U.S. Department of Agriculture
Office of Inspector General
Food Safety Initiative
Meat and Poultry Products

FOOD SAFETY AND INSPECTION SERVICE
LABORATORY TESTING OF MEAT AND POULTRY PRODUCTS

Report No. 24601-1-Ch
June 2000

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250

DATE: June 21, 2000

REPLY TO
ATTN OF: 24601-0001-Ch

SUBJECT: Laboratory Testing of Meat and Poultry Products

TO: Thomas J. Billy
Administrator
Food Safety and Inspection Service

ATTN: Margaret O' K. Glavin
Associate Administrator

This report presents the results of our audit of the Food Safety and Inspection Service's laboratory operations and activities. This review is part of the Office of Inspector General's food safety initiative, which also included the implementation of the Hazard Analysis and Critical Control Point System, District Enforcement Operations' compliance activities, and the agency's controls to ensure the safety of imported meat products. Your response to the official draft report, dated June 1, 2000, is included as exhibit B with excerpts and the Office of Inspector General's position incorporated into the Findings and Recommendations section of the report. Based on your response, management decisions have been reached on Recommendations Nos. 1, 2, 4, 6, 7, 8, 9, 11, 13, 14, 15, and 16. Please follow your agency's internal procedures in forwarding documentation for final action to the Office of the Chief Financial Officer.

Management decisions have not been reached on Recommendations Nos., 3, 5, 10, 12, and 17. Management decisions can be reached once you have provided the additional information outlined in the report sections, OIG Position.

In accordance with Departmental Regulation 1720-1, please furnish a reply within 60 days describing the corrective actions taken or planned, and the timeframes for implementation of the remaining recommendations. Please note that the regulation requires management decisions to be reached on all recommendations within 6 months of report issuance.

/s/
ROGER C. VIADERO
Inspector General

EXECUTIVE SUMMARY

LABORATORY TESTING
OF MEAT AND POULTRY PRODUCTS
AUDIT REPORT NO. 24601-1-Ch

RESULTS IN BRIEF

This report presents the results of our audit of the Food Safety and Inspection Service's (FSIS) laboratory activities and operations as administered by the FSIS Office of Public Health and Science (OPHS). This review was part of the Office of Inspector General's (OIG) food safety initiative, which also included the implementation of the Hazard Analysis and Critical Control Point System, the controls over imported meats, and District Enforcement Operations compliance activities. The objective of our audit was to evaluate whether FSIS had effective quality control procedures in place to ensure that all product is subject to testing, and that all laboratories performing tests of official product samples are adhering to applicable standards and are producing timely and accurate test results.

We found that the three FSIS field laboratories we visited were generally following the procedures prescribed by the agency and by the Association of Analytical Chemists (AOAC) when performing tests for pathogens, residues, food chemistry, and species identification on product samples obtained from meat and poultry slaughtering and processing establishments. In addition, the laboratories were producing timely and accurate test results. They correctly analyzed 180 unmarked samples we sent to them to determine if they could detect the presence or absence of the bacteria *Salmonella* and *E. coli 0157:H7*.

However, our review raised several important questions about the thoroughness of FSIS' sample testing since not all meat and poultry products prepared for the marketplace are subject to sample testing. Specifically, we noted the following control weaknesses:

- The database of meat and poultry establishments maintained by OPHS did not list all establishments which should have been subject to testing. Our reviews of 4 of the 11 "sampling frames," each of which is intended to list all establishments whose products are subject to testing under the various sampling projects, disclosed that the number of establishments listed was

understated by at least 31 percent. For instance, in our visit to one of FSIS' 17 district offices, we determined that there were at least 97 establishments in the area served by that office which produced processed meat and poultry products. FSIS sampling frames listed only 48 of the 97 establishments. Any establishment not included in its proper "sampling frame" cannot have product selected for microbiological or species identification testing. Undetected species mislabeling may affect individuals with dietary or religious needs; undetected pathogens may have their greatest effect on infants and the elderly.

- FSIS laboratories do not consistently test product samples from all the establishments in FSIS' sampling frames. We found that inspectors do not respond, on average, to 24 percent of OPHS' requests for samples to test. Although FSIS oversamples to ensure adequate numbers of test results, the degree of nonresponse leaves gaps in the sources of samples. In our review of 1,401 establishments for which product samples were requested under 3 sampling frames during the period January-May 1999, FSIS inspectors at 419 establishments (29 percent) did not respond to 2 or more requests for samples during the 5-month period of our review. Inspectors at 197 establishments (14 percent) did not respond to one or more requests during 3 or more months of our review period.

Two other deficiencies in FSIS' testing program affected the testing of product. Late deliveries of test samples to the laboratories resulted in discarded samples, and tests for nitrosamines did not ensure that all meat capable of containing the carcinogen was tested.

- We found that FSIS' overnight courier did not always provide next-day delivery of samples to laboratories on weekends. *Salmonella* samples for carcass products must be analyzed no later than the day after collection; otherwise, they must be discarded without being tested.

- Although FSIS regulations require that bacon products be tested for the presence of nitrosamines, the agency did not have a list of establishments that produced those products and did not even know the number of such establishments under FSIS inspection. Laboratory tests performed on samples from 34 different establishments during a 21-month period revealed that all contained nitrosamines, although none exceeded the established tolerance level. However, products from many establishments are not tested. At one FSIS district office with at least 30 bacon-

producing plants, only 2 such plants had product tested during the period of our review.

We also found that FSIS' quality assurance activities needed to be strengthened. The separate Quality Assurance Branches (QAB) that report to FSIS' Microbiology Division and Chemistry and Toxicology Division are responsible for monitoring the field laboratories through a combination of onsite field reviews and the periodic assessment of the laboratories' performance in analyzing "check samples" which contain known types and quantities of pathogens such as *Salmonella*, *E. coli*, and *Listeria monocytogenes*. We found that controls needed to be improved in several areas:

- The Microbiology Division's QAB did not ensure that onsite visits were conducted on a regular basis or that the results of these visits and of check samples were communicated to the laboratories. The QAB also did not ensure that laboratories responded to its review reports as required, or that they took corrective actions to address deficiencies identified by QAB.

- FSIS uses rapid "screening" test kits as part of its Salmonella testing program because the large number of tests required by the Hazard Analysis and Critical Control Points Program could not feasibly be done using the traditional culture and biochemical methods. However, the agency procured approximately 55,000 test kits that did not meet contract specifications, despite QAB tests that showed that the kits would fail to indicate the presence of Salmonella at more than twice the rate allowed by contract specifications. We issued a management alert to FSIS on this issue, and the agency is taking corrective actions to address the problem.

We consider issues involving controls over collection and testing of product samples from FSIS-inspected establishments to be material internal control weaknesses. As such, to ensure their prompt attention and correction, they should be included in the agency's annual management reports required under the Federal Manager's Financial Integrity Act (FMFIA).

Finally, we determined that laboratories need to better document their operations to assure that tests are performed according to FSIS standards and that test results are accurate. Two of the three laboratories we visited did not always document all steps in their analyses, including incubation times and temperatures. Also, the

laboratories did not always document equipment maintenance, including sterilization and calibration.

KEY RECOMMENDATIONS

We recommend that FSIS institute stronger procedures and controls to ensure that all meat and poultry establishments under Federal meat and poultry inspection acts are subject to product testing, and that FSIS inspectors at establishments selected for testing respond to sampling requests in all instances to ensure that FSIS' laboratory testing programs encompass the agency's entire universe of FSIS-inspected establishments. We also recommend that the agency strengthen its quality assurance programs to ensure that all FSIS and accredited laboratories are in full compliance with all applicable standards and are producing valid and supportable analytical results.

AGENCY RESPONSE

FSIS generally agreed with the findings and recommendations as presented, except as otherwise noted in the Agency Response sections of the report. As one of its general comments, FSIS officials stated that the report prematurely uses the International Organization for Standardization (ISO) Guide 17025 as a standard for FSIS laboratories. They believed that the agency's current standards were still valid, and were still being met.

FSIS' response to the official draft report, dated June 1, 2000, is included in its entirety as exhibit B of the audit report.

OIG POSITION

Based on the information provided in FSIS' response, we have reached management decisions on Recommendations Nos. 1, 2, 4, 6, 7, 8, 9, 11, 13, 14, 15, and 16. Management decisions have not yet been reached for Recommendations Nos. 3, 5, 10, 12, and 17.

As we stated to FSIS officials in previous meetings, OIG audited against FSIS' internal operating procedures wherever possible. However, we did make reference in several areas of the report to ISO Guide 17025 because FSIS either had not implemented its own procedures to cover certain areas of its operations or relied on draft procedures as described in Findings Nos. 6, 8 and 9. The relevance of the ISO Guide 17025 standards to the FSIS laboratories is also described in the Background section of the report.

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INTRODUCTION

BACKGROUND

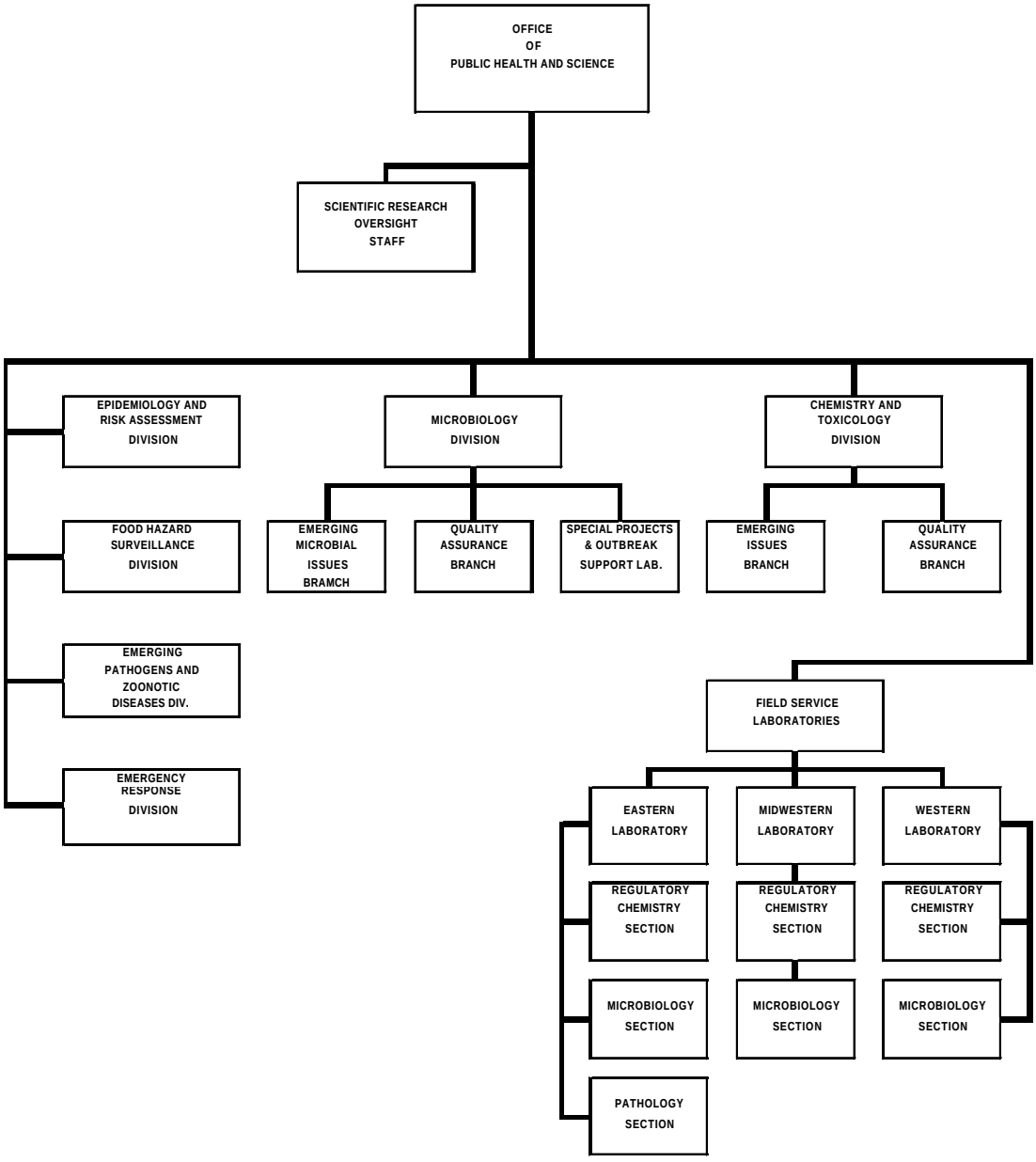
The Food Safety and Inspection Service (FSIS) was established by the Secretary of Agriculture on June 17, 1981. The mission of FSIS is to ensure that the Nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged as required by the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act.

FSIS laboratory activities include analyses of official product samples obtained from meat and poultry establishments under a variety of testing programs. These analyses include microbiology tests for pathogens such as *Salmonella* and *E.coli*, tests for antibiotic and chemical residues, food chemistry tests for fat content and for additives such as water and salt, and tests to verify the species of meat or poultry contained in product samples.

FSIS' Office of Public Health and Science (OPHS) provides microbiological, chemical, and toxicological expertise, leadership, and quality assurance and control for the agency. (See chart, next page.) OPHS also oversees field laboratory services for the agency. Within OPHS, two divisions are central to laboratory activities. The Chemistry and Toxicology Division provides scientific expertise to FSIS in chemistry, toxicology, and related science disciplines. It also manages the Accredited Laboratory Program and administers and provides technical expertise in quality assurance and quality control programs for FSIS laboratories through its Quality Assurance Branch (QAB), located in Washington, D.C. The Microbiology Division provides microbiological expertise regarding food borne pathogens, farm-to-table safety, and related public health issues. It plans and implements microbiological and analytical programs for the field support laboratories and administers microbiological quality assurance and quality control through its QAB, located in Athens, Georgia, to assure reliability of analytical data generated by FSIS laboratories. It also provides expert scientific support for investigations or foodborne disease outbreaks, extraneous materials detection, and other public health hazards.

About 7,400 full-time inspectors operating in approximately 6,200 federally inspected establishments throughout the United States assist FSIS in carrying out its mission. It is their responsibility to monitor the slaughter and processing of all meat and poultry products produced for interstate commerce in the United States.

Figure 1: FSIS Office Of Public Health and Science



In addition to the inspectors, 3 field service laboratories and 126 accredited laboratories provide analytical service support. The field service laboratories, located in Athens, Georgia; St. Louis, Missouri; and Alameda, California, provide pathological, microbiological, chemical, and other scientific examination of meat, poultry, and egg products for disease, infection, extraneous materials, drug and other chemical residues, or other types of adulterants.

In Calendar Year (CY) 1998, the three field service laboratories performed 729,661 analyses of 167,500 samples. Of the 126 accredited laboratories, 44 accredited laboratories analyzed 681 samples during the same period.

As part of their inspection duties, FSIS inspectors collect ready-to-eat and other processed product samples to be tested by the laboratories for the presence of pathogens and toxins. Since 1987, FSIS has conducted monitoring programs to identify the presence of *Listeria monocytogenes* and *Salmonella* in fully cooked, ready-to-eat meat and poultry products. Since proper cooking should destroy these pathogenic bacteria, a finding of these organisms in fully cooked, ready-to-eat products leads to regulatory action by FSIS. In Fiscal Year (FY) 1995, a monitoring program for *E.coli O157:H7* in cooked meat patties was initiated. Thirteen separate subsamples are analyzed from each product lot submitted by inspectors. In FY 1998, dry and semi-dry ready-to-eat fermented sausages were added to the *E.coli O157:H7* testing program.

In addition to the collection of ready-to-eat and other processed product samples, inspectors collect raw product samples for *Salmonella* testing. Microbiological standards for raw products did not exist prior to July 1996 (with the exception of the monitoring program for *E.coli O157:H7* in raw ground beef, which was initiated in FY 1995). On July 25, 1996, FSIS issued its landmark rule, Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems. The new, science-based system is designed to improve food safety and make better use of agency resources. In addition, the final rule established pathogen reduction performance standards for *Salmonella* in raw meat and poultry products. The FSIS inspectors collect the raw meat and poultry product samples from establishments and send them to the laboratories for *Salmonella* testing, in order to verify that establishments are meeting the pathogen reduction performance standards. Pathogen reduction performance standards for raw products are an essential component of FSIS' food safety strategy because they provide a direct measure of progress in controlling and reducing the most significant hazards

associated with raw meat and poultry products. Accordingly, the collection of samples in establishments by inspection program personnel is a significant agency priority.

Due to the addition of the large number of samples collected by inspectors under HACCP, the field service laboratories are using commercial test kits to perform an Enzyme-Linked Immunoassay (ELISA) test that screens each HACCP sample for the presence of *Salmonella*. The test identifies samples that are presumptively positive for *Salmonella*. The remaining samples are not tested further and are reported as negative. The samples that are presumptively positive will be tested using traditional laboratory procedures.

In addition to the collection of samples to be tested for pathogens and toxins, FSIS conducts the National Residue Program (NRP) for domestic products. The NRP is a multi-component analytical testing program for residues in domestic and imported meat, poultry, and egg products. The NRP provides a variety of sampling plans to verify that slaughter establishments are fulfilling their responsibilities under HACCP for preventing violative residues. The range of chemical compounds considered for inclusion in the various NRP testing programs is comprehensive in scope. It includes approved and unapproved pharmaceutical drugs and pesticides known or suspected to be present in food animals in the U.S. and in countries exporting products to the U.S. It also includes any other xenobiotic or naturally occurring compounds that may appear in meat, poultry, and egg products and that may pose a potential human health hazard.

FSIS uses several information systems to schedule the collection of samples for laboratory testing. The Performance Based Inspection System (PBIS) is used for scheduling regulatory inspection activities and reporting inspection findings. The Microbiological and Residue Computer Information System (MARCIS) is a consolidated database of analyses performed at the laboratories. In addition, for each sampling project, FSIS maintains a "sampling frame," which is a listing of establishments that produce products designated for testing by the sampling projects. The various divisions within OPHS provide information to the computer specialists regarding the numbers and types of products to sample and when. All of this information enables FSIS Headquarters to schedule the microbiology and residue samples. PBIS schedules the food chemistry samples.

A unified sampling form, FSIS Form 10,210-3, is used by inspectors for all directed sampling projects (microbiological, chemical, and residue) with the exception of the PR/HACCP *Salmonella* sampling

program. The sampling projects and the unified form establish a uniform system for sample collection and transmittal of samples to laboratories. The use of the new form and system will facilitate the eventual electronic transfer of sampling requests and the tracking of samples in the laboratories. When the form is sent to inspectors, certain blocks are pre-preprinted with information specific to the sample to be collected. Sample collectors are required to complete Part II of the form and send it with the sample to the specified laboratory. If for any reason samples are not collected, sample collectors are to complete blocks 29-33 of Part II and send the form to the specified laboratory.

The International Organization for Standardization (ISO) Standard 17025 (which replaced ISO Guide 25) details the most comprehensive set of requirements for testing and calibration laboratories. The FSIS Field Laboratories are not currently accredited by the ISO, and FSIS officials stated that few if any government food-testing laboratories in the United States possess such accreditation. However, FSIS has underway an initiative whose goal is to achieve accreditation under ISO Standard 17025.

ISO standards require that laboratories ensure the quality of results provided to clients by implementing checks, such as participation in proficiency testing. FSIS uses proficiency testing to monitor the quality and accuracy of analytical results from its laboratories. This testing provides an essential quality management tool that avoids bias and ensures accurate and reliable data. On a quarterly or semiannual basis, each FSIS field laboratory receives a series of proficiency check samples for analysis. Once the check samples have been tested, the results are reported to the QAB, which grades the laboratory's performance and forwards the graded results to FSIS Headquarters. After a review of the results, Headquarters forwards the results to the laboratory. It is the responsibility of Headquarters to ensure that the laboratory takes any necessary corrective actions.

ISO also requires that laboratories arrange for reviews of their activities at appropriate intervals to verify that operations continue to comply with the requirements of the quality system. FSIS guidelines require that QAB perform onsite reviews of each laboratory at least twice a year. These reviews are to cover all critical procedures and functions that are part of the daily routine of the laboratory.

The laboratories use the Microbiology Laboratory Guidebook (MLG) for the microbiological analysis of meat, poultry, and egg products that fall under the jurisdiction of USDA. It contains methods that the

FSIS laboratories are to use for the isolation and identification of pathogens including *Salmonella, E.coli O157:H7, Campylobacter jejuni/coli, Listeria monocytogenes, Clostridium perfringens, and Staphylococcal enterotoxins* in meat, poultry, and egg products. In addition, it contains methods for the detection and identification of extraneous materials in these foods.

The Analytical Chemistry Laboratory Guidebook—Food Chemistry is the reference book of regulatory methods for the analysis of meat and poultry products.

The FSIS laboratories are currently moving toward accreditation under ISO Standard 17025. This is a recognition of laboratory competence, and requires that each laboratory have a quality system in place for critical materials, organization and management, reviews for compliance with quality systems, personnel education and training, calibration of critical equipment and materials, test methods, and records. FSIS has estimated that the ISO Standard 17025 accreditation process will take 1 to 1-1/2 years. We believe that FSIS needs to accomplish this as expeditiously as possible.

OBJECTIVES

The overall audit objective was to determine whether all meat and poultry products were subject to testing, and if FSIS' quality assurance over laboratory activities ensured that field service and accredited laboratories maintained sample integrity through proper handling and security, and conducted tests in a timely and accurate manner. Specifically, we determined whether: (1) FSIS Headquarters effectively scheduled samples to be collected, and effectively administered their quality assurance program; and (2) the field service laboratories used prescribed methods and procedures for tests, performed tests in a timely manner, properly documented all tests, and properly maintained their equipment.

SCOPE

The audit fieldwork was performed at the FSIS National Office in Washington, DC; the three field service laboratories, located in Athens, Georgia; St. Louis, Missouri; and Alameda, California; the Quality Assurance Branch for Microbiology, located in Athens, Georgia; the Special Projects and Outbreak Support Laboratory, located in Athens, Georgia; and one FSIS district office located in Pickerington, Ohio. We also utilized

information collected at three meat and poultry establishments that were visited as part of the OIG Southeast Region's audit of HACCP. We performed the fieldwork from May 1999 through December 1999.

We selected statistical and judgmental samples of 190 food chemistry, microbiology, and residue laboratory tests out of about 181,000 that were performed between January 1998 and April 1999 for review.

We also reviewed 4 of the 11 sampling frames in FSIS' database for accuracy and completeness, and reviewed the MARCIS listings of sampling requests and associated responses for a 5-month period in 1999.

We conducted this audit in accordance with Generally Accepted Government Auditing Standards.

METHODOLOGY

At the National Office and the Quality Assurance Branch for Microbiology, we analyzed documents and conducted interviews with FSIS officials. We reviewed FSIS policies and procedures regarding the types of tests being performed, the methods for selecting samples to be collected, and the quality assurance programs in place in the microbiology, residues, and food chemistry areas, to ensure the laboratories performed timely and accurate analyses of meat and poultry products. We also reviewed the information provided by the Microbiological and Residue Computer Information System (MARCIS), which is used to track the processing of scheduled microbiological, residue, and food chemistry samples.

At the Special Projects and Outbreak Support Laboratory, we conducted interviews and reviewed documentation of analyses performed.

At the three field laboratories, we conducted interviews with laboratory directors, computer specialists, microbiologists and chemists-in-charge, quality control managers for microbiology and chemistry, analysts, and other staff, and reviewed supporting documentation. We also observed laboratory procedures in the areas of: (1) computer input of sample information; (2) sample receiving activities; (3) media preparation; and (4) microbiology, food chemistry, and residue testing procedures. For our samples of tests performed, we reviewed supporting documentation of the tests performed.

At the district office, we reviewed and analyzed documentation of the number of plants in the district and the types of products produced.

In addition, in cooperation with another USDA agency, we contracted with a private, FSIS-accredited laboratory to send a total of 180 unmarked check samples to the three field laboratories during November and December 1999, to verify the competence of the laboratories to detect the presence of *Salmonella* and *E.coli 0157:H7* in product samples.

We also used the scientific expertise of this other USDA agency to evaluate the laboratory standards, policies, and procedures of FSIS.

FINDINGS AND RECOMMENDATIONS

CHAPTER 1	CONTROLS OVER THE COLLECTION AND TESTING OF PRODUCT SAMPLES NEED TO BE IMPROVED

FSIS' Office of Public Health and Science (OPHS) selects the establishments from which products will be sampled each month. To identify its "universe" of meat and poultry establishments from which to select product samples for testing, FSIS maintains separate databases that list the establishments that could be selected under the various program areas. OPHS uses a computerized database to select establishments for product testing. This database contains separate listings of establishments, referred to as "sampling frames," which categorize establishments by the type of product they produce. A separate sampling frame is maintained for 11 different pathogen and species-identification monitoring projects (see exhibit A) administered by the various FSIS Headquarters divisions.

We found that FSIS could not ensure that all plants under inspection were available to be selected for product sampling. We found that the sampling frames contained in the agency's database were not all inclusive; for instance, in our review of one large sampling frame, we found that although 1,106 establishments were listed, at minimum it should have listed 1,606 establishments, an understatement of 31 percent. We also identified 97 establishments that produced cooked, ready-to-eat poultry products at one of FSIS' 17 district offices; however, a review of 11 sampling frames which should have included all of these establishments disclosed that only 48 were listed. Even though FSIS regulations require the agency to test bacon products for the presence of nitrosamines, a known carcinogen, FSIS could not provide us with a listing of establishments which produce this product, or even the number of such establishments under FSIS inspection.

FSIS also did not have controls to ensure that its inspectors obtained all the necessary product samples for testing by the laboratories. We found that FSIS inspectors did not respond to 24 percent of the requests for product samples sent out by OPHS between January and May 1999, either in the form of product samples sent or explanations as to why the samples could not be obtained. OPHS

officials were aware of the high nonresponse rate and oversampled to ensure that enough analyses were performed to monitor overall product processing; however, FSIS cannot assure that products from untested establishments are complying with meat and poultry inspection requirements. In addition, inspectors at many establishments did not respond to sampling requests on a repeated basis. Of 1,395 establishments selected for product sampling under 3 sampling frames between January and May 1999, inspectors at 419 establishments (30 percent) failed to respond to 1 or more requests during this period, while inspectors at 197 establishments (14 percent) failed to respond to 1 or more requests in 3 or more months.

FSIS needs to ensure that all inspected establishments are subject to being selected for product testing, and that all sampled establishments are in fact being tested. Laboratory testing for pathogens and residues is an integral part of the agency's monitoring system to ensure that meat and poultry establishments are maintained in sanitary condition and that their products are free from harmful contaminants.

FINDING NO. 1

FSIS NEEDS TO ENSURE THAT ALL ESTABLISHMENTS ARE SUBJECT TO PRODUCT TESTING

FSIS did not identify, for inclusion in its testing programs, all establishments producing processed products designated for laboratory analyses. This occurred because FSIS did not have controls to ensure that FSIS inspectors updated the agency's establishment information on the required basis, or to periodically review the agency's databases to determine whether they include all establishments subject to testing under each category. As a result, FSIS is not including all establishments in its various testing programs for microbiology, residues, food chemistry, and species identification. We found, for instance, that the 1,106 establishments included under one large sampling frame we reviewed were understated by at least 31 percent.

FSIS maintains a "sampling frame" (a listing of establishments that produce products of a designated type) for testing under each of the sampling projects. To maintain a complete and accurate sampling frame for each project, FSIS requires its inspectors at meat and poultry establishments to submit updated establishment information

twice a year to FSIS Headquarters.[1] When sample requests are made from establishments that do not produce the designated product the inspector reports to the laboratory that the product is no longer available. The laboratory then passes this information to FSIS Headquarters to remove the establishment from the sampling frame.

FSIS currently has 11 sampling projects (see exhibit A) that test for pathogens and species identification in processed products from meat and poultry establishments. The number of samples scheduled for the projects ranged from 45 samples for project MT01 (*E.coli 0157:H7* in Ready-to-Eat Meat Patties) to 768 samples for project ME15 (*Listeria* and *Salmonella* in Small Diameter Cooked Products).

We evaluated whether the sampling frames for pathogen and species identification testing included all establishments that produced the products designated for each type of testing. We compared the sampling frames for sampling projects that included the same designated products to determine if each sampling frame listed the same establishments. In addition, at one district office, we compared the office's listing of processing establishments under its jurisdiction to the comparable sampling frames to determine if the sampling frames were all-inclusive for this area. We found that the sampling frames used by FSIS to identify establishments whose products should be sampled for each type of test were both inaccurate and incomplete. Details of the conditions noted were as follows:

- The sampling frame for project MM14, Cooked Product Species Testing, lists 1,106 establishments that produce cooked, processed product. We compared this to project ME22, Salmonella/Listeria in Cooked Poultry Products, whose sampling frame listed 472 establishments which produced cooked, processed poultry products. The sampling frame for project MM14 was larger because it included all establishments producing cooked, processed meat and poultry products, whereas that of ME22 would include only those establishments producing cooked and processed poultry products. Thus, all establishments listed in the sampling frame for project ME22 should also have been included in the sampling frame for project MM14.

[1] FSIS Directive 10230.3 Rev. 2

However, we found that the sampling frame for project MM14 included 131 establishments producing cooked, processed poultry products that were not included in the sampling frame for project ME22. Conversely, the sampling frame for project ME22 contained 234 establishments that were not included in the sampling frame for project MM14.

- The sampling frame for project ME15, Salmonella/Listeria in Small Diameter Cooked Products, included 745 establishments that also should have been listed in the sampling frame for project MM14, Species Identification Testing in Cooked Meat and Poultry Products. The sampling frame for project MM14 did not include 231 of the establishments identified by project ME15's sampling frame.

- The sampling frame for project ME23, *Salmonella/Listeria*/Staphylococcus Aureus in Salads, identified 126 establishments that should also be included in the sampling frame for project MM14. The sampling frame for project MM14 did not include 61 establishments identified by the sampling frame for ME23.

Overall we found that, after adjusting for establishments listed under more than one of the sampling frames, MM14 should have included 1,606 establishments instead of the 1,106 that were listed, an understatement of 500 (31 percent).

To further evaluate the accuracy of the above sampling frames, we visited one of the 17 FSIS district offices. Although the establishment information on file at the district office did not always clearly identify the products processed by the establishments, we were able to identify 97 establishments that produced processed meat and poultry products that should have been included in the sampling frames for 11 projects designed to test for pathogens in ready-to-eat products or to conduct species testing in cooked products. The sampling frames for the 10 projects identified only 48 of the 97 establishments.

During the period of January 1, 1999, through May 31, 1999, FSIS records showed that 593 sample requests could not be obtained because the establishments did not produce the products. At 52 establishments the inspectors discarded the sample requests for 3 or more months because the establishments did not process the designated product samples. FSIS did not follow up with the inspectors to determine whether these establishments were in the wrong sampling frames.

We discussed the above issues with the OPHS official who is responsible for sending out the sampling requests, and the official stated that FSIS does not have procedures in place to ensure that the sampling frames are kept current. The official explained that FSIS makes semiannual requests for its inspectors to submit updated information on their establishments. This information is transmitted electronically to OPHS, which in turn updates the sampling frame information. However, no record is maintained to show when the information was last updated and FSIS is unable to identify establishments whose information is incorrect or out of date. In addition, FSIS information systems do not identify products processed by specific meat and poultry establishments. As a result, FSIS cannot conduct a data base analysis to determine if the sampling frames include all applicable establishments.

We consider this issue to be a material internal control weakness, since it directly impacts the agency's ability to collect and test product samples from FSIS-inspected meat and poultry establishments. As a result, we believe that this should be included in the agency's annual management report under the Federal Manager's Financial Integrity Act (FMFIA).

RECOMMENDATION NO. 1

Develop a management system to track each inspector's compliance with requirements for semiannual updates to the sampling frames. Follow up with establishment inspectors who do not respond to ensure that sampling information is up-to-date for all establishments.

FSIS Response

FSIS officials responded that they would develop an approach to follow up with inspectors. For *Salmonella* testing, FSIS developed the Pathogen Reduction Enforcement Program (PREP) that will schedule, track, and report test results. One of this program's features will provide followup with inspectors that do not provide information needed to update sampling frame information. FSIS officials stated that this program will be fully implemented by September 2000. For ready-to-eat (RTE) products, the sampling frames will be based on information in the PBIS. For *E.coli 0157:H7* and residue testing, plans are underway to incorporate PBIS plant profile data as the source for updating sampling frame information.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 2

Develop a database that identifies and segments all establishments producing products designated for sampling under the various sampling projects. Use this information to maintain current listings within the sampling frames for the sampling projects.

FSIS Response

FSIS stated that it would enhance the PBIS establishment profile by December 2000, to include all product information needed for sampling programs and require inspection personnel to keep that information up to date.

OIG Position

We accept FSIS' management decision.

FINDING NO. 2

FSIS NEEDS TO TRACK THE DISPOSITION OF PRODUCT SAMPLING REQUESTS

FSIS does not track the disposition of requests for monitoring samples sent to FSIS inspectors at meat and poultry establishments, or follow up in cases where inspectors neither provide requested samples nor report their reasons for not doing so. FSIS has the ability to track the receipt of these responses, but the agency does not have operating procedures to perform this monitoring. FSIS does not require its inspectors to keep records of the receipt and disposition of requests, thus limiting its ability to follow up at a later date to determine why required samples have not been provided.

FSIS inspectors did not respond to approximately 24 percent of the requests for monitoring samples, which include all samples from establishments other than those obtained under HAACP. Officials of OPHS stated that they oversample to account for the large number of non-responses. However, the agency's failure to obtain responses to all sampling requests could allow problems to go undetected at establishments whose products go untested for significant periods of time. As previously mentioned, our review of the sampling frames for ME15, MM11, and MT02 for the period of January 1 through May 31, 1999, showed that of 1,395 establishments selected for product

testing, the FSIS inspectors at 419 (30 percent) failed to respond to one or more sampling requests during 2 or more months. Inspectors at 197 establishments (14 percent) did not respond to one or more of the sampling requests sent during 3 or more months.

FSIS currently has 11 sampling projects under which the agency performs about 71,000 laboratory tests annually for pathogens (such as *Salmonella*, *E.coli*, and *Listeria monocytogenes)* and species identification (which verifies the type of meat in sampled products) in product samples obtained from meat and poultry establishments. In addition, FSIS has a separate testing program under which laboratory tests are performed on both raw and processed products to detect the presence of residues such as chemicals and antibiotics, and food chemistry analyses which test for fat, protein, salt, and moisture content.

Between January 1 and May 31, 1999, FSIS sent out a total of 16,830 microbiology and 12,760 residue sample requests to FSIS inspectors. OPHS officials explained that the numbers of requests sent out are based on the historical needs of the FSIS Headquarters divisions that maintain and operate the pathogen/species identification sampling projects, as well as the separate testing program for residues and food chemistry. OPHS determines the number and type of sampling requests to be sent out each month in order to meet the needs of the various testing programs. Establishments that produce the specified products are sampled through non-statistical means from the database of establishments under FSIS inspection. Sampling requests for the products are sent to the FSIS inspectors at these establishments using FSIS Form 10210-3. The FSIS inspector receiving the request is required to provide the specified product within a stated time period as shown on the sample request form. The form also specifies the FSIS field laboratory to which the sample is to be sent, and provides any other specialized instructions applicable to a particular sampling request.

In cases where the type of sample being requested is not available at the establishment during the time period specified on the request form, establishment inspectors are required to report this fact to the designated laboratory so that this information can be entered into the data base system. Justifiable reasons for not obtaining the requested sample include cases where the establishment is not operating during the specified time period, or where the establishment no longer produces the specified product. In the latter case, the inspector reports the product as being “never available,” which notifies FSIS

that further samples of that type should not be requested from that establishment.

Under current FSIS procedures, the results from these tests are to be reported to FSIS Headquarters by the laboratories, so that the various FSIS Headquarters divisions can make use of the test results. However, positive test results for harmful pathogens and residues are also to be reported to the establishment inspector and the applicable FSIS district office, so that followup action such as further testing or enforcement actions can be taken.

We found that FSIS inspectors at meat and poultry establishments frequently do not respond to the sampling requests, either by providing the required samples or the reason the samples could not be collected. Our review of the FSIS data base for the period of January 1 through May 31, 1999, showed that 16,830 sampling requests were sent out by OPHS in support of sampling projects relating to microbiology testing. However, for 4,376 of these (26 percent), no responses were received from the FSIS establishment inspectors. Similarly, we found that out of 12,760 sample requests for products to be tested for residues or food chemistry during this same time period, 2,714 (21 percent) received no responses. In addition, we reviewed the residue and food chemistry sample requests for the period of June 1 through September 30, 1999, and found that of 11,176 requests sent, 2,528 (23 percent) received no response. In total, FSIS inspectors failed to respond to 9,618 requests (24 percent).

According to the OPHS official responsible for handling the requests, an inspector's non-response to sampling requests does not generate any followup by FSIS, even if an inspector does not respond on a repeated basis. Although FSIS' computer system has the ability to identify and track non-responses to sampling requests, FSIS has no operating procedures in place to do this or to follow up with inspectors to get the requested samples. This official further stated that based on past response rates OPHS oversamples by approximately 25 percent to ensure that the requesting divisions receive a sufficiently large number of completed laboratory analyses to meet their needs. According to the OPHS official we interviewed, none of the Headquarters divisions which receive and utilize these test results have expressed concerns that they are not receiving enough test results for their purposes.

In conjunction with OIG's ongoing audit of the HACCP program, we attempted to reconcile OPHS' computerized records of samples

requested and received at three slaughtering establishments. We found, however, that this could not be accomplished because the inspectors kept no records of the sampling request forms they had received or of any samples they had sent to the laboratories. According to both the inspectors and to the OPHS official, establishment inspectors are not currently required to keep such documentation. The Assistant Deputy Administrator in charge of OPHS expressed his concerns about the lack of records in this area.

OPHS, through its policy of oversampling, was able to provide a sufficient number of test results to the various users. However, serious problems with individual establishment sanitation or product contamination could exist at establishments whose inspectors do not respond to sample requests for microbiological and residue testing.

FSIS needs to implement controls and procedures to ensure that establishment inspectors respond to its requests for samples. In addition, the agency needs to ensure the individual accountability of FSIS inspectors at meat and poultry establishments by requiring them to maintain documentation of sample requests they receive, as well as the inspector's actions to either fulfill the requests or report the reason why this could not be accomplished.

We consider this issue to be a material internal control weakness, since it directly impacts the agency's ability to collect and test product samples from FSIS-inspected meat and poultry establishments. As a result, we believe that this should be included in the agency's annual management report under the FMFIA.

RECOMMENDATION NO. 3

Institute procedures to monitor the responses to sampling requests on a monthly basis, and identify instances where inspectors do not respond. Where inspectors do not respond to sampling requests, require the district offices to follow up with the establishment inspectors to determine the reason for their failure to provide the required responses. In addition, perform immediate followup on the 197 establishments that failed to respond to 3 or more requests.

FSIS Response

FSIS officials agreed that a better process is required to monitor the responses to sampling requests on a monthly basis, and identify instances where inspectors do not respond. They stated that by September 2000 they will expand their reporting system to alert FSIS officials of inspectors not responding to ready-to-eat sample requests, similar to what is in place for *Salmonella* Performance Standard sampling. They also stated that they are working to enhance FSIS' e-mail system by including a quarterly summary that will be mailed to circuit supervisors listing all plants for which scheduled samples were not provided to the laboratories.

OIG Position

We concur with FSIS' efforts to enhance its reporting systems to identify inspectors who do not respond to requests for product samples. However, FSIS officials did not address the issue of the 197 establishments that failed to respond to 3 or more requests. To reach management decision, they need to provide us with a response to address this item.

RECOMMENDATION NO. 4

Implement a system which allows FSIS to track the status of sample requests, including their receipt and disposition by inspectors at meat and poultry establishments.

FSIS Response

FSIS agreed with the recommendation and will modify PBIS to track the status and disposition of sample requests. FSIS will create an official form, the "sample log", for inspection personnel to use in tracking sample collection and submittal, and will change FSIS Directive 10,230.5 to include instructions on maintaining the log by December 2000.

OIG Position

We accept FSIS' management decision

FINDING NO. 3

AGREEMENT WITH OVERNIGHT COURIER DID NOT GUARANTEE TIMELY WEEKEND OR HOLIDAY DELIVERIES TO FIELD LABORATORIES

FSIS' agreement with its overnight courier service did not always ensure next-day delivery of *Salmonella* samples to the field laboratories in cases where samples were sent on Fridays or on days preceding holidays. FSIS field officials had not been previously aware that samples were not being given next-day delivery in these cases, and believed that their agreement required this. However, between January 1, 1999, and December 31, 1999, the field laboratories discarded about 10 percent of the samples mailed on Fridays because of delayed shipments.

FSIS directives[2] state that carcass samples must be picked up by the overnight courier the same calendar day the sample is collected. Carcass samples must be analyzed the day after collection. If a *Salmonella* sample is not shipped on the same day it is collected, or if the sample is not received by the laboratory on the day after collection, laboratory procedures require that the sample be discarded without being tested.

As a part of our audit, we sent unmarked ("blind") check samples to the field laboratories to be tested for the presence of *Salmonella*. However, the field laboratories discarded all of the check samples sent on the first Friday of our testing period because they were not delivered until the following Monday. The FSIS official responsible for our shipping arrangements stated that this should not have occurred, since their contract required next-day delivery even if this involved samples being delivered on Saturdays and holidays.

FSIS officials provided us with information that showed, during calendar year 1999, that its overnight courier made 6,599 Saturday deliveries of HACCP *Salmonella* samples to the field laboratories. They also reported that 664 samples scheduled for Saturday delivery were discarded due to "shipping delays" by the courier. This represents approximately 10 percent of the Saturday deliveries of HACCP samples for calendar year 1999. Overall, FSIS inspectors sent over 61,000 *Salmonella* samples to the laboratories during this period.

[2] FSIS Directive 10,230.5 dated 2/4/98.

Under HACCP requirements, FSIS inspectors at meat and poultry establishments may be required to send product samples on successive days, including Fridays and days preceding holidays, to complete a sample series. However, according to an official at FSIS' Technical Service Center, this may not always be possible for a variety of reasons such as an establishment not operating on certain days. Therefore, we believe that FSIS Headquarters officials need to determine whether or not next-day delivery of samples sent on these days is necessary for the agency's laboratory testing program. If so, then FSIS needs to renegotiate its agreement with the overnight courier to ensure that these samples will reach the laboratories in time to be tested. If the agency determines that an alternative method is available to test establishments production so that it is not necessary to send samples on these days, FSIS Headquarters should notify the laboratories and all inspectors at meat and poultry establishments to discontinue shipments of product samples on these days.

RECOMMENDATION NO. 5

Determine whether it is necessary for FSIS inspectors to be able to ship product samples to the field laboratories on Fridays and on days preceding holidays. Renegotiate the existing agreement with the overnight courier to ensure next-day deliveries of such shipments, or inform the laboratories and all FSIS inspectors to discontinue shipments of product samples on these days if alternative methods are developed to test products that are produced on these days.

FSIS Response

FSIS officials stated that they have determined that it is necessary for inspectors to ship samples on Fridays and on days preceding holidays for *Salmonella* analysis. However, the agency disagrees that further negotiation of the contract is necessary, since the GSA contract with the overnight courier does require Saturday delivery of samples if these are properly labeled. FSIS officials stated that they have had Saturday delivery of HACCP samples since the initiation of the HACCP *Salmonella* Program on January 26, 1998. All laboratories receive and process samples via the overnight courier on Saturdays and selected holidays. They stated that FSIS has experienced occasional problems with Saturday deliveries in a few very remote locations. They also stated that OIG may have experienced difficulty shipping samples due to the lack of "Saturday Delivery" labels.

Regarding holiday deliveries, FSIS maintains close contact with the overnight courier to determine which holidays the courier is not operating. In situations where the courier does not deliver on a particular holiday, FSIS notifies the inspectors in all HACCP establishments so that samples are not sent. Finally, FSIS officials stated that the overnight courier recently initiated a new process that does not require the use of special labels for Saturday delivery. A new flyer is being distributed to all FSIS inspectors immediately.

OIG Position

As noted in our finding, approximately 10 percent of all planned Saturday deliveries of HACCP samples in calendar year 1999 had to be discarded due to shipping delays by the overnight courier. We do not believe that such numbers can be explained by "occasional problems with Saturday deliveries in a few very remote locations," as stated in the agency's response. If the agreement with the courier does in fact guarantee Saturday deliveries, as FSIS officials contend, then the number of delayed shipments experienced by the agency should be considered excessive. As stated earlier to FSIS officials, the boxes containing the OIG check samples had the "Saturday Delivery" labels affixed to them, as provided to us by FSIS personnel.

The FSIS response also states that the new process being implemented by the overnight courier does not require the use of special labels for Saturday delivery. However, the new instructions being sent to the FSIS inspectors at meat and poultry establishments (Attachment 4 of the response) clearly show that Saturday delivery labels are still used. Based on this information, it is not clear that there has been any significant change to the existing process that caused over 650 HACCP samples to be discarded untested in 1999.

Overall, we do not believe that FSIS has satisfactorily addressed this recommendation. To reach a management decision, FSIS needs to provide us with assurances that the overnight courier is guaranteeing that all HACCP samples mailed on Fridays or on days preceding holidays will be received the following day by the laboratories.

FINDING NO. 4

TESTING PROGRAM FOR NITROSAMINES NEEDS TO BE IMPROVED

FSIS' program to test for the presence of nitrosamines, a carcinogen that can occur in bacon products, did not ensure that all establishments producing such products were subject to testing. Although such testing is a regulatory requirement, FSIS' information systems

did not include a database or sampling frame that grouped these establishments for sample selection. Because of this, FSIS could not identify the establishments producing products that may contain nitrosamines. During the 21-month period between November 1997, and July 1999, FSIS only requested one product sample apiece from 60 establishments; by contrast, one FSIS District Office alone had 30 bacon-producing establishments under inspection. Of the 60 requested samples only 34 were actually tested, all of which were found to contain low levels of nitrosamines. Because of the relatively small number of tests performed, and the agency's inability to identify the universe of such establishments from which to draw its samples, we question whether the regulatory requirement for testing of nitrosamines was met.

Nitrosamines can occur in any bacon product where nitrite is used to cure the meat and can be formed when the bacon is fried. To ensure that bacon products are safe for consumers, FSIS issued regulations[3] that require the collection of bacon samples for testing to determine nitrosamine levels, with samples to be collected randomly throughout a selected production lot. FSIS has determined the unacceptable level of nitrosamines in any product to be anything over 15 parts per billion. In any instance where such levels are identified in a tested product sample, the agency is responsible for taking enforcement action that could include the recall of contaminated product from the marketplace.

Between November 12, 1997, and July 8, 1999, FSIS conducted only limited testing of bacon products for the presence of nitrosamines. During this period, FSIS scheduled sample selections from 60 establishments. However, in 23 instances no samples were sent from the selected establishments either because the inspectors failed to respond to the sampling requests or because they reported that the product was unavailable for testing. In 3 instances where the samples were provided, valid results could not be obtained because of "laboratory errors;" however, each of the 34 samples for which tests were successfully completed showed nitrosamine levels of between 3.01 and 14.77 parts per billion. None of these test results exceeded the tolerance level of 15 parts per billion, and thus no followup action by FSIS was required. However, these test results indicate that the presence of nitrosamines in bacon products is a common occurrence. After July 8, 1999, no further samples were requested for nitrosamines testing.

[3] 9 CFR 318.7(b)(2).

FSIS officials were unable to provide us with a listing of establishments that produce bacon products that would be subject to testing for nitrosamines, or even the total number of such establishments that are currently under FSIS inspection. This information was not available because FSIS has not compiled a sampling frame or other listing of such establishments; nor could such information be readily obtained from FSIS' databases because these do not include information on the type of products produced by each establishment. However, during our review at one FSIS District Office, we identified at least 30 establishments within the district that were producing bacon products. Of those, only 2 had been selected for nitrosamines testing during the period of our review.

We interviewed FSIS officials from each unit that has responsibilities in the area of nitrosamines testing, including the Eastern Field Laboratory, and the Scientific Research Oversight Staff. None of the officials were able to state why greater emphasis had not been given to the agency's nitrosamines testing program. The Director of Regulation Development and Analysis stated that the plan is to include nitrosamines testing as a part of HACCP and have the testing performed by the establishments. FSIS officials stated that the agency plans to publish a proposed rule covering this by March 31, 2001.

Unless all bacon-processing establishments under FSIS inspection are subject to nitrosamines testing, FSIS has limited assurance that bacon products marketed to consumers do not contain unsafe levels of this carcinogenic substance. Based on the results of the limited testing performed during the period of 1997 through 1999, we believe that FSIS needs to implement a better testing program.

RECOMMENDATION NO. 6

Ensure that all establishments producing bacon products are subject to required testing for nitrosamines. Implement a comprehensive program of testing for this substance, under which all bacon-producing establishments would have product subject to periodic testing over a predetermined period of time.

FSIS Response

By March 3, 2001, FSIS intends to publish a rule to convert nitrosamine requirements provided by 9 CFR 318.7(b) to performance standards under the establishments' HACCP procedures. The performance standard is expected to address the nitrosamine levels

as well as the potential growth of *Clostridium botulinum*. The proposed rule will require the establishments to control their production to produce safe products. FSIS will be expected to verify that the establishments are following the HACCP procedures, which may include product testing to verify nitrosamine levels.

OIG Position

We accept FSIS' management decision.

CHAPTER 2	QUALITY ASSURANCE ACTIVITIES NEED TO BE STRENGTHENED

To ensure that the FSIS laboratories are meeting all applicable quality control standards as set forth by regulations, the Microbiology Division and the Chemistry and Toxicology Division have each established a Quality Assurance Branch to perform various monitoring tasks. The Microbiology Division's QAB is responsible for all laboratory operations which involve pathogen testing and species identification, while the Chemistry and Toxicology Division's QAB administers testing programs for residues and food chemistry. Each QAB is responsible for making periodic onsite field visits to the laboratories, as well as sending check samples to the laboratories. The results of the laboratory analyses of these check samples are evaluated against pre-specified criteria by the QAB's, and are used as a means of verifying the proficiency of the laboratories in performing analyses of official product samples from meat and poultry establishments.

We found, however, that because of the way the check sampling programs had been implemented by both divisions, their results were not necessarily representative of the actual performance of the laboratories in the day-to-day testing of official product samples. Since the check sample sets were clearly marked to distinguish them from official samples, the laboratories were aware that they were being tested. We performed our own check sampling procedure, sending 60 unmarked ("blind") check samples to each laboratory for *Salmonella* and *E.coli* testing. In each instance, the FSIS field laboratories correctly identified the presence of the pathogens in our check samples.

Our audit noted, however, that the Microbiology QAB had not implemented adequate controls to ensure that all field visits were performed on the required schedule, or that the results of onsite visits and check samples were always communicated to the laboratories. The microbiology QAB did not ensure that laboratories responded to review reports as required. Without such controls, laboratories may remain unaware of deficiencies disclosed through the various QAB reviews. In addition, FSIS has no assurance that needed corrective actions have been taken by the laboratories to correct reported deficiencies. Further, the Microbiology Division had not implemented a formal training program for its analysts at the laboratories, or

required that any training provided to these analysts was documented as required under both ISO standards and the draft FSIS requirements sent to the field laboratories. Such a program needs to be implemented before it can obtain ISO accreditation.

The Microbiology QAB also performs quality control assessments on the screening test kits that the laboratories use in order to perform the large number of *Salmonella* tests required under HAACP. However, FSIS procured over 55,000 test kits from one vendor even though QAB notified FSIS Headquarters that the test kits recorded "false negative" test results in almost 7 percent of the tests performed; this was more than twice the allowable rate of 3 percent under both the procurement contract and FSIS' Microbiology Laboratory Guidelines. Based on the potential health risks to the public which excessive false negative test results could cause, we issued a management alert and FSIS is taking corrective actions.

Finally, neither OPHS nor the QAB's had implemented a quality assurance program for the Special Project and Outbreak Support Laboratory, whose functions include conducting investigations into outbreaks of foodborne illness. Overall, we believe that improvements in these various quality assurance functions would greatly enhance the assurances available to FSIS management that the laboratories are performing accurate and supportable analyses.

FINDING NO. 5

BETTER FOLLOWUP IS NEEDED WHEN DEVIATIONS ARE FOUND IN LABORATORY CHECK SAMPLE RESULTS

FSIS did not have adequate controls in place to ensure that deviations identified at the field laboratories through proficiency check samples were timely reported to FSIS Headquarters and the laboratories. In addition, FSIS did not perform the necessary monitoring to ensure that the laboratories adequately addressed the problems or deviations noted. We attributed this in part, to the FSIS Microbiology Division and its Quality Assurance Branch, which did not adequately coordinate with one another to ensure that reports were timely issued and resolved. Consequently, the field laboratories are not always made aware of deficiencies or deviations disclosed through the proficiency testing process, and FSIS has reduced assurance that such deficiencies or deviations have been corrected.

FSIS uses proficiency testing to monitor the quality and accuracy of analytical results from its laboratories. On a quarterly or semiannual

basis, each FSIS field laboratory receives a series of proficiency check samples for analysis. The check samples for microbiology are prepared under contract by a private laboratory, and are inoculated with specified quantities of pathogens such as *Salmonella* or *E.coli 0157:H7*, or with antibiotic residues. The field laboratories are notified in advance of their arrival, and the check samples are clearly marked as such on the shipping containers. The receiving laboratory then tests each check sample for both the presence of the specified pathogen or antibiotics, and its quantity in the sample, as well as for species identification.

Once the check samples have been analyzed by the field laboratory, the results are reported to the QAB. The QAB then evaluates the laboratory's performance by comparing its test results to the inoculation records for each sample provided by the contracted laboratory, as well as to the results obtained by the other field laboratories. In any instance where the field laboratory fails to detect the presence of the inoculant in a sample, records a quantitative analysis that falls outside of set parameters, or incorrectly identifies the species of a sample, a finding must be reported so that the laboratory can identify and correct any laboratory-related problems which may have caused the deviation.

The QAB forwards the graded results to the Microbiology Division in FSIS Headquarters, which has microbiology oversight responsibilities for the field laboratories. Once the Microbiology Division has reviewed the results, it informs the laboratory of its performance on the check sample analyses. In cases where deviations are noted, the Division also informs the laboratory of these and, when necessary, requests a written response detailing the corrective actions taken to correct the problems. It is the responsibility of the Microbiology Division to determine whether or not the corrective actions reported by the laboratory are sufficient to correct the noted problems.

Our review disclosed that this process was not always followed. Between October 1997, and June 1999, the three field laboratories analyzed a total of 108 proficiency check sample sets involving a total of 1,968 analyses performed on 921 individual samples (each set consists of multiple individual check samples and if one sample is in error or falls outside of set parameters, QAB policy is to report a finding); however, the QAB forwarded the results for only 61 of these sets to the Microbiology Division. The results for the remaining 47 sets were not reviewed by FSIS Headquarters nor sent to the laboratories. Of the 47 sets of results that were not forwarded by QAB, 16 identified some type of errors or deviations in the

laboratories' analyses of the check samples that required followup. In most cases, only one of the samples in the set caused the finding. Because neither of the Microbiology Division nor the laboratories had received these reports, the deficiencies had remained unreported for periods of between 3 and 11 months at the time of our audit. QAB officials stated that they were not aware that the reports had not been provided to the Microbiology Division, and agreed with the need for better controls within QAB to ensure that the reports are timely forwarded.

Of the 61 sets that were forwarded to the Microbiology Division and the laboratories, 20 disclosed some type of deviation which required followup with the laboratories. The Microbiology Division requested the laboratories to provide written responses in 16 of the 20 cases, but the laboratories only provided responses in 3 cases. FSIS did not follow up with the laboratories to obtain responses in the remaining 13 instances. Through interviews with FSIS Microbiology Division officials, we found that no one in the Division had been assigned the responsibility for monitoring the laboratories to ensure that they provided the required responses.

FSIS Headquarters officials stated that they had not been aware of these problems, and the responsible official agreed that the procedures needed to be strengthened to prevent their recurrence. One official stated that this problem had occurred because the QAB was not involved in all areas of the check sample process, and noted that the division of responsibilities between the Microbiology Division and the QAB may have been responsible for lack of follow through in obtaining laboratory responses to requests for corrective action. An FSIS official stated that she planned to amend the check sample reporting process so that QAB will have full responsibility for ensuring that test results are communicated to the laboratories, and that laboratories provide appropriate responses to the check sample results.

FSIS officials also pointed out that the 36 sample sets on which QAB noted deviations represented only 66 analyses out of 1,968 performed (3.4 percent). Of these, they stated that only 14 of the analyses actually involved laboratory errors.

RECOMMENDATION NO. 7

Establish monitoring procedures to ensure that the results of proficiency check samples are reported to the laboratories in a timely manner, and that

laboratories are required to provide written responses to ensure that appropriate corrective action, such as training or increased supervision, is taken.

FSIS Response

FSIS agreed that it can improve internal followup when deviations in check sample results are noted. The response stated that procedures can be developed to assist in the review, evaluation, and reporting of check sample results, and that additional mechanisms could be developed to ensure that any necessary corrective actions are implemented, recorded, and properly reported to the appropriate officials. FSIS officials stated that they have drafted standard operating procedures that strengthen these controls. The new procedures should be completed by September 2000.

OIG Position

We accept FSIS' management decision.

FINDING NO. 6

OAB FIELD VISITS DID NOT COMPLY WITH REQUIREMENTS

The FSIS Microbiology Division, for a period of approximately 4 years (May 1995 – March 1999), did not conduct the onsite field reviews required by FSIS procedures. These reviews are needed to assure FSIS management that the field laboratories operate as intended. When onsite visits were performed in 1995 and 1999, the results of the reviews either were not reported to the laboratories or were not reported until 8 to 14 months after the reviews were completed. Further, we found that for 5 of 6 reports that were issued, the laboratories did not provide the required responses detailing their corrective actions on the deficiencies noted. As a result, FSIS Headquarters lacked assurance that problems disclosed in reviews had been corrected.

The International Organization for Standardization (ISO) [4] requires that laboratories shall arrange for review of their activities at appropriate intervals to verify that their operations continue to comply with the requirements of the quality system governing their operations. Such reviews shall be carried out by trained and qualified staff that are, wherever possible, independent of the activity to be

[4] International Organization for Standardization, Ref. No. ISO/IEC GUIDE 25: 1990 (E).

audited. Where the review finding casts doubt on the correctness or validity of the laboratory's calibration or test results, the laboratory shall take immediate corrective action and shall immediately notify, in writing, any client whose work may have been affected. In addition, the guidelines state that it is not enough to merely discover problems; they must also be corrected. All audits and review findings and any corrective action that arise from them shall be documented.

FSIS has not implemented laboratory review procedures other than to prepare draft instructions dated June 4, 1993. The draft of these procedures [5] requires onsite reviews to be conducted at least twice a year at each field laboratory. The draft states that the reviews will cover all critical procedures and functions that are part of the daily routine of the microbiology laboratory. Also, a field review report summarizing the findings will be prepared and sent to the field laboratory. The report will require a laboratory response to show corrective actions on the reported deficiencies. QAB assumed responsibility for meeting these requirements when it was created in September 1996; prior to this, the FSIS Microbiology Division had direct responsibility.

FREQUENCY

Our review of the Microbiology Division's and QAB's onsite reviews disclosed that the frequency of reviews and the reporting process did not provide assurances to FSIS that the laboratories were providing reliable test results that can be supported by a documented quality control system. The following table summarizes the onsite reviews conducted and the subsequent reporting process.

Table 1: Listing of Microbiology QAB Onsite Reviews

LABORATORY	DATE OF REVIEW	DATE REPORT WAS ISSUED	DATE LABORATORY RESPONDED TO REPORT
Eastern	March 1995	Not Issued	Not Applicable

[5] FSIS Quality Assurance Program Microbiology Division Science and Technology Program Guidelines, (Draft) September 1992.

Midwest	March 1995	May 16, 1996	June 26, 1996
Western	May-June 1995	Not Dated	No Response
Midwest	August 1997	Sept. 3, 1997	No Response
Western	September 1997	March 2, 1998	No Response
Eastern	April 1999	Not Issued	Not Applicable
Midwest	March1999	November 1999	No Response
Western	March 1999	November 1999	No Response

As shown in the preceding table, onsite reviews of laboratory operations were not made at regular intervals or at the semiannual cycle required by FSIS procedures. The 1997 reviews were limited to the Midwest laboratory's antibiotic residue testing program and to the Western Laboratory's egg testing activities, and thus did not meet the criteria for full onsite reviews. Therefore, comprehensive reviews of the laboratories' operations were performed only in 1995 and 1999, with almost a 4-year interval between them.

REPORTING

In addition, for the reviews performed, FSIS did not always issue reports or issue them on a timely basis. For the 1995 reviews, the Microbiology Division did not issue a report to the Eastern Laboratory, and issued its report to the Midwest Laboratory 14 months after the review was conducted. For the Western Laboratory's 1995 review, the Microbiology Division did not document the date on which the report was issued. QAB issued reports on two of the 1999 reviews over 7 months after the reviews were completed, and has not yet issued a report on the third review completed in April 1999.

FSIS officials pointed out that even though reports may not have always been issued, or timely issued, the laboratory personnel would still have been aware of any problems found in the field visits because QAB personnel always held exit conferences with laboratory personnel at the conclusion of each review. However, we found that documentation of an exit conference existed for only one of the seven reviews, and in this case the documentation did not state what was discussed. In addition, personnel at the Midwest Field Laboratory stated that no exit conference was held at the conclusion of the March 1999 review. Without proper documentation, there is no guarantee that laboratory personnel were made aware of any significant problems found during the review.

RESPONSE

We also found that FSIS had not implemented controls to ensure that the laboratories responded with their proposed corrective actions taken or planned to resolve reported deficiencies. Of the eight reviews conducted between 1995 and 1999, no reports were issued on two. For the remaining six reviews, only the two 1997 reports were issued within 6 months. The other reviews were issued 8 to 14 months after the reviews were completed, during which time the laboratories had no opportunity to correct the problems noted. The laboratories provided a response to only one of the six issued reports, and no follow up was made with the laboratories to obtain responses. Thus, FSIS has no assurance that the laboratories ever took the necessary corrective actions.

The Director of the QAB agreed that FSIS had not implemented controls to track the status of the reviews and ensure that reports are issued in a timely manner, or that the laboratories provide the required written responses. This was due, in part, to the fact that the memos transmitting the reports to the laboratories did not request them to respond to the reports' recommendations. The 1993 draft procedures also did not provide timeframes for the review staff to issue the reports, or for the laboratories to provide responses.

We concluded that the lack of field visits and of controls over the reporting process reduced the assurance that problems or deficiencies with field laboratory operations were being identified and corrected. Further, QAB's lack of procedures to ensure that the reports of onsite visits are provided to the laboratories, or to routinely document exit discussions, could result in laboratories being unaware of all deficiencies disclosed by the reviews. Such problems could, therefore, remain uncorrected indefinitely.

RECOMMENDATION NO. 8

Develop and implement procedures that schedule onsite laboratory reviews at regular intervals, establish guidelines for issuing reports within specified timeframes, and require the laboratories to respond to the reports' recommendations. In addition, implement procedures for QAB to track the status of both draft and issued reports to ensure that they are processed and responded to in a timely manner.

FSIS Response

FSIS officials agreed with the recommendation and are in the process of instituting improvements to the management of reviews of the FSIS laboratories to include the areas of scheduling, auditing, reporting,

tracking, and followup on corrective actions. QAB scientists have been assigned specific tracking and followup responsibilities. Furthermore, to aid in program efficiency and management, QAB is developing standard operating procedures to help assure that reviews, responses, and corrective actions all occur in a timely, efficient, and acceptable manner. Each SOP will have a related flowchart to assist staff in meeting and following requirements. The following SOP's are under development and are expected to be completed by October 2000: (1) Preparation, submission, and Tracking of Field Service Laboratory Audit Reports; and (2) Scheduling and Conducting of Field service and Other Agency Laboratory Audits.

OIG Position

We accept FSIS' management decision.

FINDING NO. 7

SALMONELLA SCREENING TEST KITS DID NOT MEET SPECIFICATIONS

FSIS purchased *Salmonella* screening test kits that did not comply with contract specifications, even though the QAB reported the deficiencies to the responsible officials prior to their procurement. According to FSIS officials, these purchases were necessary because the inventories of screening test kits at the laboratories would not have lasted the 2 to 3-month period that it would have taken the supplier to prepare a new batch of the kits for retesting.

FSIS entered into a contract on February 16, 1999, to purchase screening test kits for *Salmonella*. The screening test kits allow the laboratories to identify the potential presence of *Salmonella* in a sample more quickly than using traditional culture and biochemical methods.

To ensure that the test kits meet the contract specifications, FSIS requires that each production lot be tested for sensitivity, specificity, false positive and negative rates, and efficiency. QAB performed quality control tests on the initial production lot, and the kits produced false positive readings at more than twice the 10 percent rate allowed by the contract. Although the high false positive rate could force the laboratories to perform many unnecessary culture and biochemical tests to confirm the presence of *Salmonella* in any official samples for which the test kits might produce inaccurate readings, FSIS went ahead with the procurement even after being notified of these results. Quality control tests also found problems in a subsequent production

lot. In addition, QAB tests on the second production lot supplied by the vendor disclosed that the test kits would produce false negative results (thus failing to identify *Salmonella* in a sample where it was actually present) at a rate of 6.9 percent, more than twice the 3 percent allowed by the contract or the MLG. In all, FSIS purchased approximately 55,000 test kits from these two production lots.

Although the specifications of FSIS' contract with the vendor conformed to the requirements of the MLG with regard to the rate at which the test kits could produce false negative results, we noted that the contract allowed for a false positive rate of up to 10 percent while the MLG specified a rate of no more than 4 percent. FSIS officials stated that a higher false positive rate does not endanger the public health as would an excessive false positive rate, and they believed that the false positive rate allowed by the contract maintained the laboratories workload at a reasonable level. Nevertheless, a reduction of this workload through more efficient test kits, which would eliminate the need to attempt confirmation of false positive test readings, would result in a more economical and efficient use of the laboratory analysts' time. Therefore, if the MLG's specified false positive rate of 4 percent is achievable, we believe that contract terms should be amended to reflect this. If FSIS determines that the rate given in the MLG is too low, then the MLG should be amended to reflect reasonable figures that can be used as the basis for future contracts.

Because of the high rate of false negative results produced by QAB's tests, and the possibility that this could cause *Salmonella* to go undetected in official samples screened using these test kits, we issued a management alert to FSIS on October 29, 1999. In the management alert, we recommended that FSIS: (1) Require the vendor to begin immediate preparation of a new production lot to replace the existing screening test kits from the two existing production lots, which could then be withdrawn from use at the field laboratories; (2) amend FSIS' contract specifications for the purchase of these test kits to comply with MLG and AOAC standards; and (3) establish an inventory reorder point to ensure that orders for new test kits are placed early enough to allow FSIS sufficient time to verify that production lots meet requirements before the laboratories exhaust their existing stocks.

RECOMMENDATION NO. 9

Require the vendor to begin immediate preparation of a new production lot of *Salmonella* test kits, which meet the MLG and AOAC standards, so that the

use of the test kits from the two existing lots can be discontinued at the earliest possible time.

FSIS Response

FSIS agreed with this recommendation. On November 19, 1999, the agency stated that the vendor had agreed to begin immediate preparation of a new production lot of *Salmonella* test kits which meet the MLG and AOAC standards so that the use of test kits from the two existing lots could be discontinued at the earliest possible time. In the response to the official draft, FSIS officials stated that they had obtained new test kits.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 10

Amend FSIS contract specifications for *Salmonella* test kits to comply with the Microbiology Laboratory Guide.

FSIS Response

FSIS stated that experience and empirical evidence in using commercially available test kits supports the conclusion that the contact specifications should not be adjusted. They also stated that more stringent specifications could preclude the finding of an acceptable rapid screening test. However, the officials stated that the agency is exploring options for changing the MLG performance characteristics.

OIG Position

If FSIS officials believe that the current MLG specification for false positive readings is too stringent, and the specifications of the existing contract are more reasonable, then the MLG should be amended. To reach a management decision, FSIS needs to provide us with a time-phased plan for bringing the contract and MLG specifications into agreement.

RECOMMENDATION NO. 11

Establish an inventory reorder point to ensure that orders for new test kits are placed early enough to allow sufficient

time for FSIS to verify that production lots meet requirements, or if necessary to obtain new test kits before the laboratories exhaust their existing stocks.

FSIS Response

FSIS agreed with this recommendation and has established an inventory point to ensure that orders for new kits are placed early enough to allow sufficient time to verify that they meet requirements and before laboratories exhaust the existing supplies.

OIG Position

We accept FSIS' management decision.

FINDING NO. 8

FSIS NEEDS TO IMPROVE TRAINING PROGRAMS FOR MICROBIOLOGY ANALYSTS

FSIS needs to ensure that the three field laboratories are providing adequate training to microbiology analysts and ensure that all training provided is adequately documented. Although the agency had drafted training procedures in August 1998 to implement the requirements of the ISO, these have remained in draft form. Further, because FSIS relied on the individual laboratories to implement the prescribed training programs, we found that ongoing training for the analysts was limited to informal on-the-job training. The laboratories did not document the training provided to the analysts as required, or management's assessment of the analysts' competence to perform various laboratory tests.

The Association of Analytical Chemist (AOAC) guidelines for the accreditation of laboratories under the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) Guide 25, provides the following guidelines for laboratory training programs:

- All staff must be adequately trained;
- Objective measurements should be used to assess competence at the completion of training, i.e. the use of proficiency samples;

- Staff must only perform tests and supporting activities if they are recognized as competent to do so, or if they do so under appropriate supervision;

- The continued competence of the staff must be monitored/appraised using appropriate means (such as proficiency samples); and

- The laboratory shall maintain records on the relevant qualifications, training, skills and experience of the technical staff.

In August 1998, FSIS prepared a set of draft of procedures titled "Personnel Training and Evaluation". This draft addressed the training guidelines provided by AOAC's ISO/IEC Guide 25. We reviewed these procedures and determined that, if properly implemented, they would adequately address the ISO requirements. Although FSIS' field laboratories are not currently accredited, the agency has stated its commitment to obtaining such accreditation at the earliest possible time.

The draft FSIS procedures further specify that one of the types of training that microbiology analysts should receive is "Professional Development Training." Section 6.2 of the procedures define this type of training as including:

- On-the-job training;
- in-house seminars;
- programmed learning courses;
- short courses such as those sponsored by AOAC, the American Chemical Society, and other scientific organizations;
- specialized training by instrument manufacturers;
- attendance at workshops and scientific meetings;
- university and college courses;
- specialized training workshops, seminars, and manuals sponsored by Federal regulatory agencies such as EPA and FDA; and
- proficiency programs.

Our reviews at the three field laboratories disclosed that analysts performing residue and food chemistry analyses had training plans on file, and that their training was documented on an annual basis. However, the microbiology sections at the three laboratories did not maintain documentation of training provided, or of any testing of their staffs' competence to perform tests and related activities. Field laboratory officials stated that their training programs consisted of informal on-the-job training that is not documented.

The need for a formal training program was recognized by the Microbiology Division's QAB in its 1997 review of the Midwest Laboratory's Antibiotic Residue Section and in its 1999 reviews at the three field laboratories to identify changes needed for accreditation under ISO/IEC Guide – 25 standards. At the Midwest Laboratory the QAB review determined that the laboratory did not document the training of either new or experienced staff members. The Midwest Laboratory did not provide a written response to the QAB's report because one was not requested. (See Finding No. 7.) The QAB's 1999 reviews of the accreditation issues at the field laboratories also concluded that the three laboratories needed a formal and documented training program.

The Director of FSIS' Microbiology Division, as well as officials at the field laboratories, stated that no documentation was available to show that the three field laboratories identified training needs for analysts, assessed the competence of staff members to perform tests, recorded the training of staff member, or recorded FSIS' recognition of its technical staff's qualifications to perform product testing. In addition, there was no indication that any Professional Development Training had been provided except for on-the-job training. Headquarters officials stated that they relied on the field laboratories to provide the training and to document the training provided to the staff.

RECOMMENDATION NO. 12

Establish a training program that will, (1) identify required training for microbiology staff members, (2) provide formal, structured training in addition to informal on-the-job training, (3) document the training provided to each staff member, (4) assess and document the competence of each staff member to perform tests and supporting activities, and (5) monitor the continued competence of each staff member to perform laboratory tests.

FSIS Response

FSIS officials agreed that further enhancement and documentation of the laboratory training programs for microbiologists are indicated. FSIS has drafted standard operating procedures and work instructions that address the items in the report's narrative as well as the recommendation. FSIS is also developing more extensive checklists for on-the-job training and is implementing a periodic testing

program for individual analysts to further demonstrate initial and continued competency.

FSIS officials took issue with the report's implications that FSIS does not provide adequate training, both in-house, and for professional development. They stated that FSIS has always devoted considerable time and effort into training analysts and consistently provide proper supervisory oversight to ensure continued competency. Although FSIS did not have readily detailed documentation of the specific training provided to each analyst at the time of the audit, more detailed, employee-specific training records were provided in March 2000.

OIG Position

AS noted in the finding, at the time of the audit the responsible officials at each of the three field laboratories stated that their training programs consisted of informal, on-the-job training that was not documented. We reviewed the additional information sent in March 2000, which FSIS referenced in its response; although it did show documentation that certain individuals attended a documented training, it does not show that laboratory analysts overall were being provided with sufficient training other than that given on the job.

However, we agreed with the corrective actions being taken by FSIS. To reach management decision, FSIS needs to advise us when the standard operating procedures, the new checklists, and the testing programs will become effective.

FINDING NO. 9

NO OUALITY ASSURANCE PROGRAM HAS BEEN IMPLEMENTED FOR THE SPECIAL PROJECT AND OUTBREAK LABORATORY

FSIS does not have a quality assurance program in place to monitor the Special Project and Outbreak Support Laboratory's (SPOSL) operations. Neither FSIS Headquarters nor the Quality Assurance Branch (QAB) has ever developed procedures in place to perform onsite reviews at this laboratory. FSIS officials agreed that it would be appropriate to conduct onsite reviews at SPOSL.

The International Organization for Standardization (ISO)[6] states that a laboratory shall arrange for audits of its activities at appropriate

[6] ISO/IEC Guide 25: 1990, Section 5.3.

intervals to verify that its operations continue to comply with the requirements of the quality system.

SPOSL is part of FSIS' Office of Public Health and Science (OPHS). OPHS provides scientific focus, leadership, and expertise in addressing public health risks related to meat, poultry, and egg products. SPOSL works with a variety of foodborne pathogens of interest to FSIS in such areas as problem-solving, support of the FSIS Field Service Laboratories, and method adaptation and validation. Their primary function is to assist the various divisions in OPHS by providing laboratory support during case or outbreak investigations by the agency or by any State requesting assistance. Scientists in SPOSL are responsible for method validation and adaptation for use in the field service laboratories and other FSIS programs. These scientists also act as subject area experts for revising the Microbiology Laboratory Guidebook.

The Headquarters Microbiology Division staff officer stated that onsite reviews of SPOSL are not being done because of the lack of available staff, time, and a system in place to do so. The Quality Assurance Branch Chief stated that it would be good for the agency to perform onsite reviews of SPOSL.

Due to the important role that SPOSL plays in OPHS, we believe that they should be subject to the same regular onsite reviews as the field service laboratories. This would provide FSIS managers with assurances as to whether SPOSL's operations are acceptable or identify deficiencies that need to be addressed.

RECOMMENDATION NO. 13

Develop and implement a quality assurance program for the Special Project and Outbreak Support Laboratory.

FSIS Response

FSIS agreed with this recommendation and has instituted a proficiency check sample program for the Special Project and Outbreak Support Laboratory (SPOSL). In addition, FSIS has scheduled SPOSL for a laboratory review by the last quarter of FY 2000.

OIG Position

We accept FSIS' management decision.

CHAPTER 3	BETTER CONTROLS OVER LABORATORY DOCUMENTATION AND SUPERVISORY REVIEWS ARE NEEDED

In our onsite reviews at the three field laboratories, we concluded that overall they conducted their operations according to applicable FSIS standards. In addition, during 1999 FSIS began an initiative to have the field laboratories accredited by the Association of Analytical Chemists, and performed QAB reviews at each laboratory to assess their present degree of compliance with these standards.

We found that laboratory personnel were following the guidelines approved by FSIS Headquarters, and in conjunction with outside technical consultants we determined that these guidelines would result in accurate analyses of official samples. Based on our observations, laboratory analysts were given adequate supervision, and based on our series of 60 blind" check samples sent to each field laboratory we determined that they were able to correctly identify the presence of *Salmonella* and *E.coli* bacteria.

However, laboratory management needed to improve the laboratories' documentation of their operations. Both FSIS and ISO standards require that for each sample analysis performed, detailed records be maintained of the procedures that were followed. However, only one of the three field laboratories was consistently requiring the necessary documentation to meet the standards. At the other two laboratories, 81 of the 124 analyses we reviewed were inadequately documented. In addition, none of the field laboratories were maintaining the required degree of documentation to demonstrate that the equipment used to perform analyses had been properly maintained, serviced, or calibrated at the required frequency.

FINDING NO. 10

BETTER DOCUMENTATION OF TESTING PROCEDURES IS NEEDED

Two of the three FSIS field service laboratories did not adequately document their sample analyses. This occurred because analysts did not always detail the work performed during testing procedures, and were not required to correct this by their supervisors in spite of documented supervisory reviews. In

addition, the quality control checklists used by two of the laboratories did not list all of the items required to be documented, while the third laboratory did not use a checklist at all.

The USDA/FSIS Microbiology Laboratory Guidebook (MLG), 3rd Edition/1998 requires that adequate documentation and recordkeeping be employed for all analytical results, test controls, quality assurance, and quality control procedures.[7] It also states that a rigorous quality assurance program must be in place to ensure that there is documentation readily available to facilitate: traceability of analytical results to the analyst performing the work, the methods and equipment used; and the status of the equipment at the time it was used.[8] In addition, the Association of Official Analytical Chemists (AOAC) International's Accreditation Criteria for Laboratories Performing Food Microbiological Testing states that the laboratory "shall retain on record all original observations, calculations, and derived data…"[9]

We reviewed the quality control worksheets used at the Eastern and Midwestern laboratories and found that, with some improvements, they would include all critical areas of analyses if documented and verified by a supervisor. FSIS should ensure that such worksheets continue to be used by the Eastern and Midwestern Field Laboratories, and are implemented by the Western Field Laboratory. The quality control worksheets, with some additions, would satisfy all the requirements of the MLG and the ISO. The worksheets are used by the analysts to document, at every critical stage in each analysis, the following:

- batch number of the media used;
- date and time that samples were put in and taken out of incubators;
- temperature of the incubators;
- initials of the analyst performing each step; and
- results of observations of negative and positive controls used.

The batch number of the media, in which microbiological cultures are grown, is a critical item of documentation because it is used to trace back to the procedure and methods used to prepare the media. The information about the incubators used, including the identifying number of the incubator used along with dates and times that samples went in

[7] General Considerations section, page iii.

[8] Volume 2, Section 36.91.

[9] Section 12.1.

and out, and the temperature at the time, is critical in any analysis. Also, the result of the observations of the negative and positive controls used is important to support that the sample results are accurate.

The following items should be added to the quality control worksheets:

- batch number or serial number of the controls used;
- documentation of identifying numbers of the major equipment used in analyses, such as the DIAS machine used, if the laboratory has more than one, and the VITEK machine and carousel used.

A supervisory review should include verification that all information regarding the analysis has been documented, and that the documentation supports the work performed.

As part of our audit at the field laboratories, we evaluated the testing procedures used by the laboratories and the timeliness of the testing process. We also evaluated the controls in place at the laboratories to ensure that testing was properly performed. We concluded, in conjunction with our technical consultants, that the laboratories were using proper procedures in performing their various testing programs; that adequate supervision was being provided to largely preclude the entry of false test results and that analyses were generally being performed on a timely basis; this included tests of raw product under HACCP, which must be initiated the day after the sample is collected, and tests of processed product which should be completed within 10 days.

We reviewed the three FSIS field laboratories' supporting documentation for 190 official samples sent to the laboratories for analysis, of which 123 were microbiology/food chemistry analyses and 67 were residue analyses. The microbiology tests we reviewed included analyses for *Salmonella*, *E.coli 0157:H7*, *Listeria*, and *campylobacter*, as well as canned food tests, extraneous material tests, and species tests. The residue tests included analyses for both chemical and antibiotic residues.

We determined that documentation for 81 of the 124 analyses we reviewed at 2 of the 3 laboratories was not complete. Our results were as follows:

- At the Western Laboratory, the documentation for all 56 of the analyses we reviewed did not clearly record incubation times and temperatures, sample preparation for analysis, quality control samples used, and/or critical control points such as temperatures and weights.

- At the Midwestern Laboratory, 2 of the 68 analyses we reviewed were not documented at all, while 11 others contained no documentation of one or more critical control points such as temperatures or weights. In another 12 instances, the required incubation log had either not been prepared or was incomplete. Overall, we found that 25 of the 68 analyses were not adequately documented.

Although we found that the sample result forms were consistently initialed by supervisory personnel, when required, to show that the work of the analysts had been reviewed, they did not ensure that the documentation was complete. Two of the laboratories (Eastern and Midwestern) used checklists that required documentation for the majority of the items needed to fulfill the MLG requirements and those which would, in the future, be required under ISO. However, they did not include certain items such as batch number or serial numbers of controls used, and identifying numbers of major equipment used. Further, the Western Laboratory did not use any form of checklist to prompt analysts as to the documentation necessary to support their analyses.

As noted earlier in the report, the Microbiology Division's QAB had not made complete onsite reviews at the laboratories for a period of approximately 4 years, between 1995 and 1999. Although the 1995 reviews did not cite any problems with the documentation being kept by the laboratories, the March and April 1999 reviews (whose purpose was to determine whether the laboratories' microbiology testing would comply with ISO-25 Guidelines' accreditation requirements) did cite such problems. These reviews disclosed an overall lack of documentation of the entire system, specifically in the areas of: 1) Quality Manual; 2) methods; 3) procedures; and 4) work instructions.

The Microbiologist in Charge and Supervisory Chemists at the Western Laboratory, and the Quality Control Manager for Microbiology at the Midwestern Laboratory agreed that more documentation was needed to support sample results. We did not find any deficiencies in the documentation on file at the Eastern Field Laboratory.

Thus, we believe that FSIS needs to implement procedures, such as a uniform checklist used by all three laboratories, and more stringent supervisory controls, to ensure that the necessary documentation is being prepared to support the analyses conducted by the field laboratories.

RECOMMENDATION NO. 14

Require the laboratories to implement a quality assurance system that ensures adequate documentation of analytical results, including but not limited to, the methods used, and incubation times and temperatures. Require supervisory personnel at the laboratories to ensure, as part of their reviews, that all necessary documentation is being prepared on an ongoing basis.

FSIS Response

FSIS agreed and is taking steps to review and, when necessary, enhance the documentation and supervisory oversight of all components of the laboratory systems by January 2001. FSIS projects that the laboratories will apply for ISO accreditation by April 2001, and anticipate becoming accredited by December 2001.

OIG Position

We accept FSIS' management decision.

FINDING NO. 11

EQUIPMENT MAINTENANCE WAS NOT ADEQUATELY DOCUMENTED

The three FSIS field service laboratories did not adequately document the maintenance performed on major pieces of laboratory equipment and instruments. This occurred because laboratory personnel stated that they were unaware that documentation of the maintenance performed was necessary, and supervisors did not verify that it had been documented.

The USDA/FSIS Microbiology Laboratory Guidebook, 3rd Edition/1998 (MLG), General Considerations, states that all instrumentation should be subjected to continuous maintenance and appropriate quality control procedures to insure unquestionably correct performance during use in all methods. Section 36.372 of the MLG states that all equipment must be maintained according to the manufacturer's instructions. It also states that all equipment dispensing a designated

volume of any testing material such as media or reagents must be calibrated at least daily. This is particularly important with automated analytical equipment, such as Enzyme-Linked Immunosorbent Assay (ELISA) filler/washers and plate fillers, in order to ensure the correct amount of reagent is being added at each step in the process. In addition, it states that a record log of all validations, repairs, servicing, replacement parts, performance deviations, and corrective actions taken must be maintained for 5 years before being discarded.

Overall, we found that additional documentation of maintenance and calibration was needed for major instruments and pieces of equipment at the three field laboratories. Specifically:

- There were no maintenance logs for the Dynex Immunoassay System (DIAS) machines at the Midwestern laboratory, and the maintenance performed on the DIAS machine at the Eastern laboratory was not done timely. The DIAS machine is an automated analytical machine used to perform the ELISA screening test in *Salmonella* analyses. It includes a reader, incubator, filler, reagent dispenser, washer, and stackers. This machine is calibrated automatically when it is turned on to ensure that the correct amount of reagents is added at each step. Also, quarterly, the temperatures should be validated, the bottles, tubes, caps, and trays should be cleaned, the O-rings should be lubricated, and the wash system checked and flushed as needed.

- The Midwestern and Western laboratories did not perform any periodic maintenance on the VITEK Reader/Incubator (VITEK) machine, and at the Eastern laboratory, the maintenance performed on the VITEK machine was not documented. The VITEK machine is an automated analytical machine that performs the important final step of biochemical confirmation in *Salmonella* and *E.coli* analyses. The VITEK machines at the Midwestern and Western laboratories were under a service contract and they will call a service technician if the machine malfunctions. However, the Midwestern laboratory did not maintain a log on the type of service performed. Various items on the VITEK machine should be maintained on a daily, weekly, or monthly schedule. Its dispenser should be cleaned, flushed, calibrated, and sterilized, the dilutent should be changed, the colorimeter should be cleaned and calibrated, the filler/sealer should be cleaned, the reader/incubator's temperature should be validated, and its trays, filters, and rubber wheels should be cleaned.

- The Western laboratory did not always adhere to their maintenance schedule for its LECO FP-2000 Protein Analyzer machines. These machines are used for protein analysis in food chemistry samples. The ballast tank should be inspected after every 1,000 tests, and the combustion tubes and O-rings should be changed quarterly.

- The Eastern laboratory did not maintain a logbook or record of maintenance for the agar sterilizer. It also did not have a temperature read-out and recorder. This machine is used to keep media hot. Some media will solidify when it cools. The temperature of the media needs to be monitored. The accurate preparation of various media is an important first step in all analyses.

A chemist at the Western Lab stated that some of the preventative maintenance may have been performed but not documented. The Quality Control Manager for Microbiology at the Eastern Lab stated that maintenance had been performed monthly as required, but not documented. The Microbiologist-in-Charge at the Midwestern Lab stated that he was not aware that logs of maintenance should be maintained.

During March and April 1999, the QAB conducted reviews at the three laboratories to determine changes needed for the laboratories' microbiology testing to comply with ISO-25 Guidelines' accreditation requirements. These reviews disclosed that at the three laboratories, there was an overall lack of documentation of the entire system, specifically in the areas of: 1) Quality Manual; 2) methods; 3) procedures; and 4) work instructions.

RECOMMENDATION NO. 15

Implement a quality assurance system to ensure that adequate maintenance, servicing, and calibration is both performed and documented as required for each piece of equipment used in testing.

FSIS Response

FSIS agreed and is developing additional procedures, work instructions, and forms that will further and more completely document the ongoing maintenance, service, and calibration of testing equipment. This will be completed by December 2000.

OIG Position

We accept FSIS' management decision.

CHAPTER 4	TIGHTER CONTROLS ARE NEEDED OVER THE ACCREDITED LABORATORY PROGRAM

FINDING NO. 12

BETTER CONTROLS OVER THE ACCREDITED LABORATORY PROGRAM NEEDED

FSIS, because of staffing restrictions, did not perform sufficient onsite monitoring to ensure that accredited, non-Federal laboratories that tested official samples met all of the criteria needed to maintain accreditation status. In addition, the agency terminated its program of split sampling in 1994, thus reducing its ability to monitor the accuracy of the accredited laboratories' test results on an ongoing basis. Finally, we found that FSIS did not have sufficient controls in place to ensure that accurate laboratory identification numbers accompanied test results submitted by accredited laboratories. As a result, the agency has reduced assurance that accredited laboratories are meeting all applicable standards, or official samples are tested only by FSIS-accredited laboratories.

A prior OIG audit (Report No. 24099-0006-At, dated June 1991) of this area reported that the Accredited Laboratory Program was not cost effective because many private laboratories sought FSIS accreditation even though they did not test official samples for the agency, while FSIS did not charge fees to the laboratories for this service. In addition, the report disclosed that based on the results of check samples and split samples, approximately 50 percent of the 310 accredited laboratories did not meet FSIS' performance standards.

Since that time, FSIS has instituted an accreditation fee of $1,500 annually for each accredited laboratory. In addition, the results of check samples sent to the accredited laboratories demonstrate a marked improvement in the proficiency of these laboratories. However, we did find weaknesses in the agency's oversight of the Accredited Laboratory Program that need to be addressed.

FSIS regulations state that in order for a laboratory to maintain accreditation it must report weekly, to the FSIS Eastern laboratory, the analytical results of all moisture, protein, fat, and salt content of official samples. In addition, for the most recent 3 years, laboratories

must maintain records of samples that have been analyzed and documentation of the receipt, analysis, and disposition of official samples. According to the Director of Chemistry and Toxicology, it is the goal of the division to annually conduct onsite reviews at one-third of the accredited laboratories.

During fiscal years 1998 and 1999 there were about 140 and 126 non-Federal laboratories, respectively, accredited by FSIS. From January 1998 through August 1999, FSIS database records show that 46 accredited laboratories analyzed a total of 920 domestic and import official samples. This represented a significant decrease in the number of accredited laboratories since our last audit. However, our review disclosed that the CTD made annual onsite reviews at less than 1 percent (1 of 140) of the accredited laboratories in fiscal year 1998; and only 5 of 126 (4 percent) of the laboratories were reviewed in fiscal year 1999. The QAB Chief stated that staffing restrictions had prevented CTD from making the required field visits. In addition, we found that the onsite reviews performed by CTD did not evaluate whether the laboratories were complying with the requirement that they maintain records of their analyses for 3 years after they are performed.

One method that FSIS could use to supplement the field visits would be to reinstitute the use of split sampling, which was discontinued in 1994. Under this system of monitoring, selected samples tested by the accredited laboratories would be "split" for testing by both the laboratory and FSIS. Since only a fraction of the currently-accredited laboratories are actually testing official samples for FSIS, more emphasis on both the field visits and split-sampling could be concentrated on these laboratories.

Our review also disclosed inaccuracies in the recording of test results to the FSIS' database of accredited laboratories. The Laboratory Sample Flow System (LSFS) database is designed to identify all laboratory activity by the assigned number that is provided by FSIS to each laboratory at the time of its accreditation. Although FSIS has procedures in place to verify the accuracy of at least eight accredited laboratory data entries whenever the LSFS database is updated, we determined this control does not ensure that only test results from FSIS-accredited laboratories are accepted because the system does not flag incorrect entries that were not selected as part of the quality control review.

We found that four nonexistent laboratories were identified as having analyzed seven official samples. Although we determined that accredited laboratories performed the tests, the laboratories were

incorrectly identified because either the plant number of internal laboratory number was incorrectly entered in the computer database as the accredited laboratory number. At the time of our audit, the database records for the laboratories had been inaccurate for over a year and because FSIS has no procedures for flagging incorrect entries, such discrepancies could remain undiscovered indefinitely.

Since laboratories are required to report official sample results weekly to the Eastern Laboratory, an accurate activity report could be a useful tool to ensure that only accredited laboratories are listed. However, the CTD management official we interviewed stated that his division does not use and has never requested this report. Consequently, he was unaware of whether or not the accredited laboratories had analyzed official samples.

Without performing field visits to accredited laboratories, FSIS' Chemistry and Toxicology Division could not ensure that these laboratories continued to demonstrate the proficiency needed to maintain their accreditation. In addition, because the LSFS does not automatically flag incorrect entries to ensure that laboratories performing tests of official samples are on the agency's accreditation list, FSIS has limited assurance that official samples are being tested only by accredited laboratories. Since non-accredited laboratories are not subject to interlaboratory check samples and other quality-control requirements required by FSIS, the agency thus has no assurance of the accuracy of test results obtained by these laboratories.

RECOMMENDATION NO. 16

Strengthen the agency's monitoring of accredited laboratories, particularly those which test official samples for FSIS, through more frequent onsite visits and/or split sampling of official product samples.

FSIS Response

FSIS officials stated that split sampling was, based on prior experience, an ineffective means to ensure the accuracy of test results. However, the agency agreed to initiate an agreement or contract to perform more frequent accredited laboratory onsite visits. FSIS will implement this action by February 2001.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 17

Ensure that all test results on official samples are performed only by FSIS-accredited laboratories.

FSIS Response

FSIS responded that it agreed with the recommendation to ensure that only FSIS-accredited laboratories perform test results on official samples. FSIS' proposed corrective actions were as follows: (1) Issue 1-year certificates of accreditation to laboratories in good standing; (2) send letters for probation/revocation by overnight mail; (3) notify personnel in the Technical Service Center of laboratories whose accreditations have been placed on probation or revoked; and (4) publish an updated listing of accredited laboratories on a regular basis. In addition, FSIS will seek a more extensive review of the Accredited Laboratory Program during FY 2001.

OIG Position

Although we agree that the corrective actions proposed by FSIS will strengthen the Accredited Laboratory Program, they do not address the fact that results from a non-accredited laboratory could potentially be accepted because FSIS' computer system does not verify the accreditation number of the submitting laboratory. To reach a management decision, FSIS needs to provide us with its plan to address this internal control weakness.

EXHIBIT A – FSIS SAMPLING PROJECTS

Sampling Project Number	Product Type	Purpose of Test	No. of Plants in Sample Frame
ME7	RTE – Jerky	*Listeria & Salmonella*	281
ME15*	RTE – Small Diameter Cooked Comminuted …	*Listeria & Salmonella*	745
ME16	RTE – Large Diameter Cooked Comminuted …	*Listeria & Salmonella*	537
ME22*	RTE – Cooked Poultry Products	*Listeria & Salmonella*	472
ME23*	RTE – Meat and Poultry Salads …	*Listeria/ Salmonella/ Staphylococcus Aurous*	126
MM9	RTE – Cooked Beef, Roast Beef, Cooked Corned Beef	*Listeria & Salmonella*	311
MM11	RTE – Sliced Ham/Luncheon Meat	*Listeria & Salmonella*	358
MM14*	RTE – Cooked Meat and Poultry	Species Identification	1106
MT01	RTE - Fully Cooked Meat Patties	E.*coli O157:H7*	100
MT02	RTE – Dry & Semi-Dry Fermented Sausages	Staphylococcal, E.*coli* O157:H7, *Salmonella*, & *Listeria*	292
MT03/MT04	**RAW** – Ground or Comminuted Beef	E.*coli O157:H7*	1,730

RTE = Ready-To-Eat
* Frames Reviewed

EXHIBIT B – AUDITEE RESPONSE TO DRAFT REPORT

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

JUN 1 2000

TO: James R. Ebbitt
Assistant Inspector General
for Audit
Office of Inspector General

FROM: for Thomas J. Billy
Administrator

SUBJECT: FSIS Response to Office of Inspector General's (OIG) Official Draft Report on Laboratory Testing of Meat and Poultry Products, Audit Number 24601-0001-Ch

Thank you for the opportunity to review and respond to the subject report. We also appreciate the opportunities you provided for constructive interchange. The Food Safety and Inspection Service (FSIS) is providing a response for each recommendation in the report.

General Comments:

In general, as stated on page "i" of the Executive Summary, the objective of the OIG "audit was to evaluate whether FSIS had effective quality control procedures in place to ensure that all product is subject to testing, and that all laboratories performing tests of official product samples are adhering to applicable standards and are producing timely and accurate test results."

While the report does mention positive features of FSIS's laboratory operations, such as our successful detection of 100% of OIG's unmarked *Salmonella* and *E. coli* O157:H7 samples, we have several general concerns about the report:

1. The report does not adequately describe the consistent high quality of FSIS's laboratory proficiency testing programs.

2. The report prematurely uses the International Organization for Standardization Guide 17025 (ISO Guide 17025) as a standard for FSIS laboratories. Although FSIS, Food and Drug Administration (FDA), and four state laboratories (Florida, New Hampshire, Massachusetts,

and Tennessee), are collaborating to meet ISO Guide 17025 requirements, and FSIS is moving toward ISO accreditation, our current standards are still valid and are being met.

Executive Summary

OIG Key Recommendations:

We recommend that FSIS institute stronger procedures and controls to ensure that all meat and poultry establishments are subject to product testing, and that FSIS inspectors at establishments selected for testing respond to sampling requests in all instances to ensure that FSIS' laboratory testing programs encompass the agency's entire universe of FSIS –inspected establishments. We also recommend that the agency strengthen its quality assurance programs to ensure that all FSIS and accredited laboratories are in full compliance with all applicable standards and producing valid and supportable analytical results.

Agency Response:

FSIS agrees with the finding that "the three FSIS laboratories we visited were generally following the procedures prescribed by the agency and by the Association of Analytical Chemists (AOAC) when performing tests for pathogens, residues, food chemistry, and species identification on product samples obtained from meat and poultry slaughtering and processing establishments".

We also compliment the OIG on performing an independent evaluation of our three laboratories (using unmarked samples) to test the ability of our laboratories to detect *Salmonella* and *E. coli* O157:H7. As a result of this evaluation, OIG stated: "They correctly analyzed 180 unmarked samples we sent them to determine if they could detect the presence or absence of the bacteria *Salmonella* and *E. coli* O157:H7". OIG's findings acknowledge the high quality of our laboratory capabilities and provide the public with added confidence in the results of our laboratory analyses.

For the most part we agree with the key recommendation, but believe it should be modified as follows: "...to ensure that all meat and poultry establishments subject to federal meat and poultry inspection acts..."

Chapter 1. Controls Over the Collection and Testing of Product Samples Need to Be Improved

Recommendation No.1:

Develop a management system to track each inspector's compliance with requirements for semiannual updates to the sampling frames. Follow up with establishment inspectors who do not respond to ensure that sampling information is up-to-date for all establishments.

Agency Response:

FSIS will continue to improve its current method of using the semiannual updates to the sampling frames to generate and maintain accurate information on products tested in establishments as explained below. FSIS will also continue development of its approach to follow up with inspectors who do not complete their sampling regime.

FSIS has already made improvements to the current system and has developed plans for future changes. The development of the FSIS Form 10,230-3 (Directive 10,230.3: Preparation and Submission of FSIS Form 10,230-3, Sampling Frame Update Form. Rev. 2, 9/1/98) (attachment 1) was one such change. This form was designed to provide a vehicle for inspection personnel to provide information to headquarters on products produced that are relevant to FSIS microbiology surveys. Although FSIS Form 10,230-3 provided improvement to the accuracy of the sampling frames, we recognized that the form did not go far enough in improving the frames. The Agency will provide a more efficient frame development approach and, in some cases, will eliminate the need for sampling frames by placing the responsibility for selecting what product is tested at the inspector level, i.e. closest to the source of the most accurate information. The enhancements are described below for each testing program.

- *Salmonella* Pathogen Reduction/Hazard Analysis Critical Control Point (PR/HACCP)

  The Pathogen Reduction Enforcement Program (PREP) (attachment 2), an automated system that schedules, tracks and reports samples was designed by FSIS during the implementation of the Hazard Analysis Critical Control Point (HACCP) system. This system has been in place since fiscal year (FY) 99 and final testing of all features is underway. PREP provides a report (testing eligibility report) to the inspectors which identifies all plants that FSIS has in sampling frames and the associated products for PR/HACCP testing. This report provides a feature to follow up with inspectors who do not respond and will be fully implemented by September 2000. This will improve the accuracy of this sampling frame in the near future. In the long term, plans are underway to enhance the Performance Based Inspection System (PBIS) plant profile and use that as a source for sampling frames.

- Ready-to-eat (RTE)

  The FSIS Sample Coordination Team (SCT) has proposed a new testing strategy for RTE product that is based on information in PBIS that correlates to the HACCP procedure codes. New sampling frames will be based on the information provided by inspectors about which procedure codes are performed in each plant. In addition, inspectors will be given more discretion in determining what product to sample. This new testing strategy will be issued as a new Directive and scheduling of samples based on the PBIS codes can begin after the Directive is completed by September 2000.

- *E. coli* O157:H7

  Generally, this sampling frame is considered to be reasonably accurate because it is high profile testing program and has been in existence for about 5 years. FSIS' inspectors provide routine feedback, in addition to form 10,230.3, on establishments producing ground beef product. FSIS plans to incorporate the improved PBIS plant profiles as the source for this sample frame. The improvements to PSIS should be completed by December 2000.

- Residue Testing

  The residue testing program uses data from the Animal Disposition Reporting System (ADRS) for sampling frames. These data are obtained directly from inspection personnel in establishments. Plans are underway to expand the slaughter information contained in the PBIS plant profile to become the source for information for sampling frames in the future. By December 2000, FSIS will enhance the PBIS establishment profile and use it as the source of product information for sampling programs.

Recommendation No. 2:

Develop a database that identifies and segments all establishments producing products designated for sampling under the various sampling projects. Use this information to maintain current listings within the sampling frames for the sample projects.

Agency Response:

FSIS will continue to make improvements in the existing establishment profile that is completed by inspection personnel in PBIS. FSIS will further enhance the PBIS establishment profile by December 2000, to include all product information needed for sampling programs and require inspection personnel to keep that information up to date. The information can then be used as the source for sampling frames.

Recommendation No. 3

Institute procedures to monitor the responses to sampling requests on a monthly basis, and identify instances where inspectors do not respond. Where inspectors do not respond to sampling requests, require the district offices to follow up with the establishment inspectors to determine the reason for their failure to provide the required responses. In addition, perform immediate follow up on the 197 establishments that failed to respond to 3 or more requests.

Agency Response:

FSIS agrees that a better process is required to monitor the responses to sampling requests on a monthly basis, and identify instances where inspectors do not respond. By September 2000, we will expand our reporting system to alert FSIS officials of inspectors not responding to ready-to-eat sample requests similar to what is in place for *Salmonella* Performance Standard sampling. Approximately two years ago, FSIS initiated an automated e-mail system that provided feedback to inspectors and circuit supervisors on the samples discarded for reasons that could be attributed to the inspector. However, nothing was provided that would indicate to a circuit supervisor that the inspector was not taking samples. FSIS is working to enhance its current e-mail system by including a summary that will be mailed quarterly to circuit supervisors (CS) listing all plants scheduled for samples during that quarter that sent nothing back to the laboratories. This new e-mail application will provide feedback to the ready-to-eat testing programs and the *E. coli* O157:H7 testing program. It should be noted that sample request forms allow the inspector to indicate if the product is no longer produced at that plant or if the product is temporarily not produced.

- *Salmonella* PR/HACCP

  The PREP system includes a non-responders report to district offices, which lists plants scheduled for a *Salmonella* set, that have not mailed in a sample within the previous 30 days. This report supplies a mechanism to district offices to improve the rate of return of samples by providing a concise listing. As this report becomes fully distributed to all district offices, the rate of return of *Salmonella* samples should improve. In the short term, the Technical Service Center (TSC) has been provided reports of non-responders by OPHS. As a result of follow-up by the TSC, the rate of return for samples has steadily improved.

- Ready-to-eat

  The sample return rate for RTE programs should improve based on the new testing approach and with the development of the CS automated e-mail report discussed above. In addition, in the more distant future a new module is planned for PREP, which will provide reporting capabilities similar to those developed for the *Salmonella* testing program.

- *E. coli* O157:H7

  The sample return rate for the *E. coli* program should improve based on the development of the CS automated e-mail report discussed above and with the development of a new PREP module for this testing program.

- Residue Testing

  The sample return rate for the residue program should improve based on the development of the CS automated e-mail report discussed above and with the development of a new PREP module for this testing program.

Recommendation No. 4:

Implement a system that allows FSIS to track the status of sample requests, including their receipt and disposition by inspectors at meat and poultry establishments.

Agency Response:

FSIS agrees with the recommendation. FSIS will create an official form, 'sample log', for inspection personnel use in tracking sample collection and submittal. This will require changes to FSIS Directive 10,230.5 (Self-Instruction Guide for Collecting Raw Meat and Poultry Product Samples for *Salmonella* Analysis. 2/4/98 Amend. 1, 7/29/98) (attachment 3), to include instructions to inspection personnel on how to maintain the log. This change will be completed to correspond with other changes to the directive and is expected in December 2000.

Recommendation No. 5

Determine whether it is necessary for FSIS inspectors to be able to ship product samples to the field laboratories on Fridays and on days proceeding holidays. Renegotiate the existing agreement with the overnight courier to ensure next-day deliveries of such shipments, or inform the laboratories and all FSIS inspectors to discontinue shipments of product samples on these days if alternative methods are developed to test products that are produced on these days.

Agency Response:

FSIS disagrees with this recommendation. FSIS has already determined that it is necessary for inspectors to ship samples on Fridays and on days proceeding holidays for *Salmonella* analysis. Further negotiation of the contract is not necessary. The GSA contract negotiated with Federal Express (FedEx) does require Saturday delivery of samples if properly labeled. Saturday delivery is available, (and utilized by FSIS for the *Salmonella* testing program) under the existing government FedEx contract. Directions are included in FSIS Directive 10,230.5, instructing inspectors on how to collect and ship for Saturday delivery.

FSIS has had Saturday deliver of HACCP samples since the initiation of the HACCP *Salmonella* Program in the Agency on January 26, 1998. The OIG may have experienced difficulty shipping their first set of blind check samples due to the lack of the "Saturday Delivery" labels. This situation demonstrated that all parties involved, including Federal Express and the FSIS laboratories, performed exactly as directed. Federal Express does not and should not deliver

samples to the laboratories on Saturday if they do not have the mandatory "Saturday Delivery" label affixed to the outer surface of the box. Because this entire set of OIG-generated check samples was missing these required labels, the samples were held by Federal Express until the following Monday. Also as directed and expected, all of these samples delivered on Monday were discarded.

FSIS agrees that Saturday deliveries can be improved and its current discard rate can be reduced. FSIS' contract with Federal Express specifies Saturday delivery and delivery on holidays when Federal Express is working and when packaging requirements are followed. All FSIS laboratories receive and process samples via Federal Express on Saturdays and selected holidays. FSIS has also experienced occasional problems with Saturday delivery in a few very remote locations.

Regarding holiday delivery of samples, FSIS maintains close contact with Federal Express to determine which holidays Federal Express is not operating. In situations where Federal Express will not be delivering on certain holidays, FSIS notifies inspectors in all HACCP plants of the situation by placing highly visible, colored fliers in returning sample boxes. These fliers instruct inspectors not to collect and submit HACCP samples on the day before these holidays.

Additionally, Federal Express recently initiated a new process that does not require the use of special labels for Saturday delivery. A new flyer is being distributed to all inspectors immediately (attachment 4).

Recommendation No. 6:

Ensure that all establishments producing bacon products are subject to required testing for nitrosamines. Implement a comprehensive program of testing for this substance, under which all bacon-producing establishments would have product subject to periodic testing over a predetermined period of time.

Agency Response:

By March 3, 2001, FSIS intends to publish a proposed rule on converting 9 CFR 318.7(b) to a performance standard. The proposed rule is expected to remove the regulatory requirement for the Agency to test bacon products and report the results to the establishment. The proposed rule is expected to require the establishment to control its production practices and to produce safe product. The Agency is expected to verify that the establishment is following its HACCP procedures. The Agency may sample and test product as a verification that the HACCP system is in control, as appropriate.

The performance standard is expected to address both the nitrosamine level as well as the potential growth of *Clostridium botulinum.* OMB designated the performance as "significant". Thus, the proposed rule will undergo extensive review within USDA and OMB prior to publication. In order to publish by the end of March 2001, the proposed rule will need to be

submitted to OMB by December 31, 2000. FSIS expects to get the proposed rule into Departmental clearance by October 31, 2000.

Chapter 2. Quality Assurance Activities Need to be Strengthened

Recommendation No.7:

Establish monitoring procedures to ensure that the results of proficiency check samples are reported.

Agency Response:

OIG's independent evaluation of our laboratories attested to the high quality of our laboratory capabilities and demonstrated the ability of our laboratories to detect *Salmonella* and *E. coli* O157:H7 (in OIG's unmarked samples) with 100% accuracy. As a result of this evaluation, OIG stated: "They correctly analyzed 180 unmarked samples we sent them to determine if they could detect the presence or absence of the bacteria *Salmonella* and *E. coli* O157:H7."

We agree that FSIS can improve internal follow up when deviations in check sample results are noted. However, FSIS maintains that very few of the check sample sets contained deviations in the sample analyses. During the period of the audit, 99.3% of the 1,968 separate check sample analyses were correctly performed. Additional procedures can be developed to assist in the review, evaluation, and reporting of check sample results, and additional mechanisms can be developed to ensure that any necessary corrective actions are implemented, recorded, and properly reported to the appropriate officials. FSIS has drafted standard operating procedures that strengthen these controls. The new procedures should be completed by September 2000.

The FSIS laboratories do correctly perform the vast majority of check sample analyses as part of a rigorous testing program. Unlike commercial check sample programs used by some organizations, the FSIS laboratory check sample programs are more rigorous in that they often require that the laboratories perform both qualitative and quantitative/Most Probable Number analyses on samples where pathogens are inoculated into meat matrices. Most commercial proficiency testing programs require that participating laboratories only identify the presence or absence (qualitative analysis) of pathogens whenever the pathogens are inoculated into meat matrix. In cases where quantitative analyses are requested, the providers may use a less problematic matrix such as mashed potatoes. Few, if any, of the commercial proficiency testing programs provide the opportunity to perform quantitative analysis of samples in meat matrix. The rationale is that meat matrix is less homogeneous than mashed potatoes, and it is also more difficult for the provider to assure that samples derived from meat matrices are not naturally contaminated.

During the seven quarters from October 1997 to June 1999, FSIS laboratories received and analyzed a combined total of 108 separate sets of check samples. Each set contained from four to 16 separate, individually prepared and packaged unknown check samples. Each of these four

to 16 samples underwent from one to six specific individual analyses. The specific number of analyses varied depending on the type of sample, the analyses requested by Quality Assurance Branch (QAB), and whether the initial findings by the laboratory indicated additional tests were required. Altogether, the FSIS laboratories conducted 1,968 separate analyses on these 108 sets of check samples.

FSIS' check sample program is designed so that any deviation from expected results on any separate analysis would potentially yield a comment on the QAB report. In many cases, deviations recorded in the FSIS check sample program can be attributed to factors beyond the control of the laboratory or to expected variations associated with the pathogen and the matrix of concern. Some examples include variations in sample preparation (including inoculum preparation), shipping conditions, or to naturally occurring organisms in the meat matrix. The following information provides a breakdown of check sample results during the audit period.

During the audit period (October 1997 to June 1999), FSIS laboratories examined 108 check sample sets containing a total of 921 separate check samples (of which 540 were pathogen samples) and performed 1,968 separate analyses on the samples. FSIS laboratories analyzed the samples as part of the check sample programs designed to determine whether the laboratories could correctly identify the presence or absence of *E.coli* 0157:H7, *Listeria monocytogenes,* and *Salmonella spp.* The FSIS laboratories correctly identified the presence or absence of these pathogens in 538 of 540 samples (99.6%). *E.coli* 0157:H7 was not identified in one sample and *Salmonella spp.* was not identified in a second sample. NO FALSE POSITIVES were detected. Of the combined total of 1,968 separate check samples analyses, 1,954 (99.3%) were correctly identified or within acceptable ranges.

Of the 108 check sample sets (consisting of the 1,968 analyses), the QAB forwarded the results for 61 of these sets to the Microbiology Division and the FSIS laboratories. The 61 sets represented 1,223 individual analyses on 480 separate samples. The results obtained from 32 of the 1,223 analyses (2.6%) deviated from those expected and were noted in 20 of the 61 reports. However, only nine of the 1,223 individual analyses (0.7%) were incorrect due to laboratory error.

The 47 of 108 sets of results that were not forwarded to headquarters and to the laboratories consisted of 745 individual tests performed on a total of 441 separate samples. The results obtained from 34 of these 745 analyses (4.6%) deviated from those expected and were noted in 16 of the 47 reports. However, only five of the 745 analyses (0.7%) were considered to be due to laboratory errors in five of the 47 reports.

Recommendation No. 8:

Develop and implement procedures that schedule onsite laboratory reviews at regular intervals, establish guidelines for issuing reports within specified timeframes, and require laboratories to respond to the report's recommendations. In addition, implement procedures for QAB to track

the status of both draft and issued reports to ensure that they are processed and responded to in a timely manner.

Agency Response:

FSIS agrees with this recommendation. FSIS is in the process of instituting improvements to the management of audits of the FSIS laboratories to include the areas of scheduling, auditing, reporting, tracking, and follow-up on corrective actions. QAB scientists have been assigned specific audit tracking and follow up responsibilities. Furthermore, to aid in program efficiency and management, QAB is developing standard operating procedures (SOPs) to help to assure audits, responses, and corrective actions all occur in a timely, efficient, and acceptable manner. Each SOP will have a related flowchart to assist staff in meeting and following requirements. The following SOP's are under development and expect to be completed by October 2000:

1. Preparation, Submission and Tracking of Field Service Laboratory Audit Reports.

2. Scheduling and Conducting of Field Service and other Agency Laboratory Audits.

Further, FSIS intends to incorporate all improvements in an ISO Guide 17025-based laboratory accreditation program currently under development.

Recommendation No. 9:

Require the vendor to begin immediate preparation of a new lot of *Salmonella* test kits, which meet the MLG and AOAC standards, so that the use of the test kits from the two existing lots can be discontinued at the earliest possible time.

Agency Response:

As a result of the OIG's management alert (issued on October 29, 1999) FSIS responded to recommendation No. 9 (as specified in this report) in November 1999, and obtained new test kits.

Recommendation No. 10:

Amend FSIS contract specifications for Salmonella test kits to comply with the Microbiology Laboratory Guide.

Agency Response:

FSIS disagrees with OIG's Recommendation No. 10 and OIG's Recommendation No. 2 in the Management Alert issued October 29, 1999, where OIG stated: "...However agency officials still need to inform us as to their decisions on Recommendation No. 2 of the management alert

regarding the amendment of the contract specifications to bring them into compliance with the requirements of the Microbiology Laboratory Guide (MLG)."

Our experience and empirical evidence in using commercially available test kits within FSIS's laboratories for the analyses of raw meat and poultry samples supports the conclusion that the contract specifications should not be adjusted. The current specifications accomplish the following:

1. The false negative rate specification protects the public health. This specification is identical to the one stated in the MLG and is the most critical when trying to prevent contaminated products from reaching consumers.

2. The false positive rate specification keeps the laboratory workload (attempted confirmation of false-positive results) at a reasonable level.

3. The current specifications allow a reliable immunoassay screening test to efficiently and reliably handle the large number of *Salmonella* HACCP samples which the laboratories must analyze.

4. More stringent specifications could preclude the finding of an acceptable rapid screening test.

The agency is exploring options for changing the MLG performance characteristics and will summarize our findings by January 2001.

Recommendation No. 11:

Establish an inventory reorder point to ensure that orders for new test kits are placed early enough to allow sufficient time for FSIS to verify that production lots meet requirements, or if necessary to obtain new test kits before the laboratories exhaust their existing stock.

Agency Response:

As a result of the OIG's management alert (issued on October 29, 1999), FSIS responded to recommendation No.11 (as specified in this report) in November 1999. FSIS has established an inventory reorder point to ensure that orders for new test kits are placed early enough to allow sufficient time to verify that they meet requirements and before laboratories exhaust the existing supplies.

Recommendation No. 12:

Establish a training program that will (1) identify required training for microbiology staff members, (2) provide formal, structured training in addition to informal on-the-job training, (3) document the training provided to each staff member, (4) assess and document the competence of each staff member to perform tests and supporting activities, and (5) monitor the continued competence of each staff member to perform laboratory tests.

Agency Response:

The OIG audited the laboratories against AOAC guidelines for training that must be followed by laboratories accredited under ISO Guide 17025. The specific points detailed in Recommendation No. 12 are derived from these guidelines.

FSIS agrees that further enhancement and documentation of the laboratory training programs for microbiology analysts are indicated. FSIS, however, takes issue with the report's implications that FSIS does not provide adequate training, both in-house and for professional development. FSIS has always devoted considerable time and effort into training analysts and consistently provides proper supervisory oversight to ensure continued competency. As evidenced in the OIG report, FSIS, at the time of the audit, did not have readily available detailed documentation on the specific training provided to each analyst. More detailed, employee-specific training records were provided to the OIG in March 2000.

As part of the ISO laboratory accreditation effort, FSIS has developed draft standard operating procedures and work instructions that address the specific items detailed in the OIG report narrative as well as in Recommendation No. 12. FSIS is currently developing more extensive checklists for on-the-job training and is implementing a periodic proficiency testing program for individual analysts to further demonstrate initial and continued competency.

Recommendation No. 13:

Develop and implement a quality assurance program for the Special Project and Outbreak Support Laboratory

Agency Response:

FSIS agrees with this recommendation and has begun participation in a proficiency check sample program. As of the first quarter of FY 2000, appropriate samples have been provided to Special Project and Outbreak Support Laboratory (SPOSL) from the proficiency check sample program and include test samples for *E. coli* O157:H7, *Salmonella,* and *Listeria*. SPOSL will be scheduled for an appropriate laboratory audit by the fourth quarter of FY 2000.

Chapter 3. Better Controls Over Laboratory Documentation and Supervisory Reviews Are Needed

Recommendation No. 14:

Require the laboratories to implement a quality assurance system that ensures adequate documentation of analytical results, including but not limited to, the methods used and incubation times and temperatures. Require supervisory personnel at the laboratories to ensure, as part of their reviews, that all necessary documentation is being prepared on an ongoing basis.

Agency Response:

FSIS agrees with the recommendation and has already taken steps to further enhance documentation and supervisory oversight of all components of the laboratory system.

FSIS plans to complete documentation development and review by January 2001. FSIS projects that the laboratories will apply for an ISO audit by April 2001, and anticipate being accredited under ISO Guide 17025 by December 2001.

Recommendation No.15:

Implement a quality assurance system to ensure that adequate maintenance, servicing, and calibration is both performed and documented as required for each piece of equipment used in testing.

Agency Response:

FSIS agrees with this recommendation and is developing additional procedures, work instructions, and forms that will further and more completely document our ongoing maintenance, service, and calibration of testing equipment. This will be completed by December 2000.

Chapter 4. Tighter Controls Are Needed Over The Accredited Laboratory Program

Recommendation No. 16:

Strengthen the agency's monitoring of accredited laboratories, particularly those, which test official samples for FSIS, through more frequent onsite visits and/or split sampling of official product samples.

Agency Response:

FSIS agrees with this recommendation. By February 2001, FSIS will initiate an agreement (or contract) to perform more frequent accredited laboratory onsite visits.

Recommendation No. 17:

Ensure that only FSIS-accredited laboratories perform test results on official samples.

Agency Response:

FSIS agrees with this recommendation and currently performs the following to address OIG's concerns:

1. Laboratories in good standing are issued certificates of accreditation's valid for one year.

2. Letters for probation/revocation of accreditation are sent by FSIS via overnight mail.

3. FSIS Field Operations Staff in Technical Service Center are notified about laboratories whose accreditation have been placed on probation or revoked.

4. Updated list of accredited laboratories are published every six months in the FSIS Meat and Poultry Inspection Directory and distributed to inspection staff.

5. Updated list of accredited laboratories are printed monthly by Quality Assurance Branch/Chemistry and Toxicology Division and provided upon request.

6. Updated list of accredited laboratories is posted about every month on the USDA-FSIS Website and sent electronically to e-mail addresses.

To further evaluate controls (in a HACCP and ISO environment) during FY 2001 we will seek a more extensive review of the ALP program with a report of recommendations to the agency by January 2002.

If you have any questions, please contact Penny Zervos, Internal Control Staff, at (202) 690-5633.

Attachments

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE	10,230.3 Rev. 2	9-1-98

PREPARATION AND SUBMISSION OF FSIS FORM 10,230-3, SAMPLING FRAME UPDATE FORM

I. PURPOSE

This directive provides instructions for completing and submitting FSIS Form 10,230-3, Sampling Frame Update. The completed form provides information needed to update records of specific categories of product produced in specific processing establishments. Monthly sample requests under established sampling projects are based on this information.

II. CANCELLATION

FSIS Directive 10,230.3, Revision 1

III. REASON FOR REISSUANCE

The directive has been revised to include additional information about ground product production and to update addresses and phone numbers.

IV. REFERENCES

MPI Regulations, Sections 318.2, 318.9, 381.145, and 381.146

V. POLICY

A. FSIS' strategy for reducing the occurrence and numbers of pathogenic microorganisms in meat and poultry products includes testing processed products for specific pathogens.

DISTRIBUTION: Inspection Offices; T/A Inspectors; Plant Mgt; T/A Plant Mgt; TRA; ABB; PRD, Import Offices

OPI: OPPDE

OCT -5 1998

Attachment 1 Page 1

B. Inspection personnel collect information about specific products being processed in establishments so that adequate samples can be collected as necessary for established sampling projects.

C. Inspection personnel will collect and submit information on FSIS Form 10,230-3 tow times each year from each processing establishment.

VI. CATEGORIES OF PRODUCTS ASSIGNED TO EACH SAMPLING PROJECT

A. Sliced Ham and Luncheon Meat: (MM11) includes cooked meat products such as sliced cooked ham, ham steaks, sliced canned ham, sliced loaf type luncheon meats, etc. Product may be formulated and cooked, and sliced and packaged at the sampled establishment or received from another establishment for slicing and packaging. This category does not include sliced sausage products described under "Large Diameter Sausage."

B. Small Diameter Cooked Sausage: (ME15) includes products formulated with either meat only, poultry only, or meat and poultry combinations; product may be cured or uncured; for example: Beef Franks, Wieners, Chicken Hot Dogs, Turkey Knockwurst, Kielbasa with Pork and Turkey, Cooked Bratwurst, Cooked Italian Sausage.

C. Large Diameter Cooked Sausage: (ME16) includes products formulated with either meat only, poultry only, or meat and poultry combinations; product may be cured or uncured; for example: Cooked Salami, Beef Bologna, Liver Sausage, Liverwurst, Cooked Salami with Pork and Turkey, Turkey Bologna.

D. Salads and Spreads: (ME23) includes perishable, refrigerated or frozen products such as: liver spreads, meat spreads, pate, chicken salad, ham salad, turkey salad, cooked teawurst, and cooked metwurst, etc. This category does not include shelf stable canned products.

E. Cooked Poultry: (ME22) includes UNCURED COOKED POULTRY PRODUCTS such as cooked whole birds, fried parts, nuggets, fritters, sliced rolls, roasted breasts, sliced breasts, cooked-diced chicken/turkey, heat and serve poultry entrees, burritos, egg rolls, snacks, hors d'oeuvres, etc.

F. Roast Beef, Cooked Beef, Cooked Corned Beef: (MM9) includes those products covered by MPI Regulations, Section 318.17.

G. Fully Cooked, Uncured Meat Patties: (MT01) includes fully cooked, uncured meat patties as defined under MPI Regulations, Section 318.23. Patties may be formulated with various flavorings, extenders, or be a component in an entree or dinner, etc.

H. Jerky: (ME7) includes any/all species of shelf stable jerky type products.

I. Dry, Semi-dry, and Fermented Products: (MT02) are ready-to-eat, comminuted, and stuffed meat products that are generally processed at temperatures above 70° F. with or without starter culture. Includes products such as Pepperoni, Cervelot, Italian Salami, Lebanon Bologna, Summer Sausage, Hard Salami, Turkey Summer Sausage, Sopressatte, etc.

J. Raw Ground Beef: (MT03) Products eligible for sampling are any raw chopped or ground beef products, such as ground beef, hamburger, beef patties, beef patty mix, etc. Product may have flavoring or extenders added, but should not contain pork or poultry.

K. Raw Ground Chicken: Products eligible for sampling are any products labeled Ground Chicken. **This category excludes product designated as Mechanically Separated (Kind).**

L. Raw Ground Turkey: Products eligible for sampling are any products labeled Ground Turkey. This category excludes product designated as Mechanically Separated (Kind).

M. Fresh Pork Sausage: Products eligible for sampling are any fresh uncured raw sausage containing **only pork and pork fat** as the meat ingredient and which meet the requirements of 9 CFR 319.141 (Fresh Pork Sausage); 319.143 (Breakfast Sausage); 319.144 (Whole Hog Sausage); and 319.145 (Italian Sausage Products [uncured]. **Also included in this category are products labeled Ground Pork.**

N. Cooked, Uncured Meat Products (other than described above): includes products such as uncured cooked meat (all species) products, except those covered by MPI Regulations, Sections 318.17 and 318.23. Examples of products included are: cooked meatballs, cooked meat dinners and entrees, cooked meat snacks and hors d'oeuvres, meat egg rolls, meat burritos, cooked meat cuts and portions, cooked crumbles, cooked uncured meat loaves (whole), etc.

O. Cooked Cured Poultry: includes products such as turkey ham, whole or sliced, cooked cured turkey parts, poultry pastrami, cured poultry loaves, cured luncheon meats, cured smoked whole birds, etc. This category does not include products covered by the Large and Small Diameter Sausage categories.

Note: Other categories may be added as new sampling projects are developed. Also, current sampling projects may not cover all categories listed above.

VII. RESPONSIBILITIES AND PROCEDURES FOR COMPLETING AND SUBMITTING THE FORM

A. Processing Establishments Currently Under Inspection

1. Office of Public Health and Science (OPHS) will mail a copy of FSIS Form 10,230-3 to the IIC at each processing establishment approximately every 6 months. The form will contain pre-printed information pertaining to the specific establishment (establishment number and similar information).

2. Inspection personnel will:

a. Be familiar with the products produced at their assigned establishment to be included under sampling project categories (See Paragraph VI.).

b. Complete FSIS Form 10,230.3 by following the instructions printed on the form.

c. Mark the appropriate spaces to indicate which sampling projects, found in paragraph VI., are applicable to the establishment specified on the form. **Note:** For the products listed in paragraphs VI. J.,K.,L., and M, shade the circle to the right of the product name if the establishment produces this product less than 26 times per year.

d. Complete the form within 30 days of receipt.

e. Sign and date the form.

f. FAX the form (if an Agency FAX machine is available for inspectors' use) to OPHS at Headquarters via FAX number (202) 501-0369.

g. Mail the form (if an Agency FAX machine is not available for inspectors' use) to OPHS at the following address:

OPHS Microbiology Division
Room 3714 Franklin Court Suite
1400 Independence Ave., NW
Washington, DC 20250-3700

h. Maintain a copy of the form in the file.

B. New Processing Establishments Coming Under Inspection

1. Inspection personnel will complete a blank FSIS Form 10,230-3 using instructions given in paragraph VII.A., above, within 30 days of an establishment coming under inspection. Blank forms are available through normal supply channels.

2. Inspection personnel will FAX or mail the form to the FAX number or address indicated in Paragraph VII.A., above.

3. Inspection personnel will maintain a copy of the form in the file.

C. OPHS will update and maintain sampling frames for sampling projects using information provided on FSIS Form 10,230-3.

Deputy Administrator
Office Policy, Program Development
and Evaluation

Attachment

1-- FSIS Form 10,230-3, (revised 4/98)

62574

Sampling Frame Update Form

Establishment

EXAMPLE	0	0	0	3	8	W		M

Survey Date ☐☐ / ☐☐ / ☐☐

Follow the instructions provided in FSIS Directive 10,230.3. It contains the definitions for the categories of products assigned to each current and potential microbiological sampling project. The inspector should shade the appropriate circles to identify the products normally processed at this establishment. Fax the completed form to (202) 501-0369. If a fax machine is not available, mail the completed form to:

Food Safety and Inspection Service, USDA
OPHS, Microbiology Division
Room 3714 Franklin Court Suite
1400 Independence Ave., SW
Washington, DC 20250-3700

Processed Product Categories: (shade all circles that apply)

- ○ Sliced Ham and Luncheon Meat (MM11)
- ○ Small Diameter Sausage (ME15)
- ○ Large Diameter Sausage (ME16)
- ○ Salads and Spreads (ME23)
- ○ Cooked, Uncured Poultry (ME22)
- ○ Roast Beef, Cooked Beef and Cooked Corned Beef (MM9)
- ○ Fully Cooked, Uncured Meat Patties (MT01)
- ○ Jerky (ME7)
- ○ Dry, Semi-dry and Fermented Products (MT02)
- ○ Raw Ground Beef (MT03) ---------- ○ Produces ground beef less than 26 times per year
- ○ Raw Ground Chicken ---------- ○ Produces ground chicken less than 26 times per year
- ○ Raw Ground Turkey ---------- ○ Produces ground turkey less than 26 times per year
- ○ Fresh Pork Sausage or Ground Pork ---- ○ Produces fresh pork sausage less than 26 times per year
- ○ Cooked, Uncured Meat other than described in Directive 10,230.3
- ○ Cooked, Cured Poultry
- ○ No products as defined in FSIS Directive 10,230.3 or listed above are produced at this establishment

_____ Signature of IIC

_____ Date

FSIS FORM 10,230-3 (Revised 4/98)

Attachment 1 Page 6

PATHOGEN REDUCTION ENFORCEMENT PROGRAM
PREP

In July 1996, FSIS published the final rule for Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) Systems. The rule stated explicitly that the testing of specified raw products for *Salmonella* would be conducted by the Agency. The preamble to this final rule outlined a comprehensive, multimillion-dollar program for *Salmonella* testing. This new program required several new concepts in testing that had previously not been used by the agency, e.g., the need to track sample results by sets of analyses conducted over a lengthy period of time. These new requirements created the need for a new automated system to schedule, track and report sampling activity. PREP was designed to fill that need.

Salmonella samples are scheduled in three ways:

1. establishments and products can be targeted based on factors such as the percentage of positive sample allowed or an establishment's previous test results;

2. establishments can be selected randomly; or

3. PREP can select a specific establishment using a feature that provides a manual override to the automated scheduling components.

PREP performs the tracking required for forms, samples and sets. Using the PR/HACCP rule, PREP specifies a number of samples (n) that comprise a set for each product. PREP schedules an appropriate number of forms for a given product and then tracks how many forms are used and still needed at each establishment. PREP counts the number of laboratory samples that are received, analyzed, and discarded. It records the sample results and then computes the results for a set; pass or fail. PREP's capabilities include the ability to transfer files and e-mail reports at specified times to headquarters personnel, laboratory personnel, and field personnel at all levels.

PREP provides reports on system events, routine (scheduled) reports and ad hoc reports. System event reports include the following: (1) notification to personnel of initiation of sample schedules; (2) warn of set failures; (3) and completion of set results. In addition, PREP notifies laboratory personnel of samples that are received but no result is entered into the system. Routine reports triggered to report on a monthly basis include: (1) non-responders report to notify the field of inspectors not providing requested samples; (2) a current testing status for all establishments within a district/circuit; (3) establishment/product eligibility listing for districts; (4) and laboratory capacity reports. Ad hoc reports can be generated by PREP to summarize performance for any given establishment, groups of establishments or product. In addition, PREP is used to respond to Freedom of Information Act (FOIA) requests.

The Agency intends to expand PREP by adding testing modules with similar capabilities for the proposed Ready-to-Eat testing program, *E. coli* O157:H7 in raw ground beef testing, and residue testing.

Attachment 2 Page 2

UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE WASHINGTON, DC CHANGE TRANSMITTAL SHEET	☐ DIRECTIVE ☐ REVISION ☒ AMENDMENT ☐ OTHER	
SELF-INSTRUCTION GUIDE FOR COLLECTING RAW MEAT AND POULTRY PRODUCT SAMPLES FOR *SALMONELLA* ANALYSIS	10,230.5 Amend. 1	7-29-98

I. PURPOSE

FSIS Directive 10,230.5 is amended by making the changes regarding sample collection as discussed in Attachment 2 of the directive and making four other corrections.

II. PRINCIPAL CHANGES

A. Table of Contents: Under **Attachments** changed Attachment 2 to reserved.

B. Page 1-1: Clarified that inspection personnel collect one sample per day of production and clarified what inspection personnel do if product is not produced.

C. Page 2-1: Removed the master list from supplies received from headquarters and changed who to call if something from headquarters is missing.

D. Page 3-1: Clarified how to sample from late production and instructed inspectors to fill out the date of collection on the form (previously it was just time).

E. Page 3-2 & 3-3: Instructed inspectors to fill out date of collection on form (previously it was just time).

F. Page 7-1: Changed instructions for "Reasons not Collected Codes" and removed code 67; revised form.

G. Page 9-1: Changed Note in the first paragraph to a reference to page 3-1.

H. Page 9-2: Changed number 5. by adding an instruction to fill in date collected.
Changed number 6. by clarifying directions to close new shipping boxes.
Changed number 8. by adding toll free lab supply number.

DISTRIBUTION: Inspection Offices, T/A Inspectors, Plant Mgt., T/A Plant Mgt., TRA, ABB, PRD, Import Offices

OPI: OPPDE

Attachment 3 Page 1

I. Attachment 1: Revised form, added example of pre-addressed lab label, and added captions to identify labels.

J. Attachment 2: Reserved because master schedule list is no longer sent to IIC's.

III. CANCELLATION

This transmittal is canceled when contents have been incorporated into FSIS Directive 10,230.5, amend. 1. For recordkeeping purposes, users may either retain or destroy this transmittal.

Deputy Administrator
Office of Policy, Program Development
and Analysis

FILING INSTRUCTION

Remove Old Pages	Insert New Pages
Table of Contents	Table of Contents
2-1-2-2	2-1-2-2
3-1-3-2	3-1-3-2
3-3	3-3
7-1	7-1
9-1- 9-2	9-1-9-2
Attachment 1	Attachment 1
Attachment 2	Attachment 2

Attachment 3 Page 2

Contents

SALMONELLA ANALYSIS

Collecting Raw Meat and Poultry Product Samples

Revised July 1998

Attachment 3 Page 3

INTRODUCTION

This sampling guide has been prepared to support the Pathogen Reduction/HACCP Regulation. Aseptic sample collection will be carried out by inspection personnel and will include:

A nondestructive whole bird rinse for chickens, the same procedure that was used in the laboratory for the Nationwide Microbiological Baseline Data Collection Program for this species.

A nondestructive sponging technique for raw beef, swine, and turkey carcass surfaces.

A 25-gram sample collected for testing raw ground meat/poultry.

Unless the District Office instructs otherwise, one sample will be collected on each day the plant produces the product indicated on the sample request form, FSIS Form 10,210-7 (see Attachment 1), and sent by overnight delivery service to the designated laboratory on a daily basis.

If the plant no longer produces the indicated product, complete one FSIS Form 10,210-7 as described in Section Seven and mail it and the entire set of sample forms by regular mail to the laboratory, using the pre-addressed laboratory mailing label.

Currently only beef, swine, chicken, and turkey are being sampled. Other species will be included as appropriate.

Target Audience

This guide is written for the **sample collector**, whether that person is the IIC or a designee.

Revised July 1998

Attachment 3 Page 4

SUPPLIES

a. From Headquarters

Inspectors-in-charge (IICs) at designated establishments will receive the following supplies from Headquarters:

Sample request forms (FSIS Forms 10,210-7) in perforated sheets of 4, with each form individually numbered. The forms will designate the type of product to be sampled. See Attachment 1.

Bar code stickers to use on each sample bag or container that identifies the type of sample. See Attachment 1.

Pre-addressed laboratory mailing labels to be used in the event samples are not collected. See Attachment 1. The procedures are described in Section Seven.

If part of the supplies from Headquarters are missing, contact the Food Hazard Surveillance Division at (202) 501-7515.

b. From Technical Service Laboratories (TSL)

All sampling supplies and shipping containers will be provided by FSIS Technical Service Laboratories. These shipping containers are to be used only for the *Salmonella* sampling program. Inside each container will be the supplies needed for collecting specific product samples. The containers will carry color-coded labels as shown on the chart on the next page.

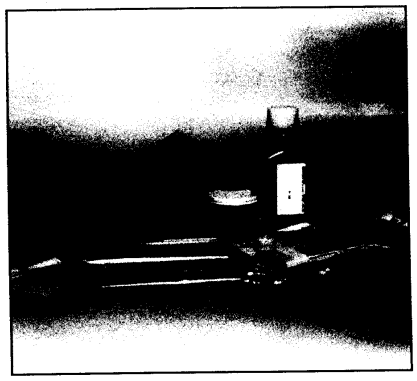
If any supplies are missing from the container, contact the designated laboratory or your district office.

The TSL will also send preaddressed FedEx Billable Stamp Receipts for sample overnight delivery to the designated laboratory. See Section Nine.

c. From Local Procurement

Sanitizing solution—See page 5-2 for instructions on preparing solution.

Tote—See page 5-3.



Revised July 1998

Attachment 3 Page 5

Label Color	Designation	Type of Sample	Supplies in Shipper
Neon Orange	SPONGE SAMPLES ONLY	Livestock (sponge)	Sterile gloves Corrugated pad (depending upon shipping container type) Gel pack(s) Sponge in sterile Whirl-Pak® bag Container with 10 ml of Buffered Peptone Water (BPW) Sterile square sampling template in bag
Neon Green	POULTRY WASH SAMPLES ONLY	Chicken (rinse)	Sterile gloves Corrugated pad (depending upon shipping container type) Gel pack(s) Container with 400 ml of Buffered Peptone Water (BPW) Sterile screw-capped jar Large sterile bag Small resealable bag
	SPONGE SAMPLES ONLY	Turkey (sponge)	Sterile gloves Corrugated pad (depending upon shipping container type) Gel pack(s) Sponge in sterile Whirl-Pak® bag Container with 10 ml of Buffered Peptone Water (BPW) Sterile rectangular sampling template in bag
Neon Pink	GROUND SAMPLES ONLY	Ground Product (product)	Sterile gloves Corrugated pad (depending upon shipping container type) Gel pack(s) Sterile Whirl-Pak® bag with sterile plastic sheet and sterile clear, rigid plastic ring template

This chart lists only the supplies sent by the TSL. A complete list of supplies needed for collecting samples can be found in the Materials section of each specific sample collection procedure.

Attachment 3 Page 6

SAMPLE SELECTIONS

Samples are to be taken **randomly** on each day the designated product is produced, until the supply of FSIS Form 10,210-7 is exhausted or the District Office instructs otherwise.

There are different methods of randomly selecting the specific carcass or product for sampling but all require the use of random numbers. Methods could include using random number tables, drawing cards, using computer-generated or calculator-generated random numbers, etc. If other programs requiring random sampling are underway at the establishment, simply use one of the methods already in use by inspection personnel.

The carcass or ground product for sampling must be selected at random from all eligible carcasses or ground products. If there are multiple shifts, rails, coolers, chillers, or grinders, randomly select one for sample collection. Each one should have an equal chance of being selected at each sampling interval.

If a carcass sponge (cattle, swine, or turkey) or chicken rinse sample cannot be shipped the same calendar day it would be collected, randomly select the carcass for sampling and hold it, refrigerated. Perform the sponge sampling or chicken rinse procedure the next business day that overnight shipping can occur.

Ground product samples can be held refrigerated until the sample can be shipped by overnight courier.

If more than one shift is operating at the plant, the sample can be taken on **any** shift if the following requirements are met.

a. Selecting a Cattle Half-Carcass

The half-carcasses eligible for sampling should be selected from those chilled for 12 hours or more after slaughter. Both the "leading" and "trailing" sides of a carcass should have an equal chance of being selected. Carcasses to be hot-boned may be sampled after the final wash.

Hide-on calves are not split. The sample unit for these calves is one carcass.

Selecting the cooler site. Select a safe and accessible site in the cooler for collecting samples from a beef half-carcass. This site may be located at the transfer chain, grading chain, a rail, or other safe, uncrowded location in the cooler.

Selecting the time. Determine the times that carcasses chilled for 12 hours or more will be on hand. Then randomly select a time from within that time frame for collecting the samples. Record the time and date of sample collection on the FSIS Form 10,210-7.

Selecting the half-carcass. At the random time you selected, go to the sampling location. Do not choose the carcass that is at the predetermined location. Instead, count back or ahead 5 sample units and choose the sixth unit to sample. (The reason for counting back or ahead 5 half-carcasses is to avoid any possible bias during selection.) Normally it should not be necessary to have the establishment move many half-carcasses to access a random one to sample.

Revised July 1998

b. Selecting a Swine Carcass

The carcasses eligible for sampling should be selected from those chilled for 12 hours or more after slaughter. Every carcass should have an equal chance of being selected. Carcasses to be hot-boned may be sampled after the final wash.

Selecting the cooler site. Select a safe and accessible site in the cooler for collecting samples from a swine carcass. This site may be located at the transfer chain, a rail, or other safe, uncrowded location in the cooler.

Selecting the time. Determine the times that carcasses chilled for 12 hours or more will be on hand. Then randomly select a time from within that time frame for collecting the samples. Record the time and date of sample collection on the FSIS Form 10,210-7.

Selecting the carcass. At the random time you selected, go to the predetermined sampling location. Do not choose the carcass that is at the predetermined location. Instead, count back or ahead 5 sample units and choose the sixth unit to sample. (The reason for counting back or ahead 5 carcasses is to avoid any possible bias during selection.) Normally it should not be necessary to have the establishment move many carcasses to access a random one to sample.

Carcasses that are routinely partially skinned may be used.

c. Selecting a Poultry Carcass (Chicken or Turkey)

Poultry carcasses will be selected at random after chilling, at the end of the drip line or at the last readily accessible point prior to packing/cut-up. A *whole* carcass is required—one that has not been trimmed. For safety reasons, do not remove a bird from moving shackles. Wait for the bird to drop and then collect it. Carcasses to be hot-boned may be sampled after the final wash.

Selecting the chiller. If more than one chiller system is in operation at the time of sample collection, randomly select the chill tank from which to take the sample. Then determine a safe, appropriate point from which to collect the sample unit. For hot-boned carcasses, randomly determine the line.

Selecting the time. Determine the times that chilled carcasses will be on hand. Then randomly select a time from within that time frame for collecting the samples. Record the time and date of sample collection on the FSIS Form 10,210-7.

Selecting the carcass. At the random time you selected, go to the predetermined point for sample collection. Count back or ahead 5 carcasses and select the next carcass for sampling. (The reason for counting back or ahead 5 carcasses is to avoid any possible bias during selection.) *Exception*: If the sixth carcass is not a whole bird (untrimmed, with or without neck), count back or ahead an additional 5 carcasses for sample selection. Repeat until a whole carcass is available.

d. Selecting Raw Ground Product

Raw ground product samples (beef, pork sausage, chicken, or turkey) will be randomly collected after the final grinding process, before any addition of spices or seasonings (if possible), and prior to final packaging. For safety reasons, such as with closed systems, it may be necessary to collect the raw ground samples after final packaging but prior to chilling or freezing.

If more than one shift is operating at the plant, the sample can be taken on any shift if the requirements below are met.

Selecting the grinder. If more than one ground product line is in operation at the time of sample collection, randomly select the ground product line from which to take the sample.

Selecting the time. Determine the times that raw ground product will be produced. Then randomly select a time from within that time frame for collecting the sample. Record the time and date of sample collection on the FSIS Form 10,210-7.

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Attachment 3 Page 9

SAMPLES NOT COLLECTED

If any sample cannot be collected, complete the "Reason If Uncollected" block on the first FSIS Form 10,210-7 in the set of sample collection forms by checking the appropriate coded box:

72—Requested species/product not produced in the last 30 days. If 30 days passes and the requested product has not been produced, check box 72 on **one** Form 10,210-7 and mail it to the designated laboratory using the pre-adressed laboratory mailing label. If another 30 days passes without production of the requested product, again send **one** Form 10,210-7 with box 72 checked to the laboratory. Continue this process until the requested product is produced again.

60—Plant does not slaughter or produce designated product. (If this box is checked, the plant will be removed from this sampling frame.) Indicate on the back of the form what product the plant does slaughter or produce that is subject to the *Salmonella* Testing Program.

53—Other. (Explain, using the back of the form if necessary.)

For codes 60 or 53, place the entire sample set of FSIS Forms 10,210-7, including the completed one, in an envelope, apply the preaddressed laboratory mailing label, and mail the envelope to the designated FSIS laboratory via regular mail.

SAMPLE COLLECTION REQUEST

FOR LAB USE ONLY

Internal lab code here	RECEIPT DATE	RECEIPT CONDITION	SEAL CONDITION	DISCARD CONDITION

FORM 12345678	LAB	PRODUCT/SPECIES	COLLECTION DATE:
	ATHENS GA	Turkey Carcass	
ESTABLISHMENT	TIME COLLECTED *(Military)*	MAIL/SHIP DATE	REASON IF UNCOLLECTED
12345 P		5/19/98	72 ☐ Not produced in last 30 days 60 ☒ No longer produced 53 ☐ Other *(explain on back)*

FSIS FORM 10,210-7 (5/98) REPLACES FSIS FORM 10,210-7 (1/98), WHICH MAY BE USED UNTIL EXHAUSTED. USDA - FSIS

7-1

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Attachment 3 Page 10

SAMPLE SHIPMENT

Samples must be picked up by the overnight courier the *same* calendar day the sample is collected. Samples must be analyzed the day after collection. If a sample is not collected and shipped on the same day or if samples are not received by the laboratory the day after collection, the sample is discarded. *Note*: See Section Three, page 3-1, paragraphs 4 and 5, for instructions on collecting samples from late production.

To ship samples:

1. Retrieve the **prechilled** shipping container you placed in the refrigerator the day before sampling. (See Section Five, **Preparation for Sample Collection**.)

2. Retrieve the gel packs placed in the freezer at the same time.

3. Place the sample you are submitting (sponge, jar, or ground product) in the prechilled shipper.

4. Place a corrugated cardboard pad on top of the sample. If a corrugated cardboard pad is not supplied, use some newspaper or similar material. This prevents the gel packs from directly contacting the sample. If the gel packs directly contact the sample, the sample temperature may be lowered enough to freeze portions of the sample, which will have an effect on the sample results. Place sufficient frozen coolant on top of the corrugated pad or paper to keep the sample refrigerated during shipment to the designated laboratory. Insert the foam plug and press it down to minimize the shipper's headspace. If your shipping container does not have a foam plug, cover the sample with the insulated lid of the shipping container.

Note: Do not tape or wrap the sample nor fill the headspace with newspaper or similar paper. This is not necessary and creates problems for the receiving laboratory.

Revised July 1998

Attachment 3 Page 11

5. Fill in the "Collection Date," "Time Collected," and "Mail/Ship Date" sections on the FSIS Form 10,210-7. Each sample should have an accompanying completed FSIS Form 10,210-7.

6. Place the FSIS Form 10,210-7 in the shipping container, **directly** on top of the foam plug. Close box flaps so that the container closure system is secure. If there are tapeless closures, do not tape the box. Do not remove old stamp receipts from the shipping container.

7. Prepare the pre-addressed FedEx Billable Stamp Receipt. Fill in the plant number, ship date, and plant phone number. Sign the receipt and remove the top copy for your records. Place the stamp receipt on the box on top of any old stamp receipt.

8. If you are missing any of the shipping supplies that you need, contact the Technical Services Laboratory designated on the sample request form to obtain the missing items.

A **toll-free** number has been established to request supplies. Call **1-877-709-1982** and follow the instructions in the recording to leave a message for the laboratory designated on the FSIS Form 10,210-7.

Note: *If you collect the sample on Friday, you will need to attach the special "Saturday Delivery" label to the shipping container. This label has special instructions to the FedEx driver to alert him or her that the lab will accept shipments on Saturday. Apply this label above the stamp receipt for Friday shipments only.*

If you do not specifically mark it, the sample will not be delivered to the lab until Monday. This is too late to run the sample for a viable analysis and the sample will be discarded.

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Attachment 3 Page 12

Attachment 1

SAMPLE COLLECTION REQUEST

FOR LAB USE ONLY

Internal lab code here	RECEIPT DATE	RECEIPT CONDITION	SEAL CONDITION	DISCARD CONDITION

FORM 12345678	LAB	PRODUCT/SPECIES	COLLECTION DATE:
	ATHENS GA	Turkey Carcass	

ESTABLISHMENT	TIME COLLECTED *(Military)*	MAIL/SHIP DATE	REASON IF UNCOLLECTED
12345 P			72 ☐ Not produced in last 30 days 60 ☐ No longer produced 53 ☐ Other *(explain on back)*

FSIS FORM 10,210-7 (5/98) REPLACES FSIS FORM 10,210-7 (1/98), WHICH MAY BE USED UNTIL EXHAUSTED. USDA - FSIS

USDA-FSIS-OPHS-EASTERN LAB
RICHARD RUSSELL RESEARCH CENTER
MICR SECT, COLLEGE STATION ROAD
ATHENS GA 30605-2720

Pre-addressed lab label

Turkey Carcass 00152650

Bar code sticker to label
sample bag or container

Revised July 1998

Attachment 3 Page 13

RESERVED

Attachment 2

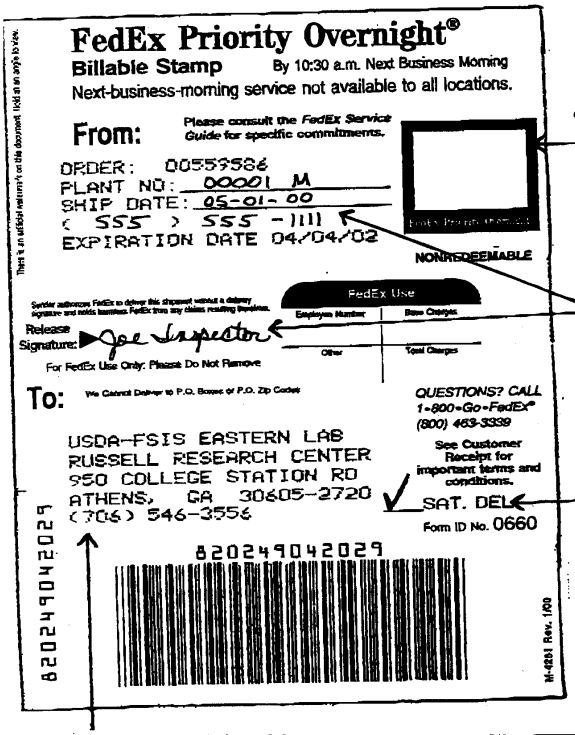
Revised July 1998

Attachment 3 Page 14

NEW BILLABLE FEDEX STAMP WITH PREPRINTED SATURDAY DELIVERY OPTION!!

We are currently phasing in a new FedEx stamp with two options.

Please read the following instructions for use of this stamp!
Call the toll free supply line if Saturday labels or billable stamps are needed: 1-877-709-1982
(This phone number is printed on each gel pack)


FedEx Priority Overnight®
Billable Stamp By 10:30 a.m. Next Business Morning
Next-business-morning service not available to all locations.
From: Please consult the FedEx Service Guide for specific commitments.
ORDER: 00559586
PLANT NO: 00001 M
SHIP DATE: 05-01-00
(555) 555 -1111
EXPIRATION DATE 04/04/02
NONREDEEMABLE
FedEx Use
Release Signature: Joe Inspector
For FedEx Use Only: Please Do Not Remove
To:
USDA-FSIS EASTERN LAB
RUSSELL RESEARCH CENTER
950 COLLEGE STATION RD
ATHENS, GA 30605-2720
(706) 546-3556
QUESTIONS? CALL 1-800-Go-FedEx® (800) 463-3339
See Customer Receipt for important terms and conditions.
SAT. DEL
Form ID No. 0660
820249042029

- The weight of the box will be entered by the FedEx driver.
- You **MUST** enter your plant number, shipping date (the day FedEx picks up your sample box), phone number and sign the stamp.
- If the box is used for shipment on a **FRIDAY**, the Saturday delivery section **MUST BE CHECKED** on the stamp and a *Saturday Delivery* label affixed to the box.
- Be sure the lab address printed here matches the lab on your sample submission form

Attachment 4 Page 1 ... labels are available from the FedEx driver

A T T E N T I O N

SATURDAY DELIVERY REQUIRED.

Please REX this shipment to add Saturday Delivery Service charge.

Label 1

FedEx. Federal Express

SEL72 3/97

Label 2

SDR

FedEx. Federal Express Saturday Delivery

15967 897

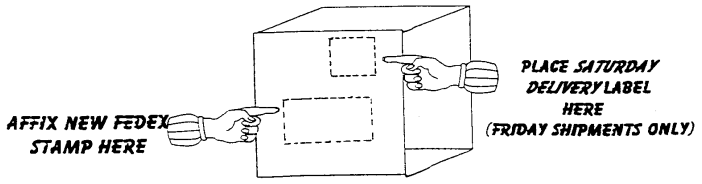
Attachment 4 Page 2

ATTENTION INSPECTOR-IN-CHARGE: NEW FEDEX LABEL ENCLOSED. PLEASE READ INSTRUCTIONS CAREFULLY!!

The enclosed *FedEx Billable Stamp Receipt* replaces the old FedEx airbills. You will receive one stamp in each shipping container returned to you from the laboratory for HACCP sample shipping.

Critical Points to Remember:

1. USE STAMP FOR HACCP SAMPLE SHIPPING ONLY!
2. DO NOT TEAR OR TRY TO REMOVE OLD STAMPS FROM THE SHIPPING CONTAINER!
3. FILL IN PLANT # (inc. all letters), SHIP DATE & PHONE # AND REMOVE TOP COPY OF SHIPPING STAMP FOR YOUR RECORDS.
4. PLACE STAMP OVER EXISTING FEDEX LABEL. BE SURE TO COVER ANY BARCODES ON EXISTING FEDEX LABELS WITH NEW STAMP OR WITH A BLACK MAGIC MARKER!
5. CALL THE EASTERN LAB AT 706-546-3561 TO REQUEST FEDEX STAMPS OR SUPPLIES!
6. THE *SATURDAY DELIVERY* LABEL MUST BE APPLIED ABOVE THE FEDEX STAMP ON YOUR FRIDAY HACCP SHIPMENTS.



Attachment 4 Page 3

ABBREVIATIONS

AOAC
Association of Analytical Chemists i

CTD
Chemistry and Toxicology Division iii

DIAS
Dynex Immunuassay System 45

ELISA
Enzyme-Linked Immunuassary 4

HACCP
Hazard Analysis And Critical Control Point System 3

ISO
International Organization For Standardization 5

MLG
Microbiology Laboratory Guidebook 5

NRP
National Residue Program 4

PBIS
Performance Board Inspection System 4

QAB
Quality Assurance Branch iii

SPOSL
Special Project and Outbreak Support Laboratory 39

GLOSSARY OF TERMS

Accredited Laboratory – A nonfederal analytical chemistry laboratory recognized by FSIS as competent to analyze official meat and poultry samples for moisture, protein, fat, and salt content, and/or certain classes of chemical residues.

Antibiotic Residue – The portion of antimicrobial drugs that remains in the tissues of food animals, which can result in human illnesses.

Campylobacter – A pathogenic organism commonly found in poultry and other food of animal origin, including pork and beef. Campylobacter infections generally cause intestinal distress.

Check Sample – A food product sample, in the form that is commonly sent to the field service laboratories for analysis, that has had a known amount of a pathogenic organism or antibiotic or chemical residue added, for the purpose of evaluating the accuracy of the service laboratory's analyses. A check sample that is unmarked, i.e. disguised as an official product sample, is referred to as a "blind" sample.

Chemical Residues – The portion of pesticides that remains in the tissues of food animals, which can result in human illnesses.

E.coli O157:H7 – The strain of the pathogenic organism *escherichia coli* that causes potentially serious illness, particularly for children and individuals with weakened immune systems. It is found in ground beef, raw milk, and chicken.

Establishment – A federally inspected meat, poultry, or eggplant whose function is to slaughter food animals and/or process food products.

Extraneous Material – Any object that is foreign to the food product in which it is found.

Farm-to-Table – The continuum of animal preparation, beginning with animal production and slaughter, continuing with processing and distribution, and ending with the sale of food products to the consumer.

Field Service Laboratories – The three FSIS laboratories that provide analytical services in the disciplines of chemistry, microbiology, and pathology, located in Athens, GA; St. Louis, MO; and Alameda, CA.

Food Chemistry – The program area that analyzes food products for moisture, protein, fat, and salt content, as well as drug, pesticide, and other chemical residues.

Foodborne Pathogens – A disease-causing microorganism that is carried or transmitted to humans by food.

Hazard Analysis and Critical Control Points System (HACCP) – FSIS' current process for inspecting meat and poultry establishments, stressing the prevention of contamination before it occurs. Under this system, establishments monitor their own production to identify and remove the threat of contamination, with FSIS providing oversight to ensure that establishments have implemented adequate HACCP programs.

Inspector – An FSIS employee who is responsible for inspecting meat, poultry, and egg products and operations in slaughter and processing establishments, for the purpose of ensuring that these food products are safe for human consumption.

Listeria monocytogenes – A pathogenic organism usually found in vegetables, milk, cheese, meat, and seafood.

Microbiological Testing – The isolation and identification of foodborne pathogenic microorganisms such as, E.coli*, Listeria*, and S*almonella*.

Nitrosamines – A carcinogenic chemical compound that is typically found in cured and processed bacon products.

Official Product Samples – Portions of raw and ready-to-eat food products collected by inspectors in Federally inspected establishments, and then sent to FSIS laboratories for analysis.

Presumptively Positive – A product sample analyzed with an enzyme-linked immunoassay screening test and found to likely contain a pathogenic organism. These samples cannot be confirmed positive until traditional culture and biochemical tests are performed.

Proficiency Testing – A program of activities that provides assurance that the laboratory is competent to perform analyses of official samples.

Ready-to-Eat Products – Food products that have been prepared to the point where they are ready for human consumption.

Salmonella – A pathogenic organism that is commonly found in poultry, eggs, beef, and other foods of animal origin. Salmonella typically causes intestinal distress, but

can be fatal to young children, the elderly, and persons with weakened immune systems.

Sample Request – A request made by FSIS' Office of Public Health and Science for an FSIS inspector to collect a specific product in a specific establishment, based on a specific sampling project. The request is made on FSIS Form 10,210-3.

Sampling Frame – A listing of establishments that produce products of a designated type. The sampling frames are maintained on FSIS' MARCIS database.

Sampling Projects – Different microbiological test(s) to be performed on specific types of products. Samples are collected from establishments that produce the type of product of interest. For example, *E.coli O157:H7* in Ready-to-Eat Meat Patties is one sampling project.

Screening Test Kit – A commercially produced kit that contains enzyme-linked immunosorbent assay (ELISA) tests that will initially screen a sample as presumptively positive or negative. This test allows the laboratory to eliminate many samples from the time-consuming traditional culture and biochemical tests that are necessary to confirm the presence of a pathogenic organism.

Species Identification Testing – An analysis to determine the species of the animal that is contained in the sample.

Xenobiotic – A chemical compound, such as a drug, pesticide, or carcinogen, that is foreign to a living organism.