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Report to the Chairman, Permanent Subcommittee on Investigations, Committee on Governmental Affairs, U.S. Senate

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# FOOD SAFETY

# Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable

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GAO

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

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The Honorable Susan M. Collins
Chairman, Permanent Subcommittee
on Investigations
Committee on Governmental Affairs
United States Senate

Dear Madam Chairman:

This report responds to your request that we evaluate the federal government's efforts to ensure the safety of imported foods. The report contains recommendations to the Congress and to the Secretaries of Agriculture and of Health and Human Services that are designed to enhance the federal government's authority to review the safety of food imports, improve the effectiveness and efficiency of systems and staff to screen imports, and strengthen internal controls.

As agreed 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 interested parties and make copies available to others upon request.

Please call me at (202) 512-5138 if you or your staff have any questions about this report. Major contributors to the report are listed in appendix VI.

Sincerely yours,

Robert A. Robinson
Director, Food and
Agriculture Issues

# Executive Summary

## Purpose

Each year, millions of Americans become ill after eating tainted foods, and thousands die. Ensuring the safety of domestically produced foods is a daunting task, but the challenge of ensuring the safety of the entire food supply is even more difficult as Americans consume more foods imported from other countries. The primary responsibility for ensuring the safety of imported foods is split between two federal agencies—the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) and the Department of Health and Human Service's Food and Drug Administration (FDA).

Concerned about the safety of imported foods, the Chairman of the Permanent Subcommittee on Investigations, Senate Committee on Governmental Affairs, asked GAO to review the efforts of federal programs to ensure the safety of food imports. Specifically, this report discusses (1) the differences in the agencies' authorities and approaches for ensuring the safety of imported foods and (2) the agencies' efforts to target their resources on foods posing risks. In addition, the report discusses weaknesses in the controls over imported foods.

## Background

Foodborne illnesses in the United States are widespread and costly. The magnitude of the problem is uncertain, however, because these illnesses are underreported and health officials often cannot determine their source. As GAO reported in May 1996,[1] up to 81 million cases of foodborne illnesses and as many as 9,100 deaths from these illnesses occur each year. According to the U.S. Department of Agriculture's Economic Research Service, the costs for medical treatment and productivity losses associated with these illnesses and deaths range from $6.6 billion to $37.1 billion. Recent outbreaks of foodborne illness demonstrate that imported foods have introduced new risks or increased the incidence of familiar illnesses. The increased consumption of imported foods in the United States further heightens the risk of illness.

FSIS has jurisdiction over meat, poultry, and some egg products, while FDA regulates all other foods. FSIS and FDA work closely with the Customs Service (Customs) and the Centers for Disease Control and Prevention (CDC). Customs refers imported foods to FSIS or FDA for their review before releasing the shipment into U.S. commerce. CDC monitors the incidence of foodborne illness; works with state and local health departments to investigate outbreaks of illness; and collaborates with FSIS, FDA, and others to conduct research on foodborne diseases.

[1] Food Safety: Information on Foodborne Illnesses (GAO/RCED-96-96, May 8, 1996).

## Results in Brief

Federal agencies cannot ensure that the growing volume of imported foods is safe for consumers. Although the Food Safety and Inspection Service and the Food and Drug Administration require imported foods to meet the same standards as domestic foods, their approaches to enforcing these requirements differ. By law, the Food Safety and Inspection Service places the principal burden for safety on the exporting countries by allowing imports only from those countries with food safety systems it deems to be equivalent to the U.S. system. The Food and Drug Administration, lacking such legal authority, allows food imports from almost any country and takes on the burden of ensuring the safety of imported foods as they arrive at U.S. ports of entry. Relying on port-of-entry inspections to detect and prevent unsafe foods is ineffective, given that (1) this approach does not ensure that foods are produced under adequately controlled conditions, (2) the Food and Drug Administration currently inspects less than 2 percent of all foreign shipments, and (3) inspection will not detect some organisms, such as Cyclospora, for which visual inspections and laboratory tests are inadequate.

The Food Safety and Inspection Service and the Food and Drug Administration are not deploying their inspection resources to maximum advantage. The Food Safety and Inspection Service focuses its inspection and testing resources on shipments from exporting firms with a history of violations, such as contamination, processing defects, and incorrect or missing shipping labels. However, many of the violations, such as the incorrect or missing shipping labels, may bear little relationship to food safety. Using available data on health-related risks from shipments that do not meet U.S. standards could help the Food Safety and Inspection Service focus more closely on the imports posing the greater risks. The Food and Drug Administration's annual work plan does not set achievable targets for inspection activities; as a result, inspectors do not have clear guidance for conducting inspections. For example, in fiscal year 1997, the Food and Drug Administration conducted only half of its planned inspections of imported foods. Furthermore, the Food and Drug Administration does not make health risk data readily available to guide inspectors' selections. In addition, when making decisions on which shipments to inspect, the Food and Drug Administration relies on importers' descriptions of shipments' contents, which are often incorrect. As a result, the agency's resources may not be focused on imported foods posing the greater safety risk.

The Food and Drug Administration's procedures for ensuring that unsafe imported foods do not reach U.S. consumers are vulnerable to abuse by

unscrupulous importers. For example, when an exporting firm has a history of violations, the Food and Drug Administration detains shipments from that firm without sampling or analysis. Importers of these detained shipments have the right to present evidence, such as private laboratory tests, showing that the product complies with U.S. standards. However, because the Food and Drug Administration does not have the explicit authority to require importers to use certain laboratories, importers can choose the laboratories that select the samples and perform the tests to prove compliance. For other shipments, importers retain control of the goods while the Food and Drug Administration decides whether to inspect them or while tests are being conducted on them. In some cases, when the Food and Drug Administration decides to inspect shipments, the importers have already marketed the goods. In other cases, when the Food and Drug Administration finds contamination and calls for importers to return shipments to the Customs Service for destruction or reexport, importers ignore this requirement or substitute other goods for the original shipment. Such cases of noncompliance seldom result in a significant penalty.

# Principal Findings

## Lack of Equivalency Authority Diminishes FDA's Ability to Protect U.S. Consumers

FSIS has the statutory authority to require the exporters of meat and poultry products to have food safety systems equivalent to the system in the United States. In enforcing this requirement, FSIS has determined that 37 countries have food safety systems equivalent to the United States' and are therefore eligible to export meat and poultry products to this country. (App. II lists the eligible countries.) FDA's authority, on the other hand, requires imported foods to meet U.S. standards. FDA does not have the authority to require the exporting country to have an equivalent safety system in place. In 1997, administration initiatives on food safety proposed that FDA be given this "equivalency authority."

FSIS has used its equivalency authority to shift the primary responsibility for food safety to the exporting countries. In so doing, the agency can leverage its resources by reviewing exporting countries' compliance with U.S. requirements, rather than by depending on resource-intensive inspections at ports of entry. FDA, on the other hand, relies on selecting and testing import samples at ports of entry to ensure that foods are safe. Such an approach, when used as the sole means of assessing the safety of

foods, has been widely discredited as an effective protective measure by the Food and Agriculture Organization of the United Nations, an FDA advisory committee, and GAO for a number of reasons. For example, individual products tested at ports of entry may not represent the health risks of the entire shipment. The ineffectiveness of FDA's approach is magnified by its inability to keep pace with a rising level of imports. FDA's coverage of import shipments has fallen from an estimated 8 percent in fiscal year 1992 to an estimated 1.7 percent in fiscal year 1997.

## Agencies Could More Effectively Target Resources on Unsafe Foods

Although both FSIS and FDA use computer systems to screen each import shipment and to help identify the import shipments requiring inspectors to take action, the agencies have not designed their systems to take the best advantage of available data so that they can target those imported foods posing the greater health risks. FSIS relies primarily on the violation history of previous shipments from the exporting firm to target entries for inspectors' action; this violation history may not always indicate the shipments more likely to pose health threats. For example, many violations, such as incorrect shipping labels, may not directly affect consumers' safety. As a result, FSIS is using some inspection resources to review shipments that pose lower food safety risks. However, information is available on the relative health risks of specific types of imported foods, such as ground or deboned beef, that would enable FSIS to further improve its computer screening system.

FDA's system for selecting imports for examination relies primarily on inspectors' judgment, and FDA's guidance and information to aid inspectors' decisions are often not useful. FDA's annual work plan, which identifies, among other things, the number of imported food inspections and tests each field office is expected to conduct, guides inspectors' judgment; but the work plan is unrealistic because it does not make allowances for the time needed to investigate emergencies and consumers' complaints. Because the number of activities set out in the work plan is generally not attainable, the work plan is not useful when making inspection and testing decisions, according to managers in field locations who reported the views of inspectors. In addition, FDA's computer system for screening imported food shipments is not programmed to help inspectors effectively use laboratory test results, violation histories, and other information to identify shipments posing the greater food safety risks. Finally, the information identifying the contents of imported food shipments is entered directly into FDA's computer system by importers, some of whom have an incentive to misrepresent their goods in the

interest of avoiding inspectors' attention. After an importer demonstrates competency with the system, FDA retrospectively verifies a sample of the importer-provided information. Although the agency frequently identifies errors, it has recently taken no corrective action other than counseling the filer. Thus, FDA has no assurance that importers are accurately describing their goods and that it is identifying shipments that should be scrutinized.

## Weaknesses in Import Controls Allow Entry of Unsafe Products

FDA and Customs have historically had problems stopping importers from distributing unsafe foods under FDA's jurisdiction. Recent investigations by Customs confirm that these problems continue. Nevertheless, the procedures for controlling suspect shipments continue to permit importers to easily circumvent them.

In particular, FDA does not maintain effective control over the products it automatically detains because of past violations. In lieu of requiring that these shipments be destroyed or reexported, FDA requires importers to establish that the contents are safe. As proof, FDA allows them to present evidence, such as private laboratory test results, to show that the shipments meet U.S. safety standards. However, because the agency does not have the explicit authority to require importers to use certain laboratories, importers are free to choose the laboratories that will perform the tests. While FDA expects these laboratories to follow the agency's written sampling guidelines and reviews the test results submitted to the agency, it does not control the selection of the samples tested by the private laboratories or certify acceptable private laboratories to perform these tests. FDA has found numerous discrepancies between its test results and those from private laboratories for the same shipments. Customs officials and FDA inspectors told GAO that importers have been known to substitute shipments that have been tested as safe for samples of other shipments that are suspect.

Unlike FSIS, which controls the storage of imported foods after they are presented for inspection until their release into the U.S. market, Customs usually allows importers to retain possession of their shipments until FDA and Customs clear them for entry into U.S. commerce. According to FDA and Customs officials, imported food shipments under FDA's jurisdiction are often not made available for FDA's inspection as required or are not properly disposed of when refused entry into U.S. commerce. Customs and FDA inspectors have found many instances in which importers substituted safe products for inspection, rather than the imported products FDA wanted to inspect. In other instances, when the tested

products failed laboratory tests, importers substituted other products for destruction, rather than the imported products FDA wanted to destroy. In each situation, FDA inspectors believe the original imported food was sold in the U.S. market and presumably consumed. A joint Customs-FDA operation to test controls over foods at one port found that evasion was common.

The evasion of safety requirements is seldom punished effectively. While FDA and Customs rely on the bonds presented by the importer, which cover the value of the shipment, as the principal deterrent against noncompliance with laws, the collection of damages against violators is uneven and uncertain. For example, at one port, Customs collected about 2 percent of the damages originally assessed in 24 cases in 1997. In a previous report, GAO found that even if the maximum damages had been collected, the importer would still have made a profit on the sale of the shipment.[2] Thus, the bonds do not represent an effective deterrent.

## Recommendations

In order to strengthen FDA's ability to ensure the safety of imported foods, GAO recommends that the Congress require all foods eligible for import to the United States, not just meat and poultry, be produced under equivalent food safety systems.

In the body of this report, GAO also makes several recommendations to the Secretary of Health and Human Services and the Secretary of Agriculture to improve the effectiveness and efficiency of their import review systems and procedures by targeting inspection resources on foods posing greater health risks.

## Agency Comments

GAO provided copies of a draft of this report to the Department of Health and Human Services' Food and Drug Administration, the U.S. Department of Agriculture's Food Safety and Inspection Service, and the Department of the Treasury's U.S. Customs Service for review and comment. Their comments and GAO's responses are in appendixes III, IV, and V, respectively. The Centers for Disease Control and Prevention provided technical comments in response to the draft report, and these have been incorporated as appropriate.

[2]Pesticides: Adulterated Imported Foods Are Reaching U.S. Grocery Shelves (GAO/RCED-92-205, Sept. 24, 1992).

FDA generally agreed with the report and said it raises a number of issues that need to be addressed. FDA agreed with GAO that FDA needs additional legislative authority to control the safety of imported foods, but the agency disagreed that any authority to require equivalency should be mandatory because such mandatory authority would disrupt trade if implemented at one time. GAO disagrees that FDA should have discretion over applying equivalency requirements and believes the agency could implement the requirements in stages. GAO believes that equivalency should be mandatory for all imported foods and could be implemented in a manner that would not unnecessarily or unfairly disrupt trade. Mandatory authority to require equivalency would address weaknesses in FDA's inspection approach at ports of entry, enable FDA to leverage its staff resources by sharing the responsibility for food safety with the exporting countries, and compel FDA to take a proactive approach in preventing food safety problems instead of requiring equivalency after problems are identified. The Congress could provide reasonable time frames that would allow equivalency to be implemented over a number of years.

FDA also generally agreed with the report's recommendation regarding its import screening system. FDA described planned actions to improve the efficiency of its automated import screening system and to take appropriate corrective actions in its electronic filer program. FDA did not agree with GAO's characterization of its system for communicating inspection priorities to its inspectors or the associated recommendation in GAO's draft report to improve this system. Specifically, FDA said that its annual work plan and compliance programs provide sufficient guidance to inspectors to help them make decisions about which shipments to inspect. GAO continues to believe that the priority-setting guidance provided to inspectors, even as it is described in FDA's comments, is confusing and inconsistent. As a result, inspectors may not be selecting shipments to inspect that pose the greater food safety risk to consumers. GAO has, however, modified its recommendation to better reflect the nature of the problem and to provide FDA with more flexibility to address it.

FSIS concurred with the facts in the report and stated that it will consider GAO's recommendation in its evaluation of port-of-entry inspection procedures and automated systems.

Customs also provided explanations of its actions to enforce requirements for controlling imported foods and raised concerns about the extent of the problem regarding the substitution of safe food products for actual products for inspection.

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### Abbreviations

| | |
|---|---|
| AIIS | Automated Import Information System |
| CDC | Centers for Disease Control and Prevention |
| CLEAN | Closing Loopholes to Ensure Acceptable Nutrition |
| FDA | Food and Drug Administration |
| FSIS | Food Safety and Inspection Service |
| GAO | General Accounting Office |
| HACCP | Hazard Analysis and Critical Control Point |
| HHS | U.S. Department of Health and Human Services |
| OASIS | Operational and Administrative System for Import Support |
| USDA | U.S. Department of Agriculture |

# Introduction

Foodborne illnesses constitute a major public health problem in the United States. In May 1996, we reported that up to 81 million cases of foodborne illnesses and as many as 9,100 deaths associated with those illnesses are estimated to occur each year.[1] While foodborne illnesses are often temporary maladies that may not require medical treatment, they can sometimes cause acute and chronic illnesses, such as kidney failure in infants and young children, stillbirths, and various types of arthritis. According to the U.S. Department of Agriculture's Economic Research Service, in 1996, the estimated annual cost of medical treatments and productivity losses associated with these illnesses ranged from $6.5 billion to $37.1 billion. The actual number of foodborne illnesses, however, is unknown because many people who become ill do not seek treatment, and doctors may not associate the illnesses they do see with a food source or, if they do, report it to state or local health agencies.[2] Even when a foodborne illness is reported, health agencies may not be able to trace the illness to a specific food or its origin.

## Imported Food's Growing Role in U.S. Food Supply

A growing percentage of the U.S. food supply is imported. The sheer volume of these imports, along with the difficulty in ensuring that they are safe, adds to the risk of foodborne illnesses.

As shown in table 1.1, the import share of some commonly consumed foods is increasing. For example, in 1995, one-third of all fresh fruits consumed in the United States were imported.

[1]Food Safety: Information on Foodborne Illnesses (GAO/RCED-96-96, May 8, 1996).

[2]Federal and state agencies began in 1995 to collect more comprehensive data on foodborne illness in the United States to overcome the scarcity of data. This effort will help identify the frequency with which specific foods are associated with certain pathogens, but it does not address the difficulties of tracing an adulterated food back to its country of origin.

**Table 1.1: Import Share of Selected Foods Consumed in the United States, 1980-95**

| Import item | Percentage of total U.S. consumption provided by imports | | | | Percent change, 1980-95 |
|---|---|---|---|---|---|
| | 1980 | 1985 | 1990 | 1995 | |
| Fish and shellfish | 45.3 | 53.8 | 56.3 | 55.3 | 22.1 |
| Fresh fruits | 24.2 | 28.0 | 30.7 | 33.3 | 37.6 |
| Fresh vegetables | 7.6 | 8.9 | 8.4 | 11.7 | 53.9 |
| Tomatoes for processing | 1.4 | 7.0 | 5.7 | 3.5 | 150.0 |
| Broccoli for processing | 9.1 | 22.2 | 57.8 | 84.9 | 833.0 |

Source: U.S. Department of Agriculture, Economic Research Service.

Some imported foods pose a significant risk of foodborne illness. They can introduce pathogens previously uncommon in the United States, such as new strains of Salmonella and the Cyclospora parasite. Imported foods may also contain pathogens, such as hepatitis A, that cannot be easily detected until illness breaks out. (App. I provides information on selected recent outbreaks of foodborne illness related to imported foods.)

As the percentage of imported foods consumed in the United States increases, the importance of ensuring that these foods are safe increases as well. Ensuring food safety therefore cannot be achieved by focusing on domestic products exclusively.

## Multiple Agencies Are Responsible for Ensuring the Safety of Imported Foods

Two federal agencies have the primary responsibility for ensuring the safety of imported foods. The Food Safety and Inspection Service (FSIS) in the U.S. Department of Agriculture (USDA) is responsible for meat, poultry, and some egg products. The Food and Drug Administration (FDA) in the Department of Health and Human Services (HHS) is responsible for all other foods.

Under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, as amended, FSIS works to ensure that products moving in interstate and foreign commerce are safe and wholesome, and correctly labeled and packaged. In calendar year 1997, FSIS used about 84 staff years, costing an estimated $3.2 million, to review about 118,000 import shipments and to determine that exporting countries met U.S. food safety requirements.

Under the Federal Food, Drug, and Cosmetics Act, as amended, FDA works to ensure that domestic and imported food products are safe, wholesome, and properly labeled.[3] In fiscal year 1997, FDA spent approximately 463 staff years (inspectors, laboratory staff, and support staff), at a cost of approximately $35.1 million, to ensure the safety of about 2.7 million imported food shipments.

To assist these agencies, the U.S. Customs Service (Customs) in the Department of the Treasury and HHS' Centers for Disease Control and Prevention (CDC) provide a number of services, including referring imported shipments for inspection and providing information on outbreaks of foodborne illnesses. Customs is the first federal agency to screen imported products, including food imports, when they enter the United States. Enforcing laws for over 40 federal agencies, Customs has, among other duties, the responsibility for collecting revenues from importers and enforcing various customs and related laws. Customs cooperates with FDA and FSIS in carrying out their regulatory roles in food safety.

CDC is the federal agency primarily responsible for monitoring the incidence of foodborne illness in the United States. CDC assists state and local health departments and other federal agencies in investigating outbreaks of foodborne illness, monitors information on foodborne illnesses, and conducts research related to these illnesses.

Since 1992, we have frequently reported on the fragmented and inconsistent organization of food safety responsibilities in the federal government.[4] These reviews have shown that inconsistencies and differences between the agencies' approaches and enforcement authorities undercut overall efforts to ensure a safe food supply. To address this problem, we recommended the formation of a single food agency. In the fiscal year 1998 appropriation act for USDA, the Congress provided $420,000 for a study by the National Academy of Sciences on the need to reorganize the federal food safety system.

[3]FDA is also responsible for ensuring that certain other products are safe. These products include drugs, cosmetics, medical devices, and electronic products that emit radiation, such as television sets.

[4]Food Safety and Quality: Uniform, Risk-Based Inspection System Needed to Ensure Safe Food Supply (GAO/RCED-92-152, June 26, 1992); Food Safety: A Unified, Risk-Based System Needed to Enhance Food Safety (GAO/T-RCED-94-71, Nov. 4, 1993); Food Safety: A Unified, Risk-Based Food Safety System Needed (GAO/T-RCED-94-223, May 25, 1994); Food Safety: Changes Needed to Minimize Unsafe Chemicals in Food (GAO/RCED-94-192, Sept. 26, 1994); and Food Safety: Fundamental Changes Needed to Improve Food Safety (GAO/RCED-97-249R, Sept. 9, 1997).

## How Import Control Processes Work

FDA and FSIS are the two agencies responsible for ensuring that the imported shipments of food entering the United States are safe. Their systems for inspecting, testing, and approving the release of these food import shipments operate independently of each other.

### FDA's System for Allowing the Entry of Imported Foods

To ensure that FDA is notified of all imported food products under its jurisdiction, an importer must file both an import notice and certain shipping information and, for shipments valued over $1,250, a bond to cover the goods for release with Customs within 5 days of the shipment's arrival at a U.S. port of entry. The import documents or electronic entry data identify the type of food product, the importer, foreign manufacturer, and country of origin. The bond, which covers potential duties, taxes, and penalties, may allow the importer to retain control of the shipment until FDA decides to inspect samples, test, or release it. If an importer fails to make an import shipment available for FDA's inspection, fails to recondition,[5] or fails to destroy or re-export the shipment, as directed by FDA, Customs may collect penalties against all or part of the bond value.

FDA relies on several sources of information to determine whether an imported food shipment will be inspected or tested or can be released into U.S. commerce. Among these sources are the following:

- FDA's annual work plan. The annual work plan establishes, among other activities, the number of inspections and tests that each FDA district office is to conduct, which are derived from guidance in specific food programs.[6] For example, the work plan for fiscal year 1997 set inspection and testing activities for 10 imported food programs, such as imported low-acid/acidified canned foods and imported seafood,[7] in four major project areas related to food safety—Foodborne Biological Hazards; Pesticide and Chemical Contaminants; Molecular Biology and Natural Toxins; and Food and Color Additives.[8]

[5]Importers can recondition imported products that do not meet U.S. standards so that the products can enter the United States. Examples of reconditioning include changing labels and fumigating raw agricultural products.

[6]FDA refers to these programs as compliance programs.

[7]Low-acid canned foods are products like green beans, mushrooms, and tuna fish. Acidified canned foods are low-acid foods to which acid is added, such as pickles and marinated artichokes. Canned products with low acidity are more prone to bacterial growth and contamination.

[8]Technical Assistance is FDA's fifth major project area related to food safety, but FDA did not identify inspection and testing activities for programs in this area in 1997.

- FDA's Import Alert Retrieval System database. This database contains a list of products that FDA automatically detains because the exporter or the specific food products have shown a history of violations in previous shipments.[9] FDA will not approve the release into U.S. commerce of these automatically detained shipments until the importer shows that the product is not in violation, usually by providing the results of a private laboratory analysis. FDA disseminates information on automatic detentions to district offices through import alerts, which identify problem commodities and/or exporters, foreign firms, the country of origin, the reasons for detention, and the food safety risk.
- FDA's Low-Acid Canned Food database. This database contains information on foreign processors of low-acid and acidified canned foods registered with FDA. Foreign processors wishing to export these foods to the United States must submit descriptions of their canning processes to FDA before it will issue a registration number for the firm and permit the entry of the firm's shipments into U.S. commerce. The descriptions include the manufacturing methods used to prevent spoilage and contamination. FDA issues each foreign establishment a registration number to help track the firm's registration and processing records.

To assist FDA in reviewing all shipments, Customs' computer system uses the information provided by the importer and FDA-developed screening rates to determine which shipments to automatically release into domestic commerce and which shipments to review further. FDA sets the screening rates using several sources of information, such as the annual work plan, compliance programs, type of product, and past violations of products or shippers. Most shipments that are believed to pose minimal safety risks, such as candy and dried pasta products, are frequently released automatically because they have low screening rates. FDA releases these shipments a few minutes after the importer enters the information. Other shipments, such as some seafood and low-acid canned foods, are less frequently or never released automatically, because they pose greater potential risks.

Customs forwards information on products that are not automatically released to FDA for further review, through FDA's automated screening system, known as the Operational and Administrative System for Import Support (OASIS). This system was pilot-tested in 1992 and installed at all

[9]FDA uses the formal term "detention without physical examination" to identify those shipments that are automatically detained.

FDA's district offices by October 1997.[10] (Before OASIS was developed, FDA manually tracked shipments through entry documents submitted by importers to Customs.) Along with the electronic information provided by the importer, FDA officials use the information in OASIS and other sources as needed—such as the databases with information on products to be automatically detained and registration numbers for foreign firms—to determine which samples of imported food shipments should be held for further action, such as inspection and/or laboratory testing, and which can be released without further review. FDA releases most shipments not requiring further review within 3 hours after the importer enters the information. FDA does not visually check or inspect these released shipments.

FDA annually inspects or conducts laboratory analyses on a small percentage—currently less than 2 percent—of all types of imported food shipments. Inspections may occur at ports of entry and at warehouses or other business establishments. If FDA decides to test an imported food shipment, an FDA inspector collects a sample from the shipment and sends it to a FDA laboratory for analysis. (FDA maintains a record of all laboratory test results in its Laboratory Management System database.) For samples found to comply with U.S. standards, FDA notifies Customs and the importer that the shipment can be released. For samples found to violate these standards, FDA notifies Customs and the importer that the shipment has been refused entry into U.S. commerce. Importers generally have three options for handling shipments refused entry. If FDA concurs, importers can recondition the shipment. Otherwise, they must either destroy or re-export the shipment. Whatever option the importer chooses, Customs officials are required to supervise proper disposition of the refused shipment.

## FSIS' System for Allowing the Entry of Imported Foods

Before foreign firms can export meat and poultry to the United States, FSIS must have determined that the exporting country has a food safety system for these products that is equivalent to the U.S. system. Unlike FDA, FSIS inspectors visually check every imported shipment of foods under their jurisdiction for correct documentation, transportation damage, and correct labeling at FSIS-approved import inspection stations. FSIS conducts more intensive inspections and tests on a portion of the imported shipments—about 20 percent in 1997—to verify the effectiveness of the foreign food safety system. FSIS calls this process "reinspection" because

[10]FDA began developing an automated system as early as 1987. OASIS succeeds an earlier version called the Import Support and Information System.

the product has already passed inspection by the exporting country's equivalent inspection system.

Importers of FSIS-regulated products, like importers of FDA-regulated products, must file an import notice and a bond with Customs within 5 days of the date that a shipment arrives at a port of entry to cover their goods for release. Unlike FDA, however, importers must hold shipments at FSIS-registered warehouses for FSIS' inspection until these shipments are released into the domestic market or refused entry.[11]

FSIS inspectors enter the information provided by importers—such as country of origin, foreign manufacturer, exporting country's health certification, and type of product—into a centralized computer system. This computer system, which was installed in 1979, is known as the Automated Import Information System (AIIS). The system scans the information it contains to determine if the country, plant, and product are eligible for import into the United States and whether the shipment will be allowed entry with only a visual check or be subjected to more intensive inspections and tests.

The AIIS system uses computer-assigned screening procedures and individual plants' performance histories to target shipments for more intensive inspection and testing. Under the system, one violation on the previous shipment of a particular product, such as boneless beef, triggers more intensive inspection and testing for the same type of product from the same foreign firm until FSIS has found at least 10 successive shipments that are free of violations and meet U.S. standards. Violations that generate more intensive inspections include food products that contain chemical residues or bone fragments, have misidentified products, or have microbial contamination. If the imported products do not meet U.S. requirements, they are stamped "U.S. Refused Entry" and must be exported, destroyed, or converted to animal food.[12] FSIS uses information on refused shipments to plan inspections in foreign countries.

## Objectives, Scope, and Methodology

Concerned over recent foodborne illnesses associated with imported foods, the Chairman, Permanent Subcommittee on Investigations, Senate

[11]FDA officials stated that they lack the authority to require that shipments be held in a specific warehouse.

[12]Because of agreements with Canada, FSIS does not stamp refused entry on each load of refused imported meat and poultry shipments from Canada. Instead, FSIS notifies Canadian officials that the shipment was refused entry and is being returned.

Committee on Governmental Affairs, asked us to review federal programs' efforts to ensure the safety of imported foods. Specifically, this report discusses (1) the differences in the agencies' authorities and approaches for ensuring the safety of imported foods and (2) the agencies' efforts to target their resources. In addition, the report discusses weaknesses in controls over food imports.

Our work focused on the two principal federal agencies with responsibility for ensuring the safety of imported foods—FDA and FSIS. We also conducted work at Customs and CDC. We reviewed agency and public information on foodborne illnesses and their relationship to imported foods. We also spoke with FDA, FSIS, and CDC officials about the link between foodborne illnesses with imported foods. We reviewed information from USDA to determine the current level of food imports into the United States, the share of imported foods in the U.S. diet, and the costs associated with foodborne illnesses.

To examine the major authorities guiding the federal agencies responsible for imported food safety, we reviewed the federal laws and regulations governing imported foods. We also reviewed FDA's and FSIS' documents describing their procedures for ensuring the safety of imported foods, and we met with agency officials to discuss their approach to inspecting imports. We also discussed with FDA officials proposals to change FDA's statutory authority and to expand the import inspection program. We reviewed various studies on the effectiveness of different inspection approaches for ensuring the safety of imported foods. We analyzed agency data on resources used, import entries reviewed, and inspection actions taken.

To evaluate the approaches each agency uses to target imports for examination, we reviewed agencies' documents describing their import review procedures and the use of automated systems to screen imports. We discussed these procedures and systems with FDA and FSIS officials. We observed and analyzed the agencies' automated screening processes, physical inspections, and sample collections at FDA's and FSIS' field offices in California, Florida, New York, New Jersey, Texas, and Washington State. We visited three FDA laboratories to discuss and observe analysis procedures. We met with Customs officials in Laredo, Texas; Los Angeles and San Francisco, California; Miami, Florida; Port Elizabeth, New Jersey; and Seattle, Washington; to discuss and observe how FDA and FSIS work with Customs to handle the initial review of imported foods.

In the course of this review, we discussed and reviewed activities related to controls over imported foods in the field offices we visited. These activities included FDA's reliance on laboratory analysis provided by importers, and agencies' practices and procedures for (1) controlling imports before their release into domestic commerce, (2) ensuring that refused entries are properly disposed of, and (3) levying penalties against violators.

We performed our work from June 1997 through April 1998 in accordance with generally accepted government auditing standards.

# FDA's Lack of Authority for Equivalent Inspection Systems in Exporting Countries Diminishes Its Ability to Protect Consumers From Unsafe Foods

FSIS shares the burden of ensuring the safety of the imported foods it regulates with the exporting country, while FDA primarily relies on inspections at the U.S. ports of entry to determine the safety of the imported foods under its jurisdiction. Before it will allow a country to export meat and poultry to the United States, FSIS is required to determine that the exporting country has a food safety inspection system for these products that is equivalent to the U.S. system. By ensuring that countries exporting meat and poultry to the United States have adopted practices that protect their products from contamination, FSIS can devote its energies to verifying the efficacy of these exporting countries' systems and thereby use its inspection resources more efficiently. FDA does not have the authority to impose such a requirement on foreign countries for fish, fruits, vegetables, and the other foods for which it is responsible. Lacking the authority to ensure that exporting countries are adopting safe practices, FDA has to rely on labor-intensive inspections of imported products at the port of entry as its primary line of defense against the entry of unsafe foods. Because FDA is currently able to inspect less than 2 percent of the foods imported under its jurisdiction there is reason to question whether this approach adequately protects U.S. consumers. Providing FDA with authority similar to FSIS' would allow it to leverage its resources and provide greater assurance that the imported foods it is responsible for are safe.

## FSIS Requires Equivalent Food Safety Systems in Exporting Countries, but FDA Lacks Similar Authority

Federal laws on meat and poultry imports require that the products shipped to the United States meet U.S. standards for safety and wholesomeness, and comply with U.S. labeling and packaging requirements. Before a country can export meat and poultry to the United States, it must demonstrate that it has a food inspection system that is at least equivalent to the U.S. system. That is, the exporting country's inspection system must include, among other components, competent, qualified inspectors with the authority to enforce national food safety laws and regulations; administrative and technical support for these inspectors; and the implementation of inspection, sanitation, quality, microbiological, and residues standards equivalent to those applied to U.S. products.

In implementing this requirement, FSIS requires exporting countries to apply for eligibility to export meat and poultry products to the United States, to supply health certificates attesting to the safety of the product with each exported item, and to submit exports for inspection at the U.S. border to verify the effectiveness of the foreign inspection system. FSIS staff visit foreign countries and firms annually to verify the effectiveness

of their systems. In 1997, for example, FSIS staff visited 30 of the 37 eligible exporting countries to verify that the countries had changed their systems to include new safety procedures required for all domestic and foreign firms. These new procedures, called Hazard Analysis and Critical Control Point (HACCP), build science-based food safety controls into food production systems. Food firms incorporate controls into processing steps, maintain records of compliance with controls, and are subject to audits of their records to verify the program's effectiveness. As of January 1, 1998, FSIS had determined that 37 countries have food inspection systems equivalent to the United States' and are eligible to export meat and/or poultry products to this country.[1] Products from countries not on the list of eligible countries are automatically refused entry.

FDA does not have similar authority to accept only foods from countries with equivalent safety inspection systems. The Federal Food, Drug, and Cosmetics Act, which covers most food items other than meat and poultry, requires imported products to comply with U.S. standards for purity, wholesomeness, safety, and hygiene. It does not, however, require the exporting countries to have inspection systems equivalent to the U.S. system. Accordingly, FDA must, with few exceptions, rely on inspections and tests of selected imported foods at the U.S. port of entry as the only defense against unsafe foods entering the United States. For a few products (infant formula and low-acid and acidified canned foods), FDA may request that foreign exporting firms grant FDA inspectors access to their plants, but these inspectors actually conduct few foreign plant inspections. In fiscal year 1996, FDA planned 90 such inspections but carried out only 9. FDA planned 37 such inspections in fiscal year 1997, carrying out 29.

Although FDA cannot currently require countries to demonstrate that they have equivalent inspection systems before granting them authority to export to the United States, it can negotiate voluntary agreements with individual countries to establish equivalent inspection systems. For example, in 1997, FDA began an intensified effort to develop equivalency agreements, on a voluntary basis, with the major seafood exporting countries, in response to new regulations requiring all seafood producers selling to the U.S. market to use new HACCP procedures. However, FDA

[1]Since Jan. 1, 1998, FSIS has suspended Paraguay from exporting because FSIS found that the country had not implemented required pathogen reduction tests and had contaminated products in foreign plants. FSIS is considering action to withdraw several other countries from the list of eligible exporting countries because they do not comply with new regulations for testing for E. coli and implementing sanitary operating procedures.

officials said the agency has not strongly pursued equivalency agreements on a broad scale because the effort would require considerable resources to review foreign countries' food safety systems. In addition, a single agreement with each country might not be adequate because many countries have multiple food safety programs for different food products or even for different stages of preparation for the same product for export. For example, one foreign agency may be responsible for the safety of fresh produce, while another agency may be responsible for processed produce.

Nonetheless, FDA believes that equivalency authority provides significant benefits. In its 1997 draft Guidance on Equivalence Criteria for Food, developed to implement HACCP requirements for seafood processors, FDA stated,

> where equivalence has been determined to exist . . . the work of the foreign regulatory authority should serve to help ensure the safety of imports for U.S. consumers. Since the foreign inspection system will have been found to be equivalent to FDA's inspection system, FDA will be able to rely on the results for the foreign inspection system. . . . As equivalence is achieved, and agreements are reached recognizing the achievement of equivalence, trade is likely to flow more freely because of the reduced need by importing countries to engage in resource-intensive sampling and examination of products being offered for entry from countries with equivalent systems. For the United States, equivalency agreements will also mean that FDA will be able to target the limited resources it has for imports towards products from countries that have not been determined to be equivalent. Thus, FDA will be able to use its resources more efficiently and effectively.

In October 1997, as part of the administration's food safety initiative, the President directed FDA to seek new authority to require equivalency in food safety systems. In response, FDA developed proposed legislation for new discretionary authority that would allow the agency to prohibit imports of some foods, unless the exporting country demonstrates that the food safety system and conditions in the exporting country achieve the same level of protection as food prepared and packed in the United States. Legislation was introduced in the House of Representatives in November 1997 and in the U.S. Senate in March 1998, and is under consideration.[2] The legislation would allow FDA to determine that an imported food is adulterated, and thus cannot be imported, if the foreign system, conditions, or measures for preparing or packing the food product are not equivalent to the level of protection required for similar foods produced in the United States.

[2]H.R. 3052, the "Safety of Imported Food Act of 1997," and S. 1707, the "Safety of Imported Food Act of 1998." No action had been taken as of Apr. 10, 1998.

## Equivalency Authority Allows for More Effective Use of Resources to Ensure Safety of Imported Foods

FSIS uses its equivalency authority to shift the primary responsibility for food safety to the exporting country. Rather than focusing on resource-intensive port-of-entry inspections, FSIS emphasizes reviews of exporting countries' compliance with U.S. requirements. In contrast, FDA relies on port-of-entry inspections to ensure that imported foods are safe. This approach does little to verify the safety of all imported foods because it does not account for the conditions under which the products were processed and packed. The efficacy of port-of-entry inspections therefore depends on inspecting an adequate sample of imports, an objective FDA has not been able to meet, particularly as import volumes have increased. In addition, inspections of imported foods may be insufficient to determine whether contamination has occurred. For example, both visual inspections and laboratory tests are inadequate to detect Cyclospora, according to CDC.

### Equivalency Enables FSIS to Leverage Its Resources by Sharing Responsibility With the Exporting Countries

By requiring exporting countries to assume responsibility for the safety of meat and poultry products sent to the United States, FSIS can extend the coverage and enhance the effectiveness of its inspection resources. In 1997, FSIS had about 12 staff involved in reviewing the continuing eligibility of foreign countries to export their meat and poultry products to the United States, through document reviews and regular inspections in those countries. It also deployed about 75 inspectors to (1) ensure that each imported shipment had a health certificate from the exporting country, (2) visually check every shipment for transportation damage and accurate shipping labels, and (3) conduct intensive inspections and tests on a sample of products as a way of verifying the performance of the exporting country's system. This approach allows FSIS to transfer the primary food safety responsibility to the exporting country. FSIS considers the eligible foreign country's inspection system—not its own inspection at the port of entry—to be the primary control for ensuring that imported meat and poultry products meet U.S. standards. If a country fails to maintain an equivalent safety system, FSIS can suspend the eligibility of that country to export FSIS-regulated products to the United States.

### FDA's Port-Of-Entry Inspections Provide Consumers Limited Protection Against Unsafe Imports

FDA's reliance on inspecting imported foods at the U.S. port of entry provides weak assurance that the foods it allows to enter the United States are safe. According to the United Nation's Food and Agriculture Organization, testing products at the port of entry involves a concentration of inspection resources on the imported product itself and is an attempt to compensate for a lack of knowledge about the processing, hygiene, and

sanitation practices of the producer. In addition, FDA's draft guidance on equivalency criteria states that, by itself, end-product inspection and testing at the port of entry cannot be relied upon to provide adequate protection because assurance that food will not present unacceptable risks requires effective processing controls that are periodically inspected and verified by a regulatory authority.

Similarly, a 1991 report by the Advisory Committee on the Food and Drug Administration called point-of-entry inspections an anachronism.[3] The process of inspecting a final product to determine if it conforms to standards and of rejecting those that do not has been "totally discredited," according to the committee, as a means of ensuring manufacturing quality or regulatory compliance for domestic products.

Likewise, in 1994, we reported that reliance on end-product testing was an ineffective, resource-intensive, and statistically invalid approach to ensuring that imported foods are not contaminated with unsafe levels of chemicals.[4] We recommended that the Congress change the federal government's role in ensuring food safety by moving away from end-product testing to an approach preventing contamination from occurring, such as the use of HACCP in production processes. In addition, we suggested the Congress consider requiring that all imported foods be produced under equivalent food safety systems. HACCP is now required for some products, such as seafood, and the Congress is considering legislation to provide FDA with equivalency authority.

The capabilities of FDA's inspection approach to protect consumers from unsafe products has been further called into question by the agency's inability to keep pace with rising import levels. Between 1992 and 1997, the number of imported food entries more than doubled, from 1.1 million to 2.7 million. As workloads increased, resources devoted to inspecting imported foods declined by 22 percent, from 328 staff years for inspectors in 1992 to 257 staff years for inspectors in 1997; thus, the average number of annual food shipments each inspector was responsible for increased from about 3,350 to about 10,500. As a result of these and other factors, FDA's inspection coverage of imported food entries has fallen from an estimated 8 percent of food entries in fiscal year 1992 to 1.7 percent in fiscal year 1997. Of the 2.7 million total food entries in 1997, 56 percent

[3]Final Report of the Advisory Committee on the Food and Drug Administration, Advisory Committee on the Food and Drug Administration, U.S. Department of Health and Human Services, May 1991.

[4]Food Safety: Changes Needed to Minimize Unsafe Chemicals in Food (GAO/RCED-94-192, Sept. 26, 1994).

were released after FDA's automated screening system reviewed the import information, 42.3 percent were released after an inspector reviewed electronic information or import documents, and the remaining 1.7 percent were held for inspection. Of the 1.7 percent held for inspection (46,295 entries), FDA conducted laboratory analyses on 16,048 entries, or 0.6 percent of the total number of food entries. (See table 2.1.)

**Table 2.1: Disposition of Import Entries That Required FDA's Review, Fiscal Year 1997**

| Disposition | Number of entries | Percentage |
|---|---|---|
| Released automatically by Customs/FDA electronic screening | 1,519,233 | 56.0 |
| Released after FDA electronic or paperwork review | 1,145,355 | 42.3 |
| FDA inspections conducted | 46,295 | 1.7 |
| **Total food entries requiring FDA's review** | **2,710,883** | **100.0** |

Source: FDA.

In contrast to the growing demands placed on FDA's inspection resources, FSIS' import inspectors have a more manageable and stable inspection burden. The number of import entries per FSIS inspector rose from about 1,236 in calendar year 1992 to about 1,645 in 1997. In addition to visually checking every shipment, FSIS performed more intensive inspections on about 20.2 percent of the 118,000 entries in 1997, somewhat less than its rate of 26.9 percent in 1992. FSIS also visited 30 countries and conducted 336 foreign plant inspections in 1997 as part of its ongoing equivalency reviews.

## Conclusions

Given its lack of authority to require equivalency in foreign food safety systems, FDA relies primarily on port-of-entry inspections and tests to ensure the safety of imported foods. Because such port-of-entry inspection and testing has been widely discredited as an effective means for ensuring safety, FDA cannot realistically ensure that unsafe foods are kept out of U.S. commerce. Even if FDA could inspect more shipments at the ports of entry than it currently does, such an approach would still lack assurance that imported foods are picked, processed, and packed under sanitary conditions. An equivalency requirement would allow FDA to shift the primary burden of ensuring safety to the exporting country while achieving better assurance that food production and processing is safe and sanitary.

## Recommendation to the Congress

To strengthen FDA's ability to ensure the safety of imported foods, we recommend that the Congress require all food eligible for importation to the United States, not just meat and poultry, be produced under equivalent food safety systems.

## Agency Comments and Our Response

In commenting on a draft of this report, FDA agreed that it needs equivalency authority to control the safety of imported foods, but it did not agree that equivalence should be a requirement for the entry of imported foods. FDA believes the authority should be discretionary, not mandatory, so that equivalency could be applied where it is most appropriate without disrupting trade. We believe that equivalency should be mandatory for all imported foods and could be implemented in a manner that would not unnecessarily or unfairly disrupt trade. Mandatory authority to require equivalency would address weaknesses in FDA's port-of-entry inspection approach, enable FDA to leverage its staff resources by sharing the responsibility for food safety with the exporting countries, and compel FDA to take a proactive approach in preventing food safety problems instead of requiring equivalency after problems are identified. The Congress could provide reasonable time frames that would allow equivalency to be implemented over a number of years.

FDA and CDC provided technical comments that we incorporated where appropriate.

# Agencies Have Not Effectively Targeted Their Resources on Imported Foods Posing Greater Risks

FSIS and FDA are not deploying their inspection resources to maximum advantage. With respect to FSIS, it is misdirecting some of its resources by targeting its inspections on the basis of all past violations—most of which are less concerned with food safety, such as missing shipping labels—rather than by focusing on violations directly related to food safety, such as contamination and decomposition. As a result, FSIS' resources are not being focused on imported foods posing the greater safety risk.

With respect to FDA, its system for identifying shipments for inspection is hampered by work plans that do not set clear priorities for inspectors in making selection decisions, a failure to make relevant health risk data readily available to its inspectors to help them select shipments to inspect, and a failure to ensure that importer-provided information on incoming shipments is accurate. Nationwide, FDA also cannot be assured that its limited resources are consistently targeting shipments posing the greater health risks.

## FSIS Does Not Use Laboratory Results to Focus Its Inspections on Shipments Posing Food Safety Risks

FSIS' Automated Import Information System (AIIS) targets shipments for more intensive inspections and testing mainly on the basis of the violation history associated with the foreign firm producing the imported product. This overall violation history may be misleading, however, because AIIS treats all violations equally, except for transportation damage, in determining how much inspection attention will be provided to an importing firm's products.[1] As a result, violations not usually posing a direct health risk to consumers—such as a missing shipping label, incorrect weight, and misidentified product—could trigger a requirement for the agency to inspect every shipment from a foreign firm until the firm reestablished a good track record. In 1996, about 86 percent of the refused shipments, excluding those refused for transportation damage, were not directly related to health risks.[2] These violations triggered a series of inspections on subsequent shipments of the same product from the same exporting firm until at least 10 consecutive shipments were found to be in compliance. When limited resources are targeted in this fashion, fewer resources are available for products posing the greater health risk.

[1]Violations resulting from transportation damage do not trigger an automatic requirement for further inspections because they are not attributed to the exporting firm.

[2]Refusals with direct health risks include excessive residues; microbiological contamination; unsound condition, such as visual deterioration or odor; and defects caused by disease.

FSIS stores the test results associated with previous inspections of imported foods—data that would help identify shipments with the highest health risks—in AIIS, its automated screening system. However, the system does not use this information to identify patterns of violations, such as firms or countries with repeated problems, that are directly related to food safety. FSIS could further improve its automated screening system if it developed information on patterns of violations, which would allow it to determine whether Salmonella contamination, for example, was a recurrent problem in a particular country or exported product and increase its inspection frequencies for such shipments. In addition, FSIS could work with the exporting country to determine the extent of the problem and to take actions to correct it.

## Several Key Problems Weaken FDA's System for Identifying Shipments to Target for Inspections

FDA's system for identifying shipments that should be targeted for inspection is undermined by problems in three key areas. First, FDA's annual work plan, which contains the number of inspections and tests each FDA district is to conduct, is not realistic. FDA inspectors attempt to use these numbers to guide their decisions on which products to inspect and test. Second, FDA's inspectors cannot readily obtain available health risk data that would help them choose the shipments likely to pose health risks. Third, FDA does not act to ensure that importer-provided information, which its screening system relies on to identify a shipment's contents, is correct. As a result of these problems, FDA's inspectors at ports of entry, working under significant time pressures to move shipments quickly into domestic commerce, make subjective decisions that may not target the riskiest shipments.

### FDA's Annual Work Plan Is Not Useful in Making Selection Decisions in District Offices

FDA's annual work plan sets the number of activities, such as the number of inspections and tests, each FDA district is to conduct for the 10 specific food programs that cover imports. These programs, such as seafood, imported low-acid canned food, or imported cheese, are consolidated under the four major project areas related to food safety—Foodborne Biological Hazards, Pesticides and Chemical Contaminants, Molecular Biology and Natural Toxins, and Food Color and Additives. For example, for FDA's Seattle District, the fiscal year 1997 work plan called for 165 inspections and 583 laboratory tests of imported seafood products. For imported seafood products nationwide, the work plan called for 2,500 inspections and 9,432 laboratory tests.

Each day, FDA inspectors must decide which shipments of food imports to inspect. The inspectors at the locations we visited typically attempt to select shipments on the basis of the work plan's targets. However, regional and district FDA officials told us that the numbers for inspections and tests contained in the work plan were not realistic because they did not take into account the time required to investigate emergencies and consumer complaints, which invariably occur. In 1997, for example, FDA spent 6,274 hours investigating the outbreaks associated with Guatemalan raspberries—time not accounted for in the work plan. As a result, FDA inspectors are not able to complete the work plan and compliance program activities and therefore rely on their judgment when determining what to inspect and test.

Meeting the annual work plan targets is a problem nationwide. Table 3.1 shows the degree to which FDA inspectors fell short of completing the number of planned inspections and tests for fiscal years 1996 and 1997 in the four areas related to food safety. For example, in fiscal year 1997, 23,000 inspections and 19,432 laboratory analyses were planned for foodborne biological hazards. However, FDA was only able to conduct 11,587 inspections and 12,874 analyses. As a result, the inspections and tests conducted varied significantly among project areas.

**Table 3.1: Planned and Completed FDA Import Inspection Activities, Fiscal Years 1996 and 1997**

| | Fiscal year 1996 | | | Fiscal year 1997 | | |
|---|---|---|---|---|---|---|
| Inspection activities[a] | Planned | Completed | Percent completed | Planned | Completed | Percent completed |
| **Foodborne Biological Hazards Project** | | | | | | |
| Foreign plant inspections | 90 | 9 | 7 | 37 | 29 | 67 |
| Import inspections conducted | 26,250 | 11,983 | 46 | 23,000 | 11,587 | 50 |
| Import samples analyzed | 19,432 | 13,710 | 71 | 19,432 | 12,874 | 66 |
| **Pesticides and Chemicals Contaminants Project** | | | | | | |
| Import samples analyzed | 8,794 | 6,228 | 71 | 8,294 | 5,675 | 68 |
| **Molecular Biology and Natural Toxins Project** | | | | | | |
| Import samples analyzed | 555 | 386 | 70 | 1,380 | 564 | 41 |
| **Food and Color Additives Project** | | | | | | |
| Import samples analyzed | 2,395 | 1,816 | 76 | 2,353 | 1,816 | 77 |

[a]A fifth area related to food safety, Technical Assistance, did not have planned inspection or testing activities for fiscal year 1997.

Source: FDA.

Inspectors use their own judgment in making decisions on inspections and laboratory analyses. We found that this judgment is highly subjective. For example, one inspector told us he believed one country did not have sanitary facilities and therefore assumed that all food products imported from that country are contaminated with filth. During our visit, he routinely selected samples of food from that country for filth tests, although the laboratory staff told us filth tests were not a high priority and, in fact, they sometimes did not conduct the tests because they already had a backlog of tests to conduct. Therefore, to the extent that the laboratory analyses were not conducted, the inspector wasted time collecting the samples.

## FDA Inspectors Cannot Readily Access Relevant Health Risk Information

FDA retains information in a number of databases on the health risks presented by certain foods from a particular exporting country and/or an exporting company. These data include the results of the laboratory tests that FDA conducts on imported foods and lists of foreign products to be

detained because they have a history of violations. In addition, FDA maintains lists of foreign plants that have registered with FDA their processes for producing low-acid canned foods and acidified canned foods. If these products have not been produced with a registered process, they are banned from entry.

With respect to laboratory tests, FDA has not integrated its laboratory database with its OASIS system, the system used to screen imports. Therefore, inspectors do not have available the results of prior laboratory tests when considering possible actions to inspect imported products. FDA plans to integrate the laboratory database with OASIS in fiscal year 1998 to make better use of staff resources in targeting defective and dangerous products. Furthermore, FDA inspectors do not have ready access to some useful data in OASIS when deciding which products to inspect. For example, inspectors can obtain information on prior violations by foreign plants or countries, but the process for doing so can be cumbersome and time-consuming. To obtain these data, inspectors have to close their OASIS database and open another database. We observed two inspectors going through this process—which took 3 to 10 minutes per shipment—at a time when one of these inspectors had to process as many as 200 shipments per day. Not all inspectors will change databases to look for this information. Instead, inspectors told us they often rely on their memory of the information in the database or notes. Similarly, to obtain information on foreign registrations, inspectors have to close OASIS and open the registration database. Again, some inspectors find the process time-consuming and accordingly often choose to rely on memory. Because inspectors have these difficulties in obtaining needed data on health-related risks and are under time pressures, they may make decisions to select samples on the basis of incomplete information.

FDA has recognized the problems associated with difficulties in obtaining health risk data. In a 1993 hearing on food imports, FDA's Director of the New York District Office stated that FDA tries to funnel its limited inspection resources towards the imports that pose the greater risk and have the greatest likelihood of being adulterated or misbranded.[3] He added that including information, such as the data discussed above, in OASIS would be very useful in helping FDA inspectors make daily decisions on which import shipments to inspect and test. Two years later, in a 1995 FDA internal review, FDA's automated system was criticized for not providing inspectors with a means for accessing other FDA databases, such as the FDA

[3]FDA's Regulation of Food Imports, Hearings before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives, June 16, 1993 (Serial no. 103-28).

Import Alert Retrieval System database.[4] The review said that such access would improve inspectors' efficiency in identifying shipments that need to be detained. According to FDA officials, the agency received money to make these improvements in the screening system in fiscal year 1998 and will begin integrating the databases (Laboratory Management System, FDA Import Alert Retrieval System, and Low-Acid Canned Food database) with OASIS this year.

## FDA Does Not Ensure the Accuracy of Importer-Provided Shipping Information

To facilitate the entry of imported foods under FDA's jurisdiction, importers enter data electronically on incoming shipments into OASIS after demonstrating competency with the system. Electronic filers that do not routinely have to provide actual shipping documents to FDA are called paperless filers. FDA inspectors rely on this electronic information in making their selections for inspections and laboratory analyses.

To ensure the accuracy of this information, FDA periodically requests the paperless filers to provide shipping documents on a sample of entries, and FDA then compares these documents against the electronically provided information for errors. Errors can include incorrectly identifying a product as exempt from FDA's regulation, entering the wrong FDA product code, or listing the wrong country of origin. Electronic filers exceeding the allowed 10-percent error rate may be removed from paperless status.

However, FDA records show that no corrective actions have been taken to remove even the most error-prone paperless filers from paperless status. According to a January 1998 FDA survey, 306, or 14.5 percent, of the 2,114 paperless filers audited had errors rates of 10 percent or greater, but none of these filers were removed from paperless status. For example, the paperless filer error rates for the New York District were 10 percent or more in 133 of the 251 audits conducted, but no electronic filers were removed from paperless status. Similarly, as of November 1997, none of the 16 electronic filers at the Miami field location with error rates of 10 percent or greater were removed from paperless filer status. In fact, the filer with the highest error rate—20 percent—has remained in paperless status without any follow-up audits since April 1996.

FDA officials at three locations we visited believed the error rates were high primarily because the product codes are complex for the importers to learn and use. In one case, for example, we found that an importer had

[4]Review of the Import Support and Information System (ISIS), FDA System Design Review Committee, June 21, 1995.

incorrectly entered the code for spaghetti, a form of pasta, instead of cappelletti, another form of pasta.

The failure to take corrective actions to remove filers from paperless status, as found in the January 1998 FDA survey, could affect decisions on selections for investigating food safety risks. Importers aware of FDA's inaction could evade FDA's inspections by incorrectly describing the contents of a shipment. For example, an FDA inspector at one port of entry said that, while most errors are accidental, he has encountered problems with importers who appeared to deliberately avoid FDA's inspections by using the wrong product code for swordfish, which is automatically held until the importer provides laboratory test results demonstrating that the product complies with U.S. standards. By entering a code for another type of fish, the importers hope that the on-screen review will not detect a discrepancy and the shipment will not be selected for inspection. Following an FDA investigation in 1993, an importer was prosecuted for deliberately misrepresenting imported foods. The importer was found guilty on 138 counts, mostly of misrepresenting the source of seafood in an attempt to avoid FDA's automatic detention.

FDA inspectors told us that when they encounter entry errors during evaluations, they inform the importer of the errors and offer help on entering the correct information. Even when these inspectors occasionally find incorrect entries that appear to be deliberate misrepresentations, they work with the importer to correct the entry problems and, in most cases, do not investigate the suspect filers further. They said that they view their role as teachers, not investigators.

## Conclusions

Given the small fraction of import entries that FDA and FSIS can inspect, the agencies need to make the best use of all the information available to help select the right shipments to review. Both agencies have information to identify relationships between foodborne pathogens and specific food products, which would be a good indicator of the food safety risks associated with import shipments, but neither agency has used the information effectively or efficiently. As a result, FSIS is using its limited inspection resources to conduct inspections and tests triggered by violations that may not be related to safety. In addition, FDA's limited inspection resources may not be targeted to the riskiest shipments for a number of reasons. Reliance by FDA field offices on numerical inspection targets that are not closely linked to the risk-based priorities identified in the compliance programs impedes inspectors' effectiveness in selecting

imported food shipments for inspections and tests, key information on firms and products is not easily accessible and thus may be overlooked, and a shipment's contents may be misrepresented.

## Recommendations

To help FSIS better identify the risks associated with specific foods and thereby further improve the Automated Import Information System's usefulness in selecting high-risk products to inspect, we recommend that the Secretary of Agriculture direct the Administrator, FSIS, to modify the Automated Import Information System so that the system can identify patterns between laboratory test results and specific foods, foreign firms, and exporting countries.

To provide more accurate and accessible information to FDA and thus minimize inconsistencies in inspectors' subjective decisions, we recommend that the Secretary of Health and Human Services direct the Commissioner, FDA, to

- clarify and emphasize the guidance inspectors should use when making decisions on which shipments to inspect and test;
- modify the Operational and Administrative System for Import Support system so that (1) it automatically reviews the Import Alert and Low-Acid Canned Food databases and recommends appropriate actions to inspectors and (2) inspectors can consider previous laboratory test results, which are stored in the Laboratory Management System database, in choosing shipments for inspections and tests; and
- ensure that the field offices are taking appropriate corrective action, when warranted, against importers that repeatedly enter incorrect shipping information into the Operational and Administrative System for Import Support database.

## Agency Comments and Our Response

In commenting on a draft of this report, FSIS agreed with our recommendation. The agency stated that it will be evaluating its port-of-entry inspection procedures and its automated systems, and will consider our recommendation during this evaluation.

FDA agreed with our recommendation to link three databases— the Import Alert database, the Low-Acid Canned Food database, and the laboratory database— to its automated import screening system, the Operational and Administrative System for Import Support (OASIS), for use by inspectors when choosing shipments for inspections and tests. FDA stated that the

automatic review of the Import Alert database and the Low-Acid Canned Food database is under development. The agency stated further that it is developing software that will allow inspectors to review previous laboratory test results through OASIS. FDA expects all these improvements will be completed and operating by the end of fiscal year 1998. FDA also agreed with our recommendation to ensure that district offices are taking appropriate corrective action against importers that repeatedly enter incorrect shipping information in OASIS.

FDA also generally agreed with the report's recommendation regarding its import screening system. FDA described planned actions to improve the efficiency of its automated import screening system and to take appropriate corrective actions in its electronic filer program. FDA did not agree with our characterization of its system for communicating inspection priorities to its inspectors or the associated recommendation in our draft report to improve this system. Specifically, FDA said that its annual work plan and compliance programs provide sufficient guidance to inspectors to help them make decisions about which shipments to inspect. We continue to believe that the priority-setting guidance provided to inspectors, even as it is described in FDA's comments, is confusing and inconsistent. As a result, inspectors may not be selecting shipments to inspect that pose the greater food safety risk to consumers. We have, however, modified our recommendation to better reflect the nature of the problem and to give FDA more flexibility to address it.

We also incorporated technical comments from FSIS and FDA where appropriate.

# Weaknesses in Controls Over Food Imports Enable Entry of Unsafe Products

In addition to the problems associated with its automated system for selecting food shipments for inspection, FDA has several weaknesses in its controls over imported products that have enabled some importers or their representatives to sell unsafe foods in the United States. First, FDA's system for automatically detaining suspicious products pending testing to confirm their safety may be easily subverted because FDA does not maintain control over the testing process. By allowing importers to choose their own laboratories to select samples and perform tests, FDA opens itself to the possibility of approving the entry of unsafe products on the basis of falsified test results. Second, FDA does not maintain control over products before releasing them into U.S. commerce. As a result, some importers have sent products to grocery stores before FDA has approved their release, and others have not returned and properly disposed of products that FDA has conditionally released but called back after testing showed them to be contaminated. In this connection, importers that violate FDA's and Customs' controls are frequently not penalized to deter such actions.

## Some Importers Introduce Potentially Unsafe Foods Into U.S. Commerce

FDA's system for controlling the importation of unsafe foods has a history of circumvention by certain unscrupulous importers. For example, we reported in 1992 that about 10 importers had repeatedly distributed pesticide-adulterated shipments in disregard of FDA orders; in total, these importers distributed 73 shipments known to have been adulterated.[1] In all, about a third of the adulterated shipments that were identified reached the market.

A 1997 investigation by Customs confirmed that importers continue to evade import controls. Recognizing problems in controlling imported shipments, Customs launched a special operation at the port of San Francisco in 1997, known as Operation Bad Apple. Customs officials told us that of the shipments FDA ordered returned to Customs for destruction or reexport, 40 percent were never redelivered, and for half of those that were redelivered, other products had been substituted for the original contaminated products. Thus, 70 percent of the shipments ordered returned because they were unsafe presumably entered into commerce, contrary to FDA's orders. FDA and Customs officials developed a joint task force in November 1997, called CLEAN (Closing Loopholes to Ensure Acceptable Nutrition), to address the problems identified in Operation Bad Apple.

[1]Pesticides: Adulterated Imported Foods Are Reaching U.S. Grocery Shelves (GAO/RCED-92-205, Sept. 24, 1992).

## FDA's System for Detaining Questionable Food Shipments Can Be Easily Evaded

FDA's automatic detention system is subject to evasion by unscrupulous importers. FDA automatically detains imported foods that, on the basis of prior violations, have a high potential for being contaminated. In these cases, rather than destroying or exporting the products, importers have the option of presenting the results of a private laboratory test to show that the detained products meet U.S. standards. However, FDA generally does not control the selection of the samples tested and cannot restrict the choice of the laboratories used to conduct the tests. According to FDA, the agency lacks explicit authority to require the use of specific laboratories importers can use. As such, importers can choose the laboratory, which selects the sample and conducts the analysis. While FDA expects these laboratories to comply with the agency's written guidance for collecting samples and performing tests, the agency generally does not control the selection of samples or witness laboratory analyses. This approach exposes FDA to the possibility that it will accept falsified test results or results from tests using improperly selected samples as a basis for releasing products into domestic commerce.

In fiscal year 1997, FDA detained 7,874 import shipments automatically. While FDA does not keep specific records, FDA officials said most shipments detained automatically are released after importers present their private laboratory results.

Customs and FDA officials are concerned about monitoring the accuracy of private laboratories chosen by importers in selecting and analyzing samples of imported foods that are on automatic detention status. Some Customs inspectors voiced concerns that some unscrupulous importers, to ensure their products meet U.S. requirements, share shipments that have already been tested and proven to be in compliance for sampling purposes—a concept referred to as "banking." FDA inspectors were also concerned about the uncontrolled sampling and testing of imported foods under FDA's jurisdiction. To verify the accuracy of tests performed by private laboratories, FDA laboratories occasionally select samples from the same shipments and perform identical tests. Officials at two field locations we visited told us that the FDA laboratories, in performing these tests, discovered violations that the private laboratory tests did not identify.

FDA is further increasing its reliance on the use of private laboratories for analyzing imported foods normally tested by FDA laboratories. Specifically, according to FDA's Procedures Manual, the increased scrutiny of import commodities and limitations on FDA resources are likely; therefore, FDA will expedite its enforcement efforts by using scientifically sound data

provided by private laboratories to determine if products should be allowed entry. In this regard, FDA is testing a new process to allow seafood importers the option of having a private laboratory select and analyze seafood samples for FDA's routine review of imported seafood. Under a pilot program at the Los Angeles District Office, if FDA selects the shipment for laboratory analysis, it will identify the product lots and sample sizes, and specify the type of analysis to be conducted, and the importer will choose the laboratory that will collect the samples and conduct the analysis.

While FDA is generally increasing its reliance on the test results of samples selected and analyzed by private laboratories, it has recognized that the practice of allowing importers to select their own product samples for testing is questionable. In this regard, importers of Guatemalan snow peas must now use third-party companies to select the laboratory samples because FDA test results have differed historically from the results of the importers' selected laboratory. In response to an internal report on the use of private laboratories, FDA approved new guidelines in March 1998 on the review of test results prepared by private laboratories. According to the guidelines, sample selection and laboratory analysis should be conducted by an independent party.[2]

## FDA and Customs Maintain Insufficient Controls Over Known and Potentially Unsafe Products

Imported foods under FDA's jurisdiction, including foods that are of concern or are proven to be adulterated, are sold in domestic commerce before FDA has released them. This occurs because (1) importers either sell imported products before FDA has had a chance to inspect them or do not properly dispose of products that FDA has found to violate U.S. standards and (2) penalties against importers have not effectively deterred such actions.

### Imported Foods Not Controlled Prior to Release

FDA-regulated foods are not controlled prior to inspection and release. Under the Federal Food, Drug, and Cosmetics Act, importers of FDA-regulated foods generally retain possession of the imported food shipments until FDA releases them and must make the shipments available for FDA's inspection if requested. In some cases, particularly for perishable items, FDA will select samples for testing and allow the shipments to continue in domestic transit—on the condition that the shipment be returned if FDA finds the shipment to be adulterated and refuses entry. If

[2]Private Laboratory Grassroots Meetings, 1996, A Final Report and Action Plan, sponsored by Division of Field Science, Office of Regional Operations, Office of Regulatory Affairs, U.S. Food and Drug Administration (undated).

importers of foods that FDA has refused entry cannot recondition the products to bring them into compliance with requirements, they have 90 days to (1) destroy the products or (2) reexport the products. The Customs Service is required to witness or attest to the fact that the refused shipment was disposed of properly, but FDA does not stamp "refused entry" on shipments found to violate safety standards, and it generally does not notify the destination country when such shipments are being reexported. According to FDA officials, FDA does not stamp refused shipments because it lacks the statutory authority to do so.

At the ports we visited, imported food shipments under FDA's jurisdiction often entered U.S. commerce before being delivered to FDA for inspection or were not properly disposed of when refused entry. For example, in Operation Bad Apple, which lasted 3 weeks, Customs officials identified 23 weaknesses in the controls over FDA-regulated imported foods. In this operation, Customs officials cited the following examples to illustrate these weaknesses.

- Substituting cargo that was en route to a holding area. On a shipment of frozen shrimp, Customs alleged that the importer removed a portion of the shipment that had thawed during transport before making the shipment available for FDA's inspection. If the thawed shrimp had not been removed, FDA would have refused entry for the entire shipment because the thawing indicated that the proper temperature controls were not maintained during transport, and thus the entire shipment may be contaminated.
- Not meeting FDA's request that the shipment be redelivered to Customs for disposition. According to Customs, about 40 percent of the imported foods released conditionally by FDA were found to violate U.S. standards during Operation Bad Apple, but were never redelivered to Customs. That is, they presumably entered into commerce and were not destroyed or reexported as required. Even when the shipments found to violate U.S. standards were redelivered, Customs officials said other products had been substituted for the violative products in about 50 percent of the shipments before redelivery. We found similar results for the nondelivery of shipments in 1992, when we reported that 60 percent of the perishable foods and 38 percent of the nonperishable foods that FDA found adulterated with illegal pesticides were released into U.S. markets and not returned to Customs for destruction or reexport.[3]

[3]Pesticides: Adulterated Imported Foods Are Reaching U.S. Grocery Shelves (GAO/RCED-92-205, Sept. 24, 1992).

Our work suggests that the evasion of imported food controls appears not to be isolated to a few importers at one port of entry. As part of Operation Bad Apple, Customs officials monitored cargo transferred from the vessel to the holding area, FDA sampled and tested the products, and did not give any conditional releases. Overall, while about 25 percent of the importers were viewed as suspicious, Customs anticipated that only 1 percent of these would be found to be evading controls. However, according to Customs officials, all of the "suspicious" importers were found to be out of compliance, and 25 percent of the other importers were also out of compliance. FDA and Customs officials told us that substitution of imported products or failure to redeliver products for inspection has been occurring at other ports.

Some Customs officials said they lack the resources needed to witness and thus ensure proper disposition of violative products refused entry. Accordingly, they generally verify only the number of containers—e.g., three containers were refused entry and three containers were reexported. Similarly, they frequently do not witness the destruction of the violative product and instead rely on a receipt from the landfill where it was disposed of. According to Customs officials, their regulations allow them to accept a receipt in lieu of witnessing the shipment's destruction.

## Penalties Do Not Effectively Deter Illegal Distribution of Imported Foods

In addition to FDA's difficulties in controlling imported foods prior to releasing them into domestic commerce, FDA's economic deterrent to noncompliance with its requirements is inadequate. Lacking the authority to fine importers who distribute adulterated food shipments or fail to retain shipments for inspection, FDA relies on a bond agreement between Customs and the importer, for those shipments valued at more than $1,250 as a way to achieve compliance. Under the bond agreement, importers are required to pay all duties, taxes, and charges; to retain control over the shipment; and to properly dispose of the shipment if it is found to be unacceptable. The bond amount is based on the importer's declared value of the imported shipment, and penalties may be assessed at up to three times the value of the bond. However, we reported in 1992 that sometimes even assessed damages of three times the value of the shipment may not deter the illegal sale of imported goods because the value of the goods on the market is greater than the tripled bond amount.[4]

[4]Pesticides: Adulterated Imported Foods Are Reaching U.S. Grocery Shelves (GAO/RCED-92-205, Sept. 24, 1992).

Customs often does not collect full damages from importers that fail to comply with FDA's requirements. For example, in fiscal year 1997, Customs in Miami assessed and collected damages for about only 25 percent of the identified cases involving the improper distribution of food products for the previous 12 months. Customs and FDA attributed the low figure to (1) lax controls in communicating information about refused shipments between Customs and FDA, (2) unclear guidance for handling the shipments by Customs officials, (3) a malfunction of the Customs computer system for storing case files, and (4) a halt in collections pending the resolution of a court case involving the collection of liquidated damages. Even when damages were assessed, they were generally reduced to about 2 percent of the original assessment. For example, in one case, the damages were $100,000, based on the declared value of the import shipment, but Customs reduced the amount to $100. According to Customs headquarters officials, any reduction in damages must be in accordance with Customs guidelines, and both Customs and FDA must agree to reduce the damages when they involve the failure to redeliver shipments that were refused entry because they violated product purity and labeling requirements.

FDA's lack of authority to impose civil penalties, and its reliance on the importer's bond agreement with Customs, have left the agency without an adequate economic deterrent to the distribution of adulterated imports. We reported in 1992 that in fiscal years 1988 through 1990, importers at four locations had distributed 336 (34 percent) of the 989 shipments found to be adulterated with pesticides. Although this rate was lower than the rates of 50 percent and 45 percent that we found in 1979 and 1988, respectively, it indicated that adulterated imports continue to be distributed to American consumers. We recommended in that report and others that FDA be given authority to issue civil penalties to violators.[5] While FDA submitted legislative proposals seeking civil penalty authority in 1993, the Congress did not pass the legislation.

## Conclusions

FDA's lack of controls over shipments selected for inspection leaves its inspection system vulnerable to unscrupulous importers. Without sufficient controls, some importers (1) may falsify laboratory test results on suspect foods to obtain an FDA release, (2) sell potentially unsafe imported foods before FDA can inspect them, and (3) sell imported foods that FDA found violative and barred from entry. Furthermore, importers'

[5]Pesticides: Adulterated Imported Foods Are Reaching U.S. Grocery Shelves (GAO/RCED-92-205, Sept. 24, 1992) and Pesticides: Status of FDA's Efforts to Improve Import Monitoring and Enforcement (GAO/T-RCED-93-55, June 16, 1993).

bonds are an ineffective deterrent against attempts to market contaminated products. As a result, FDA has little assurance that contaminated shipments are kept off U.S. grocery shelves, and it appears likely that certain importers will continue to circumvent controls over unsafe food products with impunity.

We are making no recommendations at this time because, as agreed with the Chairman, Permanent Subcommittee on Investigations, Senate Committee on Governmental Affairs, we are continuing work to identify specific actions needed to strengthen the controls over imported foods.

## Agency Comments and Our Response

In commenting on a draft of this report, FDA agreed that it needs to exercise control over the practice of permitting importers to select a private laboratory to test shipments automatically detained due to a history of violations. FDA stated that it is issuing new instructions to its district offices regarding the use of independent laboratories. However, FDA further noted that the agency lacks the explicit authority to require importers to use certain laboratories or to provide a list of accredited laboratories to importers.

Customs provided comments to correct or clarify information about its responsibilities and practices. Customs stated that it is impossible to physically inspect the destruction or export of every refused shipment and said it is more logical to target their resources to those shipments and suspected importers posing the greater risk for noncompliance. Customs said the extent of substitution is probably limited to certain products and a small number of importers. However, we found that the substitution of products for inspection has occurred at ports of entry other than in the San Francisco example we provided. FDA and Customs officials have also acknowledged that substitution is occurring at other ports, although neither we nor they know the full extent of its occurrence. Finally, Customs disagreed with our statement that violators are seldom punished effectively and the damages against violators do not represent an effective deterrent; Customs stated that the current damages assessed against violators are adequate in most cases. However, on the basis of our work extending back to 1992,[6] we have found that liquidated damages do not appear to be an effective deterrent. In 1992, for example, we reported that the U.S. market value for selected products always exceeded the declared import value of the products we surveyed; thus, importers could and, in

[6]Pesticides: Adulterated Imported Foods Are Reaching U.S. Grocery Shelves (GAO/RCED-92-205, Sept. 24, 1992).

some cases, did profit from distributing refused products even after paying damages to Customs. The example we mention in this report, in which Customs assessed damages of $100 against an importer with a shipment having a declared value of $100,000, shows that the collected damages may be far less than the declared value of the shipment. We added information in the report to explain that, according to Customs officials in Washington, D.C., any decision to mitigate damages against importers for failure to redeliver shipments that were refused entry because of product purity or labeling problems requires agreement by both Customs and FDA.

# Selected Outbreaks of Foodborne Illnesses Linked to Imported Foods, 1983-97

The Centers for Disease Control and Prevention (CDC) has linked several significant foodborne outbreaks to imported foods (see table I.1). According to CDC officials, the agency's investigation of recent outbreaks related to imported foods may indicate that food safety problems are more widespread than previously believed. For example, in the spring of 1996, multiple health departments reported cases of illness from Cyclospora, a pathogen that had not previously been proven to be transmitted by food. CDC and other public health officials were able to link illnesses from Cyclospora with raspberries from Guatemala; more than 1,000 people in various locations in the United States and Canada were affected. In 1997, additional illnesses from Cyclospora, also affecting more than 1,000 people, were also linked with raspberries from Guatemala. CDC and state and local health departments are not able to identify all cases of foodborne illness, however, because such illnesses are underreported and are difficult to trace to their source.

**Table I.1: Information on Selected Outbreaks of Foodborne Illness, 1983-97**

| Year of outbreak | Number of illnesses | Pathogen | Source | | Location |
|---|---|---|---|---|---|
| | | | Implicated food | Country of origin | |
| 1997 | 1,012 | Cyclospora | Raspberries | Guatemala | 17 states; Washington, D.C.; and Canada |
| 1997 | 270 | Hepatitis A | Frozen strawberries | Mexico (implicated) | 5 states |
| 1996 | 9<br>14 | Salmonella typhi,<br>hepatitis A | Homemade cheese | Mexico | Florida |
| 1996 | 1,465 | Cyclospora | Raspberries | Guatemala | 20 states; Washington, D.C.; and Canada |
| 1995 | 242 | Salmonella Stanley | Alfalfa sprouts | Seeds from Netherlands | 17 states and Finland |
| 1994 | 27 | Salmonella Agona phage type 15 | Kosher peanut-flavored savory snack | Israel | North America and United Kingdom |
| 1994 | 171 | Shigella flexneri, type 6 (SF6) | Green onions | Mexico (suspected) | Illinois |
| 1994 | 12 | Unidentified Norwalk-like agent | Raw limpets (molluscan shellfish) | Portugal | Massachusetts and Rhode Island |
| 1992 | 74 | Histamine poisoning (Scombroid) | “Fresh” tuna | Ecuador | Eastern seaboard |
| 1991 | 4 | Vibrio cholerae | Coconut milk in pudding | Thailand | Maryland |
| 1991 | 12 | Vibrio cholerae | Crab meat | Ecuador | New Jersey and New York |
| 1991 | 400 | Salmonella Poona | Cantaloupes | Mexico | 23 states and Canada |
| 1990 | 1,400 | E. coli O153:H45 | Raw scallops | South America | 2 U.S. cruise ships |
| 1989 | 99 | Staphylococcal toxin—food poisoning | Canned mushrooms | Peoples Republic of China | 3 states |
| 1989 | 25,000 | Salmonella Chester | Cantaloupes | Mexico | 30 states |
| 1988 | 202 | Hepatitis A | Lettuce | Mexico (suspected) | Kentucky |
| 1983 | 169 | E. coli O27:H20 | Semisoft cheese | France | 4 states and Washington, D.C. |

Source: CDC.

# Countries Certified by Food Safety and Inspection Service to Export Meat and Poultry to the United States

As of January 1, 1998, the Food Safety and Inspection Service (FSIS) had determined that the countries listed below have food inspection systems equivalent to the United States' and are eligible to export meat and/or poultry products to this country. Since January 1, 1998, FSIS has suspended Paraguay from exporting meat and poultry products to the United States because its inspection system was not adequate to prevent contamination on repeated shipments.

Argentina
Australia
Austria
Belgium
Brazil
Canada
Costa Rica
Croatia
Czech Republic
Denmark
Dominican Republic
Finland
France
Germany
Guatemala
Honduras
Hong Kong
Hungary
Iceland
Ireland
Israel
Italy
Japan
Mexico
Netherlands
New Zealand
Nicaragua
Northern Ireland
Paraguay[1]
Poland
Romania
Slovenia
Spain

[1]Suspended as of January 1, 1998.

Sweden
Switzerland
United Kingdom
Uruguay

Source: FSIS.

# Comments From the Food and Drug Administration

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR 3 1998

Mr. Robert A. Robinson
Director, Food and Agriculture Issues
General Accounting Office
441 G Street, N.W., Room 2T23
Washington, D.C. 20248

Dear Mr. Robinson:

Attached are the Food and Drug Administration's comments on the General Accounting Office draft report entitled, "FOOD SAFETY: Federal Efforts To Ensure Safety of Imported Foods Are Inconsistent And Unreliable, (GAO/RCED-98-103)."

Sincerely,

Diane E. Thompson
Associate Commissioner
For Legislative Affairs

Attachment

COMMENTS OF THE FOOD AND DRUG ADMINISTRATION ON THE GENERAL ACCOUNTING OFFICE DRAFT REPORT ENTITLED, FOOD SAFETY: Federal Efforts to Ensure Safety of Imported Foods Are Inconsistent And Unreliable GAO/RCED-98-103

Thank you for the opportunity to review the subject draft report. In general, we agree with the report, as the report raises a number of issues that need to be addressed, both by the Food and Drug Administration (FDA or Agency) and by the Congress. It is our hope that the report will provide an added impetus for resolving the issues it identifies. We strongly disagree, however, with the "Results in Brief" characterization of FDA's Workplan.

Specifically, the draft report has misinterpreted the purpose and function of FDA's Workplan. The Workplan is developed annually by Center Directors, the Office of Regional Operations, and the Office of financial Management. The plan reflects the allocation of field resources-based on a given year's established priorities. This tool is a guide for management in utilizing the field resources consistent with the established annual priorities. The Workplan is an implementing instrument for FDA's Program Management System (PMS) which incorporates all the Agency's activities into discrete, mutually exclusive programs, establishes their respective priorities, assigns the numbers of operations (e.g., wharf examinations, sample collections, and analyses) to be done, and allocates resources accordingly. The Workplan does not attempt to plan every operation that is performed by the field, nor does it provide guidance to enable inspectors to make decisions about which entries to examine or the admissibility of entries.

See comment 1.

The Compliance Programs, rather than the Workplan, provide guidance to inspectors making decisions about which entries to examine, whether an entry should be sampled and analyzed, and other relevant factors for determining an entry's compliance status. The Compliance Programs are the building blocks for the Workplan. Resources are distributed to the Compliance Programs through the Workplan, with higher-risk food programs given more resources. The risk factors have been incorporated into Operational and Administrative System for Import Support (OASIS), which automatically makes the initial decisions regarding entry admissibility. When there is a question as to which of two or more entries of equal priority to examine, inspectors refer to other guidance documents such as appropriate Compliance Programs, Import Alerts, the frequency at which a product has been examined, the country of origin, any available information about to the product, the importer, the shipper or the country of origin, and other relevant information.

The draft report characterizes the numbers of planned activities reflected in the Workplan as unrealistic, and links this alleged weakness with the difficulty inspectors have in deciding what to inspect and test. While FDA agrees that the planned number of operations most often is not achieved because inspectors may not be available to do routine import work if emergencies arise, the apparent discrepancy between planned and actual operations is not linked with individual decisions by inspectors at the import entry level. The Workplan is only a projection. The overall priorities established by the Workplan, however, remain the same for routine work, and inspectors are expected to make their decisions based on those priorities.

Moreover, there are a number of activities, such as recall and investigations of consumer complaints, for which time is allocated outside of the Workplan. In other words, the hours in these activities are considered separately from those contemplated in the Workplan. While FDA believes that the best approach is to plan for full utilization of its workforce, such planning, of course, includes consideration of the resources that might need to be directed to emergencies and consumer complaints. Emergencies are dealt with immediately, regardless of where or when they occur. Decisions are made after the fact about which category or Compliance Program will be tapped for the resources that were utilized.

AREAS OF AGREEMENT

NEED FOR STATUTORY AUTHORITY

See comment 2.

We agree that FDA needs additional authority for controlling the safety of imported foods. Legislation has been introduced in both the House of Representatives and the Senate to expand FDA authority to ensure the safety of imported food. The legislation applies to food safety systems of control. Before an action can be taken against an imported food product, the Secretary must determine that the product does not meet the U.S. food safety requirements or otherwise achieve the level of protection required. The legislation permits the Secretary to consider a refusal to allow necessary inspection, testing, or other relevant factors in determining whether imported food products meet U.S. food safety requirements or otherwise achieve the level of protection required. GAO's support of this legislation is welcomed.

UPDATES TO THE OPERATIONAL AND ADMINISTRATIVE SYSTEM FOR IMPORT SUPPORT (OASIS)

FDA currently is updating OASIS to incorporate automatic review of the Import Alert and Low Acid Canned Food (LACF) databases. The Agency also is incorporating access to the Laboratory Management System database into OASIS. Both will be completed by the end of FY1998. We agree with the General Accounting Office (GAO) that these enhancements will make the system more user friendly and reduce the amount of inspector time required to determine which entries to examine and/or sample.

THIRD PARTY SAMPLING

See comment 3.

In general, we agree with GAO that FDA needs to exercise control over the practice of permitting importers of articles subject to Detention Without Physical Examination (DWPE), which are identified on the Import Alert List, to select a laboratory to analyze their products and to certify such products do not violate the Federal Food, Drug, and Cosmetic Act (FFDCA or the Act.) To that end, FDA is issuing new instructions to the Districts regarding the use of independent laboratories. While it has been FDA's policy to accept only analyses done by well-qualified laboratories, and even then to verify the results, this policy is stated more explicitly in the new guidance. Nevertheless, the report should make it clear that FDA does not have explicit authority

to require importers to use certain laboratories, nor to provide a list of accredited laboratories to importers who may inquire. We do provide, however, the laboratory performance guidance used by the Agency upon request. This guidance should help importers select laboratories based on the qualifications of the analysts and how well the laboratories are equipped to do the particular analyses.

TAKE CORRECTIVE ACTION WHEN FILERS HAVE UNACCEPTABLY HIGH ERROR RATES

FDA is in agreement with GAO that corrective action should be taken against filers (importers and brokers) who continue to submit erroneous entry data to FDA. Since implementation of the automated electronic entry processing system, FDA has been working with the filers to help them learn the system in order to submit correct data consistently. We believe this has been an appropriate approach in light of the recent implementation and complexity of the system. To reduce filer problems in determining the correct product code to use for an entry, filers have been furnished a copy of FDA software that enables them to determine the correct product codes. As GAO is aware, FDA conducted two surveys in 1997 to determine how well filers were complying with the new electronic filing requirements. The surveys showed that the error rates were still unacceptably high overall, with some filers consistently exceeding the acceptable error rate of 10%. Consequently, on March 6, 1998 the Director of the Office of Regional Operations directed all District Directors to work with FDA's Division of Import Operations to identify filers who fail to meet the requirements and to determine what action should be taken by the Agency to improve compliance. Such action could include removing the error-prone filers from the paperless entry system by requiring that they submit both paper documentation and electronic data until they demonstrate their ability to meet the requirements for electronic filing. This dual filing approach should provide a strong incentive for improvement, because submitting paper documentation delays entries by several days.

GAO RECOMMENDATION TO CONGRESS

To strengthen FDA's ability to ensure the safety of imported foods, we recommend that the Congress require all food eligible for import to the United States, not just meat and poultry, be produced under equivalent food safety systems.

See comment 4.

FDA COMMENT

FDA has the authority, based on the implementing legislation for the World Trade Organization's Agreement on the Application of Sanitary/Phytosanitary Measures, to enter into equivalency agreements with other countries. We do not require such agreements, however, before trade can occur. The wording in the recommendation as written seems to require a finding of equivalence as a precondition of entry. If this is GAO's intent, we do not concur. Such a requirement could have the undesirable effect of forcing FDA to bar entry to imports from most of the world until such time as the Agency could make a determination of equivalency, a process which must be

done on a country-by-country basis, and potentially, a product-by product basis. In contrast, the Administration's proposed import legislation introduced in both House of Congress (S1707/HR3052) would give FDA the authority to deny entry to a food product that has been prepared, packed, or held under conditions, or subject to systems or measures that do not meet U.S. food safety requirements or otherwise achieve the U.S. level of protection. The legislation would not require that FDA have evaluated such systems, conditions, or measures and made an equivalency determination as a condition precedent to entry of imports.

GAO RECOMMENDATION

To provide more accurate and accessible information to FDA and thus minimize inconsistencies in inspectors' subjective decisions, we recommend that the Secretary of Health and Human Services direct the Commissioner, FDA, to

> make annual Workplans more realistic by setting aside time for unplanned activities, such as investigating emergencies and consumer complaints.

FDA COMMENT

See comment 1.

We do not concur. For the reasons stated above, FDA continues to believe that the current Workplan approach most clearly reflects priorities while permitting flexibility to handle emergencies as they arise.

GAO RECOMMENDATION

> Modify the Operational and Administrative System for Import Support system so that (1) it automatically reviews the Import Alert and low acid canned food databases and recommends appropriate actions to inspectors and (2) inspectors can consider previous laboratory test results, which are stored in the Laboratory Management System database, in choosing shipments for inspections and tests.

FDA COMMENT

We concur. The automatic review of the Import Alert data already is in place, and the automatic review of the low acid canned food database is under development. FDA also is developing the necessary software to provide inspectors with the capability to review previous laboratory test results through OASIS. Both of these enhancements to the system will be completed and operational by the end of FY1998.

GAO RECOMMENDATION

> Ensure that district offices are taking appropriate corrective action, when warranted, against importers that repeatedly enter incorrect shipping information into [the] Operational and Administrative System for Import Support.

FDA COMMENT

We concur. As stated above, FDA District Directors were reminded recently of the Agency's policy that non-compliant filers should be identified and appropriate corrective action taken, including removal of filers from paperless filing status. We also continue to believe that it is incumbent on the Agency to work with the filers through education and training, which is a form of corrective action, to improve compliance.

The following are GAO's comments on the Food and Drug Administration's letter dated April 3, 1998.

## GAO Comments

1. While we agree with FDA that the compliance programs contain specific guidance on inspection requirements, we found that FDA inspectors rely on the numerical inspection targets set forth in the annual work plan for guidance. These targets are sometimes inconsistent with the directions for the compliance program. We agree that FDA needs flexibility to deal with emergencies as they arise, but we disagree that the current work plan "clearly reflects priorities." The inconsistency we identified often leads inspectors to rely on subjective judgment, which may lead to inspectors' selecting shipments that do not pose the greater food safety risk to consumers.

2. We have not evaluated nor endorsed this legislation. Instead, this report addresses the need for FDA's equivalency authority. This authority would enable FDA to shift the primary responsibility for ensuring the safety of imported foods to the exporting country and to make more efficient and effective use of its limited resources.

3. We have modified the report to reflect FDA's comment that it does not have explicit authority to require importers to use certain laboratories nor to provide a list of accredited laboratories to importers.

4. Our recommendation was not intended to require the immediate implementation of equivalency requirements. Instead, we envision that such equivalency requirements would be phased in over time in a manner that would not unnecessarily disrupt trade. The mandatory authority to require equivalency would address weaknesses in FDA's approach to inspections at the port of entry, enable FDA to leverage its staff resources by sharing the responsibility for food safety with the exporting countries, and compel FDA to take an active approach in preventing food safety problems instead of requiring equivalency after problems are identified. The Congress could provide reasonable time frames that would allow equivalency to be implemented over a number of years.

We modified the report to address FDA's technical comments where appropriate.

# Comments From the Food Safety and Inspection Service

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

United States Department of Agriculture | Food Safety and Inspection Service | Washington, D.C. 20250

APR 7 1998

Mr. Robert A. Robinson
Director, RCED Division
Food and Agriculture Issues
U. S. General Accounting Office
441 G Street, NW, Room 2T23
Washington, D. C. 20548

Dear Mr. Robinson:

This letter provides Agency comments on the Draft Report, "Food Safety: Federal Efforts to Ensure Safety of Imported Foods Are Inconsistent and Unreliable." We appreciate the opportunity to review the draft and for the full discussion of the audit provided by the exit conference the General Accounting Office (GAO) held with the Agency on March 5, 1998.

As noted in the draft report, the Food Safety and Inspection Service (FSIS) has a powerful system for inspecting imported meat and poultry. We believe the system is well designed and operates effectively and efficiently. We agree that it is an excellent model for assuring the safety of all imported foods.

The draft report notes that FSIS calls inspection at import "reinspection" because the product has already passed inspection by the exporting countries equivalent inspection system. In fact, import reinspection coupled with on-site audits in foreign countries are the principal techniques used by FSIS to verify an exporting countries inspection system is continuing to operate at an acceptable level.

The information obtained through import reinspection tells a lot about the overall operation of foreign countries inspection system. We think all of this information is informative, including specific information on food safety hazards. Nevertheless, FSIS appreciates the need to focus its inspection resources on risks in meat and poultry that are directly related to public health. The Automated Import Information System (AIIS) permits FSIS to focus on risks presented by a particular product from a particular country. As noted in this report, the AIIS data could be used by FSIS to develop profiles for individual countries, exporting establishments, or product groups. With the implementation of Hazard Analysis and Critical Control Point, FSIS will be evaluating port-of-entry procedures and automated systems, and the recommendations of the GAO will be taken into account.

See comment 1.

We do not, however, understand the basis for a statement in Chapter 3 of the draft that "in 1996, more than 97 percent of all the violations identified were not directly related to health risk problems." Our AIIS data for 1996 shows that more than 80 percent of the

Mr. Robert A. Robinson 2

violations were the result of health risk problems such as laboratory analyses showing excessive residues and microbiological contamination; product examination showing unwholesome products with organoleptic defects; and lack of container integrity. The remainder of the data shows that less than 20 percent of the violations were for incorrect weight, missing shipping marks, or labeling defects.

If you have any questions or need further assistance, please contact Vincent Fayne, Director, Internal Control Staff, at (202) 720-5959.

Sincerely,

Thomas J. Billy
Administrator

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The following is GAO's comment on the Food Safety and Inspection Service's letter dated April 7, 1998.

## GAO Comment

1. In response to FSIS' comment, we (1) expanded the list of reasons for refusal that are directly related to health risks to include unsound condition and residues, as FSIS cited in its comments, and (2) excluded all refusals resulting from transportation damage because FSIS officials said these refusals do not trigger requirements for FSIS to conduct subsequent inspections. Using this expanded definition, we recalculated the percentage of rejected shipments that were not directly related to health risk. As a result, in our final report, we changed the percentage of refused shipments not related to health risk from 97 percent to 86 percent.

# Comments From the U.S. Customs Service

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

**DEPARTMENT OF THE TREASURY**

**U.S. CUSTOMS SERVICE**

APR 6 1998

AUD-1-OP TDM

Mr. Robert A. Robinson
Director
Food and Agriculture Issues
General Accounting Office
Washington, D.C. 20548

Dear Mr. Robinson:

Thank you for the opportunity to review your draft report entitled "FOOD SAFETY: Federal Efforts to Ensure Safety of Imported Foods Are Inconsistent and Unreliable".

We have the following comments for your consideration:

1) **Export of Destruction of FDA Refused Products (see Pg. 52, Paragraph 2 of GAO Report)**

Pursuant to 19 CFR 101.2, Customs Port Directors may choose the level of supervision of FDA-refused products which must be exported or destroyed. Due to workload constraints, it is obvious that Customs cannot physically inspect every FDA-refused product destined for export or destruction. Instead, it appears logical to target intensive Customs supervision for those products and suspected importers posing the greatest risk and to utilize compliance measurement techniques in this regard, as deemed appropriate.

2) **Substitution Scheme by Importers (see Pg. 8, Paragraph 1 and Pg. 51, last Paragraph of GAO Report)**

See comment 1.

Customs questions GAO's allegation of many instances in which importers substituted safe food products for the actual imported products for inspection. While this might be true with respect to a "special enforcement operation" such as "Operation Bad Apple", it would not be true when one considers the totality of all redelivery actions for FDA-refused goods.

In the case of the latter GAO claim, the extent of this occurrence is also probably limited in scope with respect to certain particular categories of merchandise and a small number of importers involved. Nevertheless, Customs will work closely with FDA to close whatever enforcement loopholes might exist in this regard.

3) **Customs Collection of Liquidated Damages in 1997 (see Pg. 53, last Paragraph of GAO Report)**

See comment 2.

The decrease in such collections in FY97 in Miami is attributed to both a seven-month automation programming problem with our electronic case system called SEACATS ("Seized Assets and Case Tracking System") and the halting of case collections due to the impact of the Customs liquidated damage legal case with sureties currently before the Court.

In addition, in order to enhance communication between Customs and FDA at the Port of Miami and improve the above situation, the two agencies have established the first joint Customs and FDA Team in the country. In the past, several Import Specialists handled FDA refusals. By creating one centrally located team, multiple handling of the Customs and FDA documents has now ceased to exist. The staff for Import Team 488 at that location now consists of a Customs and FDA official both sharing the responsibility of creating well-documented cases.

4) **Customs Mitigation of Liquidated Damage Cases/Customs Bond Deterrence (see Pg. 8 of GAO Report)**

GAO alleges the following regarding these issues:

- violators are seldom effectively punished
- Customs collections of damages against violators are uneven and uncertain
- Customs bond default assessments do not represent an effective deterrent

See comment 3.

With respect to the assessment of liquidated damages for failure to redeliver, it should be noted that such assessment is intended to compensate the Government for a breach for which money damages cannot be easily calculated. They are not intended to penalize the bond principal although clearly the report concludes this is the consequence. In addition, if Customs bond default and mitigation guidelines are considered too lenient for contaminated food shipments, Customs would be willing to further study the need for more severe assessments as an increased deterrent. However, it should be noted that Customs is of the opinion that the current liquidated damage assessment for non-redelivery of contaminated food products is definitely adequate in most cases, i.e., three times the value of the goods.

5) **Customs Mitigation Case (from $100,000 to $100, see Pg. 53, last Paragraph of GAO Report**

See comment 3.

GAO cites this case as proof that our Agency is being too lenient on violators. However, we assume that the violation was minor, not a contaminated food violation and, therefore, in accordance with Customs mitigation guidelines. The GAO Report does not refer to the fact that Customs and FDA must be in agreement on the issuance of any mitigation decision that involves failure to redeliver and involves the purity or labeling of the product.

We note that there are no specific recommendations for the Customs Service in this draft report. However, Customs is committed to improving its efforts with regard to safety of imported foods and will take into account the findings in this report and the implementation of any future GAO recommendations.

We appreciate the opportunity to comment on your draft report. If you need any additional information on this matter, please contact Mr. J. Tony Del Moral, Director, Evaluation Oversight Staff at (202) 927-0194.

Sincerely,

William F. Riley
Director, Office of Planning

The following are GAO's comments on the U.S. Customs Services' letter dated April 6, 1998.

## GAO Comments

1. We disagree with Customs' comment questioning our assertion about the extent to which importers substitute safe food products for imported products for inspection. Customs officials in San Francisco provided us the figures on import substitution to illustrate the weaknesses in controls over FDA-regulated imported foods found in Operation Bad Apple. We modified the language in the report to clarify that the 50-percent substitution rate was attributed to Operation Bad Apple. Furthermore, while we cannot report on the exact extent of product substitution, Customs and FDA officials have acknowledged that it is occurring at other ports of entry. We also found that product substitution was occurring at four of the six ports we visited.

2. We have expanded the report to reflect Customs' comment on the reasons for a decrease in collections at the Miami port of entry.

3. We do not share Customs' view that the current liquidated damage assessment for failure to redeliver contaminated food products is an adequate deterrent. Our work, beginning in 1992,[1] indicates a pattern of problems in the deterrence and punishment of violators. In 1992, for example, we reported that the U.S. market value for selected products always exceeded the declared import value of the products we surveyed; thus, importers could and, in some cases, did profit from distributing illegal products even after paying damages to Customs. The case we mentioned in this report, in which Customs assessed damages of $100 against an importer with a shipment having a declared value of $100,000, shows that the collected damages may be far less than the declared value of the shipment. We modified the report to provide further information on the reason for mitigating damages against importers.

[1]Pesticides: Adulterated Imported Foods Are Reaching U.S. Grocery Shelves (GAO/RCED-92-205, Sept. 24, 1992).

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