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Office of Inspector General

Application of FSIS Sampling Protocol for Testing Beef Trim for *E. coli* O157:H7

Audit Report 24601-0001-31

May 2012

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

DATE: May 9, 2012

REPLY TO
ATTN OF: 24601-0001-31

TO: Alfred V. Almanza
Administrator
Food Safety and Inspection Service

ATTN: William C. Smith
Assistant Administrator
Office of Program Evaluation, Enforcement and Review

FROM: Gil H. Harden
Assistant Inspector General for Audit

SUBJECT: Application of FSIS Sampling Protocol for Testing Beef Trim for *E. coli* O157:H7

Attached is a copy of the final report on the subject audit. Your written response to the official draft report, dated April 13, 2012, is attached, with excerpts from your response and the Office of Inspector General's position incorporated in the relevant Findings and Recommendations sections of the report.

Based on the agency's response to our official draft report, we accept management decisions for all recommendations in the report. You should follow your internal agency procedures for providing final action correspondence for these recommendations. In accordance with Departmental Regulation 1720-1, final action on the management decisions should be completed within 1 year of the date of the management decisions to preclude being listed in the Department's annual Performance and Accountability Report.

We appreciate the courtesies and cooperation extended to us by members of your staff during our audit fieldwork and subsequent discussions.

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Executive Summary

On November 12, 2009, the Chairwoman of the House Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies wrote to the United States Department of Agriculture's (USDA) Office of Inspector General (OIG) to express concerns about the efficacy of the testing the Food Safety Inspection Service (FSIS) performs to detect *Escherichia coli* O157:H7 (*E. coli*) in U.S. beef "trim."[1] In order to respond to this Congressional request, OIG divided its work into two phases. In Phase 1, which we completed in February 2011, we reported that FSIS' current method of sampling beef for *E. coli* —known as N-60[2]—does not yield the precision reasonable for food safety purposes, and recommended that FSIS thoroughly reevaluate its sampling program for testing beef in order to effectively verify process controls at beef processing plants.[3] In this report, we are presenting the results of Phase 2 of our review, which is based on fieldwork at beef slaughter and processing plants. OIG initiated this portion of our audit to analyze whether the beef industry's sampling and testing protocols vary among plants and differ from FSIS standards, and also to examine whether test results are used by FSIS and the beef industry to improve food safety.[4]

Based on our visits to six beef slaughter plants—directly responsible for processing about 17 percent of the U.S. beef supply[5]—we found that industry was performing thousands of *E. coli* tests daily generally following FSIS' recommended procedures. Overall, industry was taking appropriate steps to help ensure that U.S. beef is safe from *E. coli* contamination, recognizing that regardless of how stringently the industry tests for *E. coli*, there is always an inherent risk of its presence in slaughter plants. We found these large plants showed strong initiative in their efforts to control contamination and limit the ability of adulterated meat to make its way in to commerce. Plants took preemptive action, often acting on presumptive positive test results and in some instances, destroying whole days' worth of production in the name of safety. When positive test results were found, plants were conducting investigations to determine the cause and applied corrective actions to prevent future occurrence of *E. coli* contamination. We also found that these plants generally utilized nationally accredited laboratories for their sample analysis. We did, however, note several areas where FSIS and industry could further ensure food safety.

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[1] Trim consists of the pieces of meat that are cut away to make sought after cuts more desirable. Trim is normally processed into ground beef. (See photographs of beef trim at Exhibit A.)

[2] As part of N-60, FSIS inspectors take 60 small, thin sample pieces of exterior carcass material from a very large unit of trim, known as a "lot," and ship those samples to designated FSIS laboratories to be tested for the presence of *E. coli.*

[3] FSIS Sampling Protocol for Testing Beef Trim for *E. coli* O157:H7, dated February 2011.

[4] See Exhibit B for the seven questions posed by the Chairwoman and our supplemental information to fully answer each question.

[5] Since four of the plants we visited were owned and operated by major corporations and those plants may be considered representative of how those corporations operate (meaning plants within the same corporation used similar food safety safeguards and sampling techniques), the plants we visited represent, indirectly, about 70 percent of the U.S. beef supply.

Since consumers ultimately rely on industry's testing and interventions to keep our beef *E. coli* free, it is critically important that, when plants receive multiple positive test results (otherwise known as "high event" periods), the plants respond appropriately to these spikes in *E. coli* contamination. We found, however, that FSIS has not issued detailed and sufficient guidance for defining industry's plans for high event days and setting forth the agency's expectations for how industry should react. Predictably, different plants have very different high event day plans with different critical elements. By providing better guidance to plants about how they should develop their plans, and what critical elements should be included, FSIS can also make the process more transparent to industry. In this way, FSIS and industry may also avoid a situation like the one that took place in September 2011, when a plant shipped about 80,000 pounds of beef after it received multiple positive *E. coli* tests during its production. After an FSIS investigation, the plant recalled this beef. OIG maintains that, if FSIS is more explicit about how it expects plants to respond to such high event days, the agency, industry, and the public will benefit.

We also found that FSIS needs to consider shifting more of its testing resources to sampling trim, instead of ground beef, for *E. coli*. At present, each year FSIS collects and tests many more samples of raw ground beef than trim (about 12,300 compared to 1,270 in 2011) even though data strongly indicate that positives are more likely to be found in trim than raw ground beef. This has occurred because FSIS initially focused its efforts on finished ground beef, and it was not until 2007 that FSIS began testing trim. More recently, however, USDA has begun to emphasize the testing of trim, particularly in testing for other types of pathogens, such as the recent initiative to begin testing for six additional strains of *E. coli* other than O157:H7. OIG believes that FSIS should follow suit and begin testing more trim so that it can maximize its results, better promote public health, and trace contamination problems to their source.

FSIS also needs to improve the consistency with which its inspectors collect N-60 samples since we found that, although inspectors are required to take samples that weigh about 325 grams, they often took samples that were much too large. Dealing with these overweight samples taxes the laboratory's resources and dilutes the ratio of surface to interior tissue—the exterior is where *E. coli* contamination is most likely to be found. Inconsistencies of this sort occur because FSIS has not adequately evaluated how inspectors perform their work to identify and address these types of problems. If FSIS does not sample consistently, then N-60 may not be serving its intended purpose of verifying that plants' *E. coli*-preventing interventions are working as intended and that FSIS is effectively monitoring the plants' operations.

We also noted that in some cases FSIS' sampling policies and procedures allowed plants to sidestep regulations to avoid receiving noncompliance records. FSIS needs to eliminate these policy ambiguities because noncompliance records trigger more serious enforcement actions and require corrective measures that would improve how the plants control *E. coli*.

Finally, we found that FSIS needs to take steps to ensure that small plants, particularly those regulated by State meat inspection agencies as part of a cooperative agreement with USDA, are

being correctly overseen. Although Talmadge-Aiken (T/A) plants (known by the common name of the law[6] that created this arrangement), are responsible for less than 1 percent of the U.S. beef supply, our visit to one of these plants in Utah indicated that the State agency was not issuing the plant noncompliances for serious deficiencies in the plant's sanitary dressing procedures. These problems occurred because FSIS was not effectively communicating its standards and guidance and was conducting only sporadic oversight of the State agencies. FSIS officials stated that they were unaware of these problems and the agency intends to perform their own internal review to determine if T/A plants warrant increased oversight.

OIG concluded that, overall, industry was taking adequate steps to ensure that beef leaving slaughter plants is free of *E. coli* contamination, but that FSIS could take additional steps to strengthen certain elements of the *E. coli* sampling and testing system.

Recommendation Summary

Issue revised guidance to industry regarding the agency's expectations for trim sampling and how industry should plan for and react to high event day periods, including the critical elements to be included in a high event period plan and the necessary support for the high event period criteria.

Review the available scientific data and hold discussions with appropriate stakeholders to determine if FSIS sampling resources could be better utilized and if the identification of *E. coli* contamination could be improved by sampling more beef trim and less ground beef.

Reevaluate the policies for how inspectors collect trim samples, including collecting samples of proper weight. Also reevaluate noncompliance policy ambiguities and revise agency procedures to ensure that industry is not avoiding regulatory action.

Develop a detailed plan with milestones and timeframes to determine whether the quality of inspection in T/A plants is such that there is a higher potential for *E. coli* contamination in the products these plants produce. If so, require additional FSIS oversight and improve communication at T/A plants and State inspection agencies.

Agency Response

In its April 13, 2012, written response to the official draft report, FSIS expressed agreement with all our findings and recommendations. We have incorporated the FSIS response in the Findings and Recommendations section of this report, along with our comments in the applicable OIG Position sections. FSIS' response to the official draft is included in its entirety at the end of this report.

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[6] 7 U.S.C. 450 The Federal State Cooperative Act (Talmadge-Aiken) authorizes the Secretary of Agriculture to enter into cooperative arrangements with State departments of agriculture and other State agencies to assist the Secretary in the administration and enforcement of relevant Federal laws and regulations to the extent and in the manner appropriate to the public interest.

OIG Position

We concur with FSIS' proposed corrective actions and have accepted management decision for all seven recommendations. We have provided our comments on each recommendation in the applicable OIG Position sections.

Background and Objectives

Background

FSIS is the public health regulatory agency of USDA. As such, the agency protects consumers by ensuring that beef is safe, wholesome, and accurately labeled. Under the Federal Meat Inspection Act (FMIA),[7] FSIS inspects all beef sold in interstate commerce to ensure that it meets U.S. food safety standards.

According to the Centers for Disease Control and Prevention, *E. coli* are a large and diverse group of bacteria. Most strains of *E. coli* are harmless, but other strains of *E. coli,* such as *E. coli* O157:H7, cause illness by making Shiga toxin. The symptoms of Shiga toxin poisoning can include severe stomach cramps, diarrhea, and vomiting. Most people who consume beef contaminated with *E. coli* will recover within 5 to 7 days; some infections are very mild, but others can be lethal. The Centers for Disease Control and Prevention estimate that *E. coli* O157:H7 causes about 60,000 cases of Shiga poisoning annually in the United States: in 2010, 20 of these cases proved fatal. USDA's Economic Research Service[8] estimates that the total costs, such as doctor bills and hospitalization costs, associated with consuming *E. coli*-contaminated meat are about $488 million annually.

In 1994, a federal court held that the Department could reasonably consider *E. coli* O157:H7 an adulterant, and consequently that it could, as part of its statutory authority, regulate ground beef that might be contaminated.[9] FSIS relies on the authority provided by the FMIA to test ground beef and trim. Although it has not codified that authority in Federal regulations, it has issued multiple agency directives. In March 2010, FSIS issued its most recent version of Directive 10,010.1, entitled "Microbiological Testing Program and Other Verification Activities for *Escherichia coli* O157:H7 in Raw Ground Beef Products and Raw Ground Beef and Beef Patty Components." This directive includes instructions to FSIS inspection personnel and other program investigators on sampling and other verification activities for *E. coli* O157:H7 in raw beef products. In August 2008, FSIS drafted a "Compliance Guideline for Sampling Beef Trimmings for *Escherichia coli* O157:H7." The draft was published for comment so industry should be aware of FSIS' expectations, but it has yet to be finalized.

FSIS inspection staff are responsible for monitoring all operations of beef slaughter establishments. As part of their monitoring activities, FSIS inspection personnel are to review all of the plant's testing results and any monitoring activities that may impact the establishment's

[7] 21 U.S.C. 601

[8] The Economic Research Service is a primary source for economic information and research and strives to inform public and private decision making on economic and policy issues involving several agriculture-related areas including food safety, consumption, and assistance.

[9] Texas Food Industry, et al., v. Mike Espy, et al., Civ. No. A-94-CA-748 JN, U.S. District Court, Western District, Texas, Austin Division, December 13, 1994.

hazard analysis.[10] This includes all *E. coli* O157:H7 testing the plant performs. When reviewing establishment test results, inspectors should take note of multiple positive *E. coli* test results indicating a systemic breakdown of process controls (known as "high event days"). The determination of a high event day is important because decisions made regarding the disposition of product and necessary corrective and preventative actions should be addressed as part of the plant's high event plan.[11]

Ground beef is often made of less tender and less popular cuts of beef. After slaughter, the cattle carcass is cut into various primal cuts of meat (e.g., chuck, loin, ribs, rounds, etc.). Once the primal cuts are removed, the pieces of meat and fat that remain, known as "beef trim," are either ground or sold to processing plants for grinding into hamburger products.[12] The large quantity of ground beef produced in the U.S.—using nearly 4 billion pounds of trim annually[13]—is sold to a wide variety of customers, including grocery stores, restaurants, fast food establishments, and the National School Lunch Program.

Since 1994, FSIS has tested ground beef for *E. coli* O157:H7; beginning in 2007, the agency expanded its testing program to include testing beef trim. *E. coli* can contaminate beef trim when fecal material from slaughtered cattle comes into contact with, and remains on, the carcass. To prevent beef trim from becoming contaminated, plants apply interventions—safety controls such as lactic acid sprays, carcass washes, or steam cabinets, which are intended to decontaminate carcasses before they are cut into pieces or the meat is shipped from the plant. Although *E. coli* grows very slowly when it is refrigerated, cold, and even freezing temperatures, do not destroy it. The actual dose necessary to infect a person is unknown, but most scientists believe that a small amount of *E. coli* can cause serious illness and even death, especially in younger children. The only certain and practical way of destroying all *E. coli* in a serving of ground beef is to cook the product thoroughly to 160 degrees Fahrenheit or hotter, internally.

FSIS explained that its sampling and testing program for *E. coli* O157:H7 is not so much a way of guaranteeing that a given shipment of ground beef or trim is free from contamination, but rather a way of detecting breakdowns in plants' processing controls or applied interventions that would lead to unusually high levels of *E. coli* contamination. The program is also a way of communicating to plants that they are being monitored. While FSIS inspectors may sample ground beef or trim from large plants each month, they may test for *E. coli* O157:H7 in some small to medium-sized plants as seldom as one sample per quarter. It is important to recognize

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[10] Establishments are to perform a hazard analysis to understand the food safety hazards that are reasonably likely to occur in the process of producing each of their products and develop a system to address these hazards. Within their hazard control systems, USDA requires that meat plants take responsibility for reducing contamination from disease causing bacteria.

[11] FSIS "Compliance Guideline for Sampling Beef Trimmings for *Escherichia coli* O157:H7," in draft since August 12, 2008.

[12] FSIS defines beef trim in Directive 10,010.1 Rev 3 p. 9.

[13] February 2008 FSIS report titled "Risk-based Sampling for *Escherichia coli* O157:H7 in Ground Beef and Beef Trim," p. 7. The figure was an estimate of pounds of beef trim based on the estimated pounds of trim for each class of beef. The slaughter data were taken from FSIS' 2005 Electronic Animal Disposition Reporting System (eARDS) data. The eARDS system provides information concerning animal disease and welfare in the U.S.

that although repeatedly testing a given lot improves the probability of finding *E. coli*, it cannot guarantee that the sampled lot of beef is completely free from contamination.

When FSIS began developing a system to test for *E. coli* O157:H7 on beef trim, it concluded that a sampling system called N-60 was the best available. N-60 sampling is based on a sampling methodology presented by the International Commission on Microbiological Specifications for Food, which explains that the number 60 is a sufficiently rigorous sampling methodology for those food-borne hazards that are severe (cause severe illness or death) and where the pathogen's environment may increase the hazard.[14]

The N-60 sampling method requires an inspector to collect 60 pieces of beef trim from a production lot of beef cuts or trimmings that will be used for the making of ground beef. The pieces the inspector collects are small thin slices preferably from the trim cuts that were closest to the surface of the carcass since *E. coli* would not normally be located inside the animal's muscles. FSIS designates the size of each of the 60 pieces sliced from a trim cut should be 3 inches x 1 inch x 1/8 inch, approximately the size of a rubber eraser and weighing about 325 grams in total. N-60 sampling is resource intensive, often taking inspection program personnel over an hour to collect a sample. The 60 pieces are shipped as one sample to a designated FSIS laboratory where it is composited for testing to determine the presence of *E. coli* O157:H7.

Establishments sometimes do not hold product while waiting for test results, as evidenced by recalls based on *E. coli* positive tests. However, from OIG plant observations, the sampled beef is generally held from commerce until the results are returned. If *E. coli* is detected, then the sampled beef is destroyed or used in cooked product where the contaminant will be destroyed. In 2010, FSIS took steps to refine and improve its N-60 sampling program by (1) issuing more detailed guidance concerning trim sampling, follow-up sampling, and tracing product back to the source of the contamination; (2) producing an instructional video; and (3) improving its laboratory procedures.

During calendar year 2011, FSIS analyzed 1,267 N-60 trim samples compared to 12,296 ground beef samples. Onsite FSIS inspectors collect the 60 sample pieces for the tests from industry-defined "lots." A lot is a quantity of product produced from similar manufacturing conditions, product types, or time periods. A "lot" of beef trimmings is typically 10,000 pounds or less depending on the number of units in the lot.[15] Beef trimmings are often collected and transported in large bins that hold approximately 2,000 pounds of trim. The bins, or "combos," can be sampled as individual units, grouped in a five combo lot, or grouped in other lot sizes that fit a company's manufacturing process.

FSIS adopted the N-60 method not only to improve the effectiveness of its sampling, but also to encourage the regulated industry to implement the method. According to FSIS officials, the agency has recommended, in multiple documents, that establishments conduct testing of their

[14] In the proper conditions, *E. coli* O157:H7 can grow and become more numerous.
[15] FSIS allows plants that produce trim the flexibility to determine lot size. We obtained this information from industry sources.

own for *E. coli* O157:H7, since plants have considerable economic incentive to develop effective sampling and testing systems. If *E. coli* O157:H7 is found in beef trim that has left the plant, the plant is likely to bear the expense of recalling the product from commerce. In 2008, FSIS held a public meeting to discuss methods for industry sampling of beef trimmings and its related draft compliance guide. The compliance guide discusses the use of N-60 as part of industry statistical process control programs. FSIS officials stated that encouraging industry to sample product for pathogens is a goal of all FSIS sampling programs.

Large plants that sample product may collect frequent samples of N-60 for testing within a day's production in order to detect sharp spikes in *E. coli* contamination, indicating to a plant manager that an intervention or process control is not working effectively and that immediate corrective action is needed. Establishments that have an *E. coli* sampling program select a private laboratory to perform their microbiological testing; however, FSIS does not require that plants perform these tests, nor does it currently provide standards that plants must meet if they choose to test their own product. Hazard Analysis and Critical Control Point (HACCP) regulations[16] do, however, require that establishments verify, through testing or other means, that their food safety systems work. FSIS may also look at an establishment's sampling and testing methods during its food safety assessments.[17] Plants are not required to inform FSIS inspectors of positive test results, but they are required to make the test results available for the inspector's review. FSIS inspectors are required to examine the test results at least weekly to determine whether plants took appropriate corrective actions.

FSIS sees its N-60 sampling of beef trimmings as only one of a number of verification activities FSIS conducts regarding establishment process controls for *E. coli* O157:H7. Sample collection and analysis is one of the eight HACCP verification activities listed under the regulations in 9 Code of Federal Regulations (CFR) 417.8. HACCP requires that all significant hazards with the products and production environment be identified and controlled. Therefore, FSIS sampling of beef trimmings works along with these and other inspector verification activities, including FSIS sampling of ground beef and other ground beef components, as well as industry process controls and sampling, to reduce and detect *E. coli* O157:H7 in non-intact beef products (primarily ground beef). According to FSIS officials, their N-60 sampling of beef trimmings needs to be viewed as a component of the totality of verification activities within an establishment over time.

Under the Federal State Cooperative Act, the Secretary of Agriculture has the authority to enter into cooperative agreements with State departments of agriculture so that State meat inspection

[16] Meat plants are responsible for complying with 9 CFR Part 417 of FSIS HACCP regulations. 9 CFR 417.2(b) requires that every official establishment develop and implement a HACCP plan covering each product produced by that establishment when the establishment's hazard analysis reveals that one or more food safety hazards are reasonably likely to occur in the process of producing the product. In its final rule on pathogen reduction in HACCP systems, USDA required that meat plants take responsibility for reducing the hazards from disease causing bacteria.
[17] Under FSIS Directive 5100.1, Food Safety Assessments are performed by specially trained agency personnel who perform an in-depth analysis of a plant's operations including a review of the plant's compliance history, HACCP plan(s), and general sanitation.

employees can monitor slaughter plant employees instead of FSIS inspectors.[18] Though plants entered into these cooperative agreements are supervised by State employees, USDA's FSIS ultimately holds final authority. Such plants are known as Talmadge-Aiken (T/A) beef slaughter plants, and there are over 60 beef slaughter T/A plants in 9 States. Meat processed in T/A plants is given the USDA mark of inspection.

In Phase 1 of our audit, we found that FSIS' N-60 tests do not yield the precision reasonable for food safety purposes. As part of designing its N-60 sampling program, FSIS has not determined the prevalence of *E. coli* O157:H7, even though an adequate sampling method should begin with this information. Moreover, given the likely low occurrence of *E. coli* O157:H7 in U.S. beef trim, FSIS needs to collect more than the 60 pieces of beef it currently gathers from a production lot before it can reasonably state if a production lot is contaminated or not. At present, if the contamination level is very low, FSIS is more likely to miss contamination than to detect it. OIG concluded that, whenever FSIS tests beef, its tests should be designed so that the American public can have confidence in the results of those tests. OIG therefore recommended that FSIS thoroughly reevaluate its sampling program for testing beef in order to effectively verify process controls at beef processing plants across the nation. FSIS generally agreed with our findings and proposed corrective actions in response to our recommendations.[19]

See Exhibit A to view photos showing examples of USDA personnel collecting and shipping beef trim samples.

Objectives

During Phase 2 of our audit, OIG (1) observed the collection of beef trim samples by FSIS and employees at slaughter and processing establishments; (2) analyzed whether the beef industry's sampling and testing protocols vary among plants and differ from FSIS standards; (3) reviewed the quality of private laboratory services provided to the beef industry for testing and discarding samples; and (4) examined whether test results are used by FSIS and the beef industry to improve food safety.

[18] 7 USC 450, "Cooperation with State agencies in administration and enforcement of laws relating to marketing of agricultural products and control or eradication of plant and animal diseases and pests; coordination of administration of Federal and State laws".
[19] FSIS Sampling Protocol for Testing Beef Trim for *E. coli* O157:H7 (Audit No. 24601-0009-KC), issued February 2011.

Section 1: Industry's *E. coli* Testing

Finding 1: FSIS Needs to Provide Clear Guidance for How Industry Should Respond to High Event Periods

Our work in our Phase 1 audit showed that FSIS' N-60 testing, taken on its own, is insufficient to serve as the primary way of detecting *E. coli* O157:H7 in beef. Instead, FSIS verifies the implementation of industry's testing for day-to-day surveillance of beef trim, as industry is able to test beef trim thousands of times a day while FSIS, on average, tests only about five N-60 samples a day nationwide. Despite the fact that food safety is reliant on industry testing, the agency has not issued detailed and sufficient guidance for defining industry's plans for days when plants receive multiple positive test results (otherwise known as "high event" periods) and setting forth its expectations for how industry should react, including communicating with FSIS and determining what additional product should be implicated as positive when the plant has multiple positive test results.[20] We found that all six plants we visited had high event plans in place, but none of their plans resembled each other; they each contained different elements, and responded differently to high event periods. For example, plants, at present, have very different policies for determining how much beef is cooked or discarded based on multiple positive test results. FSIS said it has not yet issued this sort of detailed and sufficient guidance because it is a long and cumbersome process, and while the agency is developing guidance, it relies primarily on the plants to determine when they have a spike in adulteration that requires a response. Without the plant providing a detailed and sufficient plan for identifying and responding to a high-event period, FSIS inspectors cannot adequately ensure the plant is responding appropriately to breakdowns in its sanitary dressing procedures.

FSIS strongly encourages that plants test beef for *E. coli* O157:H7 using N-60. Though it does not require that plants test in any particular way, the agency does provide the plants with guidance. The plants follow this guidance and test trim for *E. coli* O157:H7, as they have a vested economic interest in assuring that the meat they sell is wholesome and not subject to recall. When a positive test result occurs, FSIS is responsible for verifying that the plant implements the corrective action needed to resolve any problems at the plant and to monitor the final disposition of any contaminated meat.

We found, however, that FSIS has not provided detailed guidance to plants concerning how they should respond to "high event periods"—i.e., clusters of positive test results that could signal a breakdown in the sanitary dressing procedures at the plant. Based on our visit to six plants that are responsible for processing about 17 percent of the U.S. beef supply,[21] we found a wide variation in how these plants responded to a high event period:

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[20] When a plant gets several positive test results, it has to determine what other untested or negatively tested meat should be regarded as contaminated because a negative test result does not provide 100 percent certainty that the sampled meat is *E. coli* free.

[21] The "big four" brands produce over 70 percent of the U.S. beef supply, and we visited a representative plant (meaning the plant we visited used similar food safety safeguards and sampling techniques as other plants within the same corporation) from each of the major corporate brands.

- Plants defined a "high event" differently and had a different threshold for when the plan would be activated. One plant's plan stated that the high event plan was triggered when there were three positive tests, but three other plants had no fixed number and relied on a complex mathematical model to determine when a high event was triggered.

- Of the six plants, three had a detailed written method to determine how much beef was affected by any particular positive test. When the others had a positive test result, they subjectively determined how much beef was considered contaminated.

- Of the six plants, one stated that it would proactively notify FSIS when it experienced a high event period. The other five made no mention, in writing, of their intent to notify FSIS.

- Two of the plans included "enhanced testing criteria," which involved additional testing during a high event period, such as testing at an N-90 level instead of an N-60 level and re-testing product that had already tested negative. The other four plans had no such enhanced testing methods.

- Four of the plants have very detailed plans for investigating to determine the cause of the *E. coli* contamination, but the other two, to varying degrees, had vague procedures for determining the cause of the breakdown.

- Two of the plants had very detailed plans for tracking the final disposition of the contaminated product, but the other four were less specific, or silent, about how to dispose of the product that had tested positive for *E. coli* O157:H7.

- Of the six plants, two did not address, in detail, the need to safeguard contaminated product until it is destroyed or cooked. The other four plants' plans stated that they placed product on hold when it tested positive for *E. coli* O157:H7.

OIG does not maintain that every plant's plan for responding to high event periods should be identical to other plants' plans; however, we contend that each plant's plan should address certain key elements, and that the plan should have detailed written procedures for how the plant will address these key elements when high events occur. Those written procedures should facilitate FSIS inspectors verifying that plants are responding appropriately to breakdowns in the sanitary dressing procedures at that plant.

Additionally, we found that plants were not always communicating with FSIS personnel so that FSIS was aware of how the plants planned to respond to high periods. At two of the plants, FSIS inspectors were unaware of what was addressed in the plant's high event plan. At the advice of the plant's legal counsel, managers at one plant, in fact, had not provided the plan to FSIS and refused to provide the plan to OIG, arguing that they were under no obligation to do so, as the plan is not required by regulation. OIG maintains that this approach is not helpful for ensuring that FSIS is able to monitor the plan and assure that the product passing through the plant is safe

for public consumption. FSIS agreed, and an FSIS national official stated that the plants have no right to withhold this information from its inspectors.

By providing better guidance to plants about how they should develop their plans, and what critical elements should be included, FSIS can also make the process more transparent from industry's perspective, as some plants, on their own, are not adequately responding to multiple *E. coli* O157:H7 positives. For example, on September 30, 2011, a plant recalled about 80,000 pounds of beef that it had shipped after multiple positive test results. These test results should have indicated a high event period. When FSIS became aware that the beef had shipped, the agency conducted an investigation questioning sanitary procedures at the plant and suggested the recall. OIG reviewed this plant's high event period plan and found that it was vague concerning how much beef would be considered contaminated by multiple positive test results. By being more transparent about its expectations for high event period planning, FSIS can help plants avoid this type of situation and also help protect consumers from contaminated beef products.

When we spoke to FSIS officials about these problems, they stated that they agreed that the agency could provide clearer guidance to industry about the critical elements of an effective high event period plan. They stated that they have been working on such guidance since before October 2008, and that finalizing such guidance was a long and cumbersome process.

While OIG understands that this process can be lengthy, for clarity, we maintain that FSIS needs to finalize this guidance, given the public health concerns raised by *E. coli* contamination.

Recommendation 1

Issue revised guidance to industry regarding the agency's expectations for trim sampling and how industry should plan for and react to high event periods. Include in the guidance specific information on the critical elements to be included in a high event period plan and the necessary support for the high event period criteria, such as how the plant may interact with FSIS staff, and how the plant may determine what non-tested or negatively tested product should be considered positive when the plant has multiple positive test results.

Agency Response

FSIS will issue revised guidance to beef slaughter and fabrication establishments that manufacture beef trimmings on procedures they can use to assess the effectiveness of their controls for preventing contamination during the slaughter operation. This document will include guidance that establishments can use to determine whether they are experiencing a "high event period" (HEP). HEPs are periods during which slaughter establishments experience a high rate of positive results for *E. coli* O157:H7 (or STEC or virulence markers) in trim samples. The guidance will recommend that establishments identify HEP criteria so that they can determine whether they need to withhold product from commerce when a HEP has occurred because the occurrence of a HEP may indicate more widespread adulteration of product, beyond the product found positive. The guidance will explain that if establishments identify and respond to HEPs, they will minimize the chance that they will release adulterated product into commerce. This

guidance will provide criteria establishments may use for determining whether they have experienced a HEP. Establishments may use the criteria that FSIS has provided to define a HEP, or they may develop their own criteria. As part of their supporting documentation for their hazard analysis, the guidance will recommend that establishments document their criteria for identifying a HEP. The guidance will recommend that establishments document their criteria for identifying a HEP as part of their supporting documentation for their hazard analysis.

Furthermore the document will recommend that establishments conduct sampling and testing of trim at a frequency sufficient to find evidence of contamination surviving the slaughter and dressing operation. The document explains that establishments' deviations from previously obtained percent positive rates should be construed as presumptive evidence that the process is out of control that would warrant an investigation to find and eliminate potential causes for positive results. Furthermore, to prevent the occurrence of HEPs, the document recommends more rigorous testing during the high prevalence season and effective slaughter and dressing procedures to minimize, to the maximum extent practical, cross contamination of carcasses with the contaminants from the hide and intestinal tract.

The document will also include actions that establishments should take during a high event period. Generally, if primals are not commingled by stacking or storing in common containers without individual separation before packaging, and the establishment minimizes cross contamination among primals, an individual primal can be considered a microbiologically independent lot. Normally, FSIS does not consider primal cuts designated for intact use to be adulterated if contaminated with *E. coli* O157:H7. The guidance will explain that during a HEP situation, unless the establishment has controls in place to ensure that the primals are not used for non-intact purposes, such primals may be considered adulterated because they were prepared under insanitary conditions. FSIS will be aware of establishment test results because FSIS reviews establishment results on at least a weekly basis.

Estimated Completion Date: FSIS will issue the revised guidance no later than July, 2012.

OIG Position

We accept management decision.

Section 2: FSIS and Its Testing Methodology for *E. coli*

Finding 2: FSIS Needs to Consider Shifting More Resources to Sampling Trim for *E. coli*

At present, each year FSIS collects and tests many more samples of raw ground beef than trim (about 12,300 compared to 1,270 in 2011), even though data strongly indicate that positives are more likely to be found in trim than raw ground beef. This occurred because, when FSIS began testing beef for *E. coli* O157:H7 in 1994, it focused its efforts on raw ground beef. Only in 2007 did FSIS begin testing trim, acknowledging that "FSIS considers it extremely critical to keep the percent positive rate[22] for beef trim low in order to affect the percentage of positive raw ground beef samples downward." Essentially, by emphasizing the testing of trim, FSIS can more effectively reduce the percent positive rate in ground beef, of which trim is a component. If FSIS does not begin devoting more of its limited testing resources to testing trim, it will not be using its collecting and testing capacity in ways that maximize its results, better promote public health, and trace contamination problems to their source.

FSIS has the responsibility for testing raw ground beef and trim for *E. coli* O157:H7, but its resources for collecting and testing samples are not unlimited.[23] Consequently, the agency needs to deploy those limited resources so that they are used as effectively as possible.

In 2011, we found that FSIS tested many more samples of raw ground beef than beef trim—12,296 compared to 1,267.[24] A recent study stated that trim testing has a higher probability of finding *E. coli* O157:H7 than ground beef testing. *E. coli* O157:H7 most likely contaminates the exterior surfaces of meat during hide removal or evisceration than interior muscle mass. In the production of ground beef, both potentially contaminated exterior and sterile interior tissues are combined, which dilutes any surface contamination as it becomes spread through the entire volume of the ground beef.[25]

Although FSIS is aware that sampling trim is more effective, the agency has historically sampled more raw ground beef for three reasons: (1) sampling trim is more difficult and time-consuming; (2) FSIS has established a performance measure based on testing ground beef, but not trim;[26] and (3) agency officials are responding to the public's expectation that it will test ground beef, as the final product, for *E. coli* O157:H7. Agency officials stated that they do not want to suddenly shift resources from one type of testing to another—they want to achieve an optimal balance

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[22] The "percent positive rate" is the number of microbiological *E. coli* O157:H7 trim positive test results detected by FSIS divided by the total number of trim tests analyzed by FSIS during a given period of time.
[23] Texas Food Industry, et al., v. Mike Espy, et al., Civ. No. A-94-CA-748 JN, U.S. District Court, West District, Texas, Austin Division, December 13, 1994.
[24] Based on FSIS' "Analysis of Raw Ground Beef and Raw Ground Beef Component Samples for *E. coli* O157:H7" as of December 31, 2011.
[25] "Polymerase Chain Reaction Screening for Salmonella and Enterohemorrhagic Escherichia coli on Beef Products in Processing Establishments," Institute for Environmental Health, Inc., Lake Forest Park, Washington, May 11, 2011.
[26] FSIS Strategic Plan 2011-2016, p. 26.

between sampling costs and protecting public health. They also stated that the Agency needs to continue to focus its testing on ground beef in order to reach its annual performance goals outlined in its Strategic Plan.

However, there is a growing awareness within USDA that achieving an optimal balance between keeping the costs of sampling low while promoting the public's safety requires testing more trim. Recently, the Secretary announced that USDA would begin testing for six additional strains of *E. coli.* Also, the Under Secretary for Food Safety stated that, as part of this testing, USDA would begin testing only beef trim because beef trim testing yields "the best bang for the buck."[27]

OIG maintains that FSIS is likely, also, to achieve more "bang for the buck" if it increases the trim testing it does for *E. coli* O157:H7. If the agency's performance goals are creating an obstacle for more effective testing, then the agency needs to consider revising those performance goals and measures to better reflect a more effective approach to testing. FSIS might consider a new performance measure for testing trim, or a revision that accounts for testing both trim and ground beef.

Recommendation 2

Review the available scientific data and hold discussions with appropriate stakeholders to determine if FSIS sampling resources could be better utilized and identification of *E. coli* O157:H7 contamination could be improved if the agency devoted more of its sampling efforts to sampling beef trim instead of ground beef. Shift resources, if needed, based on the scientific data and discussions. Develop a detailed plan with milestones and timeframes for implementing any proposed changes based on this review.

Agency Response

FSIS is making certain changes to its trim sampling program to make it risk based. In addition, during this calendar year and next, FSIS intends to identify additional ways to make its testing programs for *E. coli* O157:H7 more risk based, such as consideration of information available through PHIS, from inspection program personnel, and from risk analyses. FSIS intends to announce the changes in its trim sampling program in the Federal Register in the next 3-6 months and to ask for comment on the changes and other issues under consideration. Also, next calendar year, FSIS intends to conduct a study to test product from unopened containers or purge material (that is, remaining liquid, fat, and meat particles in containers or combo bins after trim contents have been removed) from suppliers' product for *E. coli* O157:H7. The purpose of this study will be to identify the source of *E. coli* O157:H7 positive raw ground beef when material from multiple suppliers was used to create the sampled ground beef that FSIS has found positive for *E. coli* O157:H7. Furthermore, FSIS intends to change how Agency verification samples are

[27] Quotation taken from USDA Press Release No. 0404.11 titled: United States of America Department of Agriculture Office of Communications Media Briefing By Secretary Vilsack USDA Takes New Steps to Fight *E. coli*, Protect the Food Supply.

scheduled such that FSIS can obtain on-going baseline prevalence information about select pathogens such as *E. coli* O157:H7. In some cases, more samples may be necessary than those currently analyzed in the verification testing program. FSIS recognizes that today the number of samples analyzed is far less than the number of samples scheduled. As the scheduled-to-analyzed rate improves through implementation of PHIS, the increase in the number of samples needed for the baseline prevalence determination may be more closely matched. Finally, while the focus of OIG was *E. coli* O157:H7, FSIS intends to begin co-analyzing all beef samples for *Salmonella* over the course of the next few years. Ground beef samples, particularly, will provide an indication of the level of process control for external contamination during slaughter, as well as the internal contamination that may result from *Salmonella* in lymph nodes. Thus, the issue of redirecting samples from the ground program to the trim program is complicated and requires further analysis before making such a change.

Estimated Completion Date: FSIS will report on the progress of these reviews and discussions and any resulting changes no later than April, 2013.

OIG Position

We accept management decision.

Recommendation 3

Work with appropriate officials inside and outside of FSIS to evaluate if the agency needs to revise its performance measure for testing for *E. coli* to account for the advantage in testing beef trimmings compared to ground beef. If agency officials determine that a revised performance measure is needed, develop a detailed plan with milestones and timeframes for implementing the new performance measure.

Agency Response

FSIS will evaluate the appropriateness of its Agency performance standards in the context of any changes to sampling algorithms or sample allocations. If necessary changes are identified, FSIS will develop proposed changes to the performance standards and elicit external input as appropriate. FSIS will complete its review of public health and FSIS resource impacts to performance standards before implementing any changes to sampling. FSIS intends to conduct this review and identify any needed changes next calendar year.

Estimated Completion Date: FSIS will report on this evaluation and any resulting changes no later than April, 2013.

OIG Position

We accept management decision.

Finding 3: FSIS Needs to Improve the Consistency in How Its Inspectors Collect N-60 Samples

Based on our observation of FSIS inspectors and FSIS sampling data, we found that they sampled trim inconsistently. For example, although inspectors are required to take samples that weigh about 325 grams, they often took samples that were much larger. We found that about 95 percent of their samples exceeded 325 grams and about 50 percent exceeded 715 grams, which is the maximum weight the labs will test. Dealing with these overweight samples taxes the laboratory's resources and dilutes the ratio of surface to interior tissue—the exterior is where *E. coli* contamination is likely to be found. Inconsistencies of this sort occur because FSIS has not adequately evaluated how inspectors perform their work to identify and address these types of problems. If FSIS does not sample consistently, then N-60 may not be serving its intended purpose of verifying that plants' *E. coli*-preventing interventions are working as intended and that FSIS is effectively monitoring the plants' operations.

FSIS' Directive 10,010.1, "Verification Activities for *Escherichia coli* O157:H7 in Raw Beef Products," generally sets out how inspectors should sample for *E. coli* in trim.

We found, however, a number of inconsistencies with how inspectors sampled trim:

(1) Thickness and Weight of Sampled Trim

Inspectors are instructed to sample pieces of trim that measure 1" x 3" x 1/8". This process will provide a total sample weight of 325 grams +/- 10 percent.[28]

Based on our review of FSIS data, we found that inspectors were not able to meet this standard: about 95 percent of their samples exceeded 357.5 grams, the maximum single sample weight,[29] and about 50 percent exceeded 715 grams, which is the maximum total weight the labs will test. Excess sample weight must be trimmed and disposed of, adding inefficiency to lab testing procedures and no value to FSIS' trim testing results. We noted at the plants that achieving the required sample size is often more difficult than it might seem. Inspectors often only sample about once a quarter, so they are not necessarily proficient. Also, we observed that it is difficult to cut material in combo bins and, in some cases, the meat in the combo bins is practically frozen. Given these conditions, inspectors were not easily able to cut a recommended sample size.

This problem impacts the labs because they have to spend more time and resources manipulating these samples so they can be tested, which may also impair the validity of the N-60 sample itself. Dealing with such oversized samples also presents an opportunity cost in that the more time and resources the labs spend dealing with a large sample, the less time and resources they can spend on other tests or testing for other possibly lethal pathogens, such as *Salmonella*. Finally, an *E. coli* test is meant to focus on the exterior

[28] FSIS Directive 10,010.1 Rev 3 p. 93.
[29] Maximum single sample weight is 357.5 grams (325 grams plus 10 percent).

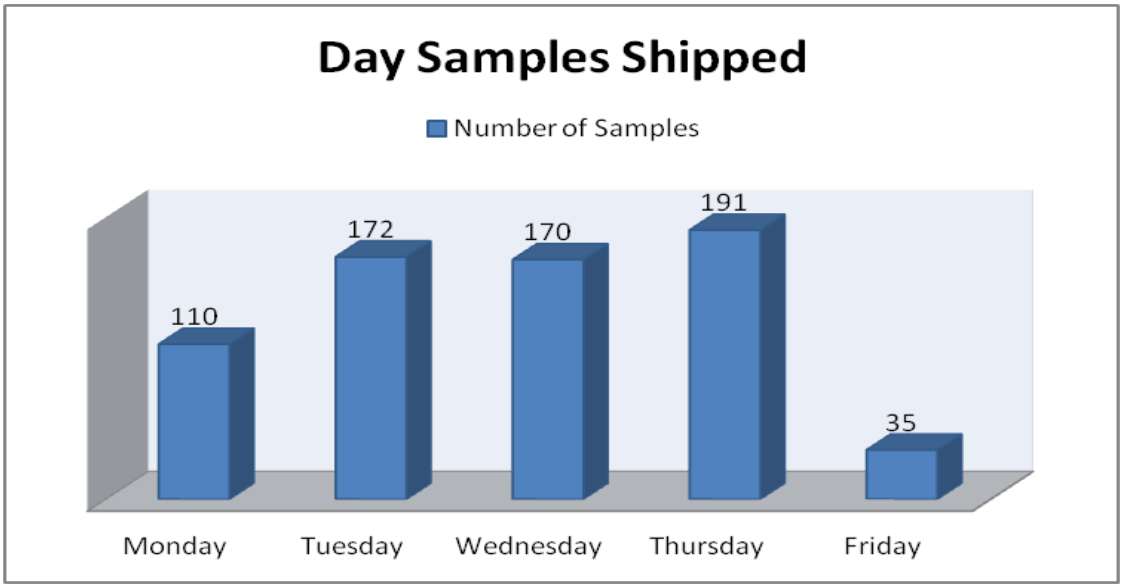
surface of trim, and especially large samples potentially interfere with that purpose by reducing the ratio of trim surface to interior sterile tissue.

When we spoke to FSIS officials about this problem, they acknowledged the issue and stated that they were trying to devise a technological solution that would aid inspectors in sampling the proper sized samples from trim. For example, they are considering issuing plastic containers or bags to inspectors so that inspectors could take samples of only a limited size.

(2) Selecting a random sample

Inspectors are required to randomly select a day, shift, and time within the sample window, as well as from randomly selected containers.[30]

We found, however, that inspectors we observed were often choosing not to sample on Fridays. FSIS data supported our observations. Out of the 678 samples we reviewed, the collection of samples on weekdays ranged from 110 to 191, but on Fridays only 35 samples were taken. The following graph shows that inspectors were much more likely to sample on any day other than Friday, taking just 35 samples on Friday compared to an average of 161 the rest of the week: [31]



Inspectors chose not to sample on Friday due to the risk that samples might be delayed in shipping and therefore rejected by the labs due to improper sample temperature.

[30] FSIS Directive 10,010.1. Rev 3 Chapter II Section I.A.6 p. 14 and Section IV.A.2 p. 22.
[31] FSIS provided data on several N-60 sampling projects. OIG specifically reviewed those project codes listed as "MT50." (MT50 is the code for *Routine Testing of Domestic Beef Manufacturing Trimmings.)* We received data on 678 MT50 samples reported as being received from April 04, 2010 to December 07, 2011.

Inspectors also refrain from testing on Friday out of courtesy to the plant because Friday sampling increases how long the sampled product must be held awaiting test results. Not only does this violate procedure and reduce the randomness of the sample, but it also permits plants to anticipate when an inspector is unlikely to test for contamination. One plant manager stated that he could predict when the inspection staff was going to select samples since he had observed their tendency over the years not to collect samples on Friday or at the end of a workday. OIG maintains that such predictability potentially interferes with the effectiveness of FSIS' monitoring efforts, which may allow plants to become less diligent in their own testing regimens.

We also noticed the following deviations from the random selection of samples at the plants we visited:

- At one plant, the plant quality assurance manager selected the combo bin the inspector would test;
- At another plant, FSIS inspectors had a choice of selecting a combo bin from two locations, yet they chose the majority of bins from the more accessible location.
- At a third plant, the FSIS inspector selected only the trim that was going to be ground inside the plant and excluded trim that was going to be ground externally.

When we brought these issues to the attention of inspectors' supervisors, they agreed that these practices did interfere with the randomness of the sample, and they took steps to correct the issues.

(3) Multiple samples from a single piece of trim

When FSIS inspectors sample a piece of trim, they are required to take 60 pieces of trim from 60 different pieces of beef product.[32]

During our visits to the plants, we observed that FSIS inspectors at three plants took multiple pieces of trim from a single beef product. For example, one inspector was taking up to four pieces from a single product—he would take two long pieces from a single piece of trim and would divide them each into two, yielding four pieces. When we spoke to this inspector and his supervisor, they stated that they were unaware they were violating any FSIS procedure. This practice is problematic because it violates FSIS procedures and interferes with inspectors' ability to verify the effectiveness of the plants' *E. coli*-preventing interventions.

When we spoke to FSIS national officials about this practice, they agreed that inspectors should not be taking multiple pieces from a single beef product.

[32] FSIS Directive 10,010.1 Rev 3 Attachment 8 p. 93.

FSIS provides training material and supervision to its inspectors on a regular basis. OIG reviewed those training materials and found that they generally provided adequate information for inspectors to learn N-60 sampling. However, inspectors have a great many responsibilities in the plants, and perfecting their N-60 sampling technique may not always be a priority. OIG maintains that in order for N-60 to be a rigorous testing methodology, FSIS needs to do more to ensure that inspectors are performing the tests consistently.

Additionally, while we were visiting the plants, we noted that plant managers sometimes exploit ambiguities in FSIS' sampling policies or procedures so that they can avoid receiving noncompliance records[33] if FSIS inspectors find a positive *E. coli* O157:H7 test result. For example, FSIS allows plants to avoid a noncompliance if they have a written policy in place to send bins to cooking that FSIS samples from and finds *E. coli*.[34] One plant quality assurance manager told OIG that the plant had implemented a policy to send every bin to cooking that FSIS samples, so that it could never receive a noncompliance due to FSIS' testing results. OIG maintains that FSIS should eliminate this policy ambiguity because noncompliance records trigger more serious enforcement actions and require corrective action that would improve how the plant controls *E. coli.* By allowing plants to routinely avoid them, FSIS is allowing plants to sidestep regulation. Furthermore, FSIS regulations state that the agency is not to test product destined for cooking,[35] yet this ambiguity in policy means that, at that plant, all product FSIS tests is being sent to cooking.

A second policy ambiguity involves FSIS allowing plants to avoid noncompliance if an FSIS test *and* a plant test both result in a positive on a single sample.[36] Plant officials at a plant we visited explained they normally would not test trim that would be ground in its own establishment—the plant waits to test the final ground product. However, when FSIS was present, we observed a different procedure. The FSIS inspector took a piece of trim and cut it in two—one piece was tested by the plant, the other by FSIS. The plant managers reasoned that, if both tests came back positive, the plant would have found the problem as well and would not be issued a noncompliance. OIG finds this practice objectionable because the plant is not following its usual testing methodology and is instead doing something unusual in response to the presence of FSIS inspectors in the plant. Furthermore, an FSIS inspector should not be taking samples that the plant will test itself and claim the results as its own.

Moreover, for *Salmonella*, FSIS has taken exception to plants altering their ordinary operations when FSIS is testing.[37] OIG finds it inconsistent that plants would be penalized for altering their operations when FSIS is testing for *Salmonella*, but not for *E. coli*.

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[33] A noncompliance record (NR) is written by FSIS whenever inspection program personnel determine that an establishment has failed to meet one or more regulatory requirements. Generally, if an FSIS trim sample tests positive for *E. coli* O157:H7 and the establishment did not also find the product positive for *E. coli* O157:H7, inspection personnel are to issue a noncompliance record to the plant.
[34] FSIS Directive 10,010.1 Rev 3 Chapter III Section III. C. p. 39.
[35] FSIS Directive 10,010.1 Rev 3 Chapter II Section I.A.9 p. 15.
[36] FSIS Directive 10,010.1 Rev 3 Chapter III Section III. B. p. 39.
[37] FSIS Notice 42-11.

OIG concludes that FSIS needs to take steps to address these policy ambiguities and ensure that its own inspectors are following its guidance for consistently taking samples for N-60. If the agency does not take these steps, then it runs the risk of introducing bias into the N-60 sampling methodology and compromising the validity of N-60.

Recommendation 4

Reevaluate the policies for how inspectors collect trim samples, including the random selection of product for sampling, collecting samples of proper weight, and not taking multiple samples from single pieces of trim. Develop a detailed plan with milestones and timeframes for implementing any corrective actions resulting from this agency reevaluation.

Agency Response

FSIS will issue instructions for collecting samples of the proper weight no later than August 2012. FSIS will evaluate the current instructions, identify any necessary changes, and reissue the directive during calendar year 2013.

Estimated Completion Date: FSIS will report on this reevaluation and any resulting changes no later than April, 2013.

OIG Position

We accept management decision.

Recommendation 5

Reevaluate noncompliance policy ambiguities in FSIS Directive 10,010.1 and revise agency procedures to ensure that industry is not avoiding regulatory action. Develop a detailed plan with milestones and timeframes for implementing any corrective actions resulting from this agency reevaluation.

Agency Response

FSIS will evaluate the current instructions, identify any necessary changes, and reissue the directive.

Estimated Completion Date: FSIS will reissue the directive no later than April, 2013.

OIG Position

We accept management decision.

Finding 4: FSIS Needs to Better Communicate with State Meat Inspection Agencies and Small Plants

Responsible for a relatively small portion of the U.S. beef supply, less than 1 percent, T/A plants are a type of plant that is not regulated directly by FSIS but by State regulatory agencies.[38] During our fieldwork, we visited one T/A plant in Utah, and found that the State agency was not issuing the plant noncompliances for serious deficiencies in the plant's sanitary dressing procedures. These deficiencies included not documenting temperature violations and not properly spacing carcasses in the coolers. These problems occurred because FSIS was not effectively communicating its standards and guidance and was conducting only sporadic oversight of the State agencies. FSIS officials stated that they were unaware of these problems and were very concerned that T/A plants may merit increased oversight. Unless FSIS takes action to strengthen its oversight, sanitary problems at these plants may continue to go unnoticed and thus uncorrected.

The Federal State Cooperative Act, known as Talmadge-Aiken, authorized the Secretary of Agriculture to enter into cooperative arrangements with State departments of agriculture and other State agencies to regulate and perform inspections of certain slaughter and meat processing plants. FSIS provides oversight of these State agencies.

Based on our visit to one T/A plant in Utah, however, we found that State inspectors were not identifying sanitary problems at the plant that warranted the issuance of noncompliances. For example, we observed that State inspectors did not note and issue a noncompliance for the following issues:

- The plant was not maintaining and recording the temperature in one combo bin at acceptable levels according to the plant's standard operating procedure. We observed that plant employees took the temperature and, if the temperature was too high, they would not record the deviation and would simply wait until later to take the temperature again. Once the temperature was within the acceptable range, they then recorded that result. The State inspection staff did not notice that this was the plant's process.

- The plant was jamming carcasses together into the hot box, which reduces how quickly carcasses cool and increases the possibility of pathogen growth, which violates the plant's standard operating procedure. The plant's quality assurance manager said that we observed the hot box at break time and that the plant employee who normally handles carcass spacing was on break and in his absence the carcasses piled up.

When OIG brought these issues to the attention of the State inspection staff, they began immediately issuing noncompliances. They explained that they had not noticed the relevant violations. We also observed plant violations that were serious, but that did not rise to the level of a noncompliance. State inspectors should have noticed and corrected the issues, but we found that they did not. For example:

[38] These T/A beef slaughter plants operate in nine States.

- The plant should collect trim samples weighing 375 to 420 grams, yet they sometimes took overweight samples weighing as much as 560 grams. The quality assurance manager said that when the samples are overweight he reduces the sample weight by trimming the sample or discarding pieces. OIG maintains that these actions add bias to the sample.

- The plant tries to process combo bins weighing 2,100 lbs, but when the combo bin weighed more, they sampled the bin, removed extra beef, and then put the excess in the following bin. This practice is problematic because it involves moving beef from bin to bin after sampling, which could invalidate the tests, and increases the chances of cross contamination. Plant officials noted that this was not plant policy and that employees would be instructed to correct their actions. The quality assurance manager stated that it is plant policy to weigh the combos first and obtain the correct weight before the plant collects its trim sample.

- The plant was not using the forms in its standard operation procedures when employees monitored chilling carcasses and combo temperatures. These procedures are important to prevent pathogen growth in processed beef.

Finally, we found that the State inspection staff made a number of errors when they collected samples:

- The inspector lost count and collected 75 pieces for the N-60 test, and the sampled pieces were overweight, weighing 885 grams instead of 325 grams required by the guidance.

- The inspector allowed the plant quality assurance manager to select the combo bin that inspectors would sample—it was not selected at random.

- The inspector collected multiple samples from a single piece of trim.

When we brought these problems to the Utah meat inspection agency, it immediately acknowledged the seriousness of the issues and developed supplemental sampling instructions that would help the inspection staff better perform their duties. FSIS officials at the national office also expressed concern that T/A plants were not being better monitored and the State agencies might need additional oversight on FSIS' part.

We also found that the operators of small plants often lacked the expertise they needed to select laboratories that were able to competently test samples for *E. coli* O157:H7. Generally, the six plants we reviewed contracted with accredited laboratories, but one was using a non-accredited laboratory to perform some of its testing. Industry representatives explained that many small plants wanted to utilize an accredited laboratory, but they do not know what type of laboratory accreditations they should be looking for when they select a laboratory services provider. Small operators sometimes relied on laboratories based on convenience, or other factors, instead of the

quality of the testing. For example, we were told that one operator selected a laboratory based on proximity, not based on its competence. Another plant decided to switch from one laboratory to another and, by doing so, increased its confirmation rate for positive *E. coli* O157:H7 testing results from 24 percent to 95 percent.

Not only do small operators need guidance on how to select quality laboratories, but they also need guidance on what documentation they should maintain for FSIS' inspectors. Small operators could benefit from being given a checklist regarding what documents FSIS looks for when it performs a food safety assessment so the plants can have documentation on hand to support their HACCP system.

When we raised these issues with FSIS national officials, they stated that they could do more to educate small plant operators about what qualities they should be looking for in a laboratory. FSIS officials informed us that they were developing guidance for selecting commercial and private microbiological laboratories for testing.[39] The guidance contains a checklist of documents FSIS looks for when it performs a food safety assessment. OIG believes that this guidance will be helpful, especially for small plants.

OIG concluded that FSIS needs to take steps to improve how it oversees State agencies and communicates with small plants. Those steps should include an assessment of the general state of sanitary procedures at T/A plants and a determination of whether additional FSIS oversight and communication are necessary. As a result of the concerns raised by OIG, FSIS officials indicated that they intended to perform their own internal review to determine if T/A plants warrant increased oversight.

Recommendation 6

Develop a detailed plan with milestones and timeframes to determine whether the quality of inspection in T/A plants is such that there is an increased possibility of *E. coli* contamination in the products that these plants produce. Based on this evaluation, determine if additional FSIS oversight and communication are needed at T/A plants and State inspection agencies. If so, determine what type of oversight and communication are needed and how they will be provided.

Agency Response

FSIS will develop a detailed plan with key milestones and schedules to determine whether the quality of inspection in T/A plants is such that it increases the possibility of *E. coli* contamination in the products that the plants produce. Based on the findings, FSIS will develop a corrective action plan to address any weaknesses in the management controls, monitoring, or communications.

[39] FSIS' draft "Compliance Guidelines Guidance for Establishments on Selecting a Commercial or Private Microbiological Laboratory," which is in Agency clearance for issuance in Spring 2012.

Estimated Completion Date: FSIS will complete the evaluation by August 2012 and the plan of action to address weaknesses no later than April 2013.

OIG Position

We accept management decision.

Recommendation 7

Improve communication by issuing guidance to industry to assist plants in selecting laboratories based on the capabilities of the testing laboratories. This guidance should provide a checklist for industry on the issues to consider and also the type of documents that plants should maintain to support their testing program.

Agency Response

On March 8, 2012, FSIS announced the availability of policy guidance for federally inspected establishments in the selection of commercial and private microbiological testing laboratories. FSIS has posted this policy guidance on its Web page *http://www.fsis.usda.gov/Regulations_&_Policies/Compliance_Guides_Index/index.asp#Micro*. FSIS encourages establishments that prepare meat, poultry, or processed egg products to follow the criteria in the guidelines in selecting commercial or private microbiological testing laboratories and in determining their capability to provide accurate and reliable results. The guidance includes a checklist for industry on the issues to consider and also the type of documents that plants should maintain to support their testing program.

OIG Position

We accept management decision.

Scope and Methodology

In November 2009, OIG received a Congressional request to evaluate the scientific merits and potential shortcomings of N-60 sampling design and the application of the test results from N-60 samples of beef trim products.

The request posed 12 questions in three broad areas that categorized "the statistical validity of the test; the sample collection and analysis; and the application of test results." OIG agreed to conduct a two phase audit of FSIS' N-60 sampling. In the first phase, we examined the adequacy and effectiveness of the sampling method and also follow up on matters reported in a previous OIG memorandum, dated January 29, 2008. In the OIG memorandum, we suggested that FSIS consider (1) pursuing the feasibility of gathering a more representative sample; (2) developing appropriate processes to minimize or eliminate discarded samples; and (3) determining if more efficient sample collection and testing procedures can be implemented to minimize the turnaround time on laboratory results.

We released our first phase audit report in February 2011. That report fully addressed five of the requested questions. In the second phase of our work, we are answering the remaining seven questions. See Exhibit B for a list of the seven question and our answers.

In order to meet our audit objectives, we visited plants and conducted interviews with industry stakeholders. Among those visited were:

- **FSIS District Offices**—We discussed *E. coli* issues with FSIS district offices to learn about their communication with the national office and their outreach with the plants.

- **FSIS National Office Representatives**—We discussed *E. coli* issues with FSIS officials from numerous offices, listed below. The team communicated with these officials on numerous occasions through email, teleconference, and face-to-face interviews.

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

    - Office of Outreach, Employee Education and Training: We conducted interviews with officials at this organization who oversee FSIS outreach and education services.

    - Office of Program Evaluation, Enforcement and Review: We conducted interviews with officials who assess FSIS' program functions and operations. We interviewed representatives from the Program Evaluation and Improvement Staff who provide leadership and technical expertise in the area of program evaluation.

    - Office of Public Health Science: We conducted interviews with senior-level officials who provide expert scientific analysis, advice, data, and recommendations on all matters involving public health and science that are of concern to FSIS. During the first phase of the audit, we spoke with officials at the Regulatory Field Services

Laboratory in Athens, Georgia, who support FSIS' farm-to-table food safety strategies at three field laboratories which conduct scientific tests in the disciplines of chemistry, microbiology, and pathology.

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

- **Private Laboratories**—We discussed *E. coli* issues with an expert on the trim sample collection who was a former directing scientist at an Agricultural Research Service facility where work is done on issues relevant to *E. coli*. We also interviewed various representatives of private laboratories.

- **Large Industry Representatives**—A meeting was held with industry representatives to discuss industry's position on N-60 sampling.

- **Large and Medium Size Plants**—We conducted fieldwork in four large-sized and two medium-sized plants to gain not only industry's perspective from the field, but also the perspective of FSIS field inspectors. We visited plants in Kansas, Minnesota, Nebraska, and Utah. Because four of these plants were owned and operated by large corporations, we viewed the trim sampling methods used in plants that slaughter about 70 percent of the nation's cattle.

- **Online Articles and Blogs**—We reviewed sources such as www.foodsafetynews.com and www.meatingplace.com to stay current on relevant industry issues.

- **Small Processor Groups—**We conducted interviews with representatives from smaller plants to learn their perspective concerning FSIS outreach, product testing, and other issues. We interviewed representatives of Niche Meat Processors Association Network and American Association of Meat Processors.

- **Small Size Plants**—We discussed *E. coli* issues with two small plants to both verify the claims of the small group processors and learn of FSIS outreach and policy implementation from the perspective of small plants operators. We visited two plants in Missouri that FSIS designated as "small or very small."[40]

- **FSIS Electronic Data Sources**—We examined FSIS electronic data sources not only to gain further understanding of the data, but also to inspect for anomalies within the data. We did not validate the accuracy of FSIS' electronic data.

Our audit field work was conducted from February 2011 to December 2011.

[40] FSIS defines "small" plants as having 10-499 employees and "very small" plants as having less than 10 employees. Both size plants must also have annual sells less than $2.5 million.

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 provides a reasonable basis for our findings and conclusions based on our audit objectives.

Abbreviations

CFR	Code of Federal Regulations
E. coli	*Escherichia coli* O157:H7
FMIA	Federal Meat Inspection Act
FSIS	Food Safety Inspection Service
HACCP	Hazard Analysis and Critical Control Point
OIG	Office of Inspector General
T/A plants	Talmadge-Aiken plants
USDA	United States Department of Agriculture

Exhibit A: Photographs of OIG's Fieldwork

Photo 1

Example of the size of a 2,000 pound combo bin of trim.

Photo 2

Trim can be small irregular cuts of meat.

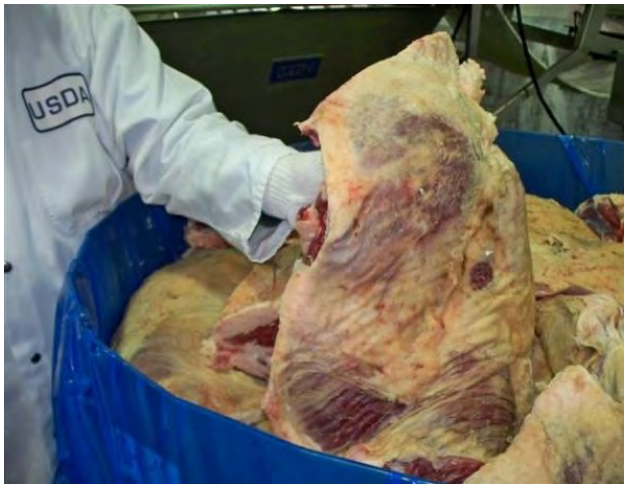

Photo 3

Trim can also be large whole muscles.

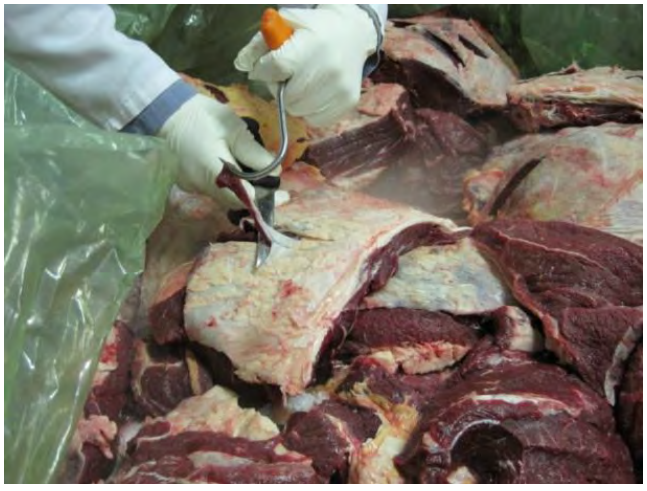

Photo 4

Example of an FSIS inspector collecting a piece of trim for an N-60 sample.

Photo 5

FSIS template showing the size of one sample piece the inspector was expected to collect for FSIS' N-60 trim sample.

Photo 6

These sample pieces were collected by an FSIS inspector; inspectors often cut the individual pieces too thick.

Photo 7

The N-60 sample pieces in a sanitary pack

Photo 8

The N-60 sample pieces in a box just prior to shipping.

Exhibit B: Response to Congressional Request for Information Regarding FSIS' *E. coli* O157:H7 Testing

The audit request on November 12, 2009, from the Chairwoman of the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies of the House Appropriations Committee posed a number of questions which we answered in Appendix A of our Phase 1 report. In seven of those responses, we stated that we would perform additional work related to the question during Phase 2 audit fieldwork. What follows are our responses in these seven areas. We have **bolded** the material that is unique to Phase 2 of our audit.

1. *What is the definition of a product "lot" used in the N-60 testing and how was this definition determined? How is this definition applied to individual processing establishments? Is this an appropriate application?*

   In our Phase 1 audit, we reported that:

   FSIS allows processing plants to define a "lot."[41] In defining lots, plants may consider a wide range of factors, including (a) any scientific, statistically based sampling program that the establishment uses to distinguish between segments of production; (b) standard operating procedures or other prerequisite programs used to control *E. coli* cross-contamination between raw beef components during production; (c) processing interventions; and (d) beef trimmings and raw beef components or rework carried from one production period to another. In the past, plants were allowed to define a lot as the beef trim produced from one clean up to the next clean up—often a full day's production. However, according to FSIS, clean up to clean up alone is no longer a supportable basis for defining a lot.

   According to FSIS officials, most large producers of beef trim define a lot as either one 2,000 pound combo-bin or multiple combo-bins (generally five combo-bins with a total weight of 10,000 pounds).[42] FSIS generally defines its sample lot to match the establishment's lot size. However, FSIS may permit an establishment that routinely samples its products under its own testing program to reduce its lot size on the day that FSIS conducts sampling, which allows it to hold less product until FSIS test results are returned. These plants must support their sampling program, define their lots microbiologically using sample data, and conduct robust sampling throughout the day to support lot sizes of less than one day's production.

   According to Hazard Analysis and Critical Control Point (HACCP) principles it is appropriate for companies to define their lot size because HACCP dictates that the establishments are themselves responsible for governing the factors that affect their production. Industry and FSIS officials are generally supportive of this principle. Under

[41] FSIS Directive 10,010.1, dated March 2010, states that "[t]he establishment is responsible for defining the sampled lot."

[42] A combo-bin for OIG's purposes is defined as a 48 inch x 40 inch x 40 inch size container of beef carcass trimmings.

HACCP, the plant determines the lot size through its hazard analysis. Whatever the plant decides, FSIS expects that the plant uses a scientific basis to meet the premise of HACCP, and FSIS inspectors are expected to verify that they have done so.

OIG agrees that a plant should use a scientific basis to support its defined lot size, and FSIS inspectors should verify it meets the premise of HACCP.

In Phase 2, we observed and analyzed this area further and found that FSIS allows processing plants to define a "lot." We discussed with industry the rationale for how operators define a "lot" and we also observed how the "lots" were sampled by FSIS and the plants. We concluded that because of the many variables, it is not feasible for FSIS to establish a standard lot size for industry's trim sampling program (i.e., a one size fits all approach).

2. *Are all samples collected, stored, shipped, and analyzed by trained FSIS employees?*

In our Phase 1 audit, we reported that:

Trim samples are collected by employees from both FSIS and industry. FSIS personnel collect all of the pieces of trim FSIS needs for its regulatory samples and the industry employees collect their own trim samples for testing. FSIS officials stated that all its field employees including inspectors in charge, frontline supervisors, and public health veterinarians are trained to properly collect, store, and ship FSIS samples.

FSIS' *E. coli* testing is performed at the agency's internationally accredited laboratories and the analysis is conducted by competent scientific personnel who have been certified to test for *E. coli* O157:H7.

In Phase 2 of our audit, we performed additional work to verify how samples are collected, shipped, stored, and analyzed by industry and FSIS and whether FSIS needs to establish standards for industry to follow when conducting trim sampling.

Our fieldwork in six slaughter plants disclosed concerns with how industry collected and prepared trim samples for shipment (see Finding 4). Our review found no adverse issues regarding how these plants stored their samples or how their laboratory service providers analyzed the trim samples. Our observations of the trim samples collected by FSIS and the Utah State meat inspection staffs at these six slaughter plants identified concerns related to how the N-60 samples were collected and shipped (see Findings 3 and 4). The audit found no adverse issues regarding how the inspection staffs stored their samples. Further, our review showed that public safety would probably be improved if FSIS more clearly defined its expectations for how industry should plan to respond to high event periods. FSIS is not providing detailed guidance to plants concerning how they should respond to "high event periods"—i.e., clusters of positive test results that could signal a breakdown in the sanitary dressing procedures at the plant. By providing better guidance to plants about how they should develop their plans, and what critical

elements should be included, FSIS can improve how industry responds to periods when a plant experiences multiple *E. coli* positives (see Finding 1).

3. *Are laboratories instructed to reject samples that do not meet minimum quality standards? If so, what are those minimum quality standards? How is it assured each sample meets them?*

   In our Phase 1 audit, we reported that:

   We confirmed that FSIS laboratories have developed internal procedures for discarding samples that do not meet minimum quality standards. When samples are received at the laboratory, to assure that each sample meets all the minimum quality standards, the laboratory technician inspects and documents the condition of the container, shipping seals, accompanying paperwork, and product. A temperature is then taken of the product and the sample information is entered into the automated laboratory tracking system, which includes any applicable information on why a sample was rejected. Laboratory procedures list over 30 reasons and sub-reasons why a sample might be rejected (including temperature, target tissue not received, no form received with sample, sample security seal problem, and sample container leaking).

   In Phase 2 of our audit, we performed additional work related to verifying the procedures used in the laboratories selected by industry and evaluating whether FSIS needs to establish standards for industry to follow when performing trim testing.

   Our audit found that the private laboratories used by five of the six slaughter plants were accredited by recognized bodies. In the sixth case, the facility used a non-accredited in-house laboratory to do a small amount of its testing (less than 10 percent) and the remainder of the plant's testing was done by accredited laboratories. The laboratories provided documentation to show that they had written laboratory procedures, which included policies for rejecting samples that were not in an adequate condition for testing and for conducting sample testing. Our work did not find that FSIS needed to set standards for laboratory service providers to meet but rather that the slaughter industry would benefit if FSIS issued guidance regarding what industry should be looking for in a laboratory services provider and what type of documentation plants need to maintain to support the testing their laboratory performs when FSIS performs a food safety assessment or other regulatory review (see Finding 4). We found nothing during this audit that would indicate that the procedures used by these private laboratories were not as stringent as those testing standards that are followed at FSIS' laboratories.

4. *Are the minimum standards associated with sample collection, storage, shipment, and analysis adequate? What type of testing standards must be met by laboratories analyzing the samples?*

   In our Phase 1 audit, we reported that:

FSIS has provided direction to inspection personnel for such responsibilities as collecting and submitting samples and acting on a positive FSIS test result. FSIS laboratories must also follow procedures that outline the minimum standards that samples must meet and that address issues like test methods, the receipt of samples, logging samples in, shipping them, and training staff. During Phase 2 of our audit, we will examine whether FSIS inspection personnel are following FSIS sampling procedures and assess their adequacy.

FSIS laboratories that analyze *E. coli* samples are accredited.[43] However, there is currently no legal or other requirement that FSIS laboratories obtain any accreditations. The International Standards Organization specifies the general requirements for a laboratory to demonstrate its competence to carry out tests. The requirements are applicable to all organizations that perform tests or calibrations. The accrediting body is the American Association for Laboratory Accreditation, which is a public service membership organization dedicated to operating a nationwide, broad spectrum laboratory accreditation system. Further, we confirmed that the American Association for Laboratory Accreditation conducts yearly external audits of FSIS' laboratories, and FSIS conducts its own internal audits to assure that the laboratories are following the accrediting body's, and the laboratory's, own policies and procedures.

In Phase 2 of our audit, we examined whether FSIS inspection personnel are following FSIS sampling procedures. We also identified and examined the testing standards followed by private laboratories doing *E. coli* O157:H7 testing for the beef industry to determine if the testing standards are as stringent as those followed by FSIS and whether FSIS needs to set minimum standards for private laboratories to follow. We discussed these areas in detail in our answers to questions 2 and 3 above.

5. *Has FSIS established a protocol for reassessing an establishment's HACCP plan based upon N-60 test results? What actions are taken at an establishment after a positive N-60 test result?*

   In our Phase 1 audit, we reported that:

   FSIS is responsible for verifying that slaughter and processing establishments implement food safety systems that comply with HACCP regulations. FSIS has established procedures for what actions should be taken after an FSIS positive *E. coli* O157:H7 test, including reviewing the establishment's HACCP plan, by specially trained personnel during a food safety assessment.

   After a positive FSIS test result, FSIS staffs are instructed to (1) collect supplier information;[44] (2) review establishment testing results; (3) verify disposition of affected

[43] "Accreditation" is a formal recognition of competence that a laboratory can perform specific tests.
[44] With the issuance of FSIS Notice 58-10, FSIS is now collecting supplier information at the time of sample collection.

product; (4) conduct follow-up sampling at the establishment and its suppliers; (5) conduct verification activities at the supplying establishment; (6) conduct a food safety assessment[45] at the establishment, and (7) take enforcement actions if warranted.

HACCP also requires that after a positive FSIS or industry test result, the establishment should use its own testing information to identify failures in its controls, take appropriate corrective actions, and reassess its HACCP plan, if applicable. For example, after a positive test result at one establishment, it was determined that an antimicrobial intervention had inadvertently been turned off and needed to be restarted. However, according to FSIS officials, there are circumstances in 9 Code of Federal Regulations 417.3 that if an establishment has already addressed *E. coli* in its HACCP plan, it may not have to reassess the plan in response to a positive test result.

In Phase 2 of our audit, we performed additional work to determine what actions FSIS and industry actually take after an *E. coli* O157:H7 positive to ascertain whether FSIS and industry are taking the proper actions after a positive test result.

We found that when a plant has a positive test result the plant may have one isolated positive at a time or the plant may experience clusters of 7, 15, 48, or more positives in one day. We noted that when a large slaughter facility has a positive *E. coli* test result, plant personnel (1) review their monitoring records; (2) determine what product might be affected (positive, negative, and non-tested product); (3) perform an investigation to attempt to find the cause of the contamination; and (4) arrange for appropriate disposition of the affected product and if applicable implement appropriate corrective actions to prevent the contamination from reoccurring. When the FSIS staff is made aware of a positive *E. coli* test result at a slaughter plant, they (1) perform a review of the plant's monitoring records; (2) review the plant's investigative documents; (3) monitor that the affected product was properly disposed of; and (4) monitor the plant's corrective actions, if applicable. In general, we found that industry and FSIS are taking appropriate actions when there is a positive *E. coli* test result; however we did identify some issues of concern relating to how plants plan for high event periods and how they communicate with FSIS regarding such events (see Finding 1).

6. *How are the FSIS N-60 test results and the establishment's N-60 test results correlated? How do N-60 testing protocols differ between FSIS and the industry?*

   In our Phase 1 audit, we reported that:

   According to agency procedures, when FSIS finds product to be *E. coli* positive, the inspection staff issues a noncompliance record, which requires the establishment to

[45] A comprehensive Food Safety Assessment considers all food safety aspects that relate to the establishment and its products, the nature and source of all materials received, the establishment's processes, and the environment of the establishment. The Food Safety Assessment is designed to examine the validity of the Sanitation Standard Operating Procedures, pre-requisite programs, testing programs, and any other programs that constitute the establishment's HACCP system.

review its control procedures and take corrective actions. The only time a noncompliance report is not issued when FSIS finds a positive is when the company simultaneously conducted a test and its test also showed a positive result, in which case the product should have been destroyed or fully cooked. Establishments with a program to routinely divert all FSIS-tested product to cooking would not receive a noncompliance report, as well. Further, the inspectors are to ensure that the product was disposed of properly.

In contrast, FSIS procedures do not allow for prompt correlation of plant testing results with FSIS test results or observation of disposition of *E. coli* positive product. According to FSIS officials, establishments are required to create a record of the positive in their HACCP system, to which FSIS has full access. However, plants are not required to notify FSIS of positive test results when they occur. FSIS procedures only require company test results be made available to FSIS inspectors, and that the results be reviewed by inspectors on a weekly basis.

FSIS has established N-60 testing protocols for its inspectors in FSIS Directive 10,010.1. However, FSIS has not defined what constitutes agency-approved N-60 sampling methods and has no requirement that industry follow any specific methodologies or standards for collection, storage, or shipping. During Phase 2 of our audit, we will review how industry sampling and testing protocols vary among plants and differ from FSIS standards.

In Phase 2 of our audit, we performed additional work to identify and examine the sampling methodologies followed by industry to determine how FSIS and industry utilize testing results and whether improvements can be made in how the testing results are used.

Our review disclosed that the N-60 trim testing methods used by industry and FSIS sometimes vary; nonetheless, the trim test results are still used by industry to improve their slaughter operations. The slaughter plants we visited did various kinds of testing for organisms like *Salmonella*, generic *E. coli,* and *E. coli* O157:H7. We observed industry using these data to proactively spot potential problems (one establishment developed a plant sanitation index) and to narrow down the sources of contamination (for an area of the plant or meat from a specific location on the carcass). FSIS and the Utah State meat inspection staffs monitored plant testing results at least weekly and followed up with plant management on any obvious adverse trends or positive test results that were noted.

Our review at six large slaughter plants showed that all of the plants had implemented a trim sampling program; however, only two of the systems exactly paralleled FSIS' N-60 trim sampling system. FSIS' N-60 trim sampling method collects 60 small piece samples from 60 larger trim pieces in the plant's production lot (generally a lot is from one to five combo bins). FSIS inspection staff uses a hook to secure the trim and a knife to remove the sample. The six plants we visited used various methods to collect their trim samples:

- **When collecting their samples, four of the plants used a knife or sharpened metal ruler to collect the sample, while the other two plants used a handheld drill and bit. In one of these plants the bit was short and it was used to remove a quarter-sized hole from the surface of the trim. At the other plant, the bit was several feet long and it was inserted deep into the combo to collect trim material.**

- **The trim sample at two of the six plants contained 60 pieces—the same as FSIS. Depending on the circumstances, three of the other plants collected 60 pieces, 75 pieces, or 90 pieces. The sixth plant did not base its sampling on the number of pieces at all but instead based its sampling on collecting at least 150 cubic centimeters of meat. FSIS accepted all of these different methods.**

We observed all of these trim sample collections in operation and found that they all had advantages and disadvantages. The fact that some of the plants used a trim sampling method that differed from FSIS' N-60 does not mean that these systems were superior or inferior to the system used by FSIS—there is no set industry standard. Downstream processors,[46] however, should be cognizant that, when a slaughter plant represents that it sampled its product for *E. coli* O157:H7, the trim may have been sampled very differently than the method used by FSIS to collect its regulatory samples. Downstream processors should become familiar with their suppliers' sampling method so that they can logically evaluate their level of confidence in the trim suppliers' testing results.

7. *What are the implications of the USDA label associated with a negative N-60 test?*

   In our Phase 1 audit, we reported that:

   The purpose of providing a USDA-approved testing label on product containers would be to give receiving establishments information regarding the testing of raw ground beef components for the presence of *E. coli*. Industry and FSIS have differing thoughts on the issues surrounding labeling of N-60 trim. Industry officials believe that this label will provide receiving establishments with necessary information regarding the testing of raw ground beef components in lieu of a certificate of analysis when a certificate does not accompany tested products sold through a distributor. FSIS officials believe grinders would assume that there is no risk in any labeled trim they are buying, and FSIS does not want to encourage this assumption since grinders have an obligation to sell final product that is not contaminated with *E. coli*.

   In Phase 2 of our audit, we determined if industry is currently labeling the product it tests. We found that industry does not place any specific labels on trim product that indicate that it has tested negative for *E. coli* O157:H7. Based on our

[46] For OIG's purposes "downstream processing" refers to smaller processors that acquire beef products from larger slaughter establishments, brokers or other processors and further prepare them for retail customers or consumers. For example, this could be a small establishment that grinds whole cuts of beef and trimmings into hamburger for sale in their local area.

discussions with industry and FSIS, we found varying opinions. Some believed that there was a chance of mislabeling or errors, and that there was a risk of placing untested product in labeled containers. Others worried that a label might give the user a false sense of the product's true safety and discourage downstream plants from taking appropriate measures to ensure the safety of the product. Those representing the interests of smaller processors indicated that a label would relieve problems of a certificate of analysis following the tested product downstream and give the small processors some assurance that the product has been tested.

FSIS officials believe grinders would assume that there is no risk in any labeled trim they are buying, and FSIS does not want to encourage this assumption since grinders have an obligation to sell final product that is not contaminated with *E. coli* O157:H7. According to FSIS National officials, they are also developing guidance for industry related to sampling and testing claims that may be made on product labels. As of March 1, 2012, this guidance was in Agency clearance to be issued in spring 2012.

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

United States Department of Agriculture | Food Safety and Inspection Service | Washington, D.C. 20250

TO: Gil Harden
Assistant Inspector General for Audit
Office of Inspector General

FROM: Alfred V. Almanza / s / April 13, 2012
Administrator
Food Safety and Inspection Service

SUBJECT: Office of Inspector General (OIG) Official Draft Audit Report – Application of FSIS Sampling Protocol for testing Beef Trim for *E. coli* O157:H7 – Phase II, Report Number 24601-0001-31

The Food Safety and Inspection Service (FSIS) has reviewed this report and responded to each of the recommendations.

Recommendation 1
Issue revised guidance to industry regarding the agency's expectations for trim sampling and how industry should plan for and react to high event periods. Include in the guidance specific information on the critical elements to be included in a high event period plan and the necessary support for the high event period criteria, such as how the plant may interact with FSIS staff, and how the plant may determine what non-tested or negatively tested product should be considered positive when the plant has multiple positive test results.

Agency Response
FSIS will issue revised guidance to beef slaughter and fabrication establishments that manufacture beef trimmings on procedures they can use to assess the effectiveness of their controls for preventing contamination during the slaughter operation. This document will include guidance that establishments can use to determine whether they are experiencing a "high event period" (HEP). HEPs are periods during which slaughter establishments experience a high rate of positive results for *E. coli* O157:H7 (or STEC or virulence markers) in trim samples. The guidance will recommend that establishments identify HEP criteria so that they can determine whether they need to withhold product from commerce when a HEP has occurred because the occurrence of a HEP may indicate more widespread adulteration of product, beyond the product found positive. The guidance will explain that if establishments identify and respond to HEPs, they will minimize the chance that they will release adulterated product into commerce. This guidance will provide criteria establishments may use for determining whether they have experienced a HEP. Establishments may use the criteria that FSIS has provided to define a HEP, or they may develop their own criteria. As part of their supporting documentation for their hazard analysis, the guidance will recommend that establishments document their criteria for identifying a HEP. The guidance will recommend that establishments document their criteria for identifying a HEP as part of their supporting documentation for their hazard analysis.

Furthermore the document will recommend that establishments conduct sampling and testing of trim at a frequency sufficient to find evidence of contamination surviving the slaughter and dressing operation. The document explains that establishments' deviations from previously obtained percent positive rates should be construed as presumptive evidence that the process is out of control that would warrant an investigation to find and eliminate potential causes for

positive results. Furthermore, to prevent the occurrence of HEPs, the document recommends more rigorous testing during the high prevalence season and effective slaughter and dressing procedures to minimize, to the maximum extent practical, cross contamination of carcasses with the contaminants from the hide and intestinal tract.

The document will also include actions that establishments should take during a high event period. Generally, if primals are not commingled by stacking or storing in common containers without individual separation before packaging, and the establishment minimizes cross contamination among primals, an individual primal can be considered a microbiologically independent lot. Normally, FSIS does not consider primal cuts designated for intact use to be adulterated if contaminated with *E. coli* O157:H7. The guidance will explain that during a HEP situation, unless the establishment has controls in place to ensure that the primals are not used for non-intact purposes, such primals may be considered adulterated because they were prepared under insanitary conditions. FSIS will be aware of establishment test results because FSIS reviews establishment results on at least a weekly basis.

Estimated Completion Date: FSIS will issue the revised guidance no later than July, 2012.

Recommendation 2

Review the available scientific data and hold discussions with appropriate stakeholders to determine if FSIS sampling resources could be better utilized and identification of *E. coli* O157:H7 contamination could be improved if the agency devoted more of its sampling efforts to sampling beef trim instead of ground beef. Shift resources, if needed, based on the scientific data and discussions. Develop a detailed plan with milestones and timeframes for implementing any proposed changes based on this review.

Agency Response

FSIS is making certain changes to its trim sampling program to make it risk based. In addition, during this calendar year and next, FSIS intends to identify additional ways to make its testing programs for *E. coli* O157:H7 more risk based, such as consideration of information available through PHIS, from inspection program personnel, and from risk analyses. FSIS intends to announce the changes in its trim sampling program in the Federal Register in the next 3-6 months and to ask for comment on the changes and other issues under consideration. Also, next calendar year, FSIS intends to conduct a study to test product from unopened containers or purge material (that is, remaining liquid, fat, and meat particles in containers or combo bins after trim contents have been removed) from suppliers' product for *E. coli* O157:H7. The purpose of this study will be to identify the source of *E. coli* O157:H7 positive raw ground beef when material from multiple suppliers was used to create the sampled ground beef that FSIS has found positive for *E. coli* O157:H7. Furthermore, FSIS intends to change how Agency verification samples are scheduled such that FSIS can obtain on-going baseline prevalence information about select pathogens such as *E. coli O*157:H7. In some cases, more samples may be necessary than those currently analyzed in the verification testing program. FSIS recognizes that today the number of samples analyzed is far less than the number of samples scheduled. As the scheduled-to-analyzed rate improves through implementation of PHIS, the increase in the number of samples needed for the baseline prevalence determination may be more closely matched. Finally, while the focus of OIG was *E. coli* O157:H7, FSIS intends to begin co-analyzing all beef samples for *Salmonella* over the course of the next few years. Ground beef samples, particularly, will provide an indication of the level of process control for external contamination during slaughter, as well as the internal contamination that may result from *Salmonella* in lymph nodes. Thus, the issue of redirecting samples from the ground program to the trim program is complicated and requires further analysis before making such a change.

Estimated Completion Date: FSIS will report on the progress of these reviews and discussions and any resulting changes no later than April, 2013.

Recommendation 3

Work with appropriate officials inside and outside FSIS to evaluate if the agency needs to revise its performance measure for testing *E.coli* to account for the advantage in testing beef trimmings compared to ground beef. If agency officials determine that a revised performance measure is needed, develop a detailed plan with milestones and timeframes for implementing the new performance measure.

Agency Response

FSIS will evaluate the appropriateness of its Agency performance standards in the context of any changes to sampling algorithms or sample allocations. If necessary changes are identified, FSIS will develop proposed changes to the performance standards and elicit external input as appropriate. FSIS will complete its review of public health and FSIS resource impacts to performance standards before implementing any changes to sampling. FSIS intends to conduct this review and identify any needed changes next calendar year.

Estimated Completion Date: FSIS will report on this evaluation and any resulting changes no later than April, 2013.

Recommendation 4

Reevaluate the policies for how inspectors collect trim samples, including the random selection of product for sampling, collecting samples of proper weight, and not taking multiple samples from single pieces of trim. Develop a detailed plan with milestones and timeframes for implementing any corrective actions resulting from this agency reevaluation.

Agency Response

FSIS will issue instructions for collecting samples of the proper weight no later than August 2012.

FSIS will evaluate the current instructions, identify any necessary changes, and reissue the directive during calendar year 2013.

Estimated Completion Date: FSIS will report on this reevaluation and any resulting changes no later than April, 2013.

Recommendation 5

Reevaluate noncompliance policy ambiguities in FSIS Directive 10,010.1 and revise agency procedures to ensure that industry is not avoiding regulatory action. Develop a detailed plan with milestones and timeframes for implementing any corrective actions resulting from this agency reevaluation.

Agency Response

FSIS will evaluate the current instructions, identify any necessary changes, and reissue the directive.

Estimated Completion Date: FSIS will reissue the directive no later than April, 2013.

Recommendation 6

Develop a detailed plan with milestones and timeframes to determine whether the quality of inspection in T/A plants is such that it increases the possibility of *E. coli* contamination in the products that these plants produce. Based on this evaluation, determine if additional FSIS oversight and communication are needed at T/A plants and State inspection agencies. If so, determine what type of oversight and communication are needed and how they will be provided.

Agency Response

FSIS will develop a detailed plan with key milestones and schedules to determine whether the quality of inspection in T/A plants is such that it increases the possibility of *E. coli* contamination in the products that the plants produce. Based on the findings, FSIS will develop a corrective action plan to address any weaknesses in the management controls, monitoring, or communications.

Estimated Completion Date: FSIS will complete the evaluation by August 2012 and the plan of action to address weaknesses no later than April 2013.

Recommendation 7

Improve communication by issuing guidance to industry to assist plants in selecting laboratories based on capabilities of the testing laboratories. This guidance should provide a checklist for industry on the issues to consider and also the type of documentation that plants should maintain to support their testing program.

Agency Response

On March 8, 2012, FSIS announced the availability of policy guidance for federally inspected establishments in the selection of commercial and private microbiological testing laboratories. FSIS has posted this policy guidance on its Web page *http://www.fsis.usda.gov/Regulations_&_Policies/Compliance_Guides_Index/index.asp#Micro*. FSIS encourages establishments that prepare meat, poultry, or processed egg products to follow the criteria in the guidelines in selecting commercial or private microbiological testing laboratories and in determining their capability to provide accurate and reliable results. The guidance includes a checklist for industry on the issues to consider and also the type of documents that plants should maintain to support their testing program.

Informational copies of this report have been distributed to:

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Director, Planning and Accountability Division

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