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December 2014

# FEDERAL FOOD SAFETY OVERSIGHT

## Additional Actions Needed to Improve Planning and Collaboration

# GAO Highlights

Highlights of [GAO-15-180](#), a report to congressional addressees

## Why GAO Did This Study

For more than a decade, GAO has reported on the fragmented federal food safety system. In 2007, GAO added federal oversight of food safety to its list of high-risk areas because of risks to the economy and to public health and safety.

GAO conducted this work under the authority of the Comptroller General to assist Congress with its food safety oversight responsibilities. This report examines (1) HHS and USDA implementation of GPRAMA requirements for addressing crosscutting efforts in their food safety strategic and performance planning and (2) the extent to which FDA and FSIS have a centralized mechanism in place to collaborate across federal food safety programs. GAO reviewed relevant legislation and agency documentation; analyzed responses from food safety experts; and interviewed OMB staff and officials from FDA and FSIS.

## What GAO Recommends

GAO recommends that HHS and USDA build upon their efforts to implement GPRAMA requirements to fully address crosscutting food safety efforts. Congress should consider (1) directing OMB to develop a government-wide food safety performance plan and (2) formalizing the FSWG through statute to help ensure sustained leadership across food safety agencies over time. GAO provided a draft of this report for review and comment to HHS, OMB, and USDA. HHS and USDA agreed with the recommendation. HHS, OMB, and USDA provided technical comments, which GAO incorporated as appropriate.

View [GAO-15-180](#). For more information, contact Steve D. Morris at (202) 512-3841 or [morris@gao.gov](mailto:morris@gao.gov).

December 2014

## FEDERAL FOOD SAFETY OVERSIGHT

### Additional Actions Needed to Improve Planning and Collaboration

## What GAO Found

The Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA) have taken steps to implement GPRAMA Modernization Act of 2010 (GPRAMA) requirements but could more fully address crosscutting food safety efforts. For example, GPRAMA requires agencies to describe in their strategic and performance planning how they are working with other agencies to achieve their goals. HHS and USDA vary in the amount of detail they provide on their crosscutting food safety efforts. In addition, they do not include several relevant crosscutting efforts, such as the National Antimicrobial Resistance Monitoring System, which tracks whether foodborne bacteria are resistant to the antibiotics used to treat and prevent illness.

Fully addressing crosscutting efforts in individual strategic and performance planning documents is an important first step toward providing a comprehensive picture of federal food safety performance. However, individual agencies' documents do not provide an integrated perspective on federal food safety performance. In 2011, GAO recommended that the Office of Management and Budget (OMB), in consultation with the federal agencies having food safety responsibilities, develop a government-wide performance plan for food safety. OMB has not acted on that recommendation. Without such a plan, Congress, program managers, and other decision makers are hampered in their ability to identify agencies and programs addressing similar missions and to set priorities, allocate resources, and restructure federal efforts, as needed, to achieve long-term goals. In addition, without such a plan, federal food safety efforts are not clear and transparent to the public. GAO continues to believe that a government-wide performance plan for food safety is necessary.

HHS's Food and Drug Administration (FDA) and USDA's Food Safety and Inspection Service (FSIS) have mechanisms in place to facilitate interagency coordination on food safety that focus on specific issues, but none provides for broad-based, centralized collaboration. For example, FDA and FSIS are collaborating with the Centers for Disease Control and Prevention through the Interagency Food Safety Analytics Collaboration to improve estimates of foodborne illness sources. However, this and other mechanisms do not allow FDA, FSIS, and other agencies to look across their individual programs and determine how they all contribute to federal food safety goals. Nearly all the experts GAO interviewed agreed that a centralized collaborative mechanism on food safety is important to foster effective interagency collaboration and could enhance food safety oversight. The Food Safety Working Group (FSWG) served as a centralized mechanism for broad-based food safety collaboration and resulted in a number of accomplishments, including improved coordination. However, the FSWG is no longer meeting. A prior centralized mechanism for broad-based collaboration on food safety also was not sustained. Without a centralized collaborative mechanism on food safety, there is no forum for agencies to reach agreement on a set of broad-based food safety goals and objectives. Experts suggested that a centralized collaborative mechanism on food safety—like the FSWG—could provide sustained leadership across agencies over time if it were formalized in statute. Without such formalization, centralized collaborative mechanisms on food safety may continue to be short-lived.

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## Abbreviations

CDC	Centers for Disease Control and Prevention
FDA	Food and Drug Administration
FoodNet	Foodborne Diseases Active Surveillance Network
FSIS	Food Safety and Inspection Service
FSMA	FDA Food Safety Modernization Act
FSWG	Food Safety Working Group
GPRA	Government Performance and Results Act of 1993
GPRAMA	GPRA Modernization Act of 2010
HHS	Department of Health and Human Services
IFORC	Interagency Foodborne Outbreak Response Collaboration
IFSAC	Interagency Food Safety Analytics Collaboration
IRAC	Interagency Risk Assessment Consortium
MOU	memorandum of understanding
NHSS	National Health Security Strategy
OMB	Office of Management and Budget
PFP	Partnership for Food Protection
PPD-8	Presidential Policy Directive 8
USDA	U.S. Department of Agriculture

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December 18, 2014

### Congressional Addressees

According to the Centers for Disease Control and Prevention (CDC), the U.S. food supply remains one of the safest in the world. Nevertheless, foodborne illness is still a common, costly, yet largely preventable, public health problem. CDC data indicate that each year, as a result of foodborne disease, roughly 1 in 6 Americans (or 48 million people) get sick, 128,000 are hospitalized, and 3,000 die. Two independent studies published in 2012 estimated the cost of foodborne illness in the United States. According to a September 2013 bulletin from the U.S. Department of Agriculture's (USDA) Economic Research Service, the study that used the more conservative approach estimated the cost to be \$14.1 billion per year. 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 foodborne illnesses, such as older adults and immune-compromised individuals, are growing.

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 federal agencies. The agencies with primary food safety oversight responsibility are USDA's Food Safety and Inspection Service (FSIS) and the Department of Health and Human Services' (HHS) Food and Drug Administration (FDA). FSIS is responsible for the safety of meat, poultry, and processed egg products.<sup>1</sup> FDA is responsible for virtually all other food.

The federal food safety system is supplemented by the states, which may have their own statutes, regulations, and agencies to address the safety and quality of food products. As is the case with many other federal

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<sup>1</sup>In addition, the 2008 Farm Bill included amendments to the Federal Meat Inspection Act to add catfish inspection and examination to USDA's responsibilities. The amendments take effect once the Secretary of Agriculture issues final regulations to carry them out. The Secretary of Agriculture previously delegated responsibility for implementing the Federal Meat Inspection Act, including issuing regulations, to FSIS. In February 2011, FSIS published a proposed rule requiring continuous inspection of catfish and catfish products. No final rule has been issued.

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## Examples of Fragmentation in Federal Food Safety Oversight

### Catfish Inspection

FDA has traditionally overseen the safety of all seafood, including catfish, but as a result of 2008 Farm Bill provisions amending the Federal Meat Inspection Act, regulatory responsibility for catfish inspection will fall to FSIS once it issues final regulations for a mandatory catfish examination and inspection program. We suggested that Congress consider repealing these provisions of the 2008 Farm Bill. However, the 2014 Farm Bill instead modified these provisions to require the Secretary of Agriculture to enter into a memorandum of understanding (MOU) with the Commissioner of FDA that would ensure that inspection of catfish conducted by FSIS and FDA are not duplicative. We maintain that such an MOU does not address the fundamental problem, which is that FSIS's catfish program, if implemented, would result in duplication of activities and an inefficient use of taxpayer funds. Duplication would result if facilities that process both catfish and other seafood were inspected by both FSIS and FDA.

### Egg Production Oversight

The 2010 nationwide recall of more than 500 million eggs because of *Salmonella* contamination also highlights fragmentation in federal food safety oversight. Several agencies have different roles and responsibilities in 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 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.

Source: GAO. | GAO-15-180

programs and policies, the existing food safety system evolved on a piecemeal basis, typically in response to particular health threats or economic crises.

For more than a decade, we have reported on the fragmented nature of federal food safety oversight. In January 2007, we added the federal oversight of food safety to our list of high-risk areas because of risks to the economy and to public health and safety.<sup>2</sup> We found that a challenge for the twenty-first century was to find a way for federal agencies with food safety responsibilities to integrate the myriad food safety programs and strategically manage their portfolios to promote the safety and integrity of the nation's food supply. We stated 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, in January 2007, we recommended that a mechanism be put in place to facilitate interagency coordination on food safety regulations and programs. In March 2009, the President established the Food Safety Working Group (FSWG) to coordinate federal efforts and develop goals to make food safer.<sup>3</sup>

In January 2007, we also suggested that Congress and the executive branch work together to develop a government-wide performance plan for food safety. In our March 2011 report on federal food safety oversight, we recommended that the Office of Management and Budget (OMB), in consultation with the federal agencies having food safety responsibilities, develop a government-wide performance plan for food safety.<sup>4</sup> We stated that a performance plan offers a framework to help ensure agencies'

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<sup>2</sup>GAO, *High Risk Series: An Update*, [GAO-07-310](#) (Washington, D.C.: January 2007). GAO's high-risk list is updated every 2 years at the start of a new Congress. It calls attention to agencies and program areas that are high risk due to their vulnerabilities to fraud, waste, abuse, and mismanagement, or are most in need of transformation to address economy, efficiency, or effectiveness challenges.

<sup>3</sup>The FSWG was convened by the White House Domestic Policy Council, and its members included HHS's FDA and CDC, USDA's FSIS, the Environmental Protection Agency, the Office of the U.S. Trade Representative, and the Departments of Commerce, Homeland Security, and State.

<sup>4</sup>GAO, *Federal Food Safety Oversight: Food Safety Working Group Is a Positive First Step but Governmentwide Planning Is Needed to Address Fragmentation*, [GAO-11-289](#) (Washington, D.C.: Mar. 18, 2011).

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goals are complementary and mutually reinforcing and to help provide a comprehensive picture of the federal government's performance on food safety. Such a plan could assist decision makers in balancing trade-offs and comparing performance when resource allocation and restructuring decisions are made. However, according to our review of actions taken since the 2007 and 2011 reports, no government-wide performance plan for food safety has been developed.<sup>5</sup>

Nonetheless, actions have been taken to improve the federal food safety system. In January 2011, the FDA Food Safety Modernization Act (FSMA)<sup>6</sup> was enacted, representing the largest expansion and overhaul of U.S. food safety authorities since the 1930s.<sup>7</sup> Also in January 2011, the statutory framework for performance management in the federal government, the Government Performance and Results Act of 1993 (GPRA), was updated by the GPRA Modernization Act of 2010 (GPRAMA).<sup>8</sup> GPRAMA adds new requirements for addressing crosscutting efforts in federal strategic and performance planning that help drive collaboration and address fragmentation. GPRAMA defines crosscutting as “across organizational (such as agency) boundaries.” For example, GPRAMA requires agencies' strategic plans and performance plans to contain a description of how they are working with other agencies to achieve their goals. GPRAMA requirements apply at the departmental or agency level, not to organizational components.<sup>9</sup>

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<sup>5</sup>In 2011, we reported that officials from OMB, FDA, and USDA told us that a July 2009 report of “key findings” developed by the FSWG was the government-wide performance plan that we had recommended. However, we found that the key findings report was not a government-wide performance plan because it was missing several elements of performance plans such as information about resources needed to achieve the goals. In addition, there were no plans to update the key findings report. See [GAO-11-289](#).

<sup>6</sup>Pub. L. No. 111-353, 124 Stat. 3885 (2011).

<sup>7</sup>FSMA strengthens a major part of the food safety system. Among other things, according to FDA, it shifts the focus of FDA regulators from responding to contamination to preventing it.

<sup>8</sup>Pub. L. No. 111-352, 124 Stat. 3866 (2011). GPRAMA amends provisions of GPRA, Pub. L. No. 103-62, 107 Stat. 285.

<sup>9</sup>We have previously reported, however, that GPRAMA requirements can serve as leading practices at lower levels within federal agencies, such as FDA and FSIS. Therefore, in their strategic plans, if FDA and FSIS were to address GPRAMA requirements—including those for crosscutting efforts—they would be implementing leading practices.

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We conducted this work under the authority of the Comptroller General to assist Congress with its oversight responsibilities for the federal food safety system. This report examines (1) HHS and USDA implementation of GPRAMA requirements for addressing crosscutting efforts in their food safety strategic and performance planning and (2) the extent to which the two agencies primarily responsible for federal food safety oversight—HHS’s FDA and USDA’s FSIS—have a centralized mechanism in place to collaborate broadly across federal food safety regulations and programs.

To answer our first objective, we reviewed GPRAMA, relevant OMB guidance on the implementation of GPRAMA, and our prior work on effective implementation of GPRAMA. We also reviewed current HHS and USDA strategic and performance plans and information about HHS and USDA agency priority goals published on a central, government-wide performance website required by GPRAMA and implemented by OMB as Performance.gov. To further address our first objective, we reviewed agency documentation related to HHS and USDA food safety goals and objectives, including FDA and FSIS strategic plans that support HHS and USDA goals and objectives, respectively. We also interviewed OMB staff and officials from HHS and USDA regarding federal food safety strategic and performance planning and crosscutting efforts.

To address our second objective, we identified existing collaborative mechanisms involving FDA and FSIS through reviews of past GAO work and agency documentation. We also interviewed experts in food safety knowledgeable about interagency collaboration, OMB staff, and officials from FDA and FSIS about the status and nature of existing collaborative mechanisms. We analyzed the scope of the existing collaborative mechanisms identified throughout the course of our review to determine whether they were broad-based or focused on specific topics. Additionally for this objective, we conducted a two-stage interview process with experts in food safety, knowledgeable about interagency collaboration, to obtain their views on existing collaborative mechanisms. We also asked them about the potential benefits, challenges, and characteristics of a new centralized collaborative mechanism for food safety. We identified these experts through a snowball sampling approach, starting with recommendations from internal GAO experts in food safety, contacting those external experts and asking them to identify other relevant experts. We interviewed 10 experts in the first round of interviews and 12 experts



in the second round.<sup>10</sup> The experts included representatives from federal agencies, trade associations, industry, and public interest groups, as well as former federal officials who had been members of the FSWG. Based on our analysis of responses provided during the first round of expert interviews, we developed questions that we used for all of the interviews during the second round. We then conducted content analyses to assess experts' responses during the second round of interviews. Appendix I presents a more detailed description of our objectives, scope, and methodology, and appendix II lists the names and affiliations of the experts we interviewed.

We conducted this performance audit from March 2014 to December 2014 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.

## Background

Of the 15 federal agencies involved in food safety oversight, FDA and FSIS have primary oversight responsibility. Table 1 summarizes the food safety responsibilities of all 15 agencies.

**Table 1: Federal Agencies' Food Safety Responsibilities**

Department and/or agency	Responsible for
U.S. Department of Agriculture	Food Safety and Inspection Service Ensuring the nation's domestic and imported commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged, and for enforcing the Humane Methods of Slaughter Act of 1978, as amended; providing voluntary fee-for-service inspections for exotic animals; catfish inspection, once the Food Safety and Inspection Service issues final regulations for a mandatory catfish examination and inspection program.
Animal and Plant Health Inspection Service	Preventing the introduction or dissemination of (1) plant pests and (2) livestock pests or diseases.
Grain Inspection, Packers and Stockyards Administration	Establishing quality standards, inspection procedures, and marketing of grain and other related products.

<sup>10</sup>Six of the experts that we interviewed in the first round of interviews we also interviewed in the second round.

Department and/or agency		Responsible for
	Agricultural Marketing Service	Establishing quality and condition standards for, among other things, dairy, fruit, vegetables, and livestock.
	Agricultural Research Service	Providing the scientific research to help ensure that the food supply is safe and secure and that foods meet foreign and domestic regulatory requirements.
	Economic Research Service	Providing analyses of the economic issues affecting the safety of the U.S. food supply.
	National Agricultural Statistics Service	Providing statistical data, including agricultural chemical usage data, related to the safety of the food supply.
	National Institute of Food and Agriculture	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.
Department of Health and Human Services	Food and Drug Administration	Ensuring that all domestic and imported foods, excluding meat, poultry, and processed egg products, are safe, wholesome, sanitary, and properly labeled.
	Centers for Disease Control and Prevention	Preventing the transmission, dissemination, and spread of foodborne illness to protect the public health.
Department of Commerce	National Marine Fisheries Service	Providing voluntary, fee-for-service examinations of seafood for safety and quality.
Environmental Protection Agency		Regulating the use of certain chemicals and substances that present an unreasonable risk of injury to health or the environment; issuing regulations to establish, modify, or revoke tolerances for pesticide chemical residues; setting national drinking water standard of quality and consulting with the Food and Drug Administration (FDA) before FDA promulgates regulations for standard of quality for bottled water.
Department of the Treasury	Alcohol and Tobacco Tax and Trade Bureau	Regulating, enforcing, and issuing permits for the production, labeling, and distribution of alcoholic beverages.
Department of Homeland Security	Customs and Border Protection	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.
Federal Trade Commission		Enforcing prohibitions against false advertising for, among other things, food products.

Source: GAO. | GAO-15-180

U.S. food safety oversight is not the only federal effort that involves multiple agencies. Many federal government initiatives require the coordinated efforts of more than one federal agency, level of government, or sector. Nevertheless, agencies face a range of challenges and barriers when they attempt to work collaboratively. The need for improved interagency collaboration has been highlighted throughout our work over many years. Our reports over the past 4 years identified more than 90 areas where opportunities exist for executive branch agencies or

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Congress to reduce fragmentation, overlap, and duplication.<sup>11</sup> We found that resolving many of these issues require better collaboration among agencies. In addition, collaboration and improved working relationships across agencies are fundamental to addressing many of the issues that we have designated as high risk due to their vulnerability to fraud, waste, abuse, and mismanagement, or because they are most in need of transformation.<sup>12</sup>

Furthermore, for almost 2 decades, we have reported on agencies' missed opportunities for improved collaboration through effective implementation of GPRA. In our June 1997 assessment of the status of GPRA implementation government-wide, we found that agencies faced challenges addressing crosscutting issues, which led to fragmentation and overlap.<sup>13</sup> In 2004—more than 10 years after GPRA's enactment—we found that there still was an inadequate focus on addressing issues that cut across federal agencies.<sup>14</sup> Now, more than 20 years since GPRA's enactment, our work continues to demonstrate that the needed collaboration is not sufficiently widespread.

Both Congress and the executive branch have recognized the need for improved collaboration across the federal government. In January 2011, GPRAMA amended provisions of GPRA to add new requirements for addressing crosscutting efforts in federal strategic and performance planning that help drive collaboration, among other things.

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<sup>11</sup>GAO, *2014 Annual Report: Additional Opportunities to Reduce Fragmentation, Overlap, and Duplication and Achieve Other Financial Benefits*, [GAO-14-343SP](#) (Washington, D.C.: Apr. 8, 2014); *2013 Annual Report: Actions Needed to Reduce Fragmentation, Overlap, and Duplication and Achieve Other Financial Benefits*, [GAO-13-279SP](#) (Washington, D.C.: Apr. 9, 2013); *2012 Annual Report: Opportunities to Reduce Duplication, Overlap and Fragmentation, Achieve Savings, and Enhance Revenue*, [GAO-12-342SP](#) (Washington, D.C.: Feb. 28, 2012); and *Government Operations: Opportunities to Reduce Potential Duplication in Government Programs, Save Tax Dollars, and Enhance Revenue*, [GAO-11-318SP](#) (Washington, D.C.: Mar. 1, 2011).

<sup>12</sup>GAO, *High-Risk Series: An Update*, [GAO-13-283](#) (Washington, D.C.: February 2013).

<sup>13</sup>GAO, *The Government Performance and Results Act: 1997 Governmentwide Implementation Will Be Uneven*, [GAO/GGD-97-109](#) (Washington, D.C.: June 2, 1997).

<sup>14</sup>GAO, *Results-Oriented Government: GPRA Has Established a Solid Foundation for Achieving Greater Results*, [GAO-04-38](#) (Washington, D.C.: Mar. 10, 2004).

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## HHS and USDA Have Taken Steps to Implement GPRAMA Requirements but Could More Fully Address Crosscutting Food Safety Efforts

Our review of HHS and USDA strategic and performance planning showed that both agencies have taken steps to implement GPRAMA's crosscutting requirements for their food safety efforts. However, the agencies do not fully address crosscutting food safety efforts in their strategic and performance planning. HHS and USDA vary in the amount of detail they provide on their crosscutting food safety efforts in their individual strategic and performance planning documents. Fully addressing crosscutting efforts in strategic and performance planning documents is important in helping to provide a comprehensive picture of the federal government's performance on food safety.

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## GPRAMA Established New Requirements for Addressing Crosscutting Efforts in Federal Strategic and Performance Planning

GPRAMA established a new framework for a more coordinated, crosscutting, and integrated approach to focus on results and improve government performance. The new GPRAMA framework could also help to ensure that agencies' goals are complementary, that strategies are mutually reinforcing, and that common performance measures are used, as appropriate. It added new requirements for addressing crosscutting efforts in federal strategic and performance planning, including the following:

- **Agency strategic goals and objectives.** GPRAMA requires agencies to include in their strategic plan a description of how they are working with other agencies to achieve their goals and objectives.
- **Agency performance goals.** GPRAMA requires agencies to include in their performance plan a description of (1) the organizations, program activities, regulations, policies, and other activities that contribute to each performance goal, both within and external to the agency and (2) a description of how the agency is working with other agencies to achieve its performance goals.
- **Agency priority goals.** Certain agencies—including HHS and USDA—are required to develop a limited number of agency priority goals every 2 years. These goals are to reflect the highest priorities of each agency and be informed by input from both federal and nonfederal stakeholders. According to OMB guidance, in developing their priority goals, agencies are to consider several criteria, including areas where cross-component or cross-agency coordination is needed to improve outcomes. Agencies are also required to conduct quarterly performance reviews. In these reviews, agencies are required to coordinate with relevant personnel within and outside the agency who contribute to the goal's accomplishment and assess

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whether organizations, program activities, regulations, policies, and other activities are contributing as planned. In addition, agencies are required to make information about each priority goal available on OMB's Performance.gov website on a quarterly basis, including a description of (1) the organizations, program activities, regulations, policies, and other activities that contribute to each goal, both within and external to the agency; (2) how the agency is working with other agencies to achieve the goal; and (3) whether relevant organizations, program activities, regulations, policies, and other activities are contributing as planned.

Our reporting on GPRAMA's implementation has found that the executive branch needs to more fully use the GPRAMA framework to address pressing federal governance challenges, including crosscutting issues.<sup>15</sup> We have found that effective GPRAMA implementation could play an important role in clarifying desired outcomes, in addressing program performance that spans multiple organizations, and in facilitating future actions to reduce, address, or better manage unnecessary duplication, overlap, and fragmentation.<sup>16</sup>

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## HHS and USDA Include Varying Levels of Detail About Crosscutting Food Safety Efforts in Their Strategic and Performance Planning

HHS and USDA strategic and performance planning documents include a number of goals and objectives related to food safety.<sup>17</sup> (See figs. 1 and 2.)

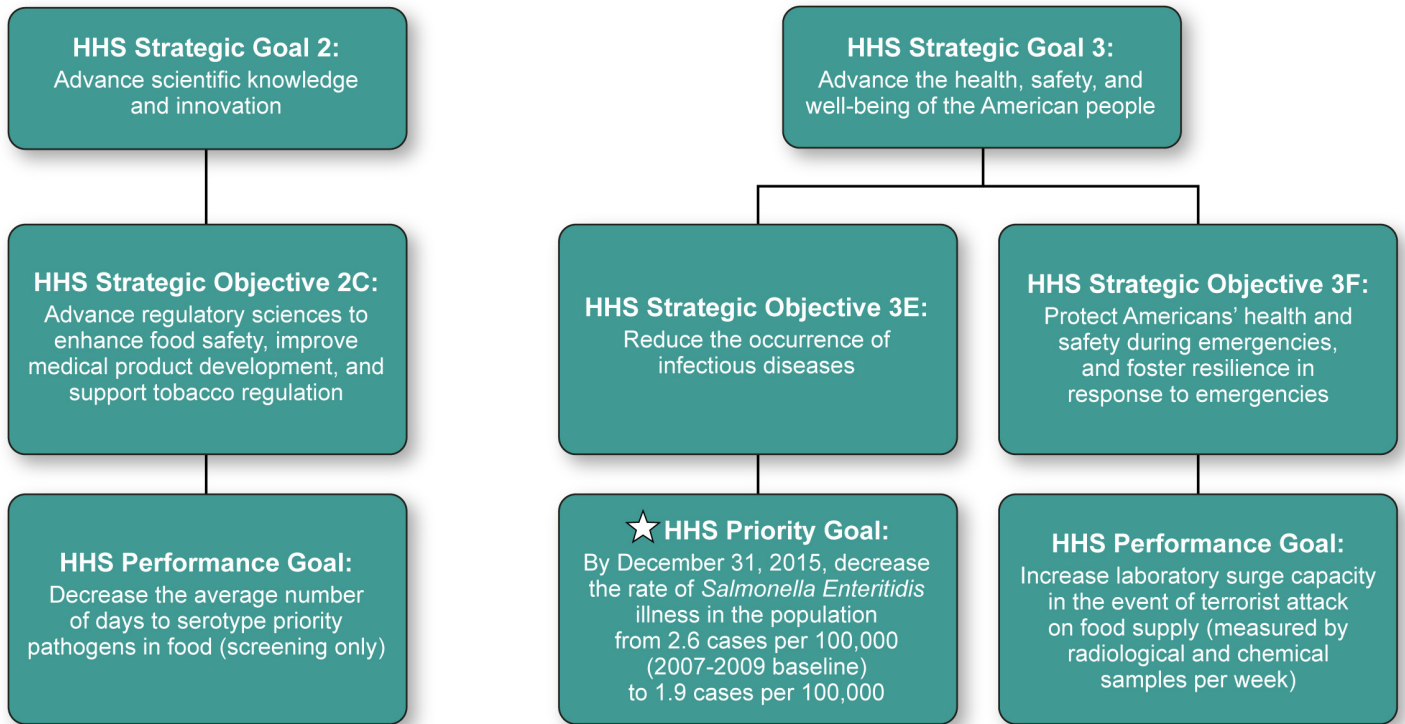
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<sup>15</sup>GAO, *Managing for Results: Executive Branch Should More Fully Implement the GPRAMA Modernization Act to Address Pressing Governance Challenges*, [GAO-13-518](#) (Washington, D.C.: June 26, 2013).

<sup>16</sup>For additional information about GPRAMA requirements and our related work, see our webpage on leading practices for results-oriented management at [www.gao.gov/key\\_issues/managing\\_for\\_results\\_in\\_government](http://www.gao.gov/key_issues/managing_for_results_in_government).

<sup>17</sup>These goals and objectives are supported by strategic and performance planning conducted by FDA and FSIS. However, GPRAMA does not apply to organizational components of agencies. Instead, agencies are expected to work with their components to implement GPRAMA requirements in a manner that is most useful to the whole organization.

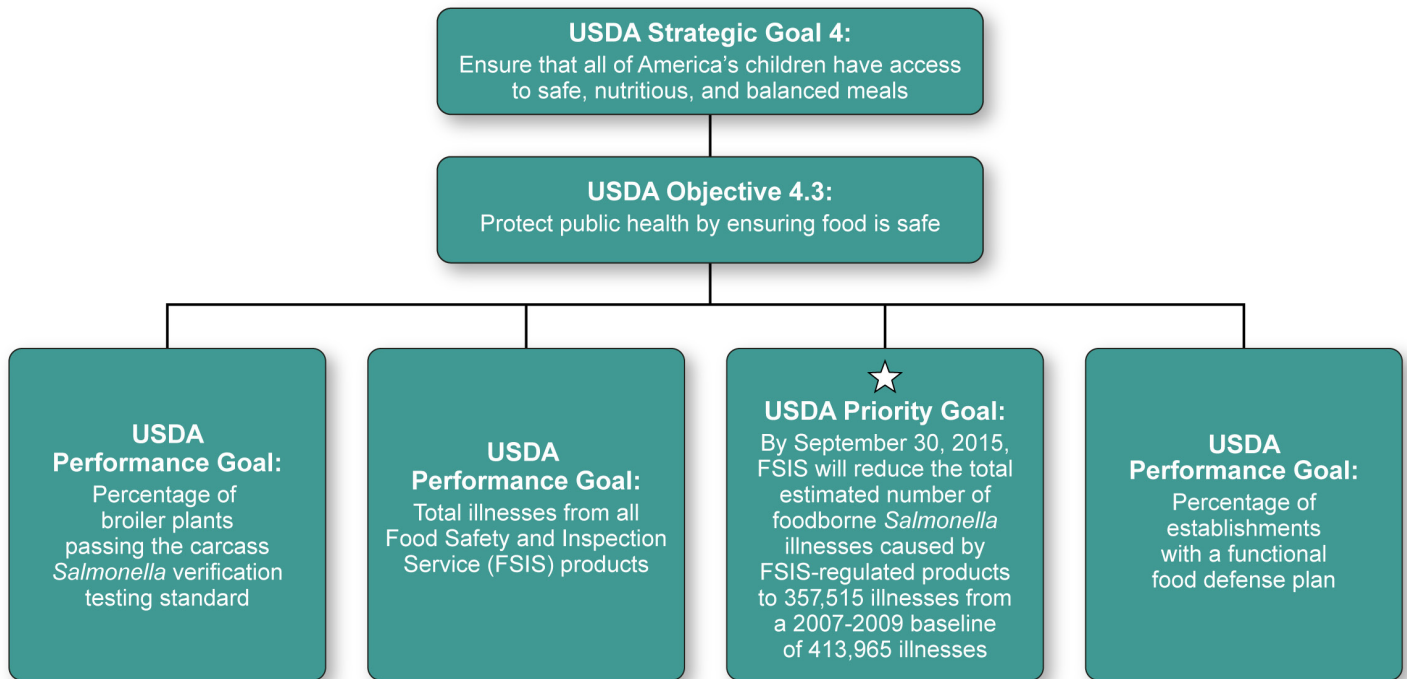
**Figure 1: Department of Health and Human Services (HHS) Food Safety Goals and Objectives**



★ Agency priority goal

Sources: GAO analysis of HHS Strategic Plan for fiscal years 2014 through 2018, HHS Performance Plan for fiscal year 2015, and HHS information published on Performance.gov in September 2014. | GAO-15-180

**Figure 2: U.S. Department of Agriculture (USDA) Food Safety Goals and Objectives**



★ Agency priority goal

Sources: GAO analysis of USDA Strategic Plan for fiscal years 2014 through 2018, USDA Performance Plan for fiscal year 2015, and USDA information published on Performance.gov in September 2014. | GAO-15-180

Our review of HHS and USDA strategic and performance planning documents found that both agencies include statements recognizing the need for joint efforts to enhance food safety, but that the level of detail regarding crosscutting efforts to meet the GPRAMA requirements varies considerably.

**Strategic Goals and Objectives**

**GPRAMA Requirement**

Agencies shall describe in their strategic plan how they are working with other agencies to achieve their goals and objectives.

Source: Pub. L. No. 111-352 § 2 (2011)(codified at 5 U.S.C. §306(a)(4)(B)).

In USDA’s current strategic plan, USDA lists one strategic goal and one strategic objective related to food safety. (See fig. 2.) USDA includes some details on the external agencies it is collaborating with to achieve this goal and objective and the nature of the collaboration. Specifically, USDA states that it “collaborates with its public health partners, especially

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the [CDC] and the [FDA] through interagency workgroups, such as the Interagency Food Safety Analytics Collaboration (IFSAC), the Interagency Foodborne Outbreak Response Collaboration (IFORC), and the Interagency Risk Assessment Consortium (IRAC) to improve the understanding of foodborne illness and which foods are responsible for making people ill.”<sup>18</sup> USDA also discusses its participation in and leadership of U.S. government agencies involved in Codex Alimentarius Commission activities.<sup>19</sup>

In its current strategic plan, HHS lists two strategic goals and three strategic objectives related to food safety. (See fig. 1.) For the strategic objective related to emergency response (3F), HHS provides some details of interagency collaboration. For the other goals and objectives, however, HHS discusses collaboration with partners but does not provide the details of which external agencies it is collaborating with or the nature of the collaboration. (See table 2.)

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<sup>18</sup>IFSAC is a collaboration involving FDA, FSIS, and CDC. IFSAC was chartered in 2011 and focuses on projects related to foodborne illness source attribution, the process of estimating the most common food sources responsible for specific foodborne illnesses. IFORC is also a collaboration involving FDA, FSIS, and CDC. It was chartered in 2013 to coordinate foodborne illness outbreak investigations. IRAC consists of representatives from U.S. government agencies, institutes, and centers with food safety responsibilities. According to its website, IRAC works to promote the conduct of scientific research that will facilitate risk assessments to assist the regulatory agencies in fulfilling their specific food-safety risk management mandates.

<sup>19</sup>The Codex Alimentarius Commission was established by the Food and Agriculture Organization of the United Nations and the World Health Organization in 1963. According to its website, the commission develops harmonized international food standards, guidelines, and codes of practice to protect the health of the consumers and ensure fair practices in the food trade, among other things.



**Table 2: HHS Strategic Plan Discussion of Crosscutting Efforts to Achieve Food Safety-Related Goals and Objectives**

Strategic goal or objective		Discussion of crosscutting food safety efforts
Strategic goals	2: Advance scientific knowledge and innovation	The Department of Health and Human Services (HHS) states that it “works with many partners” and discusses “collaboration with the private sector” and its use of “external evaluation data,” but does not provide the details of any external agencies it is collaborating with or the nature of the collaboration.
	3: Advance the health, safety, and well-being of the American people	HHS discusses “international cooperation,” improved program coordination “across government agencies,” and its work “with other federal departments and agencies,” but does not provide the details of any external agencies it is collaborating with or the nature of the collaboration.
Strategic objectives	2C: Advance the regulatory sciences to enhance food safety, improve medical product development, and support tobacco regulation	HHS discusses “collaboration with public and private partners,” but does not provide the details of any external agencies it is collaborating with or the nature of the collaboration.
	3E: Reduce the occurrence of infectious diseases	HHS discusses its collaboration “with federal and international partners to reduce the burden of infectious diseases throughout the world” and its work “with domestic and international partners to prevent and control foodborne illness outbreaks.” However, HHS does not provide the details of any external agencies it is collaborating with or the nature of the collaboration.
	3F: Protect Americans’ health and safety during emergencies, and foster resilience in response to emergencies	HHS discusses “working with its federal, state, local, tribal, and international partners” to support capacity-building efforts and strengthen linkages to promote health security at home and abroad. HHS specifically discusses its development of “the first National Health Security Strategy (NHSS), a comprehensive framework for how the nation must coordinate efforts to protect people’s health in the case of an emergency” and HHS states that it is “working with its federal, state, local, tribal, and international partners” to achieve two primary goals of the NHSS. HHS states that the HHS Assistant Secretary for Preparedness and Response “coordinates interagency activities between HHS, other federal partners, and state, local, and tribal officials responsible for emergency preparedness and the protection of the civilian population in emergencies.” HHS specifies that this includes collaboration “with the U.S. Department of Homeland Security, the Federal Emergency Management Agency, and others federal departments and agencies” in “addressing the requirements of Presidential Policy Directive 8 (PPD-8): National Preparedness,” the goal of which is to strengthen U.S. security and resilience through systematic preparation for threats among all levels of government and others.

Source: GAO analysis of HHS Strategic Plan for fiscal years 2014 through 2018. | GAO-15-180

Separate from the discussion of goals and objectives in its current strategic plan, HHS lays out 17 strategic initiatives, one of which is to implement a twenty-first century food safety system. In the discussion of that initiative, HHS mentions work with federal and other partners. For example, HHS states that it “is collaborating with its federal, state, local,

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and tribal partners to strengthen public health surveillance and regulatory systems to enhance the ability to detect outbreaks faster, use food tracing systems to identify the source and distribution of products, quickly remove products from the market, and conduct root cause analysis to correct problems and inform future prevention efforts.” However, HHS does not identify the partners to which it is referring in its strategic plan, but it specifies three collaborative mechanisms through which they work: the FSWG, the Partnership for Food Protection (PFP),<sup>20</sup> and FoodSafety.gov.<sup>21</sup>

## Performance Goals

### **GPRAMA Requirements**

Agencies shall identify in their performance plans federal organizations, program activities, regulations, policies, and other activities—both internal and external to the agency—that contribute to their performance goals. Agencies shall also describe in their performance plans how they are working with other agencies to achieve their performance goals.

Source: Pub. L. No. 111-352 § 3 (2011)(codified at 31 U.S.C. §1115(b)(5)(C), (D)).

USDA has four performance goals related to food safety, three of which USDA lists in its current performance plan and one of which—its priority goal on *Salmonella* reduction—USDA discusses separately on Performance.gov. (See fig. 2.) In its current performance plan, USDA identifies FSIS as an internal contributor to its food safety performance goals and includes some details on the external agencies it is collaborating with and the nature of that collaboration. Specifically, USDA states that “FSIS coordinates the development of its policies with other USDA agencies and other Federal agencies, including the Food and Drug Administration, the Environmental Protection Agency, the Centers for Disease Control and Prevention, as well as foreign governments and international organizations, to ensure an integrated farm-to-table approach to food safety.” USDA also notes that it recalculated its performance goal on total illnesses from all FSIS products “to reflect newly published illness estimates from the CDC, new national Healthy

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<sup>20</sup>PFP is led by a Governing Council composed of five members from FDA, one member from FSIS, one member from CDC, and six members from state and local agencies. According to FDA officials, PFP’s focus is strengthening the role of state and local agencies in the food safety system.

<sup>21</sup>HHS’s FoodSafety.gov website states that it is the gateway to food safety information provided by government agencies.

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People 2020 goals, and methodological changes.”<sup>22</sup> In addition, USDA states that its food safety work “includes the general oversight of the Office of the U.S. Manager of Codex,” which “coordinates government and non-government participation in the activities of the Codex Alimentarius Commission.”

In HHS’s current performance plan, HHS lists three performance goals related to food safety, including its priority goal on *Salmonella* reduction. (See fig. 1.) HHS identifies FDA as an internal contributor to these goals but does not discuss any work with other agencies to achieve the goals.

## Agency Priority Goals

### **GPRAMA Requirement**

Agencies shall identify agency priority goals from among the performance goals of the agency. Agencies shall identify on Performance.gov federal organizations, program activities, regulations, policies, and other activities—both internal and external to the agency—that contribute to each of their priority goals and to describe whether they are contributing as planned. Agencies shall also describe on Performance.gov how they are working with other agencies to achieve each of their priority goals.

Source: Pub. L. No. 111-352 §§ 5, 7 (2011)(codified at 31 U.S.C. §§1120(b)(1), 1122(b)(3)(C), (D); (7)).

HHS and USDA have each identified one priority goal related to food safety, both focusing on a different aspect of *Salmonella* reduction.<sup>23</sup> (See figs. 1 and 2.) On Performance.gov, HHS and USDA identify internal contributors to these goals and include some details on the external agencies they are collaborating with and the nature of the collaboration. Specifically, USDA discusses work being carried out internally by FSIS, and HHS discusses work being carried out internally by FDA and CDC, in partnership with IFSAC. Additionally, HHS identifies FSIS as an external contributor, and USDA identifies FDA and CDC as external contributors. However, HHS does not specify what FSIS is doing to contribute to HHS’s goal. USDA does provide an example of actions by CDC and FDA, but the example occurred in the past and is not a current effort to achieve

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<sup>22</sup>Healthy People 2020 is a national health promotion and disease prevention initiative that includes 42 topic areas, including food safety. FDA and FSIS colead the food safety topic area, with a goal of, among other things, reducing rates of infection caused by foodborne pathogens.

<sup>23</sup>The goals focus on *Salmonella* reduction within the agencies’ respective jurisdictions. USDA’s goal focuses on reduction of illnesses due to *Salmonella* in FSIS-regulated products. HHS’s goal focuses on reduction of illnesses due to *Salmonella Enteritidis*, a common type of *Salmonella* frequently associated with shell eggs, which are regulated by FDA.

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the goal. Specifically, USDA states that FSIS worked with FDA and CDC on the development of HHS's agency priority goal. Both agencies identify FoodNet—a collaborative program led by CDC and involving FDA, FSIS, and 10 state health departments—as the source of the data used to measure progress toward the goals.<sup>24</sup> In addition, USDA states that its goal aligns with illness reductions identified in the Healthy People 2020 initiative.

### Some Crosscutting Efforts Are Not Included

Our review found several relevant crosscutting efforts that are not identified in HHS and USDA strategic and performance planning documents. For example, FDA and FSIS officials both told us that they colead the National Antimicrobial Resistance Monitoring System, which tracks whether foodborne and other bacteria are resistant to the antibiotics used to treat and prevent the spread of illness. In addition, FDA and FSIS officials told us about their involvement with the Food Emergency Response Network, which integrates the nation's food-testing laboratories at the federal, state, and local levels to better respond to emergencies involving biological, chemical, or radiological contamination of food. The network's steering committee is cochaired by senior executives from FDA and FSIS, and its members include numerous federal and state partners. However, neither of these efforts is discussed in HHS and USDA strategic or performance plans or on Performance.gov. Furthermore, HHS and USDA have various interagency agreements in place with other food safety agencies, including the Environmental Protection Agency, aimed at assisting one another in carrying out their food safety oversight responsibilities. Moreover, in its strategic and performance planning documents, USDA discusses several collaborative mechanisms, such as IFORC and IRAC, in relation to its food safety goals and objectives. IFORC and IRAC also include HHS agencies; however, in its strategic and performance planning documents, HHS does not mention these efforts in relation to its food safety goals and objectives. Similarly, HHS discusses some collaborative mechanisms,

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<sup>24</sup>FoodNet refers to the Foodborne Diseases Active Surveillance Network. According to its website, FoodNet estimates the number of foodborne illnesses, monitors trends in incidence of specific foodborne illnesses over time, and attributes illnesses to specific foods and settings, among other things.

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such as PFP and Presidential Policy Directive 8 (PPD-8),<sup>25</sup> that include USDA agencies, but USDA does not discuss them.

By not fully addressing crosscutting program efforts in their strategic and performance planning documents, HHS and USDA miss important opportunities to help ensure that their food safety goals are complementary, and strategies are mutually reinforcing. In addition, they miss opportunities to highlight their crosscutting efforts and provide greater confidence that they are working in concert with others to achieve common outcomes in a way that conserves scarce resources and enhances the overall effectiveness of the federal effort. FDA and FSIS officials told us they recognize that more could be done to implement GPRAMA crosscutting requirements.

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### Agency Strategic and Performance Planning Documents Do Not Provide an Integrated Perspective on Federal Food Safety Performance

Fully addressing crosscutting food safety efforts in individual strategic and performance planning documents is an important first step toward providing a comprehensive picture of the federal government's performance in overseeing food safety. However, the agency-by-agency focus of individual planning documents alone does not provide the integrated perspective on federal food safety performance necessary to guide congressional and executive branch decision making, and inform the public about what federal agencies are doing to ensure food safety. Those individual documents could, however, provide building blocks toward the next, more challenging task of developing a single, government-wide performance plan for food safety. As we previously recommended to OMB in March 2011, this plan should include results-oriented goals and performance measures and a discussion of strategies and resources.<sup>26</sup> However, OMB has not taken action in almost 4 years to develop such a plan. The passage of GPRAMA in January 2011 further highlights the need for crosscutting strategic and performance planning for issues that involve multiple federal agencies and could provide the initial steps toward a government-wide performance plan for food safety. Without a government-wide performance plan for food safety, Congress, program managers, and other decision makers are hampered in their ability to identify agencies and programs addressing similar missions and

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<sup>25</sup>The goal of Presidential Policy Directive 8 is to strengthen U.S. security and resilience through systematic preparation for threats among all levels of government and others.

<sup>26</sup>[GAO-11-289](#).

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to set priorities, allocate resources, and restructure federal efforts, as needed, to achieve long-term goals. In addition, without such a plan, federal food safety efforts are not clear and transparent to the public. Currently, to understand what its government is doing to ensure the safety of the food supply, Congress, program managers, other decision makers, and the public must access and attempt to make sense of and reconcile individual documents across the 15 federal food safety federal agencies. OMB staff said that OMB could work with agencies to develop a government-wide plan performance plan for food safety, but that the Administration previously worked through the FSWG to coordinate major federal food safety activities and, most recently, through implementation of FSMA. However, as discussed above, a government-wide performance plan for food safety goes beyond coordination of agency activities to provide an integrated perspective of federal food safety performance.

Based on our prior work, we believe that, to be most effective, a government-wide plan must be more than a compilation of agency-level plans.<sup>27</sup> It should build on agency-level documents but provide value that exceeds the sum of its parts. A central and distinguishing feature should be a clear and direct discussion of government-wide goals and objectives, which can be used to help provide critical horizontal and vertical linkages across and within individual agencies. Horizontally, it can be used to integrate and foster synergies among food safety agencies. Vertically, it can be used to provide a framework within which individual agencies can align their food safety goals that would cascade down to individual employees.<sup>28</sup> Another distinguishing feature is that the plan should be organized in terms of broad goals and objectives rather than in a sequential, agency-by-agency format. Presenting information in an agency-by-agency manner is appropriate to emphasize agency accountability but tends to inadequately reflect the relative contributions

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<sup>27</sup>GAO, *The Results Act: Assessment of the Governmentwide Performance Plan for Fiscal Year 1999*, [GAO/AIMD/GGD-98-159](#) (Washington, D.C.: Sept. 8, 1998).

<sup>28</sup>We have previously found that leading organizations seek to establish clear hierarchies of performance goals and measures. Under these hierarchies, the organizations try to link the goals and performance measures for each organizational level to successive levels and ultimately to the organization's strategic goals. They have recognized that without clear, hierarchically linked performance measures, managers and staff throughout the organization will lack straightforward roadmaps showing how their daily activities can contribute to attaining organization-wide strategic goals and mission. GAO, *Executive Guide: Effectively Implementing the Government Performance and Results Act*, [GAO/GGD-96-118](#) (Washington, D.C.: June 1, 1996).

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of various agencies and strategies to the overarching goals and objectives, and it reduces opportunities to compare and assess interactions.

FDA and FSIS officials told us they recognize that a government-wide performance plan for food safety could be beneficial in providing clarity and transparency to the public regarding federal food safety efforts. They also said, however, that developing such a plan would be difficult, because statutes mandate that the agencies oversee different food products, often with different associated health risks, and using different approaches. The way one agency approaches its mandate may not be appropriate for another agency, they said, so a government-wide performance plan may be unrealistic. We acknowledge that there are challenges associated with the different statutory authorities and jurisdictions of the agencies with food safety responsibilities. However, if each agency is focused on a different aspect of food safety oversight, there is a risk that no entity will take the necessary broader view toward ensuring the safety of the overall food supply. For example, a major trend creating food safety challenges is the substantial and increasing portion of the U.S. food supply that is imported. HHS and USDA both conduct work focused on ensuring the safety of imported food and could articulate, in a government-wide performance plan, a common goal and mutually reinforcing strategies to do so, in addition to common performance measures, as appropriate, to track the nation's overall progress. Our prior reports have identified other areas of food safety that cut across different agencies—such as recall communication, seafood safety, seafood fraud, inspection of food production facilities, oversight of genetically engineered crops, and defense of food and agriculture against terrorist attacks and natural disasters<sup>29</sup>—which could form the basis of

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<sup>29</sup>See, for example, GAO, *Food Safety: FDA's Food Advisory and Recall Process Needs Strengthening*, [GAO-12-589](#) (Washington, D.C.: July 20, 2012); *Homeland Security: Actions Needed to Improve Response to Potential Terrorist Attacks and Natural Disasters Affecting Food and Agriculture*, [GAO-11-652](#) (Washington, D.C.: Aug. 19, 2011); *Seafood Fraud: FDA Program Changes and Better Collaboration among Key Federal Agencies Could Improve Detection and Prevention*, [GAO-09-258](#) (Washington, D.C.: Feb. 19, 2009); *Genetically Engineered Crops: Agencies Are Proposing Changes to Improve Oversight, but Could Take Additional Steps to Enhance Coordination and Monitoring*, [GAO-09-60](#) (Washington, D.C.: Nov. 5, 2008); *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); *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).

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common goals and objectives articulated in a government-wide performance plan. We have found that when agencies do not have a compelling rationale, such as legislation, directives, or their perceptions of the benefits from collaboration, it is difficult to overcome differences in missions and priorities and to define and articulate a common outcome that is consistent with their respective agency missions.<sup>30</sup> However, through their strategic and performance planning documents, HHS and USDA have already recognized that their food safety efforts are interconnected by, for example, including statements about their joint efforts to enhance food safety. In this regard, they have already highlighted a common goal: ensuring food safety.

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### FDA and FSIS Have Mechanisms in Place to Facilitate Interagency Coordination, but None Provides Centralized, Broad-Based Collaboration

Our analysis identified numerous collaborative mechanisms involving FDA and FSIS, but these mechanisms focus on specific issues and do not provide for broad-based, centralized collaboration that would allow FDA, FSIS, and other agencies to look across their individual food safety programs and determine how they all contribute to federal food safety goals. Experts we interviewed agreed that a centralized collaborative mechanism on food safety is important to foster effective interagency collaboration and could enhance food safety oversight. The FSWG served as a centralized mechanism for broad-based collaboration on food safety and resulted in a number of accomplishments, such as improved interagency coordination. However, our review indicated that the FSWG is no longer meeting.

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### Existing Collaborative Mechanisms Involving FDA and FSIS Are Focused on Specific Topics

Our analysis identified numerous collaborative mechanisms involving FDA and FSIS. For example, FDA and FSIS are collaborating with CDC through IFSAC to improve estimates of the most common sources of foodborne illnesses. However, these mechanisms are focused on specific issues and do not provide for broad-based, centralized collaboration that would allow FDA, FSIS, and other agencies to look across their individual food safety programs and determine how they all contribute to federal food safety goals. See table 3 for selected collaborative mechanisms involving FDA and FSIS.

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<sup>30</sup>GAO, *Results-Oriented Government: Practices That Can Help Enhance and Sustain Collaboration among Federal Agencies*, [GAO-06-15](#) (Washington, D.C.: Oct. 21, 2005).



**Table 3: Selected Collaborative Mechanisms Involving HHS’s Food and Drug Administration and USDA’s Food Safety and Inspection Service**

Name	Description
Foodborne Diseases Active Surveillance Network (FoodNet)	A collaboration involving the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Food Safety and Inspection Service (FSIS), and 10 state health departments. It estimates the number of foodborne illnesses, monitors trends in incidence of specific foodborne illnesses over time, and attributes illnesses to specific foods and settings, among other things.
Healthy People 2020	A national health promotion and disease prevention initiative that includes 42 topic areas, including food safety. FDA and FSIS colead the food safety topic area, with an objective of, among other things, reducing rates of infection caused by foodborne pathogens.
Interagency Foodborne Outbreak Response Collaboration	A collaboration involving CDC, FDA, and FSIS to coordinate foodborne illness outbreak investigations.
Interagency Food Safety Analytics Collaboration	A collaboration involving CDC, FDA, and FSIS focusing on projects related to foodborne illness source attribution, the process of estimating the most common food sources responsible for specific foodborne illnesses.
Interagency Residue Control Group	A collaboration involving the Environmental Protection Agency, FDA, FSIS, and other agencies to discuss and resolve chemical residue issues.
Interagency Risk Assessment Consortium	A collaboration involving federal agencies with food safety responsibilities. It works to promote scientific research that will facilitate risk assessments to assist regulatory agencies in fulfilling their specific food-safety risk management mandates.
National Advisory Committee on Microbiological Criteria for Foods	A collaboration involving CDC, FDA, FSIS, and other federal agencies with food safety responsibilities. It develops methodologies for assessing microbiological hazards in foods, among other things.
National Antimicrobial Resistance Monitoring System	A collaboration involving CDC, FDA, FSIS, and state and local health departments that tracks whether foodborne and other bacteria are resistant to the antibiotics used to treat and prevent the spread of illness.
PulseNet	A collaborative surveillance network involving CDC, FDA, FSIS, and public health laboratories in each state. PulseNet uses molecular fingerprinting to connect cases of foodborne infection and detect outbreaks.

Source: GAO. | GAO-15-180

FDA and FSIS also participate in many interagency agreements focusing on a variety of topics, ranging from the sharing of biological materials to collaboration on foodborne illness response. In addition, FSMA includes numerous provisions requiring interagency collaboration; however, these

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too focus on specific topics and do not provide for centralized, broad-based collaboration across food safety regulations and programs. FDA and FSIS leaders also told us they collaborate on an informal basis. For example, they see one another at conferences and other events and contact one another on an “as needed” basis, according to a senior FSIS official.

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### Experts Agreed That a Centralized Mechanism for Broad-Based Collaboration Could Enhance Food Safety Oversight

Nearly all—10 of the 12—experts in food safety we interviewed agreed that a centralized collaborative mechanism on food safety is important to foster effective interagency collaboration and could enhance food safety oversight.<sup>31</sup> The experts identified several potential benefits, challenges, and characteristics of having such a mechanism. Appendix II lists the names and affiliations of the experts we interviewed.

#### Potential Benefits

The experts cited several potential benefits of a centralized, collaborative mechanism for food safety oversight. For example, nearly all of them told us that a centralized mechanism could foster coordination, collaboration, and communication among key food safety agencies and leaders; increase visibility for food safety as an important issue within the executive branch; and build relationships and establish trust. All of the experts agreed that such a mechanism could enhance the sharing of knowledge and strategy and the use of best practices among federal agencies responsible for food safety. For example, one expert said such a mechanism could provide a forum for the regular sharing of best practices among the agencies. According to several of the experts, it could also help the agencies to look strategically and prospectively toward addressing emerging food safety issues. Specifically, several of the experts told us that a new centralized mechanism could help move the food safety agencies from a typically reactive approach—such as actions prompted by foodborne illness outbreaks—to a more proactive one. Some experts stated that, without such a mechanism, federal food

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<sup>31</sup>We use the following terms to quantify expert responses: “some” refers to responses from 2 to 4 experts; “several” refers to responses from 5 to 6 experts; “most” refers to responses from 7 to 9 experts; “nearly all” refers to responses from 10 or 11 experts; and “all” refers to responses from all 12 experts. These experts reflected a range of perspectives, with one-third representing industry or trade associations, one-third representing consumer groups, and one-third former high-level federal officials who had been members of the FSWG. See appendix I for a full description of our methodology.

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safety agencies do not have a forum for conversations on broad food safety issues. One expert noted that, without a centralized collaborative mechanism on food safety, it is difficult for the agencies to work out their differences and articulate a uniform policy to enhance food safety.

## Potential Challenges

All of the experts we interviewed acknowledged that there could be challenges in implementing a centralized mechanism for interagency collaboration on food safety. For example, nearly all of the experts agreed that unless the mechanism could hold members accountable, it would be less likely that recommendations would be acted upon. In addition, nearly all of the experts said that the agencies' different agendas could pose a challenge. For example, FDA and FSIS approach their food safety work differently because of the laws that they must comply with, so finding common ground can be difficult, according to one expert. A further challenge, according to most experts, is that a centralized collaborative mechanism would require leadership and energy from already busy agency officials. For example, one expert told us that the agencies are focused on carrying out their individual mandates, leaving little time and resources for additional responsibilities. However, some former FSWG members told us the FSWG met infrequently—once every 3 to 6 months on average.

## Potential Characteristics

The experts discussed potential characteristics of a centralized collaborative mechanism for food safety, including formalization, accountability, the frequency of meetings, and membership composition. Several of these characteristics are consistent with our prior work on key features and issues to consider when implementing collaborative mechanisms.<sup>32</sup>

### Formalization

All of the experts agreed that it would be important to formalize such a mechanism through, for example, a statute, presidential directive, or an interagency agreement, such as a memorandum of understanding (MOU) to help ensure its sustainability over time. Most of the experts told us that a statute would be the best option to formalize the mechanism; some

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<sup>32</sup>See, e.g., GAO, *Managing for Results: Implementation Approaches Used to Enhance Collaboration in Interagency Groups*, [GAO-14-220](#) (Washington, D.C.: Feb. 14, 2014) and *Managing for Results: Key Considerations for Implementing Collaborative Mechanisms*, [GAO-12-1022](#) (Washington, D.C.: Sept. 27, 2012).

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### Key Considerations for Implementing Interagency Collaborative Mechanisms

Our prior reporting has found that, although collaborative mechanisms differ in complexity and scope, they all benefit from certain key features, which raise issues to consider when implementing these mechanisms.

- **Outcomes and Accountability:** Have short-term and long-term outcomes been clearly defined? Is there a way to track and monitor their progress?
- **Bridging Organizational Cultures:** What are the missions and organizational cultures of the participating agencies? Have agencies agreed on common terminology and definitions?
- **Leadership:** How will leadership be sustained over the long-term? If leadership is shared, have roles and responsibilities been clearly identified and agreed upon?
- **Clarity of Roles and Responsibilities:** Have participating agencies clarified roles and responsibilities?
- **Participants:** Have all relevant participants been included? Do they have the ability to commit resources for their agency?
- **Resources:** How will the collaborative mechanism be funded and staffed? Have online collaboration tools been developed?
- **Written Guidance and Agreements:** If appropriate, have participating agencies documented their agreement regarding how they will be collaborating? Have they developed ways to continually update and monitor these agreements?

Source: GAO, *Managing for Results: Key Considerations for Implementing Interagency Collaborative Mechanisms*, GAO-12-1022 (Washington, D.C.: Sept. 27, 2012). | GAO-15-180

experts also told us that doing so would provide for a long lasting, effective collaboration that would also have visibility within the government. However, several experts acknowledged that enactment of a statute to formalize a collaborative mechanism would present the most challenges in terms of time and effort. Some experts said that an interagency agreement could work as a means to set up the mechanism and would likely be the easiest and most immediate option. However, most of the experts also told us that interagency agreements can be weak and may not provide the most sustainable or effective way to formalize such a group. Some other experts said a presidential directive would be the best way to formalize the mechanism because it would bring high-level visibility to such a group. On the other hand, most experts expressed concern that, if established by a presidential directive, the mechanism may not survive a change in administrations. We have found that lack of continuity is a frequent issue with collaborative mechanisms that are tied to the Executive Office of the President, particularly when administrations change.<sup>33</sup>

### Accountability

Nearly all of the experts agreed that a centralized mechanism should be held accountable for its results and suggested several options for achieving accountability. For example, most said the mechanism could establish goals that member agencies would be publicly accountable for meeting. Several experts also said the mechanism should periodically report to Congress and the public; for example, one expert said that would provide accountability. Some others said holding public meetings would be helpful to get stakeholders' views and to provide information to the public on the mechanism's activities. We have also found that outcomes and accountability are key features of any collaborative mechanism.<sup>34</sup>

### Meeting Frequency

Nearly all of the experts we interviewed emphasized the importance of regular meetings. Most told us that it would be important to have meetings quarterly. As one expert explained, such a frequency would

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<sup>33</sup>GAO-12-1022.

<sup>34</sup>GAO-12-1022.

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help to establish momentum for the mechanism. Some suggested it could be helpful to hold more frequent meetings initially, to get the mechanism off the ground. Some experts who were members of the FSWG told us that the FSWG met more frequently early on and less frequently over time. Several experts also suggested the possibility of a two-tier structure, with high-level officials meeting less frequently and another group of subject matter experts and additional staff meeting more frequently. Our prior work has highlighted the importance of in-person meetings to build relationships and trust.<sup>35</sup>

### **Membership Composition**

The experts expressed a range of views on the membership composition of a centralized collaborative mechanism on food safety. Several experts agreed that nongovernmental stakeholders, including consumer groups and industry associations, should be included in some way, for example, by getting stakeholder input during public meetings or through an advisory committee. However, most of the experts said stakeholders should not be official members of the mechanism because having only government officials as members would allow for more candid discussions and facilitate decision making. Half of the experts thought it would be important to include White House officials, such as those from OMB, in the mechanism's membership; the other half either disagreed or had no opinion on whether White House officials should be included. Some experts said White House involvement could help to elevate food safety issues and raise visibility of the group. Several others, however, told us that White House officials could potentially politicize the process. Nearly all of the experts told us that a new centralized mechanism should be led by a designated chair or an executive director; most of the experts also agreed the mechanism should have dedicated staff. Having staff or a designated chair could help to institutionalize the group, but some experts also pointed out that any independent staffing of the group would likely require funding. One expert suggested that the White House appoint a chair for up to 5 years to help to ensure the sustainability of the mechanism. We have found that including all relevant participants is an important feature of a collaborative mechanism.<sup>36</sup>

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<sup>35</sup>[GAO-14-220](#).

<sup>36</sup>[GAO-12-1022](#).

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## The FSWG Served as a Centralized Mechanism for Broad-Based Collaboration but Is No Longer Meeting

The FSWG served as a centralized mechanism for broad-based collaboration on food safety, but our review found that the group is no longer meeting. According to the FSWG's December 2011 Progress Report, the FSWG was a central coordinating mechanism for the federal government's food safety activities. The report said its mission was to strengthen federal efforts and develop short-term and long-term strategies to improve food safety. The Secretaries of HHS and USDA jointly cochaired the working group, which included several other partner agencies.<sup>37</sup> In addition, the White House Domestic Policy Council convened the group. However, FDA and FSIS officials told us that the FSWG is no longer meeting because, they believe, it served its purpose of improving interagency coordination. The last item posted under "recent actions" on the FSWG's website is its December 2011 Progress Report. FDA officials said they thought the FSWG's last meeting was in April 2011, but they could not provide an exact date.

### **FSWG Premise: Coordination is Essential**

According to the FSWG's 2011 Progress Report, the premise underlying the FSWG's creation is that coordination among federal agencies is essential to protect consumers in our highly diverse, global food system. Coordination and cooperation are necessary through every stage of the production and consumption process—"from farm to table." FSWG member departments and agencies thus share information and experience about all aspects of food safety. Such coordination strengthens the scientific and technical infrastructure to support a modern food safety system.

Source: December 2011 FSWG Progress Report | GAO-15-180

OMB staff and FDA and FSIS officials told us that the FSWG provided numerous benefits to the federal food safety system. For example, they told us that the FSWG was instrumental in helping to achieve legislative reform of food safety laws through enactment of FSMA. In addition, they told us that the FSWG helped to establish strong working relationships between agency officials, which continue to this day and which foster effective formal and informal collaboration. Moreover, they said that the FSWG provided the operational direction for work that has been done by the agencies subsequently. For example, FDA officials told us that the FSWG led to the creation of IFSAC as a means of strengthening collaboration across FDA, FSIS, and CDC in estimating the sources of foodborne illness. According to FDA officials, prior to IFSAC the agencies used different estimation approaches, with little coordination or information sharing, which made it difficult to obtain accurate estimates. FSIS officials told us that, through IFSAC, the agencies are now developing attribution estimates and methods to be used jointly in setting performance standards and developing risk assessments, economic analyses, and policies, among other things. In addition, according to a notice published by FSIS in the Federal Register, FSIS developed new performance standards for two pathogens—*Salmonella* and

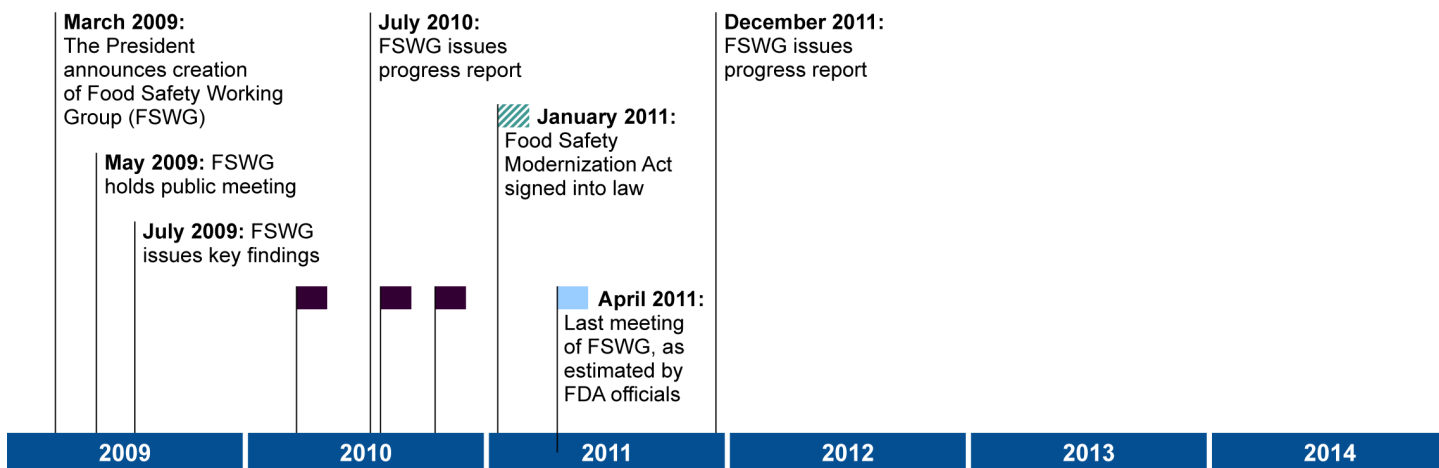
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<sup>37</sup> Partner agencies included HHS's FDA and CDC; USDA's FSIS; the Environmental Protection Agency; the Office of the United States Trade Representative; and the Departments of Commerce, Homeland Security, and State.

*Campylobacter*—in response to the work of the FSWG.<sup>38</sup> In March 2011, we found that through the FSWG federal agencies took steps designed to increase collaboration in areas that cross regulatory jurisdictions—in particular, improving produce safety, reducing *Salmonella* contamination, and developing food safety performance measures.<sup>39</sup> In the case of *Salmonella*, for example, FSIS officials told us that staff from FSIS and FDA communicated on a regular basis to coordinate efforts to develop their respective agencies’ priority goals on *Salmonella* reduction, as they are closely intertwined.

As shown in figure 3, when it was functioning, the FSWG also held public meetings, issued a report on “key findings” identifying its core principles and a number of goals and actions it was taking, or planning to take, to improve food safety, and released progress reports documenting its accomplishments.

**Figure 3: Key Food Safety Working Group Activities and Related Actions**



■ Food Safety and Inspection Service, FDA, and Centers for Disease Control and Prevention hold public meeting on measuring food safety

▨ FSWG members contribute to the passage of the law

Sources: GAO analysis of agency and FSWG data. | GAO-15-180

<sup>38</sup>76 Fed. Reg. 15282 (Mar. 21, 2011).

<sup>39</sup>GAO-11-289.

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According to senior FDA and FSIS officials and OMB staff, the FSWG is no longer needed, given the existence of other collaborative mechanisms, both formal and informal. However, as already noted, the existing mechanisms are focused on specific issues and do not allow for centralized, broad-based collaboration across federal food safety regulations and programs. For example, none provides a forum for food safety agencies to reach agreement on a set of broad-based food safety goals and objectives. Moreover, we have previously found that informal coordination mechanisms that rely on relationships between individual officials can end once the officials leave government or move to a different position.<sup>40</sup> Agency officials also said there is little time for high-level officials to meet in a group like the FSWG, given competing demands. However, some former FSWG members told us the FSWG met infrequently—once every 3 to 6 months on average.

Some agency officials acknowledged the value of having a centralized collaborative mechanism for food safety. For example, a senior FSIS official told us that reconvening the FSWG would be beneficial because it could help to ensure program transparency and produce results. A senior FDA official also told us that there would be value to having a group like the FSWG in place, because it could help to foster relationships.

An FDA official estimated that the FSWG has not met for at least 3 years; an OMB staff member confirmed that the group no longer meets and that there are no plans to meet in the future. However, the OMB staff member told us the FSWG could be reconvened if there was a need to do so, but there is not currently a need for the group. FSIS officials told us there is currently no centralized collaborative mechanism to discuss food safety issues. Agencies still refer to the FSWG in current documents as if it is an active entity. For example, HHS states in its current strategic plan that it works with multiple partners to ensure the safety of food, including the FSWG. In addition, HHS's current performance plan links to FDA's plan for addressing our high-risk designation for food safety, which cites improving interagency coordination through the FSWG as one of five key steps to address our high-risk designation. Moreover, the FSWG website is still active, but no new activities have been recorded since December 2011.

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<sup>40</sup>GAO, *National Security: Key Challenges and Solutions to Strengthen Interagency Collaboration*, [GAO-10-822T](#) (Washington, D.C.: June 9, 2010).



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In 2011, we reported that the creation of the FSWG was a positive step because it made food safety a national priority, demonstrated strong commitment and top leadership support (one of five criteria that must be met for GAO to remove a high-risk designation<sup>41</sup>), and was designed to foster interagency collaboration on the crosscutting issue of food safety.<sup>42</sup> However, we also expressed concern at the time about the group's future, given the history of the short-lived President's Council on Food Safety, which was created in 1998. It served as a coordinating mechanism encompassing all aspects of federal food safety programs, but it was disbanded in 2001 after a change in administrations. We recommended in 2001 that the President's Council on Food Safety be reconvened, but that did not happen. Instead, 8 years later, the FSWG was convened, but it stopped meeting after an estimated 2 years. Our prior reports have also identified other cases where leadership of an interagency collaborative mechanism changed, and the mechanism either disappeared or became less useful. In 2012, we found that transitions and inconsistent leadership can weaken the effectiveness of any collaborative mechanism;<sup>43</sup> in that report, we said that lack of continuity is a frequent issue with presidential advisers or mechanisms that are tied to the Executive Office of the President, particularly when administrations change. In addition, all of the experts on food safety we interviewed agreed that a collaborative mechanism on food safety should be formalized to help ensure sustained leadership over time. Without formalizing a centralized collaborative mechanism for food safety, such as in statute, they may continue to be short-lived.

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## Conclusions

HHS and USDA have both taken steps to implement GPRAMA's crosscutting requirements for their food safety efforts. However, the agencies do not fully address crosscutting food safety efforts in their strategic and performance planning documents. GPRAMA requires agencies to describe how they are working with other agencies to achieve their goals and objectives, among other things, but the agencies vary in the amount of detail they provide on such efforts. In addition, they do not

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<sup>41</sup>For additional information about the criteria for removal of a high-risk designation and our related work, see our webpage on the High Risk List at <http://www.gao.gov/highrisk/overview>.

<sup>42</sup>GAO-11-289.

<sup>43</sup>GAO-12-1022.

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include several relevant crosscutting efforts in either agency's strategic and performance planning documents. Fully addressing crosscutting food safety efforts in individual strategic and performance planning documents is an important first step toward providing a comprehensive picture of federal food safety performance. Nevertheless, the agency-by-agency focus of individual documents alone does not provide an integrated perspective on federal food safety performance. In March 2011, we recommended that OMB, in consultation with the federal agencies having food safety responsibilities, develop a government-wide performance plan for food safety. OMB has not taken action in almost 4 years to develop such a plan. GPRAMA further highlights the need for crosscutting strategic and performance planning for issues that involve multiple federal agencies and could provide the initial steps toward a government-wide performance plan for food safety. Without such a plan, Congress, program managers, and other decision makers are hampered in their ability to identify agencies and programs addressing similar missions and to set priorities, allocate resources, and restructure federal efforts, as needed, to achieve long-term goals. In addition, without such a plan, federal food safety efforts are not clear and transparent to the public. As we have previously recommended, a government-wide performance plan should include results-oriented goals and performance measures and a discussion of strategies and resources.

In addition, although a number of collaborative mechanisms on food safety involving FDA and FSIS exist, they are focused on specific issues and do not provide for broad-based, centralized collaboration. All of the experts on food safety we interviewed agreed that a centralized mechanism for broad-based collaboration could enhance the sharing of knowledge and strategy and the use of best practices among federal agencies responsible for food safety. We previously recommended that a centralized mechanism should be in place to facilitate interagency coordination across food safety regulations and programs. The FSWG, created by the Administration in March 2009, served as a centralized mechanism for broad-based collaboration on food safety, but the group is no longer meeting. The President's Council on Food Safety, a previous centralized mechanism for broad-based collaboration, was also short-lived. Challenges associated with the fragmented federal food safety system are long-standing, and centralized mechanisms for broad-based collaboration have not been sustained. Experts on food safety suggested that a centralized collaborative mechanism on food safety—like the FSWG—could provide sustained leadership across food safety agencies over time if it were formalized in statute. Without such formalization,

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centralized collaborative mechanisms for food safety may continue to be short-lived.

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## Recommendation for Executive Action

To help ensure that their food safety goals are complementary and strategies are mutually reinforcing, we recommend that the Secretary of Agriculture and the Secretary of Health and Human Services continue to build upon their efforts to implement GPRAMA requirements to address crosscutting food safety efforts, including by more fully describing in their strategic and performance planning documents how they are working with other agencies to achieve their food safety-related goals and objectives.

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## Matters for Congressional Consideration

Because challenges associated with the fragmented federal food safety system are long-standing, decision makers do not have an integrated perspective on federal food safety performance, and centralized mechanisms for broad-based collaboration have not been sustained, Congress should consider

- directing OMB to develop a government-wide performance plan for food safety that includes results oriented goals and performance measures and a discussion of strategies and resources, and
- formalizing the FSWG through statute to help ensure sustained leadership across food safety agencies over time.

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## Agency Comments and Our Evaluation

We provided a draft of this report for review and comment to the Secretary of Health and Human Services, the Director of the Office of Management and Budget, and the Secretary of Agriculture. HHS and USDA each provided written comments, which are presented in appendixes III and IV. In their written comments, HHS and USDA agreed with our recommendation that they continue to build upon their efforts to implement GPRAMA requirements to address crosscutting food safety efforts. HHS, OMB, and USDA also provided technical comments, which we incorporated as appropriate.

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We are sending copies of this report to the appropriate congressional committees, the Director of the Office of Management and Budget, the Secretary of Agriculture, the Secretary of Health and Human Services, and other interested parties. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

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If you or your staff have any questions about this report, please contact me at (202) 512-3841 or [morriss@gao.gov](mailto:morriss@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Key contributors to this report are listed in appendix V.

A handwritten signature in black ink that reads "Steve D. Morris". The signature is written in a cursive, slightly slanted style.

Steve D. Morris  
Director, Natural Resources and Environment

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*List of Addressees*

The Honorable Tom Harkin  
Chairman  
The Honorable Lamar Alexander  
Ranking Member  
Committee on Health, Education, Labor, and Pensions  
United States Senate

The Honorable Fred Upton  
Chairman  
The Honorable Henry Waxman  
Ranking Member  
Committee on Energy and Commerce  
House of Representatives

The Honorable Darrell E. Issa  
Chairman  
Committee on Oversight and Government Reform  
House of Representatives

The Honorable Mark Pryor  
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 Robert Aderholt  
Chairman  
The Honorable Sam Farr  
Ranking Member  
Subcommittee on Agriculture, Rural Development, Food and Drug  
Administration, and Related Agencies  
Committee on Appropriations  
House of Representatives

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# Appendix I: Objectives, Scope, and Methodology

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Our review provides information on: (1) Department of Health and Human Services (HHS) and U.S. Department of Agriculture (USDA) implementation of GPRAMA Modernization Act of 2010 (GPRAMA) requirements for addressing crosscutting efforts in their food safety strategic and performance planning, and (2) the extent to which the two agencies primarily responsible for federal food safety oversight—HHS’s Food and Drug Administration (FDA) and USDA’s Food Safety and Inspection Service (FSIS)—have a centralized mechanism in place to collaborate broadly across federal food safety regulations and programs.

To answer our first objective, we identified requirements for addressing crosscutting efforts in federal strategic and performance planning by reviewing GPRAMA and relevant guidance from the Office of Management and Budget (OMB) on the implementation of GPRAMA. We also reviewed our past and recent work on effective implementation of the act. Next, we reviewed current HHS and USDA strategic plans (for fiscal years 2014 through 2018), current HHS and USDA performance plans (for fiscal year 2015), and information about HHS and USDA priority goals published on the government website Performance.gov in September 2014. We analyzed this information to determine which HHS and USDA goals and objectives apply to food safety and the extent to which HHS and USDA discuss crosscutting efforts in relation to these goals and objectives through implementation of relevant GPRAMA provisions. In addition to the act’s requirements, our assessment was informed by OMB guidance applying the act and our past work on how to effectively implement the act. To further address our first objective, we reviewed agency documentation related to the goals and objectives, including FDA and FSIS strategic plans (for fiscal years 2011 through 2015 and 2011 through 2016, respectively), which are to support HHS and USDA goals and objectives, respectively. We also interviewed OMB staff and officials from HHS and USDA regarding federal food safety strategic and performance planning and crosscutting efforts.

To address our second objective, we identified existing collaborative mechanisms involving FDA and FSIS through reviews of our past work and of agency documentation and through interviews with experts in food safety knowledgeable about interagency collaboration and interviews with OMB staff and officials from FDA and FSIS. In doing so, we also analyzed relevant documentation—including memorandums of understanding (MOUs), charters and public websites—to gather information on current collaborations between FDA and FSIS. We analyzed the scope of the existing collaborative mechanisms identified throughout the course of our review to determine whether they were broad-based or focused on

specific topics. We also reviewed our past and recent work on key features and issues to consider when implementing collaborative mechanisms. To further address our second objective, we reviewed agency documentation related to Food Safety Working Group (FSWG) activities, including information posted on the FSWG website. We also interviewed OMB staff and FDA and FSIS officials regarding the FSWG, as well as former members of the FSWG who were part of our expert outreach, described below.

For our second objective, we conducted a two-stage interview process with experts in food safety knowledgeable about interagency collaboration to obtain their views on existing collaborative mechanisms and on the potential benefits, challenges, and characteristics of a new centralized collaborative mechanism for food safety. We identified these experts through a snowball sampling approach, starting with recommendations from internal GAO experts in food safety, contacting those external experts during our first round of interviews and asking them to identify other relevant experts. For the second round of interviews, we prioritized former members of the FSWG, and those closely associated with the FSWG, for inclusion, as well as other food safety experts knowledgeable about interagency collaboration on food safety. We interviewed 10 experts in the first round of interviews and 12 experts in the second round. The experts included representatives from federal agencies, industry or trade associations, and public interest groups, as well as former federal officials who had been members of the FSWG. Based on our analysis of responses provided during the first round of expert interviews, we developed a set of closed-ended and open-ended questions which we administered during the second round of interviews. We then conducted content analyses to assess experts' responses during the second round of interviews. Appendix II lists the names and affiliations of the experts we interviewed.

# Appendix II: List of Experts

Name	Affiliation
David Acheson, MD	Founder and CEO, The Acheson Group Former Chief Medical Officer, U.S. Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) Former Assistant and Associate Commissioner for Foods, FDA
Tony Corbo	Senior Lobbyist, Food and Water Watch
Joe Corby	Executive Director, Association of Food and Drug Officials
Mariano-Florentino "Tino" Cuéllar, PhD, Esq. <sup>a</sup>	Stanley Morrison Professor of Law, Stanford University Law School Former White House Special Assistant to the President for Justice and Regulatory Policy
Bob Ehart	Senior Policy and Science Advisor, National Association of State Departments of Agriculture
Sandra Eskin, Esq., and Colin Finan	Director of the Safe Food Project and Manager of the Safe Food Project, respectively, The Pew Charitable Trusts
Hank Giclas	Senior Vice President, Strategic Planning, Science and Technology, Western Growers
Elisabeth Hagen, MD <sup>a</sup>	Senior Advisor, Food Safety, Deloitte & Touche LLP Former Under Secretary for Food Safety, USDA
Dora Hughes, MD, MPH <sup>a</sup>	Senior Policy Advisor, Sidley Austin LLP Former Counselor for Science and Public Health to Secretary Sebelius, Department of Health and Human Services
Renee Johnson	Specialist in Agricultural Policy, Congressional Research Service
Barbara Kowalczyk, PhD	Senior Food Safety Risk Analyst, RTI International Former CEO and Director of Research, Center for Foodborne Illness Research and Prevention
David Lazarus, JD <sup>a</sup>	Former Senior Advisor for Rural Affairs, White House Domestic Policy Council Former Senior Advisor to Secretary Vilsack, USDA
Stuart Pape, Esq.	Partner, Squire Patton Boggs (US) LLP
Adela Ramos, PhD <sup>a</sup>	Global Registration Manager, DuPont Pioneer Former Chief of Staff to Under Secretary for Food Safety, USDA
Caroline Smith DeWaal	Food Safety Director, Center for Science in the Public Interest
Christopher Waldrop	Director, Food Policy Institute, Consumer Federation of America

Source: GAO. | GAO-15-180

<sup>a</sup>Former President's Food Safety Working Group member.



# Appendix III: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation  
Washington, DC 20201

DEC 4 2014

Steve D. Morris  
Director, Natural Resources and Environment  
U.S. Government Accountability Office  
441 G Street NW  
Washington, DC 20548

Dear Mr. Morris:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "*Federal Food Safety Oversight: Additional Actions Needed to Improve Planning and Collaboration*" (GAO-15-180).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

A handwritten signature in cursive script that reads "Jim R. Esquea".

Jim R. Esquea  
Assistant Secretary for Legislation

Attachment

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) TO THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: FEDERAL FOOD SAFETY OVERSIGHT: ADDITIONAL ACTIONS NEEDED TO IMPROVE PLANNING AND COORDINATION (GAO-15-180)**

The U.S. Department of Health and Human Services (HHS) appreciates the opportunity to review and comment on this draft report.

**GAO Recommendation**

The Secretary of Agriculture and the Secretary of HHS continue to build upon their efforts to implement GPRAMA Modernization Act of 2010 (GPRAMA) requirement to address crosscutting food safety efforts, including by more fully describing in their strategic and performance planning documents how they are working with other agencies to achieve their food safety-related goals and objectives.

**HHS Response**

HHS concurs with this recommendation. HHS will continue to build upon its efforts to implement GPRAMA requirements to address crosscutting food safety efforts, by expanding its strategic and performance planning documents along with working with other agencies to achieve food safety-related goals and objectives. HHS will draft revised descriptions in its strategic plan to fully address crosscutting food safety efforts and inter-agency collaborations.

Moreover, The FDA Food Safety Modernization Act (FSMA) envisions collaboration among federal and state agencies on food safety standard setting, technical assistance, and compliance. Ongoing collaboration among the three primary Departments responsible for food safety and food defense—HHS, the United States Department of Agriculture, and the Department of Homeland Security—has strengthened the food safety system in areas of research, risk assessment, and food defense.

# Appendix IV: Comments from the U.S. Department of Agriculture



DEPARTMENT OF AGRICULTURE  
OFFICE OF THE SECRETARY  
WASHINGTON, D.C. 20250

DEC 5 2014

Steve D. Morris  
Director  
Natural Resources and Environment  
United States Government Accountability Office  
441 G. Street, N.W.  
Washington, D.C., 20508

Dear Mr. Morris,

The United States Department of Agriculture (USDA) appreciates the opportunity to review the U.S. Government Accountability Office's (GAO) draft report entitled *Federal Food Safety Oversight: Additional Actions Needed to Improve Planning and Collaboration* (GAO-15-180). USDA appreciates GAO's work in planning, conducting and issuing this report. We have some general comments to make on the report and then we will respond to GAO's recommendation.

As noted in this report and in the requirements for GPRA Modernization Act of 2010 (GPRAMA), USDA is required to describe how we are working with other agencies in our strategic and performance planning. We will continue to work on this requirement and address our crosscutting food safety efforts with other agencies.

On page 2, footnote 2, the report says that programs are put on the high risk list because of their vulnerabilities to fraud, waste, abuse, or mismanagement, or are most in need of transformation to address economy, efficiency, or effectiveness challenges. Given this standard, USDA continues to believe that food safety should no longer be listed as high risk.

Presumably GAO still considers food safety to be high risk because the program is in need of transformation. However, this view disregards the hard work by many people in the Federal government in the years since 2011. GAO acknowledges the changes that have occurred in food safety in its report. Given the advances that have occurred, the food safety program should no longer be seen as in need of fundamental change. While we do not dispute GAO's conclusion that centralized coordination among the food safety agencies would have advantages, the improvements in effectiveness that could be expected from such coordination do not justify keeping food safety a high risk. For example, GAO raises the possibility in its report of quarterly food safety coordination meetings. GAO's consideration that such a frequency would be adequate reflects the fact that GAO recognizes that, on a day-to-day basis, food safety is being and will be well provided for by the responsible food safety agencies. Yet,

Steve D. Morris  
Page 2

the continuing high risk designation creates the impression for American consumers and our trading partners that food safety should be a source of concern in this country. Given the situation that actually prevails, we urge GAO to remove food safety from the high risk list.

USDA's response to the recommendation is included below.

**Recommendation 1:**

We recommend that the Secretary of Agriculture and the Secretary of Health and Human Services continue to build upon their efforts to implement GPRAMA requirements to address crosscutting food safety efforts, including by more fully describing in their strategic and performance planning documents how they are working with other agencies to achieve their food safety-related goals and objectives.

**USDA Response:**

USDA concurs with this recommendation. USDA will continue to implement the requirements stipulated in GPRAMA. The interagency collaboration requirement stipulates that USDA's strategic plan contain a description on how the Department is working with other Departments to achieve its general goals and objectives as well as relevant federal government priority goals. The Department is working to achieve this objective and continues to work with the Department of Health and Human Services, and other Departments, to align our strategic and performance planning to achieve our mutual food safety goals and efforts.

Again, thank you for the opportunity to review and comment on this draft report. Technical comments were submitted under a separate cover. We look forward to working with you on future Department of Agriculture engagements.

Sincerely,



Alfred V. Almanza  
Deputy Under Secretary, Office of Food Safety  
Acting Administrator, Food Safety and Inspection Service

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# Appendix V: GAO Contact and Staff Acknowledgments

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## GAO Contact

Steve D. Morris, (202) 512-3841 or [morriss@gao.gov](mailto:morriss@gao.gov)

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## Staff Acknowledgments

In addition to the individual named above, Anne K. Johnson (Assistant Director), Cheryl Arvidson, Kevin Bray, Rebecca Makar, Kristiana Moore, Steven Putansu, Emmy Rhine Paule, Dan Royer, Kiki Theodoropoulos, and Sarah Veale made key contributions to this report.

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