United States Department of Agriculture
Office of Inspector General

FSIS *E. coli* Testing of Boxed Beef

Audit Report 24601-0003-31
March 2013

Review of the FSIS *E. coli* Testing of Boxed Beef

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What Were OIG's Objectives

Our objectives were to examine whether FSIS was sampling boxed beef products, as required by agency procedures, and requesting correct samples, and whether the industry's trace back documentation is adequate and used effectively to determine the source of *E. coli* contamination.

What OIG Reviewed

We conducted fieldwork at 11 processing facilities in 5 States to gain an understanding of the testing of incoming boxed beef, bench trim, and final ground beef products. We analyzed PHIS profile data from 1,750 establishments and selected 22 for additional review.

What OIG Recommends

We recommended that FSIS take additional steps to ensure that beef to be ground throughout the production process—from Federally inspected slaughter establishments to local grocery stores—be subject to FSIS sampling and testing for *E. coli.* The agency agreed with all 12 recommendations and we accepted management decision.

OIG audited FSIS to determine how effectively the agency was testing boxed beef items that downstream processors used for ground beef production.

What OIG Found

The Office of Inspector General (OIG) found that the Food Safety Inspection Service (FSIS) needs to re-evaluate its *E. coli* testing methodology, as it relates to the downstream processing of boxed beef products. FSIS tests product designated as ground beef or likely to become ground beef, but they do not sample all boxed beef product. Some downstream processors grind such boxes of unsampled cuts of beef without sampling it for *E. coli* prior to grinding. Similarly, "retail exempt establishments"—grocery stores, butcher shops, etc.—potentially grind their own ground beef; but unlike Federally inspected plants, FSIS does not sample and test bench trim at these establishments for *E. coli*. FSIS does have a program for periodically testing the final ground beef products at downstream processors and retail exempt establishments before it enters commerce. Also, FSIS is not testing tenderized meat products for *E. coli* despite several recent recalls.

FSIS has recently transitioned to their new Public Health Information System (PHIS), which relies, in part; on correct profile information to accomplish such tasks as sending inspectors *E. coli* sampling requests. However, we found some establishments had incorrect profile information, resulting in incorrect requests for sampling. This profile error caused FSIS not to sample one establishment's "other ground beef components" for over 4 years. However, FSIS did sample the ground product before it left the plant.

Lastly, not all plants we reviewed had adequate records for tracing source material back to the originating slaughter establishment. Such information is crucial during a recall.

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

DATE: March 22, 2013

AUDIT NUMBER: 24061-0003-31

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

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

FROM: Gil H. Harden
Assistant Inspector General for Audit

SUBJECT: FSIS *E.coli* Testing of Boxed Beef

This report presents the results of the subject audit. Your written response, dated March 12, 2013, to the official draft report is included, in its entirety, at the end of this report. Your response and the Office of Inspector General's position are incorportated into the relevant sections of the report. Based on your written response, we are accepting your management decisions for all audit recommendations in the report, and no further response to this office is necessary.

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

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

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Background and Objectives

Background

As cattle are being slaughtered, the production environment in the slaughter and processing establishments can expose meat products to bacteria. Although many bacteria strains are harmless, other strains of bacteria are dangerous. One strain of bacteria, *E. coli* O157:H7, is especially harmful and can result in serious illness or even death. 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 causes about 73,000 cases of illness and 61 deaths annually in the U.S. The U.S. Department of Agriculture's (USDA) Economic Research Service estimates that the total costs associated with consuming *E. coli*-contaminated meat are about $488 million annually.[1]

Because it is the external surface of meat cuts where bacterial contamination most often occurs, certain cuts of meat carry more serious risks. "Intact product," such as steaks and roasts, provides a lower degree of risk from this pathogen[2] because the normal cooking process will expose the area most likely containing contamination to temperatures that would kill the bacteria. Non-intact product, such as ground beef and tenderized cuts, pose a higher degree of risk because the process of grinding and tenderizing relocates potentially contaminated surface tissue to the interior, where it may not be exposed to temperatures sufficient to eliminate the pathogen. Additional risk is incurred when processors tenderize beef to break down the connective tissue in the meat so that the cut is more palatable to consumers.[3]

In response to the diversity of components used by industry in non-intact products, Food Safety and Inspection Service (FSIS) has implemented a variety of different *E. coli* sampling programs for components of ground beef, which include beef manufacturing trimmings, bench trim,[4] and other components.[5] FSIS also has a limited sampling program for the ground beef being sold at

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[1] *USDA Economic Research Service Data Foodborne Illness Cost Calculator*, March 6, 2012.

[2] *The American Heritage Dictionary of the English Language* defines a "pathogen" as an agent that causes disease, such as living microorganisms like bacteria.

[3] There are two main methods of tenderizing meat, cubing (or macerating) and needle (or blade) tenderization. The cube method gives consumers cuts known as "cube steaks" or cuts used for "chicken fried steaks." However, needle tenderization is less obvious and can be used on almost any cut of steak or roast. To make tenderized product, the processor must penetrate the exterior of the cut, possibly relocating *E. coli* on the exterior to the interior of the cut. Needle tenderization can cause additional concern, especially when it is used in conjunction with marinade solutions which would allow the transfer of *E. coli* to the interior by means of the liquid solution.

[4] Bench trim is the term for the small bits and pieces the processor would remove from the larger cut to make the steak or roast easy to cook or more appealing for the consumer. FSIS defines bench trim as trim originating from a source other than the slaughter establishment which includes whole muscles (or boxed beef) that are to be ground at a downstream processor.

[5] FSIS began testing ground beef for *E. coli* O157:H7 in 1994. Beginning in 2007, the agency expanded its testing program to include testing beef trim, and in 2009, FSIS began testing bench trim.

retail establishments. In 2011, FSIS analyzed 12,422 ground beef samples, 1,267 trim samples, 677 bench trim samples, 1,024 retail samples, and 228 other raw ground beef components.

Ground beef arrives to the consumer through several methods. The large slaughter/processing establishments produce most of the ground beef consumed in the U.S and most of the source materials used in these plants are subject to FSIS testing, which OIG reviewed in a previous audit report.[6] However, downstream processors[7] also produce their own ground beef products and sometimes the components they use in their grind are not normally subjected to FSIS sampling, such as whole primal and sub-primal[8] cuts (usually chucks, rounds, or sirloins).

USDA's FSIS is responsible for protecting consumers by ensuring that beef is safe, wholesome, and accurately labeled. While slaughter and processing establishments are ultimately responsible for ensuring that their product is wholesome, FSIS provides assurance to consumers that the beef meets USDA standards. Plants use a variety of tools to help provide assurance as to the wholesomeness of their product; for example, the makers or users of boxed beef materials could apply antimicrobial treatments. Most plants often independently test their product for pathogenic bacteria and FSIS also conducts periodic testing in order to verify the effectiveness of the interventions used by the plant. Also, FSIS announced in a Federal Register Notice that when *E. coli* positive test results are found in beef trimmings at downstream processors or the originating slaughter plant, FSIS will collect multiple follow-up samples and conduct verification activities at the originating slaughter establishment. However, no method of statistical sampling and testing can guarantee a particular lot of product is entirely free from *E. coli.*[9]

While FSIS is responsible for enforcing laws related to the adulteration of ground beef by *E. coli*, Federal regulations[10] exempt retail establishments from the same level of oversight as Federally inspected slaughter plants, even when these retail establishments may be conducting the same production activities as used by their parallel processors (*viz*., they grind cuts of beef and trim into ground beef). FSIS estimated there are approximately 64,000 retail exempt facilities. Facilities that choose to grind their own ground beef generally use source material that bears a USDA mark of inspection, which means the product was produced at a Federally inspected facility.[11] While retail exempt facilities are not under the direct supervision of FSIS, they must abide by State or local codes and inspection, and FSIS' inspection or sampling is occasionally

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[6] OIG Report 24601-0001-31: *Application of FSIS Sampling Protocol for Testing Beef Trim for E. coli O157:H7* (issued May 2012).

[7] Downstream processors can include Federally and non-Federally inspected establishments ranging from mid-stream wholesalers to retail outlets such as grocery stores, hotels, and restaurants.

[8] Primals and Sub-primal cuts are muscle groups from the carcass usually consisting of the chucks, rounds, loins, and ribs.

[9] FSIS intends to implement new traceback procedures at beef manufacturing trimming suppliers that provided source materials for ground products or bench trim (trim derived from beef at an establishment other than the originating slaughter establishment) that FSIS finds positive. When FSIS implements these new traceback procedures, the Agency expects that the data gathered will enable it to better target sampling at slaughter establishments.

[10] Title 9 of the *Code of Federal Regulations,* part 303.

[11] In some instances the source product may be derived from State inspected establishments.

done on a "for cause" basis.[12] FSIS compliance investigators are instructed to collect samples when retail establishments engage in riskier grinding practices such as grinding boxed beef product that is not accompanied with negative *E. coli* test results from the upstream processing plant.[13]

As for the sampling programs, FSIS recently began using the Public Health Information System (PHIS). PHIS is a web-based information management system that FSIS uses to maintain information on Federally inspected plants.[14] Information maintained by this system includes plant production details. They system is used by FSIS to manage information and schedule tasks for the in-plant inspection personnel, such as when to collect *E. coli* samples for the various sampling programs.

While conducting fieldwork for Audit 24601-0001-31, the audit team became aware of the potential for downstream processors to grind untested boxed beef products and wanted to determine if FSIS field personnel were properly considering these products for *E. coli* sampling. The large slaughter facilities will place the meat cuts, such as chucks, rounds, or sirloins, into individually vacuum sealed bags, which are shipped in large boxes often weighing more than 60 pounds apiece. While the slaughter establishment may have intended these boxed beef products to be used as intact products (thus they were not subject to *E. coli* testing), downstream processors might choose to grind the meat. Although FSIS maintains an extensive ground beef sampling program for these Federally inspected downstream processors, the untested boxed beef and its trim might not be adequately considered for sampling prior to grinding. Studies have shown that sampling trim has a potentially higher probability of finding *E. coli* than sampling ground beef.[15]

In the course of this review, OIG focused primarily on FSIS sampling of boxed beef used in ground product. OIG also determined to review FSIS' PHIS plant production details as they related to *E. coli* sample selection. In addition, while OIG prepared for this review, a retail establishment's recall uncovered that the grinding logs to trace the contaminated product to the source were not maintained. Therefore, we wanted to determine if the same inadequate grinding logs condition existed, especially at the smaller Federally inspected downstream processors. Lastly, OIG wanted to know if the upstream slaughter plants were using labels such as "not intended for grinding" on their boxed beef and how that impacted food safety.

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[12] In addition to these routine sampling programs, most microbiology programs have a consequential (for cause) sampling component when the production process within a regulated establishment is determined to be out of control.

[13] FSIS Directive 8010.1 Rev. 3, Appendix 1, *Instructions for Collecting Surveillance Samples of Raw Ground Beef at Retail for E. coli O157:H7 Analysis*, provides the instructions for when FSIS compliance investigators should collect samples from retail exempt establishments.

[14] FSIS Directive 5,300.1, *Managing the Establishment Profile in the Public Health Information System*.

[15] OIG Audit Report 24601-0001-31 – Finding 2.

Objectives

Our objectives were to examine whether: (1) FSIS is sampling boxed beef products, as required in agency procedures; (2) FSIS is entering plant profile data correctly into PHIS to ensure the plant is eligible for trim or bench trim sampling requests; (3) industry's trace back documentation is adequate and used effectively to determine the source when *E. coli* is found; and (4) industry is identifying or labeling boxed beef product with "not intended for grinding" and how that impacts food safety.

This report does not reflect any finding(s) related to objective number 4, regarding the labeling of boxed beef product with "not intended for grinding." At the end of our prior audit, 24601-0001-31, we were informed that one plant potentially used these labels on boxed beef materials. We believed this was an issue to address because it potentially shifted the prevention of pathogen contamination responsibilities from the originating slaughter plant to the downstream processor. Therefore, on this follow up audit, we included it as part of our objectives. However, we did not find any use of "not intended for grinding" labels at the downstream processing or the upstream slaughter establishments we visited. According to FSIS, it does not approve labels with this statement. FSIS officials noted that the agency may approve instructional or disclaimer statements, but a "not intended for grinding" statement does not qualify as either an instructional or disclaimer statement. Therefore, we are not reporting on this portion of the objective.

Section 1: Boxed Beef Related Concerns

Finding 1: FSIS Needs to Ensure that All Components of Ground Beef are Included in the Agency's *E. coli* Testing Program

Although FSIS has a comprehensive system for testing the various cuts of beef that consumers may buy as ground beef, it needs to reevaluate its *E.* coli testing methodology as it relates to the downstream processing of boxed beef products. For instance, at large processing plants we visited, FSIS and the plants tested product that was designated as ground beef or trim destined to become ground beef, but they generally did not test boxed beef product, even though some downstream establishments may be grinding that product.[16] Establishments downstream receive such boxed beef product bearing the USDA mark of inspection and may assume that it is pathogen free and, therefore, safe for grinding; however, the product was seldom considered eligible for testing for *E. coli*. When we asked why this type of product was generally excluded from testing, FSIS officials explained that they intended for these boxed beef products to be tested under their procedures for testing bench trim,[17] but that they did not adequately convey their intentions to FSIS inspection personnel in the plants. As a result, some portion of the product used to produce the ground beef consumers purchase is not included in FSIS sampling, and the public has less assurance that ground beef is not contaminated. Several recalls of these types of components used in ground beef have occurred. In 2008, FSIS recalled 1.3 million pounds of boxed beef product that had contributed to making 35 people ill. In 2009, a recall of 380,000 pounds became necessary when 24 illnesses in 10 States were linked to bench trim (boxed beef) that was not eligible for FSIS' *E. coli* testing.

FSIS is responsible for performing verification sampling of ground beef components to ensure a plant's Hazard Analysis and Critical Control Points (HACCP) plan is functioning properly.[18, 19] At upstream slaughter plants, FSIS tests ground beef and trim destined to become ground beef, but the agency and industry have determined that boxed beef product intended for steaks and

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[16] For our purposes, the term "boxed beef" product means boxed whole beef cuts of primals or subprimals that are packaged at the slaughter plant into large boxes, which downstream processors might further divide into individual steaks, roasts, or other cuts, or grind into hamburger. OIG acknowledges that other cuts of trim or smaller muscle cuts, which are exposed to plant or FSIS testing, can also be shipped in boxes and sometimes referred to as boxed beef as well; however, this audit did not review this type of source material.

[17] As per FSIS Directive 10,010.1 Rev. 3, Chapter II, Section IV., B. *Sample Collection Procedures For Beef Manufacturing Trimmings*: Bench Trim may be defined as trimmings from an animal not slaughtered on the premises and may also include secondary trimming of primals, sub-primals or any other cuts designated for non-intact use, derived from cattle not slaughtered on site at the establishment. These trimmings are to be sampled under the MT55 sampling code.

[18] 9 CFR §417.8: *Agency Verification*: "FSIS will verify the adequacy of the HACCP plan(s) by determining that each HACCP plan meets the requirements of this part and all other applicable regulations."

[19] FSIS Directive 5,000.1 Rev. 3, Chapter II *HACCP* notes that 9 CFR 417.2 (b) requires that every official [Federal] establishment must develop and implement a HACCP plan covering each product produced. It is then FSIS' responsibility to perform verification activities in order to provide a basis for making informed decisions regarding whether the establishment is in compliance with its HACCP plan. According to this CFR citation, only Federal "official establishments" are required to have HACCP plans. There are many other non-federal establishments that handle meat products and there is no requirement that they have HACCP plans.

roasts does not need to be tested.[20] When such product reaches downstream processing establishments, those plants sometimes choose to grind it to make products like steak burgers or ground round. FSIS officials stated that they intend for whole boxed beef cuts that are to be ground at this stage to be sampled under the agency's bench trim testing program, and even though boxed beef itself may not have been considered eligible for testing by FSIS at the slaughter plant, the ground product at the grinder should be subject to FSIS testing.[21] FSIS officials also noted that downstream grinders should be considering and addressing the potential for pathogens in their source product when they perform their hazard analysis.

We found, however, that FSIS' directives to its in-plant inspection personnel on whether to test boxed beef product intended for grinding at downstream processors were unclear. Although one section of FSIS' directive states that boxed beef should be sampled as bench trim, the section of the directive related to sampling bench trim does not mention that boxed beef should be eligible for sampling.[22]

We visited five downstream processing plants where the plant was grinding boxed beef product and found that FSIS inspectors were not testing the boxed beef product intended for grinding for *E. coli* at four of the five plants. When we spoke to FSIS inspectors at these four plants they stated that they did not believe that boxed beef product was eligible for testing prior to being ground. One inspector noted that FSIS directives were unclear and did not explicitly direct sampling of boxed beef product. Other inspectors were confused in that they did not believe they should be sampling the whole cuts of boxed beef, but only the trimmings from the boxed beef. A supervisor also explained that this product should not be sampled. The supervisor stated that they would only instruct their staff to sample products that were cut or ground at their facilities and that if boxed beef came from another FSIS inspected facility, the inspector staff should not sample the boxed product. We found, however, that the fifth inspector was correctly sampling boxed beef whole muscle product before it was ground.

The grinding of boxed beef into ground beef in downstream processing plants has caused several recalls. In 2008, 35 people became ill in Michigan and Ohio. FSIS traced the problem back to a slaughter plant in Nebraska that had shipped boxed beef products to downstream processing plants that then ground the beef. This occurred without testing for *E. coli*. As a result, FSIS and the plants recalled approximately 1.3 million pounds of beef products.[23] In 2009, 24 people in 10 States were made ill. FSIS determined that the source of the problem was a slaughter establishment in Colorado that had shipped boxed beef products to downstream processing plants that then ground the beef, all without testing for *E. coli*. As a result, FSIS and the plants recalled

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[20] FSIS Directive 10,010.1 Rev. 3, Chapter II, Section IV, B. *Sample Collection Procedures for Beef Manufacturing Trimmings*, 2: "IPP[inspection program personnel] are not to sample product that the establishment intends for use in intact product or ready-to-eat products."

[21] FSIS recently issued High Event Period policies as guidance to industry, which address the higher likelihood that primals and sub-primals could become contaminated when slaughter plants have an increased amount of *E. coli* positive test results.

[22] OIG compared FSIS Directive 10,010.1 Rev. 3, Chapter II, Section IV., B. *Sample Collection Procedures For Beef Manufacturing Trimmings* with FSIS Directive 10,010.1 Rev. 3, Chapter II, Section V: *Routine Sampling and Testing of Beef Manufacturing Trimmings Derived From Cattle Not Slaughtered in That Establishment (Bench Trim) For E. coli O157:H7.*

[23] Product recall Nebraska Beef Ltd., Omaha, Nebraska, in 2008.

approximately 380,000 pounds of beef products.[24] Also, in September 2012, FSIS issued a public health alert noting that *E. coli* contaminated whole muscle boxed beef cuts that were produced in Canada were being recalled because they had been used to produce raw ground beef in the United States.[25]

As part of our review, we traced back boxed beef product at two of these downstream processors to a common upstream slaughter plant. At both of these downstream processors, FSIS was not sampling product prior to grinding. We visited the upstream slaughter plant and confirmed that FSIS and the plant were not sampling the boxed beef product prior to it being shipped. We concluded that this product was being ground without FSIS considering it eligible for *E. coli* contamination testing.[26]

We also noted that FSIS does suggest that downstream processors test incoming beef from upstream slaughter plants,[27] but that 9 of the 11 plants we visited were not following this guidance. Personnel at the nine plants stated they did not follow this guidance, due to either the expense involved to do the testing or product freshness issues in waiting for results. The other two plants that were testing were larger plants that had responded to more rigorous product quality demands from their customers. Under FSIS' current bench trim testing program, the agency does not consider a downstream processor's own verification testing (or lack of testing) when determining the frequency of sampling. In OIG's opinion, if a downstream processor does not perform incoming product verification testing, its production is at higher risk for *E. coli* contamination and should be considered for additional FSIS bench trim sampling.

When we brought these issues to the attention of FSIS officials at the national office, who are responsible for the design and implementation of FSIS' *E. coli* testing procedures, they agreed that boxed beef product intended for grinding at a downstream processor should be sampled and tested. They also agreed that the directive could be made clearer to ensure that plant personnel perform these tests, and stated that such grinding was potentially higher risk.[28]

FSIS also expressed concern that this report did not take into consideration the many methods of *E. coli* sampling the plants and the agency perform. OIG acknowledges that, at the upstream slaughter plants, ground beef components, such as beef trim and the outgoing ground product, are subject to plant and FSIS sampling. In addition, final ground beef products are subject to FSIS sampling at the downstream processors and retail exempt establishments. However, this report focuses on boxes of primal and sub-primal cuts—such as non-two piece chucks, rounds, and sirloins—that are normally not tested at the originating slaughter plant and are sometimes

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[24] Product recall Swift Beef Company (establishment number 969), Greeley, Colorado, case 034-2009.
[25] Public health alert XL Foods Inc., Alberta, Canada, in 2012.
[26] Although the boxed beef was not sampled and tested for *E. coli* prior to grinding, the finished ground beef would have been eligible for testing under FSIS' MT43 (Routine Testing of Raw Ground Beef) program.
[27] FSIS Draft for Stakeholder Comment, August 12, 2008: *Compliance Guideline for Sampling Beef Trimmings for Escherichia coli* O157:H7, Chapter II: General Guidance for Verification Testing of *E. coli* O157:H7: "FSIS recommends that establishments conduct verification testing directly for *E. coli* O157:H7."
[28] Specifically, agency officials believe that bench trim from the fabrication of whole muscle cuts at downsteam processors and trim from slaughter establishments is being sampled by their in-plant inspectors but they agreed that the FSIS needs "…to make sure that larger cuts that may not have been sampled at the slaughter establishment are being sampled if they are being thrown into the grinder."

used for ground beef production at the downstream processing plants. Also, consumers should be aware that grinding of untested boxed beef occurs outside the scope and jurisdiction of FSIS, such as at restaurants, institutions, and a growing trend of grinding whole muscle cuts at home. Therefore, it is prudent for the consumer to follow FSIS food safety guidelines for cooking ground beef products.[29]

Finally, we noted that PHIS is capturing information on the final products that plants are selling, but does not completely capture information on the types of source material downstream processors are using to make those final products. As a result, product to be ground may not be entered in the appropriate trim sampling program by FSIS in-plant inspectors. In order to make PHIS more useful in helping inspectors conduct required tests of bench trim, we maintain that PHIS should be improved to capture such source information. Agency officials stated that there is no reliable way for FSIS to determine what product is destined to be ground, which is purely the establishments' business decision; therefore, PHIS could not accurately capture this information. OIG acknowledges PHIS may or may not be the proper system to capture this information, but we believe that FSIS needs this information to identify the proper universe of establishments when developing the agency's sample selection algorithm that determines the bench trim sample requests.

Overall, OIG concluded that FSIS needs to take additional steps to ensure that boxed beef product being ground is considered eligible for FSIS *E. coli* testing. The agency needs to communicate this requirement to its in-plant personnel and also include important information in PHIS, so that agency officials can identify where such testing should take place.

Recommendation 1

Reevaluate procedures for sampling boxed beef product as bench trim and issue clarification to FSIS' inspectors on the agency's requirements. Also, consider the risk associated with a downstream processor's own verification testing (or lack of testing) when evaluating the frequency of sampling.

Agency Response

FSIS agrees that boxed beef product designated as intended for grinding at a "downstream" processor should be eligible for sampling and testing as "bench trim" at the grinding establishment by FSIS. FSIS has issued guidance to industry recommending that establishments conduct such verification activities to demonstrate the on-going effectiveness of their food safety systems, including prerequisite programs. The agency will clarify its instructions to agency inspection personnel in FSIS Directive 10,010.1, *Verification Activities for Escherichia coli O157:H7 in Raw Beef Products,* and in related AskFSIS questions that FSIS policy is that "bench trim" derived from boxed beef sub-primals at "downstream" grinders is subject to testing under the MT55 testing program. FSIS will clarify that whenever a whole primal or sub-primal cut is received at a non-slaughter establishment and is intended for grinding (not just the

[29] To limit a consumers exposure to possible *E. coli* contamination, USDA recommends cooking ground beef to an internal temperature of 160 degrees Fahrenheit as measured by a food thermometer.

trimmings from these cuts), the whole primal or sub-primal cut is considered to be bench trim and subject to being sampled.

Using the results of the analysis outlined under Recommendation 3, FSIS will consider adjusting the frequency of testing when "downstream" grinders maintain their own testing programs.

The estimated completion date for all parts of this response is March 2014.

OIG Position

We accept management decision for this recommendation.

Recommendation 2

Prepare a plan with reasonable timeframes to evaluate whether PHIS or another system should be modified or developed to capture additional information regarding the type of incoming product (i.e., boxes of whole muscles beef cuts) that is being ground by downstream processing establishments, in order to improve FSIS' ability to assign the appropriate *E. coli* sampling program requests, and implement any necessary actions based on the evaluation.

Agency Response

FSIS will perform a survey using a new functionality in PHIS to determine which downstream (non-slaughter) establishments receive whole primal or sub-primal cuts and then grind them. FSIS will then update these establishments' profiles in PHIS to reflect this fact. This information will help identify those establishments where whole primal or sub-primal cuts are eligible for sampling and testing under the MT55 testing program. A mechanism to capture this information in PHIS will soon be operational. PHIS will have a survey functionality that will be operational in June 2013, which will allow inspection program personnel to input answers to survey questions. FSIS will use the new survey function to collect information on which downstream establishments grind whole primal or sub-primal cuts, and then PHIS establishment profiles will be updated accordingly.

The estimated completion date for all parts of this response is December 2013.

OIG Position

We accept management decision for this recommendation.

Finding 2: FSIS Needs to Improve How It Oversees the Grinding of Bench Trim at Retail Exempt Establishments

Although FSIS is responsible for ensuring that ground beef is free from *E. coli* contamination, a significant amount of bench trim is ground in the nation's approximately 64,000 "retail exempt establishments"—grocery stores, wholesale clubs, and butcher shops—where FSIS may periodically visit, but the agency does not sample and test bench trim for *E. coli* like it does in Federally inspected plants.[30] These establishments are directly regulated by State and local health authorities and since these retail exempt establishments do not have Federally required HACCP plans, FSIS is not required to perform the *E. coli* sampling that it would ordinarily perform for monitoring and verifying HACCP plans at a larger Federally inspected plant.[31] Agency officials agreed that they could look more closely at the food safety risk posed by grinding at retail exempt establishments.[32] Consumers who purchase ground beef that was ground in retail exempt establishments are not receiving the same safeguards from *E. coli* pathogen testing as those who purchase ground product prepared in a Federally inspected establishment. Recent recalls from these types of establishments have been related to over a dozen illnesses.

FSIS is responsible for enforcing the laws intended to ensure that ground beef is not contaminated with *E. coli*, but the requirements of the Federal Meat Inspection Act (FMIA)[33] and the regulations for inspection of the preparation of products do not apply to operations traditionally conducted at retail stores and restaurants, when sold in normal retail quantities.[34] Specifically, bench trim that is being ground into hamburger at retail exempt establishments is not included in FSIS' *E. coli* trim sampling program. To qualify as retail exempt, these facilities must use source material that bears the USDA or State mark of inspection. However, FSIS has acknowledged that retailers sometimes engage in high risk practices, such as grinding boxed beef along with store displayed primal and sub-primal cuts that are at the end of their shelf-lives, thereby treating boxed beef and exposed beef without distinction.

The vast preponderance of FSIS' testing resources are being directed at approximately 1,700 Federally inspected plants. At present, FSIS compliance investigators visit retail exempt establishments, but they do so infrequently (once a year at best), and they take relatively few *E. coli* samples. Investigators are to collect ground beef samples when retail establishments grind primals, sub-primals, purchased trim, boxed beef, or other components that are not accompanied by records of negative *E. coli* O157:H7 test results. Additionally, investigators are to collect ground beef samples at retailers that fail to keep records sufficient for trace back, or

[30] FMIA gives FSIS the authority to ensure that meat products are wholesome and not adulterated; however, under FSIS' current *E. coli* sampling program, the agency has chosen to utilize its limited sampling resources to sample only ground beef at retail establishments, and not bench trim.
[31] 9 CFR§ 417.8 (g).
[32] FMIA specifically provides for exemptions from federal inspection requirements for some establishments. Within the context of FMIA, 9 CFR 303.1 (d) (2) further defines the types of meat processing operations that can be conducted at retail stores and restaurants without direct FSIS oversight. The Act provides for certain exemptions to Federal inspections, which limits FSIS' ability to closely regulate and provide oversight for all the food handling activities that occur in retail exempt establishments.
[33] Federal Meat Inspection Act, Title 21 U.S.C., Chapter 12, Meat Inspection, section 601 et seq.
[34] 9 CFR§ 303.1(d),(2),(ii).

retailers that grind store-generated bench trim derived from their own operation. However, only 1,024 of 13,446 (7.6 percent) samples of finished ground beef that FSIS took in 2011 were taken from retail exempt establishments.[35] Given that there are about 64,000 retail exempt establishments, FSIS sampled less than two percent of the retail establishments during 2011.[36] As a result, a substantial quantity of beef is being ground with little chance of FSIS sampling at the retail level, and in no case at present does FSIS test the bench trim at retail exempt establishments before it is ground.[37]

Retail establishments have been involved in recalls resulting from pathogen contamination. For example, a large grocery store chain in the northeast was forced to recall a large amount of ground beef, produced from in-store beef grinding, after at least 14 persons became ill.[38] During another recall involving beef ground at retail locations, customers were made ill by *E. coli*-tainted ground beef they purchased that was derived from bench trim.[39]

FSIS officials have tended to limit the types of activities, like sampling, that they perform in retail establishments because FMIA provides operations that conduct less complex food handling activities with relief from the requirement of continuous FSIS inspection. Regulations provide that these exempt food handling activities may include things like slicing, grinding, freezing, curing, cooking, smoking, wrapping, and rewrapping. Establishments that conduct these "retail" and similar type meat handling operations are therefore exempt from direct daily FSIS oversight.[40] When we spoke to FSIS officials and presented to them our concerns about the lack of oversight of bench trim at retail exempt establishments, they agreed that they would look more closely at the food safety risk posed by grinding at such establishments.

FSIS officials stated that they had actually reduced their classification of the risk posed by such establishments, based on the findings and recommendations of an outside scientific study.[41] That scientific study, OIG contends, is based on the assumption that adequate oversight is being performed by State and local officials at retail exempt establishments. However, those officials are not looking specifically for *E. coli* contamination, and they may not visit these establishments more than once a year. We are concerned that the average consumer is unaware of the difference between the testing of the ground beef that has come from a Federally inspected plant versus ground beef that is ground onsite at a local grocery store. The former is subjected to an

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[35] *Testing of Raw Ground Beef and Raw Ground Beef Component Samples for E. coli O157:H7: Year-to-Date Totals: Results from Analysis of Raw Ground Beef Samples As of Dec 31, 2011*.

[36] The figure of about 64,000 retail establishments was defined by FSIS as "supermarkets" that included chain stores, smaller chain stores, and individual "mom and pop" stores.

[37] FSIS maintains that sampling raw ground beef products produced in retail establishments targets those beef products that may present the highest risk to consumers. Therefore, the raw ground beef products are subject to sampling as outlined in FSIS Directive 8010.1 Rev. 3, Appendix 1, *Instructions for Collecting Surveillance Samples of Raw Ground Beef at Retail for E. coli O157:H7 Analysis.*

[38] Product recall Hannaford, Scarborough, Maine, in 2008, for *Salmonella Typhimurium*.

[39] Product recall Swift Beef Company (establishment number 969), Greeley, Colorado, case 034-2009.

[40] 9 CFR§ 303.1(d),(2).

[41] *FSIS Annual Sampling Program Plan: Microbiological and Residue Sampling Programs: Fiscal Year 2012* cites a formal review of FSIS in-commerce activities by the National Academies of Science (NAS), which resulted in the agency lowering the estimated risk level posed by retail establishments from Tier 2 to Tier 3.

additional layer of FSIS *E. coli* testing of trim that has been subject to FSIS *E. coli* sampling, while the latter is only subject to final product testing.

FSIS officials noted that they do not believe that bench trim in retail exempt establishments has statistically more risk than trim or ground products that are being sampled. FSIS also believes subjecting trim to testing at slaughter establishments is a better use of agency resources. Nonetheless, OIG maintains that FSIS should reach a determination about the health hazard posed by grinding beef at retail exempt establishments, which could easily be millions of pounds a week,[42] and determine if it should implement a more proactive and vigorous testing program for bench trim at these businesses.

Recommendation 3

Initiate an assessment, which provides an estimate of the risk associated with the potential volume of untested boxed beef and store-generated bench trim derived from the retailers' own operations that is being ground in retail exempt establishments. Consider using a survey to gather the information on exempt retailers' practices.

Agency Response

FSIS will develop an assessment that will compare the level of STEC O157 contamination in ground beef produced from boxed beef to the level of STEC O157 in ground beef produced from trim (i.e. trimmings produced at slaughter/processing establishments). This assessment will use information from previously published risk assessments to determine the beginning levels of contamination in the two different types of product.

The levels of contamination in ground product can be extended to predictions of risk per serving if storage, preparation, consumption, and other factors are assumed to be identical for both ground beef from boxed beef and ground beef from trim. At this time, there is no evidence to indicate the ground beef produced from boxed beef is stored, prepared, or consumed differently than ground beef produced from trim.

Predictions of numbers of human illnesses due to STEC O157 contamination in ground beef produced from boxed beef cannot be developed at this time. Before such illness estimates can be developed, information on the volume and distribution of ground beef produced from boxed beef is needed.

FSIS will also evaluate the likelihood of detecting positive lots of product (boxed beef, bench trim, or ground beef) under various testing schemes including processor and/or FSIS verification testing and end product testing. Such an assessment could include an estimate of any predicted reductions in risk of illness associated with product testing. Again, such an assessment would first require data regarding retail practices on volume and distribution of ground beef from boxed beef.

[42] An industry group (Nielsen Perishables Group FreshFacts) estimated in its May 2012 newsletter that retail ground beef volumes were averaging around 50 million pounds a week.

FSIS will gather information on exempt retailers' practices by means that conform to established agency protocol for risk assessments which may be subject to peer review.

The estimated completion date for all parts of this response is December 2013.

OIG Position

We accept management decision for this recommendation.

Recommendation 4

If the agency determines that there is a significant amount of risk associated with grinding of boxed beef and store-generated bench trim in retail establishments, develop a plan with milestones and reasonable timeframes to implement a testing program to sample and test bench trimmings that are ground in retail establishments, including reallocating FSIS' limited testing resources to include beef trim as well as final product at retail exempt establishments. Seek public input on the plan, consider any comments provided, and conclude whether or not to implement a new bench trim sampling program in retail establishments.

Agency Response

If FSIS determines that there is a significant amount of risk associated with grinding of boxed beef and store-generated bench trim in retail establishments as a result of the assessment described in response to recommendation 3, FSIS will develop a plan with milestones and reasonable timeframes to implement a testing program to sample and test bench trimmings that are ground in retail establishments. In preparing the plan, FSIS will make a determination as to allocation of testing resources between beef trim and final product at retail exempt establishments.

The estimated completion date for this response is March 2014.

OIG Position

We accept management decision for this recommendation.

Finding 3: FSIS Does Not Sample Tenderized Meat Products for *E. coli* Testing

FSIS does not, at present, test tenderized meat products,[43] even though these products present some additional risk for *E. coli* contamination.[44] When a steak is tenderized through a needling or needling marinade process, the risk of contamination increases because any *E. coli* on the outside of the meat could be pushed into the interior. If the tenderized steak is then not fully cooked, there is the possibility that a consumer could be made ill by the contaminated meat. We visited five downstream processors that offered tenderized product for distribution to consumers or retail establishments and found that FSIS did not sample tenderized product in any of the five establishments. FSIS officials told us that they do not sample these products because they consider them to be at a low level of risk for *E. coli* and did not see the need for testing. Industry representatives noted that the more obvious tenderized cuts, such as minute steaks or chicken fried steak patties, often orginate from tougher and less desirable cuts and consumers tend to thoroughly cook them. However, in other cuts it is not as obvious to the consumer that they have been tenderized. Additionally, FSIS officials acknowledged that tenderized products that are also marinated seem to have more problems with pathogen contamination than non-marinated products. FSIS officials told us that they have developed a proposed rule that is currently under review, which would require new labeling for mechanically tenderized product, but they do not plan to begin an *E. coli* sampling program. OIG maintains that these tenderized cuts do have some degree of risk. They have been subject to a number of different recalls, including 248,000 pounds of chopped steak product that caused 19 illnesses in 16 States, as well as about 1,000 pounds of tenderized and other product that made 3 students ill.

Typically, primals and sub-primals are not considered at risk for *E. coli* contamination because they are intact, and any *E. coli* on their surface should be destroyed during cooking. Therefore, no sampling and testing is required on these cuts of meat. However, establishments may produce primals or sub-primals that are processed into non-intact consumer-ready steak and roast products (e.g., tenderized steaks). FSIS' sampling directive requires that FSIS inspectors verify establishments producing tenderized beef products have evidence that the establishments considered the potential hazard of *E. coli* contamination and have addressed the risk in their intervention processes. If a Federally inspected establishment makes these types of raw non-intact products, then FSIS is responsible for ensuring that the tenderized products are not contaminated with *E. coli*.[45]

We found, however, that FSIS was not requiring the sampling of tenderized products. We confirmed this observation at the five plants we visited, and both the FSIS inspectors and plant management said that testing these types of tenderized products was not required, so they did not sample from such products.

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[43] Tenderized product may include beef that an establishment has injected with solutions; beef that an establishment has mechanically tenderized by needling, cubing, Frenching, or pounding devices (with or without marinade); and beef that an establishment has reconstructed into formed entrees.

[44] Although FSIS does not directly test mechanically tenderized products, if the establishment should later use bench trim derived from tenderized products for ground beef production, that material would be subject to FSIS testing.

[45] FSIS Directive 10,010.1 Rev. 3, Chapter V, B and Directive 5,300.1 Attachment 1.

Tenderized meat products have been involved in several recent recalls. One national restaurant chain became involved in a recall that made 19 people in 16 States ill. FSIS traced the source of the problem back to a slaughter establishment in Oklahoma that produced tenderized and marinated steaks from boxed beef.[46] In another case in Massachusetts, three middle school students become ill after eating tenderized beef products. FSIS and the processing plant responsible responded by recalling about 1,000 pounds of meat.[47] In 2012, a slaughter establishment that ships beef throughout the United States and Canada recalled over 1 million pounds of primal and sub-primal cuts of meat that were used, in part, to produce mechanically tenderized steaks and roasts.[48]

When we brought this issue to the attention of the FSIS national officials responsible for designing and implementing the testing program for *E. coli*, they stated that, given their limited testing resources, they had not emphasized the testing of tenderized products, as they considered these products to be of lower risk than bench trim. They stated that the agency has developed a proposed rule that is currently under review, which would require new labeling for mechanically tenderized product because industry and consumer groups have realized the potential risks associated with undercooking these products. FSIS officials noted that they are performing a non-intact beef risk assessment, which will examine the risk associated with tenderized product. Further, the agency is planning to survey industry to gather more information on the establishment practices associated with tenderized product. FSIS officials felt that if a testing program is needed for mechanically tenderized beef, a testing program that was geared more to sampling the surface area (a component of the meat) of the product would be more effective than sampling the entire steak or roast.

Given the fact that there have been recalls and concerns about both tenderized product and marinated tenderized product, OIG maintains that FSIS should perform a study to determine the health risk associated with these products and whether a more proactive testing program is merited.

Recommendation 5

Complete the agency's non-intact beef risk assessment and the planned industry survey on industry practices related to tenderized products. Using this information, perform an analysis of the risk associated with the amount and types (e.g., needle tenderized, marinated) of tenderized product being produced by industry.

Agency Response

The non-intact beef risk assessment and industry survey on industry practices related to tenderized products is near completion. The risk assessment includes an analysis of the risk associated with the amount and types of tenderized product being produced by industry.

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[46] Product recall National Steak Processors, Owasso, Oklahoma, case 067-2009.
[47] Product recall Crocetti's Oakdale Packing, Brockton, Massachusetts, case 057-2009.
[48] Public health alert XL Foods Inc., Alberta, Canada.

The estimated completion date for this response is April 2013.

OIG Position

We accept management decision for this recommendation.

Recommendation 6

If the agency determines that there is a significant amount of risk associated with the consumption of mechanically tenderized beef products, then develop a plan with milestones and reasonable timeframes for sampling and testing the tenderized products or their components. Seek public input on the plan, consider any comments provided, and conclude whether or not to implement a new tenderized product sampling program.

Agency Response

The risk assessment developed under Recommendation 5 will be utilized along with other information to support an agency determination of the risk associated with the consumption of mechanically tenderized beef products.

If FSIS finds a significant amount of risk associated with the consumption of mechanically tenderized beef products, FSIS will develop a plan with milestones and reasonable timeframes for establishing a sampling and testing program for tenderized products or their components. The implementation plan will include a step to develop and issue a Federal Register Notice to publicize the sampling program and seek public comment. FSIS will finalize the policy, and develop and issue a Directive establishing the policy and sampling procedures to be carried out by field personnel.

The estimated completion date for all parts of this response is March 2014.

OIG Position

We accept management decision for this recommendation.

Finding 4: FSIS Needs to Ensure PHIS Contains Accurate Data, so that Establishments are Correctly Sampling Beef for *E. coli* Testing

FSIS in-plant inspectors rely on PHIS to generate periodic tasks indicating what type of *E. coli* sampling they should be performing to ensure food safety. Those sampling tasks are based on information contained in the establishment profiles that have been loaded into PHIS. The plant profile would indicate what sort of meat products are produced at a slaughter or processing plant, which in turn triggers the corresponding types of sampling requests the inspector should perform. However, based on our review of 22 of about 1,750 establishments, we determined that FSIS either had incorrect profile information, or the establishment was incorrectly included or excluded on various sampling programs for 18 of these establishments. In part, this occurred because FSIS recently transitioned to PHIS and, when it did, the agency attempted to migrate data from its old information system. This data migration encountered problems, so the agency instructed FSIS district personnel to manually enter data into the profiles. OIG notes, however, that the data may not always have been correct in the older system. Due to this and other data migration problems, FSIS was not correctly sampling and testing either for ground beef or its components at these 18 plants. At one plant alone, FSIS did not take *E. coli* samples because of a profile error in PHIS data. As a result, FSIS inspectors did not receive tasks directing them to sample over 50 million pounds of ground beef production over a period of about 5 months.[49] At another plant, FSIS did not sample other raw ground beef components[50] for over 4 years, and it was not until OIG brought the issue to the agency's attention in May 2012 that the agency began sampling these components at the plant—over 50 million pounds of product were not tested under the appropriate *E. coli* sampling program.[51]

FSIS inspectors perform various forms of *E. coli* verification sampling to ensure the validity of an establishment's HACCP plan. FSIS uses the establishment's profile information in PHIS to generate the agency's sample requests.[52] Inspection personnel are responsible for keeping the establishment profile up-to-date and accurate.[53]

In the process of selecting which plants we should visit, we noted that many plants were producing meat products that indicated they should be included in various *E. coli* sampling programs other than finished ground beef. Likewise, plants were sampling bench trim, but they were not included in the final ground beef testing program. These discrepancies led us to visit plants, acquire some additional data, and work with FSIS' data analysis group to confirm that many of these plants had PHIS profiles that included inaccurate information and were not prompting agency sampling requests for the products being produced at those plants.

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[49] At this establishment, source ground beef materials were from other FSIS inspected facilities and were included in FSIS *E. coli* sampling programs.

[50] FSIS Directive 10,010.1, Rev. 3, Chapter I, Section V (f.). Other raw ground beef components may include such products as cheek meat, head meat, and raw esophagus (weasand).

[51] If these products were ground at an FSIS inspected downstream processor, the ground beef product should have been included in FSIS' ground beef *E. coli* sampling program.

[52] PHIS Directive 5300.1, Section VIII: *Establishment Profile* (A.).

[53] PHIS Directive 5300.1, Section X: *IPP Responsibilities For Performing the Establishment Profile Inspection Task* (A.).

As we looked at individual plants, we were informed by FSIS plant personnel that the information in the profiles was incorrect and that the incorrect profile information was interfering with sampling. Each month, PHIS generates a task that prompts FSIS personnel to review and update the profile to verify the plant's product and the volume being produced; however, we found that updates were not being performed adequately.

In addition, we found that inspectors often are not familiar enough with PHIS to properly update some important profile information, nor do they know what plant profile information is critical for determining the establishments' proper *E. coli* sampling program eligibility. At three establishments we visited, we identified problems in the plant profile or problems with the sampling program at each establishment. The inspectors and one front line supervisor said they did not know which data fields in the PHIS profile were preventing or causing the establishment's FSIS inspector to receive proper or improper sampling requests.

When we brought this issue to the attention of FSIS national officials responsible for the design of the agency's *E. coli* testing system, they stated that they were aware that there were problems with the accuracy of the PHIS profiles because of data migration failures which required manual entry by FSIS personnel. They had approached the issue from a nationwide perspective to monitor the overall level of inspection activity and had identified substantial gaps only during the implementation of PHIS. We also directed them to an FSIS notice that requires FSIS to select a sample of establishment profiles to review and ensure PHIS profile data accuracy on a plant-by-plant basis.[54] FSIS officials stated that they have not performed this data analysis of establishment profiles because they had to adjust the type of data analysis they performed to a higher level of review, due to the data migration problems. Instead of performing analysis on a plant-by-plant basis, they would continue monitoring the overall level of inspection activity and various aspects of PHIS data to identify gaps in the PHIS implementation. FSIS officials did mention that Enforcement Investigations and Analysis Officers (EIAOs)[55] will be conducting periodic Food Safety Assessments (FSAs)[56] of establishments, which will include a review of their records and documentation.[57] They stated that these reviews should correct the problems with plant profiles.

However, we noted that at 2 of the 22 plants we reviewed, FSAs had been previously performed and the EIAOs did not note that the plants were not in the correct *E. coli* sampling programs. The FSA review guide did not specifically require the reviewer to determine if the FSIS sampling programs correctly reflected the operations of the establishment. FSIS officials agreed that these reviews should look more closely at these issues.

To improve its PHIS sample selection during the new system's implementation, FSIS also used historical plant sampling data as an input—historical sampling means, simply, that if FSIS has conducted a certain type of sampling at a plant in the past, it should sample again for that

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[54] FSIS Notice 17-11 PHIS Transition (VI).
[55] FSIS Directive 5100.1 Rev 3 Part 1 V.A: EAIOs are trained to assess the design and validity of food safety systems and to prepare administrative enforcement reports.
[56] FSIS Directive 5100.1 Rev 3 Chapter 1 I (C): FSAs are a review of the establishment's food safety systems. Establishments receive FSA reviews once every 4 years.
[57] FSIS Directive 5100.1 Rev 3 Chapter 2 Section II.

product. However, FSIS discontinued using historical sampling data for one of its sampling programs because the agency believed that the plants' PHIS profiles were complete. As a result, for at least one plant, this change resulted in the plant no longer receiving the correct sampling requests. The plant had historically been sampling ground beef weekly, but from April 2012 to August 2012, the plant stopped receiving requests for ground beef samples. FSIS inspectors at the plant did not resume sampling until we inquired concerning why they were not sampling ground beef. This establishment produces about 600,000 pounds of ground beef products daily for a large national fast food restaurant chain.[58] We acknowledge that the source materials used to produce the ground beef were received from other FSIS inspected facilities and should have been included in FSIS's *E coli* sampling program at the upstream facilities.

At another establishment—one of the top 10 slaughter establishments in the United States—FSIS did not take *E. coli* samples for other ground beef components, such as head meat, cheek meat, and weasand[59] meat products. The FSIS inspector did not sample these products because his understanding was that these products were not being ground at the establishment and therefore should not be included in the FSIS *E. coli* sampling program. FSIS did not take these samples from 2008 until May 2012, when we questioned why FSIS was not sampling other ground beef components at the plant. Even though an FSA was performed at this establishment, the review did not identify that the establishment was not in the correct *E. coli* sampling program. As a result, over 50 million pounds of other ground beef components were not subject to required FSIS *E. coli* sampling at this slaughter establishment.[60]

OIG concluded that FSIS needs to take steps to ensure the accuracy of establishment profiles in PHIS. If it does not do so, then inspectors will not be sampling product, as required by FSIS procedures. We maintain that the agency should make use of its data analysis group to periodically verify the accuracy of PHIS profiles for individual establishments.

Recommendation 7

Follow up with the field personnel assigned to the 18 plants where OIG noted *E. coli* sampling program issues and assure all omissions or errors in PHIS are correct and that these establishments are eligible for *E. coli* sampling in all the appropriate sampling programs.

Agency Response

FSIS will follow up with inspection program personnel at the 18 cited establishments to correct data errors in the PHIS Establishment Profile. The Office of Data Integration and Food Protection's Data Analysis and Integration Group will coordinate with the Office of Field Operations to follow-up in the 18 plants OIG identified with sampling issues to ensure that they are being sampled appropriately. The Data Analysis and Integration Group, in conjunction with

[58] The establishment does perform *E. coli* sampling on final ground product every 15 minutes.
[59] Weasand is raw esophagus.
[60] Although FSIS was not testing this product at the slaughter establishment, the ground beef produced at an FSIS inspected facility that included this source material would have been eligible for sampling under FSIS' ground beef *E. coli* sampling program prior to entering commerce.

the Office of Field Operations, will conduct quarterly reviews of those 18 plants to ensure that they remain correctly sampled.

The estimated completion date for all parts of this response is September 2013.

OIG Position

We accept management decision for this recommendation.

Recommendation 8

Develop and implement a plan for FSIS to periodically analyze its pathogen sampling databases for anomalies related to which establishments are eligible for the various pathogen sampling programs. This periodic analysis should include non-profile data, such as historical sampling data. The plan should include directions on how to notify field personnel, how to investigate the concern, and how to properly resolve any questionable database issues that are found related to an establishment's eligibility for a pathogen sampling program.

Agency Response

The Office of Data Integration and Food Protection's Data Analysis and Integration Group will compare historic *E. coli*, *Listeria monocytogenes*, *Salmonella*, and residue sampling at the single establishment level as reported in PBIS with current sampling as reported in PHIS. Through that analysis, the Office of Data Integration and Food Protection's will identify discrepancies between historical and current sampling, and work with the Office of Field Operations to follow-up on those discrepancies that warrant further investigation. Procedures will be developed to perform the analysis, notify field personnel, investigate concerns, and resolve issues identified during the analysis.

Going forward, the Office of Data Integration and Food Protection will conduct an annual review of changes to the sampled population of establishments, including a review of discrepancies with the Office of Field Operations. Similar procedures will be developed to notify field personnel, investigate concerns, and resolve issues identified during the analysis.

The estimated completion date for this response is September 2013.

OIG Position

We accept management decision for this recommendation.

Recommendation 9

Revise the procedures for performing FSAs to ensure that EIAOs verify that the establishment being reviewed is included in all the correct FSIS pathogen sampling programs.

Agency Response

A report will be developed to list the sampling programs for which the establishment is eligible based on its production. When EIAOs perform FSAs, they can review the establishment profile at the establishment to verify its accuracy and ensure that it is included in the appropriate sampling frames for the products it produces. FSIS will update Directive 5100.1, Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology, to reflect the revised procedures.

The estimated completion date for all parts of this response is March 2014.

OIG Position

We accept management decision for this recommendation.

Recommendation 10

Issue additional guidance to FSIS personnel regarding common profile entry errors that are causing establishments to be placed in inappropriate sampling programs.

Agency Response

FSIS will ascertain the most common profile errors and revise FSIS Directive 5300.1, Managing the Establishment Profile in the Public Health Information System (PHIS), to add a list of most common errors and reiterate that establishment profile review and update task should be performed monthly.

The estimated completion date for this response is December 2013.

OIG Position

We accept management decision for this recommendation.

Finding 5: FSIS Needs to Ensure Processors Maintain Sufficient Records for Trace Back and Recall Purposes

When beef processing establishments grind trim and other components, it is standard industry practice to maintain "grinding logs," which can be used to trace back source material in case of a recall. Of the 11 Federal processing establishments we reviewed, we found that 3 establishments' grinding logs did not provide the necessary source information to enable FSIS to trace the material back to the originating slaughter establishment. This has occurred because, while FSIS has provided establishments with guidance concerning the need for grinding logs and the specific information that should be included, the agency has been reluctant to require that detailed grinding logs be maintained. While most large establishments maintain very detailed grinding logs, we found that other, smaller establishments are reluctant to do so, perceiving the logs as burdensome. Without the necessary source information from the grinding logs, the processing establishments may not be able to accurately identify the source of *E. coli* contamination. If the source of contamination cannot be properly identified, supplying establishments will not be able to properly address the issues concerning how the source product was contaminated and correct the problem upstream.

FSIS requires food handling firms, including establishments that grind boxed beef material, to keep and make available full and correct business records to FSIS.[61] Grinding logs are not, strictly speaking, required; however, they are suggested, and they can be crucially important in case of a recall.

Of the 11 Federally inspected processing establishments we visited, we found that all the larger establishments prepared detailed grinding logs that captured a great deal of relevant information. However, 3 of the 11 establishments did not maintain grinding logs with sufficient information to identify contaminated source material in the event of an *E. coli*-related recall. When we spoke to the FSIS inspectors about the inadequacy of the grinding logs, they stated that they knew the logs would not suffice to trace back source material in case of a recall. On the other hand, plant managers varied in their attitudes toward the importance of maintaining detailed grinding logs. One manager stated that he would quit grinding, rather than maintain adequate grinding logs; another agreed that the establishment could improve its practices. All parties noted that detailed grinding logs are currently not required by FSIS.

When we spoke to FSIS national officials about this problem, they agreed that adequate grinding logs and recall plans were necessary for trace back in case of a recall. First, agency officials noted that FSIS has issued compliance guidelines to industry for maintaining adequate grinding logs and the agency is in the process of finalizing a rule which would establish requirements for maintaining these records. In addition, they stated that the agency has issued a Federal Register notice, requiring all Federally inspected establishments to develop written recall plans. According to the new requirement, large establishments had until November 5, 2012, and small and very small establishments have until May 8, 2013, to develop their recall plans.[62] They noted that, in order for a recall plan to be effective, the establishment would have to be able to

[61] 21 U.S.C. § 642: *Recordkeeping Requirements* (a).
[62] Federal Register/Vol. 77, No. 89, Tuesday, May 8, 2012, Rules and Regulations.

identify source material—hence the need for detailed grinding logs. FSIS officials stated that they would emphasize the importance of adequate grinding logs as the inspection staff reviewed the new recall plans.

OIG concludes that adequate grinding logs are essential to conducting effective recalls. As FSIS moves to require establishments to prepare and maintain recall plans, the agency should ensure that these logs are maintained and are of sufficient detail to facilitate a recall at any Federally inspected establishment.

Recommendation 11

Finalize and publish the agency's final rule, establishing requirements for industry to maintain grinding logs.

Agency Response

FSIS intends to propose to amend its recordkeeping regulations to address this issue. FSIS must follow established rulemaking procedures which will likely take more than one year to implement. FSIS is proposing to amend its recordkeeping regulations to specify that all official establishments and retail stores that grind raw beef products for sale in commerce must keep records that disclose the identity and contact information of the supplier of all source materials that they use in the preparation of each lot of raw ground beef and identify the names of those supplied source materials, including any beef components and any carryover from one production lot to the next. The records would also be required to document the amount of the beef component used in each lot (in lbs), the date and time each lot of raw ground beef product was produced, and the date and time when grinding equipment and other related food-contact surfaces were cleaned and sanitized. Official establishments and retail stores would also have to comply with the proposed recordkeeping requirements with respect to raw beef products that are ground at an individual customer's request. FSIS must assess the response to the proposed rule and make a decision whether to finalize the rule.

The estimated completion date for all parts of this response is May 2013.

OIG Position

We accept management decision for this recommendation.

Recommendation 12

When the rule on grinding logs has been finalized, develop procedures for FSIS field personnel to evaluate whether establishments are maintaining adequate grinding logs that can be used to trace back implicated product to the source supplier in the event of a recall, with examples and criteria to assist inspection personnel in reviewing grinding logs to determine if the logs are suitable. Those procedures should also include specific actions to take when an establishment's grinding logs are found to be inadequate.

Agency Response

Should the proposed rule become final, FSIS will develop procedures for FSIS field personnel to verify the rule on grinding logs; however, this process may take more than one year. FSIS is currently in the process of amending its recordkeeping regulations to address this issue. Should the rule become final, FSIS will develop and issue a Directive providing instructions to inspection program personnel to verify the rule on grinding logs. The Directive will instruct inspection program personnel to evaluate whether establishments are maintaining adequate grinding logs that can be used to trace back implicated product to the source supplier in the event that adulterated product has been produced, and will include examples and criteria to assist inspection personnel in reviewing grinding logs to determine if the logs are suitable. Those procedures will also include specific actions to take when an establishment's grinding logs are found to be in adequate.

The estimated completion date for this response is April 2014.

OIG Position

We accept management decision for this recommendation.

Scope and Methodology

While conducting fieldwork for Audit 24601-0001-31, *Food Safety and Inspection Service N-60 Testing Protocol on Beef Trim for Escherichia coli O157:H7—Phase 2*, the audit team became aware of the potential for downstream processors to grind untested boxed beef products. Due to time and travel constraints, OIG chose to issue the report for Audit 24601-0001-31 and initiate a separate audit to examine the identified potential food safety issues.

To meet our audit objectives, we interviewed personnel from multiple offices within the FSIS national office, visited processing facilities and a slaughter establishment, and interviewed a representative of a national trade group, which represents small and very small slaughter and processing facilities. We also analyzed data we received from FSIS. Among those visited and interviewed were:

- **FSIS National Office Representatives:** We discussed *E. coli* testing programs, sampling process, and testing procedures with personnel from the offices listed below. The audit team communicated with these officials on numerous occasions by interview, phone, and e-mail.

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

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

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

- **Processors' Representative:** We conducted an interview with a representative of the American Association of Meat Processors, an industry trade group. The interview included gaining insight into the group's opinions and practices regarding *E. coli* testing at the processor level, as well as their concerns regarding traceability and labeling.

- **Processing Facilities:** We conducted field work at 11 processing facilities in five States to gain an understanding of the testing of incoming boxed beef used for grinding, bench trim derived from the incoming boxed beef, and final ground beef products. We judgmentally chose these processing plants, based on travel considerations and either our data analysis or recommendations from FSIS personnel. At each establishment, we conducted interviews with both FSIS personnel and plant

management to determine the extent of FSIS and establishment testing, as well as to identify the types of incoming products that were ground and the end use of the ground product. The facilities we visited were located in Illinois, Iowa, Kansas, Missouri, and Nebraska.

- **Slaughter Establishment:** We conducted fieldwork at one Nebraska slaughter establishment. We visited the establishment to trace source materials that we identified at downstream processors, back upstream. By doing so, we verified aspects of *E. coli* testing, interventions, and the traceability of the source product to the originating establishment.

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

- **FSIS Electronic Data:** We received electronic data from FSIS related to agency *E. coli* O157:H7 sampling. We examined this electronic sampling data for obvious anomalies and, for a limited number of these anomalies, we validated the accuracy of the agency electronic data. We attempted to confirm selected agency electronic sampling data through plant documents, internet websites, FSIS documents, interviews with plant management, and interviews with FSIS field and national office officials. We verified only a small portion of the electronic sampling data that we obtained from FSIS' electronic information systems; therefore, we make no representation regarding the adequacy of the agency's computer systems.

Our audit fieldwork was conducted from March 2012 to September 2012. During our audit work, we focused on the testing of boxed beef products purchased and processed during the period January 1, 2010 through March 31, 2012.

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

Abbreviations

E. coli	Escherichia coli
EIAO	Enforcement Investigations and Analysis Officers
FMIA.....	Federal Meat Inspection Act
FSA	Food Safety Assessment
FSIS	Food Safety and Inspection Service
HACCP	Hazard Analysis and Critical Control Point
OIG	Office of Inspector General
PHIS.....	Public Health Information System
USDA.....	U. S. Department of Agriculture

USDA'S
FSIS'
RESPONSE TO AUDIT REPORT

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

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

FROM: Alfred V. Almanza **/s/ March 12, 2013**
Administrator
Food Safety and Inspection Service

SUBJECT: Office of Inspector General (OIG) Official Draft Report – Food Safety and Inspection Service *E. coli* Testing of Boxed Beef (Audit 24601-0003-31)

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

Responses to Recommendations

Recommendation 1:
Reevaluate procedures for sampling boxed beef product as bench trim and issue clarification to FSIS' inspectors on the agency's requirements. Also, consider the risk associated with a downstream processor's own verification testing (or lack of testing) when evaluating the frequency of sampling.

FSIS Response:
FSIS agrees that boxed beef product designated as intended for grinding at a "downstream" processor should be eligible for sampling and testing as "bench trim" at the grinding establishment by FSIS. FSIS has issued guidance to industry recommending that establishments conduct such verification activities to demonstrate the on-going effectiveness of their food safety systems, including prerequisite programs. The Agency will clarify its instructions to Agency inspection personnel in FSIS Directive 10,010.1, *Verification Activities for Escherichia coli O157:H7 in Raw Beef Products,* and in related AskFSIS questions that FSIS policy is that "bench trim" derived from boxed beef sub-primals at "downstream" grinders is subject to testing under the MT55 testing program. FSIS will clarify that whenever a whole primal or sub-primal cut is received at a non-slaughter establishment and is intended for grinding (not just the trimmings from these cuts), the whole primal or sub-primal cut is considered to be bench trim and subject to being sampled.

Using the results of the analysis outlined under Recommendation 3, FSIS will consider adjusting the frequency of testing when "downstream" grinders maintain their own testing programs.

Estimated Completion Date:
Revised FSIS Directive 10,010.1, December 2013. Related AskFSIS questions, January 2014. Sampling frequency updates, March 2014.

Recommendation 2:
Prepare a plan with reasonable timeframes to evaluate and implement whether the Public Health Inspection System (PHIS) or another system should be modified or developed to capture additional information regarding the type of incoming product (i.e., boxes of whole muscles beef cuts) that is being ground by downstream processing establishments in order to improve FSIS' ability to assign the appropriate *E. coli* sampling program requests.

FSIS Response:
FSIS will perform a survey using a new functionality in PHIS to determine which downstream (non-slaughter) establishments receive whole primal or sub-primal cuts and then grind them. FSIS will then update these establishments' profiles in PHIS to reflect this fact. This information will help identify those establishments where whole primal or sub-primal cuts are eligible for sampling and testing under the MT55 testing program. A mechanism to capture this information in PHIS will soon be operational. PHIS will have a survey functionality that will be operational in June 2013, which will allow IPPS to input answers to survey questions. FSIS will use the new survey function to collect information on which downstream establishments grind whole primal or sub-primal cuts, and then PHIS establishment profiles will be updated accordingly.

Estimated Completion Date:
Implementation of PHIS survey functionality, June 2013. Conduct survey and update plant profiles in PHIS, December 2013.

Recommendation 3:
Initiate an assessment, which provides and estimate of the risk associated with the potential volume of untested boxed beef and store-generated bench trim derived from its own operations that is being ground in retail exempt establishments. Consider using a survey to gather the information on exempt retailers' practices.

FSIS Response:
FSIS will develop an assessment that will compare the level of STEC O157 contamination in ground beef produced from boxed beef to the level of STEC O157 in ground beef produced from trim (i.e. trimmings produced at slaughter/processing establishments). This assessment will use information from previously published risk assessments to determine the beginning levels of contamination in the two different types of product.

The levels of contamination in ground product can be extended to predictions of risk per serving if storage, preparation, consumption, and other factors are assumed to be identical for both ground beef from boxed beef and ground beef from trim. At this time there is no evidence to indicate the ground beef produced from boxed beef is stored, prepared, or consumed differently than ground beef produced from trim.

Predictions of numbers of human illnesses due to STEC O157 contamination in ground beef produced from boxed beef cannot be developed at this time. Before such illness estimates can be developed, information on the volume and distribution of ground beef produced from boxed beef is needed.

FSIS will also evaluate the likelihood of detecting positive lots of product (boxed beef, bench trim, or ground beef) under various testing schemes including processor and/or FSIS verification testing and end product testing. Such an assessment could include an estimate of any predicted reductions in risk of illness associated with product testing. Again, such an assessment would first require data regarding retail practices on volume and distribution of ground beef from boxed beef.

FSIS will gather information on exempt retailers' practices by means that conform to established agency protocol for risk assessments which may be subject to peer review.

Estimated Completion Date:
Risk assessment complete December 2013.

Recommendation 4:
If the agency determines that there is a significant amount of risk associated with grinding of boxed beef and store-generated bench trim in retail establishments, develop a plan with milestones and reasonable timeframes to implement a testing program to sample and test bench trimmings that are ground in retail establishments, including reallocating their limited testing resources to include beef trim vs. final product at retail exempt establishments. Seek public input on the plan, consider any comments provided, and conclude whether or not to implement a new bench trim sampling program in retail establishments.

FSIS Response:
If FSIS determines that there is a significant amount of risk associated with grinding of boxed beef and store-generated bench trim in retail establishments as a result of the assessment described in response to recommendation 3, FSIS will develop a plan with milestones and reasonable timeframes to implement a testing program to sample and test bench trimmings that are ground in retail establishments. In preparing the plan, FSIS will make a determination as to allocation of testing resources between beef trim and final product at retail exempt establishments.

Estimated Completion Date:
Development of plan March 2014.

Recommendation 5:
Complete the agency's non-intact beef risk assessment and the planned industry survey on industry practices related to tenderized products. Using this information, perform an analysis of the risk associated with the amount and types (needle tenderized, marinated, etc.) of tenderized product being produced by industry.

FSIS Response:
The non-intact beef risk assessment and industry survey on industry practices related to tenderized products is near completion. The risk assessment includes an analysis of the risk associated with the amount and types of tenderized product being produced by industry.

Estimated Completion Date:
Publication of non-intact beef risk assessment, industry survey on tenderized products, and analysis of risk of tenderized product April 2013.

Recommendation 6:
If the agency determines that there is a significant amount of risk associated with the consumption of mechanically tenderized beef products, then develop a plan with milestones and reasonable timeframes for sampling and testing the tenderized products or their components. Seek public input on the plan, consider any comments provided, and concluded whether or not to implement a new tenderized product sampling program.

FSIS Response:
The risk assessment developed under Recommendation 5 will be utilized along with other information to support an agency determination of the risk associated with the consumption of mechanically tenderized beef products.

If FSIS finds a significant amount of risk associated with the consumption of mechanically tenderized beef products, FSIS will develop a plan with milestones and reasonable timeframes for establishing a sampling and testing program for tenderized products or their components. The implementation plan will include a step to develop and issue a Federal Register Notice to publicize the sampling program and seek public comment. FSIS will finalize the policy, and develop and issue a Directive establishing the policy and sampling procedures to be carried out by field personnel.

Estimated Completion Date:
Risk assessment complete April 2013. If needed, development of implementation plan for a testing program March 2014.

Recommendation 7:
Follow up with the field personnel assigned to the 18 plants where OIG noted *E. coli* sampling program issues and assure all omissions or errors in PHIS are correct and that these establishments are eligible for *E. coli* sampling in al the appropriate sampling programs.

FSIS Response:
FSIS will follow-up with IPP at the 18 cited establishments to correct data errors in the PHIS Establishment Profile. The Office of Data Integration and Food Protection's (ODIFP's) Data Analysis and Integration Group (DAIG) will coordinate with the Office of Field Operations (OFO) to follow-up in the 18 plants OIG identified with sampling issues to ensure that they are

being sampled appropriately. DAIG, in conjunction with OFO, will conduct quarterly reviews of those 18 plants to ensure that they remain correctly sampled.

Estimated Completion Date:
Follow-up at 18 establishments completed June 2013. Quarterly reviews of 18 plants, starting September 2013, for one year.

Recommendation 8:
Develop and implement a plan for FSIS to periodically analyze its pathogen sampling data bases for anomalies related to which establishments are eligible for the various pathogen sampling programs. This periodic analysis should include non-profile data, such as historical sampling data. The plan should include directions for how field personnel will be notified, how to investigate the concern, and how to properly resolve any questionable database issues that are found related to an establishment's eligibility for a pathogen sampling program.

FSIS Response:
The Office of Data Integration and Food Protection's (ODIFP's) Data Analysis and Integration Group (DAIG) will compare historic *E. coli*, *Listeria monocytogenes*, *Salmonella*, and residue sampling at the single establishment level as reported in PBIS with current sampling as reported in PHIS. Through that analysis, ODIFP will identify discrepancies between historical and current sampling, and work with the Office of Field Operations (OFO) to follow-up on those discrepancies that warrant further investigation. Procedures will be developed to perform the analysis, notify field personnel, investigate concerns, and resolve issues identified during the analysis.

Going forward, ODIFP will conduct an annual review of changes to the sampled population of establishments, including a review of discrepancies with OFO. Similar procedures will be developed to notify field personnel, investigate concerns, and resolve issues identified during the analysis.

Estimated Completion Date:
Initial analysis and procedures September 2013.

Recommendation 9:
Revise the procedures for performing FSAs to ensure that EIAOs verify that the establishment being reviewed is included in all the correct FSIS pathogen sampling programs.

FSIS Response:
A report will be developed to list the sampling programs for which the establishment is eligible based on its production. When EIAOs perform FSAs, they can review the establishment profile at the establishment to verify its accuracy and ensure that it is included in the appropriate sampling frames for the products it produces. FSIS will update Directive 5100.1, *Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology*, to reflect the revised procedures.

Estimated Completion Date:
Develop sampling report July 2013. Update Directive 5100.1, March 2014.

Recommendation 10:
Issue additional guidance to FSIS personnel regarding common profile entry errors that are causing establishments to be placed in inappropriate sampling programs.

FSIS Response:
FSIS will ascertain the most common profile errors and revise FSIS Directive 5300.1, *Managing the Establishment Profile in the Public Health Information System (PHIS),* to add a list of most common errors, and reiterate that establishment profile review and update task should be performed monthly.

Estimated Completion Date:
Revise Directive 5300.1, December 2013.

Recommendation 11:
Finalize and publish the agency's final rule, establishing requirements for industry to maintain grinding logs.

FSIS Response:
FSIS intends to propose to amend its recordkeeping regulations to address this issue. FSIS must follow established rulemaking procedures which will likely take more than one year to implement. FSIS is proposing to amend its recordkeeping regulations to specify that all official establishments and retail stores that grind raw beef products for sale in commerce must keep records that disclose the identity and contact information of the supplier of all source materials that they use in the preparation of each lot of raw ground beef and identify the names of those supplied source materials, including any beef components and any carryover from one production lot to the next. The records would also be required to document the amount of the beef component used in each lot (in lbs), the date and time each lot of raw ground beef product was produced, and the date and time when grinding equipment and other related food-contact surfaces were cleaned and sanitized. Official establishments and retail stores would also have to comply with the proposed recordkeeping requirements with respect to raw beef products that are ground at an individual customer's request. FSIS must assess the response to the proposed rule and make a decision whether to finalize the rule.

Estimated Completion Date:
Proposed rule on Grinding logs, May 2013.

Recommendation 12:
When the rule on grinding logs has been finalized, develop procedures for FSIS field personnel to evaluate whether establishments are maintaining adequate grinding logs that can be used to trace back implicated product to the source supplier in the event of a recall, with examples and criteria to assist inspection personnel in reviewing grinding logs to determine if the logs are

suitable. Those procedures should also include specific actions to take when an establishment's grinding logs are found to be in adequate.

FSIS Response:
Should the proposed rule become final, FSIS will develop procedures for FSIS field personnel to verify the rule on grinding logs, however, this process may take more than one year. FSIS is currently in the process of amending its recordkeeping regulations to address this issue. Should the rule become final, FSIS will develop and issue a Directive providing instructions to IPP to verify the rule on grinding logs. The Directive will instruct IPP to evaluate whether establishments are maintaining adequate grinding logs that can be used to trace back implicated product to the source supplier in the event that adulterated product has been produced, and will include examples and criteria to assist inspection personnel in reviewing grinding logs to determine if the logs are suitable. Those procedures will also include specific actions to take when an establishment's grinding logs are found to be in adequate.

Estimated Completion Date:
Develop procedures to verify rule on grinding logs, should the rule become final, April 2014.

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