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FEDERAL OVERSIGHT OF FOOD SAFETY

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

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Highlights of [GAO-07-785T](#), a testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, 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. The outbreaks of *E. coli* in spinach and *Salmonella* in peanut butter, along with contamination in pet food, have highlighted the risks posed by accidental food contamination. The attacks of September 11, 2001, heightened awareness that the food supply could also be vulnerable to deliberate contamination. This testimony focuses on the (1) role that GAO's high-risk series can play in raising the priority and visibility of the need to transform federal oversight of food safety, (2) fragmented nature of federal oversight of food safety, and (3) limitations in federal food recall programs.

What GAO Recommends

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

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

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

FEDERAL OVERSIGHT OF FOOD SAFETY

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

What GAO Found

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

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

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

Mr. Chairman 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 and, specifically, the limitations in the government's food recall programs. 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. Further, as the population grows older and more vulnerable to foodborne illness, food safety will become increasingly important. The recent outbreaks of *E. coli* in spinach and *Salmonella* in peanut butter, for example, along with contamination in pet food, have highlighted the risks posed by accidental food contamination.

Ensuring the safety of the nation's food supply 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. 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. 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 agricultural exports, which exceeded \$68 billion in fiscal year 2006.

We added the federal oversight of food safety to our list of high-risk programs needing urgent attention and transformation to ensure that our federal government functions in the most economical, efficient, and effective manner possible.¹ 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 federal government can more efficiently and effectively protect our nation's food supply. In addition, food recalls are voluntary, and the U.S. Department of Agriculture (USDA) and the Food

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

and Drug Administration (FDA), which have primary responsibility for food safety, have no authority to compel companies to carry out most recalls, except for FDA's authority to require a recall for infant formula. Instead, USDA and FDA provide guidance for companies to carry out voluntary recalls. We have reported that USDA and FDA could do a better job in carrying out their food recall programs so they can quickly remove potentially unsafe food from the market place.²

Because of your responsibility for oversight of federal agencies, 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 food safety, and (3) limitations in federal food recall programs. My testimony is based on published GAO products that were developed in accordance with generally accepted government auditing standards.

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

We designated the federal oversight of food safety as a high-risk area to raise the priority and visibility of the need to transform this system. Overall, our High-Risk Series has identified and helped 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.

In designating federal oversight of food safety as high risk, we considered whether it had national significance or a management function that was key to performance and accountability. Further, we considered qualitative factors, such as whether food safety

- involved 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.

²GAO, *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).

Clearly, these factors weighed heavily into our deliberations to place the federal oversight of food safety on our high-risk list. For example, food contamination, such as the recent *E. coli* outbreaks, can have a detrimental impact on public health and the local economy. According to FDA, the outbreak resulted in 205 confirmed illnesses and three deaths. In addition, industry representatives estimate losses from the recent California spinach *E. coli* outbreak to range from \$37 million to \$74 million.

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 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.

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

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 contaminated food, and focus on promoting the safety and integrity of the nation's food supply. While 15 agencies collectively administer at least 30 laws related to food safety, two agencies have primary responsibility—USDA, which is responsible for the safety of meat, poultry, and processed egg products, and FDA, which is responsible for virtually all other foods.

The food safety system is further complicated by the subtle differences in food products that dictate which agency regulates a product. For example, which agency is responsible for ensuring the safety of frozen pizzas depends on whether or not meat is used as a topping. USDA inspects manufacturers of frozen pepperoni pizza, while FDA inspects manufacturers of frozen cheese pizza. In other instances, 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).

We have identified examples where the federal government's resources and enforcement activities can better align with the risks of food contamination. For example, the majority of federal expenditures for food safety inspection have been 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. Also, 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.³ FDA has jurisdiction over the food products involved in the recent food contamination outbreaks I mentioned today.

The 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 federal food safety system and reported that the system has caused inconsistent oversight, ineffective coordination, and inefficient use of resources. We have cited the need to integrate this fragmented 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.⁴

To help decisionmakers update programs to meet present and future challenges within current and expected resource levels, we framed illustrative questions for them 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

³GAO, *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).

⁴GAO, *21st Century Challenges: Reexamining the Base of the Federal Government*, [GAO-05-325SP](#) (Washington, D.C.: February 2005).

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.

Many of our recommendations to agencies to promote the safety and integrity of the nation's food supply have been acted upon. For example, we recommended that FDA adopt a risk-based approach to overseeing states' shellfish safety programs.⁵ In response to our recommendation, FDA designed a risk-based approach to reviewing the states' shellfish safety programs and incorporated it into their fiscal year 2003 to 2005 compliance program, which FDA's shellfish specialists use to evaluate state programs.

Nevertheless, as we discuss in the 2007 High-Risk Series, a fundamental reexamination of the federal food safety system is warranted. 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. Others have also 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.⁶

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 decisionmakers balance trade-offs and compare performance when resource allocation and restructuring decisions are made.

⁵GAO, *Food Safety: Federal Oversight of Shellfish Safety Needs Improvement*, [GAO-01-702](#) (Washington, D.C.: July 9, 2001).

⁶Institute of Medicine, *Ensuring Safe Food from Production to Consumption*, Washington, D.C.: National Academy Press, 1998.

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.⁷ Members of this subcommittee and others have introduced food safety legislation, none of which has been enacted thus far. 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. 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.

Limitations in Federal Agencies' Recall Programs Heighten the Risk that Unsafe Food Will Reach Consumers

Among the reasons we designated federal oversight of food safety as a high-risk area is that limitations in the federal government's food recalls heighten the risk that unsafe food will remain in the food supply and ultimately be consumed. Food recalls are largely voluntary, and federal agencies responsible for food safety have no authority to compel companies to carry out recalls in these cases, with the exception of FDA's authority to require a recall for infant formula. Specifically, USDA does not have authority to issue a mandatory recall order for meat, poultry, and processed egg products. Similarly, FDA, which is responsible for virtually all other foods, does not have recall authority beyond infant formula.

Government agencies that regulate the safety of other products, such as toys and automobile tires, have recall authority not available to USDA and 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 it has distributed a potentially unsafe product,
- order a recall,
- establish recall requirements, and

⁷GAO, *Food Safety and Security: Fundamental Changes Needed to Ensure Safe Food*, [GAO-02-47T](#) (Washington, D.C.: Oct. 10, 2001).

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- impose monetary penalties if a company does not cooperate.

For example, manufacturers of many consumer goods are generally required to notify the Consumer Product Safety Commission within 24 hours of obtaining information that suggests a product could create a substantial risk of injury. The commission has the authority to impose monetary penalties of up to \$1.825 million if a company does not inform the commission promptly about an unsafe product. Furthermore, the National Highway Traffic Safety Administration has the authority to establish recall requirements to require companies to directly notify the purchasers of vehicles with defects and to remedy the defects. Likewise, FDA has authority to order recalls of unsafe biological products and medical devices—and it has used this authority in the past. In addition, FDA can impose penalties of up to \$100,000 per day on companies that do not recall unsafe biological products, such as vaccines.⁸

Even in the context of their limited recall authority, we reported in October 2004 that USDA and FDA could do a better job in carrying out their food recall programs so they could quickly remove potentially unsafe food from the marketplace.⁹ Specifically:

- USDA and FDA did not know how promptly and completely companies were carrying out recalls. The agencies were not using their data systems to effectively monitor and manage their recall programs. They did not track important dates to calculate how long companies take to carry out recalls and the percentage of food that is recovered. Furthermore, managers did not receive routine reports on the progress of ongoing recalls to target program resources. Moreover, neither agency's guidance provided time frames for how quickly companies should initiate and carry out recalls. Consequently, companies may have had less impetus to notify downstream customers and remove potentially unsafe food from the marketplace.
- USDA and FDA did not promptly verify that recalls had reached all segments of the distribution chain, yet monitoring the effectiveness of a company's recall actions is the agencies' primary role in a food recall. For the 10 USDA recalls in 2003 we examined in depth, USDA staff

⁸The statute requires that this be adjusted annually for inflation. We have not adjusted the \$100,000 figure for inflation.

⁹[GAO-05-51](#).

averaged 38 days to complete verification checks, and for the 10 FDA recalls we examined in depth, FDA staff averaged 31 days. These time frames exceeded the expected shelf life for some perishable foods that were recalled, such as fresh ground beef and fresh-cut bagged lettuce.

- The procedures USDA and FDA used to alert consumers to a recall—press releases and Web postings—may not have been effective. According to consumer groups and others, relatively few consumers may see that information. They identified additional methods to notify the public, such as posting recall notices in grocery stores and directly notifying consumers using “shoppers’ club” information.

We have proposed that Congress consider legislation that would require companies to alert USDA or FDA when they discover they have distributed potentially unsafe food and that would give both agencies mandatory food recall authority. Congress has not enacted legislation granting agencies general mandatory recall authority. We have also recommended that USDA and FDA better track and manage food recalls, achieve more prompt and complete recalls, and determine if additional ways are needed to alert consumers about recalled food that they may have in their homes. According to agency officials, USDA and FDA are taking actions to address some of our recommendations. Specifically, they are currently updating their recall data systems. In addition, USDA amended a directive in order to improve its recall effectiveness checks and how it communicates information about recalls. FDA is also conducting a quality management review of its food recall system with a goal of providing a documented, uniform, and streamlined recall process. We have not reviewed these actions to determine if they adequately address our recommendations.

The recent outbreaks of *E. coli* in spinach and *Salmonella* in peanut butter, along with outbreaks of contaminated pet food, underscore the need of a broad-based transformation of the federal oversight of food safety to achieve greater economy, efficiency, effectiveness, accountability, and sustainability. GAO’s 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. Among the reasons we designated the federal oversight of food safety as a high-risk area is that USDA and FDA have limited recall authority. Even within this limited authority, we found that these agencies could have done better in carrying out their food recall programs. Positively, agency officials are taking actions intended to improve their

food recall programs. However, we have not reviewed these actions to determine if they adequately address our recommendations.

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, Acting Director, Natural Resources and Environment at (202) 512-3841 or ShamesL@gao.gov. Key contributors to this statement were José Alfredo Gómez, Bart Fischer, Terrance N. Horner, Alison O'Neill, Beverly Peterson, and Rebecca Yurman.

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