



March 2018

FOOD SAFETY

USDA Should Take Further Action to Reduce Pathogens in Meat and Poultry Products

This Report Is Temporarily Restricted Pending Official Public Release.

GAO Highlights

Highlights of [GAO-18-272](#), a report to congressional requesters

Why GAO Did This Study

The U.S. food supply is generally considered safe, but the Centers for Disease Control and Prevention (CDC) estimate that *Salmonella* and *Campylobacter* in food cause about 2 million human illnesses per year in the United States. In 2014, GAO identified challenges USDA faced in reducing pathogens in poultry products, including standards that were outdated or nonexistent and limited control over factors that affect pathogen contamination outside of meat and poultry slaughter and processing plants, such as practices on the farm.

GAO was asked to review USDA's approach to reducing pathogens in meat and poultry products. This report examines (1) the extent to which USDA has developed standards for meat and poultry products and (2) any additional steps USDA has taken to address challenges GAO identified in 2014. GAO reviewed relevant regulations, documents, and data and interviewed officials from USDA and CDC, as well as 17 stakeholders representing industry, consumer groups, and researchers selected based on their knowledge of USDA's meat and poultry slaughter inspections and food safety.

What GAO Recommends

GAO is making three recommendations, including that USDA document its process for deciding which products to consider for new standards and that it include information on the effectiveness of on-farm practices in its guidelines for *Salmonella* control in hogs. USDA agreed with GAO's recommendations and described actions it will take to implement them.

View [GAO-18-272](#). For more information, contact Steve D. Morris at (202) 512-3841 or morriss@gao.gov.

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What GAO Found

To help ensure the safety of our nation's food supply, the U.S. Department of Agriculture (USDA) has developed standards limiting the amount of *Salmonella* and *Campylobacter*—pathogens that can cause foodborne illness in humans—permitted in certain meat (beef and pork) and poultry (chicken and turkey) products, such as ground beef, pork carcasses, and chicken breasts. However, the agency has not developed standards for other products that are widely available, such as turkey breasts and pork chops. Further, its process for deciding which products to consider for new standards is unclear because it is not fully documented, which is not consistent with federal standards for internal control. For example, USDA has informed stakeholders that it will take into account factors including consumption and illness data, but the agency has not documented this process going forward. Previously, USDA had developed new standards after widespread outbreaks indicated the need. For example, in 2016, USDA concluded that new standards were needed for certain poultry products to reduce *Salmonella* after reviewing outbreaks from these products in 2011, 2013, and 2015—outbreaks in which 794 people were sickened and 1 died. By documenting the agency's process for deciding which products to consider for new standards, USDA could better ensure that such decisions will be risk-based.

USDA is taking steps to address challenges GAO identified in 2014 for reducing pathogens in poultry products, but these challenges are ongoing and could affect USDA's ability to reduce pathogens in meat as well. For example, one challenge GAO identified is that the level of pathogens in poultry products can be affected by practices on farms where poultry are raised. GAO recommended in 2014 that to help overcome this challenge, USDA guidelines on practices for controlling *Salmonella* and *Campylobacter* on farms include information on the effectiveness of each of the practices, consistent with a recommendation from a USDA advisory committee. Since GAO's 2014 report, USDA drafted revised guidelines to include information on the effectiveness of on-farm practices for controlling pathogens in poultry and beef cattle, in 2015 and 2017, respectively. However, USDA's draft guidelines for controlling *Salmonella* in hogs do not contain such information. By including such information as it finalizes its draft guidelines, USDA could better inform industry of the potential benefits of adopting on-farm practices included in the guidelines and encourage implementation of such practices.



Illustrations of *Salmonella* (left) and *Campylobacter* (right).

Sources: Centers for Disease Control and Prevention; James Archer (content provider for illustrations). | GAO-18-272

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Abbreviations

AMS	Agricultural Marketing Service
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
HACCP	Hazard Analysis and Critical Control Point
USDA	U.S. Department of Agriculture

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March 19, 2018

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

The Honorable Dianne Feinstein
United States Senate

The Honorable Richard J. Durbin
United States Senate

The U.S. food supply is generally considered safe, but foodborne illness remains a common, costly, yet largely preventable public health problem. The Centers for Disease Control and Prevention (CDC) estimated in 2011—its most recent estimate—that each year, one in six people in the United States gets sick from eating contaminated food. According to CDC, while the source of foodborne outbreaks is often unknown,¹ certain pathogens in food cause more than 9 million human illnesses per year in the United States, 2 million of which are caused by *Salmonella* and *Campylobacter*.² For example, according to a CDC outbreak investigation report, in 2015, 192 people in five states became ill from eating pork contaminated with *Salmonella*.³

The U.S. Department of Agriculture (USDA) is responsible for ensuring the safety and wholesomeness of meat and poultry products that enter commerce, as provided by the Federal Meat Inspection Act and the Poultry Products Inspection Act.⁴ Accordingly, USDA's Food Safety and Inspection Service (FSIS) inspects and regulates the production of

¹According to CDC's website, when two or more people get the same illness from the same contaminated food or drink, the event is called a foodborne outbreak.

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

³Centers for Disease Control and Prevention, *2015 Outbreaks: Multistate Outbreak of Multidrug-Resistant Salmonella I 4, [5], 12:i:- and Salmonella Infantis Infections Linked to Pork* (Final Update) (Atlanta, GA: December 2, 2015).

⁴21 U.S.C. §§ 601-683 and 21 U.S.C. §§ 451-472.

domestic meat and poultry products sold for human consumption. For meat and poultry processing and slaughter plants (hereafter referred to as plants) under its jurisdiction, FSIS sets pathogen reduction performance standards (hereafter referred to as pathogen standards) limiting the allowable levels of *Salmonella* or *Campylobacter*.⁵ FSIS personnel perform inspection activities at nearly 6,500 plants nationwide, including testing samples of meat and poultry products to assess compliance with the pathogen standards, which vary by product. For fiscal year 2016, Congress appropriated more than \$1 billion to FSIS for its activities, including its food safety inspection program, through the annual appropriations process.

In September 2014, we found that USDA had taken a number of actions to reduce the levels of *Salmonella* and *Campylobacter* in poultry (chicken and turkey) products but that the agency needed to do more to assess the effects of these actions on the incidence of foodborne illnesses.⁶ As a result, we recommended that USDA develop performance measures to monitor whether its activities to reduce the levels of *Salmonella* and *Campylobacter* in domestic poultry products are meeting agency goals. USDA agreed with and implemented this recommendation. We also identified several challenges that could hinder USDA's ability to reduce levels of pathogens in poultry products; in particular, we found that pathogen standards for poultry products were outdated or nonexistent. Other challenges we identified included limited USDA control over factors that affect pathogen contamination outside of plants, plants not designating pathogens as hazards, and the complex nature of pathogens, among others. We recommended that FSIS include in its guidelines information on the effectiveness of on-farm practices to reduce the level of pathogens in live poultry. USDA agreed with and is taking steps to implement this recommendation.

However, according to CDC data, consumption of poultry products continues to be associated with foodborne illness in the United States, as

⁵FSIS pathogen standards apply to meat and poultry products that are raw or not fully cooked. When USDA purchases raw ground beef for certain programs, such as the National School Lunch Program, it does not allow for any *Salmonella* contamination. For additional information, see appendix I.

⁶GAO, *Food Safety: USDA Needs to Strengthen Its Approach to Protecting Human Health from Pathogens in Poultry Products*, [GAO-14-744](#) (Washington, D.C.: Sept. 30, 2014). Additional GAO reports in the area of food safety are listed in "Related GAO Products" at the end of this report.

does the consumption of meat (such as beef and pork).⁷ Further, according to a 2016 CDC report, the United States is not on track to reach its public health goals for reducing foodborne illnesses caused by *Salmonella* and *Campylobacter*.⁸

You asked us to review USDA's approach to reducing the level of pathogens in domestic meat and poultry products, including its use of pathogen standards. This report examines (1) the extent to which USDA has developed pathogen standards for meat and poultry products and (2) any additional steps that USDA has taken to address challenges we identified in 2014 in reducing the level of pathogens.

To examine the extent to which USDA has developed pathogen standards for meat and poultry products, we reviewed our prior findings and recommendations from September 2014 on pathogen standards for poultry products.⁹ We also reviewed relevant laws and regulations, FSIS strategic plans covering the period from 2011 through 2021, and FSIS annual performance plans from 2014 through 2018. We reviewed relevant *Federal Register* notices on specific pathogen standards for meat and poultry from 1996, when FSIS first established the standards, through 2016, when the agency set or revised the most recent pathogen standards.¹⁰ We identified relevant performance goals and measures in FSIS annual performance plans from 2012 through 2017. We reviewed FSIS reports on pathogens in meat and poultry products and annual sampling plans—estimates of the type and number of products the agency will test for certain pathogens—to understand the range of meat and poultry products FSIS monitors for pathogens.¹¹ In addition, we interviewed current and former FSIS officials on the history of the 1996 Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP)

⁷Centers for Disease Control and Prevention, *Surveillance for Foodborne Disease Outbreaks, United States, 2015: Annual Report* (Atlanta, GA: 2017).

⁸Centers for Disease Control and Prevention, *Healthy People 2020 Midcourse Review* (Atlanta, GA: 2016).

⁹[GAO-14-744](#).

¹⁰61 Fed. Reg. 38,806 (July 25, 1996); 81 Fed. Reg. 7285 (Feb. 11, 2016).

¹¹FSIS's annual sampling plan describes the major activities related to microbiological sampling and the agency's overall strategy for directing its sampling resources.

regulations,¹² related pathogen standards, and the process and criteria for developing new pathogen standards and revising existing ones. We reviewed documents and interviewed staff from USDA's Agricultural Marketing Service—which purchases commodities, including meat and poultry products, for federal nutrition assistance programs such as the National School Lunch Program—to determine any additional steps USDA takes to prevent pathogens in meat and poultry products used for school meals.¹³ We reviewed data FSIS collected on compliance rates for meat and poultry plants from 2014 through 2017 and data on foodborne illness rates from CDC from 1998 through 2016, the most recent data available. To assess the reliability of the data, we interviewed CDC officials about the steps they took to ensure the reliability of the data and determined that these data were sufficiently reliable for viewing trends in compliance rates and trends in foodborne illness rates.

We identified an initial group of stakeholders from our prior work, specifically from those we interviewed in our 2013 report on USDA's changes to poultry and hog inspections and our 2014 report on poultry pathogens.¹⁴ In addition, we asked these groups for recommendations on other stakeholders we should consider contacting and expanded the list, as needed. We selected these stakeholders because they are knowledgeable about FSIS's food safety programs and provide a range of views on the topic. In the end, we identified a nongeneralizable sample of 17 stakeholders: 7 representatives from industry, 4 representatives from consumer advocacy groups, 4 food safety researchers, and 2 former federal food safety experts. Views from those we selected based on their

¹²61 Fed. Reg. 38806 (July 25, 1996). Under the HACCP approach, industry—rather than federal inspectors—is responsible for (1) identifying food safety hazards that are reasonably likely to occur and (2) establishing controls that prevent or reduce these hazards. Plants are required to consider hazards that can occur before, during, and after entry into the establishment. As part of the HACCP approach, 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. Plants must also conduct activities to verify the plans are being effectively implemented.

¹³Commodities include foods procured by USDA and provided to states at no charge for schools to serve in school meal programs. School meal programs include the National School Lunch Program, which, in addition to providing lunches, provides after-school snacks; the School Breakfast Program; and Special Milk Program. For additional information, see appendix I.

¹⁴GAO, *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); [GAO-14-744](#).

knowledge cannot be generalized to all stakeholders who have knowledge about FSIS's food safety programs (i.e., those we did not interview), but they provide illustrative examples. We obtained information from agency documentation and interviews with FSIS officials regarding the process for developing new pathogen standards and compared this process with federal standards for internal control.¹⁵ We also obtained information from FSIS documentation and interviews with agency officials on the agency's plans to review or revise pathogen standards. We compared these plans with the Project Management Institute's standards and leading practices for project management.¹⁶

To examine any additional steps that USDA has taken to address the challenges we identified in 2014 that it faces in reducing the level of pathogens in meat and poultry, we reviewed agency documentation on the steps it has taken to address these challenges since 2014, including documentation on relevant laws and regulations; *Federal Register* notices; FSIS's 2017-2021 strategic plan, annual performance plans and related performance reports from 2015 through 2017, and 2016 Establishment-Specific Data Release Strategic Plan;¹⁷ and USDA and FSIS websites. We reviewed FSIS guidance regarding on-farm practices for reducing the level of pathogens in live animals before they enter plants and compared this information with recommendations on such practices made in 2011 by the USDA National Advisory Committee on Meat and Poultry Inspection. We also reviewed reports from the Interagency Food

¹⁵GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: September 2014).

¹⁶The Project Management Institute is a not-for-profit association that provides global standards for, among other things, project and program management. These standards are utilized worldwide and provide guidance on how to manage various aspects of projects, programs, and portfolios. See Project Management Institute, Inc., *The Standard for Program Management*®, Third Edition (2013).

¹⁷FSIS's 2016 establishment-specific data release strategic plan is separate from the agency's strategic plan. The document provides a framework under which FSIS plans to responsibly and effectively release plant-level data collected by the agency. Among other things, it describes FSIS's data collection activities, data release procedures, and a prioritized list of data for public release.

Safety Analytics Collaboration,¹⁸ USDA's Office of Inspector General, and the National Academy of Sciences.

We obtained testing data from FSIS for the period from May 2016 through August 2017, the most recent data available, to determine the number of plants that did not meet the chicken carcass *Salmonella* and *Campylobacter* standards. To assess the reliability of FSIS's data, we interviewed FSIS officials about the steps they took to ensure the reliability of the data and determined that the data were sufficiently reliable for analyzing the number of plants that did not meet the pathogen standards during the reporting period. We reviewed CDC data on foodborne illness outbreaks from beef and pork from 2006 through 2016 and obtained recall documents from FSIS on plants that produced products involved in those outbreaks. We interviewed FSIS officials about any challenges the agency faces in reducing pathogens in meat and poultry and steps the agency has taken since 2014 to address previously identified challenges. Additionally, we interviewed FSIS and CDC officials on steps the agencies have taken to improve the methods used to estimate the burden of foodborne illness in the United States and the use of emerging technologies to detect the pathogen strains most harmful to human health. Further, we interviewed the stakeholder groups we identified for our first objective about USDA's efforts to address the challenges we identified in 2014.

We conducted this performance audit from June 2016 to January 2018 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.

¹⁸To enhance the safety of our food, CDC, USDA, and FSIS teamed up in 2011 to create the Interagency Food Safety Analytics Collaboration. According to the interagency collaboration's website, its goal is to improve the coordination of federal food safety analytic efforts and address cross-cutting priorities for food safety data collection, analysis, and use. Projects and studies by the interagency collaboration aim to identify foods that are important sources of illnesses.

Background

Salmonella



According to the Centers for Disease Control and Prevention (CDC), *Salmonella* bacteria can cause illness in humans—salmonellosis. There are thousands of serotypes—groups within a single species that share distinctive surface structures—of *Salmonella* but not all cause illness in people.

CDC estimates that approximately 1 million illnesses occur annually in the United States because of *Salmonella* in food. Most people infected with *Salmonella* develop diarrhea, fever, and abdominal cramps within 12 to 72 hours. The illness usually lasts 4 to 7 days, and most individuals recover without treatment.

In some cases, however, diarrhea may be so severe that the patient needs hospitalization, according to CDC. The *Salmonella* infection may also spread from the intestines to the bloodstream, and then to other body sites. In these cases, *Salmonella* can cause death unless the person is treated promptly with antibiotics. The elderly, infants, and those with impaired immune systems are more likely to have a severe illness.

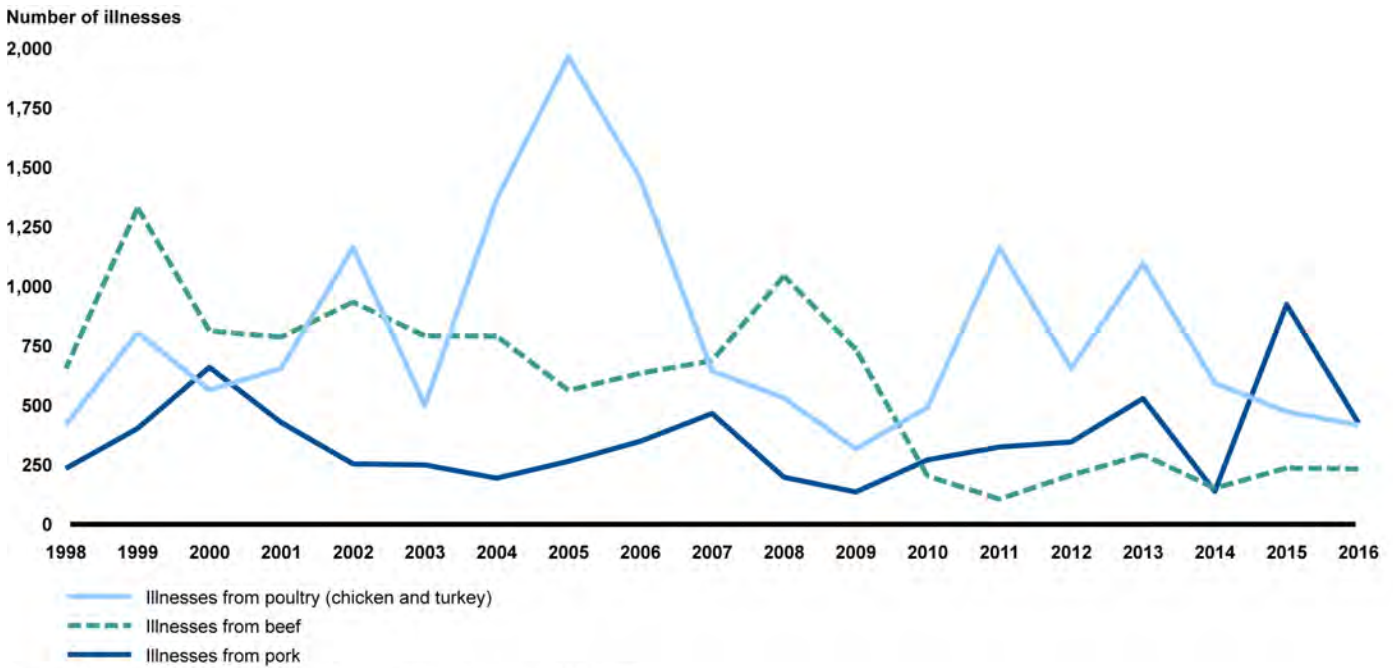
Source: GAO analysis of information provided by CDC.
Image: Courtesy of CDC, James Archer. | GAO-18-272

Contact with infected animals or consumption of contaminated water and food—including produce, meat, poultry, and processed products—can cause foodborne illness. Many different pathogens can contaminate food, including harmful bacteria such as *Salmonella* and *Campylobacter*. CDC reported that in 2015 there were 902 foodborne disease outbreaks reported in the United States that resulted in 15,202 illnesses, 950 hospitalizations, 15 deaths, and 20 food product recalls.¹⁹ According to CDC, fish, chicken, and pork were the most common single food categories implicated in these outbreaks. More recently, in 2016, there were 233 foodborne illnesses from 10 outbreaks linked to beef, 426 foodborne illnesses from 17 outbreaks linked to pork, and 417 foodborne illnesses from 20 outbreaks linked to poultry, according to CDC's National Outbreak Reporting System (see fig. 1).²⁰ Common symptoms of foodborne diseases include nausea, vomiting, stomach cramps, and diarrhea. Symptoms can sometimes be severe, and some foodborne illnesses can be life-threatening. Although anyone can get a foodborne illness, some people are more likely to have one. Those groups include young children, older adults, pregnant women, and people with immune systems weakened from medical conditions, such as diabetes, liver, and kidney disease. Patients receiving chemotherapy or radiation treatment are also more susceptible.

¹⁹Centers for Disease Control and Prevention, *Surveillance for Foodborne Disease Outbreaks United States, 2015: Annual Report* (Atlanta, GA: 2017).

²⁰These data are from CDC's National Outbreak Reporting System, a web-based platform that uses a standard data collection form. An outbreak reported to the system is defined as the occurrence of two or more cases of a similar illness resulting from a common exposure. Reporting of outbreaks to CDC is voluntary; outbreaks are likely underreported due to limited resources and training in health departments.

Figure 1: Foodborne Outbreak-associated Illness Linked to Beef, Pork, and Poultry Products, 1998 through 2016



Source: GAO analysis of Centers for Disease Control and Prevention data. | GAO-18-272

Notes: These data are from the Centers for Disease Control and Prevention’s (CDC) National Outbreak Reporting System, a web-based platform that uses a standard data collection form. An outbreak reported to the system is defined as the occurrence of two or more cases of a similar illness resulting from a common exposure. Reporting of outbreaks to CDC is voluntary; outbreaks are likely underreported because of limited resources and training in health departments. These data include outbreaks in all 50 states (including outbreaks occurring in multiple states), the District of Columbia, and U.S. territories. These data include outbreaks with one or more bacterial, viral, chemical or toxin, parasitic, or unknown causes and suspected and confirmed etiologies. Implicated foods in outbreaks are classified into 1 of 24 single food categories (e.g., beef, pork, chicken, or turkey) if a single contaminated ingredient was identified or if all ingredients belonged to that category.

Campylobacter



According to the Centers for Disease Control and Prevention (CDC), *Campylobacter* bacteria can cause illness in humans—campylobacteriosis. In contrast, *Campylobacter* seems to be well adapted to birds, which carry it without becoming ill. Most campylobacteriosis in humans is caused by one species, *Campylobacter jejuni*, but other species can also cause human illness. *Campylobacter* can infect anyone, but campylobacteriosis is more common in males, children younger than 5 years, and people ages 65 years and older.

According to CDC, *Campylobacter* is one of the most common causes of diarrheal illness in the United States; other common symptoms include fever, abdominal cramps, nausea, and vomiting. Some infected people do not have any symptoms. Symptoms usually start within 2 to 5 days after exposure and last about a week. Most cases occur as isolated events, not as part of recognized outbreaks. CDC estimates that *Campylobacter* in food causes 850,000 illnesses each year in the United States. Campylobacteriosis occurs more frequently in the summer months than in the winter.

Although most people who get ill from *Campylobacter* recover completely, according to a 2011 CDC study on foodborne illnesses acquired in the United States, approximately 76 persons with *Campylobacter* infections die each year.

Source: GAO analysis of information provided by CDC. Image: Courtesy of CDC, James Archer. | GAO-18-272

We have previously reported that to improve its food safety approach, FSIS moved to an increasingly science-based, data-driven, risk-based approach by adopting the Pathogen Reduction; HACCP regulations in 1996.²¹ Under the HACCP approach, each plant 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 in its processes. As part of this approach, 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. FSIS inspectors at slaughter and processing plants routinely check records to verify a plant's compliance with those plans. FSIS inspectors also observe operations at plants as part of their inspection activities. Under the 1996 HACCP regulations, the agency also established *Salmonella* pathogen standards used to assess the effectiveness of plants' controls in reducing levels of pathogens in meat and poultry products. According to the regulations, FSIS selected *Salmonella* for pathogen standards because, among other things, it was the most common bacterial cause of foodborne illness, and they believed that intervention strategies aimed at reducing fecal contamination and other sources of *Salmonella* on raw product should be effective against other pathogens.²² FSIS has a verification-testing program in which FSIS inspectors at plants collect samples of certain products and test them to determine whether plants meet the pathogen standards. Test results from this program help FSIS inspectors verify that plant HACCP plans are working and identify and assist plants whose process controls may be underperforming. FSIS also requires products to be labeled with instructions for safe handling.

²¹ GAO-14-744; 61; *Fed. Reg.* 38,806 (July 25, 1996).

²² According to CDC's website, other foodborne pathogens found in meat and poultry include *Clostridium perfringens*, *Listeria monocytogenes*, and *Yersinia enterocolitica*.

Multistate Outbreak of *Escherichia coli* O157:H7 Infections from Hamburgers, 1992-1993



In the early 1990s, a strain of *Escherichia coli* (*E. coli*) bacteria linked to hamburger resulted in a deadly foodborne outbreak and led to changes in food regulations. *E. coli* are bacteria found in the environment, food, and intestines of people and animals. *E. coli* are a large and diverse group of bacteria. Most strains of *E. coli* are generally harmless, but others can cause diarrhea, urinary tract infections, respiratory illness and pneumonia, other illnesses, and death.

From November 1992 through February 1993, more than 500 laboratory-confirmed infections with *E. coli* O157:H7 and four associated deaths occurred in four states—Washington, Idaho, California, and Nevada. During the outbreak, contaminated hamburger patties were traced to a fast food restaurant chain and then ultimately to five slaughter plants in the United States and one in Canada as likely sources of carcasses used to produce the contaminated ground beef. No one slaughter plant or farm was identified as the source. In 1994, USDA's Food Safety and Inspection Service declared that any raw ground beef found contaminated with *E. coli* O157:H7 would be adulterated under the Federal Meat Inspection Act—rendering the meat unlawful to sell in commerce.

Source: GAO analysis of Centers for Disease Control and Prevention and U.S. Department of Agriculture (USDA) documents. Image: Courtesy of USDA. | GAO-18-272

In contrast to *Salmonella* and *Campylobacter*, which are subject to pathogen standards, FSIS considers certain serotypes of *Escherichia coli* (*E. coli*),²³ another type of disease-causing pathogen, adulterants under the definition of “adulterated” in the Meat Inspection Act and the Poultry Inspection Act.²⁴ The acts define an adulterant in meat and poultry products to include, among other things, “any poisonous or deleterious substance which may render it injurious to health.” Meat and poultry products contaminated with any level of adulterants are not permitted to enter commerce—a stricter standard than the pathogen standards, which allow certain levels of contamination. FSIS initially declared *E. coli* O157:H7 as an adulterant in ground beef following an outbreak from 1992 to 1993 that involved Jack-in-the-Box hamburgers and, in 2011, declared an additional six non-O157 Shiga-toxin-forming *E. coli* in certain raw beef products as adulterants.

²³*E. coli* bacteria live in the intestines of healthy cattle and have a symbiotic relationship with the cattle, an association in which the *E. coli* derives the benefit and the cattle are not harmed. A cow with *E. coli* in its intestinal system typically “sheds” the organism through its feces. As cattle shed *E. coli*, the bacteria can contaminate the hides and then the meat as the cattle are slaughtered. Several strains of *E. coli* are highly pathogenic and capable of causing death when they infect humans. See GAO, *Food Safety: Preslaughter Interventions Could Reduce E. coli in Cattle*, GAO-12-257 (Washington, D.C.: Mar. 9, 2012).

²⁴21 U.S.C. §§ 601-683 and 21 U.S.C. §§ 451-472.

Meat and Poultry in the United States

Beef: According to the U.S. Department of Agriculture (USDA), beef is a highly consumed meat in the United States, averaging 56 pounds per person per year. Beef comes from full-grown cattle that are about 2 years old and weigh about 1,000 pounds. There are at least 50 breeds of beef cattle, but fewer than 10 make up most cattle produced. Veal is meat from a calf (young cattle) that weighs about 150 pounds. Calves that are mainly milk-fed usually are less than 3 months old.

Pork: According to the USDA, the United States is the world's third-largest producer and consumer of pork and pork products. Pork is meat from hogs, or domestic swine, and is from young animals (6 to 7 months old) that weigh from 175 to 240 pounds.



Poultry: According to USDA, consumption of poultry (chicken and turkey) in the United States is higher than beef or pork. Chicken includes broiler-fryer chickens and roaster chickens. Broiler-fryer chickens are young, tender chickens about 7 weeks old that weigh from 2 ½ to 4 ½ pounds. Roaster chickens are young chickens from 8 to 12 weeks old with a ready-to-cook carcass weight of 5 pounds or more. Turkey is a large, widely domesticated North American bird. They grow to full maturity in about 4 to 5 months, depending on the desired market weight.

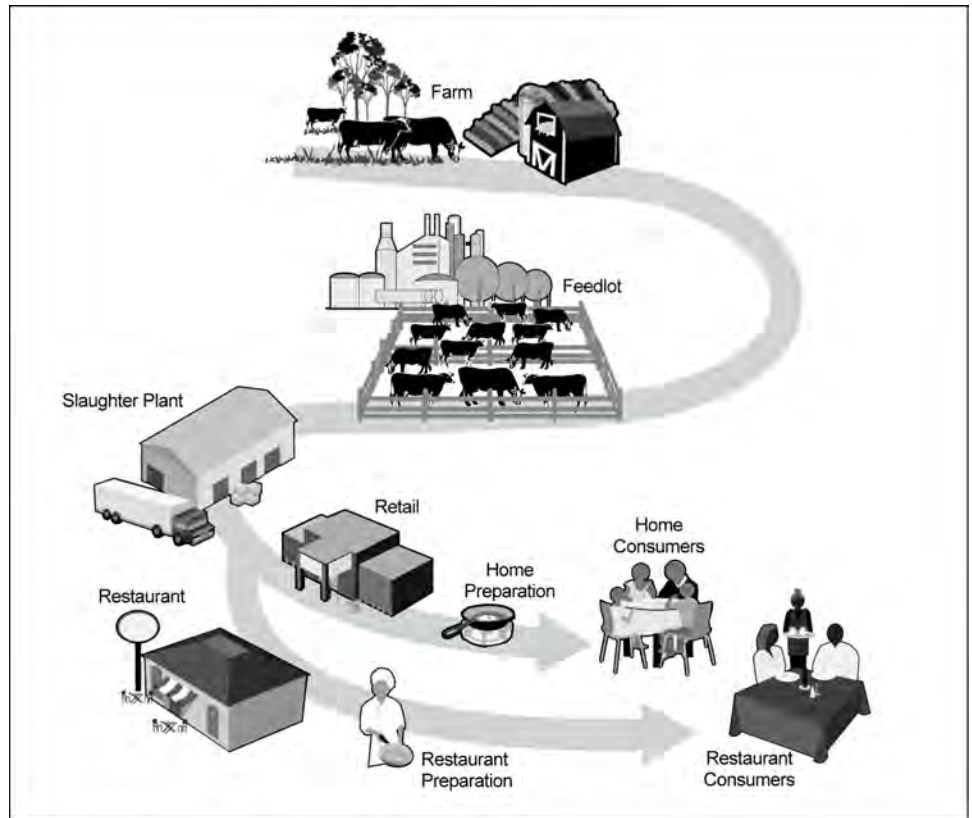
Source: GAO analysis of information provided by USDA.
Image: Courtesy of USDA, Lance Cheung. | GAO-18-272

FSIS coordinates with numerous federal agencies, state agencies, and local entities to help ensure the safety of meat and poultry products from the farm to the consumer (known as the farm-to-table continuum).²⁵ FSIS coordinates with USDA's Animal and Plant Health Inspection Service (APHIS) to share information when investigating foodborne illnesses. FSIS also coordinates with the Department of Health and Human Services' Food and Drug Administration (FDA) and with CDC on a number of activities. For example, FSIS works collaboratively with FDA and CDC through the Interagency Food Safety Analytics Collaboration to, among other things, estimate foodborne illness source attribution. Attribution entails identifying which foods are the most important sources of selected major foodborne illnesses.²⁶ According to FSIS officials, determining the sources of illness is an important part of identifying opportunities to improve food safety. FSIS also coordinates with CDC and state health departments to respond to foodborne illness outbreaks, including identifying the pathogen, the product, and where the product became contaminated along the farm-to-table continuum (see fig. 2).

²⁵The farm-to-table continuum for food safety includes all facets of the production process: on the farm, animal slaughter in FSIS-regulated plants, food processing within regulated plants, retail or market establishments (e.g., grocery stores), and home environments.

²⁶FSIS is responsible for the safety of meat, poultry, and processed egg products. A provision of the Food, Conservation, and Energy Act of 2008, Pub. L. No. 110-246 § 11016(b) amended the Federal Meat Inspection Act to, among other things, subject catfish to the inspection requirements of the Federal Meat Inspection Act. The Agricultural Act of 2014, Pub. L. No. 113-79 §12106(a), among other things, amended the 2008 provision to instead make all fish of the order Siluriformes subject to Federal Meat Inspection Act inspections. The order *Siluriformes* includes the families of *Ictaluridae*, *Clariidae*, and *Pangasiidae*. FDA is responsible for virtually all other food.

Figure 2: Example of Farm-to-Table Continuum for Beef



Sources: Centers for Disease Control and Prevention and GAO. | GAO-18-272

Note: According to the U.S. Department of Agriculture, conventional beef production includes placing cattle on feedlots. Other types of cattle are produced through alternate systems. For example, beef from alternate production systems—including natural, organic, and grass- or forage-fed—account for about 3 percent of the U.S. beef market.

Additionally, FSIS, CDC, FDA, representatives from state and local regulatory offices, and stakeholders outside the government developed Healthy People 2020 food safety targets to reduce rates of infection caused by certain foodborne pathogens, including *Salmonella* and *Campylobacter*, by the year 2020. According to FSIS officials, FSIS will continue to co-lead the Healthy People Food Safety Working Group, which includes setting Healthy People 2030 targets for reductions in foodborne illness and monitoring progress.

USDA Has Developed or Revised Standards for Reducing the Level of Pathogens in Certain Products but Not Others

USDA's FSIS has developed or revised pathogen standards for assessing the effectiveness of plants' controls in reducing the level of pathogens in certain meat and poultry products. More specifically, the agency has developed pathogen standards for some beef, pork, chicken, and turkey products but not for other products that are widely available, and its basis for deciding which products to consider for new pathogen standards is unclear. In addition, as of 2011, the agency has revised pathogen standards for chicken and turkey products, but standards for other products are outdated, with no time frames for revision.

USDA Has Developed Standards for Some Meat and Poultry Products but Not Others, and Its Basis for Deciding Which Products to Consider for New Standards Is Unclear

FSIS has developed pathogen standards for beef, pork, chicken, and turkey carcasses; specific chicken parts (i.e., breasts, thighs, and legs); and ground beef, chicken, and turkey (see Figure 3). The initial pathogen standards FSIS developed in 1996 were all for *Salmonella* because, among other things, it was the most common bacterial cause of foodborne illness and intervention strategies aimed at reducing *Salmonella* in raw products might be effective against other pathogens, according to agency documents. Subsequently, in 2011, FSIS developed *Campylobacter* standards for chicken and turkey carcasses and in 2016 developed *Salmonella* and *Campylobacter* standards for chicken parts.

Figure 3: Raw Meat and Poultry Products with Pathogen Standards

Products with <i>Salmonella</i> standards	
Beef	
	Carcass ^a
	Ground
Pork	
	Carcass
Chicken	
	Carcass
	Parts
	Comminuted (including ground)
Turkey	
	Carcass
	Comminuted (including ground)
Products with <i>Campylobacter</i> standards	
Chicken	
	Carcass
	Parts
	Comminuted (including ground)
Turkey	
	Carcass
	Comminuted (including ground)

Source: GAO analysis of U.S. Department of Agriculture (USDA) documents. | GAO-18-272

Notes: Ground pork is a type of comminuted (i.e., broken into a number of pieces) product that also includes sausage and patties. Ground poultry is a type of comminuted product that also includes deboned products, among others. Chicken parts include breasts, legs, and wings. USDA originally selected *Salmonella* for pathogen standards because it was the most common cause of foodborne illness associated with meat and poultry products and because FSIS believed that intervention strategies aimed at reducing fecal contamination and other sources of *Salmonella* in raw products might be effective against other pathogens. According to USDA, *Campylobacter* is most often isolated from the intestinal tract of poultry and from poultry products.

^aUSDA has separate pathogen standards for cows/bulls and steers/heifers.

FSIS has not developed pathogen standards for other widely available products, such as pork cuts (e.g., pork chops), turkey parts (e.g., turkey breasts), and ground pork. The agency is taking steps that may lead to the development of new pathogen standards for additional products. For example, according to FSIS documents, the agency is collecting information on the presence of *Salmonella* and other pathogens in pork

cuts and ground pork, among other pork products.²⁷ According to FSIS officials, this could lead to the development of new standards.

However, the agency's process for deciding which products to consider for new pathogen standards is unclear because it is not fully documented. In December 2016, the agency documented a part of its process: who will make the decisions about which products to consider. According to the December 2016 document, certain agency officials are to meet as needed to discuss emerging food safety risks and propose related data collection efforts to senior management, who will decide which products to consider for new standards. However, the document does not explain the basis for management's decisions. FSIS has informed stakeholders that it will take into account factors including consumption and foodborne-illness data, as it did when setting standards for chicken parts, but the agency has not documented this process going forward. Several researchers and consumer advocacy representatives we interviewed questioned whether the agency's process proactively addresses food safety risks.

Previously, FSIS developed new pathogen standards after the agency was directed to do so or after widespread outbreaks indicated the need. For example, in 2011, FSIS revised *Salmonella* standards for chicken and turkey carcasses and developed new standards for *Campylobacter* in these same products after being charged with doing so by the Presidential Food Safety Working Group.²⁸ Additionally, in a 2016 *Federal Register* notice,²⁹ FSIS, after reviewing outbreaks from these products in 2011, 2013, and 2015—outbreaks in which 794 people were sickened and 1 died—concluded that new pathogen standards were needed for comminuted (including ground and other mechanically separated) poultry and chicken parts.

²⁷According to FSIS officials, any potential new pathogen standards for pork products may be directed at comminuted pork, which includes ground pork.

²⁸In March 2009, the President established the Food Safety Working Group to coordinate federal efforts and establish food safety goals to make food safer. This working group served as a centralized mechanism for broad-based food safety collaboration and resulted in a number of accomplishments, including improved coordination. However, the working group is no longer meeting. See GAO, *Federal Food Safety Oversight: Additional Actions Needed to Improve Planning and Collaboration*, [GAO-15-180](#) (Washington, D.C.: Dec. 18, 2014).

²⁹81 Fed. Reg. 7285 (February 11, 2016).

Under federal standards for internal control, federal entities are to design control activities to achieve objectives and respond to risks, including appropriate documentation of transactions and internal control.³⁰ With appropriate documentation of internal control, management clearly documents internal control and allows the documentation to be readily available for examination; the documentation may appear in management directives, administrative policies, or operating manuals. Until FSIS clearly documents its process for deciding which products to consider for new pathogen standards, including the basis on which such decisions should be made, FSIS will not have assurance that its decisions are risk-based and that agency personnel will know the process when making such decisions.

USDA Has Revised Some Existing Pathogen Standards but Has Not Revised Others in Decades and Has No Time Frames for Revision

USDA's FSIS has revised *Salmonella* standards for chicken and turkey carcasses and for comminuted chicken and turkey but has not revised other *Salmonella* standards since 1996, and the agency has not set time frames for determining whether revisions are needed. Specifically, as noted above, FSIS revised *Salmonella* standards for chicken and turkey carcasses in 2011 in response to a charge from the President's Food Safety Working Group that the agency develop new or revised standards to reduce the prevalence of *Salmonella* in poultry products. The agency revised the pathogen standards for comminuted chicken and turkey in 2016 to help achieve public health goals for reducing human illness from *Salmonella*, among other things.³¹ The revisions have generally involved reductions in the maximum allowable percentage of products that test positive for this pathogen. For example, in 2016, when the agency revised the *Salmonella* standards for comminuted chicken, the allowable percentage changed from 44.6 to 25.0. (See table 1.)

³⁰GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: September 2014).

³¹FSIS developed these goals, and associated targets, in coordination with other federal agencies, including CDC and FDA.

Table 1: USDA Pathogen Standards and the Year Developed or Revised

Product	Maximum acceptable percentage of products sampled to test positive for <i>Salmonella</i>		Maximum acceptable percentage of products sampled to test positive for <i>Campylobacter</i>	
	Initial standard (year set)	Current standard (year revised)	Initial standard (year set)	Current standard (year revised)
Beef				
Steers/heifers carcass	1.0 (1996)	1.0 (not revised)	n/a ^d	n/a ^d
Cows/bulls carcass	2.7 (1996)	2.7 (not revised)	n/a ^d	n/a ^d
Ground	7.5 (1996)	7.5 ^a (not revised)	n/a ^d	n/a ^d
Pork				
Carcass	8.7 (1996)	8.7 (not revised)	n/a ^d	n/a ^d
Chicken				
Carcass	20 (1996)	9.8 (2011)	15.7 (2011)	15.7
Parts ^b	15.4 (2016)	15.4	7.7 (2016)	7.7
Comminuted ^c	44.6 (1996)	25.0 (2016)	1.9 (2016)	1.9
Turkey				
Carcass	19.6 (2005)	7.1 (2011)	5.4 (2011)	5.4
Comminuted ^c	49.9 (1996)	13.5 (2016)	1.9 (2016)	1.9

Legend: n/a = no pathogen standard developed.

Source: GAO analysis of U.S. Department of Agriculture (USDA) documents. | GAO-18-272

Note: Pathogen standards set in 1996 for beef, pork, chicken carcasses, and ground beef are expressed as a prevalence level, i.e. the proportion of a product that would test positive for a pathogen if the entire population of that product was sampled and analyzed during a specific period. Pathogen standards set or revised in 2011 or 2016 are calculated as the percentage of samples with detectable levels of pathogens from a specified set of samples, which varies by pathogen standard.

^aIn a 2014 *Federal Register* notice, USDA announced that it intended to propose new *Salmonella* standards for ground beef. 79 Fed. Reg. 32,436 (June 5, 2014). USDA has not yet proposed such standards.

^bChicken parts includes breasts, legs, and wings.

^cComminuted chicken and turkey include ground and deboned products.

^dA 2017 report from the Interagency Food Safety Analytics Collaboration—a tri-agency group created by the Centers for Disease Control and Prevention, the U.S. Food and Drug Administration, and USDA—on the percentage of foodborne illnesses related to *Campylobacter* in 2013 attributed 29.2 percent of foodborne illnesses to chicken, 6.5 percent to pork, 4.9 percent to turkey, 1.6 percent to beef, and 12 other food groups accounted for the remainder.

However, FSIS has not revised the *Salmonella* standards for beef and pork carcasses and ground beef since they were first developed in 1996. Although USDA announced in a 2014 *Federal Register* notice that it intended to propose new pathogen standards for ground beef,³² FSIS has not done so. Furthermore, FSIS set the pathogen standards for beef and pork carcasses and ground beef at industry-wide prevalence levels found at that time,³³ not at levels intended to be protective of human health. In 2017, FSIS reviewed data on *Salmonella* in beef carcasses and ground beef and determined that the agency will not reach public health goals for reducing foodborne illness from *Salmonella* without further reduction in *Salmonella* contamination in beef. FSIS officials said that the agency is developing options for how it might move forward and could determine that revised or new standards are not needed and that other policies could suffice in addressing pathogens in beef. In the meantime, however, the agency in 2014 suspended monitoring against the existing *Salmonella* standards for ground beef until the agency develops a revised standard.³⁴ The agency also suspended monitoring whether plants were meeting the pathogen standard for *Salmonella* on pork carcasses because, according to agency officials, the percentage of pork carcass samples that tested positive for *Salmonella* was consistently low. FSIS officials said that the agency is collecting data on pathogens in pork that could lead to new standards for pork products.³⁵ In the absence of testing against the standards, the agency has other tools to ensure plants are controlling pathogens. For example, the agency continues to test beef for levels of *E. coli*, and FSIS inspectors at plants are to routinely check records to verify a plant's compliance with its HACCP plans. FSIS officials told us that they would begin monitoring against the *Salmonella* standards for these products if the standards are revised or determined to be sufficient (in the case of beef and pork carcasses and ground beef) or if the agency develops new standards (in the case of pork cuts and ground pork). Generally, FSIS begins monitoring against a standard once the agency

³²79 Fed. Reg. 32,436 (June 5, 2014).

³³Prevalence is the proportion of a product that would test positive for a pathogen if the entire population of that product was sampled and analyzed during a specific period of time.

³⁴Per agency officials, USDA was also to use those resources for other exploratory sampling programs that could result in revised standards for beef carcasses and ground beef or new standards for pork parts.

³⁵In 2015, FSIS sampled various pork products for *Salmonella*, *Campylobacter*, *Toxoplasma gondii*, *Yersinia enterocolitica*, and other pathogens. In 2016, FSIS extended sampling for certain pork products.

announces a standard and after a phase-in period has ended. For example, when FSIS developed new *Campylobacter* and *Salmonella* standards for chicken parts in 2016, the agency began monitoring whether plants met the standard 5 months after the standards were announced in the *Federal Register*.

Monitoring for compliance with pathogen standards is a key tool as envisioned by the 1996 Pathogen Reduction; HACCP Systems final rule for verifying the effectiveness of a plant's processing controls to prevent, eliminate, or reduce food safety hazards. It is unclear when FSIS plans to resume the use of this tool and complete the revisions of the *Salmonella* standards for beef carcasses or ground beef or develop new standards for additional pork products because the agency has not set time frames for doing so. According to FSIS officials, developing or revising pathogen standards takes time and resources, in part because the agency must first collect and analyze 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. However, according to FSIS officials, the agency has no time frames for determining what actions to take. Program schedule planning is recognized as a leading practice to ensure organizational activities are completed as planned, according to the Project Management Institute's Standard for Program Management. Such planning includes setting time frames for completing a project. By setting time frames for determining what pathogen standards or additional policies are needed to address pathogen levels in beef carcasses, ground beef, and pork products, FSIS could better ensure it completes these activities in a timely manner to protect human health.

USDA Is Taking Additional Steps to Address Pathogen Reduction Challenges That We Identified in 2014, but These Challenges Are Ongoing

In addition to taking steps to develop or revise pathogen standards, USDA's FSIS is addressing other challenges we identified in September 2014 with respect to poultry pathogens, but these challenges are ongoing and also apply to meat products. These challenges include FSIS's limited control over factors that affect the level of pathogens outside of plants, pathogens not designated as hazards, the complex nature of *Salmonella*, limited *Campylobacter* research and testing, limited enforcement authority,³⁶ absence of mandatory recall authority, and insufficient prevalence estimates.

Limited Control Outside of Plants

Limited Control Outside of Plants

In September 2014, we found that the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) faced a challenge in reducing levels of *Salmonella* and *Campylobacter* in poultry products in part because the agency did not have regulatory jurisdiction over farm practices to reduce contamination in poultry before they reach a plant for slaughter and processing. At the time, we noted that FSIS had worked to address the on-farm limitation by issuing guidelines that detailed, among other things, several on-farm practices to reduce *Salmonella* and *Campylobacter* in live poultry. We recommended that in future revisions of the guidelines, FSIS include information on the effectiveness of on-farm practices to explain the potential benefits of adopting such practices on poultry farms. USDA concurred with our recommendation. In addition, we found that once poultry products leave a plant, factors beyond FSIS's control may affect contamination of poultry products, such as cross-contamination from poultry products (i.e., when bacteria spread from a food to a surface, from a surface to another food, or from one food to another) that can occur at retail establishments, in restaurants, and in consumers' homes, according to a food safety researcher we interviewed.

Source: GAO | GAO-18-272

Since our September 2014 report, FSIS has taken steps to help overcome not having regulatory jurisdiction to reduce the level of pathogens before and after slaughter and processing. With respect to reducing pathogens before slaughter and processing, the agency has implemented our recommendation to include information on effectiveness in its guidelines about on-farm practices to reduce *Salmonella* and *Campylobacter* in live poultry. The agency has also included such

³⁶We identified limited enforcement authority as a potential challenge, rather than a challenge, because FSIS officials told us that the agency had tools to overcome enforcement authority limitations.

information in guidelines for beef cattle.³⁷ However, it has not taken similar action for hogs. Specifically:

- Poultry: FSIS drafted revised guidelines in 2015 regarding, among other things, on-farm practices for reducing *Salmonella* and *Campylobacter* in live chickens and turkeys, with information on the effectiveness of these practices, as a USDA advisory committee recommended in 2011 (for livestock and poultry) and as we recommended in September 2014 for poultry.³⁸ According to FSIS officials, the agency has kept the poultry guidelines in draft form while it responds to public comments on the document.
- Beef: The agency has already taken similar action to reduce *Salmonella* in beef cattle. Specifically, in 2014, FSIS revised guidelines regarding on-farm practices for reducing Shiga-toxin-producing *E. coli* in cattle—practices that, according to agency officials, may also assist in reducing *Salmonella*. These guidelines included information about the application of on-farm practices and research on their effectiveness. For example, the 2014 guidelines describe research on the effects of different feed—such as hay, grain, and grass—on reducing pathogens in cattle. In 2017, FSIS issued revised guidelines that also include information from the 2014 document on the effectiveness of on-farm practices.

³⁷According to USDA data on livestock slaughtered under federal inspection, less than 10 percent of beef is from dairy cows. The agency's guidelines for beef cattle, which includes information regarding on-farm practices and the effectiveness of these practices, also includes some information for dairy cattle.

³⁸[GAO-14-744](#).

Pathogen Contamination after Products Leave the Plant

According to the Centers for Disease Control and Prevention (CDC), even if meat and poultry products leave the processing or slaughter plant with no detectable pathogen, it does not ensure that the products are safe, as opportunities exist for them to become contaminated at any point along the farm-to-table continuum.

To illustrate, frozen hamburger patties might be trucked from a plant to a supplier, stored in the supplier's warehouse for a few days, trucked again to a local distribution facility, and then delivered to a restaurant. According to CDC, if refrigerated food is left on a loading dock during transportation for an extended time in warm weather, the food could reach temperatures that allow pathogens to grow.



Contamination can also occur during preparation in consumers' homes if food is not properly stored, prepared, heated, or served. For example, according to CDC, once contamination occurs, if meat and poultry are stored or cooked at unsafe temperatures, pathogens will grow quickly, which may lead to foodborne illness.



Source: GAO analysis of information provided by CDC. Top image: Courtesy of U.S. Department of Agriculture (USDA), Lance Cheung. Bottom image: Courtesy of USDA. | GAO-18-272

- Pork: FSIS has had draft guidelines in place since 2013 concerning, among other things, on-farm practices to reduce levels of *Salmonella* contamination in hogs. The draft *Salmonella* guidelines are available on the agency's website. Even though the guidelines are not yet finalized, FSIS encourages producers to use them, according to agency officials we interviewed. However, unlike the poultry and beef cattle guidelines, the draft *Salmonella* guidelines do not contain information on the effectiveness of on-farm practices, as recommended in 2011 by USDA's National Advisory Committee on Meat and Poultry Inspection.³⁹ According to the draft guidelines, when a plant makes changes at the appropriate processing location, process control should result in raw pork products that have less contamination with pathogens, including *Salmonella*. FSIS officials we interviewed told us that there is not as much research available for such practices for hogs as there is for beef cattle and poultry. However, the officials agreed that including available information would be beneficial. By including available information on the effectiveness of these practices to reduce the level of pathogens as it finalizes its guidelines for controlling *Salmonella* in hogs, FSIS would have better assurance that it is keeping industry informed of the potential benefits of adopting on-farm practices and encourage their implementation.

With respect to reducing pathogens after slaughter, FSIS continues to update its guidance to consumers and work with federal partners to ensure the safety of meat and poultry products after they leave the plant. For example:

- In 2015, the agency developed the FoodKeeper mobile application to educate consumers on how to use food while at peak quality and store food properly.⁴⁰ It updated the application in 2017 so users could receive automatic notifications when FDA or FSIS announces food safety recalls.
- In 2016, FSIS and FDA announced that they would work together to revise the FDA Food Code—a model that local, state, tribal, and

³⁹Established 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).

⁴⁰The application provides consumers with information on proper cooking temperatures and how long food can be stored.

federal regulators use to ensure food safety at retail stores, restaurants, and institutions such as nursing homes, among others—to ensure consistency with FSIS regulations and guidance.⁴¹

- In 2017, FSIS expanded the operating hours for its Meat and Poultry Hotline, through which consumers could speak with an agency representative or listen to recorded messages regarding food safety, such as the proper storage, handling, and preparation of meat and poultry products.

Pathogens Not Designated as Hazards

Pathogens Not Designated as Hazards

In September 2014, we found that the U.S. Department of Agriculture’s Food Safety and Inspection Service (FSIS) faced a challenge in reducing *Salmonella* and *Campylobacter* contamination in poultry products when plants do not designate these pathogens as hazards. Under the Hazard Analysis and Critical Control Point (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. FSIS’s 2014 final rule for modernizing poultry slaughter inspection requires plants to develop, implement, and maintain written procedures to prevent contamination of carcasses and parts by enteric pathogens—bacteria that normally reside in the intestines of many animals, including humans, such as *Salmonella* and *Campylobacter*—as well as fecal material.⁴² Plants must incorporate these procedures into their HACCP plans, sanitation procedures, and other programs.

Source: GAO | GAO-18-272

Since our September 2014 report, FSIS has not required hog and beef plants to designate *Salmonella* or *Campylobacter* as hazards likely to occur, but it has taken other steps to reduce *Salmonella* and *Campylobacter* contamination when plants do not designate these pathogens as hazards.⁴³ More specifically, in February 2018, FSIS

⁴¹ According to its website, FDA published the Food Code in its current format every 2 years from 1993 to 2001. With the support of the Conference for Food Protection, FDA decided to move to a 4-year interval between complete Food Code editions. During the interim period between full editions, FDA may publish a Food Code Supplement that updates, modifies, or clarifies certain provisions. The 2005 Food Code was the first full edition published on the new 4-year interval, and it was followed by the Supplement to the 2005 Food Code, which was published in 2007. The 2013 Food Code is the most recent full edition published by FDA.

⁴² 79 Fed. Reg. 49,566 (Aug. 21, 2014).

⁴³ A 2017 report from the Interagency Food Safety Analytics Collaboration, a tri-agency group created by CDC, FDA, and FSIS, on the percentage of foodborne illness related to *Campylobacter* in 2013 attributed 29.2 percent of foodborne illnesses to chicken, 6.5 percent to pork, 4.9 percent to turkey, 1.6 percent to beef, and 12 other food groups accounted for the remainder.

proposed a rule to modernize hog slaughter inspections. The proposed rule would require plants to develop, implement, and maintain written procedures to prevent contamination by enteric pathogens in pork.

Stakeholders we interviewed representing industry and consumer advocacy groups disagreed on whether plants should be required to designate specific pathogens as a hazard reasonably likely to occur. However, in response to instances in which inadequate validation of HACCP plans led to the production of adulterated food, and in some cases illnesses, FSIS released compliance guidance outlining best practices for designing and implementing adequate HACCP plans for all plants in 2015. According to FSIS, plants can use the guidance to properly design and execute HACCP plans and reduce the likelihood of contamination of the products they produce. Specifically, the guidance outlines, among other things, best practices for gathering scientific and technical support, as part of the HACCP plan validation process, to demonstrate that the plants' processes prevent, reduce, or eliminate the hazards identified.

Complex Nature of *Salmonella*

Complex Nature of *Salmonella*

In September 2014, we found that the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) faced a challenge in reducing *Salmonella* contamination in poultry products because of the complex nature of this pathogen. The majority of the representatives from industry and consumer groups we interviewed at the time, as well as FSIS officials, agreed that *Salmonella* is difficult to control in poultry products because it is widespread in the natural environment. According to Centers for Disease Control and Prevention officials we interviewed for our past work, there are more than 2,500 serotypes of *Salmonella* (with different strains), some of which pose greater risk to human health than others. Therefore, it is important to understand the genetic makeup of each to determine which ones are more or less likely to cause human illness.

Source: GAO | GAO-18-272

FSIS officials said that, in the future, there may be opportunities to improve how the agency protects human health by focusing inspections on plants and products that have tested positive for the more dangerous strains of *Salmonella* in meat and poultry products.⁴⁴ To this end, FSIS collaborates with USDA's Agricultural Research Service and APHIS,

⁴⁴A strain refers to a specific subtype of a microorganism, such as a bacterium or virus, that has distinctive traits in its shape or genes that separate it from other strains of the same microorganism. A serotype is one way to group strains that share distinctive surface structures. For example, *Salmonella* bacteria look alike under the microscope but can be separated into many serotypes based on two structures on their surface. These surface structures reflect the antigenic composition—molecular structures that are recognized by the immune system and are capable of triggering an immune response—of a strain.

CDC, FDA, and local and state public health partners to develop new technologies that can more precisely determine if a strain of *Salmonella* detected is particularly dangerous to people. One such technology is whole genome sequencing, which allows the agency to determine the complete set of genes, or strain, within a *Salmonella* serotype.⁴⁵

According to FSIS officials, it is more challenging to link the strain associated with an illness to a specific meat or poultry product that has sickened consumers; whole genome sequencing technology can more definitively identify the strain involved in an outbreak and help reduce incidents of illness or death due to foodborne pathogens. FSIS is currently planning how to integrate this technology into its food safety program. For example, current pathogen standards are based on the presence or absence of generic *Salmonella*, not on specific strains. FSIS held a public meeting in October 2017 to get input from state, federal, and international public health partners and other stakeholders on the use of this technology in a regulatory setting to improve food safety and public health.

Limited *Campylobacter* Research and Testing

Limited *Campylobacter* Research and Testing

In September 2014, we found that the U.S. Department of Agriculture's Food Safety and Inspection Service faced a challenge in reducing levels of *Campylobacter* in poultry products in part because less was known about *Campylobacter* than about *Salmonella*. Specifically, technologies, such as clinical diagnostics, used to detect *Campylobacter* may have underdiagnosed cases of illness from this pathogen, and the methods used by many diagnostic laboratories to isolate *Campylobacter* from samples were not standardized, according to a 2012 World Health Organization report on illnesses from the pathogen. Additionally, the agency's ability to measure a reduction in *Campylobacter* illnesses depended on its ability to attribute *Campylobacter* illnesses to poultry and other food types, according to agency officials, and attribution analyses needed improvement.

Source: GAO | GAO-18-272

⁴⁵Whole genome sequencing (also known as full genome sequencing, complete genome sequencing, or entire genome sequencing) is the process of determining the complete DNA sequence of an organism's genome at a single time. This technique allows detailed comparisons among samples. According to FSIS officials, the agency typically uses sequencing technology to identify a sequence, but not the whole genome. However, this is still referred to as "whole genome sequencing." According to CDC, whole genome sequencing is like comparing all of the words in a book, instead of just the number of chapters, to see if the books are the same or different. In March 2017, we reported on efforts by USDA, CDC, and FDA to use whole genome sequencing to identify and report on antibiotic-resistant bacteria through the National Antimicrobial Resistance Monitoring System. See GAO, *Antibiotic Resistance: More Information Needed to Oversee Use of Medically Important Drugs in Food Animals*, [GAO-17-192](#) (Washington, D.C.: Mar. 2, 2017).

Since our report in September 2014,⁴⁶ FSIS has had efforts under way with other agencies to improve foodborne illness source attribution to meat and poultry products and has independent data collection efforts under way to determine the presence of *Campylobacter* on these products. More specifically, in collaboration with CDC and FDA through the Interagency Food Safety Analytics Collaboration, FSIS has taken steps to improve and standardize methods to estimate the source attribution for *Campylobacter* foodborne illness. In 2015, this interagency collaboration improved the method for estimating the number of *Campylobacter* illnesses from meat and poultry products by standardizing the approach used by all three food safety agencies. The interagency collaboration's new estimates for the proportion of *Campylobacter* illnesses included all food products—including beef, pork, and poultry. The interagency collaboration also released updated foodborne illness source attribution estimates in December 2017. According to FSIS officials, the three agencies are collaborating on multiple analytic projects, in line with the interagency collaboration's 2017–2021 strategic plan, to improve models to estimate foodborne illnesses from *Campylobacter* and other pathogens. These projects involve using new methods and whole genome sequencing and other data sources.

In addition to this interagency effort, in 2015, FSIS tested about 200 samples of pork products for *Campylobacter* as part of an exploratory sampling effort, according to agency documents summarizing the efforts. FSIS found that about 1 percent of products tested were positive for *Campylobacter* and, therefore, chose not to continue testing pork products for this pathogen.⁴⁷ For poultry, in 2016, FSIS revised a laboratory guidebook describing standard protocols for isolating and analyzing *Campylobacter* in raw products. In 2017, the agency concluded a literature review of *Campylobacter* contamination in beef and, as of October 2017, is discussing the development of an exploratory sampling project to test for *Campylobacter* in beef products, according to agency officials.

⁴⁶GAO-14-744.

⁴⁷We did not examine whether FSIS's sample was sufficient to determine the risk of *Campylobacter* in pork products.

Limited Enforcement Authority

Limited Enforcement Authority

In September 2014, we found that the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) faced a potential challenge in reducing *Salmonella* contamination in poultry products, according to agency officials and representatives of some stakeholder groups we interviewed, because (1) a 2000 federal court ruling stated that FSIS could not withdraw inspectors, effectively shutting down the plant, solely because a plant did not meet *Salmonella* pathogen standards,⁴⁸ and (2) FSIS has not classified *Salmonella* as an adulterant in raw poultry products, so products contaminated with this pathogen generally may be permitted to enter commerce.

- FSIS adopted the position that the court ruling did not affect its ability to use the *Salmonella* pathogen standards as part of verifying a plant's sanitation and Hazard Analysis and Critical Control Point plans and that it had tools, such as food safety assessments (an evaluation of a plant's food safety system), to prevent contaminated products from entering the market. Representatives from consumer groups we interviewed at the time said that even with these tools, the agency does not have sufficient authority to ensure plants comply with the standards because FSIS cannot shut down plants when they fail the *Salmonella* standards alone. Representatives from industry groups we interviewed at the time disagreed and stated that FSIS has sufficient authority to ensure plants comply with standards because the agency has broad statutory authority and oversight.
- Regarding FSIS not classifying *Salmonella* as an adulterant, representatives from consumer groups we interviewed for our previous work said that the agency should declare some serotypes of *Salmonella* as adulterants, such as those with specific antibiotic-resistant patterns. FSIS officials we interviewed for our previous work said they found no conclusive evidence that antibiotic-resistant strains of *Salmonella* or *Campylobacter* have a greater resistance to the interventions used in plants but that the agency would continue to review relevant scientific evidence to identify any potential challenges these serotypes may present to public health.

Source: GAO | GAO-18-272

Since our report in September 2014, FSIS continues to stand by the position that the 2000 court ruling does not affect its ability to use pathogen standards as a tool to prevent contaminated products from entering the market. FSIS reaffirmed its position in a 2016 *Federal Register* notice.⁴⁹ Our review of FSIS data from 2016 through 2017 for

⁴⁸Supreme 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.

⁴⁹81 Fed. Reg. 7,285 (Feb. 11, 2016).

poultry plants shows that some plants are still not meeting pathogen standards—in some cases repeatedly not meeting the standards—and are allowed to operate.⁵⁰ We were unable to review similar data for beef or hog plants since, as noted above, FSIS suspended monitoring these plants against pathogen standards. FSIS stands by its assessment that its enforcement tools are sufficient. Moreover, in 2015, FSIS announced an additional tool to help FSIS identify and assess problems or trends that may be of concern. Specifically, FSIS investigators must now conduct a public health risk evaluation at every plant that does not meet a pathogen standard. This is a positive step for those products that have pathogen standards, such as chicken parts. However, as previously stated, FSIS does not test for whether plants producing beef carcasses, ground beef, and pork carcasses meet the pathogen standards for those products, and other products such as ground pork do not have pathogen standards. Representatives from consumer groups and industry we interviewed continue to disagree on whether FSIS' existing enforcement tools are sufficient to ensure that meat and poultry plants meet pathogen standards.⁵¹

Regarding antibiotic-resistant strains of *Salmonella*, FSIS officials continue to state that the pathogen does not meet the criteria for classifying it as an adulterant and that the agency will continue to examine options for regulating the presence of antibiotic-resistant strains

⁵⁰Because FSIS does not test against the beef and pork standards, we reviewed FSIS data to determine the extent to which plants were not meeting chicken carcasses pathogen standards. Specifically, our review of FSIS monthly data from May 2016 through August 2017 on whether plants producing chicken carcasses met the pathogen standards showed that 50 plants of 210 did not meet the *Salmonella* pathogen standard for at least 1 month of the data reporting period, and 20 plants of 210 did not meet the *Campylobacter* standard for at least 1 month in the same period. In some cases, these plants did not meet the standard for the entire period that we reviewed: 2 plants did not meet the *Salmonella* standard and 4 plants did not meet the *Campylobacter* standard at all during this period.

⁵¹Specifically, 8 of the 17 stakeholders we interviewed (6 stakeholders from industry and 2 food safety researchers) told us that FSIS's enforcement authority is sufficient. In contrast, 9 of the 17 stakeholders we spoke with (1 stakeholder from industry, 4 stakeholders from consumer advocacy groups, 2 food safety researchers, and 2 former federal food safety experts) stated that FSIS's enforcement tools are limited because the agency cannot legally shut down a plant for poor performance, among other reasons.

of *Salmonella* in raw meat and poultry products.⁵² Agency officials told us that to classify a pathogen as an adulterant in raw meat and poultry products, FSIS must determine that the pathogen meets certain criteria established both in its authorizing statutes and by case law. Specifically, in *American Public Health Association v. Butz*, a federal appeals court in 1974 held that *Salmonella* did not adulterate raw poultry because ordinary consumer methods of preparing and cooking the product would eliminate the pathogen. In contrast, FSIS declared certain types of *E. coli* as adulterants in beef, as discussed above, because ordinary consumer cooking does not eliminate the pathogen. According to FSIS officials, the available data do not appear to indicate that *Salmonella* presents the same issues as *E. coli* or meets the necessary criteria, regardless of whether it is resistant or susceptible to antibiotics. This issue continues to be contentious among the stakeholders we interviewed. Six of the seven industry stakeholders we interviewed stated that FSIS's current enforcement authority is sufficient. Two of four food safety researchers we interviewed stated that the agency does not need additional authority to label *Salmonella* as an adulterant because FSIS has labeled other pathogens as adulterants when it made sense to do so, such as *E. coli*, and there is no need to label naturally occurring bacteria as adulterants on raw product. In contrast, all four of the consumer advocacy groups and two of the four food safety researchers we interviewed stated that FSIS needs more authority to label *Salmonella* as an adulterant.

No Mandatory Recall Authority

No Mandatory Recall Authority

In September 2014, we found that the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) faced a challenge in reducing *Salmonella* and *Campylobacter* contamination in poultry products because it did not have mandatory food recall authority similar to that of the Food and Drug Administration (FDA) for the food products FDA regulates, such as milk, seafood, fruits, and vegetables. In 2011, Congress passed the FDA Food Safety Modernization Act, giving FDA mandatory recall authority. We recommended in October 2004 that Congress consider legislation to increase FSIS's

⁵²For information about USDA's efforts to address antibiotic resistance in livestock and poultry, see GAO, *Antibiotic Resistance: Federal Agencies Need to Better Focus Efforts to Address Risk to Humans from Antibiotic Use in Animals*, [GAO-04-490](#) (Washington, D.C.: Apr. 22, 2004); *Antibiotic Resistance: Agencies Have Made Limited Progress Addressing Antibiotic Use in Animals*, [GAO-11-801](#) (Washington, D.C.: Sept. 7, 2011); and *Antibiotic Resistance: More Information Needed to Oversee Use of Medically Important Drugs in Food Animals*, [GAO-17-192](#) (Washington, D.C.: Mar. 2, 2017).

authority to include mandatory recalls, but the agency continues to not have such authority.⁵³ Instead, to protect human health from potentially contaminated meat and poultry products, FSIS can issue public health alerts, which notify the public on specific actions to take to avoid illness, or request voluntary recalls, which are voluntary actions taken by plants, among other actions. Before requesting a voluntary recall, FSIS must gather sufficient evidence through its investigation and determine that a product is adulterated and mislabeled, among other things. In September 2014, we reported that this can be challenging to do. FSIS officials told us at the time that rather than focusing on the lack of mandatory recall authority, it was more productive to work aggressively with the tools they had, such as withdrawing inspectors, thus preventing products from entering commerce. According to FSIS officials, this can be as effective for keeping unsafe food from the marketplace as FDA's recall authority.

Source: GAO | GAO-18-272

⁵³GAO, *Food Safety: USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food*, [GAO-05-51](#) (Washington, D.C.: Oct. 6, 2004).

USDA's Release of Plant Performance Information



To encourage poultry slaughter and processing plants to control for *Salmonella* and *Campylobacter*—disease-causing pathogens that can sicken consumers—USDA publicly releases information on individual plant performance for reducing these pathogens. According to the agency's 2017 annual plan, publishing plant-specific data allows consumers to make more informed choices, motivates individual plants to improve performance, and leads to industry-wide improvements in food safety. USDA's Economic Research Service found that publicly releasing the identities of plants with poor or mediocre performance on tests for *Salmonella* is strongly correlated with about a 60 percent decline of chicken carcass samples testing positive for *Salmonella* from 2006 to 2010.

In 2016, USDA temporarily replaced posting information on individual plants' performance for chicken and turkey carcasses, chicken parts, and comminuted poultry (e.g., ground), with information on aggregate results to allow time for plants to update their food safety systems. In January 2018, FSIS began reposting individual plants' category status for poultry carcasses on a monthly basis. According to the agency's annual plan for fiscal year 2017, USDA intends to resume publicly releasing individual plant performance information for turkey carcasses and to add data for plants producing chicken parts and comminuted chicken and turkey. The agency also intends to release data for plants producing some beef products, according to its 2016 strategic plan on publicly releasing data.

Source: GAO analysis of information provided by the U.S. Department of Agriculture (USDA). Image: Courtesy of USDA, Alice Welch. | GAO-18-272

Since our September 2014 report, FSIS officials said that they continue to believe that mandatory recall authority is not necessary for the reasons previously mentioned. According to FSIS officials, the agency continues to refine and improve its procedures for requesting voluntary recalls of adulterated and misbranded meat and poultry products, confirming the effectiveness of these recalls, and alerting the public about adulterated and misbranded products that may remain in commerce.⁵⁴ Therefore, FSIS officials stated that the agency does not see the lack of mandatory recall authority as an obstacle or hindrance to its efforts to protect public health and ensure that meat and poultry products are safe, wholesome, and properly labeled. In contrast, FDA officials told us that having mandatory recall authority protects human health from foodborne illness because the agency does not have to rely upon manufacturers' voluntary recall efforts or obtain a court order to remove contaminated or misbranded food, other than infant formula, from the food supply. In our review of FDA's annual reports to Congress on the use of mandatory recall authority from 2013 to 2016, the most recent available, the agency has used its mandatory recall authority twice. The majority (12 of 17) of the stakeholders we interviewed stated that the absence of mandatory recall authority is not a challenge for FSIS in reducing pathogen contamination of meat and poultry products. However, according to 3 of 4 stakeholders from consumer groups and 1 of 4 food safety researchers we interviewed, acquiring mandatory recall authority would enable FSIS to better protect human health because the agency would then have an additional tool to stop an outbreak of foodborne illness and address the level of pathogens in products once they leave the plant.

Insufficient Prevalence Estimates

Insufficient Prevalence Estimates

In September 2014, we found that the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) faced a challenge in reducing *Salmonella* and *Campylobacter* contamination in poultry products as a result of not having sufficient prevalence estimates. Prevalence is the proportion of a product that would test positive

⁵⁴Voluntary 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 may 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.

for a pathogen if the entire population of that product was sampled and analyzed during a specific period of time. FSIS collects and analyzes data to estimate the prevalence of pathogens when the agency develops or revises pathogen standards for products it regulates. However, we reported that there were numerous problems with the data FSIS used to estimate prevalence. For example, assessing levels of poultry pathogens across the entire industry was difficult using data from FSIS's verification-testing program because the program was not designed to assess prevalence of pathogens industry-wide and the agency does not randomly select plants for inspection. According to USDA's National Advisory Committee on Microbiological Criteria for Food, 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. FSIS officials told us at that time that the agency had plans to propose a new testing approach for all of its poultry products, which would allow for more frequent data collection and improve prevalence estimates, among other things.

Source: GAO | GAO-18-272

In 2016, FSIS implemented this new testing approach for all poultry products for which there are pathogen standards and for some meat products, but according to officials, the agency did not do so for all products that it regulates because of resource constraints. Specifically, according to a 2016 *Federal Register* notice, FSIS now routinely samples chicken and turkey carcasses, chicken parts (legs, wings, and breasts), and comminuted chicken and turkey for *Salmonella* and *Campylobacter* pathogens over an entire year—rather than a set period of time—based on the volume of poultry products produced in plants.⁵⁵ It also uses this approach to test for *Salmonella* in ground beef, beef manufacturing trimmings, and other ground beef components, according to a 2014 *Federal Register* notice.⁵⁶ This new approach allows for better prevalence estimates and for monitoring changes in prevalence over time, according to agency officials. As discussed earlier, FSIS began exploratory sampling of pork products, including pork cuts and comminuted (including ground) pork, in 2015. According to a 2017 agency notice describing the sampling, FSIS collects and analyzes samples of pork products in a way that allows for prevalence estimates. FSIS does not use the same approach to sample other products, such as raw components used in ground beef (e.g., esophagus, head meat, cheek meat, and hearts), chicken half carcasses, and chicken necks, because of limited resources, according to agency officials. These officials stated that the agency first conducts exploratory sampling—such as its current program for pork

⁵⁵81 Fed. Reg. 7,285 (Feb. 11, 2016).

⁵⁶79 Fed. Reg. 32,436 (Jun. 5, 2014).

products—to determine if FSIS should allocate resources for routine sampling of these products that would allow for prevalence estimates.

Conclusions

To help ensure the safety of meat and poultry products and protect against foodborne illness, USDA's FSIS has transitioned to an increasingly science-based, data-driven, risk-based approach. As part of this approach, FSIS has taken several actions to reduce levels of *Salmonella* and *Campylobacter* in poultry products, including strengthening existing pathogen standards for *Salmonella* in poultry carcasses and developing new *Salmonella* and *Campylobacter* standards for certain chicken parts. However, the agency has not set pathogen standards for many widely available products, such as pork cuts and ground pork, and the agency's process for deciding which products to consider for new pathogen standards is not fully documented. Previously, FSIS has developed new pathogen standards after the agency has been directed to do so or after widespread outbreaks indicated the need. Until FSIS clearly documents its process for deciding which products to consider for new pathogen standards, including the basis on which such decisions should be made, FSIS will not have assurance that its decisions will be risk-based and that agency personnel will know the process when making such decisions.

As part of its new approach, FSIS is collecting data that could enable it to set new pathogen standards for pork cuts and ground pork, and the agency is analyzing data that could lead to revising the *Salmonella* standards for beef carcasses and ground beef—which are decades old and not set at levels that are health protective. However, the agency has not set time frames for completing these efforts. In the absence of pathogen standards against which the agency tests, the agency is not using a valuable tool that could be used to help verify that plants' processing controls to prevent, eliminate, or reduce food safety hazards are working. By setting time frames for determining what pathogen standards or additional policies are needed to address pathogens in these products, FSIS could better ensure it completes these activities in a timely manner to better protect human health.

In addition, FSIS continues to face several challenges that hinder its ability to reduce the level of pathogens in meat and poultry products. For example, practices outside the slaughter plant, such as conditions on cattle, hog, and poultry farms, can affect levels of pathogens on meat and poultry products. To help overcome this challenge, the agency has developed draft guidance on practices for controlling levels of *Salmonella*

and *Campylobacter* on beef cattle, hog, and poultry farms, but the draft guidance for hogs does not include available information on the effectiveness for each practice, as an internal agency committee recommended. As FSIS finalizes this guidance, FSIS could better inform industry of the potential benefits of adopting on-farm practices and encourage implementation of these practices by including available information on their effectiveness.

Recommendations for Executive Action

We are making three recommendations to FSIS. Specifically:

The Administrator of FSIS should document the agency's process for deciding which products to consider for new pathogen standards, including the basis on which such decisions should be made. (Recommendation 1).

The Administrator of FSIS should set time frames for determining what pathogen standards or additional policies are needed to address pathogens in beef carcasses, ground beef, pork cuts, and ground pork. (Recommendation 2).

The Administrator of FSIS should include available information on the effectiveness of on-farm practices to reduce the level of pathogens as it finalizes its guidelines for controlling *Salmonella* in hogs. (Recommendation 3).

Agency Comments and Our Evaluation

We provided a draft of this report to USDA and the Department of Health and Human Services. In written comments, reproduced in appendix II, USDA agreed with our three recommendations and described actions it will take to implement them.

In particular, with respect to our first recommendation, USDA stated that FSIS will complete an internal document that delineates the agency's process for creating or updating pathogen standards. However, USDA stated that although it agrees it can take additional steps to document its process, it does not agree that FSIS does not have assurance its decisions are risk based. In particular, it cited a *Federal Register* notice indicating that it designed its pathogen standards for chicken parts and comminuted chicken and turkey to achieve certain reductions in illnesses from *Salmonella* and *Campylobacter*. USDA also stated that FSIS has consistently documented and published its process in the *Federal Register*, and it noted that agency personnel use these *Federal Register*

notices as guidance and historical reference. While these notices can be a useful historical record and document the steps FSIS took to ensure that agency decisions were risk-based, we continue to believe that, until FSIS clearly documents its process for deciding which products to consider for new pathogen standards going forward—including the basis on which such decisions should be made—FSIS will not have assurance that its decisions will be risk-based and that agency personnel know the process when making such decisions in the future. Completing documentation of the agency’s process would address our recommendation.

Concerning our second recommendation, USDA stated that in 2018 FSIS will continue to assess data from sampling projects, along with baseline data and outbreak/illness data, to determine whether new or revised standards or additional policies are needed to address *Salmonella* in beef products. USDA further stated that in 2019, it will use data collected during its raw pork exploratory study to determine whether standards or additional policies (e.g., training, guidance to industry, or instructions to field personnel) are needed to address *Salmonella* in pork products. Finalizing analysis of these data and determining if additional standards or policies are needed to address *Salmonella* in beef in 2018 or pork in 2019 would address our recommendation.

In response to our third recommendation, USDA stated that FSIS will include available scientific information on the effectiveness of each recommended farm practice in the guidelines for reducing *Salmonella* in market hogs. Doing so would address our recommendation.

USDA also provided technical comments. We incorporated these comments as appropriate. The Department of Health and Human Services did not have any comments.

As agreed with your offices, unless you publicly announce the contents earlier, we plan no further distribution of this report until 30 days from the report date. At that time, we will send copies of this report to the appropriate congressional committees, the Secretary of Agriculture, the Administrator of the Food Safety and Inspection Service, 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 have any questions about this report, please contact me at (202) 512-3841 or morriss@gao.gov. Contact points for our Offices

of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix III.

A handwritten signature in black ink that reads "Steve D. Morris". The signature is written in a cursive style with a large, stylized "S" and "M".

Steve D. Morris
Director, Natural Resources and Environment

Appendix I: *Salmonella* Testing for Beef Purchased for the National School Lunch Program

In addition to regulating meat and poultry sold in commerce, the U.S. Department of Agriculture (USDA) also purchases food and, in some cases, has additional food safety requirements for food it purchases.

USDA's Agricultural Marketing Service (AMS) purchases beef and other food for various federal nutrition assistance programs, including the National School Lunch Program.¹ USDA provides this food to states in support of about 100,000 public and private nonprofit schools that provide lunches to about 30 million children. Ground beef is a staple of school menus. For example, according to AMS officials, during fiscal year 2016, the agency purchased more than 110 million pounds of raw beef, over 90 percent of which was delivered to the National School Lunch Program. Further, according to AMS officials, about 41 million pounds (37 percent) were delivered raw while the rest was delivered to a federally inspected processing facility for cooking prior to delivery to school lunch program agencies.

Beef to be delivered raw to the National School Lunch program is tested for pathogens (*Salmonella* and Shiga-toxin-producing *E. coli*, two pathogens that can cause foodborne illness in humans) and certain microorganisms such as aerobic plate count bacteria, coliform bacteria, and generic *E. coli* that serve as indicators of the effectiveness of slaughter and processing plants' process controls to limit pathogens.

¹AMS purchases for the National School Lunch Program under authority of the Richard B. Russell National School Lunch Act. Pub .L. No. 79 P.L. 396, 60 Stat. 230 (codified and amended as the Richard B. Russell National School Lunch Act at 42 U.S.C. § 1751–1769j).

Appendix I: Salmonella Testing for Beef Purchased for the National School Lunch Program

National School Lunch Program

According to USDA, the National School Lunch Program is a federally assisted meal program operating in public and nonprofit private schools and residential childcare institutions. It provides nutritionally balanced, low-cost or free lunches to children each school day. The program was established under the National School Lunch Act, signed by President Harry Truman in 1946.

USDA's Food and Nutrition Service administers the program at the federal level. At the state level, the program is administered by state agencies, operating through agreements with school food authorities. Participating school districts and independent schools receive cash subsidies and food. In exchange, participating institutions must serve lunches that meet federal nutrition requirements and offer the lunches at a free or reduced price to eligible children. USDA's Agricultural Marketing Service purchases beef and other food for various federal nutrition assistance programs, including the National School Lunch Program.



Source: GAO analysis of U.S. Department of Agriculture (USDA) documents. Image: Courtesy of USDA. | GAO-18-272

According to AMS officials, these indicator microorganisms indicate the quality of the food safety controls at the plant. For raw beef products that AMS considers for purchase for its programs, the agency rejects any beef that tests positive for *Salmonella*, a pathogen that can cause foodborne illness in humans. According to AMS officials, this requirement that beef purchased for these programs not test positive for *Salmonella* differs from the regulatory standard for beef inspected by USDA's Food Safety and Inspection Service (FSIS).² Further, according to AMS officials, AMS set this requirement because raw beef was considered the product with the most risk for recipients and enough plants were able to meet the requirement. AMS officials said that as a purchaser for various federal nutrition assistance programs, the agency has discretion to set requirements for qualified suppliers, and plants can choose whether to become qualified suppliers.

²FSIS has set the maximum acceptable percentage of raw ground beef sampled to test positive for *Salmonella* at 7.5 percent.

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



United States Department of Agriculture

Food Safety and
Inspection Service

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

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

FEB 16 2018

Dear Mr. Morris,

The United States Department of Agriculture (USDA) appreciates the opportunity to review the U.S. Government Accountability Office's (GAO) draft report entitled *Food Safety: USDA Should Take Further Action to Reduce Pathogens in Meat and Poultry Products* (GAO-18-272). We also wish to acknowledge the audit team's professionalism and focus on ensuring the facts in this report were accurate and the findings germane.

General Comments

FSIS has a few general comments regarding your findings and characterization of FSIS' programs and addresses these below. We also provide our planned corrective actions for each of the recommendations for executive action. We further provide several technical edits to ensure the document is factually correct.

Performance standards are one piece of the overall food safety approach to mitigate the risk of foodborne illness. There are many steps that FSIS takes to ensure the safety of the product including verifying that establishments are controlling pathogens through their Hazard Analysis and Critical Control Point (HACCP) systems, providing guidance for industry and consumers, and requiring that product be labeled with safe handling instructions for consumers. FSIS uses pathogen reduction performance standards to assess process control of establishments that prepare meat and poultry products.

GAO asserts on its Highlights page and on pages 15 and 30 that FSIS needs to clearly document its process for deciding which products to consider for new pathogen standards and, that until this process is clearly documented, the Agency will not have assurance its decisions are risk-based and Agency personnel will know the process when making such decisions. Although FSIS agrees that it can take additional steps to internally document its process for creating and updating pathogen reduction performance standards, it does not agree with GAO that the Agency does not have assurance its decisions are risk based and that Agency personnel will not know the process when making decisions. FSIS has consistently documented and published its process within the *Federal Register* through which

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FSIS announces or proposes new standards.¹ Agency personnel use these *Federal Register* notices (FRN) as guidance and as historical reference when developing new standards. In addition, in *Federal Register* 81 FR 7285; February 11, 2016,² FSIS indicates that it designed its new performance standards for raw chicken parts and comminuted chicken and turkey to achieve at least a 30 percent reduction in illnesses from *Salmonella*, and a 33 percent reduction in illnesses from *Campylobacter* in line with the reduction goals in Healthy People 2020. This FRN demonstrates how FSIS uses risk to drive policy decisions and make changes to its performance standards.

We include a few important technical comments in addition to those previously provided to GAO:

- GAO leaves out two key points in explaining what establishments are required to do under HACCP. In footnote 12 on page 3, FSIS requests GAO add language clarifying that the establishment also needs to validate the steps to prevent, eliminate, or reduce each hazard will be effective, and then it needs to verify that its food safety system is working as intended on an ongoing basis.³ Page 9 also omits that FSIS inspectors at slaughter and processing establishments observe operations as part of their inspection tasks, in addition to GAO's statement regarding checking records to verify an establishment's compliance with its HACCP plans.
- On GAO's Highlights page and page 14, GAO states that FSIS has not developed performance standards for "widely available" products, such as turkey breasts. However, as FSIS states in 80 FR 3940, "about 85 percent of poultry products available to consumers are chicken," and the "amount of chicken parts available from fabricated broiler carcasses is larger than that of turkey carcasses that are fabricated into raw turkey parts and available to consumers." Furthermore, it states, "there is more contamination of broiler carcasses with *Salmonella* and *Campylobacter* compared to turkey carcasses. For example, in 2008, FSIS found that broiler carcasses had a *Salmonella* prevalence of 7.5 percent, while in 2009 turkey carcasses had *Salmonella* prevalence of 1.7 percent." Given the lower exposure from/to turkey parts, and the lower hazard from turkeys in general, FSIS made a risk-based decision

¹Please see (1) "Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems" final rule, (61 FR 38806; July 25, 1996), available on the FSIS website at <https://www.fsis.usda.gov/wps/wcm/connect/e113b15a-837c-46af-8303-7317e11fb666/93-016E.pdf?MOD=AJPERES>. See page 38835, section: Role of Microbiological Performance Criteria and Standards in FSIS Food Safety Strategy. (2) "New Performance Standards for *Salmonella* and *Campylobacter* in Young Chicken and Turkey Slaughter Establishments; New Compliance Guides," (75 FR 27288; May 14, 2010), available at: <https://www.gpo.gov/fdsys/pkg/FR-2010-05-14/pdf/2010-11545.pdf>. See page 27289, section: *Salmonella* Performance Standards. (3) "Changes to the *Salmonella* and *Campylobacter* Verification Testing Program: Proposed Performance Standards for *Salmonella* and *Campylobacter* in Not-Ready-to-Eat Comminuted Chicken and Turkey Products and Raw Chicken Parts and Related Agency Verification Procedures and Other Changes to Agency Sampling," (80 FR 3940; January 26, 2015), and available on the FSIS website at <https://www.fsis.usda.gov/wps/wcm/connect/55a6586e-d2d6-406a-b2b9-c5d83c110511/2014-0023.pdf?MOD=AJPERES>. See page 3940, section: Background.

²The "New Performance Standards for *Salmonella* and *Campylobacter* in Not-Ready-to-Eat Comminuted Chicken and Turkey Products and Raw Chicken Parts and Changes to Related Agency Verification Procedures: Response to Comments and Announcement of Implementation Schedule," was published in the *Federal Register* (81 FR 7285; February 11, 2016), is available on the FSIS website at <https://www.fsis.usda.gov/wps/wcm/connect/b90ac243-af49-43a9-9f62-00md090345b/2014-0023.pdf?MOD=AJPERES>.

³See 80 FR 27557, and <https://www.fsis.usda.gov/wps/wcm/connect/3ba826ec-6e79-4f17-85fe-29200f4e8d05/2009-0019-2015.pdf?MOD=AJPERES>.

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to not include turkey parts in its baseline study and not to develop performance standards for turkey parts.

- On pages 18, 27, and 28, GAO refers to the Agency not having mandatory recall authority as a challenge to reducing *Salmonella* and *Campylobacter* contamination in poultry. However, *Salmonella* and *Campylobacter* are not ordinarily adulterants in raw product and FSIS does not consider a recall if the product is not adulterated (e.g., raw product with *Salmonella* or *Campylobacter* under normal circumstances). If the product is adulterated, FSIS requests a recall. As noted on page 27 of the report, if an establishment refuses to recall the product, FSIS has authority to withdraw inspectors, and seize or detain products, thus preventing the establishment's products from entering commerce, which effectively protects human health. Consequently, mandatory recall authority is not a challenge in protecting public health.
- Page 29 of the report references FSIS testing for *Salmonella* in certain components of ground beef. However, the report omits that FSIS also analyzes for *Salmonella* in ground beef, and beef manufacturing trimmings, and other raw ground beef components. This new approach allows for better prevalence estimates and for monitoring changes in prevalence over time.

USDA Responses to GAO Recommendations for Executive Action

GAO Recommendation 1:

The Administrator of FSIS should document the agency's process for deciding which products to consider for new standards, including the basis on which such decisions should be made.

USDA Response:

FSIS concurs with this recommendation. FSIS will complete an additional internal document that delineates the Agency's process for creating or updating performance standards and its basis for decision-making.

GAO Recommendation 2:

The Administrator of FSIS should set "timeframes" for determining what pathogen standards or additional policies are needed to address pathogens in beef carcasses, ground beef, pork cuts, and ground pork.

USDA Response:

FSIS concurs with this recommendation specific to "timeframes" within its control. In 2014, FSIS began analyzing all raw beef samples it collects for Shiga-toxin producing *E. coli* (STEC) analysis for *Salmonella* (79 FR 32436). In 2018, FSIS will continue to assess the data from these sampling projects, along with baseline data and outbreak/illness data, to help assess the risks. FSIS will use this data to determine whether new or revised standards or additional policies (e.g., training, guidance to industry, or instructions to field personnel) are needed to address *Salmonella* in beef products.

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In June 2017, FSIS began the second phase of the Raw Pork Products Exploratory Study; Phase 2 will continue for approximately one year (May 2018). FSIS will analyze the data collected in the Raw Pork Products Exploratory Sampling Program, along with baseline data and outbreak/illness data, to help assess the risks from STEC in pork. In 2019, the Agency will use this data to determine whether standards or additional policies (e.g., training, guidance to industry, or instructions to field personnel) are needed to address *Salmonella* in pork products.

GAO Recommendation 3:

The Administrator of FSIS should include available information on the effectiveness of on-farm practices to reduce the level of pathogens as it finalizes its guidance for controlling *Salmonella* in hogs.

USDA Response:

FSIS concurs with this recommendation. FSIS does not have on-farm (pre-harvest) jurisdiction, yet it will incorporate available pre-harvest related research results from the published literature into its compliance guidelines. FSIS is currently revising its draft compliance guidelines to address the reduction of *Salmonella* in market hogs, and has encouraged establishments to use the on-farm component in the draft guidelines while the guidelines have been out for comment. The Agency will include available scientific information on the effectiveness of each recommended farm practice to reduce *Salmonella* in market hogs in those guidelines.

Thank you for the opportunity to review and comment on this draft report.

Sincerely,



Carmen Rottenberg
Acting Deputy Under Secretary
Office of Food Safety

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

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

Staff Acknowledgments

In addition to the contact named above, Mary Denigan-Macauley (Assistant Director); Thomas Cook (Assistant Director); James R. Jones, Jr. (Assistant Director); David Bennett (Analyst in Charge); Kevin Bray; Cindy Gilbert; Cynthia Norris; Gloria Ross; and Kiki Theodoropoulos made key contributions to this report.

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Foot-and-Mouth Disease: USDA's Evaluations of Foreign Animal Health Systems Could Benefit from Better Guidance and Greater Transparency. [GAO-17-373](#). Washington, D.C.: April 28, 2017.

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