from profiting from the sale of these shipments. Second, importers are often able to avoid, reduce, or postpone the payment of damages.

Profits From Illegal Distributions Exceed Bond Damages

Bond damages are not intended as a penalty for endangering public health. Consequently, they do not serve as economic deterrents for importers selling adulterated food. Bond amounts are based on the import value of goods, in accord with federal law implementing an international agreement, and are set at a maximum of three times this value. The import value is generally the "transaction value," that is, the price actually paid or payable for the imported merchandise to the exporter in the foreign country, plus certain additional costs. Even when tripled, this purchase price may be far less than the price importers can get from U.S. wholesalers.

We compared import value and U.S. market prices for products for which data were readily available. The analysis showed that the wholesale market value always exceeded the import value. For example, in 1990, one firm failed to export or destroy six shipments of snow peas that FDA had refused because of residues of EDBCs, fungicidal chemicals suspected of causing cancer. The shipments' import value was set at about $13,000 by the importer. Customs assessed damages of about $27,000. USDA's 1990 wholesale market data for snow peas show a local wholesale value for the six shipments of around $75,000, or about six times the import value. On September 24, 1991, Customs canceled $10,000 of the original assessed damages for "legal insufficiency," and the remaining $17,000 assessment

has yet to be resolved. However, even if Customs had collected triple damages on all six shipments, the importer would have realized a profit from the unlawful sale of adulterated produce.

The absence of an effective deterrent is demonstrated by a 1990 incident described by Customs and FDA officials in Texas. Importers were bringing in cabbages that were suspect because of previous violations. When the shipments arrived at the border, FDA inspectors told the importers that the product had to be held, but the importers shipped the cabbages anyway. The market price for the cabbages was $1.50 per head, while the cabbages were valued at only $0.15 per head. Even with triple damages, the maximum penalty that Customs could assess was only $0.45 per head.

Collection of Bond Damages Is Uneven and Uncertain

Besides the inherent problems of bond damages as a deterrent to unlawful distribution, the collection of damages is uneven and uncertain even when bond conditions are violated. First, Customs assesses no damages when shipments have an import value of less than $100 or when importers are not required to post a bond. Second, procedural errors, such as an erroneous release by Customs or FDA, can nullify the government's ability to claim the bond. Third, Customs sometimes reduces or cancels damages for first-time violators. Finally, importers can often stall the collection of damages.

As shown in table 2.3, during 1988-90 in the four districts we reviewed, Customs assessed damages for only 90 of 336, or 27 percent, of improper distribution cases. Damages were not assessed for the remaining 246 cases, or 73 percent, for a variety of reasons. Among the reasons cited were that (1) the importer had no bond (102 instances), (2) Customs had already released the bond, (27 instances), and (3) FDA had made errors, such as not communicating the test results promptly to Customs (21 instances).

Table 2.3: Bond Actions and Damages Paid, Fiscal Years 1988-90

District	Adulterated shipments distributed	Number of bond actions	Actions canceled	Actions pending	Cases in which damages were paid
Dallas	104	62	9	6	47
Miami	177	24	9	10	5
Philadelphia	19	2	0	0	2
San Francisco	36	2	0	0	2
Total	**336**	**90**	**18**	**16**	**56**[a]

[a]In one case, records were not available to indicate conclusively whether or not damages had been paid. We treated this case as if damages had been paid.

The import value of the 90 cases shown in table 2.3 for which damages were assessed totaled $383,000. In 18 of the 90 cases, damages were subsequently canceled. As of April 1992, 56 cases had been settled for a total of $44,400, and 16 cases valued at a total of about $150,000 were still pending. Thus, after 2 years, less than 12 percent of the damages has been collected, with 50 percent already written off.

When shipments have a low import value—less than $1,250—Customs may permit entry without a bond. For these "informal entries," no bond is available to be forfeited if the importer fails to comply with an FDA order to dispose of the goods. Informal entries were a problem during 1988 and 1989 in Miami, where Customs could not assess damages in 84 of 123, or 68 percent, of the unlawful distribution cases. However, Customs officials in Miami and the other locations we visited have begun requiring bonds on low-value shipments to correct this situation.

Despite requirements for bonds, low-value shipments may still slip through without the payment of damages because Customs has a policy of collecting damages only for shipments valued in excess of $100, to minimize its administrative burden. Even though a $100 import value is modest, the total quantities of imported food represented by such small shipments could be quite large. In Texas, for example, damages for 6 of 57 unlawful distributions during 1990 went uncollected because the import value of the goods was under $100. These six shipments, nevertheless, represented 4,201 pounds of chayote, 3,153 pounds of squash, and 265 pounds of peppers. We believe the policy of not collecting damages for these low-value shipments means that Customs has, in effect, removed any deterrent to distributing these adulterated shipments.

When Customs assesses liquidated damages, importers are often able to resist them with disputes, petitions, and appeals. Of the 74 cases settled, damages were canceled in 18 cases and reduced in 11, often because of untimely government action or the low value of the shipments. Assessing liquidated damages also takes considerable time to complete. For example, in Customs' Dallas office, the average time from assessment to payment exceeded 200 days. Customs officials told us that significant damages may result in petitions for relief that take years to settle. According to several Customs officials, the damages procedure works best when it can be used flexibly, with mitigation, to encourage compliance. Otherwise, importers may choose to fight each case, creating a paperwork burden for Customs.

Existing Authority Is Not Strong Enough

Although FDA regulations require importers to maintain control over sampled goods until notified by FDA or Customs, the Federal Food, Drug, and Cosmetic Act does not provide a sanction for failing to comply with this requirement. Such distribution of sampled goods before FDA has released them is not included in the list of prohibited acts under section 301 of the act. Consequently, FDA generally would need to show that the importer had violated one of the enumerated prohibited acts in addition to distributing the food prematurely.[2] For example, it is illegal under section 301(a) to distribute adulterated food in interstate commerce. FDA might take action against an importer who distributed a shipment before it was released if FDA found that a sample of that shipment was adulterated. However, proving that the distributed food was adulterated would be difficult in most cases because, unless FDA retained a reserve sample for retesting in an enforcement case, no physical evidence would be available for independent verification. If distribution of sampled goods before release were a prohibited act, proof of adulteration would not be required.

FDA is also hampered in enforcing the Federal Food, Drug, and Cosmetic Act because the act provides only for criminal, rather than civil penalties.[3] Like most federal agencies, FDA must rely on the Department of Justice to initiate lawsuits to enforce the act. According to FDA attorneys, the strict burden of proof for criminal cases—guilt beyond a reasonable doubt—and the low priority given to these cases by the Department of Justice have

[2]Under FDA's Regulatory Procedures Manual, distribution of a product before FDA has had an opportunity to sample it might be considered a refusal to permit inspection, a violation of section 301(f). Distribution before sampling generally has not been a problem, however.

[3]The Federal Food, Drug, and Cosmetic Act also authorizes injunctions and seizures of adulterated shipments. These remedies also require court actions. In addition, FDA may issue warning letters and request voluntary recalls of adulterated products.

resulted in few prosecution attempts. Authorizing FDA to enforce civil administrative penalties would make it easier to bring an action for several reasons: First, the standard of proof for a civil action—a preponderance of the evidence—is easier to meet than the standard for a criminal case. Second, administrative penalty authority would allow FDA to assess penalties directly, rather than having to persuade the Department of Justice to file a case in federal court. FDA could thus better control the enforcement of the authority it administers over imported food.

Furthermore, the penalty could be fashioned to suit the violation, taking into account its seriousness and the importer's financial gain. For example, the retail value of the goods, the risk to public health from pesticide exposure, warnings from FDA, and mitigating factors (such as the importer's efforts to ensure the product's integrity) could be considered in setting a penalty.

A Few Repeat Offenders Cause the Bulk of the Problem

FDA does not have sufficient authority to stop the few repeat offenders who are responsible for distributing the majority of adulterated food shipments. Despite the economic incentive to distribute food shipments even when they are adulterated and the lack of an adequate deterrent for violating restrictions, the majority of importers comply with import regulations. During 1990, of the 122 importers whose shipments were rejected in the locations we reviewed, 76, or 62 percent, properly disposed of each rejected shipment. A few repeat offenders, however, were responsible for the bulk of the problem of distribution of adulterated foods. Removing the opportunity for these offenders to distribute sampled shipments could be an additional way to reduce the number of prohibited distributions.

The data we reviewed suggest that importers who distribute adulterated food fall into two categories: those who violate restrictions on sampled food once or twice—perhaps by mistake—and then refrain from further violations, and those who repeatedly ignore restrictions.

As table 2.4 shows, during 1990, 73 out of 115, or 64 percent, of the improper distributions were the responsibility of 10 importers who each violated restrictions more than twice. Thirty once-only violators accounted for 26 percent of the improper shipments, while 6 two-time offenders accounted for the remaining 10 percent.

Table 2.4: Adulterated Shipments Attributable to Repeat Offenders During Fiscal Year 1990

Adulterated shipments each importer distributed	Number of importers	Total number of shipments distributed
0	76	0
1	30	30
2	6	12
3 to 5	7	25
Over 5	3	48
Total	**122**	**115**

Repeat offenders are not now required to store sampled shipments in Customs-bonded warehouses. Public bonded warehouses are commercial facilities used for the storage of imported merchandise at the importer's expense. Customs regulations give its district directors supervision and control over bonded warehouse operations within their districts. Bonded warehouses accept goods as authorized by the district director, and they are responsible for the quantity and condition of the goods. Warehouse operators post bonds with Customs to guarantee that they will account for the inventory. Goods cannot be withdrawn from bonded warehouses without direct Customs supervision or written authorization from the government.

USDA oversees the importation of meat and poultry products, with responsibilities generally parallel to FDA's for other foods. Unlike FDA, USDA must inspect and approve each imported shipment. Each shipment must be held within Customs custody until transferred to a USDA-approved facility, usually a warehouse, for inspection by USDA. When a shipment is found, by inspection or test results, to be unacceptable, USDA immediately places it into a controlled area. USDA allows access to the area only to add other goods found unacceptable or to release goods to a bonded carrier for export or destruction.

If importers who repeatedly distribute adulterated foods were required to place their shipments in controlled storage until they had been tested, FDA could effectively deter the distribution of pesticide-adulterated food by those importers. Since controlled storage is more expensive and less convenient for importers than retaining control over shipments, importers would have an economic incentive to avoid this restriction. In addition, continued violations would be unlikely once storage is controlled.

The Federal Food, Drug, and Cosmetic Act, however, does not provide FDA with an inspection and approval scheme similar to USDA's. Customs and FDA officials we interviewed could recall few instances in which Customs, at FDA's request, required the storage of sampled shipments in a bonded warehouse. In one case, for example, FDA officials in Miami requested Customs to require an importer who had a history of ignoring FDA's restrictions to bring shipments into a Customs-bonded warehouse until the government was satisfied that the shipments were acceptable. Over 2 months in 1990, the importer had distributed three shipments adulterated with pesticides. The importer had been warned formally twice and informally a number of times before the agencies required controlled storage of the importer's shipments.

According to Customs officials, while controlled storage was used in this instance, the Federal Food, Drug, and Cosmetic Act does not provide for Customs to routinely retain control of sampled shipments of FDA-regulated goods. The officials told us that Customs still takes the position stated in a July 1989 opinion.[4] In that document, Customs' Chief Counsel confirmed the agency's advice to FDA that "neither the Food, Drug, and Cosmetic Act nor Customs regulations allow Customs to detain (not release) imported merchandise that has not been released by FDA."

Conclusions

The absence of both an adequate deterrent and an effective control mechanism for shipments being sampled allows a few importers to repeatedly violate restrictions on distributing adulterated foods. In many cases, an importer can pay the maximum damages that Customs assesses for illegal distribution and still make a profit by selling the pesticide-adulterated food. Even when Customs assesses triple damages, importers can frequently profit by illegally distributing and selling the food. Furthermore, since importers who illegally distribute pesticide-adulterated foods are seldom prosecuted, they suffer no other consequences.

Although there may be opportunities for improving Customs' administration of damage actions in pesticide cases, increasing the bond amounts on which these damages are based is not practicable for several reasons. First, bond amounts are based on the import value of the goods, which is set by federal law implementing an international agreement. Second, since bond conditions include agreements to pay duties, taxes,

[4]Letter from Michael T. Schmitz, Chief Counsel, U.S. Customs Service, to the Chairman, Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, July 5, 1989.

and charges—in addition to the agreement to redeliver to Customs any shipment found to be adulterated—setting a bond amount not related to these fees would be problematic.

Furthermore, damages assessed by Customs under bonds do not reflect the potential harm that unregistered or banned pesticides may pose to human health. It is the role of FDA, not Customs, to test for and protect the public from potentially harmful pesticide residues on food. Customs' bond damage actions are not effectively helping FDA to carry out its pesticide enforcement responsibilities.

FDA could deter the illegal distribution of pesticide-adulterated imported foods by prosecuting some of these cases. However, there are practical difficulties in obtaining sufficient evidence and changing the priorities for criminal prosecution that make this course of action seem remote. The Congress could help FDA by giving it authority to bring actions for distribution of shipments without FDA's release and to levy penalties against importers who distribute pesticide-adulterated foods. This added authority could help remove the economic incentive for unlawful distribution and take into account the potential danger to the health of U.S. consumers. In addition, giving FDA authority to deny repeat offenders the opportunity to distribute shipments before FDA releases them could eliminate most of the problem.

Matters for Congressional Consideration

To effectively deter importers from distributing pesticide-adulterated foods and to penalize them appropriately when they do so, the Congress may wish to consider amending the Federal Food, Drug, and Cosmetic Act to

- add to the list of prohibited acts the distribution of sampled foods without FDA's release and
- provide the Secretary of Health and Human Services with authority to (1) impose civil administrative penalties on importers who illegally distribute food shipments commensurate with the potential danger posed to public health and in an amount sufficient to deter such distributions and remove an importer's economic incentive for distributing adulterated foods and (2) order importers who have repeatedly distributed shipments before FDA releases them to store sampled shipments in Customs-controlled warehouses until they are released.

FDA Could Enhance Detection of Pesticide-Adulterated Shipments

FDA could make more effective use of its limited sampling resources by controlling food shipments that have a higher than average probability of violating pesticide regulations because a sampled shipment from the same grower is found to be adulterated. Between the arrival of a shipment and the determination that it is adulterated, multiple additional shipments may arrive from the same grower. Although these shipments—termed companion shipments—are likely to contain the same illegal residues as those found in the sampled shipment, FDA's current procedures allow companion shipments to proceed to market without examination. These shipments escape detection because FDA waits for the test results on sampled foods before placing distribution restrictions on companion shipments.

Once imported foods are identified as adulterated with illegal pesticides, FDA districts do considerable sampling of subsequent shipments of that product from the same grower while they await authorization to impose automatic detention status from FDA headquarters. When a product and grower are placed on automatic detention, the importer—instead of FDA—is responsible for obtaining a laboratory certification that each new shipment of imported food is not adulterated. Expediting implementation by allowing FDA's districts to (1) perform the required technical reviews of the laboratory test results and (2) authorize automatic detention would allow FDA to redirect sampling resources and broaden the scope of its sampling.

Shipments From the Same Source Have an Increased Probability of Pesticide Contamination

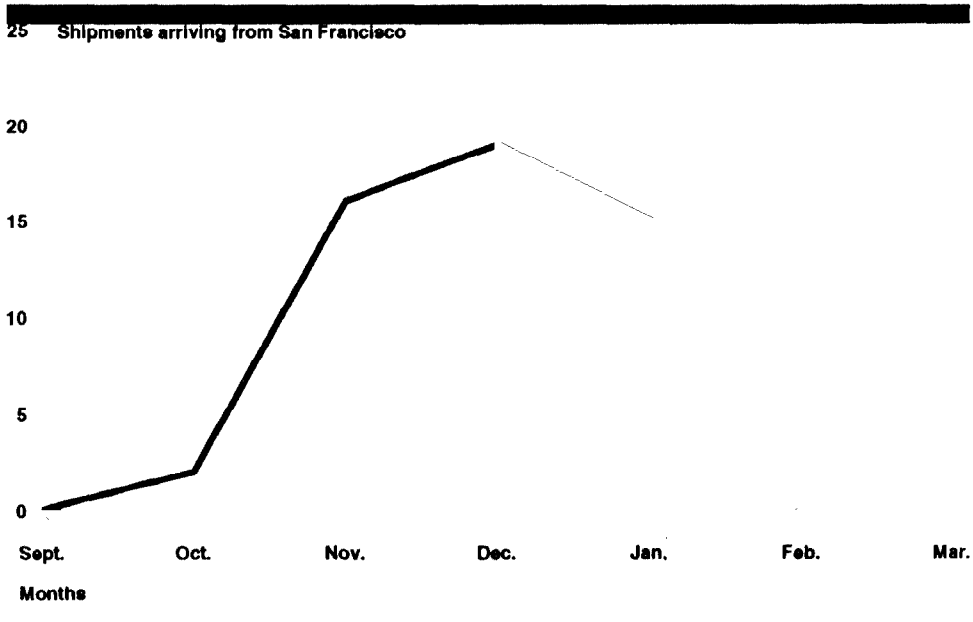
Shipments of food originating from the same source as shipments previously determined to contain illegal residues have a higher than average likelihood of containing illegal pesticide residues. Such shipments are therefore considered suspect by FDA. For example, in fiscal year 1990, samples of foods from growers or shippers who had previously violated restrictions had a violation rate of 15 percent, compared with 4.3 percent for routine samples. Table 3.1 shows violation rates for fiscal years 1988-90.

Table 3.1: Percentage of Suspect and Routine Samples Found to Be Adulterated

Fiscal year	Suspect samples	Routine samples
1988	14.5	4.2
1989	16.0	3.5
1990	15.0	4.3
Average	15.2	4.0

Because of the seasonal nature of agriculture, shipments of a given product from a given source are usually concentrated during the harvest season. Since most products and countries have a limited growing season, distribution follows a bell-shaped curve. (Fig. 3.1 shows, for example, shipments of strawberries imported in San Francisco over the 1991-92 harvest season.) A foreign producer will sell a few shipments to a variety of U.S. importers at the beginning of the season, building up to the bulk of sales during the harvest's peak and tapering off as the harvest is completed. Consequently, shipments may arrive simultaneously at many U.S. ports. In fiscal year 1988, for example, strawberry producers in one country exported 3,065 shipments of strawberries to the United States. Over 80 percent of these shipments were received within 6 months in 14 different ports.

Figure 3.1: Shipments to San Francisco From One Country During the 1991-92 Strawberry Season



FDA's 363 field staff responsible for monitoring imports make decisions to sample or release over a million shipments a year. With these resources, FDA can test less than 1 percent of incoming food shipments for pesticide residues.

Distribution of Companion Shipments Increases the Likelihood of Adulterated Food Entering Commerce

To provide broad coverage of products and sources, FDA's reviewers at ports of entry generally sample only one of a grower's shipments and release other companion shipments of the same product from the same source. Although districts are alerted to sample future shipments from the same source once a violation is identified, FDA procedures do not provide for districts to restrict the distribution of companion shipments that arrive during the time a shipment is being sampled and tested.

The amount of time that passes between collecting a sample and completing laboratory testing varies according to each district's laboratory location, resources, and work load as well as the perishability of the product. FDA's procedures call for highly perishable food to be analyzed within 24 hours of sampling when possible. For less perishable commodities, including processed foods, district officials estimated that laboratory results may not be available for up to 1 week after sampling. In our review, less-perishable foods contained illegal pesticide residues seven times more frequently than did highly perishable foods. FDA could establish procedures for companion shipments by setting a deadline for giving the test results to Customs and the importer so as not to delay the distribution of the companion shipments.

Between the arrival of a shipment and the identification of any illegal residues, multiple shipments may arrive from the same grower. FDA releases these companion shipments for distribution before the test results from the sampled shipment are known. For example, on April 29, 1992, an FDA inspector in Hidalgo, Texas, sampled a shipment of cantaloupes—one of seven such shipments arriving in Hidalgo that day from a particular source. The grower's other six shipments proceeded to market. When FDA's testing laboratory informed the inspector the next day that the sampled cantaloupes were adulterated with illegal pesticide residues, the inspector began sampling all subsequent cantaloupe shipments from that source. FDA's testing laboratory continued to detect illegal residues. However, because FDA does not maintain control of companion shipments, the six original shipments that the inspector released presumably reached consumers.

The Director of FDA's Import Operations agreed that when a food shipment is sampled, its companion shipments should not be released and allowed to proceed into domestic commerce before test results are known. As a way to control the premature release of these shipments, she said that FDA reviewers could issue "documentary sampling" notices requiring importers to maintain control over all companion shipments until test results on the

sampled shipment are known. Documentary sampling notices are currently used by FDA for other import programs, such as drugs and medical devices, to maintain control over all of a company's companion shipments until the acceptability of the sampled shipment is verified. FDA's Import Operations Director said that requiring importers to test companion shipments after a sampled shipment was found to violate pesticide regulations could maximize the agency's goal of stopping as many adulterated shipments as possible without disrupting the agency's objectives of providing broad sampling coverage.

Delay Before Districts Can Automatically Detain Shipments Results in Unnecessary Sampling

To reduce the level of resources devoted to testing while maintaining the same level of consumer protection, FDA has adopted a policy known as automatic detention, under which the importer of a food shipment found to contain illegal pesticides is required to pay for a private laboratory analysis of subsequent shipments of the same food item. However, FDA's policy requires districts to obtain headquarters' approval in most instances before implementing this procedure. Headquarters' review is both a technical review of the laboratory results to validate the finding that the food is adulterated and a compliance review to ensure consistent treatment among the districts of the many products tested and the varying levels of residues. While headquarters' approval is pending, districts physically sample and test subsequent shipments of the same product from the same source, using FDA resources that could be redirected towards sampling a greater number of routine shipments.

The automatic detention policy reduces the amount of FDA resources needed to test subsequent shipments of foods that were previously found to contain illegal pesticides. When a grower and his food product is placed on automatic detention, the importer must use a private laboratory to test each future shipment of this product. If the importer does not provide FDA with a valid certificate of analysis from a qualified private laboratory showing that the goods are free of unacceptable pesticide residues, FDA will refuse to release the imported food. As we pointed out in chapter 2, however, importers retain possession of shipments on automatic detention and can still distribute food that a private laboratory finds is adulterated.

Imposing Automatic Detention Is a Slow Process

Placing a grower and his food product on automatic detention status involves several steps. FDA's field laboratories must perform the necessary analysis to identify and quantify the illegal residue. FDA's field compliance staff must review the laboratory's findings relative to current EPA

tolerances, prepare the recommendation for automatic detention, and send the recommendations to both FDA's Division of Import Operations and Policy and Center for Food Safety and Applied Nutrition (CFSAN). CFSAN reviews the documentation to confirm the technical support for the recommendation and notifies Import Operations that automatic detention has been approved. Import Operations informs all of FDA's field offices that the grower and his food product have been placed on automation detention status. In the cases we examined, the average time from when the shipment was sampled until automatic detention was imposed was 27 days. An example of the multistep process for implementing automatic detention is the following case, in which 31 days elapsed between the initial sampling of snow peas and the implementation of automatic detention:

- On October 4, 1991, FDA sampled a shipment of snow peas imported into the Orlando, Florida, district.
- On October 16, the district laboratory documented that the shipment was adulterated with pesticides.
- On October 21, district staff recommended that CFSAN grant automatic detention status.
- On November 1, CFSAN approved the recommendation.
- On November 4, Import Operations placed the grower's snow peas on automatic detention status.

Resources May Be Wasted Because of Delays in Implementing Automatic Detention

Delays in imposing automatic detention cause sampling and testing resources to be expended by FDA instead of the importers. In the above example, the district tested all subsequent shipments of snow peas from the same source after the district laboratory documented that the shipment was adulterated. FDA records show that between October 16 and November 4, six shipments of snow peas containing illegal pesticides were received at the Orlando port and tested by FDA. If the district had had authority to approve automatic detention following the October 16 laboratory finding, the importer and not FDA would have incurred the expense of testing the six subsequent shipments.

Even a short delay in implementing automatic detention can drain FDA's testing resources. For example, in one case, headquarters' approval of automatic detention took a week after the Dallas district detected adulterated spinach. During that week, the district received, sampled, and tested three shipments of spinach from the same grower. FDA thus used its resources to test the suspect shipments that arrived before automatic

detention was implemented rather than being able to require the importer to pay for private testing of those shipments.

During the 3 years covered by our review, FDA districts sampled 1,852 shipments before automatic detention was implemented. FDA officials in Dallas and Miami estimated that about 30 percent of the samples currently tested by their labs are shipments of imported food awaiting approval of automatic detention status.

One way to speed up the automatic detention process is to delegate a significant portion of the technical review to the district laboratories. Headquarters rarely turns down a district's request for automatic detention in pesticide cases. For example, during the first 6 months of fiscal year 1992, headquarters turned down only 4 of over 140 requests. Two of these cases were turned down because the pesticide levels detected were extremely close to the permitted tolerance, and FDA could not establish that the food was adulterated. In the other two cases, the amount of an unregistered pesticide residue detected on a product could not be satisfactorily measured and confirmed.

Despite the infrequency of disapprovals, FDA officials have considered it necessary to retain CFSAN review to ensure that each recommendation meets all technical and policy requirements. An FDA official stated that the four cases in which a request for automatic detention was disapproved were significant. If automatic detention had been implemented in these cases, FDA believes it would not have been able to defend the decision. FDA officials were concerned that FDA would be liable to pay for losses suffered as a consequence of an inappropriate sanction.

The requirement for review was changed in September 1991, when the districts were given the responsibility for technical review of the chemists' analytical work and the authority to place a grower's product on automatic detention status in cases in which residues of approved pesticides exceed acceptable limits, known as overtolerance cases. In these cases, districts may send requests directly to Import Operations for implementation of automatic detention. However, overtolerance cases represent less than 20 percent of all pesticide violations. CFSAN approval is still required for the other cases, in which shipments contain residues of a pesticide (1) not approved for use on that product (60 percent) or (2) never registered in the United States (20 percent).

To assess the effect of delegating more responsibility to the districts, we examined FDA's records of automatic detention requests for the first 6 months of fiscal year 1992. While considerable time continues to elapse between the testing of a product and the implementation of automatic detention, district technical review reduced processing time by about 15 days. In 11 overtolerance cases, in which automatic detention was approved by districts, implementation took place 12 days after sampling. In contrast, in 113 cases of use of unregistered pesticides, CFSAN took an average of 27 days to approve automatic detention. FDA officials believe the time that districts take to approve automatic detention will diminish further as the districts gain familiarity with the new district review procedures.

We discussed with FDA officials the feasibility of delegating additional authority for technical review to the district offices. The officials agreed that speeding up implementation of automatic detention would save the agency's sampling and testing resources, since importers—not FDA—would arrange and pay for sampling and testing. CFSAN officials agreed that further delegation of authority may be appropriate in cases involving unapproved uses of pesticides registered with EPA, which comprise about 60 percent of all violations. However, they believe they must first quantify the minimum residue levels that district laboratories can routinely and reliably measure, to avoid imposing automatic detention in doubtful cases. In addition, they wish to retain review of cases involving residues of pesticides not registered by EPA, because the district laboratories may have insufficient expertise to decide these cases.

We understand CFSAN's desire to be cautious in the case of unregistered pesticides, in which districts may not have sufficient capability. However, delegating additional authority to the districts for the remaining cases—that is, unapproved uses of pesticides registered with EPA—would cover the bulk of all automatic detention cases and could help make better use of FDA's limited resources.

Conclusions

FDA could be more effective in preventing pesticide-adulterated foods from entering U.S. commerce if it prevented distribution of shipments of the same product from the same source that arrive while food samples are being tested for possible adulteration. Although these companion shipments have a higher than average likelihood of containing illegal pesticide residues if the sampled shipment is adulterated, FDA does not identify and maintain control of these shipments. Once a sample is found

to violate pesticide requirements, it is too late to detain companion shipments that have already been released. According to FDA's Director of Import Operations, this problem could easily be resolved by advising districts to issue documentary notices of sampling, under which release of companion shipments would be delayed until test results are known. She said that she is considering adopting such a policy. In cases involving companion shipments, FDA could establish deadlines for providing test results to Customs and the importer to prevent undue delays for the importer's companion shipments.

FDA could also use its resources more effectively if it allowed its district offices greater discretion in placing growers and their imported foods on automatic detention status. FDA's policy requires that, while awaiting CFSAN approval for imposing automatic detention, districts sample and test subsequent shipments from a grower whose food was found to contain illegal pesticides. Giving districts greater authority to initiate automatic detention would result in an earlier transfer of testing responsibility to the importers. This, in turn, would reduce FDA's work load by decreasing the number of companion shipments FDA's districts are now testing while awaiting approval of automatic detention from headquarters. These resources could be used to broaden the sampling of other food shipments, providing greater assurance that adulterated food is kept out of the United States.

Recommendations

To increase the effectiveness of FDA's efforts to detain suspect shipments, we recommend that the Secretary of Health and Human Services direct the Commissioner of FDA to

- instruct districts to issue documentary sampling notices to ensure that shipments of the same food from the same grower arriving simultaneously with or soon after sampled shipments are not distributed until the sample is determined to be free of prohibited pesticide residues, with a reasonable deadline for the test results to be communicated to Customs and the importer, and
- extend to the districts the responsibility for technical review and initiation of automatic detention without CFSAN's approval when doing so is within the districts' technical capability.

Major Contributors to This Report

Resources, Community, and Economic Development Division, Washington, D.C.	Peter F. Guerrero, Associate Director J. Kevin Donohue, Assistant Director Robert J. Tice, Assignment Manager
San Francisco Regional Office	Steven G. Reed, Issue Area Manager Albert T. Voris, Evaluator-in-Charge Heather O'Brian, Staff Evaluator Caitlin A. Schneider, Staff Evaluator Jonathan Silverman, Reports Analyst
Philadelphia Regional Office	Clifford Martin, Issue Area Manager William Hamilton, Senior Evaluator Mark A. Tremba, Staff Evaluator
Office of General Counsel	Doreen Stolzenberg Feldman, Senior Attorney

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