

FDA FOOD CODE 1999

PHOTOCOPY
PRESERVATION

**U. S. Department of Health and Human Services
Public Health Service
Food and Drug Administration**

FDA FOOD CODE

Introduction **Obtaining the 1999 Food Code** **Obtaining the 1997 Food Code**

Introduction

The Food and Drug Administration publishes the *Food Code*, a reference that guides retail outlets such as restaurants and grocery stores and institutions such as nursing homes on how to prevent foodborne illness.

Local, state and federal regulators use the FDA *Food Code* as a model to help develop or update their own food safety rules and to be consistent with national food regulatory policy. Also, many of the over 1 million retail food establishments apply *Food Code* provisions to their own operations.

The *Food Code* is updated every two years, to coincide with the biennial meeting of the Conference for Food Protection. The conference is a group of representatives from regulatory agencies at all levels of government, the food industry, academia, and consumer organizations that works to improve food safety at the retail level.

Obtaining the 1999 Food Code

Copies of the 1999 *Food Code* are available in the following formats:

- 1999 *Food Code* in HTML or PDF versions.
 - Summary of Changes
- Download the full 1999 *Food Code* in PDF format. (1Mb; 1.2Mb uncompressed)
(Obtain a PDF reader.)
- Word Perfect 6/7/8 version compressed in self-extracting zip format (623Kb; 2Mb uncompressed)
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 - Spiral bound order number: PB99-115925
 - Docutek order number: PB99-115917
 - Electronic Edition on CD-ROM (also includes the Adobe Reader, Draft HACCP Guide, and Plan Review Manual) order number: PB99-500506

- Electronic Edition on Diskette order number: PB99-501033
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Obtaining the *1997 Food Code*

Copies of the 1997 *Food Code* are available in the following formats:

- HTML version of the 1997 *Food Code*
- PDF version of the 1997 *Food Code*
(Obtain a PDF reader.)
 - Part I: Introductions, Chapters 1-8, Annex 1 (1.2 Mb)
 - Part II: Annex 2-7 (1.4 Mb)

Note: The above files contain links to external files, such as CFR references contained in the *Food Code*, that were intended to work when loaded onto a pc and not over the internet. Therefore, these external links do not work over the internet. However, you may download the entire *Food Code*, below, with the references, and use it locally on your hard drive if you want to be able to access these additional file links.

- 1997 *Food Code* Electronic Edition including associated references (e.g. CFR references) in PDF format, compressed in zip format (5.0 Mb; 6.5 Mb unzipped)
- Word Perfect 6.1 version compressed in zip format (636 Kb; 2.7Mb unzipped)
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- Printed copies and computer disks from the National Technical Information Service

Status of Food Code Adoptions

Home	Prime Connection	Industry Assistance	Foodborne Illness	Food Safety Initiative	www.FoodSafety.gov
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Hypertext updated by dms 1999-APR-15

Food Code

**U. S. DEPARTMENT OF HEALTH AND HUMAN
SERVICES**

**Public Health Service
Food and Drug Administration
Washington, DC 20204**

1999

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**1999 Recommendations of the
United States Public Health Service
Food and Drug Administration**



The Food Code consists of model requirements for safeguarding public health and ensuring food unadulterated and honestly presented when offered to the consumer.

This model is offered for adoption by local, state, and federal governmental jurisdictions for administration by the various departments, agencies, bureaus, divisions, and other units within each jurisdiction which have been delegated compliance responsibilities for food service, retail food stores, or food vending operations.

For public sale by:
U.S. Department of Commerce
Technology Administration
National Technical Information Service
5285 Port Royal Road, Springfield, VA 22161
(703) 605-6000, refer to report number PB99-115925

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**Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are
Inconsistent and Unreliable**

(Chapter Report, 04/30/98, GAO/RCED-98-103).

EXECUTIVE SUMMARY

Concerned about the safety of imported foods, the Chairman of the Permanent Subcommittee on Investigations, Senate Committee on Governmental Affairs, asked GAO to review the efforts of federal programs to ensure the safety of food imports.

PURPOSE:

To discuss:

1. the differences in the agencies' authorities and approaches for ensuring the safety of imported foods.
2. the agencies' efforts to target their resources on foods posing risks and the weaknesses in the controls over imported foods.

BACKGROUND:

- The primary responsibility for ensuring the safety of imported foods is split between **USDA's Food Safety and Inspection Service (FSIS)** and **FDA**.
- Jurisdiction:
FSIS: Meat, poultry, and some egg products.
FDA: All other foods.
- FSIS and FDA work closely with **Customs** and **CDC**.

Role:

CUSTOMS: Refers imported foods to FSIS or FDA for review before releasing the shipment into U.S. commerce.

CDC: Monitors the incidence of foodborne illness, works with state and local health departments to investigate outbreaks, and collaborates with FSIS, FDA, and others to conduct research.

- FSIS and FDA require imported foods to meet the same standards as domestic foods, but their approaches to enforcing these requirements differ:
 - *By law*, **FSIS** places the principal responsibility of safety to the exporting countries by allowing imports only from countries with food safety systems deemed equivalent to the U.S.
 - **FDA**, lacks this legal authority and allows food imports from almost any country, taking on the burden of ensuring the safety of imported foods as they arrive at U.S. ports of entry.

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RESULTS:

1. LACK OF EQUIVALENCY AUTHORITY DIMINISHES FDA'S ABILITY TO PROTECT U.S. CONSUMERS.

Relying on port-of-entry inspections to detect and prevent unsafe foods is ineffective:

- It does not ensure that foods are produced under adequately controlled conditions.
- FDA currently inspects less than 2 percent of all foreign shipments.
- Inspection will not detect some organisms, such as *Cyclospora*, for which visual inspections and laboratory tests are inadequate.

2. AGENCIES COULD MORE EFFECTIVELY TARGET RESOURCES ON UNSAFE FOODS.

Federal agencies cannot ensure that imported foods are safe for consumers because FSIS and FDA are not deploying their inspection resources to maximum advantage:

- FSIS focuses on exporting firms with a history of non-health related violations (processing defects, incorrect shipping labels, etc...), yet using available data on exports with a history of health-related violations would allow inspectors to focus on imports posing the greater risks.
- FDA does not make health risk data readily available to guide inspectors' selections and when making deciding on which shipments to inspect, they rely on importers' descriptions of shipments' contents, which are often incorrect. As a result, the agency's resources may not be focused on imported foods posing the greater safety risk.

3. WEAKNESSES IN IMPORT CONTROLS ALLOW ENTRY OF UNSAFE PRODUCTS.

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

- Because FDA does not have the explicit authority to require importers to use certain laboratories, importers can choose the laboratories that select the samples and perform the tests to prove compliance.
- FDA has often found discrepancies between their test results and those from private laboratories for the same shipment.
- Customs and FDA inspectors have also found that importers substitute safe products for inspection, rather than the imported products FDA wanted to inspect.

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RECOMMENDATIONS:

- (1) That the Congress require all foods eligible for import to the United States, not just meat and poultry, be produced under equivalent food safety systems.

Agency Response: 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 that the authority should be discretionary, not mandatory, so that equivalency could be applied where it is most appropriate without disrupting trade.

- (2) The Secretary of Health and Human Services and the Secretary of Agriculture improve the effectiveness and efficiency of their import review systems and procedures by targeting inspection resources on foods posing greater health risks.

The report recommends that the Secretary of Agriculture improve the Automated Import Information System's usefulness so that the system can identify patterns between laboratory test results and specific foods, foreign firms and exporting countries.

The report recommends to the Secretary of HHS to direct the Commissioner, FDA, to:

- Clarify the guidance inspectors should use when making decisions on which shipments to inspect and test.
- Modify the Operational and Administrative System for Import Support (OASIS) System.
- Ensure that the field offices are taking the appropriate corrective action, when warranted, against importers that repeatedly enter incorrect shipping information into the OASIS database.

Agency Response: FSIS agreed with GAO's recommendation, and that it will be evaluating its port-of-entry inspection procedures and consider GAO's recommendations.

FDA agreed with GAO's recommendation to link three databases (the Import Alert database, the Low-Acid Canned Food database, and the laboratory database) to the Operational and Administrative System for Import Support for use by inspectors when choosing shipments for inspections and tests.

FDA also agreed generally with other specific recommendations regarding its import screening system.

- (3) No Recommendation for the third result.

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GAO REPORT

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1998

SOCIAL SECURITY FINANCING: IMPLICATIONS OF GOVERNMENT STOCK INVESTING FOR THE TRUST FUND, THE FEDERAL BUDGET, AND THE ECONOMY

For the Social Security trust fund, government stock investing offers the prospect of higher returns but greater risk. For the federal budget, stock investing would have the immediate effect of decreasing the surplus or increasing any deficit, because, under current budget scoring rules, stock purchases would be treated as outlays. Stock investing would not significantly affect the economy and would have no appreciable effect on future national income. (AIMD/HEHS-98-74)

FOOD SAFETY: FEDERAL EFFORTS TO ENSURE THE SAFETY OF IMPORTED FOODS ARE INCONSISTENT AND UNRELIABLE

Federal agencies cannot ensure that the growing volume of imported food is safe for consumers. The Food Safety and Inspection Service, responsible for meat and poultry, places the principal burden for safety on the exporting countries and only allows imports from countries with food safety systems equivalent to the U.S. system. The Food and Drug Administration, responsible for all other foods, inspects foods when they arrive at U.S. ports of entry. In this report, GAO recommended that the Congress require that all imported foods be produced under equivalent food safety systems. (RCED-98-103)

TELECOMMUNICATIONS: TELEPHONE SLAMMING AND ITS HARMFUL EFFECTS

Testimony of Eljay B. Bowron, Assistant Comptroller General, Office of Special Investigations

Slamming is the switching of a customer from one long-distance provider to another without the consumer's knowledge and consent. The Federal Communications Commission (FCC), the states, and the telecommunications industry are not sufficiently protecting consumers from telephone slamming. Because of lack of FCC diligence, an unscrupulous company can easily file a tariff or application with FCC to provide long-distance service and slam consumers with impunity. In addition to consumers, long-distance carriers are victims of slamming because this fraud increases industry costs. (T-OSI-98-11)

AIM-9X ACQUISITION: MISSILE RISK REDUCTION UNDERWAY BUT SYSTEM PRODUCTION PLANS NEED TO BE REEXAMINED

The Navy and the Air Force are jointly developing the AIM-9X short-range air-to-air missile. In this report, GAO expresses concern that low-rate initial production is planned to start before decisionmakers have enough verifiable information to make an informed production decision. GAO recommends revisions to the AIM-9X acquisition strategy to allow enough testing to demonstrate that the AIM-9X can meet its minimum performance requirements before production begins. (NSIAD-98-45)

YEAR 2000 COMPUTING CRISIS: POTENTIAL FOR WIDESPREAD DISRUPTION CALLS FOR STRONG LEADERSHIP AND PARTNERSHIPS

There is a high risk that critical services provided by the government and the private sector could be severely disrupted by the Year 2000 computing crisis. Financial transactions could be delayed, flights grounded, power lost, and national defense affected. The many interdependencies that exist among governments and within key economic sectors could cause a single failure to have adverse repercussions. While the government and the private sector work to mitigate these risks, much work remains to be done and time is running out. (AIMD-98-85)

GAO

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

April 1998

FOOD SAFETY

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





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

Resources, Community, and
Economic Development Division

B-279329

April 30, 1998

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

Dear Madam Chairman:

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

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

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

Sincerely yours,

A handwritten signature in cursive script that reads "Robert A. Robinson".

Robert A. Robinson
Director, Food and
Agriculture Issues

Executive Summary

Purpose

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

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

Background

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

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

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

Results in Brief

- 1 Federal agencies cannot ensure that the growing volume of imported foods is safe for consumers. Although the Food Safety and Inspection Service and the Food and Drug Administration require imported foods to meet the same standards as domestic foods, their approaches to enforcing these requirements differ. By law, the Food Safety and Inspection Service places the principal burden for safety on the exporting countries by allowing imports only from those countries with food safety systems it deems to be equivalent to the U.S. system. The Food and Drug Administration, lacking such legal authority, allows food imports from almost any country and takes on the burden of ensuring the safety of imported foods as they arrive at U.S. ports of entry. Relying on port-of-entry inspections to detect and prevent unsafe foods is ineffective, given that (1) this approach does not ensure that foods are produced under adequately controlled conditions, (2) the Food and Drug Administration currently inspects less than 2 percent of all foreign shipments, and (3) inspection will not detect some organisms, such as *Cyclospora*, for which visual inspections and laboratory tests are inadequate.
- 2 The Food Safety and Inspection Service and the Food and Drug Administration are not deploying their inspection resources to maximum advantage. The Food Safety and Inspection Service focuses its inspection and testing resources on shipments from exporting firms with a history of violations, such as contamination, processing defects, and incorrect or missing shipping labels. However, many of the violations, such as the incorrect or missing shipping labels, may bear little relationship to food safety. Using available data on health-related risks from shipments that do not meet U.S. standards could help the Food Safety and Inspection Service focus more closely on the imports posing the greater risks. The Food and Drug Administration's annual work plan does not set achievable targets for inspection activities; as a result, inspectors do not have clear guidance for conducting inspections. For example, in fiscal year 1997, the Food and Drug Administration conducted only half of its planned inspections of imported foods. Furthermore, the Food and Drug Administration does not make health risk data readily available to guide inspectors' selections. In addition, when making decisions on which shipments to inspect, the Food and Drug Administration relies on importers' descriptions of shipments' contents, which are often incorrect. As a result, the agency's resources may not be focused on imported foods posing the greater safety risk.
- 3 The Food and Drug Administration's procedures for ensuring that unsafe imported foods do not reach U.S. consumers are vulnerable to abuse by

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

Principal Findings

① Lack of Equivalency Authority Diminishes FDA's Ability to Protect U.S. Consumers

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

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

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

Agencies Could More Effectively Target Resources on Unsafe Foods

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

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

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

③ Weaknesses in Import Controls Allow Entry of Unsafe Products

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

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

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

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

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

Recommendations

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

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

Agency Comments

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

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

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

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

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

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

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Abbreviations

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

Introduction

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

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

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

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

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

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

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

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

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

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

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

Multiple Agencies Are Responsible for Ensuring the Safety of Imported Foods

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

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

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

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

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

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

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

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

How Import Control Processes Work

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

FDA's System for Allowing the Entry of Imported Foods

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

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

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

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

⁶FDA refers to these programs as compliance programs.

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

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

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

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

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

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

FDA's district offices by October 1997.¹⁰ (Before OASIS was developed, FDA manually tracked shipments through entry documents submitted by importers to Customs.) Along with the electronic information provided by the importer, FDA officials use the information in OASIS and other sources as needed—such as the databases with information on products to be automatically detained and registration numbers for foreign firms—to determine which samples of imported food shipments should be held for further action, such as inspection and/or laboratory testing, and which can be released without further review. FDA releases most shipments not requiring further review within 3 hours after the importer enters the information. FDA does not visually check or inspect these released shipments.

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

FSIS' System for Allowing the Entry of Imported Foods

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

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

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

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

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

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

Objectives, Scope, and Methodology

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

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.

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

FSIS

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

FDA

- 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

FSIS

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.

NO RECS

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,

A handwritten signature in cursive script, reading "Diane E. Thompson".

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.

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.

a 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

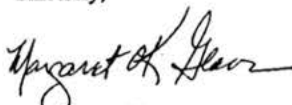
Mr. Robert A. Robinson

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-I-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.

See comment 2.

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

See comment 3.

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

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

See comment 3.

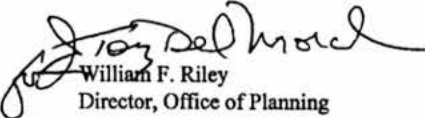
GAO cites this case as proof that our Agency is being too lenient on violators. However, we assume that the violation was minor, not a contaminated food violation and, therefore, in accordance with Customs mitigation guidelines. The GAO Report does not refer to the fact that Customs and FDA must be in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

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

Keith W. Oleson, Assistant Director
Dennis Richards, Project Leader
Daniel F. Alspaugh
Judy K. Hoovler
John M. Nicholson, Jr.
Carol Herrnstadt Shulman
Jonathan M. Silverman

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IMPERIAL FOOD SAFETY ACT
FOOD SAFETY DIRECTIVES JULY 1997

PHOTOCOPY
PRESERVATION

Presidential Directive to Take Action to Prevent the Importation of Unsafe Foods

July, 1999

President Clinton directed the Secretary of Health and Human Services (HHS) and the Secretary of the Treasury to report back within 90 days on the available steps they will take to:

- (1) Prevent distribution of imported unsafe food by means such as requiring food to be held until reviewed by FDA. Requiring food to be held in a secure storage facility until released by FDA will prevent "bad actor" importers from distributing and selling potentially unsafe imported food before FDA has completed its review.
- (2) Destroy imported food that poses a serious public health threat. Requiring destruction of such food will protect American consumers by removing the goods from commerce (thus preventing their re-entry at another port) and will also protect consumers around the world by preventing importers from exporting the contaminated foods to other countries.
- (3) Prohibit "port shopping"-- in which importers whose cargo is denied entry at one port try to introduce it at another -- though a new FDA requirement to mark shipping containers and/or papers of imported food that is denied admission for safety reasons. The unsafe food will be clearly marked, "Refused U.S.".
- (4) Set standards for private laboratories for the collection and analysis of samples of imported food for the purpose of gaining entry into the United States.
- (5) Increase the amount of the bond posted for imported foods when necessary to deter premature and illegal entry into the United States. Increasing the bond amount will prevent unscrupulous importers from forfeiting the bond amount (which is currently based only on the wholesale value of the shipment), selling the shipment before FDA completes its review, and turning a significant profit anyway.
- (6) Enhance enforcement for violations of United States laws related to the importation of foods, including the imposition of civil monetary penalties. Food Safety Initiative and Legislation.

The President also called on Congress to provide full funding for his requested \$72 million increase for the Food Safety Initiative, which supports:

- (1) Enabling FDA to hire new inspectors to inspect at least annually every domestic manufacturer of high-risk food products.
- (2) Permitting USDA to assist states in order to create a seamless national inspection program; enabling FDA to more than double the number of inspections conducted of foreign food processors.

- (3) Allowing the agencies to expand research to develop more effective ways of testing for and identifying dangerous contaminants such as Salmonella and Cyclospora.

The House-passed Agricultural Appropriations bill fails to fund \$27 million of the much-needed requested increase, and the Senate Appropriations Committee bill fails to fund \$18 million of the requested increase.

The President also called on Congress to pass two pieces of legislation that:

- (1) Ensures that imports of fruits, vegetables, and other food products meet U.S. food safety requirements or provide the same level of protection as is required for U.S. products. (Sponsored by Senators Mikulski, Kennedy, Durbin and Representative Eshoo).
- (2) Will give USDA the authority to issue mandatory recalls and impose civil penalties for unsafe meat and poultry. (Sponsored by Senator Harkin).

Imported Food Safety Improvement Act
May 26, 1999

TITLE: Cited as the 'Imported Food Safety Improvement Act of 1999'.

TITLE I: IMPROVEMENTS TO THE FOOD SAFETY IMPORT SYSTEM.

SPONSORS: Senators Mikulski, Kennedy and Durbin

PURPOSES: To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of imported food, and for other purposes.

- (1) It requires that FDA make equivalence determinations on imported food. Senator Kennedy and Senator Mikulski developed this with the FDA in consultation with the consumer groups.
 - It will allow FDA to look at the production at its source and take preventive measures.
 - FDA will be able to be proactive, rather than just reactive.
- (2) It covers emergency situations by allowing FDA to ban imported food that has been connected to outbreaks of food borne illness and grants the Secretary of Health and Human Services the authority to issue an emergency ban.
- (3) It enhances enforcement measures through the creation of additional employment positions for laboratory, inspection, and compliance personnel.

IMPORTED FOOD SAFETY ACT (Senate - May 26, 1999)

[Page: S6045]

Mr. FRIST. Mr. President, I rise to join with Senator **Collins** in introducing S. 1123, the Imported Food Safety Act of 1999. This legislation will address a growing problem that affects everyone in this nation, the safety of the food that we eat.

The Centers for Disease Control and Prevention estimates as many as 9,100 deaths are attributed to foodborne illness each year in the United States. In addition there are tens of millions of cases of foodborne illness that occur, the majority of which go unreported due to the fact that they are not severe enough to warrant medical attention.

The legislation that Senator **Collins** and I have crafted will target one of the most critical areas in helping to provide Americans with the safest food possible--the safety of imported food. The CDC has recognized that as trade and economic development increases, the globalization of food supplies is likely to have an increasing impact on foodborne illnesses.

Currently, one-half of all the seafood and one-third of all the fresh fruit consumed in the U.S. comes from overseas. In fact, since the 1980's food imports to the U.S. have doubled, but federal inspections by Food and Drug Administration have dropped by 50 percent.

Over the years there have been foodborne pathogen outbreaks involving raspberries from Guatemala, strawberries from Mexico, scallions, parsley and cantaloupes from Mexico, carrots from Peru, coconut milk from Thailand, canned mushrooms from China and others. These outbreaks have serious consequences. The Mexican frozen strawberries I have just noted were distributed in the school lunch programs in several states, including my home state of Tennessee, were attributed to causing an outbreak of Hepatitis A in March of 1997.

The Collins-Frist bill will do several vital things to safeguard against potentially dangerous imported food. The bill would allow the U.S. Customs Service, using a system established by FDA, to deny entry of imported food that has been associated with repeated and separate events of foodborne disease.

The bill would also allow the FDA to require food being imported by entities with a history of import violations to be held in a secure storage facility pending FDA approval and Customs release.

To improve the surveillance of imported food, we authorize CDC to enter into cooperative agreements and provide technical assistance to the States to conduct additional surveillance and studies to address critical questions for the prevention and control of foodborne diseases associated with imported food, and authorize CDC to conduct applied research to develop new or improved diagnostic tests for emerging foodborne pathogens in human specimens, food, and relevant environmental samples.

These are just a few of the many provisions in this bill that will help improve the quality and safety of the imported food that we consume every day. I applaud the leadership of my colleague, Senator **Collins**, who as Chairman of the Senate Permanent Subcommittee on Investigations held 4 comprehensive hearings last year on the issue of food safety. As Chairman of the Senate Subcommittee on Public Health, I look forward to working with Senator **Collins** and the rest of my colleagues on the issue of food safety and our overall efforts in improving our Nation's public health infrastructure. We must continue to fight infectious diseases and ensure that this legislation is enacted to help protect our citizens and provide them with the healthiest food possible.

END

Commission shall apply a presumption in favor of unconditional approval of the application. If the Commission fails to issue a final decision within the 60-day period described in paragraph (2), the application shall be deemed to have been granted unconditionally by the Commission.'

By Ms. MIKULSKI (for herself, Mr. **Kennedy**, and Mr. **Durbin**):

S. 1126. A bill to amend the Federal Food, Drug, and Cosmetic Act to improve the safety of imported food, and for other purposes; to the Committee on Agriculture, Nutrition, and Forestry.

IMPORTED FOOD SAFETY IMPROVEMENT ACT OF 1999

Ms. MIKULSKI. Mr. President, I rise today to introduce the 'Imported Food Safety Act of 1999.' I am proud to be the sponsor of this important legislation which guarantees the improved safety of imported foods.

The health of Americans is not something to take chances with. It is important that we make food safety a top priority. Every person should have the confidence that their food is fit to eat. We should be confident that imported food is as safe as food produced in this country. Cars can't be imported unless they meet U.S. safety requirements. Prescription drugs can't be imported unless they meet FDA standards. You shouldn't be able to import food that isn't up to U.S. standards, either.

We import increasing quantities of fresh fruits and vegetables, seafood, and many other foods. In the past seven years, the amount of food imported into the U.S. has more than doubled. Out of all the produce we eat, 40% of it is imported. Our food supply has gone global, so we need to have global food safety.

The impact of unsafe food is staggering. There have been several frightening examples of food poisoning incidents in the U.S. When Michigan schoolchildren were contaminated with Hepatitis A from imported strawberries in 1997, Americans were put on alert. Thousands of cases of cyclospora infection from imported raspberries--resulting in severe, prolonged diarrhea, weight loss, vomiting, chills and fatigue were also reported that year. Imported cantaloupe eaten in Maryland sickened 25 people. As much as \$663 million was spent on food borne illness in Maryland alone. Overall, as many as 33 million people per year become ill and over 9000 die as a result of food borne illness. It is our children and our seniors who suffer the most. Most of the food-related deaths occur in these two populations.

These incidents have scared us and have jump-started the efforts to do more to protect our nation's food supply. Now, I believe in free trade, but I also believe in fair trade. FDA's current system of testing import samples at ports of entry does not protect Americans. It is ineffective and resource-intensive. Less than 2% of imported food is being inspected under the current system. At the same time, the quantity of the imported foods continues to increase.

What this law does is simple: It improves food safety and aims at preventing food borne illness of all imported foods regulated by the FDA. This bill takes a long overdue, big first step.

First, it requires that FDA make equivalence determinations on imported food. This was developed with the FDA by Senator **Kennedy** and myself in consultation with the consumer groups.

Today, FDA has no authority to protect Americans against imported food that is unsafe until it is too late. Last year, the GAO found that FDA lacks the authority to require that food coming into the U.S. is produced, prepared, packed or held under conditions that provide the same level of food safety protection as those in the U.S. This means that currently, food offered for import to the U.S., can be

imported under any conditions, even if those conditions are unsanitary. The Imported Food Safety Act of 1999, will allow FDA to look at the production at its source. This means that FDA will be able to take preventive measures. FDA will be able to be proactive, rather than just reactive.

That means that when you pack your childrens' lunches for school or sit down at the dinner table, you can rest assured that your food will be safe. Whether your strawberries were grown in a foreign country or on the Eastern Shore, in Maryland, those strawberries will be held to the same standard. You won't have to worry or wonder where your food is coming from. You won't have to worry that your children or families are going to get sick. You will know that the food coming into this country will be subject to equivalent standards.

Secondly, this bill contains strong enforcement measures. Last year, the Permanent Subcommittee on Investigations, under the leadership of Senator **Sue Collins**, held numerous hearings on the safety of imported food. These enforcement measures are largely a product of those facts uncovered during those hearings. Senator **Collins** developed these enforcement provisions and introduced a bill which focuses on enforcement. I refer those with special interest in enforcement to also consider her bill.

Finally, this bill covers emergency situations by allowing FDA to ban imported food that has been connected to outbreaks of food borne illness. When our children, parents and communities are getting seriously sick, the Secretary of Health and Human Services can immediately issue an emergency ban. We don't have to wait till someone else gets seriously sick or dies. We no longer have to go through the current bureaucratic mechanism that is inefficient and resource intensive. We can stop the food today, to protect our citizens.

My goal is to strengthen the food supply, whatever the source of the food may be. This bill won't create trade barriers. It just calls for free trade of safe food. It calls for international concern and consensus on guaranteeing standards for public health.

This bill is important because it will save lives and makes for a safer world. Everyone should have security in knowing that the food they eat is fit to eat. I'd like to thank FDA for their advice and consultation in developing this legislation. I also want to thank the Consumer Federation of America for their insight and recommendations.

I look forward to working on a bipartisan basis to enact this legislation. I pledge my commitment to fight for ways to make America's food supply safer. This bill is an important step in that direction.

Mr. President, I ask unanimous consent that the statement of Ms. Carol Tucker Foreman, Distinguished Fellow and Director of the Food Policy Institute, be printed in the **Record**.

There being no objection, the material was ordered to be printed in the **Record**, as follows:

[Page: S6053]

Statement of Carol Tucker Foreman, Distinguished Fellow and Director of the Food Policy Institute

~~I am~~ here today on behalf of the Consumer Federation of America and the National Consumers' League to endorse the Imported Food Safety Act of 1999. I thank Senators Mikulski, Kennedy and Durbin and Congresswoman Eshoo for introducing this very important legislation.

It will improve the Food and Drug Administration's capacity to protect American consumers from food-borne illness caused by adulterated imported food.

Food-borne illness is a serious public health problem in the U.S. Food poisoning kills 9,000 Americans each year and causes as many as 33 million illnesses. It costs us at least \$5 billion each year in medical costs and time lost from work. The human toll is incalculable.

Americans eat from a global plate. We want a wide variety of foods available on a year round basis. Health experts urge us to eat more fruits and vegetables. Imports make fresh fruits available to us even in the middle of February.

But no one wants imported foods served with a side helping of food poisoning. We want all our food, domestic and imported, to be safe.

We have not had that assurance. In recent years there have been a number of incidents of food-borne illness arising from imported food products. Last year, the Senate Permanent Subcommittee on Investigations revealed serious problems with the Food and Drug Administration's capacity to protect Americans from unsafe food.

The General Accounting Office reported that FDA can't protect us because the agency has no authority to require that foods coming into the United States be produced and packaged under circumstances that provide the same level of health protection required for domestic food producers and processors.

Most American consumers, and frankly most food producers and processors as well, would be shocked to learn that imported food is not required to be produced in a manner that provides the same level of health protection as domestic products and that FDA has no authority to check, in advance, for adequate public health safeguards. FDA can act only after the fact--after adulterated food has been found or someone has gotten sick.

The USDA inspects meat, poultry and egg products. GAO noted that USDA has the necessary power to protect consumers. The Department has the authority to require that meat and poultry produced abroad and imported into the U.S. be produced in a system that provides a level of health protection equivalent to that imposed on U.S. producers. That level of protection may include limits on bacteria that cause human illness. In addition, USDA has federally sworn inspectors who examine the foreign systems and check food at the docks.

The Food and Drug Administration has jurisdiction over all other food products, including the fresh fruits and vegetables that are so susceptible to contamination. FDA has no similar authority, no inspectors who visit foreign plants and virtually no inspectors to check food at the docks. Last year, FDA checked only two percent of the food imported into the U.S. In fact, FDA has established only a limited number of performance standards for domestically produced foods.

That point bears repeating. If you eat meat and poultry produced in another country and imported into the U.S., you can do so knowing they were produced under circumstances at least as clean and sanitary as meat, poultry and eggs produced in the U.S. If you consume fresh fruits and vegetables produced in another country, you have no such assurance, even though you will cook your meat, poultry and eggs but may well eat the fruits and vegetables raw, increasing the chance that you will consume disease causing bacteria.

In a recent study, the Center for Science in the Public Interest surveyed 225 food-borne illness outbreaks that occurred between 1990 and 1998. Foods regulated by the FDA caused over twice as many outbreaks as foods regulated by the USDA. Fruits, vegetables and salads caused 48 outbreaks. Seafood, both finfish and shellfish, caused 32 outbreaks.

USDA's more rigorous system of inspection has certainly not stopped foreign produced meat

products from entering the country. We import hundreds of millions of pounds of meat each year from Australia, to Argentina and Denmark and a host of other countries. Neither foreign nor domestic producers have suffered any loss of trade.

The Imported Food Safety Act sets up a system for the Secretary of Health and Human Services to use in establishing equivalency; gives FDA more authority to visit other countries; provides important enforcement authority and controls over imported foods; prohibits port shopping and increases penalties for importing contaminated foods and authorizes new funding for FDA to carry out these functions.

Americans do care about food safety. The Food Marketing Institute, the nation's super market trade association, recently released its annual survey of trends among super market shoppers. Ninety percent of those surveyed said food safety was very important or somewhat important to them in making food selections. The Imported Food Safety Act will increase assurance among consumers that the food supply is safe.

The Imported Food Safety Act is an important part of a package of food safety legislation which Congress should address this year. Other parts of the package include legislation to promote the use of specific microbial standards for both domestic and foreign produce, introduced by Senator Harkin; require registration of importers, introduced by Senator Dorgan. Congress should act now before confidence is diminished.

Mr. KENNEDY. Mr. President, it is a privilege to be a sponsor of this important bill, and I commend Senator **Mikulski** for her leadership on this legislation to close the critical gaps in our imported food safety laws.

Citizens deserve to know that the food they eat is safe and wholesome, regardless of its source. The United States has one of the safest food supplies in the world. Yet every year, millions of Americans become sick, and thousands die, from eating contaminated food. Billions of dollars a year in medical costs and lost productivity are caused by food-borne illnesses. Often, the source of the problem is imported food.

We've heard recently about the thousands of cases of illness from *Cyclospora* in raspberries from Guatemala. But this high profile case is by no means the only case.

In 1997, school children in five states contracted Hepatitis A from frozen strawberries served in the school cafeterias. Fecal contamination is a potential source of Hepatitis A, and the strawberries the children ate came from a farm in Mexico where workers had little access to sanitary facilities.

Earlier this year, cases of typhoid fever in Florida were linked to a frozen tropical fruit product from Guatemala. Again, poor sanitary conditions appear to be at the root of the problem.

Gastrointestinal illness has been linked to soft cheeses from Europe. Bacterial food poisoning has been attributed to canned mushrooms from the Far East.

The emergence of highly virulent strains of bacteria, and an increase in the number of organisms that are resistant to antibiotics, make microbial contamination of food a major public health challenge.

Ensuring the safety of imported food is a huge task. Americans now enjoy a wide variety of foods from around the world and have access to fresh fruits and vegetables year round. In 1997, the Food Safety Inspection Service of the Department of Agriculture handled 118,000 entries of imported meat and poultry. The FDA handled far more-- 2.7 million entries of other imported food. Current FDA procedures and resources allowed for less than two percent of those 2.7 million imports to be physically inspected. Clearly, we need to do better.

The authority of the FDA is not sufficient to prevent contaminated food imports from reaching our shores. The Agency has no legal authority to require that food imported into the United States is prepared, packed and stored under conditions that provide the same level of public health protection as similar food produced in the U.S. Under current procedures, the FDA takes random samples of imports as they arrive at the border. The imports often continue on their way to stores in all parts of the country while testing is being done, and it is often difficult to recall the food if a problem is found. Unscrupulous importers make the most of the loopholes in the law, including substituting cargo, falsifying laboratory results, and attempting to bring a refused shipment in again, at a later date or at a different port.

The legislation we are introducing today will give the Secretary of Health and Human Services the additional authority needed to assure that food imports are as safe as food grown and prepared in this country.

It will give the FDA greater authority to deal with outbreaks of food-borne illness and to bar further imports of dangerous foods until improvements at the source can guarantee the safety of future shipments. This authority covers foods that have repeatedly been associated with food-borne disease, have repeatedly been found to be adulterated, or have been linked to a catastrophic outbreak of food-borne illness.

It will close loopholes in the law and give the FDA better tools to deal with unscrupulous importers.

It will authorize the Centers for Disease Control and Prevention to target resources toward enhanced surveillance and prevention activities to deal with food-borne illnesses, including new diagnostic tests, better training of health professionals, and increased public awareness about food safety.

Too many citizens today are at unnecessary risk of food-borne illness. The measure we are proposing is designed to reduce that risk as much as possible, both immediately and for the long term. We know that there are powerful special interests that put profits ahead of safety, but Americans need and deserve laws that better protect their food supply. This is essential legislation, and I look forward to working with my colleagues to see that it is enacted as soon as possible.

[Page: S6054]

By Mr. KYL (for himself, Mr. **Kerrey**, Mr. **Nickles**, Mr. **Breaux**, Mr. **Mack**, Mr. **Robb**, and Mr. **Gramm**):

S. 1128. A bill to amend the Internal Revenue Code of 1986 to repeal the Federal estate and gift taxes and the tax on generation-skipping transfers, to provide for a carryover basis at death, and to establish a partial capital gains exclusion for inherited assets; to the Committee on Finance.

ESTATE TAX ELIMINATION ACT OF 1999

Mr. KYL.

Mr. President, I rise today with my colleagues, Senators **Bob Kerrey**, **Don Nickles**, **John Breaux**, **sConnie Mack**, **Chuck Robb**, and **Phil Gramm** to introduce a bill that attempts to forge bipartisan consensus with regard to the future of the federal estate tax. The legislation we are offering today is titled the Estate Tax Elimination Act of 1999.

Mr. President, we know that many Americans are troubled by the estate tax's complexity and high

S 1126 IS

106th CONGRESS

1st Session

S. 1126

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of imported food, and for other purposes.

IN THE SENATE OF THE UNITED STATES**May 26, 1999**

Ms. MIKULSKI (for herself, Mr. KENNEDY, and Mr. DURBIN) introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of imported food, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the 'Imported Food Safety Improvement Act of 1999'.

TITLE I--IMPROVEMENTS TO THE FOOD SAFETY IMPORT SYSTEM**SEC. 101. EQUIVALENCE AUTHORITY TO PROTECT THE PUBLIC HEALTH FROM CONTAMINATED IMPORTED FOODS.**

(a) EQUIVALENCE DETERMINATIONS, AND MEASURES, SYSTEMS, AND CONDITIONS TO ACHIEVE PUBLIC HEALTH PROTECTION- Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended--

(1) by redesignating subsections (d), (e), and (f) as subsections (f), (g), and (h), respectively; and

(2) by inserting after subsection (c) the following:

`(d)(1) Subject to paragraphs (2) and (3), any food offered for import into the United States shall be prepared (including produced), packed, and held under a system or conditions, or subject to measures, that meet the requirements of this Act or that have been determined by the Secretary to be equivalent to a system, conditions, or measures for such food in the United States and to achieve the level of public health protection for such food prepared, packed, and

held in the United States. Consistent with section 492 of the Trade Agreements Act of 1979 (19 U.S.C. 2578a), the Secretary shall make, where appropriate, equivalence determinations described in that section relating to sanitary or phytosanitary measures (including systems and conditions) that apply to the preparation, packing, and holding of food offered for import into the United States.

`(2) In carrying out this subsection, the Secretary shall conduct systematic evaluations of the systems, conditions, and measures in foreign countries that apply to the preparation, packing, and holding of food offered for import into the United States.

`(3) The Secretary shall develop a plan for the implementation of the authority under this subsection within 2 years after the date of enactment of the Imported Food Safety Improvement Act of 1999. In developing the plan, the Secretary shall provide an opportunity for, and take into consideration, public comment on a proposed plan.'

(b) GENERAL AUTHORITY- Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381), as amended in subsection (a), is further amended by inserting after subsection (d) the following:

`(e)(1)(A) The Secretary shall establish a system, for use by the Secretary of the Treasury, to deny the entry of any food offered for import into the United States if the Secretary of Health and Human Services makes and publishes--

`(i) a written determination that the food--

`(I) has been associated with repeated and separate outbreaks of foodborne disease or has been repeatedly determined by the Secretary to be adulterated within the meaning of section 402;

`(II) presents a reasonable probability of causing significant adverse health consequences or death; and

`(III) is likely, without systemic intervention or changes, to cause disease or be adulterated again; or

`(ii) an emergency written determination that the food has been strongly associated with a single outbreak of foodborne disease that has caused serious adverse health consequences or death.

`(B)(i) The Secretary shall make a determination described in subparagraph (A) with respect to--

`(I) a food from a specific producer, manufacturer, or shipper; or

`(II) a food from a specific growing area or country;

that meets the criteria described in subparagraph (A).

`(ii) Only the food from the specific producer, manufacturer, shipper, growing area, or country for which the Secretary makes the determination shall be subject to denial of entry under this subsection.

`(C) The denial of entry of any food under this paragraph shall be done in a manner consistent with bilateral, regional, and multilateral trade agreements and the rights and obligations of the

United States under the agreements.

`(D)(i) Before making any written determination under subparagraph (A)(i), the Secretary shall consider written comments, on a proposed determination, made by any party affected by the proposed determination and any remedial actions taken to address the findings made in the proposed determination. In making the written determination, the Secretary may modify or rescind the proposed determination in accordance with such comments.

`(ii)(I) The Secretary may immediately issue an emergency written determination under subparagraph (A)(ii) without first considering comments on a proposed determination.

`(II) Within 30 days after the issuance of the emergency determination, the Secretary shall consider written comments on the determination that are made by a party described in clause (i) and received within the 30-day period. The Secretary may affirm, modify, or rescind the

emergency determination in accordance with the comments.

`(III) The emergency determination shall be in effect--

`(aa) for the 30-day period; or

`(bb) if the Secretary affirms or modifies the determination, until the Secretary rescinds the determination.

`(2)(A) The food initially denied entry under paragraph (1) may be imported into the United States if the Secretary finds that--

`(i) the written determination made under paragraph (1) no longer justifies the denial of entry of the food; or

`(ii) evidence of remedial action submitted from the producer, manufacturer, shipper, specific growing area, or country for which the Secretary made the written determination under paragraph (1) addresses the determination.

`(B)(i) The Secretary shall take action on evidence submitted under subparagraph (A)(ii) within 90 days after the date of the submission of the evidence.

`(ii) The Secretary's action may include--

`(I) lifting the denial of entry of the food; or

`(II) continuing to deny entry of the food while requesting additional information or specific remedial action from the producer, manufacturer, shipper, specific growing area, or country.

`(iii) If the Secretary does not take action on evidence submitted under subparagraph (A)(ii) within 90 days after the date of submission, effective on the 91st day after the date of submission, the food initially denied entry under paragraph (1) may be imported into the United States.

`(3) The Secretary shall by regulation establish criteria and procedures for the system described in paragraph (1). The Secretary may by regulation modify those criteria and procedures, as the Secretary determines appropriate.'

(c) TECHNICAL AND CONFORMING AMENDMENTS-

(1) Section 351(h) of the Public Health Service Act (42 U.S.C. 262(h)) is amended by striking 'section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 (e))' and inserting 'section 801(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(g)(1))'.

(2) Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended--

(A) in paragraph (t), by striking 'section 801(d)(1)' and inserting 'section 801(f)(1)'; and

(B) in paragraph (w)--

(i) by striking 'sections 801(d)(3)(A) and 801(d)(3)(B)' and inserting 'subparagraphs (A) and (B) of section 801(f)(3)';

(ii) except as provided in clause (i), by striking 'section 801(d)(3)' each place it appears and inserting 'section 801(f)(3)'; and

(iii) by striking 'section 801(e)' and inserting 'section 801(g)'.

(3) Section 303(b)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(b)(1)(A)) is amended by striking 'section 801(d)(1)' and inserting 'section 801(f)(1)'.

(4) Section 304(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(d)(1)) is amended--

(A) by striking 'section 801(e)(1)' and inserting 'section 801(g)(1)'; and

(B) except as provided in subparagraph (A), by striking 'section 801(e)' each place it appears and inserting 'section 801(g)'.

(5) Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended--

(A) in subsection (a), in the third sentence, by striking 'subsection (b) of this section' and inserting 'subsection (b) or subsection (e)(2)(A) (in the case of a food described in that subsection)';

(B) in paragraph (3)(A) of subsection (f), as redesignated in subsection (a), by striking 'section 801(e) or 802' and inserting 'subsection (g), section 802,'; and

(C) in paragraph (1) of subsection (h), as redesignated in subsection (a), by striking 'subsection (e)' and inserting 'subsection (g)'.

(6) Section 802 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 382) is amended--

(A) in subsection (a)(2)(C), by striking 'section 801(e)(2)' and inserting 'section 801(g)(2)';

(B) in subsection (f)(3), by striking 'section 801(e)(1)' and inserting 'section 801(g)(1)'; and

(C) in subsection (i), by striking 'section 801(e)(1)' and inserting 'section 801(g)(1)'.

SEC. 102. PROHIBITION AGAINST THE DISTRIBUTION OF CERTAIN FOOD.

(a) ADULTERATED FOODS- Section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) is amended by adding at the end the following:

'(h)(1) If--

'(A) it is a food being imported or offered for import into the United States;

'(B) the food has been designated by the Secretary for sampling, examination, or review for the purpose of determining whether the food is in compliance with this Act;

'(C) the Secretary requires, under section 801(a)(2)(B), that the food not be distributed until the Secretary authorizes the distribution of the food; and

'(D) the food is distributed before the Secretary authorizes the distribution.

'(2) In this paragraph, the term 'distributed', used with respect to food, means--

'(A) moved for the purpose of selling the food, offering the food for sale, or delivering the food for

the purpose of selling the food or offering the food for sale; or

'(B) delivered contrary to any bond requirement.'.

(b) PROHIBITION- Section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended--

(1) in the third sentence, by redesignating paragraphs (1) through (3) as subparagraphs (A) through (C), respectively;

(2) by striking '(a) The' and inserting '(a)(1) The';

(3) in the last sentence, by striking 'Clause (2)' and inserting 'Subparagraph (B)';

(4) by moving the fourth sentence to the end;

(5) in the sentence so moved, by striking 'The Secretary' and inserting the following:

'(2)(A) The Secretary'; and

(6) by adding at the end the following:

'(B) The Secretary of Health and Human Services may require that a food being imported or

offered for import into the United States not be distributed until the Secretary authorizes distribution of the food.'.

SEC. 103. REQUIREMENT OF SECURE STORAGE OF CERTAIN IMPORTED FOOD.

(a) ADULTERATED FOODS- Section 402 of the Federal Food, Drug, and Cosmetic Act, as amended in section 102(a), is further amended by adding at the end the following:

`(i) If--

`(1) it is a food being imported or offered for import into the United States;

`(2) the Secretary requires, under section 801(a)(2)(C), that the food be held in a secure storage facility until the Secretary authorizes distribution of the food; and

`(3) the food is not held in a secure storage facility as described in section 801(a)(2)(C) until the Secretary authorizes the distribution.'.

(b) REQUIREMENT- Section 801(a)(2) of the Federal Food, Drug, and Cosmetic Act, as amended in section 102(b), is further amended by adding at the end the following:

`(C)(i) The Secretary of Health and Human Services may require that a food that is being imported or offered for import into the United States be held, at the expense of the owner or consignee of the food, in a secure storage facility until the Secretary authorizes distribution of the food, if the Secretary makes the determination that the food is--

`(I) being imported or offered for import into the United States by a person described in clause (ii); or

`(II) owned by or consigned to a person described in clause (ii).

`(ii) An importer, owner, or consignee referred to in subclause (I) or (II) of clause (i) is a person against whom the Secretary of the Treasury has assessed liquidated damages not less than twice under subsection (b) for failure to redeliver, at the request of the Secretary of the Treasury, food subject to a bond under subsection (b).'

SEC. 104. REQUIREMENT OF ADMINISTRATIVE DESTRUCTION OF CERTAIN IMPORTED FOOD.

(a) ADULTERATED FOODS- Section 402 of the Federal Food, Drug, and Cosmetic Act, as amended in section 103(a), is further amended by adding at the end the following:

`(j) Notwithstanding subsections (a)(2)(A) and (b) of section 801, if--

`(1) it is a food being imported or offered for import into the United States;

`(2) the food presents a reasonable probability of causing significant adverse health consequences or death;

`(3) the Secretary, after the food has been refused admission under section 801(a), requires under section 801(a)(2)(D) that the food be destroyed; and

`(4) the owner or consignee of the food fails to comply with that destruction requirement.'.

(b) REQUIREMENT- Section 801(a)(2) of the Federal Food, Drug, and Cosmetic Act, as amended in section 103(b), is further amended by adding at the end the following:

`(D) The Secretary of Health and Human Services may require destruction, at the expense of the owner or consignee, of food imported or offered for import into the United States that presents a reasonable probability of causing significant adverse health consequences or death.'.

SEC. 105. PROHIBITION AGAINST PORT SHOPPING.

Section 402 of the Federal Food, Drug, and Cosmetic Act, as amended in section 104(a), is further amended by adding at the end the following:

`(k) If it is an article of food being imported or offered for import into the United States, and the article of food previously has been refused admission under section 801(a), unless the person reoffering the article affirmatively establishes, at the expense of the owner or consignee of the article, that the article complies with the applicable requirements of this Act, as determined by the Secretary.'.

SEC. 106. PROHIBITION OF IMPORTS BY DEBARRED PERSONS.

Section 402 of the Federal Food, Drug, and Cosmetic Act, as amended in section 105, is further amended by adding at the end the following:

`(l) If it is a food being imported or offered for import into the United States by a person debarred under section 306(b)(4).'.

SEC. 107. AUTHORITY TO MARK REFUSED ARTICLES.

(a) MISBRANDED FOODS- Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end the following:

`(t) If--

`(1) it has been refused admission under section 801(a);

`(2) the food has not been required to be destroyed under subparagraph (A) or (B) of section 801(a)(2); and

`(3) the packaging of the food does not bear a label or labeling described in section 801(a)(2)(E).'.

(b) REQUIREMENT- Section 801(a)(2) of the Federal Food, Drug, and Cosmetic Act, as amended in section 104(b), is further amended by adding at the end the following:

`(E) The Secretary of Health and Human Services may require the owner or consignee of food that has been refused admission under paragraph (1), and has not been required to be destroyed under subparagraph (A) or (B), to affix to the packaging of the food a label or labeling that--

`(i) clearly and conspicuously bears the following statement: `United States: Refused

Entry.';

`(ii) is affixed to the packaging until the food is brought into compliance with this Act; and

`(iii) has been provided at the expense of the owner or consignee of the food.'.

SEC. 108. EXPORT OF REFUSED ARTICLES.

Paragraph (2)(A) of section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)), as designated in section 102(b), is amended by striking `ninety days' and inserting `30 days'.

SEC. 109. COLLECTION AND ANALYSIS OF SAMPLES OF FOOD IMPORTS.

Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381), as amended in section 101(a), is further amended by adding at the end the following:

`(i) The Secretary may issue regulations or guidance as necessary to govern the collection and analysis by entities other than the Food and Drug Administration of samples of food imported or offered for import into the United States to ensure the integrity of the samples collected and the validity of the analytical results.'.

TITLE II--ENFORCEMENT AND PENALTIES FOR IMPORTING CONTAMINATED FOOD

SEC. 201. ENHANCED BONDING REQUIREMENTS FOR PRIOR INVOLVEMENT IN IMPORTING ADULTERATED OR MISBRANDED FOOD.

Section 801(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(b)) is amended--

(1) by inserting `(1)' after `(b)'; and

(2) by adding at the end the following:

`(2)(A) The Secretary of the Treasury, acting through the Commissioner of Customs, shall issue regulations that establish a rate for a bond required to be executed under paragraph (1) for an article of food if an owner, consignee, or importer of the food has committed a covered violation.

`(B) The regulations shall require the owner or consignee to execute such a bond--

`(i) at twice the usual rate; or

`(ii) if the owner, consignee, or importer has committed more than 1 covered violation, at a rate that increases with the number of covered violations committed, as determined in accordance with a sliding scale established in the regulations.

`(C) In this paragraph:

`(i) The term `committed' means been convicted of, or found liable for, a violation by an appropriate court or administrative officer.

`(ii) The term 'covered violation' means a violation relating to--

`(I) importing or offering for import into the United States--

`(aa) an article of food during a period of debarment under section 306(b) (4);

`(bb) an article of food that is adulterated within the meaning of paragraph (h), (i), (j), (k), or (l) of section 402; or

`(cc) an article of food that is misbranded within the meaning of section 403 (t); or

`(II) making a false or misleading statement in conduct relating to the import or offering for import of a food into the United States.

`(iii) The term 'usual rate', used with respect to a bond, means the rate that would be required under paragraph (1) for the bond by a person who has not committed a covered violation.'

SEC. 202. DEBARMENT OF REPEAT OFFENDERS AND SERIOUS OFFENDERS.

(a) IN GENERAL- Section 306(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a(b)) is amended--

(1) in paragraph (1), in the paragraph heading, by striking 'IN GENERAL- ' and inserting 'DEBARMENTFORVIOLATIONSRELATINGTODRUGS- ';

(2) in paragraph (2), in the paragraph heading, by striking 'PERSONS SUBJECT TO PERMISSIVE DEBARMENT- ' and inserting 'PERSONS SUBJECT TO PERMISSIVE DEBARMENT FOR VIOLATIONS RELATING TO DRUGS- ';

(3) in paragraph (3), in the paragraph heading, by striking 'STAY OF CERTAIN ORDERS- ' and inserting 'STAY OF CERTAIN ORDERS RELATING TO DEBARMENT FOR VIOLATIONS RELATING TO DRUGS- '; and

(4) by adding at the end the following:

`(4) DEBARMENT FOR VIOLATIONS RELATING TO FOOD IMPORTS-

`(A) IN GENERAL- The Secretary may debar a person from importing a food or offering a food for import into the United States, if--

`(i) the Secretary finds that the person has been convicted for conduct that is a felony under Federal law and relates to the importation or offering for importation of any food into the United States; or

`(ii) the Secretary makes a written determination that the person has repeatedly or deliberately imported or offered for import into the United States a food adulterated within the meaning of paragraph (h), (i), (j), or (k) of section 402, or misbranded within the meaning of section 403(t).

`(B) IMPACT- On debaring a person under subparagraph (A), the Secretary shall provide notice of the debarment to the Secretary of the Treasury, who shall deny entry of food offered for import by the person.'.

(b) TECHNICAL AND CONFORMING AMENDMENTS-

(1) IN GENERAL- Section 306 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a) is amended--

(A) in subsection (c)--

(i) in paragraph (1)--

(I) in subparagraph (B), by striking `, and' at the end and inserting a comma;

(II) by redesignating subparagraph (C) as subparagraph (D); and

(III) by inserting after subparagraph (B) the following:

`(C) shall, during the period of a debarment under subsection (b)(4), prohibit the debarred person from importing a food or offering a food for import into the United States, and';

(ii) in paragraph (2)(A), by inserting after clause (iii) the following:

`(iv) The period of debarment of any person under subsection (b)(4) shall be not less than 1 year.'; and

(iii) in paragraph (3)--

(I) in subparagraph (C)--

(aa) by striking `suspect drugs' and inserting `suspect drugs or food'; and

(bb) by striking `fraudulently obtained' and inserting `fraudulently obtained or on food wrongfully imported into the United States'; and

(II) in subparagraph (E), by inserting `in the case of a debarment relating to a drug,' after `(E)';

(B) in subsection (d)--

(i) in paragraph (3)--

(I) in subparagraph (A)--

(aa) in clause (i), by striking `or (b)(2)(A)' and inserting `or paragraph (2)(A) or (4) of subsection (b)'; and

(bb) in clause (ii)(II), by inserting 'in the case of a debarment relating to a drug,' after '(II)'; and

(II) in subparagraph (B)--

(aa) in clause (i), by striking 'or clause (i), (ii), (iii) or (iv) of subsection (b)(2)(B)' and inserting ', clause (i), (ii), (iii), or (iv) of subsection (b)(2)(B), or subsection (b)(4)'; and

(bb) in clause (ii), by striking 'subsection (b)(2)(B)' and inserting 'paragraph (2)(B) or (4) of subsection (b)'; and

(ii) in paragraph (4)--

(I) in subparagraph (A), by striking '(a)(2)' and inserting '(a)(2) or (b)(4)';

(II) in subparagraph (B)--

(aa) in clause (ii), by striking 'involving the development or approval of any drug subject to section 505' and inserting 'involving, as appropriate, the development or approval of any drug subject to section 505 or the importation of any food'; and

(bb) in clause (iv), by striking 'drug' each place it appears and inserting 'drug or food'; and

(III) in subparagraph (D), in the matter following clause (ii), by inserting ', in the case of a debarment relating to a drug,' before 'protects'; and

(C) in subsection (l)(2), in the second sentence, by striking '(b)(2)(B)' and inserting '(b)(2)(B), subsection (b)(4),'

(2) CIVIL PENALTIES- Paragraphs (6) and (7) of section 307(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335b(a)) are amended by striking '306' and inserting '306 (except section 306(b)(4))'.

SEC. 203. INCREASED ENFORCEMENT TO IMPROVE THE SAFETY OF IMPORTED FOOD.

Subchapter A of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

'SEC. 712. POSITIONS TO IMPROVE THE SAFETY OF IMPORTED FOOD.

'There is authorized to be appropriated such sums as may be necessary for each of fiscal years 2000 through 2002 to enable the Commissioner, in carrying out chapters IV and VIII, to decrease the health risks associated with imported food through the creation of additional employment positions for laboratory, inspection, and compliance personnel.'

TITLE III--IMPROVEMENTS TO PUBLIC HEALTH INFRASTRUCTURE AND AWARENESS

SEC. 301. IMPROVEMENTS.

Title II of the Public Health Service Act (42 U.S.C. 202 et seq.) is amended by adding at the end the following:

'PART C--PUBLIC HEALTH INFRASTRUCTURE AND AWARENESS

'SEC. 251. DEFINITIONS.

'In this part:

'(1) INSTITUTION OF HIGHER EDUCATION- The term 'institution of higher education' has the meaning given the term in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)).

'(2) SECRETARY- The term 'Secretary' means the Secretary of Health and Human Services,

acting through the Director of the Centers for Disease Control and Prevention.

'SEC. 252. PUBLIC HEALTH SURVEILLANCE ENHANCEMENT.

'(a) IN GENERAL- The Secretary may--

'(1) make grants to, enter into cooperative agreements with, and provide technical assistance to eligible agencies to enable the agencies to enhance their capacity to carry out activities relating to surveillance and prevention of foodborne pathogen-related disease, particularly pathogen-related disease associated with imported food, as described in subsection (b)(1); and

'(2) carry out the activities described in subsection (b)(2).

'(b) USE OF ASSISTANCE-

'(1) AGENCIES- An eligible agency that receives assistance under subsection (a) shall use the assistance to enhance the capacity of the agency--

'(A) to identify, investigate, and contain threats of foodborne pathogen-related disease, particularly pathogen-related disease associated with imported food; and

'(B) to conduct additional surveillance and studies to address prevention and control of the disease.

'(2) CENTERS FOR DISEASE CONTROL AND PREVENTION- The Secretary may use not more than 30 percent of the funds appropriated to carry out this section--

'(A) to assist an agency described in paragraph (1) in enhancing the capacity described in paragraph (1) by providing standards, technologies, information, materials, and other resources; and

'(B) to enhance national surveillance systems, including the ability of domestic and international agencies and entities to respond to food safety issues associated

with imported food that are identified through such systems.

`(c) ELIGIBLE AGENCIES- To be eligible to receive assistance under subsection (a)(1), an agency shall be a State or local health department.

`(d) APPLICATION- To be eligible to receive assistance under subsection (a)(1), an agency shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

`(e) AUTHORIZATION OF APPROPRIATIONS- There are authorized to be appropriated to carry out this section such sums as may be necessary for fiscal years 2000 through 2002.

`SEC. 253. PATHOGEN DETECTION RESEARCH AND DEVELOPMENT.

`(a) IN GENERAL- The Secretary may conduct applied research, directly or by grant or contract, to develop new or improved methods for detecting and subtyping emerging foodborne pathogens in human specimens, food, and relevant environmental samples. The Secretary may use funds appropriated to carry out this section to support applied research by State health departments or institutions of higher education.

`(b) APPLICATION- To be eligible to receive a grant or enter into a contract under subsection (a), an entity shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

`(c) AUTHORIZATION OF APPROPRIATIONS- There are authorized to be appropriated to carry out this section such sums as may be necessary for fiscal years 2000 through 2002.

`SEC. 254. TRAINING, EDUCATION, AND PUBLIC INFORMATION.

`(a) IN GENERAL- The Secretary may--

`(1) make grants and enter into contracts with eligible entities, to support training activities and other collaborative activities with the entities to inform health professionals about foodborne disease, including strengthening training networks serving State, local, and private entities; and

`(2) increase and improve the activities carried out by the Centers for Disease Control and Prevention to provide information to the public on foodborne disease.

`(b) ELIGIBLE ENTITIES- To be eligible to receive a grant or enter into a contract under subsection (a), an entity shall be a medical school, a nursing school, an entity carrying out clinical laboratory training programs, a school of public health, another institution of higher education, a professional organization, or an international organization.

`(c) APPLICATION- To be eligible to receive a grant or enter into a contract under subsection (a), an entity shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

`(d) CONSULTATION- In carrying out this section, the Secretary shall consult with Federal, State, and local agencies, international organizations, and other interested parties.

`(e) AUTHORIZATION OF APPROPRIATIONS- There are authorized to be appropriated to carry out this section such sums as may be necessary for fiscal years 2000 through 2002.

SEC. 255. INTERNATIONAL PUBLIC HEALTH TRAINING AND TECHNICAL ASSISTANCE.

(a) IN GENERAL- The Secretary shall, directly or by agreement, provide training and technical assistance to agencies and entities in foreign countries, to strengthen the foodborne disease surveillance and investigation capacities of the agencies and entities, including establishing or expanding activities or programs such as the Field Epidemiology and Training Program of the Centers for Disease Control and Prevention.

(b) APPLICATION- To be eligible to enter into an agreement under subsection (a), an entity shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(c) AUTHORIZATION OF APPROPRIATIONS- There are authorized to be appropriated to carry out this section such sums as may be necessary for fiscal years 2000 through 2002.

SEC. 256. SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.

(a) IN GENERAL- On the request of a recipient of assistance under section 252, 253, 254, or 255, the Secretary may, subject to subsection (b), provide supplies, equipment, and services for the purpose of aiding the recipient in carrying out the section involved and, for such purpose, may detail to the grant recipient any officer or employee of the Department of Health and Human Services. Such detail shall be without interruption or loss of civil service status or privilege.

(b) CORRESPONDING REDUCTION IN PAYMENTS- With respect to a request described in subsection (a), the Secretary shall reduce the amount of payments under the section involved by an amount equal to the cost of detailing the officer or employee and the fair market value of the supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such a request, expend the amounts withheld.

END

THE SAFE FOOD ACT 1999

PHOTOCOPY
PRESERVATION

THE SAFE FOOD ACT
1999

TITLE: The Safe Food Act of 1999 (S. 1281)

SPONSOR (S): Senators Durbin, Toricelli, Mikulski and Cleland.

A BILL

To consolidate in a single independent agency in the executive branch the responsibilities regarding food safety, labeling, and inspection currently divided among several Federal agencies.

PURPOSES:

- (1) To establish a single agency, the Food Safety Administration, that will be responsible for the regulation of food safety and labeling and for conducting food safety inspections to ensure, with reasonable certainty, that no harm will result from the consumption of food, by preventing food-borne illnesses due to microbial, natural, or chemical hazards in food; and
- (2) To transfer to the Food Safety Administration the food safety, labeling, and inspection functions currently performed by other Federal agencies, to achieve more efficient management and effective application of Federal food safety laws for the protection and improvement of public health.

By Mr. DURBIN (for himself, Mr. **Torricelli**, Ms. **Mikulski**, and Mr. **Cleland**):

S. 1281. A bill to consolidate in a single independent agency in the executive branch the responsibilities regarding food safety, labeling, and inspection currently divided among several Federal agencies.

THE SAFE FOOD ACT

Mr. DURBIN. Mr. President, today I am introducing legislation that would replace the current fragmented federal food safety system with a single, independent agency responsible for all federal food safety activities--the Safe Food Act of 1999 (S. 1281). I am pleased to be joined by Senators **Torricelli**, **Mikulski**, and **Cleland** in this important effort.

Make no mistake, our country has been blessed with one of the safest and most abundant food supplies in the world. However, we can do better. Foodborne illness is a significant problem.

The safety of our nation's food supply is facing tremendous pressures with regard to emerging pathogens, an aging population with a growing number of people at high risk for foodborne illnesses, broader food distribution patterns, an increasing volume of food imports, and changing consumption patterns.

The General Accounting Office (GAO) estimates that as many as 81 million people will suffer food poisoning this year and more than 9,000 will die. Children and the elderly are especially vulnerable. In terms of medical costs and productivity losses, foodborne illness costs the nation up to \$37 billion annually. The situation is not likely to improve without decisive action. The Department of Health and Human Services predicts that foodborne illnesses and deaths will increase 10-15 percent over the next decade.

In 1997, a Princeton Research survey found that 44 percent of Americans believe the food supply in this country is less safe than it was 10 years ago. American consumers spend more than \$617 billion annually on food, of which about \$511 billion is spent on foods grown on U.S. farms. Our ability to assure that the safety of our food and to react rapidly to potential threats to food safety is critical not only for public health, but also to the vitality of both domestic and rural economies and international trade.

Many of you are probably following the dioxin crisis in Belgium. Days before the national elections poultry, eggs, pork, beef, and dairy products were withdrawn from supermarket shelves. Butcher shops closed and livestock farms were quarantined. Since then countries, worldwide, have restricted imports of eggs, chickens, and pork from the European Union. Public outrage in Belgium over the dioxin scandal led to a disastrous showing by the ruling party in the national and European elections on June 14, and the government was forced to resign. Food safety concerns and fears are global.

Today, food moves through a global marketplace. This was not the case in the early 1900's when the first federal food safety agencies were created. Throughout this century, Congress responded by adding layer upon layer--agency upon agency--to answer the pressing food safety needs of the day. That's how the federal food safety system got to the point where it is today. And again as we face increasing pressures on food safety, the federal government must respond. But we must respond not only to these pressures but also to the very fragmented nature of the federal food safety structure.

Fragmentation of our food safety system is a burden that must be changed to protect the public health from these increasing pressures. Currently, there are at least 12 different federal agencies, 35 different laws governing food safety, and 28 House and Senate subcommittees with food safety oversight. With overlapping jurisdictions, federal agencies often lack accountability on food safety-related issues.

Last August, the National Academy of Sciences (NAS) released a report recommending the establishment of a 'unified and central framework' for managing federal food safety programs, 'one that is headed by a single official and which has the responsibility and control of resources for all federal food safety activities.' I agree with this conclusion.

The Administration has stepped forward on the issue of food safety--the President's Food Safety Initiatives and the President's Council on Food Safety have focused efforts to track and prevent microbial foodborne illnesses. I commend President Clinton and Secretaries Glickman and Shalala for their commitment to improving our nation's food safety and inspection systems. Earlier this year in response to the NAS report, the President's Council on Food Safety stated its support for the NAS recommendation calling for a new statute that establishes a unified framework for food safety programs with a single official with control over all federal food safety resources.

An independent single food safety agency is needed to replace the current, fragmented system. My proposed legislation would combine the functions of USDA's Food Safety and Inspection Service, FDA's Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine, the Department of Commerce's Seafood Inspection Program, and the food safety functions of other federal agencies. This new, independent agency would be funded with the combined budgets from these consolidated agencies.

With overlapping jurisdictions, federal agencies many times lack accountability on food safety-related issues. There are simply too many cooks in the kitchen. A single, independent agency would help focus our policy and improve enforcement of food safety and inspection laws.

The General Accounting Office has been unequivocal in its recommendation for consolidation of federal food safety programs. GAO's April 1998 report states that 'since 1992, we have frequently reported on the fragmented and inconsistent organization of food safety responsibilities in the federal government.' In a May 25, 1994 report, GAO cites that its 'testimony is based on over 60 reports and studies issued over the last 25 years by GAO, agency

Inspectors General, and others.' The Appendix to the 1994 GAO report lists: 49 reports since 1977, 9 USDA Office of Inspector General reports since 1986, 1 HHS Office of Inspector General report in 1991, and 15 reports and studies by Congress, scientific organizations, and others since 1981.

Again, earlier this year, GAO in its 21-volume report on government waste, pointed to the lack of coordination of the federal food safety efforts as an example. 'So many cooks are spoiling the broth,' says the GAO while highlighting the absurdity of having one federal agency inspecting frozen meat pizza and another inspecting frozen cheese pizza.

Over 20 years ago, the Senate Committee on Governmental Affairs advised that consolidation is essential to avoid conflicts of interest and overlapping jurisdictions. In a 1977 report the committee stated, 'While we support the recent efforts of FDA and USDA to improve coordination between the agencies, periodic meetings will not be enough to overcome [these] problems.' This statement is just as true today as it was then.

It's time to move forward. Let us stop using multiple federal agencies to inspect pizza. Instead let us 'deliver' what makes sense--a single, independent food safety agency.

A single, independent agency with uniform food safety standards and regulations based on food hazards would provide an easier framework for implementing U.S. standards in an international context. When our own agencies don't have uniform safety and inspection standards for all potentially hazardous foods, the establishment of uniform international standards will be next to impossible.

Research could be better coordinated within a single agency than among multiple programs. Currently, federal funding for food safety research is spread over at least 20 federal agencies, and coordination among those agencies is ad hoc at best.

New technologies to improve food safety could be approved more rapidly with one food safety agency. Currently, food safety technologies must go through multiple agencies for approval, often adding years of delay.

In this era of limited budgets, it is our responsibility to modernize and streamline the food safety system. The U.S. simply cannot afford to continue operating multiple systems. This is not about more regulation, a super agency, or increased bureaucracy, it's about common sense and more effective marshaling of our existing federal resources.

With the incidence of food recalls on the rise, it is important to move beyond short-term solutions to major food safety problems. A single, independent food safety and inspection agency could more easily work toward long-term solutions to the frustrating and potentially life-threatening issue of food safety.

Mr. President, together, we can bring the various agencies together to eliminate the overlap and confusion that have, unfortunately, at times characterized our food safety efforts. We need action, not simply reaction. I encourage my colleagues to join me in this effort to consolidate the food safety and inspection functions of numerous agencies and offices into a single, independent food safety agency.

Mr. President, I ask unanimous consent that the text of the bill be printed in the **Record**.

There being no objection, the bill was ordered to be printed in the **Record**, as follows:

Research could be better coordinated within a single agency than among multiple programs. Currently, federal funding for food safety research is spread over at least 20 federal agencies, and coordination among those agencies is ad hoc at best.

New technologies to improve food safety could be approved more rapidly with one food safety agency. Currently, food safety technologies must go through multiple agencies for approval, often adding years of delay.

In this era of limited budgets, it is our responsibility to modernize and streamline the food safety system. The U.S. simply cannot afford to continue operating multiple systems. This is not about more regulation, a super agency, or increased bureaucracy, it's about common sense and more effective marshaling of our existing federal resources.

With the incidence of food recalls on the rise, it is important to move beyond short-term solutions to major food safety problems. A single, independent food safety and inspection agency could more easily work toward long-term solutions to the frustrating and potentially life-threatening issue of food safety.

Mr. President, together, we can bring the various agencies together to eliminate the overlap and confusion that have, unfortunately, at times characterized our food safety efforts. We need action, not simply reaction. I encourage my colleagues to join me in this effort to consolidate the food safety and inspection functions of numerous agencies and offices into a single, independent food safety agency.

Mr. President, I ask unanimous consent that the text of the bill be printed in the **Record**.

There being no objection, the bill was ordered to be printed in the **Record**, as follows:

[Page: S7602]

S. 1281

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) **Short Title:** This Act may be cited as the 'Safe Food Act of 1999'.

(b) **Table of Contents:** The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Findings and purposes.

Sec. 3. Definitions.

Sec. 4. Establishment of independent Food Safety Administration.

Sec. 5. Consolidation of separate food safety and inspection services and agencies.

Sec. 6. Additional authorities of the Administration.

Sec. 7. Limitation on authorization of appropriations.

Sec. 8. Effective date.

SEC. 2. FINDINGS AND PURPOSES.

(a) **Findings:** Congress finds the following:

- (1) The safety and security of the food supply of the United States requires efficient and effective management of food safety regulations.
- (2) The safety of the food supply of the United States is facing tremendous pressures with regard to the following issues:
 - (A) Emerging pathogens and the ability to detect them.
 - (B) An aging population with a growing number of people at high risk for foodborne illnesses.
 - (C) An increasing volume of imported foods, without adequate monitoring and inspection.
 - (D) Maintenance of adequate inspection of the domestic food processing and food service industry.
- (3) Federal food safety inspection, enforcement, and research efforts should be based on scientifically supportable assessments of risks to public health.
- (4) The Federal food safety system is fragmented, with at least 12 primary Federal agencies governing food safety.

(b) **Purposes:** It is the purpose of this Act--

- (1) to establish a single agency, the Food Safety Administration, that will be responsible for the regulation of food safety and labeling and for conducting food safety inspections to ensure, with reasonable certainty, that no harm will result from the consumption of food, by preventing food-borne illnesses due to microbial, natural, or chemical hazards in food; and
- (2) to transfer to the Food Safety Administration the food safety, labeling, and inspection functions currently performed by other Federal agencies, to achieve more efficient management and effective application of Federal food safety laws for the protection and improvement of public health.

SEC. 3. DEFINITIONS.

For purposes of this Act:

- (1) **Administration:** The term 'Administration' means the Food Safety Administration established under section 4.
- (2) **Administrator:** The term 'Administrator' means the Administrator of Food Safety appointed under section 4.
- (3) **Food safety laws:** The term 'food safety laws' means the following:
 - (A) The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).
 - (B) The Poultry Products Inspection Act (21 U.S.C. 451 et seq.).
 - (C) The Egg Products Inspection Act (21 U.S.C. 1031 et seq.).

(D) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), with regard to food safety, labeling, and inspection under that Act.

(E) Such other laws and portions of laws regarding food safety, labeling, and inspection as the President may designate by Executive order as appropriate to consolidate under the administration of the Administration.

SEC. 4. ESTABLISHMENT OF INDEPENDENT FOOD SAFETY ADMINISTRATION.

(a) **Establishment of Administration; Administrator:** There is established in the executive branch an agency to be known as the 'Food Safety Administration'. The Administration shall be an independent establishment, as defined in section 104 of title 5, United States Code. The Administration shall be headed by the Administrator of Food Safety, who shall be appointed by the President, by and with the advice and consent of the Senate.

(b) **Responsibilities:** The Administrator shall administer and enforce the food safety laws for the protection of the public health and shall oversee the following functions of the Administration:

(1) Implementation of Federal food safety inspection, enforcement, and research efforts, based on scientifically supportable assessments of risks to public health.

(2) Development of consistent and science-based standards for safe food.

(3) Coordination and prioritization of food safety research and education programs with other Federal agencies.

(4) Coordination of the Federal response to foodborne illness outbreaks with other Federal agencies and State agencies.

(5) Integration of Federal food safety activities with State and local agencies.

[Page: S7603]

SEC. 5. CONSOLIDATION OF SEPARATE FOOD SAFETY AND INSPECTION SERVICES AND AGENCIES.

(a) **Transfer of Functions:** For each Federal agency specified in subsection (b), there are transferred to the Administration all functions that the head of the Federal agency exercised on the day before the effective date specified in section 8 (including all related functions of any officer or employee of the Federal agency) that relate to administration or enforcement of the food safety laws, as determined by the President.

(b) **Covered Agencies:** The Federal agencies referred to in subsection (a) are the following:

(1) The Food Safety and Inspection Service of the Department of Agriculture.

(2) The Center for Food Safety and Applied Nutrition of the Food and Drug Administration.

(3) The Center for Veterinary Medicine of the Food and Drug Administration.

(4) The National Marine Fisheries Service of the National Oceanic and Atmospheric Administration of the Department of Commerce as it relates to the Seafood Inspection Program.

(5) Such other offices, services, or agencies as the President may designate by Executive order to further the purposes of this Act.

(c) **Transfer of Assets and Funds:** Consistent with section 1531 of title 31, United States Code, the personnel, assets, liabilities, contracts, property, records, and unexpended balances of appropriations,

authorizations, allocations, and other funds that relate to the functions transferred under subsection (a) from a Federal agency shall be transferred to the Administration. Unexpended funds transferred pursuant to this subsection shall be used by the Administration only for the purposes for which the funds were originally authorized and appropriated.

(d) **References:** After the transfer of functions from a Federal agency under subsection (a), any reference in any other Federal law, Executive order, rule, regulation, document, or other material to that Federal agency or the head of that agency in connection with the administration or enforcement of the food safety laws shall be deemed to be a reference to the Administration or the Administrator, respectively.

(e) **Savings Provisions:** The transfer of functions from a Federal agency under subsection (a) shall not affect--

(1) an order, determination, rule, regulation, permit, agreement, grant, contract, certificate, license, registration, privilege, or other administrative action issued, made, granted, or otherwise in effect or final with respect to that agency on the day before the transfer date with respect to the transferred functions; or

(2) any suit commenced with regard to that agency, and any other proceeding (including a notice of proposed rulemaking), or any application for any license, permit, certificate, or financial assistance pending before that agency on the day before the transfer date with respect to the transferred functions.

SEC. 6. ADDITIONAL AUTHORITIES OF THE ADMINISTRATION.

(a) **Officers and Employees:** The Administrator may appoint officers and employees for the Administration in accordance with the provisions of title 5, United States Code, relating to appointment in the competitive service, and fix the compensation of the officers and employees in accordance with chapter 51 and with subchapter III of chapter 53 of such title, relating to classification and General Schedule pay rates.

(b) **Experts and Consultants:** The Administrator may procure the services of experts and consultants as authorized by section 3109 of title 5, United States Code, and pay in connection with the services travel expenses of individuals, including transportation and per diem in lieu of subsistence while away from the homes or regular places of business of the individuals, as authorized by section 5703 of such title.

(c) **Bureaus, Offices, and Divisions:** The Administrator may establish within the Administration such bureaus, offices, and divisions as the Administrator may determine to be necessary to discharge the responsibilities of the Administration.

(d) **Rules:** The Administrator may prescribe, in accordance with chapters 5 and 6 of title 5, United States Code, such rules as the Administrator determines to be necessary or appropriate to administer and manage the functions of the Administrator.

SEC. 7. LIMITATION ON AUTHORIZATION OF APPROPRIATIONS.

For the fiscal year that includes the effective date of this Act, the amount authorized to be appropriated to carry out this Act shall not exceed--

(1) the amount appropriated for that fiscal year for the Federal agencies described in section 5(b) for the purpose of administering or enforcing the food safety laws; or

(2) the amount appropriated for these agencies for such purpose for the preceding fiscal year, if, as of the effective date of this Act, appropriations for these agencies for the fiscal year that includes the effective date have not yet been made.

SEC. 8. EFFECTIVE DATE.

This Act shall take effect on the earlier of--

(1) the date that is 180 days after the date of the enactment of this Act; and

(2) such date during that 180-day period as the President may direct in an Executive order.

S 1281 IS

106th CONGRESS

1st Session

S. 1281

To consolidate in a single independent agency in the executive branch the responsibilities regarding food safety, labeling, and inspection currently divided among several Federal agencies.

IN THE SENATE OF THE UNITED STATES**June 24, 1999**

Mr. DURBIN (for himself, Mr. TORRICELLI, Ms. MIKULSKI, and Mr. CLELAND) introduced the following bill; which was read twice and referred to the Committee on Governmental Affairs

A BILL

To consolidate in a single independent agency in the executive branch the responsibilities regarding food safety, labeling, and inspection currently divided among several Federal agencies.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE- This Act may be cited as the 'Safe Food Act of 1999'.

(b) TABLE OF CONTENTS- The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Findings and purposes.

Sec. 3. Definitions.

Sec. 4. Establishment of independent Food Safety Administration.

Sec. 5. Consolidation of separate food safety and inspection services and agencies.

Sec. 6. Additional authorities of the Administration.

Sec. 7. Limitation on authorization of appropriations.

Sec. 8. Effective date.

SEC. 2. FINDINGS AND PURPOSES.

(a) FINDINGS- Congress finds the following:

(1) The safety and security of the food supply of the United States requires efficient and effective management of food safety regulations.

(2) The safety of the food supply of the United States is facing tremendous pressures with regard to the following issues:

(A) Emerging pathogens and the ability to detect them.

(B) An aging population with a growing number of people at high risk for foodborne illnesses.

(C) An increasing volume of imported foods, without adequate monitoring and inspection.

(D) Maintenance of adequate inspection of the domestic food processing and food service industry.

(3) Federal food safety inspection, enforcement, and research efforts should be based on scientifically supportable assessments of risks to public health.

(4) The Federal food safety system is fragmented, with at least 12 primary Federal agencies governing food safety.

(b) PURPOSES- It is the purpose of this Act--

(1) to establish a single agency, the Food Safety Administration, that will be responsible for the regulation of food safety and labeling and for conducting food safety inspections to ensure, with reasonable certainty, that no harm will result from the consumption of food, by preventing food-borne illnesses due to microbial, natural, or chemical hazards in food; and

(2) to transfer to the Food Safety Administration the food safety, labeling, and inspection functions currently performed by other Federal agencies, to achieve more efficient management and effective application of Federal food safety laws for the protection and improvement of public health.

SEC. 3. DEFINITIONS.

For purposes of this Act:

(1) ADMINISTRATION- The term 'Administration' means the Food Safety Administration established under section 4.

(2) ADMINISTRATOR- The term 'Administrator' means the Administrator of Food Safety appointed under section 4.

(3) FOOD SAFETY LAWS- The term 'food safety laws' means the following:

(A) The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).

(B) The Poultry Products Inspection Act (21 U.S.C. 451 et seq.).

(C) The Egg Products Inspection Act (21 U.S.C. 1031 et seq.).

(D) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), with regard to food safety, labeling, and inspection under that Act.

(E) Such other laws and portions of laws regarding food safety, labeling, and inspection as the President may designate by Executive order as appropriate to consolidate under the administration of the Administration.

SEC. 4. ESTABLISHMENT OF INDEPENDENT FOOD SAFETY ADMINISTRATION.

(a) ESTABLISHMENT OF ADMINISTRATION; ADMINISTRATOR- There is established in the executive branch an agency to be known as the 'Food Safety Administration'. The Administration shall be an independent establishment, as defined in section 104 of title 5, United States Code. The Administration shall be headed by the Administrator of Food Safety, who shall be appointed by the President, by and with the advice and consent of the Senate.

(b) RESPONSIBILITIES- The Administrator shall administer and enforce the food safety laws for the protection of the public health and shall oversee the following functions of the Administration:

- (1) Implementation of Federal food safety inspection, enforcement, and research efforts, based on scientifically supportable assessments of risks to public health.
- (2) Development of consistent and science-based standards for safe food.
- (3) Coordination and prioritization of food safety research and education programs with other Federal agencies.
- (4) Coordination of the Federal response to foodborne illness outbreaks with other Federal agencies and State agencies.
- (5) Integration of Federal food safety activities with State and local agencies.

SEC. 5. CONSOLIDATION OF SEPARATE FOOD SAFETY AND INSPECTION SERVICES AND AGENCIES.

(a) TRANSFER OF FUNCTIONS- For each Federal agency specified in subsection (b), there are transferred to the Administration all functions that the head of the Federal agency exercised on the day before the effective date specified in section 8 (including all related functions of any officer or employee of the Federal agency) that relate to administration or enforcement of the food safety laws, as determined by the President.

(b) COVERED AGENCIES- The Federal agencies referred to in subsection (a) are the following:

- (1) The Food Safety and Inspection Service of the Department of Agriculture.
- (2) The Center for Food Safety and Applied Nutrition of the Food and Drug

Administration.

(3) The Center for Veterinary Medicine of the Food and Drug Administration.

(4) The National Marine Fisheries Service of the National Oceanic and Atmospheric Administration of the Department of Commerce as it relates to the Seafood Inspection Program.

(5) Such other offices, services, or agencies as the President may designate by Executive order to further the purposes of this Act.

(c) TRANSFER OF ASSETS AND FUNDS- Consistent with section 1531 of title 31, United States Code, the personnel, assets, liabilities, contracts, property, records, and unexpended balances of appropriations, authorizations, allocations, and other funds that relate to the functions transferred under subsection (a) from a Federal agency shall be transferred to the Administration. Unexpended funds transferred pursuant to this subsection shall be used by the Administration only for the purposes for which the funds were originally authorized and appropriated.

(d) REFERENCES- After the transfer of functions from a Federal agency under subsection (a), any reference in any other Federal law, Executive order, rule, regulation, document, or other material to that Federal agency or the head of that agency in connection with the administration or enforcement of the food safety laws shall be deemed to be a reference to the Administration or the Administrator, respectively.

(e) SAVINGS PROVISIONS- The transfer of functions from a Federal agency under subsection (a) shall not affect--

(1) an order, determination, rule, regulation, permit, agreement, grant, contract, certificate, license, registration, privilege, or other administrative action issued, made, granted, or otherwise in effect or final with respect to that agency on the day before the transfer date with respect to the transferred functions; or

(2) any suit commenced with regard to that agency, and any other proceeding (including a notice of proposed rulemaking), or any application for any license, permit, certificate, or financial assistance pending before that agency on the day before the transfer date with respect to the transferred functions.

SEC. 6. ADDITIONAL AUTHORITIES OF THE ADMINISTRATION.

(a) OFFICERS AND EMPLOYEES- The Administrator may appoint officers and employees for the Administration in accordance with the provisions of title 5, United States Code, relating to appointment in the competitive service, and fix the compensation of the officers and employees in accordance with chapter 51 and with subchapter III of chapter 53 of such title, relating to classification and General Schedule pay rates.

(b) EXPERTS AND CONSULTANTS- The Administrator may procure the services of experts and consultants as authorized by section 3109 of title 5, United States Code, and pay in connection with the services travel expenses of individuals, including transportation and per diem in lieu of subsistence while away from the homes or regular places of business of the individuals, as authorized by section 5703 of such title.

(c) BUREAUS, OFFICES, AND DIVISIONS- The Administrator may establish within the Administration such bureaus, offices, and divisions as the Administrator may determine to be

necessary to discharge the responsibilities of the Administration.

(d) RULES- The Administrator may prescribe, in accordance with chapters 5 and 6 of title 5, United States Code, such rules as the Administrator determines to be necessary or appropriate to administer and manage the functions of the Administrator.

SEC. 7. LIMITATION ON AUTHORIZATION OF APPROPRIATIONS.

For the fiscal year that includes the effective date of this Act, the amount authorized to be appropriated to carry out this Act shall not exceed--

- (1) the amount appropriated for that fiscal year for the Federal agencies described in section 5(b) for the purpose of administering or enforcing the food safety laws; or
- (2) the amount appropriated for these agencies for such purpose for the preceding fiscal year, if, as of the effective date of this Act, appropriations for these agencies for the fiscal year that includes the effective date have not yet been made.

SEC. 8. EFFECTIVE DATE.

This Act shall take effect on the earlier of--

- (1) the date that is 180 days after the date of the enactment of this Act; and
- (2) such date during that 180-day period as the President may direct in an Executive order.

END

RETAIN & REEVALUATE SAFETY

747

PHOTOCOPY
PRESERVATION

THE FRUIT AND VEGETABLE SAFETY ACT
1999 (S. 823)

PURPOSE: To establish a program to assure the safety of processed produce intended for human consumption, and for other purposes.

SPONSOR (S): Senators Harkin, Durbin and Kerry.

PURPOSE: This bill establishes that:

- Persons who process produce for human consumption have the responsibility to prevent or minimize food safety hazards related to their products.
- Consumption of fresh fruits and vegetables can promote health and prevent disease, and should be encouraged.
- Rising consumer demand for processed produce, the growing market for various kinds of domestic and imported processed produce, and the increasing variety of processing techniques for produce, are causing newly recognized or unpredicted safety hazards.
- Uniform sanitation practices, applied to processing of produce, will minimize these hazards.

By Mr. HARKIN (for himself and Mr. **Durbin**):

S. 823. A bill to establish a program to assure the safety of processed produce intended for human consumption, and for other purposes; to the Committee on Agriculture, Nutrition, and Forestry.

THE FRUIT AND VEGETABLE SAFETY ACT

Mr. HARKIN. Mr. President, today I am introducing legislation to bridge obvious gaps in the safety of fresh fruits and vegetables. This legislation will establish basic standards of sanitation for processed fruits and vegetables, simple standards that will help assure that Americans can enjoy these foods safely.

American families are on the front lines of this food safety battle three times a day--breakfast, lunch and dinner. Health experts advise us to eat at least five servings a day of fresh fruits and vegetables as part of a healthy lifestyle. Studies show these foods can cut our risks of cancer and heart disease. Americans have listened, and our consumption of fresh fruits and vegetables has grown every year. We can now find a variety of out-of-season produce, imported and exotic foods. We also enjoy convenience foods, ready-to-eat mixed salads, sprouts, mixed juices, a variety of frozen berries, dried spices, and other treats unavailable a few decades ago.

Americans can buy produce that is the safest in the world, and food safety problems from produce are rare. But these problems can be devastating for victims, and consumers are demanding stronger laws to protect themselves from food borne illness. Since 1990, more than 40 outbreaks of foodborne illness have been linked to fresh fruit, vegetable and juice products consumed in the United States. More than 6300 illnesses were reported, with victims in almost all 50 states. Domestic melons, imported strawberries, lettuce, sprouts and orange juice each took their toll.

Processed or ready-to-eat produce may be more easily contaminated because it is handled extensively, cut up and rinsed, and then is eaten by the consumer without further preparation. It is essential that the processor handle these foods safely, because there is nothing the consumer can do once these products are contaminated.

This bill will improve the safety of these products by requiring that they are always processed under sanitary conditions. These are the same conditions you would use in your own kitchen, and should expect from a processor. The guidelines are simple; that rinse water be clean and sewage be kept away from the food, that workers can and do wash their hands, that flies, birds and rodents be kept out of the processing plant.

Under the bill provisions, FDA will inspect processors, domestic and importing, annually, to be sure they are following sanitary guidelines. FDA will also coordinate with other food safety agencies to develop research programs aimed at setting standards for safe agricultural practices for produce, and for testing methods that can verify that fruit or vegetable products has been processed safely.

Last August, the National Academy of Sciences, in evaluating the federal food safety system, advised that food safety agencies be able to 'mandate minimum sanitation standards for food.' Food safety should be a requirement--not a suggestion. We have had basic sanitation standards in place for meat and poultry for 93 years. FDA needs strong mandatory sanitation guidelines for produce. My bill would establish basic sanitation standards for processed fruits and vegetables. Most processors in the US are already following these reasonable standards, and are keeping their products safe. This bill will bring everyone up to par domestically, and allow FDA to address produce sanitation problems in importing countries.

Agriculture is clearly our nation's largest employer, providing jobs for millions from the farm to the corner markets. Agricultural communities cannot afford to have the American public question the

safety of the food in their grocery stores. This is not just a public health issue, it is also an economic issue.

I believe these simple standards of cleanliness are reasonable, are long overdue, and will help assure that Americans can safely make these foods a part of every meal.

S 823 IS

106th CONGRESS

1st Session

S. 823

To establish a program to assure the safety of processed produce intended for human consumption, and for other purposes.

IN THE SENATE OF THE UNITED STATES**April 15, 1999**

Mr. HARKIN (for himself and Mr. DURBIN) introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

A BILL

To establish a program to assure the safety of processed produce intended for human consumption, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE- This Act may be cited as the 'Fruit and Vegetable Safety Act'.

(b) TABLE OF CONTENTS- The table of contents for this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Findings.

Sec. 3. Definitions.

TITLE I--FOOD SAFETY ACTIVITIES

Sec. 101. Administration of national program.

Subtitle A--Processed Produce

Sec. 111. Good manufacturing practices.

Sec. 112. Inspections of processors.

Sec. 113. State and Federal cooperation.

Subtitle B--Raw Agricultural Commodities

Sec. 121. Good agricultural practices.

Sec. 122. Inspections of facilities.

TITLE II--RESEARCH AND EDUCATION

Sec. 201. Public health assessment system.

Sec. 202. Public education and advisory system.

Sec. 203. Research.

TITLE III--IMPORTED FOOD

Sec. 301. Criteria for deeming imported food adulterated.

SEC. 2. FINDINGS.

Congress finds that--

- (1) persons who process produce for human consumption have the responsibility to prevent or minimize food safety hazards related to their products;
- (2) consumption of fresh fruits and vegetables can promote health and prevent disease, and should be encouraged;
- (3) rising consumer demand for processed produce, the growing market for various kinds of domestic and imported processed produce, and the increasing variety of processing techniques for produce, are causing newly recognized or unpredicted safety hazards; and
- (4) uniform sanitation practices, applied to processing of produce, will minimize these hazards.

SEC. 3. DEFINITIONS.

In this Act:

- (1) **CONTAMINANT**- The term 'contaminant' includes a bacterium, a chemical contaminant, a natural toxin, a virus, a parasite, a physical hazard, or other substance, that when found on or in produce can cause human illness or injury.
- (2) **PROCESS**- The term 'process'--
 - (A) means to carry out the commercial preparation or manufacture of produce, including--
 - (i) the freezing, dehydration, salting, sprouting, peeling, coring, stemming,

trimming, fermentation, mashing, or shredding of produce;

(ii) the cutting of produce after harvesting;

(iii) the final washing of produce that will be presented for sale so as appear to the average consumer to be ready for consumption without further washing or preparation; and

(iv) the mixing or blending of produce with other produce; and

(B) does not include carrying out the harvesting, washing (except as provided in subparagraph (A)(iii)), waxing, packing, or sorting, of a raw agricultural commodity.

(3) PRODUCE- The term 'produce'--

(A) means any perishable agricultural commodity, as defined in section 1(b) of the Perishable Agricultural Commodities Act, 1930 (7 U.S.C. 499a(b));

(B)(i) includes, except as provided in clause (ii), a mixture of--

(I) a commodity described in subparagraph (A); and

(II) any other food, as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321); and

(ii) does not include the other food in the mixture described in clause (i)(II); and

(C) does not include an article used for food or drink for animals, or an article used for a component of such an article.

(4) RAW AGRICULTURAL COMMODITY- The term 'raw agricultural commodity' means a perishable agricultural commodity, as defined in section 1(b) of the Perishable Agricultural Commodities Act, 1930 (7 U.S.C. 499a(b)) that is a raw agricultural commodity, as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(5) SECRETARY- The term 'Secretary' means the Secretary of Health and Human Services.

TITLE I--FOOD SAFETY ACTIVITIES

SEC. 101. ADMINISTRATION OF NATIONAL PROGRAM.

(a) IN GENERAL-

(1) NATIONAL PROGRAM- The Secretary shall administer a national program for the purpose of protecting human health by ensuring that--

(i) the produce processing industry has effective programs in place to assure the safety of produce processed in the United States; and

(ii) producers of raw agricultural commodities have effective programs in place to

assure the safety of those commodities produced in the United States.

(2) **BASIS FOR PROGRAM-** The program shall take into consideration the distinctive characteristics of produce processing and the production of raw agricultural commodities.

(b) **PROGRAM ELEMENTS-** The program shall provide for implementation of the authorities described in--

(1) sections 402A, 402B, 407A, and 407B of the Federal Food, Drug, and Cosmetic Act, as added in subtitles A and B;

(2) section 113; and

(3) title II.

Subtitle A--Processed Produce

SEC. 111. GOOD MANUFACTURING PRACTICES.

(a) **IN GENERAL-** Chapter IV of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 402 (21 U.S.C. 342) the following:

`SEC. 402A. GOOD MANUFACTURING PRACTICES FOR PRODUCE.

`(a) **GOOD MANUFACTURING PRACTICE REGULATIONS-** Not later than 1 year after the date of enactment of this section, the Secretary shall by regulation issue standards for good manufacturing practices for the processing of produce.

`(b) **APPLICATION-**

`(1) **IN GENERAL-** The regulations issued under subsection (a) shall be the same as the provisions of the good manufacturing practice regulations that apply to the processing of food (notwithstanding any exclusions in Federal law relating to establishments engaged solely in the harvesting, storage, or distribution of raw agricultural commodities), except as provided in paragraph (2).

`(2) **EXCEPTIONS-** In issuing regulations under subsection (a), the Secretary may modify the provisions described in paragraph (1) if the Secretary determines, for good cause shown and stated together with the regulations, that--

`(A) a modification of such provisions would be more effective to prevent the contamination of, or promote the sanitation of, processed produce; or

`(B) the application of a portion of such provisions would not result in the prevention of contamination of, or promotion of sanitation of, processed produce.

`(c) **EFFECTIVE DATE-** The regulations described in subsection (a) take effect 2 years after the date of enactment of this section.

`(d) **DEFINITIONS-** In this section:

`(1) **CONTAMINANT; PROCESS; PRODUCE-** The terms 'contaminant', 'process', and

'produce' have the meanings given the terms in section 3 of the Fruit and Vegetable Safety Act.

'(2) GOOD MANUFACTURING PRACTICE REGULATIONS- The term 'good manufacturing practice regulations' means the good manufacturing practice regulations for manufacturing, packing, or holding food, issued under sections 402, 701, and 704 and under section 361 of the Public Health Service Act (42 U.S.C. 264).'

(b) VIOLATION- Section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) is amended by adding at the end the following:

'(h) It is an article of produce processed in violation of section 402A.'

SEC. 112. INSPECTIONS OF PROCESSORS.

(a) IN GENERAL- Chapter VII of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 704 (21 U.S.C. 374) the following:

'SEC. 704A. INSPECTIONS OF PROCESSORS.

'(a) NATURE OF INSPECTIONS-

'(1) IN GENERAL- The Secretary shall provide for unannounced inspections of processing facilities to determine if produce processed in the facilities is in compliance with the requirements of this Act that relate to produce.

'(2) SCHEDULE-

'(A) IN GENERAL- The Secretary shall establish a schedule for the unannounced inspections, which shall provide for--

'(i) annual inspections for the facilities, except as provided in clause (ii); and

'(ii) less frequent inspections for facilities classified as low-risk facilities under subparagraph (B).

'(B) LOW-RISK FACILITIES- The Secretary may classify processing facilities as low-risk facilities. In making the classification, the Secretary shall classify facilities by considering the hazards associated with the type of produce being processed at a facility, the facility's history of compliance and food safety problems, and such other factors as the Secretary may determine to be appropriate.

'(3) EXAMINATION OF CLASSIFICATIONS- Each such inspection of a facility shall include an examination of whether the facility is appropriately classified under paragraph (2).

'(b) CONDUCT OF INSPECTIONS-

'(1) SCOPE- An inspection under subsection (a) of any facility described in subsection (a) shall extend to all things in the facility (including records required to be maintained under subsection (d)(1)(A)), processes, controls, and premises) that bear on whether processed produce is in compliance with the requirements of this Act that relate to produce. Access to records may include the copying of the records.

`(2) AUTHORITIES- In conducting such an inspection, an officer or employee duly designated by the Secretary shall have the same authorities and duties as the officer or employee would have under subsection (a)(1), (c), or (d) of section 704 to inspect establishments in which food is processed.

`(3) REPORT- Immediately after completion of the inspection, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a written report setting forth any conditions or practices observed that indicate that any produce from the facility is in violation of the requirements of this Act that relate to produce.

`(c) PRODUCT DETENTION AND CONDEMNATION-

`(1) IN GENERAL- If, during an inspection conducted under this section, an officer or employee making the inspection determines that processed produce is in violation of the requirements of this Act that relate to produce, the officer or employee

may order the produce segregated, impounded, and if objection is not made within 48 hours after the issuance of the impoundment order, condemned. If objection is made within that 48 hours, processed produce that is perishable may be processed to the extent necessary to prevent spoilage, and the Secretary shall expeditiously commence a hearing regarding the determination and any action required for compliance with the requirements of this Act that relate to produce. The decision of the Secretary following the hearing shall be considered to be a final agency action.

`(2) RELEASE- If the Secretary determines that, through relabeling or other action, the produce can be brought into compliance with the requirements of this Act that relate to produce, the produce may be released following a determination by the Secretary that the relabeling or other action as specified by the Secretary has been performed.

`(3) DESTRUCTION- Any processed produce condemned under paragraph (1)--

`(A) in a case in which no objection is made under paragraph (1);

`(B) after the hearing and any judicial review; or

`(C) after failure of the owner, operator, or agent to perform relabeling or other action described in paragraph (2);

shall be destroyed under supervision of the Secretary.

`(d) MAINTENANCE OF RECORDS-

`(1) IN GENERAL- The owner, operator, or agent in charge of each processing facility shall maintain such records as the Secretary may prescribe. The records shall be maintained for a reasonable period of time as determined by the Secretary. The records shall include information concerning--

`(A)(i) the origin, receipt, delivery, sale, movement, holding, and disposition of produce processed at the facility;

`(ii) the processing of the produce; and

`(iii) other matters reasonably related to whether produce processed at the facility

may be in violation of the requirements of this Act that relate to produce; and

`(B)(i) the origin, receipt, delivery, sale, movement, holding, and disposition of ingredients used in the produce processed at the facility, including sufficient information to permit lot identification to facilitate traceback of produce found to be adulterated under the requirements of this Act that relate to produce, or to be causing human illness or injury;

`(ii) the identity and amount of ingredients used in the produce;

`(iii) the results of laboratory, sanitation, or other quality control tests performed on the produce or in the facility; and

`(iv) consumer complaints concerning the produce or the packaging of the produce.

`(2) AVAILABILITY OF RECORDS- The owner, operator, or agent shall--

`(A) make available, during an inspection conducted under subsection (a), the records described in paragraph (1)(A); and

`(B) at the request of the Secretary, if the officer or employee finds as a result of the inspection that produce from the facility is associated with foodborne disease or poses an imminent health hazard, make available for inspection the records described in paragraph (1)(B).

`(e) DEFINITIONS-

`(1) FACILITY- The term 'facility' includes any factory, warehouse, or establishment, in which produce is processed.

`(2) PROCESS; PRODUCE- The terms 'process' and 'produce' have the meanings given the terms in section 3 of the Fruit and Vegetable Safety Act.'.

(b) REMEDIES-

(1) IN GENERAL- Paragraphs (f) and (n) of section 301, and section 304(g)(1), of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 334(g)(1)) are amended by striking 'section 704' and inserting 'section 704 or 704A'.

(2) PROHIBITED DISCLOSURES- Section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)) is amended by striking '704,' and inserting '704, 704A,'.

(c) CONFORMING AMENDMENT- Section 742(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379l(a)(2)) is amended by striking 'section 704' and inserting 'section 704 or 704A'.

SEC. 113. STATE AND FEDERAL COOPERATION.

(a) IN GENERAL- The Secretary shall work with the States in undertaking activities and programs that contribute to the national program established under section 111 so that State food safety programs involving the safety of processed produce and the national program

function in a coordinated and cost-effective manner. With the assistance provided under subsection (b), the Secretary shall encourage States to--

- (1) establish, continue, or strengthen State food safety programs, especially with respect to the regulation of retail commercial food establishments; and
 - (2) establish procedures and requirements for ensuring that processed produce under the jurisdiction of the State food safety programs is not unsafe for human consumption.
- (b) ASSISTANCE- The Secretary may provide to a State, for planning, developing, and implementing such a food safety program--
- (1) advisory assistance;
 - (2) technical assistance, training, and laboratory assistance (including necessary materials and equipment); and
 - (3) financial and other assistance.

(c) SERVICE AGREEMENTS- The Secretary may, under an agreement entered into with a Federal, State, or local agency, use, on a reimbursable basis or otherwise, the personnel, services, and facilities of the agency to carry out the responsibilities of the agency under this Act. The agreement shall provide that any compliance records, notices, or reports that are recorded or issued in connection with activities under the agreement, and are in the possession of the agency that entered into the agreement shall be made available in accordance with section 552 of title 5, United States Code. An agreement entered into with a State agency under this subsection may provide for training of State employees.

Subtitle B--Raw Agricultural Commodities

SEC. 121. GOOD AGRICULTURAL PRACTICES.

(a) IN GENERAL- Chapter IV of the Federal Food, Drug, and Cosmetic Act, as amended by section 111(a), is further amended by inserting after section 402A the following:

`SEC. 402B. GOOD AGRICULTURAL PRACTICES FOR RAW AGRICULTURAL COMMODITIES.

`(a) GOOD AGRICULTURAL PRACTICE REGULATIONS- Not later than 2 years after the date of enactment of this section, the Secretary, in consultation with the Secretary of Agriculture, shall by regulation issue standards for good agricultural practices for the production of raw agricultural commodities, in order to minimize the adulteration and maximize the safety of those commodities.

`(b) IMPLEMENTATION PLAN- Not later than 3 years after the date of enactment of this section, the Secretary, in consultation with the Secretary of Agriculture, shall issue and carry out an implementation plan for the implementation of the standards.

`(c) EFFECTIVE DATE- The regulations described in subsection (a) take effect 3 years after the date of enactment of this section.

`(d) DEFINITION- The term 'raw agricultural commodity' means a perishable agricultural commodity, as defined in section 1(b) of the Perishable Agricultural Commodities Act, 1930 (7

U.S.C. 499a(b)) that is a raw agricultural commodity, as defined in section 201.'

(b) VIOLATION- Section 402(h) of the Federal Food, Drug, and Cosmetic Act, as added by section 111(b), is amended by inserting before the period the following: 'or a raw agricultural commodity produced in violation of section 402B'.

SEC. 122. INSPECTIONS OF FACILITIES.

(a) IN GENERAL- Chapter VII of the Federal Food, Drug, and Cosmetic Act, as amended by section 112(a), is further amended by inserting after section 704A the following:

`SEC. 704B. INSPECTIONS OF FACILITIES.

`(a) NATURE OF INSPECTIONS- Officers and employees duly designated by the Secretary shall have the authority to inspect appropriate facilities to determine compliance with the standards described in section 402B.

`(b) REGULATIONS- Not later than 2 years after the date of enactment of this section, the Secretary, in consultation with the Secretary of Agriculture, shall by regulation issue procedures for conducting the inspections.

`(c) EFFECTIVE DATE- Subsection (a) and the regulations described in subsection (b) take effect 3 years after the date of enactment of this section.'

(b) REMEDIES-

(1) IN GENERAL- Paragraphs (f) and (n) of section 301, and section 304(g)(1), of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)), as amended in section 112(b), are further amended by striking 'or 704A' and inserting ', 704A, or 704B'.

(2) PROHIBITED DISCLOSURES- Section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(j)), as amended in section 112(b), is further amended by inserting '704B,' after '704A,'.

(c) CONFORMING AMENDMENT- Section 742(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379l(a)(2)), as amended in section 112(c), is further amended by striking 'or 704A' and inserting ', 704A, or 704B'.

TITLE II--RESEARCH AND EDUCATION

SEC. 201. PUBLIC HEALTH ASSESSMENT SYSTEM.

(a) COOPERATION WITH THE CENTERS FOR DISEASE CONTROL AND PREVENTION- The Commissioner of Food and Drugs, in cooperation with the Secretary of Agriculture, the Director of the Centers for Disease Control and Prevention, and the Administrator of the Environmental Protection Agency, shall establish and maintain an active surveillance system, for surveillance of a representative proportion of the population of the United States, to assess more accurately the frequency and sources of human illness in the United States associated with the consumption of produce.

(b) PUBLIC HEALTH SAMPLING-

(1) GUIDELINES- Not later than 12 months after the date of enactment of this Act, the

Commissioner of Food and Drugs, in cooperation with the Secretary of Agriculture, the Director of the Centers for Disease Control and Prevention, and the Administrator of the Environmental Protection Agency, shall establish guidelines for a sampling system under which the Commissioner and the Secretary of Agriculture shall collect and analyze samples of produce to assist the Commissioner in carrying out this Act and the requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) that relate to produce, and to assess more accurately the nature, frequency of occurrence, and amounts of contaminants in the produce.

(2) **MONITORING AND OTHER INFORMATION-** In carrying out the sampling system, the Commissioner of Food and Drugs and the Secretary of Agriculture shall provide for--

(A) statistically valid monitoring, including the conduct of market-basket studies, on the nature, frequency of occurrence, and amounts of contaminants in produce available to consumers; and

(B) at the request of the Commissioner, the collection and analysis of such other information, including analysis of information from monitoring and verification samples, as the Commissioner determines may be useful in assessing the occurrence of contaminants in produce.

(3) **PROCESS VERIFICATION STANDARD-** The Commissioner of Food and Drugs and the Secretary of Agriculture shall conduct sampling to identify--

(A) a contaminant, or other substance, that is commonly found on processed produce and, when present at low levels, accurately indicates that the produce has been appropriately processed, with adequate sanitation; and

(B) a standard for the level of that substance that indicates that the produce has been processed as described in subparagraph (A).

SEC. 202. PUBLIC EDUCATION AND ADVISORY SYSTEM.

(a) **PUBLIC EDUCATION-** The Commissioner of Food and Drugs, in cooperation with private and public organizations, including the State cooperative extension services and appropriate State entities, shall design and implement a national public education program on food safety relating to produce. In carrying out the program, the Commissioner shall--

(1) provide information to the public regarding Federal standards and good manufacturing practice requirements relating to food safety and promote public awareness, understanding, and acceptance of the standards and requirements; and

(2) provide such other information or advice to the produce processing industry, the food service and retail industry, consumers, and other persons as the Commissioner determines will promote the purposes of this Act.

(b) **HEALTH ADVISORIES-** The Commissioner of Food and Drugs, in cooperation with the Secretary of Agriculture, the Director of the Centers for Disease Control and Prevention, the Administrator of the Environmental Protection Agency, States, and other appropriate entities, shall--

(1) develop and distribute regional and national advisories concerning food safety relating to produce;

(2) develop standardized formats for written and broadcast advisories concerning food safety relating to produce; and

(3) incorporate State and local advisories, at the election of the States and local entities, concerning food safety relating to produce into the national public education program required under subsection (a).

SEC. 203. RESEARCH.

(a) **IN GENERAL-** The Commissioner of Food and Drugs shall conduct research to assist in the implementation of this Act and the requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) that relate to produce, including studies relating to--

(1) improving sanitation and food safety practices in the processing of produce;

(2) developing improved techniques for the monitoring of produce and inspection of produce;

(3) developing efficient, rapid, and sensitive methods for determining and detecting the presence of contaminants in produce;

(4) determining the sources of contamination of produce, including contamination from growing, harvesting, and processing produce and post-processing contamination of produce; and

(5) developing consumption data with respect to produce (including processed produce).

(b) **CONTRACT AUTHORITY-** The Commissioner of Food and Drugs is authorized to enter into contracts and agreements with States, institutions of higher education, other government agencies, and other persons to carry out the activities described in this section.

TITLE III--IMPORTED FOOD

SEC. 301. CRITERIA FOR DEEMING IMPORTED FOOD ADULTERATED.

(a) **AMENDMENT TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT-** Section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342), as amended by sections 111(b) and 121(b), is further amended by adding at the end the following:

'(i) If it is food consisting of processed produce or a raw agricultural commodity (as defined in section 402A or 402B) that is offered for import into the United States and that has not been prepared, packed, and held under a system or conditions, or subject to measures, that meet the requirements of this Act (including sections 402A and 402B), or that otherwise achieve the level of protection required, as determined by the Secretary, for such food prepared, packed, or held in the United States. In determining whether a system, conditions, or measures meet the requirements of this Act or otherwise achieve the level of protection required, the Secretary may consider whether an officer or employee duly designated by the Secretary has requested, and has been refused, access to the establishment or location where such food was prepared, packed, or held for the purpose of inspection (including sample collection), including inspection under subsection (a)(1), (b), or (d) of section 704A or section 704B, testing, or other relevant procedures, at a reasonable time and in a reasonable manner, and may deny the importation of such food from such establishment or location on the basis of such refusal and other relevant factors.'

(b) IMPLEMENTATION OF AUTHORITY; PLAN- The Secretary of Health and Human Services shall develop a plan for the initial implementation of the authority under section 402 (i) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), and shall carry out the authority of such section consistent with such plan.

END

SAFETY MEAT & POULTRY ACT

PHOTOCOPY
PRESERVATION

SAFE AND FAIR ENFORCEMENT AND RECALL FOR MEAT AND POULTRY ACT
(SAFER Meat and Poultry Act)
1999

TITLE(S):

- SHORT TITLE(S) AS INTRODUCED:
Safe and Fair Enforcement and Recall for Meat and Poultry Act
Safer Meat and Poultry Act
- OFFICIAL TITLE AS INTRODUCED:
A bill to amend the Federal Meat Inspection Act and the Poultry Products Inspection Act to provide for improved public health and food safety through enhanced enforcement.

SPONSOR(S): Senators Harkin, Daschle, Mikulski, Torricelli, Leahy, Johnson, Kennedy, Durbin and Boxer.

PURPOSE:

- A. To amend the Federal Meat Inspection Act and the Poultry Products Inspection Act to provide for improved public health and food safety through enhanced enforcement.
- B. Safe and Fair Enforcement and Recall for Meat and Poultry Act (SAFER Meat and Poultry Act) - Amends the Federal Meat Inspection Act and the Poultry Products Inspection Act to:
 - Provide the Secretary with authority for voluntary and mandatory non-distribution and recall, withdrawal of inspectors from violating facilities, and civil penalties.
 - Require that someone who knows about a contaminated food product, other than a consumer, must notify the Secretary of Agriculture.

By Mr. HARKIN (for himself, Mr. **Daschle**, Mr. **Johnson**, Ms. **Mikulski**, Mr. **Kennedy**, Mr. **Torricelli**, Mr. **Durbin**, Mr. **Leahy**, Mrs. **Boxer**, Mr. **Dorgan**, Mr. **Wellstone**, Mr. **Bryan**, Mr. **Moynihan**, and Mr. **Kerry**):

S. 18. A bill to amend the Federal Meat Inspection Act and the Poultry Products Inspection Act to provide for improved public health and food safety through enhanced enforcement; to the Committee on Agriculture, Nutrition, and Forestry.

[Page: S387]

SAFER MEAT AND POULTRY ACT

Mr. HARKIN. Mr. President, I am pleased to introduce S. 18 as part of the Democratic package, the SAFER Meat and Poultry Act, a bill that will make meat and poultry products safer for our families and our children. The bill provisions are simple, obvious authorities the USDA needs to assure that meat and poultry products are as safe as possible.

In 1998, we had a record 13 recalls for deadly E. coli 0157:H7, involving more than 2 million pounds of meat products. Tragically, just over the recent holidays, a nationwide outbreak of Listeria was recognized, leading to the massive recall of hotdogs and cold cuts. At least a dozen people lost their lives during that outbreak just over the recent holiday season.

Just last Friday, another recall for Listeria was announced. So despite the progress we have made in controlling some foodborne pathogens through improved meat inspection laws, problems with other pathogens may be getting worse.

Mr. President, the bill really is targeted at kids, because it is our kids who are the most vulnerable. And this chart shows that. These are the numbers of cases just for the State of Iowa. And as you see by age, here is the number of cases. Here are the ages: 0 to 5, 6 to 10, up to 80 years of age. You can see, the bulk of the illnesses from foodborne pathogens happens when you are less than 6 years of age--our kids who have not built up the immunity that they need that get the sickest from these foodborne pathogens. This is for Salmonella, E. coli, and Campylobacter. It is really necessary to protect our children from these pathogens.

S. 18 strengthens our laws in a number of ways. One is to give the Secretary of Agriculture the authority to mandate a recall. Most people assume that the Secretary has this authority, but he does not. Some argue that a packer or distributor will recall the tainted meat voluntarily, but recalls don't always go smoothly.

In June of last year, a company challenged the USDA on a Federal test for E. coli. The Federal test showed E. coli was there. The company said no, it was not. They contested it. And, therefore, valuable time was lost in recalling that meat product.

Consumers were shocked in 1997 by the largest recall in history, when a Hudson plant recalled 25 million pounds of ground beef linked to illnesses.

When the Secretary of Agriculture is given recall authority, he can mandate what tasks must be done and whose responsibility these tasks will be. Communication is the most essential element of a timely recall.

Another provision of the bill gives the Secretary the authority to levy civil fines for violations of meat and poultry laws. Right now, all the Secretary can do is close a plant down. That may not be the wisest course of action. You have people working there. It would put people out of work. The

problem may not be their fault at all.

Last year, the USDA referred dozens of cases for criminal prosecution for violation of meat and poultry laws. So clearly the current authorities are not an adequate incentive to protect consumer safety.

I have here a chart, Mr. President, that shows what civil penalty authority the Secretary has. For example, if there is an introduction of an animal disease anywhere in the United States, the Secretary of Agriculture can levy a fine. If you mistreat an animal, you can be fined by the Secretary of Agriculture. If you have a deceptive practice, if you violate the Pecan Promotion Act, you can be fined by the Secretary of Agriculture. But if you violate the food safety laws, you cannot be fined.

Civil fines are consistent with the new HACCP regulation for meat and poultry processing, and provide a 'just right' option for the Secretary to assure compliance with food safety laws.

What the Secretary has is an atom bomb. He can drop the atom bomb and close the plant down, which may not be the best course of action, but he cannot levy a civil fine, which may be the best action for certain violations.

Finally, the bill requires, Mr. President, that someone who knows about a contaminated food product, other than a consumer, must notify the Secretary of Agriculture. These are commonsense authorities.

Last year we saw a 50% increase in outbreaks, and a record number of recalls for the deadly E. coli O157-H7 in ground beef. More and more testing is done by grocery stores, and by purchasers for school lunch programs and restaurant chains. This bill would require that these parties notify the Secretary of Agriculture when there is a positive test. This law would allow public health authorities to oversee a recall that is timely and complete, and truly protects people from devastating illness.

These are common sense authorities that most consumers assume the Secretary already has. I hope my colleagues will join me in supporting this important piece of food safety legislation.

I also wish to indicate my strong support for legislation introduced today that will help restore and enhance farm income protection. Our farm sector, including livestock and crop production, is experiencing one of the worst downturns in over a decade. Pork producers have just experienced the worst real hog prices in history. There's a critical need for Congress to respond to this financial crisis that is threatening the livelihoods and life savings of America's farm families, and eroding the economies of rural communities.

I hope my colleagues will join me in supporting this good, important piece of food safety legislation.

Mr. KENNEDY. Mr. President, I am pleased to be a sponsor of this important bill, and I commend Senator **Harkin** for his leadership on this issue. With the high incidence of foodborne illnesses, it is essential for regulatory agencies to have the authority necessary to prevent or minimize outbreaks of these illnesses, and combat food contamination.

Microbial contamination of food is an increasing problem. The emergence of highly virulent strains of common bacteria, such as E. coli O157, is a significant cause of foodborne illnesses. Common infections that were once easily treatable are now a major public health threat, as the microorganisms acquire the ability to resist destruction by antibiotics.

The current enforcement authority of the Department of Agriculture is not sufficient. Our bill gives the Secretary of Agriculture the additional authority he needs in order to recall adulterated or misbranded meat or poultry products, and to assess civil penalties against processors who repeatedly violate meat and poultry safety standards. Most processors comply responsibly with USDA requests

This is correct

for voluntary recalls of unsafe products. This additional authority will ensure more timely and comprehensive removal of potentially dangerous foods from supermarket shelves.

Such new enforcement tools are necessary to improve food safety in general and to reduce the risk of future outbreaks of foodborne illnesses. Families across the country deserve to have confidence that the meat and poultry they eat are safe, and I look forward to early action by Congress on this important legislation.

Assurance of safe meat and poultry is just one part of the challenge of guaranteeing safe food. The safety of produce and of processed food, including imported food, is the responsibility of the Food and Drug Administration and a major part of President Clinton's Food Safety Initiative. I plan to develop legislation, in cooperation with other Senators, to ensure that no matter where our food is grown, processed, or packaged, it meets uniform high standards of safety.

S 48 IS

106th CONGRESS

1st Session

S. 48

To amend the Federal Meat Inspection Act and the Poultry Products Inspection Act to provide for improved public health and food safety through enhanced enforcement.

IN THE SENATE OF THE UNITED STATES

January 19, 1999

Mr. HARKIN (for himself, Mr. DASCHLE, Mr. JOHNSON, Ms. MIKULSKI, Mr. KENNEDY, Mr. TORRICELLI, Mr. DURBIN, Mr. LEAHY, and Mrs. BOXER) introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

A BILL

To amend the Federal Meat Inspection Act and the Poultry Products Inspection Act to provide for improved public health and food safety through enhanced enforcement.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the 'Safe And Fair Enforcement and Recall for Meat and Poultry Act' (SAFER Meat and Poultry Act).

SEC. 2. FOOD SAFETY ENFORCEMENT FOR MEAT AND MEAT FOOD PRODUCTS.

(a) IN GENERAL- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.) is amended--

(1) by redesignating section 411 (21 U.S.C. 681) as section 414; and

(2) by inserting after section 410 (21 U.S.C. 679a) the following:

'SEC. 411. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED ARTICLES.

'(a) NOTIFICATION- A person (other than a household consumer) that has reason to believe that a carcass, part of a carcass, meat, or meat food product of cattle, sheep, swine, goats, horses, mules, or other equines (referred to in this section as an 'article') transported, stored, distributed, or otherwise handled by the person is adulterated or misbranded shall immediately notify the Secretary, in such manner and by such means as the Secretary may by regulation

promulgate, of the identity and location of the article.

“(b) NONDISTRIBUTION AND RECALL-

“(1) VOLUNTARY ACTIONS- On receiving the notification under subsection (a) or otherwise, if the Secretary finds that an article is adulterated or misbranded and that there is a reasonable probability that human consumption of the article would present a threat to public health, as determined by the Secretary, the Secretary shall provide all appropriate persons, as determined by the Secretary, that transported, stored, distributed, or otherwise handled the article with an opportunity to--

“(A) cease distribution of the article;

“(B) notify all persons transporting, storing, distributing, or otherwise handling the article, or to which the article has been transported, sold, distributed, or otherwise handled, to immediately cease distribution of the article;

“(C) recall the article; and

“(D) in consultation with the Secretary, provide notice to consumers to whom the article is, or may have been, distributed.

“(2) MANDATORY ACTIONS- If the person refuses to or does not voluntarily take the actions described in paragraph (1) with respect to an article within the time and in the manner prescribed by the Secretary, the Secretary shall, by order, require the person to immediately--

“(A) cease distribution of the article; and

“(B) notify all persons transporting, storing, distributing, or otherwise handling the article, or to which the article has been transported, sold, distributed, or otherwise handled, to immediately cease distribution of the article.

“(3) NOTICE TO CONSUMERS- The Secretary shall, as the Secretary considers necessary, provide notice to consumers to whom the article was, or may have been, distributed.

“(4) NONDISTRIBUTION BY NOTIFIED PERSONS- A person transporting, storing, distributing, or otherwise handling the article, or to which the article has been transported, sold, distributed, or otherwise handled, that is notified under paragraph (1) (B) or (2)(B) shall immediately cease distribution of the article.

“(c) INFORMAL HEARING ON ORDER-

“(1) IN GENERAL- The Secretary shall provide a person subject to an order under subsection (b) with an opportunity for an informal hearing (pursuant to such rules or regulations as the Secretary shall prescribe) on the actions required by the order and on why the article that is the subject of the order should not be recalled.

“(2) TIMING- The Secretary shall hold the informal hearing as soon as practicable, but not later than 2 days, after the issuance of the order.

“(d) RECALL OR OTHER ACTIONS-

`(1) IN GENERAL- If, after providing an opportunity for an informal hearing under subsection

(c), the Secretary determines that there is a reasonable probability that human consumption of the article that is the subject of an order under subsection (b) presents a threat to public health, the Secretary may--

`(A) amend the order to require recall of the article or other appropriate action;

`(B) specify a timetable during which the recall will occur;

`(C) require periodic reports to the Secretary describing the progress of the recall; and

`(D) provide notice to consumers to whom the article is, or may have been, distributed.

`(2) VACATION OF ORDER- If, after providing an opportunity for an informal hearing under subsection (c), the Secretary determines that adequate grounds do not exist to continue the actions required by the order, the Secretary shall vacate the order.

`(e) ADDITIONAL REMEDIES- The remedies provided in this section shall be in addition to any other remedies that may be available.

`SEC. 412. REFUSAL OR WITHDRAWAL OF INSPECTION OF ESTABLISHMENTS.

`(a) IN GENERAL- The Secretary may, for such period, or indefinitely, as the Secretary considers necessary to carry out this Act, refuse to provide or withdraw inspection under title I with respect to an establishment if the Secretary determines, after opportunity for a hearing on the record is provided to the applicant for, or recipient of, inspection, that the applicant or recipient, or any person responsibly connected with the applicant or recipient (within the meaning of section 401), has committed a willful violation or repeated violations of this Act (including a regulation promulgated under this Act).

`(b) DENIAL OR SUSPENSION OF INSPECTION PENDING HEARING- The Secretary may deny or suspend inspection under title I, pending opportunity for an expedited hearing, with respect to an action under subsection (a), if the Secretary determines that the denial or suspension is in the public interest to protect the health or welfare of consumers or to ensure the effective performance of an official duty under this Act.

`(c) JUDICIAL REVIEW-

`(1) IN GENERAL- A determination and order of the Secretary with respect to the refusal or withdrawal of inspection under this section shall be final and conclusive unless, not later than 30 days after the effective date of the order, the affected applicant for, or recipient of, inspection--

`(A) files a petition for judicial review of the order; and

`(B) simultaneously sends a copy of the petition by certified mail to the Secretary.

`(2) REFUSAL OR WITHDRAWAL OF INSPECTION PENDING REVIEW- Inspection shall be refused or withdrawn as of the effective date of the order pending any judicial review of the order unless the Secretary directs otherwise.

`(3) VENUE; RECORD- Judicial review of the order shall be--

`(A) in--

`(i) the United States court of appeals for the circuit in which the applicant for, or recipient of, inspection resides or has its principal place of business; or

`(ii) the United States Court of Appeals for the District of Columbia; and

`(B) on the record on which the determination and order are based.

`(d) ADDITIONAL REMEDIES- The remedies provided in this section shall be in addition to any other remedies that may be available.

`SEC. 413. CIVIL PENALTIES.

`(a) IN GENERAL-

`(1) ASSESSMENT- The Secretary may assess a civil penalty against a person that violates this Act (including a regulation promulgated or order issued under this Act) of not more than \$100,000 for each violation.

`(2) SEPARATE OFFENSES- Each violation and each day during which a violation continues shall be a separate offense.

`(3) NOTICE AND OPPORTUNITY FOR HEARING- The Secretary shall not assess a civil penalty under this section against a person unless the person is given notice and opportunity for a hearing on the record before the Secretary in accordance with sections 554 and 556 of title 5, United States Code.

`(4) AMOUNT- The amount of a civil penalty under this section shall be--

`(A) assessed by the Secretary by written order, taking into account--

`(i) the gravity of the violation;

`(ii) the degree of culpability;

`(iii) the size and type of the business; and

`(iv) any history of prior offenses under this Act; and

`(B) reviewed only in accordance with subsection (b).

`(b) JUDICIAL REVIEW-

`(1) IN GENERAL- An order assessing a civil penalty against a person under subsection (a) shall be final and conclusive unless the person--

`(A) not later than 30 days after the effective date of the order, files a petition for judicial review in--

`(i) the United States court of appeals for the circuit in which the person resides or has its principal place of business; or

`(ii) the United States Court of Appeals for the District of Columbia; and

`(B) simultaneously sends a copy of the petition by certified mail to the Secretary.

`(2) RECORD- The Secretary shall promptly file in the court a certified copy of the record on which the violation was found and the civil penalty assessed.

`(c) COLLECTION ACTION FOR FAILURE TO PAY ASSESSMENT-

`(1) REFERRAL TO ATTORNEY GENERAL- If a person fails to pay a civil penalty after the order assessing the civil penalty has become final and unappealable, the Secretary shall refer the matter to the Attorney General.

`(2) ACTION BY ATTORNEY GENERAL- The Attorney General shall bring a civil action to recover the amount of the civil penalty in United States district court.

`(3) SCOPE OF REVIEW- In the collection action, the validity and appropriateness of the order of the Secretary imposing the civil penalty shall not be subject to review.

`(d) REFUSAL OR WITHDRAWAL OF INSPECTION PENDING PAYMENT- If a person fails to pay the amount of a civil penalty after the order assessing the civil penalty becomes final and unappealable, the Secretary may refuse to provide or withdraw inspection under title I of the person until the civil penalty is paid or until the Secretary directs otherwise.

`(e) PENALTIES IN LIEU OF OTHER ACTIONS- Nothing in this Act requires the Secretary to report for prosecution, or for the institution of an action, a violation of this Act if the Secretary believes that the public interest will be adequately served by assessment of a civil penalty.

`(f) ADDITIONAL REMEDIES- The remedies provided in this section shall be in addition to any other remedies that may be available.'

(b) CONFORMING AMENDMENTS-

(1) Section 1 of the Federal Meat Inspection Act (21 U.S.C. 601) is amended by adding at the end the following:

`(w) PERSON- The term `person' means any individual, partnership, corporation, association, or other business unit.'

(2) The Federal Meat Inspection Act (21 U.S.C. 601 et seq.) is amended--

(A) by striking `person, firm, or corporation' each place it appears and inserting

`person';

(B) by striking `persons, firms, and corporations' each place it appears and inserting `persons'; and

(C) by striking `persons, firms, or corporations' each place it appears and inserting `persons'.

SEC. 3. FOOD SAFETY ENFORCEMENT FOR POULTRY AND POULTRY FOOD PRODUCTS.

The Poultry Products Inspection Act (21 U.S.C. 451 et seq.) is amended--

(1) in the first sentence of section 5(c)(1) (21 U.S.C. 454(c)(1))--

(A) by striking `, by thirty days prior to the expiration of two years after enactment of the Wholesome Poultry Products Act,'; and

(B) by striking `sections 1-4, 6-10, and 12-22 of this Act' and inserting `sections 1 through 4, 6 through 10, 12 through 22, and 31 through 33'; and

(2) by adding at the end the following:

`SEC. 31. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED ARTICLES.

`(a) NOTIFICATION- A person (other than a household consumer) that has reason to believe that any poultry or poultry product (referred to in this section as an `article') transported, stored, distributed, or otherwise handled by the person is adulterated or misbranded shall immediately notify the Secretary, in such manner and by such means as the Secretary may by regulation promulgate, of the identity and location of the article.

`(b) NONDISTRIBUTION AND RECALL-

`(1) VOLUNTARY ACTIONS- On receiving notification under subsection (a) or otherwise, if the Secretary finds that an article is adulterated or misbranded and that there is a reasonable probability that human consumption of the article would present a threat to public health, as determined by the Secretary, the Secretary shall provide all appropriate persons, as determined by the Secretary, that transported, stored, distributed, or otherwise handled the article with an opportunity to--

`(A) cease distribution of the article;

`(B) notify all persons transporting, storing, distributing, or otherwise handling the article, or to which the article has been transported, sold, distributed, or otherwise handled, to immediately cease distribution of the article;

`(C) recall the article; and

`(D) in consultation with the Secretary, provide notice to consumers to whom the article is, or may have been, distributed.

`(2) MANDATORY ACTIONS- If the person refuses to or does not voluntarily take the

actions described in paragraph (1) with respect to an article within the time and in the manner prescribed by the Secretary, the Secretary shall, by order, require the person to immediately--

`(A) cease distribution of the article; and

`(B) notify all persons transporting, storing, distributing, or otherwise handling the article, or to which the article has been transported, sold, distributed, or otherwise handled, to immediately cease distribution of the article.

`(3) NOTICE TO CONSUMERS- The Secretary shall, as the Secretary considers necessary, provide notice to consumers to whom the article was, or may have been, distributed.

`(4) NONDISTRIBUTION BY NOTIFIED PERSONS- A person transporting, storing, distributing, or otherwise handling the article, or to which the article has been transported, sold, distributed, or otherwise handled, that is notified under paragraph (1) (B) or (2)(B) shall immediately cease distribution of the article.

`(c) INFORMAL HEARING ON ORDER-

`(1) IN GENERAL- The Secretary shall provide a person subject to an order under subsection (b) with an opportunity for an informal hearing (pursuant to such rules or regulations as the Secretary shall prescribe) on the actions required by the order and on why the article that is the subject of the order should not be recalled.

`(2) TIMING- The Secretary shall hold the informal hearing as soon as practicable, but not later than 2 days, after the issuance of the order.

`(d) RECALL OR OTHER ACTIONS-

`(1) IN GENERAL- If, after providing an opportunity for an informal hearing under subsection (c), the Secretary determines that there is a reasonable probability that human consumption of the article that is the subject of an order under subsection (b) presents a threat to public health, the Secretary may--

`(A) amend the order to require recall of the article or other appropriate action;

`(B) specify a timetable during which the recall will occur;

`(C) require periodic reports to the Secretary describing the progress of the recall; and

`(D) provide notice to consumers to whom the article is, or may have been, distributed.

`(2) VACATION OF ORDER- If, after providing an opportunity for an informal hearing under subsection (c), the Secretary determines that adequate grounds do not exist to continue the actions required by the order, the Secretary shall vacate the order.

`(e) ADDITIONAL REMEDIES- The remedies provided in this section shall be in addition to any other remedies that may be available.

`SEC. 32. REFUSAL OR WITHDRAWAL OF INSPECTION OF ESTABLISHMENTS.

`(a) IN GENERAL- The Secretary may, for such period, or indefinitely, as the Secretary considers necessary to carry out this Act, refuse to provide or withdraw inspection under this Act with respect to an establishment if the Secretary determines, after opportunity for a hearing on the record is provided to the applicant for, or recipient of, inspection, that the applicant or recipient, or any person responsibly connected with the applicant or recipient (within the meaning of section 18(a)), has committed a willful violation or repeated violations of this Act (including a regulation promulgated under this Act).

`(b) DENIAL OR SUSPENSION OF INSPECTION PENDING HEARING- The Secretary may deny or suspend inspection under this Act, pending opportunity for an expedited hearing, with respect to an action under subsection (a), if the Secretary determines that the denial or suspension is in the public interest to protect the health or welfare of consumers or to ensure the effective performance of an official duty under this Act.

`(c) JUDICIAL REVIEW-

`(1) IN GENERAL- A determination and order of the Secretary with respect to the refusal or withdrawal of inspection under this section shall be final and conclusive unless, not later than 30 days after the effective date of the order, the affected applicant for, or recipient of, inspection--

`(A) files a petition for judicial review of the order; and

`(B) simultaneously sends a copy of the petition by certified mail to the Secretary.

`(2) REFUSAL OR WITHDRAWAL OF INSPECTION PENDING REVIEW- Inspection shall be refused or withdrawn as of the effective date of the order pending any judicial review of the order unless the Secretary directs otherwise.

`(3) VENUE; RECORD- Judicial review of the order shall be--

`(A) in--

`(i) the United States court of appeals for the circuit in which the applicant for, or recipient of, inspection resides or has its principal place of business; or

`(ii) the United States Court of Appeals for the District of Columbia; and

`(B) on the record on which the determination and order are based.

`(d) ADDITIONAL REMEDIES- The remedies provided in this section shall be in addition to any other remedies that may be available.

`SEC. 33. CIVIL PENALTIES.

`(a) IN GENERAL-

`(1) ASSESSMENT- The Secretary may assess a civil penalty against a person that

violates this Act (including a regulation promulgated or order issued under this Act) of not more than \$100,000 for each violation.

`(2) SEPARATE OFFENSES- Each violation and each day during which a violation continues shall be a separate offense.

`(3) NOTICE AND OPPORTUNITY FOR HEARING- The Secretary shall not assess a civil penalty under this section against a person unless the person is given notice and opportunity for a hearing on the record before the Secretary in accordance with sections 554 and 556 of title 5, United States Code.

`(4) AMOUNT- The amount of a civil penalty under this section shall be--

 `(A) assessed by the Secretary by written order, taking into account--

 `(i) the gravity of the violation;

 `(ii) the degree of culpability;

 `(iii) the size and type of the business; and

 `(iv) any history of prior offenses under this Act; and

 `(B) reviewed only in accordance with subsection (b).

`(b) JUDICIAL REVIEW-

 `(1) IN GENERAL- An order assessing a civil penalty against a person under subsection (a) shall be final and conclusive unless the person--

 `(A) not later than 30 days after the effective date of the order, files a petition for judicial review in--

 `(i) the United States court of appeals for the circuit in which the person resides or has its principal place of business; or

 `(ii) the United States Court of Appeals for the District of Columbia; and

 `(B) simultaneously sends a copy of the petition by certified mail to the Secretary.

 `(2) RECORD- The Secretary shall promptly file in the court a certified copy of the record on which the violation was found and the civil penalty assessed.

`(c) COLLECTION ACTION FOR FAILURE TO PAY ASSESSMENT-

 `(1) REFERRAL TO ATTORNEY GENERAL- If a person fails to pay a civil penalty after the order assessing the civil penalty has become final and unappealable, the Secretary shall refer the matter to the Attorney General.

 `(2) ACTION BY ATTORNEY GENERAL- The Attorney General shall bring a civil action to recover the amount of the civil penalty in United States district court.

 `(3) SCOPE OF REVIEW- In the collection action, the validity and appropriateness of

the order of the Secretary imposing the civil penalty shall not be subject to review.

`(d) REFUSAL OR WITHDRAWAL OF INSPECTION PENDING PAYMENT- If a person fails to pay the amount of a civil penalty after the order assessing the civil penalty becomes final and unappealable, the Secretary may refuse to provide or withdraw inspection under this Act of the person until the civil penalty is paid or until the Secretary directs otherwise.

`(e) PENALTIES IN LIEU OF OTHER ACTIONS- Nothing in this Act requires the Secretary to report for prosecution, or for the institution of an action, a violation of this Act if the Secretary believes that the public interest will be adequately served by assessment of a civil penalty.

`(f) ADDITIONAL REMEDIES- The remedies provided in this section shall be in addition to any other remedies that may be available.'.

END

FOOD SAFETY STATISTICS

PHOTOCOPY
PRESERVATION

10/10/70
10/10/70

10/10/70

PHOTOCOPY
PRESERVATION

→ Lauren Chot.

official
campaign



FOOD SAFETY FACTS

- Today, fifty cents of every food dollar is spent on food prepared outside the home. This includes ready-to-eat foods from restaurants and supermarkets. There are also a large number of Americans who have their meals prepared and served in hospitals, nursing homes, and day care and senior centers.
- The number of people that are considered at higher risk for foodborne illness has also increased. Today, nearly twenty-five percent of people in the United States fall into this category: the elderly, young children, pregnant women and the immuno-compromised. Moreover, the size of the vulnerable population is growing. Due to increased longevity, the senior population is now the fastest growing sector of society.
- Fifty years ago scientists had identified four foodborne pathogens; today five times that number have been identified.
- The General Accounting Office (GAO) estimates that as many as 81 million people will suffer food poisoning this year and more than 9,000 will die.
- In terms of medical costs and productivity losses, foodborne illness costs the nation up to \$37 billion annually.
- The Department of Health and Human Services predicts that foodborne illnesses and deaths will increase 10-15 percent over the next decade.
- In 1997, a Princeton Research survey found that 44 percent of Americans believe the food supply in this country is less safe than it was 10 years ago.
- American consumers spend more than \$617 billion annually on food, of which about \$511 billion is spent on foods grown on U.S. farms.
- Since 1990, more than 40 outbreaks of foodborne illness have been linked to fresh fruit, vegetable and juice products consumed in the United States. More than 6300 illnesses were reported, with victims in almost all-50 states. (Harkin Testimony 4/99).
- In 1998, we had a record of 13 recalls for deadly E. coli 0157:H7, involving more than 2 million pounds of meat products. (Harkin Testimony 01/99).
- Over the 1998 holidays, a nationwide outbreak of Listeria was recognized, leading to the massive recall of hotdogs and cold cuts. At least a dozen people lost their lives during that outbreak just over the recent holiday season.

- The bulk of the illnesses from foodborne pathogens happen to children younger than 6 years of age--kids have not built up the immunity that they need get the sickest from these foodborne pathogens, such as Salmonella, E. coli, and Campylobacter.
- Currently (May, 1999), one-half of all the seafood and one-third of all the fresh fruit consumed in the U.S. comes from overseas. In fact, since the 1980's food imports to the U.S. have doubled, but federal inspections by Food and Drug Administration have dropped by 50 percent. (Testimony of Senator Frist, May 1999).
- Over the years there have been foodborne pathogen outbreaks involving raspberries from Guatemala, strawberries from Mexico, scallions, parsley and cantaloupes from Mexico, carrots from Peru, coconut milk from Thailand, canned mushrooms from China and others. These outbreaks have serious consequences. The Mexican frozen strawberries I have just noted were distributed in the school lunch programs in several states, including my home state of Tennessee, were attributed to causing an outbreak of Hepatitis A in **March of 1997**. (Testimony of Senator Frist, May 1999).
- In the past seven years, the amount of food imported into the U.S. has more than doubled. Out of all the produce we eat, 40% of it is imported. (Testimony of Sen. Mikulski May, 1999).
- Michigan schoolchildren were contaminated with Hepatitis A from imported strawberries in 1997, Americans were put on alert. Thousands of cases of cyclospora infection from imported raspberries--resulting in severe, prolonged diarrhea, weight loss, vomiting, chills and fatigue were also reported that year. Imported cantaloupe eaten in Maryland sickened 25 people. As much as \$663 million was spent on food borne illness in Maryland alone. Overall, as many as 33 million people per year become ill and over 9000 die as a result of food borne illness. (Testimony of Sen. Mikulski May, 1999).
- In 1998, there was a 50 percent increase in outbreaks and a record number of recalls for the deadly E.Coli 0157-H7 in ground beef. (Testimony of Harkin 01/99).
- Between 1992-1997, for foods regulated by FDA, the number of imported food entries more than doubled from 1.1 million to 2.7 million (GAO Report 04/98).
- Between 1992-1997, as workloads increased for FDA regulated foods, 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.
- This decrease meant that the average number of annual food shipments each inspector was responsible for increased from about 3,350 to about 10,500.

CD TESTIMONY TO THE
SENATE MARCH 1999

PHOTOCOPY
PRESERVATION

STATEMENT OF
JEFFREY P. KOPLAN, M.D., M.P.H.
DIRECTOR
CENTERS FOR DISEASE CONTROL AND PREVENTION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
BEFORE THE
COMMITTEE ON APPROPRIATIONS
SUBCOMMITTEE ON
AGRICULTURE, RURAL DEVELOPMENT, AND RELATED AGENCIES
U.S. SENATE
MARCH 16, 1999

I am Dr. Jeffrey Koplan, Director of the Centers for Disease Control and Prevention (CDC). I am accompanied by Dr. Stephen Ostroff of the National Center for Infectious Diseases, which is the organizational component with lead responsibility for food safety issues at CDC. I would like to thank the Committee for the opportunity to be here today with my colleagues from the U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA) to describe our Nation's food safety activities.

Today I will discuss CDC's role in the area of foodborne diseases and food safety, including how CDC has used resources obtained through the National Food Safety Initiative to strengthen the Nation's ability to detect and respond to emerging foodborne disease threats. I will also use examples from surveillance reports and from recent outbreak investigations to demonstrate how these resources are being applied to today's public health practice.

At its most fundamental level, CDC is the agency that keeps its finger on the pulse of the Nation's health. CDC is the cornerstone Federal agency for identifying and monitoring foodborne and other illness and for documenting the effectiveness of prevention and control efforts, including both voluntary and regulatory measures. Using this information, we then work to develop ways to improve disease control and prevention actions. CDC collaborates with partners ranging from State and local health departments, clinical medicine, academic centers, industry, other countries, and international organizations. In food safety, CDC works in very close coordination with the other agencies represented in today's hearing.

Foodborne and waterborne diseases is a target area in CDC's recently released plan, Preventing Emerging Infectious Diseases: A Strategy for the 21st Century. Public health priorities in the plan are organized under four broad, interdependent goals, each of which can be applied specifically to the prevention of foodborne illness: improving surveillance and response capacity, addressing applied

research priorities, repairing the Nation's public health infrastructure and training programs, and strengthening prevention and control programs required to control emerging, reemerging, and drug-resistant infectious diseases. Copies of CDC's plan have been provided to the Subcommittee.

CDC's Role in Foodborne Diseases and Food Safety

CDC plays a critical and unique role as a monitoring, investigative, and advisory agency that is separate from regulatory agencies, but that works closely with them. CDC monitors the occurrence of human foodborne disease in the United States. This includes not only traditional public health concerns, such as illness caused by pathogens such as *Salmonella*, but also newer foodborne threats such as *E. coli* O157:H7 and *Cyclospora* parasites. CDC works with State and local health departments to conduct ongoing surveillance of cases of foodborne illness and to investigate disease outbreaks, which often provide the first clue of new or different threats to the food supply. CDC uses both surveillance data and results of outbreak investigations to identify the factors responsible for illness so that immediate control measures can be taken and longer term prevention strategies can be developed. While other agencies measure success of interventions via reductions in food contamination, CDC's role in measuring the success of interventions is to see whether they translate into reductions in the incidence of human cases of foodborne illness. The ultimate test of all prevention efforts is whether they prevent human illness.

Once an outbreak is detected, the first response is usually from the State or local health department. Due to limited resources at State and local levels, not all outbreaks can be adequately investigated and reported. CDC will often be invited by the State health departments to participate in the investigation if an outbreak is very large or significant, is thought to involve an unusual pathogen or unexpected food vehicle, affects multiple states or countries, or when preliminary investigations do not reveal a source. When investigating an outbreak of a foodborne illness, public health officials must combine laboratory diagnostic techniques and epidemiologic investigative methods to determine the causative agent of the illness, the food vehicle responsible for transmission, and the environmental factors that contributed to the outbreak. If a food is identified as the source of illness, CDC collaborates with FDA or USDA on the investigation and control of the outbreak, based upon which agency regulates the suspected food.

In addition to our surveillance and response activities, CDC also conducts applied foodborne illness research. Some examples include developing laboratory diagnostic tests where none currently exist, such as detection of hepatitis A virus in food and detection of Norwalk-like viruses or *Cyclospora* in clinical specimens and foods; developing methods to subtype, or Afingerprint@, bacteria, viruses, and parasites causing foodborne illness; conducting risk factor studies for foodborne illness in special populations, such as the immunocompromised; and performing cost-effectiveness studies of potential prevention measures such as routine use of hepatitis A vaccine in food workers.

The public health infrastructure is the underlying foundation that supports the planning, delivery, and evaluation of public health activities and practices. CDC's ongoing effort to rebuild the U.S. public health infrastructure that addresses infectious diseases is critical to improve the capacity of health departments, health care delivery organizations, and clinical and public health laboratories to detect and report cases of foodborne and other illness and to implement prevention and control strategies. Part of this effort includes enhancing capacity to respond to disease outbreaks and training public health professionals to be able to respond to emerging threats now and in the future.

CDC also engages in educational activities targeted to health care professionals and the public. Some examples include producing videos on laboratory methods to diagnose foodborne pathogens and materials on how to avoid foodborne illness among immunocompromised, high-risk persons. CDC actively participates with FDA, USDA, and other Federal agencies, industry, and consumer organizations in the Partnership for Food Safety Education, an ambitious public-private partnership created to reduce the incidence of foodborne illness by educating Americans about safe food-handling practices through many activities, including the national Fight BAC!™ Campaign. The

purpose of the Fight BAC!™ Campaign is to help educate consumers about the problem of foodborne illness and motivate them to take basic sanitation and food-handling steps that will reduce the risk of foodborne illness.

The Challenges of Food Safety

Although the United States has one of the safest food supplies in the world, the public health burden of foodborne diseases is still substantial, and we continue to face challenges to the safety of our foods. New foodborne pathogens are emerging, old foodborne pathogens are showing up in new foods, and antimicrobial resistance in foods is increasing. The eating habits of Americans have changed. We now consume more fresh produce and seafood and demand a constant supply throughout the year. Changing food habits can result in a changing pattern of foodborne illness. To meet the demand, an ever increasing proportion of our food is imported, especially from developing parts of the world. As a result, we are being exposed to pathogens not commonly found in the United States, as demonstrated by the *Cyclospora* outbreaks associated with raspberries imported from Guatemala. The array of new products and processing methods, such as pre-packaged salad mixes, presents another challenge, as does mass production and distribution of foods, which has the potential to produce diffuse, nationwide illness outbreaks of unprecedented scale.

New challenges require new, creative ways to do our job more effectively and efficiently. The President's National Food Safety Initiative, launched in 1997, recognizes this need and is moving our food safety system forward. CDC has been an active partner in the development and implementation of the Food Safety Initiative. Our resources under this initiative have primarily been targeted to harnessing the information and laboratory technology revolution to propel our Nation's foodborne disease surveillance system into the 21st century.

FoodNet

I will provide two examples of CDC's progress in this area. First is the Foodborne Diseases Active Surveillance Network (FoodNet). The FoodNet system is a joint effort by CDC, FDA, USDA, and State health departments to capture a more accurate and complete picture of trends in the occurrence of illness caused by priority foodborne pathogens. It is built on the foundation of CDC's emerging infectious disease activities, which provides the basic infrastructure to conduct active disease surveillance. Before 1996, the Nation's foodborne disease surveillance system was based on passive reports of illness from clinicians and laboratories which were submitted to local health departments and then onward to the State health department and from the State to CDC. Such information lacks timeliness, is often incomplete, and is highly variable from one place to the next depending on the resources invested at the state and local level.

FoodNet is part of CDC's Emerging Infections Programs (EIP's). CDC funds EIP cooperative agreements with State and local health departments to conduct population-based surveillance and research that go beyond the routine functions of health departments. In these sites, the program, which usually involves a partnership between the State health department and an academic center, canvasses laboratories and other data sources for illnesses caused by seven different pathogens on an active, ongoing basis using standardized data collection methods, standard definitions, and standard techniques. Each case is reviewed and strains are collected and analyzed. Special case-control studies are conducted across FoodNet sites in order to identify the major risk factors for sporadic illness, and community surveys are conducted to help determine the overall burden of foodborne illness, which include mild illnesses which do not come to medical attention or patients who do not have diagnostic testing performed. Data are electronically submitted to CDC for collation with rapid turnaround. FoodNet gives high quality data never before available and also allows determination that any differences across sites are real and not due to differing surveillance intensity or methodology.

As a demonstration of how rapidly these data can be analyzed and disseminated, provisional 1998 data was released on March 11, 1999, in CDC's *Morbidity and Mortality Weekly Report*. The results

are very encouraging. For the five original FoodNet sites which have been collecting data since 1996, the incidence of *Salmonella* infections declined 13% between 1996 and 1998. For *Salmonella* Enteritidis (SE), the *Salmonella* subtype associated with egg contamination which became a major problem in the 1980s, the decline was especially pronounced. Between 1996 and 1998, the incidence of SE in FoodNet sites declined by 44%. For *Campylobacter*, the most common bacterial foodborne pathogen in the United States, there was an increase in incidence between 1996 and 1997, but now we have documented a 15% decline from 1997 to 1998. The incidence of infection with the parasite *Cyclospora* decreased to virtually zero after the importation of raspberries from Guatemala was suspended. These provisional data use 1997 census estimates. When 1998 census estimates are available later this year, these 1998 rates will be recalculated and are likely to be slightly lower due to population increases. Although there may be other explanations for these impressive declines, the fact that they were seen across sites suggests they are not surveillance artifacts and may be an indication that prevention measures being implemented by USDA and FDA are working.

PulseNet

A second system to highlight is PulseNet, a system developed in partnership with State health departments and the Association of Public Health Laboratories. PulseNet is a network of molecular subtyping (fingerprinting) laboratories at State health departments, FDA, USDA, and CDC, which enhances the ability of laboratory-based surveillance to rapidly identify clusters of related foodborne infections of certain pathogens, sometimes scattered over large geographic areas. This system uses a methodology known as Pulsed Field Gel Electrophoresis (PFGE) to digest bacterial DNA into fragments which can be run on gels to produce unique patterns. Like human fingerprints, each bacteria and its offspring have a unique PFGE pattern. If two bacteria are found with an indistinguishable pattern, it is likely that they have a common source, meaning they may be part of an outbreak of many similar cases. CDC has standardized PFGE methodology for *E. coli* O157:H7 and for *Salmonella*. Last fall CDC standardized PFGE methodology for *Listeria*, not long before there was a multi-state outbreak of listeriosis associated with contaminated hot dogs. Using funds from CDC's Epidemiology and Laboratory Capacity (ELC) cooperative agreements and from the Food Safety Initiative, state health laboratories have obtained PFGE equipment, and CDC has provided training and standardized methodology to them to test for foodborne pathogens. USDA and FDA laboratories also participate in the network to allow comparison between animal, food, and human isolates. By the end of 1999, 33 laboratories will be linked into this network. Eventually, CDC hopes to include all state laboratories.

To enhance the power of the PulseNet system, in 1998, CDC created a national computer database of PFGE patterns that is housed at CDC. Now states can submit PFGE patterns to the database over the Internet. The computer then automatically scans previously submitted patterns searching for matches. If a match is found, a signal is given to the submitter that duplicate patterns are present and where they came from, so that an investigation can begin to look for a common source. All of this happens in real time, allowing the early warning system for nascent outbreaks that we all desire.

The impact of PulseNet has been enormous, both in identifying outbreaks that would otherwise have gone unnoticed, and in allowing us to focus our investigations to determine the true source and extent of an outbreak. For example in late 1998, an increased number of cases of listeriosis were noticed. Using PulseNet technology, CDC tested the strains from several states and determined that many had the same PFGE pattern. Epidemiologic investigations found a strong association with hot dog consumption in patients with the outbreak strain, leading to recalls which occurred just before Christmas. Since then, CDC has continued to work with states to test all available *Listeria* isolates from patients since last summer, in order to determine how many cases and deaths occurred as part of the outbreak and to confirm that the outbreak is over. As of late February, a total of 97 outbreak-associated cases have been identified in 22 states with 14 fatalities and 6 still births.

Some of the strains which were tested were different from the outbreak strain. Among these a second cluster of strains with a common PFGE pattern was found. Investigation of these cases found they were linked to consumption of a specific imported cheese. Other small clusters of cases have been

identified and are under investigation. If not for the ability to do the subtyping, these outbreaks never would have been discovered and investigated, and prevention measures would not have been undertaken.

Another PulseNet example involves *Shigella*, a bacterial pathogen that can be foodborne but most often is not. The Minnesota Department of Health, a FoodNet site, routinely fingerprints its *Shigella* isolates, and last summer they identified a cluster of strains with a similar pattern. Epidemiologic investigations found that illness was linked to eating chopped parsley in two different restaurants. By informing other states and searching databases for places with an increased number of cases, similar outbreaks were identified in five other states and Canada. The *Shigella* from these outbreaks also had the same PFGE fingerprint. All of the outbreaks were parsley associated. Working with FDA, the implicated parsley was traced to production fields in Mexico. Again, if not for routine utilization of PFGE, the links between the outbreaks would have been missed, the source would not have been identified, and the outbreak would have spread much further.

PFGE is a powerful tool. It allows us to detect widely dispersed outbreaks and small clusters that would have previously been missed. This illustrates a central tenet of epidemiology: better surveillance leads to better and more accurate disease detection, which in turn leads to more investigations. This causes increased burdens, not only on CDC and other Federal agencies, but also on state and local partners.

Therefore, as surveillance improves, more outbreaks, not fewer, will be detected. However, this should not be interpreted as a failure. Rather, it represents success, because only by finding and investigating the outbreaks can we define risks, develop and implement interventions, and over the long term target and ultimately eliminate the risk.

National Food Safety Initiative at CDC in FY 2000

CDC is committed to continuing to build a sensitive, timely, and accurate public health infrastructure for the Nation. To this end, the President's request for CDC for fiscal year 2000 National Food Safety Initiative is \$10,000,000 above the fiscal year 1999 appropriation of \$19,476,000. CDC plans to devote these resources to continue to build the national network of labs capable of performing PFGE technology and participating in the PulseNet system. We will increase the number of pathogens monitored in the system in order to detect additional outbreaks. Other funds will go to expanding the FoodNet system and adding surveillance components for viral gastroenteritis. In the future, we hope to expand and incorporate subtyping methods for viral agents and to support the development of subtyping methods for *Cyclospora* and *Cryptosporidium*, parasitic agents for which subtyping is not sufficiently developed. And finally we will continue to support a system known as DPDx, which harnesses telemedicine technology to transmit images of parasites under the microscope to our experts at CDC for appropriate diagnosis. In concert, CDC will continue to use emerging infections resources to build State health department capacity to conduct appropriate epidemiologic investigations.

Conclusions

In conclusion, these activities represent a small sample of how CDC supports its state and local partners and other Federal agencies in monitoring, controlling, and preventing foodborne illness. Foodborne diseases remain a challenge for public health. To address this challenge will require continued investments in our public health infrastructure and strong partnerships among State and local health departments and Federal agencies.

Thank you for the opportunity to discuss the surveillance of foodborne disease. We will be happy to answer questions you or other members of the Subcommittee may have.

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Food Safety and Inspection Service
United States Department of Agriculture
Washington, D.C. 20250-3700

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- Statement by Associate Administrator Margaret Glavin Regarding Imports from the EU (July 2, 1999)
- Glickman Applauds Election of Tom Billy as Chairman of International Food Standards Organization (June 29, 1999)
- Glickman Offers Safety Tips for Americans During Summer BBQ Season (June 23, 1999)
- Statement by Administrator Thomas Billy Regarding Imports from the EU (June 18, 1999)
- Sausages Recalled in Hawaii Because of *Listeria monocytogenes* (June 18, 1999)
- Chicken Nuggets Recalled for Undeclared Whey (June 15, 1999)
- Statement by Administrator Tom Billy Regarding Imports from the European Union (June 11, 1999)
- Statement by Acting Administrator Mark Mina Regarding Imports from the European Union (June 3, 1999)
- Australian Meat Safety Enhancement Program (MSEP) Approved (June 2, 1999)
- North Dakota Meat Company Recalls Wieners for Listeria Contamination (June 1, 1999)
- Codex Alimentarius To Hold Public Meeting; FSIS Seeks Comments On Codex Standards (May 28, 1999)
- Pennsylvania Meat Company Recalls Weisswurst Sausage For Listeria Contamination (May 28, 1999)
- USDA Recommends Safeguards for Consumers At Increased Risk for Listeriosis (May 25, 1999)
- FSIS Announces Strategy To Control Listeria Monocytogenes In Ready-To-Eat Meat And Poultry Products (May 25, 1999)
- MEDIA ADVISORY: FSIS to Announce Strategy to Control Listeria Monocytogenes in Ready-to-Eat Meat and Poultry Product (May 25, 1999)
- USDA Announces Dedication of Technical Service Center (May 21, 1999)
- National Advisory Committee On Microbiological Criteria For Foods To Hold Public Meeting (May 21, 1999)
- MEDIA ADVISORY: USDA and Nebraska State Officials to Participate in The Dedication of USDA Technical Service Center (May 20, 1999)
- North Carolina Firm Recalls Luncheon Meats For Potential Listeria Contamination (May 14, 1999)
- Utah Firm Recalls Ham With Potential Salmonella (May 13, 1999)
- Wisconsin Firm Recalls Polish Sausages Because of Salmonella (April 22, 1999)
- National Advisory Committee On Meat And Poultry Inspection To Hold Public Meeting (April 21, 1999)
- New York Grocery Recalls Ground Beef Contaminated With *E. Coli* O157:H7 (April 13, 1999)
- USDA Declares Product From Thorn Apple Valley Unfit For Human Consumption (April 13, 1999)

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- FSIS To Hold Public Meeting To Discuss Equivalency Evaluation Process (April 12, 1999)
 - New Jersey Firm Recalls Franks (March 18, 1999)
 - Salmonella Threat Reduced By New Meat and Poultry Inspection System (March 9, 1999)
 - Related news release from CDC: Salmonella and Campylobacter Illnesses on the Decline (March 11, 1999)
 - Los Angeles Firm Recalls Egg Rolls for Undeclared Egg Whites (March 2, 1999)
 - FSIS To Hold Public Meeting, Explore Policy Changes On E. Coli Contaminated Beef (March 1, 1999)
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 - Ontario Meat Company Recalls Cooked Sausage for Listeria Contamination (February 5, 1999)
 - FSIS to Hold Public Meeting, Develop Strategy to Fight Listeria (February 5, 1999)
 - Bil Mar Listeria Recall--Additional Brands Sold at Retail (January 28, 1999)
 - Thorn Apple Valley Listeria Recall--Update and Amended List (January 28, 1999)
 - Thorn Apple Valley Frankfurters And Lunch Combination Products Recalled For Potential Listeria Contamination (January 22, 1999)
 - Ohio Meat Company Recalls Deli Meat For Listeria (January 22, 1999)
 - New Meat and Poultry Inspection System Greatly Reduces Threat of Salmonella (January 21, 1999)
 - MEDIA ADVISORY: FSIS To Highlight Meat & Poultry Food Safety Systems (January 20, 1999)
 - FSIS Issues Policy Statement on Beef and E. coli O157:H7; Updated Ground Beef Guidelines Also Available (January 19, 1999)
 - Oscar Mayer Recalls Deli Meat for Listeria (January 15, 1999)
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 - Organic Labeling Claim Allowed on Meat and Poultry Products (January 14, 1999)
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 - New Positions Announced for Food Safety and Inspection Service (January 6, 1999)
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For Further Information, Contact:

FSIS Food Safety Education and Communications Staff
Media Communications
Phone: (202) 720-9113
Fax: (202) 690-0460

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**Food Safety and Inspection Service
United States Department of Agriculture
Washington, D.C. 20250-3700**

News and Information

Media Communications Office
(202) 720-9113; FAX: (202) 690-0460
Contact: Beth Gaston

FSIS Announces Strategy To Control *Listeria monocytogenes* In Ready-To-Eat Meat And Poultry Products

WASHINGTON, May 25, 1999--Today, the Food Safety and Inspection Service announced several short-term steps to help industry control *Listeria monocytogenes* in ready-to-eat products and thus better protect public health. First, FSIS is publishing a notice in the *Federal Register* advising plants to reassess their HACCP preventive control plans to ensure they are adequately addressing the pathogen. Second, the agency is providing guidance to industry recommending environmental and end-product testing. And third, FSIS is carrying out extensive educational efforts targeted to "at risk" consumers.

The prevention-oriented Hazard Analysis and Critical Control Points (HACCP) system requires plants to identify critical points along their production lines and ensure that practices at those points minimize or prevent the likelihood of bacterial contamination or growth. The *Federal Register* notice on view today indicates that, based on the outbreak of listeriosis in late 1998 and early 1999, recent recalls, and other information on the pathogen, *Listeria monocytogenes* is a hazard reasonably likely to occur in ready-to-eat meat and poultry products. The agency advises plants to re-examine their HACCP plans to determine if they adequately address *Listeria*.

To assist industry, FSIS is at the same time providing guidance to producers of ready-to-eat products recommending environmental and end-product testing. Because a number of trade associations have developed guidelines that cover areas such as sanitation, the handling of raw materials, and employee hygiene, FSIS is complementing those materials by focusing on testing by plants to verify that their HACCP plans and sanitation procedures are producing pathogen-free product.

FSIS recommends that plants: conduct environmental testing for general *Listeria* species; test product contact surfaces for general *Listeria* species; and test end-products for the pathogen *Listeria monocytogenes*.

"As summer begins, Americans need to be able to grill hotdogs or pack sandwiches for a picnic with confidence that their food is safe," said Tom Billy, FSIS administrator. "Working together with industry and consumers, we can take steps to better protect the public from foodborne illness."

Consumption of food contaminated with *Listeria monocytogenes* can cause listeriosis, an uncommon but potentially fatal disease. Healthy people rarely become seriously ill after exposure to *Listeria monocytogenes*. However, listeriosis can cause miscarriages and stillbirths. The most common manifestation of listeriosis is meningitis, which produces high fever, severe headache, neck stiffness, and nausea, as well as serious and sometimes fatal infections in those with weak immune systems--infants, the frail or elderly, and persons with chronic disease, HIV infection, or taking chemotherapy.

FSIS also has the following four longer-term initiatives:

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- First, the agency is drafting a protocol to study the post-production growth of *Listeria monocytogenes* in a wide variety of ready-to-eat products and will ask USDA's Agricultural Research Service to conduct the study during FY 2000.
- Second, FSIS is developing an in-depth verification protocol that can be used to evaluate plants' HACCP plans for ready-to-eat products, particularly regarding *Listeria monocytogenes*.
- Third, a risk assessment of *Listeria monocytogenes* in conjunction with the Food and Drug Administration is underway that will focus on all foods, but in particular refrigerated, ready-to-eat foods.
- And, fourth, FSIS is developing food safety standards for ready-to-eat products that will address the need to control all pathogens, including *Listeria monocytogenes*.

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NOTE: Access news releases and other information at the FSIS Web Site on the World Wide Web at <http://www.fsis.usda.gov>

For Further Information, Contact:

FSIS Food Safety Education and Communications Staff

Media Communications

Phone: (202) 720-9113

Fax: (202) 690-0460

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**Food Safety and Inspection Service
United States Department of Agriculture
Washington, D.C. 20250-3700**

News and Information

Media Communications Office
(202) 720-9113; FAX: (202) 690-0460
Contact: Elizabeth Gaston
elizabeth.gaston@usda.gov
Liz Lapping

FSIS To Hold Public Meeting To Discuss Equivalency Evaluation Process

NOTE: The referenced document is available online in **PDF** format. To read and print a PDF file, you must have the Adobe® Acrobat® Reader installed on your PC. You can download a version suitable for your system, free of charge, from the Adobe Home Page.

WASHINGTON, April 12, 1999--The U.S. Department of Agriculture's Food Safety and Inspection Service will hold a public meeting on April 14 to discuss the process that it uses to evaluate whether other country's systems for ensuring the safety of meat and poultry products are equivalent to that of the U.S. A document that describes the agency's process is available for comment.

The document, "FSIS Process for Evaluating the Equivalence of Foreign Meat and Poultry Systems," outlines how FSIS evaluates the equivalence of either a foreign country's entire meat and poultry regulatory system or a foreign country's specific sanitary measure.

Countries shipping meat and poultry products to the United States must have equivalent inspection systems that furnish the same level of public health protection as the U.S. inspection system.

Copies of "FSIS Process for Evaluating the Equivalence of Foreign Meat and Poultry Regulatory Systems," are available from the FSIS Docket Clerk, Room 102 Cotton Annex, 300 12th Street, SW, Washington, DC 20250-3700. A copy may also be obtained from the FSIS home page at <http://www.fsis.usda.gov> under "What's New."

Written comments on the equivalence evaluation document may be sent to the FSIS Docket Clerk, Docket #99-009N, at the address shown above until May 11, 1999.

The public meeting will be held from 8:30 a.m. to 4:30 p.m. on Wednesday, April 14, at the Washington Plaza Hotel at 10 Thomas Circle NW, Washington, DC 20009, (202) 842-1300. No preregistration is required. For further information, contact Mark Manis, Director, International Policy Division; Office of Policy, Program Development, and Evaluation; (202) 720-6400, or by electronic mail to mark.manis@usda.gov.

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For Further Information, Contact:

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FSIS/FDA Sign Memorandum Of Understanding To Improve Public Health Protection

WASHINGTON, Feb. 23, 1999--Working with the President's Food Safety Council, the Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA) have signed a Memorandum of Understanding (MOU) to facilitate the exchange of information at the field level about food establishments and operations that are subject to the jurisdiction of both agencies. District offices of each agency will notify their counterparts of food safety recalls, instances of product contamination and mislabeling, and conditions at facilities that could result in unsafe or unwholesome food.

"Exchanging information on food safety operations will permit more efficient use of both agencies' resources and will contribute to improved public health protection," said Thomas J. Billy, FSIS Administrator.

"Food safety challenges are becoming increasingly complex and frequently a problem involves both agencies. This MOU ensures that communication between the agencies remains open and that information flows without delays," said Dr. Jane E. Henney, FDA Commissioner.

The agencies determined that changes in inspection activities, available resources, and food safety hazards necessitated updating an agreement signed in 1983. FSIS and FDA will pursue, where feasible, joint enforcement activities, and work to develop a joint electronic communications system for field offices.

On August 25, President Clinton signed the order creating the President's Food Safety Council, which he charged with developing a comprehensive strategic plan for Federal food safety activities and ensuring that Federal agencies develop coordinated food safety budgets each year.

FSIS is responsible for implementing and enforcing the Federal Meat Inspection Act, the Poultry Products Inspection Act, and parts of the Egg Products Inspection Act. In carrying out its responsibilities under these acts, FSIS places inspectors in meat and poultry slaughterhouses and egg processing plants and inspects meat and poultry processing plants daily. FSIS also has compliance officers visit warehouses, transporters, retail stores, restaurants, and other places where meat, poultry, and egg products are handled and stored. In addition, FSIS conducts voluntary inspections under the Agricultural Marketing Act. FSIS determines the inspection system equivalence of foreign countries and requires all eligible imports of meat, poultry, and egg products to be presented for reinspection by FSIS.

FDA is responsible for implementing and enforcing the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, the Fair Packaging and Labeling Act, and parts of the Egg Products Inspection Act which covers eggs in the shell. In carrying out its responsibilities under these acts,

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FDA conducts inspections of establishments that manufacture, process, pack, or hold foods, including seafood, fruits, vegetables, and all other foods not regulated exclusively by FSIS. FDA also inspects vehicles and other conveyances, such as boats, trains, and airplanes, in which foods are transported or held in interstate commerce.

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For Further Information, Contact:

FSIS Food Safety Education and Communications Staff

Media Communications

Phone: (202) 720-9113

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 FDA: Larry Bachorik (301) 827-6250

NEW EGG SAFETY STEPS ANNOUNCED, SAFE HANDLING LABELS AND REFRIGERATION WILL BE REQUIRED

WASHINGTON, July 1, 1999--Continuing their joint efforts to combat food the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) and Department of Health and Human Service's Food and Drug Administration (FDA) today announced three important new measures to prevent illnesses caused by contaminated

The FDA is proposing to require safe handling statements on labels of shell eggs to consumers about the risk of illness caused by Salmonella Enteritidis (SE). FDA's p handling instructions will contain the following statement on each carton of eggs:

SAFE HANDLING INSTRUCTIONS: Eggs may contain harmful bacteria known to cause serious illness, especially in children, the elderly, and persons with w immune systems. For your protection: Keep eggs refrigerated; cook eggs until firm; and cook foods containing eggs thoroughly.

In addition, for the first time, there will be a uniform federal requirement that a products packed for consumers be refrigerated at 45 degrees or below. Retail estab governed by the proposed FDA regulation include supermarkets, restaurants, delis, c vending operations, hospitals, nursing homes and schools. In addition, FSIS is iss directive applying the refrigeration requirement to warehouses and other distributi that store shell eggs packed into containers destined for consumers, including tran A joint FDA-FSIS risk assessment found that refrigeration makes it more difficult f bacteria to grow.

Finally, the President's Council on Food Safety will develop by November 1 a strate further improve the safety of shell eggs and processed egg products. The strategic address the issue of controlling pathogens, including SE, and will suggest further better coordinate egg safety from the farm to the table.

"The Clinton Administration has made ensuring food safety a top priority," said Agr Secretary Dan Glickman. "These additional steps will help educate consumers and re foodborne illness caused by contaminated eggs."

"Eggs are a good source of protein and can be a healthy and economical contribution balanced diet," said HHS Secretary Donna Shalala. "However, they need proper handl could potentially be the source of foodborne illness."

From 1996 to 1998, there has been a 44 percent decrease in the number of illnesses SE, according to the Foodborne Diseases Active Surveillance Network, known as "Food collaborative effort of FSIS, FDA, and the Centers for Disease Control and Preventi measures announced today may prevent up to 66,000 illnesses and 40 deaths per year.

SE outbreaks have been attributed to undercooked eggs or foods containing undercook served in homes, private gatherings, commercial establishments such as restaurants, nursing homes and schools. Persons infected with SE microorganisms may experience fever, abdominal cramps, headache, nausea and vomiting. Children, the elderly and weakened immune systems may develop severe or even life-threatening illness.

FDA and FSIS share federal regulatory responsibility for egg safety, with the regul eggs primarily the responsibility of FDA. In May 1998, FSIS and FDA announced plan additional measures to ensure the safety of eggs and requested public comments on t Today's announcements are the latest steps in that ongoing effort.

The FDA proposal is on display today in the Federal Register. Written comments and recommendations on the proposed rule will be accepted for the next 75 days. FSIS's

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takes effect on August 27, 1999.

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