FEDERAL FOOD SAFETY OVERSIGHT

Food Safety Working Group Is a Positive First Step but Governmentwide Planning Is Needed to Address Fragmentation

March 2011

GAO-11-289
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Why GAO Did This Study

For more than a decade, GAO has reported on the fragmented nature of federal food safety oversight and how it results in inconsistent oversight, ineffective coordination, and inefficient use of resources. In 2007, GAO added this issue to its high-risk list. In March 2009, the President established the Food Safety Working Group (FSWG) to coordinate federal efforts and establish food safety goals to make food safer.

What GAO Found

Creation of the FSWG elevated food safety as a national priority, demonstrated strong commitment and top leadership support, and was designed to foster interagency collaboration on this cross-cutting issue. The FSWG includes officials from the Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), the Office of Management and Budget (OMB), and other federal agencies. Through the FSWG, federal agencies have taken steps designed to increase collaboration in some areas that cross regulatory jurisdictions—in particular, improving produce safety, reducing Salmonella contamination, and developing food safety performance measures.

However, the FSWG has not developed a governmentwide performance plan for food safety that provides a comprehensive picture of the federal government’s food safety efforts. When GAO added food safety oversight to its high-risk list in 2007, it said that what remains to be done is to develop a governmentwide performance plan for food safety that is mission based, results oriented, and provides a cross-agency perspective. Officials from OMB, FDA, and USDA told us that the FSWG’s July 2009 “key findings” represent the governmentwide plan for food safety. However, most of the goals outlined in the key findings are not results oriented and do not include performance measures. Further, the FSWG has not provided information about the resources that are needed to achieve its goals. Our prior work has identified results oriented goals and performance measures and a discussion of strategies and resources as standard elements of performance plans.

What GAO Recommends

GAO recommends that the Director of OMB, in consultation with the federal food safety agencies, develop a governmentwide performance plan for food safety that includes results oriented goals and performance measures for food safety oversight and a discussion about strategies and resources. OMB declined to comment on a draft of this report. USDA and Health and Human Services provided technical comments.

View GAO-11-289 or key components.
For more information, contact Lisa Shames at (202) 512-3841 or shamesl@gao.gov.
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March 18, 2011

Congressional Committees

For more than a decade, GAO has reported on the fragmented nature of federal food safety oversight. While the Food and Drug Administration (FDA) and U.S. Department of Agriculture’s (USDA) Food Safety and Inspection Service (FSIS) have primary oversight responsibilities, a total of 15 agencies collectively administer at least 30 food-related laws. In 2007, we added the federal oversight of food safety to our list of high-risk areas in need of broad-based transformation to achieve greater economy, efficiency, effectiveness, accountability, and sustainability.¹ We also cited the need to integrate this fragmented system as a challenge for the 21st century.²

The 2010 nationwide recall of more than 500 million eggs due to Salmonella contamination highlights how this fragmentation persists, with several agencies having different roles and responsibilities throughout the egg production system. For example, FDA is generally responsible for ensuring that eggs in their shells—referred to as shell eggs—including eggs at farms such as those where the outbreak occurred, are safe, wholesome, and properly labeled. FSIS, on the other hand, is responsible for the safety of eggs processed into egg products. In addition, USDA’s Agricultural Marketing Service (AMS) sets quality and grade standards for shell eggs, such as Grade A, but does not test the eggs for bacteria such as Salmonella. Further, while USDA’s Animal and Plant Health Inspection Service manages the program that helps ensure laying hens are free from Salmonella at birth, FDA oversees the safety of the feed they eat.

Many of our reports have found that fragmentation in the nation’s food safety system results in inconsistent oversight, ineffective coordination, and inefficient use of resources. In 2005, we reported that federal agencies spend resources on overlapping activities, including inspections of domestic and imported foods, training, research, risk assessment,

education, and rulemaking. We recommended that federal agencies take a number of steps to reduce overlap, leverage resources, and enhance coordination. For example, to better use FDA’s limited inspection resources and leverage USDA’s resources, we recommended that, if appropriate and cost effective, the Commissioner of the FDA enter into an agreement to commission USDA inspectors to carry out FDA’s inspection responsibilities for food establishments that are under the jurisdiction of both agencies. We have made several other recommendations intended to address the fragmented federal oversight of the nation’s food supply. In 2001, we recommended that the Secretary of Agriculture, the Secretary of Health and Human Services, and the Assistant to the President for Science and Technology, as joint chairs, reconvene the President’s Council on Food Safety to facilitate interagency coordination on food safety regulation and programs. The council had disbanded earlier that year. Positively, in March 2009, the President established the Food Safety Working Group (FSWG), which is co-chaired by the Secretaries of Agriculture and Health and Human Services, to coordinate federal efforts and develop goals to make food safer. When we added food safety oversight to our high-risk list in 2007, we said that what remains to be done is to develop a governmentwide performance plan for food safety that is mission based, has a results orientation, and provides a cross-agency perspective. Finally, in reports dating back to 2001 we have been suggesting that Congress consider commissioning the National Academy of Sciences or a blue ribbon panel to conduct a detailed analysis of alternative organizational food safety structures and consider enacting comprehensive food safety legislation.

New food safety legislation that was signed into law in January 2011—FDA Food Safety Modernization Act—strengthens a major part of the food safety system. It shifts the focus of FDA regulators from responding to contamination to preventing it, according to FDA, and expands FDA’s

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5GAO-07-310.

6GAO-02-47T.

oversight authority. For example, the law directs FDA to increase the frequency of its inspections, and allocate resources to inspect facilities according to the facilities’ known safety risks, with high-risk facilities being inspected the most frequently. The law also has several sections that require interagency collaboration on food safety oversight in areas such as inspections, seafood safety, and food imports. While the new law is a positive development, it does not apply to the federal food safety system as a whole. In particular, it does not address USDA’s authorities, which remain separate and distinct from FDA’s.

A new statutory requirement mandates that GAO identify federal programs, agencies, offices, and initiatives with duplicative goals and activities within departments and governmentwide. Under that mandate, this review examines: (1) steps, if any, that the FSWG has taken to increase collaboration among federal food safety agencies, and (2) options we and others have identified to reduce fragmentation, overlap, and potential duplication in food safety oversight. To complete our work we reviewed food safety reports and legislation, and interviewed officials from USDA, FDA, and the Office of Management and Budget (OMB). We also collected and analyzed information about the FSWG, its activities, and its governmentwide plan for food safety, as well as alternative organizational structures for food safety. More detailed information about our scope and methodology appears in appendix I. We conducted this performance audit from July 2010 to March 2011 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.

The safety and quality of the U.S. food supply is governed by a highly complex system stemming from at least 30 laws related to food safety that are collectively administered by 15 agencies. The two primary food safety agencies are USDA and FDA. USDA is responsible for the safety of meat, poultry, processed egg products, and, as soon as recently proposed regulations are finalized, catfish. FDA is responsible for virtually all other food, including seafood. In fiscal year 2009, budget obligations for FDA’s

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Federal food safety activities include inspecting domestic food-processing facilities and imported food at ports of entry, visiting foreign countries or firms to inspect and evaluate foreign food safety systems, analyzing samples collected at food-processing facilities to identify possible contamination, rulemaking and standard setting, and developing guidance for industry, among other things. Appendix II summarizes the federal agencies’ food safety responsibilities and main authorizing statutes. The federal food safety system is supplemented by the states, which may have their own statutes, regulations, and agencies for regulating and inspecting the safety and quality of food products.

The existing food safety system, like many other federal programs and policies, evolved piecemeal, typically in response to particular health threats or economic crises. Existing statutes give agencies different regulatory and enforcement authorities for different food products. For example, the 2008 Farm Bill gave USDA responsibility for inspecting catfish, but left general responsibility for seafood safety with FDA, making the system more fragmented. According to USDA officials, USDA estimates it will spend no more than $5 million in fiscal year 2011 and did not request funding for fiscal year 2012 for its catfish inspection program.³

Three major trends also create food safety challenges. First, a substantial and increasing portion of the U.S. food supply is imported. Second, consumers are eating more raw and minimally processed foods. Third, segments of the population that are particularly susceptible to food-borne

³*Budget of the U.S. Government, Fiscal Year 2011* (Washington, D.C.: February 2010). Fiscal year 2009 budget obligations for FDA’s Foods Program include funds that were appropriated to FDA in fiscal year 2008 but available for obligation through fiscal year 2009, according to FDA officials. Budget obligations for FDA do not include food safety activities in the Office of the Commissioner through the Office of Foods, or the Animal Drugs and Feed program. Fiscal year 2009 budget obligations for FSIS do not include additional fees FSIS collects from establishments, importers, and exporters to offset costs for overtime inspection services.

³In September 2010, USDA officials told us the agency estimated it would have to spend approximately $30 million in fiscal years 2011 and 2012 to develop and implement its catfish inspection program. Because of the need for considerable stakeholder engagement and regulatory development before the program’s adoption and implementation, USDA officials revised their estimate for fiscal year 2011 and no funding was proposed for the program in the President’s fiscal year 2012 budget.
illnesses, such as older adults and immune-compromised individuals, are growing.

The FSWG Has Taken Steps Designed to Improve Collaboration among Federal Agencies but Has Not Developed a Comprehensive Governmentwide Performance Plan for Food Safety

Creation of the FSWG by the President in March 2009 elevated food safety as a national priority, demonstrated strong commitment and top leadership support, and was designed to foster interagency collaboration on this crosscutting issue. However, the FSWG has not developed a governmentwide performance plan that provides a comprehensive picture of the federal government’s food safety efforts. The FSWG is co-chaired by the Secretaries of Health and Human Services and Agriculture. It also includes officials from FDA, FSIS, the Centers for Disease Control and Prevention (CDC), the Environmental Protection Agency, the Department of Homeland Security, the Department of Commerce, the Department of State, and several offices in the Executive Office of the President, including OMB. Both FDA and FSIS have created executive positions to focus agency efforts on food safety, and officials from both agencies told us that the FSWG has increased interagency collaboration. However, while creating the FSWG is a positive first step, we have reported that the continuity of food safety coordination efforts can be hampered by changes in executive branch leadership.\(^{11}\) As a presidentially appointed working group, the FSWG’s future is uncertain, and the experience of the former President’s Council on Food Safety, which disbanded less than 3 years after it was created, illustrates that this type of approach can be short lived.

Nevertheless, through the FSWG, federal agencies have taken steps designed to increase collaboration in some areas that cross regulatory jurisdictions—in particular, improving produce safety, reducing Salmonella contamination, and developing food safety performance measures.

- **Produce safety.** Preventing contamination of fresh produce is an FSWG priority. In 2009, FDA issued draft guidance for industry on produce safety to minimize food safety hazards and contamination of leafy greens, tomatoes, and melons. FDA has also publicly announced that it is developing a proposed regulation setting enforceable standards for fresh produce safety at farms and packing houses, and FDA and AMS officials told us the agencies are collaborating on the rulemaking process, as AMS

\(^{11}\)GAO-02-47T.
establishes quality and condition standards the food industry can voluntarily adopt for marketing purposes through marketing agreements. Specifically, an AMS employee who USDA describes as having extensive experience working with the produce industry for over 20 years has been temporarily assigned to work as a Senior Policy Analyst in FDA’s Office of Foods from October 2009 to March 2011 to help develop the regulation. The AMS employee told us she is providing FDA with information about practices on farms and in packing houses that FDA officials are using to inform their rulemaking. She is also helping FDA leverage existing AMS-industry relationships to conduct outreach to farms and packing houses before the produce safety regulation goes into effect. In addition, AMS has publicly announced that it is developing a proposed national marketing agreement for leafy greens that will include food safety standards. The purpose of the proposed marketing agreement is to enhance the quality of fresh leafy green vegetable products through the application of good agricultural and handling practices, and to improve consumer confidence, among other things. Based on our review of Federal Register documents and interviews with AMS and FDA officials, we found that AMS is coordinating with FDA to ensure that the standards in the proposed marketing agreement are consistent with the standards FDA is setting in the produce safety regulation.

- *Salmonella contamination.* According to FSIS, FDA, and OMB officials, FSIS and FDA worked together to establish complementary performance goals under the High Priority Performance Goal initiative—a White House management initiative—for reducing illness caused by *Salmonella*. FSIS officials told us that staff from FSIS and FDA communicated on a regular basis to coordinate efforts to develop their respective agencies’ goals, as they are closely intertwined. *Salmonella* contamination can occur in poultry and egg products, which are under FSIS’s regulatory jurisdiction, and shell eggs, which are primarily under FDA’s jurisdiction. Both agencies set goals to reduce illness from *Salmonella* within their own areas of egg safety jurisdiction by the end of 2011. According to the FSIS officials, FSIS and FDA coordinated on ensuring that the goals complemented one another, utilized the same datasets, and covered the same time period so that the agencies measure their progress consistently. FSIS’s goal is to reduce the rate of illness due to *Salmonella* in FSIS-regulated products to 5.3 cases per 100,000 people by 2011, a reduction of approximately 22,600 illnesses below the current baseline with an associated cost reduction of $404 million. FDA’s goal is a 10 percent decrease by 2011 over the 2007-2009 average baseline rate of *Salmonella*.
Enteritidis illness in the population. The agencies have taken additional actions to address Salmonella. Specifically, in May 2010, FSIS announced new performance standards that poultry establishments must meet for Salmonella and released a compliance guide for industry. In July 2009, FDA issued a final rule requiring shell egg producers to implement measures to prevent Salmonella Enteritidis from contaminating eggs and, in August 2010, issued draft guidance for producers on implementing the rule.

- **Food safety performance measures.** FSWG members have proposed 21 performance measures for assessing the federal government’s progress toward meeting its crosscutting food safety goals. For example, to assess progress in preventing harm to consumers from unsafe food, one of the performance measures the FSWG is proposing is to track the prevalence of selected foodborne hazards in key commodity groups. As a next step, FSIS and FDA are beginning to set quantitative targets for the measures. For example, one of FSIS’s proposed quantitative targets is to reduce the prevalence of Salmonella Enteritidis in FSIS prepasteurized egg products from 14.12 percent (the fiscal year 2009 baseline) to 12.71 percent by fiscal year 2015. FDA is developing its own quantitative targets. FSWG and agency documents show that both agencies, with support from CDC, are coordinating to pilot-test a framework for developing the quantitative targets for Salmonella Enteritidis that covers multiple agencies’ oversight jurisdictions. FSIS officials told us this framework could identify data gaps and help target areas where more attention is needed. An FDA official told us that the agencies plan to use this framework to assess progress toward other food safety goals, but could not estimate when the agencies will finish developing a complete set of quantitative targets for the food safety performance measures.

In addition, we found that federal food safety agencies are taking actions in two other areas. First, FDA is leading an effort involving other federal agencies including CDC, USDA, and the Department of Homeland Security, to increase the inspection, laboratory, and outbreak-response capacities of state and local food safety agencies. FDA issued a draft paper describing its vision and established working groups of federal, state, and local government representatives to address issues such as national standards for food regulatory programs and standardized laboratory practices and procedures, among others. It has also hosted two national

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12 According to CDC, Salmonella Enteritidis is one of the most common variations of Salmonella bacteria reported worldwide.
meetings that were attended by public health and food safety officials from federal, state, local, and territorial government agencies. Second, in February 2011, federal food safety agencies established a Multi-Agency Coordination group intended to improve the response to outbreaks of foodborne illness, an FSWG priority. According to agency documents, the group will be used to coordinate the response of federal agencies, and state, local, and tribal governments, in managing large-scale foodborne illness outbreaks, prioritizing the allocation of critical resources, and making policy decisions. It is co-chaired by USDA and the Department of Health and Human Services and participating federal agencies include FDA, CDC, FSIS, AMS, the Food and Nutrition Service, the Animal and Plant Health Inspection Service, the Foreign Agricultural Service, the Environmental Protection Agency, and the Departments of Homeland Security, State, and Justice.

However, while the FSWG has taken steps to increase interagency collaboration on food safety, it has not developed a governmentwide performance plan that provides a comprehensive picture of the federal government’s food safety efforts. When we added food safety oversight to our high-risk list in 2007, we said that what remains to be done is to develop a governmentwide performance plan for food safety that is mission based, results oriented, and provides a cross-agency perspective.\(^{13}\) We also said this plan could be used to help decision makers balance trade-offs and compare performance when resource allocation and restructuring decisions are made. Officials from OMB, FDA, and USDA told us the FSWG’s July 2009 “key findings” represent the governmentwide plan for food safety.\(^{14}\) The key findings identify the FSWG’s three core principles for improving the safety of the U.S. food supply—prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery—and outline a number of goals and actions the agencies are taking, or plan to take, to improve food safety. The key findings are mission based and offer a cross-agency perspective. For example, both FSIS and FDA are contributing to goals for reducing illness from *Salmonella* and *E. coli*, and multiple federal agencies are contributing to goals for improving the response to outbreaks of foodborne illness.

\(^{13}\)GAO-07-310.

\(^{14}\)See key findings at [http://www.foodsafetyworkinggroup.gov/](http://www.foodsafetyworkinggroup.gov/).
Some of the goals are results oriented, such as FSIS’s goal to have 90 percent of poultry establishments meeting its new standards to reduce *Salmonella* in turkeys and poultry by the end of 2010, and FDA’s goal to reduce foodborne illness from shell eggs by approximately 60 percent by issuing a final rule to control *Salmonella* during egg production. However, most of the goals are not results oriented and do not include performance measures, focusing instead on specific actions the agencies plan to take in the near term. For example, to reduce illness from *E. coli*, FSIS’s goal is to issue improved instructions to its workforce and increase its sampling. It is not clear the extent to which these one-time actions will help reduce illness from *E. coli*.

Further, it is not clear how the key findings align with the 21 performance measures for food safety proposed by the FSWG. Our prior work has identified results oriented goals and performance measures as standard elements of performance plans. Because the FSWG’s key findings generally lack results oriented goals and performance measures, they do not provide a concrete statement of the federal government’s expected performance for food safety that can be used for subsequent comparison with its actual performance. Identifying performance gaps can help decision makers target scarce resources. In addition, the key findings do not include information about the resources that are needed to achieve the FSWG’s goals. A discussion of the strategies and resources needed to achieve annual goals is also a standard element of performance plans. The key findings also do not address the entire food supply; for example none of the goals specifically addresses food imports, which represent 60 percent of fresh fruits and vegetables and 80 percent of seafood.

Although performance plans are to be updated on an annual basis, OMB officials told us there are currently no plans to update the key findings, which were issued in 2009. Those officials also told us that, instead, the intent was to integrate the FSWG’s planning into the agencies’ budgeting processes, which include developing performance goals. While individual agency documents provide important and useful information, they do not

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provide a broader and more integrated picture of food safety oversight throughout the federal government. Without a governmentwide performance plan for food safety, decision makers do not have a comprehensive picture of the federal government’s performance on this crosscutting issue. Further, performance plans provide an opportunity for agencies to identify factors that influence the accomplishment of their goals and discuss the strategies they plan to take to leverage or mitigate the influence such factors can have on achieving results. For example, a governmentwide plan for food safety could recognize that the federal agencies’ food safety oversight authorities differ and recognize and address other external factors, such as the actions of state and local governments, which influence the accomplishment of federal food safety goals.

Recent legislation reinforces the need for and importance of governmentwide planning. The GPRA Modernization Act of 2010, which updates the requirements for strategic plans and performance plans, also recognizes the importance of governmentwide planning on crosscutting issues. In addition, the recently enacted FDA Food Safety Modernization Act calls for coordination among federal agencies. Specifically, the Act directs the Secretary of Health and Human Services to improve coordination and cooperation with the Secretaries of Agriculture and Homeland Security to target food inspection resources and to submit annual reports to Congress describing those efforts and providing other information about FDA’s inspections. The Act also requires the Secretaries of Health and Human Services and Agriculture, in consultation with the Secretary of Homeland Security, to prepare a National Agriculture and Food Defense Strategy. It also requires the Secretary of Health and Human Services, in coordination with the Secretaries of Agriculture and Homeland Security, to submit a comprehensive report to Congress that identifies programs and practices that are intended to promote the safety and security of the food supply and prevent foodborne outbreaks. The information provided in those reports could help inform a governmentwide performance plan for food safety. Moreover, we have reported that establishing mutually reinforcing or joint strategies is a key practice that can help enhance and sustain interagency collaboration among federal agencies. Such strategies help in aligning the collaborating


agencies’ activities, core processes, and resources to accomplish a common outcome. In this current fiscal environment, we and others have called for agencies to leverage scarce resources for food safety and other issues.

Our past work on other interagency planning may provide models for governmentwide planning on food safety. While FDA and USDA have collaborated on setting food safety goals for Healthy People—a multiagency initiative to improve public health—they are long-term goals, set every 10 years, and are not linked to resources. We have reported on interagency planning for sharing health resources for military service members and veterans and managing wildland fires.

- **Health resource sharing.** The Department of Veterans Affairs (VA) and Department of Defense (DOD) collaborate to use federal health resources, such as space in medical facilities, under the Veterans Administration and Department of Defense Health Resources Sharing and Emergency Operations Act. In addition, the VA/DOD Joint Executive Council develops a joint strategic plan to shape, focus, and prioritize the coordination and sharing efforts, as directed by Congress and recommended by a presidential task force. The council has developed a new joint strategic plan each year since 2003, which is included in the council’s annual report to the VA and DOD Secretaries on the status of implementing its collaboration and sharing activities. We reported that, according to DOD, the joint strategic plan outlines actionable objectives, assigns accountability, and establishes performance targets.¹⁸

- **Wildland fire management.** Five federal agencies that share responsibility for wildland fire management—the Forest Service at USDA and the Bureau of Indian Affairs, Bureau of Land Management, Fish and Wildlife Service, and National Park Service at the Department of Interior—have long coordinated their fire suppression efforts. The intergovernmental Wildland Fire Leadership Council, which was recommended by GAO and established by the Secretaries of Agriculture and the Interior in 2002, seeks to support implementation of federal fire management policy by coordinating agency policies and providing strategic direction.¹⁹ In reports


dating back to 1999, we have recommended that the agencies develop a cohesive strategy that identifies options and funding for preventing and responding to fires. At the direction of Congress, the council began developing a cohesive wildland fire management strategy in 2010 that is required to address fire suppression, prevention, and resource allocation issues.

We, the National Academy of Sciences, the Produce Safety Project, and the former President’s Council on Food Safety have identified options to reduce fragmentation and overlap in food safety oversight in the form of alternative organizational structures (see app. III), but a detailed analysis of their advantages and disadvantages and the potential challenges that could arise if they are implemented has yet to be conducted. In 2001, we first suggested that Congress consider commissioning the National Academy of Sciences or a blue ribbon panel to conduct a detailed analysis of alternative organizational structures for food safety and reiterated the suggestion over the years, most recently in the 2011 high-risk list update.

Some of the alternative organizational structures that we and others have identified include:

- **Single food safety agency.** All aspects of food safety at the federal level could be consolidated into a single food safety agency, either housed within an existing agency or established as an independent entity. This consolidation would bring oversight of all foods under a single administrator and consolidate tasks that are currently dispersed.

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21 The Produce Safety Project is an initiative of the Pew Charitable Trusts at Georgetown University. The President’s Council on Food Safety was created by the President in 1998 and disbanded in 2001.

22 GAO-02-47T.

throughout multiple federal agencies, such as inspections, risk assessment, standard setting, research, and surveillance.

- **Food safety inspection agency.** Food safety inspection activities, but not other activities such as surveillance, could be consolidated under USDA or FDA. As we reported in the past, any new inspection system should employ a unified risk-based approach, which would require Congress to modify the current legislative structure.\(^{24}\)

- **Data collection and risk analysis center.** Data collection and risk analysis could be consolidated into a single center that would disseminate the results of its analyses to the food safety agencies. For example, this center could consolidate food safety surveillance data collected from a variety of sources and analyze it at the national level to support risk-based decision making. While the center would be independent from the regulatory agencies to give its analyses scientific credibility, it would also consult with the agencies to understand their needs, but would not preempt any agency’s authority to develop its own food safety management approach.

- **Coordination mechanism.** Centralized, executive leadership could be provided for the existing organizational structure using a coordination mechanism with representatives from the agencies, similar to the FSWG. However, unlike the FSWG, the coordination mechanism would be led by a central chair who would be appointed by the President and have control over resources.

While a detailed analysis of the alternatives has not been conducted, organizations have offered some preliminary observations on some of their benefits. For example, in its strategic plan, the former President’s Council on Food Safety stated that consolidation could eliminate duplication and fragmentation, create a centralized leadership, clarify lines of authority, and facilitate priority setting and resource allocation based on risk. Similarly, in its 2010 report *Enhancing Food Safety: The Role of the Food and Drug Administration*, the National Academy of Sciences concluded that the core federal food safety responsibilities should reside within a single entity having a unified administrative structure, clear mandate, dedicated budget, and full responsibility for oversight of the entire food supply. In its report, the National Academy of Sciences also stated that centralizing data collection and risk analysis would eliminate

the need for each agency to develop its own comprehensive expertise in risk and decision analysis; promote communication, collaboration, and data sharing among federal agencies; and could be a first step toward accomplishing the more challenging goal of consolidating all federal food safety activities into a single agency.

We recognize that reorganizing federal food safety responsibilities would be a complex process. Further, our work on other agency mergers and transformations indicates that reorganizing food safety could have short-term disruptions and transition costs. We reported that a merger or transformation is a substantial commitment that could take years before it is completed, and therefore must be carefully and closely managed. In particular, the experience of major private sector mergers and acquisitions has been that productivity and effectiveness actually decline initially, in part because attention is concentrated on critical and immediate integration issues and diverted from longer-term mission issues. Our work on seven other countries' experiences between 1997 and 2004 in consolidating their food safety systems found that while the extent to which those countries consolidated their food systems varied considerably, they faced similar challenges in deciding whether to place the new agency within the existing health or agriculture agency or establish it as a stand-alone agency and in determining what responsibilities the new agency would have. We also reported that the countries experienced benefits, such as improved public confidence in their food safety systems. In addition, each country modified its existing legal framework to give legal authority and responsibility to the new food safety agency. Some European Union (EU) countries were further prompted to consolidate in order to comply with new EU food safety legislation that became effective, in large part, in January 2006. The EU adopted comprehensive food safety legislation in 2004 intended to create a single, transparent set of food safety rules applicable to both animal and nonanimal products.

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We and other organizations have regularly paired proposals for alternative food safety organizations with calls for comprehensive, unified, risk-based food safety legislation. Existing statutes give agencies different regulatory and enforcement authorities, and we have reported that legislation governing the agencies’ authorities, jurisdictions, and inspection frequencies is not the product of strategic design as to how to protect public health.\(^{28}\) In May 2004, we reported that a critical step in designing and implementing a risk-based food safety system is identifying the most important food safety problems across the entire food system from a public health perspective and concluded that comprehensive, uniform, and risk-based food safety legislation is needed to provide the foundation for this approach.\(^{29}\) The National Academy of Sciences also concluded that to create a science-based food safety system current laws must be revised, and recommended that Congress change federal statutes so that inspection, enforcement, and research efforts can be based on risks to public health. While the new food safety law strengthens a major part of the food safety system and expands FDA’s oversight authority, it does not apply to the federal food safety system as a whole or create a new risk-based food safety structure. In February 2011, we reiterated our suggestion for comprehensive, unified, risk-based food safety legislation.\(^{30}\)

**Conclusions**

We are encouraged by the executive branch’s attention to food safety through the FSWG and its initial efforts designed to improve interagency collaboration on this very important crosscutting issue. However, food safety remains fragmented and much work remains to be done on several of the FSWG initiatives. Further, the collaboration that has begun under the FSWG may be short lived, putting some of the longer-term efforts, such as developing results-oriented food safety goals and measures, at risk of not being completed. Because food safety oversight faces ongoing challenges, it is important that this issue be given sustained attention; as we have previously reported, the continuity of food safety coordination efforts can be hampered when executive branch leadership changes. Thus, it is critical that the primary food safety agencies engage in comprehensive, governmentwide planning to increase interagency


\(^{29}\)GAO-04-832R.

\(^{30}\)GAO-11-278.
collaboration under the current system. Such a plan, paired with comprehensive risk-based food safety legislation and a detailed analysis of alternative organizational structures for food safety oversight, could be an important tool for addressing fragmentation in federal food safety oversight. However, without an annually updated governmentwide performance plan for food safety that contains results-oriented goals and performance measures and a discussion of strategies and resources used by the agencies with food safety responsibilities, decision makers do not have a comprehensive picture of the federal government’s performance on this crosscutting issue. Further, without such information, decision makers may be hampered in their efforts to make key resource allocation and restructuring decisions.

### Recommendation for Executive Action

In order to improve collaboration among federal agencies on food safety oversight and provide an integrated perspective on this crosscutting issue we are making the following recommendation.

The Director of the Office of Management and Budget, in consultation with the federal agencies that have food safety responsibilities, should develop a governmentwide performance plan for food safety. The performance plan should include results-oriented goals and performance measures for food safety oversight throughout the federal government, as well as a discussion about strategies and resources. It should be updated on an annual basis.

### Agency Comments

We provided USDA, the Department of Health and Human Services, and OMB with drafts of this report for review. OMB declined to comment on the draft report. USDA and Health and Human Services provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Agriculture, Director of the Office of Management and Budget, Commissioner of the Food and Drug Administration, and other interested parties. The report also is available at no charge on the GAO website at [http://www.gao.gov](http://www.gao.gov).
If you or your staffs have any questions about this report, please contact me at (202) 512-3841 or shamesl@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix IV.

Lisa Shames
Director, Natural Resources and Environment
List of Committees

The Honorable Deborah Stabenow
Chair
The Honorable Patrick Roberts
Ranking Member
Committee on Agriculture, Nutrition and Forestry
United States Senate

The Honorable Thomas Harkin
Chairman
The Honorable Michael Enzi
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Joseph Lieberman
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The Honorable Susan Collins
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United States Senate

The Honorable Herb Kohl
Chairman
The Honorable Roy Blunt
Ranking Member
Subcommittee on Agriculture, Rural Development, Food and
Drug Administration and Related Agencies
Committee on Appropriations
United States Senate

The Honorable Frank Lucas
Chairman
The Honorable Collin Peterson
Ranking Member
Committee on Agriculture
House of Representatives
Appendix I: Scope and Methodology

A new statutory requirement mandates that GAO identify programs, agencies, offices, and initiatives with duplicative goals and activities within departments and governmentwide.¹ Under that mandate this review examines: (1) steps, if any, that the Food Safety Working Group (FSWG) has taken to increase collaboration among federal food safety agencies, and (2) options we and others have identified to reduce fragmentation, overlap, and potential duplication in food safety oversight.

To complete our work we reviewed food safety reports and legislation, and interviewed officials from the Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Office of Management and Budget (OMB). To address the first question we also collected and analyzed information about the FSWG, its activities, and its plan for food safety. We also collected documentation about the FSWG’s activities from the agencies, the Federal Register, and budget documents. We assessed the FSWG’s “key findings,” which FSWG officials told us represent the governmentwide plan for food safety, against GAO’s criteria for performance plans.² To identify options for reducing fragmentation, overlap, and potential duplication, we identified alternative organizational structures for food safety by reviewing reports by GAO, the National Academy of Sciences, the Produce Safety Project, and the former President’s Council on Food Safety. We also reviewed reports by GAO about federal agency and private sector mergers and organizational transformations. We did not independently verify the foreign laws discussed in this report.

We conducted this performance audit from July 2010 to March 2011 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.


### Appendix II: Federal Agencies with Food Safety Responsibilities

<table>
<thead>
<tr>
<th>Agency</th>
<th>Programs</th>
<th>Program Type</th>
<th>Responsibilities and main authorizing statutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 USDA Food Safety and Inspection Service</td>
<td>Meat, Poultry, Egg Products, and Catfish Inspection; Voluntary Fee for Service Inspections</td>
<td></td>
<td>- Responsible for: Ensuring that the nation’s domestic and imported commercial supply of meat, poultry, egg products, and catfish is safe, wholesome, and correctly labeled and packaged, and for enforcing the Humane Methods of Slaughter Act of 1978, as amended. Responsible for providing voluntary fee-for-service inspections for exotic and other edible animals.</td>
</tr>
<tr>
<td>2 USDA Animal and Plant Health Inspection Service</td>
<td>Plant Protection and Quarantine; Veterinary Services</td>
<td></td>
<td>- Responsible for: Preventing the introduction or dissemination of plant pests. Responsible for preventing the introduction or dissemination of livestock pests or diseases.</td>
</tr>
<tr>
<td>3 USDA Grain Inspection, Packers and Stockyards Administration</td>
<td>Federal Grain Inspection Service</td>
<td></td>
<td>- Responsible for: Establishing quality standards, inspection procedures, and marketing of grain and other related products.</td>
</tr>
</tbody>
</table>
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<tr>
<td>4 USDA</td>
<td>Agricultural Marketing Service</td>
<td><strong>Commodity Programs; Science and Technology Programs; School Lunch Commodity Purchases</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Responsible for</strong>: Establishing quality and condition standards for, among other things, dairy, fruit and vegetables, livestock.</td>
</tr>
<tr>
<td>5 USDA</td>
<td>Agricultural Research Service</td>
<td><strong>Nutrition, Food Safety, and Quality</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Responsible for</strong>: Providing the scientific research to help ensure that the food supply is safe and secure and that foods meet foreign and domestic regulatory requirements.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Main authorizing statutes</strong>: 7 U.S.C. ss. 1622, 2204, 3101, 3121, 3318, 3319a; also e.g., 7 U.S.C. ss. 136i-2, 391, 7654.</td>
</tr>
<tr>
<td>6 USDA</td>
<td>Economic Research Service</td>
<td><strong>Food Safety Research</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Responsible for</strong>: Providing analyses of the economic issues affecting the safety of the U.S. food supply.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Main authorizing statutes</strong>: 7 U.S.C. ss. 1622, 2204, 3101, 3121, 3318, 3319a; also e.g., 7 U.S.C. ss. 136i-2, 391, 7654.</td>
</tr>
<tr>
<td>7 USDA</td>
<td>National Agricultural Statistics Service</td>
<td><strong>Statistical Program on Food Safety</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Responsible for</strong>: Providing statistical data, including agricultural chemical usage data, related to the safety of the food supply.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Main authorizing statutes</strong>: 7 U.S.C. ss. 1622, 2204, 3101, 3121, 3318, 3319a; also e.g., 7 U.S.C. ss. 136i-2, 391, 7654.</td>
</tr>
<tr>
<td>8 USDA</td>
<td>National Institute of Food and Agriculture</td>
<td><strong>National Integrated Food Safety Research Initiative</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Responsible for</strong>: Supporting food safety projects in the land-grant university system and other partner organizations that demonstrate an integrated approach to solving problems in applied food safety research, education, or extension.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Main authorizing statutes</strong>: 7 U.S.C. ss. 361a-361i, 3121, 3151, 3155, 3318, 3319a, 6917(f); also e.g., 7 U.S.C. ss. 450i, 3902.</td>
</tr>
<tr>
<td>9 HHS</td>
<td>Food and Drug Administration</td>
<td><strong>Foods Program; Animal Drugs and Feeds Program; Regional Operations and Enforcement</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Responsible for</strong>: Ensuring that all domestic and imported foods, excluding meat and poultry products, are safe, wholesome, sanitary, and properly labeled.</td>
</tr>
</tbody>
</table>
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</thead>
</table>
| 10     | HHS      | • Responsible for: Preventing the transmission, dissemination, and spread of foodborne illness to protect the public health.  
| 11     | Commerce | • Responsible for: Providing voluntary, fee-for-service examinations of seafood for safety and quality  
| 12     | EPA      | • Responsible for: Regulating the use of certain chemicals and substances that present an unreasonable risk of injury to health or the environment. Responsible for issuing regulations to establish, modify, or revoke tolerances for pesticide chemical residues. Responsible for setting national drinking water standard of quality and consulting with FDA before FDA promulgates regulations for standard of quality for bottled water.  

Figure continued
Appendix II: Federal Agencies with Food Safety Responsibilities

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<tr>
<th>Agency</th>
<th>Programs</th>
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</tr>
</thead>
</table>
| 13 Treasury                   | Alcohol                                     | • Responsible for: Regulating, enforcing, and issuing permits for the production, labeling, and distribution of alcoholic beverages.  
|                               | Alcohol, Tobacco, Firearms, and Explosives   |                                                                                                              |
| 14 Department of Homeland Security | Customs and Border Protection               | • Responsible for: Inspecting imports, including food products, plants, and live animals, for compliance with U.S. law and assisting all federal agencies in enforcing their regulations at the border.  
| 15 Federal Trade Commission  |                                             | • Responsible for: Enforcing prohibitions against false advertising for, among other things, food products.  

Source: GAO analysis.

*The 2008 Farm Bill amended the Federal Meat Inspection Act to give USDA responsibility for the inspection of catfish. The amendments specified that they would not apply until USDA issues final regulations implementing them, a process that was not yet complete as of February 2011.*
Appendix III: Reports Identifying Options for Alternative Organizational Structures for Food Safety Oversight


Appendix IV: GAO Contact and Staff

Acknowledgments

Lisa Shames, (202) 512-3841 or shamesl@gao.gov

In addition to the contact named above, José Alfredo Gómez (Assistant Director), Annamarie Lopata (Analyst-in-Charge), Kevin Bray, Diana Goody, Tesfaye Negash, Alison O’Neill, and Katherine Raheb made key contributions to this report.
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