

September 2009

FOOD SAFETY

Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food



GAO

Accountability * Integrity * Reliability



Highlights of [GAO-09-873](#), a report to congressional committees

Why GAO Did This Study

Imported food makes up a substantial and growing portion of the U.S. food supply. To ensure imported food safety, federal agencies must focus their resources on high risk foods and coordinate efforts.

In this context, GAO was asked to (1) assess how Customs and Border Protection (CBP), the Food and Drug Administration (FDA), and the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) are addressing challenges in overseeing the safety of imported food; (2) assess how FDA leverages resources by working with other entities, such as state and foreign governments; and (3) determine how FDA is using its Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting (PREDICT) system to oversee imported food safety. GAO analyzed CBP, FDA, and FSIS procedures, reports, and regulations and interviewed agency officials and key stakeholders.

What GAO Recommends

GAO recommends, among other things, that FDA seek authority from the Congress to assess civil penalties on firms and persons who violate FDA laws, and that the FDA Commissioner explore ways to improve the agency's ability to identify foreign firms with a unique identifier. CBP and FDA generally agreed with our recommendations. FSIS provided technical comments only.

View [GAO-09-873](#) or [key components](#). For more information, contact Lisa Shames at (202) 512-3841 or shamesl@gao.gov.

FOOD SAFETY

Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food

What GAO Found

CBP, FDA, and FSIS have taken steps to address challenges in ensuring the safety of the increasing volume of imported food. For example, CBP maintains the system that importers use to provide information to FDA on food shipments; FDA electronically reviews food imports and inspects some foreign food production facilities to prevent violative food from reaching U.S. shores; and FSIS employs an equivalency system that requires countries to demonstrate that their food safety systems provide the same level of protection as the U.S. system. However, gaps in enforcement and collaboration undermine these efforts. First, CBP's computer system does not currently notify FDA or FSIS when imported food shipments arrive at U.S. ports, although efforts are underway to provide this information to FDA for air and truck shipments. This lack of communication may potentially increase the risk that unsafe food could enter U.S. commerce without FDA review, particularly at truck ports. Second, FDA has limited authority to ensure importers' compliance with its regulations. Third, CBP and FDA do not identify importers with a unique number; as a result, FDA cannot always target food shipments originating from high risk importers. Finally, CBP faces challenges in managing in-bond shipments—those that move within the United States without formally entering U.S. commerce—and such shipments possibly could be diverted into commerce.

FDA generally collaborates with select states and foreign governments on imported food safety. FDA has entered into a contract, several cooperative agreements, and informal partnerships for imported food with certain states, and some state officials told GAO that they would like to collaborate further with FDA on food imports. However, citing legal restrictions, FDA does not fully share certain information, such as product distribution lists, with states during a recall. This impedes states' efforts to quickly remove contaminated products from grocery stores and warehouses. FSIS has begun to make available to the public a list of retail establishments that have likely received food products that are subject to a serious recall. FDA is also expanding efforts to coordinate with other countries. In particular, through its Beyond Our Borders initiative, FDA intends to station investigators and technical experts in China, Europe, and India, to provide technical assistance and gather information about food manufacturing practices to improve risk-based screening at U.S. ports.

According to FDA, PREDICT will analyze food shipments using criteria that include a product's inherent food safety risk and the importer's violative history, among other things, to estimate each shipment's risk. A 2007 pilot test of PREDICT indicated that the system improved FDA's ability to identify products it considers to be high risk while allowing a greater percentage of products it considers low risk to enter U.S. commerce without a manual review. However, FDA has not yet developed a plan to measure the system's performance, and GAO previously identified shortcomings in FDA's information technology modernization efforts. FDA plans to begin deploying PREDICT at all ports and for all FDA-regulated products in September 2009.

Contents

Letter		1
	Results in Brief	4
	Background	10
	Three Federal Agencies Are Taking Actions to Better Ensure the Safety of Imported Food, but Enforcement and Collaboration Gaps Undermine These Efforts	16
	FDA Collaborates with States and Foreign Governments, but Does Not Fully Share Information with States During a Recall	26
	PREDICT Testing Indicates that the System May Improve FDA's Risk-Based Import Screening Efforts, but Further Actions Are Needed	34
	The EU Has Developed Some Practices That Could Inform CBP, FDA, and FSIS Practices	39
	Conclusions	41
	Recommendations for Executive Action	42
	Agency Comments and Our Evaluation	44
Appendix I	Objectives, Scope, and Methodology	47
Appendix II	FDA Field Examinations, Fiscal Years 2006 through 2009	49
Appendix III	FSIS Inspections at Ports of Entry, Fiscal Years 2006 through 2008	50
Appendix IV	Agencies' Processes to Oversee Imported Food	51
Appendix V	FDA's Overseas Inspections	61
Appendix VI	FDA's Funding for Imported Food by Activity, Fiscal Years 2002 through 2009	62

Appendix VII	FSIS's Funding for Food Imports, Fiscal Years 2006 through 2009	63
Appendix VIII	Comments from the Department of Homeland Security	64
Appendix IX	Comments from the Department of Health and Human Services	67
Appendix X	GAO Contact and Staff Acknowledgments	72
Table	Table 1: FDA's Planned Staffing Levels for Foreign Posts (35 U.S. nationals)	32
Figures	Figure 1: FDA Staff Examining Food at the Port of Baltimore	14
	Figure 2: FDA's Process for Electronically Screening Imported Food Shipments	53
	Figure 3: FDA's Process for Examining Selected Imported Food Shipments Before Allowing Entry into U.S. Commerce	54
	Figure 4: FSIS's Process for Reinspecting Imported Meat, Poultry, and Processed Egg Products	58

Abbreviations

ACE	Automated Commercial Environment
ACS	Automated Commercial System
AIIS	Automated Import Information System
CBP	Customs and Border Protection
EU	European Union
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
MDA	Michigan Department of Agriculture
NYSDAM	New York State Department of Agriculture and Markets
OASIS	Operational and Administrative System for Import Support
PREDICT	Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting
TRACES	Trade Control and Expert System
USDA	U.S. Department of Agriculture

This is a work of the U.S. government and is not subject to copyright protection in the United States. The published product may be reproduced and distributed in its entirety without further permission from GAO. However, because this work may contain copyrighted images or other material, permission from the copyright holder may be necessary if you wish to reproduce this material separately.



United States Government Accountability Office
Washington, DC 20548

September 15, 2009

The Honorable Henry A. Waxman
Chairman
The Honorable Joe Barton
Ranking Member
The Honorable John D. Dingell
Chairman Emeritus
Committee on Energy and Commerce
House of Representatives

The Honorable Bart Stupak
Chairman
The Honorable Greg Walden
Ranking Member
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives

Food imported from more than 150 countries and territories constitutes a substantial and increasing percentage of the U.S. food supply. According to the Food and Drug Administration (FDA), the number of food entry lines has nearly doubled in the last 10 years. (An entry line is each portion of an import shipment that is listed as a separate item on an entry document. Items in an import entry having different tariff descriptions or FDA product codes must be listed separately.) According to U.S. Department of Agriculture (USDA) data, imported food comprises 15 percent of the U.S. food supply, including 60 percent of fresh fruits and vegetables and 80 percent of seafood. Additionally, the volume of agricultural and seafood products imported for consumption increased 29 percent between fiscal years 2003 and 2008, and the value of these products increased 65 percent.

Imported foods have been associated with recent outbreaks of foodborne illnesses. For example, in 2008, more than 50 people became ill with *Salmonella* from Honduran cantaloupes, and more than 1,400 people became ill with *Salmonella* from Mexican peppers. Ensuring the safety of this large and growing volume of imported food challenges federal agencies to better target their resources on the foods posing the greatest risks to public health and to coordinate efforts so that unsafe food does not enter U.S. commerce.

In the United States, two agencies—FDA, under the U.S. Department of Health and Human Services, and the Food Safety and Inspection Service (FSIS), under USDA—have primary responsibility for food safety. FSIS oversees the safety of meat, poultry, and processed egg products, both domestic and imported, and verifies that shipments of these products meet FSIS requirements. FDA is responsible for the safety of virtually all other foods, including milk, seafood, fruits, and vegetables. Owing in part to the volume of imported products it regulates, FDA physically examines only approximately 1 percent of imported food; however, the agency is developing the Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting (PREDICT) computer system to improve its targeted screening efforts. In addition, Customs and Border Protection (CBP), under the Department of Homeland Security, is responsible for enforcing FDA's food safety regulations at the border, among other things. CBP's computerized screening system processes all imported shipments, including food, and CBP requires importers to (1) give a manufacturer identification number for each imported shipment and (2) post a monetary bond for formal entries (i.e., all shipments exceeding \$2,000 or certain shipments valued below that amount) to provide assurance that these shipments meet U.S. requirements, among other things. Sometimes, CBP may allow an imported food shipment to proceed from the U.S. port of arrival to another U.S. port without appraising the merchandise or requiring payment of duties until the product reaches the port where it is officially entered into U.S. commerce or exported. This movement of a product between ports is referred to as an in-bond movement. All three agencies—CBP, FDA, and FSIS—participate in the Interagency Working Group on Import Safety, which in 2007 recommended, among other things, that agencies harmonize federal procedures and requirements for processing import shipments.

Food safety responsibility is further divided among the 50 states, which may have their own statutes, regulations, and agencies for regulating and inspecting the safety and quality of food products. Food safety concerns are not unique to the United States. As we reported in 2008, increased public concern about food safety recently led the European Union (EU) to reorganize its food safety system, including its procedures for overseeing food imports.¹ The procedures discussed in that report may provide

¹GAO, *Food Safety: Selected Countries' Systems Can Offer Insights into Ensuring Import Safety and Responding to Foodborne Illness*, [GAO-08-794](#) (Washington, D.C.: June 10, 2008).

insights into keeping food safe at the U.S. border. Specifically, in April 2004, the EU adopted comprehensive food safety legislation to create a single, transparent set of EU food safety rules applicable to both animal and nonanimal products.

In this context, you asked us to (1) assess how CBP, FDA, and FSIS are addressing challenges in overseeing the safety of imported food; (2) assess how FDA leverages resources in overseeing imported food safety by working with other entities, such as state and foreign governments; and (3) determine how FDA is using PREDICT to oversee the safety of imported food. In addition, to learn about leading practices in other countries, we examined how the EU screens and monitors food imports at two ports of entry.

To assess how the agencies are addressing challenges in overseeing the safety of imported food, we collected documents, such as strategic plans and procedure manuals; interviewed officials from CBP, FDA, and FSIS; and spoke with industry representatives—including trade associations and customs brokers—as well as consumer advocacy groups and other food safety experts. We focused primarily on CBP and FDA because the USDA Inspector General has conducted several detailed reviews of FSIS's import procedures in recent years. In addition, we visited five U.S. ports—Baltimore, Maryland; Buffalo, New York; Laredo, Texas; Los Angeles/Long Beach, California; and Miami, Florida—and observed how agency officials examine incoming shipments. We selected these ports because they are located on different borders or coasts with different modes of transportation. To assess the extent to which FDA leverages resources for overseeing the safety of imported food by working with state governments, we spoke with officials from FDA, as well as with officials in Arizona, California, Florida, Illinois, Michigan, New Mexico, New York, Texas, and Washington. We selected Illinois because it is an inland state that receives a high volume of in-bond shipments, and the other states are border states and home to large, high-volume ports. To assess the extent to which FDA leverages resources with foreign governments on imported food issues, we reviewed agency documentation and spoke with a senior FDA official who is responsible for FDA's international initiative. We focused primarily on FDA because it regulates roughly 80 percent of the food supply and because of our longstanding concerns regarding the agency's need to better leverage its limited resources. To determine how FDA is using PREDICT to oversee the safety of imported food, we reviewed and summarized formal assessments of PREDICT, spoke with FDA officials responsible for managing and implementing the system to obtain their views, and observed the system's use at the Los Angeles/Long

Beach and Buffalo ports. We also leveraged recent GAO work assessing FDA's information technology modernization efforts. We did not review PREDICT's hardware or software environments or testing activities. To learn about leading practices for screening food imports in the EU, we visited two EU ports—Antwerp, Belgium and Rotterdam, the Netherlands—which, according to EU officials, are known for using leading practices. Under the Federal Food, Drug, and Cosmetic Act, FDA's authorizing legislation, the term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article. We use this definition, which also includes meat, poultry, and egg products, in this report.

We conducted this performance audit from July 2008 to September 2009 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives. More information on our objectives, scope, and methodology is presented in appendix I.

Results in Brief

While CBP, FDA, and FSIS have taken steps to address challenges in ensuring the safety of the increasing volume of imported food, gaps in enforcement and collaboration undermine these efforts. CBP addresses key challenges by maintaining the system that importers use to provide information to FDA on food shipments and using its authority to issue civil penalties against importers that fail to comply with food safety regulations, among other things. FDA electronically reviews all formal entries for food products and inspects some foreign food production facilities to prevent violative food from reaching U.S. shores. FSIS's equivalency system requires that countries exporting meat and poultry and processed egg products to the United States demonstrate that their food safety standards are equivalent to those of the United States. The agency is also developing a new information technology initiative, called the Public Health Information System, which is a Web-based application. According to FSIS, this application will replace many of FSIS's legacy systems and is expected to allow the agency to receive foreign health certificates electronically and provide secure and timely advance notice of a foreign shipment certified by a foreign government. Despite the actions these three agencies have taken, we identified the following four gaps in enforcement and collaboration that could allow high risk foods to enter domestic commerce without assurance that these products are examined.

-
- *Agencies' computer systems do not share key information.* CBP's import screening system does not notify FDA's or FSIS's systems when imported food shipments arrive at U.S. ports. Without access to time-of-arrival information, FDA and FSIS may not know when shipments that require examinations or reinspections arrive at the port, which could potentially increase the risk that unsafe food may enter U.S. commerce. This is of particular concern at truck ports. The agencies have begun to take steps to address this gap, but work remains. For example, FDA and CBP developed an interagency agreement under which CBP would modify its existing system to provide shipment time-of-arrival information to FDA. According to CBP officials, the agency has completed these modifications for air and truck ports. CBP does not have a similar agreement with FSIS. In addition, CBP is upgrading its import screening system in part to improve data-sharing with other government agencies such as FDA and FSIS, but CBP officials told us that development of key system components has been delayed because of budget shortfalls and unforeseen difficulties in programming the system to meet agency requirements. Moreover, according to agency officials, it is unknown whether this new system will address the agency's inability to routinely communicate time-of-arrival information. Effective practices for collaboration and internal controls call for agencies to address the compatibility of data systems and ensure adequate means of obtaining information from external stakeholders that have a significant impact on agency goals.² In addition, the Interagency Working Group on Import Safety recommended in 2007 that, among other things, agencies improve the interoperability of government and private sector computer systems to facilitate the exchange of information on imported products.
 - *FDA has limited authority to ensure importer compliance.* Importers can retain possession of their food shipments until FDA approves their release into U.S. commerce. FDA relies on a bond between CBP and the importer to discourage the premature release of FDA-regulated shipments. If importers do not comply with the requirements, they may be required to forfeit the amount of the bond. However, as we reported in 1998, the shipment's maximum bond value is often not sufficient to deter the sale of imported goods that FDA has not yet released.³ In a February 2009

²GAO, *Standards for Internal Control in the Federal Government*, [GAO/AIMD-00-21.3.1](#). (Washington, D.C.: November 1999); and GAO, *Results-Oriented Government: Practices That Can Help Sustain Collaboration Among Federal Agencies*, [GAO-06-15](#) (Washington, D.C.: Oct. 21, 2005).

³GAO, *Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable*, [GAO/RCED-98-103](#) (Washington, D.C.: Apr. 30, 1998).

testimony, FDA requested several additional authorities, but did not include civil penalties authority in this request. However, FDA officials told us that if the agency had its own authority to impose civil penalties on importers, it might be possible to deter future violations.

- *CBP and FDA do not provide unique identification numbers to firms.* The identification numbers FDA uses to target manufacturers that have violated FDA standards in the past are not unique. As a result, these manufacturers, and their shipments, may evade FDA review, which increases the possibility that high risk foods may enter the U.S. market. This occurs in part because FDA relies on entry-filer generated identification numbers to create FDA's own identifiers for firms at the time of importation, a process that, over time, often results in multiple identifiers for a single firm. (An entry filer is the individual or firm responsible for filing an entry—usually the broker or importer.) CBP is responsible for validating the manufacturer identification numbers and ensuring they are unique, but FDA officials told us that some foreign food facilities have multiple identification numbers.
- *CBP faces challenges in managing in-bond shipments.* According to CBP, food is one of the most common types of products to be shipped in-bond. We reported in the past that CBP does not effectively manage in-bond shipments. In 2007, for example, we recommended, among other things, that CBP amend a regulation to reduce the time allowed for transporting cargo and to limit importers' ability to change the final destination of in-bond shipments without the agency's knowledge.⁴ CBP has taken steps to address some of our recommendations, and CBP officials told us they had drafted the amendments to the regulation, but as of July 2009, the agency had not issued a final regulation. Until it does so, concerns remain that imports of violative food—food that does not meet U.S. safety standards or labeling requirements—could be shipped in-bond and enter U.S. commerce undetected.

Although the agencies face multiple challenges in improving their oversight of food safety imports, FDA and CBP officials at the ports of Buffalo and Miami have developed practices that could improve agency collaboration at other ports. At both ports, the two agencies employ joint initiatives to better coordinate actions when a food shipment violates or

⁴GAO, *International Trade: Persistent Weaknesses in the In-Bond Cargo System Impede Customs and Border Protection's Ability to Address Revenue, Trade, and Security Concerns*, [GAO-07-561](#) (Washington, D.C.: Apr. 17, 2007).

appears to violate FDA regulations. These initiatives have simplified agency procedures and, according to FDA and CBP officials, have improved importers' compliance with regulations for destroying or returning to the importer food products that violate FDA's safety standards.

FDA has formal and informal mechanisms to work with states on imported food safety. FDA generally leverages resources by collaborating with select states but does not fully share information with the states during a recall, whether of imported or domestic food. According to the Interagency Working Group on Import Safety, federal and state governments' roles and resources for ensuring the safety of imported food are complementary. That is, the federal government can interdict unsafe imported goods at ports of entry, and states can address unsafe imported food products within their borders. We also found that FDA collaborates with foreign governments on certain food safety issues. Specifically:

- *FDA collaborates with some states to leverage resources.* For imported foods, FDA has entered into a contract, several cooperative agreements, and informal partnerships with some states. Specifically, FDA has contracted with Michigan to fund state inspectors to sample and test imported food. FDA also uses cooperative agreements—in which FDA provides funding for state services that primarily benefit the state as a proxy for the “public,” rather than the federal government—to leverage state resources for imported food safety. For example, FDA has agreements with six states to establish rapid response teams to address emergencies, including incidents associated with imported food. FDA also has several informal partnerships for food imports to facilitate federal-state cooperation, although the partnerships are not legally binding and do not involve federal funding. For example, at FDA's request, New York State food inspectors will enter warehouses specializing in food from a particular country to look for violative imported products in domestic commerce. Some state officials told us that they would like to collaborate further with FDA on food imports, and they can act more quickly than FDA when contaminated food is initially identified.
- *FDA does not always share certain information during a recall.* According to officials from several states, during food recalls, FDA is reluctant to share certain information, such as product distribution lists. This lack of information-sharing impedes states' efforts to quickly remove contaminated products from grocery stores and warehouses. FDA believes that product distribution lists are confidential commercial information and cannot be shared with states except as allowed by law. FSIS discloses certain information to the public during a recall—specifically, the names

and locations of retail consignees of meat and poultry products that have been recalled by a federally inspected meat or poultry establishment—if the product has been recalled at the retail level.

- *FDA is expanding its efforts to coordinate with other countries in a number of ways.* According to a senior agency official, FDA initiated its Beyond Our Borders program in an effort to prevent food that fails to meet U.S. standards from reaching the United States. Under this program, FDA intends to station food investigators and technical experts in China, Europe, and India to provide technical assistance and conduct inspections, among other things. Furthermore, FDA expects to get direct access to information about foreign facilities' food manufacturing practices so that its staff at U.S. ports of entry can make informed decisions on which food imports to examine. FDA also holds yearly meetings with officials in other countries, such as Australia, Canada, and New Zealand, to share information and strategize over food safety and other public health issues.

According to FDA, the PREDICT system is intended to improve the agency's ability to target shipments for inspection that are more likely to violate FDA's regulations. PREDICT is to estimate the risk of FDA-regulated imports (e.g., food, drugs, and medical devices) using criteria such as the violative histories of the product, importer, and country of origin. FDA entry reviewers are to use these risk estimates to target for examination shipments the agency considers to be high risk while the system allows shipments the agency considers to be low risk to enter U.S. commerce without further review. A 2007 pilot test of PREDICT at one location for seafood products indicated that the system improved FDA's ability to (1) identify products that were more likely to violate FDA regulations, (2) identify product violations that posed more severe public health risks, and (3) allow a greater percentage of products the agency considers to be low risk to enter U.S. commerce without requiring an entry reviewer's intervention. However, FDA has not yet developed a plan to monitor and assess the system's ability to identify high risk products once it is deployed. Under federal standards on internal controls, agencies are to engage in the ongoing monitoring of programs to assess performance over time, including establishing policies and procedures to ensure that findings of reviews are promptly resolved.⁵ Additionally, we reported in June 2009 that FDA lacks a comprehensive information technology

⁵[GAO/AIMD-00-21.3.1.](#)

strategic plan for PREDICT and other modernization projects.⁶ Without such a plan, FDA's modernization efforts, including PREDICT, may not adequately meet the agency's urgent mission needs. We also identified shortcomings in the agency's enterprise architecture (i.e., modernization blueprints that describe an organization's operation in terms of business and technology) and information technology human capital management. These shortcomings reduce FDA's assurance that it will be able to effectively modernize its systems and have the appropriate staff to implement and support its modernization efforts. FDA generally agreed with our recommendations in the June 2009 report and, while recognizing the need for further agency actions, plans to begin deploying PREDICT on a district-by-district basis at all ports and for all FDA-regulated products in September 2009.

The EU takes a comprehensive, risk-based approach to screening and monitoring food imports to ensure the safety of these foods by targeting products that are more likely to present risk, and taking steps to ensure that violative products do not enter EU countries. Because the EU considers live animals and products of animal origin to be particularly high risk, owing to past problems with *bovine spongiform encephalopathy* ("mad cow disease"), all such imports must enter the EU through approved border inspection posts, where veterinarians are present, and cannot leave the port without veterinary approval. The EU's new computer system, which automatically updates information about products of animal origin entering the EU, is linked to the EU's Rapid Alert System for Food and Feed (which covers all types of food) in order to communicate alerts to all border inspection posts. If port officials reject a food shipment, whether of animal or nonanimal origin, the shipment cannot leave government custody for exportation to another, non-EU country until that country's counterpart agency officially accepts the shipment in writing.

To better ensure the safety of imported food, we are making several recommendations. For example, we are recommending that the FDA Commissioner seek authority from the Congress to assess civil penalties on firms and persons who violate FDA's food safety laws. We further recommend that the Commissioner determine what violations should be subject to this new FDA civil penalties authority, as well as the appropriate

⁶GAO, *Information Technology: FDA Needs to Establish Key Plans and Processes for Guiding Systems Modernizations Efforts*, [GAO-09-523](#) (Washington, D.C.: June 2, 2009).

nature and magnitude of the penalties. In addition, we are recommending that the CBP Commissioner ensure that the agency's new import screening system, the Automated Commercial Environment (ACE), is able to accept a unique identification number for foreign firms that export FDA-regulated foods, and that the FDA Commissioner explore ways to improve the agency's ability to identify foreign firms with a unique identifier.

We provided a draft of this report to CBP, FDA, and FSIS for their review and comment. CBP agreed with our recommendations, but disagreed that the in-bond entry process is a gap in the enforcement of food imports. FDA also generally agreed with our recommendations. Although the agency agreed in principle with our recommendation on developing a joint refusal/redelivery process, it does not believe that a study is warranted, noting that discussions with CBP on this topic have already begun. FSIS did not provide formal comments. All three agencies provided technical comments, which we incorporated into the report as appropriate. CBP's and FDA's comments are included in appendixes VIII and IX, respectively.

Background

We have been concerned about ensuring the safety of imported food for many years. In 1998, we assessed the federal government's efforts to ensure the safety of imported foods and determined that federal agencies could not be certain that the growing volume of imported food was safe for consumers.⁷ For example, we found that (1) the agencies' import screening systems did not take advantage of available data in order to target imported foods that posed the greatest health risks, (2) FDA did not maintain effective control over the violative products it detained and did not have adequate measures to ensure the integrity of sampling and testing procedures for suspect food shipments, and (3) the evasion of safety requirements was seldom punished effectively. The agencies relied on the penalties the importer would incur if the importer violated the terms of the bond as the principal mechanism to ensure compliance with laws; however, these penalties did not represent an effective deterrent.

Over the past 30 years, we have detailed problems with the current fragmented federal food safety system. A total of about 15 federal agencies, including FDA and FSIS, share some responsibility for food

⁷[GAO/RCED-98-103](#).

safety, and we have reported that the system has caused inconsistent oversight, ineffective coordination, and inefficient use of resources. This fragmentation is the key reason that we added federal oversight of food safety to our high risk series in January 2007 and called for a governmentwide examination of the food safety system.⁸

Furthermore, as we have reported, when an issue, such as imported food safety, cuts across federal agency jurisdictions, the agencies involved must collaborate to deliver results more efficiently and effectively. Our previous work indicates that federal agencies can efficiently and effectively collaborate when they establish (1) joint strategies to achieve goals and (2) procedures and policies for working together systematically across agency lines, among other things.⁹

CBP, FDA, and FSIS each uses its own processes to screen imports, and all three share certain information with each other to enhance their efforts. CBP and FDA rely to a large extent on information that brokers and importers provide; FSIS reviews a health certificate, as well as an application of import inspection that an importer or broker is required to present with an incoming shipment. More specifically:

- CBP seeks to interdict shipments of contraband and the illegal importation of food and other products. CBP requires importers to notify it about all shipments in advance. Specifically, importers or their brokers electronically submit information on the shipment to either CBP's legacy computer system, the Automated Commercial System (ACS), or ACE, the agency's new system that is operating in conjunction with ACS at some ports. CBP tracks each shipment throughout the importation process and determines whether it needs to conduct a more detailed examination. Once CBP clears a food shipment for U.S. commerce, it requires the importer to agree to return the goods to the port of entry upon a CBP demand for redelivery within 30 days.

CBP also requires importers shipping formal entries to post a monetary bond to provide assurance that the importer will meet the obligations imposed by law or regulation. For example, an importer's bond obligations require the importer to pay duties and submit entry summary documentation at the times required by law, and to redeliver merchandise

⁸GAO, *High-Risk Series: An Update*, [GAO-07-310](#) (Washington, D.C.: January 2007).

⁹[GAO-06-15](#).

to CBP upon a lawful demand. A bond is thus like an insurance policy that guarantees payment to CBP if a required act is not performed.

- Under the Federal Food, Drug, and Cosmetic Act—the primary legislation governing FDA’s activities—any foreign company can export food products to the United States provided, among other things, that it first registers with the agency, if registration is required. FDA’s approach to overseeing imported food safety encompasses (1) preventing food safety problems by promoting corporate responsibility; (2) intervening through targeted inspections, sampling, and surveillance; and (3) responding to food safety emergencies when they occur.

FDA Relies on Importers to Supply Accurate Information

FDA relies on information that importers or brokers provide when determining the risk a food product may pose to human health. It is therefore critical that importers provide accurate information. However, in 1998 we found that some importers had an incentive to misrepresent their goods in order to avoid FDA inspections, and FDA officials indicated that the agency is still concerned about information quality.

To evaluate the accuracy of the information that importers and brokers provide, FDA conducts “filer evaluations” (filers are generally importers and brokers). If filers electronically submit information that is not at least 90 percent accurate, FDA will require the filers to submit subsequent shipment information on paper entry forms in order to import products into the United States. According to agency officials, the use of paper entries is disadvantageous for filers because it triggers an FDA examination of the shipment at the port of entry before the shipment is allowed to enter U.S. commerce. Therefore, according to these officials, the filer evaluations serve as an incentive for compliance.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (also called the Bioterrorism Act), directs FDA to, by regulation, require Prior Notice for food imported or offered for import into the United States. The purpose of Prior Notice is to enable such food to be inspected at the ports of entry. To meet the requirements of FDA’s regulation, filers are to submit electronically to FDA, among other things, the (1) submitter’s name, phone number, and e-mail address; (2) identity of the article of food, including the FDA product code and the estimated quantity; (3) name and address of the manufacturer, grower (if known), and shipper; (4) country from which the product is shipped; and (5) anticipated port of arrival. Filers can submit Prior Notice either through FDA directly or through CBP’s Automated Broker Interface, which is linked to ACS.¹⁰ An article of food that arrives at the port of entry with inadequate Prior Notice is subject to refusal and may not be delivered to the importer, owner, or consignee.

Once a food shipment has passed Prior Notice screening, it undergoes a second, separate assessment, called admissibility review, in which the shipment is screened for regulatory standards and requirements, misbranding, adulteration, and safety. During the admissibility process, FDA electronically screens information about food and other products it regulates using data that the broker provides on behalf of the importer and automatically transmits its screening decisions to CBP. When deciding on

¹⁰Generally, Prior Notice must be filed at least 2 hours before a food shipment arrives by road, at least 4 hours before arriving by rail or air, and at least 8 hours before arriving by water. However, there are certain exemptions from Prior Notice requirements (e.g., food that is imported and exported without leaving the port of arrival until export). CBP also generally requires advance notification for all shipments, including FDA- and FSIS-regulated foods; this notification is independent of the Bioterrorism Act requirements.

whether a food shipment's documents should be reviewed or the shipment physically examined, FDA reviewers consider, among other data, the product type as well as the manufacturer, based in part on the facility's identification number, which is automatically generated from information that CBP maintains.

FDA reviewers analyze information about food shipments and use their professional judgment to select shipments—approximately 1 percent—for physical examination. In addition, some shipments may be detained on the basis of information other than a physical examination at any time (for example, on the basis of a company's past compliance information). Appendix II provides detailed information on FDA's field examination activities for 2006 to 2008. According to a 2008 USDA Economic Research Service study on FDA data on shipments that had been refused entry between 1998 and 2004, FDA's data on refusals highlights recurring food safety problems found in imports, as well as where FDA focuses its import screening. However, the report noted that the data do not necessarily reflect the full distribution of risk, since the data are in part a reflection of FDA's particular screening criteria.¹¹ Figure 1 shows an FDA staff person examining food products at the Port of Baltimore.

¹¹Buzby, Jean C.; Laurian J. Unnevehr; and Donna Roberts. *Food Safety and Imports: An Analysis of FDA Food-Related Import Refusal Reports*, EIB-39, U.S. Department of Agriculture, Economic Research Service (September 2008).

Figure 1: FDA Staff Examining Food at the Port of Baltimore



Source: GAO.

FDA is developing PREDICT, which it expects will improve its electronic screening process by calculating a detailed risk score for food shipments. FDA reviewers will use this risk score, in addition to their professional judgment, to determine which imports should be physically examined before entering U.S. commerce. FDA uses PREDICT to screen certain seafood shipments at two locations.

- FSIS uses a three-part approach to overseeing the safety of imported food: an equivalency system, whereby countries that wish to export meat and poultry products to the United States must demonstrate that their food safety systems meet standards that are equivalent to those of the U.S. system; audits to verify that their system remains equivalent; and reinspection of all imported shipments arriving at approximately 150 FSIS-approved import facilities located near about 30 U.S. ports of entry. Appendix III provides detailed information on FSIS's inspections at U.S. ports of entry for 2006 to 2008.

FSIS's computer system does not share information with CBP about food shipments, although the agency does notify CBP officials manually in certain circumstances, such as when a noncompliant product must be sent

back to its country of origin. Although FSIS physically inspects all food imports that it regulates, it occasionally targets a shipment for a higher level of inspection, primarily on the basis of the foreign country's recent track record and the risk of the product. This higher level of inspection may involve laboratory testing or additional physical inspections. Additional detail on the processes FDA and FSIS use to oversee imported food is presented in appendix IV.

As food safety problems increasingly cut across jurisdictional lines and have national consequences, experts anticipate that the role of state and local agencies in the national food safety system will continue to grow.¹² Most state governments are involved in food safety prevention and response functions, generally through both their health departments and agriculture departments or other agencies that play food safety regulatory roles in some states. States conduct the majority of all food safety-related laboratory testing and more than 80 percent of all nonretail food establishment inspections (excluding FSIS-inspected meat and poultry establishments). These include many inspections of food manufacturing and processing facilities, which they conduct under contract to FDA. Some states also inspect retail and food service establishments.¹³ State officials told us that their agencies are mainly concerned with food in domestic commerce; they do not have any formal jurisdiction over imports. However, these officials told us that they are concerned with imported food if it causes illnesses within their borders after it is cleared for domestic consumption.

¹²Taylor, Michael R. and Stephanie D. David, *Stronger Partnerships for Safer Food*. Department of Health Policy, School of Public Health and Health Services, The George Washington University. (Washington, D.C.: April 2009).

¹³Taylor et al. 2009.

Three Federal Agencies Are Taking Actions to Better Ensure the Safety of Imported Food, but Enforcement and Collaboration Gaps Undermine These Efforts

Federal Agencies Have Taken Actions to Prevent Potentially Violative Food Products from Entering U.S. Commerce

CBP, FDA, and FSIS have each taken actions to better oversee the growing volume of imported foods. CBP addresses key challenges by maintaining the system that importers use to provide information to FDA on food shipments and has the authority to issue civil penalties against importers that fail to comply with regulations, among other things. CBP has also developed a national trade strategy, which is based upon six priority trade initiatives. One of the initiatives is an import safety strategy, which is a broad category that includes several general food safety provisions and goals, such as the detection and prevention of the unintentional introduction of unsafe food into the country. Furthermore, CBP has taken on a leadership role throughout the government on certain import-related issues. For example, CBP coordinates communication within government agencies to ensure that harmonized government procedures and requirements exist for shipments arriving by sea. The agency has also contributed to a special interagency effort called Operation Guardian, aimed at investigating imports of substandard, tainted, and dangerous products.

FDA electronically reviews all formal entries and inspects some foreign food production facilities to prevent violative food from reaching U.S. shores. For example, in 2008, FDA inspected 153 foreign food facilities out of an estimated 189,000 foreign food facilities registered with FDA; the agency estimates that it will conduct 200 inspections in 2009 and 600 in 2010. Inspections may entail reviewing documentation of adherence to safety controls, such as seafood Hazard Analysis and Critical Control Point procedures. (These procedures are designed to improve the safety of food by having industry identify and control biological, chemical, and physical hazards in products before they enter the market.) FDA officials told us

that they face logistical challenges in conducting foreign inspections, and to some extent must rely on the cooperation of manufacturers in advance of the inspection. During these visits, FDA may offer information to firms on how to bring their facilities into compliance with applicable FDA requirements. In 2008, we testified that if FDA were to inspect each of the 189,000 registered foreign facilities—at the FDA Commissioner’s estimated cost of \$16,700 per inspection—it would cost FDA approximately \$3.16 billion to inspect all of these facilities once.¹⁴ Appendix V provides data on FDA’s overseas facility inspections, while appendixes VI and VII present data on FDA’s and FSIS’s funding for food imports.

FSIS’s equivalency system requires that countries exporting meat, poultry, and processed egg products to the United States demonstrate that their food safety standards are equivalent to those of the United States. In addition, FSIS annually audits the food regulatory system in every country that exports meat or poultry products to the United States and physically examines 100 percent of the imported food shipments it regulates. FSIS is also developing the Public Health Information System, a new, Web-based computer system that will replace the agency’s current import screening system, the Automated Import Information System (AIIS). According to FSIS officials, the new system, which GAO has not reviewed, will allow FSIS to receive foreign health certificates electronically and will provide secure and timely advance notice of a foreign shipment certified by a foreign government. Once the new Public Health Information System becomes operational, FSIS officials expect that it will also streamline import processing procedures and enable the agency to electronically send and receive information on imported food shipments to and from CBP’s ACE system. However, CBP noted that its deployment of ACE has been significantly delayed.

¹⁴GAO, *Federal Oversight of Food Safety: FDA has Provided Few Details on the Resources and Strategies Needed to Implement its Food Protection Plan*, [GAO-08-909T](#) (Washington, D.C.: June 12, 2008).

Federal Agencies Face Gaps in Enforcement and Collaboration That Undermine Efforts to Ensure the Safety of Imported Food

We identified four gaps in enforcement and collaboration that could allow violative food products to enter U.S. commerce: (1) lack of information-sharing between agencies' computer systems, (2) FDA's limited authority to assess civil penalties on certain violators, (3) lack of unique identifiers for firms exporting FDA-regulated products, and (4) CBP's challenges in overseeing in-bond shipments. However, at two of the ports we visited, CBP and FDA officials are working together to overcome these problems.

Information-sharing between Computer Systems

CBP's computer system does not notify FDA or FSIS when imported food shipments arrive at U.S. ports, which increases the risk that potentially unsafe food may enter U.S. commerce, particularly at truck ports. If FDA chooses to examine a shipment as part of its admissibility review, the agency notifies both CBP and the importer or broker. FDA communicates this decision to CBP through its import screening system—the Operational and Administrative System for Import Support (OASIS)—informing CBP of FDA's intent to examine a product when it arrives at the port. However, once the shipment arrives at the port and clears CBP's inspection process, the importer is not required to wait at the port for FDA to conduct its examination. Instead, the importer may choose to transport the shipment to the importer's or consignee's warehouse or other facility within the United States. This may occur because CBP and FDA do not have the same hours of operation at some ports, and FDA's port office may be closed when the shipment arrives. In such cases, as a condition of the bond with CBP, the importer agrees to hold the shipment intact and not distribute any portion of it into commerce until FDA has examined it.

CBP and FDA officials told us that, occasionally, an importer will transport the shipment to the consignee's facility without first notifying FDA. If this occurs, FDA will not quickly know that the shipment has arrived and been transported to a U.S. warehouse or facility because CBP's ACS system does not notify OASIS when the shipment arrives at the port. Instead, from the perspective of an FDA entry reviewer using OASIS, it will appear as if the shipment's arrival is still pending. FDA port officials told us that it could be two or three days before FDA entry reviewers become suspicious and contact CBP to inquire about the shipment's arrival status. By this time, an unscrupulous importer could have distributed the shipment's contents into U.S. commerce without FDA's approval. If CBP communicated time-of-arrival information directly to OASIS, then FDA would be able to quickly identify shipments that are transported into the United States without agency notification and make arrangements to examine them before they are distributed to U.S. markets. Similarly, CBP's ACS system does not communicate with FSIS's AIIS

system to notify the agency when a shipment arrives at a port. This is problematic because FSIS-regulated shipments that clear CBP's inspection process must be transported to an FSIS-approved import facility near the port for reinspection. Since FSIS does not know when a shipment arrives, it cannot detect importers or brokers that fail to report to an import facility and present for reinspection imported meat, poultry, or processed egg products.

FDA officials at several ports told us that they have developed informal workaround solutions to alleviate the challenges posed by insufficient information-sharing between FDA's and CBP's computer systems. For example, at one port, officials told us that FDA entry reviewers contact CBP by phone or in person if they notice that a shipment designated in OASIS for examination does not appear to have arrived after several days. In this way, FDA can determine whether a shipment is still in transit to the port or whether the shipment has already arrived and the importer failed to notify FDA. At another port, FDA officials stated that when a shipment designated for FDA review arrives at the port, a CBP port official usually will notify FDA via telephone. However, agency officials also told us that successful informal collaboration depends on positive interagency working relationships between FDA and CBP port officials. These positive working relationships may be lacking at other ports.

The agencies have taken steps to address the lack of systematic time-of-arrival information. For example, FDA and CBP developed an interagency agreement that calls for CBP to modify its existing software to provide FDA with time-of-arrival information for air and land shipments. CBP stated that it had completed these software modifications and is working with FDA to test the system, in accordance with the interagency agreement. However, CBP has not developed a similar interagency agreement with FSIS.

In addition, CBP is in the process of updating its computer systems from ACS to ACE as part of its ongoing modernization efforts. One component of ACE is Cargo Control and Release, which comprises several modules and is intended to provide FDA, FSIS, and other agencies with a single, integrated system to more efficiently control and evaluate shipments for security and commercial compliance. However, it is unclear whether the addition of Cargo Control and Release modules to the ACE system would address the lack of timely notification of arrival. According to CBP, communicating time-of-arrival information to FDA and FSIS through ACE would require "a significant amount of work." Moreover, CBP has not scheduled a completion date for Cargo Control and Release and has not

even begun to develop this system. The Department of Homeland Security's Office of Inspector General reported in 2008 that the agency had scheduled Cargo Control and Release to be fully operational by July 2010.¹⁵ Since then, CBP has encountered delays in completing Cargo Control and Release owing to budget shortfalls and unforeseen difficulties in programming the system to meet agency requirements, according to CBP officials. We anticipated these problems in a prior report on ACE. Specifically, we reported in 2005 that, although the Department of Homeland Security had taken actions to help address ACE's cost and schedule overruns, these actions likely would not prevent similar problems in the future. We also found that the department had met its revised cost and schedule commitments in part by relaxing system quality standards, which we predicted would likely affect future system deployments.¹⁶

To its credit, CBP has developed ACE "portals" that grant FDA and FSIS staff "read-only" access to ACE data at ports where ACE is already operating in conjunction with ACS. After FSIS gained access to the ACE portal in 2006, for example, the agency's detection of illegally imported meat and poultry products increased sixty-fold. Nonetheless, these portals do not communicate time-of-arrival information to FDA's or FSIS's computer systems. Effective practices for collaboration and internal controls call for agencies to address the compatibility of data systems to ensure adequate means of obtaining information from external stakeholders that have a significant impact on agency goals.¹⁷ Moreover, in 2007, the Interagency Working Group on Import Safety recommended, among other things, that agencies improve the interoperability of government and private sector computer systems, to the extent allowable by law, to facilitate the exchange of information on imported products.

¹⁵Department of Homeland Security, Office of Inspector General, *Additional Controls Can Enhance the Security of the Automated Commercial Environment System* (Redacted), OIG-08-64 (June 2008).

¹⁶GAO, *Information Technology: Customs Automated Commercial Environment Program Progressing, but Need for Management Improvements Continues*, [GAO-05-267](#) (Washington, D.C.: Mar. 14, 2005).

¹⁷[GAO-06-15](#) and [GAO/AIMD-00-21.3.1](#).

FDA Has Limited Authority to Ensure Importers' Compliance

Importers can retain possession of their food shipments until FDA approves their release into U.S. commerce. FDA and CBP officials do not believe that CBP's current bonding procedures for FDA-regulated food effectively deter importers from introducing violative food products into U.S. commerce. According to these officials, many brokers and importers still consider the occasional payment of liquidated damages as part of the cost of doing business.¹⁸ Indeed, as we reported in 1998,¹⁹ forfeiture of the shipment's maximum bond value is often not sufficient to deter the sale of imported goods that FDA has not yet released. In its written response to our report, FDA agreed with this finding. According to FDA's regulatory procedures manual, the bond penalty is intended to make the unauthorized distribution of articles unprofitable, but liquidated damages incurred by importers are often so small that they, in effect, encourage future illegal distribution of imported shipments. Even though the bond may be up to three times the value of the shipment, for a large importer, this sum may be negligible, especially when the importer successfully petitions CBP to reduce the amount. FDA officials told us that if the agency had the authority to impose penalties on importers, it might be possible to better deter violations.

CBP and FDA Do Not Provide Unique Identification Numbers to Firms

High risk foods may enter U.S. commerce because the identification numbers that FDA uses to target manufacturers that have violated FDA standards in the past are not unique and therefore these manufacturers, and their shipments, may evade FDA review. Brokers or importers generate a manufacturer identification number at the time of import, when, among other things, they electronically file entry information with CBP. (CBP is responsible for validating the manufacturer identification numbers and ensuring they are unique.) CBP electronically sends this information to FDA's computer system. From a new manufacturer identification number, FDA's computer system automatically creates an FDA firm identification number—called the FDA establishment identifier. Officials told us that a single firm may often have multiple CBP manufacturer identification numbers—and therefore multiple FDA establishment identifiers. FDA officials told us that because CBP has multiple identification numbers for many firms, FDA has an average of three "unique" identifiers per firm, and one firm had 75 identifiers.

¹⁸CBP refers to the amount of the forfeited bond as liquidated damages; FDA sometimes refers to this amount as a bond penalty.

¹⁹[GAO/RCED-98-103](#).

The creation of multiple identifiers can happen in a number of ways. For example, if information about an establishment—such as its name—is entered by brokers incorrectly at the time of filing with CBP, a new manufacturer identification number, and therefore a new FDA establishment identifier, could be created for an establishment that already has an FDA number. In this scenario, a broker may—intentionally or unintentionally—enter a firm’s name or address slightly differently from the way it is displayed in FDA’s computer system. This entry would lead to the creation of an additional FDA number for that firm. If an import alert was set using the original FD establishment identifier, a shipment that should be subject to the import alert may be overlooked because the new number does not match the one identified in the alert.²⁰

In addition, foreign facilities that manufacture, process, pack, or hold food for consumption in the United States, with some exceptions, are required to register with FDA. Upon registration, FDA assigns a registration number. FDA calculated that in 2008, 189,000 foreign firms were registered under this requirement. However, some of the firms included in that total may be duplicates because the facility may have been reregistered without the original registration being canceled, and consequently FDA may not know the precise number of foreign firms registered.

FDA officials told us they are working to address the unique identifier problem by establishing an interactive process in which FDA’s systems recognize when a product’s identifier does not match its manufacturer’s registration number. In the interim, FDA officials told us that they have developed informal workarounds to address the problem. For example, they can identify and merge duplicate records, a process that is done manually, or, to some extent, can be done electronically. Furthermore, officials told us that the new PREDICT screening system has a feature that will assign higher risk scores to firms perceived by the system to be new, which may also include firms with multiple identifiers in FDA’s system.

FDA could consider requiring food manufacturers to use a unique identification number that FDA or a designated private sector firm provides at the time of import. However, the use of this unique number would necessitate collaboration with CBP, since importers would use such

²⁰Import alerts communicate information and policy to FDA field staff. Usually, they provide information that products covered by the alert are subject to detention. If detained, the importer can prove that the imported product is compliant, such as by providing FDA with the results of third-party laboratory analysis of the product.

a number each time they file with CBP to ship goods to the United States. That is, CBP's computer system would need to be programmed to accept an FDA unique identification number. According to CBP officials, it is unknown if or when CBP's system will have this capability.

CBP Faces Challenges in Overseeing In-Bond Shipments

To facilitate trade, CBP allows imported cargo intended for either U.S. or foreign markets to move from one U.S. port to another without duties or appraisal of the cargo and without entering U.S. commerce. This cargo—referred to as an in-bond shipment—requires a responsible party to obtain a CBP-approved bond and agree to comply with applicable regulations. Some CBP port officials have estimated that in-bond shipments represent from 30 percent to 60 percent of goods received at their ports. CBP officials told us that food is one of the most common types of products shipped using the in-bond system; other products include auto parts, textiles, and machinery.

Importers and shipping agents can use three types of in-bonds. First, the Immediate Transportation in-bond allows a shipment arriving at a U.S. port to be transported to another U.S. port, where it is entered into commerce. Alternatively, these types of in-bond shipments can be admitted to a bonded warehouse or foreign trade zone.²¹ Second, Transportation and Exportation in-bonds cover shipments that are in transit through the United States. For example, a shipment may arrive at a U.S. port and be transported through the United States and exported from another U.S. port. Finally, Immediate Exportation in-bonds are used for shipments that arrive and are unloaded at the U.S. port but are to be exported from that same port. FDA neither distinguishes between these various types of in-bonds, nor does the agency differentiate between in-bonds and other types of imported shipments. (Since FDA generally does not review or examine shipments for admissibility until the broker files entry, the agency is not concerned with the status of shipments prior to that stage). According to a CBP official, even though the agency does not examine in-bond shipments at the port of arrival, it can still deny an in-bond movement if it has reason to believe a given shipment contains a high risk product. However, some CBP, FDA, and FSIS officials expressed concern that in-bond cargo, including some

²¹For merchandise that is admitted into a foreign trade zone or bonded warehouse, duties and taxes are deferred until the goods are withdrawn for consumption. Goods may also be withdrawn from a bonded warehouse for export, thereby avoiding the payment of U.S. duties and taxes. Goods admitted to a foreign trade zone may be further processed and incorporated into new products, such as automobiles or refined petroleum products.

potentially violative food products, may be diverted from their final destination and illegally sold in the U.S. market.

We reported in 2007 that CBP did not effectively track in-bond shipments.²² For example, we reported that CBP did not consistently reconcile the in-bond documents issued at the arrival port with documents at the destination port to ensure that a shipment is either officially entered into U.S. commerce—with appropriate duties or quotas applied—or is re-exported. We made several recommendations to improve CBP's oversight of in-bonds that the agency has since addressed. For example, CBP has implemented our recommendation to use certain shipment-related information to ensure that the agency can adequately track in-bond shipments between the arrival and destination ports. In addition, CBP told us that they have provided guidance to field personnel on measuring importers' compliance with in-bond regulations. However, CBP has not yet finalized one of our key recommendations. Specifically, CBP agreed to amend a regulation to reduce the time allowed for transporting cargo and to limit importers' ability to change the final destination of in-bond shipments without the agency's knowledge. We found in 2007 that in-bond regulations provide unusual flexibility for the trade community, but create challenges for CBP. The regulations currently allow bonded carriers 15 to 60 days, depending on the mode of shipment, to reach their final destination and allow them to change a shipment's final destination without notifying CBP. According to agency officials, CBP has drafted amendments to the regulation, but as of July 2009, CBP had not issued a final regulation and was awaiting the Department of Homeland Security's approval for these amendments. Although it is commendable that CBP has taken this step, until the agency finalizes the regulation, concerns remain that potentially violative food imports could be shipped in-bond and enter U.S. commerce undetected.

CBP and FDA Officials Are Working to Overcome Enforcement and Collaboration Issues

Although the agencies have gaps in enforcement and collaboration, FDA and CBP have implemented joint initiatives at two ports we visited that, according to officials from both agencies, have improved interagency coordination. At the ports of Buffalo and Miami, FDA and CBP coordinate their efforts to issue a joint notice of action to the importer or broker when FDA identifies a food shipment that is violative or appears to be violative. This joint notice—which is issued through a unified arrangement

²²[GAO-07-561](#).

at the Buffalo port and by a formal joint operations team at the Miami port—combines FDA’s notice of refusal and CBP’s notice of redelivery, which are typically issued separately. According to agency officials, these separate notices can confuse importers and brokers because each agency has different (1) documentation requirements for the importer’s response to its notice, (2) procedures and deadlines with which the importer must comply, and (3) points of contact for responding to importer inquiries. Although the same information is communicated to the importer regardless of whether the notices are issued separately or jointly as a single notice, agency officials in Buffalo and Miami told us that the joint notice simplifies the import refusal process for CBP and FDA and is also less confusing to importers. The formal joint operations team in Miami provides a single point of contact for importers, which further simplifies the process. FDA and CBP officials, as well as a customs broker representative, told us that lack of coordination between agencies also occurs at other ports and results in confusion for industry. According to FDA and CBP officials, the joint notice of action appears to benefit both agencies; officials from both ports told us that (1) importer compliance with FDA’s refusal procedures and CBP’s redelivery procedures has improved and (2) FDA and CBP can better ensure that violative food products are either exported or destroyed. FDA’s guidance for imports recognizes that some FDA districts have developed joint notices of action and encourages districts to “follow local procedures” in this regard, but it also states that the use of joint notices of action has not been approved nationally.

Agency officials noted that to successfully develop a joint team, the two agencies should ideally be co-located, and managers must have good relationships. Moreover, effective practices for agency coordination call for agencies to establish strategies that work in concert with those of their partners or are joint in nature.²³ Such mutually reinforcing strategies help in aligning activities, core processes, and resources to accomplish a common outcome.

²³ [GAO-06-15](#).

FDA Collaborates with States and Foreign Governments, but Does Not Fully Share Information with States During a Recall

FDA has formal and informal mechanisms to work with the states on imported food safety. However, FDA does not always share market distribution information with states in the event of a recall, which makes it difficult for states to find and remove contaminated products from store shelves within state borders. According to the Interagency Working Group on Import Safety, federal and state governments have complementary roles and resources for ensuring the safety of imported food. Internationally, FDA has started opening offices overseas to collect information, collaborating with foreign counterparts, and educating exporters on U.S. food safety laws and regulations. FDA also exchanges food safety information with officials in counterpart agencies in several countries.

FDA Collaborates with Some States to Leverage Resources

As the Interagency Working Group on Import Safety noted in 2007, federal and state government can take complementary actions to ensure the safety of imported food. While the federal government can interdict unsafe imported goods at ports of entry, states can address unsafe imported products within their borders. The federal or state governments may have access to information relevant to protecting consumers that the other does not possess. For example, the federal government may have relevant information about the foreign source of the imported product and about the importer. This information can help state officials track down an unsafe imported product within their jurisdiction. On the other hand, state officials may identify an unsafe imported product during transport or at the point-of-sale, if the product does get into the country, and can tip off federal officials to prevent future shipments from entering domestic commerce. Therefore, FDA has entered into one contract, several cooperative agreements, and several informal partnership agreements with various states. In general, FDA uses a contract when it believes that it will benefit directly from the contract. It has such a contract with Michigan. Under this contract, the Michigan Department of Agriculture (MDA), the state's food safety body, has added imported products to its routine food inspections. An FDA employee in the Detroit district office determines the type of food to be inspected. As part of the 2008 through 2009 contract, for example, MDA sampled baked goods (turnovers), canned products (maraschino cherries), flour, bottled water, bulk cherries in drums, and fresh produce (peppers). MDA approached FDA about adding imports to its FDA contract because it recognized that Detroit was a major port for imported food. In addition, after melamine was found to have contaminated U.S. human and pet food products in 2007, Michigan focused more attention on imports. FDA concurred and added imports to the Michigan contract.

Under FDA's contract with the state of Michigan, if a violative situation is determined with an imported ingredient or an imported finished product, the state agrees to, in addition to its routine procedures, do the following:

- Conduct field examination so imported foods while in either import or domestic status at the establishment being inspected.
- Collect samples of imported goods while in either import or domestic status if indicated.
- Analyze samples of imported goods using FDA-approved methods and procedures.
- Supervise destruction or exportation, including marking activities, of imported products refused entry by FDA.
- Conduct traceback investigations of imported goods related to consumer complaints, adverse events, recalls, or other reports indicating significant health and safety problems associated with the products. The tracebacks will attempt to identify the foreign source or origin of the implicated product. The tracebacks will consist only of paper review at establishments.

According to an FDA official, FDA also enters into cooperative agreements with states. Cooperative agreements are appropriate when the principal purpose of the transaction is the transfer of money, property, services, or anything of value to accomplish a public purpose of support authorized by federal statute. Moreover, under a cooperative agreement, substantial involvement is anticipated between FDA and the recipient during performance of the funded activity. For example, FDA has 3-year cooperative agreements with six states to establish Food Hazard Rapid Response Teams to address emergencies, which may include incidents associated with imported food. The six states participating in these rapid response cooperative agreements are California, Florida, Massachusetts, Michigan, Minnesota, and North Carolina. The goal of these agreements is to develop, implement, exercise, and integrate an all-hazards food and foodborne illness response capability to rapidly react to potential threats to the U.S. food supply. To support these state efforts, FDA provides funding for program assessment, additional equipment, supplies, funding for personnel, training, and the development and coordination of the rapid response teams' exercises.

Finally, FDA enters into informal partnerships with states when both benefit. FDA has several informal partnerships for food imports; these partnerships facilitate federal-state cooperation but do not involve federal funding. The New York State Department of Agriculture and Markets (NYSDAM) and FDA's New York district office, for example, have partnerships for a joint inspection protocol and a joint sampling protocol. As part of the joint inspection protocol, NYSDAM food inspectors will enter warehouses specializing in food from a particular country or culture to look for violative imported products in domestic commerce. The state has the ability to immediately seize the product. (In exercising its food seizure authority, NYSDAM may prohibit the movement of food anywhere within the state.) A NYSDAM official told us that the joint inspection protocol has helped FDA generate a number of import alerts since it began. However, if NYSDAM finds that a sample tests positive for contamination, it must still send the sample to FDA for verification before FDA will take regulatory or enforcement actions, such as voluntary recalls or import alerts. FDA does not accept the results of states' laboratory tests at face value without further review or verification as the basis for an import alert because states typically use their own sampling, testing, and reporting standards, rather than FDA's generally stricter standards. FDA

may accept state results as the basis of a class I or class II recall.²⁴ At this time, FDA reviews the data, and then a decision is made on a case-by-case basis to either use the data or to verify the results before taking action. FDA can also adjust OASIS to target future shipments of the violative product type at the border.

Under the joint sampling initiative, NYSDAM collects food samples in the marketplace for analysis and sends them to a state laboratory for testing. If the product is imported, and if the state laboratory finds the sample to be violative, NYSDAM personnel will inform FDA and conduct a risk assessment. If FDA agrees, when NYSDAM staff go back to seize the product (if still present) they will collect a sample and send it to an FDA laboratory. FDA will process the sample in its computer system and submit it for laboratory analysis. If the FDA laboratory confirms that the sample is violative, the agency will issue an import alert.

In addition to the joint inspection and sampling initiatives, NYSDAM helps FDA track down a product in the marketplace if a food safety violation is detected after the product has entered commerce. In 2004 for example, according to New York state officials, a Chinese infant formula manufacturer produced a formula that was found to be deficient in several key ingredients and hence could not provide adequate nutrition for an infant. Although FDA had advised NYSDAM that there had been no entries listed in FDA's OASIS system for this imported infant formula, NYSDAM sent inspectors into Chinese-American neighborhoods, where they found the smuggled product for sale in an Asian market. NYSDAM seized, sampled, and tested the product and supervised its destruction after receiving confirmation from the state food laboratory that the product lacked appropriate nutritional value.

²⁴FDA categorizes all recalls into one of three classes, according to the level of hazard involved. Class I recalls are for dangerous or defective products that predictably could cause serious health problems or death, such as food found to contain botulinum toxin or food with undeclared allergens. Class II recalls are for products that might cause a temporary health problem or pose only a slight threat of a serious nature, such as the presence of dry milk—an allergen—as an ingredient in sausage without mention of the dry milk on the label. Class III recalls are for products that are unlikely to cause any adverse health reaction, but that violate FDA labeling or manufacturing regulations, such as a minor container defect or lack of English labeling in a retail food. However, with the exception of infant formula, FDA does not have the authority to order a recall of a food product. In most cases, food manufacturers voluntarily recall the product when there is a problem.

Other states also have informal partnerships with FDA on imports. For example:

- At FDA’s request, some states, including California, Illinois, New Mexico, and Washington, sometimes embargo imported foods that are found to be contaminated or violative and have already entered U.S. commerce.
- Florida’s Department of Agriculture and Consumer Services has “stop-sale” authority, granted under state law, which it can use if it determines that a food product is imminently dangerous or in violation of state public health law. FDA can ask the department to issue a stop-sale notice if circumstances warrant. An embargo or stop-sale action prevents the product from being sold to consumers, which allows FDA enough time to sample and test the product to determine whether, for example, a voluntary recall notice is warranted.
- New Mexico’s Environment Department performs surveillance of local grocery stores, looking for illegal imports from Mexico, such as *queso fresco*, a type of cheese often made from unpasteurized milk.
- The Texas Department of State Health Services has a Partnership Agreement with FDA’s Southwest Import District, based in Dallas, to coordinate surveillance of imported items in domestic commerce, including *queso fresco* and candies from Mexico. In addition, because the department has the authority to detain a product as soon as it detects a suspected violation, it can issue a food recall more quickly than FDA, which must conduct extensive, often time-consuming analysis to classify a food recall. (Recalls made by the state of Texas are independent of those made by FDA.) Once it confirms the violation, the state notifies FDA of its laboratory results and its intent to issue a recall letter or require the importer or wholesaler to do so. FDA may then notify its staff at the border to watch for the violative product and may also issue an import alert—but only after conducting the appropriate reviews. In some instances—particularly if the product is distributed nationally—FDA may request that a producer initiate a recall at the national level.
- Illinois has participated informally in a joint initiative with FDA in which state inspectors visited warehouses that were known to store imported products and performed checks for specific types of products from targeted companies. A state official told us that when FDA has requested this assistance, Illinois uses FDA forms and provides FDA with copies of inspection and laboratory results.

Given the range of possibilities for working with FDA, some state officials told us that they would like to collaborate further with FDA on food imports. For example, one state official told us that there could be value in having states inspect warehouses where imported goods are stored before entering into commerce. Another state official said that, budgets permitting, her agency would like to coordinate more on surveillance of imports in retail establishments. A third state official expressed interest in collaborating with FDA on testing for pesticide residues on imports. FDA has pointed out the need to work quickly when food contamination occurs and to coordinate a rapid response among FDA, state, and local governments. Because some states can issue recalls more quickly than FDA, a state official said it might be advantageous for FDA to leverage state resources so that violative products can be more quickly detained while FDA takes the legal steps necessary to ask the company to recall the product.

Although some state officials see opportunities for more collaboration with FDA, other state officials told us that, with limited resources, it is likely to be burdensome for them to divert resources to working with FDA on imports. These states prefer to focus their work on the domestic food supply, leaving FDA to focus on imported food.

FDA Does Not Always Share Product Distribution Information During a Recall

According to officials from several states, during food recalls, FDA generally does not share certain distribution-related information, such as a recalling firm's product distribution lists, which impedes the states' efforts to quickly remove contaminated products from grocery stores and warehouses. According to one state official, because FDA does not provide this information, the state has to spend time tracking it down on its own. Public health may be at risk during the time it takes for the states to independently track distribution information when a product is found to be contaminated. FDA told us that it usually considers such information to be confidential commercial information, the disclosure of which is subject to statutory restrictions, such as the Trade Secrets Act. However, FDA's regulations allow for sharing of confidential commercial information with state and local government officials if, for example,

- the state has provided a written statement that it has authority to protect the information from public disclosure and that it will not further disclose the information without FDA's permission and FDA has determined that disclosure would be in the interest of public health;
- such sharing is necessary to effectuate a recall;

-
- the information is shared only with state and local officials who are duly commissioned to conduct examinations or investigations under the Federal Food, Drug, and Cosmetic Act. In certain circumstances, FDA may also seek a firm's consent to disclose its market distribution information.

FSIS discloses certain distribution-related information to the public during a recall—specifically, the names and locations of the retail consignees of meat and poultry products that have been recalled by a federally inspected meat or poultry establishment if the recalled product has been distributed to the retail level. According to FSIS, the agency discloses information only when there is a reasonable probability that the use of the recalled product will cause serious adverse health consequences or death (class I recalls). FSIS officials stated that they do not consider this a release of business confidential or proprietary information because it is not releasing a firm's distribution list to the public. FSIS also does not post the names and locations of any of the intermediate consignees that received the recalled product or that routinely receive product from that firm. Rather, FSIS is making public a list that FSIS personnel compile only of the retail consignees that received recalled products. FSIS officials believe this information helps consumers reduce their risk of foodborne illness by providing more information that may assist them in identifying recalled products.

FDA Is Expanding Its Efforts to Coordinate with Other Countries in a Number of Ways

According to FDA, the agency initiated its Beyond Our Borders program in an effort to help prevent food that violates U.S. standards from reaching the United States. Under this program, FDA intends to open offices in China, Europe, India, Latin America, and the Middle East to provide technical assistance and conduct inspections, among other things. FDA will station investigators in some of the overseas locations, although FDA has decided not to station investigators in Latin American countries because of the region's close proximity to the United States. The program is also expected to provide FDA with direct access to information about foreign facilities' food manufacturing practices so that its staff at U.S. ports of entry can make informed decisions on which food imports to examine. For example, FDA expects that its overseas staff will be able to work with staff at counterpart regulatory agencies overseas, as well as with U.S. expatriates who may be knowledgeable about certain industries. Overseas staff will also educate local exporters to make sure they understand U.S. food safety laws and regulations. The offices in China (Beijing, Guangzhou, and Shanghai) opened in November 2008. FDA plans to post staff at the U.S. Mission to the EU in Brussels, Belgium; in the European Medicines Agency in London, England; and at the European

Food Safety Authority in Parma, Italy. The office in New Delhi, India, opened in January 2009; a second office in Mumbai, India, is expected to open later in 2009. FDA opened an office in San, José, Costa Rica, in January 2009 and also intends to open offices in Mexico City, Mexico, and Santiago, Chile. FDA has not opened offices in the Middle East because its request to do so was denied by the Department of State owing to security concerns. See table 1 for an overview of the locations and staffing of these planned offices. While it is too early to evaluate the program, an FDA official told us that the information the agency will acquire through its in-country presence may enable FDA staff at U.S. ports of entry to make more informed, risk-based decisions about which food imports to examine.

Table 1: FDA’s Planned Staffing Levels for Foreign Posts (35 U.S. nationals)^a

Geographic region and staff category	Number of staff (current as of 8/20/09)	Date first US national FDA employee arrived at post
China (Beijing, Guangzhou, and Shanghai)	4 (at post in Beijing) 2 (at post in Guangzhou) 2 (at post in Shanghai)	November 8, 2008 (Beijing) July 3, 2009 (Guangzhou) May 29, 2009 (Shanghai)
Foods	3 (including 2 inspectors)	
Medical products	4 (including 2 inspectors)	
Both	1 (office director)	
EU (Belgium, Italy, and United Kingdom)	1 (at post in Brussels) 1 (at post in London) 1 (not yet at foreign post)	May 11, 2009 (U.S. Mission to the EU in Brussels) June 25, 2009, FDA liaison at the European Medicines Agency (London) Plan is to have FDA liaison at the European Food Safety Agency (Parma) in early 2010
Foods	1	
Medical products	1	
Both	1 (office director)	
India (Mumbai and New Delhi)	5 (at post in New Delhi) 2 (at post in Mumbai) 5 (not yet at foreign post) ^b	December 9, 2008 (New Delhi) June 20, 2009 (Mumbai)
Foods	5 (including 3 inspectors)	
Medical products	6 (including 2 inspectors)	
Both	1 (office director)	

Geographic region and staff category	Number of staff (current as of 8/20/09)	Date first US national FDA employee arrived at post
Latin America (Chile, Costa Rica, and Mexico) ^c	4 (at post in San José) 1 (at post in Santiago) 3 (not yet at foreign post) ^d	April 29, 2009 (San José, Costa Rica) August 13, 2009 (Santiago, Chile) Plan is to have U.S. nationals at post in Mexico City on or around November 1, 2009
Foods	5	
Medical products	2	
Both	1 (office director)	
Middle East (Israel and Jordan)	0 (at post in Amman) 0 (at post in Tel Aviv) 4 (not yet at foreign post) ^e	Deployment date to Amman and Tel Aviv is uncertain at this time; FDA is still in discussions with the Department of State over site and timing of any deployments to the Middle East
Foods	1	
Medical products	1	
Both	2 (office director and 1 inspector)	

Source: FDA.

^aThese numbers include only U.S. nationals and only staff that are located (or to be located) in-country. Using these funds, FDA will also employ foreign nationals to assist with administrative and other support.

^bOne additional employee, an inspector, is scheduled to be at the post by the end of December 2009. FDA is in the process of filling the remaining four positions.

^cAn FDA official stated that it is not necessary to permanently station inspectors in Latin America because of the region's geographic proximity to the southern United States.

^dOf the three remaining positions, one has been hired for Mexico City and is expected to deploy on or around November 1, 2009. The second Mexico City position will be filled with a detailee also starting in Mexico on or around November 1, 2009. The third position is the second person FDA had hoped to post to Santiago, Chile. Owing to space considerations, however, the embassy in Santiago agreed to only one U.S. national. That position will be filled and posted in Rockville, Maryland until an alternative site can be agreed on or until the embassy agrees to the posting there.

^eFor now, FDA has established the Middle East Office in the Office of International Programs in Rockville, Maryland. The Director and the Medical Products Specialist are on board, and FDA is in the process of hiring the remaining two positions.

Furthermore, according to an FDA official, the agency works with its counterpart regulatory agencies in countries such as Australia, Canada, and New Zealand. High-level officials from the United States and these three countries hold a formal meeting every year and a teleconference every 3 months to strategize over food safety; exchange information, such as laboratory findings; and set public health limits on certain substances, such as pesticides. FDA also maintains confidentiality agreements with counterpart agencies in Canada, the EU, and the United Kingdom that allow FDA to share nonpublic information—with the exception of trade secret information. Routine information-sharing also occurs at the desk officer level in the event of an outbreak. For example, the Canadian Food Inspection Agency informally notified FDA when it detected a shipment of

caviar with dangerously low salt concentrations. (Salt is needed to prevent the growth of *Botulism* bacteria.) The Canadian agency ordered the product out of the country, so the importer attempted to return it to the United States. However, when FDA examined the returning shipment at the border, they found that not all of the caviar was accounted for, and some unlabeled cans were actually tuna. They notified counterparts in Canada, and Canadian officials were able to locate some of the product. Since the caviar was mislabeled, CBP treated the case as a smuggling incident, and the importer pled guilty to a misdemeanor FDA violation. Information also flows in the other direction. For example, in 2009, when peanuts from an American firm were found to be contaminated with *Salmonella*, FDA staff coordinated with their counterparts at the Canadian Food Inspection Agency. During the outbreak, FDA staff told their Canadian counterparts about the problem so Canadian officials could be on the alert for products from the Georgia company and remove them from the market.

PREDICT Testing Indicates that the System May Improve FDA's Risk-Based Import Screening Efforts, but Further Actions Are Needed

PREDICT, which uses FDA-developed criteria to estimate the risk of imported food shipments, reflects FDA's planned strategy of identifying food vulnerabilities and assessing risks, focusing inspections and sampling based on risk, and using science and modern technology systems. A 2007 pilot test of PREDICT in Los Angeles for seafood products indicated that the system, compared with baseline OASIS data, improved FDA's ability to target imports that the agency considers to be high risk for field or laboratory examinations. It also allowed a greater percentage of products the agency considers to be low risk to enter U.S. commerce without requiring an entry reviewer's intervention. Further actions are needed, however, to help ensure the system's success.

PREDICT Is a Risk-Based Screening System that Quantifies the Risk of Imported Food Shipments

According to FDA, it is developing PREDICT to improve its ability to target shipments for inspection that are more likely to violate FDA's regulations. The agency pilot-tested the system at several ports in the metropolitan Los Angeles area—including Los Angeles/Long Beach, the nation's busiest ports for seafood as ocean cargo, and Los Angeles International Airport, one of the busiest ports for seafood as air cargo—from June through September 2007 for seafood imports. FDA plans to begin deploying PREDICT on a district-by-district basis at all ports and for all FDA-regulated products (e.g., food, drugs, and medical devices) in September 2009 over a 6-week period.

PREDICT is to generate a numerical risk score for all FDA-regulated products by analyzing importers' shipment information using sets of FDA-developed risk criteria. These criteria are to incorporate, among other things, the violative histories of the product, importer, manufacturer, consignee, and country of origin; the results of laboratory analyses and foreign facility inspections; and general intelligence on recent world events—such as natural disasters, foreign recalls, and disease outbreaks—that may affect the safety of a particular imported food product. According to FDA, PREDICT will also randomly select a small number of shipments for examination and incorporate criteria—such as certain import alerts and import bulletins²⁵—historically used in OASIS to screen imports. In addition, agency officials stated that PREDICT will assign higher risk scores to firms for which the system does not have historical data. FDA believes that in some cases, these firms are new importers that do not have established track records with the agency, while in other cases these firms may be intentionally using multiple manufacturer identifiers to circumvent FDA's targeting screening criteria, including import alerts.

According to FDA, after PREDICT estimates the risk that an imported food shipment poses, the system is to present to entry reviewers the shipment's risk score if the score is above an FDA-specified threshold. Shipments that are below the threshold are to receive a system "may proceed" (cleared) message unless other conditions are present, such as an FDA import alert that flags the products for examination or detention without physical examination. FDA intends for entry reviewers using PREDICT to also be able to view the specific risk factors that contributed to the shipment's risk score, such as whether the product or importer has a history of FDA violations. FDA expects entry reviewers to use PREDICT to supplement, rather than replace, their professional judgment when deciding what food products to inspect.

PREDICT is also designed to improve screening efficiency by automating certain "data lookup" activities that entry reviewers currently must perform manually in several other systems, according to FDA.²⁶ For some

²⁵Import bulletins are generally informational only. While some import bulletins may identify potential problems with a product, unlike some import alerts, they do not provide information regarding detention without physical examination or other FDA action, although in some cases they may advise sample collections.

²⁶For example, according to agency officials, for low-acid canned food imports, entry reviewers must manually determine whether the importer's manufacturing facility is certified in additional FDA-required safeguards.

entries, the results of these data lookups may provide evidence that the product is low risk and does not require further FDA review. In such cases, an automated data lookup process would enable the system to “may proceed” these low risk entries—that is, automatically clear these shipments for U.S. commerce without a manual review. According to agency officials, FDA entry reviewers spend a significant amount of time performing these manual data lookups. The agency expects that PREDICT will substantially increase the system “may proceed” rate; as a result, entry reviewers will have more time to spend on higher-risk products.

Preliminary Data Suggest that PREDICT Could Improve FDA’s Screening Efforts

FDA’s PREDICT pilot test suggests that the system could enhance FDA’s risk-based import screening efforts. First, PREDICT improved the agency’s ability to identify imports that were more likely to violate FDA regulations. Specifically, PREDICT nearly doubled the percentage of field examinations—and increased by approximately one-third the percentage of laboratory examinations—that resulted in violative findings, relative to baseline OASIS data. Second, according to FDA, the violations in shipments that entry reviewers targeted using PREDICT, on average, posed a greater risk to human health than the violations that OASIS detected. In particular, the severity of the violations that FDA detected in field and laboratory examinations during the pilot increased by approximately 47 and 43 percent, respectively. Finally, PREDICT allowed a greater percentage of shipments the agency considers to be low risk to enter U.S. commerce without requiring manual review. The effective system “may proceed” rate for seafood imports increased from 6 percent to 39 percent during the pilot, which improved screening effectiveness and allowed entry reviewers to spend more time reviewing shipments FDA considers to be higher-risk.

FDA officials acknowledged a methodological limitation in the PREDICT pilot. Specifically, during the pilot FDA excluded all aquaculture-produced Chinese seafood from the comparison between OASIS and PREDICT. According to these officials, these products accounted for approximately 30 percent of the total volume of seafood shipments FDA screened during the pilot. According to agency officials, FDA excluded these products because it had previously issued an import alert during the pilot under which several types of seafood produced in China were subject to detention without physical examination because they appeared to violate applicable requirements, such as the presence of unsafe new drugs or food additives. Since these shipments were subject to detention without physical examination at the border, entry reviewers could not use PREDICT’s risk assessments to guide their decision to “may proceed” or

review the shipments. Agency officials stated that they do not believe that excluding these products significantly affected PREDICT's results, and the agency concluded that the pilot demonstrated PREDICT's benefits to import screening compared with the OASIS system.

Further Agency Action Is Needed to Help Ensure PREDICT's Success

Although the PREDICT pilot produced positive results and demonstrated the system's potential to improve import screening efforts, further agency actions are needed to help ensure that the system is effective. For example, FDA has not yet developed a performance measurement plan to evaluate, among other things, PREDICT's ability to identify high risk shipments for manual review while simultaneously returning "may proceed" messages for low risk shipments and enabling them to enter U.S. commerce. According to officials, a working group charged with developing an evaluation plan has met, but has not yet completed a plan. FDA officials told us that they intend to evaluate PREDICT after it has been in operation long enough to permit officials to collect and analyze a sufficient amount of data—officials provided a rough estimate of 3 months—but as of June 2009, the agency had not yet developed a plan to do so. Under federal standards for internal controls, agencies are to engage in the ongoing monitoring of programs to assess performance over time, including establishing policies and procedures to ensure that findings of reviews are promptly resolved.²⁷

We recently identified information technology management concerns that might hinder the rollout of FDA modernization projects such as PREDICT.²⁸ Specifically, we reported in June 2009 that FDA does not have a comprehensive information technology strategic plan to guide its efforts to modernize its information technology initiatives. Until it develops such a plan, FDA's efforts to modernize its information technology may not adequately meet the agency's urgent mission needs. We also found that FDA does not (1) have a well-defined enterprise architecture to efficiently and effectively guide and constrain the agency's modernization efforts,²⁹ and (2) strategically manage information technology human capital to

²⁷ GAO/AIMD-00-21.3.1.

²⁸ GAO-09-523.

²⁹ An enterprise architecture is a set of descriptive models (e.g., diagrams and tables) that define, in business and technology terms, how an organization operates today, how it intends to operate in the future, and how it intends to invest in technology to transition from today's operational environment to tomorrow's.

identify existing gaps between skills on hand and future needs. Without an effective enterprise architecture and information technology human capital management that is based on a strategic vision for the agency's information technology systems, FDA has less assurance that it will be able to modernize effectively and have the appropriate staff to implement and support its efforts to modernize. FDA generally agreed with our recommendations, stating that it is drafting a strategic plan for information management and has set a goal to complete the draft plan by the end of fiscal year 2009. FDA intends to include PREDICT in this plan. FDA also commented that it has made significant progress in developing an enterprise architecture program management plan and is assessing its workforce needs and developing hiring plans and priorities that will be used to recruit skilled personnel to the agency. However, FDA could not provide documentation to demonstrate its progress in developing the enterprise architecture program management plan, which we recommended should include a detailed work breakdown of the tasks, activities, and timeframes associated with developing the architecture, as well as the funding and staff resources needed.

According to agency officials, FDA intends to deploy PREDICT on a district-by-district basis for all FDA-regulated products beginning in September 2009. The agency previously intended to implement PREDICT in April 2009 but postponed the deployment because of unexpected delays in developing a system interface between PREDICT and OASIS. These delays, in turn, postponed necessary system testing and user training. Since 2005, FDA has spent approximately \$9 million on PREDICT. The agency estimates that PREDICT will cost an additional \$12.7 million over the next 5 years, plus additional funding for three or four full-time equivalent staff per year to manage the program once it is fully operational.

The EU Has Developed Some Practices That Could Inform CBP, FDA, and FSIS Practices

We reported in 2008 that increased public concern about food safety recently led the EU to reorganize its food safety system, including its procedures for overseeing food imports.³⁰ These procedures may provide insights into keeping food safe at the U.S. border. According to EU officials, the EU and the United States are facing many of the same challenges and have many of the same concerns related to food safety and imported food safety in particular. The EU takes a comprehensive, risk-based approach to ensure the safety of imported food by targeting products that are more likely to present risk, and taking steps to ensure that violative products do not enter EU countries.

Because the EU considers live animals and products of animal origin to be particularly high risk, mainly owing to past problems with *bovine spongiform encephalopathy* (mad cow disease), all such imports must enter the EU through approved border inspection posts, where government veterinarians are present. Imports are only permitted from approved third countries—non-EU countries intending to export to the EU—and approved establishments in these countries and must be accompanied by official certification of their compliance with EU animal health and food safety requirements. These shipments cannot leave the port without veterinary approval. Like FDA and FSIS, which are developing new computer systems to better manage risks associated with imported foods, the EU has implemented a new computer system, called the Trade Control and Expert System (TRACES). According to officials, nearly all member states already use TRACES. The system automatically updates information about live animals and products of animal origin entering the EU and is linked to the EU's Rapid Alert System for Food and Feed (which covers all types of food) in order to automatically communicate alerts to all border inspection posts.³¹ The link between TRACES and the Rapid Alert System makes it easier to quickly see if products arriving at the border have been flagged for closer inspection. According to EU officials we spoke with, the creation of this computer system was largely motivated by the need for EU policymakers to have a more complete, centralized view of the entire supply chain for high risk products and to facilitate greater traceability. As such, TRACES provides a

³⁰ [GAO-08-794](#).

³¹ For information on the U.S. animal identification system, see GAO, *National Animal Identification System: USDA Needs to Resolve Several Key Implementation Issues to Achieve Rapid and Effective Disease Traceback*, [GAO-07-592](#) (Washington, D.C.: July 6, 2007).

single window for all points of trade and government regulatory actions related to public health and animal health for all imported products of animal origin and live animals—tracking these products before they enter the EU, during the entry process at ports, and once they are released by the veterinary authority. EU officials told us this system will enhance their ability to track products throughout the supply chain—“trace back” and “trace forward”—during outbreaks of foodborne illness or other emergencies, which is a goal that FDA has stated it is pursuing for the products it regulates. In addition, when products are rejected for entry, all border inspection posts are automatically notified about this rejection through TRACES. This practice is intended to prevent importers from attempting to have rejected goods enter the EU through a different port, that is, “port-shopping,” which is also a concern in the United States.

In addition to concerns about port-shopping, the EU has concerns regarding “transshipment” violations, in which goods intended for export to non-EU countries illegally enter the EU market while in transit to those countries through the EU.³² In order to be allowed to transship products of animal origin through the EU, the products must meet all EU animal health requirements—according to officials, this is an important way of lowering risks in the event that these products are sold in the EU rather than exported as intended. Additionally, the EU has implemented a monitoring system to ensure that these products leave the EU through an exit border inspection post, which has to confirm to the entry border inspection post that the shipment in fact left the EU.

Unlike products of animal origin, foods of nonanimal origin—except for certain high risk foods (including, for example, certain nuts and spices)—may enter the EU through any port, as they do in the United States, and screening systems vary somewhat from country to country. To inspect these types of food products, the EU allows member states to use their own sampling methodologies and their own national laboratories, which are most often accredited by a nongovernmental body, the International Standards Organization. This approach may be of interest to U.S. agencies as they seek to leverage their resources, where appropriate, by using data from state agencies and third parties.

³²For more information on transshipment involving seafood, see GAO, *Seafood Fraud: FDA Program Changes and Better Collaboration among Key Federal Agencies Could Improve Detection and Prevention*, [GAO-09-258](#) (Washington, D.C.: Feb. 19, 2009).

If veterinary or port officials reject a food shipment, whether of animal or nonanimal origin, the shipment cannot leave government custody for exportation to another, non-EU country until that country's counterpart agency officially accepts the shipment in writing. Officials told us that this requirement increases their confidence that such goods will not re-enter the EU through another port. Furthermore, EU laws place the primary responsibility for food safety on producers and other private sector entities, recognizing the important role industry plays in food safety, as it does in the United States. In the EU, for example, importers bear the cost of mandatory inspections and mandatory laboratory tests. In addition, the monetary burden for noncompliance with government regulations (for example, the cost of destroying rejected goods) is placed on importers or the next private sector entity involved in the importation process, such as a port terminal operator or warehouse owner. Because of the financial responsibilities noncompliance entails, officials told us that there is a climate of peer pressure among industry actors to adhere to government regulations. This approach may be of interest to U.S. agencies in light of concerns about the insufficiency of present measures to deter importer noncompliance.

Conclusions

Increasing amounts of fresh produce, fish, and other food products from around the world have enriched U.S. diets and allowed Americans to enjoy certain foods in all seasons. But these benefits also carry with them the increased risk of foodborne illnesses, some of which can damage health over the long-term and even cause death. While CBP, FDA, and FSIS have taken steps to address food safety challenges, gaps in enforcement and collaboration limit confidence in CBP's, FDA's, and FSIS's efforts to prevent potentially unsafe imported food from entering U.S. commerce.

Problems in identifying and tracking food shipments can begin at the port of entry. Effective communication between CBP's computer system and those FDA and FSIS use to track shipments is essential so that potentially violative food products can be screened as expeditiously as possible. CBP and FDA have developed an interagency agreement to provide time-of-arrival information to FDA using CBP's ACS system. However, it is unclear whether CBP's new system (ACE), as currently planned, will keep either FDA or FSIS informed about the arrival times of incoming food shipments, particularly in light of delays in this system's development and deployment. We believe that this lack of communication among the agencies is problematic because it may allow potentially violative food to enter U.S. commerce without FDA's or FSIS's knowledge or approval. Equally problematic is FDA's lack of authority to assess civil penalties to

deter importers from bringing violative goods into the country. According to FDA's regulatory procedures manual, liquidated damages that importers incur are often so small that they, in effect, encourage future illegal distribution of imported shipments. Finally, the importer's ability to appeal CBP's decisions on the bond amount further limits the bond's effectiveness as a deterrent. Even if these first two problems were effectively addressed, FDA is still hampered in its efforts to target potentially unsafe shipments of imported food because of the multiple CBP identifiers that may be associated with a single foreign firm. As a result, importers may circumvent FDA's systems for targeting higher-risk imported food products.

To their credit, FDA and CBP officials at some ports have worked together to facilitate the redelivery of food shipments that FDA has identified as violating food safety standards. As these officials told us, this approach has facilitated importer compliance with refusal and redelivery procedures and therefore better ensures that violative food products are either exported or destroyed. We believe that such a joint initiative could be feasible at other ports.

FDA also cooperates to some extent with state governments to inspect and sample imported products, although states have identified additional opportunities for federal-state collaboration on import safety. For example, states can quickly remove violative food from stores while FDA goes through the often time-consuming legal process required to ask the company to recall its product. Furthermore, we believe that it is in the public's interest that FDA share with states as much information as possible under the law on product distribution to facilitate the recall of violative imported food in order to minimize potential harm to public health.

Finally, FDA's PREDICT system, which could improve the agency's ability to screen imported food products on the basis of risk, is a step in the right direction, but some actions have not yet been taken to ensure that the program will fully succeed. For example, without a plan to measure the system's performance, FDA cannot assess PREDICT's effectiveness or determine whether additional actions are needed.

Recommendations for Executive Action

To help ensure that CBP, FDA, and FSIS are able to effectively oversee the safety of imported food, we are making the following ten recommendations:

To ensure that FDA and FSIS receive the information they need to adequately oversee imported food safety, we recommend that the CBP Commissioner ensure that CBP's new screening system communicates time-of-arrival information to FDA's and FSIS's screening systems. Furthermore, until this new system is capable of communicating this information, we recommend that CBP implement its interagency agreement with FDA to provide time-of-arrival information and explore opportunities to implement a similar agreement with FSIS.

To enhance FDA's authority to oversee the safety of imported food, we recommend that the FDA Commissioner seek authority from the Congress to assess civil penalties on firms and persons who violate FDA's food safety laws. We further recommend that the Commissioner determine what violations should be subject to this new FDA civil penalties authority, as well as the appropriate nature and magnitude of the penalties.

To improve CBP's and FDA's ability to identify foreign firms with violative histories, we recommend the following actions:

- The CBP Commissioner should ensure that ACE is able to accept a unique identification number for foreign firms that export FDA-regulated foods.
- The FDA Commissioner should explore ways to improve the agency's ability to identify foreign firms with a unique identifier.

To enhance agency coordination and to streamline FDA's refusal process with CBP's redelivery process, we recommend that the FDA Commissioner and the CBP Commissioner jointly study, with input from agency field officials, ports where a joint initiative would be feasible.

To better leverage state resources for protecting the safety of imported food, we recommend that the FDA Commissioner reach out to states to find opportunities for additional collaboration through contracts, cooperative agreements, and informal partnerships.

To enhance public safety, we recommend that the FDA Commissioner find ways to share with states product distribution lists, to the extent permitted by law, while also protecting confidential commercial information, and if necessary, consider what regulatory or legislative changes may be needed to allow FDA to share otherwise protected information with states while preventing public disclosure.

To help ensure that PREDICT is effectively targeting high risk imported food shipments for field and laboratory examinations, we recommend that the FDA Commissioner develop a performance measurement plan prior to deploying the system at additional U.S. ports.

Agency Comments and Our Evaluation

We provided a draft of this report to CBP, FDA, and FSIS for their review and comment. CBP agreed with our recommendations but disagreed with some of our conclusions. Specifically, CBP stated that we provided no evidence that in-bond shipments are (1) riskier than other shipments, or (2) unlawfully diverted into commerce because of CBP's failure to update its regulations on reducing the time allowed for transporting cargo and limiting the ability of carriers to change the final destination for cargo without CBP knowledge. However, as we described in our 2007 report, we found that CBP's in-bond regulations provide unusual flexibility for the trade community but create challenges for CBP. One regulation currently allows in-bond shipments 15 to 60 days, depending on the mode of shipment, to reach their final destination and allow importers to change a shipment's final destination without notifying CBP. In response to our recommendation, CBP agreed to amend this regulation, but as of July 2009, CBP had not yet finalized it; we continue to believe that the agency should do so.

In addition, while CBP acknowledged that its computer system is unable to communicate time-of-arrival information at this time, the agency noted that this has a limited impact on FDA's enforcement. Specifically, CBP stated that (1) FDA is made aware that products of interest are about to arrive or have arrived in the United States via other communication mechanisms, and (2) FDA can assess the risk of incoming shipments through its Prior Notice requirement and the transmission of data through the CBP entry process. However, as we have pointed out, other communication mechanisms, such as informal workarounds between the agencies, may not be effective at all ports. Moreover, Prior Notice only provides a general time frame for arrival of goods and may not be specific enough for FDA to know precisely when a given shipment that it has designated for examination will arrive at the port. Similarly, information submitted through the CBP entry process does not include precise time-of-arrival information.

Finally, CBP provided an update of its efforts to modify ACS to convey time-of-arrival information for FDA-regulated air and truck shipments. We have incorporated this information in the report.

FDA also generally agreed with our recommendations. Although the agency agreed in principle with our recommendation on developing a joint refusal/redelivery process, FDA does not believe that a study is warranted, noting that discussions with CBP on this topic have already begun. We continue to believe that a study is valuable because (1) it would document best practices and lessons learned at ports where joint initiatives are currently underway and would identify potential obstacles to joint initiatives, and (2) it would provide evidence of collaborative efforts. In its technical comments, FDA noted that the lack of time-of-arrival information does not increase the risk that potentially unsafe food may enter U.S. commerce without FDA review. Rather, FDA pointed out that the bond between CBP and the importer, not the FDA examination, is the deterrent to the distribution of the cargo without release. However, FDA's Import Procedures Manual states that "very often penalties are so small that [they] in effect encourage the illegal distribution of future imported [shipments]." In addition, FDA agreed with our recommendation that the agency seek authority from the Congress to assess civil penalties on firms and persons who violate FDA's food safety laws. Moreover, although time-of-arrival information would not prevent importers from distributing food shipments prior to FDA review, it would represent additional information the agency could use to enhance its review process.

FSIS only provided technical comments, which we included as appropriate.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to CBP, FDA, FSIS, and other interested parties. The report will also be available at no charge on the GAO Web site at <http://www.gao.gov>.

If you or your staff members have any questions about this report, please contact me at (202) 512-3841 or shamesl@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix X.



Lisa Shames
Director, Natural Resources
and Environment

Appendix I: Objectives, Scope, and Methodology

To respond to the question of how the agencies address challenges in overseeing the safety of imported food, we collected documents, such as strategic plans and procedure manuals, analyzed the procedures agencies follow to screen imported food, and interviewed officials from Customs and Border Protection (CBP), the Food and Drug Administration (FDA), and the Food Safety and Inspection Service (FSIS). However, we focused primarily on CBP and FDA because the U.S. Department of Agriculture Office of Inspector General has conducted several detailed reviews of FSIS's import procedures in recent years. We also spoke with representatives of industry—including trade associations and customs brokers—as well as consumer advocacy groups and other food safety experts. In addition, we visited five U.S. ports on different borders or coasts where differing modes of transportation—ship, airplane, and truck—are used to bring products into the country. These ports were at Baltimore, Maryland; Buffalo, New York; Laredo, Texas; Los Angeles/Long Beach, California; and Miami, Florida. At each port, we interviewed agency officials and observed agency officials physically examining incoming shipments to determine whether the shipments met U.S. food safety standards and labeling requirements. In four of the five ports, we observed staff reviewing imports electronically. We assessed the agencies' collaboration efforts using criteria that we have developed in prior work on agency collaboration and coordination.

To determine the extent to which FDA leverages resources for overseeing the safety of imported food by working with state governments, we spoke with officials from FDA, as well as officials in Arizona, California, Florida, Michigan, New Mexico, New York, Texas, and Washington; all of these states are border states, and are also home to large, high-volume ports. We also interviewed officials in one inland state—Illinois—because Chicago's O'Hare International Airport receives a high volume of in-bond shipments from other ports. To determine the extent to which FDA leverages resources with foreign governments for imported food safety, we reviewed agency documentation and spoke with a senior FDA official who is responsible for FDA's international initiative. We focused primarily on FDA because it regulates roughly 80 percent of the food supply and because of our longstanding concerns regarding the agency's need to better leverage its limited resources.

To describe how the Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting (PREDICT) is being used to oversee the safety of imported food, we reviewed and summarized formal assessments of PREDICT that both FDA and one of its contractors had conducted. We also spoke with FDA officials responsible for managing and implementing

PREDICT, as well as several FDA contractors charged with developing the system, and we observed its use at the Los Angeles/Long Beach and Buffalo ports. In addition, we leveraged recent GAO work assessing FDA's information technology modernization efforts. We did not review PREDICT's hardware or software environments and testing activities or assess the quality of the criteria the system will use to quantify risk.

To learn about leading practices at EU ports, we visited two EU ports, Antwerp, Belgium and Rotterdam, the Netherlands. We selected these ports because they are two of the largest in the EU and accept shipments of high risk products. Moreover, according to EU officials, these ports are known for using leading practices in screening food imports. We did not independently verify statements of EU law.

Under the Federal Food, Drug, and Cosmetic Act, FDA's authorizing legislation, the term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article. We use this definition, which also includes meat, poultry, and egg products, in this report.

We conducted this performance audit from July 2008 to September 2009 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: FDA Field Examinations, Fiscal Years 2006 through 2009

	2006	2007	2008	2009 (estimated)
Import lines ^a	8,883,999	9,356,074	9,441,024	9,526,745
Import field exams and tests ^b	94,545	94,743	100,718	120,000
Import laboratory samples analyzed	20,662	24,558	23,052	26,200
Import physical exam subtotal	115,207	119,301	123,770	146,200
Percent of import lines physically examined	1.30%	1.28%	1.31%	1.53%

Source: FDA.

^aAll imported food entry lines, each of which represents a separate FDA decision under Section 801(a) of the Federal Food, Drug, and Cosmetic Act. An entry line is each portion of a shipment that is listed as a separate item on an entry document.

^bIncludes import sample collections, import label exams, import entry reviews, and other import investigations.

Appendix III: FSIS Inspections at Ports of Entry, Fiscal Years 2006 through 2008^a

	2006	2007	2008
Shipments presented	219,979	217,634	208,409
“Skipped” shipments ^b	188,820	195,532	188,854
“Inspected” shipments ^c	31,159	22,102	19,555
Percent of shipments inspected	14.2 %	10.2 %	9.4 %
Total pounds presented	3,888,188,159	3,896,425,509	3,278,956,513
Total pounds refused^d (percentage)	177,034 (0.005%)	149,173 (0.004%)	93,731 (0.003%)
Total pounds rejected^e (percentage)	12,124,451 (0.312%)	9,124,547 (0.234%)	2,715,089 (0.083%)
Total pounds accepted (percentage)	3,875,876,497 (99.683%)	3,887,151,789 (99.762%)	3,276,147,693 (99.914%)

Source: FSIS.

^aAfter an incoming shipment has met CBP and other requirements, it must be reinspected at an FSIS-approved import inspection facility.

^bFor “skipped” shipments, an FSIS inspector examines the shipment’s general condition and ensures that it is labeled correctly and has proper documentation.

^cFor “inspected” shipments, an FSIS inspector may physically examine the shipment for visible defects, collect samples for laboratory analysis, or both. As with “skipped” shipments, FSIS inspectors examine “inspected” shipments’ general condition and ensure they are labeled correctly and have proper documentation. See appendix IV for more detail on FSIS screening processes.

^dProducts are refused reinspection if (1) the foreign country is not eligible; (2) the foreign establishment is not listed; (3) USDA’s Animal and Plant Health Inspection Service has placed animal disease restrictions on the country; (4) the product presented for reinspection is not eligible; or (5) there are duplicate shipping marks.

^eProducts are rejected if they fail to meet U.S. import requirements.

Appendix IV: Agencies' Processes to Oversee Imported Food

CBP, FDA, and FSIS have unique responsibilities for implementing federal laws on imported food products, and they work together to ensure the safety of these products.

CBP

CBP enforces the import regulations of 46 federal agencies. If an agency, such as FDA or FSIS, detects a problem with a particular shipment, CBP will levy the appropriate fines and penalties and oversee exportation or destruction of the violative goods.

Importers or their brokers must notify CBP of an incoming shipment, whether food or other products, by electronically submitting information on the shipment to either CBP's legacy computer system, the Automated Commercial System (ACS), or the Automated Commercial Environment (ACE), the agency's replacement system, depending on which system operates at the port. CBP screens the incoming information primarily for national security purposes and potential terrorism threats. With respect to high risk imports, CBP uses ACS or ACE to determine whether to inspect incoming shipments using multiple criteria.

In addition to Prior Notice information,¹ brokers, acting on behalf of importers, generally must submit an invoice to CBP that describes the merchandise, quantity, value, country of origin and Harmonized Tariff Schedule classification, which is a schedule of tariffs associated with individual products. Collectively, these documents are referred to as "entry documents." All entry documents must be filed before the imported goods are allowed to be released ("entered") into U.S. commerce, and entry must occur within 15 days after the shipment arrives in the United States. ("Arrival" occurs when a shipment physically comes within port limits. "Entry" occurs when the documentation on the shipment is filed and a CBP officer authorizes the shipment's release.) CBP has the authority to conditionally release goods and may demand redelivery of the merchandise within 30 days if problems are discovered. If the importer does not redeliver the goods to CBP once a notice for redelivery has been issued, the importer is subject to liquidated damages. CBP is also authorized to detain merchandise upon arrival in order to determine

¹Under FDA regulations promulgated in response to the Public Health, Security, and Bioterrorism Preparedness and Response Act of 2002, FDA must receive Prior Notice information in advance of the food shipment's arrival. This information includes the names and addresses of the importer, owner, and consignee; FDA product code for the food; and country of production.

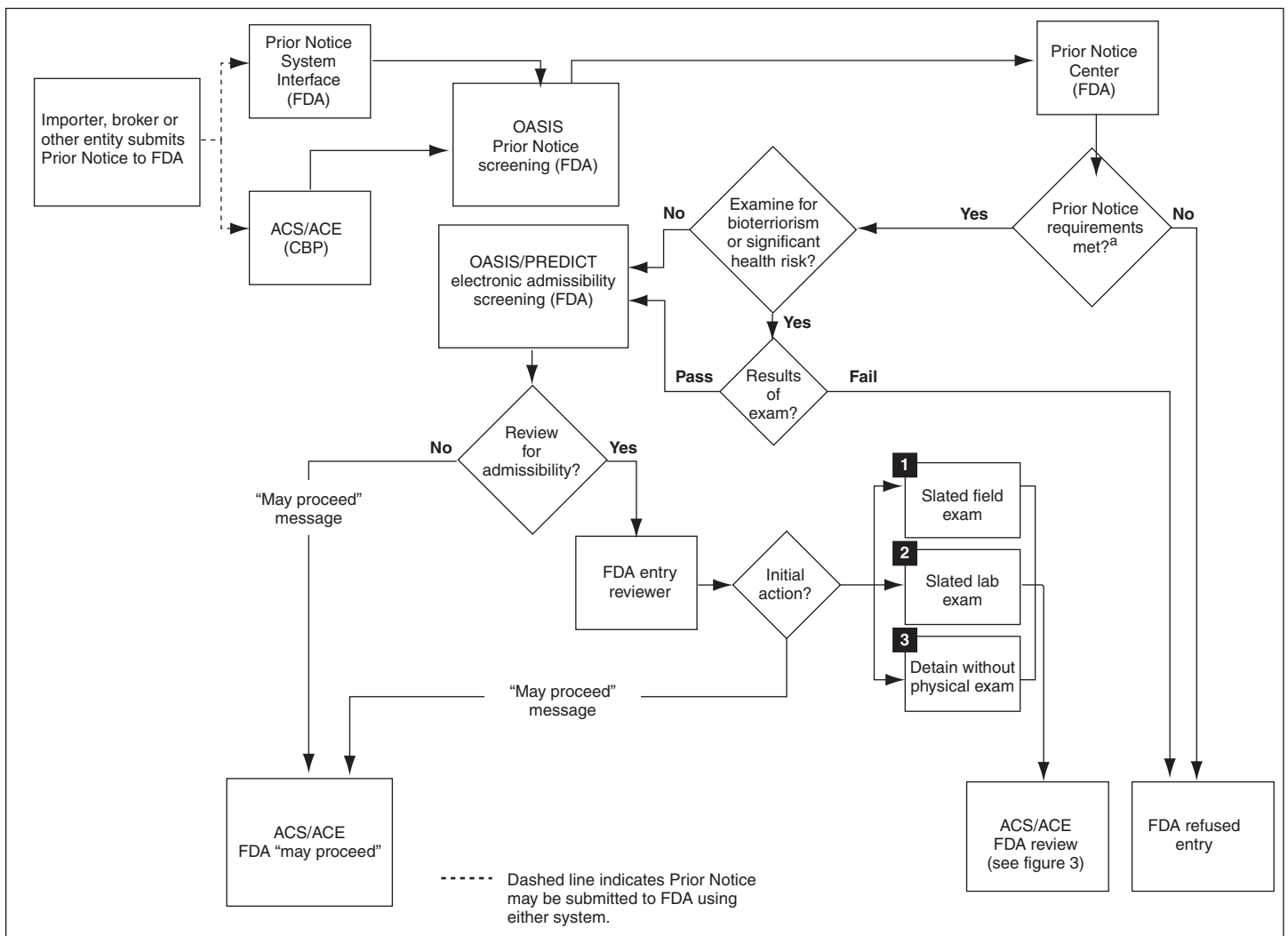
whether the goods are admissible into the United States and may seize the merchandise if warranted.

All formal entries (i.e., those valued at more than \$2,000, as well as certain other entries under that amount) must be covered by a bond, which guarantees payment to CBP if the importer violates a condition of the bond. Importers may use two types of bonds: (1) a single transaction bond, which covers a one-time transaction, or (2) a continuous bond, which covers multiple transactions (i.e., if the importer frequently imports to the United States). A bond may be secured by a surety (corporation or individual) or by the deposit of U.S. government obligations or cash. After the shipment has been released, the importer must file an “entry summary,” the final step in the import process, and pay the appropriate duties and taxes within 10 working days after the release. The entry summary is closed out, usually within a period of 314 days—that is, CBP determines that the shipments are admissible and closes the books on them, collecting any outstanding taxes or duties that were estimated at entry. At any point prior to this, if the importer fails to pay any additional duty determined to be due on liquidation or violates a condition of the bond, CBP will issue a bill for payment of any duty owed or may issue a claim for liquidated damages amounting to up to three times the value of the shipment. However, the importer can request administrative review of such actions within 180 days after the entry summary is closed out. Based on this review, for which there are strict guidelines, CBP may mitigate (i.e., reduce) the amount of liquidated damages assessed.

FDA

Figures 2 and 3 show the processes that FDA follows for shipments. Figure 2 shows the initial process FDA follows to review all shipments, while figure 3 shows the procedures that are followed when FDA decides further review is necessary.

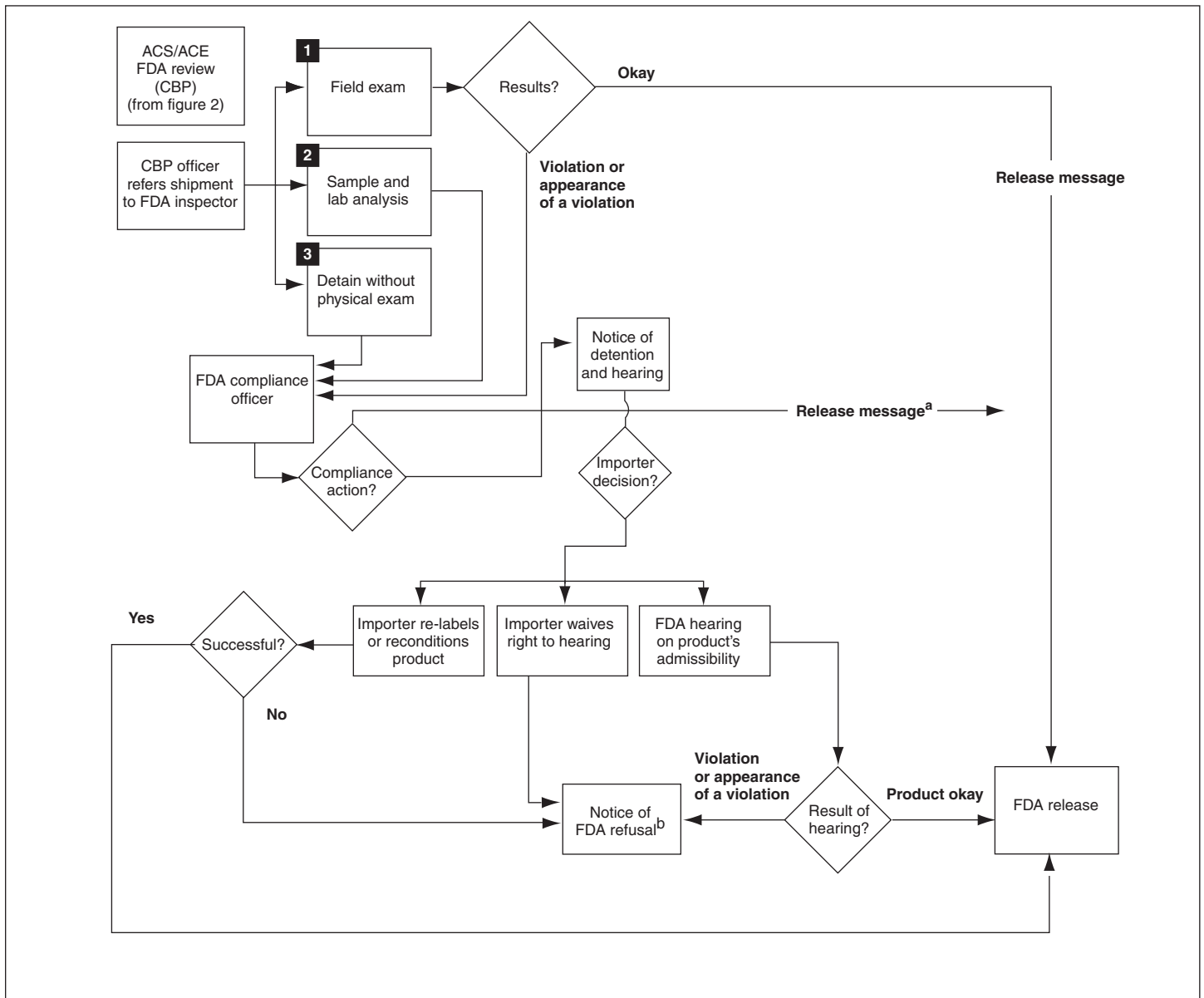
Figure 2: FDA's Process for Electronically Screening Imported Food Shipments



Source: GAO.

*FDA officials told us that in certain cases when Prior Notice information requirements are not met, the agency will notify the submitter and allow the information to be amended if the problem is easily corrected. In such cases, FDA would allow the shipment to proceed to admissibility screening, provided the amended Prior Notice satisfied FDA requirements.

Figure 3: FDA's Process for Examining Selected Imported Food Shipments Before Allowing Entry into U.S. Commerce



Source: GAO.

^aIn some cases, a shipment may not fully comply with FDA requirements, but the violation is not sufficient to warrant an FDA detention. In such cases, the shipment may receive a “released with comment” message.

^bIf FDA issues a notice of refusal, the importer must decide whether to re-export or destroy the refused product. Some unscrupulous importers may choose to distribute the product and pay liquidated damages under the terms of the CBP bond.

Under FDA regulations promulgated in response to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, (1) food facilities must be registered with FDA and (2) FDA must receive Prior Notice information in advance of the food shipment's arrival. Prior Notice information—which includes the names and addresses of the importer, owner, and consignee; FDA product code for the food; and country of production—can be submitted to CBP or directly to FDA. In either case, Prior Notice information is automatically transmitted to the Operational and Administrative System for Import Support (OASIS), FDA's computerized food import screening system. FDA reviews the information to ensure that the Prior Notice requirements have been met and to determine whether the food potentially poses a bioterrorism or other significant health risk such that FDA should deploy resources to the port of arrival so that an inspection can be conducted before the product enters the United States. If the Prior Notice requirements are not met, the food is subject to refusal and, if refused, must be held until adequate Prior Notice is submitted.

Once FDA has verified that the Prior Notice requirements have been met and the results of FDA's Prior Notice screening indicate that the shipment does not appear to be a potential bioterrorism or significant public health threat, the shipment is allowed to proceed for further processing, including FDA's admissibility review. For the admissibility review, the agency electronically screens the product using OASIS to determine whether it should be automatically "may proceeded" (i.e., allowed to proceed into U.S. commerce without further FDA action). A product is automatically "may proceeded" by OASIS if the system can determine that it is not covered by an existing rule in the system, such as an import alert, import bulletin, or other agency regulation (e.g., FDA's requirement that facilities that manufacture low-acid canned foods must be certified in applicable safeguards). If the product is not automatically "may proceeded" after this initial electronic screening, it is referred to an FDA entry reviewer at the district office for a manual "on-screen" review. During manual reviews, entry reviewers use their professional judgment—as well as available FDA intelligence, such as import alerts and import bulletins—to determine whether FDA should take further action on a shipment or if the shipment should be manually "may proceeded" and released into U.S. commerce. For example, if the entry reviewer determined that a particular shipment was high risk, the entry reviewer could select it for an FDA examination at the port or another location, flag it for a laboratory analysis at one of FDA's 11 (out of 13 total) regional laboratories that perform testing on food, or if the food appears to be noncompliant, detain it without physical examination. Once the entry

reviewer decides whether to “may proceed” the shipment or take further action, FDA transmits this information to CBP’s ACS or ACE system. FDA’s new PREDICT system is intended to replace OASIS for both electronic admissibility screening and manual review.

If FDA determines that a shipment should be physically examined in the field—either at the port of entry or at another location, such as the importer’s or consignee’s warehouse or a cold storage facility—this examination must occur before the shipment can enter U.S. commerce. An FDA official would examine the product for such things as rodent or insect activity, inadequate refrigeration, and label compliance, and may take samples from the product for a laboratory analysis to test for pesticide residues, suspected microbiological contamination, and other toxic elements. If the examination and analysis indicate that the product is in compliance, FDA releases the shipment into U.S. commerce. However, if FDA finds a violation or an appearance of a violation, it will issue a notice of detention and hearing to the importer or consignee. FDA may also detain a product without physical examination, if, for example, a food product is on a certain type of import alert. The owner or consignee may control the shipment pending the results of FDA’s examination, but the shipment must be held intact and not distributed until FDA clears it. If the owner or consignee distributes the shipment’s merchandise without FDA’s approval, FDA can ask CBP to take action against the shipment’s entry bond.

If a product is detained, the owner or consignee is given the opportunity at a hearing to provide evidence that the shipment complies with FDA standards or, in some situations, can request authorization to relabel or recondition the shipment to bring it into compliance. If the owner or consignee fails to recondition the shipment or provide sufficient evidence that it already complies with FDA standards, or waives the right to a hearing, FDA issues a notice of refusal. The importer can then either re-export the product or destroy it. FDA and CBP coordinate with each other to verify that one of these two outcomes has occurred; if the importer fails to comply and instead releases the product into commerce despite FDA’s refusal notice, FDA will report the incident to CBP, which issues the redelivery notice. Ultimately, CBP has the authority to issue a claim for liquidated damages if the importer fails to redeliver the shipment, as required by the terms of the bond.

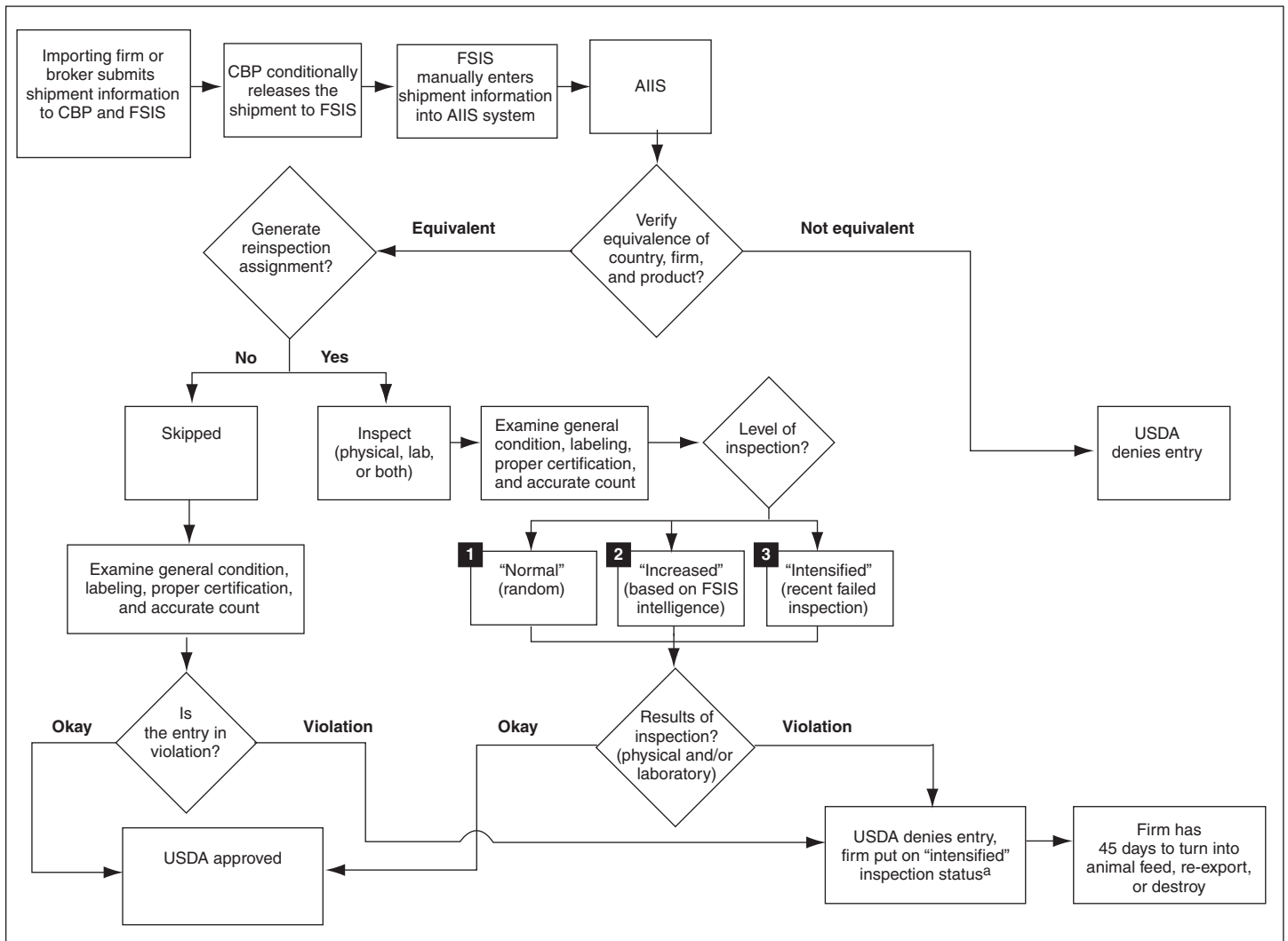
FSIS

FSIS evaluates foreign meat and poultry and processed egg product food regulatory systems through an equivalency process that determines whether a foreign country’s food safety system provides the same level of

protection from food safety hazards as the U.S. system. A foreign country must receive a determination of equivalency before it can export meat and poultry or processed egg product products to the United States. To make this determination, FSIS reviews the documentation provided by the country and conducts an initial equivalency audit of the country's meat or poultry food regulatory system. After FSIS determines that a country has an equivalent system and is eligible to export to the United States, FSIS relies on the country to effectively oversee food inspection activities and enforce U.S. requirements.

Once FSIS designates a foreign country as having equivalent food safety standards, it ensures that the country maintains this designation using a three-part process. First, FSIS conducts a document analysis of the foreign country's food regulatory system to (1) verify that it has adequate authority and funding, (2) determine whether it requires U.S.-equivalent sanitary measures for industry, and (3) evaluate written procedures for overseeing industry and enforcing requirements. Second, FSIS conducts routine systems audits at least once a year. It uses this systems audit to evaluate the foreign country's inspection program and verify equivalence, not to inspect individual foreign establishments. Systems audits focus on, among other things, industry practices—including standard operating procedures, quality assurance systems, and laboratory testing programs—and the foreign government's capacity to monitor and verify the effectiveness of industry practices. Finally, FSIS conducts port-of-entry reinspections for all meat, poultry, and processed egg products imported into the United States before they enter domestic commerce, as depicted in Figure 4.

Figure 4: FSIS's Process for Reinspecting Imported Meat, Poultry, and Processed Egg Products



Source: GAO.

^aIf a product fails a physical reinspection, AIIIS generates an “intensified” reinspection assignment for the importing firm’s next 10 shipments. If a product fails a laboratory inspection, AIIIS generates an “intensified” reinspection assignment for either (1) the firm’s next 15 shipments, or (2) until FSIS has tested enough subsequent shipments from that firm to comprise 15 times the weight of the failed shipment without another positive laboratory test result (whichever comes first).

Before an FSIS-regulated shipment arrives at a port, the importer or broker must submit information about the shipment, such as product type and country of origin, to both CBP and FSIS. FSIS’s import screening system, the Automated Import Information System (AIIIS), is unable to

receive information electronically, so the foreign establishment typically faxes it to the agency. Once the shipment clears CBP's screening, a CBP officer refers the shipment to an FSIS facility, where FSIS personnel manually enter the shipment's information into FSIS's AIIS import screening system. After verifying the eligibility of the foreign country and foreign establishment, AIIS assigns a type of inspection of either "skipped" or "inspection." In either case, an FSIS inspector examines the shipment's general condition and ensures that it is labeled correctly and has proper documentation. If AIIS generates an "inspection" assignment, however, the system also dictates whether FSIS should conduct a physical, laboratory, or combination inspection. AIIS also designates shipments at different inspection "levels." For example, some shipments are inspected at random (called "normal" inspections), while other inspections are the result of an FSIS management decision to increase inspection rates for a specific product or country of origin. If a shipment fails reinspection, AIIS automatically designates the foreign establishment for intensified inspection status, which means that FSIS will inspect the establishment's next 10 or 15 shipments, depending on the nature of the failed test. If a shipment passes reinspection, it is marked accordingly and allowed to enter U.S. commerce. However, if a product fails reinspection, FSIS refuses it entry and the product must be turned into animal feed, exported, or destroyed within 45 days. Foreign countries or establishments that repeatedly fail port-of-entry reinspections may forfeit their eligibility to export FSIS-regulated products to the United States.

FSIS is replacing AIIS with the Public Health Information System, a Web-based application. According to agency officials, FSIS will deploy this new system in 2010. FSIS officials told us that the Public Health Information System will enable FSIS to receive foreign health certificates electronically, thereby providing a secure and timely advance notice of a foreign shipment certified by a foreign government. This certification will then be verified upon arrival in the United States. The Public Health Information System, according to FSIS, will be able to communicate with CBP's ACE system, enhancing FSIS's ability to track (1) the receipt of certain import shipments at official import inspection establishments and (2) the rejection of ineligible shipments at ports of entry. In addition, the Public Health Information System is expected to allow FSIS to systematically verify the effectiveness of foreign food safety systems by providing an automated audit planning process for foreign countries, which includes expanded information collection from the foreign governments. While awaiting deployment of the new system, FSIS has instituted a number of steps to fill the communication and coordination gap with CBP. According to FSIS, these interim steps have largely

succeeded in closing that gap, although agency officials believe that the permanent solution offered by the Public Health Information System is still needed. GAO has not reviewed the development of the Public Health Information System.

Appendix V: FDA's Overseas Inspections

FDA Inspections of Food Firms in Foreign Countries, Fiscal Years 2001 through 2008

	2001	2002	2003	2004	2005	2006	2007	2008	Total
Mexico	17	15	8	15	7	16	26	29	133
Ecuador	8	0	11	24	0	11	10	0	64
Thailand	4	10	0	10	0	22	0	12	58
Chile	13	0	15	6	7	11	0	5	57
Peru	13	0	0	18	1	9	9	4	54
Brazil	0	12	6	7	21	0	0	7	53
China	0	9	2	6	16	0	0	13	46
Taiwan	9	7	0	9	0	7	0	7	39
Canada	13	0	13	1	0	7	4	0	38
Costa Rica	0	11	0	4	5	7	0	7	34
Honduras	9	8	0	0	7	0	0	8	32
Vietnam	0	9	0	10	8	0	0	4	31
Argentina	7	5	0	0	0	0	19	0	31
India	6	0	10	0	7	7	0	0	30
South Korea	14	0	0	1	7	0	6	0	28
Australia	12	0	6	0	0	9	0	0	27
Jamaica	2	6	0	3	0	3	0	8	22
Fiji	0	0	8	0	0	0	13	0	21
Guatemala	0	10	0	0	6	0	0	5	21
Singapore	10	0	0	8	0	0	0	3	21
Nicaragua	0	8	0	0	0	7	0	4	19
El Salvador	0	0	8	0	6	0	0	4	18
Germany	5	4	4	0	0	1	1	2	17
Estonia	8	0	0	8	0	0	0	0	16
Panama	0	0	7	0	0	0	0	9	16
South Africa	5	0	11	0	0	0	0	0	16
Malaysia	0	0	0	0	9	0	0	6	15
28 additional countries ^a									
Total number of countries that had firms inspected by FDA during the specific fiscal year listed above	26	22	22	20	16	15	11	24	56
Total inspections	211	169	148	153	132	125	95	153	1186

Source: GAO analysis of FDA data.

^aCountries with a total of 14 or fewer inspections between 2001 and 2008 are not listed in the table. These countries include: Italy (14 inspections), Latvia (14), Uruguay (14), Venezuela (14), Morocco (13), New Zealand (13), Poland (13), Trinidad and Tobago (12), France (11), Norway (11), Romania (10), Surinam (10), Iceland (9), Bulgaria (8), Colombia (8), United Kingdom (8), Cyprus (7), Turkey (5), Belize (4), Spain (4), Belgium (3), Greece (3), Hungary (3), Indonesia (3), Finland (2), Haiti (2), Japan (2), and the Netherlands (2).

Appendix VI: FDA Funding for Imported Food by Activity, Fiscal Years 2002 through 2009

FDA Funding and Full-Time Equivalents (FTEs), Fiscal Years 2002 through 2009

(Dollars in thousands)

Fiscal years	Field laboratory analyses		Field foreign inspections		Field import activities ^b		Field activities		Field and center food activities (imports and domestic) ^d		All FDA (all products and programs) ^e	
	Dollars	FTE	Dollars	FTE ^a	Dollars	FTE ^c	Dollars	FTE	Dollars	FTE	Dollars	FTE
2002	\$39,763	286	\$4,152	30	\$30,142	217	\$74,057	533	\$393,256	2,734	\$1,537,000	9,468
2003	46,940	400	2,552	22	63,103	536	112,595	958	406,824	3,167	1,627,700	10,257
2004	46,687	395	2,538	21	69,040	530	118,265	946	407,052	3,082	1,678,900	10,141
2005	46,792	359	2,544	20	72,887	524	122,223	903	435,517	2,943	1,777,500	9,910
2006	51,573	353	1,540	11	67,547	463	120,660	827	438,721	2,774	1,862,700	9,698
2007	48,720	316	904	6	66,444	431	116,068	753	457,104	2,569	1,974,100	9,569
2008	57,080	324	2,867	16	79,974	438	139,921	778	507,797	2,614	2,245,000	9,811
2009 (est.)	70,600	364	18,440	82	93,111	493	182,151	939	648,722	3,019	2,668,000	10,953

Source: GAO analysis of FDA data.

Note: The funding and FTEs include all infrastructure support. This support includes investigator salary and benefits, import sample collections, import label exams, import entry review functions, the Prior Notice Center, compliance officers, information technology, training, and equipment, as well as management and information technology support for the field. The funding also includes rent and other facility costs.

^aOf the 82 FTEs estimated for fiscal year 2009, FDA has allocated six to conduct inspections of foreign food establishments.

^bThis category includes all nonlaboratory activities, such as field examinations and tests, import sample collections, import label exams, Prior Notice Center security reviews, import entry reviews, and other import investigations.

^cFDA has allocated 272 FTEs to conduct examinations of imported foods at U.S. ports of entry for fiscal year 2009.

^dThe Center for Food Safety and Applied Nutrition is the only FDA center included in this total, since it has primary responsibility for food safety-related work concerning human foods. Other FDA centers conduct some food safety-related work.

^eTotal FDA dollars include user fees.

Appendix VII: FSIS's Funding for Food Imports, Fiscal Years 2006 through 2009

FSIS Funding for Food Imports, Fiscal Years 2006 through 2009

(Dollars in thousands)

	Import inspection ^a		International equivalence ^b		Total import inspection activities	
	Dollars	FTE	Dollars	FTE	Dollars	FTE
2006	\$7,947	104	\$1,378	11	\$9,325	115
2007	7,632	88	1,248	10	8,880	98
2008	8,771	99	1,229	8	10,000	107
2009 (est.)	9,034	99	1,266	8	10,300	107

Source: FSIS.

^aIncludes funding for the process of reinspecting FSIS-regulated shipments imported into the U.S. at approved import inspection facilities.

^bIncludes funding for the process of determining equivalence, which involves foreign program document reviews, on-site audits, and activities to verify ongoing equivalence.

Appendix VIII: Comments from the Department of Homeland Security

U.S. Department of Homeland Security
Washington, DC 20528



**Homeland
Security**

September 2, 2009

Lisa Shames
Director, Natural Resources and Environment
U.S. Government Accountability Office
441 G St., NW
Washington, DC 20548

Dear Ms. Shames:

The Department of Homeland Security (DHS) appreciates the opportunity to review and comment on the Government Accountability Office's (GAO's) draft report GAO-09-873: *Food Safety: Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food*. DHS concurs with the four GAO recommendations addressed to the U.S. Customs and Border Protection (CBP). The content of the report, as well as, the aforementioned recommendations have been addressed below; technical comments have been provided under separate cover.

In the report, the GAO singles out the in-bond entry process as a gap in the enforcement of foodstuffs. CBP considers this an unfounded conclusion as the GAO provides no evidence that the risk of diversion of foodstuffs is greater in the in-bond environment than any other environment. The GAO also concludes that CBP does not effectively manage in-bond shipments. CBP disagrees with this conclusion as it is based solely on the premise that in-bond transit times have not yet been changed. Moreover, the GAO does not offer any specific examples to support its conclusion that unlawfully diverted foodstuffs are due to existing regulatory transit times for in-bond shipments. CBP has made significant improvements to how in-bond shipments are tracked and reported and has provided appropriate guidance and training to field personnel. CBP continues to improve its management of the in-bond process with even greater enhancements to the Automated Commercial Environment.

The report characterizes CBP's computer systems as failing to communicate with the Food and Drug Administration's (FDA) systems regarding time-of-arrival information. While CBP's systems are unable to communicate time-of-arrival information at this time, it should have a limited impact on FDA's enforcement as FDA is made aware that products of interest are about to arrive or have arrived in the U.S. via the other communication mechanisms. In addition, the GAO report does not acknowledge that FDA has multiple opportunities to assess the risk of incoming shipments prior to release of the cargo through the Receipt of Prior Notice and the transmission of data through the CBP electronic entry process.

- 2 -

Lastly, the report states that CBP has not yet developed a schedule to provide time-of-arrival information under the current interagency agreement with FDA. The report should be clarified to state that CBP completed the development of the modification to the software that will provide FDA with the transmission of the conveyance arrival message and information for air and truck shipments. CBP has been working with FDA to complete the testing and requests that GAO change the wording in the report to reflect ongoing activities with the FDA to implement the interagency agreement between CBP and FDA.

The GAO report makes nine recommendations for executive action, four of which are addressed to CBP. The following are DHS's recommendation specific comments:

Recommendation 1:

The CBP Commissioner ensures that CBP's new screening system communicates time-of-arrival information to FDA's and Food Safety and Inspection Service's (FSIS) screening systems.

CBP Response:

Concur. Once CBP begins gathering time-of-arrival data in its new screening system, CBP will have the capability to provide that data to FDA providing that FDA requests, and has legal authority to collect, the information.

If it is decided that an interface will be developed between FSIS and CBP, CBP may accommodate a request from FSIS to receive the data, provided that CBP and FSIS have the legal authority for this data exchange. It should be noted that the requesting agency may be responsible for CBP programming and other automation expenses to support its request.

Recommendation 2:

Furthermore, until this new system is capable of communicating this information, we recommend that CBP implement its interagency agreement with FDA to provide time-of-arrival information and explore opportunities to implement a similar agreement with FSIS.

CBP Response:

Concur. CBP has completed the development of two work requests that will send the arrival information to FDA for both Air and Truck entries. The work requests are awaiting testing by FDA before deployment.

If it determined that an interface will be developed between FSIS and CBP, CBP may accommodate a request from FSIS to receive the data, provided that CBP and FSIS have the legal authority for this data exchange. It should be noted that the requesting agency may be responsible for CBP programming and other automation expenses to support its request.

Recommendation 5:

To improve CBP's and FDA's ability to identify foreign firms with violative histories, we recommend the CBP Commissioner should ensure that Automated Commercial Environment (ACE) is able to accept a unique identification number for foreign firms that export FDA-regulated foods.

- 3 -

CBP Response:

Concur. CBP will implement the specific participating government agency (PGA) requirement for ACE that states "ACE shall accept a unique identification number for foreign firms that export FDA-regulated foods or other entities so designated by a PGA." This requirement currently exists and will be delivered when the Cargo Release process is brought into ACE.

Recommendation 7:

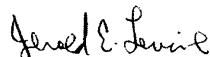
To enhance agency coordination and streamline FDA's refusal process with CBP's redelivery process, we recommend that the FDA Commissioner and the CBP Commissioner jointly study, with input from agency field officials, ports where a joint initiative would be feasible.

CBP Response:

Concur. CBP agrees that a study can be undertaken and will work with field offices and FDA through ongoing joint initiatives.

Again, DHS would like to thank you for the opportunity to review and comment on your draft report. We look forward to working with you on future homeland security issues.

Sincerely,



Jerald E. Levine
Director
Departmental GAO/OIG Liaison Office

Appendix IX: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

SEP 4 2009

Lisa Shames, Director
Natural Resources and Environment
U.S. Government Accountability Office
441 G Street N. W.
Washington, DC 20548

Dear Ms. Shames:

Enclosed are comments on the U.S. Government Accountability Office's (GAO) report entitled: "Food Safety: Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food" (GAO-09-873).

The Department appreciates the opportunity to review this report before its publication.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrea Palm", written over a horizontal line.

Andrea Palm
Acting Assistant Secretary for Legislation

Enclosure

Appendix IX: Comments from the Department
of Health and Human Services




DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

DATE: September 2, 2009
TO: Acting Assistant Secretary for Legislation
FROM: Principal Deputy Commissioner of Food and Drugs
SUBJECT: FDA's General Comments to GAO's Draft Report entitled, *FOOD SAFETY: Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food (GAO-09-873)*

FDA is providing the attached general comments to the U.S. Government Accountability Office's draft report entitled: *FOOD SAFETY: Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food (GAO-09-873)*.

FDA appreciates the opportunity to review and comment on this draft report before it is published.



Joshua M. Sharfstein, M.D.
Principal Deputy Commissioner of
Food and Drugs

Attachment

FDA's General Comments to the U.S. Government Accountability (GAO) Draft Report Entitled, Food Safety—Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food (GAO-09-873)

The Food and Drug Administration (FDA) appreciates the opportunity to review and comment on the Government Accountability Office's (GAO) draft report. GAO has raised some important issues in this report. FDA thanks GAO for its recommendations and will incorporate them as appropriate into both short-term and long-term initiatives that will continue to help ensure the safety of imported foods.

FDA strives to improve the safety and oversight of imported food. To this end, FDA is working with regulatory partners such as the National Oceanic and Atmospheric Administration, the Customs and Border Protection (CBP), and the States to coordinate efforts and to find new ways to collaborate. FDA also recognizes the need to continually update its systems and processes. For example, when fully deployed, FDA's Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) system will improve import screening and targeting to prevent the entry of adulterated, misbranded or otherwise violative foods and will expedite the entry of non-violative foods. The new system will provide additional information to FDA staff to help them make improved decisions about targeting lines. FDA will continue to evaluate and strengthen PREDICT as the project moves forward.

Pending legislation, if enacted, would also strengthen FDA's efforts in this area. For example, the Food Safety Enhancement Act (H.R. 2749) as passed by the House would enhance FDA's ability to prioritize prevention, strengthen FDA's surveillance and enforcement efforts, and improve FDA's response and recovery functions. The legislation would also enable FDA to implement further preventative measures, such as by issuing new food safety regulations, and would provide mechanisms to help ensure such measures are appropriately implemented.

Responses to GAO Recommendations for Executive Action

To enhance FDA's authority to oversee the safety of imported food, GAO recommends that the FDA Commissioner seek authority from the Congress to assess civil penalties on firms and persons who violate FDA's food safety laws.

FDA agrees with this recommendation. FDA is working with Congress to include civil money penalty authority in food safety legislation.

Section 135 of H.R. 2749, the Food Safety Enhancement Act, which was passed by the House of Representatives on July 30, 2009, would establish civil monetary penalties that FDA would be able to impose for violations relating to food.

The Administration has issued a Statement of Administration Position in support of H.R. 2749.

GAO further recommends that the Commissioner determine what violations should be subject to this new FDA civil penalties authority, as well as the appropriate nature and magnitude of the penalties.

FDA's General Comments to the U.S. Government Accountability (GAO) Draft Report Entitled, *Food Safety—Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food (GAO-09-873)*

FDA agrees that the agency should determine whether or not to seek civil money penalties for particular violations under any new authority and that FDA would take into account, as appropriate under such authority, the nature of the violation and other factors in determining the magnitude of a penalty.

The CBP Commissioner should ensure that ACE is able to accept a unique identification number for foreign firms that export FDA-regulated foods.

FDA has supported and will continue to support CBP's efforts in this area.

The FDA Commissioner should explore ways to improve the agency's ability to identify foreign firms with a unique identifier.

FDA agrees that the use of a unique identifier would improve the agency's ability to accurately identify foreign firms. Use of unique identifiers would also aid FDA in targeting high risk shipments, which are currently hindered when a firm that FDA has previously identified and targeted due to history of exporting high risk shipments, uses a different identifier, or where a new identifier is assigned to the firm by the database that receives the import entry information.

FDA supports new authority to require the use of a unique identifier by food facilities. FDA is currently working with Congress to include such new authority in food safety legislation. The House of Representatives recently passed H.R. 2749, the Food Safety Enhancement Act, which contains a provision (Section 206) that would give FDA the authority to specify the unique numerical identifier system under which persons must submit such unique identifiers as part of the requirement to register their food facilities with FDA. The Administration has issued a Statement of Administration Position in support of H.R. 2749.

To enhance agency coordination and to streamline FDA's refusal process with CBP's redelivery process, GAO recommends that the FDA Commissioner and the CBP Commissioner jointly study, with input from agency field officials, ports where a joint initiative would be feasible.

FDA does not believe a study is warranted, but does believe that continuing to engage with CBP to develop a joint refusal/redelivery process is important. CBP and FDA have begun discussions of the joint form, as a prerequisite to consider this joint notice as a national procedure. Additional discussions are needed to complete this evaluation, after which it may be that national procedures can be drafted, cleared, and implemented.

If approved, the joint notice should:

- Improve importer compliance with FDA refusal procedures;
- Help ensure that violative products are exported or destroyed; and
- Expedite the response time for the entry refusal process.

FDA's General Comments to the U.S. Government Accountability (GAO) Draft Report Entitled, *Food Safety—Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food (GAO-09-873)*

To better leverage state resources for protecting the safety of imported food, GAO recommends that the FDA Commissioner reach out to states to find opportunities for additional collaboration through contracts, cooperative agreements, and informal partnerships.

FDA agrees with this recommendation and its Office of Regulatory Affairs has included an option in the state contracts for import work for the past 5 years. Future planned State Infrastructure and National Integrated Food Safety System Cooperative Agreements would include the sharing of information on imported products and coordination of both import and domestic import surveillance. The long term solution would also involve enhancing the IT infrastructure of FDA to develop portals or other IT solutions to connect this data to programs such as eSAF (electronic State Access to FACTS) or other state accessible programs.

However, even if FDA receives funding to increase the number of inspections conducted by states under contract, it may be difficult to get states to commit to new or significantly more inspections. Several states, under current food safety contracts, are now requiring furlough days each month because of state budgets and regardless of contract funding. In addition, even if FDA food contract funding is significantly increased for one year, FDA must be able to ensure funding on a long term basis for states to invest in the staff needed to conduct increased inspections.

To enhance public safety, GAO recommends that the FDA Commissioner find ways to share with states product distribution lists, to the extent permitted by law, while also protecting confidential commercial information, and if necessary, consider what regulatory or legislative changes may be needed to allow FDA to share otherwise protected information with states while preventing public disclosure.

FDA agrees with this recommendation and already shares product distribution lists and other confidential commercial information with states in certain circumstances when permitted by law. However, FDA also supports changes to existing law to strengthen the ability of the agency to share information with states. The Food Safety Enhancement Act includes such legislative changes.

The Administration has issued a Statement of Administration Position in support of H.R. 2749.

To help ensure that PREDICT is effectively targeting high-risk imported food shipments for field and laboratory examinations, GAO recommends that the FDA Commissioner develop a performance measurement plan prior to deploying the system at additional U.S. ports.

FDA agrees that a performance measurement plan is key to successfully evaluating PREDICT and modifying it as appropriate prior to widespread deployment. FDA is currently developing such a plan.

Appendix X: GAO Contact and Staff Acknowledgments

GAO Contact:

Lisa Shames (202) 512-3841 or shamesl@gao.gov

Staff Acknowledgments:

Other key contributors to this report were José Alfredo Gómez (Assistant Director), Anne K. Johnson (Analyst-in-Charge), Brenna Guarneros, Jeff C. Jensen, Carol Herrnstadt Shulman, John Wheeler, and Rebecca Yurman. Important contributions were also made by Kevin Bray, Michele Fejfar, Kim Raheb, and Kiki Theodoropoulos.

GAO's Mission

The Government Accountability Office, the audit, evaluation, and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through GAO's Web site (www.gao.gov). Each weekday afternoon, GAO posts on its Web site newly released reports, testimony, and correspondence. To have GAO e-mail you a list of newly posted products, go to www.gao.gov and select "E-mail Updates."

Order by Phone

The price of each GAO publication reflects GAO's actual cost of production and distribution and depends on the number of pages in the publication and whether the publication is printed in color or black and white. Pricing and ordering information is posted on GAO's Web site, <http://www.gao.gov/ordering.htm>.

Place orders by calling (202) 512-6000, toll free (866) 801-7077, or TDD (202) 512-2537.

Orders may be paid for using American Express, Discover Card, MasterCard, Visa, check, or money order. Call for additional information.

To Report Fraud, Waste, and Abuse in Federal Programs

Contact:

Web site: www.gao.gov/fraudnet/fraudnet.htm

E-mail: fraudnet@gao.gov

Automated answering system: (800) 424-5454 or (202) 512-7470

Congressional Relations

Ralph Dawn, Managing Director, dawnr@gao.gov, (202) 512-4400
U.S. Government Accountability Office, 441 G Street NW, Room 7125
Washington, DC 20548

Public Affairs

Chuck Young, Managing Director, youngc1@gao.gov, (202) 512-4800
U.S. Government Accountability Office, 441 G Street NW, Room 7149
Washington, DC 20548

