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FOOD SAFETY

FDA Could Strengthen Oversight of Imported Food by Improving Enforcement and Seeking Additional Authorities

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Highlights of [GAO-10-699T](#), testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

Food imported from around the world constitutes a substantial and increasing percentage of the U.S. food supply. Ensuring the safety of imported food challenges the Food and Drug Administration (FDA) to better target its resources on the foods posing the greatest risks to public health and to coordinate efforts with the Department of Homeland Security's Customs and Border Protection (CBP) so that unsafe food does not enter U.S. commerce.

This testimony focuses on (1) FDA's overseas inspections, (2) identified gaps in agencies' enforcement efforts to ensure the safety of imported food, and (3) statutory authorities that GAO has identified that could help FDA's oversight of food safety. This testimony is principally based on GAO's September 2009 report, *Food Safety: Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food* (GAO-09-873) and has been updated with information from FDA.

What GAO Recommends

GAO previously recommended that FDA explore a unique identifier for firms, among other things. GAO also recommended FDA seek statutory authorities as needed, such as for preventive controls. FDA has agreed with these recommendations and has sought needed authorities.

View [GAO-10-699T](#) or key components. For more information, contact Lisa Shames at (202) 512-3841 or shamesl@gao.gov.

FOOD SAFETY

FDA Could Strengthen Oversight of Imported Food by Improving Enforcement and Seeking Additional Authorities

What GAO Found

While the number of FDA overseas inspections has fluctuated, FDA has opened up several overseas offices to address the safety of imported food at the point of origin, and is testing a computer-based system to target high-risk imports for additional inspection when they arrive at ports of entry. Specifically, in 2008, FDA inspected 153 foreign food facilities out of an estimated 189,000 such facilities registered with FDA; in 2007, FDA inspected 95 facilities. FDA estimated that it would conduct 200 inspections in 2009 and 600 in 2010. In addition, FDA opened offices in China, Costa Rica, and India and expects to open offices in Mexico and Chile and to post staff at European Union agencies. Furthermore, FDA's testing of a new computer screening system—the Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting (PREDICT)—indicates that the system could enhance FDA's risk-based screening efforts at ports of entry, but the system is not yet fully operational. 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 and to target for inspection products that have a high risk score.

GAO previously identified several gaps in enforcement that could allow food products that violate safety laws to enter U.S. commerce. For example, FDA has limited authority to assess penalties on importers who introduce such food products, and the lack of a unique identifier for firms exporting food products may allow contaminated food to evade FDA's review. In addition, FDA's and CBP's computer systems do not share information. FDA does not always share certain distribution-related information, such as a recalling firm's product distribution lists with states, which impedes states' efforts to quickly remove contaminated products from grocery stores and warehouses.

GAO identified certain statutory authorities that could help FDA in its oversight of food safety. Specifically, GAO previously reported that FDA currently lacks mandatory recall authority for companies that do not voluntarily recall food products identified as unsafe. Limitations in FDA's food recall authorities heighten the risk that unsafe food will remain in the food supply. In addition, under current FDA regulations, companies may conclude a food ingredient is generally recognized as safe without FDA's approval or knowledge. GAO recommended that if FDA determines that it does not have the authority to implement one or more recommendations, the agency should seek the authority from Congress. Finally, GAO reported that FDA has identified a need for explicit authority from Congress to issue regulations requiring preventive controls by firms producing foods that have been associated with repeated instances of serious health problems or death. FDA already has preventive regulations for seafood and juice, which require firms to analyze safety hazards and implement plans to address those hazards.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss findings from our work on the Food and Drug Administration's (FDA's) efforts to ensure the safety of imported food and on our other recently issued food safety work. According to U.S. Department of Agriculture (USDA) data, food imported from more than 150 countries and territories constitutes a substantial and increasing percentage of the U.S. food supply. Imported food constitutes 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 from fiscal years 2003 to 2008, and the value of these products increased 65 percent. Ensuring the safety 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.

We have reported on 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.¹ More recently, we reported in September 2009 that agencies need to address gaps in enforcement and collaboration to enhance the safety of imported food.² Federal agencies involved in the oversight of food imports include the following:

- FDA—which is responsible for roughly 80 percent of the food supply, including dairy products, seafood, fruits, and vegetables—oversees imported food safety through targeted inspections, sampling, and surveillance, among other things. Owing in part to the volume of imported products it regulates, FDA physically examines 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.

¹GAO, *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).

²GAO, *Food Safety: Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food*, [GAO-09-873](#) (Washington, D.C.: Sept. 15, 2009).

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- Customs and Border Protection (CBP), under the Department of Homeland Security, is responsible for inspecting food imports for compliance with U.S. law and coordinating with FDA to enforce food safety laws at the border, among other things. CBP's computerized screening system processes all imported shipments, including food. CBP requires importers to (1) give a manufacturer identification number for each imported shipment and (2) post a monetary bond for formal entries to provide assurance that these shipments meet U.S. requirements, among other things.
 - USDA's Food Safety and Inspection Service (FSIS) has responsibility for the safety of imported meat and poultry and relies on an equivalency system whereby exporting countries must demonstrate that their systems meet standards that are equivalent to those of the U.S. system.

Furthermore, 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. 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.³

Several food safety bills have recently been introduced in Congress, and a comprehensive bill, H.R. 2749, passed the House of Representatives in July 2009. The House bill would require importers to register annually with FDA and to submit an appropriate unique facility identifier as a condition of such registration, among other provisions. The bill would also authorize FDA to issue a mandatory recall of foods that may cause serious adverse health consequences or death to humans or animals and would expand the agency's authority to assess criminal and civil penalties. Our September 2009 report made some of the same recommendations.

My testimony today will focus on three key issues: (1) FDA overseas inspections to address the safety of imported food, (2) identified gaps in agencies' enforcement that undermine efforts to ensure the safety of imported food, and (3) statutory authorities that we have identified that could help FDA's oversight of food safety.

³GAO, *High-Risk Series: An Update*, [GAO-07-310](#) (Washington, D.C.: January 2007).

As detailed in our reports, we found the following:

- First, while the number of FDA's foreign inspections has fluctuated, the agency has opened several overseas offices to address the safety of imported food at the point of origin. In addition, FDA testing of PREDICT indicates that the system could enhance FDA's risk-based screening efforts, but the system is not yet fully operational. FDA officials stated that a scheduled nationwide rollout this summer of PREDICT has been delayed primarily because of technical problems, such as server crashes and overloads, which are affecting FDA's field data systems nationwide.
- Second, gaps in FDA's and other agencies' enforcement could allow violative food products to enter U.S. commerce. For example, FDA has limited authority to assess penalties on importers who introduce violative food products, and the lack of a unique identifier for firms exporting food products may allow contaminated food to evade FDA review.
- Finally, we have made several recommendations that would help FDA improve food safety oversight. For example, we recommended that FDA seek additional authorities, such more explicit authority to create preventive controls for high-risk foods, and we have recommended that Congress consider giving FDA additional authority, such as mandatory recall authority. FDA agreed with our recommendations and has sought authority to order food safety recalls and issue additional preventive controls for high-risk foods.

This testimony is largely based on our September 2009 report on imported food safety, as well as other recent reports, and updated with information from FDA. See appendixes I-IV for highlights of our prior work. We conducted our work in accordance with generally accepted government auditing standards.

**While the Number of
FDA Overseas
Inspections Has
Fluctuated, the
Agency Has Opened
Overseas Offices, and
Has Piloted PREDICT**

In 2008, FDA inspected 153 foreign food facilities out of an estimated 189,000 such facilities registered with FDA and estimated that it would conduct 200 inspections in 2009 and 600 in 2010.⁴ In 2007, FDA inspected 95 facilities. Table 1 shows the number of FDA inspections of foreign food facilities, by country, from fiscal years 2001 through 2008. As the table shows, FDA conducted 1,186 inspections in 56 countries from fiscal years 2001 through 2008; the majority of FDA inspections were in Mexico, followed by Ecuador, Thailand, and Chile. FDA conducted a total of 46 inspections in China during this period.

⁴FDA was not able to provide 2009 inspection data in time for this statement, according to FDA officials.

Table 1: 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 | 1,186 |

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).

For fiscal year 2009, FDA allocated 272 full-time employees to examine imported food shipments at U.S. ports of entry and estimated a budget of approximately \$93.1 million for field import activities.⁵ The total estimated 2009 FDA budget for all FDA products and programs, including food, drugs, medical devices, and other products, was \$2.7 billion. 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 \$3.2 billion to inspect all of these facilities once.⁶

Since November 2008, FDA has opened overseas offices to help prevent food that violates U.S. standards from reaching the United States. These offices are 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 more informed decisions about which food imports to examine. For example, FDA’s overseas staff are working with staff at counterpart regulatory agencies overseas, as well as with other stakeholders who may be knowledgeable about certain industries. Overseas staff are also educating local exporters to make sure they understand U.S. food safety laws and regulations and FDA expectations. FDA opened offices in China (Beijing, Guangzhou, and Shanghai); in Europe (Brussels, London, and soon in Parma, Italy); in Latin America (San Jose, Costa Rica; Santiago, Chile; and Mexico City, Mexico); and in India (New Delhi and Mumbai). The FDA Middle East Office is operating out of FDA headquarters because the Department of State denied its request to locate in Amman, Jordan, due to security concerns.

In addition to having overseas offices assist FDA’s oversight of imported food, the agency is developing PREDICT. PREDICT is intended to assist FDA’s oversight of imported food and uses FDA-developed criteria to estimate the risk of imported food shipments. 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

⁵This 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, as well as associated infrastructure support.

⁶GAO, *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).

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. In addition, agency officials stated that PREDICT will assign higher risk scores to firms for which the system does not have historical data.

PREDICT generates a numerical risk score for all FDA-regulated products. According to FDA, PREDICT is to present the shipment’s risk score to FDA reviewers 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.⁷ FDA intends that reviewers using PREDICT will 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 reviewers to use PREDICT to supplement, rather than replace, their professional judgment when deciding what food products to inspect.

A 2007 pilot test of PREDICT in Los Angeles for seafood products indicated that the system could enhance FDA’s risk-based import screening efforts. When compared with baseline data from FDA’s existing import screening system, the Operational and Administrative System for Import Support (OASIS), PREDICT improved FDA’s ability to target imports that the agency considers to be high risk for further examinations and allowed a greater percentage of products the agency considers to be low risk to enter U.S. commerce without requiring a reviewer’s intervention. Specifically, PREDICT nearly doubled the percentage of field examinations—and increased by approximately one-third the percentage of laboratory examinations—that resulted in violations, relative to baseline OASIS data. In addition, according to FDA, the violations in shipments that reviewers targeted using PREDICT, on average, posed a greater risk to human health than the violations that OASIS detected.

FDA told us on April 12, 2010, that PREDICT is fully operational in the Los Angeles and New York districts, but due to technical problems, FDA has not determined when the system will be deployed in the Seattle district. In

⁷Import alerts communicate information and policy to FDA field staff. Usually, they provide information that products covered by the alert are subject to detention. If a product is detained, the importer is provided an opportunity to prove that the imported product is compliant, such as by providing FDA with the results of third-party laboratory analysis of the product.

addition, FDA officials stated that a scheduled nationwide rollout of PREDICT this summer has been delayed, primarily because of technical problems, such as server crashes and overloads, which are affecting FDA's field data systems nationwide.

Although the PREDICT pilot produced positive results and demonstrated the system's potential to improve import screening efforts, we reported that further agency actions were needed to help ensure that the system is effective. For example, FDA had 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. We recommended FDA develop such a plan. According to agency officials, since our report was issued in September 2009, FDA had completed a draft performance measurement plan. However, we have not reviewed this draft plan.

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

We identified specific gaps in enforcement that could allow violative food products to enter U.S. commerce: (1) FDA's limited authority to assess civil penalties on certain violators; (2) lack of unique identifiers for firms exporting FDA-regulated products; (3) lack of information-sharing between agencies' computer systems and (4) FDA's not sharing product distribution information during a recall.

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. However, 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. Specifically, importers post a monetary bond for formal entries (i.e., all shipments exceeding \$2,000 and certain shipments valued below that amount) to provide assurance that these shipments meet U.S. requirements. According to these officials, many importers still consider the occasional payment of forfeited bonds as part of the cost of doing business. Indeed, as we reported in 1998, 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 response to our September 2009 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.

We recommended that the FDA Commissioner seek authority from Congress to assess civil penalties on firms and persons who violate FDA's food safety laws and 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 agreed with this recommendation and was working with Congress to include civil penalty authority in food safety legislation. FDA officials also told us that if the agency had the authority to impose civil penalties on importers, which is also provided for in H.R. 2749, FDA might be better able to deter violations.

FDA and CBP 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. 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 this 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.

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 importers 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, an importer 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 FDA 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.

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 cancellation of the original registration; consequently FDA may not know the precise number of foreign firms registered. As we previously reported, 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.

As we reported, 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 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. To improve FDA's and CBP's ability to identify foreign firms with violative histories, we recommended that the FDA Commissioner explore ways to improve the agency's ability to identify foreign firms with a unique identifier and that the CBP Commissioner ensure that its computer system is able to accept a unique identification number for foreign firms that export FDA-regulated foods. Both FDA and CBP agreed with our recommendation, and CBP officials told us that the agency has developed a plan for implementing a unique identifier. However, we have not reviewed this plan. We observe that H.R. 2749 contains a provision that may allow the Secretary of Health and Human Services, in consultation with the Commissioner of CBP, to specify the unique numerical identifier system to be used, taking into account compatibility with CBP's automated systems. Such actions would help prevent high-risk foods from entering U.S. commerce.

Information Is Not Shared between Computer Systems

When we issued our report in September 2009, we reported that CBP's computer system did not notify FDA's or FSIS's systems 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 through its computer system, OASIS. 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 consignee's warehouse or other facility within the United States. The importer might choose to do so because, for example, 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 U.S. commerce until FDA has examined it.

CBP and FDA officials told us that, occasionally, an importer will transport the shipment to the consignee's warehouse 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 because CBP's computer system does not notify FDA's OASIS computer system when the shipment arrives at the port. Instead, from the perspective of an FDA reviewer using OASIS, it will appear as if the shipment's arrival is still pending. FDA port officials told us that it could be 2 or 3 days before FDA 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. As we reported, 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 arrange to examine them before they are distributed to U.S. markets. Since our report was issued in September 2009, CBP told us that it had modified its software to notify FDA of a shipment's time of arrival. However, we have not reviewed the effectiveness of these modifications. We are still waiting to see whether CBP has an agreement with FSIS regarding time of arrival modifications.

FDA Does Not Always Share Product Distribution Information During a Recall

One key issue of concern, according to officials we spoke with from several states, is that FDA does not always share with states 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 the 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, if such sharing is necessary to effectuate a recall, or
- 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.

Statutory Authorities We Identified Could Help FDA Oversee Food Safety

In our past work, we have pointed out that mandatory recall—the authority to require a food company to recall a contaminated product—would help ensure that unsafe food does not remain in the food supply. We also reported that FDA should strengthen its oversight of food ingredients determined to be generally recognized as safe for their intended use and to seek the authority if the agency deems necessary. Likewise, we reported that FDA has identified a need for explicit authority from Congress to issue regulations to require preventive measures by firms producing foods that have been associated with repeated instances of serious health problems or death.

FDA Lacks Mandatory Recall Authority

We have reported that food recalls are largely voluntary and that federal agencies responsible for food safety, including FDA, have no authority to compel companies to recall contaminated foods, with the exception of FDA's authority to require a recall for infant formula.⁸ FDA does have authority, through the courts, to seize, condemn, and destroy adulterated or misbranded food under its jurisdiction and to disseminate information about foods that are believed to present a danger to public health. However, government agencies that regulate the safety of other products, such as toys and automobile tires, have recall authority not available to FDA for food and have had to use their authority to ensure that recalls were conducted when companies did not cooperate.

We have noted that limitations in the FDA's food recall authorities heighten the risk that unsafe food will remain in the food supply and have proposed that Congress consider giving FDA similar authorities. H.R. 2749 authorizes the Secretary of Health and Human Services to request that a person recall an article of food if the Secretary has reason to believe it is adulterated, misbranded, or otherwise in violation of the Federal Food, Drug, and Cosmetic Act and to require a person to cease distribution if the Secretary has reason to believe the article of food "may cause serious adverse health consequences or death to humans or animals." It also requires the Secretary to order a recall of such an article of food if the Secretary determines (after an informal hearing opportunity) it is necessary. Finally, it authorizes the Secretary to proceed directly to a mandatory recall order if the Secretary has credible evidence that an article of food subject to an order to cease distribution presents an imminent threat of serious adverse health consequences or death to humans or animals. As our previous work has shown, mandatory recall authority would allow FDA to ensure that unsafe food does not remain in the food supply.

⁸GAO, *Food Safety: USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food*, [GAO-05-51](#) (Washington, D.C.: Oct. 6, 2004) and GAO, *Federal Oversight of Food Safety: High Risk Designation Can Bring Attention to Limitations in the Federal Government's Food Recall Programs*, [GAO-07-785T](#) (Washington, D.C.: Apr. 24, 2007).

FDA Has Limited Oversight of Food Ingredients Determined to be Generally Recognized as Safe

We have reported that FDA should strengthen its oversight of food ingredients determined to be generally recognized as safe (GRAS) for their intended use.⁹ Manufacturers add these substances—hundreds of spices and artificial flavors, emulsifiers and binders, vitamins and minerals, and preservatives—to enhance a food’s taste, texture, nutritional content, or shelf life. Currently, companies may conclude a substance is GRAS without FDA’s approval or knowledge. We reported that FDA only reviews those GRAS determinations that companies submit to the agency’s voluntary notification program. The agency generally does not have information about other GRAS determinations companies have made because companies are not required to inform FDA of them. Among other things, we recommended to FDA that it develop a strategy to require any company that conducts a GRAS determination to provide the agency with basic information about this determination, and to incorporate such information into its public Web site.

We also reported that FDA is not systematically ensuring the continued safety of current GRAS substances. According to FDA regulations, the GRAS status of a substance must be reconsidered as new scientific information emerges, but the agency has not systematically reconsidered GRAS substances since the 1980s. Rather, FDA officials said, they keep up with new developments in the scientific literature and, on a case-by-case basis, information brought to the agency’s attention could prompt them to reconsider the safety of a GRAS substance. We recommended that FDA develop a strategy to conduct reconsiderations of the safety of GRAS substances in a more systematic manner. We also recommended that, if FDA determines that it does not have the authority to implement one or more of our recommendations, the agency should seek the authority from Congress. FDA generally agreed with the report’s findings and recommendations.

In addition, we reported that FDA has taken steps to make information about its GRAS notification program available to the public by posting its inventory of all GRAS notices FDA has received on its Web site. By placing information about the GRAS notice and its response on its Web site, FDA enhances the ability of Congress, stakeholders, and the general public to be better informed about GRAS substances. H.R. 2749 contains provisions on GRAS substances, including a requirement that the Secretary post on

⁹GAO, *Food Safety: FDA Should Strengthen Its Oversight of Food Ingredients Determined to Be Generally Recognized as Safe (GRAS)*, [GAO-10-246](#) (Washington, D.C.: Feb. 3, 2010).

FDA's Web site information about GRAS notices submitted to FDA within 60 days of receipt of the notice.

FDA Lacks Explicit Authority to Issue Regulations Requiring Food-Producing Firms to Institute Preventive Measures

We have also reported that FDA should strengthen its oversight of fresh produce.¹⁰ For example, we noted that FDA has identified a need for explicit authority from Congress to issue regulations requiring preventive controls (risk-based safety regulations) by firms producing foods that have been associated with repeated instances of serious health problems or death. FDA already has preventive regulations for seafood and juice, which require firms to analyze safety hazards and implement plans to address those hazards. According to FDA, such authority would strengthen the agency's ability to implement risk-based processes to reduce illnesses from high-risk foods. FDA officials told us that issuing preventive regulations may be one of the most important things they can do to enhance their oversight of fresh produce. We therefore recommended that the Commissioner of FDA seek authority from Congress to make explicit FDA's authority to adopt preventive controls for high-risk foods. FDA agreed with this recommendation and has sought authority to issue additional preventive controls for high-risk foods. Furthermore, H.R. 2749 requires FDA to create preventive controls for produce and certain raw agricultural commodities. Such measures could help the agency reduce illnesses from these high-risk foods.

In conclusion, food imports from around the world constitute a substantial and increasing volume of imported foods. Our work has shown that FDA could strengthen its oversight of imported food by improving its enforcement, such as by assessing civil penalties and providing unique identification numbers to firms. Additional statutory authorities, such as mandatory recall authority, could also help FDA oversee food safety. FDA generally agreed with our recommendations and has some taken actions to address them.

Mr. Chairman, this concludes my statement. I would be pleased to answer any questions that you or other Members of this Subcommittee may have.

¹⁰GAO, *Food Safety: Improvements Needed in FDA Oversight of Fresh Produce*, [GAO-08-1047](#) (Washington, D.C.: Sept. 26, 2008).

Contact and Staff Acknowledgments

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Appendix I: GAO-09-873 (Food Imports)

September 2009



Highlights of GAO-09-873, a report to congressional committees

FOOD SAFETY

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

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.

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.

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Appendix II: GAO-07-785T (Food Recalls)



Highlights of GAO-07-785T, a testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

April 24, 2007

FEDERAL OVERSIGHT OF FOOD SAFETY

High-Risk Designation Can Bring Needed Attention to Limitations in the Government's Food Recall Programs

Why GAO Did This Study

Each year, about 76 million people contract a foodborne illness in the United States; about 325,000 require hospitalization; and about 5,000 die. The outbreaks of *E. coli* in spinach and *Salmonella* in peanut butter, along with contamination in pet food, have highlighted the risks posed by accidental food contamination. The attacks of September 11, 2001, heightened awareness that the food supply could also be vulnerable to deliberate contamination. This testimony focuses on the (1) role that GAO's high-risk series can play in raising the priority and visibility of the need to transform federal oversight of food safety, (2) fragmented nature of federal oversight of food safety, and (3) limitations in federal food recall programs.

What GAO Recommends

While many of GAO's recommendations to promote the safety of the nation's food supply have been acted upon, others have not yet been addressed. For example, GAO recommended that the executive branch reconvene the President's Council on Food Safety to facilitate interagency coordination. GAO also proposed that Congress enact comprehensive, uniform, and risk-based food safety legislation; analyze alternative organizational food safety structures; and consider legislation giving agencies authority to order food recalls.

What GAO Found

GAO's High-Risk Series is intended to raise the priority and visibility of government programs that are in need of broad-based transformation to achieve greater economy, efficiency, effectiveness, accountability, and sustainability. These reports also help Congress and the executive branch carry out their responsibilities while improving the government's performance and enhancing its accountability for the benefit of the American people. In January 2007, as part of our regular update of this series for each new Congress, GAO designated the federal oversight of food safety as a high-risk area for the first time.

We designated federal oversight of food safety as a high-risk area because of the need to transform this system to reduce risks to public health as well as the economy. While this nation enjoys a plentiful and varied food supply that is generally considered to be safe, the federal oversight of food safety is fragmented, with 15 agencies collectively administering at least 30 laws related to food safety. The two primary agencies are the U.S. Department of Agriculture (USDA), which is responsible for the safety of meat, poultry, and processed egg products, and the Food and Drug Administration (FDA), which is responsible for virtually all other food. We have identified examples where the federal government's resources and enforcement activities can better align with the risks of food contamination. For example, the majority of federal expenditures for food safety inspection were directed toward USDA's programs for ensuring the safety of meat, poultry, and egg products; however, USDA is responsible for regulating only about 20 percent of the food supply. In contrast, FDA, which is responsible for regulating about 80 percent of the food supply, accounted for only about 24 percent of expenditures.

Among the reasons we designated federal oversight of food safety as a high-risk area is that limitations in the federal government's food recalls heighten the risk that unsafe food will remain in the food supply and ultimately be consumed. Food recalls are voluntary, and federal agencies responsible for food safety have no authority to compel companies to carry out recalls—with the exception of FDA's authority to require a recall for infant formula. USDA and FDA provided guidance for companies to carry out voluntary recalls. We have reported that USDA and FDA could do a better job carrying out their food recall programs so they can quickly remove potentially unsafe food from the marketplace. At the time of our review, these agencies did not know how promptly and completely companies were carrying out recalls, did not promptly verify that recalls had reached all segments of the distribution chain, and used procedures that may not have been effective to alert consumers to a recall.

www.gao.gov/cgi-bin/getrpt?GAO-07-785T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Lisa Shames at (202) 512-3841 or ShamesL@gao.gov.

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Appendix III: GAO-10-246 (GRAS)



Highlights of GAO-10-246, a report to congressional requesters

February 2010

FOOD SAFETY

FDA Should Strengthen Its Oversight of Food Ingredients Determined to Be Generally Recognized as Safe (GRAS)

Why GAO Did This Study

The Food and Drug Administration (FDA), which is responsible for ensuring the safety of most of the U.S. food supply, is not required to review substances, such as spices and preservatives, added to food that are generally recognized as safe (GRAS) for their intended use. Currently, companies may determine a substance is GRAS without FDA's approval or knowledge. However, a few substances previously considered GRAS have later been banned, and concerns have been raised about the safety of other GRAS substances, including those containing engineered nanomaterials, materials manufactured at a tiny scale to take advantage of novel properties. GAO was asked to review the extent to which (1) FDA's oversight of new GRAS determinations helps ensure the safety of these substances, (2) FDA ensures the continued safety of current GRAS substances, and (3) FDA's approach to regulating engineered nanomaterials in GRAS substances helps ensure the safety of the food supply. GAO reviewed FDA data on GRAS substances and interviewed a range of stakeholders, among other things.

What GAO Recommends

GAO recommends that FDA take steps to better ensure the safety of GRAS substances, including developing a strategy to require any company that conducts a GRAS determination to provide FDA with basic information about it. FDA generally agreed, while raising concerns about certain aspects of several of the recommendations.

View GAO-10-246 or key components. For more information, contact Lisa Shames at (202) 512-3841 or shamesl@gao.gov.

What GAO Found

FDA's oversight process does not help ensure the safety of all new GRAS determinations. FDA only reviews those GRAS determinations that companies submit to the agency's voluntary notification program—the agency generally does not have information about other GRAS determinations companies have made because companies are not required to inform FDA of them. Furthermore, FDA has not taken certain steps that could help ensure the safety of GRAS determinations, particularly those about which the agency has not been notified. FDA has not issued guidance to companies on how to document their GRAS determinations or monitored companies to ensure that they have conducted GRAS determinations appropriately. Lastly, FDA has yet to issue a final regulation for its 1997 proposed rule that sets forth the framework and criteria for the voluntary notification program, potentially detracting from the program's credibility.

FDA is not systematically ensuring the continued safety of current GRAS substances. While, according to FDA regulations, the GRAS status of a substance must be reconsidered as new scientific information emerges, the agency has not systematically reconsidered GRAS substances since the 1980s. FDA officials said they keep up with new developments in the scientific literature and, on a case-by-case basis, information brought to the agency's attention could prompt them to reconsider the safety of a GRAS substance. However, FDA has largely not responded to concerns about GRAS substances, such as salt and the trans fats in partially hydrogenated vegetable oils, that individuals and consumer groups have raised through 11 citizen petitions submitted to the agency between 2004 and 2008. In fact, FDA has decided on the validity of these concerns in only 1 of 11 cases. In addition, FDA does not know to what extent, or even whether, companies track evolving scientific information about their GRAS substances.

FDA's approach to regulating nanotechnology allows engineered nanomaterials to enter the food supply as GRAS substances without FDA's knowledge. While some uses of engineered nanomaterials have the potential to help ensure food safety, uncertainties remain about how to determine their safety in food. After reviewing the uncertainties associated with the safety of engineered nanomaterials, FDA has decided that it does not need additional authority to regulate products containing such materials. Rather, FDA encourages, but does not require, companies considering using engineered nanomaterials in food to consult with the agency regarding whether such substances might be GRAS. Because GRAS notification is voluntary and companies are not required to identify nanomaterials in their GRAS substances, FDA has no way of knowing the full extent to which engineered nanomaterials have entered the U.S. food supply as part of GRAS substances. In contrast to FDA's approach, all food ingredients that incorporate engineered nanomaterials must be submitted to regulators in Canada and the European Union before they can be marketed.

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Appendix IV: GAO-08-1047 (Fresh Produce)



Highlights of GAO-08-1047, a report to congressional requesters

September 2008

FOOD SAFETY

Improvements Needed in FDA Oversight of Fresh Produce

Why GAO Did This Study

In recent years, both domestic and imported produce have been linked to reported outbreaks of foodborne illness. Contamination in produce is of particular concern because produce is often consumed raw. The Food and Drug Administration (FDA) has primary responsibility for ensuring the safety of both domestic and imported fresh produce. GAO was asked to examine (1) the resources FDA has spent on fresh produce safety and how it has allocated those resources, (2) the effectiveness of FDA's actions to oversee fresh produce safety, and (3) the extent to which FDA's planned actions to enhance fresh produce oversight address identified challenges. For this review, GAO analyzed FDA spending data and estimates and FDA activities data, reviewed FDA plans, and interviewed FDA officials and others.

What GAO Recommends

GAO recommends, among other things, that the Commissioner of FDA update its guidance on good agricultural practices and its regulations on current good manufacturing practice for food, and seek explicit authority from the Congress to adopt preventive controls for high-risk foods and authority for enhanced access to records.

FDA agreed with most of GAO's recommendations but believed that it had sought authority from the Congress. FDA should continue to take steps to obtain these authorities so that it can conduct its oversight responsibilities.

To view the full product, including the scope and methodology, click on GAO-08-1047. For more information, contact Lisa Shames at (202) 512-3841 or shamesl@gao.gov.

What GAO Found

While FDA has considered fresh produce safety a priority for many years, resource constraints and other work—including counterterrorism efforts and unplanned events such as foodborne illness outbreaks—have caused FDA to delay key produce safety activities. FDA has no formal program devoted exclusively to fresh produce and has not consistently and reliably tracked its fresh produce spending. Based on FDA estimates, FDA spent at least \$20 million and 130 staff years on fresh produce in fiscal year 2007—or about 3 percent of its food safety dollars and 4 percent of its food safety staff years. In addition, FDA had few staff dedicated solely to fresh produce safety. Moreover, FDA acknowledged that it has not yet been able to conduct certain fresh produce work crucial to understanding the incidence of contamination of produce by pathogens such as *E. coli* O157:H7 or *Salmonella*, because it has lacked the resources to either fund its extramural research grant program or perform some critical research internally. Finally, FDA delayed issuing final fresh-cut produce guidance at least 6 years because it had to shift staff to counterterrorism and outbreak investigation work.

FDA has provided limited oversight of domestic and imported fresh produce. For example, while FDA has issued guidance for industry on recommended practices for reducing the risk of contamination during the processing of fresh-cut produce, it has not issued regulations requiring firms to take action to prevent contamination, even though some industry groups would like it to do so. FDA's intervention efforts have also been limited. Specifically, domestic fresh produce firms were inspected infrequently. Furthermore, FDA examined less than 1 percent of the 7.6 million fresh produce lines imported from fiscal years 2002 through 2007. Finally, FDA has improved some elements of its emergency response by, for example, partnering with California on outbreak investigations. However, it faces challenges in tracing an outbreak involving fresh produce back to its source because produce is highly perishable and may no longer be available for testing. Also, when product is available, it may be unlabeled or mixed in packages containing products from multiple sources.

FDA has proposed changes through its *Food Protection Plan* that could significantly enhance its fresh produce oversight. However, the agency is still in the planning stages for several enhancements and has not provided specific information on strategies and resources, making it difficult to assess the likelihood of success. To help prevent contamination, FDA plans to update its existing guidance on good agricultural practices and regulations on current good manufacturing practice for food, and has identified a need for explicit authority to issue preventive safety regulations for high-risk foods and enhanced access to records. To enhance intervention efforts, FDA plans to use more rigorous risk-based criteria to target domestic firm inspections and is testing a new import screening software tool. To improve response efforts, FDA is examining best practices for tracing contaminated foods to their source.

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