



January 2017

FOOD SAFETY

A National Strategy Is Needed to Address Fragmentation in Federal Oversight

GAO Highlights

Highlights of [GAO-17-74](#), a report to congressional requesters

Why GAO Did This Study

Although the U.S. food supply is generally considered safe, foodborne illness remains a common, costly, yet largely preventable public health problem. The safety and quality of food involves 16 federal agencies. For more than 4 decades, GAO has reported on the fragmented federal food safety oversight system. Because of potential risks to the economy and to public health and safety, food safety has remained on GAO's list of high-risk areas since 2007.

GAO was asked to examine efforts toward and options for addressing fragmentation in the federal food safety oversight system. This report (1) describes the actions HHS, USDA, and OMB have taken since 2014 to address fragmentation and evaluates the extent to which these agencies have addressed two prior GAO recommendations for government-wide planning and (2) assesses actions that food safety and other experts suggest are needed to improve the federal food safety oversight system. GAO convened an expert meeting, reviewed agency documents, and interviewed agency officials.

What GAO Recommends

GAO recommends that the appropriate entities within the EOP, in consultation with stakeholders, develop a national strategy to guide the federal food safety oversight system and address ongoing fragmentation. HHS, OMB, and the Domestic Policy Council did not comment on the recommendation. USDA disagreed with the need for a national strategy but cited factors to consider should changes be proposed. GAO believes the recommendation should be implemented.

View [GAO-17-74](#). For more information, contact Steve D. Morris at (202) 512-3841 or morris@gao.gov.

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What GAO Found

Since 2014, the Department of Health and Human Services' (HHS) Food and Drug Administration (FDA) and the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS), the federal agencies with primary responsibility for food safety oversight, have taken some actions to address fragmentation in the federal food safety oversight system, and HHS has updated its strategic plan to address interagency coordination on food safety. However, USDA has not yet fully implemented GAO's December 2014 recommendation that it describe interagency collaboration on food safety in its strategic and performance planning documents. In addition, the Office of Management and Budget (OMB) has not addressed GAO's March 2011 recommendation to develop a government-wide plan for the federal food safety oversight system.

At a 2-day meeting GAO hosted in June 2016, 19 food safety and other experts agreed that there is a compelling need to develop a national strategy to address ongoing fragmentation and improve the federal food safety oversight system. This is consistent with a prior GAO finding that complex interagency and intergovernmental efforts can benefit from developing a national strategy. The experts identified the following key elements of such a strategy:

- **Purpose:** The starting point for a national strategy includes defining the problem, developing a mission statement, and identifying goals.
- **Leadership:** The national strategy should establish sustained leadership at the highest level of the administration with authority to implement the strategy and be accountable for its progress. The strategy also needs to identify roles and responsibilities and involve all stakeholders.
- **Resources:** The national strategy should identify staffing and funding requirements and the sources of funding for its implementation.
- **Monitoring:** The national strategy should establish milestones that specify time frames, baselines, and metrics to monitor progress. The strategy should be sufficiently flexible to incorporate changes identified through monitoring and evaluation of progress.
- **Actions:** In addition to long-term actions, the national strategy should include short-term actions to gain traction in improving the food safety system. Actions should focus on preventing, rather than reacting to, outbreaks of foodborne illnesses.

These elements are consistent with characteristics GAO has previously identified as desirable in national strategies. Past efforts to develop high-level strategic planning for food safety have depended on leadership from the Executive Office of the President (EOP). By developing a national strategy to guide the federal food safety oversight system and address ongoing fragmentation, the EOP, in consultation with relevant federal agencies and other stakeholders, could provide a framework for making organizational and resource decisions. Among other things, such a strategy also could provide a framework for addressing GAO's recommendation for a government-wide plan and for removing food safety oversight from GAO's High-Risk List.

Contents

Letter		1
	Background	6
	HHS and USDA Have Taken Some Actions Since 2014 to Address Fragmentation, but USDA and OMB Have Not Fully Addressed the Need for Government-Wide Planning	14
	Food Safety and Other Experts Suggested That a National Strategy Is Needed to Improve the Federal Food Safety Oversight System	19
	Conclusions	29
	Recommendation for Executive Action	29
	Agency Comments and Our Evaluation	29
Appendix I	Participants in the June 9-10, 2016, Meeting of Experts	35
Appendix II	Options GAO Has Identified to Improve the Federal Food Safety Oversight System	37
Appendix III	Actions Identified by Experts to Consider Including in a National Strategy to Improve Food Safety Oversight	39
Appendix IV	Comments from the Department of Health and Human Services	41
Appendix V	Comments from the U.S. Department of Agriculture	43
Appendix VI	GAO Contact and Staff Acknowledgments	46
Tables		
	Table 1: Federal Agencies' Food Safety Responsibilities	6
	Table 2: Selected Collaborative Mechanisms Involving the Department of Health and Human Services' Food and Drug Administration (FDA) and the U.S. Department of	

Agriculture’s Food Safety and Inspection Service (FSIS), as reported in December 2014	12
Table 3: Status of Federal Efforts to Address Criteria for Removing Oversight of Food Safety from GAO’s High- Risk List, as of February 2015	13
Table 4: FDA Food Safety Modernization Act Foundational Rules and Their Status	16
Table 5: GAO’s Desirable Characteristics for National Strategies and the Related Key Elements of a National Strategy for Food Safety Oversight Identified by Experts	24
Table 6: Names and Affiliations of Participants in the June 9-10, 2016, Meeting of Experts	35
Table 7: Options to Improve the Federal Food Safety Oversight System Identified by GAO	37
Table 8: Actions Identified by Experts to Consider Including in a National Strategy to Improve Food Safety Oversight	39

Abbreviations

AMS	Agricultural Marketing Service
APHIS	Animal and Plant Health Inspection Service
CDC	Centers for Disease Control and Prevention
DPC	Domestic Policy Council
EOP	Executive Office of the President
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
FSMA	FDA Food Safety Modernization Act
FSWG	Food Safety Working Group
Gen-FS	Interagency Collaboration on Genomics and Food Safety
GMA	Grocery Manufacturers Association
GPRA	Government Performance and Results Act of 1993
GPRAMA	GPRA Modernization Act of 2010
HACCP	Hazard Analysis and Critical Control Point
HHS	Department of Health and Human Services
National Academies	National Academies of Sciences, Engineering, and Medicine
NIH	National Institutes of Health
OMB	Office of Management and Budget
OSTP	Office of Science and Technology Policy
PFP	Partnership for Food Protection
USDA	U.S. Department of Agriculture

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January 13, 2017

The Honorable Kirsten Gillibrand
Ranking Member
Subcommittee on Livestock, Marketing, and Agriculture Security
Committee on Agriculture, Nutrition, and Forestry
United States Senate

The Honorable Richard Blumenthal
United States Senate

The Honorable Richard Durbin
United States Senate

The Honorable Dianne Feinstein
United States Senate

Although the U.S. food supply is generally considered safe, foodborne illness remains a common, costly, yet largely preventable public health problem. A 2011 estimate by the Centers for Disease Control and Prevention (CDC)—its most recent estimate—indicates that, as a result of foodborne illness, roughly 1 in 6 Americans (48 million people) gets sick each year, 128,000 are hospitalized, and 3,000 die. CDC data also show that the number of reported multistate foodborne illness outbreaks is increasing. This is notable because, although multistate outbreaks make up a small proportion of total outbreaks, they affect greater numbers of people. For example, according to CDC data, 3 percent of reported outbreaks from 2010 to 2014 were multistate, but these outbreaks were associated with 11 percent of illnesses, 34 percent of hospitalizations, and 56 percent of deaths. CDC cites several potential contributors to the increase in reported multistate outbreaks, including greater centralization of food processing practices, wider food distribution, and improved detection and investigation methods.

Most who get sick from a foodborne illness will recover without any lasting effects; however, some individuals may suffer long-term health effects, such as kidney failure, chronic arthritis, or nerve damage. For example, according to CDC data, each year in the United States, an estimated 1.3 million people are affected by an infection with the foodborne pathogen *Campylobacter*. Of these, approximately 1 in 1,000 develop Guillain-Barré syndrome, a disorder in which a person's immune system attacks the body's own nerves. Researchers have also linked exposure to *E. coli*,

Salmonella, and other foodborne pathogens to a long-term risk of developing Crohn's disease, a chronic inflammatory bowel disease. According to a May 2015 estimate from the U.S. Department of Agriculture's (USDA) Economic Research Service, the most common 15 foodborne pathogens together impose an economic burden related to foodborne illnesses, hospitalizations, and deaths in the United States of over \$15.5 billion annually.¹ That same year, researchers at the Department of Health and Human Services' (HHS) Food and Drug Administration (FDA) estimated health costs associated with foodborne illness at about \$36 billion annually.²

In addition to the human health toll, foodborne illness outbreaks can impose high costs on industry from food recalls. An October 2011 study published by the Grocery Manufacturers Association (GMA), in partnership with Covington & Burling LLP and Ernst & Young, estimated the cost of food recalls.³ The study surveyed 36 GMA member companies and found that more than half had been affected by a product recall in the prior 5 years. Of the companies that had faced a recall in the past 5 years, 48 percent estimated their financial impact to be less than \$9 million; 29 percent, from \$10 million to \$29 million; and 23 percent, \$30 million or more. According to the survey results, the four largest costs that companies face as a result of a recall are business interruption or lost profits; recall execution costs, such as destroying and replacing recalled products; liability risk; and company or brand reputation damage.

As we reported in December 2014, three major trends create food safety challenges.⁴ First, a substantial and increasing portion of the U.S. food supply is imported, which stretches the federal government's ability to ensure the safety of these foods. Second, consumers are eating more raw and minimally processed foods, which in general are more

¹Economic burden measures the impact of disease on the welfare of all individuals in a society—also referred to as welfare loss. Economists measure the economic burden of a disease as the sum of the willingness to pay by all individuals in society to reduce its incidence or likelihood.

²The difference between the estimates may be explained by the number of identified pathogens included, whether or not unidentified causes of foodborne illness were included, and analytical methods used for developing the estimate.

³GMA, Covington & Burling LLP, and Ernst & Young, *Capturing Recall Costs: Measuring and Recovering the Losses* (Washington, D.C.: October 2011).

⁴GAO, *Federal Food Safety Oversight: Additional Actions Needed to Improve Planning and Collaboration*, [GAO-15-180](#) (Washington, D.C.: Dec. 18, 2014).

susceptible to foodborne pathogens. 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, both domestic and imported, are governed by a highly complex system stemming from at least 30 federal laws that are administered by 16 federal agencies. The federal agencies with primary responsibility for food safety oversight are USDA's Food Safety and Inspection Service (FSIS) and FDA. FSIS is responsible for the safety of meat, poultry, processed egg products, and catfish.⁵ FDA is responsible for virtually all other food. As we reported in May 2016, the federal food safety oversight system is supplemented by states, localities, tribes, and territories, which may have their own laws and agencies to address the safety and quality of food.⁶ In all, more than 3,000 nonfederal agencies perform the great majority of government food safety activities. Among other things, these agencies investigate and contain illness outbreaks; conduct illness surveillance and monitor the food supply for contamination; inspect restaurants, grocery stores, and food processing plants; and take regulatory action to remove unsafe or unsanitary products from the market.⁷

For more than 4 decades, we have reported on the fragmented federal food safety oversight system.⁸ In January 2007, because of risks to the

⁵As a result of 2008 Farm Bill provisions amending the Federal Meat Inspection Act, regulatory responsibility for catfish inspection fell to FSIS in December 2015, when FSIS issued final regulations for a mandatory catfish examination and inspection program. The program regulations became effective in March 2016. 80 Fed. Reg. 75,590 (Dec. 2, 2015).

⁶GAO, *Food Safety: FDA Coordinating with Stakeholders on New Rules but Challenges Remain and Greater Tribal Consultation Needed*, [GAO-16-425](#) (Washington, D.C.: May 19, 2016).

⁷According to the Foodborne Disease Active Surveillance Network website, agencies conduct illness surveillance to provide information about the occurrence of foodborne diseases through reports of infections from selected laboratories; surveys of laboratories, physicians, and the general population; and population-based epidemiologic studies.

⁸GAO, *High-Risk Series: An Update*, [GAO-15-290](#) (Washington, D.C.: Feb. 11, 2015); [GAO-15-180](#); 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); GAO, *High-Risk Series: An Update*, [GAO-07-310](#) (Washington, D.C.: January 2007); GAO, *Food Safety: A Unified, Risk-Based System Needed to Enhance Food Safety*, [T-RCED-94-71](#) (Washington, D.C.: Nov. 4, 1993); GAO, *Food Safety and Quality: Uniform, Risk-based Inspection System Needed to Ensure Safe Food Supply*, [RCED-92-152](#) (Washington, D.C.: June 26, 1992); and GAO, *Need to Reassess Food Inspection Roles of Federal Organizations*, [B-168966](#) (Washington, D.C.: June 30, 1970).

economy and to public health and safety, we added the federal oversight of food safety to our list of areas at high risk for fraud, waste, abuse, and mismanagement, or most in need of transformation.⁹ In March 2011, 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.¹⁰ In December 2014, we recommended that USDA and HHS more fully describe in their strategic and performance planning documents how they are working with other agencies to achieve their food-safety-related goals and objectives.¹¹ In our February 2015 High-Risk Update, we reported that these recommendations had not been implemented.¹²

You asked us to examine efforts toward and options for addressing fragmentation in the federal food safety oversight system. This report (1) describes the actions HHS, USDA, and OMB have taken since 2014 to address fragmentation in the federal food safety oversight system and evaluates the extent to which the three agencies have addressed our two previous recommendations for government-wide planning and (2) assesses actions that food safety and other experts suggest are needed to improve the federal food safety oversight system.

To address our first objective, we reviewed documents and interviewed officials from HHS, USDA, and OMB on the actions the agencies have taken since our December 2014 report and the effect of these actions on addressing fragmentation in the federal food safety oversight system. To address our second objective, in June 2016, with the assistance of the National Academies of Sciences, Engineering, and Medicine (National Academies), we convened a 2-day GAO meeting of experts to discuss fragmentation in the U.S. federal food safety oversight system and suggest actions to improve the system. Through discussions with National Academies staff and our subject matter experts, we selected food safety and government performance experts on the basis of the relevance of their knowledge; their prominence in the public discourse on food safety issues; and their diversity of experience working in food safety, such as through prior experience working for FDA, CDC, or USDA

⁹[GAO-07-310](#).

¹⁰[GAO-11-289](#).

¹¹[GAO-15-180](#).

¹²[GAO-15-290](#).

or current experience working for the food industry. We started by categorizing the types of expertise we needed, such as detailed knowledge pertaining to (1) the organization and structure of the current federal food safety oversight system, including recent efforts to enhance collaboration among food safety agencies; (2) public organizational structure and performance or organizational transformation; and (3) other countries' recent efforts to restructure their food safety oversight systems.¹³ We developed an initial list of potential participants. We further developed this list through a literature review, recommendations from food safety experts, and recommendations from our subject matter experts. Nineteen experts representing a range of expertise and interests participated in the meeting. The experts included officials who had formerly worked on food safety at senior levels in the federal government as well as representatives from food-related industries, nongovernmental research organizations, state agencies, foreign food safety agencies, academia, and advocacy groups.¹⁴ (See app. I for a list of these experts and their affiliations.) In addition to convening the meeting, we interviewed additional food safety and other experts, including a recently retired senior FSIS official. We also reviewed relevant laws; regulations; our prior reports; reports from the National Academies; and other relevant documents, such as the 2001 Food Safety Strategic Plan produced by the President's Council on Food Safety.¹⁵

We conducted this performance audit from November 2015 to January 2017 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.

¹³Throughout this report, we refer to those with expertise in public organizational structure and performance or organizational transformation as "government performance experts."

¹⁴We invited past, rather than current, federal employees because we believed individuals not currently working for the federal government would be able to speak more openly about government actions.

¹⁵President Clinton established the President's Council on Food Safety through an executive order in 1998 to develop a comprehensive strategic plan for federal food safety activities. It disbanded less than 3 years after it was created.

Background

This section discusses the federal oversight of food safety, past reviews of the federal food safety oversight system, and the status of federal efforts to address criteria for removing oversight of food safety from our High-Risk List.

Federal Oversight of Food Safety

Of the 16 federal agencies that collectively administer at least 30 federal laws governing food safety and quality, FDA and FSIS have primary responsibility for food safety oversight. Table 1 summarizes the food safety responsibilities of all 16 agencies.

Table 1: Federal Agencies' Food Safety Responsibilities

Agency		Responsible for
U.S. Department of Agriculture (USDA)	Food Safety and Inspection Service	Ensuring the nation's domestic and imported commercial supply of meat, poultry, catfish, and egg products is safe, wholesome, and correctly labeled and packaged; enforcing the Humane Methods of Slaughter Act of 1978, as amended; and providing voluntary fee-for-service inspections for exotic animals.
	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 and inspection procedures, and marketing, for grain and other related products.
	Agricultural Marketing Service	Establishing quality and condition standards for, among other things, dairy, fruit, vegetables, and livestock.
	Agricultural Research Service	Providing 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 (FDA)	Ensuring that all domestic and imported foods, excluding meat, poultry, catfish, 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.

Agency		Responsible for
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 the national drinking water standard of quality; and consulting with FDA before FDA promulgates regulations for the standard of quality for bottled water.
U.S. Department of Transportation		Establishing procedures for safety inspections to help ensure the sanitary transportation of food.
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-17-74

Note: This table does not include agencies with responsibility for ensuring the safety of food distributed by those agencies as part of a specific program. For example, it does not include USDA's Food and Nutrition Service's responsibility for ensuring the safety of school meals (42 U.S.C. § 1769j) or the Food Safety Office within the Department of Defense's Defense Logistics Agency, which is responsible for food safety issues and technical and quality assurance policies for food for the U.S. military worldwide.

As we said earlier, for more than 4 decades, we have reported on the fragmented nature of federal food safety oversight.¹⁶ For example, in our past work, we described how FDA is generally responsible for ensuring that eggs in their shells (referred to as shell eggs) are safe, wholesome, and properly labeled; FSIS is responsible for the safety of eggs processed into egg products; USDA's Agricultural Marketing Service (AMS) sets quality and grade standards for shell eggs, such as Grade A; USDA's Animal and Plant Health Inspection Service (APHIS) manages the program that helps ensure laying hens are free from *Salmonella* at birth; and FDA oversees the safety of the feed that hens eat.¹⁷ In addition, we reported that FDA has primary responsibility for regulating manufacturers of frozen cheese pizzas, FSIS has primary responsibility for regulating manufacturers of frozen pizzas with meat, and multiple additional federal agencies play roles in regulating the components of

¹⁶ GAO-15-290; GAO-15-180; GAO-11-289; GAO-07-310; T-RCED-94-71; RCED-92-152; and B-168966.

¹⁷ GAO-11-289.

either type of pizza.¹⁸ Similarly, we have noted that FSIS inspects manufacturers of packaged open-face meat or poultry sandwiches (i.e., those with one slice of bread), but FDA inspects manufacturers of packaged closed-face meat or poultry sandwiches (i.e., those with two slices of bread).¹⁹ However, establishments producing closed-faced meat or poultry sandwiches intended for export to Canada can be inspected for Hazard Analysis and Critical Control Point (HACCP) compliance by FSIS under a voluntary inspection program, and samples collected by FSIS will be tested for certain pathogens by AMS.²⁰

Past Reviews of the Federal Food Safety Oversight System

In an August 1998 report, the National Academies concluded that the fragmented federal food safety oversight system was not well-equipped to meet emerging challenges.²¹ In response to the academies' report, the President established a Council on Food Safety later that year and charged it with developing a comprehensive strategic plan for federal food safety activities, among other things. The council's Food Safety Strategic Plan, released on January 19, 2001, recognized the need for a comprehensive food safety statute and concluded that the organizational structure of the food safety system makes it more difficult to achieve future improvements in efficiency, efficacy, and allocation of resources based on risk. In October 2001, we recommended that USDA, HHS, and the Assistant to the President for Science and Technology, as joint chairs

¹⁸GAO, *Food Safety: U.S. Needs a Single Agency to Administer a Unified, Risk-Based Inspection System*, T-RCED-99-256 (Washington, D.C.: Aug. 4, 1999).

¹⁹GAO, *Food Safety and Security: Fundamental Changes Needed to Ensure Safe Food*, GAO-02-47T (Washington, D.C.: Oct. 10, 2001).

²⁰In 2013, the Canadian Safety Inspection Agency audited the U.S. food safety oversight system for meat and poultry products intended for export to Canada and found that HACCP plans and *Listeria* controls were not required by FDA for ready-to-eat meat products. Specifically, under HACCP, food producers are responsible for identifying where in their processing system one or more hazards are reasonably likely to occur—hazard analysis—and implementing control techniques to prevent or mitigate these hazards. Producers are to lay out their hazard analysis and control techniques in HACCP plans. Consequently, the Canadian government has required that closed-faced sandwiches manufactured in the United States and destined for Canada be produced under a HACCP plan and tested for *Listeria*. As a result, as of February 1, 2016, closed-faced sandwiches destined for export to Canada are to be inspected by FSIS, and AMS will test establishments' control of *Listeria* and *Salmonella*. FDA will continue to inspect closed-face meat or poultry sandwiches intended for domestic consumption.

²¹Institute of Medicine and National Research Council, *Ensuring Safe Food from Production to Consumption* (Washington, D.C.: National Academy Press, August 1998).

of the President's Council on Food Safety, reconvene the council, which had disbanded earlier that year, to facilitate interagency coordination on food safety regulation and programs.²²

In our prior work, we have also identified options for reducing fragmentation and overlap in food safety oversight, including alternative organizational structures. These options include establishing a single food safety agency,²³ a food safety inspection agency,²⁴ a data collection and risk analysis center,²⁵ and a coordination mechanism led by a central chair.²⁶ We also suggested that Congress might wish to assess the need for comprehensive, uniform, risk-based food safety legislation or to amend FDA's and USDA's existing authorities.²⁷ (For descriptions of selected options, see app. II.)

When we added the federal oversight of food safety to our list of high-risk areas in January 2007, we found that a challenge for the 21st 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.²⁸ We noted that we had detailed problems with the fragmented federal food safety oversight system and had found that the system had caused inconsistent oversight, ineffective coordination, and inefficient use of resources. We stated that Congress and the executive branch could 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 the January 2007 High-Risk Update, we reported that we had recommended that a mechanism be put in place to facilitate interagency coordination on food

²²[GAO-02-47T](#).

²³GAO, *Food Safety: Changes Needed to Minimize Unsafe Chemicals in Food*, [RCED-94-192](#) (Washington, D.C.: Sept. 26, 1994); GAO, *Food Safety: A Unified, Risk-Based Food Safety System Needed*, [T-RCED-94-223](#) (Washington, D.C.: May 25, 1994); and [RCED-92-152](#).

²⁴[GAO-11-289](#).

²⁵[GAO-11-289](#).

²⁶[GAO-15-180](#).

²⁷[GAO-15-290](#).

²⁸[GAO-07-310](#).

safety regulations and programs.²⁹ We also suggested that Congress and the executive branch work together to develop a government-wide performance plan for food safety.

A number of actions have been taken since we added federal oversight of food safety to our High-Risk List in 2007.³⁰ In March 2009, the President established the Food Safety Working Group (FSWG) to coordinate federal efforts and develop goals to make food safer. In January 2011, the FDA Food Safety Modernization Act (FSMA) was enacted, representing the largest expansion and overhaul of U.S. food safety authorities since the 1930s.³¹ Also in January 2011, the statutory framework for performance management in the federal government, originally set out in the Government Performance and Results Act of 1993 (GPRA), was updated by the GPRA Modernization Act of 2010 (GPRAMA).³² GPRAMA adds new requirements for addressing crosscutting efforts in federal strategic and performance planning that help drive collaboration and address fragmentation.³³ For example, GPRAMA requires agencies' strategic plans and performance plans to contain a description of how the agencies are working with other agencies to achieve their goals and objectives. GPRAMA requirements apply at the departmental or agency level, not to organizational components.³⁴

²⁹[GAO-07-310](#).

³⁰[GAO-07-310](#).

³¹Pub. L. No. 111-353, 124 Stat. 3885 (2011). Prior to FSMA, FDA focused on reacting to foodborne illnesses after they occurred. FSMA requires that FDA focus on preventing foodborne illnesses. The law also provides FDA with new enforcement authorities designed to achieve higher rates of compliance with prevention- and risk-based food safety standards and to better respond to and contain problems when they do occur. For example, FSMA required new preventive controls and food safety plans at some food processing facilities and farms, enhanced FDA's capacity to trace foodborne illness outbreaks within the nation's food distribution channels, and expanded FDA's authority to conduct a mandatory recall of contaminated food products.

³²Pub. L. No. 111-352, 124 Stat. 3866 (2011). GPRAMA amends provisions of GPRA, Pub. L. No. 103-62, 107 Stat. 285.

³³GPRAMA defines crosscutting as "across organizational (e.g., agency) boundaries."

³⁴We 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.

In March 2011, we recommended that OMB, in consultation with the federal agencies having food safety responsibilities, develop an annually updated government-wide performance plan for food safety.³⁵ We stated that a performance plan offers a framework to help ensure agencies' goals are complementary and mutually reinforcing and to help provide a comprehensive picture of the federal government's performance on food safety. Furthermore, we stated that such a plan could assist decision makers in balancing trade-offs and comparing performance when resource allocation and restructuring decisions are made. In December 2014, because OMB had not taken action to develop a government-wide performance plan for food safety and the FSWG was no longer meeting, we suggested matters for Congress to consider, including (1) 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 (2) formalizing the FSWG through statute to help ensure sustained leadership across food safety agencies over time.³⁶ Congress has not taken action.

We found that FDA and FSIS were involved in numerous mechanisms to facilitate interagency coordination on food safety; however, the mechanisms focused on specific issues and none provided for broad-based, centralized collaboration. As of September 2016, federal oversight of food safety remained on our High-Risk List. Table 2 shows nine selected collaborative mechanisms involving FDA and FSIS, as reported in December 2014.³⁷

³⁵ [GAO-11-289](#).

³⁶ [GAO-15-180](#).

³⁷ [GAO-15-180](#). In December 2014, we also reported that FDA participated in the Partnership for Food Protection (PFP). PFP's focus is strengthening the role of state and local agencies in the food safety system. 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.

Table 2: Selected Collaborative Mechanisms Involving the Department of Health and Human Services' Food and Drug Administration (FDA) and the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS), as reported in December 2014

Name	Description
Foodborne Diseases Active Surveillance Network (FoodNet)	A collaboration involving the Centers for Disease Control and Prevention (CDC), FDA, 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 encompasses 42 topic areas, including food safety. FDA and FSIS co-lead 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 the investigation of foodborne illness outbreaks.
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 could 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-17-74

Status of Federal Efforts to Address Criteria for Removing Oversight of Food Safety from Our High-Risk List

We have identified five criteria, all of which must be fully met for an area to be removed from our High-Risk List. In our February 2015 High-Risk Update, we found that for federal oversight of food safety, three of the criteria had been partially met, and two had not been met (see table 3).³⁸

Table 3: Status of Federal Efforts to Address Criteria for Removing Oversight of Food Safety from GAO’s High-Risk List, as of February 2015

Criterion	Description	Status of federal efforts
Leadership commitment	Demonstrated strong commitment and top leadership support.	Partially met
Capacity	Agency has the capacity (i.e., people and resources) to resolve the risk(s).	Partially met
Action plan	A corrective action plan exists that defines the root cause, identifies solutions, and provides for substantially completing corrective measures, including steps necessary to implement any solutions we recommended.	Not met
Monitoring	A program has been instituted to monitor and independently validate the effectiveness and sustainability of corrective measures.	Not met
Demonstrated progress	Ability to demonstrate progress in implementing corrective measures and in resolving the high-risk area.	Partially met

Source: GAO. | GAO-17-74

Our assessment of whether the criteria were met focused largely on efforts Congress and the executive branch had made toward developing a government-wide performance plan for food safety and establishing a centralized mechanism for broad-based collaboration, such as the FSWG. In our February 2015 High-Risk Update, we noted that, with the enactment of GPRAMA in January 2011, Congress and the executive branch demonstrated leadership commitment to improving collaboration across the federal government.³⁹ We also noted that HHS and USDA had taken steps toward our December 2014 recommendation to implement GPRAMA’s crosscutting requirements for their food safety efforts but could more fully address crosscutting food safety efforts in their individual strategic and performance planning documents and thereby provide building blocks toward implementing our March 2011 recommendation

³⁸ [GAO-15-290](#).

³⁹ [GAO-15-290](#).

that OMB develop a government-wide performance plan on food safety. However, as of February 2015, OMB had not taken action on our recommendation to develop such a plan. In addition, we noted that the President had demonstrated leadership commitment and progress by establishing the FSWG to coordinate federal efforts and develop goals to make food safer. However, as of February 2015, the working group was no longer meeting, and nothing had taken its place. Federal food safety agencies also have the capacity to participate in a centralized, collaborative mechanism on food safety—like the FSWG—but congressional action would be required to formalize such a mechanism through statute.

HHS and USDA Have Taken Some Actions Since 2014 to Address Fragmentation, but USDA and OMB Have Not Fully Addressed the Need for Government-Wide Planning

HHS and USDA have taken some actions since 2014 to address fragmentation in the federal food safety oversight system, and OMB has focused on implementing FSMA, but USDA's and OMB's actions have not fully addressed our two recommendations for government-wide planning. Since 2014, HHS and USDA have continued and expanded collaboration on specific food safety issues, and HHS has updated its strategic plan to address interagency coordination on food safety. OMB has focused its efforts on working with agencies to facilitate implementation of FSMA. The facilitation, collaboration, and updates are positive steps, but USDA's and OMB's actions do not fully address our two recommendations for government-wide planning.

Since 2014, HHS and USDA Have Enhanced Collaboration, and HHS Has Updated Its Strategic Plan to Address Crosscutting Food Safety Issues

The two agencies with primary responsibility for food safety within HHS and USDA—FDA and FSIS, respectively—continue to use the nine collaborative mechanisms that we reported on in December 2014, all of which focus on specific issues.⁴⁰ For example, FDA and FSIS continue to collaborate with CDC through the Interagency Food Safety Analytics Collaboration to improve estimates of the most common sources of foodborne illnesses. According to CDC's website, the three agencies teamed up to create this collaboration. Its goal is to improve coordination of federal food safety analytic efforts and address crosscutting priorities

⁴⁰[GAO-15-180](#).

for food safety data collection, analysis, and use.⁴¹ FSIS and FDA also serve as the co-lead organizations for the food safety topic area under Healthy People 2020, a national health promotion and disease prevention initiative that provides 10-year national objectives for improving the health of all Americans and includes 42 topic areas. The food safety topic area has six objectives related to the goal of reducing foodborne illnesses in the United States, such as reducing infections caused by key pathogens transmitted commonly through food and increasing the proportion of consumers who follow key food safety practices. According to USDA officials, Healthy People 2020 informs their agency goals and their work with CDC and FDA.

In addition, over the past 2 years, FDA and FSIS have developed one new collaborative mechanism, according to FDA and FSIS officials. The mechanism, called the Interagency Collaboration on Genomics and Food Safety (Gen-FS), also includes CDC and the National Institutes of Health (NIH). Gen-FS focuses on sequencing the complete DNA of pathogens for surveillance, detection and investigation of outbreaks, and antibiotic resistance for pathogens causing intestinal illnesses transmitted by food and other routes, according to FSIS officials. The Gen-FS steering committee meets monthly to discuss harmonization of training, laboratory methodologies, and data access and analysis, according to FDA officials.

Furthermore, FDA officials said that implementing FSMA has been the agency's major food safety focus over the past 2 years, and FDA is partnering with nongovernmental stakeholders, state and local governments, and federal agencies to ensure FSMA's successful implementation. Under FSMA, FDA is responsible for more than 50 regulations, guidelines, and studies. This includes seven foundational rules. Table 4 provides additional information on the foundational rules.

⁴¹ According to information on CDC's website, the collaboration's projects and studies aim to identify foods that are important sources of illnesses. The current focus of the Interagency Food Safety Analytics Collaboration's activities is foodborne illness source attribution, defined as the process of estimating the most common food sources responsible for specific foodborne illnesses.

Table 4: FDA Food Safety Modernization Act Foundational Rules and Their Status

Rule	Description	Status
Preventive Controls for Human Food	Modernizes existing Current Good Manufacturing Practices and requires preventive controls for human food.	Final as of September 2015
Preventive Controls for Animal Food	Establishes Current Good Manufacturing Practices and preventive controls for food for animals.	Final as of September 2015
Produce Safety	Establishes science-based standards for growing, harvesting, packing, and holding produce on domestic and foreign farms.	Final as of November 2015
Foreign Supplier Verification Program	Requires importers to verify that food imported into the United States has been produced in compliance with Hazard Analysis and Critical Control Point, standards for produce safety, and is not adulterated, among other things.	Final as of November 2015
Third-Party Certification	Establishes a program for the accreditation of third-party auditors to conduct food safety audits and issue certifications of foreign facilities producing food for humans or animals.	Final as of November 2015
Sanitary Transportation	Requires those who transport food to use sanitary practices to ensure the safety of food.	Final as of April 2016
Intentional Adulteration	Requires domestic and foreign facilities to address hazards that may be introduced with the intention to cause wide-scale public health harm.	Final as of May 2016

Source: GAO analysis of Food and Drug Administration (FDA) information. | GAO-17-74

For example, FDA issued the final FSMA rule on produce, one of the foundational FSMA rules, in November 2015. The rule establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption. To develop the rule, which went into effect on January 26, 2016, FDA officials said they worked directly with farmers, which required a significant amount of collaboration with USDA and the states.⁴² In addition, these officials said they worked with the Environmental Protection Agency (EPA) on water quality and safety aspects of the produce rule, with the Department of Homeland Security on the intentional adulteration rule, and with the Department of Transportation on the sanitary transportation rule. Furthermore, in May 2016, we found that FDA had taken numerous steps to ensure meaningful and timely input from nonfederal officials during development

⁴²On August 24, 2016, FDA published an extension and clarification on compliance dates for a number of produce rule provisions. 81 Fed. Reg. 57784 (Aug. 24, 2016).

of the FSMA-mandated rules on produce, human food, and animal food but did not fully meet its tribal consultation responsibilities.⁴³

OMB staff told us that their main food safety-related focus since 2014 has been on meeting with agencies to oversee FSMA implementation. OMB staff stated that they meet with FDA and FSIS officials via conference calls on a regular basis to discuss the implementation of FSMA, as well as the agencies' budgets, regulations, and food safety issues more broadly. These meetings occur at times separately and at times with both FDA and FSIS officials present, according to OMB staff. These staff also said that they work on an agency-specific basis, helping agencies develop agency-specific performance plans, talking to agencies about how to improve performance, and working with agencies to collaborate on FSMA implementation.

In December 2014, we found that HHS and USDA did not fully address crosscutting food safety efforts in their individual strategic and performance planning documents and that doing so could help provide a comprehensive picture of the federal government's performance on food safety.⁴⁴ We recommended that both HHS and USDA more fully describe how they are working with other agencies to achieve food-safety-related goals in their strategic and performance planning documents, as required by GPRAMA, and the agencies agreed with our recommendation. Since then, in taking steps to update its strategic and performance planning documents to better address crosscutting food safety efforts, HHS implemented our recommendation. Specifically, in February 2015, HHS updated its strategic plan to more fully describe how it is working with other agencies to achieve its food-safety-related goals and objectives. Among other things, HHS described its collaboration with USDA, EPA, and others through collaborative mechanisms such as the National Antimicrobial Resistance Monitoring System, the Partnership for Food Protection (PFP), and the Food Emergency Response Network.⁴⁵ However, USDA has not fully implemented our recommendation,

⁴³[GAO-16-425](#).

⁴⁴[GAO-15-180](#).

⁴⁵PFP is a collaborative partnership of federal, tribal, state, and local governments that is intended to develop and implement procedures, best practices, and other work products that would advance integration of the U.S. food safety system. The Food Emergency Response Network integrates the nation's food-testing laboratories at the local, state, and federal levels into a network to better respond to emergencies involving biological, chemical, or radiological contamination of food.

although it has taken some steps toward doing so. For example, FSIS included more information on crosscutting food safety efforts in its fiscal year 2017-2021 strategic plan and in its draft fiscal year 2017 annual plan than it did in its prior strategic and annual plans. In its fiscal year 2017-2021 strategic plan, it included a list of collaborations, and the draft fiscal year 2017 annual plan includes a section on enhancing collaboration with partners. In addition, FSIS officials told us that FSIS is partnering with CDC, FDA, and NIH on the HHS agency priority goal to reduce foodborne illness caused by *Listeria*. The priority goal includes (1) sequencing the complete DNA of *Listeria* strains to improve the detection and investigation of *Listeria* outbreaks and (2) FDA and FSIS jointly reporting on their activities to reduce *Listeria* at various points across the food supply chain. USDA plans to include information on interagency collaboration in its next strategic plan, according to USDA officials.

OMB's Efforts Since 2014 Do Not Address Our Recommendation for a Government-Wide Plan

As noted above, HHS's and USDA's efforts since 2014 are positive steps toward government-wide planning, but OMB has not addressed our recommendation for a government-wide plan for the federal food safety oversight system. Without an annually updated government-wide performance plan for food safety that includes results-oriented goals, performance measures, and a discussion of strategies and resources, which we recommended to OMB in March 2011, 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.⁴⁶ Also, without such a plan, federal food safety efforts are not clear and transparent to the public.⁴⁷

OMB staff told us that they were not aware of any current plans to develop a government-wide performance plan for food safety. OMB staff said that OMB works on an agency-specific basis, providing input on agencies' performance plans and offering suggestions on how to improve performance. However, agencies' individual performance plans alone do 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. A government-wide performance plan would provide a

⁴⁶[GAO-11-289](#).

⁴⁷[GAO-15-290](#).

coordinated action plan for food safety and a plan for monitoring and measuring agencies' activities. We continue to believe that a government-wide plan is important for federal food safety oversight efforts.

Food Safety and Other Experts Suggested That a National Strategy Is Needed to Improve the Federal Food Safety Oversight System

Food safety and government performance experts identified the development and implementation of a national strategy for food safety as a first step toward improving the federal food safety oversight system. Experts identified examples of negative effects that continue to occur as a result of fragmentation in the federal food safety oversight system. These experts agreed that there is a compelling need to develop a national strategy to provide a framework for strengthening that system and addressing fragmentation and described five key elements that should be included in such a strategy. Developing a national strategy for food safety oversight could also provide a framework for addressing our March 2011 recommendation for a government-wide plan, our December 2014 matters for Congress to consider for leadership and planning, and criteria for removing federal food safety oversight from the High-Risk List.

Food Safety and Government Performance Experts Cited Negative Effects of Fragmentation in the Federal Food Safety Oversight System

During the 2-day meeting we hosted with the assistance of the National Academies, food safety and government performance experts cited examples of the negative effects that continue to occur as a result of fragmentation in the federal food safety oversight system. These examples further illustrate negative effects we have highlighted in our past work, including our 2015 High-Risk Update.⁴⁸ For example, experts noted that FDA and FSIS have different statutory authorities. One expert noted that the two agencies' statutory authorities result in two fundamentally different approaches to inspections. FDA's authority requires a risk-based approach, in which inspection rates vary depending on the level of risk associated with a food product. FSIS's authority, in contrast, directs the agency to examine the carcasses and parts of covered animal species and all processed food products before they

⁴⁸[GAO-15-290](#).

enter the food supply.⁴⁹ Because of these differences, an expert raised questions about the proper allocation of resources based on risk.

Commenting on the food safety system more broadly, several experts noted that the allocation of resources is not necessarily connected to the risk of foodborne illness. For example, one expert noted that at the federal level, FSIS and FDA receive close to the same amount of funding for food safety oversight but that FSIS is responsible for the safety of 20 percent of the food supply, and FDA is responsible for ensuring the safety of 80 percent of it.⁵⁰ Furthermore, because FSIS must meet continuous inspection requirements, it may be allocating too many resources to inspecting low-risk food processing facilities that produce foods that do not pose substantial threats to public health, according to another expert.⁵¹ For example, the expert highlighted the differences in resource allocation by comparing inspection rates at facilities producing cheese and pepperoni pizzas. A production line at the facility producing cheese pizza, which is regulated by FDA, may be inspected once every 5 years. On the other hand, a production line producing pepperoni pizza, which is regulated by FSIS, is inspected daily. The expert said the risk of foodborne pathogens related to both types of pizza is low because the pizzas are cooked. While raw meat is a high-risk food, meat that is thoroughly cooked, such as pepperoni on pizza, does not pose the same level of risk because the process of cooking eliminates existing pathogens.

⁴⁹Although FSIS is required to perform continuous inspection, FSIS uses risk to inform some of its processes. For example, FSIS officials noted that FSIS adjusts its resources to apply more intense or specific activities in poorly performing establishments. However, the degree to which FSIS can make its processes risk-based is limited by its statutory mandate.

⁵⁰According to agency budget justification documents for fiscal year 2017, FDA received an estimated \$998,914,000 in funding for fiscal year 2016 food activities, and FSIS received an estimated \$1,216,854,000. The Congressional Research Service has estimated that FSIS is responsible for the safety of 10 to 20 percent of the food supply, and FDA is responsible for 80 to 90 percent.

⁵¹FSIS officials noted that FSIS does not inspect all commodities the same way. Inspectors are always present on slaughter lines but may visit meat and poultry processors only once per shift.

Experts Agreed That There Is a Compelling Need to Develop a National Food Safety Strategy and Identified Its Key Elements

The 19 experts attending our 2-day meeting agreed that there is a compelling need to develop a national strategy to provide a framework for strengthening the federal food safety oversight system and addressing fragmentation. The experts identified and described five key elements that should be included in a national strategy for food safety oversight. These five key elements follow.

- **Purpose:** The starting point for developing a national strategy includes defining the problem, developing a mission statement, and identifying goals.
- **Leadership:** The national strategy should establish sustained leadership to achieve progress in food safety oversight. The leadership should reside at the highest level of the administration and needs to have authority to implement the national strategy and be accountable for its progress. The strategy also needs to identify roles and responsibilities for implementing the national strategy and involve all stakeholders, including federal, tribal, state, and local government agencies; industry; consumer groups; academia; and key congressional committees.
- **Resources:** The national strategy should identify staffing and funding requirements and the sources of funding for implementing the strategy.
- **Monitoring:** The national strategy should establish milestones that specify time frames, baselines, and metrics to monitor progress. The national strategy should be sufficiently flexible to incorporate changes identified through monitoring and evaluation of progress.
- **Actions:** In addition to long-term actions, the national strategy should include short-term actions, such as improving training for food safety officials, to gain traction on improving the food safety system. Actions should focus on preventing, rather than reacting to, outbreaks of foodborne illnesses. For example, several experts mentioned modifying the statutes that FSIS implements, such as the Federal Meat Inspection Act and the Poultry Improvement Act, to align the authorities of USDA with the Federal Food, Drug, and Cosmetic Act, as amended by FSMA, which outlines FDA's responsibilities. This could help ensure a consistent approach across food commodities.⁵² See appendix III for a list of actions identified by the experts that could

⁵²Such actions would be consistent with our prior suggestion that Congress may wish to assess the need for comprehensive, uniform, risk-based food safety legislation or to amend FDA's and USDA's existing authorities.

be considered for inclusion in a national strategy for food safety oversight.

The experts' call for a national strategy for food safety oversight is consistent with our past work on national strategies.⁵³ We found that complex interagency and intergovernmental efforts, which could include food safety, can benefit from developing a national strategy and establishing a focal point with sufficient time, responsibility, authority and resources to lead the effort.⁵⁴ For example, in August 2007, we reported on another area involving significant coordination and collaboration across all levels of government, as well as the private sector: preparing for and responding to an influenza pandemic.⁵⁵ We found that, as part of its efforts to address the potential threat of an influenza pandemic, the executive branch had developed a National Strategy for Pandemic Influenza and an associated implementation plan and had started working toward completing the plan's action items. In February 2004, we reported that national strategies themselves are not endpoints, but rather, starting points, and, as with any strategic planning effort, implementation is the key.⁵⁶

The five key elements of a national strategy identified by the experts are also consistent with characteristics we have identified as desirable in a national strategy. In our February 2004 report, we found that national strategies are not required, either by executive or legislative mandate, to address a single, consistent set of characteristics.⁵⁷ However, on the basis of a review of numerous sources, we identified six desirable characteristics to aid responsible parties in further developing and implementing national strategies. Table 5 lists and describes the six desirable characteristics and shows how the elements of a national

⁵³GAO, *Biosurveillance: Efforts to Develop a National Biosurveillance Capability Need a National Strategy and a Designated Leader*, [GAO-10-645](#) (Washington, D.C.: June 30, 2010).

⁵⁴[GAO-10-645](#).

⁵⁵GAO, *Influenza Pandemic: Further Efforts Are Needed to Ensure Clearer Federal Leadership Roles and an Effective National Strategy*, [GAO-07-781](#) (Washington, D.C.: Aug. 14, 2007).

⁵⁶GAO, *Combating Terrorism: Evaluation of Selected Characteristics in National Strategies Related to Terrorism*, [GAO-04-408T](#) (Washington, D.C.: Feb. 3, 2004).

⁵⁷[GAO-04-408T](#).

strategy for food safety oversight identified by experts align with the six desirable characteristics.

Table 5: GAO’s Desirable Characteristics for National Strategies and the Related Key Elements of a National Strategy for Food Safety Oversight Identified by Experts

GAO’s desirable characteristic for a national strategy	Description of characteristic	Examples of what the characteristic might encompass	Related key elements identified by experts (element)
Purpose, scope, and methodology	Addresses why the strategy was produced, the scope of its coverage, and the process by which it was developed.	<ul style="list-style-type: none"> • Statement of broad or narrow purpose, as appropriate. • Comparison with other national strategies. • Major functions, mission areas, or activities covered by the strategy. • Principles or theories that guided the strategy’s development. • Impetus for strategy (e.g., statutory requirement or event). • Process to produce strategy (e.g., interagency task force; state, local, or private input). • Definition of key terms. 	<ul style="list-style-type: none"> • A mission statement and goals for the food safety oversight system. (Purpose)
Problem definition and risk assessment	Addresses the particular national problems and threats the strategy is directed towards.	<ul style="list-style-type: none"> • Discussion or definition of problems, their causes, and operating environment. • Risk assessment, including an analysis of threats and vulnerabilities. • Quality of data available (e.g., constraints, deficiencies, and “unknowns”). 	<ul style="list-style-type: none"> • Definition of problems in the food safety oversight system. (Purpose)
Goals, subordinate objectives, activities, and performance measures	Addresses what the strategy is trying to achieve and the steps to achieve those results, as well as the priorities, milestones, and performance measures to gauge results.	<ul style="list-style-type: none"> • Overall results desired. • Hierarchy of strategic goals and subordinate objectives. • Specific activities to achieve results. • Priorities, milestones, and outcome-related performance measures. • Specific performance measures. • Process for monitoring and reporting on progress. • Limitations on progress indicators. 	<ul style="list-style-type: none"> • Milestones that specify time frames, baselines, and metrics to monitor progress. (Monitoring) • Sufficient flexibility to incorporate changes identified through monitoring and evaluation of progress. (Monitoring) • Short-term and long-term actions. (Actions)

GAO's desirable characteristic for a national strategy	Description of characteristic	Examples of what the characteristic might encompass	Related key elements identified by experts (element)
Resources, investments, and risk management	Addresses what the strategy will cost, the sources and types of resources and investments needed, and where resources and investments should be targeted by balancing risk reductions and costs.	<ul style="list-style-type: none"> • Resources and investments associated with the strategy. • Types of resources required, such as budgetary, human capital, information technology, research and development, and contracts. • Sources of resources (e.g., federal, state, local, and private). • Economic principles, such as balancing benefits and costs. • Resource allocation mechanisms, such as grants, in-kind services, loans, or user fees. • Importance of fiscal discipline. • "Tools of government" (e.g., mandates or incentives to spur action). • Linkage to other resource documents (e.g., federal budget). • Risk management principles. 	<ul style="list-style-type: none"> • Identification of staffing and resource requirements and funding sources. (Resources)
Organizational roles, responsibilities, and coordination	Addresses who will be implementing the strategy, what their roles will be compared to others, and mechanisms for them to coordinate their efforts.	<ul style="list-style-type: none"> • Roles and responsibilities of specific federal agencies, departments, or offices. • Roles and responsibilities of state, local, private, and international sectors. • Lead, support, and partner roles and responsibilities. • Accountability and oversight framework. • Potential changes to current organizational structure. • Specific processes for coordination and collaboration. • Process for resolving conflicts. 	<ul style="list-style-type: none"> • Identification of roles and responsibilities for achieving the objectives. (Leadership) • Sustained leadership to oversee the development of the strategy and direct its implementation. (Leadership)

GAO's desirable characteristic for a national strategy	Description of characteristic	Examples of what the characteristic might encompass	Related key elements identified by experts (element)
Integration and implementation	Addresses how a national strategy relates to other strategies' goals, objectives, and activities, and to subordinate levels of government and their plans to implement the strategy.	<ul style="list-style-type: none"> • Integration with other national strategies (horizontal). • Integration with relevant documents from implementing organizations (vertical). • Details on specific federal, state, local, or private strategies and plans. • Implementation guidance. • Details on subordinate strategies and plans for implementation (e.g., human capital, and enterprise architecture). 	<ul style="list-style-type: none"> • Involvement of all relevant stakeholders: federal, tribal, state, and local authorities; industry; consumer groups; academia; and key congressional committees. (Leadership)

Source: GAO. | GAO-17-74

Note: The information in this table was drawn from GAO, *Combating Terrorism: Evaluation of Selected Characteristics in National Strategies Related to Terrorism*, GAO-04-408T (Washington, D.C.: Feb. 3, 2004) and GAO analysis of expert statements. Analysis of expert statements was performed through a review of meeting transcripts and a follow-up questionnaire sent to meeting participants.

Although the experts did not specify which entity should lead the national strategy, past efforts to develop high-level strategic planning for food safety have depended on leadership from entities within the Executive Office of the President (EOP), such as the Domestic Policy Council (DPC), the Office of Science and Technology Policy (OSTP), and OMB.⁵⁸ For example, the President's Council on Food Safety was co-chaired by OSTP, along with HHS and USDA, and involved staff and officials from OMB and the DPC among others. Similarly, the FSWG was led by USDA and HHS and was convened by the DPC. OMB staff and FDA officials stated that a national strategy for improving food safety could be beneficial. However, FDA officials cautioned that timing would be an important consideration given that FDA is focused on FSMA implementation. FSIS officials said that they would defer to OMB regarding questions on the potential benefit of a national strategy for food

⁵⁸Established by Executive Order in 1993, the DPC coordinates the domestic policy-making process in the White House, ensures that domestic policy decisions and programs are consistent with the President's stated goals, and monitors implementation of the President's domestic policy agenda. The DPC is chaired by the President and consists of heads of various executive branch agencies and other officials designated by the President.

safety.⁵⁹ OMB staff said that OMB relies on direction from the administration to determine national priorities.

Entities within the EOP also play a leadership role in other ongoing strategies that require cross-agency collaboration. For example, since December 2013, OSTP and the National Security Council have led a multi-agency effort, including HHS and USDA, to develop the National Strategy for Combating Antibiotic-Resistant Bacteria, with a goal of preventing, detecting, and controlling outbreaks of antibiotic-resistant pathogens.⁶⁰ In addition, OMB has established a cross-agency priority goal of improving science, technology, engineering, and mathematics education.⁶¹ Since May 2013, OSTP has taken a lead role, along with the National Science Foundation, in working with multiple agencies to implement a 5-year strategic plan.⁶² By developing a national strategy to guide the nation's efforts to improve the federal food safety oversight system and address ongoing fragmentation, the appropriate entities within the EOP, in consultation with relevant federal agencies and other stakeholders, could provide a comprehensive framework for considering organizational changes and making resource decisions.

⁵⁹Agency officials pointed to Healthy People 2020 as a collaboration that involves cross-agency goal-setting on food safety. Although this is a positive example of cross-agency collaboration, it lacks key elements of the national strategy that we and experts have envisioned, including a discussion of resources and specific action items needed to achieve Healthy People 2020's objectives for food safety.

⁶⁰The National Strategy for Combating Antibiotic-Resistant Bacteria illustrates another example of addressing fragmentation in the federal food safety oversight system. USDA's surveillance activities under the strategy will require the coordination of FSIS and APHIS because FSIS has authority to inspect slaughter and processing facilities, but not farms, while APHIS has authority to go on the farm in the event of an animal disease outbreak.

⁶¹Among other things, GPRAMA requires OMB to coordinate with agencies to develop federal government priority goals (known as cross-agency priority or CAP goals)—4-year outcome-oriented goals covering a number of crosscutting mission areas—to improve the performance and management of the federal government.

⁶²GAO, *Managing for Results: OMB Improved Implementation of Cross-Agency Priority Goals, But Could Be More Transparent About Measuring Progress*, [GAO-16-509](#) (Washington, D.C.: May 20, 2016).

A National Strategy Could Provide a Framework for Addressing Our Recommendation for a Government-Wide Plan, Our Matters for Congress to Consider for Leadership and Planning, and Criteria for Removing Federal Food Safety Oversight from Our High-Risk List

Developing a national strategy for food safety oversight, as suggested by the experts, could provide a framework for addressing our March 2011 recommendation for a government-wide plan and our December 2014 matters for congressional consideration for leadership and government-wide planning. As we mentioned previously, we have found that complex interagency and intergovernmental efforts can benefit from developing a national strategy and establishing a focal point with sufficient time, responsibility, authority, and resources to lead the effort.⁶³ The national strategy, as described by the experts and possessing the desirable characteristics described in our past work, could fulfill the intent behind our March 2011 recommendation for OMB to develop a government-wide performance plan for food safety.⁶⁴ Such a strategy could include all of the elements of a government-wide performance plan for federal food safety oversight, such as government-wide goals and performance indicators. In addition to addressing our recommendation for a government-wide plan, to the extent that a national strategy for food safety oversight establishes sustained leadership for the issue, it could fulfill the intent behind our December 2014 matter for Congress to consider formalizing the FSWG through statute to help ensure sustained leadership across food safety agencies over time.⁶⁵

In addition, developing and implementing a national strategy could provide a framework for addressing the five criteria for removing federal food safety oversight from our High-Risk List. As discussed previously, experts agreed that a national strategy should include sustained leadership, which could address the criterion for leadership commitment. In addition, the national strategy, by including information on resource requirements, actions, and milestones and metrics to monitor progress, could also meet our criteria for capacity, an action plan, and monitoring, respectively. Finally, depending on its contents, a national strategy could demonstrate progress in implementing corrective measures, the final criterion for removing federal food safety oversight from our High-Risk List.

⁶³[GAO-10-645](#).

⁶⁴[GAO-11-289](#). The national strategy also could fulfill the intent of our December 2014 matter for Congress to consider directing OMB to develop a government-wide performance plan ([GAO-15-180](#)).

⁶⁵[GAO-15-180](#).

Conclusions

Since 2014, the primary federal agencies responsible for ensuring a safe food supply—FDA and FSIS—have taken actions to address fragmentation in the federal food safety oversight system. However, food safety and government performance experts who participated in the meeting we convened cited examples of the negative effects that continue to occur as a result of fragmentation in the federal food safety oversight system and generally agreed that there is a need for a national food safety strategy. These examples further illustrate negative effects that we have highlighted in our past work. The experts identified five key elements that should be included in such a strategy: stating the purpose, establishing sustained leadership, identifying resource requirements, monitoring progress, and including actions for gaining traction. These elements are consistent with characteristics that we have identified as desirable in a national strategy. By developing a national strategy to guide the nation’s efforts to improve the federal food safety oversight system and address ongoing fragmentation, the appropriate entities within the EOP, in consultation with relevant federal agencies and other stakeholders, could provide a comprehensive framework for considering organizational changes and making resource decisions. Experts identified the following stakeholders as key contributors to a national strategy for food safety: federal, tribal, state, and local government agencies; industry; consumer groups; academia; and key congressional committees. Such a national strategy also could provide a framework for addressing our recommendation for a government-wide plan, our matters for Congress to consider for leadership and planning, and criteria for removing federal food safety oversight from our High-Risk List.

Recommendation for Executive Action

To guide the nation’s efforts to improve the federal food safety oversight system and address ongoing fragmentation, we recommend that the appropriate entities within the EOP, in consultation with relevant federal agencies and other stakeholders, develop a national strategy that states the purpose of the strategy, establishes high-level sustained leadership, identifies resource requirements, monitors progress, and identifies short- and long-term actions to improve the food safety oversight system.

Agency Comments and Our Evaluation

We provided a draft of this report to HHS, USDA, OMB, and DPC for their review and comment. In written comments, HHS did not comment on our recommendation to the EOP. USDA disagreed with the need for a national strategy but cited factors to consider should changes be proposed. USDA also discussed several points related to the report’s findings. HHS’s and USDA’s written comments are reproduced in

appendixes IV and V, respectively. In addition, HHS and USDA provided technical corrections, which we incorporated as appropriate. Also, according to an e-mail from the Special Assistant to the President of the EOP, OMB and DPC did not have comments on the draft report.

To guide the nation's efforts to improve the federal food safety oversight system and address ongoing fragmentation, we recommended that the appropriate entities within the EOP, in consultation with relevant federal agencies and other stakeholders, develop a national strategy that states the purpose of the strategy, established high-level sustained leadership, identifies resource requirements, monitors progress, and identifies short- and long-term actions to improve the food safety oversight system. USDA stated that it is not yet convinced that developing and implementing a national strategy would result in significantly different outcomes in protecting public health by preventing foodborne illness with its partners. However, USDA also noted that, should major changes to the federal food safety system be proposed, it is imperative that they are data-driven, well-designed, collaborative, and ultimately, continue to enable the United States to have the safest food supply in the world. Even with USDA's reservations, we continue to believe that a national strategy would provide a comprehensive framework for considering organizational changes and resource decisions to improve the federal food safety oversight system.

USDA made a number of other comments related to the report's findings. First, USDA stated the report does not appear to explain or acknowledge the depth and breadth of key federal agency efforts and activities to work together within the bounds of existing statutory authorities, particularly across FSIS, FDA, CDC, and other federal food safety partners. In addition, USDA said that the report appears to significantly underestimate the complexity of modifying statutes that FSIS and FDA currently implement with the intent of better alignment. Related to acknowledging the depth and breadth of key federal efforts and activities, in our December 2014 report, we identified and described numerous collaborative mechanisms involving FDA and FSIS to highlight these positive efforts, and for this report, we requested information on any additional collaborative mechanisms developed since 2014, which we included. However, we found and continue to believe that 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. Related to underestimating the complexity of modifying statutes that FSIS and FDA currently

implement, we discuss modifying statutes as an example of the numerous actions that experts identified could be considered for inclusion in a national strategy for food safety oversight. We envision that ultimately it will be up to the stakeholders participating in such a strategy to decide which actions to pursue.

Second, USDA stated that FSIS continues to strongly disagree with the draft report in that it undervalues and diminishes the many collaborative mechanisms that are in place among FSIS and FDA, as well as with CDC and other federal and non-federal food safety and public health partners. In addition, FSIS said that the characterizations of all collaborations as “narrow” and “specific,” and the implication that broad-based collaboration does not occur through FSIS’s deeply integrated engagement, is inaccurate. Further, USDA stated that the implication that the collaborations are not well-targeted or sufficient appears to reflect a lack of understanding of how agencies with food safety/public health responsibilities operate in sync with each other. USDA also stated that FSIS’s activities with FDA, CDC, and other food safety partners are strategic, highly outcome- and mission-driven, and fully address the GPRAMA crosscutting requirements for federal strategic and performance planning that help drive collaboration and address fragmentation. USDA stated that it is important to note that we did not present or provide any evidence for any area where sufficient collaboration does not occur. As we said earlier, we found and continue to believe that these collaborative 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.

Third, USDA stated that it appreciated that our report attempts to recognize new collaborations since 2014; however, it does not include three of four new collaborations on which FSIS provided testimonial or written information to us—the HHS agency priority goal for foodborne *Listeria monocytogenes* illnesses interagency effort, PFP, and the One Health Initiative. Related to the HHS agency priority goal, in the report, we stated that FSIS officials told us that FSIS is partnering with CDC, FDA, and NIH on the HHS agency priority goal to reduce foodborne illness caused by *Listeria*. PFP and the One Health Initiative were established prior to 2014; however, in the report, we did discuss PFP in the context of presenting examples of collaborative mechanisms involving FDA and FSIS that we reported on in December 2014 and collaborative mechanisms described by HHS in its updated strategic plan.

Fourth, USDA stated that our report indicates that USDA has not fully implemented our prior recommendation to address crosscutting food safety efforts in its strategic and performance planning documents, because USDA, at the department level, did not alter its just-published fiscal year 2014-2018 strategic plan to mention food safety collaboration across USDA's large, broad, multi-agency portfolio. USDA stated that FSIS believes our continued focus on USDA not editing and reissuing its departmental strategic plan to include such reference to be misplaced. Further, USDA stated that food safety collaboration is addressed in the USDA fiscal year 2014-2018 strategic plan's key food safety illness indicator, which directly reflects FSIS's broad, long-standing collaborative activity with FDA and CDC associated with Healthy People, and in FSIS's fiscal year 2011-2016 and fiscal year 2017-2021 strategic plans. In our December 2014 report, we stated that 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. In addition, we stated that 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. In December 2014, we found several relevant crosscutting efforts that were not identified in USDA's fiscal year 2014-2018 strategic plan, and recommended that USDA more fully describe in its strategic and performance planning documents how it is working with other agencies to achieve its food-safety-related goals and objectives. In December 2014, USDA concurred with our recommendation, and USDA plans to include information on interagency collaboration in its next strategic plan, according to USDA officials.

Fifth, USDA stated that it is concerned about the implication that many of the possible actions to include in a national strategy do not require congressional approval and can be taken by executive branch agencies without such approval; USDA stated that they cannot. In addition, USDA stated that while the recommendation for executive action is quite general, the specifics, as outlined in appendix III of our report, appear far too prescriptive for us to typically recommend, and place disproportionate value on expert opinion rather than on data-driven analysis. Further, USDA stated that we appear to place importance on expert opinions, including citing many statements that were factually incorrect or misrepresented in a prior draft, and some of whose testimonial statements we removed. This included statements that implicitly supported assertions that FDA's statutory authorities could be appropriate to apply to the products that FSIS regulates. USDA stated that no data, study, or evidence supports this approach as being more protective of

public health and prevention of foodborne illness. USDA also stated that it continues to be concerned about our selective and dominant use of expert opinion studies to support its findings. In addition, USDA stated that we cite certain prior studies and panels from 1998, 2001, and more recently, yet other studies, such as one in 2002 by a White House-established Policy Coordinating Committee, concluded that the goals of the Administration were better advanced through enhanced interagency coordination rather than through, for example, the development of legislation to create a single food safety agency. Related to USDA's concerns about the actions listed in appendix III requiring congressional approval and appearing too prescriptive, the purpose of the appendix was to present a list of actions identified by the experts that could be considered for inclusion in a national strategy for food safety. As we stated earlier, we envision that ultimately it will be up to the stakeholders participating in such a strategy to decide which actions to pursue. Related to USDA's concern about the apparent importance we place on expert opinions and our use of expert opinion studies to support our findings, we selected food safety and government performance experts on the basis of the relevance of their knowledge; their prominence in the public discourse on food safety issues; and their diversity of experience working in food safety, such as through prior experience working at senior levels for FDA, CDC, or USDA or current experience working for the food industry. We took steps to confirm the accuracy of information the experts provided before including it in our final product. Related to USDA's concern about the development of legislation to create a single food safety agency, we discuss this option in an appendix in which we list a number of options we have identified in our past work to improve the federal food safety oversight.

Sixth, USDA stated that in prior reports, we have written 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 said that it continues to assert that food safety should no longer be listed as high risk. We have identified five criteria, all of which must be fully met for an area to be removed from our High-Risk List.⁶⁶ In our February 2015 High-Risk Update, we found that for federal oversight of food safety, three of the criteria had been partially met, and two had not

⁶⁶The five criteria that we have identified are leadership commitment, capacity, action plan, monitoring, and demonstrated progress.

been met.⁶⁷ Our assessment of whether the criteria were met focused largely on efforts Congress and the executive branch had made toward developing a government-wide performance plan for food safety and establishing a centralized mechanism for broad-based collaboration, such as the FSWG. However, we found that USDA's and OMB's actions since 2014 have not fully addressed the need for government-wide planning. In addition, we acknowledge that congressional action would be required to formalize in statute a centralized, collaborative mechanism on food safety, like the FSWG; however, federal food safety agencies do have the capacity to participate in such a mechanism. We believe that a national strategy for food safety could provide a framework for addressing the five criteria for removing federal food safety oversight from our High-Risk List.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the appropriate congressional committees; the Secretary of Health and Human Services; the Secretary of Agriculture; the Director, Office of Management and Budget; and other interested parties. In addition, the report will be available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff members have any questions regarding this report, please contact me at (202) 512-3841 or 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 VI.



Steve D. Morris
Director, Natural Resources and Environment

⁶⁷[GAO-15-290](#). We plan to issue a High-Risk Update in February 2017.

Appendix I: Participants in the June 9-10, 2016, Meeting of Experts

On June 9 and 10, 2016, with the assistance of the National Academies of Sciences, Engineering, and Medicine, we convened a 2-day meeting of food safety and government performance experts to discuss fragmentation in the U.S. federal food safety oversight system and suggest actions to improve that system. Table 6 lists the experts who participated in the meeting, along with their affiliations. We selected food safety and government performance experts on the basis of the relevance of their knowledge; their prominence in the public discourse on food safety issues; and their diversity of experience working in food safety, such as through prior experience working on food safety at senior levels in the federal government as well as through current work in food-related industries, nongovernmental research organizations, state agencies, foreign food safety agencies, academia, and advocacy groups.¹

Table 6: Names and Affiliations of Participants in the June 9-10, 2016, Meeting of Experts

Name	Affiliation
Manojit Basu, M.S., Ph.D.	Technical Lead, Science and Regulatory Affairs, Grocery Manufacturers Association, and Adjunct Faculty at Johns Hopkins University
Robert Buchanan, M.S., M. Phil., Ph.D.	Director, University of Maryland Center for Food Safety and Security Systems; former Deputy Administrator for Science with the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS); and former Senior Science Advisor with the Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition
Tony Corbo, M.A.	Senior Lobbyist, Food and Water Watch
Joseph Corby	Executive Director, Association of Food and Drug Officials, and former Director of the Division of Food Safety and Inspection for the New York State Department of Agriculture and Markets
Michael P. Doyle, M.S., Ph.D.	Regents Professor and Director, Center for Food Safety, University of Georgia, Griffin
Sandra Eskin, J.D.	Director of Food Safety, PEW Charitable Trusts
Jill Hollingsworth, D.V.M.	Former Senior Vice President for Food Safety Programs, Food Marketing Institute, and former Assistant Deputy Administrator of FSIS
Jocelyn M. Johnston, M.P.A., Ph.D.	Professor and Associate Chair, Department of Public Administration and Policy, American University School of Public Affairs
John Kamensky, M.P.A.	Senior Fellow, IBM Center for the Business of Government
Anne Khademian, M.P.A., Ph.D.	Director, Virginia Tech's School of Public and International Affairs, College of Architecture and Urban Studies, and Professor at the Center for Public Administration and Policy

¹We invited past, rather than current, federal employees because we believed individuals not currently working for the federal government would be able to speak more openly about government actions.

**Appendix I: Participants in the June 9-10, 2016,
Meeting of Experts**

Ali S. Khan, M.P.H., M.D.	Dean of the College of Public Health at the University of Nebraska Medical Center; former Assistant Surgeon General; and former Senior Director, Centers for Disease Control and Prevention
Barbara Kowalcyk, Ph.D.	Senior Food Safety and Public Health Scientist, RTI International
Paul Mayers	Vice President of Policy and Programs, Canadian Food Inspection Agency
Stuart Pape, J.D.	Shareholder and Practice Chair, Polsinelli, and former Associate Chief Counsel for Food, Office of the Chief of Counsel, FDA
David Plunkett, J.D., J.M.	Senior Staff Attorney, Center for Science in the Public Interest
Mike Robach	Vice President, Corporate Food Safety, Quality, and Regulatory Affairs, Cargill
Michael Scannell	Director for the Food Chain-Stakeholder and International Relations, Directorate General for Health and Food Safety, European Commission
Michael Taylor, J.D.	Senior Fellow at Freedman Consulting; former Deputy Commissioner for Foods and Veterinary Medicine, FDA; and former Administrator of FSIS
Frank Yiannas, M.P.H.	Vice President of Food Safety, Wal-Mart

Source: GAO. | GAO-17-74

Appendix II: Options GAO Has Identified to Improve the Federal Food Safety Oversight System

In our previous work, we have identified several options to improve the federal food safety oversight system. These options include establishing a coordination mechanism led by a central chair, a food safety inspection agency, a data collection and risk analysis center, and a single food safety agency and are described in table 7.

Table 7: Options to Improve the Federal Food Safety Oversight System Identified by GAO

Option	Description
Coordination mechanism	In March 2011, we reported that centralized, executive leadership could be provided for the existing organizational structure using a coordination mechanism with representatives from the agencies led by a central chair who would be appointed by the President and have control over resources. ^a Subsequently, in December 2014, we suggested that Congress consider formalizing through statute the Food Safety Working Group to help ensure sustained leadership across food safety agencies over time. ^b
Food safety inspection agency	In March 2011, we reported that, as one alternative for reducing fragmentation, food safety inspection activities—but not other activities such as surveillance—could be consolidated under the U.S. Department of Agriculture or the Food and Drug Administration. We noted that any new inspection system should employ a unified, risk-based approach, which would require Congress to modify the current legislative structure. ^c
Data collection and risk analysis center	The same March 2011 report also indicated, based on our own work and the work of others, that data collection and risk analysis could be consolidated into a single center that would disseminate the results of its analyses to the food safety agencies. For example, this center could consolidate food safety surveillance data collected from a variety of sources and analyze it at the national level to support risk-based decision making. The center would be independent from the regulatory agencies to give its analyses scientific credibility, but it would also consult with the agencies to understand their needs. However, it would not preempt any agency’s authority to develop its own food safety management approach. ^d
Government-wide performance plan	In our January 2007 High-Risk Update, we reported that the development of a government-wide performance plan for food safety that is mission-based, has a results-oriented approach, and provides a cross-agency perspective would offer a framework to help ensure agencies’ goals are complementary and mutually reinforcing. ^e We noted that with pressing fiscal challenges, such a plan could assist decision makers in balancing trade-offs and comparing performance when resource allocation and restructuring decisions are made. Two years later, in our January 2009 update to the High-Risk List, we again stated that the executive branch should develop a results-oriented government-wide performance plan to help ensure agencies’ goals are complementary. ^f In our March 2011 report on federal food safety oversight, we recommended that the Office of Management and Budget, in consultation with the federal agencies having food safety responsibilities, develop a government-wide performance plan for food safety. ^g In December 2014, we suggested that, because the executive branch did not address our previous recommendation of developing a government-wide performance plan, Congress consider directing the Office of Management and Budget to do so. ^h
Single food safety agency	In June 1992, we suggested that Congress hold oversight hearings to evaluate options for revamping the federal food safety and quality system, including creating a single food safety agency responsible for administering a uniform set of food safety laws. ⁱ In subsequent products, we expanded on this recommendation, calling for all aspects of food safety at the federal level to be consolidated into a single food safety agency, either housed within an existing agency or established as an independent entity. We concluded that consolidation would bring oversight of all foods under a single administrator and consolidate tasks that are dispersed throughout multiple federal agencies, such as inspections, risk assessment, standard setting, research, and surveillance. ^j

Appendix II: Options GAO Has Identified to Improve the Federal Food Safety Oversight System

Option	Description
Comprehensive, uniform, risk-based food safety legislation	Another option we suggested that Congress evaluate in our June 1992 report was to preserve the existing agency structure but to enact a uniform and comprehensive set of food safety laws that would be administered by the existing federal food safety agencies. ^k We proposed a similar matter for congressional consideration in an October 2001 report and as part of our March 2011 report on duplication, overlap, and fragmentation across the federal government, which also included a discussion of the fragmented food safety oversight system. ^l

Source: GAO. | GAO-17-74

^aGAO, *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).

^bGAO, *Federal Food Safety Oversight: Additional Actions Needed to Improve Planning and Collaboration*, [GAO-15-180](#) (Washington, D.C.: Dec. 18, 2014).

^c[GAO-11-289](#).

^d[GAO-11-289](#).

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

^fGAO, *High-Risk Series: An Update*, [GAO-09-271](#) (Washington, D.C.: January 2009).

^g[GAO-11-289](#).

^h[GAO-15-180](#).

ⁱGAO, *Food Safety and Quality: Uniform, Risk-based Inspection System Needed to Ensure Safe Food Supply*, [RCED-92-152](#) (Washington, D.C.: June 26, 1992).

^j[GAO-11-289](#); GAO, *Food Safety: Changes Needed to Minimize Unsafe Chemicals in Food*, [RCED-94-192](#) (Washington, D.C.: Sept. 26, 1994); and GAO, *Food Safety: A Unified, Risk-Based Food Safety System Needed*, [T-RCED-94-223](#) (Washington, D.C.: May 25, 1994).

^k[RCED-92-152](#).

^lGAO, *Food Safety and Security: Fundamental Changes Needed to Ensure Safe Food*, [GAO-02-47T](#) (Washington, D.C.: Oct. 10, 2001) and GAO, *Opportunities to Reduce Potential Duplication in Government Programs, Save Tax Dollars, and Enhance Revenue*, [GAO-11-318SP](#) (Washington, D.C.: Mar. 1, 2011).

Appendix III: Actions Identified by Experts to Consider Including in a National Strategy to Improve Food Safety Oversight

During the 2-day meeting we convened with the assistance of the National Academies of Sciences, Engineering, and Medicine, experts identified a number of actions to consider including in a national strategy to improve food safety oversight. At least 10 of the 19 experts agreed that each of these actions described in table 8 could be appropriate to consider for inclusion in a national strategy, but not all of the experts agreed that every identified action should be considered. We are not endorsing any of these actions. These actions were identified by experts for consideration.

Table 8: Actions Identified by Experts to Consider Including in a National Strategy to Improve Food Safety Oversight

Action	Description
Allocate resources on the basis of risk	A comprehensive examination of the food safety system to evaluate how resources are currently being used could guide the implementation of a science-based, prevention-oriented national strategy that would allocate resources on the basis of risk. Under such a strategy, changes in resource allocation would be directly linked to reductions in foodborne illness risk. The evaluation and deployment of resources should consider both funding and human capital resource requirements. It should also integrate federal, tribal, state, and local resources to better coordinate and take advantage of resources already being expended at other levels of government and by industry. Any national strategy should make the allocation of resources flexible so that resources can be deployed and redeployed according to the changing needs of the food safety oversight system.
Manage risks consistently across commodities	A risk management model could be outlined through a national strategy to ensure a consistent approach across food commodities. For example, a risk management model could be used to inform a decision to modify the statutes that the Food Safety and Inspection Service implements, such as the Federal Meat Inspection Act and the Poultry Improvement Act, so that the U.S. Department of Agriculture's (USDA) inspection model is risk-based. This would help to align the authorities of USDA with the Federal Food, Drug, and Cosmetic Act, as amended by the FDA Food Safety Modernization Act, which outlines the Food and Drug Administration's (FDA) responsibilities. Moreover, ensuring a consistent approach to risk management across food commodities could benefit industry by reducing the resources companies expend for regulatory compliance rather than for managing risk.
Streamline food safety functions	By analyzing major functions of the food safety system—such as recalls or inspections—and identifying cross-agency functional areas, stakeholders can evaluate the oversight system holistically rather than by commodity. Such a review of the system could lead to ways to streamline and improve food safety oversight—for example, consolidating federal risk assessment functions or enhancing existing collaborative mechanisms for risk assessment.
Consider intra-agency consolidation	Unifying food safety functions within the Department of Health and Human Services (HHS) could elevate the importance of food safety within the department and reduce the effects of fragmentation. Unifying the food safety functions of FDA was identified as an option. Alternatively, or as a secondary step, food safety functions could be consolidated under a separate agency outside FDA, but remaining under HHS.
Consider inter-agency consolidation	A national strategy could include a long-term goal to consolidate food safety functions into a single food safety agency. However, experts cautioned that it may not be feasible in the near-term. Instead, experts emphasized the importance of interim steps, such as consolidating food safety functions within agencies and harmonizing food safety functions across agencies.
Align federal funding provided to states for food safety	A national strategy could include aligning support to states from the Centers for Disease Control and Prevention, FDA, and other federal agencies involved in food safety. This could include aligning federal support to state health departments for food safety issues and communication.

Appendix III: Actions Identified by Experts to Consider Including in a National Strategy to Improve Food Safety Oversight

Action	Description
Improve information infrastructure	Improving the information infrastructure is needed to improve the reliability, accessibility, and usability of data for food safety oversight. A national strategy should address how data are collected and shared among the relevant entities. It should also ensure the availability of data that can be used to improve risk analysis. This could involve a number of both short- and long-term actions. Short-term actions could include agreements to aid in the transferability of data among entities responsible for collecting data related to food safety and an increase in research funding for understanding the public health impact of foodborne disease. Long-term actions could include establishing a centralized data collection center and establishing a centralized risk assessment center.
Improve risk communication among agencies and to the public	Improvements in risk communication could increase public confidence in the management of foodborne illness outbreaks, as well as confidence in the safety of the U.S. food supply and the performance of agencies responsible for overseeing the food supply.
Invest in training and professional development for food safety officials	Investing in training and professional development for food safety officials is essential for ensuring the efficient and effective functioning of the food safety oversight system. This includes developing the capacity of food safety officials to understand risk assessment, to work across agencies, and to use technology and data to increase the efficiency and effectiveness of operations. This also includes fostering a culture of food safety at agencies engaged in food safety activities.

Source: GAO analysis. | GAO-17-74

Note: GAO analysis included a review of experts' statements in meeting transcripts and analysis of a follow-up questionnaire sent to meeting participants.

Appendix IV: 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 20 2016

Steve 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, "*Food Safety: A National Strategy Is Needed to Address Fragmentation in Federal Oversight*" (GAO-17-74).

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) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: FOOD SAFETY, A NATIONAL STRATEGY IS NEEDED TO ADDRESS FRAGMENTATION IN FEDERAL OVERSIGHT (GAO-17-74)

The United States Department of Health and Human Services (HHS) appreciates the opportunity to review and comment on the draft Government Accountability Office (GAO) report.

We value GAO's recognition of both historical and developing collaborative mechanisms that facilitate coordination between the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) on food safety. We have made extensive efforts to work together within the bounds of existing statutory authorities across the HHS (FDA and the Centers for Disease Control and Prevention (CDC)), USDA's Food Safety and Inspection Service (FSIS), as well as with other federal, state, local, tribal, territorial, and food safety partners. These collaborative mechanisms, including those recognized in the report, are at the core of our strategic objectives for organizational excellence as well as FDA's current strategic plans to enhance food safety and public health.

For example, our work in developing and expanding the Partnership for Food Protection (PFP), from its inception in 2008 to the creation of a multi-year strategic plan in 2014 and its implementation in 2015, demonstrates this interagency commitment to collaboration. The PFP, a group of dedicated professionals from federal (including FDA, USDA, and CDC), state, and local governments, has worked to develop and implement procedures, best practices, and other work products to advance integration and implementation of the national Integrated Food Safety System.

As with the food safety partnerships mentioned in the report, our approach to establishing the preventive, risk-based food safety system mandated by the FDA Food Safety Modernization Act (FSMA) involves close collaboration with federal, state, local, tribal, and territorial regulatory partners, and numerous other stakeholder communities. We cannot make FSMA a reality without our regulatory partnerships, especially now that the first significant FSMA compliance dates have arrived for the largest firms. Depending on the size and type of industry, other firms will be required to comply with the new FSMA rules on a phased schedule extending beyond 2020.

Successful FSMA implementation is among our highest priorities as is ensuring that our engagement in the many collaborative intergovernmental food safety efforts continues. While we maintain our focus on transforming FDA's food safety framework into one that prevents hazards instead of just responding to them, we will continue to look for new opportunities to cooperate with other federal agencies to best protect public health.

Appendix V: Comments from the U.S. Department of Agriculture



United States Department of Agriculture

Food Safety and
Inspection Service

1400 Independence
Avenue, SW,
Washington, D.C.
20250

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

DEC 16 2016

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 *Food Safety, A National Strategy Is Needed to Address Fragmentation in Federal Oversight* (GAO-17-74). We have general and specific comments to make on the draft report, as outlined below.

First, the report does not appear to explain or acknowledge the depth and breadth of key federal agency efforts and activities to work together within the bounds of existing statutory authorities, in particular across USDA's Food Safety and Inspection Service (FSIS), the Department of Health and Human Services' (DHHS) Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and other federal food safety partners. In addition, the report appears to significantly underestimate the complexity of modifying statutes that FSIS and FDA currently implement with the intent of better alignment.

Second, FSIS continues to strongly disagree with the draft report in that it undervalues and diminishes the many collaborative mechanisms that are in place among FSIS and FDA, as well as with CDC and other federal and non-federal food safety/public health partners. Our collaborative efforts cover primary and major roles and responsibilities of agencies related to food safety/public health, and represent a significant portfolio of FSIS' priority activities each year. The characterizations of all collaborations as "narrow" and "specific," and the implication that broad-based collaboration does not occur through our deeply integrated engagement, is inaccurate. Our position is that it is both appropriate and necessary to have a mix of broader and more specific collaborations, including those integrated with other sectors as appropriate, to ensure effective cross-agency operations and achievement of mutually beneficial outcomes. The implication that they are not well-targeted or sufficient appears to reflect a lack of understanding of how agencies with food safety/public health responsibilities operate in sync with each other.

FSIS activities with FDA, CDC, and other food safety partners are strategic, highly outcome- and mission-driven, and fully address the GPRA Modernization Act of 2010 (GPRAMA) crosscutting requirements for federal strategic and performance planning that help drive collaboration and address fragmentation. For example, the Healthy People (HP) Initiative (listed in Table 2 of selected collaborative mechanisms) created a

set of health objectives for the Nation to achieve over a decade. The HP initiative has served as a science-based framework for FSIS, FDA, and CDC food safety/public health activities for years. The HP 2020 goals/outcomes are directly reflected in FSIS' and USDA's prior and current Strategic Plans as key performance areas and measures, such as pathogen prevalence and illness indicators, *Salmonella* and *Campylobacter* Pathogen Reduction Performance Standards, and the DHHS Agency Priority Goal to reduce illnesses from *Lm*, for which FSIS is a contributor. These are all foundational to food safety/public health. It is important to note that GAO did not present or provide any evidence for any area where sufficient collaboration does not occur.

Third, we appreciate that the report attempts to recognize new collaborations since 2014; however, it does not include three of four new collaborations that FSIS provided testimonial or written information on to GAO—the DHHS Agency Priority Goal for foodborne *Lm* illnesses interagency effort, the Partnership for Food Protection (PFP), and the One Health Initiative. The latter is a worldwide strategy for expanding interdisciplinary collaborations and communications in all aspects of diseases for humans, animals, and the environment.

Fourth, GAO's report indicates that USDA has not fully implemented a prior GAO recommendation to address crosscutting food safety efforts in its strategic and performance planning documents, as USDA (at the Department level) did not alter its just-published FY 2014-2018 Strategic Plan to provide mention of food safety collaboration across USDA's large, broad, multi-agency portfolio. FSIS believes GAO's continued focus on not editing and reissuing USDA's Departmental strategic plan to include such reference to be misplaced. Food safety collaboration is addressed in the USDA FY 2014-2018 Strategic Plan's key food safety illness indicator—which directly reflects FSIS' broad, longstanding collaborative activity with FDA and CDC associated with HP—and in FSIS' FY 2011-2016 and FY 2017-2021 Strategic Plans. Specifically, as USDA's primary food safety agency, FSIS included multiple priority activities in its FY 2011-2016 Strategic Plan (two goals of eight on collaboration, as well as multiple measures), its FY 2017-2021 Strategic Plan (front section to emphasize prominence, as well as priorities throughout), and the pre-published FY 2017 Annual Plan that FSIS provided to GAO. USDA continues to maintain that alignment across FSIS, FDA, and CDC agency-level plans—FSIS' FY 2017-2021 Strategic Plan, FSIS' FY 2017 Annual Plan, FDA's Foods and Veterinary Medicine Program's Strategic Plan for FY 2016-2025, and CDC's National Center for Emerging and Zoonotic Infectious Diseases FY 2012-2017 Strategic Plan, and CDC's National Center for Environmental Health, Agency for Toxic Substances and Disease Registry Strategic Plan for FY 2014-2016—is noteworthy. FSIS held stakeholder meetings with FDA and CDC during its FY 2017-2021 Strategic Plan development and finalization process, and these plans' goals and keys outcomes are easily mapped to each other.

Fifth, USDA is concerned about the implication that many of the possible actions to include in a national strategy do not require Congressional approval, and can be taken by executive branch agencies without such approval; they cannot. This includes actions such as re-allocating funding dollars, modifying the statutes FSIS implements, inter-agency consolidation, or intra-agency consolidation. In addition, while the Recommendation for Executive Action is quite general, the specifics, as outlined in GAO's appendix III, appear far too prescriptive for GAO to typically recommend, and place disproportionate value on expert opinion rather than on data-driven analysis. Further, GAO appears to place importance on expert opinions—including citing many statements that were factually incorrect or misrepresented in a prior draft, and some of whose testimonial

GAO-17-74

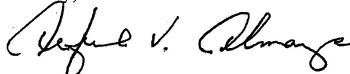
statements GAO removed (see below). This included statements that implicitly supported assertions that that FDA's statutory authorities could be appropriate to apply to the products that FSIS regulates. There is no data, study, or evidence that supports this approach as being more protective of public health and prevention of foodborne illness. USDA continues to be concerned about GAO's selective and dominant use of expert opinion studies to support its findings. GAO also cites certain prior studies and panels from 1998, 2001, and more recently, yet other studies, such as one in 2002 by a White House-established Policy Coordinating Committee, concluded that the goals of the Administration were better advanced through enhanced interagency coordination rather than through, for example, the development of legislation to create a single food safety agency.

Sixth, in prior reports, GAO has written 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 assert that food safety should no longer be listed as high risk. USDA would very much appreciate further dialogue with GAO about sufficient actions the Department can take to be removed from the high risk list—especially as USDA has both maintained, and added to as appropriate, broad-based and specific collaborations to protect public health by preventing foodborne illness.

Finally, we recognize that GAO's Recommendation for Executive Action is underpinned by a conclusion that developing and implementing a National Strategy would provide the centralized coordination among the food safety agencies that GAO believes to be necessary. USDA continues to believe that its strategic and operational interagency coordination and collaboration mechanisms are effective, including in working within the current statutory framework. USDA also greatly values its collaboration and coordination efforts with its food safety partners, and continues to be proactive and responsive in identifying new or enhanced opportunities, as most recently evidenced by Gen-FS and the One Health Initiative. USDA is not yet convinced that developing and implementing a National Strategy would result in significantly different outcomes in protecting public health by preventing foodborne illness with our partners. Should major changes to the federal food safety system be proposed, it is imperative that they are data-driven, well-designed, collaborative, and ultimately, continue to enable the United States to have the safest food supply in the world.

Again, thank you for the opportunity to review and comment on this draft report. Technical comments were submitted under a separate cover.

Sincerely,



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

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Appendix VI: GAO Contact and Staff Acknowledgments

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Staff Acknowledgments

In addition to the contact named above, Anne K. Johnson (Assistant Director), Kevin Bray, Candace Carpenter, Stephen Cleary, Michelle Duren, Ellen Fried, Kirsten Lauber, Benjamin T. Licht, Marya Link, Rekha Vaitla, Walter Vance, and Sarah Veale made key contributions to this report.

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