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FEDERAL OVERSIGHT OF FOOD SAFETY

FDA Has Provided Few Details on the Resources and Strategies Needed to Implement its Food Protection Plan

Statement of Lisa Shames, Director
Natural Resources and Environment

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Highlights

Highlights of GAO-08-909T, a testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

The Food and Drug Administration (FDA) is responsible for ensuring the safety of roughly 80 percent of the U.S. food supply, including $417 billion worth of domestic food and $49 billion in imported food annually. Changing demographics and consumption patterns along with an increase in imports have presented challenges to FDA. At the same time, recent outbreaks, such as *E. coli from* spinach and *Salmonella* from tomatoes, have undermined consumer confidence in the safety of the food supply. In November 2007, FDA released its *Food Protection Plan*, which articulates a framework for improving food safety oversight. In January 2008, GAO expressed concerns about FDA's capacity to implement the *Food Protection Plan* and noted that more specific information about the strategies and resources needed to implement the plan would facilitate congressional oversight.

This testimony focuses on (1) FDA's progress in implementing the *Food Protection Plan*, (2) FDA's proposal to focus inspections based on risk, and (3) FDA's implementation of previously issued GAO recommendations intended to improve food safety oversight. To address these issues, GAO reviewed FDA documents, such as FDA's operations plan, and FDA data related to the plan. GAO also interviewed FDA officials regarding the progress made. GAO also analyzed FDA data on domestic and foreign food firm inspections. GAO also analyzed the status of past recommendations.

To view the full product, including the scope and methodology, click on GAO-08-909T. For more information, contact Lisa Shames at (202) 512-3841 or shamesl@gao.gov.

What GAO Found

Since FDA's *Food Protection Plan* was first released in November 2007, FDA has added few details on the resources and strategies required to implement the plan. FDA plans to spend about $90 million over fiscal years 2008 and 2009 to implement several key actions, such as identifying food vulnerabilities and risk. From the information GAO has obtained on the *Food Protection Plan*, however, it is unclear what FDA's overall resource need is for implementing the plan, which could be significant. For example, based on FDA estimates, if FDA were to inspect each of the approximately 65,500 domestic food firms regulated by FDA once, the total cost would be approximately $524 million. In addition, timelines for implementing the various strategies in the plan are also unclear, although a senior level FDA official estimated that the overall plan will take 5 years to complete. Importantly, GAO has noted that public reporting is the means through which the federal government communicates the results of its work to the Congress and the American people. FDA officials told GAO that they had prepared a draft report on progress made in implementing the *Food Protection Plan*, but as of June 4, 2008, FDA told GAO that the Department of Health and Human Services had not cleared the report for release.

The *Food Protection Plan* identifies the need to focus safety inspections based on risk, which is particularly important as the numbers of food firms have increased while inspections have decreased. For example, between 2001 and 2007, the number of domestic firms under FDA's jurisdiction increased from about 51,000 to more than 65,500, while the number of firms inspected declined slightly, from 14,721 to 14,566. Thus, conducting safety inspections based on risk has the potential to be an efficient and effective approach for FDA to target scarce resources based on relative vulnerability and risk.

FDA has implemented few of GAO's past recommendations to leverage its resources and improve food safety oversight. Since 2004, GAO has made a total of 34 food safety related recommendations to FDA, and as of May 2008, FDA has implemented 7 of these recommendations. For the remaining recommendations, FDA has not fully implemented them, however, in some cases, FDA has taken some steps. However, the planned activities in the *Food Protection Plan* could help address several of the recommendations that FDA has not implemented. For example, in January 2004, GAO recommended that FDA make it a priority to establish equivalence agreements with other countries. We found that such agreements would shift some of FDA's oversight burden to foreign governments. As of May 2008, FDA has not yet established equivalence agreements with any foreign countries. The *Food Protection Plan* requests that Congress allow the agency to enter into agreements with exporting countries to certify that foreign producers' shipments of designated high-risk products comply with FDA standards.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss the Food and Drug Administration's (FDA) progress in implementing the *Food Protection Plan*, which articulates FDA's plans to improve the oversight of food safety. FDA is responsible for ensuring the safety of roughly 80 percent of the U.S. food supply—virtually all foods except for meat, poultry, and processed egg products—including $417 billion worth of domestic food and $49 billion in imported food annually. As you know, in January 2007, we designated the federal oversight of food safety as a high-risk area needing urgent attention and transformation.[1] A key reason for that designation is that FDA is one of 15 agencies that collectively administer at least 30 laws related to food safety. Around the time of this designation, consumers faced several outbreaks of foodborne illnesses, including *E. coli* from spinach and *Salmonell*a from peanut butter. Subsequently, the U.S. has seen more outbreaks of foodborne illnesses, such as *Salmonella* from imported cantaloupes and raw tomatoes. Not surprisingly, public trust in FDA's ability to protect the food supply has fallen. A 2008 Harris poll showed that U.S. adults have little confidence—and less confidence than last year—in the safety of packaged or prepared foods that have been imported from countries like China, India, or South Africa. In addition, a recent public opinion poll conducted by the Trust for America's Health[2] found that 67 percent of Americans are worried about food safety, ranking it higher than concerns about, for example, pandemic flu or natural disasters.

Concerns about food safety oversight are not new. GAO and others have consistently reported on a lack of adequate oversight of food safety by FDA, and have provided many recommendations for better leveraging FDA's limited resources and suggestions for additional authorities that would allow FDA to better fulfill its responsibilities. In 1998, we reported that limitations in FDA's authority and its need to more effectively target limited resources could adversely affect its ability to ensure food safety.[3] A decade later, the story remains the same and has only taken on a greater sense of urgency due to changing demographics and consumption patterns

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

[2] Trust for America's Health is a non-profit, non-partisan organization dedicated to protecting the public's health.

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

that, according to FDA, have put more of the U.S. population at risk of contracting foodborne illnesses. Populations at high risk of foodborne illnesses—older adults, young children, pregnant women, and immune compromised individuals—now make up 20 to 25 percent of the U.S. population. In addition, U.S. consumers are increasingly eating raw or minimally processed foods, which are often associated with foodborne illnesses. For example, the consumption rate of leafy greens—the category of produce most likely to be associated with an outbreak—increased 180 percent between 1992 and 2005, according to the U.S. Department of Agriculture. Compounding the challenges, the number of FDA-regulated domestic food establishments has increased more than 10 percent in the last five years and the number of food import entry lines has tripled in the past ten years.[4]

To respond to the need for better oversight of food safety, FDA released its *Food Protection Plan* in November 2007, which articulates FDA's framework for overseeing the safety of food and outlines three core elements—prevention, intervention, and response—that are the focus of FDA's efforts to improve oversight.[5] At the same time, a twelve-agency working group presented to the President its *Action Plan for Import Safety*,[6] which contains, among other things, recommendations for improving the safety of food imports entering the United States. Both plans spell out numerous actions FDA plans to take to enhance food safety, including writing new food protection guidelines for industry and helping foreign countries improve their regulatory systems. The plans also request new legislative authorities, such as enhanced access to a food company's records during food safety emergencies.

Also, in November 2007, FDA's Science Board, an advisory board to the agency, released a report entitled, *FDA Science and Mission at Risk*.[7] This report concluded that FDA is not positioned to meet current or emerging

[4]According to FDA, 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 must be listed separately.

[5]Department of Health and Human Services, U.S. Food and Drug Administration, *Food Protection Plan* (Washington, D.C., 2007).

[6]Interagency Working Group on Import Safety, *Action Plan for Import Safety* (Washington, D.C., 2007).

[7]FDA Science Board, Subcommittee on Science and Technology, *FDA Science and Mission at Risk* (Washington, D.C., November 2007).

regulatory needs, and stated that FDA does not have the capacity, such as staffing and technology, to ensure the safety of the nation's food supply. According to the Science Board report, FDA's resources have not kept pace with its increasing responsibilities, and this disparity has made it increasingly "impossible" for FDA to maintain its historic public health mission. In addition, the report finds that food safety resources have increasingly been diverted away from routine surveillance and other tasks to managing crises as they arise and the nation's food supply is at risk. In February 2008, the Science Board estimated that, to implement its recommendations to protect the nation's food supply, FDA's base budget would need to increase by a total of $755 million by fiscal year 2013, phased in over time starting with $128 million in fiscal year 2009.

In response to these concerns, Congress has expressed considerable interest in enhancing FDA's oversight of food safety, and the House Energy and Commerce Committee has held hearings to consider a draft bill entitled The Food and Drug Administration Globalization Act of 2008 which, in part, would provide some of FDA's requested authorities.[8] This draft bill also contains provisions that are consistent with several past GAO recommendations to FDA and matters for congressional consideration regarding FDA's food safety programs. For example, the draft bill contains provisions that would allow FDA to leverage resources using outside organizations, such as third-party inspectors.

As part of its congressional oversight of FDA's challenges in meeting its responsibilities, we testified in January 2008 before this subcommittee and reported that FDA's *Food Protection Plan* proposes positive first steps for FDA.[9] For example, FDA requests authority to order food recalls and issue additional preventive controls for high-risk foods, both of which we previously recommended. However, we expressed concerns about FDA's capacity to implement the plan and noted that more specific information about its strategies and the resources FDA needs to implement the plan would facilitate congressional oversight. We recognized that without a clear description of resources and strategies, it would be difficult for

[8]Committee on Energy and Commerce, U.S. House of Representatives, Discussion Draft: The Food and Drug Administration Globalization Act of 2008 (Apr. 16, 2008), *available at* http://energycommerce.house.gov/FDAGlobalAct-08/index.shtml

[9]GAO, *Federal Oversight of Food Safety: FDA's Food Protection Plan Proposes Positive First Steps, but Capacity to Carry Them Out is Critical*, GAO-08-435T (Washington, D.C.: Jan. 29, 2008).

Congress to assess the likelihood that the plan will achieve its intended results.

In this context, my testimony today focuses on FDA's progress in implementing the *Food Protection Plan*, FDA's proposal to focus inspections based on risk, and FDA's implementation of previously issued GAO recommendations intended to improve food safety oversight. In summary, we have found (1) FDA has added few details on the resources and strategies required to implement its *Food Protection Plan*, (2) FDA's proposal to focus inspections based on risk can help target scarce resources, and (3) FDA has implemented few of our recommendations intended to help leverage resources and improve operations. This testimony is based on new and previously issued work.

To assess FDA's progress in implementing the *Food Protection Plan*, we reviewed FDA documents, such as FDA's operations plan and work plan, and FDA data related to the plan. In addition, we interviewed FDA officials regarding the progress made to date in implementing the *Food Protection Plan*. To review FDA's proposal to focus inspections based on risk, we analyzed FDA's data on past domestic and foreign food firm inspections. To determine actions that FDA has taken on our past recommendations, we obtained and analyzed information from FDA on the status of these recommendations. We conducted our work between May and June 2008 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 the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

FDA Has Added Few Details on the Resources and Strategies Required to Implement Its *Food Protection Plan*

In light of the federal government's long-term fiscal challenges, it is critical that agencies can justify the needed resources and develop effective, efficient strategies to achieve their mission. We testified in January 2008 that, while FDA officials had acknowledged that implementing the *Food Protection Plan* would require additional resources, FDA had not provided specific information on the resources it anticipates the agency will need to implement this plan to improve its oversight of food safety. For example, the *Food Protection Plan* proposes to enhance FDA's information technology systems related to both domestic and imported foods which the Science Board report suggests could cost hundreds of millions of dollars. At that time, FDA officials stated they would provide specific information on how much additional funding would be necessary to

implement the *Food Protection Plan* when the President's budget was publicly released in the coming weeks.

In its fiscal year 2008 budget, FDA received approximately $620 million for food protection, an increase of about $56 million over fiscal year 2007, and directed $48 million of that amount toward implementing the *Food Protection Plan*, according to FDA. FDA requested approximately $662 million for food safety for fiscal year 2009, an increase of about $42 million over fiscal year 2008. According to the Department of Health and Human Services' budget justification, FDA plans to direct the $42 million to strategic actions described in its *Food Protection Plan*. As shown in table 1, the plan outlines spending on all three core elements of the *Food Protection Plan*—a total of about $21 million for prevention, about $34 million for intervention, and about $23 million for response for fiscal years 2008 and 2009. FDA also reported that, in fiscal year 2008, the agency intends to hire nearly 1,500 full time equivalents (FTE), including approximately 730 to fill vacant positions. Of these, 161 will be new FTEs funded by congressional increases dedicated to food safety activities. In addition, in fiscal year 2009, FDA plans to hire 94 new FTEs for food safety activities.

Table 1: Current and planned spending for *Food Protection Plan* Core Elements and Strategic Actions, Fiscal Years 2008 and 2009

Food Protection Plan core elements and strategic actions	Fiscal year 2008 increase	Fiscal year 2009 increase	Total current/planned spending for fiscal years 2008 and 2009
Total for core element 1: prevention	**10,024,000**	**11,414,000**	**21,438,000**
1.1: Promote increased corporate responsibility to prevent foodborne illnesses	3,108,000	6,311,000	9,419,000
1.2: Identify food vulnerabilities and assess risks	5,580,000	4,302,000	9,882,000
1.3: Expand the understanding and use of effective mitigation measures	1,336,000	801,000	2,137,000
Total for core element 2: intervention	**18,509,000**	**15,606,000**	**34,115,000**
2.1: Focus inspections and sampling based on risk	16,187,000	14,864,000	31,051,000
2.2: Enhance risk-based surveillance of imported foods at the border	2,322,000	742,000	3,064,000
2.3: Improve the detection of food system "signals" that indicate contamination	0	0	0
Total for core element 3: response	**19,589,000**	**3,174,000**	**22,763,000**
3.1: Improve immediate response	19,589,000	2,954,000	22,543,000
3.2: Improve risk communications to the public, industry and other stakeholders	0	220,000	220,000
Sub-total	**48,122,000**	**30,194,000**	**78,316,000**
Cost of living pay increase for onboard food protection employees	0	12,038,000	12,038,000
Total for entire *Food Protection Plan*	**48,122,000**	**42,232,000**	**90,354,000**

Source: FDA.

Furthermore, in May 2008, FDA's Commissioner of Food and Drugs provided his professional judgment in response to a congressional request of FDA's immediate resource needs to implement key initiatives across the core elements of the *Food Protection Plan*. The Commissioner called for an additional $125 million for food protection in fiscal year 2008 beyond the $48 million that FDA had already allocated for implementing the *Food Protection Plan* in this fiscal year. According to the Commissioner, this increase will allow FDA to address some of the plan's strategic actions, such as identifying and targeting the greatest threats from intentional and unintentional contamination and conducting more risk-based inspections. The Commissioner's assessment also calls for 250 additional FTEs to accomplish the goals of the *Food Protection Plan*. After the Commissioner provided his assessment of FDA's resource needs, the Senate passed an Iraq War Supplemental that included an additional $119 million for food safety to be available through fiscal year 2009. In addition, on June 9, 2008, the Department of Health and Human Services announced that the

Administration is amending its fiscal year 2009 budget request to include, in part, a $125 million increase for food safety. This amount would add to the $42 million increase originally proposed in the fiscal year 2009 budget justification (see table 1) and appears to be consistent with the Commissioner's professional judgment response. To accompany this amendment, FDA has posted information on steps it is taking to invest in its transformation in areas such as domestic medical products, import products, and domestic food safety. For example, under transforming domestic food safety, FDA reports that it issued final fresh cut produce guidance to limit contamination of fresh-cut fruits and vegetables. In addition, FDA conducted inspections and took action against processors of low acid canned foods that were deviating from required standards.

In addition, in January 2008, we testified that the *Food Protection Plan* does not discuss the strategies it needs in the upcoming years to implement this plan. When we asked FDA for more specificity on the strategies for implementing the plan, FDA officials told us that they have internal plans for implementing the *Food Protection Plan* that detail timelines, staff actions, and specific deliverables. More recently, a senior level FDA official provided us with an estimate of 5 years for fully implementing the plan. However, FDA has not provided us with timelines for the various strategies described in the plan. For example, under the plan's strategic action 2.3—to improve the detection of food system "signals" that indicate contamination (see table 1)—FDA has recently identified three additional action steps with deliverables that will be needed to identify, develop, and deploy new screening tools and methods to identify pathogens and other contaminants. However, FDA could not provide us with an estimate of how long it would take to implement these steps or the overall strategic action. Without this type of information, we are not able to assess whether FDA's estimated 5-year time frame is feasible.

Similarly, while FDA's *Food Protection Plan* recognizes the need to partner with Congress to obtain 10 additional statutory authorities to transform the safety of the nation's food supply, FDA's congressional outreach strategy is general. When we asked FDA officials if they had a congressional outreach strategy, FDA officials told us that they had met with various congressional committees to discuss the *Food Protection Plan*. When asked if they had provided draft language to congressional committees on the various authorities, FDA officials explained that they only provided technical assistance, such as commenting on draft bills, to congressional staff when asked.

FDA appears to be refining its implementation plan over time. Most recently, in June 2008, FDA provided us with a draft work plan that it characterizes as a dynamic document that changes on a daily basis to implement the *Food Protection Plan*. While this draft work plan provides more information on the action steps and deliverables to achieve the core elements, we continue to have concerns about FDA's lack of specificity on the necessary resources and strategies to fully implement the plan. For example, as part of the plan's strategic action 1.1—to promote increased corporate responsibility to prevent foodborne illnesses (see table 1)—FDA has identified a goal of analyzing food import trend data and focusing inspections based on risk, and the draft work plan shows six deliverables, such as analysis of import data sets and an import risk ranking, associated with this goal. However, the timelines for these deliverables are unclear. In addition, the agency plans to dedicate a total of $673,000 to this goal in fiscal years 2008 and 2009, and FDA officials told us that the agency considers this funding to be a down payment toward achieving this goal. However, it is unclear what the total cost will be to meet this goal. While the work plan provides some basic information, more specific information, such as estimated resources needed to implement the various strategies—the core elements, goals, and deliverables—as well as the overall plan and timeframes for implementing the strategies, are needed to assess FDA's progress in implementing the plan or in acquiring the resources and authorities it needs.

Anticipating the cost of the overall plan is important because, while some activities, such as meeting with industry experts to discuss corporate responsibility, may be accomplished within one budget cycle, others, such as the establishment of an FDA field office in China will likely require a long-term commitment of agency resources. From the information we have obtained on the *Food Protection Plan*, it is unclear what FDA's overall resource need is for implementing the plan. The overall resource need could be significant. For example, if FDA were to inspect each of the approximately 65,500 domestic food firms regulated by FDA, at the Commissioner's May 2008 estimate of $8,000 for a domestic food safety inspection, it would cost approximately $524 million to inspect all of these facilities once. Similarly, if FDA were to inspect each of the 189,000 registered foreign facilities (which includes facilities that manufacture, process, pack, or hold foods consumed by Americans) at the Commissioner's estimated cost of $16,700 per inspection, it would cost FDA approximately $3.16 billion to inspect all of these facilities once. These figures underscore the need for FDA to focus safety inspections based on risk.

Ultimately, a results-oriented organization needs to take a long-term view of the goals it wants to accomplish and describe them in a strategic plan. To facilitate congressional oversight, strategic plans should discuss (1) long-term goals and objectives for all major functions; (2) approaches to achieve the goals and objectives, and in particular the required resources including human capital and information technology; (3) a relationship between the long-term goals and the annual performance goals; and (4) an identification of key factors that could significantly affect achievement of the strategic goals. Such discussions in the *Food Protection Plan* could help clarify FDA's organizational priorities to the Congress, other stakeholders, and the public.

Lastly, when we testified before this subcommittee in January, we reported that FDA planned to keep the public informed of their progress on implementing the *Food Protection Plan*. In addition, in March 2008, FDA officials indicated that a progress report on actions taken to implement the *Food Protection Plan* would be issued in April 2008. In May, FDA officials told us that they had prepared a draft progress report, but as of June 4, 2008, FDA had not made this report public. FDA officials told us that the progress report is still being cleared by the Department of Health and Human Services, and they could not provide us with the report until it was cleared by the department. Instead, FDA officials provided us with a broad overview of FDA's actions and, subsequently, provided us with a list of accomplishments drawn out of numerous public documents. For example, FDA issued a Federal Register Notice to solicit stakeholder comments on the implementation of the *Food Protection Plan* as part of a broad outreach plan.

We have noted that public reporting is the means through which the federal government communicates the results of its work to the Congress and the American people. Such reporting is in the public interest and promotes transparency in government operations. While it is important to show what progress has been made, having such information in a consolidated document at a readily accessible location reassures Congress and the public that actions have been taken.

FDA's Proposal to Focus Inspections Based on Risk Can Help Target Scarce Resources

The *Food Protection Plan* identifies the need to focus safety inspections based on risk, which is particularly important as the numbers of food firms have increased while inspections have decreased. In its *Food Protection Plan*, FDA has identified some actions to better identify food vulnerabilities and assess risks. For example, FDA plans to use enhanced modeling capability, scientific data, and technical expertise to evaluate and prioritize the relative risks of specific food and animal feed agents that may be harmful. According to FDA officials, the agency has assigned a risk-based steering committee to identify models for ranking and prioritizing risk.

Conducting inspections based on risk has the potential to be an efficient and effective approach for FDA to target scarce resources, particularly when the number of inspections has not kept pace with the growth in firms between 2001 and 2007. Specifically, while the number of domestic firms under FDA's jurisdiction increased from about 51,000 to more than 65,500, the number of firms inspected declined slightly, from 14,721 to 14,566. FDA also reported declines in the number of inspections at overseas firms between 2001 and 2007—even as the United States has imported hundreds of thousands of different food products from tens of thousands of foreign food firms in more than 150 countries. Appendix I has information on the number of FDA inspections of food firms in foreign countries from fiscal years 2001 through 2007.

GAO Has Issued Recommendations Intended to Help Leverage Resources and Improve Operations, but FDA Has Implemented Few of Them

FDA has implemented few of our past recommendations to improve food safety oversight. Our recommendations are designed to correct identified problems and improve programs and operations. We have made 34 food safety related recommendations to FDA since 2004 and, as of May 2008, FDA has implemented 7. For the remaining recommendations, FDA has not fully implemented them, however, in some cases, FDA has taken some steps. As shown in table 2, these recommendations fall into two broad categories: improving monitoring and enforcement processes and leveraging resources. The planned activities in the *Food Protection Plan* could help address several of these recommendations.

Table 2: FDA's Implementation of GAO's Food Safety Recommendations, Since 2004

Category of recommendation	Total recommendations	Recommendations FDA has implemented	Recommendations FDA has not fully implemented
Improving monitoring and enforcement processes	21	3	18
Leveraging resources	13	4	9
Total Recommendations	**34**	**7**	**27**

Source: GAO and FDA.

In light of the federal government's long-term fiscal challenges, agencies, including FDA, need to seek out opportunities to better leverage their resources. We have made 13 recommendations to help FDA better leverage its resources since 2004, and FDA has implemented 4 of them. In a January 2004 report regarding seafood safety, we recommended that, among other things, FDA make it a priority to establish equivalence agreements with other countries.[10] We found that such agreements would shift some of FDA's oversight burden to foreign governments. FDA did not concur with this recommendation, and as of May 2008, has not yet established equivalence agreements with any foreign countries. In the same report, we recommended that FDA give priority to taking enforcement actions when violations that pose the most serious health risk occur; consider the cost and benefits of implementing an accreditation program for private laboratories; and explore the potential of implementing a certification program for third-party inspectors. Although FDA concurred with these recommendations and has taken some limited action such as requesting public comments on the use of third-party certification programs, none were fully implemented. The *Food Protection Plan* requests that Congress allow the agency to enter into agreements with exporting countries to certify that foreign producers' shipments of high-risk products comply with FDA standards.

Since 2004, we have made 21 recommendations to FDA to improve monitoring and enforcement processes, and FDA has implemented 3 of

[10]GAO, *Food Safety: FDA's Imported Seafood Safety Program Shows Some Progress, but Further Improvements are Needed*, GAO-04-246 (Washington, D.C.: Jan. 30, 2004).

them. For example, in October 2004, we recommended that FDA develop a sound methodology for district staff to verify that companies have quickly and effectively carried out recalls.[11] At the time of our review, we found that FDA was not calculating the recovery rate for recalls. As a result, the agency did not know how much food was actually recovered, although the agency told us recovery was an important indicator of a successful recall. FDA initially commented that we had not demonstrated that weaknesses in FDA's recall process resulted in little recovery of food, but as of May 2008, the agency is in the process of conducting a quality management system review of its recall activities and, once the review is completed, it will include recommendations for verifying that a company's recall was effective, according to FDA.

To conclude, FDA's release of the *Food Protection Plan* is a positive first step toward modernizing FDA's approach to food safety to better meet the challenges of an increasingly global food supply and respond to shifting demographics and consumption patterns. Given that FDA's resources have not kept pace with its increasing responsibilities, FDA's plan to take a risk-based approach to inspections could help FDA make the most effective and efficient use of its limited resources. However, FDA's *Food Protection Plan* can only be as effective as its implementation, and without specificity on the resources and strategies needed to fully implement the plan—and in the absence of public reporting—neither Congress nor the public can gauge the plan's progress or assess its likelihood of success in achieving its intended results. In addition, no one is better poised than FDA to identify the resources and authorities needed to implement the plan; therefore, FDA's capacity to provide such information can be questioned. Meanwhile, as foodborne illness outbreaks continue, FDA is missing valuable opportunities to reassure Congress and the public that it is doing all it can to protect the nation's food supply.

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

[11]GAO, *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).

Contact and Staff Acknowledgments

Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. For further information about this testimony, please contact Lisa Shames, Director, Natural Resources and Environment at (202) 512-3841 or shamesl@gao.gov. Key contributors to this statement were José Alfredo Gómez, Assistant Director; Kevin Bray; Candace Carpenter; Alison Gerry Grantham; Thomas McCabe; Alison O'Neill; and Barbara Patterson.

Appendix I: Number of FDA Inspections of Food Firms in Foreign Countries, as of December 2007

FDA Inspections of Foreign Food Firms, Fiscal Years 2001 - 2007								
	2001	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**	**Total**
Mexico	17	15	8	15	7	16	26	104
Ecuador	8		11	24		11	10	64
Chile	13		15	6	7	11		52
Peru	13			18	1	9	9	50
Brazil		12	6	7	21			46
Thailand	4	10		10		22		46
Canada	13		13	1		7	4	38
China		9	2	6	16			33
Taiwan	9	7		9		7		32
Argentina	7	5					19	31
India	6		10		7	7		30
South Korea	14			1	7		6	28
Australia	12		6			9		27
Costa Rica		11		4	5	7		27
Vietnam		9		10	8			27
Honduras	9	8			7			24
Fiji			8				13	21
Singapore	10			8				18
Estonia	8			8				16
Guatemala		10			6			16
South Africa	5		11					16
Germany	5	4	4			1	1	15
Nicaragua		8				7		15
31 additional countries[a]	58	61	54	26	40	11	8	258
Total number of countries inspected	**26**	**22**	**22**	**20**	**16**	**15**	**11**	**54**
Total Inspections	**211**	**169**	**148**	**153**	**132**	**125**	**96**	**1034**

Source: GAO analysis of FDA data.

Note: [a]Countries with a total of 14 or fewer inspections between 2001 and 2007 are not listed in the table. These countries include: El Salvador (14 inspections), Jamaica (14), Latvia (14), Uruguay (14), Venezuela (14), Italy (13), Morocco (13), New Zealand (13), Poland (13), Norway (11), France (10), Romania (10), Suriname (10), Iceland (9), Malaysia (9), Bulgaria (8), Columbia (8), Cyprus (7), Panama (7), Trinidad and Tobago (7), United Kingdom (6), Turkey (5), Spain (4), Belgium (3), Greece (3), Hungary (3), Finland (2), Haiti (2), Japan (2), and the Netherlands (2). FDA also inspected food firms in Hong Kong (8).

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