



Testimony

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**FEDERAL OVERSIGHT OF
FOOD SAFETY**

**FDA's Food Protection Plan
Proposes Positive First
Steps, but Capacity to Carry
Them Out Is Critical**

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Highlights of [GAO-08-435T](#), 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. The recent outbreaks of *E. coli* in spinach, *Salmonella* in peanut butter, and contamination in pet food highlight the risks posed by the accidental contamination of FDA-regulated food products. Changing demographics and consumption patterns underscore the urgency for effective food safety oversight. In response to these challenges, in November 2007, FDA and others released plans that discuss the oversight of food safety. FDA's *Food Protection Plan* sets a framework for food safety oversight. In addition, FDA's Science Board released *FDA Science and Mission at Risk*, which concluded that FDA does not have the capacity to ensure the safety of the nation's food supply.

This testimony focuses on (1) federal oversight of food safety as a high-risk area that needs a governmentwide reexamination, (2) FDA's opportunities to better leverage its resources, (3) FDA's *Food Protection Plan*, and (4) tools that can help agencies to address management challenges. To address these issues, GAO interviewed FDA officials; evaluated the *Food Protection Plan* using a GAO guide for assessing agencies' performance plans; and reviewed pertinent statutes and reports. GAO also analyzed data on FDA inspections and resources.

To view the full product, including the scope and methodology, click on [GAO-08-435T](#). For more information, contact Lisa Shames at (202) 512-3841 or ShamesL@gao.gov.

FEDERAL OVERSIGHT OF FOOD SAFETY

FDA's Food Protection Plan Proposes Positive First Steps, but Capacity to Carry Them Out Is Critical

What GAO Found

FDA is one of 15 agencies that collectively administer at least 30 laws related to food safety. This fragmentation is the key reason GAO added the federal oversight of food safety to its High-Risk Series in January 2007 and called for a governmentwide reexamination of the food safety system. We have reported on problems with this system—including inconsistent oversight, ineffective coordination, and inefficient use of resources.

FDA has opportunities to better leverage its resources. Efficient use of resources is particularly important at FDA because we found that its food safety workload has increased in the past decade, while its food safety staff and funding have not kept pace. GAO has recommended that FDA establish equivalence agreements with other countries to shift some oversight responsibility to foreign governments, explore the potential for certifying third party inspections, and consider accrediting private laboratories to inspect seafood, among other actions. We also reported that FDA and the U.S. Department of Agriculture (USDA) conduct similar inspections at 1,451 facilities that produce foods regulated by both agencies. To reduce overlaps, we recommended that, if cost-effective, FDA enter into an agreement to commission USDA inspectors at such facilities. FDA incorporated some of these recommendations in its *Food Protection Plan*.

FDA's *Food Protection Plan* also proposes some positive first steps intended to enhance its oversight of food safety. Specifically, FDA requests authority to order food safety recalls and issue additional preventive controls for high-risk foods, both of which GAO has previously recommended. However, more specific information about its strategies and the resources FDA needs to implement the plan would facilitate congressional oversight. FDA officials acknowledge that implementing the *Food Protection Plan* will require additional resources. Without a clear description of resources and strategies, it will be difficult for Congress to assess the likelihood of the plan's success in achieving its intended results.

The Science Board cites numerous management challenges that have contributed to FDA's inability to fulfill its mission, including a lack of a coherent structure and vision, insufficient capacity in risk assessment, and inadequate human capital recruitment and retention. In light of these challenges, GAO has identified through other work some tools that can help agencies improve their performance over time. For example, a Chief Operating Officer/Chief Management Officer can help an agency address longstanding management problems that are undermining its ability to accomplish its mission and achieve results. In addition, a well-designed commission can produce specific practical recommendations that Congress can enact. Critical success factors that can help ensure a commission's success include a statutory basis with adequate authority, a clear purpose and timeframe, leadership support, an open process, a balanced membership, accountability, and resources.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss the resources the Food and Drug Administration (FDA) uses to meet one of its key regulatory responsibilities, the oversight of food safety. 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. Contaminated food can harm human health, have severe economic consequences, and undermine consumer confidence in the government's ability to ensure the safety of the U.S. food supply. The recent outbreaks of *E. coli* in spinach, *Salmonella* in peanut butter, and contamination in pet food, highlight the risks posed by the accidental contamination of FDA-regulated food products. For example, according to FDA, the recent California spinach *E. coli* outbreak resulted in 205 confirmed illnesses and 3 deaths, and industry representatives estimate that economic losses ranged from \$37 million to \$74 million.

Changing demographics and consumption patterns underscore the urgency for effective food safety oversight. According to FDA, shifting demographics mean that more of the U.S. population is, and increasingly will be, susceptible to foodborne illnesses. The risk of severe and life-threatening symptoms from infections caused by foodborne pathogens is higher for older adults, young children, pregnant women, and immune compromised individuals. According to FDA, these groups make up about 20 to 25 percent of the U.S. population. In addition, we are increasingly eating foods that are consumed raw or with minimal processing and often associated with foodborne illness. For example, according to the U.S. Department of Agriculture (USDA), leafy greens such as spinach, are the category of produce most likely to be associated with an outbreak, and the average consumer ate 2.4 pounds of fresh spinach in 2005—a 180 percent increase over 1992.

In response to these increasing challenges, FDA and other agencies recently released plans that discuss the oversight of food safety. In November 2007, FDA released its *Food Protection Plan*, which sets forth FDA's framework for overseeing the safety of food.¹ Concurrently, a twelve-agency working group presented to the President its *Action Plan*

¹Department of Health and Human Services, U.S. Food and Drug Administration, *Food Protection Plan* (Washington, D.C., 2007).

for Import Safety,² 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. One requested legislative authority is for enhanced access to a food company's records during food safety emergencies. Subsequently, FDA's Science Board, an advisory board to the agency, released a report titled, *FDA Science and Mission at Risk*.³ This report, which is the focus of today's hearing, concluded that FDA is not positioned to meet current or emerging 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. In addition, the report found that FDA's ability to provide its basic food system inspection, enforcement, and rulemaking functions is severely eroded, as is its ability to respond to outbreaks of foodborne illnesses in a timely manner and to develop and keep pace with the science needed to prevent food safety problems. The report stated that the system cannot be fixed using available resources, and its primary food safety recommendation was that FDA needs additional resources to fulfill its regulatory mandate.

I will focus on four key points: (1) federal oversight of food safety is a high-risk area that needs a governmentwide reexamination, (2) FDA has opportunities to better leverage its resources, (3) FDA's *Food Protection Plan* proposes some positive first steps but additional information on the plan's strategies and resources can facilitate congressional oversight, and (4) tools such as a commission or chief operating officer can help agencies to address management challenges. This testimony is based on new and previously issued work. Today, GAO is also testifying on another FDA regulatory responsibility—inspections of medical device manufacturers.⁴ These and other recent testimonies on food and drug safety offer observations on FDA's management capacity.

²Interagency Working Group on Import Safety, *Action Plan for Import Safety* (Washington, D.C., 2007).

³FDA Science Board, Subcommittee on Science and Technology, *FDA Science and Mission at Risk* (Washington, D.C., November 2007).

⁴GAO, *Medical Devices: Challenges for FDA in Conducting Manufacturer Inspections*, [GAO-08-428T](#) (Washington, D.C.: Jan. 29, 2008).

To assess FDA's *Food Protection Plan*, we interviewed FDA officials; reviewed pertinent statutes and reports; and evaluated the plan using a GAO guide for assessing agencies' performance plans. To analyze data on FDA inspections, we examined data from FDA and determined that they were sufficiently reliable for our analyses. We also reviewed funding data from the Science Board and analyzed the data in real terms. To provide updated information on our previously issued reports, we gathered information on the status of our recommendations. We conducted our work in January 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 that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Federal Oversight of Food Safety Is a High-Risk Area that Needs a Governmentwide Reexamination

While part of today's hearing focuses specifically on FDA's responsibilities for the oversight of food safety, it is important to note that FDA is one of 15 federal agencies that collectively administer at least 30 laws related to food safety. This fragmentation is a key reason we designated federal oversight of food safety as a high-risk area. Two agencies have primary responsibility—FDA is responsible for the safety of virtually all foods except for meat, poultry, and processed egg products, which are the responsibility of USDA. In addition, among other agencies, the National Marine Fisheries Service (NMFS) in the Department of Commerce conducts voluntary, fee-for-service inspections of seafood safety and quality; the Environmental Protection Agency (EPA) regulates the use of pesticides and maximum allowable residue levels on food commodities and animal feed; and the Department of Homeland Security is responsible for coordinating agencies' food security activities. This federal regulatory system for food safety, like many other federal programs and policies, evolved piecemeal, typically in response to particular health threats or economic crises.

In January 2007, we added the federal oversight of food safety to our High-Risk Series,⁵ which 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. Over the past 30 years, we have reported on issues—for

⁵GAO, *High-Risk Series: An Update*, [GAO-07-310](#) (Washington, D.C.: Jan. 31, 2007).

example, the need to transform the federal oversight framework to reduce risks to public health as well as the economy—that suggest that the federal oversight of food safety could be designated as a high-risk area. The fragmented nature of the federal food oversight system calls into question whether the government can plan more strategically to inspect food production processes, identify and react more quickly to outbreaks of foodborne illnesses, and focus on promoting the safety and integrity of the nation’s food supply.

While we have reported on problems with the federal food safety system—including inconsistent oversight, ineffective coordination, and inefficient use of resources—most noteworthy for today’s hearing is that federal expenditures for the oversight of food safety have not been commensurate with the volume of foods regulated by the agencies or consumed by the public. We have reported that four agencies—USDA, FDA, EPA, and NMFS—spent a total of \$1.7 billion on food safety-related activities in fiscal year 2003.⁶ USDA and FDA were responsible for nearly 90 percent of those federal expenditures. However, 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 even though USDA is responsible for regulating only about 20 percent of the food supply. In contrast, FDA accounted for only 24 percent of expenditures even though it is responsible for regulating about 80 percent of the food supply.

Others have called for fundamental changes to the federal food safety system overall. In 1998, the National Academy of Sciences concluded that the system is not well equipped to meet emerging challenges.⁷ In response to the Academy’s report, the President established a Council on Food Safety which released a Food Safety Strategic Plan in January 2001. The plan recognized the need for a comprehensive food safety statute and concluded, “the current organizational structure makes it more difficult to achieve future improvements in efficiency, efficacy, and allocation of resources based on risk.”

While many of the recommendations we made have been acted upon, a fundamental reexamination of the federal food safety system is warranted.

⁶GAO, *Overseeing the U.S. Food Supply: Steps Should be Taken to Reduce Overlapping Inspections and Related Activities*, [GAO-05-549T](#) (Washington, D.C.: May 17, 2005).

⁷Institute of Medicine, *Ensuring Safe Food from Production to Consumption* (Washington, D.C., 1998).

Taken as a whole, our work indicates that Congress and the executive branch can and should create the environment needed to look across the activities of individual programs within specific agencies, including FDA, and toward the goals that the federal government is trying to achieve. To that end, we have recommended, among other things, that Congress enact comprehensive, uniform, and risk-based food safety legislation and commission the National Academy of Sciences or a blue ribbon panel to conduct a detailed analysis of alternative organizational food safety structures.⁸ We have also recommended that the executive branch reconvene the President's Council on Food Safety to facilitate interagency coordination on food safety regulation and programs. According to documents on the council's Web site, the current administration has not reconvened the council.

These actions can begin to address the fragmentation in the federal oversight of food safety. Going forward, to build a sustained focus on the safety and integrity of the nation's food supply, Congress and the executive branch can integrate various expectations for food safety with congressional oversight and through agencies' strategic planning processes, including FDA's. We have previously reported that the development of a governmentwide performance plan that is mission-based, is results-oriented, and provides a cross-agency perspective offers a framework to help ensure agencies' goals are complementary and mutually reinforcing. Further, with pressing fiscal challenges, this plan can help decision makers balance trade-offs and compare performance when resource allocation and restructuring decisions are made.

FDA Has Opportunities to Better Leverage its Resources

In response to the nation's fiscal challenges, agencies may have to explore new approaches to achieve their missions, and we have identified options for FDA to better leverage its resources. Efficient use of resources is particularly important at FDA because, while its food safety workload has increased in the past decade, resources have not kept pace. FDA has proposed actions toward implementing some of these options.

Our analysis of FDA data shows that while FDA received increased funding for new bioterrorism-related responsibilities in 2003, subsequent staffing levels and funding have not kept pace with the agency's growing

⁸GAO, *Food Safety and Security: Fundamental Changes Needed to Ensure Safe Food*, GAO-02-47T (Washington, D.C.: Oct. 10, 2001).

responsibilities. Specifically, the number of FDA-regulated domestic food establishments increased more than 10 percent from fiscal years 2003 to 2007—from about 58,260 in 2003 to about 65,520 in 2007. Additionally, FDA notes that there have been dramatic changes in the volume, variety, and complexity of FDA-regulated products arriving at U.S. ports, and recently reported that the number of food import entry lines has tripled in the past ten years.⁹ Meanwhile, staffing for FDA’s Center for Food Safety and Applied Nutrition (CFSAN) has decreased. According to the Science Board, the number of staff years for CFSAN operations at headquarters dropped about 14 percent, from 950 in fiscal year 2003 to 812 in fiscal year 2006. During that same time period, field-based staff responsible for carrying out inspection and enforcement activities for CFSAN-regulated products dropped by 255 staff years, or about 11.5 percent—from 2,217 in fiscal year 2003 to 1,962 in fiscal year 2006. In addition, while CFSAN-related funding at headquarters and in the field increased from \$407 million in fiscal year 2003 to \$439 million in fiscal year 2006, this represents a decrease in real terms from about \$457 million to about \$451 million during that period. One consequence is that foreign inspections have declined: GAO analysis of FDA data shows that inspections of foreign food firms, which number almost 190,000, decreased from 211 in fiscal year 2001 to fewer than 100 in fiscal year 2007. The Science Board considered the funding issues to be more acute for CFSAN than for other FDA programs: unlike the FDA programs responsible for drugs, biologics, and medical devices, which charge manufacturers hundreds of millions of dollars in user fees each year, CFSAN is not authorized to charge user fees for its services.

Recent GAO work has identified opportunities for FDA to better leverage its resources. Specifically, in 2004 we reviewed FDA’s imported seafood safety program and identified several options that FDA could consider to augment its resources and enhance its current program.¹⁰ We found that FDA’s seafood safety program had shown some progress from a 2001 review. For example, FDA increased its laboratory testing of seafood products at ports of entry from less than 1.0 percent in fiscal year 1999 to about 1.2 percent in fiscal year 2002. We also recommended several

⁹According 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.

¹⁰GAO, *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).

options for enhancing FDA's oversight of seafood while leveraging outside resources. Some of these options are presented in FDA's *Food Protection Plan*. We recommended that FDA:

- *Make it a priority to establish equivalence agreements with other countries.* Subject to its jurisdiction, FDA could certify that countries exporting food products to the United States have equivalent food safety systems before food products from those countries can enter the United States. Such agreements would shift some of FDA's oversight burden to foreign governments. While 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.
- *Explore the potential for certifying third-party inspectors.* FDA could consider developing a program that uses certified third-party inspectors to conduct inspections on its behalf, both at foreign processing firms and domestic importers of seafood. FDA's *Food Protection Plan* requests authority from Congress to accredit third parties to conduct voluntary inspections for foods, and FDA officials told us that they envision using third-party inspectors to inspect foreign facilities, where FDA conducts few inspections. If FDA receives this authority, it can take lessons from its own implementation of third-party inspection programs for medical device manufacturing establishments. As we are reporting in a separate statement today, few inspections of these establishments have been conducted through FDA's two accredited third-party inspection programs.
- *Consider accrediting private laboratories to test seafood.* Currently, FDA does not accredit or use any private laboratories to collect or analyze seafood samples. However, for some seafood violations, it allows seafood firms to use private laboratories to provide evidence that imported seafood previously detained because of safety concerns is now safe and can be removed from the detention list at the port of entry. We recommended that FDA consider accrediting private laboratories because it could leverage outside resources while providing FDA greater assurance about the quality of the laboratories importers use to demonstrate that their products are safe. FDA has not formally changed its policies or practices, but the *Action Plan for Import Safety* notes that FDA intends to issue guidance by mid-2008 on sampling and testing of imported products, including the use of accredited private laboratories submitting data to FDA on food safety.

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- *Develop a memorandum of understanding with the National Oceanic and Atmospheric Administration (NOAA) to use NOAA's Seafood Inspection Program resources to complete inspections on FDA's behalf.* NOAA officials said that they could provide various services to augment FDA's regulatory program for imported seafood, including inspection, training, and product sampling services. FDA has been working on a program to refer certain export-related work to NOAA, and it is in discussions with NOAA about commissioning its inspectors, but to date, nothing is finalized or operational.

We have not reviewed these actions to determine whether they adequately address our recommendations.

We separately reported on overlaps we identified in the federal oversight of food safety, such as overlapping inspection and training activities that exist among the agencies conducting food safety functions.¹¹ Such overlaps mean that federal agencies are spending resources on similar activities, which may waste scarce resources and limit effectiveness. Specifically, we found that FDA food safety activities may overlap with, if not duplicate, the efforts of other agencies, including USDA and NMFS. FDA could take practical steps to reduce overlap and duplication and thereby free resources for more effective oversight of food safety, but FDA has made little progress since our report. For example:

- *Domestic inspections.* In fiscal year 2003, FDA and USDA spent most of their food safety resources—about \$900 million—on inspection and enforcement activities. A portion of these activities included overlapping and even duplicative inspections of 1,451 domestic food-processing facilities that produce foods regulated by both agencies. Under authority granted by the Bioterrorism Act of 2002,¹² FDA could authorize USDA to inspect these facilities on its behalf, but FDA has not yet reached an agreement with USDA to do this. We recommended that, if cost effective, FDA enter into an agreement to commission USDA inspectors at jointly regulated facilities. FDA told us that they are working with USDA to consider which products might be covered by each agency under such an agreement.

¹¹GAO, *Oversight of Food Safety Activities: Federal Agencies Should Pursue Opportunities to Reduce Overlap and Better Leverage Resources*, [GAO-05-213](#) (Washington, D.C.: Mar. 30, 2005).

¹²Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594.

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- *Import inspections.* FDA and USDA both inspect shipments of imported food at ports of entry and also visit foreign countries that export food to the United States. We found that both FDA and USDA maintain inspectors at 18 U.S. ports of entry to inspect imported food. In fiscal year 2003, FDA spent more than \$115 million on imported food inspections, and USDA spent almost \$16 million. The two agencies do not share inspection resources at these ports. Although USDA maintains a daily presence at these facilities, the FDA-regulated products may remain at the facilities for some time awaiting FDA inspection. Further, FDA conducted inspections in 6 of the 34 countries that USDA evaluated in 2004 to determine whether their food safety systems for ensuring the safety of meat and poultry are equivalent to that of the United States. We recommended that FDA consider the findings of USDA's foreign country equivalence agreements when determining which countries to visit. In their response to our recommendation, the agency noted that they will consider USDA's foreign country evaluations when making such determinations.
 - *Inspectors' training.* FDA and USDA spend resources to provide similar training to food inspection personnel. FDA spent about \$1.6 million and USDA spent \$7.8 million in fiscal year 2003. We found that, to a considerable extent, food inspection training addresses the same subjects, such as plant sanitation and good manufacturing practices. While other agencies have consolidated training activities that have a common purpose and similar content, FDA and USDA have not. We recommended that USDA and FDA consider joint training programs, but to date, FDA has told us that they have identified no training needs common to both agencies.

FDA's *Food Protection Plan* Proposes Some Positive First Steps, but Additional Information on the Plan's Strategies and Resources would Facilitate Congressional Oversight

FDA's *Food Protection Plan* proposes several positive first steps that are intended to enhance food safety oversight, including requesting several authorities recommended by GAO, but more specific information about its strategies and the resources needed to implement the plan would facilitate congressional oversight. Positively, FDA's *Food Protection Plan* aims to shift the agency's focus to prevention of foodborne illness instead of intervention after contamination and resulting illnesses occur—an important shift given that experts consider prevention to be a core element of an effective food safety system. FDA says that its key prevention steps are promoting corporate responsibility, identifying food vulnerabilities, assessing risks, and expanding its understanding and use of effective mitigation measures.

In addition to the actions we discuss earlier to address resource constraints, FDA's *Food Protection Plan* requests other authorities to

enhance oversight of food safety that begin to respond to prior GAO recommendations. Specifically, the plan requests authority for FDA to:

- *Order food recalls.* The *Food Protection Plan* requests the authority to order a recall when FDA has reason to believe that food is adulterated and presents a threat of serious adverse health consequences or death, to be imposed only if a company refuses or unduly delays conducting a voluntary recall. Currently, food recalls are largely voluntary—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. 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. These agencies have the authority to require a company to notify the agency when the company has distributed a potentially unsafe product, order a recall, establish recall requirements, and impose monetary penalties if a company does not cooperate. In a report and testimony before this subcommittee,¹³ we 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. While FDA’s *Food Protection Plan* requests mandatory recall authority, this request could also include recall authorities held by other agencies, including establishing recall requirements and imposing penalties for noncompliance. FDA officials noted that while recall requirements and penalties for noncompliance were not explicitly stated in the *Food Protection Plan*, they are encompassed in the request. Further, the plan does not propose a definition of “undue delay” by a company, another critical element of recall authority given that timing is essential in reacting to outbreaks, and delays can cost lives.
- *Issue additional preventive controls for high-risk foods.* FDA is requesting explicit authority from Congress to issue regulations requiring

¹³GAO, *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 *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).

foods that have been associated with repeated instances of serious health problems or death to be prepared, packed, and held under a system of preventive food safety controls. According to FDA, this would clarify the agency's ability to require industries to implement preventive Hazard Analysis and Critical Control Point (HACCP) systems, which it currently requires for companies that process seafood and juice. HACCP systems are designed to improve food safety by having industry identify and control hazards in products before they enter the market. FDA officials told us that they are asking for explicit authority to put measures in place for other high-risk foods, such as leafy greens. Officials told us that this request, if granted, would allow the agency to focus its preventive efforts on foods that present the highest risk for contamination, consistent with the agency's risk-based focus. However, others have expressed concern that requiring a history of repeated outbreaks before issuing preventive controls would not allow FDA to proactively establish regulations for foods before they cause additional illnesses.

While FDA officials have acknowledged that implementing the *Food Protection Plan* will require additional resources, FDA has not provided specific information on the resources it anticipates the agency will need to implement this plan. For example, the *Food Protection Plan* proposes to develop food protection guidelines for industry; however FDA's Science Board reported that modernizing safety standards for fresh produce and other raw foods and developing and implementing inspection programs could cost \$210 million. Additionally, 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. FDA officials have declined to provide specific information on how much additional funding it believes will be necessary to implement the *Food Protection Plan*, saying that finalizing the amounts will take place during the budget process. Similarly, the *Food Protection Plan* does not discuss the strategies it needs in the upcoming years to implement this plan. FDA officials told us that they have internal plans for implementing the *Food Protection Plan* that detail timelines, staff actions, and specific deliverables. While FDA officials told us they do not intend to make these plans public, they do plan to keep the public informed of their progress. Without a clear description of resources and strategies, it will be difficult for Congress to assess the likelihood of the plan's success in achieving its intended results.

Tools that Agencies Can Use to Address Management Challenges

The Science Board cites numerous management challenges that have contributed to FDA's inability to fulfill its mission, such as a lack of a coherent structure and vision, insufficient capacity in risk assessment, and inadequate human capital recruitment and retention. The Science Board also noted that public confidence in FDA's abilities has diminished. In light of these challenges, we have identified through other work some tools that can help agencies improve their performance, which may also be relevant to FDA.

For example, we reported on the use of a Chief Operating Officer (COO)/Chief Management Officer (CMO) as one way to address longstanding management problems that are undermining agencies' abilities to accomplish their missions and achieve results.¹⁴ Agencies with such challenges, including FDA, could benefit from a senior leader serving as a COO/CMO who can elevate, integrate, and institutionalize responsibility for key management functions. While GAO has long advocated the need for a COO/CMO position at the Department of Defense and the Department of Homeland Security, a relatively stable or small organization could use the existing deputy or related position to carry out the role. In addition to GAO, a number of other organizations have supported the need for the creation of COO/CMO positions in federal agencies. McKinsey & Company recommended that a COO be established in many federal agencies as the means to help those agencies successfully achieve transformation.¹⁵ In addition, a working group within the National Academy of Public Administration (NAPA) recommended creating COO positions in federal agencies to oversee the full range of management functions, including procurement, finance, information technology, and human capital.¹⁶

Another tool that can help federal agencies address their management challenges is a well-designed commission that can produce specific practical recommendations that Congress can enact. For example,

¹⁴See for example, GAO, *A Call for Stewardship: Enhancing the Federal Government's Ability to Address Key Fiscal and Other 21st Century Challenges*, [GAO-08-93SP](#) (Washington D.C.: November 2007) and *Organizational Transformation: Implementing Chief Operating Officer/Chief Management Officer Positions in Federal Agencies*, [GAO-08-34](#) (Washington, D.C.: Nov. 1, 2007).

¹⁵McKinsey & Company, *How Can American Government Meet its Productivity Challenge?* (July 2006).

¹⁶NAPA, *Moving from Scorecard to Strategic Partner: Improving Financial Management in the Federal Government* (October 2006).

Congress created the National Commission on Restructuring the Internal Revenue Service (IRS) in 1995 to review current practices at IRS and report on requirements for improvement. Congress subsequently passed the IRS Restructuring and Reform Act of 1998, which was influenced by the Commission's report, and reorganized the structure and management of IRS, revised the mission of IRS, and mandated numerous other detailed changes.¹⁷ Based on our recent analysis of several commissions, there are several critical success factors that can be applied to ensure a commission's success including:¹⁸

- *A statutory basis with adequate authority.* When provided with a clear mandate and adequate authority, a commission can comprehensively access and analyze information related to a given policy issue and thereby provide more informed policy options for the President and Congress to consider.
- *A clear purpose and timeframe.* A commission should have a clear purpose for its objectives and activities to help guide the members in carrying out their responsibilities. In addition, a fixed agenda and timeframe can help keep a commission focused and on track. However, a commission should have a broad enough scope to help ensure it has the authority to address all the issues necessary in order to come up with a comprehensive and integrated solution without encountering any constraints in the process as to what it can or cannot consider.
- *Key leadership support.* Institutional leadership, commitment, and support from the President and Congress are necessary to help a commission succeed.
- *An open and transparent process.* By having an open and transparent process, such as public hearings, a commission can help build consensus among the public for its goals by gaining their input and support.
- *A balanced and capable membership.* Balanced and capable membership can help lessen political influences and build consensus among the commission members when carrying out its purpose. Specifically, a commission should involve current or former Members of Congress as well as experts and professionals on the topic. Current or former elected

¹⁷Pub. L. No. 105-206 (July 22, 1998).

¹⁸GAO, *Long-Term Fiscal Challenge: Comments on the Bipartisan Task Force for Responsible Fiscal Action Act*, [GAO-08-238T](#) (Washington, D.C.: Oct. 31, 2007).

officials can ensure viability of a commission's legislative proposals due to their experience.

- *Accountability.* Clear accountability for a commission can help foster specific, useful outputs that could help inform the public and provide specific policy options and, hopefully, recommendations for Congress and the President.
- *Resources.* The success of the commission is dependent on having the adequate resources to carry out its purpose and any potential recommendations.

Generally, one concern regarding commissions may be whether or not there is sufficient buy-in from key stakeholders on the purpose of the commission along with a commitment to act on any resulting recommendations. Any recommendations by a commission in a final report are generally advisory in nature and may not automatically result in any public policy changes. Congressional action through subsequent legislation with Presidential support may be necessary for the commission's recommendations to be implemented and for any changes to occur.

Food safety concerns not only continue but will likely become more urgent in view of changing demographics and consumption patterns. Clearly, FDA plays a critical role in the federal oversight of food safety because of the breadth of its responsibilities. Thus its ability to carry out those responsibilities is necessary to help ensure the safety of the nation's food supply in the most efficient, effective, accountable, and sustainable way. Nevertheless, in light of the federal government's long-term fiscal challenges, agencies, including FDA, need to seek out opportunities to better leverage their resources. FDA's *Food Protection Plan* is a step in the right direction and proposes to implement many of the recommendations made by GAO. However, additional information on the strategies and resources needed to implement the plan can help Congress assess the likelihood of its success. Further, concerns over FDA's management challenges, such as those identified by the Science Board could hinder the implementation of the plan. Tools such as commissions and positions like a COO/CMO can help agencies address management challenges and make needed progress to achieve their missions. Continued congressional oversight, including today's hearing, and additional legislative action are key to achieving that progress and to promoting the safety and integrity of 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.

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 Candace Carpenter, Bart Fischer, José Alfredo Gómez, and Alison O'Neill.

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