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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

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

¹²Because 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

¹Since 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.

²H.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

³Final 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.

⁴Food 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.

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

²Refusals 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.

Chapter 3
Agencies Have Not Effectively Targeted
Their Resources on Imported Foods Posing
Greater Risks

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

Inspection activities ^a	Fiscal year 1996			Fiscal year 1997		
	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

^aA 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

³FDA'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 error 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

⁴Review 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.

¹Pesticides: 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

²Private 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

³Pesticides: 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

⁴Pesticides: 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'

⁵Pesticides: 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

⁶Pesticides: 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.

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

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	<u>Cyclospora</u>	Raspberries	Guatemala	17 states; Washington, D.C.; and Canada
1997	270	Hepatitis A	Frozen strawberries	Mexico (implicated)	5 states
1996	9 14	<u>Salmonella typhi</u> , hepatitis A	Homemade cheese	Mexico	Florida
1996	1,465	<u>Cyclospora</u>	Raspberries	Guatemala	20 states; Washington, D.C.; and Canada
1995	242	<u>Salmonella Stanley</u>	Alfalfa sprouts	Seeds from Netherlands	17 states and Finland
1994	27	<u>Salmonella Agona</u> phage type 15	Kosher peanut-flavored savory snack	Israel	North America and United Kingdom
1994	171	<u>Shigella flexneri</u> , 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	<u>Vibrio cholerae</u>	Coconut milk in pudding	Thailand	Maryland
1991	12	<u>Vibrio cholerae</u>	Crab meat	Ecuador	New Jersey and New York
1991	400	<u>Salmonella Poona</u>	Cantaloupes	Mexico	23 states and Canada
1990	1,400	<u>E. coli</u> 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	<u>Salmonella Chester</u>	Cantaloupes	Mexico	30 states
1988	202	Hepatitis A	Lettuce	Mexico (suspected)	Kentucky
1983	169	<u>E. coli</u> 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
Paraguay¹
Poland
Romania
Slovenia
Spain

¹Suspended as of January 1, 1998.

**Appendix II
Countries Certified by Food Safety and
Inspection Service to Export Meat and
Poultry to the United States**

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.

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 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.

See comment 1.

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

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

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

See comment 2.

See comment 3.

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.

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

See comment 4.

**Appendix III
Comments From the Food and Drug
Administration**

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

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.

See comment 1.

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.

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

See comment 1.

**Appendix IV
Comments From the Food Safety and
Inspection Service**

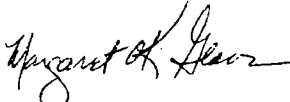
Mr. Robert A. Robinson

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

cc:

J. Prucha, OPPDE
M. Manis, OPPDE
K. Stuck, OPPDE
S. Stratmoen, OPPDE
C. Danford, OPPDE
R. Beck, OFO
E. Walker, OPHS

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)

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.

See comment 1.

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

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

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)**

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.

See comment 2.

See comment 3.

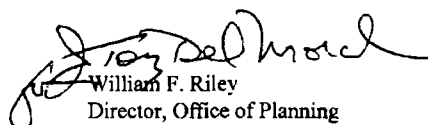
See comment 3.

Appendix V
Comments From the U.S. Customs Service

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.

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

Major Contributors to This Report

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**Not for Use Before 1:30 p.m.
Wednesday, March 4, 1998**

**Statement of Caroline Smith DeWaal
Director of Food Safety
on the Introduction of the Safety of Imported Foods Act of 1998**

**The White House
March 4, 1998**

Today, the Clinton administration is making another important contribution to improve the safety of the US food supply. Outbreaks from imported produce over the last few years have shown that our current system of inspecting a minimal amount of food at the border won't protect American consumers from most food safety hazards.

FDA's hands are tied when it comes to protecting consumers from unsafe imported foods. Today, FDA inspectors can't visit foreign countries to check that the water supply is clean, that the farm worker sanitation standards are enforced, or even that the government food safety programs are in operation. While USDA approves every country and each meat or poultry plant that wants to export its products to the United States, FDA doesn't have similar authority. Instead, FDA only examines one or two percent of food shipments at the border, while the rest rolls in with no inspection whatsoever. Better inspections, both at the border and in foreign countries, are urgently needed to restore consumers' faith in the safety of imported foods.

Senator Mikulski, Senator Kennedy, Representative Eshoo, and Representative Pallone are to be congratulated for introducing the Safety of Imported Foods Act of 1998 to address this serious public health threat. CSPI also vigorously supports the President's request for \$25 million in increased funding to hire new import inspectors to better enforce our food safety standards. We also support other legislation pending in Congress to strengthen and streamline our federal food safety programs (HR 2801, S. 1465, S. 1264, and HR 3070). Now it is up to the leadership in Congress to move these bills forward quickly.

For more information, contact Penelope Miller, (202) 332-9110, ext 358.





October 2, 1997

**MEMORANDUM FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES
THE SECRETARY OF AGRICULTURE**

Message Creation Date was at 2-OCT-1997 11:39:00

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

October 2, 1997

October 2, 1997

MEMORANDUM FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES
THE SECRETARY OF AGRICULTURE

SUBJECT: Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables

American consumers today enjoy the safest food supply in the world, and I am proud of my Administration's record in this area. We have taken significant steps to ensure that we maintain the safest food possible. We have put in place improved safety standards for meat, poultry, and seafood products, and we have begun the process of developing enhanced safety standards for fruit and vegetable juices. We have also expanded research, education, and surveillance activities through coordinated efforts of all agencies involved in food safety issues. Together, these measures will greatly improve the safety of the Nation's food supply.

We need to build on these efforts, and today I ask you to do so by focusing on the safety of fruits and vegetables. Although the produce Americans eat is very safe, we can and must do even better, especially at a time when Americans are eating more fruits and vegetables from all over the world. Last year, 38 percent of the fruit and 12 percent of the vegetables consumed by Americans came from overseas. We must ensure that fruits and vegetables coming from abroad are as safe as those produced in the United States, especially as we upgrade our own domestic standards.

To help accomplish this task, I plan to send to the Congress proposed legislation that will require the Food and Drug Administration (FDA) to halt imports of fruits, vegetables, or other food from any foreign country whose food safety systems and standards are not on par with those of the United States. This legislation, which will be similar to existing law requiring the USDA to halt the importation of meat and poultry from such countries, will enable the FDA to prevent

the importation of potentially unsafe foreign produce. My Fiscal Year 1999 budget will provide the necessary funds to enable the FDA to expand dramatically its international food inspection force. With this greatly increased ability to inspect food safety conditions abroad and at points of entry, the FDA will be able to determine when to halt the importation of fruits and vegetables from foreign countries.

Today, I hereby direct two administrative actions that will better ensure the safety of fruits and vegetables coming from abroad, while continuing to improve the safety of domestic produce.

more

(OVER)

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First, I direct the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture and in close cooperation with the agricultural community, to issue within 1 year from the date of this memorandum, guidance on good agricultural practices and good manufacturing practices for fruits and vegetables. This guidance should address ways to prevent potential sources of contamination, should take into account differences in both crops and regions, and should address food safety issues throughout the food production and distribution system. By providing the first-ever specific safety standards for fruits and vegetables, the guidance will improve the agricultural and manufacturing practices of all those seeking to sell produce in the U.S. market. To ensure that this guidance has the widest possible effect, I also direct the development of coordinated outreach and educational activities.

Second, I direct the Secretary of Health and Human Services and the Secretary of Agriculture, to report back to me within 90 days from the date of this memorandum with a status report and complete schedule for the good agricultural and manufacturing practices, and a plan on how to improve the monitoring of agricultural and manufacturing practices abroad, to assist foreign countries to improve those practices where necessary, and to prevent the importation of unsafe produce, including by detecting unsafe food at the dock or border. I especially urge you to consider the best ways to target inspection and testing toward those areas where problems are most likely to occur.

In addition to taking these actions, you should accelerate whatever food safety research is necessary to support them. You should also call upon the Environmental Protection Agency, the Department of Labor, and other agencies as necessary to provide you with assistance in achieving this goal. These steps, taken together and in coordination with the proposed legislation I will send to the Congress, will improve the safety of fruits and vegetables for all Americans.

WILLIAM J. CLINTON

#



THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

October 2, 1997

REMARKS BY THE PRESIDENT ON FOOD SAFETY REGULATIONS

The Rose Garden

10:59 A.M. EDT

THE PRESIDENT: Thank you, Mr. Vice President, Secretary Shalala, Deputy Secretary Rominger, Cathie Woteki, Dr. Friedman, all the representatives of the groups that have helped us come to this day.

Our government made a fundamental promise to the American people of a bountiful and safe food supply way back at the beginning of this century. It is a promise that we have had to renew our commitment to periodically over the years, and a promise that needed a lot of work when I became President. From the day I took office, I worked very hard to honor that commitment, to make our food supply -- the world's safest -- even safer.

In 1993, the Vice President's national performance review recommended an overhaul of our food safety procedures so that we could use the best scientific technology available in inspection methods, to make sure that we had put in the best preventive controls to keep our food supply the world's safest.

Since then, we have taken major steps. We first put in place rigorous new safety standards for seafood, meat and poultry products, throwing out archaic and ineffective methods of inspection that had not been updated for nearly a century. We've required slaughterhouses to test for deadly E. Coli and salmonella bacteria. We've begun developing new safety standards for fruit and vegetable juices. We've strengthened our system of guaranteeing that our drinking water will remain safe, and improved public health protections for pesticide uses on food. And we brought a host of federal agencies together to boost food safety research, education and surveillance efforts around our nation. In so doing, we're using the world's best science to help prevent food contamination tragedies before they happen, to make sure our supply of food is as safe as it can be.

Today, our food supply remains the world's safest, but we can't rest on those accomplishments. We have to do more. At the time when Americans are eating more and more food from around the globe, we must spare no effort to ensure the safety of our food supply from whatever source.

Today, I want to tell you the new steps we're taking to ensure that our fruits and vegetables, including those imported from other countries, meet the highest health and safety standards. First, I'm asking Congress to give the Food and Drug Administration the power and the obligation to ban the importation of fruits, vegetables and other foods from countries whose safety precautions do not meet American standards. This new law would be similar to a law that already requires the United States Department of Agriculture to keep meat and poultry

from countries with inferior food safety systems out of our stores.

In my next budget, I will provide enough funds to ensure that the FDA can fully implement this new legislation by dramatically expanding its international food inspection force. With these

efforts, we can make sure that no fruits and vegetables cross our borders, enter our ports, or reach our dinner tables without meeting the same strict standards as those grown here in America. Our food safety system is the strongest in the world, and that's how it's going to stay.

I'm also directing the Secretary of Health and Human Services and the Secretary of Agriculture to work together in close cooperation with the agricultural community to develop the first-ever specific safety standards for the growing, processing, shipping and selling of fruits and vegetables. These standards will address potential food safety problems throughout the production and distribution system, and they'll improve the sanitation and safety practices of all those seeking to sell produce in the United States market.

I'm asking Secretary Shalala and Glickman to report back to me within 90 days with a complete schedule for developing these standards within a year. I'll also ask them to submit a comprehensive plan to improve the monitoring of food safety programs abroad, to help foreign countries upgrade their safety precautions and toughen food inspections at the border.

Being a parent is perhaps the toughest job in the world. Our parents deserve the peace of mind that comes from knowing the food they set before their children is safe. With today's new actions, we can help make their jobs much easier.

And, again, let me thank all of those who were involved in this effort as I sign this order. Thank you very much.

(The order is signed.)

THE PRESIDENT: Thanks. (Applause.)

Q Mr. President, will you be using the line item veto

THE PRESIDENT: Excuse me?

Q Will you be using the line item veto on any of the appropriations bills that you've just passed -- that you've just signed?

THE PRESIDENT: Well, let me say, I have received only -- I've received one memorandum for my staff on one bill. And that came in late last night, so I haven't read it. But I will consider it -- as the bills come in, I will ask for a review of the potential uses by specific bill and make judgments as we go along. I have nothing to report at this time, because I have received only one memorandum and I haven't read it.

Q What about the census, sir? Do you have any concerns concerning the Commerce bill and the particular ways that the money will be used for the census?

THE PRESIDENT: Well, my feeling is that we ought to do the census as well as we can. I don't think this is a complicated issue. The National Science Foundation has recommended this statistical sampling method. The man who did President Bush's census says that it's the only way to get the most accurate count. I just want to do whatever the Census Bureau believes, the full-time professionals, believe is the most accurate thing to do.

I think that's a heavy constitutional responsibility we have, to conduct a census that is as

accurate as possible based on what the professionals say. This ought to be a professional, not a political judgment. And that's the position I will take throughout.

Q Mr. President, did the Democratic Party send money to the states because of federal election law restrictions?

Q Mr. President, there are fresh fruit and vegetables producers that are saying --

THE PRESIDENT: Well, wait a minute. I'll take both of them. Go ahead first.

Q There are fresh fruit and vegetable producers that are saying that you're acting with this action as the world food police and that your actions here today are unwarranted and that's going to complicate the trade environment.

THE PRESIDENT: Well, I hope it doesn't complicate the trade environment. But, you know, it seems to me that we have no higher responsibility than to protect the health and safety of our citizens, and everyone who has been following all of your reporting over the last four or five years knows that we have had continuing challenges in food safety. We have millions of people who get sick every year. And we're not trying to unfairly target foreign producers of food into our market; we don't ask them to meet any standards we don't meet. And indeed, if you look at the actions of this administration over the last four years, when we started, I think you can make a compelling case that we started working on things that were problems coming out of the American market first. So I just don't think that's right.

I don't want it to complicate the trade environment, but I'm not interested in trade in things that will make the American people sick.

Q Mr. President, did the Democratic National Committee send money to the states in order to get around the federal spending limits that went along with accepting federal money for the national campaign, sir?

THE PRESIDENT: It's my understanding that everything the Democratic National Committee did had the prior approval of the lawyers. If they cleared it all in advance, then it was perfectly legal. And when this issue was raised about a year ago, the exact issue, I believe that that was clarified at that time. I'm sure that they had legal advice that they followed, and I believe the Republicans said that they did some of the same things and also had prior legal clearance.

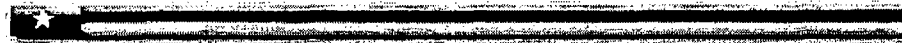
Q Mr. Clinton, do you that Mrs. Reno -- she's been advised to go forward with the 90-day investigation into the fundraising calls of the Vice President -- and perhaps Mr. Gore would like to comment, too --

THE PRESIDENT: I think that --

Q -- do you feel that the 90-day investigation would be helpful?

THE PRESIDENT: Well, if you read the statute, she can consider certain things in the 90-day period that are not permitted in the 30-day period. But I think this is a legal question and it should be done based on an independent legal review with no pressure from the outside, from me or from anyone else. And that's the way I intend to keep it, at least on my part.

Thank you.



COLUMNS

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Tougher food import checks

President Clinton has acted wisely in proposing tighter screening of imported fruit and vegetables, a rising share of Americans' diet, to prevent illness and death from diseases borne by food. Imported fruit now accounts for 38 percent of American consumption, and vegetables about 12 percent, figures that have doubled over the past decade.

The vast bulk of these imports are safe, but occasional lapses lead to illness, even deaths, when tainted products slip through. The US Department of Agriculture only samples about one percent of imports, and while this is statistically sound, it is inadequate.

The Clinton approach moves further back in the chain by adding the exporting country's inspection and regulatory systems to the standards they must meet for access to the American market. This is to the best interests of all parties because exporting countries also benefit from tighter controls over agricultural production for their own consumption as well as for exports.

It is useful to exporters in another context. As important as inspection and regulation are in protecting food safety, mistakes do occur, and the impact is severe in both health and economic terms. Widely reported incidents of disease connected with specific products from exporters like Guatemala, Mexico, Chile, or Thailand lead American consumers to avoid buying all products from those countries for at least a while - much as reports of trouble with American products like apples treated with alar or unpasteurized cider have cut into those sales. Tighter management by exporters will reduce such incidents.

Disputes over standards are inevitable and will require deft handling by American officials responsible for appraising other nations' efforts to avoid charges that they are merely an attempt to protect American producers. If that principle is followed, food for everyone will be both safer and more available.

This story ran on page A A16 16 of the Boston Globe on 10/14/97.
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PRESIDENT CLINTON ANNOUNCES INITIATIVE TO ENSURE THE SAFETY OF IMPORTED AND DOMESTIC FRUITS AND VEGETABLES

October 2, 1997

Today President Clinton will announce an initiative to upgrade domestic food safety standards and to ensure that fruits and vegetables coming from overseas are as safe as those produced in the United States. The President will ask Congress to enact legislation that will require the Food and Drug Administration (FDA) to halt imports of fruits, vegetables and other food products produced in countries that do not meet U.S. food safety requirements. The President will direct the Department of Health and Human Services (HHS) and the Department of Agriculture (USDA) to work cooperatively with the agricultural community to develop guidance on good agricultural and manufacturing practices for fruits and vegetables.

Enhanced FDA Oversight for Imported Foods. The President will send legislation to Congress that will require the FDA to halt imports of fruits, vegetables and other food products from any foreign country with food safety systems and standards that are not on par with those of the United States. The legislation also will require the FDA to halt imports from countries or facilities that do not allow FDA inspections to occur. This legislation --comparable to existing law that requires the USDA to halt the importation of meat and poultry from such countries --will enable the FDA to prevent the importation of potentially unsafe foreign produce. The President will also commit to providing the necessary funds in his Fiscal Year 1999 budget to enable the FDA to dramatically expand its international food inspection force. With this greatly increased ability to inspect food safety conditions abroad and at points of entry, the FDA will be able to make effective use of its new authority.

Development of Guidance on Good Agricultural and Manufacturing Practices. The President will direct the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture and in cooperation with the agricultural community, to develop guidance on good agricultural and manufacturing practices within one year. This guidance will take into account differences in both crops and regions and will address potential food safety problems throughout the food production and distribution system such as sanitation, worker health, and water quality. The guidance --the first-ever specific safety standards for fruits and vegetables --will improve the agricultural and manufacturing practices of all those seeking to sell produce in the U.S. market. To ensure that this guidance has the widest possible effect, the President will also direct the FDA and USDA to develop coordinated outreach and educational activities.

Improvement of Monitoring and Inspection Activities Abroad. In addition to committing substantial resources to expand the FDA's international food inspection force, the President will direct the Secretaries of Health and Human Services and Agriculture to report within 90 days on how to improve the monitoring of agricultural and manufacturing practices abroad, to assist foreign countries to improve these practices where necessary, and to prevent the importation of unsafe produce. The President will urge consideration of ways to target inspection and testing toward those areas where problems are most likely to occur.

Clinton Administration Accomplishments In Improving Food Safety

The President's announcement builds on a strong record of food safety initiatives, ensuring that Americans eat the safest possible food. The Administration has put into place improved safety standards for meat, poultry and seafood products, and has begun the process of developing enhanced standards for fruit and vegetable juices. The Administration also has expanded research, education and surveillance activities throughout the food safety system.

- October, 1997. President announces new initiative to enhance FDA oversight over imported foods and develop guidance on good agricultural and manufacturing

practices for fruits and vegetables.

- May, 1997. Administration announces comprehensive new initiative to improve the safety of nation's food supply --"Food Safety from Farm to Table" --detailing a \$43 million food safety program, including measures to improve surveillance, outbreak response, education, and research.
- January, 1997. President announces new Early-Warning System to gather critical scientific data to help stop food borne disease outbreaks quickly and to improve prevention systems further.
- August, 1996. President signs Safe Drinking Water Act of 1996. The law requires drinking water systems to protect against dangerous contaminants like cryptosporidium, and gives people the right to know about contaminants in their tap water.
- August, 1996. President signs Food Quality Protection Act of 1996, which streamlines regulation of pesticides by FDA and EPA and puts important new public-health protections in place, especially for children.
- July, 1996. President Clinton announces new regulations that modernize the nation's meat and poultry inspection system for the first time in 90 years. New standards help prevent E.coli bacteria contamination in meat.
- December, 1995. Administration issues new rules to ensure seafood safety. Utilizes HACCP regulatory programs to require food industries to design and implement preventive measures and increase the industries' responsibility for and control of their safety assurance actions.
- 1994. CDC embarks on strategic program to detect, prevent, and control emerging infectious disease threats, some of which are food borne, making significant progress toward this goal in each successive year.
- 1993. Vice-President's National Performance Review issues report recommending government and industry move toward a system of preventive controls.

REMARKS BY PRESIDENT CLINTON



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MEMORANDUM FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES
SECRETARY OF AGRICULTURE

SUBJECT: Initiative to Ensure the Safety of Imported and Domestic Fruits
and Vegetables

As you know, American consumers today enjoy the safest food supply in the world, and I am proud of the Administration's record in this area. During my Administration, we have taken significant steps to ensure that we maintain the safest food possible. We have put in place improved safety standards for meat, poultry, and seafood products, and we have begun the process of developing enhanced safety standards for fruit and vegetable juices. We have also expanded research, education, and surveillance activities through coordinated efforts of all agencies involved in food safety issues. Together, these measures will greatly improve the safety of the nation's food supply.

We need to build on these efforts, and today I ask you to do so by focusing on the safety of fruits and vegetables. Although the produce Americans eat is very safe, we can and must do even better, especially at a time when Americans are eating more fruits and vegetables from all over the world. Last year, 38 percent of the fruit and 12 percent of the vegetables consumed by Americans came from overseas. We must ensure that fruits and vegetables coming from abroad are as safe as those produced in the United States, especially as we upgrade our own domestic standards.

To help accomplish this task, I plan to ask Congress to enact legislation that will require the Food and Drug Administration (FDA) to halt imports of fruits, vegetables, or other food from any foreign country whose food safety systems and standards are not on par with those of the United States. This legislation, which will be similar to existing law requiring the USDA to halt the importation of meat and poultry from such countries, will enable the FDA to prevent the importation of potentially unsafe foreign produce. In addition, I will provide the necessary funds in my Fiscal Year 1999 budget to enable the FDA to expand dramatically its international food inspection force. With this greatly increased ability to inspect food safety conditions abroad and at points of entry, the FDA will be able to determine when to halt the importation of fruits and vegetables from foreign countries.

I also hereby direct two administrative actions that will better ensure the safety of fruits and vegetables coming from abroad, while continuing to improve the safety of domestic produce.

First, I direct the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture and in close cooperation with the agricultural community, to issue within one year guidance on good agricultural practices and good manufacturing practices for fruits and vegetables. This guidance should address ways to prevent potential sources of contamination, should take into account differences in both crops and regions, and should address food safety issues throughout the food production and distribution system. By providing the first-ever specific safety standards for fruits and vegetables, the guidance will improve the

agricultural and manufacturing practices of all those seeking to sell produce in the U.S. market. To ensure that this guidance has the widest possible effect, I also direct the development of coordinated outreach and educational activities.

Second, I direct the Secretary of Health and Human Services and the Secretary of Agriculture, to report back to me within 90 days with a status report and complete schedule for the good agricultural and manufacturing practices, and a plan on how to improve the monitoring of agricultural and manufacturing practices abroad, to assist foreign countries to improve those practices where necessary, and to prevent the importation of unsafe produce, including by detecting unsafe food at the dock or border. I especially urge you to consider the best ways to target inspection and testing toward those areas where problems are most likely to occur.

In addition to taking these actions, you should accelerate whatever food safety research is necessary to support them. These steps, taken together and in coordination with the legislation I will send to Congress, will improve the safety of fruits and vegetables for all Americans. I also will direct the Administrator of the Environmental Protection Agency and the Secretary of Labor and other necessary agencies to provide you with assistance in achieving this goal.

Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables

Today President Clinton announced an initiative to ensure that fruits and vegetables coming from overseas are as safe as those produced in the United States, as well as to upgrade our own domestic standards. The President stated that he will ask Congress to enact legislation that will require the Food and Drug Administration (FDA) to halt imports of fruits, vegetables, and other food products produced in countries that do not meet U.S. food safety requirements. The President also directed the Department of Health and Human Services (HHS) and the Department of Agriculture (USDA) to work cooperatively with the agricultural community to develop guidance on good agricultural and manufacturing practices for fruits and vegetables.

Enhanced FDA Oversight for Imported Foods. The President announced that he will send legislation to Congress that will require the FDA to halt imports of fruits, vegetables, and other food products from any foreign country with food safety systems and standards that are not on par with those of the United States. The legislation also will require the FDA to halt imports from countries or facilities that do not allow FDA inspections to occur. This legislation -- comparable to existing law that requires the USDA to halt the importation of meat and poultry from such countries -- will enable the FDA to prevent the importation of potentially unsafe foreign produce. The President also committed to providing the necessary funds in his Fiscal Year 1999 budget to enable the FDA to expand dramatically its international food inspection force. With this greatly increased ability to inspect food safety conditions abroad and at points of entry, the FDA will be able to make effective use of its new authority.

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Improvement of Monitoring and Inspection Activities Abroad. In addition to committing to substantial additional resources to expand the FDA's international food inspection force, the President directed the Secretaries of Health and Human Services and Agriculture to report within 90 days with a plan on how to improve the monitoring of agricultural and manufacturing practices abroad, to assist foreign countries to improve these practices where necessary, and to prevent the importation of unsafe produce, including by detecting unsafe food at the dock and border. The President urged consideration of ways to target inspection and testing toward those areas where problems are most likely to occur.

A Record of Improving Food Safety. The President's announcement builds on a strong record of food safety initiatives ensuring that Americans eat the safest food possible. The Administration has put into place improved safety standards for meat, poultry, and seafood products, and has begun the process of developing enhanced safety standards for fruit and vegetable juices. The Administration also has expanded research, education, and surveillance activities throughout the food safety system.

Editorial

The New York Times
ON THE WEB

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October 3, 1997

Safety Standards for Imported Food

Global trade allows Americans to satisfy their appetites for strawberries in spring, apples in midsummer and asparagus in autumn. Last year 38 percent of fruits and 12 percent of vegetables consumed here came from foreign fields. But getting fresh produce year round also means that consumers are exposed to foreign food production systems that may not be well regulated. Although the vast majority of the 30 billion tons of food imported annually is wholesome, recent incidents of illness caused by tainted Guatemalan raspberries and E. coli-contaminated domestic meat and fruit juices have made food safety a public concern.

Yet even as food imports have doubled since the 1980's, Federal health inspections of imports have been cut in half.

Since the Food and Drug Administration samples less than 1 percent of food imports at the docks, tainted food can easily reach consumers undetected.

In a sensible effort to tighten food safeguards, President Clinton asked Congress yesterday to give the F.D.A. power to halt imports of fruits, vegetables and other food products from countries that do not maintain food safety standards equivalent to those in the United States. That would give the agency the same authority that the Department of Agriculture has long exercised over imports of meat and poultry. Monitoring the agricultural and food handling practices in exporting nations will be far more effective than random checks at the border. The Administration will seek \$24 million in 1999 to send F.D.A. inspectors abroad.

The President is also asking government agencies and representatives of the agricultural sector to draft standards of good agricultural practices, such as keeping latrines away from vegetable fields and screening food workers for hepatitis, to guide both domestic and foreign growers.

Foreign producers are already denouncing the plan as an unfair trade barrier. But there is no reason to believe that asparagus growers in Mexico will be asked to live by higher standards than growers in Washington State. In the long run, Federal efforts to bolster consumer confidence in the wholesomeness of imported food will help the American appetite for foreign produce grow.

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HEADLINE: REMARKS BY PRESIDENT BILL CLINTON AND
VICE PRESIDENT AL GORE
TOPIC: FOOD SAFETY
THE WHITE HOUSE, THE ROSE GARDEN
WASHINGTON, DC

BODY:

VICE PRESIDENT GORE: Ladies and gentlemen, on behalf of the president, it's my honor to welcome you here to the Rose Garden and acknowledge the distinguished guests, including, of course, Secretary Donna Shalala of the Department of Health and Human Services, who's been such a great leader on the issue the president is addressing today, along with acting Administrator of the FDA Michael Friedman; Richard Rominger, deputy secretary of the Department of Agriculture; Cathy Woteki, who is undersecretary for food safety at USDA; Carol Tucker Foreman (sp), director of the Safe Food Coalition; Carolyn Smith De Waal (sp), director of food safety for the Center for Science in the Public Interest; Nancy Donling (sp), with the Safe Tables Our Priority organization, STOP; Manley Mopus (sp), president of the Grocery Manufacturers Association; Thomas Stensil (sp), president of the United Fresh Fruit and Vegetables Association; and Anita Brown (sp), with the Western Growers Association.

I'd like to just briefly place the president's announcement in a context that I think -- in which I think it deserves to be seen. For the last five years President Clinton has pursued a series of policies designed to help families in this country -- and, more specifically, to help parents do the job they want to do in raising their children safely and well. And a lot of things parents need to do and want to do are done more easily if government policies work well. The president has, therefore, pursued policies to help parents protect their children from sickness and disease and from harmful influences that are all around us. And it's one of the reasons I'm so proud to serve with him. No president has done more to protect the health of our children and help America's families succeed.

The record speaks for itself, and it speaks volumes. And it includes the largest investment in children's health care since Medicaid was enacted, providing health care to as many as 5 million uninsured children; the toughest ever measures to cut off children's access to tobacco and to stop tobacco advertising aimed at our children; the passage of the Kassebaum-Kennedy health-care law, which helps millions of children keep their health coverage when their parents change jobs or lose jobs; child immunizations that are at an all-time high, now reaching over 90 percent of our children, with the most critical vaccines; the largest single investment in juvenile diabetes research ever; making sure prescription-drug manufacturers determine the proper dosages for children, as well as adults, so parents and doctors know how to treat their children.

There can be no doubt this administration has fought hard to protect America's children, and we've had real results.

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Today, the president leads our country with another step forward. Each year, in our nation, unsafe food is responsible for as many as 33 million illnesses and up to 9,000 deaths, and children are the most vulnerable to these illnesses. That is simply unacceptable. We have by far the safest food supply in the entire world and the best by far, but we still have more to do.

And our administration has a strong record of accomplishment when it comes to food safety. That record is due, in no small measure, to a president who understands, as a parent himself, that parents should not have to worry about the fruit juice or sandwiches or apples or vegetables that their children are eating. And so I am very pleased and honored to present to you a true champion of America's children and parents, President Bill Clinton. (Applause.)

PRESIDENT CLINTON: Thank you very much.

Thank you, Mr. Vice President; Secretary Shalala, Deputy Secretary Rominger; Kathy Woteki (and ?) Dr. Friedman and all the representatives of the groups that have helped us come to this day.

Our government made a fundamental promise to the American people of a bountiful and safe food supply way back at the beginning of this century. It is a promise that we have had to renew our commitment to, periodically over the years, and a promise that needed a lot of work when I became president.

From the day I took office, I worked very hard to honor that commitment to make our food supply, the world's safest, even safer.

In 1993, the vice president's National Performance Review recommended an overhaul of our food safety procedures so that we could use the best scientific technology available and inspection methods to make sure that we had put in the best preventive controls to keep our food supply the world's safest.

Since then, we have taken major steps. We first put in place rigorous new safety standards for seafood, meat and poultry products, throwing out archaic and ineffective methods of inspection that had not been updated for nearly a century. We've required slaughter-houses to test for deadly E. coli and salmonella bacteria. We've begun developing new safety standards for fruit and vegetable juices. We've strengthened our system of guaranteeing that our drinking water will remain safe, and improved public health protections for pesticide uses on food. And we brought a host of federal agencies together to boost food safety research, education and surveillance efforts around our nation. In so doing, we're using the world's best science to help prevent food contamination tragedies before they happen, to make sure our supply of food is as safe as it can be.

Today, our food supply remains the world's safest, but we can't rest on those accomplishments. We have to do more. At the time when Americans are meeting -- are eating more and more food from around the globe, we must spare no effort to ensure the safety of our food supply from whatever source. Today I want to tell you the new steps we're taking to ensure that our fruits and vegetables, including those imported from other countries, meet the highest health and safety standards.

First, I'm asking Congress to give the Food and Drug Administration the power and the obligation to ban the importation of fruits, vegetables and other foods from countries whose safety precautions do not meet American standards. This new law would be similar to a law that already requires the United States Department of Agriculture to keep meat and poultry from countries with inferior food safety systems out of our stores. In my next budget, I will provide enough funds to ensure that the FDA can fully implement this new legislation by dramatically expanding its international food inspection force.

With these efforts, we can make sure that no fruits and vegetables cross our borders, enter our ports, or reach our dinner tables without meeting the same

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strict standards as those grown here in America. Our food safety system is the strongest in the world, and that's how it's going to stay. I'm also directing the secretary of Health and Human Services and the secretary of Agriculture to work together in close cooperation with the agricultural community to develop the first-ever specific safety standards for the growing, processing, shipping and selling of fruits and vegetables.

These standards will address potential food safety problems throughout the production and distribution system, and they'll improve the sanitation and safety practices of all those seeking to sell produce in the United States market.

I'm asking Secretaries Shalala and Glickman to report back to me within 90 days with a complete schedule for developing these standards within a year. I'll also ask them to submit a comprehensive plan to improve the monitoring of food safety programs abroad to help foreign countries upgrade their safety precautions in toughened food inspections at the border.

Being a parent is perhaps the toughest job in the world. Our parents deserve the peace of mind that comes from knowing the food they set before their children is safe. With today's new actions we can help make their job much easier.

And again, let me thank all of those who were involved in this effort as I sign this order. Thank you very much.

(Signs order, applause, laughter.)

Q (Off mike) -- will you be using the line item veto?

PRESIDENT CLINTON: Excuse me?

Q Will you be using the line item veto on any of the appropriations bills that you've just (asked ?), or you've just --

PRESIDENT CLINTON: Well, let me say I have received only -- I've received one memorandum from my staff on one bill. And that came in late last night, so I haven't read it. But I will consider it as the bills come in. I will ask for a review of the potential uses by specific bill and make judgments as we go along. I have nothing to report at this time because I've received only one memorandum, and I haven't read it.

Q What about the census, sir? Do you have any concerns concerning the commerce bill and the particular ways that the money will be used for the census?

PRESIDENT CLINTON: Well, my feeling is that we ought to use -- we ought to do the census as well as we can. I don't think this is a complicated issue. The National Science -- the National Science Foundation has recommended this statistical sampling method, the man who did President Bush's census says that it's the only way to get the most accurate count. I just want to do whatever the Census Bureau believes -- the full-time professionals believe is the most accurate thing to do. I think that's a heavy constitutional responsibility we have, to conduct a census that is as accurate as possible, based on what the professionals say. This ought to be a professional, not a political judgment, and that's the position I will take throughout.

Q Mr. President, did the Democratic Party send money to the states because of federal election law restrictions?

Q Mr. President, there are fresh fruit and vegetable producers that are saying --

PRESIDENT CLINTON: Well wait a minute, I'll take both of them. Just a minute. Go ahead, first.

Q There are fresh fruit and vegetable producers that are saying that you're acting, with this action, as the world food police, and that your actions here today are unwarranted and that's going to complicate the trade environment.

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PRESIDENT CLINTON: Well, I hope it doesn't complicate the trade environment. But, you know, it seems to me that we have no higher responsibility than to protect the health and safety of our citizens. And everyone who has been following all of your reporting over the last four or five years knows that we have had continuing challenges in food safety. We have millions of people who get sick every year.

And we're not trying to unfairly target foreign producers of food into our market. We don't ask them to meet any standards we don't meet. And indeed, if you look at the actions of this administration over the last four years, when we started, I think you can make a compelling case that we started working on things that were problems coming out of the American market first. So I just don't think that's right. I don't want it to complicate the trade environment, but I'm not interested in trade in things that will make the American people sick. Q Mr. President, did the Democratic National Committee send money to the states in order to get around the federal spending limits that went along with accepting federal money for the national campaign, sir?

PRESIDENT CLINTON: It's my understanding that everything the Democratic National Committee did had the prior approval of the lawyers, that they cleared it all in advance and it was perfectly legal. And when this issue was raised about a year ago, the exact issue, I believe that that was clarified at that time. I'm sure that they had legal advice that they followed. And I believe that Republicans said that they did this -- some of the same things, and also had prior legal clearance.

Q Mr. Clinton, do you think that Mrs. Reno -- she's been advised to go forward with the 90-day investigation into the fund-raising calls of the vice president. And perhaps Mr. Gore would like to comment, too.

PRESIDENT CLINTON: I think that --

Q Do you feel that the 90-day investigation would be helpful?

PRESIDENT CLINTON: Well, if you read the statute, she can consider certain things in the 90-day that are not permitted in the 30-day period. But I think this is a legal question and it should be done based on an independent legal review with no pressure from the outside, from me or from anyone else. And that's the way I intend to keep it, at least on my part.

Thank you.

Q Mr. President, are you considering taking over the Race Advisory Board, possibly?

(No response as the president leaves the podium.)

END

LANGUAGE: ENGLISH

LOAD-DATE: October 3, 1997

Q&A for Presidential Initiative to Improve the Safety of Imported Fruits and Vegetables
October 2, 1997

Q: What is the President proposing?

A: The President is proposing legislative and executive actions that will further improve the safety of fresh fruits and vegetables, especially those imported into the U.S. The legislation will require the FDA to halt imports of fruits, vegetables, or other food from any foreign country whose food safety systems and standards are not on par with those of the U.S. The President will back up this legislation by providing the necessary funds in his FY99 budget to enable FDA to expand dramatically its international food inspection force so that it can make good use of this new authority.

In addition, the President has asked the Secretaries of Health and Human Services and Agriculture to take additional steps to improve the safety of both imported and domestic fruits and vegetables. Specifically, he has asked the Secretaries to issue within one year guidance on good agricultural practices and good manufacturing practices for fruits and vegetables. By providing the first-ever specific safety standards for fruits and vegetables, the guidance will improve the agricultural and manufacturing practices of all those, foreign and domestic, seeking to sell produce in the U.S. market.

Finally, the President has asked for a plan on how to improve the monitoring of agricultural and manufacturing practices abroad, to assist foreign countries to improve those practices where necessary, and to prevent the importation of unsafe produce, including by detecting unsafe food at the dock or border.

These efforts all build on the Clinton Administration's long-term commitment to strengthening our food safety system. With the help of the Vice-President's National Performance Review, we have fundamentally improved the way we ensure the safety of meat, poultry, and seafood. We have also put in place important new protections against the risks of pesticides in our food, especially for our children. And we are hopeful Congress will provide the \$43 million the President requested in his FY98 budget to improve food safety.

Q: Why is the President proposing these actions?

A: There have been dramatic changes in the produce department of the grocery store. Thirty years ago, most produce sections only had around a dozen items year round, increasing to as many as 50 in the summer. Today, no matter where you live in the United States, the chances are that there are 400 or more items in the produce section and they are there all year round. Last year, 38 percent of the fruit and 12 percent of the vegetables Americans ate were imported.

We have changed as well. Americans are eating more fresh fruits and vegetables than ever before, and our nation's health experts tell us we will live longer, better quality lives as a result. Our environment is also changing. We are finding "new" exotic bugs such as cyclospora and *E. coli* O157:H7 on our food that once were not there.

We must ensure that these changes do not increase the risk to American consumers of foodborne illnesses. Although raw produce -- including that imported from foreign countries -- is now safe, experts have suggested ways to make further improvements, and the President's actions today accord with their recommendations.

Q: But aren't these actions just a response to the negative news articles of recent days that have pointed out the shortcomings in the inspection of imported produce?

A: No. We couldn't possibly have developed these initiatives following the publication of those articles. The Department of Health and Human Services have been laying the groundwork for this initiative for over a year. We knew that some reporters were making inquiries about this issue, and those inquiries may have accelerated the final part of the policy development process. But that process has been underway for some time, and this same initiative would have been announced with or without those articles.

Q: Why has the Administration waited until now to take these steps? [An article published today reveals that today's actions were suggested by Commissioner Kessler years ago, but that no action was taken. Why has it taken so long to act?]

A: No one can tackle everything at once, and the President's food safety initiatives have addressed priority items in the way best calculated to ensure their achievement. One of the first challenges the President faced after taking office was an outbreak of *E. Coli* in hamburger in the northwest. The President responded by putting in place a new system to ensure the safety of meat, poultry, and seafood products. With this process now underway, the FDA in 1995 began to investigate the problem of pathogens in fresh produce and develop proposed approaches for preventing foodborne illnesses from these food products.

Q: Are these actions meant to provide political cover with respect to the food safety issue because it has become a part of the Fast Track trade debate?

A: No. Again, the policy development process that led to this initiative began in 1995. This is a part of the President's food safety agenda -- his longstanding commitment to ensuring that Americans' food supply is the safest in the world. It does not relate to Fast Track.

Q: What makes you think this new legislation can be effective? Do you seriously think you are going to be able to put FDA inspectors in every country abroad?

A: Our proposed legislation would give the FDA the same kind of responsibility that the USDA already has for meat and poultry. The USDA system has worked very well to ensure that countries with inferior safety standards can't import their meat and poultry. We see no reason why the FDA can't run a similarly effective system that inspects food safety system and standards abroad and prevents imports from countries that do not provide the protections that the U.S. does.

Of course, making good use of this authority will take additional resources, so that FDA can dramatically expand its international food inspection force. Although the President will not announce a specific dollar figure until publication of his FY 99 budget, he has committed to investing the resources to ensure that FDA can make good use of this new authority.

Q: Doesn't this legislation impose trade barriers to food imports at a time when you are saying you want to lower them? Wouldn't we object if another country tried to keep out our food products on this basis?

A: This legislation is completely consistent with free trade principles and all our treaty obligations. We have no obligation to open our borders to imports that pose a greater risk than domestic products to American consumers. As long as we are not imposing any greater requirements on foreign countries -- as long as we are only holding them to our standards -- we are acting consistently with our trade policy.

There aren't many countries in the world with higher safety standards than the U.S., so not many countries would be in a position to halt our imports on this basis. If we did, we would not and could not object.

Q: Are you saying that imported produce is unsafe?

A: There is no data indicating that imported fruits and vegetables are more unsafe than domestic products. But some recent outbreaks of foodborne illness have been traced back to imports and it is important that foreign fruits and vegetables be held to the same safety standards as American products. The steps we are taking today are adding additional layers of protection. We are making sure that there are no gaps in our food safety system -- that high safety standards apply to imported as well as domestic food, and to fruits and vegetables as well as to meat, poultry, and seafood.

Q: Since HACCP has been successful for meat, poultry, and seafood, why don't you require HACCP for fresh fruits and vegetables? Why are you only doing good agricultural and manufacturing practices?

A: HACCP is a science-based approach for identifying and controlling hazards in food

production. We need better scientific data before we can develop HACCP for fresh fruits and vegetables. The Administration's plan is to develop and issue guidance that will help companies interpret existing safety requirements for fruits and vegetables, and that will lead to the science needed for HACCP. The agency is contemplating guidance on basic, common-sense sanitation and employee practices in the form of Good Agricultural Practices (GAPs) for farms and Good Manufacturing Practices (GMPs) applicable for those who sort, wash, and otherwise handle fresh fruits and vegetables.

Q: Aren't these guidelines only voluntary? If so, what effect will they have?

A: The Good Agricultural and Manufacturing Practices will be what is called "interpretive guidance." It will help companies interpret and follow existing, very broadly written safety requirements for fruits and vegetables by spelling out specific practices involving such matters as sanitation, worker health, and water quality. The guidance does not itself have legal force. But it tells growers, processors, and others what the FDA looks to when it enforces existing safety standards. There is no doubt that such guidance -- especially when it is developed, as it will be, in concert with the agricultural community -- will improve safety standards.

Q: Will foreign countries have to comply with Good Agricultural and Manufacturing Practices if they want to export fruits and vegetables to the U.S.?

A: We expect that exporting countries will develop similar practices that address potential food safety problems in their countries for one simple reason: they want to be able to sell food in our market, and they want that food to be safe.

We cannot yet know whether a country that does not comply with the guidance will be able to import fruits and vegetables into the United States. The answer to this question depends on the exact content of the guidance, as well as an intricate legal determinations regarding equivalency between different countries' food safety systems. What is clear is that the FDA will have to cut off imports from countries that do not comply with existing legal standards. And at the very least, the FDA will target countries that do not comply with the Good Agricultural and Manufacturing Practices for increased inspection and testing.