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OFFICE OF INSPECTOR GENERAL

FSIS Ground Turkey Inspection and Safety Protocols

24601-0004-31

July 2015

FSIS Ground Turkey Inspection and Safety Protocols

Audit Report 24601-0004-31

What Were OIG's Objectives

Our objective was to review FSIS' inspection of ground turkey, including sampling and testing protocols, to evaluate the effectiveness of the program.

What OIG Reviewed

We interviewed FSIS officials at the national, district, and local levels; turkey processing plant management; an industry trade group; and a consumer advocacy group. We observed plant and FSIS personnel perform their duties in turkey slaughter and processing plants and analyzed various types of plant and FSIS data, procedures, and records.

What OIG Recommends

We recommended that FSIS review and improve (1) its SIP approval and monitoring processes; (2) the data recorded and collected on NRs to better gauge the significance of the noted violations; (3) how it tracks the timely updating of directives; (4) its pathogen sampling policies; and (5) the guidance provided to industry for developing its prerequisite programs.

OIG reviewed how FSIS oversees the safety of ground turkey and other turkey products.

What OIG Found

The Office of Inspector General (OIG) determined that the Food Safety and Inspection Service (FSIS) could improve how it monitors the safety of turkey products. OIG found that the three turkey plants that participated in the *Salmonella* Initiative Program (SIP) either did not increase pathogen sampling when they exceeded the allowable number of *Salmonella* positive test results, or they did not implement their pathogen interventions at the control limits outlined in their agreement. Further, we identified that, while FSIS noncompliance records (NR) adequately documented failures to comply with regulations, they were not always adequate indicators of potential problems with the plants' food safety system. Additionally, we found that FSIS did not have a formal process to periodically update its directives.

We found that FSIS could improve its pathogen sampling system to enhance food safety. FSIS' current sampling approach does not allow FSIS to regularly sample over 60 percent of U. S. turkey slaughter plants, over 75 percent of the active processing plants, or the over 11 million pounds of ground turkey products imported during calendar years 2012 and 2013. Finally, we noted that five slaughter plants had flaws in the implementation and documentation of their prerequisite programs (programs applied by industry to ensure that food safety hazards are not reasonably likely to occur). The more robust a plant's prerequisite program is the more likely it is that the turkey products produced at the plant will be safe for human consumption.

The agency agreed with our recommendations and we were able to reach management decision on all recommendations.

United States Department of Agriculture
Office of Inspector General
Washington, D.C. 20250

DATE: July 29, 2015

AUDIT NUMBER: 24601-0004-31

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

ATTN: Steven Fisher
Chief Financial Officer

FROM: Gil H. Harden
Assistant Inspector General for Audit

SUBJECT: FSIS Ground Turkey Inspection and Safety Protocols

This report presents the results of the subject audit. Your written responses to the official draft report dated June 30, 2015, are included, in their entirety, at the end of the report. Your responses and the Office of Inspector General's position are incorporated into the relevant sections of the report. Based on your written responses, we are accepting your management decisions for all the audit recommendations in the report, and no further response to this office is necessary.

In accordance with Departmental Regulation 1720-1, final action needs to be taken within 1 year of each management decision to prevent being listed in the Department's annual Agency Financial Report. Please follow your internal agency procedures in forwarding final action correspondence to the Office of the Chief Financial Officer.

We appreciate the courtesies and cooperation extended to us by members of your staff during our audit fieldwork and subsequent discussions. This report contains publicly available information and will be posted in its entirety to our website (http://www.usda.gov/oig) in the near future.

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Background and Objectives

Background

The consumption of turkey products is no longer simply a Thanksgiving and Christmas holiday activity for American consumers; there is year round demand for turkey products. The average person in the United States consumes about 16 pounds of turkey annually, which, when combined with exports, translates into an economic impact of about $5 billion on our nation's farms.[1] United States farmers produced about 250 million turkeys, with Minnesota, North Carolina, Arkansas, Missouri, and Virginia being the top producing States.[2] In order to prepare these live turkeys for consumers, there are about 240 active turkey processing establishments in the United States that produce ground, other non-intact, or mechanically separated turkey, including about 40 plants that slaughter turkeys as well.[3]

The Department of Agriculture (USDA) Center for Nutrition Policy and Promotion encourages consumers to include in their diets sources of lean protein, including ground turkey.[4] The turkey industry has experienced significant growth in the last 20 years and, in the last 10 years, a major contributor to that growth can be attributed to ground turkey. Turkey is a lean protein source that can be used as a substitute for ground beef. Because of the growing popularity of ground turkey among American consumers, the Office of Inspector General (OIG) initiated this review of the process the Food Safety and Inspection Service (FSIS) uses to monitor and inspect ground turkey products.

For OIG to fully understand the challenges FSIS faces in assuring the wholesomeness of ground turkey products, we first had to understand how turkey slaughter and processing operations are performed. Our auditors observed the entire slaughter process, including receiving and unloading of live turkeys, feather plucking, organ removal, various dressing procedures, "chiller" tanks, and packaging or parting of the turkeys. Ultimately, our auditors observed turkey parts being put into mechanical grinders and ground. During the entire process, from ante mortem inspection through grinding, we also observed how the FSIS Inspection Program Personnel[5] performed their inspection tasks.

FSIS is the public health regulatory agency that ensures the safety, wholesomeness, correct labeling, and packaging of poultry products. FSIS sets standards for food safety, inspects, and regulates all raw and processed poultry products sold in interstate commerce, including imported products. The Poultry Products Inspection Act provides FSIS with the legal authority for regulatory inspection and enforcement activities over poultry.[6] The agency has implemented

[1] Agricultural Marketing Resource Center publication, dated November 2013.
[2] USDA Economic Research Service data from 2011.
[3] Per data provided by FSIS.
[4] From ChooseMyPlate.gov - USDA, Tips to Help You Make Wise Choices from the Protein Foods Group.
[5] Inspection Program Personnel are FSIS staff that is assigned to poultry slaughter establishments who verify that the establishment is performing sanitary dressing procedures in a manner that prevents the creation of insanitary conditions, and the adulteration of product.
[6] Poultry Products Inspection Act, 21 U.S.C. 451 et seq. (1957).

regulations and directives that contain instructions to inspection personnel about how to implement and enforce the rules. Directives provide information about inspection methods, regulatory decision making, documentation of noncompliance, and appropriate enforcement actions.

In 1996, FSIS established requirements for poultry establishments designed to reduce the occurrence and numbers of pathogenic microorganisms on poultry products in order to reduce the incidence of foodborne illness. Agency regulations require (1) that each establishment develop and implement written sanitation procedures, and (2) that all poultry establishments develop and implement a system of preventive controls designed to improve the safety of their products, which is known as the Hazard Analysis and Critical Control Points (HACCP) system. HACCP is a framework for building science-based process controls that will prevent food safety hazards that are reasonably likely to occur in an establishment's food production operation.

Even under a HACCP framework, as turkeys are being slaughtered, the production environment in the slaughter and processing establishments can expose meat products to bacteria. Although many bacteria serotypes are harmless, other strains such as *Salmonella* and *Campylobacter* that occur in turkeys can cause serious illness or even death. According to the Centers for Disease Control and Prevention (CDC), both *Salmonella* and *Campylobacter* can cause symptoms such as diarrhea, fever, and abdominal cramps. In total, the CDC estimates that each year 2.7 million U.S. residents are sickened by *Salmonella* or *Campylobacter* from all food sources, with about 475 of the cases proving fatal.

The Poultry Products Inspection Act gives FSIS jurisdiction over turkey products; however, FSIS does not have the authority to regulate *Salmonella* as an adulterant in raw meat. Court cases have established that *Salmonella* is not an adulterant[7] because it may be inherent to poultry products. In one such case, the court found that products are not to be considered adulterated merely due to the presence of *Salmonella*.[8] In a second case, the court found that regulations promulgated by the Secretary of Agriculture, which deal with the levels of *Salmonella* in raw meat product, fall outside the USDA's statutory rulemaking authority.[9] The court found that, because the USDA's *Salmonella* tests do not necessarily evaluate the conditions of a meat processor's establishment, they cannot serve as the basis for finding a plant's meat adulterated.[10]

Although *Salmonella* is not considered an adulterant, consumers have shown concern over its presence in ground turkey products. For example, in 2011, two large recalls from the same plant caused concern over the safety of ground turkey products. A corporation recalled approximately 36 million pounds of ground turkey products, and then the following month the same corporation recalled approximately 185,000 additional pounds of ground turkey. Product from the first recall was linked to the illnesses of 79 persons in 26 States, who were infected with the antibiotic resistant Heidelberg strain of *Salmonella*. FSIS has begun a renewed effort to reduce the number

[7] *E. coli* O157:H7 is considered an adulterant and should not be present on meat products, which gives FSIS greater recall authority. Because *Salmonella* is not an adulterant, the pathogen can be present on meat products, and recalling an item because of the presence of *Salmonella* is more difficult.
[8] *American Public Health Ass'n* v. Butz, 511 F.2d 331 (D.C. Cir. 1975).
[9] *Supreme Beef Processors v. U.S.D.A.*, 275 F.3d 432 (5th Cir. 2001).
[10] *Supreme Beef Processors v. U.S.D.A.*, 275 F.3d 432 (5th Cir. 2001).

of illnesses being caused by *Salmonella*, and has adopted a strategy to address the threat of *Salmonella* in poultry products.

While *Salmonella* is not an adulterant in meat, FSIS performs pathogen sampling of both ground turkey and whole birds for pathogens such as *Salmonella* and *Campylobacter*. Product testing is used to gauge the safety of regulated product and the sampling serves as an incentive for the poultry industry to reduce the presence of pathogens on products they produce. For whole birds, FSIS conducts set sampling to determine how the plant measures up to FSIS standards. Set sampling consists of collecting daily sponge samples from the turkey carcass for 56 consecutive days of production. The maximum number of positives to pass a 56 sample set for whole turkeys is 4 for *Salmonella* and 3 for *Campylobacter*. FSIS historically used set sampling to test ground turkey as well; however, FSIS currently uses the Not-Ready-To-Eat (NRTE) Comminuted Poultry Exploratory Sampling Project (NCPESP) to determine the prevalence of *Salmonella* and *Campylobacter* in NRTE comminuted poultry product, produced at federally inspected establishments.[11]

Additionally, during 2008, FSIS announced in the Federal Register the *Salmonella* Initiative Program (SIP) in an effort to improve *Salmonella* control in establishments. SIP is a voluntary program that provides incentives for establishments to maintain consistent process control to minimize *Salmonella* levels and conduct microbial testing to demonstrate that they are maintaining process control. In return, the establishments can receive waivers of certain provisions of the regulations, such as those establishing limitations on chilling time and temperature. Establishments submit a request to participate in the program, which is known as a protocol. The protocol details any waivers from agency regulations the plant is requesting and the alternative procedures the establishment intends to implement, including microbial sampling and testing. The protocol is reviewed by FSIS policy officials and FSIS issues a SIP letter waiving the specified provisions of the regulations and describing the procedures, which the establishment receiving the waiver must implement.

Objectives

Our objectives were to review the FSIS' inspection of ground turkey, including sampling and testing protocols, to evaluate the effectiveness of the program.

[11] "NRTE comminuted poultry product" is any non-breaded, non-battered raw poultry product that has been (1) ground, (2) mechanically separated, or (3) hand- or mechanically-deboned and further chopped, flaked, minced, or otherwise processed to reduce particle size. NCPESP consists of sampling NRTE comminuted products at an establishment once per week for a minimum of 3 months as compared to the sampling of ground product for 53 consecutive days. In contrast, turkey carcass sampling lasts for 56 consecutive days of production.

Section 1: National Office Level Procedures

Finding 1: Improvement Needed for the Salmonella Initiative Program

During our review, we visited three turkey plants that have SIP letters[12] and found FSIS oversight problems at all three plants, which we believe reflects the need for improvement in SIP. This occurred because FSIS' Inspection Program Personnel's monitoring of the plant's compliance with the SIP letter needs improvement and there is confusion at the plant level over which SIP document is the authoritative document. At two of the three SIP plants we reviewed, we found the plants exceeded the allowable number of *Salmonella* positive test results allowed under the SIP letter without the FSIS Inspection Program Personnel, and later the Enforcement Investigations and Analysis Officers (EIAO), realizing this had occurred. Additionally, FSIS Inspection Program Personnel, as well as the EIAO, did not adequately monitor the adjustment the third SIP plant made to its food safety steps, as defined in the SIP protocol. We believe that confusion in the authority of the SIP letter over the plant's SIP protocol could have added to this problem. We concluded that if FSIS does not ensure that plants operate within the SIP protocols and agreements, plants have the potential to become less vigilant in their approach to food safety. More importantly, the establishments may not adequately control their pathogen levels or may arbitrarily change the pathogen intervention control limits.

Under SIP, FSIS agrees to waive certain aspects of its sampling program on the condition that the plants will do additional sampling and testing of whole turkeys for *Salmonella*, *Campylobacter* (if applicable), and generic *E. coli*, or other indicator organisms (e.g., Aerobic Plate Count (APC)).[13] The plant also agrees to share all sample results with FSIS. To apply for this program, the plant sends to FSIS the procedures it intends to use and the microbial sampling and testing it agrees to follow in a document called a SIP protocol. Then FSIS will draft its official response of acceptance with FSIS expectations in a document called the SIP letter.[14] In addition, FSIS requires that once a week, Inspection Program Personnel are to verify the proper execution of the SIP protocol or the plant's alternative procedures used in place of each waived

[12] At the time of the audit fieldwork, FSIS had a total of 72 plants with SIP letters; 63 of the SIP plants slaughter and/or process poultry products, and the remaining 9 plants slaughter and/or process pork products. Of the 63 SIP poultry plants, 14 are turkey plants. For our fieldwork, we visited eight turkey plants, including three with SIP waivers. Six of the eight plants slaughtered and processed turkeys and turkey parts. Of the six slaughter plants we visited, three were SIP and three were traditional turkey slaughter establishments. Additionally, we visited two plants that only processed turkey, for a total of eight plants. From 2013 FSIS data, we determined that the universe of plants includes about 40 turkey plants that slaughter and process turkey and about 200 that only process turkey. We chose the eight plants based on factors such as location, slaughter or production volume, plant category, and size. With the implementation of the New Poultry Inspection System, FSIS will have 32 establishments with SIP letters, including poultry and market hogs.

[13] FSIS Directive 5000.5, "Verification of Less Than Daily Sanitation Procedures in Processing Operations," notes that the APC is a microbial test method that is an indicator of the level of bacteria in a food product, or the sanitary conditions of food contact surfaces. APC does not measure the entire bacterial population, but rather the number of bacteria that grow in the presence of oxygen (aerobically) and in the medium temperature range (70-110º F). If performed after sanitation, it can be used to gauge the effectiveness of the cleanup process.

[14] FSIS Directive 5020.1 requires the plant protocol to identify the provisions of FSIS regulations to be waived under the SIP agreement, alternative procedures to be used in place of any waived regulations, and a description of the microbiological sampling and testing procedures the plant will implement, and to agree to share microbiological and other data with FSIS.

regulation. FSIS' Public Health Information System (PHIS) provides periodic tasks, which provide the opportunity for the Inspection Program Personnel to verify that the plant's SIP protocol is implemented, as addressed in the SIP letter FSIS sent to the plant.[15]

Since SIP generates microbiological data in lieu of FSIS' prescriptive food safety regulations by promoting a heavier reliance on the plant's own sampling and reporting of those results, we believe it is imperative that FSIS ensure that the verification aspect of this program is adequate. In addition, FSIS recently implemented its New Poultry Inspection System (NPIS), which was based on the principles of its HACCP-Based Inspection Models Project (HIMP) inspection system[16] pilot project. Therefore, the implications of FSIS needing to adequately verify plant sampling and reporting activities could extend beyond just SIP.[17] In two of the three SIP plants we reviewed, we found times when the plants exceeded the threshold of allowable positive test results, and FSIS Inspection Program Personnel did not identify any problems. In each of these circumstances, neither the plant nor the FSIS Inspection Program Personnel took any of the actions defined in the SIP letter.

Based on the SIP letter for these establishments, FSIS relied on the plant's daily sampling programs to evaluate whether the plants maintained adequate controls of *Salmonella*. These sampling programs were comprised of collecting 1 sample per shift and evaluating the sampling results in a 56 test sampling frame.[18] Under these SIP letters, if the plant exceeds four positives within this sampling frame, the plant agreed to collect additional daily *Salmonella* samples to demonstrate that it was controlling *Salmonella* in its establishment.

However, at these two plants, we found instances when the plant exceeded the four positive thresholds. The FSIS Inspection Program Personnel did not realize the thresholds had been exceeded, and on one occasion, the plant did not realize it had occurred as well. In one plant, we found two 56-unit samples where testing showed 8 and 9 *Salmonella* positives, without any actions by the plant to address the requirements in the SIP letter. The second plant received six positive pathogen test results in one sampling period during 2014, but because of its inadequate monitoring measures, the plant did not realize it had exceeded the four positives threshold. Therefore, no attempt was made to comply with the measures in the SIP letter.

We noted that the methods by which the plants monitored the sampling data and FSIS' accessibility to the monitoring data could have played a role in FSIS Inspection Program Personnel not realizing the thresholds were exceeded. In both instances, since the plants agreed

[15] FSIS Directive 5020.1.

[16] According to FSIS, HIMP was developed to produce a flexible, more efficient, fully integrated poultry inspection system. The HIMP system, in contrast to the traditional inspection system, is designed to focus more responsibilities for food safety and other consumer protection activities on the establishment, with agency personnel focusing on carcass and verification system activities.

[17] We did identify inspection concerns at one of the two HIMP plants we visited that were unique to plants under the HIMP inspection system, but OIG management determined that since the agency is phasing out the specific HIMP requirements under the NPIS, it would be more appropriate to develop and report on these potential issues during any chicken inspection audit work we may be performing in the future.

[18] Each establishment had only one slaughter line; however, one of the establishments had two shifts, which required two *Salmonella* samples per day be collected while the other establishment had one shift thus only requiring one *Salmonella* sample per day.

to provide sampling and testing data to FSIS, the plants fill out a monthly FSIS electronic spreadsheet that tracks the positive and negative test results, then forward this spreadsheet electronically to a data analysis division in FSIS, but the Inspection Program Personnel did not receive these data or any analysis from it. At both plants, the Inspection Program Personnel were verbally informed when the plant received a positive test result, but the Inspection Program Personnel were not given hard documents showing the data that were transmitted to the FSIS national office. In both cases the information was not prepared or presented to FSIS in a format where the Inspection Program Personnel could view the testing data results in a 56 sample block. One of the two plants kept its own monitoring record that consisted of a 56 interval spreadsheet; however, the plant did not offer FSIS access to this document. We believe that FSIS should specify in the plant's SIP letter what tools the plant will make available, so the Inspection Program Personnel can fully and adequately monitor the plant's compliance with the SIP letter.

In addition, at the third SIP plant, we found the FSIS Inspection Program Personnel, as well as the EIAO, did not adequately monitor the adjustment the plant management made to the plant's food safety steps, as defined in the SIP protocol and letter. The SIP protocol and letter spelled out that the plant would maintain the pH level of its chlorinated water system at between 6 and 7; however, plant management unilaterally lowered the pH level, based on plant data that showed a target level of 5.8 is more effective at controlling pathogens. FSIS Directive 5020.1, Section VIII, requires that the Inspection Program Personnel "are to conduct verification procedures according to which of these programs the establishment has chosen to contain the alternative procedures and SIP protocol including its *Salmonella* sampling and testing." However, we found the Inspection Program Personnel and the EIAO did not know that the change had occurred.[19]

When we noted issues regarding compliance with the SIP letters, we began asking the Inspection Program Personnel about their understanding of SIP. We noted that, at this level, there are several factors related to the authority of the two documents that causes confusion. The SIP protocol outlines what steps the plant is offering to perform so that FSIS will waive various regulatory requirements. FSIS reviews the plant protocol and then sends the plant back a signed SIP letter, which outlines what the agency and plant are agreeing to do. However, the SIP letter does not always address everything in the SIP protocol, and sometimes the two documents can contain conflicting information. We compared the SIP letter and the SIP protocol for all three SIP plants, and found six examples where the SIP protocol and the SIP letter contained procedures that did not match. When we questioned FSIS officials about this, they stated that the SIP letter is the authoritative document because it delineates what the agency is agreeing to with the plant. However, we noted that, although the SIP letter is the authoritative document, even FSIS directives require its Inspection Program Personnel to consider the SIP protocol as part of their review process.

For example, we found multiple differences between the SIP protocol and the SIP letter related to the number of positive *Salmonella* tests required to trigger an increase in sampling. We also found the SIP protocol for one plant recommended the plant remain a Category 1 plant, but the

[19] The EIAO performed a specialized review at the establishment called a Food Safety Assessment (FSA), which did include some review of the SIP; however, the EIAO's review did not reveal this as an issue.

SIP letter remained silent on the category status.[20] Lastly, one SIP letter said that the plant would operate two lines per shift; however, the plant only operated one line.

Although FSIS Directive 5020.1, Section VIII, requires that Inspection Program Personnel conduct verification procedures of SIP, we noted that at all three plants, the FSIS Inspection Program Personnel did not identify instances where plants were not in compliance with their SIP letter. In addition, we found when the FSIS EIAO later performed a Food Safety Assessment (FSA) at these plants, the EIAO also did not note these situations. Later, FSIS did make changes to the EIAO FSA tool, a checklist of questions that the EIAO uses to perform the FSA, to more specifically target SIP-related issues.

We believe the following two actions would help FSIS make SIP more easily managed. First, FSIS needs to incorporate the SIP protocol and the SIP letter into one easily understood document that spells out exactly what steps plants are to perform and exactly what the Inspection Program Personnel would monitor. Second, FSIS Inspection Program Personnel need to be routinely provided with the appropriate plant monitoring tools (sampling spreadsheets or pH monitoring forms) so the Inspection Program Personnel can ensure that the establishment is fulfilling all the requirements detailed in the SIP letter, including staying below the threshold for pathogen positives. Therefore, if a plant did change parts of its food safety program or exceeded the threshold amount compared to what was agreed to in the SIP letter, the Inspection Program Personnel should be able to note this condition and ensure the SIP letter is updated.

When we discussed our issues from the three SIP plants with FSIS officials, they did not think that these issues were indicative of a systemic problem with the remainder of the SIP plants. The officials said that, at the time of the audit, FSIS had 72 plants with SIP letters and issues at these 3 SIP plants did not mean all SIP plants had issues with properly implementing the requirements in their SIP letter and protocol. With the implementation of the NPIS, FSIS will have 32 establishments with SIP letters, including poultry and market hogs. We believe that there is enough evidence to support our position that FSIS should make an effort to perform a review of some SIP plants, using similar tools such as those the EIAOs use in their verification of SIP procedures while performing an FSA. FSIS should perform enough reviews to determine if there truly is an adverse trend of plants not following their SIP letter or Inspection Program Personnel not adequately monitoring plant compliance. Based on the results of its review, FSIS should then take appropriate corrective actions.

Recommendation 1

For future *Salmonella* Initiative Program (SIP) letters, if the Agency elects to issue new SIP waivers, at the approval process, develop one consolidated document including appropriate attachments that clearly and concisely outlines the waived procedures, the plant's requirements based on the waiver, and supporting documents the plant will make available so that the

[20] A "Category 1 plant" is an establishment where the total number of positive *Salmonella* samples is at or below 50 percent of FSIS' performance standard. This performance demonstrates the best process control for this pathogen.

Inspection Program Personnel can fully and adequately monitor the plant's compliance with the SIP letter.

Agency Response

For future letters that FSIS sends when approving an establishment's request for a waiver from regulatory requirements under SIP, FSIS will send a consolidated document that includes appropriate attachments that clearly and concisely outline the waived procedures, the procedures the plant is required to follow based on the waiver, and other supporting documents. These letters will be available to Inspection Program Personnel in the establishments granted the SIP waivers for verification purposes. As revised or new SIP Letters are issued, FSIS will implement these changes starting July 1, 2015.

OIG Position

We accept management decision for this recommendation.

Recommendation 2

To determine compliance with SIP letters and Inspection Program Personnel monitoring of the SIP letter, perform a review of plants with SIP letters using similar tools to those which Enforcement Investigation and Analysis Officers (EIAO) use in their verification of SIP procedures while performing Food Safety Assessments (FSA).

Agency Response

FSIS issued new directives for FSAs, FSIS Directive 5100.1 Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment (FSA) Methodology and FSIS Directive 5100.4, Enforcement, Investigations, and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology. During the FSA, the EIAO is to review any procedures associated with an establishment's SIP program, any other waivers, and any no objection letters as part of his or her assessment of the overall food safety system. Planning for this review will be based upon FSIS Directive 5100.4. According to this directive, the EIAO is to develop an Assessment Plan prior to performing an FSA. The development of an Assessment Plan helps to ensure that the assessment is thorough and well organized. Additionally, FSIS will perform PHREs on a random sample of 16 of the 32 establishments with SIP waivers and if any warrant additional review, FSIS will conduct an FSA, as instructed by FSIS Directive 5100.1. FSIS will also perform an analysis of the 16 PHREs conducted by May 2016. FSIS will perform PHREs on a random sample of 16 of the 32 establishments and analyze the results of all conducted PHREs by July 2016.

OIG Position

We accept management decision for this recommendation.

Recommendation 3

Based on the results of FSIS' review of plants with SIP letters, take appropriate actions to modify procedures for monitoring compliance with existing SIP letters and all future SIP letters.

Agency Response

FSIS will review results of the FSA activities under the new directives in December 2015. Based on analysis of EIAO findings, FSIS will determine whether changes to Directive 5020.1, Verification of SIP are necessary. If changes are necessary, FSIS will make those changes to the directive by April 2016.

OIG Position

We accept management decision for this recommendation.

Finding 2: FSIS Management Needs to Improve How Sanitation Noncompliance Records Are Written and Evaluated

Our audit of sample turkey plants revealed that the FSIS noncompliance records (NR) process is sufficient to document failures to comply with regulations, but it is inadequate to use as an indicator of process control. This occurred because of current limitations on how NR data are recorded and utilized. Without an improved NR reporting model from FSIS, the agency cannot accurately tally sanitation violations based on frequency, severity, and risk. Consequently, FSIS is not utilizing NRs in a manner that will truly identify plants that have lost process control. This creates a risk of unsanitary plant conditions or unsafe food products going undetected and uncorrected.

FSIS requires Inspection Program Personnel to document regulation noncompliances in NRs using the Public Health Information System (PHIS).[21] FSIS directs Inspection Program Personnel to record all regulations whose requirements the plant did not meet in clear, concise terms, including the problem, time of occurrence, location, and effect on product, if any.[22] PHIS will allow Inspection Program Personnel to document one or more noncompliances within a single NR.[23] With the NR data it collects, FSIS does predictive analysis to identify trends and anomalies. One use of this predictive analysis is that FSIS uses data from sanitation NRs, including the number written at a plant during a specified time frame, in an algorithm to identify plants requiring for-cause a Food Safety Assessment (FSA). Also, FSIS' predictive analysis includes alerts for high rates of noncompliance in an establishment based on the number of NRs over time.

We observed inconsistencies in how "sanitation" NRs are written in the plants we visited. Sanitation NRs are particularly important because the cleanliness of a plant directly relates to the potential of their products producing illnesses.[24] In PHIS, there are various options open to Inspection Program Personnel when they write an NR. The Inspection Program Personnel might document multiple sanitation violations on one NR, numbering each violation in the narrative as they go, while other Inspection Program Personnel at a different plant might write multiple NRs with a single violation on each. Additionally, Inspection Program Personnel at another plant might not number the violations on one NR at all, and instead just provide a long unnumbered narrative in the NR. FSIS uses data from these sanitation NRs in an algorithm for initiating for-cause FSAs, but this algorithm does not account for this variability among those writing the NRs.

FSIS has various predictive analysis tools that utilize NR data. For our example, we focused on how these data are used to identify plants requiring for-cause FSAs. The FSIS algorithm uses various criteria, including the number of sanitation NRs written at a plant during a specified time frame. We found two plants where we questioned why for-cause FSAs were not timely scheduled by the agency.

[21] FSIS Directive 5000.1, Chapter V, paragraph II.C.
[22] FSIS Directive 5000.1, Chapter V, paragraph II. D.1.
[23] FSIS Directive 5000.1, Chapter V, paragraph I. E.2.
[24] FSIS Directive 6410.3, paragraphs I, VI, VII, and VIII.

In the first case, we noted that a plant with the best level of pathogen control (a Category 1 plant) had 102 sanitation NRs, with some documenting multiple sanitation incidents over a 27 month period.[25] In-Plant Personnel and their supervisors were concerned about the plant's sanitation activities, but neither FSIS District Office managers nor the agency algorithm identified the plant as needing a for-cause FSA. During the 27 month timeframe, the plant failed two *Salmonella* sample sets and went from being a Category 1 plant to a Category 3 plant (the worst level of pathogen control), which directly related to the increase in positive test results for pathogens and FSIS considered a highly variable process control.[26] Although category status is not directly tied to sanitation or sanitation NRs, OIG believes that frequent and multiple sanitation NRs also reflects on a plant's process control. However, the large number of sanitation NRs and FSIS personnel's concerns did not trigger a for-cause FSA, which only occurred when the plant had actually dropped to a Category 3 status.

Discussions with plant management disclosed that, at the time, the plant was also concerned about sanitation activities due to the fact that the establishment had added a new processing shift, had experienced excessive turnover in the staffing of the sanitation crew, and had new plant construction. These factors converged to adversely affect the plant's sanitation activities.

In the second case, another Category 1 plant had 328 sanitation NRs in a similar 27 month period, but no for-cause FSA was performed (this plant still maintains a Category 1 status).[27] We questioned if the NR count properly illustrated the conditions seemingly reflected within the actual NRs, which may have warranted a for-cause FSA. Many of these NRs had multiple citations showing unsanitary conditions. Our review of these NRs suggested that the actual number of sanitation violations is considerably higher than suggested by the number of NRs; however, the manner in which the NRs were documented hindered our ability to compile a specific count of the violations.[28] For example, we found that about 90 of the 328 NRs specifically enumerated the violations in the NR; however, for the remaining sanitation NRs, we could not determine the exact number of individual sanitation issues. The Inspection Program Personnel and supervisor told us they were not concerned with the plant's sanitation activities and did not think the plant needed a for-cause FSA. Although FSIS did not seem concerned about the sanitation issues, a plant manager told us about past concerns with the activities of the plant's cleaning crew and the general sanitation of the plant.

Agency officials have explained to us that their Inspection Program Personnel are following agency policy when they cite multiple sanitation issues within one NR. Agency managers are concerned that putting one citation per NR would waste resources doing extra documentation that would be better spent doing other food safety activities in the establishments. While FSIS officials have acknowledged OIG's concerns about whether NRs with multiple citations are properly being considered when that agency uses its for-cause algorithm, they are resistant to

[25] These NRs were written between January 1, 2012, and March 31, 2014.
[26] According to FSIS Directive 10,250.1, a plant's Category status is based on *Salmonella* set testing results, which FSIS considers a reflection of "consistent process control" for a Category 1 plant or "highly variable process control" for a Category 3 plant.
[27] Category status does not depend on NRs written; rather it depends on FSIS *Salmonella* set sampling.
[28] We could not determine the exact number of individual sanitation issues that are noted in the 328 sanitation NRs written at the plant between January 1, 2012, and April 16, 2014, because some of the NRs did not specifically list the unsanitary conditions in a 1, 2, 3, etc., format; some were written in long unnumbered narratives.

making changes to the current system, citing the possibility of unintended consequences. Agency managers are afraid that putting in a mechanism to complete a count of each citation in a multiple citation NR could become a competition between Inspection Program Personnel staff to see who could accumulate the most citations. Also, they are concerned that the algorithm cannot be adjusted to reflect how many occurrences the Inspection Program Personnel reviewed that were correct or how quickly the plant management responded to correct the problems. For example, the Inspection Program Personnel may have looked at 50 pieces of equipment, of which 45 were properly sanitized, while 5 pieces of equipment had some sanitary issue. Agency officials questioned how they could properly consider in the algorithm the 45 pieces of equipment that were acceptable for use.

Other agency officials stated that one isolated NR with multiple citations does not indicate that there is a sanitation crisis at an establishment. We agree; however, in about a 45-day period, the Inspection Program Personnel at the Category 3 establishment wrote 24 NRs that had a series of about 79 sanitation citations which would seem to indicate a pattern of unsanitary conditions.[29] Further, we found that agency documents suggest that "...there may be multiple pages to one NR. Each page documents a different [noncompliance] or [noncompliances]." We found a number of instances where this was not being done. Also, the documents note that "FSIS believes that individual instances of regulatory noncompliance is [sic] a better way to measure an establishment's performance than the numbers of procedures or NRs issued." This seems to support OIG's assertion that FSIS should be tracking individual citations within each NR, since these data can be relevant to PHIS inspection verification activities.[30]

Lastly, FSIS officials stated that there are other avenues for the Inspection Program Personnel to direct their concerns to appropriate agency supervisors. However, we noted that in these two cases, either the Inspection Program Personnel did not forward any concerns or their concerns did not stimulate any for-cause FSAs. We understand that a for-cause FSA is a discretionary matter with FSIS district offices; however, one district did not know about the number of sanitation issues related to the NRs at one of these two plants, and the other district did not respond until after the plant became a Category 3 plant. We believe these two cases show that FSIS could improve on how it captures and disseminates instances of sanitation issues in its NR process, either through the use of its algorithm or other means of communication.

We believe the agency could benefit from considering the number of sanitation citations in each NR. Managers in the field would have a better understanding of the full scope of the sanitation issues identified by Inspection Program Personnel. One possible approach to this issue would be that NRs should not only allow a narrative with multiple citations, but should also include a numeric portion to give a count of the citations, and from these data, FSIS could develop a second algorithm that would give another report for agency management to use when they consider where to schedule for-cause FSAs. Further, knowing and considering the number of citations in an NR may allow FSIS to improve its predictive analysis processes.

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[29] The 45-day period ranged from March 11, 2013 through April 24, 2013. We reviewed the NR information FSIS provided to us and estimated that the 24 NRs in this period documented 79 different sanitation issues. Since each sanitation instance is written in a narrative and not necessarily individually identified, we used our judgment to extrapolate the number of sanitation instances cited in the NRs.

[30] FSIS PHIS Inspection Verification Features presentation.

Recommendation 4

Review the process of how sanitation NRs are drafted and the data that are recorded, in order to develop a methodology to assure the information recorded in them can be better utilized by the agency to determine the scope and complexity of any underlying plant process control issues. Based on the review, FSIS should develop a plan with appropriate timeframes and milestones to implement the new and improved methodology.

Agency Response

FSIS utilizes information in PHIS about the regulations cited in non-compliances to assess the severity of non-compliances. When certain regulations are cited at a high enough rate, establishments may be scheduled for a public health risk evaluation (PHRE), and, depending on the outcome of the PHRE, a Food Safety Assessment (FSA) or enforcement action. FSIS recently issued instructions on this process in FSIS Directives 5,100.1 and 5,100.4 and describes its methodology for evaluating regulation citations in the Fiscal Year (FY) 2015 Public Health Regulations report on the FSIS website. As part of the PHRE, EIAOs are to review establishment compliance history including all NRs, sanitation included, issued to the establishment within a specified time period. FSIS will conduct an evaluation of this new decision-making process, which will include evaluating how sanitations NRs are drafted and the data that is recorded, and consider how the scope and complexity of sanitation NRs might be better utilized to evaluate an establishment's underlying plant process control. Based on the results of this review FSIS will take appropriate actions, if necessary. FSIS will complete its evaluation by June 2016.

OIG Position

We accept management decision for this recommendation.

Finding 3: FSIS Needs to Update Older Directives Related to Poultry

During our review, we found four poultry-related FSIS Directives that were written before FSIS' major Hazard Analysis and Critical Control Points (HACCP) policy initiative (1996) and refer to items no longer applicable. This problem arose because FSIS does not have a system in place to periodically update and remove irrelevant information from its directives. If this issue is not addressed, outdated directives may cause confusion at the Inspection Program Personnel level.

An FSIS directive notes that "FSIS Directives provide specific instructions or establish new procedures that [a]gency personnel need to follow to implement FSIS requirements." The FSIS directive notes further that "directives identify the specific [a]gency personnel that are to carry out the activities in the directive. Directives are effective until canceled by another directive or notice."[31]

Agency officials also claim to informally track directive updates. They believe that this process allows agency managers to update relevant directives so that Inspection Program Personnel can address developing food safety concerns such as *Salmonella* and *Campylobacter* in regulated products. FSIS noted additionally that its Directives concerning *Salmonella* and *Campylobacter* control were recently updated.

We nevertheless believe that outdated directives can cause confusion among FSIS personnel and that FSIS' informal tracking system is not updating directives adequately. For example, one directive we found references the Deputy Administrator, Meat and Poultry Inspection Operations, a position that no longer exists. Another directive references a grading region that, likewise, no longer exists. Other directives discuss office items no longer in use, such as typewriters and carbon paper. More seriously, the absence of a system that ensures review and update of directives may erode confidence in the accuracy of all directives, and could result in minor policy misinterpretations by Inspection Program Personnel or could lead to more serious legal and food safety repercussions for the agency if any Inspection Program Personnel rely on outdated information in a directive.

A broader consequence of outdated directives is that they can give the impression that FSIS is out of touch with issues that are relevant to the industry. For example, FSIS is in the process of requiring safe labeling of mechanically tenderized beef; we found a directive that treats this issue (Directive 7235.1), but was last updated more than 20 years ago, in 1994. Our audit revealed another directive (Directive 10230.2), which was last revised in 1992. This directive advises Inspection Program Personnel to collect 250 gram samples for microbial analysis; currently, FSIS Notice 06-14 recommends a 325 gram sample. The persistence of outdated directives such as these may also create problems in sampling and monitoring procedures, which potentially could make it difficult for FSIS to detect lapses in industry's food safety controls. FSIS' managers were receptive to the idea of establishing a methodology to assure the agency's directives remain current.

[31] FSIS Directive 1230.1, paragraph III.A.

Recommendation 5

Establish a formal system to periodically review and update Agency directives to assure that they are still applicable and technically accurate.

Agency Response

FSIS has developed a chart that includes all current FSIS Directives in the 1,000-13,000 series. This chart is reviewed and updated quarterly by FSIS program areas to determine whether the directives are up-to-date, or whether they need to be revised or cancelled. As a result of instituting this process, FSIS has identified a number of directives that FSIS plans to revise or cancel over the next year. FSIS has completed establishing a formal system to periodically review and update Agency directives.

OIG Position

We accept management decision for this recommendation.

Section 2: Sampling-Related Concerns

Finding 4: FSIS Could Improve its Pathogen Sampling to Enhance Food Safety

We found that FSIS could improve its pathogen sampling system to enhance food safety. This issue exists because FSIS uses its limited resources to conduct a set-based sampling approach for *Salmonella*. Set sampling consists of collecting samples daily for a specified number of days in order to discern an establishment's capability to sustain long term process control. However, this method inhibits FSIS' ability to sample some sources of turkey products, especially if there is not a consistent daily production of turkey products. As a result, FSIS' current set sampling approach does not allow it to regularly sample over 60 percent of the turkey slaughter plants and over 75 percent of the active processing plants.[32] We calculated that the non-sampled slaughter plants combined were estimated to slaughter over 143,000 birds in fiscal year 2014.[33] FSIS' set sampling approach also kept it from sampling over 11 million pounds of imported ground turkey products during calendar years 2012 and 2013.[34] Also, FSIS' set sampling approach means FSIS is not routinely sampling plants that have consistent process control, also known as "Category 1" plants.[35] The sampling approach limits FSIS' ability to estimate pathogen prevalence.

The overall purpose of FSIS inspection activities is to verify that establishments meet requirements to control physical, chemical, and microbiological hazards in regulated product. Verification activities serve to protect the public from foodborne hazards. A key component of FSIS' inspection activities is the sampling of product to test for microbiological contaminants or chemical residues. FSIS' current *Salmonella* sampling approach schedules between 75 and 90 *Salmonella* sample sets each month. Under current FSIS policy, a set is a collection of samples collected on consecutive days of production at a single establishment. The sets for whole birds currently consist of 56 samples. FSIS has discontinued all ground turkey sets, except for plants with highly variable process control, known as "Category 3" plants. Instead, FSIS Notice 06-14 instructs FSIS Inspection Program Personnel, at plants that have products such as ground turkey, to sample such products as part of the Not-Ready-to-Eat Comminuted Poultry Exploratory Sampling Project (NCPESP). FSIS intends to use the results of NCPESP to establish pathogen reduction performance standards for *Salmonella* (and possibly for *Campylobacter*). Prior to NCPESP, FSIS sampled and tested 53 unit sample sets for ground turkey.

[32] Plants slaughtering fewer than 20,000 birds per year, producing less than 1,000 pounds of ground turkey per day, or that have all of their product go to ready-to-eat products are exempt from testing under current FSIS regulations.
[33] Based on data provided by FSIS, we calculated that 66 of 109 active slaughter plants are not regularly sampled and 219 of 287 active processing plants that produce raw turkey product are not regularly sampled.
[34] This product was imported from Canada and Chile between May 29, 2012, and December 31, 2013.
[35] Consistent Process Control (Category 1): Establishments with the total number of positive *Salmonella* samples in the two most recently completed sets at 50 percent or less of the performance standard, i.e., the number of positives is at or below half of the performance standard. This performance demonstrates the best process control for this pathogen.

Very Small Establishments Are Not Currently Sampled

A prior OIG report[36] identified there were hundreds of plants nationwide that had been exempted from *Salmonella* testing. OIG recommended that the agency develop a risk assessment to support its policy of excluding establishments or conduct testing in all plants. While FSIS has since acknowledged that product testing is particularly important in gauging the safety of regulated product and sampling serves as a strong incentive for the poultry industry to reduce the presence of pathogens on products it produces, FSIS responded at the time that it believed consumer exposure was minimal from these establishments and that FSIS' sampling should focus on production volume.[37] However, FSIS provided documentation acknowledging that it does not have *Salmonella* or *Campylobacter* data from these establishments for young chickens, turkeys, NRTE comminuted chicken or turkey, and raw chicken parts, which we believe could affect its assessment.

Because FSIS uses set sampling to determine a plant's capability to sustain long term process control, it does not have the resources to collect samples from many very small plants. This means that FSIS does not currently sample whole birds at over 60 percent of turkey slaughter plants or for ground turkey at over 75 percent[38] of active processing plants. FSIS is not able to sample at these plants because FSIS needs a continuous flow of product in order to fill the 56 unit sample sets. FSIS exempts these plants because of the difficulty in scheduling set sampling, and it considers small batches of product as providing less risk to the public than a plant with a large volume of product. When we discussed other possibilities for performing set samples, FSIS agreed that the sample set sizes may need to be lowered or new approaches to sampling may need to be considered to help address these gaps in sampling. For example, if FSIS reduced the number of daily samples collected in its sampling sets, it would allow the agency to free up additional sampling resources to conduct pathogen sampling at these low volume establishments.

FSIS officials also stated that the agency is developing new pathogen performance standards that will allow FSIS to begin sampling for pathogens at very small plants in the future. Specifically, FSIS said at the time when the new pathogen reduction performance standards that are currently out for comment are implemented, FSIS intends to begin sampling eligible product three to four times per year from poultry establishments that had been exempted from *Salmonella* verification testing. For comminuted turkey, FSIS is proposing a pathogen reduction performance standard designed to achieve at least a 30 percent reduction in illnesses from *Salmonella*. We are recommending that FSIS move forward with a plan to routinely sample for pathogens in ground product at these plants.

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[36] Audit Report 24601-0007-Ch, *Review of Pathogen Reduction Enforcement Program Sampling Procedures*, September 28, 2006.
[37] Audit Report, 24601-0007-Ch, *Review of Pathogen Reduction Enforcement Program Sampling Procedures*, September 28, 2006.
[38] Based on data provided by FSIS, we calculated 66 of 109 active slaughter plants are not regularly sampled and 219 of 287 active processing plants that produce raw comminuted turkey product are not regularly sampled.

Imports Are Not Currently Sampled for Pathogens

As with very small plants, we found that FSIS does not currently collect samples from imported turkey products for *Salmonella* or *Campylobacter* analysis because, according to FSIS officials, there is not a continuous flow of product from any particular plant, which is required under current set sampling procedures. We found that the United States imported over 11 million pounds of ground turkey product and just over 770,000 whole birds over a 19-month period during calendar years 2012 and 2013.[39]

While FSIS does not collect imported raw poultry products for *Salmonella* analysis, on June 29, 2014, it began sampling and testing imported beef for *Salmonella*, in addition to its *Escherichia coli* (STEC) samples. FSIS officials indicated that in calendar year 2015, they plan to begin sampling imported raw broiler and turkey carcasses, NRTE comminuted chicken and turkey products, and raw chicken parts for *Salmonella*. We are recommending that FSIS continue to move forward with a plan to routinely sample imported turkey products for pathogens.

Category 1 Plants Are Not Regularly Sampled

We found that FSIS' sample collection is disproportionately focused on poorer performing establishments, and Pathogen Category 1 plants can go over 1 year between sample sets due to FSIS' scheduling algorithm. Although the volume of product does not necessarily relate to a plant's Pathogen Category, some Category 1 plants can produce a high volume of turkey product that may not be tested routinely. For instance, we visited a Category 1 plant that produced over 600,000 pounds of ground turkey a day. "Well-performing" plants (Category 1) such as this might not be scheduled for sampling for a year or more, whereas poorer performing plants (Category 3) are prioritized for sampling over this and other Category 1 plants that have not been sampled for over 660 days. Additionally, the sampling algorithm is problematic from a process control perspective because there are no available data over a long period for so-called "well-performing" (Category 1) establishments. Thus, it is unknown whether these establishments are consistently maintaining good process control, or if their good performance was a temporary result of announced sampling.

When we discussed this issue with FSIS officials, they acknowledged that regular sampling of Category 1 establishments was an issue, and they stated that the agency has proposed modifying its sampling procedures. Specifically, FSIS has proposed replacing its traditional *Salmonella* sampling set-approach with a routine sampling approach[40] for all FSIS-regulated products subject to *Salmonella* and *Campylobacter* verification testing. This includes sampling of broiler and turkey carcasses and chicken parts. FSIS has already moved to routine sampling for comminuted poultry, ground beef, and beef manufacturing trimmings. Therefore, we are recommending that FSIS move forward with a routine sampling approach to address the issues that currently result from the infrequent sampling of Category 1 establishments.

[39] The product imported over this time period was from Canada and Chile.
[40] A routine sampling approach consists of sampling plants throughout the year instead of set samples.

Current Set Sampling Cannot be Used to Estimate Pathogen Prevalence

We found that FSIS has determined that its current set-based *Salmonella* sampling program cannot be used to estimate prevalence. Calculating an accurate prevalence estimate using the current *Salmonella* verification data is not possible because certain key elements in the data requirements are not being met.[41] This is important because FSIS needs timely and accurate estimates of pathogen prevalence in order to better understand how contamination rates change over time, set performance standards to reduce product contamination, develop targeted interventions and policies, and measure the agency's performance towards meeting FSIS strategic planning goals. FSIS also uses prevalence estimates in economic analyses and risk assessments. Routinely updated prevalence estimates would allow the agency to more rapidly and effectively update existing analyses. Finally, prevalence estimates provide FSIS with a proxy measure of the agency's public health impact, in situations where direct illness outcome measures are lacking.

FSIS has determined that its current set-based *Salmonella* sampling program cannot be used to estimate prevalence for several reasons. First, FSIS' scheduling algorithm disproportionately focuses sample collection based on past performance under the *Salmonella* performance standards. The current scheduling algorithm is risk-based, which is critical in positively affecting public health, but as previously mentioned focuses more sample collection on Category 3 plants. For this reason, not all establishments in the collection frame have a known probability of selection each month. Also, because *Salmonella* samples are scheduled in the current set-approach, this results in a high degree of clustering. Establishments are sampled intensively and then not at all for a period of time. Because FSIS plans to use sampling results to develop new pathogen reduction performance standards based on prevalence, we are recommending that FSIS take steps to implement routine sampling so that these sampling results can be used to estimate prevalence.

Recommendation 6

Develop a plan with appropriate timeframes and milestones to revise the agency's pathogen sampling program in order to consider the following issues: (1) sampling of imports, (2) sampling of currently exempt plants, (3) sampling of Category 1 plants, and (4) sampling to determine the estimated prevalence of *Salmonella*.

Agency Response

FSIS has completed the first three sub-parts of the recommended actions, and they are noted and summarized in the Salmonella Action Plan and in the Federal Register. FSIS will make public the FY 2015 prevalence estimate for comminuted poultry products by December 31, 2015. FSIS will make public preliminary prevalence estimates for turkey and broiler carcasses and chicken parts, based on data collected through September 30, 2015, by December 31, 2015. Finally,

[41] The missing key elements under the *Salmonella* Verification Program include the population, probability of selection, and production volume for raw ground product. We used the following source: Use of FSIS Regulatory Verification Sampling to Generate Prevalence Estimates, DCC Prevalence Estimate Workgroup, April 2012.

FSIS will develop a schedule, with milestones, for periodically updating Salmonella prevalence estimates by December 2015.

OIG Position

We accept management decision for this recommendation.

Section 3: Plant Level Guidance

Finding 5: FSIS Should Enhance Its Oversight of Plants' Prerequisite Programs

Turkey establishments implement prerequisite programs in their plants to ensure that food safety hazards are not reasonably likely to occur. Our audit of five of the eight plants[42] showed flaws in how these plants' prerequisite programs were implemented and documented. While FSIS and industry consider prerequisite programs integral to a plant's food safety system, these programs nevertheless showed deficiencies that were not detected by plant employees or FSIS personnel who oversee the plants. Although individual plants are responsible for developing and implementing the prerequisite programs, we believe these conditions occur because the plants do not have sufficient guidance on what would constitute best practices. As a result, Inspection Program Personnel and plant employees did not always assure that a plant's food safety system was sufficiently developed and implemented. With more robust oversight of prerequisite programs, this increases the likelihood that the plant's turkey products will be safer for human consumption.

The proper design, implementation, and documentation of plant monitoring programs are becoming more important, especially as FSIS transitions to the Modernization of Poultry Slaughter Inspection, which will place more emphasis on plants documenting their protocols. For example, the final rule requires that all poultry slaughter establishments use written procedures (including prerequisite programs) to prevent contamination of carcasses by pathogens and fecal material throughout the slaughter and dressing operation, and that plants incorporate these procedures into their Hazard Analysis and Critical Control Point (HACCP) systems. Establishments are required to document the implementation and monitoring of these procedures daily, so that both FSIS and the plant's own oversight personnel can verify the ongoing effectiveness of safety measures.

Because they outline fundamental environmental and operational conditions that are critical to food safety, prerequisite programs (including such items as standard operating procedures (SOP), good manufacturing practices, and sanitation SOPs) are the foundation of plants' HACCP systems. Our audit revealed a variety of ways in which a lack of oversight of plant monitoring programs, specifically these prerequisite programs, increased the potential for unsafe food production.

[42] For our fieldwork, we visited six turkey slaughter plants that also processed turkeys and turkey parts. In addition to the six plants, we also visited two turkey processing plants that did not do any slaughtering. We found prerequisite problems at five of the six slaughter plants. We chose the six plants based on factors such as location, slaughter or production volume, plant category ranking, size, etc. At all the plants, we observed operations and reviewed FSIS and plant records to make determinations summarized in this finding.

Planned Use of Chlorine Was Outside Established FSIS Limits

In its guidance to turkey processing plants, FSIS prescribes ranges of antimicrobial agents for use in processing operations. These ranges ensure that concentrations of antimicrobial agents are high enough to eliminate pathogens, but the levels of any residual chemical are low enough that the treated poultry remains safe for human consumption.

In the prerequisite plan of one of the plants we visited, we found program documents that allowed levels of the antimicrobial chlorine as high as 20-550 parts per million (ppm), a major divergence from the FSIS standard for chlorine levels, which is 20-50 ppm. Plant officials describe this mistake as a typographical error, and there is no evidence that the plant's chlorine levels actually exceeded the limit set by FSIS. However, if plant personnel relied on the document with this clerical error, it could have allowed for the potential use of unsafe levels of chlorine—more than ten times the prescribed maximum—to be in use at this plant.

We also found documentation requiring turkey parts that had contacted the floor to be cleaned in a solution of chlorine with a concentration of between 1 and 50 ppm. FSIS regulations specify that the minimum level of chlorine in this situation is 20 ppm. Thus, turkey parts that come in contact with the floor at this plant may not be sanitized to FSIS standards before they are returned to the production line.

Plant Personnel Did Not Adequately Address Situations When Target Ranges in Prerequisite Programs Were Not Met

FSIS establishes ranges for the safe application of antimicrobial chemicals on turkeys. Within these ranges, plants often set tighter parameters for antimicrobials or for the pH level of water that contacts the turkeys as they are slaughtered and processed. Four of the five slaughter plants we visited were only occasionally out of their own set target ranges or FSIS' safe application range, and readily adjusted to appropriate levels. However, our audit of the fifth plant found that plant monitoring documentation showed frequent fluctuations outside the plant's and FSIS' tolerances.

In this plant's pH and antimicrobial monitoring documents for November and December of 2013, we found over 400 instances where the process was out of the plant's prescribed tolerance. The plant had established a target range of 15 to 90 ppm for the antimicrobial used in its chiller; however, we found recorded antimicrobial levels as low as 0 and as high as 120 ppm, which are outside the plant's self-prescribed limits. Plant management explained further that, when antimicrobial levels went to zero, often it is because the totes containing the antimicrobial chemicals run empty. This plant's lack of attention to its prerequisite plan could create an unsafe meat processing environment if the antimicrobial chemical application is a primary process to control dangerous pathogens. We believe that, since the totes running dry is a recurring issue, it is not adequate for plant management to simply direct that the empty totes be replaced. Plant management should develop processes to notify the appropriate plant personnel before the tote is empty, such as an alarm or more frequent monitoring when the level of antimicrobial in the tote becomes low.

Plant management responded to our discovery by insisting that these fluctuations are normal and are addressed on a case-by-case basis. We disagree with their assessment, and we believe that over 400 variances in two months indicates a systemic problem requiring the attention of plant and FSIS Inspection Program Personnel.

Prerequisite Program Forms are Outdated, Missing, and Incomplete

At the plants we visited, we found several problems with prerequisite forms themselves. Some monitoring forms were not in the HAACP system of documents at all; in other instances, outdated forms were either on file in the HACCP system of documents or in use on the kill floor.[43] In other instances, monitoring forms were missing vital information: on some forms, corrective actions were not explained at all; on other forms, the corrective action was not noted in sufficient detail.

In two of the plants, we found that outdated monitoring forms were used on the slaughter or processing floor when there were newer revisions filed with the prerequisite program documents. For example, we found in one plant that staff were using monitoring forms for the salvage station, dated 4-22-10, when the new form was dated 2-14-13. Plant management explained the outdated monitoring forms used on the kill floor probably came from old photocopies someone kept in their desk or were printed from an outdated file stored on their computer. Conversely, two of the plants were using new monitoring forms in the plant, while older versions of the monitoring forms were still filed with the prerequisite plans.

Further, we noted that when plant employees in two establishments found and noted problems on their monitoring forms, there was no corrective action noted (the designated spot on the form for the employee to document the actions taken to correct the issue was blank) or the corrective action was ambiguous. At one of the plants, the monitoring forms often just had the name of the plant employee that was notified of the tolerance being exceeded—the specific corrective action was not documented.

Proper form management is not always simple for organizations to achieve, but we believe that appropriate form administration is a key component in providing confidence and assurance to senior plant managers and FSIS that the plant's prerequisite programs are capable of addressing the critical food safety hazards in the plant. After we pointed out our concerns regarding form management, the quality assurance managers at two of the plants stated that they were going to institute a new policy to periodically review all of their HACCP system documents to assure they were up to date.

[43] The older forms lacked operational information desired by plant management, whereas the current version of the forms provided additional space(s) for plant monitoring personnel to record this recently required information.

Prerequisite Program Documents Were Unclear Regarding the Safety of Antimicrobial Agents

Concerns about one microbial agent arose at one plant. During our fieldwork we requested that a plant provide additional documentation regarding the use of an antimicrobial on its product. To support that use of the antimicrobial was safe, plant management provided us with a 2009 letter, explaining that this microbial agent "is acceptable for use as a sanitizer on all surfaces not always requiring a rinse in and around food processing areas. Before using this compound, food product and packaging materials must be removed from the room or carefully protected." Further, the letter explains that "surfaces are [to be] adequately drained [of antimicrobial] before contact with food so that little or no residue remains which can adulterate […] edible products." We took this to mean that the antimicrobial was not safe to apply directly to turkey products.

On a tour of the slaughter plant, we noted that this antimicrobial was being sprayed directly onto turkeys in the slaughter line, an action that would be out of compliance with the plant's documentation to use this antimicrobial only as a disinfectant for work surfaces. As a result of our audit inquiry and our observation on the slaughter line, the plant turned off the antimicrobial spray bar and FSIS required that the bar remain off until the establishment could provide data to support that the product was safe to apply on the product. While the plant personnel eventually obtained documentation to show that the chemical could be applied safely directly on turkey products, we believe this shows FSIS was not aware of the documentation in the plant's prerequisite program.

Examples of Additional Concerns with Prerequisite Programs

We also identified several other areas of potential improvements with the prerequisite programs in five of the slaughter plants we visited that were less likely to impact food safety, but still require attention. These concerns included, for example, five plants that were collecting samples for pathogen testing without written sampling procedures for at least some aspect of their sampling programs. One plant did not have written sampling instructions for ground product and had not developed written instructions for whole birds, and none of the five plants had developed instructions for mechanically separated turkey sampling. Other examples of prerequisite problems included omissions on monitoring forms for such items as a supervisory review or instructions on properly documenting the form. One plant had to change how it followed up on its monitoring activities because plant managers found that employees were completing the forms, noting deficiencies, and filing the forms away without assuring the appropriate corrective action was taken. Additionally, at two plants, we observed vials that were not properly cleaned or were so stained they impaired the ability of plant employees to monitor the level of the antimicrobial agents being applied in the plant.

FSIS national office officials were receptive to informing industry and FSIS Inspection Program Personnel of the issues we noted in this finding and providing direction to them on how these conditions could be addressed. Overall, with FSIS' transition to Modernization of Poultry Slaughter Inspection, we believe that more robust oversight of prerequisite programs by FSIS and industry will reduce the food safety risks associated with consumption of turkey products

and specifically ground turkey. We believe that FSIS could achieve this by providing guidance to industry on what a food prerequisite program should include.

Additionally, FSIS Inspection Program Personnel periodically perform Hazard Analysis Verification (HAV) tasks, which are in-depth reviews of a plant's food safety system. The HAV is designed to identify isolated noncompliances, as well as to evaluate how the system has been developed and implemented. We believe FSIS should consider if the HAV directives need revision or if the quality of these HAV reviews may be improved by agency management providing examples of the guidance sent to industry and to FSIS' Inspection Program Personnel. FSIS officials agreed that the additional guidance to industry could also benefit FSIS Inspection Program Personnel.

Recommendation 7

Develop a plan with appropriate timeframes and milestones to issue appropriate guidance to establishments on how to improve their turkey prerequisite programs in order to correct the specific concerns addressed in this finding.

Agency Response

FSIS is drafting the 4th edition of the Compliance Guideline for Controlling Salmonella and Campylobacter in Raw Poultry. The Agency intends to address the following issues in the updated guideline: 1) Recommended best practices, 2) information on the components of a prerequisite program, 3) recommendations for maintaining sanitary conditions during operations, 4) information explaining that sampling procedures should be described in a written program, 5) information explaining that interventions used (and their operational parameters) need to be safe and suitable, 6) information on how establishments should document their use of antimicrobial interventions, and 7) information on actions that establishments should take if they find steps in their prerequisite programs have not been properly implemented or followed. FSIS intends to issue the draft revised compliance guideline by October 2015.

OIG Position

We accept management decision for this recommendation.

Recommendation 8

Review the Hazard Analysis Verification (HAV) Directive, as related to the issues from this finding. Determine if the concerns raised in our report should be incorporated into FSIS procedures for field personnel when they perform a HAV task. If warranted, develop a plan with appropriate timeframes and milestones to provide additional guidance to the FSIS Inspection Program Personnel or revise and reissue the FSIS HAV Directive.

Agency Response

The Office of Policy and Program Development will review the effectiveness of FSIS Directive 5000.6, Performance of the Hazard Analysis Verification (HAV) Task, as it relates to all species and processes under FSIS jurisdiction, including ground turkey. As part of this review, FSIS will evaluate how inspection program personnel are assessing establishments' prerequisite programs during the HAV task. Based on this evaluation, FSIS will determine whether FSIS needs to issue new instructions for field personnel when they perform a HAV task in some or all types of establishments. FSIS will also assess inspectors' findings during the HAV task to assess whether additional guidance to industry (in addition to that discussed in response to recommendation # 7) would be beneficial. FSIS will complete its assessment and determine whether it is necessary to revise the directive by May 2016.

OIG Position

We accept management decision for this recommendation.

Scope and Methodology

We conducted our audit of FSIS' inspection of ground turkey and other turkey products at the FSIS national office located in Washington, D.C., and eight turkey establishments across the United States. We also held discussions with the respective FSIS district offices with oversight responsibility for the establishments we visited.

During the course of our review, we performed audit work in two turkey slaughter plants that participate in FSIS' HACCP-Based Inspection Models Project (HIMP) inspection system.[44] We identified a number of general food safety concerns at these two plants, which are discussed in Findings 1, 2, and 5 of this report; however, the issues we present in these findings are not exclusively found in turkey plants that have implemented the HIMP inspection system. We did identify inspection concerns at one of the HIMP plants that are unique to plants under the HIMP inspection system, but OIG management determined that these potential issues would be more appropriate to develop and report during any future New Poultry Inspection System (NPIS) audit work.

To select our sample of plants to visit, we obtained a list from FSIS in December 2013 of 261 establishments that produced ground turkey, from less than 1,000 pounds to over 600,000 pounds of ground turkey daily. To choose the establishments we visited, we used a non-statistical basis with factors such as establishment size and volume, type of inspection program, and slaughter versus processing or both. We also considered the travel necessary to visit the plant.

To meet our audit objectives, we reviewed FSIS and establishment records;[45] interviewed personnel from multiple FSIS offices, a trade association, and a consumer advocate; and visited selected processing and slaughter establishments. Among those visited and interviewed were:

- FSIS national office representatives: We discussed turkey inspection, *Salmonella* and *Campylobacter* testing programs, sampling processes, and testing procedures with personnel from the offices listed below. The audit team communicated with these officials on numerous occasions by interview, phone, and e-mail.

- Office of Field Operations: We conducted interviews with senior-level officials who manage national inspection activities.

- Office of Policy and Program Development: We conducted interviews with senior-level officials who provide leadership in the identification of policy needs and develop policy solutions to address the intent and application of verification and enforcement policy in plant activities.

[44] According to FSIS, HIMP was developed to produce a flexible, more efficient, fully integrated poultry inspection system. The HIMP system, in contrast to the traditional inspection system, is designed to focus more responsibilities for food safety and other consumer protection activities on the establishment with agency personnel focusing on carcass and verification system activities.

[45] Our record reviews consisted of information and data from calendar years 2012 and 2013 up to the time of our plant visit. The last plant visit concluded in July 2014.

- Office of Data Integration and Food Protection: We conducted interviews with senior-level officials who coordinate FSIS' data collection, analysis, and integration activities across all program areas. This group is responsible for evaluating individual FSIS data streams, ensuring data analyses are consistent and of high quality, and conducting data analyses for the agency's decision makers.

- Office of Public Health Science: We conducted interviews with senior-level officials who oversee the development of scientific information related to meat, poultry, and egg products, from their production to consumption, and use that information to assess potential human health risks.

- Trade Group: We conducted an interview with representatives of an industry trade group. The interview included gaining insight into the group's opinions regarding turkey inspection, *Salmonella*, and *Campylobacter* testing at the processor level, and concerns regarding recalls.

- Consumer Advocacy Organization: We conducted an interview with representatives of a consumer advocacy organization. The interview included gaining insight into the group's opinions regarding turkey inspection, *Salmonella*, and *Campylobacter* testing at the processor level, performance standards, and recall authority.

- Slaughter Establishments and Processing Facilities: We conducted field work at eight establishments in six States to gain an understanding of the testing of turkey for *Salmonella* and *Campylobacter*. Of these eight establishments, six conducted slaughter and processing operations, while the other two were only processing facilities. At each establishment, we conducted interviews with both FSIS Inspection Program Personnel and plant management and reviewed data and information from the plant and FSIS records. Both the records reviews and interviews were used to determine the extent of FSIS inspection and oversight, as well as to verify aspects of FSIS and establishment *Salmonella* and *Campylobacter* testing, interventions, and the traceability of product. The facilities we visited were located in Arkansas, Indiana, Minnesota, Michigan, Pennsylvania, and South Dakota.

- Online Articles and Blogs: We reviewed industry, consumer safety, and various news sources to stay current on relevant industry issues.

- FSIS Electronic Data: We received electronic data from FSIS related to turkey establishments, *Salmonella* and *Campylobacter* sampling, and NRs. However, we did not access the FSIS databases containing this information, and we verified a portion of the electronic data that we obtained from FSIS using plant documents, FSIS documents, interviews with plant management, and interviews with FSIS representatives from the eight plants we visited. Therefore, we make no

representation regarding the adequacy of the agency's information technology systems.

During the audit, we focused on FSIS inspection of ground turkey and products used to make ground turkey, with an emphasis on sampling and testing protocols and the supporting documentation. Our audit fieldwork was conducted from December 2013 to October 2014.

We conducted this performance audit 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 provided a reasonable basis for our findings and conclusions based on our audit objectives.

Abbreviations

APC.....aerobic plate count
CDC .....Centers for Disease Control and Prevention
EIAO.....Enforcement Investigation and Analysis Officer
FSA .....Food Safety Assessment
FSIS.....Food Safety and Inspection Service
FY .....Fiscal Year
HACCP .....Hazard Analysis and Critical Control Point
HAV.....Hazard Analysis Verification
HIMP.....HACCP-Based Inspection Models Project
NCPESP.....NRTE Comminuted Poultry Exploratory Sampling Project
NPIS.....New Poultry Inspection System
NR.....Noncompliance Record
NRTE .....not-ready-to-eat
OIG .....Office of Inspector General
PHIS.....Public Health Information System
PHRE .....Public Health Risk Evaluation
ppm .....parts per million
SIP.....*Salmonella* Initiative Program
SOP .....standard operating procedure
STEC.....Shiga toxin-producing *Escherichia coli*
USDA.....Department of Agriculture

USDA'S
FOOD SAFETY AND INSPECTION SERVICE
RESPONSE TO AUDIT REPORT

United States Department of Agriculture

Food Safety and Inspection Service

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

TO: Gil H. Harden
Assistant Inspector General
Office of Inspector General

FROM: Alfred V. Almanza / s / June 30, 2015
Deputy Under Secretary, Office of Food Safety
Acting Administrator, Food Safety and Inspection Service

SUBJECT: Office of Inspector General (OIG) Official Draft Report – Food Safety and Inspection Service Ground Turkey Inspection and Safety Protocols, Report Number 24601-0004-31

We appreciate the opportunity to review and comment on this Official Draft report. The Food Safety and Inspection Service (FSIS) reviewed the Official Draft report and has responded to each of the recommendations.

Responses to Recommendations

Recommendation 1:
For future Salmonella Initiative Program (SIP) letters, if the Agency elects to issue new SIP waivers, at the approval process, develop one consolidated document including appropriate attachments that clearly and concisely outlines the waived procedures, the plant's requirements based on the waiver, and supporting documents the plant will make available so that the Inspection Program Personnel can fully and adequately monitor the plant's compliance with the SIP letter.

FSIS Response:
For future letters that FSIS sends when approving an establishment's request for a waiver from regulatory requirements under SIP, FSIS will send a consolidated document that includes appropriate attachments that clearly and concisely outline the waived procedures, the procedures the plant is required to follow based on the waiver, and other supporting documents. These letters will be available to IPP in the establishments granted the SIP waivers for verification purposes.

Estimated Completion Date:
As revised or as new SIP Letters are issued, FSIS will implement these changes starting July 1, 2015.

Recommendation 2:
To determine compliance with SIP letters and Inspection Program Personnel monitoring of the SIP letter, perform a review of plants with SIP letters using similar tools to those which Enforcement Investigation and Analysis Officers (EIAO) use in their verification of SIP procedures while performing Food Safety Assessments (FSA).

FSIS Response:
FSIS issued new directives for FSAs, **FSIS Directive 5100.1** *Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment (FSA) Methodology and* **FSIS Directive 5100.4**, *Enforcement, Investigations, and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology.*

During the FSA, the EIAO is to review any procedures associated with an establishment's SIP program, any other waivers, and any no objection letters as part of his or her assessment of the overall food safety system. Planning for this review will be based upon FSIS Directive 5100.4. According to this directive, the EIAO is to develop an Assessment Plan prior to performing an FSA. The development of an Assessment Plan helps to ensure that the assessment is thorough and well organized.

Additionally, FSIS will perform PHREs on a random sample of 16 of the 32 establishments with SIP waivers and if any warrant additional review, FSIS will conduct an FSA, as instructed by FSIS Directive 5100.1. FSIS will also perform an analysis of the 16 PHREs conducted by May 2016.

Estimated Completion Date:
FSIS will perform PHREs on a random sample of 16 of the 32 establishments and analyze the results of all conducted PHREs by July 2016.

Recommendation 3:
Based on the results of FSIS' review of plants with SIP letters, take appropriate actions to modify procedures for monitoring compliance with existing SIP letters and all future SIP letters.

FSIS Response:
FSIS will review results of the FSA activities under the new directives in December 2015. Based on analysis of EIAO findings, FSIS will determine whether changes to Directive 5020.1, *Verification of SIP* are necessary.

Estimated Completion Date:
If changes are necessary, FSIS will make those changes to the directive by April 2016.

Recommendation 4:
Review the process of how sanitation NRs are drafted and the data that are recorded, in order to develop a methodology to assure the information recorded in them can be better utilized by the agency to determine the scope and complexity of any underlying plant process control issues. Based on the review, FSIS should develop a plan with appropriate timeframes and milestones to implement the new and improved methodology.

FSIS Response:
FSIS utilizes information in PHIS about the regulations cited in non-compliances to assess the severity of non-compliances. When certain regulations are cited at a high enough rate, establishments may be scheduled for a public health risk evaluation (PHRE), and, depending on the outcome of the PHRE, a Food Safety Assessment

(FSA) or enforcement action. FSIS recently issued instructions on this process in FSIS Directives 5,100.1 and 5,100.4 and describes its methodology for evaluating regulation citations in the FY2015 Public Health Regulations report on the FSIS website. As part of the PHRE, EIAOs are to review establishment compliance history including all NRs, sanitation included, issued to the establishment within a specified time period. FSIS will conduct an evaluation of this new decision-making process, which will include evaluating how sanitations NRs are drafted and the data that is recorded, and consider how the scope and complexity of sanitation NRs might be better utilized to evaluate an establishment's underlying plant process control. Based on the results of this review FSIS will take appropriate actions, if necessary.

Estimated Completion Date:
FSIS will complete its evaluation by June 2016.

Recommendation 5:
Establish a formal system to periodically review and update Agency Directives to assure that they are still applicable and technically accurate.

FSIS Response:
FSIS has developed a chart that includes all current FSIS Directives in the 1,000-13,000 series. This chart is reviewed and updated quarterly by FSIS program areas to determine whether the directives are up-to-date, or whether they need to be revised or cancelled. As result of instituting this process, FSIS has identified a number of directives that FSIS plans to revise or cancel over the next year.

Estimated Completion Date:
FSIS has completed establishing a formal system to periodically review and update Agency directives.

Recommendation 6:
Develop a plan with appropriate timeframes and milestones to revise the agency's pathogen sampling program in order to consider the following issues: (1) sampling of imports, (2) sampling of currently exempt plants, (3) sampling of Category 1 plants, and (4) sampling to determine the estimated prevalence of *Salmonella*.

FSIS Response:
Consistent with what we announced in the *Salmonella Action Plan*[1] and in the *Federal Register,*[2]

(1) In July 2013, FSIS began testing imported raw beef collected for Shiga toxin-producing *E. coli* (STEC) analysis for *Salmonella*.[3] FSIS has posted aggregate results of imported beef testing on the FSIS Web site as part of its quarterly report on *Salmonella*.[4]

[1] http://www.fsis.usda.gov/salmonella
[2] 80 FR 3940; Jan. 26, 2015
[3] FSIS Notice 18-15; available at http://www.fsis.usda.gov/wps/wcm/connect/e4c58f67-d6fc-48b1-a54a-84f733224f57/18-15.pdf?MOD=AJPERES.
[4] The FSIS *Salmonella* Quarterly Progress Report is available at http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/quarterly-reports-salmonella.

Starting in July, FSIS will begin analyzing for *Salmonella* and *Campylobacter* imported raw broiler and turkey carcasses, not-ready-to-eat (NRTE) comminuted chicken and turkey products, and raw chicken parts. Instructions for collecting samples are at: http://www.fsis.usda.gov/wps/wcm/connect/41a60d0e-060e-479c-a2c0-4096d8a542f2/32-15.pdf?MOD=AJPERES&CONVERT_TO=url&CACHEID=41a60d0e-060e-479c-a2c0-4096d8a542f2

Just as it does with test results for imported beef product, FSIS will enumerate and serotype *Salmonella* positive samples to determine whether an isolate has a historical association with human illness.[5]

(2) FSIS does not currently sample eligible product for *Salmonella* from poultry establishments that produce less than 1,000 pounds per day (i.e., very small establishments) or from poultry slaughter establishments that operate under a religious exemption. At the time that the new pathogen reduction performance standards are implemented, FSIS intends to begin sampling eligible product 3-4 times per year from these establishments. FSIS anticipates that it will begin sampling eligible product that had been exempted from *Salmonella* verification testing in approximately 95 poultry slaughter establishments operating under a religious exemption, and approximately 580 poultry establishments that produce less than 1,000 pounds per day. FSIS expects to eventually implement pathogen reduction performance standards to assess process control at these poultry establishments.[6]

(3) In May 2015, FSIS began using a moving window approach for all poultry products subject to an existing performance standard (i.e., broilers and young turkey carcasses).[7] Under this new approach, FSIS no longer collects sample sets but samples all eligible establishments, including establishments in Category 1, on a routine basis. The frequency of sampling within the moving window is dependent on the establishment's average production volume of young chicken or young turkey carcasses. FSIS had already moved to routine sampling for all categories of establishments producing ground beef in June 2014.[8] By sampling establishments with a proper frequency and continuously throughout the year, FSIS will be able to calculate the national prevalence of *Salmonella* (and *Campylobacter*), without the need to conduct a separate baseline.[9]

(4) Over the years, FSIS has conducted various prevalence assessments of young chicken (broiler) and turkey carcasses - the most recent being the FSIS Nationwide Microbiological Baseline Data Collection Programs: The Young Chicken Baseline Survey (YCBS)[10] and the Young Turkey Baseline Survey (YTBS).[11] Based on

[5] 80 FR at 3945
[6] 80 FR at 3946
[7] FSIS Notice 22-15; available at http://www.fsis.usda.gov/wps/wcm/connect/3379df49-cc8d-47f7-83c3-d4d802668f6c/22-15.pdf?MOD=AJPERES
[8] 79 FR 32436; Jun. 5, 2014
[9] 80 FR at 3945
[10] An overview of the YCBS is available at http://www.fsis.usda.gov/wps/wcm/connect/deab6607-f081-41a4-90bf-8928d7167a71/Baseline_Data_Young_Chicken_2007-2008.pdf?MOD=AJPERES.
[11] An overview of the YTBS is available at http://www.fsis.usda.gov/wps/wcm/connect/92af6a03-c85d-4270-bf27-2243c49f6290/Baseline_Data_Young_Turkey_2008-2009.pdf?MOD=AJPERES.

volume-weighted YCBS data, FSIS estimates the national prevalence of *Salmonella* in broiler carcasses is about 7.5 percent, and that the national prevalence of *Campylobacter* broiler carcasses is about 10.4 percent.[12] Based on volume-weighted YTBS data, FSIS estimates the national prevalence for *Salmonella* in turkey carcasses is about 1.7 percent, and the national prevalence for *Campylobacter* in turkey carcasses is about .79 percent.[13]

FSIS conducted the Nationwide Microbiological Baseline Data Collection Programs: Raw Chicken Parts Baseline Survey (RCPBS) from January 2012 to August 2012 to estimate the percent positive of various raw chicken parts (breast, legs, and wings) sampled and the levels of *Salmonella, Campylobacter*, and indicator bacteria on these products.[14] Based on volume-weighted RCPBS baseline data, FSIS estimates that the national prevalence of *Salmonella* in four-pound portions of raw chicken parts is about 28 percent, and that the national prevalence of *Campylobacter* in four pound portions of raw chicken parts is about 15.5 percent.[15]

In March 2015, FSIS began sampling raw chicken parts (breasts, legs, and wings) on an on-going basis.[16] This new sampling will allow FSIS to gain experience in scheduling, collecting, and analyzing raw chicken parts for *Salmonella* and *Campylobacter*. FSIS will analyze the new data and will discuss it in the *Federal Register* notice announcing the final standards. If the data change substantially based on the new testing so that FSIS determines it should change the standards, FSIS will re-propose the standards.[17] In addition, in August 2015, FSIS intends to begin sampling other raw chicken parts (necks, hearts, livers, gizzards, and half and quarter carcasses) to ascertain the level of process control in individual establishments and to estimate that part's contribution to *Salmonella* and *Campylobacter* illnesses.[18]

FSIS began routine sampling and testing NRTE comminuted chicken and turkey products in June 2013.[19] FSIS used these sampling results to determine the prevalence of *Salmonella* and *Campylobacter* in NRTE comminuted chicken and turkey. Using the first eight months of volume-weighted data, FSIS estimates the national prevalence for *Salmonella* in NRTE comminuted chicken is about 49 percent and in NRTE comminuted turkey is about 20 percent. FSIS estimates the national prevalence for *Campylobacter* in NRTE comminuted chicken is about three percent, and in NRTE comminuted turkey is about one percent.[20]

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[12] 80 FR at 3945
[13] Id.
[14] 80 FR at 3941; an overview of the RCPBS is available at http://www.fsis.usda.gov/shared/PDF/Baseline_Data_Raw_Chicken_Parts.pdf.
[15] 80 FR at 3943
[16] FSIS Notice 16-15; available at http://www.fsis.usda.gov/wps/wcm/connect/5233e84c-f4a6-4959-b861-926a4d912eff/16-15.pdf?MOD=AJPERES.
[17] 80 FR at 3944
[18] Id.
[19] Instructions to inspectors were re-issued in FSIS Notice 31-15; available at http://www.fsis.usda.gov/wps/wcm/connect/bd9e83c2-bb74-4f92-9d95-5603bc722e52/31-15.pdf?MOD=AJPERES.
[20] 80 FR at 3945

From August 2010 to August 2011, FSIS conducted the Nationwide Microbiological Baseline Data Collection Program: Market Hogs Survey[21] and found that the national prevalence of *Salmonella* in market hogs is about 1.66 percent. In addition, in May 2015, FSIS began exploratory sampling of raw pork products for pathogens of public health concern, including *Salmonella*, as well as for indicator organisms.[22]

Finally, in June 2014, FSIS began analyzing for *Salmonella* all raw beef samples it collects for Shiga Toxin-producing *E. coli* (STEC) analysis.[23] FSIS has begun evaluating results generated from its raw ground beef and beef manufacturing trimming verification sampling programs to estimate the *Salmonella* prevalence in those products and to possibly develop a new *Salmonella* performance standard for ground beef product.

FSIS is taking these actions to gain additional information concerning *Salmonella* and *Campylobacter* in imported products, to gain additional information concerning *Salmonella* and *Campylobacter* in product under FSIS jurisdiction currently not subject to testing for these pathogens, to more routinely test all domestic products currently subject to testing, and to better estimate prevalence. All these changes will help the Agency improve its verification activities in the establishments it regulates and better address these pathogens in products under FSIS jurisdiction.

Estimated Completion Date:
FSIS has completed the first three sub-parts of the recommended actions, and they are noted and summarized in the *Salmonella Action Plan*[24] and in the *Federal Register.* FSIS will make public the FY 2015 prevalence estimate for comminuted poultry products by December 31, 2015. FSIS will make public preliminary prevalence estimates for turkey and broiler carcasses and chicken parts, based on data collected through September 30, 2015, by December 31, 2015. Finally, FSIS will develop a schedule ,with milestones, for periodically updating *Salmonella* prevalence estimates by December 2015.

Recommendation 7:
Develop a plan with appropriate timeframes and milestones to issue appropriate guidance to establishments on how to improve their turkey prerequisite programs in order to correct the specific concerns addressed in this finding.

FSIS Response:
FSIS is drafting the 4th edition of the *Compliance Guideline for Controlling Salmonella and Campylobacter in Raw Poultry*. The Agency intends to address the following issues in the updated guideline:

[21] An overview of the Market Hog Survey is available at http://www.fsis.usda.gov/wps/wcm/connect/d5c7c1d6-09b5-4dcc-93ae-f3e67ff045bb/Baseline_Data_Market_Hogs_2010-2011.pdf?MOD=AJPERES.
[22] FSIS Notice 23-15; available at http://www.fsis.usda.gov/wps/wcm/connect/41f2bd6b-2c06-4384-935d-2ac31e3e77e9/23-15.pdf?MOD=AJPERES.
[23] FSIS Notice 28-14; available at http://www.fsis.usda.gov/wps/wcm/connect/9756afb6-f7c1-4e5c-9aa8-28cf6137639b/28-14.pdf?MOD=AJPERES.
[24] http://www.fsis.usda.gov/salmonella

1) Recommended best practices, 2) information on the components of a prerequisite program, 3) recommendations for maintaining sanitary conditions during operations, 4) information explaining that sampling procedures should be described in a written program, 5) information explaining that interventions used (and their operational parameters) need to be safe and suitable, 6) information on how establishments should document their use of antimicrobial interventions, and 7) information on actions that establishments should take if they find steps in their prerequisite programs have not been properly implemented or followed.

Estimated Completion Date:
FSIS intends to issue the draft revised compliance guideline by October 2015.

Recommendation 8:
Review the Hazard Analysis Verification (HAV) Directive, as related to the issues from this finding. Determine if the concerns raised in our report should be incorporated into FSIS procedures for field personnel when they perform a HAV task. If warranted, develop a plan with appropriate timeframes and milestones to provide additional guidance to the FSIS Inspection Program Personnel or revise and reissue the FSIS HAV Directive.

FSIS Response:
OPPD will review the effectiveness of FSIS Directive 5000.6, *Performance of the Hazard Analysis Verification (HAV) Task*, as it relates to all species and processes under FSIS jurisdiction, including ground turkey. As part of this review, FSIS will evaluate how inspection program personnel are assessing establishments' prerequisite programs during the HAV task. Based on this evaluation, FSIS will determine whether FSIS needs to issue new instructions for field personnel when they perform a HAV task in some or all types of establishments. FSIS will also assess inspectors' findings during the HAV task to assess whether additional guidance to industry (in addition to that discussed in response to recommendation # 7) would be beneficial.

Estimated Completion Date:
FSIS will complete its assessment and determine whether it is necessary to revise the directive by May 2016.

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