Ben White
331-5543

USDA

FAX COVER SHEET
OFFICE OF THE UNDER SECRETARY
FOR FOOD SAFETY

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TO: Tom Freedman

FAX NUMBER: 456-7431

FROM:
- ☒ CATHERINE E. WOTEKI, UNDER SECRETARY
- ☐ KRISTIE D. KELM
- ☐ CAREN A. WILCOX, DEPUTY UNDER SECRETARY
- ☐ JOYCE E. SMITH
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COMMENTS:

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Dr. Joao Carlos de Souza Meirelles
Secretario de Agricultura e Abastecimento
Governo do Estado de Sao Paulo
Av. Miguel Estefano, 3900
CEP 04301-903 - Sao Paulo
Brazil

Dear Dr. Meirelles:

As a follow up-to our meeting on October 28, I would like first of all to thank you and Dr. Brandling-Bennett for visiting with me. I would also like to confirm the interest of the U.S. Department of Agriculture in continuing discussions on the convening of a hemispheric food safety conference at the presidential level during the upcoming year.

As we discussed, the time for preparing for such a major conference is getting very short, and we need to make decisions very soon. You referred to an invitation from President Cordosa to President Clinton to visit Brazil. Does this invitation make any reference to food safety or to the proposed hemispheric conference? If not, will Brazil approach the United States officially with the proposal for such a conference? As you indicated during our discussion, I assume that Brazil will offer to host the conference; and if so, will Brazil also offer to prepare a first draft agenda? As soon as the U.S. has been approached officially to be the co-organizer of such a conference, a preparatory committee consisting of high officials of the departments of agriculture and health of our two countries as well as of the Pan American Health Association would need to be established to start the planning process.

I know that you recognize the extreme time pressures that we will face to convene the conference, and I look forward to your response.

Sincerely yours,

Catherine E. Woteki, Ph.D., R.D.
Under Secretary

cc: David Brandling-Bennett, M.D.
David Satcher, M.D.
Jane Henney, M.D.

bcc: Fritz Kaferstein
Gus Schumacher
Mike Dunn
Isi Siddiqui
Eric Olsen

DEPARTMENT OF THE TREASURY

DEPARTMENT OF HEALTH & HUMAN SERVICES

The Honorable William J. Clinton
President
The White House
Washington, D.C. 20500

Dear Mr. President:

As you directed in your memorandum of July 3, 1999, we are submitting the enclosed joint report on steps that the Department of Health and Human Services (HHS) and the Department of the Treasury (Treasury) will take to protect consumers from unsafe imported foods. Your memorandum directs that we target the "bad actor" importers who violate the rules and work to subvert the system by moving unsafe food into U.S. markets.

You have asked both departments to take whatever steps are possible, within existing statutory authority and resource limitations, to develop new operational procedures to protect public health. In responding to your directive, we have given particular attention to six specific objectives that you emphasized in your memorandum:

(1) Prevent distribution of imported unsafe food by means such as requiring food to be held until reviewed by the Food and Drug Administration - The Food and Drug Administration (FDA) of the HHS is preparing guidelines that include criteria for identifying problem importers as well as procedures for imposition of sanctions. The U.S. Customs Service (Customs) of the Treasury is preparing guidelines for its field personnel to ensure that shipments of food products for FDA-designated problem importers can be identified at the time of arrival and held in secure storage until released by FDA.

(2) Destroy imported food that poses a serious public health threat - FDA will establish criteria for determining which health and safety violations are sufficiently serious to require destruction of the imported food. Customs currently has ample seizure and forfeiture authority, and procedures to allow FDA destruction orders to be carried out.

(3) Prohibit the re-importation of food that has been previously refused admission and has not been brought into compliance with United States laws and regulations (so called "port shopping"), and require the marking of shipping containers and/or papers of imported food that is refused admission for safety reasons - FDA will publish regulations that will provide for marking of refused food products as well as other initiatives discussed in this report. Customs inspectors at ports of entry will enforce the FDA marking requirement.

(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 - FDA has sufficient statutory authority to issue regulations in this area, and will develop a plan to address sample

collection and laboratory issues as well as other initiatives discussed in the enclosed report.

(5) Increase the amount of the bond posted for imported foods when necessary to deter premature and illegal entry into the United States - Customs has already published proposed regulations to increase the liquidated damages from three times the entered value to the full domestic value in cases where refused shipments are not redelivered, exported, or destroyed in accordance with law or regulation. The proposed regulations would remove the possibility of monetary gain from the illegal importation and sale of refused food.

(6) Enhance enforcement against violation of United States laws related to the importation of foods, including through the imposition of civil monetary penalties - Customs has instituted aggressive enforcement programs under existing statutory authorities that allow for the imposition of monetary penalties. Customs will ensure that FDA is aware of the assessment of civil monetary penalties against violators involving unsafe food, and FDA will ensure that Customs is aware of any events for which civil monetary penalties are an appropriate regulatory action.

The enclosed report further elaborates on our plan of action in these six areas. The report summarizes progress already made by the Food and Drug Administration and the U.S. Customs Service as well as future activities that will prevent problem importers from jeopardizing the safety of our Nation's food supply.

Sincerely,

Lawrence H. Summers
Secretary of the Treasury

Sincerely,

Donna E. Shalala
Secretary of Health
and Human Services

Enclosure

Presidential Initiative - Safety of Imported Food
Status Report

I. Background

American consumers enjoy one of the safest food supplies in the world. Enhancing the safety of the U.S. food supply is a high priority of the Clinton Administration as evidenced by funding requests for food safety initiatives, the establishment of the Food Safety Council, and directives to improve the safety of the food supply. On July 3, 1999, President Clinton expanded his food safety efforts by directing the Secretary of Health and Human Services and the Secretary of the Treasury to take additional action to further protect consumers from unsafe imported foods. While most imported foods are safe, and most importers comply with U.S. food safety requirements, a few importers try to sidestep U.S. laws to bring unsafe or contaminated food into the country. The President specifically directed the Food and Drug Administration (FDA), the agency responsible for the safety of most imported foods, and the United States Customs Service (Customs) to take all actions available to:

(1) Prevent distribution of imported unsafe food by means such as requiring food to be held until reviewed by FDA;

(2) Destroy imported food that poses a serious public health threat;

(3) Prohibit the re-importation of food that has been previously refused admission and has not been brought into compliance with U.S. laws and regulations, and require the marking of shipping containers and/or papers of imported food that is refused admission for safety reasons;

(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; and

(6) Enhance enforcement against violations of U.S. laws related to the importation of foods, including through the imposition of civil monetary penalties.

The President further directed the Secretary of Health and Human Services and the Secretary of the Treasury to consult with his Food Safety Council and relevant federal agencies, particularly the United States Department of Agriculture (USDA) and the United States Trade Representative (USTR), to develop steps in the above areas to protect consumers from unsafe imported foods.

II. This Report

The President asked the Secretary of Health and Human Services and the Secretary of the Treasury to report on the steps they will take in each area identified in his directive to protect consumers from unsafe imported foods. This report presents the status of progress made in each area and a plan for accomplishing the President's "problem importers" directive.

To meet the President's goal of curtailing the effect that problem importers may have on the safety of the U.S. food supply, the Departments will exercise the full extent of their statutory authorities to:

(1) Require controlled storage of merchandise entered by firms with a history of failing to hold products, of making false declaration, or of substituting products;

(2) Seize and/or destroy merchandise that poses a serious health threat;

(3) Promulgate regulations to require importers or consignees to mark food products that have been deemed unsafe and refused admission into the United States and prohibit the re-importation of any food product that has been previously refused entry;

(4) Promulgate regulations to establish requirements pertaining to sample collection and private laboratories;

(5) Assess liquidated damages equal to the domestic value of merchandise that has not been redelivered to Customs or that has not been exported or destroyed within the time period prescribed by law after refusal; and

(6) Collaborate more effectively in enforcing the Customs program of assessing civil monetary penalties to importers who attempt to import any food by means of any material false statement, act or omission.

In his directive, the President recognized that there are limitations on the Departments' resources and statutory authorities to take measures to protect consumers against unsafe imported foods. Included in this report are discussions of proposed rulemaking and resource costs to FDA and Customs to enact the new procedures and implement new regulations.

Because public notice and/or comment is desirable and, in some instances, required for the implementation procedures, the Departments plan to invite discussion and comment on these initiatives. This report and its accompanying operational procedural guidance and regulatory enforcement programs will be posted on the Internet sites of FDA and Customs.

The actions outlined in this report are intended to deal with problem importers and unsafe food shipments. The proposed steps are fully in accord with World Trade Organization agreements and should not pose barriers to trade for importers who routinely follow U.S. regulations and procedures.

Food is defined as articles used for food or drink for man or other animals in section 201(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(f)(1)). Animal food or feed is also imported into this country. Unless stated otherwise, use of the word food in this report includes animal food or feed.

III. Participants

FDA and Customs have the primary responsibility for the plans to accomplish and implement this directive. A joint task force, which developed this report and implementation plan, consisted of members representing various offices within Customs and FDA, as well as the Environmental Protection Agency (EPA), and USDA's Food Safety and Inspection Service (FSIS) and Animal and Plant Health Inspection Service (APHIS). Copies of the working draft were shared with representatives of USDA's Foreign Agriculture Service (FAS) and the USTR. The report was also submitted for comment to the President's Food Safety Council.

IV. Action Areas

1. Prevent distribution of imported unsafe food by means such as requiring food to be held until reviewed by FDA.

Status: FDA and Customs have developed procedures by which importers who have repeatedly distributed imported foods before they were released by FDA, or have provided the U.S. government with false or misleading information on imported foods, will be required to store future shipments in secure facilities operated by an independent third party, under the supervision of Customs, until FDA has reviewed and released the shipments into domestic commerce. If FDA ultimately determines that the food is not admissible into the United States, the importer would be allowed to remove the food from the secure storage facility only for immediate export or destruction. The importer would bear storage costs. Since FDA and Customs expect that, nationwide, no more than two or three dozen importers will be subject to this procedure at any given time, there should be no significant impact on port storage requirements.

Plan: Customs port directors already possess sufficient authority to implement this plan. FDA will draft internal guidance for its field personnel on how to work with Customs under this plan. FDA's internal guidance will include criteria for identifying problem importers as well as

internal procedures for submission of recommendations for review and concurrence by FDA headquarters. Customs will draft internal guidance for its field personnel to ensure that problem importers are identified and that the food products imported by the problem importers are held in secure storage until released by FDA.

Timeframe:

October-December 1999

a. Customs has drafted and will issue field guidance
b. FDA will draft and issue field guidance

January-March 2000

a. FDA will identify importers meeting the criteria for secure storage
b. Customs will load FDA importer data into Customs Screening System (OAS)
c. Implementation of the program

2. Destroy imported food that poses a serious public health threat.

Status: Under section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)), the Secretary of the Treasury is directed to destroy any product refused admission into the United States, unless it is exported within 90 days following such refusal. FDA and Customs have discussed procedures whereby, once FDA has determined that a shipment of imported food poses a significant risk to the public health or safety, rather than issue a Refusal of Admission, FDA will refer the shipment to Customs for seizure under 19 U.S.C. 1595a(c)(importation contrary to law). Following forfeiture procedures, the product will be destroyed. These procedures would be consistent with seizure actions normally taken by the FDA against domestic food products that pose a serious risk to public health.

Under Customs' forfeiture provisions, the government is responsible for storage and destruction costs. Preliminary estimates are that approximately 1,500 destructions will occur annually and that the government's cost will range from 1.5 to 3 million dollars. This procedure will impact Customs resources as funds have not been specifically appropriated for destruction of seized foods.

Plan: This plan will use existing Customs seizure and forfeiture authority and procedures. FDA will identify criteria for determining which health and safety violations are sufficiently serious to require destruction of the imported food using FDA's Class I Recall criteria as a basis. Also, FDA will develop guidance for its field personnel on submission of recommendations to FDA headquarters for Customs seizure/forfeiture/destruction actions. Customs will develop guidance for its field personnel to expedite processing of FDA seizure/forfeiture/destruction requests.

Timeframe:

October - December 1999

a. FDA will develop criteria for identifying which health and safety violations are sufficiently significant to require destruction of the imported food

b. FDA will develop guidance for the field on submission of recommendations to FDA headquarters for Customs seizure/forfeiture actions

c. Customs will draft and issue field guidance

January - March 2000

Implementation of the program

3. Prohibit the re-importation of food that has been previously refused admission and has not been brought into compliance with U.S. laws and regulations, and require the marking of shipping containers and/or papers of imported food that is refused admission for safety reasons.

Status: FDA, in consultation with Customs, is drafting a proposed rule regarding the marking of refused food shipments. FDA is considering requiring an importer or consignee to affix a permanent mark to the outside container of the food product and to an invoice, bill of lading, or other shipping document accompanying the food. (If the mark cannot be affixed to an outside container, as in the case of bulk agricultural products, the proposed rule would consider only requiring the mark to be affixed to an invoice, bill of lading, or other shipping document accompanying the food.) Additionally, the proposed rule would consider requiring that the mark be affixed before the food product leaves the port where refusal occurred and be clear, conspicuous, and permanent. The mark would be similar to a mark used by USDA on imported meat and meat food products that are refused entry into the United States. The mark would facilitate the identification of previously refused food products.

FDA is also considering prohibiting importers and consignees from: 1) refusing to affix a mark on a refused food product; 2) importing or offering to import any food product that has been previously refused admission into the United States and marked as such unless it has been reconditioned to conform with U.S. law; and 3) altering, removing, tampering with, or concealing a refused mark. Failure to comply could result in seizure or other penalties, as appropriate.

Plan: FDA will finalize a proposed rule and publish it in the *Federal Register* for public comment. The agency will develop a plan to invite comment and discussion about marking refused food products as well as other initiatives discussed in this report. FDA has sufficient statutory authority to issue regulations in this area. Customs would verify the FDA export marking requirement. The additional budgetary need for Customs to enforce this new requirement is estimated to be 28 person-years.

Timeframe:

October 1999 - April 2000

a. FDA to complete drafting of the proposed rule and publish in the *Federal Register* for public comment
b. FDA will draft a guidance document for field implementation
c. Customs will draft a guidance document for field implementation

May 2000 - August 2000

a. FDA to evaluate comments submitted to the proposed rule
b. FDA to prepare a final rule

September - October 2000

a. FDA to publish final rule in the *Federal Register*
b. FDA will issue field guidance
c. Customs will issue field guidance

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.

Status: FDA is considering proposing a rule that would establish requirements for importers and other persons who use sample collection services and/or private laboratories to demonstrate compliance with FDA law, and would establish requirements and standards for the collection and analysis of samples. The proposal would consider requiring persons who use sample collection services and private laboratories to notify FDA of their intent to use a sample collection service or a private laboratory and to explain the reasons for the sample collection or laboratory analysis. The proposal would also consider provisions to ensure that samples are properly identified, collected, maintained, and analyzed. Additionally, the proposal would consider requiring laboratories analyzing samples to be accredited, to use validated or recognized methods to analyze samples, and to submit analytical packages directly to FDA. The proposed rule would be intended to help ensure the integrity and scientific validity of data and results submitted to FDA.

Plan: FDA has sufficient statutory authority to issue regulations in this area. FDA will finalize a proposed rule and publish it in the *Federal Register* for public comment. FDA will develop a plan to invite comment and discussion about sample collection and laboratory issues as well as other initiatives discussed in this report.

Timeframe:

October 1999 - April 2000

a. FDA to complete drafting of the proposed rule and publish in the *Federal Register* for public comment
b. FDA will draft guidance document for field implementation

May 2000 - August 2000

a. FDA to evaluate comments submitted to the proposed rule
b. FDA to prepare a final rule
c. Customs to draft guidance document for field implementation

September - October 2000

a. FDA will publish final rule in the *Federal Register*
b. FDA will issue field guidance
c. Customs will issue field guidance

5. Increase the amount of the bond posted for imported foods when necessary to deter premature and illegal entry into the United States.

Status: Current Customs regulations provide for the assessment of liquidated damages under an import bond equal to three times the entered value of the shipment of food when the importer defaults on the condition of the Customs bond concerning redelivery of the goods. The entered value, however, is generally the price paid by the importer for the merchandise (with certain minor adjustments) prior to shipment to the United States. If a shipment is refused admission by FDA and not redelivered to Customs, exported, or destroyed in accordance with law or regulation, liquidated damages are assessed for breach of the bond. The General Accounting Office (GAO) has reported that even liquidated damages of three times the entered value of the shipment may not deter the illegal sale of imported food because the value of the food on the domestic retail market (i.e., the domestic value) may be far greater than three times the entered value.

Responding to GAO's concern, on August 2, 1999, Customs published a proposed rule to increase the liquidated damages from three times the entered value to the full domestic value in cases where refused shipments are not redelivered, exported, or destroyed in accordance with law or regulation (64 Fed. Reg. 41851). Since the importer normally sells at the domestic value, the proposed rule would remove any possibility of monetary gain from the illegal importation and sale of refused food.

Plan: The comment period for this rule closed October 1, 1999. Customs will conduct an analysis of comments and subsequently draft a final rule for publication in the *Federal Register.*

Timeframe:

October-December 1999

Customs will analyze comments and draft a final rule

January-March 2000

Customs will publish the final rule in the *Federal Register*

6. Enhance enforcement against violations of United States laws related to the importation of foods, including through the imposition of civil monetary penalties.

Status: Customs has instituted aggressive enforcement programs under existing statutory authorities that allow for the imposition of monetary penalties. Under 19 U.S.C. 1592, Customs can penalize any person including any importer that enters or attempts to enter any food (including meats and poultry) by means of any material false statement, act or omission. Penalties can be issued in amounts up to the domestic value of merchandise so imported. Under 19 U.S.C. 1595a(b), Customs can assess penalties against any parties that attempt to import merchandise contrary to law. Penalties assessed under 1595a(b) are also in an amount equal to the domestic value of the merchandise. Customs is successfully using this latter statute against importers that, at the time of exportation of food that has been refused entry by FDA, attempt to substitute other merchandise in place of that which has been refused. In addition to the above, FDA and Customs have pursued, and will continue to pursue, joint criminal investigations and prosecutions, as appropriate.

***Plan*:** While this procedure is currently in operation at Customs, FDA is not always aware of the assessment of civil monetary penalties involving importers of foods. Customs will take steps to ensure that FDA is aware of the assessment of civil monetary penalties against violators involving unsafe food and that Customs is aware of any events for which civil monetary penalties are an appropriate regulatory action. FDA and Customs will take steps to ensure that USDA's Food Safety and Inspection Service is aware of any such regulatory actions that may include meats and poultry.

Timeframe:

October-January 2000

a. FDA will issue field guidance
b. Customs will issue field guidance
c. FDA and Customs will meet with FSIS to discuss appropriate procedures and field guidance

V. Outreach to Public and Trade

Many of the planned activities described in this report represent a significant change in operation of the FDA import program. FDA plans to conduct a series of public meetings to present and discuss these planned activities to both the trade and to the public. Customs will participate in the public meetings and will invite discussion of procedural changes. Where appropriate, the procedural changes will be posted on each agency's Internet website. The proposed and final rules will also be posted on the appropriate agency's Internet website.

VI. Conclusion

The development and implementation of the planned activity in the six areas specified by the President will increase the tools available to the FDA and Customs to protect American consumers from unsafe imported foods. FDA and Customs will use these tools to focus on problem importers. Many of the procedures described in this report will likely serve as a deterrent not only to problem importers but also to any others considering whether to sidestep U.S. laws to bring unsafe or contaminated food into the country.

FDA and Customs anticipate continuing efforts to work together, in cooperation with EPA, FSIS, APHIS, FAS, USTR and the President's Food Safety Council, to protect consumers from unsafe imported food. FDA and Customs also look forward to working with Congress on ways to enhance the agencies' efforts to further ensure the safety of the U.S. food supply.

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edited:ABCrawford:HF-40:9/28/99 to correct odd symbol typos.
[compared to fax copy from Customs ? one edit noted on p. 5 under last sentence of ?Plan? section ? that Customs asked for, but does not show up in Customs copy ? kept edit in ? ABC 9/28/99]
ABCrawford:HF-40:9/28/99: incorporated OCC edits per MEckel/CCopp
rename doc: G:\Wp\ANNEC\Import Food Safety\CLFNL921Treasrev.doc
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REVISED: Mayling: revised timeframes regarding rulemaking procedures to accommodate timeframes for economic impact evaluation and OMB review: 10/7/99
REVISED: J. Oliver, A. Borsetti, revised wording on timelines for (6) Civil Money penalties. 10/07/99
REVISED: A Borsetti incorporate M. Eckel, revised wording on (4) add "demonstrate compliance with FDA law". 10/08/99.
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Q&A for GAO Report on Imported Foods
May 11, 1998

Q: What are the GAO's major findings regarding imported foods?

A: The GAO affirmed the Clinton Administration's conclusions that greater attention should be paid to the safety of imported foods. In particular, the report states that "[i]n order to strengthen FDA's ability to ensure the safety of imported foods, GAO recommends that the Congress require food eligible for import to the United States, not just meat and poultry, be produced under equivalent food safety systems." The Administration submitted legislation to Congress earlier this year which addresses this concern. The major conclusion that FDA needs additional authority is consistent with the Administration's position about how to strengthen protection against unsafe foods imported into the United States.

Q: Are there some findings and recommendations in the GAO report that FDA disagrees with?

A: Only relatively minor points. For example, the report notes that each year FDA plans to conduct a certain number of import inspections yet falls short of those plans. The "workplan" is merely a way of targeting resources, not a mandatory exercise whose failure to carry out to the letter will result in a threat to the public health. FDA does not expect to carry out 100 percent of the plan, as emergencies arise that pull staff off of routine duties.

Q: The report also notes that some importers illegally distribute imported foods into U.S. commerce and that FDA does not have adequate deterrent power to prevent those imports. Does the Administration agree with GAO's recommendation that Congress give FDA civil money penalty authority for these violations?

A: Yes, FDA agrees with the recommendation that civil monetary penalties would be an effective tool.

Q: What does the Administration's legislation do?

A: This legislation gives FDA the authority to refuse imports of any food regulated by the FDA, including fruits and vegetables, from any country or facility that does not meet U.S. food safety requirements or otherwise achieve the level of protection required. The legislation also permits FDA to consider refusal of inspection as a factor in halting imports from a facility or country.

Q: Is Congress moving to enact the legislation that the Administration has submitted to give FDA greater authority over food imports?

A: No hearings have been scheduled, and this issue does not appear to be on the Congressional agenda for this year.

Q: Why did your Administration propose new legislation?

A: There have been dramatic changes in the produce department of the grocery store. Thirty years ago, most produce sections only had around a dozen items year round, increasing to as many as 50 in the summer. Today, the chances are that there are 400 or more items in the produce section and they are there all year round. Last year, 38 percent of the fruit and 12 percent of the vegetables Americans ate were imported.

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

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

Q: Are you saying that imported produce is unsafe?

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

Q: What steps is the Administration taking to improve food safety?

A: Last year we launched a new Presidential food safety initiative, and added more than $40 million to the FY '98 budget. With that money we started putting in place new science-based preventive systems to improve the safety of seafood, meat and poultry and began work on a new early warning system to help detect and respond to outbreaks of foodborne illness. This year, our budget seeks an even more substantial increase in resources, $101 million, to improve food safety. The resources will go to a variety of initiatives, including: giving FDA authority to prevent the import of produce from countries without safety precautions equivalent to our own; hiring FDA inspectors to improve the safety of our nation's fruits and vegetables, both domestic and imported; developing new ways for federal inspectors to detect food-borne illnesses in meat and poultry and determine the source of contamination; improving educational outreach on

A: Under current law, FDA already has authority to inspect establishments where food is prepared, packed, or held, which would include places where food is grown, such as domestic farms. While such inspections are infrequent, FDA has taken action against a U.S. farmer when a violation occurs. When FDA is involved in a food safety problem that is found to originate on a farm, the agency's focus generally is on identifying the source of the problem and removing the unsafe food from commerce.

Q. Doesn't this legislation impose trade barriers to food imports at a time when you are saying you want to lower them? Is this legislation consistent with free trade?

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

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

A: The new legislation would give the FDA the same kind of responsibility that the USDA already has for meat and poultry. The USDA system has worked well to ensure that unsafe meat and poultry, produced in foreign facilities which do not provide the same level of protection that is required in domestic facilities, will not be imported. The FDA should be able to run a similarly effective system that ensures food safety and prevents imports from any foreign country or facility that does not meet U.S. food safety requirements or otherwise achieve the level of protection required.

Imported Foods

Q&A for GAO Report on Imported Foods
May 11, 1998

Q: What are the GAO's major findings regarding imported foods?

A: The GAO affirmed the Clinton Administration's conclusions that greater attention should be paid to the safety of imported foods. In particular, the report states that "[i]n order to strengthen FDA's ability to ensure the safety of imported foods, GAO recommends that the Congress require food eligible for import to the United States, not just meat and poultry, be produced under equivalent food safety systems." The Administration submitted legislation to Congress earlier this year which addresses this concern. The major conclusion that FDA needs additional authority is consistent with the Administration's position about how to strengthen protection against unsafe foods imported into the United States.

Q: Are there some findings and recommendations in the GAO report that FDA disagrees with?

A: Only relatively minor points. For example, the report notes that each year FDA plans to conduct a certain number of import inspections yet falls short of those plans. The "workplan" is merely a way of targeting resources, not a mandatory exercise whose failure to carry out to the letter will result in a threat to the public health. FDA does not expect to carry out 100 percent of the plan, as emergencies arise that pull staff off of routine duties.

Q: The report also notes that some importers illegally distribute imported foods into U.S. commerce and that FDA does not have adequate deterrent power to prevent those imports. Does the Administration agree with GAO's recommendation that Congress give FDA civil money penalty authority for these violations?

A: Yes, FDA agrees with the recommendation that civil monetary penalties would be an effective tool.

Q: What does the Administration's legislation do?

A: This legislation gives FDA the authority to refuse imports of any food regulated by the FDA, including fruits and vegetables, from any country or facility that does not meet U.S. food safety requirements or otherwise achieve the level of protection required. The legislation also permits FDA to consider refusal of inspection as a factor in halting imports from a facility or country.

Q: Is Congress moving to enact the legislation that the Administration has submitted to give FDA greater authority over food imports?

A: No hearings have been scheduled, and this issue does not appear to be on the Congressional agenda for this year.

Q: Why did your Administration propose new legislation?

A: There have been dramatic changes in the produce department of the grocery store. Thirty years ago, most produce sections only had around a dozen items year round, increasing to as many as 50 in the summer. Today, the chances are that there are 400 or more items in the produce section and they are there all year round. Last year, 38 percent of the fruit and 12 percent of the vegetables Americans ate were imported.

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

Q: Are you saying that imported produce is unsafe?

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

Q: What steps is the Administration taking to improve food safety?

A: Last year we launched a new Presidential food safety initiative, and added more than $40 million to the FY '98 budget. With that money we started putting in place new science-based preventive systems to improve the safety of seafood, meat and poultry and began work on a new early warning system to help detect and respond to outbreaks of foodborne illness. This year, our budget seeks an even more substantial increase in resources, $101 million, to improve food safety. The resources will go to a variety of initiatives, including: giving FDA authority to prevent the import of produce from countries without safety precautions equivalent to our own; hiring FDA inspectors to improve the safety of our nation's fruits and vegetables, both domestic and imported; developing new ways for federal inspectors to detect food-borne illnesses in meat and poultry and determine the source of contamination; improving educational outreach on

proper food handling; and further expanding our early warning system and strengthening state surveillance activities for foodborne illnesses.

Questions on Food Safety Legislation

Q: What does the legislation do?

A: This legislation helps ensure that the FDA will refuse imports of any food regulated by the FDA, including fruits and vegetables, from any country or facility that does not meet U.S. food safety requirements or otherwise achieve the level of protection required. The legislation also permits FDA to consider refusal of inspection as a factor in halting imports from a facility or country.

Q: How is this different from current authority?

A: This legislation increases the FDA's authority to refuse imports for foods from countries or facilities that do not meet U.S. food safety requirements or otherwise achieve the level of protection required. Currently, the FDA can only refuse imports after inspection or testing at the border when the FDA determines that the food appears to be unsafe or otherwise violates U.S. law. This new legislation will enable the FDA to ensure that food products entering this country were grown and processed in conditions that meet U.S. food safety requirements or otherwise achieve the level of protection required. This authority is necessary because experience has shown that inspection and testing of products at the border may not be sufficient in all cases to ensure the safety of food products. It may be necessary to identify and address the source of potential contamination to ensure that products offered for sale in the United States meet domestic food safety requirements or otherwise achieve the level of protection required. FDA currently has such authority with respect to domestic production.

Q: Does this legislation give FDA additional authority to inspect in other countries?

A: No. Foreign inspections will continue to be done by consent. In making the determination that a food offered for import into the U.S. is adulterated, the legislation does permit the Secretary to consider whether FDA has been refused access to conduct inspection of the places where such food has been prepared, packed or held. The Secretary may deny importation to foods from such location or establishment on the basis of such refusal and other relevant factors. Because denying reasonable access is one factor in making that determination, the exporting country and the food establishment both have a strong incentive to allow such access.

Q: There is concern that this legislation is the first step in providing FDA with the authority to inspect farms in the U.S. Is that next?

A: Under current law, FDA already has authority to inspect establishments where food is prepared, packed, or held, which would include places where food is grown, such as domestic farms. While such inspections are infrequent, FDA has taken action against a U.S. farmer when a violation occurs. When FDA is involved in a food safety problem that is found to originate on a farm, the agency's focus generally is on identifying the source of the problem and removing the unsafe food from commerce.

Q. **Doesn't this legislation impose trade barriers to food imports at a time when you are saying you want to lower them? Is this legislation consistent with free trade?**

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

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

A: The new legislation would give the FDA the same kind of responsibility that the USDA already has for meat and poultry. The USDA system has worked well to ensure that unsafe meat and poultry, produced in foreign facilities which do not provide the same level of protection that is required in domestic facilities, will not be imported. The FDA should be able to run a similarly effective system that ensures food safety and prevents imports from any foreign country or facility that does not meet U.S. food safety requirements or otherwise achieve the level of protection required.

106TH CONGRESS
1ST SESSION

S. _____

IN THE SENATE OF THE UNITED STATES

_____ introduced the following bill; which was read twice and referred to the Committee on _____

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".

gina_Tesano@
OVP.EOP.gov

TITLE I—IMPROVEMENTS TO THE FOOD SAFETY IMPORT SYSTEM

SEC. 101. [EQUIVALENCE] AUTHORITY TO PROTECT THE PUBLIC HEALTH FROM CONTAMINATED IMPORTED FOODS.

(a) AGREEMENTS.—Section 803 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 383) is amended by adding at the end the following:

"(d)(1) The Secretary shall, in consultation with the United States Trade Representative, enter into, where appropriate, [agreements] relating to the importation of food.

"(2) In this subsection, the term 'agreement' means a bilateral, regional, or multilateral agreement on recognition of specified sanitary or phytosanitary measures, systems, or conditions, that provide the level of protection that is required for food prepared (including produced), packed, and held in the United States.".

(b) GENERAL AUTHORITY.—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)(A) The Secretary may 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 makes and publishes—

"(i) a written determination that the food—

"(I) has been associated with repeated and separate events 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 serious 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 event 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 transporter; 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, transporter, 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 [and other] 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;

"(ii) an agreement described in section 803(d) is implemented that addresses the written determination made under paragraph (1); or

"(iii) evidence of remedial action submitted from the producer, manufacturer, transporter, 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)(iii) 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, transporter, specific growing area, or country.

"(iii) If the Secretary does not take action on evidence submitted under subparagraph (A)(iii) 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), based on the criteria and procedures set forth in the Food and Drug Administration's August 1995 Regulatory Procedures Manual regarding import procedures.

The Secretary may by regulation modify those criteria and procedures, as the Secretary determines appropriate.

"(e)(1)(A) The Secretary shall require that a food offered for import into the United States has been prepared (including produced), packed, and held under a system or conditions, or subject to measures, that meet the requirements of this Act or that otherwise achieve the level of protection required for such food prepared, packed, and held in the United States. In determining whether the food meets the requirements of this subparagraph, the Secretary shall consider whether an agreement described in section 803(d) is implemented that relates to the food.

"(B) The Secretary of the Treasury shall deny entry to food that the Secretary of Health and Human Services determines does not meet the requirements of subparagraph (A).

"(2) In carrying out this subsection, the Secretary of Health and Human Services 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. In developing the plan, the Secretary shall provide an opportunity for, and take into consideration, public comment on a proposed plan.".

(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(f)(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), subsection (d)(1)(A) (in the case of a food described in that subsection), or subsection (e)(1)(A) (in the case of a food that fails to meet the requirements of that section)";

(B) in paragraph (3)(A) of subsection (e), as redesignated in subsection (b), by striking

"section 801(e) or 802" and inserting "subsection (g), section 802,"; and

(C) in paragraph (1) of subsection (g), as redesignated in subsection (b), 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 poses a strong likelihood of causing serious 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 poses a strong likelihood of causing serious 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(b), 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 "DEBARMENT FOR VIOLATIONS RELATING TO DRUGS.—";

(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 debarring 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 development 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, tech-

nologies, 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 Preven-

tion 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.".

Imported Food - CAD sent

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COMMENTS:

United States General Accounting Office

GAO

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

Draft Report

April 1998

FOOD SAFETY

Federal Efforts To Ensure Safety of Imported Foods Are Inconsistent And Unreliable

Themes
- overall agree
- Take issue w/ Results in Brief
- workplan
- Correct inaccuracies

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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 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 federal programs' efforts to ensure the safety of food imports. Specifically, this report discusses (1) 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 food.

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]

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

up to 81 million cases of foodborne illnesses and as many as 9,100 deaths each year result in costs for medical treatment and productivity losses ranging from $6.6 billion to $37.1 billion. Recent outbreaks of foodborne illnesses demonstrate that imported foods have introduced new risks or intensified with familiar illnesses. The increased consumption of imported foods in the United States heightens the risks of illness.

The Food Safety and Inspection Service and the FDA have the primary responsibility for ensuring the safety of imported foods. The Food Safety and Inspection Service has jurisdiction over meat, poultry, and some egg products, while FDA regulates all other foods. The Inspection Service and FDA work closely with the Customs Service and the Centers for Disease Control and Prevention. The Customs Service refers imported foods to the Inspection Service or FDA for their approval before releasing the shipment into U.S. commerce. The Centers for Disease Control and Prevention monitors the incidence of foodborne illness and works with the Food Safety and Inspection Service and FDA to investigate outbreaks of illnesses and conduct research on foodborne diseases.

RESULTS IN BRIEF

Federal agencies cannot ensure that the growing amount of imported foods are safe for consumers. Although the Food Safety and Inspection Service and FDA require imported foods to meet the same standards as domestic foods, their approaches to enforcing these requirements differ. By law, the Inspection Service places the principal burden of 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. FDA, 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 solely 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 proper conditions and (2) FDA currently inspects less than 2 percent of all foreign shipments.

The Inspection Service and FDA are not deploying their inspection resources to maximum advantage. The 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, 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 Inspection Service focus more closely on the imports posing the greater risks. FDA's annual workplan does not set clear or achievable priorities for conducting inspections. For example, in fiscal year 1997, FDA only conducted half of the planned imported food inspections in its workplan because other activities, such as investigations of emergencies and consumer complaints took priority. Furthermore, FDA does not make health risk data readily available to guide inspectors' selections. In addition, when making decisions on which shipments to inspect, FDA relies on importers' descriptions of shipment contents, which are often incorrect. As a result, resources may not be focused on imported foods posing the greatest safety risk.

FDA's procedures for ensuring that unsafe imported foods do not reach U.S. consumers are vulnerable to abuse by unscrupulous importers. For example, FDA automatically detains shipments when the exporting firm has a history of violations. However, FDA allows importers to select the laboratories that perform sampling and analysis that it accepts as proof of safety. For other shipments, importers retain control of the goods while FDA decides whether to inspect the shipment or while tests are being conducted on it. In some cases, when FDA decides to inspect a shipment,

the importers have already marketed the goods. In other cases, when FDA finds contamination and calls for importers to return shipments to the Customs Service for destruction or reexport, importers ignore this requirement or are found to have substituted other goods for the original shipment. Such cases of noncompliance seldom result in a significant penalty.

PRINCIPAL FINDINGS

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

The Inspection Service has the statutory authority to require the exporters of meat and poultry products to have food safety systems equivalent to systems in the United States. In enforcing this requirement, the Inspection Service 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. (See app. II for list of the eligible countries.) FDA's authority, on the other hand, requires imported foods to meet U.S. standards, but 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 equivalency authority for FDA.

The Inspection Service has used equivalency authority to shift the primary responsibility for food safety to the exporting country. 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 port inspections. 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 has been widely discredited by the United Nations Food and Agriculture Organization, an FDA Advisory Committee, and

GAO as an effective protective measure because, among other things, individual products tested at the 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 agencies use computer systems to screen each import shipment and to help identify the import shipments requiring inspector action, neither agency has designed its system to take the best advantage of available data so that they can target those imported foods posing the greater health risks. The Inspection Service relies primarily on the violation history of previous shipments from the exporting firm to target entries for inspector action, which may not always indicate the shipments more likely to pose health threats. For example, many violations, such as incorrect shipping labels, do not directly affect consumer safety. However, information is available on the relative health risks of specific types of imported foods, such as ground or deboned beef.

FDA's system for selecting imports for examination relies primarily on inspectors' judgment and FDA guidance and information to aid their decisions are often not useful. FDA's annual workplans which identify, among other things, the number of imported food inspections and tests each district is expected to conduct are supposed to guide inspectors' judgment, but the workplans are unrealistic because they do not set aside time for investigating emergencies and consumer complaints. Because the workplan activities are generally not attainable, inspectors said they are not useful

when making inspection and testing decisions. 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 greatest 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. FDA retrospectively verifies a sample of the importer-provided information, but although it frequently identifies errors it takes no corrective action when it discovers errors. Thus FDA has no assurance that importers are accurately describing their goods and that FDA is identifying shipments that should be scrutinized.

Weaknesses in Import Controls Allow
Entry of Unsafe Products

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

In particular, FDA does not maintain effective control over products it has automatically detained 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 private laboratory test results to show that the shipment meets U.S. safety standards. However, the agency does not have guidelines to control the selection of the samples tested by the private laboratories or to 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 share shipments that have been tested as safe, substituting them for samples of other shipments.

Unlike the Inspection Service, which controls the storage of imported foods after they are presented for inspection until their release into U.S. domestic markets, FDA usually allows importers to retain possession of their shipments until FDA and the Customs Service 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 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 actual imported products. In other instances, importers substituted other products for destruction, rather than the actual imported products, when the tested products failed laboratory tests. In each situation, FDA inspectors believe the original imported food was sold in U.S. markets and presumably consumed. A joint Customs-FDA operation to test controls over foods at one port found that evasion was common.

Evasion probably occurs because it is seldom effectively punished. While FDA and the Customs Service rely on the bonds presented by the importer as the principal deterrent against noncompliance with laws, Customs' collection of damages against violators by Customs is uneven and uncertain. For example, at one port, the Customs Service collected about 2 percent of the damages originally assessed in 24 cases in 1997. In previous reports, 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. 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 food 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, Department of Health and Human Services and the Secretary, Department of Agriculture to improve the effectiveness and efficiency of their import review systems and procedures by targeting inspection resources at foods posing greater health risks.

AGENCY COMMENTS

- DRAFT -

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Abbreviations

AIIS	Automated Import Information System
CDC	Centers for Disease Control and Prevention
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
FFDCA	Federal Food, Drug, and Cosmetics Act
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

CHAPTER 1

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 9,100 deaths are estimated to occur each year. 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. In 1996, the estimated annual cost of medical treatments and productivity losses associated with these illnesses range 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 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 difficulty in ensuring that they are safe, adds to the risk of foodborne illnesses.

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[2]Federal and state agencies began steps 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 that 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.

As demonstrated 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.

Table 1.1 Import Share of Selected Foods Consumed in the United States, 1980-1995

Import Item	Percentage of Total U.S. Consumption Provided by Imports				Percent Change, 1980-1995
	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: United States 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. Also, imported foods may 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 illnesses 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 primary responsibility for ensuring the safety of imported foods. The Food Safety and Inspection Service (FSIS) in the U.S. Department of Agriculture has responsibility for meat, poultry, and some egg products. The Food and Drug Administration in the Department of Health and Human Services (HHS) has responsibility 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 (FFDCA), as amended, FDA works to ensure that domestic and imported food products are safe, wholesome, and properly labeled.[3] In 1997, FDA spent approximately 463 staff years, at a cost of

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

approximately $35.1 million, to ensure the safety of about 4.2 million import shipments.

To assist these agencies, the U.S. Customs Service 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. The U.S. Customs Service is the first federal agency to screen imported products, including food imports, when they enter the United States. Among duties enforcing laws for over 40 federal agencies, Customs is responsible for collecting revenues and enforcing various customs and related laws. Customs cooperates with FDA and FSIS in carrying out their regulatory role in food safety.

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

Since 1992, we have frequently reported on the fragmented and inconsistent structure of food safety responsibilities in the federal government.[4] These reviews have shown that inconsistencies and differences between the agencies' approaches and

[4]Food Safety and Quality: Uniform, Risk-Based Inspection System Needed to Ensure Safe Food Supply (GAO/RCED-92-152, June 26, 1992); Food Safety: A Unified, Risk-Based System Needed to Enhance Food Safety (GAO/T-RCED-94-71, November 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, September 26, 1994); and Food Safety: Fundamental Changes Needed to Improve Food Safety (GAO/RCED-97-249R, September 9, 1997)

enforcement authorities undercut overall efforts to ensure a safe food supply. To address this problem, we recommended formation of a single food agency. In the fiscal year 1998 USDA appropriation act, the Congress provided $420,000 for a study by the National Academy of Sciences on the need for reorganization of the federal food safety system.

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 food products under its jurisdiction that are imported into the United States, an importer must file an import notice along with certain shipping information and, for shipments valued over $1250, file a bond to cover the goods for release with the Customs Service within 5 days of the shipment's U.S. port-of-entry arrival date. The import documents or electronic entry data identify the type of food product, importer, foreign manufacturer, and country of origin, as well shipping information. 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 the products. If a importer fails to make an import shipment available for FDA inspection or fails to recondition, 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 will be inspected or tested or can be released into U.S. commerce. Among them are the following:

-- FDA's annual workplan establishes, among other activities, the number of inspections and tests that each FDA district is to conduct. The fiscal year 1997 workplan set inspection and testing activities for 23 food programs, such as imported low acid/acidified canned foods and imported seafoods,[5] in 4 major food safety related projects areas--Foodborne Biological Hazards; Pesticide and Chemical Contaminants; Molecular Biology and Natural Toxins; and Food and Color Additives.[6]

-- FDA's Import Alert Retrieval System database which lists products that FDA automatically detains because the exporter or the specific food products have shown a history of violations in previous shipments. FDA will not approve the release into U.S. commerce of these automatically detained shipments until the importer provides a private laboratory analysis showing that the product meets U.S. standards. FDA disseminates information on automatic detentions to district offices through Import Alerts which identify problem commodities and/or exporters, foreign firms, country of origin, the reasons for detention, and the food safety risk.

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

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

-- FDA's Low Acid Canned Food database which contains information on foreign processors of low-acid and acidified canned foods registered with FDA. Foreign processors wishing to export these foods into the United States must submit descriptions of their canning processes to FDA before it will issue a registration number for the firm and approve 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, the Customs Service 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 need further review. FDA sets the screening rates using several sources of information, such as annual workplans, 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. Shipments, such as some seafood and low acid canned foods, are less frequently released automatically because they pose greater risks.

Customs forwards information on products that are not automatically released to FDA for further review, through FDA's automated screening system, known as Operational and Administrative System for Import Support (OASIS). This system

was pilot tested in 1992 and installed at all FDA's district offices by October 1997.[7] (Before OASIS was developed, FDA manually tracked shipments through entry documents submitted by importers to the U.S. Customs Service.) 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 inspects or conducts laboratory analyses on a small percent of all types of imported food shipments--currently less than 2 percent--annually. Inspections may occur at ports-of-entry and at warehouses or other business establishments. If FDA decides to test the imported food shipment, a 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 is refused entry into U.S. commerce. Importers generally have three options for handling refused entry shipments. If FDA concurs, importers can recondition the shipment, destroy the shipment, or re-export the shipment. Whatever option the importer chooses,

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

Customs Service 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 the product has already passed inspection by the exporting countries' equivalent inspection system.

Importers of FSIS-regulated products, like importers of FDA-regulated products, must file an import notice and file a bond with the Customs Service within 5 days of the date of arrival of a shipment 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 they are released into the domestic market or refused entry.

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 information in its memory 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 plant 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 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, bone fragments, misidentified products, and 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.[8] 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 Committee on Governmental Affairs, asked us to review how well federal programs are ensuring the safety of imported foods. Specifically, this report discusses (1) differences in the agencies' authorities and approaches for ensuring the safety of imported foods and (2) how they target their resources. In addition, the report discusses weaknesses in controls over food imports.

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

Our work focused on the two principal federal agencies with responsibility for ensuring the safety of imported food--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 the U.S. Department of Agriculture to determine the current level of food imports into the United States, the share of imported foods in the U.S. diet, and 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 imported food safety, 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 agency documents describing their import review procedures and the use of automated import screening systems. 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 the states of California, Florida, New York, New Jersey, Texas, and Washington. We visited three FDA laboratories to discuss and observe analysis procedures. We met with Customs officials in Laredo, Texas; Los Angeles; Miami;

Port Elizabeth, New Jersey; San Francisco; and Seattle; 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 provide by importers 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 March 1998 in accordance with generally accepted government auditing standards.

CHAPTER 2

FDA'S LACK OF AUTHORITY FOR EQUIVALENT FOOD SAFETY INSPECTION SYSTEMS IN EXPORTING COUNTRIES DIMINISHES ITS ABILITY TO PROTECT CONSUMERS FROM UNSAFE FOODS

FSIS shares the burden of ensuring the safety of 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 imported foods under 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 fruits, vegetables, and other foods for which it is responsible. Lacking 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 covers are safe.

FSIS REQUIRES EQUIVALENT FOOD SAFETY SYSTEMS IN EXPORTING COUNTRIES, BUT FDA LACKS SIMILAR AUTHORITY

Federal laws covering meat and poultry imports require that the products shipped to the United States meet U.S. standards for safety, 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, backed up with administrative and technical support, and implementing inspection, sanitation, quality, microbiological, and residues standards equivalent to those applied to products produced in the United States.

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 with each exported item attesting to the safety of the product, 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 planned visits to every eligible exporting country 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 records to verify program 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.[9] Products from countries not on the list of eligible countries are automatically refused entry.

FDA does not have similar authority to only accept foods from countries with equivalent safety inspection systems. The Federal Food, Drug and Cosmetic 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. inspection 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 requires foreign exporting firms to grant FDA inspectors access to their plants, but actually conducts few foreign plant inspections. In fiscal year 1996, it planned 90 such inspections but only carried out 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,

[9]Since January 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 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.

domestic and foreign, to use new HACCP procedures. However, FDA 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, FDA said 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 preparing 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, the administration introduced a food safety initiative seeking new FDA authority to require equivalency in food safety systems. The initiative required FDA to develop a plan and propose legislative authority 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 is under consideration.[10] The legislation would allow FDA to determine that an imported food is adulterated (and thus not allowed for import) 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.

EQUIVALENCY AUTHORITY ALLOWS FOR MORE EFFECTIVE USE OF RESOURCES TO ENSURE SAFETY OF IMPORTED FOODS

FSIS uses its equivalency authority to shift primary food safety responsibilities 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 assure imported foods are safe. While this approach verifies the safety of the few shipments actually inspected it 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.

Equivalency Enables FSIS To Leverage Its Resources By Sharing Responsibility With The Exporting Countries

[10]H.R. 3052, the "Safety of Imported Food Act of 1997," was introduced in the House of Representatives on November 13, 1997. No action had been taken as of March 1, 1998.

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 to determine the presence of accurate shipping labels, and (3) conduct extensive 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 Provides 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 United States are safe. According to the Food and Agriculture Organization of the United Nations (FAO), 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 periodically inspected and verified by a regulatory authority.

Similarly, a 1991 report by the Advisory Committee on the FDA, called point-of-entry inspections an anachronism.[11] The process of inspecting a final product to determine if it conforms to standards and rejecting those that do not has been "totally discredited" as a means of assuring 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 imported foods are not contaminated with unsafe levels of chemicals.[12] 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 food 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 equivalency authority.

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

[12]FOOD SAFETY: Changes Needed to Minimize Unsafe Chemicals in Food, (GAO/RCED-94-192, September 26, 1994)

The capabilities of FDA's inspection approach to protect consumers from unsafe products has been further called into question by its 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 in 1992 to 257 staff years 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 level of 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 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 Review During 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 of food entries that required FDA 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 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 assure 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 food is 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 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.

CHAPTER 3

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 focusing on violations directly related to food safety, such as contamination and decomposition. As a result, resources are not being focused on imported foods posing the greatest safety risk.

With respect to FDA, its system for identifying shipments for inspection is hampered by workplans 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 cannot be assured that its limited resources are consistently targeting shipments posing the greatest 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,

except for transportation damage, equally in determining how much inspection attention will be provided to an importing firm's products. As a result, violations not 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, more than 97 percent of all the violations identified were not directly related to health risk problems. 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 are found to be in compliance. When limited resources are targeted in this fashion, fewer resources are available for products posing the greatest health risk.

FSIS has the test results associated with previous inspections of imported foods--data that would help identify shipments with the highest health risks--in the 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. If FSIS developed information on patterns of violations, it could determine whether Salmonella contamination, for example, was a recurrent problem in a particular country or exported product and could 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, the number of inspections and

tests established for each FDA district in the annual workplan are 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 to choose shipments that are likely to pose health risks. Third, FDA does not act to ensure that importer-provided information, which its screening system relies on to identify what the shipments contain, 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 Inspection Workplans Are Not Useful to Inspectors in Making Selection Decisions

FDA's annual workplan sets the number of activities, such as the number of inspection and tests, each FDA district is to conduct for 23 specific food programs, such as imported seafood, imported low acid canned food, or imported cheese, under the four major food safety related project areas--Foodborne Biological Hazards, Pesticides and Chemical Contaminants, Molecular Biology and Natural Toxins, and Food Color and Additives. FDA inspectors attempt to use the number of inspections and tests contained in the workplans and compliance programs over the course of the year when determining which imported food shipments to select for inspections and tests. For example, for FDA's Seattle District, the fiscal year 1997 workplan called for 165 inspections and 583 laboratory tests of imported seafood products. For imported seafood products nationwide, the workplan called for 2,500 inspections and 9,432 laboratory tests.

Each day FDA inspectors must decide which shipments of food imports to select for inspection. The inspectors typically attempt to select shipments using the workplans

as the basis for their decisions. However, FDA regional and district officials told us that the number of inspections and tests contained in the workplans and compliance programs were not realistic because they do 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. As a result, FDA inspectors are not able to meet the workplan and compliance program activities and therefore rely on their judgment when determining what to inspect and test.

Meeting the annual workplans is a problem nationwide. Table 3.1 shows the degree to which FDA inspectors fell short of planned inspections and tests for fiscal years 1996 and 1997 in the four food projects 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 Accomplished FDA Import Inspection Activities, Fiscal Years 1996 and 1997

Inspection Activities[a]	Fiscal Year 1996			Fiscal Year 1997		
	Planned	Accomplished	Percent Accomplished	Planned	Accomplished	Percent Accomplished
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 Chemical Contaminants Project						
-- Import Samples Analyzed	8,794	6,228	71	8,294	5,675	68
Molecular Biology and Natural Toxins Project						
-- Import Samples Analyzed	555	386	70	1,380	564	41
Food and Color Additives Project						
- Import Samples Analyzed	2,395	1,816	76	2,353	1,816	77

[a]A fifth food project 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 and can be affected by personal perspectives. For example, one inspector told us he believed one country did not have sanitary and clean product 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, sometimes did not conduct the tests because it already had a backlog of tests to conduct. As a result, to the extent 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 the OASIS system, the system used to screen imports, thus inspectors do not have the results of prior laboratory tests available in 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 making their decisions on 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 that 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 shut down OASIS and open up 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 make decisions to select samples on the basis of incomplete information.

FDA has recognized the problems associated with difficulties in obtaining health risk data. FDA's Director of the New York District Office stated in a 1993 hearing on food imports that FDA tries to funnel its inspection resources towards the imports that pose the greatest risk and have the greatest likelihood of being adulterated or misbranded.[13] He added that including information, such as the data discussed above, in OASIS--its automated screening system--would be a very useful tool to help FDA inspectors make decisions on what import shipments to inspect and test. In a 1995 internal review, however, FDA's automated system was criticized for not providing inspectors with a means for accessing other FDA databases, such as the FDA Import Alert Retrieval System database.[14] 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

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

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

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 entry of imported foods under its jurisdiction, importers electronically enter data 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, which it then compares against the electronically provided information. Errors can include incorrectly identifying a product as exempt from FDA 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 for even the most error-prone paperless filers. According to a January 1998 FDA survey, 306, or 14.5 percent, of the 2,114 paperless filers audited had errors rates of 10 percent or greater, but none of these filers were removed from paperless status. For example, the New York District paperless filer error rates 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 Resident Post 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 corrective actions or 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. We observed in one case, for example, that an importer incorrectly entered the code for spaghetti, a form of pasta, instead of cappelletti, another form of pasta.

The failure to take corrective actions or followup on high error rates, as found in the January 1998 FDA survey, could affect decisions on selections concerned with food safety risks. Importers aware of FDA's inaction could evade FDA 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 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 a FDA investigation in 1993, an importer was prosecuted for deliberately misrepresenting imported foods. The importer was found guilty on 138 counts, mostly by misrepresenting the source of seafood, in an attempt to avoid automatic detention by FDA.

FDA inspectors told us that when they encounter incorrect entry errors during evaluations, they inform the importer of the errors and offer help on entering correct information about import shipments. 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 further the suspect filers. 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 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 safety-related. In addition, FDA's limited inspection resources may not be targeted to the riskiest shipments. Unrealistic annual workplans impede 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 shipment contents may be misrepresented.

RECOMMENDATIONS

To help FSIS better identify the risks associated with specific foods and thereby make the Automated Import Information System more useful 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.

DRAFT

To provide more accurate and accessible information to FDA and inconsistencies in inspectors' subjective decisions, we recommend 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;
- modify the Operational and Administrative System for Import Support syst so that (1) it automatically reviews the Import Alert and low acid canned f databases and recommends appropriate actions to inspectors and (2) inspec can consider previous laboratory test results, which are stored in the Laboratory Management System database, in choosing shipments for inspections and tests.
- ensure that district offices are taking appropriate corrective action, when warranted, against importers that repeatedly enter incorrect shipping information into Operational and Administrative System for Import Suppo

CHAPTER 4

WEAKNESSES IN CONTROLS OVER FOOD IMPORTS ENABLE ENTRY OF UNSAFE PRODUCTS

In addition to the problems associated with its automated system for selecting which food shipments to inspect, we observed several weaknesses in FDA's controls over imported products that have enabled some importers or their representatives to sell unsafe foods in U.S. commerce. 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 generally accepting the test results from any laboratory, even an importer's own in-house laboratory, 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 store shelves 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. Importers who violate FDA and Customs controls are frequently not penalized to deter such actions.

SOME IMPORTERS DISTRIBUTE 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 about 10 importers who repeatedly distributed pesticide-adulterated shipments in disregard of FDA orders; in total they distributed 73 shipments known to have been

adulterated.[15] In all, about a third of the adulterated shipments that were identified reached market.

A 1997 investigation by the Customs Service 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, for 70 percent of the shipments ordered returned, the unsafe products presumably entered into commerce in disregard of FDA 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.

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 or restrict the choice of the laboratories used to conduct the tests. Instead, FDA allows

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

importers to choose the laboratory, which selects the sample and conducts the analysis. FDA generally recognizes the results from any private, independent laboratory, even the firm's own in-house laboratory. This approach exposes FDA to the possibility that it will accept falsified test results as a basis for releasing products into domestic commerce.

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

Customs Service 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 Service 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 Customs inspectors called "banking".

FDA inspectors also voiced concerns over uncontrolled sampling and testing of imported foods under FDA 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 the analysis of imported foods normally tested by FDA laboratories. For example, according to FDA's Procedures Manual, increased scrutiny of import commodities and

limitations on FDA resources are likely; therefore, enforcement efforts will be expedited by the use of 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 import review process. 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 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 historically FDA test results differed 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.[16]

FDA AND CUSTOMS MAINTAIN INSUFFICIENT CONTROLS OVER KNOWN AND POTENTIALLY UNSAFE PRODUCTS

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

Imported foods under FDA's jurisdiction, including foods of concern or proven to be adulterated, are sold in domestic commerce before FDA has released them. This occurs because (1) importers 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) FDA and Customs have not effectively penalized these importers to deter such actions.

Imported Foods Not Controlled Prior to Release

FDA regulated foods are not controlled prior to inspection and release. Under the FFDCA, 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 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. Importers of FDA-regulated foods that are refused entry have 90 days to (1) recondition the products (such as relabeling products to bring them into compliance with requirements), (2) destroy the products, or (3) 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 statutory authority.

At the ports we visited, imported food shipments under FDA's jurisdiction often entered U.S. commerce before delivery to FDA for inspection or were not properly disposed of when refused entry. For example, in operation Bad Apple, Customs

Service officials identified 23 weaknesses in the control over FDA regulated imported foods. In this on-going operation, Customs officials cited the following examples to illustrate these weaknesses.

- One weakness involved substituting cargo that was enroute 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 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.

- Another weakness involved a case where an importer did not meet FDA's request that the shipment be redelivered to Customs for disposition after FDA found the shipment was unsafe and did not meet U.S. standards. According to Customs, about 40 percent of the imported foods on FDA conditional release that were found to violate U.S. standards during this operation were never redelivered to Customs (i.e., they presumably entered into commerce, not destroyed or reexported as required). We found similar results, in 1992, when we reported that 60 percent of perishable foods and 38 percent of nonperishable foods that FDA found adulterated with illegal pesticides were released into U.S. markets and not returned to the Customs Service for destruction or reexport.[17] 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.

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

Based on our work the evasion of imported food controls appears not to be isolated to a few importers at one port-of-entry. As part of this 3-week operation at the San Francisco port-of-entry in 1997, Customs officials monitored cargo transferred from the vessel to the holding area, FDA sampled and tested (or an FDA-selected laboratory tested) the products, and no conditional releases were given. 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 they have ongoing investigations at other ports regarding substitution of imported products or failure to redeliver products for inspection.

Some Customs officials said they lack the resources needed to witness and thus ensure proper disposition of violative products refused entry. Accordingly, they generally just make a container for container verification--e.g., 3 containers were refused entry and 3 containers were reexported. Similarly, in accordance with Customs regulations, they frequently do not witness actual destruction of violative product and instead rely on the landfill disposal receipt. As such, Customs officials told us they often do not open and inspect the contents of containers being reexported or destroyed to verify they actually contained the violative products that were refused entry.

Penalties Do Not Effectively Deter Illegal Distribution of Imported Foods

In addition to difficulties in controlling imported foods prior to releasing them into domestic commerce, FDA relies on an inadequate economic deterrent to noncompliance with its requirements. Lacking authority to fine importers who

distribute adulterated food shipments or fail to retain shipments for inspection, FDA relies on a bond agreement between the Customs Service and the importer, for those shipments valued more than $1,250, as a way to compel 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 illegal sale of imported goods because the value of the goods on the market is greater than the tripled bond amount.[18] Furthermore, even a tripled bond amount may not deter the illegal sale of imported goods because the collection of damages has been limited.

Customs often does not collect full damages from importers who fail to comply with FDA requirements. For example, in fiscal year 1997 the Customs Service in Miami assessed and collected damages for about only 25 percent of the identified cases involving improper distribution of food products for the previous 12-month period. Customs and FDA attributed the low figure to lax controls in communicating refused entries between Customs and FDA, unclear guidance for handling the entries by Customs officials, and nationwide malfunction of the Customs computer system for storing case files. Even when damages were assessed, Customs on average reduced the damages collected to about two percent of the original assessment. For example, in one case where the liquidated damages were $100,000, based on the declared value of the import shipment, the Customs Service reduced the amount to $100. Customs

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

officials told us any reduction in liquidated damages would have been with Customs guidelines.

FDA's lack of civil penalty authority, and its reliance on the importer's bond agreement with the Customs Service, has left it without an adequate economic deterrent to the distribution of adulterated imports for a long time. 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.[19] While FDA submitted legislative proposals to grant them civil penalty authority in 1993, Congress did not pass the legislation.

CONCLUSIONS

FDA's lack of control over shipments selected for inspection leaves the system vulnerable to unscrupulous practices. 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. Further, importers' 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.

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

grocery shelves, and it appears likely that certain importers will continue to circumvent controls over unsafe food products with impunity.

We are making no recommendations at this time. 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 controls over imported foods.

APPENDIX I

SELECTED OUTBREAKS OF FOODBORNE ILLNESSES LINKED TO IMPORTED FOODS, 1983-1997

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, its 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 a formerly unrecognized food pathogen, Cyclospora. CDC and other public health officials were able to link illnesses from cyclospora affecting more than 1,000 people in various locations of the United States and Canada with raspberries from Guatemala. In 1997, additional illnesses from cyclospora, affecting more than 1,000 people, were also linked with raspberries from Guatemala. CDC is not able to identify all cases of foodborne illness, however, because such illnesses are underreported and they are difficult to trace to their source.

Table I.1 Information on Selected Outbreaks of Foodborne Illness, 1983 to 1997

Year of Outbreak	Number of Illnesses	Pathogen	Source		Location
			Contaminated Food	Country of Origin	
1997	1,012	Cyclospora	Raspberries	Guatemala	17 states; Washington, DC; and Canada
1997	270	Hepatitis A	Frozen strawberries	Mexico (Implicated)	5 states
1996	9 14	Salmonella typhi, Hepatitis A	Homemade cheese	Mexico	Florida
1996	1,465	Cyclospora	Raspberries	Guatemala	20 states; Washington, DC; and Canada
1995	242	Salmonella Stanley	Alfalfa sprouts	Seeds from Netherlands	17 U.S. states and Finland
1994	27	Salmonella Agona phage type 15	Kosher peanut-flavored savory snack	Israel	North America and U.K.
1994	171	Shigella flexneri, type 6 (SF6)	Green onions	Mexico (suspected)	Illinois
1994	12	Unidentified Norwalk-like agent	Raw limpets (molluscan shellfish)	Portugal	Massachusetts and Rhode Island
1992	74	Histamine poisoning (Scombroid)	"Fresh" Tuna	Ecuador	Eastern seaboard
1991	4	Vibrio cholerae	Coconut milk in pudding	Thailand	Maryland
1991	12	Vibrio cholerae	Crab meat	Ecuador	New Jersey and New York
1991	400	Salmonella Poona	Cantaloupes	Mexico	23 states and Canada
1990	1,400	E. coli O153:H45	Raw scallops	South America	2 U.S. cruise ships

1989	99	Staphylococcal toxin - food poisoning	Canned mushrooms	Peoples Republic of China	3 states
1989	25,000	Salmonella Chester	Cantaloupes	Mexico	30 states
1988	202	Hepatitis A	Lettuce	Mexico (suspected)	Kentucky
1983	169	E. coli O27:H20	Semisoft cheese	France	4 states and Washington, DC

Source: CDC

APPENDIX II

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 following countries have food inspection systems equivalent to the United States and are eligible to export meat and/or poultry products to this country. Since January 1, 1998, FSIS has suspended Paraguay from exporting meat and poultry products to the United States because its inspection system was not adequate to prevent contamination on repeated shipments.

Argentina
Australia
Austria
Belgium
Brazil
Canada
Costa Rica
Croatia
Czech Republic
Denmark
Dominican Republic
Finland
France
Germany
Guatemala
Honduras
Hong Kong
Hungary
Iceland
Ireland
Israel
Italy
Japan
Mexico
Netherlands
New Zealand
Nicaragua
Northern Ireland
Paraguay
Poland
Romania
Solvenia
Spain
Sweden
Switzerland
United Kingdom
Uruguay

Source: FSIS

APPENDIX V

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Total Pages: 7

LRM ID: RJP280

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

Tuesday, June 2, 1998

LEGISLATIVE REFERRAL MEMORANDUM

TO:	Legislative Liaison Officer - See Distribution below
FROM:	Janet R. Forsgren (for) Assistant Director for Legislative Reference
OMB CONTACT:	Robert J. Pellicci
	PHONE: (202)395-4871 FAX: (202)395-6148
SUBJECT:	**HHS Fact Sheets on HR3052 Safety of Imported Food Act of 1997**
DEADLINE:	**1:00 p.m. Wednesday, June 3, 1998**

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President. **Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.**

COMMENTS: The attached FDA-prepared fact sheets are designed to illustrate the benefits of enhanced FDA food import authority. These one-pagers would be distributed to congressional staff.

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LRM ID: RJP280 **SUBJECT:** HHS Fact Sheets on HR3052 Safety of Imported Food Act of 1997

RESPONSE TO
LEGISLATIVE REFERRAL
MEMORANDUM

If your response to this request for views is short (e.g., concur/no comment), we prefer that you respond by e-mail or by faxing us this response sheet. If the response is short and you prefer to call, please call the branch-wide line shown below (NOT the analyst's line) to leave a message with a legislative assistant.

You may also respond by:
(1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); or
(2) sending us a memo or letter
Please include the LRM number shown above, and the subject shown below.

TO: **Robert J. Pellicci Phone: 395-4871 Fax: 395-6148**
Office of Management and Budget
Branch-Wide Line (to reach legislative assistant): 395-7362

FROM: _____ **(Date)**

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The following is the response of our agency to your request for views on the above-captioned subject:

_____ **Concur**

_____ **No Objection**

_____ **No Comment**

_____ **See proposed edits on pages** _____

_____ **Other:** _____

_____ **FAX RETURN of** ____ **pages, attached to this response sheet**

Benefits of Enhanced FDA Import Authority
Example of Microbial Contamination of Imported Soft Cheeses

The Situation:

In 1983, several outbreaks of gastrointestinal illness affecting in Washington, DC, Illinois and Wisconsin were associated with the consumption of Brie, a type of soft cheese produced in France. Unlike processes in the U.S., many soft cheeses in France are produced using non-pasteurized milk. FDA analysis revealed high levels of *Escherichia coli*, an indication of insanitary practices, in many soft cheeses imported from France. FDA initiated detention actions against products from the individual firms responsible for the contamination. In 1986 and 1987, numerous recalls of Brie cheese from France were initiated by FDA due the presence of a pathogen, *Listeria monocytogenes*. *Listeria monocytogenes* can be serious and sometimes fatal to the very young, the old and those with weakened immune systems. It may also cause miscarriage and stillbirths in pregnant women. *Listeria monocytogenes* is not controlled by refrigeration, unlike other bacteria, in that it grows at normal refrigeration temperatures. During this time frame, FDA also documented microbial contamination of soft cheese from other European countries. In 1986, 71 samples of soft cheese from Italy were analyzed and 26.8% were found to be contaminated with *Listeria monocytogenes* or *Escherichia coli*.

The Problem:

Because they are made from non-pasteurized milk, soft cheeses from France and other several European countries had high potential for adverse health effects from microbial contamination. FDA therefore issued an import alert in February 1987 placing all soft cheeses from France and selected manufacturers from other countries on detention without physical examination. The only exception was for soft cheeses from France that were certified by the French government under an agreement with FDA. The agreement required soft cheeses to be produced using pasteurized milk and in accordance with good manufacturing practices aimed at prevention of microbial contamination.

Benefit Under the Proposed Legislation:

Under existing authority, FDA is obligated to consider each shipment-specific certification. Under the proposed legislation, FDA would have an additional enforcement tool permitting denial of entry to food when the Secretary has determined that the exporting country's systems, conditions, and measures do not achieve the U.S. level of protection for the commodity in question. Except for French certified cheeses, FDA had such information and would have been able to make a determination that soft cheeses from other countries in Europe would have been deemed adulterated, and denied entry. This determination would have prevented illnesses and allowed for a better allocation of resources by reducing the need for FDA inspection of product from country(ies) determined to not provide our level of protection. A preventive determination could create an incentive for the European governments and cheese producers to upgrade their food safety systems and requirements.

Benefits of Enhanced FDA Import Authority
Example of Cyclospora on Raspberries From Guatemala

The Situation:
In the spring of 1997, multiple *Cyclospora* outbreaks affecting approximately 7,000 people, were traced to imported raspberries. *Cyclospora* is a newly recognized protozoan parasite that infects the human digestive tract causing gastrointestinal distress, including prolonged diarrhea. The pathogen is transmitted by ingestion of water or food contaminated with *Cyclospora.* Other symptoms include loss of appetite, weight loss, bloating, stomach cramps, nausea, vomiting, tiredness, muscle aches, and low grade fever.

The Problem:
Cyclospora is extremely difficult to detect microscopically, except in the stage of its life cycle when it is present in stool samples. Consequently, epidemiologists can only trace the source of infection through meticulous questioning of the victims to determine the common food that may have caused the infection and then trace the food back to its place of origin.

CDC, working in collaboration with FDA, epidemiologically linked raspberries from Guatemala as the common food that caused the illnesses. FDA then initiated a major effort to examine a large number of berry shipments from Guatemala in an attempt to identify the source(s) of the contamination. Because of the inability to find the organism in raspberries, FDA was hindered severely in its ability to control the import of the suspect berries. Despite one year of intense effort by FDA working with the Guatemalan raspberry producers, the problem remains unresolved.

Benefit Under the Proposed Legislation:
Under existing authority, because testing methods were unable to find the problem organism on the raspberries, FDA did not believe it appropriate to detain shipments of Guatemalan raspberries based solely on preliminary epidemiological data that only suggested raspberries as the problem. FDA was obligated to sample and analyze numerous shipments in an attempt to demonstrate that the parasite was present on raspberries. Under the proposed legislation, FDA would have an additional enforcement tool permitting denial of entry to food when the Secretary has determined that the exporting country's systems, conditions, and measures do not achieve the U.S. level of protection for the commodity in question. FDA had such information regarding the conditions of production for Guatemalan raspberries and would have been able to make a determination such that all raspberries from Guatemala would have been deemed adulterated, and denied entry. This determination would have prevented several hundred illnesses and allowed for a better allocation of resources by reducing the need for FDA inspection of product from a country determined to not provide our level of protection. A preventive determination could create an early incentive for the Guatemalan government and raspberry growers to upgrade their food safety system.

Benefits of Enhanced FDA Import Authority
Staphylococcal Enterotoxin in Canned Mushrooms from China and Other Countries

The Situation:
In 1989, there were four confirmed outbreaks of staphylococcal food poisoning attributed to canned mushrooms processed in the Peoples Republic of China (PRC) affecting 112 people. Staphylococcal food poisoning comes from a toxin produced by the *Staphylococcus* bacteria. Symptoms are nausea, vomiting, diarrhea, abdominal pains, headaches, muscular cramping and, on rare occasions, death. Subsequent sampling and analysis of imported Chinese mushrooms by FDA found staphylococcal enterotoxin (SE) in canned mushrooms processed by nine factories located in six PRC provinces. FDA also found SE in canned mushrooms from Korea, Hong Kong, Thailand and Malaysia, but using the same brined mushrooms that are the source of the problem and originating in the PRC.

The Problem:
FDA found SE in mushrooms processed by 14 of 79 registered canners which are located in 7 of the 12 provinces that process mushrooms. Due to the apparent widespread contamination in the PRC canning plants and the serious nature of the toxin, in October 1989 all canned mushrooms from the PRC were placed under detention without physical examination. Shipments of such mushrooms could not enter the United States unless they were accompanied by documentation from acceptable third party experts demonstrating the absence of SE. The nine year process has been extremely resource intensive for FDA and the current "lot-by-lot release" arrangement remains burdensome.

Benefit Under the Proposed Legislation:
Under existing authority, FDA is obligated to consider each shipment-specific certification. Under the proposed legislation, FDA would have an additional enforcement tool permitting denial of entry to food when the Secretary has determined that the exporting country's systems, conditions, and measures do not achieve the U.S. level of protection for the commodity in question. FDA had such information and could have been able to make a determination that all canned mushrooms from the PRC and other Asian countries using contaminated brined mushrooms from the PRC could have been deemed adulterated under the proposed legislation, and denied entry. This preventive determination would have prevented illnesses and allowed for a better allocation of resources by reducing the need for FDA inspection of product from a country determined to not provide our level of protection. A preventive determination could create an incentive for the PRC government and mushroom producers to upgrade their food safety system.

Benefits of Enhanced FDA Import Authority
Example of Illegal Use of Pesticides in Snow Peas from Guatemala

The Situation:
Since the late 1980's, FDA surveillance monitoring of snow peas from many growers in Guatemala routinely found residues of chlorothalonil (a fungicide) and methamidophos (an insecticide) for which there are no established residue tolerances in the United States. Despite FDA actions against individual producers, the problems continued unabated with the number of firm-specific detentions increasing as the number of snow pea shipments from Guatemala increased.

The Problem:
In 1992, in an attempt to stem the flow of illegal shipments, FDA placed all snow peas from Guatemala on detention without physical examination. The Guatemalan Snow Pea Committee, an industry and government consortium, developed and implemented an export certification program with features that included control of pesticide usage at farm level among the hundreds of individual snow pea producers, and export controls including sampling and analysis of each exported shipment. Despite genuine efforts in Guatemala exemplified by these programs, it became clear through FDA audit sampling and review of analytical data from private laboratories that the problem was continuing and that authorities in Guatemala could not prevent the misuse of the pesticides.

Under its existing authority, FDA could have detained individual shipments based on an "appearance" of adulteration, but it was obligated to allow shipments of snow peas into the country if the shipment was accompanied by acceptable documentation demonstrating its compliance. FDA, therefore, was forced to retain the burden of reviewing shipment-specific documentation from laboratories attesting to such compliance. Review of such paperwork, which included laboratory data sheets and sample integrity documents, is resource intensive.

Benefit Under Proposed Legislation:
Under existing authority, FDA is obligated to consider each shipment-specific certification. Under the proposed legislation, FDA would have an additional enforcement tool permitting denial of entry to food when the Secretary has determined that the exporting country's systems, conditions, and measures do not achieve the U.S. level of protection for the commodity in question. FDA had such information and would have been able to make a determination that all snow peas from Guatemala would have been deemed adulterated, and denied entry. This determination would have allowed for a better allocation of resources by reducing the need for FDA inspection of product from a country determined to not provide our level of protection. A preventive determination could create an incentive for the Guatemalan government and snow pea growers to upgrade their food safety system.

Benefits of Enhanced FDA Import Authority
Example of Filth and Decomposition in Shrimp from India

The Situation:
In early 1979, FDA sampling and analyses revealed a high violation rate in fresh or fresh frozen Indian shrimp for filth and decomposition. While no illnesses were traced to this product, decomposed shrimp can result in a severe allergic reaction to histamine. FDA issued an import alert, placing all shrimp from India under detention without physical examination. Under the alert, no shrimp from India could enter the United States unless it was accompanied by acceptable documentation demonstrating the absence of filth and decomposition.

The Problem:
In response to the situation, the Indian shrimp industry, along with the Indian government, proposed a shipment-specific control program to prevent the safety and sanitation problems for shrimp exported to the United States. In January 1980, a certification program was implemented by FDA and the Indian government that allowed the Indian government to certify compliance with FDA requirements. Indian officials assured FDA that stringent shipment-specific testing and improvements in export controls were implemented by the Indian government. FDA conducted audit sampling of shrimp and occasional review of laboratory results provided by Indian authorities. FDA repealed the certification program in 1992 after an audit and surveillance sampling program demonstrated a high violation rate in Indian shrimp for filth, and decomposition.

Benefit under the Proposed Legislation:
Under existing authority, FDA is obligated to consider each shipment-specific certification. Under the proposed legislation, FDA would have an additional enforcement tool permitting denial of entry to food when the Secretary has determined that the exporting country's systems, conditions, and measures do not achieve the U.S. level of protection for the commodity in question. FDA had such information and would have been able to make a determination that shrimp imported from India would have been deemed adulterated, and denied entry. This determination would have allowed for a better allocation of resources by reducing the need for FDA inspection of product from a country determined to not provide our level of protection. A preventive determination could create an incentive for the Indian government and shrimp producers to upgrade their food safety system.