



September 2014

FOOD SAFETY

USDA Needs to Strengthen Its Approach to Protecting Human Health from Pathogens in Poultry Products

FOOD SAFETY

USDA Needs to Strengthen Its Approach to Protecting Human Health from Pathogens in Poultry Products

Why GAO Did This Study

USDA is responsible for ensuring the safety of poultry products. The Centers for Disease Control and Prevention (CDC) report the U.S. food supply is one of the safest in the world, yet estimate that *Salmonella* and *Campylobacter* contamination in food causes more than 2 million human illnesses per year. Poultry products contaminated with pathogens cause more deaths than any other commodity. GAO was asked to examine USDA's approach to reduce these pathogens in poultry products.

GAO's objectives were to (1) describe actions USDA has taken since 2006 to reduce *Salmonella* and *Campylobacter* contamination in poultry products, (2) evaluate USDA's efforts to assess the effects of these actions on the incidence of human illnesses from *Salmonella* and *Campylobacter* in poultry products, and (3) determine challenges USDA faces in reducing these pathogens in poultry products. GAO reviewed relevant regulations and documents and interviewed officials from USDA and CDC, as well as 11 industry, consumer, and government employee stakeholder groups selected based on knowledge of USDA's poultry slaughter inspections and food safety.

What GAO Recommends

GAO recommends that USDA develop additional performance measures for *Salmonella* and *Campylobacter* contamination in poultry products and ensure future guidelines for controlling *Salmonella* and *Campylobacter* on farms include information on the effectiveness of each practice. USDA agreed with GAO's recommendations.

View [GAO-14-744](#). For more information, contact J. Alfredo Gómez at (202) 512-3841 or gomezj@gao.gov.

What GAO Found

Since 2006, the U.S. Department of Agriculture (USDA) has taken a number of actions to reduce contamination from *Salmonella* and *Campylobacter* (disease-causing organisms, i.e., pathogens) in poultry (chicken and turkey) products. USDA's actions to reduce these pathogens include, for example, tightening existing standards limiting the allowable amount of *Salmonella* contamination in young poultry carcasses, implementing the first standards limiting *Campylobacter* contamination in young poultry carcasses in 2011, and developing an action plan detailing a priority list of actions, such as developing new enforcement strategies, to reduce *Salmonella*. More recently, in August 2014, USDA published its final rule to modernize poultry slaughter inspections, which according to the agency, will play a role in reducing *Salmonella* and other poultry pathogen contamination by allowing better use of agency resources, among other things.

To help assess the effects of these actions on the incidence of human illness from *Salmonella* and *Campylobacter*, USDA conducted research on the effects of agency actions to reduce these pathogens and developed performance measures for certain poultry products to help monitor progress toward agency goals. For example, USDA developed a measure to indicate whether agency actions to ensure compliance with the standard for *Salmonella* contamination in young chicken carcasses are helping the agency achieve its goal of maximizing domestic compliance with food safety policies. However, USDA has not developed measures for *Salmonella* contamination in ground poultry or young turkey carcasses, even though standards for such contamination have been in place since 1996 and 2005, respectively, or for *Campylobacter* contamination in young poultry carcasses. USDA believes it is not appropriate to establish measures for ground poultry until the agency has revised standards, or for *Campylobacter* contamination until the agency has obtained more information on compliance levels—both of which the agency expects to do by the end of 2014. USDA officials stated that they will review the agency's strategic plan to determine what performance measures, if any, are needed. USDA does not believe a measure for young turkey carcasses is needed since historically data have shown that plants are meeting the standard but, in calendar year 2013, two plants did not meet it; USDA officials told GAO that these plants are no longer noncompliant. Without performance measures for these standards, USDA is not publicly reporting performance information and cannot assess the effects of its actions related to these standards in meeting the goal of maximizing domestic compliance with food safety policies and, ultimately, protecting public health.

GAO identified several challenges—based, in part, on the views of 11 stakeholder groups—that could hinder USDA's ability to reduce contamination in poultry products. For example, contamination of poultry products can be affected by practices on poultry farms. To help overcome this challenge, the agency developed guidelines in 2010 on practices for controlling *Salmonella* and *Campylobacter* on farms, but the guidelines did not include information on the effectiveness of each of these practices, consistent with a recommendation from an agency advisory committee. USDA did not confirm that it plans to include this information in future guidelines. Without providing this information in future guidelines, USDA is not fully informing the poultry industry of the potential benefits of adopting these practices and encouraging their implementation.

Contents

Letter		1
	Background	4
	USDA Actions Have Largely Sought to Reduce <i>Salmonella</i> in Poultry, with <i>Campylobacter</i> More Recently Addressed	9
	In Assessing Its Actions, USDA Does Not Have Measures for All Poultry Pathogen Standards to Track Progress in Protecting Human Health and Relies on Data with Limitations	20
	USDA Faces Several Challenges in Reducing <i>Salmonella</i> and <i>Campylobacter</i> in Poultry Products across the Farm-to-Table Continuum	27
	Conclusions	39
	Recommendations for Executive Action	40
	Agency Comments and Our Evaluation	41
Appendix I	Objectives, Scope, and Methodology	43
Appendix II	Case Study Outbreak Summary Tables	48
Appendix III	Comments from the U.S. Department of Agriculture	55
Appendix IV	GAO Contact and Staff Acknowledgments	62
Tables		
	Table 1: USDA <i>Salmonella</i> Standards for Poultry Products	12
	Table 2: USDA <i>Campylobacter</i> Standards for Poultry Products	18
	Table 3: 2013 – 2014 Multistate Outbreak of <i>Salmonella</i> Linked to Chicken Products Produced in California	50
	Table 4: 2012 – 2013 Multistate Outbreak of <i>Salmonella</i> Linked to Chicken Products	51
	Table 5: 2012 <i>Campylobacter</i> Outbreak Linked to Chicken Livers in Vermont	52
	Table 6: 2011 Multistate Outbreak of <i>Salmonella</i> Linked to Broiled Chicken Liver Products	53

Table 7: 2011 Multistate Outbreak of *Salmonella* Linked to Ground Turkey

54

Figures

Figure 1: Farm-to-Table Continuum for Poultry Products

7

Figure 2: Foods Associated with One-Third of *Salmonella* Outbreaks, 2004 through 2008

8

Abbreviations

APHIS	Animal and Plant Health Inspection Service
CDC	Centers for Disease Control and Prevention
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
GPRA	Government Performance and Results Act of 1993, as amended
HACCP	Hazard Analysis and Critical Control Point
USDA	U.S. Department of Agriculture

This is a work of the U.S. government and is not subject to copyright protection in the United States. The published product may be reproduced and distributed in its entirety without further permission from GAO. However, because this work may contain copyrighted images or other material, permission from the copyright holder may be necessary if you wish to reproduce this material separately.



September 30, 2014

The Honorable Kirsten E. Gillibrand
Chairman
Subcommittee on Livestock, Dairy, Poultry, Marketing and Agriculture
Security
Committee on Agriculture, Nutrition, and Forestry
United States Senate

The Honorable Dianne Feinstein
United States Senate

The U.S. Department of Agriculture (USDA) is responsible for ensuring the safety of poultry (chicken and turkey) products. According to the Department of Health and Human Services' Centers for Disease Control and Prevention (CDC), the U.S. food supply remains one of the safest in the world.¹ Nevertheless, foodborne pathogens,² such as *Salmonella* and *Campylobacter*, cause human illnesses in the United States. Specifically, CDC estimates that *Salmonella* causes more than 1 million illnesses per year and over 20,000 hospitalizations and that *Campylobacter* causes more than 1 million illnesses annually. Poultry products contaminated with pathogens—including *Salmonella*—cause more deaths than any other food product.³ Pathogens in poultry products are especially concerning because Americans consume considerably more poultry products than beef or pork.

The Federal Meat Inspection Act and Poultry Products Inspection Act gives USDA overall responsibility for ensuring the safety and wholesomeness of meat and poultry products that enter into commerce.⁴

¹We did not independently verify the data underlying CDC's statement.

²Pathogens are disease-causing organisms including bacteria such as *Salmonella* and *Campylobacter*.

³John A. Painter et. al., "Attribution of Foodborne Illnesses, Hospitalizations, and Deaths to Food Commodities by using Outbreak Data, United States, 1998-2008," *Emerging Infectious Diseases* 19, no. 3 (2013), 407-415.

⁴21 U.S.C. §§ 601-683 and 21 U.S.C. §§ 451-472. The Federal Meat Inspection Act was originally enacted in 1907 as part of the USDA appropriations act, and the Poultry Products Inspection Act was enacted in 1957. Both pieces of legislation have been amended a number of times throughout the years.

USDA's Food Safety and Inspection Service (FSIS) inspects and regulates the production of most domestic poultry products sold for human consumption. FSIS proscribes standards for poultry slaughter plants under its jurisdiction for limiting *Salmonella* and *Campylobacter*.⁵ FSIS also verifies that such plants have process controls that are intended to ensure food safety. Congress appropriated \$1 billion dollars in fiscal year 2014 to FSIS for its activities including the food safety inspection program.

In 2006, FSIS launched an initiative to reduce *Salmonella* in raw meat and poultry products. According to CDC's food safety progress report for 2013, however, *Salmonella* infections in humans have not decreased, and the incidence of *Campylobacter* in humans increased by 13 percent in 2013 compared with previous years from 2006 through 2008 based on CDC's long-term comparison.⁶ In this context, we were asked to examine USDA's approach to protecting human health by reducing these pathogens in poultry products. Our objectives for this report were to (1) describe actions USDA has taken since 2006 to reduce *Salmonella* and *Campylobacter* contamination in poultry products that it regulates; (2) evaluate USDA's efforts to assess the effects of these actions on the incidence of human illnesses from *Salmonella* and *Campylobacter* in poultry products; and (3) determine what challenges, if any, USDA faces in reducing these pathogens in poultry products.

To describe actions USDA has taken to reduce *Salmonella* and *Campylobacter* contamination in poultry products since 2006, we reviewed FSIS documents, including *Federal Register* notices, directives, and budget documents, among other things. We also interviewed officials at FSIS headquarters about such actions. To evaluate USDA's efforts to assess the effects of these actions on the incidence of human illnesses from *Salmonella* and *Campylobacter* in poultry products, we reviewed USDA and FSIS strategic plans, as well as USDA annual performance

⁵FSIS standards apply to poultry products that are raw or not fully cooked to eliminate *Salmonella* or *Campylobacter*, and the agency has a zero tolerance for these pathogens in fully cooked, also known as ready-to-eat, poultry products.

⁶In CDC's food safety progress report for 2013, CDC used surveillance data that include *Salmonella* and *Campylobacter* illnesses attributed to other sources in addition to FSIS-regulated products.

reports to identify relevant performance measures, targets, and goals.⁷ We also evaluated the source data, statistical methodology, and results of FSIS research articles and a study to determine whether the conclusions drawn about the effects of actions taken were adequately supported by the evidence. In addition, we interviewed FSIS headquarters officials about the effects of actions taken on the incidence of human illnesses from these pathogens, and we interviewed FSIS and CDC officials about an interagency group to improve data and coordinate analyses. To determine any challenges USDA faces in reducing *Salmonella* and *Campylobacter* in poultry products, we reviewed reports by FSIS, the USDA Office of Inspector General, and the National Academy of Sciences on FSIS's inspections and management challenges. We interviewed FSIS and CDC officials; two food safety researchers we selected based on recent academic work; and 12 industry, consumer, and government employee stakeholder groups we selected based on our previous experience with large national groups with food safety and slaughter inspection knowledge from our August 2013 report on poultry and hog inspections.⁸ We conducted a two-stage interview process with stakeholder groups. First, we conducted exploratory interviews with representatives from 12 stakeholder groups to identify potential challenges. After analyzing the results of these interviews to identify commonly cited potential challenges, we then conducted structured interviews with representatives from 11 of the 12 stakeholder groups,⁹ using questions that covered the most common potential challenges cited in the exploratory interviews. The stakeholders we selected reflected a broad range of stakeholder groups, but the views of these stakeholders cannot be generalized to other stakeholder groups, and it is possible that their views did not include opinions some experts may have. Additionally,

⁷The Government Performance and Results Act of 1993 as amended by the GPRA Modernization Act of 2010 (GPRA) requires executive agencies to complete strategic plans in which they define their missions, establish results-oriented goals, and identify the strategies that will be needed to achieve those goals. GPRA also requires agencies to complete annual performance plans that establish performance goals—which contribute to the strategic goals—and measure performance toward achieving performance goals. Performance measures are important management tools that help agencies monitor and report progress toward their goals. Numerical targets are a key attribute of successful performance measures because they allow managers to compare planned performance with actual results.

⁸GAO, *Food Safety: More Disclosure and Data Needed to Clarify Impact of Changes to Poultry and Hog Inspections*, [GAO-13-775](#) (Washington, D.C.: Aug. 22, 2013).

⁹One of the initial 12 stakeholder groups was not available for a structured interview.

we reviewed five *Salmonella* and *Campylobacter* outbreaks attributed to poultry products with the highest number of illnesses to better understand any challenges that may have contributed to the outbreaks; these outbreaks started during the time period from fiscal year 2011 through fiscal year 2013.¹⁰ Appendix I contains more detailed information on the objectives, scope, and methodology of our review.

We conducted this performance audit from July 2013 to September 2014 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Salmonella and *Campylobacter* are bacteria that can cause disease in humans and animals. More than 2,500 different types of *Salmonella*—known as serotypes¹¹—exist, and 17 different types of *Campylobacter* exist—known as species.¹² *Salmonella* live in the intestinal tracts of humans and animals, while *Campylobacter* live in the intestinal tracts of animals. Some serotypes cause illness in humans or in animals. According to CDC officials, *Salmonella* Enteritidis is a common serotype frequently associated with poultry. *Salmonella* Enteritidis causes the most human illnesses among other *Salmonella* serotypes, according to CDC's 2011 *Salmonella* annual report.¹³ For *Campylobacter*, most human illness is caused by one species of the pathogen, called *Campylobacter jejuni*.

Foodborne illness occurs when bacteria or other harmful substances are ingested. Poultry is an important source of human *Salmonella* and *Campylobacter* infections, but *Salmonella* and *Campylobacter* transmission is not limited to poultry products. Contact with infected

¹⁰An outbreak consists of two or more cases of a similar illness that come from consumption of a common food, according to CDC.

¹¹Serotypes are groups within a single species of microorganisms, such as bacteria, that share distinctive surface structures.

¹²Species are the largest group of microorganisms capable of reproduction.

¹³CDC, *National Enteric Disease Surveillance: Salmonella Annual Report, 2011* (Atlanta, Ga: 2013).

animals and consumption of contaminated water and foods, including milk, eggs, and produce can also transmit the bacteria to humans. According to CDC's website, typical symptoms of illness from *Salmonella* or *Campylobacter* are abdominal cramps, fever, and diarrhea. *Salmonella* infections are more likely than *Campylobacter* infections to lead to bloodstream infections, particularly for infants, the elderly, and people with weak immune systems. *Salmonella* bloodstream infections can lead to life-threatening conditions including meningitis. In rare cases, both *Salmonella* and *Campylobacter* infections can result in long-term secondary complications such as reactive arthritis,¹⁴ according to CDC's website.

To improve its food safety approach, FSIS has moved to an increasingly science-based, data-driven, risk-based approach. In 1996, FSIS adopted the risk-based Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) regulations.¹⁵ Under the HACCP approach, industry—rather than federal inspectors—is responsible for (1) identifying food safety hazards, such as fecal material, that are reasonably likely to occur and (2) establishing controls that prevent or reduce these hazards. As part of this approach, slaughter plants must develop plans that identify the point (known as the critical control point) where they will take steps to prevent, eliminate, or reduce each hazard identified. Under FSIS regulations, all plants must also have site-specific standard operating procedures for sanitation. FSIS inspectors at slaughter plants routinely check records to verify a plant's compliance with those procedures. FSIS also has a verification testing program in which FSIS inspectors at slaughter plants collect samples of poultry products to determine whether a pathogen is present (known as positive rate). Test results help FSIS inspectors to verify that plant sanitation procedures are working and to identify and assist plants whose process controls may be underperforming.

¹⁴Reactive arthritis is a form of inflammatory arthritis that develops in reaction to an infection by bacteria and can last for years.

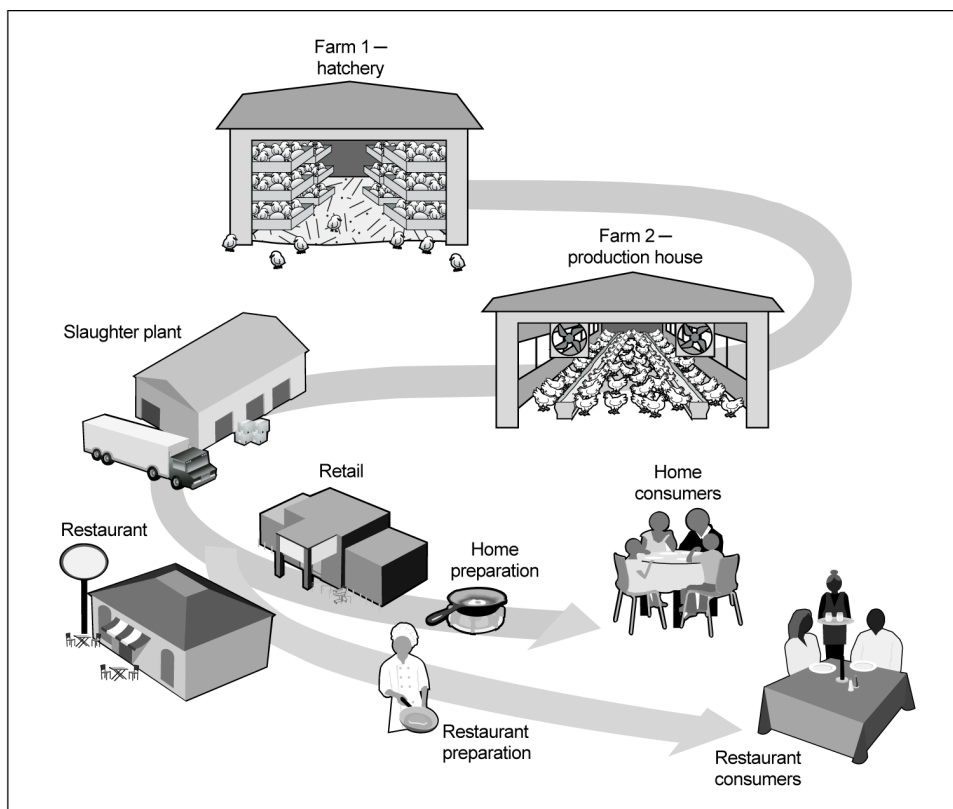
¹⁵61 Fed. Reg. 38806 (July 25, 1996).

FSIS coordinates with numerous federal agencies, state agencies, and local entities to help ensure a safe poultry product from the farm to the consumer (known as the farm-to-table continuum—see fig. 1).¹⁶ For example, on the farm, USDA’s Animal and Plant Health Inspection Service (APHIS) administers voluntary programs to evaluate and certify that poultry are free of certain diseases. FSIS coordinates with APHIS to share information when investigating foodborne illnesses. FSIS also works with the Department of Health and Human Services’ Food and Drug Administration (FDA) to, for example, approve chemical interventions that slaughter plants use to reduce or eliminate *Salmonella* and *Campylobacter*.¹⁷ FSIS also coordinates with CDC and state health departments to respond to foodborne illness outbreaks, among other things.

¹⁶The farm-to-table continuum for food safety includes all facets of the food production process: on the farm, animal slaughter in FSIS-regulated poultry plants, food processing within regulated plants, retail or market establishments (e.g., grocery stores), and home environments.

¹⁷Chemical interventions are processing aides, such as chlorine rinses, used to eliminate or reduce pathogens.

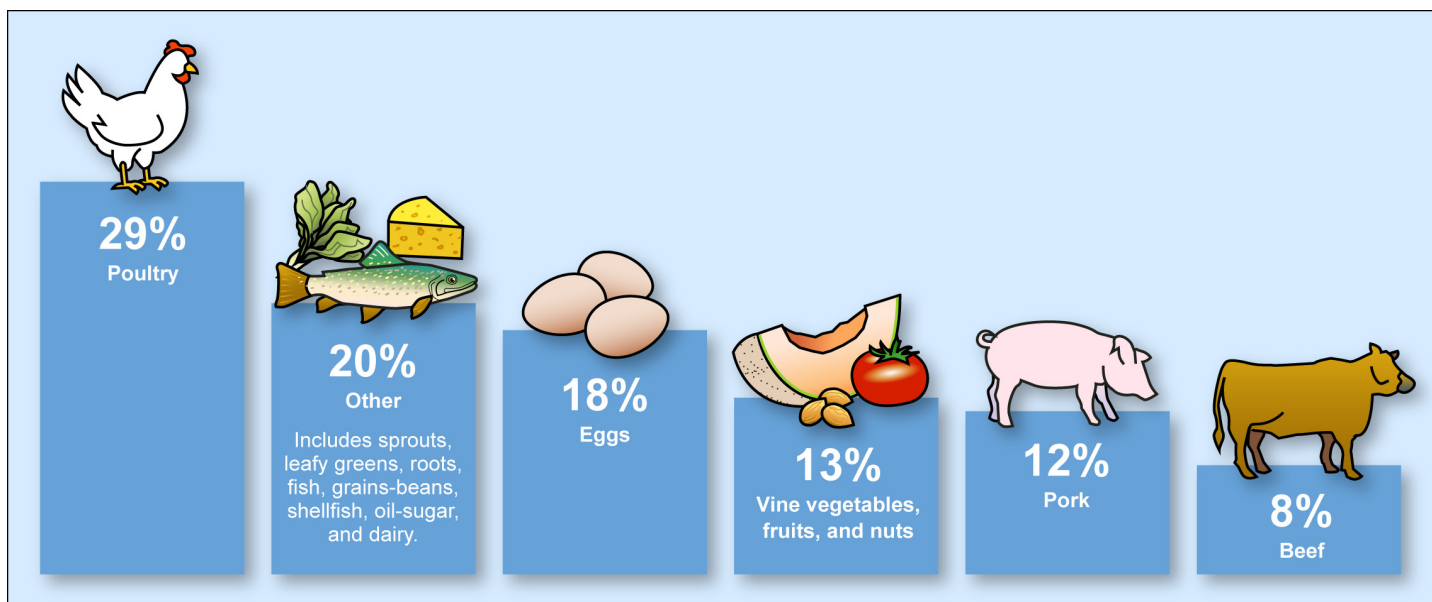
Figure 1: Farm-to-Table Continuum for Poultry Products



Sources: GAO and Centers for Disease Control and Prevention. | GAO-14-744

CDC coordinates with FSIS and others on investigations of multistate foodborne outbreaks. To identify an outbreak, CDC monitors data voluntarily reported from state health departments on cases of laboratory confirmed illness and conducts analyses to identify elevated rates of disease that may indicate an outbreak, according to CDC officials. CDC also analyzes and summarizes foodborne illness information on a national basis. According to CDC's website, determining the food source of human illness is an important part of improving food safety (see fig. 2). Moreover, analyses to estimate the number or proportion of specific foodborne illness associated with each food and nonfood source responsible for causing illness (known as foodborne illness source attribution) relies heavily on outbreak data, according to CDC officials.

Figure 2: Foods Associated with One-Third of *Salmonella* Outbreaks, 2004 through 2008



Source: GAO figure derived from Centers for Disease Control and Prevention data. | GAO-14-744

In addition to these coordination efforts, FSIS was a partner in the President's Food Safety Working Group. In 2009, this group recommended that FSIS develop new standards to reduce the prevalence of *Salmonella* in poultry and establish a goal of having 90 percent of poultry slaughter plants meeting the new *Salmonella* standards by the end of 2010.¹⁸ In consultation with the working group, FSIS also committed to developing *Campylobacter* standards.

¹⁸Prevalence is the proportion of poultry that would test positive for pathogens if the entire population of poultry products were sampled and analyzed during a specific period of time.

USDA Actions Have Largely Sought to Reduce *Salmonella* in Poultry, with *Campylobacter* More Recently Addressed

USDA's actions in recent years to reduce *Salmonella* and *Campylobacter* contamination in poultry products have largely focused on reducing *Salmonella*, with the agency addressing *Campylobacter* more recently and to a lesser degree.

For *Salmonella*, USDA Took Actions, Including Revising Existing Standards, Promoting Information Sharing, and Developing an Action Plan

Since 2006, USDA's FSIS has taken a number of actions intended to reduce *Salmonella* contamination in poultry products. These actions include revising existing *Salmonella* standards; taking steps to develop standards; promoting enhanced information sharing with industry; publicizing noncompliance for chicken slaughter plants not meeting the agency's *Salmonella* standards; developing a *Salmonella* Action Plan; and finalizing a rule to modernize the poultry slaughter inspection process.

Revising Standards

In March 2011, FSIS finalized revisions to the agency's *Salmonella* standards for young chicken and turkey carcasses to further limit the amount of allowable contamination.¹⁹ Specifically, the revised standards set the expectation that no more than 7.5 percent of a plant's young chicken carcasses (reduced from 20 percent) and 1.7 percent of a plant's young turkey carcasses (reduced from 19.6 percent) will be contaminated

¹⁹76 Fed. Reg. 15282 (Mar. 21, 2011). FSIS's revised *Salmonella* standards for young chicken and turkey carcasses took effect in July 2011. FSIS finalized these standards based on data it evaluated for young chickens from July 2007 through June 2008 and for young turkeys from August 2008 through July 2009. In this report, we use "young chickens" to refer to chickens raised for consumption that are less than 10 weeks of age at the time of slaughter and "young turkeys" to refer to turkeys raised for consumption that are less than 8 months of age at the time of slaughter.

with *Salmonella*.²⁰ When FSIS revised the standards, it also made corresponding changes to the maximum number of samples allowed to test positive for contamination during agency testing; the results from the agency's testing are used to determine whether or not a plant is in compliance with the agency's standards. Specifically, for young chicken carcasses, FSIS now allows a maximum of 5 out of 51 samples collected by the agency to test positive for *Salmonella*, compared with the previous allowed positive rate of 12 out of 51.²¹ Similarly, for young turkey carcasses, FSIS now allows a maximum positive rate of 4 out of 56 samples tested by the agency, compared with the previous allowed positive rate of 13 out of 56. To help industry meet these revised standards, FSIS issued an update to its compliance guideline for controlling *Salmonella* and *Campylobacter*.²² Specifically, the guidelines articulate how industry can meet FSIS expectations regarding control of food safety hazards, including control points for *Salmonella* and *Campylobacter*.

²⁰In 1996, FSIS established the first *Salmonella* standard for young chicken carcasses, which set the expectation that no more than 20 percent of a plant's young chicken carcasses will be contaminated with *Salmonella*. 61 Fed. Reg. 38806, 38867 (July 25, 1996) (codified at 9 C.F.R. § 381.94(b)(1), *rescinded by* 79 Fed. Reg. 49566, 49636) (Aug. 21, 2014). FSIS established this standard, as well as *Salmonella* standards for ground chicken and ground turkey, as part of a larger agency effort designed to reduce both the presence of poultry pathogens and the incidence of foodborne illnesses associated with the consumption of poultry products, among other things. In 2005, FSIS established its initial *Salmonella* standard for young turkey carcasses, which set the expectation that no more than 19.6 percent of a plant's young turkey carcasses will be contaminated with *Salmonella*. 70 Fed. Reg. 8058 (Feb. 17, 2005).

²¹The agency has set this maximum at a number that, when expressed as a percentage of the sample set, is higher than the percentage of allowable contamination stated in the standard. Therefore, if 5 out of the 51 (about 9.8 percent) samples collected by the agency actually test positive for *Salmonella*, the plant would still be in compliance even though it exceeds the agency's standard of 7.5 percent. According to FSIS, the number of samples tested and the number of positive results allowed from those samples were calculated to provide a plant with about an 80 percent chance of passing agency testing when the plant is operating just within the standards. Because the 51 samples are randomly selected, and the sample size is relatively small compared with total production, FSIS adopted this approach to minimize the chances of a false finding of noncompliance for plants that are operating within the agency's standard for young chicken carcasses.

²²FSIS, *Compliance Guideline for Controlling Salmonella and Campylobacter in Poultry*, 3rd ed. (May 2010). FSIS issued the updated guideline after initially announcing the agency's new *Salmonella* and *Campylobacter* standards in a May 2010 *Federal Register* notice. The guideline includes recommendations rather than regulatory requirements.

To verify a chicken slaughter plant's compliance with the agency's *Salmonella* standard, FSIS inspectors collect and test one young chicken carcass per day for 51 consecutive days and determine whether the number of positive results in that sample set of 51 is above the maximum allowed. For turkey slaughter plants, FSIS inspectors collect and test one young turkey carcass per day for 56 consecutive days and likewise determine whether the number of positive results is above the maximum allowed.

In addition, the agency has recently begun taking steps to strengthen its *Salmonella* standards for ground poultry. More specifically, in December 2012, FSIS announced that it planned to perform additional *Salmonella* sampling and testing of ground chicken and ground turkey products as part of an agency effort to revise the existing standards for those products—which currently set the expectation that no more than 44.6 percent of a plant's ground chicken and 49.9 percent of a plant's ground turkey will be contaminated with *Salmonella*.²³ FSIS officials told us the agency has begun performing additional *Salmonella* sampling and testing of these products. According to an April 2014 *Federal Register* notice, FSIS intends to announce and request comment in the *Federal Register* on the proposed revisions to the ground poultry standards before the end of fiscal year 2014.²⁴ (See table 1 for details regarding FSIS *Salmonella* standards for poultry products.)

²³77 Fed. Reg. 72686 (Dec. 6, 2012). According to FSIS research analysis documents, ground products may have a higher incidence of *Salmonella* than whole raw carcasses because the grinding process increases the surface area and distributes pathogen microorganisms, originally present only on the surface, throughout the product where the environment is favorable for their growth.

²⁴79 Fed. Reg. 22084 (Apr. 21, 2014).

Table 1: USDA *Salmonella* Standards for Poultry Products

Poultry product	Initial standard for maximum percentage of <i>Salmonella</i> contamination ^a (year set)	Maximum number of positive tests allowed during agency testing ^b	Current standard for maximum percentage of <i>Salmonella</i> contamination ^a (year updated)	Maximum number of positive tests allowed during agency testing ^b
Young chicken carcasses	20.0% ^c (1996)	12 out of 51 samples tested	7.5% (2011)	5 out of 51 samples tested
Young turkey carcasses	19.6% ^d (2005)	13 out of 56 samples tested	1.7% (2011)	4 out of 56 samples tested
Chicken and turkey parts (e.g., thighs, breasts, and wings)	None exists	Not applicable	None exists ^e	Not applicable
Ground chicken	44.6% ^c (1996)	26 out of 53 samples tested	44.6% (not updated) ^f	26 out of 53 samples tested
Ground turkey	49.9% ^c (1996)	29 out of 53 samples tested	49.9% (not updated) ^f	29 out of 53 samples tested
Mechanically separated chicken and turkey (used in products such as hot dogs and bologna) ^g	None exists	Not applicable	None exists ^h	Not applicable

Sources: GAO analysis of USDA *Federal Register* notices and agency documents. | GAO-14-744

^aThe percentage listed refers to the agency's maximum acceptable limit for *Salmonella* contamination expected at a plant.

^bUSDA's Food Safety and Inspection Service (FSIS) has set this maximum at a number that, when expressed as a percentage of the sample set, is higher than the percentage of allowable contamination stated in the standards. FSIS has done so in order to minimize the chances of falsely finding that plants are not operating within the standards.

^cFSIS codified its *Salmonella* standards for young chicken carcasses, ground chicken, and ground turkey in regulations in 1996. When the standards for young chicken carcasses, ground chicken, and ground turkey were set, FSIS was still collecting data on young turkey carcasses. 61 Fed. Reg. 38806, 38867 (July 25, 1996).

^dFSIS announced its *Salmonella* standard for young turkey carcasses in February 2005 and based the standard on data collected from July 1997 to June 1998.

^eThere are currently no *Salmonella* standards for raw poultry parts. FSIS has begun taking steps to develop a standard for raw chicken parts. According to a May 2014 letter from the Secretary of USDA, FSIS expects to announce and request comment on the proposed *Salmonella* standard for chicken parts by the end of fiscal year 2014.

^fAccording to an April 2014 *Federal Register* notice, FSIS intends to announce and request comment in the *Federal Register* on the proposed revisions to the standards for ground chicken and ground turkey products before the end of fiscal year 2014.

^gMechanically separated poultry is defined in FSIS regulations as any product resulting from the mechanical separation and removal of most of the bone from the attached skeletal muscle and other tissue of poultry carcasses, and as parts of carcasses that have a paste-like form and consistency, that may or may not contain skin with attached fat. 9 C.F.R. § 381.173(a).

^hThere are currently no *Salmonella* standards for mechanically separated poultry products. FSIS plans to develop standards for mechanically separated poultry by the end of fiscal year 2014.

Developing Standards

Since 2012, FSIS has taken steps to develop standards for poultry parts and mechanically separated poultry, for which there currently are no standards. For example, FSIS intends to develop a *Salmonella* standard for raw chicken parts.²⁵ According to FSIS officials, the agency is determining which chicken parts, such as thighs, breasts, and wings, will be subject to the new standard and intends to announce that information in a future *Federal Register* notice. Moreover, in June 2013, FSIS began additional *Salmonella* sampling to determine the estimated prevalence of *Salmonella* in mechanically separated poultry products. FSIS announced in April 2014 that it would continue to test samples of mechanically separated poultry products for *Salmonella* and analyze the results as part of the agency's efforts to develop *Salmonella* standards for those products.²⁶ According to the agency's December 2013 *Salmonella* Action Plan,²⁷ FSIS plans to complete a risk assessment,²⁸ which will be used to estimate the impact of this action, including any potential change in human health, and develop new standards for poultry parts and mechanically separated poultry by the end of fiscal year 2014.

Promoting Information Sharing

In January 2008, FSIS announced a voluntary initiative—known as the *Salmonella* Initiative Program—to improve controls for *Salmonella* and *Campylobacter* at young chicken and turkey slaughter plants.²⁹ Under this program, FSIS granted plants participating in the initiative waivers from certain regulatory requirements, such as time and temperature chilling requirements for when poultry carcasses are placed in a chiller,³⁰ in order to test new procedures, equipment, or processing techniques intended to reduce *Salmonella* contamination. In return for such waivers, participating

²⁵FSIS conducted a baseline survey of poultry plants producing raw chicken parts from January 2012 to August 2012 and used data collected from the samples to estimate prevalence of *Salmonella* in raw chicken parts.

²⁶79 Fed. Reg. 22084 (Apr. 21, 2014).

²⁷The plan details a priority list of actions the agency plans to undertake as part of its continued efforts to address *Salmonella* in poultry products.

²⁸A risk assessment is a systematic way of preparing, organizing, and analyzing information to help make regulatory decisions, establish programs, and prioritize research and development efforts.

²⁹71 Fed. Reg. 9772 (Feb. 27, 2006).

³⁰The chiller is the location where eviscerated carcasses—carcasses that have had internal organs and any processing defects removed—are chilled in order to inhibit microbial growth and meet the regulatory requirements of 9 C.F.R. § 381.66(b)(1).

Publicizing Noncompliance on Agency Website

plants agreed to collect their own product samples every day during each shift, test the samples for common foodborne pathogens including *Salmonella* and *Campylobacter*, and then share these data with FSIS. In July 2011, FSIS announced that plants operating under regulatory waivers previously granted by the agency would have to join the *Salmonella* Initiative Program in order to continue operating under those waivers.³¹ In September 2013, FSIS completed initial analyses of program data showing that participating plants have maintained consistent process controls to keep levels of *Salmonella* within the standards while operating under waivers from the time and temperature chilling requirements. FSIS reported that, as of June 2014, 158 of 281 (56 percent) poultry slaughter plants were participating in the program.

In February 2006, to encourage industry to produce safer poultry products, FSIS announced in a *Federal Register* notice that completed sample set results would be recorded in one of three categories based on the plants' ability to meet existing *Salmonella* standards.³² In general, according to an FSIS document on inspection methods, those plants in Category 1 are said to be demonstrating consistent process controls to meet the existing *Salmonella* standards and that plants in Categories 2 and 3 are not. Specifically, FSIS defines the three categories as follows:

- Category 1 plants have results from their two most recently completed sample sets that are at or below half of the existing standard, meaning, for example, that for young chicken carcasses, this would be 2 positive samples out of a set of 51;
- Category 2 plants have results from their most recently completed sample set that are higher than half of the existing standard but do not exceed the standard, meaning, for example, that for young chicken

³¹76 Fed. Reg. 41186 (July 13, 2011). Examples of the types of waivers previously granted by FSIS include those made for on-line reprocessing, the HACCP-Based Inspection Models Project, or other waivers that impact slaughter processes. Previously, FSIS established additional program criteria to which plants participating in the *Salmonella* Initiative Program must adhere, including that the number of samples collected by FSIS or by plant personnel that tests positive for *Salmonella* needs to be maintained at or below half the acceptable number of positive samples under the agency's existing standard. 73 Fed. Reg. 4767 (Jan. 28, 2008). FSIS based the program criteria on criteria initially developed in August 2007 for a prototype of the *Salmonella* Initiative Program.

³²71 Fed. Reg. 9772 (Feb. 27, 2006).

carcasses, this would be 3 to 5 positive samples out of a set of 51; and

- Category 3 plants have results from their most recently completed sample set that exceed the existing standard for *Salmonella*, meaning, for example, that for young chicken carcasses, this would be 6 or more positive samples out of 51.

In the February 2006 *Federal Register* notice, FSIS also announced that it would use the categories to determine the frequency of the agency's *Salmonella* verification testing. According to FSIS's sampling methodology, Category 1 plants are tested at least once every 2 years; Category 2 plants are scheduled for testing at least once a year until their category changes (e.g., a plant improves to Category 1); and Category 3 plants are scheduled for testing as close to continuously as possible until they produce better results and their category changes.

In addition, in a January 2008 *Federal Register* notice, FSIS announced that it planned to begin publishing on the agency's website the results for young chicken slaughter plants that were inconsistent in complying with existing *Salmonella* standards, stating that it believed making such information available to the public would provide an incentive to industry to attain "consistent, good control for *Salmonella*."³³ The agency began publishing this information on its website in March 2008. At present, FSIS publishes the names of young chicken slaughter plants that are in Category 3.³⁴ For example, in August 2014, FSIS published on its website the names of seven young chicken slaughter plants found to be in Category 3. Under FSIS policy, the names of young turkey slaughter plants not in compliance with the agency's young turkey standard can also be published on FSIS's website. As of August 2014, there are no names of turkey plants posted on the website because no turkey plants were in Category 3 based on recent testing.

³³73 Fed. Reg. 4767, 4770 (Jan. 28, 2008).

³⁴76 Fed. Reg. 15282 (Mar. 21, 2011). As noted above, FSIS started publishing monthly the names of young chicken slaughter plants that fell into Category 2 or Category 3 on the agency's website in March 2008. However, starting in July 2011, following implementation of FSIS's revised *Salmonella* standards for young chicken and turkey carcasses, the agency ceased publishing on its website the names of plants in Category 2.

Developing a *Salmonella* Action Plan

FSIS's *Salmonella* Action Plan, issued in December 2013, details a priority list of actions the agency plans to undertake as part of its continued efforts to address *Salmonella* in poultry products. According to the plan, FSIS intends to, among other things, (1) conduct food safety assessments at plants that produce ground and mechanically separated poultry products by the end of fiscal year 2014;³⁵ (2) consider modifying the way it publishes the category status of poultry plants, such as by publishing on its website the names of plants in Category 1 and Category 2, in addition to those in Category 3, by the end of fiscal year 2014; (3) develop new enforcement strategies that take into account plants' compliance history and *Salmonella* category under the standards, among other things, which, according to the plan, will take over a year to accomplish; and (4) host a meeting with APHIS and other stakeholders to focus on poultry farm practices that could help decrease *Salmonella* contamination on FSIS-regulated poultry products and use the information gathered to inform best practice guidelines, requiring the completion of additional actions prior to the meeting.³⁶

Finalizing a Rule to Modernize Poultry Slaughter Inspection

On August 21, 2014, FSIS published its final rule to amend the agency's poultry slaughter inspection process.³⁷ Young chicken and turkey slaughter plants may choose to operate under the new poultry inspection system included in the rule or may continue to operate under the current inspection system. According to FSIS's final rule, modernizing poultry slaughter inspections will play a role in reducing *Salmonella* and other poultry pathogen contamination. Currently, FSIS inspectors conduct a variety of duties at positions on and off the slaughter line. For example, FSIS inspectors positioned on the line conduct inspections of every poultry carcass and its parts for defects, and inspectors working off the line move freely about the plant and collect samples of carcasses to test

³⁵A food safety assessment is performed to assess the design and validity of food safety systems in a plant. Moreover, food safety assessments are conducted routinely and periodically and also "for cause" when prompted by sample results testing positive for pathogens, potential production and shipment of adulterated products, or any other high-priority food-safety-related incident.

³⁶The additional actions to be completed prior to the meeting include developing a document that, among other things, summarizes lessons learned from previous meetings discussing poultry and beef farm practices and continuing to work with members of industry on specific outbreaks to identify best practices they have developed for on-farm practices, according to FSIS's *Salmonella* Action Plan.

³⁷79 Fed. Reg. 49566 (Aug. 21, 2014). The final rule will take effect on October 20, 2014.

for pathogens (e.g., *Salmonella*); perform food safety checks, such as verifying that carcasses are free of fecal material; and ensure that carcasses comply with the agency's food quality standards for defects such as bruises on chickens, which do not affect food safety. For those poultry slaughter plants that choose to operate under the new poultry inspection system, plant employees would assume more responsibility for conducting the types of activities currently performed by FSIS inspectors on the slaughter line. For example, plant personnel would be responsible for identifying defects in carcasses, taking corrective actions if the defects can be corrected through trimming, and condemning unacceptable carcasses as part of on-line inspections. According to FSIS's final rule, these changes will allow FSIS to assign fewer inspectors for on-line inspections and allow inspectors to conduct more off-line inspections in plants operating under the new poultry inspection system. Moreover, according to the rule, the new poultry inspection system may facilitate reduction of pathogen levels in poultry by permitting FSIS to conduct more food-safety-related off-line inspection activities and allowing better use of FSIS inspection resources, among other things. In particular, in July 2014, FSIS issued an updated risk assessment that estimated that there would be a reduction of 3,980 *Salmonella* illnesses attributable to young chicken and turkey plants combined.³⁸

Other Actions

FSIS has also taken other actions that are intended to help reduce *Salmonella* contamination in poultry products. For example, in light of several *Salmonella* outbreaks associated with the consumption of ground turkey products, FSIS announced in a December 2012 *Federal Register* notice that it was requiring all poultry plants producing ground or mechanically separated chicken and turkey products to reassess their HACCP plans.³⁹ In May 2013, FSIS instructed its inspectors at plants

³⁸We did not analyze the updated risk assessment as part of this report. For our August 2013 report, we were unable to determine if the results of the previous risk assessment conducted by FSIS to estimate the public health impact of the proposed rule accurately stated the public health benefits because the risk assessment did not include sufficient detail about its methodology. See [GAO-13-775](#).

³⁹77 Fed. Reg. 72686 (Dec. 6, 2012). The agency's HACCP regulations require that every plant reassess the adequacy of its HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. In the agency's view, the occurrence of these recent *Salmonella* outbreaks represented a change in the sanitary conditions involved in the manufacture of these products and therefore a change that could affect the hazard analysis or alter the HACCP plans for ground and mechanically separated chicken and turkey products.

producing these types of products to verify that the plants had reassessed their HACCP plans. In addition, FSIS announced that it would expand its *Salmonella* verification testing program—which previously was limited to ground chicken and ground turkey—to include plants producing all forms of ground and mechanically separated chicken and turkey products.

For *Campylobacter*, USDA Established Standards and Began Considering Further Actions

FSIS began taking actions specifically aimed at reducing *Campylobacter* contamination in poultry products in 2011. Specifically, in July 2011, FSIS implemented the first standards that define the amount of allowable contamination from *Campylobacter* for young chicken and turkey carcasses.⁴⁰ Under the new standards, FSIS set the expectation that no more than 10.4 percent of a plant’s young chicken carcasses and 0.79 percent of a plant’s young turkey carcasses will be contaminated with *Campylobacter*. In addition, FSIS established maximum numbers of positive samples allowed during agency testing: 8 out of 51 samples for young chicken carcasses and 3 out of 56 samples for young turkey carcasses (see table 2).

Table 2: USDA *Campylobacter* Standards for Poultry Products

Poultry product	Current standard for maximum percentage of <i>Campylobacter</i> contamination ^a (year set)	Maximum number of positive tests allowed during agency testing ^b
Young chicken carcasses	10.4% (2011)	8 out of 51 samples tested
Young turkey carcasses	0.79% (2011)	3 out of 56 samples tested
Chicken and turkey parts (e.g., thighs, breasts, and wings)	None exists ^c	Not applicable
Ground chicken	None exists ^d	Not applicable
Ground turkey	None exists ^d	Not applicable
Mechanically separated chicken and turkey (used in products such as hot dogs and bologna)	None exists ^d	Not applicable

Sources: GAO analysis of USDA *Federal Register* notices and agency documents. | GAO-14-744

⁴⁰76 Fed. Reg. 15282 (Mar. 21, 2011). FSIS’s new *Campylobacter* standards for young chicken and turkey carcasses took effect in July 2011.

^aThe percentage listed refers to the agency's maximum acceptable limit for *Campylobacter* contamination expected at a plant.

^bUSDA's Food Safety and Inspection Service (FSIS) has set this maximum at a number that, when expressed as a percentage of the sample set, is higher than the percentage of allowable contamination stated in the standards. FSIS has done so in order to minimize the chances of falsely finding that plants are not operating within the standards.

^cAccording to a May 2014 letter from the Secretary of USDA, FSIS is working on developing a standard for *Campylobacter* for raw chicken parts and plans to announce the standard in the *Federal Register* by the end of fiscal year 2014.

^dAccording to a May 2014 letter from the Secretary of USDA, FSIS is investigating the appropriateness of *Campylobacter* standards for ground and mechanically separated poultry products.

FSIS is also considering other actions to address *Campylobacter* contamination in poultry products. According to FSIS officials, the agency plans to announce and request comment on a proposed standard for *Campylobacter* for raw chicken parts in the *Federal Register* by the end of fiscal year 2014. Furthermore, according to a May 2014 letter from the Secretary of USDA, FSIS is investigating the appropriateness of *Campylobacter* standards for ground and mechanically separated poultry products.

FSIS did not take actions specifically aimed at reducing *Campylobacter* contamination before 2011, in part, because the agency believed its actions to reduce *Salmonella* would also reduce other pathogens such as *Campylobacter*. Moreover, according to documents from FSIS and the National Advisory Committee on Microbiological Criteria for Foods, it was not until 2005 that the agency began using a less time-consuming and more reliable sampling method for determining the presence of *Campylobacter* on poultry products. In addition, the agency was concerned about the observed increases in *Salmonella* rates, such as an increase in the percentage of positive *Salmonella* results during agency testing from 11.5 percent in 2002 to 16.3 percent in 2005.

In Assessing Its Actions, USDA Does Not Have Measures for All Poultry Pathogen Standards to Track Progress in Protecting Human Health and Relies on Data with Limitations

To help assess the effects of the agency's actions on the incidence of human illnesses from *Salmonella* and *Campylobacter* contamination in poultry products, FSIS has developed performance measures and conducted research, but these efforts fall short in two ways: (1) the agency did not establish performance measures for certain commonly consumed poultry products or *Campylobacter* and (2) the agency has relied on data with limitations that affect their usefulness.

FSIS Did Not Establish Performance Measures for Certain Commonly Consumed Poultry Products or *Campylobacter*

First, consistent with requirements of the Government Performance and Results Act of 1993 (GPRA) to measure performance toward the achievement of agency strategic goals, FSIS established a performance measure for *Salmonella* contamination in young chicken carcasses. We previously concluded that performance measures, which typically have numerical targets, are important management tools that help an agency monitor and report progress toward its goals.⁴¹ FSIS's *Salmonella* measure indicates whether agency actions to ensure compliance with the applicable standard are helping the agency meet its goal. The agency's goal is to maximize domestic and international compliance with food safety policies, which aligns with USDA's objective of protecting public health by ensuring food is safe.⁴² Specifically, the measure tracks the percentage of poultry slaughter plants complying with the *Salmonella* standard for young chicken carcasses; the agency then compares this percentage to a target level of compliance to monitor progress in meeting its goal. For example, FSIS set the fiscal year 2013 target at 91 percent compliance and reported that 90 percent of plants complied with the

⁴¹GAO, *Homeland Security: An Overall Strategy Is Needed to Strengthen Disease Surveillance in Livestock and Poultry*, [GAO-13-424](#) (Washington, D.C.: May 21, 2013) and *Performance Management and Evaluation: Definitions and Relationships*, [GAO-11-646SP](#) (Washington, D.C.: May 2, 2011).

⁴²USDA, Food Safety and Inspection Service Strategic Plan Fiscal Year 2011-2016.

standard.⁴³ According to FSIS's 2011-2016 strategic plan and a National Academy of Sciences report, verification testing data available on the exposure of the public to raw poultry products contaminated with *Salmonella*, including young chicken carcasses, provide a reasonable proxy for the relative risk associated with those products.⁴⁴

However, the agency has not established similar performance measures and targets for other types of commonly consumed poultry products for which it has established *Salmonella* standards—that is, young turkey carcasses, ground chicken, and ground turkey. The agency has not established performance measures even though the standards for young turkey carcasses have been in place since 2005, with a revision in 2011, and the standards for ground chicken and ground turkey have been in place for more than a decade. The majority of poultry that industry markets and Americans consume is ready-to-eat and further processed products, such as ground poultry and poultry parts, according to the United States International Trade Commission 2014 report. *Salmonella*-contaminated ground poultry and poultry parts put consumers at greater risk of becoming ill than whole poultry carcasses because these products generally are more likely to be contaminated. As previously noted, FSIS is developing a *Salmonella* standard for raw chicken parts; therefore, the agency has not developed corresponding performance measures and targets. Moreover, FSIS has not established performance measures for *Campylobacter* contamination, even though it implemented standards for this pathogen in 2011. According to FSIS officials, at the time that the 2011 to 2016 strategic plan was written, FSIS had only recently implemented the first ever *Campylobacter* standards for poultry, and so the agency did not have a basis to create a performance measure for that pathogen. FSIS officials also stated that, in the absence of performance measures, the agency routinely collects and reviews data on individual plants' compliance with *Salmonella* and *Campylobacter* standards and reports quarterly the results of pathogen testing on its website. According

⁴³USDA, Fiscal Year 2013 Annual Performance Report. According to USDA, the target was set as an attainable target based on the agency's assessment of industry performance when it revised the standard in 2011, and past agency experience with industry's response to *Salmonella* policies.

⁴⁴Institute of Medicine of the National Academies, *Review of the Use of Process Control Indicators in the FSIS Public Health Risk-Based Inspection System: A Letter Report* (Washington, D.C.: The National Academies Press, 2009).

to FSIS officials, these data are sent to FSIS leadership, and trends are highlighted, as appropriate.

FSIS officials agreed that performance measures and targets should be developed for additional poultry products and stated that the agency will review its current strategic plan to determine what further updates are needed, namely new performance measures for ground chicken and ground turkey. As previously mentioned, FSIS established *Salmonella* standards for ground chicken and ground turkey in 1996, and the agency has yet to establish corresponding performance measures and targets. According to FSIS officials, it is not appropriate for the agency to set a performance measure or target for *Salmonella* contamination in ground chicken or ground turkey until it finishes revising the standards for those products, which it expects to do by the end of fiscal year 2014. In addition, for *Campylobacter* contamination in young chicken and turkey carcasses, FSIS officials told us that the agency has not developed performance measures in part because it is still in the process of developing plant categories, similar to those for *Salmonella*,⁴⁵ to determine levels of plant compliance with *Campylobacter* standards. The agency will publish *Campylobacter* categories before December 31, 2014, according to FSIS's fiscal year 2014 annual performance plan. FSIS officials told us that the agency has not developed a performance measure for determining the agency's success in controlling *Salmonella* in young turkey carcasses because testing data have shown that young turkey plants where the agency has routinely collected and reviewed data are meeting the standard. However, FSIS stated in its fourth quarter calendar year 2013 report on pathogen testing that 2 out of 35 (about 6 percent) of the turkey slaughter plants were in Category 3, meaning these plants did not meet the standard. In July 2014, FSIS officials told us these plants are no longer in Category 3 based on recent testing. However, without performance measures and targets for compliance with standards for these pathogens in commonly consumed poultry products, FSIS cannot quantitatively gauge its progress in assessing the effects of its actions related to these standards toward meeting the agency's goal of maximizing domestic compliance with food safety policies and, ultimately,

⁴⁵According to FSIS documents, those plants in Category 1 are said to be demonstrating consistent process controls to meet the existing *Salmonella* standards while plants in Categories 2 and 3 are not maintaining consistent process controls.

protecting public health.⁴⁶ Performance measures and targets are reported in the agency's strategic and annual plans but, in the absence of such measures and targets, performance information such as the trends supplied to FSIS leadership, is not being publicly reported. Without publicly reporting such information, FSIS loses the opportunity to enhance transparency by providing this information to the public and Congress about its progress in meeting this important goal, potentially limiting oversight and accountability.⁴⁷

In addition to the performance measure for young chicken carcasses, FSIS established, in 2009, an "all-illness" performance measure to evaluate its efforts to reduce foodborne human illness resulting from consumption of FSIS-regulated products contaminated with *Salmonella* and two other pathogens.⁴⁸ According to FSIS officials, the all-illness measure is an estimate of the number of illnesses from these pathogens resulting from the consumption of all FSIS-regulated products—including meat, poultry, and processed egg products. The officials said FSIS develops this estimate using CDC laboratory-confirmed illness data, CDC outbreak data, U.S. census data, and foodborne illness estimation data from a CDC peer-reviewed publication. The all-illness measure has an associated target level of performance, set by the agency, for the maximum number of human illnesses from these pathogens attributed to

⁴⁶As we have previously found, without performance measures, agencies cannot determine whether the activities they are carrying out are accomplishing the goals they intend to achieve. See GAO, *Results Oriented Government: GPRA Has Established a Solid Foundation for Achieving Greater Results*, [GAO-04-38](#) (Washington, D.C.: Mar. 10, 2004).

⁴⁷As we have previously reported, having pertinent and reliable performance information available is necessary for Congress to adequately assess agencies' progress in making performance and management improvements and ensure accountability for results. GAO, *Managing for Results: A Guide for Using the GPRA Modernization Act to Help Inform Congressional Decision Making*, [GAO-12-621SP](#) (Washington, D.C.: June 15, 2012).

⁴⁸According to USDA, *Salmonella* is the largest component of the measure, representing 92 percent of foodborne human illnesses from the three pathogens. The two other pathogens are *Listeria* and *Escherichia coli* O157:H7 (*E. coli*).

FSIS-regulated products.⁴⁹ For example, FSIS set the fiscal year 2013 target at 394,770 human illnesses from the three pathogens, including *Salmonella*. USDA reported in 2013 that FSIS did not meet its target; there were 427,171 human illnesses. As part of the all-illness measure, FSIS also set individual targets for the maximum number of human illnesses from each of the three pathogens attributed to FSIS-regulated products, including a *Salmonella* target. The annual report did not break out the results for each of the three pathogens, but the agency's fiscal year 2013 year-in-review report showed that FSIS did not meet the *Salmonella* target specifically. According to FSIS officials, historically the agency has not met the *Salmonella* target for the all-illness measure. However, recent actions FSIS has taken and plans to take are intended to address human illnesses from *Salmonella* attributed to FSIS regulated products, according to the agency's *Salmonella* Action Plan.

FSIS Has Relied on Data with Limitations That Affect Their Usefulness

According to USDA's National Advisory Committee on Microbiological Criteria for Foods, which provides impartial, scientific advice to federal food safety agencies,⁵⁰ the impact of FSIS's regulatory activities on the incidence of human illnesses from pathogens cannot be measured directly because of limitations in the foodborne illness attribution data the agency uses.⁵¹ For example, the outbreak data available from CDC

⁴⁹FSIS links the target level of performance to the Healthy People 2020 goals. Healthy People 2020 provides a set of goals and objectives with 10-year targets, designed to guide national health promotion and disease prevention efforts, improving the health of all people in the United States. FSIS collaborated with the Department of Health and Human Services when the department developed human health goals for *Salmonella* and *Campylobacter*. The Healthy People 2020 goal for *Salmonella* illnesses is 11.4 cases per 100,000 people, an increase from 6.8 cases per 100,000 people—the Healthy People 2010 goal. For *Campylobacter*, the 2020 goal is 8.5 cases per 100,000 people.

⁵⁰The National Advisory Committee on Microbiological Criteria for Foods was established in 1988 to advise the Secretaries of Agriculture and Health and Human Services. The committee covers public health issues relative to the safety and wholesomeness of the U.S. food supply, including development of microbiological criteria, as well as evaluation of data and methodologies for assessing microbiological hazards in foods. The committee's work also assists the CDC and the Departments of Commerce and Defense. The committee is the outcome of recommendations from the National Academy of Sciences and U.S. House of Representatives Committee on Appropriations.

⁵¹National Advisory Committee on Microbiological Criteria for Foods. "Response to Questions Posed by the Food Safety and Inspection Service Regarding Determination of the Most Appropriate Technologies for the Food Safety and Inspection Service to Adopt in Performing Routine and Baseline Microbiological Analyses," *Journal of Food Protection* 73, no. 6 (2010).

depend on voluntary reporting of illnesses and do not always identify the food product that caused an outbreak; we have previously found limitations in these data, including delayed reporting and incompleteness.⁵² According to FSIS officials, as with most performance measures that seek to evaluate human health outcomes, the all-illness measure is subject to limitations based on the availability of data and the challenges in capturing accurate foodborne illness attribution. In commenting on this report, USDA agreed that there are limitations in the data but stated the agency uses the best available data. FSIS is considering including *Campylobacter* in the all-illness measure as well, but there is no broadly accepted estimate for the proportion of illnesses attributed to *Campylobacter*, according to FSIS officials.

In 2011, FSIS, CDC, and FDA formed an interagency group to improve food safety data and coordinate analyses. Some of the group's efforts involve identifying links between contamination of poultry products and human illness, among other things.⁵³ For example, FSIS, CDC, and FDA are working collaboratively to perform a detailed analysis of data on *Salmonella* outbreaks to better estimate the proportion of human illnesses caused by different food sources, including poultry products. According to FSIS officials, this effort will assist in better estimating the proportion of *Salmonella* illnesses associated with poultry products, and the agencies plan to present results from ongoing projects in 2015.

In addition to performance measures, FSIS conducted research to assess the effects of its actions on the incidence of human illnesses from the consumption of poultry products, but this research also has data limitations. For example, in February 2012, after revising its *Salmonella* standards for young chicken carcasses, FSIS completed research

⁵²GAO, *Food Safety: CDC Is Working to Address Limitations in Several of Its Foodborne Disease Surveillance Systems*, [GAO-01-973](#) (Washington, D.C.: Sept. 7, 2001). FSIS officials acknowledged that the all-illness performance measure depends on data from CDC, and these data have several limitations when used for foodborne illness attribution. For example, the data do not always identify the food product that caused the outbreak, data are not complete because CDC relies on states voluntarily reporting outbreak data, and outbreak data are not readily available due to delayed reporting.

⁵³In 2011, FSIS, CDC, and FDA formed the chartered Interagency Food Safety Analytics Collaboration which is focused on analytic collaboration on foodborne illness attribution. The group operates with the understanding that data improvements and development of multiple analytic methods are needed to generate good estimates across the broad range of food commodities and along all points in the food supply chain.

evaluating whether reductions of *Salmonella* contamination from young chicken carcasses across the industry would offer public benefits, in the form of reduced human illness rates.⁵⁴ However, in attempting to evaluate the effect of reductions of *Salmonella* contamination across the industry, FSIS relied on its verification testing data from individual plants, which the agency later concluded in April 2012 cannot be used to estimate prevalence across the industry because the agency does not randomly select plants for verification testing, among other things.⁵⁵ FSIS also used CDC outbreak and individual illness case data in its research to identify the number of human illness from *Salmonella* contamination but, as we mentioned above, these data do not always distinguish illnesses derived from poultry products specifically.

While FSIS's research efforts are a positive step, data limitations make it difficult to directly correlate agency actions to reductions in the rates of human illness from poultry products contaminated with *Salmonella*. To help address these limitations, FSIS has taken steps, such as developing a statistical model in 2012, to estimate the reduction in human illnesses from revised *Salmonella* and newly created *Campylobacter* standards.⁵⁶ More importantly, in 2013, FSIS created a new testing approach for ground poultry to estimate prevalence of *Salmonella*, among other things. According to FSIS officials, the new verification testing program includes continuous weekly sampling and testing at all poultry slaughter plants producing raw ground poultry and increases the sensitivity of analysis so that lower levels of contamination can be detected. FSIS officials told us that the agency plans to expand this approach to other poultry products. According to FSIS's working group on prevalence estimates, testing for prevalence is necessary in order for the agency to effectively measure or understand how contamination rates change over time; set standards; develop targeted interventions; and measure the agency's performance toward meeting FSIS long-term strategic goals. The new testing approach

⁵⁴FSIS, *A comparison of Salmonella serotype incidence in FSIS-regulated products and salmonellosis cases*, February 2012.

⁵⁵FSIS, *Use of FSIS Regulatory Verification Sampling to Generate Prevalence Estimates*, April 2012.

⁵⁶Ebel, et.al. "Simplified framework for predicting changes in public health from performance standards applied in slaughter establishment," *Food Control* 28 (2012), 250-257.

using continuous sampling affords a more direct measure of prevalence across the industry, according to FSIS officials.

USDA Faces Several Challenges in Reducing *Salmonella* and *Campylobacter* in Poultry Products across the Farm-to-Table Continuum

Limited Control Outside of Plants

We identified several challenges that FSIS faces in reducing *Salmonella* and *Campylobacter* contamination in poultry products and one potential challenge. These include limited control outside of slaughter plants, pathogens not designated as hazards, limited enforcement authority,⁵⁷ absence of mandatory recall authority, outdated or nonexistent standards, insufficient prevalence estimates, the complex nature of *Salmonella*, and limited *Campylobacter* research and testing. We identified these challenges and the potential challenge based on our analyses and the views of representatives of 11 stakeholder groups, a number of academic researchers, and FSIS officials; the stakeholder groups representing consumers and those representing industry generally had differing views.

FSIS faces a challenge in reducing *Salmonella* and *Campylobacter* contamination in poultry products outside of slaughter plants because the agency does not have regulatory jurisdiction over (1) farm practices to reduce contamination in live poultry before they reach a plant or (2) some factors that may affect contamination of poultry products once they leave a plant. According to FSIS officials, they would like to address on-the-farm problems, but the agency is limited in its activities related to farms because its jurisdiction starts when products enter slaughter plants. In 2010, FSIS published updated compliance guidelines that detail, among other things, several on-farm practices to reduce *Salmonella* and *Campylobacter* in live poultry. For example, the guidelines recommend that farms test water to make sure it is free of pathogens and ensure water stations are free of leaks. As of July 2014, FSIS's compliance guidelines do not discuss the effectiveness of each recommended practice to reduce pathogens in live poultry. Thus, FSIS has not provided complete information to the poultry industry about the potential benefits of adopting certain practices. In contrast, when the agency developed guidelines for on-farm practices for reducing *E. coli* O157:H7 in beef cattle, it described several practices and their effectiveness.

In 2011, USDA's National Advisory Committee on Meat and Poultry Inspection recommended that (1) FSIS coordinate with APHIS, among

⁵⁷We identified limited enforcement authority as a potential challenge, rather than a challenge, because FSIS officials told us that the agency has tools to overcome enforcement authority limitations.

other agencies, to develop best practices on the farm and (2) develop compliance guidelines for livestock and poultry producers, including information on the effectiveness of the practices in controlling pathogens.⁵⁸ Representatives from two consumer groups told us that because the poultry industry is vertically integrated—meaning that individual poultry companies own or contract for all phases of production and processing—it is well suited to implement on-farm best practices to help ensure healthier birds prior to slaughter. As previously mentioned, according to FSIS’s December 2013 *Salmonella* Action Plan, the agency will continue to work with industry to identify on-farm best practices, host a meeting with APHIS and other stakeholders to focus on on-farm practices that could help decrease *Salmonella* contamination on FSIS-regulated poultry products, and use the information gathered from these actions to inform future policies and compliance guidelines. FSIS officials told us that the agency is currently working with stakeholders such as FDA and APHIS to gather information about on-farm practices. However, even with the planned actions identified in the agency’s *Salmonella* Action Plan, it remains unclear whether FSIS intends to incorporate information on the effectiveness of all practices in the guidelines as the National Advisory Committee on Meat and Poultry Inspection recommended. FSIS officials told us that the agency will publish another revision of the compliance guidelines by the end of calendar year 2014 but did not respond when asked directly about whether they would incorporate such information. Without providing information on the effectiveness of these practices in future guidelines, FSIS is not fully informing industry of the potential benefits of adopting them to encourage implementation of recommended practices.

In addition to not having regulatory jurisdiction over reducing contamination in live poultry before they reach a plant, once poultry products leave the plant,⁵⁹ factors beyond FSIS’s control may affect

⁵⁸Established in 1971, the National Advisory Committee on Meat and Poultry Inspection advises the Secretary of Agriculture on matters affecting federal and state inspection program activities. National Advisory Committee on Meat and Poultry Inspection, *Final Report – NACMPI Recommendations for FSIS on Pre-Harvest Salmonella* (Washington, D.C.: September 2011).

⁵⁹However, after poultry products leave a plant, FSIS has authority to ensure that poultry products are correctly labeled and packaged.

Pathogens Not Designated as Hazards

contamination of poultry products. For example, cross-contamination⁶⁰ from poultry products can occur at retail establishments, in restaurants, and in consumers' homes, according to a food safety researcher we interviewed. According to FSIS officials, the agency has been aggressive in educating consumers on the importance of safe handling of raw poultry products, such as through an advertising campaign and changes to the safe handling label. In 2014, FSIS proposed enhancing the safe food handling label for poultry products packaged for consumers to include updated information on proper handling.

FSIS faces a challenge in reducing *Salmonella* and *Campylobacter* contamination in poultry products when these pathogens are not designated as hazards by slaughter plants. Under the HACCP approach, plants have discretion about whether to include *Salmonella* or *Campylobacter* as a hazard "reasonably likely to occur" in their HACCP plans and develop mitigation strategies to reduce these pathogens in poultry products.⁶¹ Representatives from all six consumer groups we interviewed stated that this approach is not adequate to keep contamination levels below standards. In contrast, representatives from all four industry groups we interviewed stated that the current voluntary designation is sufficient. Moreover, representatives from two industry groups we interviewed said that HACCP has proven itself to work well in lowering contamination in poultry products. In the five outbreaks we reviewed, FSIS found that plants linked to three of the four *Salmonella* outbreaks had inadequate HACCP plans because they had not appropriately designated *Salmonella* as a hazard reasonably likely to occur. For example, in 2011, FSIS investigated a company's plant linked to an outbreak from ground turkey and determined that the plant was in violation of federal regulation because it failed to identify hazards reasonably likely to occur, namely *Salmonella*. In a 2013 outbreak we

⁶⁰Cross-contamination occurs when bacteria spread from a food to a surface, from a surface to another food, or from one food to another.

⁶¹Federal regulations require plants to conduct a hazard analysis to determine food safety hazards "reasonably likely to occur" in the production process and identify the preventive measures the plant can apply to control those hazards. According to FSIS directive 5000.6, Rev.-1, all plants must conduct a hazard analysis that is an evaluation by a plant of its operations to determine the food safety hazards specific to the plant's operations that, if not controlled, are reasonably likely to occur and to cause injury or illness. Some plants may not have a HACCP plan because they can support that there is not a food safety hazard that is reasonably likely to occur; instead, the plants would maintain a record of their hazard analysis for inspection purposes.

reviewed, FSIS issued a “Notice of Intended Enforcement” action, which warns the plant before the initiation of a specific enforcement action, based on the company’s inability to support why it had not designated *Salmonella* as a hazard reasonably likely to occur in its HACCP plan. FSIS officials we interviewed believe the agency should require plants to identify *Salmonella* and *Campylobacter* in their HACCP plans as hazards reasonably likely to occur.⁶² FSIS’s final rule for modernizing poultry slaughter inspection requires plants to develop, implement, and maintain written procedures to prevent contamination by enteric pathogens,⁶³ such as *Salmonella* and *Campylobacter*.

Limited Enforcement Authority

FSIS faces a potential challenge in reducing *Salmonella* contamination in poultry products because, according to the agency and some stakeholder groups, its authority to enforce its *Salmonella* standards is limited for two reasons: (1) a federal court ruling and (2) FSIS has not classified *Salmonella* as an adulterant in raw poultry products.⁶⁴

First, in 2000, a federal court ruled that FSIS could not withdraw inspectors, which would effectively shut down the plant, based solely on a plant’s failure to meet *Salmonella* standards. A federal appeals court

⁶²In addition, CDC officials told us its data show that, in 2002, 6 years after the HACCP/Pathogen Reduction Rule had been introduced, they found no change in the incidence of *E. coli* O157:H7 and that CDC was investigating many *E. coli* O157:H7 outbreaks due to contaminated ground beef. In that year, FSIS noticed that HACCP plans from meat grinding operations rarely included *E. coli* O157:H7 as an explicitly named hazard. Later that year, FSIS directed all U.S. meat grinders to declare *E. coli* O157:H7 explicitly in their HACCP plans. According to CDC officials, in 2003 there was a major drop in *E. coli* O157:H7 infections and FSIS noted a significant drop in frequency of contamination of ground beef with *E. coli* O157:H7.

⁶³79 Fed. Reg. 49566 (Aug. 21, 2014). Enteric pathogens are bacteria that reside normally in the guts of many animals, including humans, and some are pathogenic, causing disease in certain animal species.

⁶⁴FSIS defines an adulterant in meat and poultry products to include “any substance that contains any poisonous or deleterious substance which may render it injurious to health.”

upheld the decision in 2001.⁶⁵ Subsequently, the agency adopted the position that the court ruling did not affect its ability to use the standards as part of verifying a plant's sanitation and HACCP plans. For example, after a plant fails *Salmonella* testing for its first sample set, FSIS can require a reassessment of the plant's HACCP plan and then conduct a food safety assessment (evaluation of a plant's food safety system);⁶⁶ conduct additional sampling; or issue a "Notice of Intended Enforcement" action, according to FSIS officials. FSIS can also condemn products that are contaminated with filth (or otherwise adulterated) or mislabeled, or it can condemn parts of products,⁶⁷ and detain them so they cannot progress down the marketing chain. Even with these tools, representatives from four out of six consumer groups we interviewed told us that the agency does not have sufficient authority to ensure plants comply with FSIS's standards because FSIS cannot shut down plants when they fail *Salmonella* standards alone. Representatives of all four industry groups we interviewed disagreed and stated that FSIS has sufficient authority to ensure plants comply with standards because the agency has broad statutory authority and oversight.

⁶⁵Supreme Beef Processors v. U.S. Dep't of Agric., 113 F. Supp. 2d 1048 (N.D. Tex. 2000). A federal appeals court upheld this decision in 2001. The appeals court held that USDA's *Salmonella* standards conflict with the agency's authority to enforce the prohibition against meat or meat products prepared, packed, or held in insanitary conditions and the agency could not use *Salmonella* verification tests results on products alone to determine whether a plant was in compliance with sanitary requirements. Supreme Beef Processors v. U.S. Dep't of Agric. 275 F. 3d 432 (5th Cir. 2001). On a day-to-day basis, if an FSIS inspector finds plant conditions or procedures insanitary, the inspector can refuse to perform inspection and temporarily suspend the plant's operation until the problem is corrected.

⁶⁶As previously noted, FSIS's final rule for modernizing poultry slaughter inspection requires plants to develop, implement, and maintain written procedures to prevent contamination by *Salmonella* and *Campylobacter*.

⁶⁷The carcass of a whole raw chicken or turkey that failed inspection would undergo a cutting process for removal of the part of the whole bird that caused inspection failure, and the part is condemned as contaminated.

Second, because FSIS has not classified *Salmonella* as an adulterant in raw poultry products, products contaminated with this pathogen generally are permitted to enter commerce.⁶⁸ However, according to FSIS officials, the agency can consider raw poultry products contaminated with *Salmonella* as adulterated on a case-by-case basis—for example, during a voluntary recall, as discussed later in this report. Representatives from five out of six of the consumer groups we interviewed said they believe that some serotypes of *Salmonella* should be declared an adulterant, such as those with specific antibiotic-resistance patterns. According to CDC officials, antibiotic resistance can be associated with a higher risk of hospitalization in infected individuals. For example, in two of the four *Salmonella* outbreaks we reviewed, ill persons were hospitalized twice as frequently as is normally seen in *Salmonella* outbreaks, according to CDC officials. Since 2013, more than a dozen consumer groups have supported a petition for FSIS to declare specific antibiotic-resistant serotypes of *Salmonella* as adulterants when found in poultry. In July 2014, FSIS denied one of the consumer group’s petitions to have antibiotic-resistant *Salmonella* declared an adulterant.⁶⁹ FSIS officials told us that they have found no conclusive scientific evidence that antibiotic-resistant strains⁷⁰ of *Salmonella* or *Campylobacter* have a greater resistance to interventions currently used in FSIS-inspected poultry plants, but the agency continues to review the relevant scientific evidence to identify any potential challenges that these serotypes may present to public health.

⁶⁸In contrast, raw beef products contaminated with any level of *E. coli* O157:H7 are not permitted to enter commerce since this pathogen is classified as an adulterant. FSIS declared this serotype of *E. coli* an adulterant in beef—the first time a foodborne pathogen on raw product was declared an adulterant under meat inspection law—after the 1992-1993 Jack-in-the-Box incident, which sickened more than 500 people and killed four children. The symptoms for *E. coli* vary for each person but often include severe stomach cramps, diarrhea, and vomiting.

⁶⁹On July 31, 2014, FSIS announced that the agency denied the Center for Science in the Public Interest’s petition to declare antibiotic-resistant *Salmonella* as an adulterant. On May 28, 2014, the Center for Science in the Public Interest filed a lawsuit to compel FSIS to respond to a petition it submitted on May 25, 2011, that requested FSIS declare specific antibiotic-resistant patterns of *Salmonella* as adulterants when found in ground poultry. The four strains of antibiotic-resistant *Salmonella* subject to the petition are *Salmonella* Hadar, *Salmonella* Heidelberg, *Salmonella* Newport, and *Salmonella* Typhimurium. The Center for Science in the Public Interest is a nonprofit, nongovernmental consumer advocacy organization focused primarily on nutrition, health, and food safety issues.

⁷⁰A strain refers to a specific biologic version of a microorganism, such as bacteria, within a specific serotype defined by its genetic makeup identified through DNA fingerprinting.

Representatives from a government employee stakeholder group we interviewed said that rather than classifying all of *Salmonella* an adulterant in raw poultry products, FSIS should consider the top *Salmonella* serotypes causing most human illnesses. For example, the representatives said that FSIS should consider declaring a narrow range of *Salmonella* serotypes in select raw poultry products as adulterants similar to the classification of *E. coli* O157:H7 as an adulterant in beef. CDC has identified three *Salmonella* serotypes in poultry associated with causing the highest number of human illnesses: *Salmonella* Enteritidis, *Salmonella* Typhimurium, and *Salmonella* Heidelberg. According to FSIS's risk-based inspection protocols, FSIS considers the top *Salmonella* serotypes identified through CDC data when ranking plants to determine the frequency of verification testing and inspections. Moreover, according to FSIS documents, the agency provides plants with data on which *Salmonella* serotypes were identified through verification testing. FSIS officials told us prior court cases have set a precedent that the presence of *Salmonella* in raw poultry products is not sufficient to declare the pathogen an adulterant because *Salmonella* can be killed through proper cooking.

Representatives from all four industry groups we interviewed disagreed that any serotypes of *Salmonella* should be classified as adulterants for several reasons. Representatives from two industry groups told us rapid identification of the serotype is not available and that it can take several weeks for FSIS to identify specific serotypes from positive *Salmonella* verification test results. Representatives from another industry group we spoke with said *Salmonella* is already classified as an adulterant in fully cooked poultry products and that, for raw poultry products, FSIS includes instructions on proper handling and thorough cooking to prevent cross-contamination and eliminate the pathogen. In contrast with *Salmonella*, *Campylobacter* has received less attention from FSIS and stakeholder groups, in part because the pathogen is not frequently associated with outbreaks, making it difficult to attribute illnesses to this pathogen.

No Mandatory Recall Authority

FSIS faces a challenge in reducing *Salmonella* and *Campylobacter* contamination in poultry products because it does not have mandatory food recall authority similar to that of FDA. In 2011, Congress passed the FDA Food Safety Modernization Act, giving FDA mandatory recall authority. We recommended in October 2004 that Congress should consider legislation to increase FSIS's authority to include mandatory recalls, but the agency continues not to have such enforcement authority.⁷¹ Instead, FSIS can issue public health alerts⁷² or request voluntary recalls,⁷³ among other actions, to protect human health from potentially contaminated meat and poultry products. Before requesting a voluntary recall, FSIS must gather sufficient evidence through its investigation and determine that a product is adulterated or mislabeled, among other things.⁷⁴ According to FSIS officials, the agency requests a voluntary recall when the agency links a product to an ill person and obtains specific information on the source of the product (plant), product type, production date, and product distribution. In the five outbreaks we reviewed, three of the five companies voluntarily recalled or stopped distributing poultry products implicated in outbreaks before FSIS requested a recall. For the fourth outbreak, in July 2014, FSIS requested that Foster Farms conduct a voluntary recall of select chicken parts involved in an outbreak, which had been ongoing since March 2013, after definitively linking the product to an ill person; the company recalled the products. By contrast, in the fifth outbreak, CDC reported that

⁷¹GAO, *Food Safety: USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food*, [GAO-05-51](#) (Washington, D.C.: Oct. 7, 2004).

⁷²If FSIS personnel have reason to believe that a meat or poultry product may be associated with human illnesses, but they cannot identify a specific product that FSIS could recommend be recalled, then FSIS can issue a public health alert to notify the public including actions to take to avoid illnesses.

⁷³Such recalls are voluntary actions taken by plants under the direction of their company. When companies discover that they may have distributed food that is contaminated with disease-causing bacteria, or that contains allergens that can cause serious illness or death, they will usually conduct a voluntary recall. That is, they will contact their customers and instruct them to contact the wholesalers, retailers, and others in the food's distribution chain and ask them to return or destroy the potentially unsafe food. If a plant conducts a recall, FSIS provides assistance and monitors the recall. If a plant does not conduct a recall that FSIS has requested, FSIS is limited to its authority to detain and seize the products in question.

⁷⁴FSIS's recall committee determines the reason a particular product may need to be removed from commerce and whether there is a statutory basis to recommend a voluntary recall.

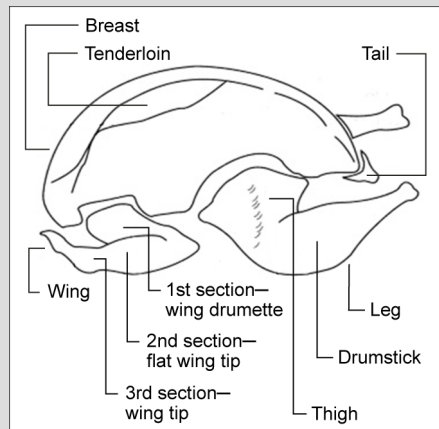
collaborative investigative efforts by local, state, and federal officials indicated that Foster Farms chicken products were the most likely source of an outbreak of *Salmonella* Heidelberg that took place from June 2012 until May 2013. However, FSIS did not request, and Foster Farms did not conduct, a voluntary recall because the agency was unable to definitively link the company's product to an ill person (see app. II). FSIS officials told us that, rather than focusing on the lack of mandatory recall authority, it is more productive to work aggressively with the tools they have. For example, FSIS officials told us that withdrawing inspectors or withholding the agency's mark of inspection, thus preventing poultry products from entering commerce, can be as effective and faster tool for keeping unsafe food from the marketplace than FDA's recall authority.⁷⁵

⁷⁵FSIS applies the official mark of inspection to all meat and poultry products produced under federal inspection. The presence of the official mark of inspection indicates that the product was produced in compliance with federal regulations and under federal oversight.

Outdated or Nonexistent Standards

Poultry Production and Consumption

U.S. consumption of poultry products (chicken and turkey) is considerably higher than pork or beef, but less than total red meat consumption. According to USDA's Economic Research Service, the U.S. poultry industry is the world's largest producer and the second-largest exporter of poultry. Before the 1970s, poultry was largely retailed on a "whole bird" basis. For example, chicken meat sold as parts, such as wings and breasts, was a small component of the domestic U.S. market. Chicken meat retailed as parts came about largely as a consequence of the inspection process at slaughter plants; that is, the carcass of a whole raw chicken that failed inspection would be cut to remove the part of the whole bird that caused inspection failure. The remainder of the bird was then further broken down and marketed as chicken parts. Market changes began to indicate to processors that consumers preferred particular chicken parts rather than whole birds. To satisfy consumers, processors began to break whole chickens into parts for retail sale. Trays of whole birds broken into constituent parts evolved into packages or bags of drumsticks, wings, and breasts, among other products.



Source: USDA Economic Research Service; USDA (graphic).
| GAO-14-744

FSIS faces a challenge in reducing *Salmonella* and *Campylobacter* contamination in poultry products because of outdated or nonexistent standards. FSIS does not revise and develop standards frequently enough to reflect changes in industry practices and poultry consumption patterns. For example, it has taken FSIS nearly 2 decades to begin revising its *Salmonella* standard for ground chicken. The FSIS standard established in 1996 for ground chicken set an expectation that up to 44.6 percent of a plant's production could be contaminated with *Salmonella* without the plant being required to take corrective action. According to industry groups we spoke with, since the implementation of the standard, industry developed newer technologies to reduce contamination below the levels in the standard. FSIS officials agreed and stated that the majority of poultry slaughter plants perform at levels better than the standard.

In addition, as noted earlier, FSIS has not completed development of a *Salmonella* standard for chicken parts, even though chicken parts are now more frequently consumed than whole chickens. As a result, plants are able to meet standards for young chicken carcasses but then have an outbreak associated with chicken parts, such as occurred with the 2013 Foster Farms *Salmonella* outbreak. According to FSIS officials, revising standards takes time and resources, in part because the agency must first collect data to estimate the prevalence of pathogens in FSIS-regulated products, notify the public of proposed standards, and open a comment period, all of which can take years. As previously mentioned, FSIS expects to announce and request comment on the proposed *Salmonella* standard for chicken parts by the end of fiscal year 2014.

Insufficient Prevalence Estimates

FSIS faces a challenge in reducing *Salmonella* and *Campylobacter* contamination in poultry products as a result of not having sufficient prevalence estimates. FSIS collects and analyzes data to estimate the prevalence of pathogens when the agency revises or creates standards for its regulated products. However, as discussed above, standards are not created or revised often, and agency officials we interviewed agree that this type of data collection and analysis is done infrequently.⁷⁶ Moreover, the data from FSIS's verification testing program makes it difficult for the agency to assess contamination levels of poultry pathogens across the entire industry because the verification testing program was not designed to assess prevalence of pathogens industry-wide, and the agency does not randomly select plants for inspection. Also, as we said earlier, in April 2012, FSIS concluded that its verification testing data from individual plants cannot be used to estimate prevalence across the industry because the agency does not randomly select plants for verification testing.

According to USDA's National Advisory Committee on Microbiological Criteria for Foods, estimating the prevalence of pathogens in food is critical to understanding and addressing the public health risk of foodborne illness, and these estimates provide a mechanism for measuring performance against public health goals, among other things. Similarly, the majority of representatives of consumer groups and some industry groups we spoke with stated that FSIS needs estimates of prevalence of *Salmonella* in poultry products to set its *Salmonella* public health goal. As previously mentioned, FSIS recently created a new testing approach for ground poultry to estimate prevalence.⁷⁷ According to FSIS officials, the agency plans to propose adopting this new testing approach for all of its poultry products, which would allow for more frequent data collection and improve prevalence estimates, among other things.

⁷⁶This data collection and analyses is known as a baseline study. The most recent baseline study is on chicken parts: FSIS, "*The Nationwide Microbiological Baseline Data Collection Program: Raw Chicken Parts Survey*" (Washington, D.C.: January 2012-August 2012).

⁷⁷The agency is using the results from the new testing approach to revise its performance standards for raw ground poultry products and create new standards for mechanically separated poultry.

Salmonella's Complex Nature

FSIS faces a challenge in reducing *Salmonella* contamination in poultry products because of the complex nature of *Salmonella*. The majority of the representatives from industry and consumer groups we interviewed, as well as FSIS officials, agreed that *Salmonella* is difficult to control in poultry products because it is widespread in the natural environment. For example, according to CDC officials, there are over 2,500 serotypes of *Salmonella* that have been identified—not all of which are equally harmful to humans. In many cases, most serotypes are rarely involved in human illness cases and outbreaks. In addition, a food safety researcher we interviewed mentioned that some serotypes of *Salmonella* are more likely to cause human illness; therefore, it is important to understand the genetic makeup of each serotype to determine which ones are more or less likely to cause human illness. Furthermore, the serotypes that are important in human disease and food contamination can differ considerably in different parts of the world, and different serotypes may also be associated with different animal hosts, habitats, and paths of transmission, according to CDC officials.

Limited *Campylobacter* Research and Testing

Reducing levels of *Campylobacter* in poultry products poses a challenge for FSIS in part because less is known about *Campylobacter*. In addition, CDC officials told us that *Campylobacter* is less likely to be associated with outbreaks. Furthermore, technologies to detect *Campylobacter* might underdiagnose cases and the methods used by many diagnostic laboratories to isolate *Campylobacter* from samples are not standardized. Therefore, the efficacy of these tests varies considerably. Some countries such as New Zealand experienced greater success in reducing *Campylobacter* levels from poultry products, where *Campylobacter* cases were reduced by approximately 59 percent from 2006-2008 after its government and industry implemented several proactive measures and alterations to critical control points.⁷⁸ New Zealand is leading the international risk-based framework for *Campylobacter* control in poultry.⁷⁹ Representatives from an industry group cautioned, however, that although the decline in illnesses in New Zealand is impressive, it is difficult to extrapolate this success to other parts of the world. FSIS

⁷⁸A critical control point is a point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

⁷⁹The Codex Alimentarius Commission is regarded as a key body for international food related standard setting activities. Codex was set up jointly by the Food and Agriculture Organization of the United Nations and the World Health Organization in 1963.

officials also cautioned that the agency's ability to measure a reduction in *Campylobacter* illnesses will depend on its ability to attribute *Campylobacter* illnesses to poultry and other food types and said that an interagency analysis with CDC is under way to improve such attribution.

Conclusions

Ensuring the safety of poultry products is critical because Americans consume considerably more poultry products than beef or pork. To help ensure the safety of poultry products, USDA's FSIS has transitioned to an increasingly science-based, data-driven, risk-based approach. As a part of this approach, USDA's FSIS has taken several actions to reduce *Salmonella* and *Campylobacter* contamination in poultry products to protect human health, including tightening existing standards for *Salmonella* contamination in young chicken and turkey carcasses, as well as developing a *Salmonella* Action Plan. FSIS has also finalized a rule to modernize the poultry slaughter inspection process which, according to the agency, will play a role in reducing *Salmonella* and other poultry pathogen contamination. To assess the effects of its actions on the incidence of human illness from *Salmonella* and *Campylobacter*, FSIS has developed performance measures and associated targets for young chicken carcasses to monitor whether activities to bring plants into compliance with the standards are meeting the agency's goals, which is consistent with requirements of GPRA to measure performance toward achievement of agency strategic goals. However, the agency has not developed performance measures and targets for certain commonly consumed poultry products, in particular ground chicken and ground turkey, even though the standards for *Salmonella* contamination in these products have been in place since 1996. Similarly, it has not developed performance measures for *Campylobacter* contamination in young chicken and turkey carcasses, or for *Salmonella* contamination in turkey carcasses.

FSIS believes it is not appropriate to establish measures for ground poultry until it has revised *Salmonella* standards for it; similarly, FSIS believes it is not appropriate to establish measures for *Campylobacter* until it has established plant compliance categories for *Campylobacter* in young chicken and turkey carcasses. According to agency officials, revised standards will be proposed and plant compliance categories for *Campylobacter* established by the end of 2014. FSIS officials told us that a performance measure is not necessary for *Salmonella* in young turkey carcasses because young turkey plants are meeting the standard, but an agency report on pathogen testing results from the fourth quarter of calendar year 2013 indicated that not all turkey slaughter plants met the

standard. FSIS officials told us that all turkey slaughter plants are meeting the standard as of July 2014. As previously mentioned, FSIS is developing a *Salmonella* standard for raw chicken parts; therefore, the agency has not developed corresponding performance measures and targets.

In the absence of performance measures and associated targets for these pathogens in commonly consumed poultry products, FSIS cannot quantitatively assess the effects of its actions related to these standards in meeting the agency's goal of maximizing domestic compliance with food safety policies and, ultimately, protecting public health. Performance measures and targets are reported in the agency's strategic and annual plans but, in the absence of such measures and targets, performance information, such as data and trends supplied to FSIS leadership, is not being publicly reported. Without publicly reporting such information, FSIS loses the opportunity to enhance transparency by providing this information to the public and Congress about its progress in meeting this important goal, potentially limiting oversight and accountability. Expedient development of these measures and targets is particularly important for ground poultry given that these products are a higher risk for contamination than whole carcasses and that the popularity of these products has grown over the years.

In addition, USDA faces several challenges that could hinder its ability to reduce contamination in poultry products. For example, practices outside the slaughter plant, such as conditions on poultry farms, can affect contamination of poultry products. To help overcome this challenge, the agency has developed guidelines on practices for controlling *Salmonella* and *Campylobacter* on farms, but the guidelines do not include information on the effectiveness for each practice, as recommended by an internal agency committee. FSIS is working with industry, APHIS, and other stakeholders to collect information on on-farm practices to inform future guidelines, but the agency has not confirmed that it would include information on the effectiveness of each on-farm practice. Without providing this information in future revisions of the guidelines, USDA is not fully informing industry of the potential benefits of adopting these practices and encouraging implementation of such practices.

Recommendations for Executive Action

We recommend that the Secretary of Agriculture direct the Administrator of the Food Safety and Inspection Service (FSIS) to take the following four actions to help ensure that FSIS efforts protect human health by

reducing *Salmonella* and *Campylobacter* contamination in FSIS-regulated poultry products:

- Once FSIS revises its *Salmonella* standards for ground chicken and ground turkey, the agency should expeditiously develop *Salmonella* performance measures with associated targets for these products to monitor whether activities to bring plants into compliance with the standards are meeting the agency's goals.
- Once FSIS establishes plant compliance categories for *Campylobacter* in young chicken and turkey carcasses, the agency should expeditiously develop *Campylobacter* performance measures with associated targets for these products to monitor whether activities to bring plants into compliance with the standards are meeting the agency's goals.
- FSIS should expeditiously develop *Salmonella* performance measures with associated targets for young turkey carcasses to monitor whether activities to bring plants into compliance with the standards are meeting the agency's goals.
- In future revisions of the compliance guidelines on controlling *Salmonella* and *Campylobacter*, FSIS should ensure the inclusion of information on the effectiveness of each recommended farm practice to reduce these pathogens in live poultry.

Agency Comments and Our Evaluation

We provided a draft of this report for review and comment to the Department of Agriculture and Department of Health and Human Services. In written comments, USDA concurred with our four recommendations; USDA's written comments and our detailed response are presented in appendix III. According to USDA, the agency will establish appropriate measures and targets after collecting adequate data to determine whether establishments are meeting the standards for *Salmonella* in ground chicken and turkey and in young turkey carcasses, and for *Campylobacter* in young chicken and turkey carcasses. USDA also stated that it is committed to decreasing the number of *Salmonella* and *Campylobacter* illnesses associated with its regulated products, including poultry products, and to using performance standards and performance measures to achieve that reduction. Concerning the agency's compliance guidelines on controlling *Salmonella* and *Campylobacter*, USDA said that it is currently revising the guidelines to address the reduction of *Salmonella* and *Campylobacter* in live poultry and will include all available scientific information on the effectiveness of each recommended farm practice to reduce *Salmonella* in live poultry.

USDA also provided technical comments, as did the Department of Health and Human Services, and we incorporated those comments as appropriate.

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 Agriculture, the Secretary of Health and Human Services, 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 about this report, please contact me at (202) 512-3841 or gomezj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix IV.

A handwritten signature in black ink, reading "Alfredo Gómez". The signature is written in a cursive style with a large, stylized "G" and a long, sweeping underline.

J. Alfredo Gómez
Director, National Resources and Environment

Appendix I: Objectives, Scope, and Methodology

This report responds to your request that we review U.S. Department of Agriculture's (USDA) approach to protecting human health by reducing *Salmonella* and *Campylobacter* contamination in poultry products. Our objectives for this report were to: (1) describe actions USDA has taken since 2006 to reduce *Salmonella* and *Campylobacter* contamination in poultry products that it regulates; (2) evaluate USDA's efforts to assess the effects of these actions on the incidence of human illnesses from *Salmonella* and *Campylobacter* in poultry products; and (3) determine what challenges, if any, USDA faces in reducing these pathogens in poultry products.

To describe actions USDA has taken since 2006 to reduce *Salmonella* and *Campylobacter* contamination in poultry products that it regulates, we reviewed USDA regulations and documentation on actions taken from February 2006 to June 2014, including *Federal Register* notices, USDA's Food Safety and Inspection Service¹ (FSIS) notices, directives, and the December 2013 *Salmonella* Action Plan. We chose the time frame because FSIS introduced several initiatives in 2006 to reduce *Salmonella*. We also reviewed FSIS budget documents from fiscal year 2006 to fiscal year 2015, including the agency's budget explanatory notes. It is not clear how much FSIS has spent or will continue to spend on these actions because our review of FSIS budget documents from fiscal year 2006 to fiscal year 2015 found that the agency does not provide cost data on specific poultry pathogen reduction actions, and the agency was unable to provide such data other than \$2.5 million spent on poultry-related sampling programs. We interviewed officials at FSIS headquarters and district offices about recent actions taken to directly address *Salmonella* and *Campylobacter* contamination of poultry products including actions identified in *Federal Register* notices.

To evaluate USDA's efforts to assess the effects of actions taken on the incidence of human illnesses from *Salmonella* and *Campylobacter* in poultry products, we reviewed USDA and FSIS strategic plans, as well as USDA annual performance reports to identify relevant performance

¹FSIS is the agency responsible for inspections at all meat and poultry slaughter processing plants and for ensuring plants' compliance with regulatory requirements.

measures, targets, and goals.² We also reviewed FSIS quarterly progress reports on *Salmonella* and *Campylobacter* testing of poultry products. We evaluated the source data, statistical methodology, and results of FSIS research articles and a study to determine whether the conclusions drawn on the effects of agency actions were adequately supported by the evidence. We interviewed FSIS headquarters officials about the effects of actions taken on the incidence of human illnesses from these pathogens. We reviewed FSIS, Centers for Disease Control and Protection (CDC), and Food and Drug Administration (FDA) interagency group (Interagency Food Safety Analytics Collaboration) documentation to describe the purpose of the group, as well as completed and planned analytic projects. We also interviewed FSIS and CDC officials about the group's projects to improve food attribution data.

To determine any challenges USDA faces to reduce *Salmonella* and *Campylobacter* in poultry products it regulates, we reviewed FSIS, USDA Office of Inspector General, and National Academy of Sciences reports on FSIS's inspections and management challenges. We also interviewed officials from USDA's Animal and Plant Health Inspection Service (APHIS),³ FSIS, and CDC to identify and describe any challenges facing USDA. Additionally, we conducted interviews with stakeholder groups.

We conducted a two-stage interview process with industry, consumer, and government employee stakeholder groups. We selected an initial set of 12 stakeholder groups identified based on our previous experience with large national groups with food safety and slaughter inspection knowledge from our August 2013 report on poultry and hog inspections.⁴

²The Government Performance and Results Act of 1993 as amended by the GPRA Modernization Act of 2010 (GPRA) requires executive agencies to complete strategic plans in which they define their missions, establish results-oriented goals, and identify the strategies that will be needed to achieve those goals. GPRA also requires agencies to complete annual performance plans that establish performance goals—which contribute to the strategic goals—and measure performance toward achieving performance goals. Performance measures are important management tools that help agencies monitor and report progress toward their goals. Numerical targets are a key attribute of successful performance measures because they allow managers to compare planned performance with actual results.

³APHIS oversees voluntary programs to evaluate and certify that poultry are free of certain diseases.

⁴GAO, *Food Safety: More Disclosure and Data Needed to Clarify Impact of Changes to Poultry and Hog Inspections*, [GAO-13-775](#) (Washington, D.C.: Aug. 22, 2013).

These stakeholder groups were the American Meat Institute, the Center for Foodborne Illness Research and Prevention, the Center for Science in the Public Interest, the Consumer Federation of American, Food and Water Watch, the Government Accountability Project, the National Association of Federal Veterinarians, the National Chicken Council, the National Turkey Federation, the North American Meat Association and the Pew Charitable Trusts. We conducted an initial interview with the American Federation of Government Employees/National Joint Council of Food Inspection Locals to identify potential challenges, but we were unsuccessful in obtaining a subsequent structured interview. The sample captures a broad range of major stakeholder groups but, because it is a nongeneralizable sample, it is possible that this group did not include opinions that some experts on the topic may have. During the first round, we conducted exploratory interviews. We analyzed the results by identifying common challenges. During the second round, we conducted structured interviews using questions that covered the most common potential challenges cited in the exploratory interviews.

We list the five key structured interview questions we are reporting on that stakeholders previously identified as challenges and potential challenges during exploratory interviews. For questions listed below, respondents had the following choices as responses: definitely yes, probably yes, definitely no, probably no, or don't know. There were several questions that would have required respondents to have in-depth information about FSIS, such as details about the technology the agency uses for identifying specific serotypes or specifics about how the agency would implement actions from its *Salmonella* Action Plan. Lacking this information, many respondents were only able to give us qualified answers with caveats. Therefore, we concluded that these responses were not standardized to be reported, and we excluded them from our report.

List of Selected Structured Interview Questions

- **Enforcement**

FSIS sets performance standards for *Salmonella* and *Campylobacter*. Do you think FSIS has sufficient authority to ensure that poultry plants comply with FSIS performance standards?

FSIS has declared some pathogen strains adulterants, such as E-coli 0157. Do you think it is necessary for FSIS to declare some strains of *Salmonella*, particularly strains more likely to cause severe illness, as adulterants in order to meet its *Salmonella* public health goal?

Currently, poultry plants decide whether *Salmonella* and *Campylobacter* are hazards reasonably likely to occur in their HACCP. Do you think this approach is adequate to keep contamination at FSIS regulated plants within FSIS performance standards?

- **Verification Testing and Sampling**

FSIS recently evaluated its pathogen sampling program and assessed that it could not measure prevalence of *Salmonella* in poultry products over time, in part because it does not conduct random sampling. Do you think FSIS needs estimates of prevalence of *Salmonella* in poultry products to set its *Salmonella* public health goal?

Salmonella is known to be ubiquitous and persistent in the natural environment. Do you think these traits make it difficult to control *Salmonella* in poultry products FSIS regulates?

To make sure that our results were presented in an accurate and balanced manner, we evaluated responses in terms of the extent of agreement among the three stakeholder groups. Where there was stark disagreement among the groups, we presented the results separately. Where there was general agreement, we reported overall results. We conducted 11 structured phone interviews from March 2014 to May 2014. We selected 4 of the 11 stakeholder groups and pretested the initial structured interview questions to ensure that the questions were relevant and clearly stated; based on those results, we made adjustments to the structured interview as necessary. Apart from the stakeholder interviews, we also spoke with two academic food safety researchers we identified based on academic work and participation in a 2014 food safety conference and discussed challenges related to controlling *Salmonella* and *Campylobacter* in poultry products.

Additionally, we reviewed five *Salmonella* and *Campylobacter* outbreaks attributed to poultry products with the highest number of illnesses to better understand any challenges that may have contributed to the outbreaks; these outbreaks started during the time period from fiscal year 2011 through fiscal year 2013. The case study included four *Salmonella* outbreaks from poultry products and one *Campylobacter* outbreak from poultry products. These outbreaks are not generalizable to all outbreaks from *Salmonella* and *Campylobacter* contaminated poultry products. The selected outbreaks provided illustrative examples of challenges USDA faces. To describe the selected outbreaks, we interviewed state officials from departments of health or agriculture from California, New York, Texas, Vermont, and Washington. These states had the highest number

of illnesses for each outbreak in our review. We also interviewed CDC officials with knowledge of the outbreaks and FSIS officials familiar with each outbreak investigation to learn about any challenges USDA faced and other challenges related to investigating outbreaks. We also reviewed states', CDC, and FSIS documentation on each outbreak to describe each outbreak.

For our three objectives, we visited poultry plants in California to gain a better understanding of poultry plant operations and FSIS inspection activities. We chose California because the state has a number of small and large chicken and turkey plants. California also produces a high volume of chicken and turkey in the United States. We reviewed prior GAO reports on food safety, surveillance systems, and performance management.

We conducted this performance audit from July 2013 to September 2014 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: Case Study Outbreak Summary Tables

During the course of our review, we examined a nongeneralizable sample of recent *Salmonella* and *Campylobacter* outbreaks linked to poultry products since 2011. We limited the scope of our review to four of the six most recent *Salmonella* outbreaks that had the highest number of confirmed illnesses that the Centers for Disease Control and Prevention (CDC) and the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) investigated since 2009. In addition, we also identified one *Campylobacter* outbreak that occurred within the time period established for those *Salmonella* outbreaks included in our review. As this was a review of a nongeneralizable sample of outbreaks, the information is not generalizable to all outbreaks but provides important illustrative information.

In addition to the information provided for each of the five outbreaks in the summary tables below (see tables 3-7), other findings from our review included the following:

- Each plant linked to the four *Salmonella* outbreaks included in our review was a Category 1 plant at the time the outbreaks occurred, meaning that the plants were considered by FSIS to be demonstrating consistent process controls to meet the agency's existing *Salmonella* standards.
- During the five outbreaks, FSIS requested that one company conduct a voluntary recall. FSIS made the request after the agency and CDC linked a person sickened by an outbreak strain of *Salmonella* Heidelberg to chicken produced by that company and collected from the ill person's home. According to FSIS officials, FSIS did not request voluntary recalls during the other outbreaks for several reasons. First, for two of the *Salmonella* outbreaks, the companies initiated voluntary recalls before FSIS could make a formal request. Second, for the remaining *Salmonella* outbreak, FSIS did not identify the level of information necessary to request a voluntary recall. Finally, for the *Campylobacter* outbreak, the company voluntarily elected to cease harvesting and selling of raw chicken livers.
- During the five outbreaks, FSIS issued two public health alerts. Specifically, FSIS issued an alert for the outbreak of *Salmonella* linked

to ground turkey products and another for the outbreak of *Salmonella* linked to specific brands of chicken products.¹

- FSIS found that each of the plants linked to three of the four *Salmonella* outbreaks had inadequate Hazard Analysis and Critical Control Point (HACCP) plans.
- FSIS found that each of the plants linked to three of the four *Salmonella* outbreaks failed to maintain sanitary conditions and comply with the agency's regulatory requirements for sanitation.
- FSIS determined that each of the plants linked to three of the four *Salmonella* outbreaks had not adequately supported parts of their hazard analyses because they did not identify *Salmonella* as a food safety hazard reasonably likely to occur during certain production processes.
- In response to the *Campylobacter* outbreak, FSIS conducted a food safety assessment and found that the plant failed to correctly identify *Campylobacter* as a pathogen of concern in its hazard analyses, a noncompliance with FSIS regulations.

¹In two of the other *Salmonella* outbreaks, state departments of health investigating the outbreaks issued public health notices independent of FSIS. No health alerts were issued in response to the *Campylobacter* outbreak.

Appendix II: Case Study Outbreak Summary
Tables

Table 3: 2013 – 2014 Multistate Outbreak of *Salmonella* Linked to Chicken Products Produced in California

Outbreak pathogen	States affected by outbreak	Number of reported illnesses ^a	Number of hospitalizations	Product recalled?	Antibiotic resistance identified?
<i>Salmonella</i> Heidelberg	29, plus Puerto Rico	634 (77% of cases reported from California)	200 of 528 (38%) based on available information	Yes	Yes
Summary	According to CDC's outbreak investigation report, an outbreak linked to Foster Farms brand chicken products sickened a reported 634 people between March 2013 and July 2014. CDC first reported a number of illnesses linked to a strain of <i>Salmonella</i> Heidelberg to FSIS in June 2013. Additional investigation identified illness onset dates linked to this outbreak that began in March 2013. Epidemiologic, laboratory, and traceback investigations conducted by officials in local, state, and federal public health, agriculture, and regulatory agencies identified Foster Farms brand chicken as the likely source of this outbreak. For example, FSIS inspectors identified one or more of the outbreak strains of <i>Salmonella</i> in the company's chicken products while conducting intensified <i>Salmonella</i> testing at three Foster Farms plants in California linked to the outbreak. In addition, health investigators linked seven strains of <i>Salmonella</i> Heidelberg to this outbreak, including four strains rarely reported to CDC. Moreover, 15 percent of those sickened developed blood infections as a result of their illness. Typically, approximately 5 percent of persons ill with <i>Salmonella</i> infections develop blood infections. CDC also found that the outbreak strains were resistant to antibiotics, with some being multidrug resistant; none of the reported antibiotics that the strains were found to be resistant to were those commonly used to treat serious <i>Salmonella</i> infections in humans (e.g., fluoroquinolones and third generation cephalosporins). On October 7, 2013, FSIS issued a public health alert due to concerns that illnesses caused by strains of <i>Salmonella</i> Heidelberg were associated with raw chicken products produced at three Foster Farms plants in California. On October 8, the Kroger Company, which owns a number of grocery stores, announced that it was removing all raw chicken products produced at the three Foster Farms plants from its stores and warehouses. In addition, a Costco location in California later conducted two voluntary recalls—the first on October 12 and the second on October 17—of its rotisserie chicken products (which used Foster Farms brand chickens) as those products may have been contaminated with <i>Salmonella</i> Heidelberg as a result of cross-contamination. On July 3, 2014, Foster Farms announced it was conducting a voluntary recall of an undetermined amount of its chicken products that may be contaminated with one of the outbreak strains of <i>Salmonella</i> Heidelberg. According to CDC's outbreak investigation report, the recall resulted from FSIS identifying one of the outbreak strains of <i>Salmonella</i> Heidelberg in leftover Foster Farms brand chicken with labeling information collected from the home of a person infected with the same strain in California. Prior to the July 2014 recall, FSIS officials said that the agency had not requested that Foster Farms conduct a voluntary recall of any of its chicken products because the agency had not made a definitive connection between a sickened patient and a specific Foster Farms chicken product that provided information pertaining to production lot numbers and production dates, among other things. On July 31, 2014, CDC announced that it believed that the outbreak was over after it determined that the number of reported infections had returned to levels the agency normally expects to see.				

Sources: GAO summary of FSIS and CDC documents. | GAO-14-744

^aAccording to CDC's food safety progress report for 2013, among all *Salmonella* cases reported to CDC, for each reported case there are 29 cases not diagnosed or reported. Therefore, the number of people sickened as a result of this outbreak is likely substantially higher than the official case count.

Appendix II: Case Study Outbreak Summary
Tables

Table 4: 2012 – 2013 Multistate Outbreak of *Salmonella* Linked to Chicken Products

Outbreak pathogen	States affected by outbreak	Number of reported illnesses ^a	Number of hospitalizations	Product recalled?	Antibiotic resistance identified?
<i>Salmonella</i> Heidelberg	13	134 (about 43% of cases reported from Washington)	33 of 105 (31%) based on available information	No	Yes
Summary	According to CDC's outbreak investigation report, an outbreak linked to Foster Farms chicken products sickened a reported 134 people between June 2012 and May 2013. The Oregon Health Authority and the Washington State Department of Health first identified the outbreak in June 2012 after identifying a number of illnesses caused by a strain of <i>Salmonella</i> Heidelberg. In August, CDC detected additional <i>Salmonella</i> illnesses matching the previously identified outbreak pattern. Working together, local, state, and federal agencies conducted a traceback investigation and determined the likely source was chicken products produced by Foster Farms. Specifically, Washington State Public Health Laboratories conducted tests on four samples of chicken collected from three ill persons' homes in Washington and identified the outbreak strain in those samples, which were then traced back to two Foster Farms slaughter plants. In addition, the National Antimicrobial Resistance Monitoring System—Enteric Bacteria, a collaborative surveillance program between state and local public health departments, CDC, and the U.S. Food and Drug Administration, among others, isolated the outbreak strain of <i>Salmonella</i> Heidelberg from Oregon and Washington Foster Farms retail chicken samples. In February 2013, the states of Washington and Oregon issued public health alerts warning the public about the outbreak of <i>Salmonella</i> and that it had been linked to chicken produced in Foster Farms plants in Washington and California. FSIS, however, did not issue a public health alert in response to this outbreak. According to FSIS officials, the agency was unable to make a definitive connection between a sickened patient and a specific Foster Farms chicken product that provided information pertaining to production lot numbers and production dates, among other things. As a result, FSIS did not request that Foster Farms conduct a voluntary recall of any of its chicken products, and Foster Farms did not act independently to initiate a voluntary recall during this outbreak. On July 10, 2013, CDC announced that it believed that the outbreak was over after it determined that the number of reported infections had returned to levels the agency normally expects to see.				

Sources: GAO summary of CDC and Washington State Department of Health documents. | GAO-14-744

^aAccording to CDC's food safety progress report for 2013, among all *Salmonella* cases reported to CDC, for each reported case there are 29 cases not diagnosed or reported. Therefore, the number of people sickened as a result of this outbreak is likely substantially higher than the official case count.

Appendix II: Case Study Outbreak Summary
Tables

Table 5: 2012 *Campylobacter* Outbreak Linked to Chicken Livers in Vermont

Outbreak pathogen	States affected by outbreak	Number of reported illnesses ^a	Number of hospitalizations	Product recalled?	Antibiotic resistance identified?
<i>Campylobacter jejuni</i>	3	6 (67% of cases reported from Vermont)	2 (33%) based on available information	No ^b	Yes
Summary	According to CDC's Morbidity and Mortality Weekly Report, an outbreak linked to chicken livers from an establishment in Vermont sickened a reported six people from April 2012 to September 2012. Vermont's Department of Health identified the outbreak in October 2012 after identifying three cases of <i>Campylobacter</i> infection in Vermont residents. The department, in collaboration with its Health Laboratory, carried out the investigation, interviewed patients, conducted human and food laboratory testing, and initiated the traceback actions to identify the source of the outbreak. As a result of its investigative work, the Vermont Department of Health determined that all six of those sickened had either been exposed to or consumed raw or undercooked chicken livers that had been produced at the same poultry establishment. It was also able to trace the chicken livers back to a single source, Establishment A, located in Vermont. In response to the outbreak, FSIS conducted a food safety assessment at the establishment. No major violations were identified, but the FSIS inspector determined that the plant had failed to correctly identify <i>Campylobacter</i> as a pathogen of concern in its hazard analyses, a noncompliance with FSIS regulations. In addition, the establishment responded to the outbreak by electing to cease harvesting and selling chicken livers on November 9, 2012. According to the Vermont Department of Health, this outbreak is of note because it was the first-ever documented multistate outbreak of <i>Campylobacter</i> due to chicken liver consumption in the United States and the first <i>Campylobacter</i> outbreak in which the outbreak strain was found in the chicken livers.				

Sources: GAO summary of FSIS, CDC, and Vermont Department of Health documents. | GAO-14-744

^aAccording to CDC's food safety progress report for 2013, among all *Campylobacter* cases reported to CDC, for each reported case there are 30 cases not diagnosed or reported. Therefore, the number of people sickened as a result of this outbreak is likely substantially higher than the official case count.

^bNo recall occurred during this outbreak. However, in December 2012, the establishment formally notified FSIS of its decision to stop harvesting and selling chicken livers as a result of the outbreak.

Table 6: 2011 Multistate Outbreak of *Salmonella* Linked to Broiled Chicken Liver Products

Outbreak pathogen	States affected by outbreak	Number of reported illnesses ^a	Number of hospitalizations	Product recalled?	Antibiotic resistance identified?
<i>Salmonella</i> Heidelberg	6	190 (57% of cases reported from New York)	30 of 154 (19%) based on available information	Yes	Not Known ^b
Summary	According to CDC's outbreak investigation report, an outbreak linked to broiled chicken livers produced by Schreiber Processing Corporation sickened a reported 190 people from April 1 to November 17, 2011. CDC first identified the outbreak in August 2011 when the agency observed a sustained increase in the number of <i>Salmonella</i> Heidelberg illnesses reported from New York and New Jersey. Collaborative investigative efforts of local, state, and federal public health and regulatory agencies linked the outbreak to eating broiled chicken livers from Schreiber Processing Corporation. On November 8, 2011, FSIS announced that Schreiber Processing Corporation was conducting a voluntary recall of an undetermined amount of broiled chicken liver products. On November 9, the New York State Health Department and the New York City Department of Health and Mental Hygiene issued public health warnings as an additional measure to inform consumers about the recall and the link between broiled chicken livers produced by Schreiber Processing and the <i>Salmonella</i> outbreak. Following the recall, Schreiber Processing elected to stop producing these particular broiled chicken liver products. FSIS also conducted a food safety assessment at the company's plant from November 30, 2011 to January 18, 2012. Based on its findings, FSIS determined that the manner in which the broiled chicken liver products were labeled played a role in the outbreak. Specifically, the products appeared to be ready-to-eat, but were in fact partially cooked, and therefore needed to be fully cooked before eating. As a result, consumers may have incorrectly thought the use of "broiled" meant the chicken livers were cooked and ready-to-eat. In response to these findings, FSIS is considering revising its safe food handling label. Prior to the conclusion of FSIS's food safety assessment, CDC announced on January 11, 2012, that the outbreak was over.				

Sources: GAO summary of FSIS, CDC, New York State Department of Health, and New York City Department of Health and Mental Hygiene documents. | GAO-14-744

^aAccording to CDC's food safety progress report for 2013, among all *Salmonella* cases reported to CDC, for each reported case there are 29 cases not diagnosed or reported. Therefore, the number of people sickened as a result of this outbreak is likely substantially higher than the official case count.

^bDuring our review, FSIS and CDC officials told us that they were unable to determine whether the outbreak strain showed any antibiotic resistance.

Table 7: 2011 Multistate Outbreak of *Salmonella* Linked to Ground Turkey

Outbreak pathogen	States affected by outbreak	Number of reported illnesses ^a	Number of hospitalizations	Product recalled?	Antibiotic resistance identified?
<i>Salmonella</i> Heidelberg	34	136 (13% of cases reported from Texas)	37 of 94 (39%) based on available information	Yes	Yes
Summary	According to CDC's outbreak investigation report, an outbreak linked to ground turkey produced by Cargill Meat Solutions Corporation was associated with one death and sickened a reported 136 people from February to September 2011. CDC identified the outbreak in May 2011 when it observed an increase in <i>Salmonella</i> Heidelberg illnesses in multiple states. Collaborative investigative efforts of state, local, and federal public health and regulatory agencies led to the identification of matching strains of <i>Salmonella</i> obtained from ground turkey products purchased at different retail locations. Preliminary information indicated that these products originated from a common source: a Cargill plant in Springdale, Arkansas. FSIS began its initial traceback investigation in July 2011. On July 29, 2011, FSIS released a public health alert warning the public that frozen and fresh ground turkey products had been linked to an outbreak of <i>Salmonella</i>. That same day, FSIS informed Cargill that the results of its investigative work indicated that the company's Springdale, Arkansas plant was the likely, but not definitive, source of the outbreak. On August 3, 2011, Cargill voluntarily recalled approximately 36 million pounds of ground turkey products produced at the Springdale plant. Cargill also suspended its ground turkey operations at the plant in order to identify the source of the <i>Salmonella</i> Heidelberg and to implement corrective actions. Production resumed 2 weeks later. However, Cargill conducted a second voluntary recall of approximately 185,000 pounds of ground turkey products on September 11, 2011. The second recall occurred after product samples at the plant tested positive for the outbreak strain of <i>Salmonella</i> Heidelberg based on sample results from an intensive in-plant investigation performed by FSIS. Cargill again suspended operations and sought to implement further corrective actions. According to CDC's outbreak investigation report, no further illnesses were reported after September 13, 2011, and on November 10, 2011, it announced that the outbreak appeared to be over. In December 2011, following USDA's approval of its enhanced food safety plan, Cargill's Springdale plant resumed its ground turkey production.				

Sources: GAO summary of FSIS and CDC documents and Cargill press releases. | GAO-14-744

^aAccording to CDC's food safety progress report for 2013, among all *Salmonella* cases reported to CDC, for each reported case there are 29 cases not diagnosed or reported. Therefore, the number of people sickened as a result of this outbreak is likely substantially higher than the official case count.

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

Note: GAO comments supplementing those in the report text appear at the end of this appendix.



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

SEP 15 2014

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

Dear Mr. Gómez:

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: USDA Needs to Strengthen Its Approach to Protecting Human Health from Pathogens in Poultry Products* (GAO-14-744). USDA appreciates GAO's work in planning, conducting and issuing this report. There are a few general comments we would like to make on the report.

The GAO report discusses the Agency's *Salmonella* and *Campylobacter* performance standards and the performance measures and targets that the Agency has set to track its progress. We would like to highlight that one of the key performance measures that FSIS has set a target for and tracks is the All-Illness Measure. An important component of that measure is the estimated number of *Salmonella* illnesses attributed to FSIS-regulated products. As part of monitoring the All-Illness Measure, FSIS tracks the estimated number of *Salmonella* illnesses from FSIS-regulated products on a quarterly basis. Poultry is the source of a large percentage of those *Salmonella* illnesses, making this a very important performance measure related to poultry pathogens. FSIS uses its evaluation of progress on that measure to inform its policy decisions related to poultry pathogens. For example, examinations and discussions of the Agency's progress toward its All-Illness Measure targets were part of the impetus for FSIS' Strategic Performance Working Group to develop the Agency's *Salmonella* Action Plan.

As GAO notes, the Agency has not established formal performance measures for all poultry product and pathogen combinations. We would like to emphasize, however, that FSIS has established or is in the process of establishing performance standards for a number of pathogen-product pairs for poultry. The development of performance standards is a formal, rigorous process that often includes the conduct of baseline studies or pathogen sampling, risk assessments, and numerous analyses, all of which often takes a couple of years to accomplish and therefore reflects a substantial effort by the Agency. Once formal performance standards are developed and implemented,

J. Alfredo Gómez
Page 2

then FSIS can establish performance measures to track progress related to those standards. Although the Agency has highlighted specific targets through the establishment of some formal performance measures and targets, FSIS does not limit its ability to set goals and track its progress and the progress of the industries it regulates to those specific measures. FSIS tracks, and in some cases makes public, that progress regardless of whether it has formalized performance measures in place. For example, FSIS does not have a specific performance measure and target for the percentage of establishments in different categories of *Campylobacter* performance, but the Agency reports publicly on the turkey establishments in the different categories and percentage of positives for *Campylobacter*. That information allows for routine assessment of trends by those within and outside the Agency, and provides the opportunity for FSIS and the regulated industry the ability to adjust food safety activities on the basis of those trends.

We have also noted a few more technical aspects in the report that we would like to clarify. Throughout this report, GAO uses the terms “mechanically separated” and “ground” when referring to poultry products. FSIS prefers the word ‘comminuted’ and its standard definition.

FSIS would also like to clarify and correct a statement made on page 2 of the report. The data on the incidence of *Salmonella* and *Campylobacter* in humans is misleading and provides an inaccurate assessment of the burden of *Salmonella* illnesses specifically attributed to FSIS-regulated products. The CDC data being cited in this section of the report comes from the CDC-led FoodNet program and represents all *Salmonella* illnesses captured through the program, not just those attributed to FSIS-regulated products. *Salmonella* attribution to FSIS-regulated products has actually decreased over the past 5 years. If additional language is needed, please consider the following discussion of FSIS attribution:

FY2014 data:

- Thus far in FY2014, FSIS met its targets for *Salmonella* illnesses reductions for all quarters (Q1-Q3, FY2014).

From FSIS 2013 Year-End Report:

- The overall number of illnesses in the U.S. population caused by *Salmonella* declined by 7.6% over the course of FY 2013, which positively affected the Agency’s All-Illness measure.
- Of the number of *Salmonella* outbreaks associated with FSIS-regulated products—or FSIS’ attribution fraction for *Salmonella*—there was a decrease from 33.1% in the 2008-2010 period to 31.7% in the 2009-2011 period.
- The Agency closed the gap on the All-Illness measure from FY 2012 to FY 2013. (In FY 2012, the Agency missed the All-Illness measure by 18%. In FY 2013, the Agency only missed the All-Illness measure by 8%).

See comment 1

See comment 2

J. Alfredo Gómez
Page 3

See comment 3

We would also like to note the work of the Interagency Food Safety Analytics Collaboration (IFSAC). IFSAC is a major effort for the Agency, as well as the US Centers for Disease Control and Prevention (CDC) and the US Food and Drug Administration (FDA). The current focus of IFSAC's activities is foodborne illness source attribution, defined as the process of estimating the most common food sources responsible for specific foodborne illnesses. Since 2009, IFSAC has completed four projects and 2 external collaborations. IFSAC also held a public meeting in 2012, broadcast two public webinars to share results from completed projects, launched a new web resource, and is in the process of planning a public meeting for 2015 to share results from completed and on-going projects. A number of these interagency efforts involve work to better estimate attribution for *Salmonella* and *Campylobacter*, including evaluating a pathogen subtype model to better estimate the number of *Salmonella* illnesses associated with different food sources and the development of a new, robust method to produce harmonized attribution estimates for *Salmonella*, *Campylobacter*, *E. coli* O157:H7 and *Listeria monocytogenes*. This project will assist FSIS in better estimating the proportion of *Salmonella* illnesses associated with poultry. On page 20 of its report, GAO discusses the limitations of the data on which FSIS relies for measuring illnesses. FSIS agrees that there are limitations in the data, but would like to point out that it uses the best data that are available. The limitations in the data are why, in part, IFSAC was formed.

See comment 4

USDA recommends consulting with CDC to address some inaccuracies in the text regarding outbreak investigations, specifically the text and figure on page 6. FSIS typically does not identify outbreaks through the CDC outbreak data, it is the State and local health departments that do so.

See comment 5

On page 26 of the report where there is discussion of limited enforcement authority, the report states that "...after a plant fails *Salmonella* testing for its first sample set, FSIS can require a reassessment of the plant's HACCP plan and then conduct a food safety assessment; conduct additional sampling or issue a notice of intended enforcement action,". This is not quite accurate. The final rule requires that establishments address enteric pathogens such as *Salmonella* and *Campylobacter* in a written plan. This plan can be in their HACCP, sanitation SOP, or other prerequisite program and therefore the establishment's food safety system.

On page 31 the report states that FSIS' prevalence estimates are insufficient. FSIS acknowledges this issue and plans to remedy it by implementing routine sampling throughout the year for *Salmonella*. FSIS has announced in two Federal Register Notices (FRN) that for *Salmonella* verification sampling it is considering an approach that involves routine sampling throughout the year, overlaid with a moving window to determine an establishment's compliance with the performance standard. One option that FSIS is considering is a moving window sampling plan in which FSIS would evaluate a set number of sequential results from a single establishment to assess process control (78 FR 53019 and 79 FR 32437). FSIS would put the moving window approach into effect when the revised performance standard is implemented.

J. Alfredo Gómez
Page 4

FSIS appreciates and concurs with the recommendations from GAO. The Agency's response to each recommendation is included below.

Recommendation 1:

Once FSIS revises its *Salmonella* standards for ground chicken and ground turkey, the Agency should expeditiously develop a *Salmonella* performance measure with associated targets for these products to monitor whether activities to bring plants into compliance with the standards are meeting the Agency's goals.

USDA Response:

FSIS concurs with this recommendation. FSIS is committed to decreasing the number of *Salmonella* illnesses associated with its regulated products, including poultry products, and to using performance standards and performance measures to achieve that reduction. FSIS has already begun additional *Salmonella* sampling and testing of comminuted poultry as a part of an Agency effort to revise the existing standards. As GAO notes in its report, FSIS is also in the process of developing performance standards for *Salmonella* and *Campylobacter* in raw chicken parts and comminuted poultry (chicken and turkey). The Agency anticipates the release of the FRN with those standards within this calendar year. Those risk assessment-based standards are designed to integrate performance metrics into the standards, and link establishment compliance levels with targeted decreases in *Salmonella* illnesses, which are aligned to the Agency's All-Illness Measure. The FRN also establishes a framework for monitoring the standards through categorizing establishments and posting establishment categories on FSIS' website. After the standards have been implemented and adequate data are gathered to determine the percentage of industry complying with the standards, FSIS will set additional measures and targets, as necessary, to meet its public health goals.

Recommendation 2:

Once FSIS establishes plant compliance categories for *Campylobacter* in young chicken and turkey carcasses, the Agency should expeditiously develop *Campylobacter* performance measures with associated targets for these products to monitor whether activities to bring plants into compliance with the standards are meeting the Agency's goals.

USDA Response:

FSIS concurs with this recommendation. FSIS is committed to decreasing the number of *Campylobacter* illnesses from its regulated products, including poultry products, and to using performance standards and performance measures to achieve that reduction. As is stated in the previously mentioned FRN that FSIS anticipates publishing this calendar year, FSIS also intends to develop categories for establishments with *Campylobacter* sampling results for young chicken and turkeys, on the basis of the 2011 performance standards for *Campylobacter* in those products. Once FSIS has collected enough data to determine whether establishments are

J. Alfredo Gómez
Page 5

meeting the existing performance standards, the Agency will establish appropriate measures and targets and also appropriate follow up actions if establishments are not meeting the standards.

Recommendation 3:

FSIS should expeditiously develop *Salmonella* performance measures with associated targets for young turkey carcasses to monitor whether activities to bring plants into compliance with the standards are meeting the Agency's goals.

USDA Response:

FSIS concurs with this recommendation. FSIS is committed to decreasing the number of *Salmonella* illnesses from its regulated products, including poultry products, and to using performance standards and performance measures to achieve that reduction. FSIS developed performance standards for *Salmonella* in turkey establishments in 2011. Similar to the *Campylobacter*-related activities outlined in the Agency's response to Recommendation 2, FSIS informed turkey establishments of their *Salmonella* category status at the end of 2013. The Agency also posts sampling data on its website on a quarterly basis. Once FSIS has collected adequate data to determine whether establishments are meeting the performance standards, the Agency will establish appropriate measures and targets and also appropriate follow up actions if the establishments are not meeting the standards.

Recommendation 4:

In future revisions of the compliance guidelines on controlling *Salmonella* and *Campylobacter*, FSIS should ensure the inclusion of information on the effectiveness of each recommended farm practice to reduce these pathogens in live poultry.

USDA Response:

FSIS concurs with this recommendation. FSIS does not have authority over pre-harvest activities, but it does incorporate pre-harvest-related research results from the published literature into its compliance guidelines. FSIS is currently revising compliance guidelines to address the reduction of *Salmonella* and *Campylobacter* in live poultry. The Agency will include all available scientific information on the effectiveness of each recommended farm practice to reduce *Salmonella* in live poultry in those guidelines. Although FSIS is not a research organization and is not able to conduct its own research on farm practices, it does recognize the importance of such research to carry out its mission. The Agency has highlighted the need to "[e]valuate the potential effectiveness of pre-harvest interventions on finished products" as a top research priority. FSIS has posted that particular priority and more specific research objectives on its website

(<http://www.fsis.usda.gov/wps/portal/fsis/topics/science/food-safety-research-priorities>), and collaborates with its research partners—including government, academic and industry researchers—encouraging them to conduct that research.

J. Alfredo Gómez
Page 6

Again, thank you for the opportunity to review and comment on this draft report. We look forward to working with you on future USDA engagements.

Sincerely,



Brian Ronholm
Deputy Under Secretary
Food Safety

GAO Comments

The following are GAO's comments on the U.S. Department of Agriculture's (USDA) letter dated September 15, 2014.

1. USDA commented that, throughout our report, we use the terms "mechanically separated" and "ground" when referring to poultry products and that the agency prefers the term "comminuted" and its standard definition. USDA defines comminuted poultry products as "poultry (chicken or turkey) products that have been ground, mechanically separated, or hand- or mechanically-deboned and further chopped, flaked, minced, or otherwise processed to reduce particle size." For our report, it is important to distinguish among these products because there are standards for ground poultry products but not for mechanically separated or other products that are included under the umbrella of "comminuted" poultry.
2. USDA commented that our use of data from the Centers for Disease Control and Prevention (CDC) for describing the incidence of *Salmonella* and *Campylobacter* is misleading and provides an inaccurate assessment of the burden of *Salmonella* illnesses specifically attributed to products regulated by USDA's Food Safety and Inspection Service (FSIS). The purpose of these data in the introduction is to provide general context for our review, not to provide information on illnesses specifically attributed to FSIS-regulated products, which are discussed later in the report. We modified our report to note that CDC's data for describing the incidence of *Salmonella* and *Campylobacter* include illnesses attributed to other sources in addition to FSIS-regulated products.
3. USDA commented that it agrees that there are limitations in the data that it relies upon for measuring illness but stated that the agency uses the best data that are available. We modified our report to state that, according to USDA, the agency is using the best data available.
4. We provided a draft of this report to the Department of Health and Human Services, which includes CDC. We incorporated the agency's technical comments as appropriate.
5. USDA commented that our statement about an example of limited enforcement authority did not include a new requirement under the agency's final rule to modernize poultry slaughter inspection. We modified our report to note this new requirement.

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

J. Alfredo Gómez, (202) 512-3841 or gomezj@gao.gov

Staff Acknowledgments

In addition to the individual named above, Mary Denigan-Macauley (Assistant Director), Carl Barden, Kevin Bray, Mark Braza, Nkenge Gibson, Cynthia Norris, Josephine Ostrander, and Kevin Remondini made key contributions to this report.

GAO's Mission

The Government Accountability Office, the audit, evaluation, and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through GAO's website (<http://www.gao.gov>). Each weekday afternoon, GAO posts on its website newly released reports, testimony, and correspondence. To have GAO e-mail you a list of newly posted products, go to <http://www.gao.gov> and select "E-mail Updates."

Order by Phone

The price of each GAO publication reflects GAO's actual cost of production and distribution and depends on the number of pages in the publication and whether the publication is printed in color or black and white. Pricing and ordering information is posted on GAO's website, <http://www.gao.gov/ordering.htm>.

Place orders by calling (202) 512-6000, toll free (866) 801-7077, or TDD (202) 512-2537.

Orders may be paid for using American Express, Discover Card, MasterCard, Visa, check, or money order. Call for additional information.

Connect with GAO

Connect with GAO on [Facebook](#), [Flickr](#), [Twitter](#), and [YouTube](#). Subscribe to our [RSS Feeds](#) or [E-mail Updates](#). Listen to our [Podcasts](#). Visit GAO on the web at www.gao.gov.

To Report Fraud, Waste, and Abuse in Federal Programs

Contact:

Website: <http://www.gao.gov/fraudnet/fraudnet.htm>

E-mail: fraudnet@gao.gov

Automated answering system: (800) 424-5454 or (202) 512-7470

Congressional Relations

Katherine Siggerud, Managing Director, siggerudk@gao.gov, (202) 512-4400, U.S. Government Accountability Office, 441 G Street NW, Room 7125, Washington, DC 20548

Public Affairs

Chuck Young, Managing Director, youngc1@gao.gov, (202) 512-4800, U.S. Government Accountability Office, 441 G Street NW, Room 7149, Washington, DC 20548

