U.S. Department of Agriculture

Office of Inspector General

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

**Audit Report 24601-9-KC**
**February 2011**

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington, D.C. 20250

DATE: February 24, 2011

REPLY TO
ATTN OF: 24601-9-KC

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 /s/
Assistant Inspector General
for Audit

SUBJECT: FSIS Sampling Protocol for Testing Beef Trim for *E. coli* O157:H7 – Phase I

This report presents the results of the subject audit. Your written response to the draft report, dated January 28, 2011, is attached with excerpts and the Office of Inspector General's (OIG) position incorporated into the Finding and relevant Recommendation sections of the report.

We agree with management decision on Recommendation 1 of the report. However, we are unable to accept management decision on Recommendations 2, 3 and 4. Documentation and/or actions needed to reach management decisions for these recommendations are described in the OIG position section of the report.

In accordance with Departmental Regulation 1720-1, please furnish a reply within 60 days describing the corrective action taken or planned and the timeframes for implementing the recommendations for which management decision has not been reached. Please note that the regulation requires management decision to be reached on all recommendations within 6 months from report issuance, and final action to be taken within 1 year of each management decision to prevent being listed in the Department's annual Performance and Accountability Report. Please follow your agency's internal procedures in forwarding documentation for final action to the Office of the Chief Financial Officer.

We appreciate the courtesies and cooperation extended to us by members of your staff during this audit.

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## Executive Summary

### Results in Brief

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 U.S. 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* (*E. coli*) O157:H7 in U.S. beef "trim."[1] A recent outbreak of *E. coli* O157:H7 contamination had resulted in at least two deaths and more than two dozen illnesses in 11 States, and the Congresswoman posed a number of questions about whether FSIS' sampling protocol is statistically valid; how FSIS collects and analyzes samples; and how the agency and industry respond to test results.

In order to expedite this Congressional request, OIG divided its work into two phases. In this report, we are presenting the results of Phase I of our review of FSIS' sampling method, our direct answers to the Congresswoman's questions (see Appendix A), and our followup observations pertaining to the memorandum we issued in January 2008 related to *E. coli* O157:H7 testing (see Appendix B). In Phase II, we will perform fieldwork at beef processing plants to expand upon information presented in this report and also to pursue issues such as whether plants are testing for *E. coli* O157:H7 consistently and if FSIS personnel are following FSIS procedures for sampling and testing.[2]

At beef slaughter and fabrication plants (processing plants) nationwide, FSIS inspectors sample beef trim and then it is tested to detect *E. coli* O157:H7 contamination. When FSIS began performing these tests on beef trim in 2007, it chose a sampling method that it believed to be the most scientifically rigorous available: N-60. 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* O157:H7.

According to FSIS officials, N-60 is not designed to find *E. coli* O157:H7 in any given lot at a specific statistical confidence, but to verify that *E. coli* O157:H7-preventing interventions at processing plants (such as carcass washes or steam cabinets) are working as intended, and to

[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.

[2] OIG acknowledges that both FSIS and the industry perform N-60 *E. coli* O157:H7 pathogen testing. However, we have not reviewed or examined industry's efforts in their N-60 sampling programs, and we do not intend this report to reflect on those efforts. This report is exclusively directed towards the FSIS N-60 sampling program in beef trim.

emphasize to the plants that they are being monitored. Food safety, from FSIS' perspective, is best assured by interventions such as these because no method of statistical sampling and testing can guarantee with absolute certainty that a particular lot of beef trim is entirely free from *E. coli* O157:H7 contamination. While OIG agrees that testing alone cannot suffice to ensure that consumers are safe from a pathogen like *E. coli* O157:H7, we found that FSIS' N-60 sampling method is not designed to yield the statistical precision that is reasonable for food safety or to verify that plant controls or interventions are working as intended.

The dilemma facing FSIS is that as plants' controls and interventions become more effective at eliminating fecal material on carcasses, the presence (or prevalence rate) of *E. coli* O157:H7 contamination in beef trim becomes lower. Statistically, the lower the prevalence rate, the more difficult the pathogen is to find and the more samples need to be taken to detect it. We found that FSIS' current sampling model of collecting just 60 sample pieces may not provide a reasonable likelihood of finding *E. coli* O157:H7 contamination at a very low prevalence rate given the following problems:

- FSIS has not determined the rate at which *E. coli* O157:H7 can be found in beef trim, or its "prevalence rate," even though the design of an adequate sampling method should begin with this information. FSIS should also determine how often the prevalence rate should be reassessed.

- FSIS has not evaluated or justified the contamination level for *E. coli* O157:H7 that is associated with its N-60 sample size and confidence level (essentially the amount of contaminated trim that might slip through N-60 without being detected)—in an FSIS sample of N-60, there is a 5 percent probability of missing actual contamination that is present in 5 percent of a given lot. There is also a 55 percent probability of missing actual contamination that is present in 1 percent of a given lot—in other words, if the contamination level is very low, FSIS is more likely to miss contamination than to detect it.

Given its shortcomings and the presumed low occurrence of this pathogen, the N-60 sample size and design may not be adequate for detecting *E. coli* O157:H7 in beef trim.

FSIS officials have stated that they are reluctant to increase the number of pieces in samples beyond N-60 because taking a large number of sample pieces is impractical due to the associated time and cost to take a sample and limitations on sampling and testing resources. Yet the probable scarcity of *E. coli* O157:H7 requires that more than 60 sample pieces be taken if FSIS is to obtain results which provide a higher degree of confidence in detecting the *E. coli* O157:H7 pathogen and signal an establishment's failure to execute effective interventions or process controls. To ease the burden on FSIS resources, the agency could designate a specialized team (or individual) that would supplement onsite inspectors for the more intensive sample collections.

OIG acknowledges that increasing FSIS' sample size would strain the agency's sampling and laboratory testing resources. For this reason, we are also recommending that FSIS move to an inspection system that will determine which processing plants are at a higher risk of *E. coli* O157:H7 contamination. This would enable the agency to focus its testing resources on

those plants. We also believe that FSIS should take advantage of the fact that many plants, especially the larger and more sophisticated ones, are independently performing hundreds of their own *E. coli* O157:H7 tests daily, some more rigorously than others. If FSIS could assure itself these plants' samples and tests for *E. coli* O157:H7 at least met FSIS standards, or even more rigorous ones, then FSIS could utilize these plants' testing results to augment its own. The plants, after all, have compelling economic reasons to have an effective testing program since they bear the costs of any recalls.

OIG concludes that FSIS needs to take steps to thoroughly reevaluate its N-60 sampling program for testing beef trim. The design should provide the American public a high degree of confidence that FSIS tests are accurately identifying *E. coli* O157:H7 in order to detect an establishment's failure to execute effective interventions or process controls and, ultimately, prevent the distribution and consumption of *E. coli* O157:H7-contaminated meat.

## Recommendation Summary

Develop and implement a plan with specific timeframes and milestones to prioritize and perform necessary baseline studies of beef trim and ground beef in order to determine the estimated prevalence rate of *E. coli* O157:H7 for redesigning FSIS' sampling program. The plan should include how often the prevalence should be reassessed.

Re-evaluate its sample parameters (size and confidence level) and redesign a sampling program for *E. coli* O157:H7 in beef trim that provides higher confidence in FSIS accurately detecting contaminated product in order to effectively verify process controls at beef processing plants across the nation.

Thoroughly document the scientific support and rationale for FSIS' revised *E. coli* O157:H7 sampling program design, including the contamination level that will be associated with the new sample parameters and how the estimated prevalence rate impacts the new design. Publish FSIS' revised *E. coli* O157:H7 sampling design, along with its support and design rationale, for public comment, and consider any recommended changes before implementing the new sampling program.

Develop a detailed operational plan with specific timeframes and milestones to implement an inspection system that focuses *E. coli* O157:H7 sampling and testing resources primarily at plants that are likely to be of higher risk, and consider the use of specialized sample collection teams.

## Agency Response

In its January 28, 2011, written response to the official draft report, FSIS generally expressed agreement with our finding and recommendations. Also, included in the FSIS' response were general comments regarding the agency's trim sampling program. 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.

## OIG Position

We concur with FSIS' proposed corrective actions and have accepted management decision for Recommendation 1. However, FSIS did not provide sufficient detail regarding their planned corrective actions on Recommendations 2, 3 and 4 for us to accept management decisions for these recommendations at the issuance of this report. We have provided our comments and what is required to reach management decision on each recommendation in the applicable OIG Position sections.

# Background & 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, 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 disease 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* O157:H7 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 caused about 70,000 cases of Shiga poisoning annually in the United States: in 2009, 52 of these cases proved fatal. USDA's Economic Research Service estimates that the total costs, such as doctor bills and hospitalization costs, associated with consuming *E. coli* O157:H7-contaminated meat are about $405 million annually.

In 1994, the U.S. District 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.[3] FSIS relies on the authority provided by this statute 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, but has yet to be finalized.

Ground beef is made up of less tender and less popular cuts of beef. After slaughter, the cattle carcass is cut into various intact cuts of meat (e.g., loin, ribs, roasts, and steaks). After the intact 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. The large quantity of ground beef produced in the United States—using nearly 4 billion pounds of trim annually[4]—is sold to a

[3] Texas Food Industry, et al., v. Mike Espy, et al., Civ. No. A-94-CA-748 JN, United States District Court, West District, Texas, Austin Division, December 13, 1994.

[4] 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 was taken from 2005 eARDS data.

wide variety of customers, including grocery stores, restaurants, fast food establishments, and the National School Lunch Program, for the most part.

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* O157:H7 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* O157:H7 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* O157:H7 can cause serious illness and even death, especially in younger children. The only certain and practical way of destroying all *E. coli* O157:H7 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 beef 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* O157:H7 contamination, and also as a way of communicating to plants that they are being monitored. While FSIS inspectors may sample from large plants each month, they may test for *E. coli* O157:H7 in some small to medium-sized plants as little as one sample per quarter. It is important to recognize that no system of statistical analysis can arrive at 100 percent certainty that any given lot of beef trim is free of *E. coli* O157:H7. Although repeatedly testing a given lot improves the probability of finding *E. coli* O157:H7, 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.[5]

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.[6] 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* O157:H7 would not normally be located inside the animal's muscles. N-60 sampling is resource intensive, often taking inspection program personnel over an hour to collect a sample. The sample is shipped to a designated FSIS laboratory where it is composited for testing to determine the presence of *E. coli* O157:H7.

[5] In the proper conditions, *E. coli* O157:H7 can grow and become more numerous.

[6] 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. The 60 pieces are composited and sent as one sample for testing at a FSIS laboratory.

Establishments sometimes do not hold product pending test results, as evidenced by recalls based on *E. coli* O157:H7 positive test results. However, the sampled beef is generally held from commerce until the results are returned. If *E. coli* O157:H7 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 method by (1) issuing more detailed guidance concerning trim sampling, followup sampling, and tracing product back to the source of the contamination; (2) producing an instructional video; and (3) improving its laboratory procedures.

Each year, FSIS schedules approximately 4,400 sample collections of beef trim using N-60 samples.[7] 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.[8] 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 also 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 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* O157:H7 contamination, indicating to a plant manager that an intervention or process control is not working effectively and immediate corrective action is needed. 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 do, however, require that establishments verify, through testing or other means, that their food safety systems work. FSIS may also look at establishment's sampling and testing methods during its Food Safety Assessments. Plants are also 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.

[7] The FSIS website publishes the number of collected product samples that are analyzed every year: 2319 in 2008, 2728 in 2009, and 2492 as of November 21, 2010.

[8] FSIS allows plants that produce trim the flexibility to determine lot size. We obtained this information from industry sources.

It is important to note that 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 FR 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. 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.

## Objectives

Our objective in this phase of the audit was to follow up on matters reported in our memorandum, "Food Safety and Inspection Service Sampling and Testing of *E. coli*," issued January 29, 2008, related to examining the adequacy and effectiveness of FSIS' N-60 sampling method.

# Section 1: FSIS Needs to Improve Its Methodology to Test for *E. coli* O157:H7 Contamination

## Finding 1: FSIS Should Take Steps to Reevaluate and Solicit Public Comment on Redesigning Its Beef Trim Sampling Methodology in Order to Improve the Detection of *E. coli* O157:H7 Contamination

We found that FSIS' N-60 sampling program is not adequately designed to yield the statistical precision that is reasonable for food safety purposes or to verify that a plant's interventions and process controls are working as intended. FSIS' sampling dilemma is that given the likely low occurrence of *E. coli* O157:H7 in U.S. beef trim, FSIS must collect more than 60 pieces before it can attain the precision that is reasonable for food safety purposes. With just 60 sample pieces, FSIS is currently more likely *not* to find *E. coli* O157:H7 than it is to find it in a sample of product with, for example, 1 percent contamination.[9] The problems with N-60 occurred because FSIS, from the outset, did not design its sampling program to achieve a specific level of statistical precision. This was because FSIS perceived its sample and collection analysis as only one component of its eight HACCP verification activities[10] and, also, as a method to encourage the regulated industry to conduct testing of their own for *E. coli* O157:H7. We believe FSIS needs to correct N-60's limitations by redesigning its sampling program to provide a higher degree of confidence that its beef trim tests are accurately identifying contaminated product in order to detect an establishment's failure to execute effective interventions or process controls; thus, preventing the establishment from distributing *E. coli* O157:H7-contaminated meat.

The Federal Meat Inspection Act states that FSIS is to protect the health and welfare of consumers by preventing the distribution of meat products that are unwholesome or adulterated. In 1994, USDA won a case in the U.S. District Court, which upheld that that the Department could reasonably consider *E. coli* O157:H7 an adulterant, and that consequently it could, as part of its statutory authority, regulate beef that might be contaminated.[11] Since the 1990s, FSIS has maintained a testing program for raw ground beef, but starting in 2007, the agency began testing the components of ground beef, most notably trim.

FSIS adopted the N-60 sampling method because the agency believed that N-60 was the most rigorous method identified in the scientific literature, yet it did so without fully communicating, in advance, to the public and to Congressional decision-makers the shortcomings of this method. According to FSIS officials, the agency did not hold a public meeting on N-60 sampling until 2008, although it has briefed industry and consumer groups multiple times since. Moreover,

[9] At 1 percent contamination, N-60 yields only a 45 percent level of confidence that the adulterant would be found, which is far short of the level of confidence normally considered statistically desirable. Since this is a question of food safety, we use 1 percent in our example.

[10] 9 Code of Federal Regulations 417.8 proscribes eight activities that FSIS performs to verify a plant's HACCP, including sample collection and analysis.

[11] Texas Food Industry, et al., v. Mike Espy, et al., Civ. No. A-94-CA-748 JN, United States District Court, West District, Texas, Austin Division, December 13, 1994.

when FSIS adopted N-60, it did not take the steps necessary to adapt the sampling program so that it would correctly identify contaminated product, such as determining the rate at which *E. coli* O157:H7 can be found in U.S. beef trim. Instead, it designated the number 60 as an ideal sample size in order to achieve a balance between collecting a representative sample while not over-burdening its inspection staff.

FSIS officials, academics, and industry representatives all agree that the expected occurrence rate of *E. coli* O157:H7 in the U.S. beef trim supply is very low; however, FSIS has not formally determined the prevalence of *E. coli* O157:H7, which should have been the first step in developing an effective sampling design. In 2008, FSIS did publish a baseline data collection program, which reported partial results indicating the positive rate for *E. coli* O157:H7 was 0.68 percent.[12] However, the study also stated that this rate was "only a raw number and should not be considered as the national prevalence." FSIS did not put forward 0.68 percent as a rate of national prevalence in part because the agency gave industry advance notice that testing was going to be performed, and then relied on samples from product that industry had already tested.[13] FSIS had intended to issue a prevalence rate based on this study, but had not done so at the time of our fieldwork because of competing priorities that delayed completing the project.

In followup discussions during November and December, 2010, FSIS officials informed us they had a draft document that established a national prevalence rate from the 2008 baseline study that they planned to finalize and issue soon. They stressed that the national prevalence rate was not based on current positive test results because the data for the baseline study was from 2007 and 2008. They also pointed out that the testing data were based on N-60 sampling results, since that has been the standard sampling method used by FSIS and the industry. We believe that any national prevalence rate based on these data may already be outdated, particularly because many plants may have improved their intervention methods in recent years. We also question the reliability of N-60 sampling to support the rate of positive test results used in determining the national prevalence rate. In Phase II, we will further review the methodology and scientific support used to compute the national prevalence rate FSIS issues.

Additionally, OIG found that FSIS' N-60 relies on sample parameters that are questionable from a food safety standpoint. This is because FSIS has not evaluated or justified the contamination level for *E. coli* O157:H7 that is associated with its N-60 sample size and confidence level—essentially, the amount of contaminated trim that might slip through N-60 without being detected. For instance, in an FSIS sample of N-60, there is a 5 percent probability of missing actual contamination that is present in 5 percent of a given lot. There is also a 55 percent probability of missing actual contamination that is present in 1 percent of a given lot—in other words, if the contamination level is very low, FSIS is more likely to miss contamination than to detect it. Therefore, to maintain a high probability of detecting a pathogen with presumably as

[12] In "Nationwide Microbiological Baseline Data Collection Program for the Raw Ground Beef Component: Domestic Beef Trimmings," FSIS tested 1,900 samples and found that 13 samples were positive, for a percent positive rate of 0.68 percent. In this description, each of the "samples" was a group of 60 pieces of trim.

[13] In plants that conduct their own testing, the product that FSIS samples has already been tested and passed (approved for entry into commerce as raw beef trim) by industry, and that the FSIS test is not an independent test in which FSIS chooses a lot off the production line before industry has gotten a test result for it.

low a level of contamination as *E. coli* O157:H7, FSIS' sample size must increase.[14] For example, if the contamination rate of 5 percent were lowered to a rate more reflective of the occurrence of *E. coli* O157:H7, such as 1.5 percent, then to achieve a 95 percent confidence level in detecting *E. coli* O157:H7, the sample size must increase substantially, even to perhaps N-200. Otherwise, if the sample size remains at 60, then the level of confidence in finding *E. coli* O157:H7 would drop from 95 percent to 60 percent. At a contamination rate of 1 percent, it would drop to only 45 percent.

OIG maintains that testing for *E. coli* O157:H7 without a well supported prevalence rate hinders the design of an appropriate sample and that FSIS must determine how to detect a lethal contaminant that is quite scarce, even if its sample size must rise above 60 pieces. We concluded that N-60's limitations are severe enough that the use of this method of sampling for *E. coli* O157:H7 is not especially useful for verifying that plant controls or applied interventions are working as intended or providing assurance that establishments are not distributing *E. coli* O157:H7-contaminated meat for consumption.

In order to design a better sampling method for testing for *E. coli* O157:H7, FSIS must first determine the prevalence of *E. coli* O157:H7 in trim.[15] Ideally, FSIS would develop a process for determining a baseline prevalence for *E. coli* O157:H7 in beef trim that is ongoing, relevant from year-to-year, and that takes into account seasonal variations due to increased summer heat, and other factors. The process should also include how often the prevalence rate should be reassessed. Additionally, in collaboration with Congress, the industry, and the public, FSIS should specify and justify its sample parameters and the associated contamination level that is suitable for food safety purposes. In order to develop the best possible sampling program and ensure transparency, FSIS should publish its proposed sampling design for public comment before the agency implements any changes. If these steps are taken, then it is probable that the number of sample pieces the agency needs to collect will rise.

During final processing of our report, FSIS released its "National Prevalence Estimate of Pathogens in Domestic Beef Manufacturing Trimmings (Trim) December 2005 – January 2007", dated January 2011. In the report, FSIS estimated that the national prevalence of *E. coli* O157:H7 in beef trim for use in the manufacture of raw ground beef was 0.39 percent, with a 95 percent confidence interval was between 0.05 percent and 0.73 percent. The 0.39 percent prevalence rate represents the occurrence of lots tested that showed positive results for *E. coli* O157:H7; it does not reflect the prevalence, or level, of contamination in a given lot of beef trim. Therefore, we question how useful this prevalence rate will actually be in determining the number of sample pieces to collect in redesigning FSIS' N-60 sampling program.

[14] For any sample size, there is some probability of failing to detect contamination that is actually present in the lot. However, for a specified sample size, such as N-60, the probability of failing to detect actual contamination increases as the percent of actual contamination decreases.

[15] In September 2003, we made this type of recommendation in our audit of FSIS' Oversight of Production Process and Recall at a ConAgra Plant (Report 24601-02-KC, dated September 30, 2003).

OIG acknowledges that collecting additional sample pieces would strain FSIS' collection and laboratory resources.[16] At present, FSIS estimates that it has the resources to perform about 4,400 tests for N-60 samples yearly. To help mitigate the strain on FSIS' resources, OIG suggests that FSIS consider moving to a more risk-based sampling and testing approach, similar to its ground beef sampling program. FSIS could develop profiles of high-risk plants based on factors such as the number and quality of interventions at the plant; the volume of meat processed; the time of the year; the plant's number of noncompliances; the type, frequency, and quality of the *E. coli* O157:H7 sampling and testing being performed by the plant; and the percent of FSIS positive test results. FSIS should then direct its limited sampling and testing resources towards high-risk plants.

Though sampling at higher levels may increase the workload on FSIS inspectors, we believe that by designating a specialized team (or individual) that would supplement onsite inspectors for these more intensive sample collections, FSIS could provide the resources it needs to improve its sampling and testing program. FSIS is already considering this change. USDA is familiar with using teams of this sort since the Agricultural Marketing Service is currently using contractors to collect ground beef samples for the product it buys for the National School Lunch Program.

Additionally, some large plants are already testing hundreds of samples daily for *E. coli* O157:H7. Currently, FSIS has little direct assurance that these samples and tests are being performed according to its standards, or that the tests plants perform are similar to one another. If FSIS could ensure that industry sampling and testing at least met FSIS standards, it could potentially rely on industry's results, which would allow the agency to add industry's much greater testing capacity to its own relatively limited resources. Such an approach would be beneficial because (1) it would help FSIS eliminate the bottleneck caused by its own resource limitations; and (2) it would help FSIS monitor the immediate effectiveness of controls and interventions in place at those plants. According to FSIS officials, direct and regular collection of industry test results by FSIS for its verification programs could raise several logistical and legal issues, especially if the industry data were to be used for enforcement, which should first be considered. However, the agency could consider the confidence it places in a given plant's sampling and testing system as one of the factors in whether it considers the plant to be at high risk or not, which would allow it to focus its own efforts on plants where industry testing does not meet FSIS standards.

It is also important to recognize that as more effective control measures are adopted by the industry, the prevalence of *E. coli* O157:H7 contamination should continually decrease. Eventually, a point may be reached where product testing may be of limited benefit and greater benefit may be achieved by shifting FSIS resources to comprehensive analysis of plants' validation of their interventions and control systems.

In any event, OIG concludes that FSIS needs to take steps to thoroughly reevaluate its sampling and testing program. As long as the agency is performing tests for *E. coli* O157:H7 contamination, its sampling methodology should be providing the American public a high degree

[16] FSIS officials stated that an inspector requires about 1 hour to collect and prepare an N-60 sample for shipment to FSIS' laboratory.

of confidence in the accuracy of its testing results to detect an establishment's failure to execute effective interventions or process controls and, ultimately, prevent the distribution and consumption of meat contaminated with *E. coli* O157:H7.

## Recommendation 1

Develop a plan with specific timeframes and milestones to prioritize and perform necessary baseline studies of beef trim and ground beef in order to determine the estimated prevalence rate of *E. coli* O157:H7 for redesigning FSIS' sampling program. The plan should include how often the prevalence should be reassessed.

## Agency Response

FSIS will develop a plan for prioritizing and performing *E. coli* O157:H7 baseline studies of beef, including ground beef, trim and other ground beef components, for the purpose of informing and improving overall FSIS verification programs for control of the pathogen. FSIS will publish the plan for comment before it is made final.

Planned Completion Date: December 2011

## OIG Position

We accept management decision.

## Recommendation 2

Re-evaluate its sample parameters (size and confidence level) and redesign a sampling program for *E. coli* O157:H7 in beef trim that provides higher confidence in FSIS accurately detecting contaminated product in order to effectively verify process controls at beef processing plants across the nation.

## Agency Response

FSIS will evaluate its sampling program in the context of prevalence data and inspection verification data. FSIS believes that effective verification of food safety systems must include inspection of an establishment's production process to ensure that controls are adequately designed and implemented to prevent, eliminate or reduce contamination with *E. coli* O157:H7. To improve inspection program personnel verification of process controls for the reduction of *E. coli* O157:H7 at both beef slaughter and processing establishments, FSIS will be taking the following actions during 2011. Together, these actions will give inspection program personnel comprehensive, aggregate data on establishment process controls for *E. coli* O157:H7.

- FSIS will revise Directive 6410.1, *Verifying Sanitary Dressing and Process Control Procedures in Slaughter Operations of Cattle of Any Age*, with a special emphasis on improving and clarifying verification of sanitary dressing, given that contamination of

carcasses is the primary cause of ground beef component adulteration by *E. coli* O157:H7.

- FSIS will issue a new Notice regarding traceback methodology for *E. coli* O157:H7 in ground beef components after FSIS or other Federal or State agencies find ground beef or bench trim tests presumptive positive for *E. coli* O157:H7. This Notice will provide instructions concerning how to conduct product traceback from the grinder or bench trim establishment and what to do at originating supplier slaughter establishments following a confirmed positive for *E. coli* O157:H7 in ground beef, including assessing whether evidence of a high event period may have occurred and how to manage information gathered during a product traceback.

- FSIS will implement a new inspection procedure, the Hazard Analysis Verification (HAV), which will examine an establishment's hazard analysis and decision making documents. The HAV will serve as a screening process to identify issues of concern in the design of the establishments' food safety systems. HAVs will be performed at specified frequencies and when certain information prompts identify establishments that may have modified their HACCP system or may have failed to change their HACCP plan in response to a significant change in the establishments' process. A HAV will verify that the establishment's hazard analysis addresses the applicable food safety hazards for the process, product, and intended use. It will also verify that there is at least one CCP[17] for the hazards that are reasonably likely to occur and that there is support for any decisions that applicable hazards are not reasonably likely to occur. It will also verify that any prerequisite programs (such as an SOP[18], GMP[19], purchase specifications, etc.) which are intended to prevent the occurrence of the food safety hazard are adequately justified and properly implemented.

Planned Completion Date: December 2011

## OIG Position

We agree that FSIS would benefit from an evaluation of its sampling program in the context of prevalence data and inspection verification data. Further, we are pleased to see that the agency has outlined specific plans to improve the inspection program personnel verification of process controls for the reduction of *E. coli* O157:H7 in establishments in 2011. However, the agency response does not provide clarification regarding how the planned notice, directive, and HAV process will specifically improve the agency's trim sampling program. Therefore, we cannot reach management decision. In addition, FSIS' planned procedures on HAVs should articulate what corrective or enforcement measures will be taken on deficiencies exposed by these HAVs.

[17] Critical Control Point

[18] Standard Operating Procedure

[19] Good Manufacturing Practices

## Recommendation 3

Thoroughly document the scientific support and rationale for FSIS' revised *E. coli* O157:H7 sampling program design, including the contamination level that will be associated with the new sample parameters and how the estimated prevalence rate impacts the new design. Publish FSIS' revised *E. coli* O157:H7 sampling design with its support and rationale for public comment, and consider any recommended changes before implementing the new sampling program.

## Agency Response

FSIS will develop a plan for prioritizing and performing *E. coli* O157:H7 baseline studies of beef, including ground beef, trim and other ground beef components, for the purpose of informing and improving FSIS verification programs for control of the pathogen. FSIS will publish the plan for comment before it is made final.

FSIS also will be taking the following actions in 2011 (as stated above in response to Recommendation #2) to improve inspection program personnel verification of food safety systems for the prevention, elimination or reduction of *E. coli* O157:H7 at both raw beef slaughter and processing establishments. Together, these actions will give inspection program personnel comprehensive, aggregate data on establishment process controls for *E. coli* O157:H7.

- FSIS will revise Directive 6410.1, *Verifying Sanitary Dressing and Process Control Procedures in Slaughter Operations of Cattle of Any Age*, with a special emphasis on improving and clarifying verification of sanitary dressing, given that contamination of carcasses is the primary cause of ground beef component adulteration by *E. coli* O157:H7.

- FSIS will issue a new Notice regarding traceback methodology for *E. coli* O157:H7 in ground beef components after FSIS or other Federal or State agencies find ground beef or bench trim tests presumptive positive for *E. coli* O157:H7. This Notice will provide instructions concerning how to conduct product traceback from the grinder or bench trim establishment and what to do at originating supplier slaughter establishments following a confirmed positive for *E. coli* O157:H7 in ground beef, including assessing whether evidence of a high event period may have occurred and how to manage information gathered during a product traceback.

- FSIS will implement a new inspection procedure, the HAV, which will examine an establishment's hazard analysis and decision making documents. The HAV will serve as a screening process to identify issues of concern in the design of the establishments' food safety systems. HAVs will be performed at specified frequencies and when certain information prompts identify establishments that may have modified their HACCP system or may have failed to change their HACCP plan in response to a significant change in the establishments' process. A HAV will verify that the establishment's hazard analysis addresses the applicable food safety hazards for the process, product, and intended use. It will also verify that there is at least one CCP for the hazards that are reasonably likely to occur and that there is support for any decisions that applicable

hazards are not reasonably likely to occur. It will also verify that any prerequisite programs (such as an SOP, GMP, purchase specifications, etc.) which are intended to prevent the occurrence of the food safety hazard are adequately justified and properly implemented.

Planned Completion Date: December 2011

## OIG Position

We agree that FSIS would benefit from performing *E. coli* O157:H7 baseline studies for the purpose of informing and improving FSIS verification programs for control of the pathogen. We are also pleased to see that the agency has outlined specific plans to improve the inspection program personnel verification of process controls for the reduction of *E. coli* O157:H7 in establishments in 2011. However, the agency response does not provide clarification regarding how the planned baseline studies, notice, directive, and HAV process will specifically improve the agency's trim sampling program or cited inspection activities. Therefore, we cannot reach management decision. FSIS needs to document and publish for comment the scientific support and rationale for its revised *E. coli* O157:H7 sampling program design, including the contamination level that will be associated with the new sample parameters and how the estimated prevalence rate impacts the new design and inspection procedures.

## Recommendation 4

Develop a detailed operational plan with specific timeframes and milestones to implement an inspection system that focuses *E. coli* O157:H7 sampling and testing resources primarily at plants that are likely to be of higher risk, and consider the use of specialized sample collection teams.

## Agency Response

FSIS will evaluate its sampling program in the context of prevalence data and inspection verification data. FSIS believes that effective verification of food safety systems must include inspection of an establishment's production process to ensure that controls are adequately designed and implemented to prevent, eliminate or reduce contamination with *E. coli* O157:H7. To improve inspection program personnel verification of process controls for the reduction of *E. coli* O157:H7 at both beef slaughter and processing establishments, FSIS will be taking the following actions during 2011. Together, these actions will give inspection program personnel comprehensive, aggregate data on establishment process controls for *E. coli* O157:H7.

- FSIS will revise Directive 6410.1, *Verifying Sanitary Dressing and Process Control Procedures in Slaughter Operations of Cattle of Any Age*, with a special emphasis on improving and clarifying verification of sanitary dressing, given that contamination of carcasses is the primary cause of ground beef component adulteration by *E. coli* O157:H7.

- FSIS will issue a new Notice regarding traceback methodology for *E. coli* O157:H7 in ground beef components after FSIS or other Federal or State agencies find ground beef or bench trim tests presumptive positive for *E. coli* O157:H7. This Notice will provide instructions concerning how to conduct product traceback from the grinder or bench trim establishment and what to do at originating supplier slaughter establishments following a confirmed positive for *E. coli* O157:H7 in ground beef, including assessing whether evidence of a high event period may have occurred and how to manage information gathered during a product traceback.

- FSIS will implement a new inspection procedure, the HAV, which will examine an establishment's hazard analysis and decision making documents. The HAV will serve as a screening process to identify issues of concern in the design of the establishments' food safety systems. HAVs will be performed at specified frequencies and when certain information prompts identify establishments that may have modified their HACCP system or may have failed to change their HACCP plan in response to a significant change in the establishments' process. A HAV will verify that the establishment's hazard analysis addresses the applicable food safety hazards for the process, product, and intended use. It will also verify that there is at least one CCP for the hazards that are reasonably likely to occur and that there is support for any decisions that applicable hazards are not reasonably likely to occur. It will also verify that any prerequisite programs (such as an SOP, GMP, purchase specifications, etc.) which are intended to prevent the occurrence of the food safety hazard are adequately justified and properly implemented.

Planned Completion Date: December 2011

## OIG Position

We agree that FSIS would benefit from an evaluation of its sampling program in the context of prevalence data and inspection verification data. We are also pleased to see that the agency has outlined specific plans to improve the inspection program personnel verification of process controls for the reduction of *E. coli* O157:H7 in establishments in 2011. However, the agency response does not provide clarification regarding how the planned notice, directive, and HAV process will specifically improve the agency's trim sampling program and inspection activities to focus on plants that are likely to be of higher risk. Therefore, we cannot reach management decision. FSIS needs to develop a detailed operational plan with specific timeframes and milestones to implement an inspection system that focuses *E. coli* O157:H7 sampling and testing resources primarily at plants that are likely to be of higher risk and consider the use of specialized sample collection teams.

# Scope and Methodology

In November 2009, because of concerns regarding the efficacy of *E. coli* O157:H7 testing of beef trim products, the Chairwoman of the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies of the House Appropriations Committee requested that USDA's Inspector General investigate the scientific merits and potential shortcomings of N-60 sampling design and application of the test results from N-60 samples of beef trim products.

Between January and June 2010, we performed our audit at FSIS Headquarters in Washington, D.C., and the Eastern Laboratory in Athens, Georgia. In addition to working with FSIS officials, we spoke with representatives of two meat industry groups, officials from two consumer groups, academics from four universities, and representatives of three other agencies inside USDA to gain perspective on the challenges facing FSIS when sampling and testing for *E. coli* O157:H7. In addition, we reviewed documentation from FSIS; international agencies such as the Food and Agriculture Organization of the United Nations, World Health Organization, Codex Alimentarius, and the European Union's Food Standards Agency; and scientific literature from organizations devoted to food safety and illness prevention.

**FSIS Headquarters**

At FSIS Headquarters, we interviewed the appropriate senior-level officials and determined the responsibilities of the following divisions as they relate to *E. coli* O157:H7 sampling and testing:

- Policy and Program Development—this division provides leadership in the identification of policy needs, develops policy solutions to address the intent and application of verification and enforcement policy in plant activities, and provides direct technical support to FSIS field personnel.

- Field Operations—this division manages the national inspection and enforcement activities. Further, within this division we conducted additional interviews with representatives of the recall group that coordinates all recall activities.

- Program Evaluation, Enforcement, and Review—this division assesses 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.

- Data Integration and Food Protection—this division coordinates all emergency response, food defense, and data analysis activities within FSIS. We interviewed representatives of the Data Analysis and Integration Group, which is responsible for evaluating individual FSIS data streams, ensuring data analyses are consistent and of high quality, and conducting data analyses for agency decisions.

- Public Health Science—this division provides expert scientific analysis, advice, data, and recommendations on all matters involving public health and science that are of concern

to FSIS. 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.

**Others Outside of USDA**

We also interviewed the following groups, entities, and universities about *E. coli* O157:H7 sampling, testing, and control:

- Beef industry groups—one group represented U.S. cattle producers and the other represented companies that process red meat in the United States and their suppliers throughout America.

- Consumer advocates—one consumer group is a non-profit organization that advocates for policies it believes will result in healthy, safe food and the other group is a non-profit public health group dedicated to preventing illness and death from food-borne pathogens.

- Academic sources—professors with expertise in food safety were interviewed from the University of Nebraska-Lincoln, Kansas State University, Iowa State University, and Texas A&M University about *E. coli* O157:H7 issues currently facing the meat industry.

**Other Agencies Within USDA**

We talked to the following USDA agencies about *E. coli* O157:H7 detection and control:

- The Agricultural Research Service conducts research to develop solutions to agricultural problems of high national priority, in part to ensure high quality food, ensure safe food, sustain a competitive agricultural economy, enhance natural resources, and provide economic opportunities for rural communities.

- The Agricultural Marketing Service develops quality grading standards for agricultural commodities, administers marketing regulatory programs, oversees marketing agreements and orders, and makes food purchases for Federal food assistance programs.

- The Animal and Plant Health Inspection Service is charged with protecting and promoting U.S. agricultural health, regulating genetically engineered organisms, administering the Animal Welfare Act, and carrying out wildlife management activities.

We conducted this performance audit in accordance with 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.

During the course of our audit we did not verify information in any FSIS electronic information system, and make no representation regarding the adequacy of any agency computer systems or the information generated from them.

# Appendix A: Response to Congressional Request for Information Regarding FSIS' *E. coli* O157:H7 Testing

The audit request 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. What follows are our responses in these areas:

1. *What is the prevalence of E. coli O157:H7 in domestic beef trim used for raw ground beef production at processing facilities in the United States? When and how was this estimate reached? How frequently will it be re-assessed?*

   FSIS has not established a prevalence rate for *E. coli* O157:H7 in a given lot of beef trim. As discussed in the finding in this report, we are recommending that FSIS develop and implement a plan with specific timeframes and milestones to prioritize and perform necessary baseline studies of beef trim and ground beef in order to determine the estimated prevalence rate of *E. coli* O157:H7 for redesigning FSIS' sampling program. This plan should include how often the prevalence should be reassessed.

   During final processing of our report, FSIS released its "National Prevalence Estimate of Pathogens in Domestic Beef Manufacturing Trimmings (Trim) December 2005 – January 2007", dated January 2011. In the report, FSIS estimated that the national prevalence of *E. coli* O157:H7 in beef trim for use in the manufacture of raw ground beef was 0.39 percent, with a 95 percent confidence interval was between 0.05 percent and 0.73 percent. It also includes the methods used to calculate the pathogen estimates and provides additional information on the statistical procedures used in the study. The 0.39 percent prevalence rate represents the occurrence of lots tested that showed positive results for *E. coli* O157:H7; it does not reflect the prevalence, or level, of contamination in a given lot of beef trim. Therefore, we question how useful this prevalence rate will actually be in determining the number of sample pieces to collect in redesigning FSIS' N-60 sampling program.

2. *What is the confidence level of the N-60 sampling method as currently performed? Is that level appropriate for ground beef [trim]?*

   In FSIS' current sample of N-60, there is a 95 percent confidence level of detecting contamination when it is present in 5 percent of the lot. There is just a 45 percent confidence level of detecting *E. coli* O157:H7 contamination when it is present in only 1 percent of the lot—in other words, if the contamination level is very low, FSIS is more likely to miss contamination than to detect it. Therefore, to maintain a high probability of detecting a pathogen with presumably as low a level of contamination as *E. coli* O157:H7, FSIS' sample size must increase. As discussed in the finding in this report, we are recommending that FSIS re-evaluate its sample parameters (size and confidence level) and redesign a sampling program for *E. coli* O157:H7 in beef trim that provides higher confidence in FSIS accurately detecting contaminated product in order to effectively verify process controls at beef processing plants across the nation.

3. *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?*

   FSIS allows processing plants to define a "lot."[20] 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* O157:H7 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).[21] 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 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 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. We will observe and analyze this area further in our Phase II audit.

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

[21] 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.

4. *How does this definition affect the statistical viability of this test? How confident are we that lots testing negative are truly negative if the definition of "lot" varies among establishments?*

   The lot, from a statistical perspective, is the universe from which FSIS takes its 60 samples. Since the lots are generally quite large, variability in their size has relatively little, if any, effect on the viability of testing. For example, if all other variables are constant, it makes little difference if one takes 60 samples from one 2,000 pound combo lot or a lot of five combos (total weight of 10,000 pounds).

   As discussed in our finding in this report, OIG questions the effectiveness of N-60 sampling, but not due to problems with the size of the lot, or the universe. It is important to emphasize that no method of statistical sampling will result in absolute certainty that the lot is free of *E. coli* O157:H7 contamination, particularly since *E. coli* O157:H7 has such a low occurrence rate in final trim product and is not randomly dispersed throughout the lot.

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

   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 (IIC), Frontline Supervisors (FLS) and Public Health Veterinarians (PHV) are trained to properly collect, store, and ship FSIS samples.

   FSIS' *E. coli* O157:H7 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 II of our audit, we will review how FSIS and the industry employees are trained to collect, store, ship, and analyze samples.

6. *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?*

   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 II of our audit, we will review how the industry ensures its private labs are rejecting samples that do not meet minimum quality standards.

7. *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?*

   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 II 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* O157:H7 samples meet two accreditations.[22] However, there is currently no legal or other requirement that FSIS laboratories obtain any accreditations. The first accreditation is by the International Standards Organization, which 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 second accreditation is the American Association for Laboratory Accreditation (A2LA), which is a public service membership organization dedicated to operating a nationwide, broad spectrum laboratory accreditation system. Further, we confirmed that A2LA 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.

   During Phase II of our audit, we will also review the standards industry follows associated with sample collection and laboratory analysis.

8. *Because E. coli O157:H7 is not necessarily distributed homogeneously in a product, how did the agency decide on its current collection methodology? Are samples collected truly representative of the entire lot?*

   FSIS officials realized that in selecting a robust trim sampling program they needed to consider the fact that *E. coli* O157:H7 is not homogeneously distributed. Research has shown that *E. coli* O157:H7 is most likely found on the surface tissue of the trim and does not reside in the inner tissue. Therefore, FSIS samples surface tissue in order to increase the likelihood that it will find the pathogen.

   Combo bins are often over three feet deep and due to concerns for the safety of their sample collectors, FSIS requires that inspectors sample only the top layers of trim. Based

[22] "Accreditation" is a formal recognition of competence that a laboratory can perform specific tests.

on our discussions with agency and industry officials, as well as academics, we agree that so long as the bins are filled without prejudice, sampling from the top layers of trim should not impair the sample design. Samples gathered in this fashion can be considered as representative of the entire lot.

9. *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?*

   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;[23] (2) review establishment testing results; (3) verify disposition of affected product; (4) conduct followup sampling at the establishment and its suppliers; (5) conduct verification activities at the supplying establishment; (6) conduct a Food Safety Assessment [24] 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* O157:H7 in their HACCP plan, they may not have to reassess their plan in response to a positive test result.

   During Phase II of our audit, we will review how FSIS and the industry use positive N-60 test results.

10. *What is the implication of a positive N-60 test result on the individual lot tested? On other lots from the same establishment produced on the same date?*

[23] With the issuance of FSIS Notice 58-10, FSIS is now collecting supplier information at the time of sample collection.

[24] 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.

FSIS requires lots with a positive FSIS or industry test result for *E. coli* O157:H7 to be destroyed or used in a product that has a validated lethality treatment, such as cooking.[25]

The implication for other lots produced at the same establishment and on the same date depends on the establishment's operations and materials used. When ground beef is produced, it may be manufactured from trim and other ground beef components obtained from one or multiple suppliers. If product from one lot was found positive for *E. coli* O157:H7, HACCP regulations require a plant to provide a scientific basis to justify why any raw ground product produced from these source materials should not be considered adulterated. If the plant cannot demonstrate how its final production lots are scientifically independent, then all final product lots produced using the same source materials would be implicated and subject to cooking, discard, or recall.

11. *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?*

    According to agency procedures, when FSIS finds product to be *E. coli* O157:H7 positive, the inspection staff issues a noncompliance record, which requires the establishment to 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* O157:H7 positive product. According to FSIS officials, establishments are required to create a record of the positive in their HACCP system, in 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 II of our audit, we will review how industry sampling and testing protocols vary among plants and differ from FSIS standards.

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

[25] Directive 10,010.1, March 2010 notes this requirement in FSIS tested product.

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* O157:H7. 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 (COA) when a COA 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* O157:H7.

During Phase II of our audit, we will review if and how industry is currently labeling FSIS N-60 tested trim.

# Appendix B: Update to January 2008 Memorandum to Former Deputy Secretary Conner on *E. coli* Sampling and Testing

We followed up on matters reported in our memorandum, "Food Safety and Inspection Service Sampling and Testing of *E. coli*," issued January 29, 2008, related to examining the adequacy and effectiveness of FSIS' N-60 sampling method. In the memorandum, we reported that (1) FSIS needs to gather a more representative sample; (2) FSIS needs to minimize or eliminate discarded samples; and (3) FSIS needs to reduce turnaround time on laboratory results. To address our objective, we conducted interviews with USDA and non-USDA officials and reviewed FSIS documents and data produced since our January 29, 2008, letter.

According to industry experts, academics, and USDA officials, large producers have moved towards taking multiple samples from the same ground beef lot at intervals during the day, some as often as every 15 minutes. In addition, in July 2010, the Agricultural Marketing Service strengthened its National School Lunch Program purchase specifications for ground beef to include increasing microbiological sampling frequency for finished products to every 15 minutes and instituting additional rejection criteria for source trimmings. We believe that these changes should result in plants gathering a more representative sample, but we will not reach any conclusions until we have an opportunity to visit plants during Phase II of our audit.

FSIS has also taken steps to minimize the discarding of samples by documenting the reasons for discards and sending a monthly report to the districts for a followup review. An analysis of discard rates conducted by OIG for calendar years 2008, 2009, and part of 2010 found that there has been a significant decrease in the number of samples discarded by FSIS' laboratories.[26] In addition, officials expressed confidence that the new sample reservation system in FSIS' Public Health Information System (PHIS) will correct the problem of uncollected samples. When PHIS is implemented, FSIS needs to monitor the system to assure that PHIS will minimize or eliminate discard samples and help the agency to reach its *E. coli* O157:H7 sampling goals.

FSIS continues to experience delays in returning testing results to plants. We will followup in the next phase of this audit to determine whether FSIS or industry have identified any potential solutions for reducing these delays at this time.

Overall, FSIS sees its testing program as a means for ensuring that plants take adequate safety precautions. From the agency's perspective, in order to ensure food safety, plants must implement effective and supportable HACCP systems including microbiological intervention. In addition, consumers must be educated about properly cooking ground beef. During the course of our review, we found that FSIS has made a number of improvements to its *E. coli* O157:H7 sampling and testing program to accomplish these intended program objectives, including such things as:

[26] Our analysis shows that for the discard categories selected by OIG, there was a 40 percent drop in discards from 2008 to 2009 levels (865 to 516 discards) and indications of a deeper drop in 2010 (showing only 132 discards as of May 2010).

(1) Updating guidance concerning trim sampling, followup sampling, tracing product back to the source of the contamination, and conducting food safety assessments;

(2) Analyzing the results of controls used by industry to control *E. coli* O157:H7 in beef operations (based in part on this information, FSIS issued a best practices document);

(3) Participating in the President's Food Safety Working Group, which is advising on how to improve the U.S. food safety system for the twenty-first century; and

(4) Expanding its mode of food safety outreach to include Twitter, Facebook, and YouTube. The FSIS twitter feed, USDAFoodSafety, grew from 751 followers in 2009 to more than 55,000 in 2010.

During the course of our review we also identified that the industry is researching technology to reduce *E. coli* O157:H7 contamination to include developing more effective interventions to reduce or eliminate *E. coli* O157:H7 and developing vaccines to control *E. coli* O157:H7 in living animals.

We will assess the impact of these improvements in Phase II of our audit while performing steps to (1) observe the collection of beef trim samples by FSIS and employees at slaughter and processing establishments; (2) analyze how the beef industry's sampling and testing protocols vary among plants and compare to FSIS standards; (3) review the quality of private laboratory services provided to the beef industry for testing and discarding samples; and (4) examine how test results are used by FSIS and the beef industry to improve food safety.

## Abbreviations

| | |
|---|---|
| A2LA | American Association for Laboratory Accreditation |
| CCP | Critical Control Point |
| COA | Certificate of Analysis |
| FLS | Front Line Supervisor |
| GMP | Good Manufacturing Practices |
| FSIS | Food Safety and Inspection Service |
| HACCP | Hazard Analysis and Critical Control Points |
| HAV | Hazard Analysis Verification |
| IIC | Inspector-In-Charge |
| PHIS | Public Health Information System |
| PHV | Public Health Veterinarian |
| OIG | Office of Inspector General |
| SOP | Standard Operating Procedure |
| USDA | United States Department of Agriculture |

# USDA'S

# FOOD SAFETY AND INSPECTION SERVICE

# 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/ January 28, 2011
Administrator
Food Safety and Inspection Service

**SUBJECT:** Office of Inspector General (OIG) Official Draft Audit Report – Food Safety and Inspection Service N-60 Testing Protocol for *E. coli* O157:H7 – Phase I, Report number 24601-09-KC

The Food Safety and Inspection Service (FSIS) has reviewed this report and responded to each of the recommendations. We also have provided some general comments on the audit report findings, which clarify our proposed actions in response to the recommendations. We appreciate OIG's efforts to accurately characterize the N-60 sampling program and to provide creative recommendations that give FSIS the latitude needed to improve it.

General Comments

As noted in the report, sample collection and analysis is only one of the HACCP verification activities provided for under the regulations in 9 CFR 417. And specifically, FSIS sees N-60 sampling of beef trim as only one of a number of verification activities that FSIS conducts regarding establishment process controls for *E. coli* O157:H7. FSIS sampling of beef trim works along with inspection and other verification activities, including FSIS sampling of ground beef and other ground beef components and the review of establishment testing results, to detect and reduce *E. coli* O157:H7 in beef products.

In response to the Congressional requestor, the audit report focuses on the statistical design and outcome of discrete N-60 sampling events. We do not dispute the statistics presented in the report on this subject, but emphasize, as stated above, that a single N-60 sampling result is not viewed apart from other verification activities. Note that along with sampling and carcass-by-carcass inspection, more than 500,000 inspection procedures were performed in CY2010 at roughly 650 slaughter establishments that would also be subject to trim sampling. These inspection procedures, performed daily at slaughter establishments, play an important role in ensuring establishments are producing safe and wholesome products.

Further, to detect changes over time, an N-60 result often is analyzed along with not only other verification data but also other N-60 results. This is especially true among establishments who themselves take numerous N-60 samples over time as part of a statistical process control program. Notably, FSIS has recommended that industry take numerous, regular N-60 samples as part of a statistical process control program since 2008.[1] Thus, although a single N-60 sample result may not indicate definitively the success or failure of an establishment's process

[1] *Compliance Guideline for Sampling Beef Trimmings for* Escherichia coli *O157:H7*, Draft for Stakeholder Comment, FSIS, August 12, 2008.

controls for beef trim, it can be an important component of process control and verification programs, especially if the establishment or FSIS has taken multiple N-60 samples over time.

In regard to the recommendation that FSIS determine a national prevalence, FSIS agrees that this is important information for properly designing a sampling program.[2] However, a national prevalence estimate is not sufficient information to determine how to collect a sample from a lot, owing to the distinction between determining how many lots to test and how to collect a sample from each lot. In other words, prevalence data could inform how many lots to test nationwide, but not how to collect a sample from each lot. A sampling program, such as FSIS' trim sampling program, is a different concept than a sample collection method, such as N-60.

Our responses to the recommendations should be read in light of this discussion. Although the audit report acknowledges FSIS' approach of using sampling and inspection to verify an establishment's food safety plan and to ensure the safety of the food supply, the report does not consider the combined effect of these activities and instead considers sampling in isolation. The audit report criticizes FSIS' trim sampling program for having insufficient statistical power to detect contaminated product with high confidence. FSIS' mission is not to screen the food supply through testing, but to ensure production of safe and wholesome food through inspection.

In response to the recommendations, needed improvements to FSIS verification of process controls for *E. coli* O157:H7 in beef trim and other ground beef components will include changes to multiple inspection and analytical activities, focusing on the improved collection and integration of various data to better identify establishments with process control problems. Further, FSIS agrees that a plan for conducting additional baselines for beef trim and other products is necessary, but these baselines also will be used to inform FSIS verification of establishment food safety systems over time, rather than to design an acceptance testing method for individual lots of product.

Recommendation 1

Develop a plan with specific timeframes and milestones to prioritize and perform necessary baseline studies of beef trim and ground beef in order to determine the estimated prevalence rate of *E. coli* O157:H7 for redesigning FSIS' sampling program. The plan should include how often the prevalence should be reassessed.

Agency Response

FSIS will develop a plan for prioritizing and performing *E. coli* O157:H7 baseline studies of beef, including ground beef, trim and other ground beef components, for the purpose of informing and improving overall FSIS verification programs for control of the pathogen. FSIS will publish the plan for comment before it is made final.

Completion Date: December 2011

[2] FSIS recently published the national prevalence estimate of pathogen contamination of trim based on the 2005-07 beef trim baseline study: http://www.fsis.usda.gov/PDF/Baseline_Data_Domestic_Beef_Trimmings_Rev.pdf.

Recommendation 2
Re-evaluate its sample parameters (size and confidence level) and redesign a sampling program for *E. coli* O157:H7 in beef trim that provides higher confidence in FSIS accurately detecting contaminated product in order to effectively verify process controls at beef processing plants across the nation.

Agency Response

FSIS will evaluate its sampling program in the context of prevalence data and inspection verification data. FSIS believes that effective verification of food safety systems must include inspection of an establishment's production process to ensure that controls are adequately designed and implemented to prevent, eliminate or reduce contamination with *E. coli* O157:H7. To improve inspection program personnel verification of process controls for the reduction of *E. coli* O157:H7 at both beef slaughter and processing establishments, FSIS will be taking the following actions during 2011. Together, these actions will give inspection program personnel comprehensive, aggregate data on establishment process controls for *E. coli* O157:H7.

- FSIS will revise Directive 6410.1, *Verifying Sanitary Dressing and Process Control Procedures in Slaughter Operations of Cattle of Any Age*, with a special emphasis on improving and clarifying verification of sanitary dressing, given that contamination of carcasses is the primary cause of ground beef component adulteration by *E. coli* O157:H7.
- FSIS will issue a new Notice regarding traceback methodology for *E. coli* O157:H7 in ground beef components after FSIS or other Federal or State agencies find ground beef or bench trim tests presumptive positive for *E. coli* O157:H7. This Notice will provide instructions concerning how to conduct product traceback from the grinder or bench trim establishment and what to do at originating supplier slaughter establishments following a confirmed positive for *E. coli* O157:H7 in ground beef, including assessing whether evidence of a high event period may have occurred and how to manage information gathered during a product traceback.
- FSIS will implement a new inspection procedure, the Hazard Analysis Verification (HAV), which will examine an establishment's hazard analysis and decision making documents. The HAV will serve as a screening process to identify issues of concern in the design of the establishments' food safety systems. HAVs will be performed at specified frequencies and when certain information prompts identify establishments that may have modified their HACCP system or may have failed to change their HACCP plan in response to a significant change in the establishments' process. A HAV will verify that the establishment's hazard analysis addresses the applicable food safety hazards for the process, product, and intended use. It will also verify that there is at least one CCP for the hazards that are reasonably likely to occur and that there is support for any decisions that applicable hazards are not reasonably likely to occur. It will also verify that any prerequisite programs (such as an SOP, GMP, purchase specifications, etc.) which are intended to prevent the occurrence of the food safety hazard are adequately justified and properly implemented.

Completion Date: December 2011

Recommendation 3

Thoroughly document the scientific support and rationale for FSIS' revised *E.coli* O157:H7 sampling program design, including the contamination level that will be associated with the new sample parameters and how the estimated prevalence rate impacts the new design. Publish FSIS' revised *E. coli* O157:H7 sampling design with its support and rationale for public comment, and consider any recommended changes before implementing the new sampling program.

Agency Response

FSIS will develop a plan for prioritizing and performing *E. coli* O157:H7 baseline studies of beef, including ground beef, trim and other ground beef components, for the purpose of informing and improving FSIS verification programs for control of the pathogen. FSIS will publish the plan for comment before it is made final.

FSIS also will be taking the following actions in 2011 (as stated above in response to Recommendation #2) to improve inspection program personnel verification of food safety systems for the prevention, elimination or reduction of *E. coli* O157:H7 at both raw beef slaughter and processing establishments. Together, these actions will give inspection program personnel comprehensive, aggregate data on establishment process controls for *E. coli* O157:H7.

- FSIS will revise Directive 6410.1, *Verifying Sanitary Dressing and Process Control Procedures in Slaughter Operations of Cattle of Any Age*, with a special emphasis on improving and clarifying verification of sanitary dressing, given that contamination of carcasses is the primary cause of ground beef component adulteration by *E. coli* O157:H7.
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prerequisite programs (such as an SOP, GMP, purchase specifications, etc.) which are intended to prevent the occurrence of the food safety hazard are adequately justified and properly implemented.

Completion Date: December 2011

Recommendation 4
Develop a detailed operational plan with specific timeframes and milestones to implement an inspection system that focuses *E. coli* O157:H7 sampling and testing resources primarily at plants that are likely to be of higher risk and consider the use of specialized sample collection teams.

Agency Response

FSIS will evaluate its sampling program in the context of prevalence data and inspection verification data. FSIS believes that effective verification of food safety systems must include inspection of an establishment's production process to ensure that controls are adequately designed and implemented to prevent, eliminate or reduce contamination with *E. coli* O157:H7. To improve inspection program personnel verification of process controls for the reduction of *E. coli* O157:H7 at both beef slaughter and processing establishments, FSIS will be taking the following actions during 2011. Together, these actions will give inspection program personnel comprehensive, aggregate data on establishment process controls for *E. coli* O157:H7.

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- FSIS will implement a new inspection procedure, the Hazard Analysis Verification (HAV), which will examine an establishment's hazard analysis and decision making documents. The HAV will serve as a screening process to identify issues of concern in the design of the establishments' food safety systems. HAVs will be performed at specified frequencies and when certain information prompts identify establishments that may have modified their HACCP system or may have failed to change their HACCP plan in response to a significant change in the establishments' process. A HAV will verify that the establishment's hazard analysis addresses the applicable food safety hazards for the process, product, and intended use. It will also verify that there is at least one CCP for the hazards that are reasonably likely to occur and that there is

support for any decisions that applicable hazards are not reasonably likely to occur. It will also verify that any prerequisite programs (such as an SOP, GMP, purchase specifications, etc.) which are intended to prevent the occurrence of the food safety hazard are adequately justified and properly implemented.

Completion Date: December 2011