

**GAO**

Testimony

Before the Subcommittee on Agriculture,  
Rural Development, FDA, and Related  
Agencies, Committee on Appropriations,  
House of Representatives

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# FEDERAL OVERSIGHT OF FOOD SAFETY

## High-Risk Designation Can Bring Needed Attention to Fragmented System

Statement of David M. Walker  
Comptroller General of the United States





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# Highlights

Highlights of [GAO-07-449T](#), a testimony before the Subcommittee on Agriculture, Rural Development, FDA, and Related Agencies, Committee on Appropriations, House of Representatives

## 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. While the recent E. coli outbreaks highlighted the risks posed by accidental 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) need to address federal oversight of food safety as a 21st century challenge. This work is based on previously issued reports.

## What GAO Recommends

While many of GAO's recommendations to promote the safety of the nation's food supply have been acted upon, others that are not yet addressed could help Congress and the executive branch transform the federal oversight of food safety. For example, GAO recommended that Congress enact comprehensive, uniform, and risk-based food safety legislation, and analyze alternative organizational food safety structures. GAO also recommended that the executive branch reconvene the President's Council on Food Safety to facilitate interagency coordination. Finally, the development of a governmentwide performance plan could help ensure agencies' goals are complementary.

[www.gao.gov/cgi-bin/getrpt?GAO-07-449T](http://www.gao.gov/cgi-bin/getrpt?GAO-07-449T).

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](mailto:ShamesL@gao.gov).

# FEDERAL OVERSIGHT OF FOOD SAFETY

## High-Risk Designation Can Bring Needed Attention to Fragmented System

### 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. 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.

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 other food. In many previous reports, GAO found that this fragmented system has caused inconsistent oversight, ineffective coordination, and inefficient use of resources. For example:

- Existing statutes give agencies different regulatory and enforcement authorities. Under current law, thousands of USDA inspectors must examine all slaughtered carcasses and visit all processing facilities at least once during each operating day. However, federal law does not mandate the frequency of inspection for foods that are under FDA's jurisdiction.
- Food recalls are generally voluntary. While USDA and FDA provide guidance to companies for carrying out voluntary recalls, they do not know how promptly and completely companies carry out recalls and do not promptly verify that recalls have reached the entire distribution chain. In addition, they use procedures that may not be effective to alert consumers to a recall.
- Federal agencies are spending resources on overlapping food safety activities. USDA and FDA both inspect shipments of imported food at 18 U.S. ports of entry but do not share inspection resources at these ports.

Integrating the fragmented federal food safety system is a significant challenge for the 21st century, particularly in light of the nation's current deficit and growing structural fiscal imbalance. To help Congress review and reconsider the base of federal spending, GAO framed illustrative questions for decision makers to consider in *21st Century Challenges: Reexamining the Base of the Federal Government*. Among these questions are how agencies can integrate and share accountability for their activities on crosscutting issues and how they can adopt more innovative methods to contribute to the achievement of national outcomes. While framing these questions, GAO specifically cited the myriad of food safety programs managed across several federal agencies.

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Madam Chairwoman and Members of the Subcommittee:

I am pleased to be here today to discuss the designation of federal oversight of food safety as a high-risk area in the January 2007 update to our High-Risk Series. Let me state at the outset that this nation enjoys a plentiful and varied food supply that is generally considered to be safe. However, each year, about 76 million people contract a foodborne illness in the United States; about 325,000 require hospitalization; and about 5,000 die, according to the Centers for Disease Control and Prevention. In addition, as we have repeatedly reported, our fragmented food safety system has resulted in inconsistent oversight, ineffective coordination, and inefficient use of resources. With 15 agencies collectively administering at least 30 laws related to food safety, the patchwork nature of the federal food safety oversight system calls into question whether the government can more efficiently and effectively protect our nation's food supply. As a result, we added the federal oversight of food safety to our list of programs needing urgent attention and transformation in order to ensure that our national government functions in the most economical, efficient, and effective manner possible.<sup>1</sup>

Our high-risk status reports are provided at the start of each new Congress to help in setting congressional oversight agendas and to help in raising the priority and visibility of government programs needing transformation. 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 this regard, I recently provided congressional leadership with a set of recommendations based on GAO's work, including work on some areas we have designated as high risk, for its consideration in developing the oversight agenda of the 110th Congress.<sup>2</sup> Together, the high-risk update and the recommendations for oversight can help congressional decision makers focus on the programmatic challenges facing the nation.

Because of your continuing interest in the effective use of food safety resources, I will focus on three key points: (1) the role of GAO's High-Risk Series in raising the priority and visibility of the need to transform federal oversight of food safety, (2) the fragmented nature of federal oversight of

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

<sup>2</sup>GAO, *Suggested Areas for Oversight for the 110th Congress*, [GAO-07-235R](#) (Washington, D.C.: Nov. 17, 2006).

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food safety, and (3) the need to address federal oversight of food safety as a 21st century challenge. My testimony is based on published GAO products that were developed in accordance with generally accepted government auditing standards. Appendix I includes highlights of selected reports.

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## GAO's High-Risk Series Raises the Priority and Visibility of the Need to Transform Federal Oversight of Food Safety

Overall, our High-Risk Series has served to identify and help resolve serious government weaknesses in areas that involve substantial resources and provide critical services to the public. Since we began reporting on high-risk areas, the government has taken high-risk problems seriously and has made long-needed progress toward correcting them. With that in mind, we designated the federal oversight of food safety as a high-risk area to raise the priority and visibility of the need to transform the federal government's oversight system.

Since 1990, GAO has reported on government operations that we identified as high risk and has periodically reported on the status of progress to address high-risk areas and updated our high-risk list. Historically, high-risk areas have been so designated because of traditional vulnerabilities related to their greater susceptibility to fraud, waste, abuse, and mismanagement. As our high-risk program has evolved, we have increasingly used the high-risk designation to draw attention to areas needing broad-based transformations to achieve greater economy, efficiency, effectiveness, accountability, and sustainability of selected key government programs and operations.

In determining whether a government program or operation is high risk, we consider whether it has national significance or a management function that is key to performance and accountability. Further, we consider qualitative factors, such as whether the risk

- involves public health or safety, service delivery, national security, national defense, economic growth, or privacy or citizens' rights; or
- could result in significantly impaired service, program failure, injury or loss of life, or significantly reduced economy, efficiency, or effectiveness.

Clearly, these factors weighed heavily into our deliberations to place the federal oversight of food safety on our high-risk list.

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We remove a high-risk designation when legislative and agency actions, including those in response to our recommendations, result in significant and sustainable progress toward resolving a high-risk problem. Key determinants include a demonstrated strong commitment to and top leadership support for addressing problems, the capacity to do so, a corrective action plan, and demonstrated progress in implementing corrective measures. The sustained attention and commitment by Congress and agencies to resolve serious, long-standing high-risk problems have paid off; because of sufficient progress, we were able to remove the high-risk designation from 18 areas—more than half of our original list. As we have with areas previously removed from the high-risk list, we will continue to monitor these programs, as appropriate, to ensure that the improvements we have noted are sustained.

For areas that remain on our high-risk list for 2007, there has been important—but varying levels of—progress. Top administration officials have expressed their commitment to ensuring that high-risk areas receive adequate attention and oversight. The Office of Management and Budget (OMB) has led an initiative to prompt agencies to develop detailed action plans for each area on our high-risk list. These plans are intended to identify specific goals and milestones that address and reduce the risks we identified within each high-risk area. Further, OMB has encouraged agencies to consult with us regarding the problems our past work has identified and the many recommendations for corrective actions we have made. While progress on developing and implementing plans has been mixed, concerted efforts by agencies and ongoing attention by OMB are critical.

In addition to the programs that remain on the list, we recently designated three new areas as high risk, including the need to transform federal oversight of food safety. For these recently added areas, along with those remaining on the list, we expect that continued perseverance will ultimately yield significant benefits. To begin to address the weaknesses in federal oversight of food safety, executive agencies can start by implementing our recommendations intended to improve the problems we previously identified. Further, continued congressional oversight, including today's hearing, and additional legislative action will also be key to achieving progress, particularly in addressing challenges in the broad-based transformation needed to promote the safety and integrity of the nation's food supply.

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## Fragmented Federal Oversight of Food Safety Led to High-Risk Designation

For several years, we have reported on issues that suggest that food safety could be designated as a high-risk area because of the need to transform the federal oversight framework to reduce risks to public health as well as the economy. Specifically, the patchwork 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 contaminated food, and focus on promoting the safety and the integrity of the nation's food supply. This challenge is even more urgent since the terrorist attacks of September 11, 2001, heightened awareness of agriculture's vulnerabilities to terrorism, such as the deliberate contamination of food or the introduction of disease to livestock, poultry, and crops.

An accidental or deliberate contamination of food or the introduction of disease to livestock, poultry, and crops could undermine consumer confidence in the government's ability to ensure the safety of the U.S. food supply and have severe economic consequences. Agriculture, as the largest industry and employer in the United States, generates more than \$1 trillion in economic activity annually, or about 13 percent of the gross domestic product. The value of U.S. agricultural exports exceeded \$68 billion in fiscal year 2006. An introduction of a highly infectious foreign animal disease, such as avian influenza or foot-and-mouth disease, would cause severe economic disruption, including substantial losses from halted exports. Similarly, food contamination, such as the recent *E. coli* outbreaks, can harm local economies. For example, industry representatives estimate losses from the recent California spinach *E. coli* outbreak to range from \$37 million to \$74 million.

While 15 agencies collectively administer 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 foods. Among other agencies with responsibilities related to food safety, 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 (DHS) is responsible for coordinating agencies' food security activities.

The food safety system is further complicated by the subtle differences in food products that dictate which agency regulates a product as well as the

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frequency with which inspections occur. For example, how a packaged ham and cheese sandwich is regulated depends on how the sandwich is presented. USDA inspects manufacturers of packaged open-face meat or poultry sandwiches (e.g., those with one slice of bread), but FDA inspects manufacturers of packaged closed-face meat or poultry sandwiches (e.g., those with two slices of bread). Although there are no differences in the risks posed by these products, USDA inspects wholesale manufacturers of open-face sandwiches sold in interstate commerce daily, while FDA inspects manufacturers of closed-face sandwiches an average of once every 5 years.

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. During the past 30 years, we have detailed problems with the current fragmented federal food safety system and reported that the system has caused inconsistent oversight, ineffective coordination, and inefficient use of resources. Our most recent work demonstrates that these challenges persist. Specifically:

- Existing statutes give agencies different regulatory and enforcement authorities. For example, food products under FDA's jurisdiction may be marketed without the agency's prior approval. On the other hand, food products under USDA's jurisdiction must generally be inspected and approved as meeting federal standards before being sold to the public. Under current law, thousands of USDA inspectors maintain continuous inspection at slaughter facilities and examine all slaughtered meat and poultry carcasses. They also visit each processing facility at least once during each operating day. For foods under FDA's jurisdiction, however, federal law does not mandate the frequency of inspections.<sup>3</sup>
- Federal agencies are spending resources on overlapping food safety activities.<sup>4</sup> USDA and FDA both inspect shipments of imported food at 18 U.S. ports of entry. However, these two agencies do not share inspection resources at these ports. For example, USDA officials told us that all USDA-import inspectors are assigned to, and located at,

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<sup>3</sup>GAO, *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, 2004).

<sup>4</sup>GAO, *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).

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USDA-approved import inspection facilities and some of these facilities handle and store FDA-regulated products. USDA has no jurisdiction over these FDA-regulated products. Although USDA maintains a daily presence at these facilities, the FDA-regulated products may remain at the facilities for some time awaiting FDA inspection. In fiscal year 2003, USDA spent almost \$16 million on imported food inspections, and FDA spent more than \$115 million.

- 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 provide guidance to companies for carrying out voluntary recalls. We reported that USDA and FDA can do a better job in carrying out their food recall programs so they can quickly remove potentially unsafe food from the marketplace.<sup>5</sup> These agencies do not know how promptly and completely companies are carrying out recalls, do not promptly verify that recalls have reached all segments of the distribution chain, and use procedures that may not be effective to alert consumers to a recall.
- The terrorist attacks of September 11, 2001, have heightened concerns about agriculture’s vulnerability to terrorism. The Homeland Security Act of 2002 assigned DHS the lead coordination responsibility for protecting the nation against terrorist attacks, including agroterrorism. Subsequent presidential directives further define agencies’ specific roles in protecting agriculture and the food system against terrorist attacks. We reported that in carrying out these new responsibilities, agencies have taken steps to better manage the risks of agroterrorism, including developing national plans and adopting standard protocols.<sup>6</sup> However, we also found several management problems that can reduce the effectiveness of the agencies’ routine efforts to protect against agroterrorism. For example, there are weaknesses in the flow of critical information among key stakeholders and shortcomings in DHS’s coordination of federal working groups and research efforts.
- More than 80 percent of the seafood that Americans consume is imported. We reported in 2001 that FDA’s seafood inspection program

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<sup>5</sup>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).

<sup>6</sup>GAO, *Homeland Security: Much Is Being Done to Protect Agriculture from a Terrorist Attack, but Important Challenges Remain*, [GAO-05-214](#) (Washington, D.C.: Mar. 8, 2005).



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did not sufficiently protect consumers.<sup>7</sup> For example, FDA tested about 1 percent of imported seafood products. We subsequently found that FDA's program has improved: More foreign firms are inspected, and inspections show that more U.S. seafood importers are complying with its requirements.<sup>8</sup> Given FDA officials' concerns about limited inspection resources, we also identified options, such as using personnel in the National Oceanic and Atmospheric Administration's (NOAA) Seafood Inspection Program to augment FDA's inspection capacity or state regulatory laboratories for analyzing imported seafood. FDA agreed with these options.

- In fiscal year 2003, four agencies—USDA, FDA, EPA, and NMFS—spent a total of \$1.7 billion on food safety-related activities.<sup>9</sup> USDA and FDA together were responsible for nearly 90 percent of federal expenditures for food safety. However, these expenditures were not based on the volume of foods regulated by the agencies or consumed by the public. 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.

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## Federal Oversight of Food Safety Should Be Addressed as a 21st Century Challenge

We have cited the need to integrate the fragmented federal food safety system as a significant challenge for the 21st century, to be addressed in light of the nation's current deficit and growing structural fiscal imbalance.<sup>10</sup> The traditional incremental approaches to budgeting will need to give way to more fundamental reexamination of the base of government. While prompted by fiscal necessity, such a reexamination can serve the vital function of updating programs to meet present and future challenges within current and expected resource levels. To help Congress

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<sup>7</sup>GAO, *Food Safety: Federal Oversight of Seafood Does Not Sufficiently Protect Consumers*, [GAO-01-204](#) (Washington, D.C.: Jan. 31, 2001).

<sup>8</sup>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).

<sup>9</sup>GAO, *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).

<sup>10</sup>GAO, *21st Century Challenges: Reexamining the Base of the Federal Government*, [GAO-05-325SP](#) (Washington, D.C.: February 2005).

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review and reconsider the base of federal spending, we framed illustrative questions for decision makers to consider. While these questions can apply to other areas needing broad-based transformation, we specifically cited the myriad of food safety programs managed across several federal agencies. Among these questions are the following:

- How can agencies partner or integrate their activities in new ways, especially with each other, on crosscutting issues, share accountability for crosscutting outcomes, and evaluate their individual and organizational contributions to these outcomes?
- How can agencies more strategically manage their portfolio of tools and adopt more innovative methods to contribute to the achievement of national outcomes?

Integration can create synergy and economies of scale and can provide more focused and efficient efforts to protect the nation's food supply. Further, to respond to the nation's pressing fiscal challenges, agencies may have to explore new ways to achieve their missions. We have identified such opportunities. For example, as I already mentioned, USDA and FDA spend resources on overlapping food safety activities, and we have made recommendations designed to reduce this overlap. Similarly, regarding FDA's seafood inspection program, we have discussed options for FDA to use personnel at NOAA to augment FDA's inspection capacity.

Many of our recommendations to agencies to promote the safety and integrity of the nation's food supply have been acted upon. Nevertheless, as we discuss in the 2007 High-Risk Series, a fundamental reexamination of the federal food safety system is warranted. Such a reexamination would need to address criticisms that have been raised about USDA's dual mission as both a promoter of agricultural and food products and an overseer of their safety. 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 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

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structures.<sup>11</sup> We also recommended that the executive branch reconvene the President's Council on Food Safety to facilitate interagency coordination on food safety regulation and programs.

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 the 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. 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, this plan can help decision makers balance trade-offs and compare performance when resource allocation and restructuring decisions are made.

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As I have discussed, GAO designated the federal oversight of food safety as a high-risk area that is in need of a broad-based transformation to achieve greater economy, efficiency, effectiveness, accountability, and sustainability. The high-risk designation raises the priority and visibility of this necessary transformation and thus can bring needed attention to address the weaknesses caused by a fragmented system. GAO stands ready to provide professional, objective, fact-based, and nonpartisan information and thereby assist Congress as it faces tough choices on how to fundamentally reexamine and transform the government. Lasting solutions to high-risk problems offer the potential to save billions of dollars, dramatically improve service to the American public, strengthen public confidence and trust in the performance and accountability of our national government, and ensure the ability of government to deliver on its promises.

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

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<sup>11</sup>GAO, *Food Safety and Security: Fundamental Changes Needed to Ensure Safe Food*, [GAO-02-47T](#) (Washington, D.C.: Oct. 10, 2001).

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## 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, Acting Director, Natural Resources and Environment at (202) 512-3841 or [ShamesL@gao.gov](mailto:ShamesL@gao.gov). Key contributors to this statement were Erin Lansburgh, Bart Fischer, Alison O'Neill, and Beverly Peterson.

# Appendix I: Highlights of Selected GAO Food Safety Reports



Highlights of GAO-05-213, a report to congressional requesters

## Why GAO Did This Study

GAO has documented many problems resulting from the fragmented nature of the federal food safety system and recommended fundamental restructuring to ensure the effective use of scarce government resources. In this report, GAO (1) identified overlaps in food safety activities at USDA, FDA, EPA, and NMFS; (2) analyzed the extent to which the agencies use interagency agreements to leverage resources; and (3) obtained the views of stakeholders.

## What GAO Recommends

Recognizing the statutory constraints under which the agencies operate, GAO, among other things, recommends that (1) if cost effective, FDA use available authority to enter into an agreement to commission USDA inspectors at jointly regulated facilities; (2) USDA and FDA consider joint training programs; and (3) USDA, FDA, EPA and NMFS inventory, evaluate, and update active interagency agreements. USDA generally did not appear to agree with GAO's recommendations but recognized the benefits of joint training for food inspectors. HHS (FDA) agreed with GAO's recommendations to inventory, evaluate, and update the interagency agreements and with GAO's recommendation to use USDA's foreign country evaluations, but it disagreed with others. NMFS agreed with GAO's recommendations, and EPA took no position.

[www.gao.gov/cgi-bin/getrpt?GAO-05-213](http://www.gao.gov/cgi-bin/getrpt?GAO-05-213).

To view the full product, including the scope and methodology, click on the link above. For more information, contact Robert A. Robinson at (202) 512-3841 or [robinsonr@gao.gov](mailto:robinsonr@gao.gov).

March 2005

## OVERSIGHT OF FOOD SAFETY ACTIVITIES

### Federal Agencies Should Pursue Opportunities to Reduce Overlap and Better Leverage Resources

#### What GAO Found

Several statutes give responsibility for different segments of the food supply to different agencies to ensure that the food supply is safe. The U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA) within the Department of Health and Human Services (HHS) have the primary responsibility for regulating food safety, with the Environmental Protection Agency (EPA) and the National Marine Fisheries Service (NMFS) also involved. In carrying out their responsibilities, with respect to both domestic and imported food, these agencies spend resources on a number of overlapping activities, such as inspection/enforcement, training, research, or rulemaking. For example, both USDA and FDA conduct similar inspections at 1,451 dual jurisdiction establishments—facilities that produce foods regulated by both agencies. Under authority granted by the Bioterrorism Act of 2002, FDA could authorize USDA inspectors to inspect these facilities, but it has not done so. Furthermore, USDA and FDA maintain separate training programs on similar topics for their inspectors that could be shared. Ultimately, inspection and training resources could be used more efficiently.

#### Common Elements of USDA and FDA Inspections

Hazard Analysis and Critical Control Point:	Sanitation:	Good Manufacturing Practices:
<ul style="list-style-type: none"> <li>Check to ensure facility maintains a HACCP plan that identifies potential sources of food contamination</li> <li>Check to ensure the facility is implementing its HACCP plan</li> </ul>	<ul style="list-style-type: none"> <li>Check food contact surfaces</li> <li>Check for pests</li> <li>Check the facility's hand-washing area</li> </ul>	<ul style="list-style-type: none"> <li>Check cleanliness of employees' outer garments and gloves</li> <li>Check equipment design to see if it is cleanable and properly maintained</li> </ul>

Source: GAO analysis of FSIS and FDA documents.

GAO identified 71 interagency agreements that the agencies entered into to better protect public health and to coordinate their food safety activities. However, the agencies have weak mechanisms for tracking these agreements that, in some cases, lead to ineffective implementation. Specifically, USDA and FDA are not fully implementing an agreement to facilitate the exchange of information about dual jurisdiction establishments, which both agencies inspect. In addition, FDA and NMFS are not implementing an agreement designed to enable each agency to discharge its seafood responsibilities effectively.

GAO spoke with selected industry associations, food companies, consumer groups, and academic experts, and they disagree on the extent of overlap and on how best to improve the food safety system. Most of these stakeholders agreed that laws and regulations should be modernized to more effectively and efficiently control food safety hazards, but they differed about whether to consolidate food safety functions into a single agency.

United States Government Accountability Office

October 2004



Highlights of GAO-05-51, a report to congressional requesters

## FOOD SAFETY

### USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food

#### Why GAO Did This Study

Two large food recalls completed in 2003 were associated with 8 deaths and nearly 100 serious illnesses in at least 16 states. Manufacturers voluntarily recall potentially unsafe food by notifying their customers to return or destroy it. The U.S. Department of Agriculture (USDA), for meat, poultry, and egg products, and the Food and Drug Administration (FDA), for other food, have programs to monitor voluntary food recalls, verify that companies contact their customers, and maintain recall data. GAO (1) examined the recall programs and procedures USDA and FDA use to protect consumers from unsafe foods and (2) compared their food recall authority with the authority of agencies to recall other consumer products.

#### What GAO Recommends

GAO proposes that Congress consider legislation requiring a company to notify USDA or FDA if it discovers it has distributed unsafe food and giving agencies authority to order food recalls, and recommends that the agencies take actions to ensure prompt, complete recalls and better recall monitoring. USDA said the report was generally accurate and its May 2004 directive will address weaknesses GAO found. FDA did not believe its system lengthened recalls or its processes reduced recovery. FDA disagreed with some recommendations. GAO continues to believe its recommended actions are needed to protect consumers.

[www.gao.gov/cgi-bin/getrpt?GAO-05-51](http://www.gao.gov/cgi-bin/getrpt?GAO-05-51).

To view the full product, including the scope and methodology, click on the link above. For more information, contact Lawrence J. Dyckman at (202) 512-3841 or [dyckmanl@gao.gov](mailto:dyckmanl@gao.gov).

#### What GAO Found

Weaknesses in USDA's and FDA's food recall programs heighten the risk that unsafe food will remain in the food supply and ultimately be consumed. Specifically, USDA and FDA do not know how promptly and completely the recalling companies and their distributors and other customers are carrying out recalls, and neither agency is using its data systems to effectively track and manage its recall programs. For these and other reasons, most recalled food is not recovered and therefore may be consumed. GAO's analysis of recalls in 2003 showed that about 38 percent and 36 percent of recalled food was ultimately recovered in recalls overseen by USDA and FDA, respectively. These agencies also told GAO of instances in which companies were slow to reveal where they had distributed the food or provided inaccurate customer lists. That distribution information is critical because USDA's and FDA's primary role in recalls is to monitor the effectiveness of a company's recall actions. To do so, the agencies contact a sample of the distribution chain from these lists to verify that customers in the food distribution chain received notice of the recall, and that they located the food and removed it from the marketplace. However, the methodology that the agencies use for selecting the customers to check can result in entire segments of complex distribution chains being overlooked. Moreover, GAO found that the agencies did not complete verification checks for some recalls before the shelf life of the food expired. In addition, consumer groups and others question the usefulness of USDA's and FDA's efforts to communicate with the public, suggesting alternatives such as posting notices in grocery stores and direct notification of consumers.

Agencies responsible for the safety of products, such as toys, heart pacemakers, and automobiles, have specific recall authority not available to USDA and FDA for food. This includes the authority to (1) require a company to notify the agency when it has distributed a potentially unsafe product, (2) order a recall, (3) establish recall requirements, and (4) impose monetary penalties if a company violates recall requirements. For example, by law, companies must promptly notify the Consumer Product Safety Commission after learning that a product may pose an unreasonable risk of serious injury or death, or face penalties of up to \$1.65 million. Likewise, FDA has recall authority for unsafe biological products, medical devices, radiation emitting electronic products, and infant formula. Moreover, in contrast to its inability to penalize a company that is slow to conduct a food recall, FDA can impose penalties of up to \$100,000 per day for a company that fails to recall a defective biological product, such as a vaccine.

United States Government Accountability Office



Highlights of GAO-05-214, a report to congressional requesters

### Why GAO Did This Study

U.S. agriculture generates more than \$1 trillion per year in economic activity and provides an abundant food supply for Americans and others. Since the September 11, 2001, attacks, there are new concerns about the vulnerability of U.S. agriculture to the deliberate introduction of animal and plant diseases (agroterrorism). Several agencies, including the U.S. Department of Agriculture (USDA), the Department of Homeland Security (DHS), the Department of Health and Human Services (HHS), the Environmental Protection Agency (EPA), and the Department of Defense (DOD), play a role in protecting the nation against agroterrorism. GAO examined (1) the federal agencies' roles and responsibilities to protect against agroterrorism, (2) the steps that the agencies have taken to manage the risks of agroterrorism, and (3) the challenges and problems that remain.

### What GAO Recommends

To enhance the agencies' ability to reduce the risk of agroterrorism, GAO recommends, among other things, that (1) USDA examine the costs and benefits of developing stockpiles of ready-to-use vaccines and (2) DHS and USDA determine the reasons for declining agricultural inspections. USDA, DHS, and HHS generally agreed with our recommendations. DOD and EPA made technical comments but took no position on the report's recommendations.

[www.gao.gov/cgi-bin/getrpt?GAO-05-214](http://www.gao.gov/cgi-bin/getrpt?GAO-05-214).

To view the full product, including the scope and methodology, click on the link above. For more information, contact Robert Robinson, 202-512-3841, [Robinsonr@gao.gov](mailto:Robinsonr@gao.gov).

March 2005

## HOMELAND SECURITY

### Much Is Being Done to Protect Agriculture from a Terrorist Attack, but Important Challenges Remain

#### What GAO Found

After the terrorist attacks of September 11, 2001, federal agencies' roles and responsibilities were modified in several ways to help protect agriculture from an attack. First, the Homeland Security Act of 2002 established DHS and, among other things, charged it with coordinating U.S. efforts to protect against agroterrorism. The act also transferred a number of agency personnel and functions into DHS to conduct planning, response, and recovery efforts. Second, the President signed a number of presidential directives that further define agencies' specific roles in protecting agriculture. Finally, Congress passed legislation that expanded the responsibilities of USDA and HHS in relation to agriculture security.

In carrying out these new responsibilities, USDA and other federal agencies have taken a number of actions. The agencies are coordinating development of plans and protocols to better manage the national response to terrorism, including agroterrorism, and, along with several states, have conducted exercises to test these new protocols and their response capabilities. Federal agencies also have been conducting vulnerability assessments of the agriculture infrastructure; have created networks of laboratories capable of diagnosing animal, plant, and human diseases; have begun efforts to develop a national veterinary stockpile that intends to include vaccines against foreign animal diseases; and have created new federal emergency coordinator positions to help states develop emergency response plans for the agriculture sector.

However, the United States still faces complex challenges that limit the nation's ability to respond effectively to an attack against livestock. For example, USDA would not be able to deploy animal vaccines within 24 hours of an outbreak as called for in a presidential directive, in part because the only vaccines currently stored in the United States are for strains of foot and mouth disease, and these vaccines need to be sent to the United Kingdom (U.K.) to be activated for use. There are also management problems that inhibit the effectiveness of agencies' efforts to protect against agroterrorism. For instance, since the transfer of agricultural inspectors from USDA to DHS in 2003, there have been fewer inspections of agricultural products at the nation's ports of entry.

Burning Carcasses during the 2001 U.K. Outbreak of Foot and Mouth Disease



Source: U.S. Department of Agriculture.

United States Government Accountability Office



Highlights of GAO-04-246, a report to congressional requesters

January 2004

## FOOD SAFETY

# FDA's Imported Seafood Safety Program Shows Some Progress, but Further Improvements Are Needed

### Why GAO Did This Study

More than 80 percent of the seafood that Americans consume is imported. The Food and Drug Administration (FDA) is responsible for ensuring that imported seafood is safe and produced under sanitation and safety systems comparable to those of the United States. Since GAO reported in 2001 that FDA's seafood inspection program did not sufficiently protect consumers, additional concerns have arisen about imported seafood containing banned substances, such as certain antibiotics. In this review, GAO was asked to evaluate (1) FDA's progress in implementing the recommendations in the 2001 report and (2) other options to enhance FDA's oversight.

### What GAO Recommends

GAO recommends that FDA (1) work toward developing a memorandum of understanding with NOAA to use NOAA's resources; (2) make it a priority to establish equivalence or other agreements, starting with countries having high-quality food safety systems; (3) develop a system to track the time involved in processing enforcement actions; (4) give enforcement priority to violations posing the most serious risks; (5) consider accrediting private laboratories; and (6) explore the potential for certifying third-party inspectors. FDA generally agreed with all but the recommendation on making it a priority to establish equivalence or other agreements.

[www.gao.gov/cgi-bin/getrpt?GAO-04-246](http://www.gao.gov/cgi-bin/getrpt?GAO-04-246).

To view the full product, including the scope and methodology, click on the link above. For more information, contact Lawrence J. Dyckman at (202) 512-3841 or [ldyckman@gao.gov](mailto:ldyckman@gao.gov).

### What GAO Found

Since GAO's January 2001 report, FDA's imported seafood safety program has shown some improvement. FDA inspects more foreign firms, and its inspections show that more U.S. seafood importers are complying with its requirements. FDA also slightly increased the number of seafood products it tests at U.S. ports of entry to just over 1 percent. However, FDA still has not established equivalence agreements with seafood exporting countries as GAO recommended in its 2001 report. Equivalence agreements that commit U.S. trading partners to maintain comparable food safety systems are an efficient way to ensure imported seafood safety. Unlike the U.S. Department of Agriculture, FDA is not legally required to certify that countries exporting food products to the United States have equivalent food safety systems. According to a panel of nationally recognized experts that GAO convened to address this and other issues, establishing these types of agreements would shift some of FDA's burden for ensuring seafood safety to foreign governments. This shift, in turn, would allow FDA to focus its limited resources on seafood products from countries with less advanced food safety systems.

FDA also made little progress regarding the recommendation GAO made in 2001 that FDA communicate to U.S. port-of-entry personnel serious deficiencies identified during inspections so that potentially contaminated imported seafood is examined before it enters the United States. GAO found that FDA continues to experience long delays between finding deficiencies and taking action. For example, GAO's review of foreign firm inspection records found that it took an average of 348 days for FDA to alert port-of-entry personnel about serious safety problems identified at six foreign firms. Moreover, GAO found that FDA does not prioritize enforcement actions when violations that pose the most serious public health risk occur or have an automated system to track the time involved in documenting, reviewing, and processing enforcement actions.

FDA officials acknowledged some of the problems that GAO identified regarding FDA's current imported seafood inspection program, but they also raised concerns about limited inspection resources and competing priorities, such as the recent need to implement provisions of the Bioterrorism Act of 2002. GAO identified several options that FDA could consider to augment its resources and enhance its current program, including (1) commissioning seafood inspectors from the National Oceanic and Atmospheric Administration's (NOAA) Seafood Inspection Program, (2) using state regulatory laboratories and/or private laboratories to augment FDA's testing of imported seafood, and (3) developing a program to use third-party inspectors to augment its program.

United States General Accounting Office



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# Related GAO Products

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*Homeland Security: Management and Coordination Problems Increase the Vulnerability of U.S. Agriculture to Foreign Pests and Disease.* [GAO-06-644](#). Washington, D.C.: May 19, 2006.

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

*Food Safety: Experiences of Seven Countries in Consolidating Their Food Safety Systems.* [GAO-05-212](#). Washington, D.C.: February 22, 2005.

*Food Safety: USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food.* [GAO-05-51](#). Washington, D.C.: October 6, 2004.

*Antibiotic Resistance: Federal Agencies Need to Better Focus Efforts to Address Risk to Humans from Antibiotic Use in Animals.* [GAO-04-490](#). Washington, D.C.: April 22, 2004.

*School Meal Program: Few Instances of Foodborne Outbreaks Reported, but Opportunities Exist to Enhance Outbreak Data and Food Safety Practices.* [GAO-03-530](#). Washington, D.C.: May 9, 2003.

*Food-Processing Security: Voluntary Efforts Are Under Way, but Federal Agencies Cannot Fully Assess Their Implementation.* [GAO-03-342](#). Washington, D.C.: February 14, 2003.

*Meat and Poultry: Better USDA Oversight and Enforcement of Safety Rules Needed to Reduce Risk of Foodborne Illnesses.* [GAO-02-902](#). Washington, D.C.: August 30, 2002.

*Genetically Modified Foods: Experts View Regimen of Safety Tests as Adequate, but FDA's Evaluation Process Could Be Enhanced.* [GAO-02-566](#). Washington, D.C.: May 23, 2002.

*Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and "Functional Foods."* [GAO/RCED-00-156](#). Washington, D.C.: July 11, 2000.

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