USDA

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

Food Safety and Inspection Service

- HACCP Implementation
- Pathogen Testing Program
- Foreign Country Equivalency
- Compliance Activities

Reports Nos. 24001-3-At
24601-1-Ch
24099-3-Hy
24601-4-At
June 2000

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250

June 21, 2000

REPORT TO THE SECRETARY ON THE MEAT AND POULTRY INSPECTION PROCESS

FROM: Roger C. Viadero
Inspector General

SUBJECT: Food Safety Initiative

The Office of Inspector General initiated a series of audits of the U.S. Department of Agriculture's Food Safety Inspection Service (FSIS) to determine whether FSIS' meat and poultry inspection program remains effective under the science-based Hazard Analysis and Critical Control Point (HACCP) System. Our initiative included reviews of three facets of the new inspection system—HACCP, laboratory analyses, and foreign imports—and a review of the compliance program that carried over from the previous system.

The results of our Food Safety Initiative demonstrate that FSIS has taken positive steps to secure the safety of meat and poultry products. However, more needs to be done in all four of the areas we reviewed. For the science-based system to reach its full potential, FSIS needs to take maximum advantage of the expanding role that science now plays as a control over the meat and poultry that enters the marketplace. Some of this control is seen directly in the identification of pathogens; some is seen in the integration of scientific techniques (e.g., operational procedures, reliance on objective data) into the systems being established.

Most significantly, we found that FSIS needs to command a more aggressive presence in the inspection and verification process. FSIS has not always established needed procedures or apprised itself of all areas where inspection is critical; consequently, it has reduced its oversight short of what is prudent and necessary for the protection of the consumer.

FSIS initiated its conversion to HACCP in July 1996 when it issued the rules regarding HACCP and the Pathogen Reduction system. These rules clarified the respective roles of Government and industry in food safety: Industry is accountable for producing safe food; Government is responsible for setting food safety standards, maintaining inspection oversight, and maintaining an enforcement program to ensure that establishments that do not meet standards are appropriately sanctioned.

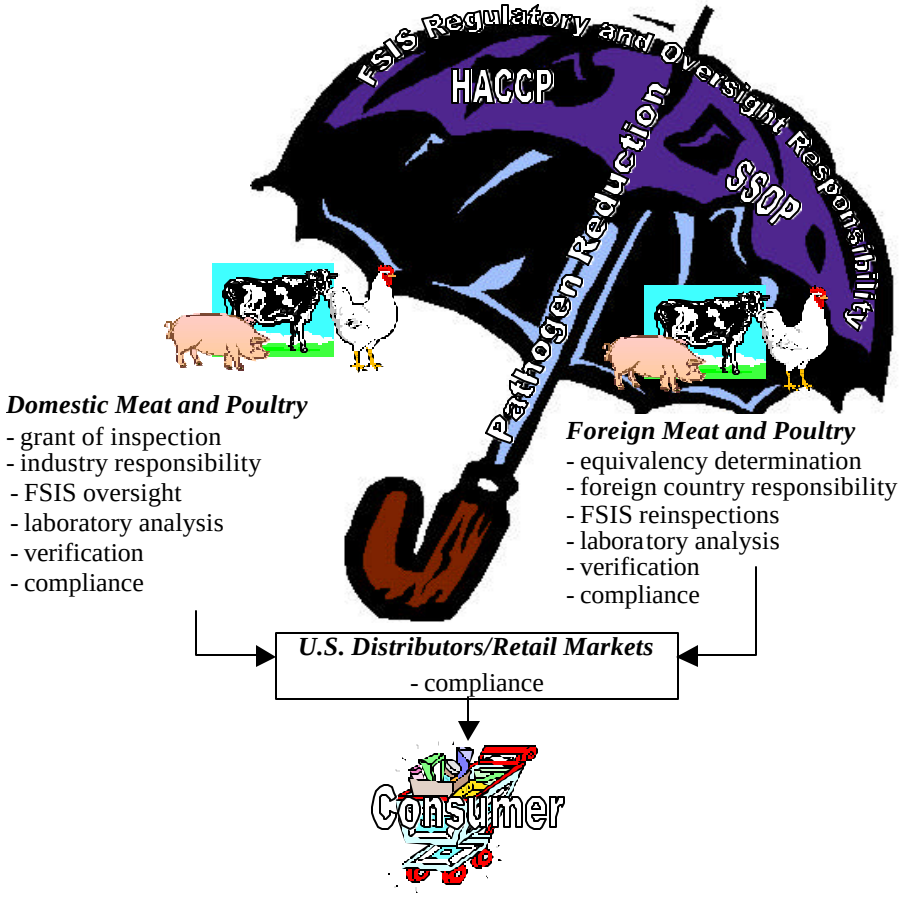
The key elements that constitute FSIS' transition from its former methodology to a science-based system include testing for *Salmonella* and other harmful pathogens and residues, ensuring the implementation of sanitation standard operating procedures (SSOP) at each of the 6,000 meat and poultry establishments under Federal inspection, and monitoring HACCP operating plans for each of these establishments. FSIS also implemented an "equivalency" program through which the food safety standards of foreign countries could be judged according to the requirements of the HACCP and Pathogen Reduction systems.

As the transition took form, we proactively monitored FSIS' implementation plans. Our goal was to ensure that the guarantee of product safety and wholesomeness existing under FSIS' former methodology would continue under the science-based system.

We reviewed FSIS' activities across a broad spectrum of meat and poultry inspection operations to assess the agency's major inspection and control components. Our reviews focused on—

- implementation of the HACCP program and of sanitation standard operating procedures, including efforts to test for pathogens and reduce their presence,
- FSIS' quality assurance programs over its laboratory facilities and operations, product sample integrity, and laboratory testing operations,
- FSIS' process to determine whether foreign countries' safety inspection systems are equivalent to that of the United States, and
- the effectiveness of FSIS' compliance review program in detecting violations of meat and poultry inspection laws at non-federally inspected firms.

The graphic on the following page depicts the relationship of the four evaluated areas. HACCP and laboratory testing are integral to FSIS' domestic industry oversight. FSIS also determines the "equivalency" of foreign systems, whose meat and poultry may then flow into domestic industry or directly to the marketplace. FSIS' program of enforcement and compliance monitors both the industry and the marketplace to verify compliance with meat and poultry inspection laws and the wholesomeness of meat and poultry products.



FSIS needs to strengthen its oversight in all four areas we reviewed. For example:

- FSIS allowed establishments to limit or reduce the number of critical control points identified in their HACCP plans and thereby limit Government oversight.

- FSIS' data base did not list all establishments subject to tests for pathogens and residues (i.e., pesticides, etc.).

- FSIS did not list all firms subject to compliance reviews and did not always target reviews at major metropolitan and geographic areas or at firms that could be regarded as high-risk.

- FSIS approved equivalency status to foreign countries without adequately developing and implementing procedures for determining the equivalency of foreign inspection systems or clearly documenting such determinations. Unclear lines of authority, the absence of inspection system verification, and minimal FSIS oversight did not always validate that foreign food safety inspection systems were equivalent to U.S. standards.

FSIS also needs to be more aggressive in using laboratory analyses and scientific expertise as a control against unwholesome product. We found that pathogen and residue testing were underutilized in many areas. For example:

- FSIS did not always review establishments' microbial testing plans and protocols to ensure the samples taken under the HACCP system were scientifically selected and accurately tested.

- FSIS did not enforce the requirement that foreign countries submit annual residue test plans and results.

- FSIS did not always adequately document the involvement of technical subject-matter experts in its determinations of foreign country equivalency, and it did not always timely use the results of microbiological tests to update its reinspection data of those countries.

- FSIS inspectors at meat and poultry establishments did not always provide required product samples to the FSIS laboratories for testing, thus leaving gaps in the sources of samples.

We also concluded that FSIS should expand its own testing requirements to increase the number of tests taken of *E. coli*, *Listeria*, and *Salmonella*, and to include other pathogens in those requirements. FSIS does not currently test for some major foodborne pathogens, such as *Campylobacter*, that are now scientifically detectable.

In the area of compliance, we concluded that FSIS needs to act more aggressively against repeat violators of the meat and poultry inspection laws. FSIS does not have authority to impose civil penalties in cases that do not warrant criminal prosecution. Letters of warning are often the only enforcement tool applied.

Overall, we are recommending that FSIS strengthen its procedures over the food safety system. It needs to institute stronger procedures to ensure that all establishments are tested. In the case of imported meats and poultry, FSIS needs to develop and implement formal procedures over its entire equivalency process and enforce existing regulatory requirements. For compliance verification, FSIS needs to refine its existing compliance plan to establish the universe and scope of its reviews and target its

resources, and it needs to seek authority to impose monetary penalties and ensure that violations of the meat and poultry inspection laws are met with these penalties and other sanctions commensurate with the violation.

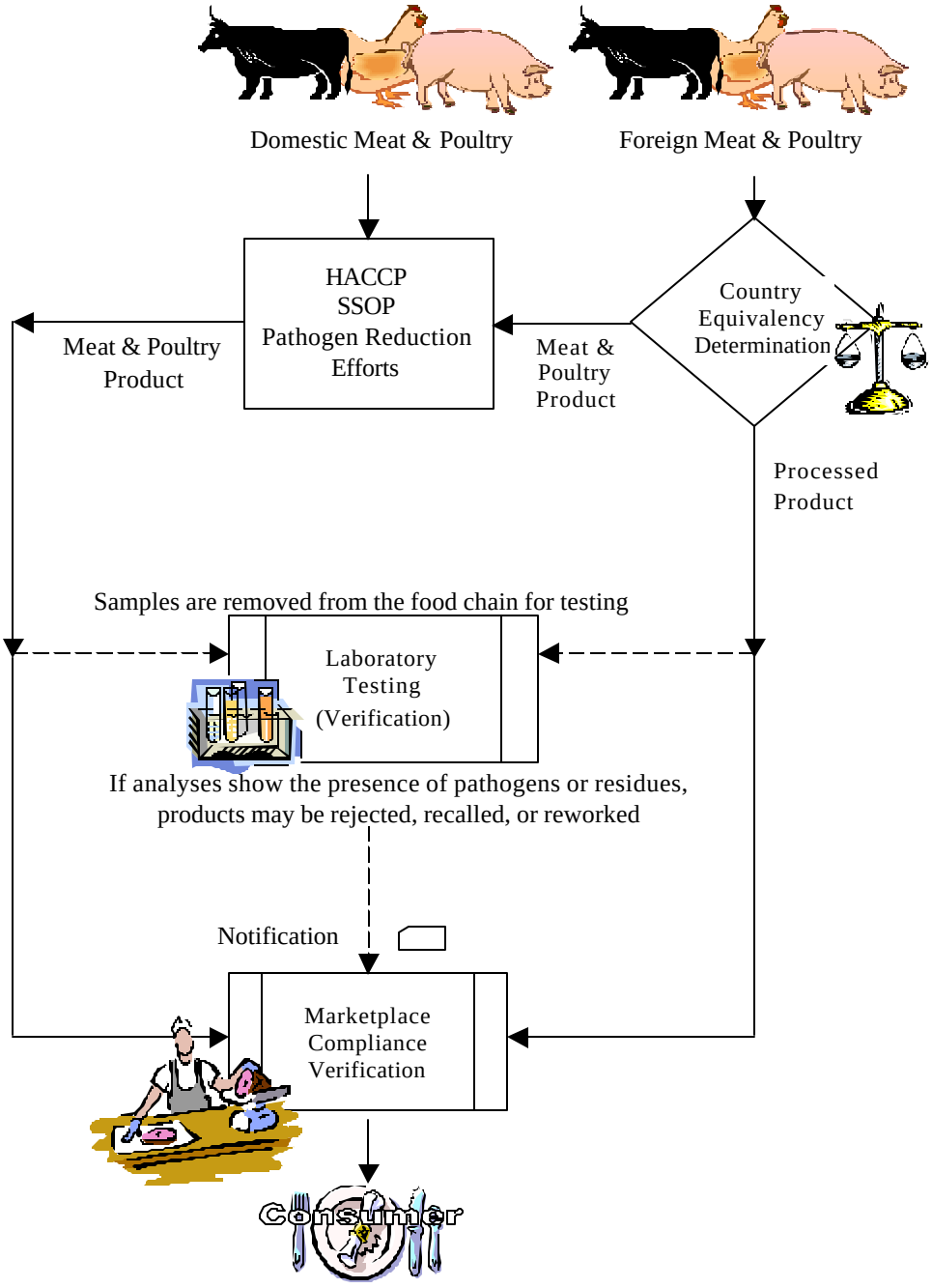
We are also recommending that FSIS assert its authorities over the HACCP system to ensure that the intent of the program is met. To this end, FSIS needs to enhance its grant of inspection so it functions like a contract, stipulating exactly what is required of the establishments and defining the authorities and responsibilities FSIS has over their operations.

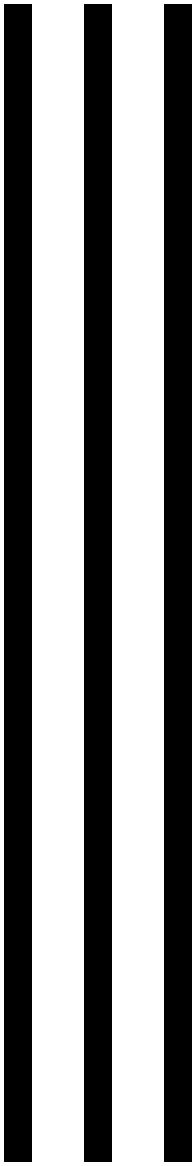
FSIS' responses to each of the audit reports are contained in the appropriate sections of this report.

The results of our Food Safety Initiative are presented in four sections:

I. Implementation of the Hazard Analysis and Critical Control Point System (24001-3-At) (FSIS' response is found beginning on page 75.)
II. Laboratory Testing of Meat and Poultry Products (24601-1-Ch) (FSIS' response is found beginning on page 58.)
III. Imported Meat and Poultry Inspection Process (24099-3-Hy) (FSIS' response is found beginning on page 91.)
IV. District Enforcement Operations—Compliance Activities (24601-4-At) (FSIS' response is found beginning on page 67.)

The diagram on the following page depicts the control points in the farm-to-table process that we reviewed through our initiative.


Domestic Meat & Poultry
Foreign Meat & Poultry
HACCP
SSOP
Pathogen Reduction
Efforts
Country
Equivalency
Determination
Meat & Poultry Product
Meat & Poultry Product
Processed Product
Samples are removed from the food chain for testing
Laboratory
Testing
(Verification)
If analyses show the presence of pathogens or residues, products may be rejected, recalled, or reworked
Notification
Marketplace
Compliance
Verification
Consumer



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

FOOD SAFETY AND INSPECTION SERVICE
IMPLEMENTATION OF THE HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM

Report No.
24001-3-At
June 2000

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250

DATE: June 21, 2000

REPLY TO
ATTN OF: 24001-3-At

SUBJECT: Implementation of the Hazard Analysis and Critical Control Point System

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 implementation of Hazard Analysis and Critical Control Point System to ensure that domestic meat and poultry products are safe and wholesome. This review is part of the Office of Inspector General's food safety initiative, which also included the District Enforcement Operations' compliance activities, oversight and controls over imported meat and poultry products, and the agency's procedures established for testing meat and poultry products. Your response to the official draft report, dated May 18, 2000, is included as exhibit D 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. 7, 13, 14, and 19. 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. 1 through 6, 8 through 12, 15 through 18, and 20. 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

FOOD SAFETY AND INSPECTION SERVICE
IMPLEMENTATION OF THE HAZARD ANALYSIS
AND CRITICAL CONTROL POINT SYSTEM
AUDIT REPORT NO. 24001-3-At

RESULTS IN BRIEF

This report presents the results of our audit of the Hazard Analysis and Critical Control Point (HACCP) inspection system, administered by the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS). The purpose of our audit was to evaluate FSIS' implementation of the HACCP program and to determine whether the program was effective in ensuring the wholesomeness of the meat and poultry sold to consumers. This audit was part of the Office of Inspector General's (OIG) food safety initiative, which also included reviews of imported meat, compliance operations, and USDA's laboratory testing procedures.

The HACCP system, which was recommended by USDA's National Advisory Committee on Microbiological Criteria for Foods and endorsed by the scientific community, established seven principles for plants to implement in their food safety system. It replaced FSIS' longstanding program of meat and poultry inspection. Under the pre-HACCP system, the production of meat and poultry products was monitored at every stage by Government employees rather than by in-plant production managers. The HACCP program reversed this arrangement by allowing a plant to monitor itself. It gave industry, not Government, the primary responsibility for ensuring the safety of meat and poultry products. Industry was required to implement a HACCP system that identified and controlled (1) physical, chemical, and biological hazards to the production process and (2) a program of ongoing microbial testing that served as verification that the system was working.

Overall, we concluded that FSIS and the industry were making progress in changing from the traditional inspection methodology to the type of science-based production control system that had been recommended by various studies over several years. FSIS developed regulations and guidance that was consistent with the seven HACCP principles, and plants developed HACCP plans that

addressed these principles. In reviewing both the production process and the microbial testing programs under HACCP, we found no instances at plants visited in which plants or slaughterhouses flagrantly violated standards of environmental hygiene. We concluded, however, that for HACCP to realize its full potential, FSIS must assert its authorities under the program to ensure that the intent of the program is met. Because FSIS was uncertain of its HACCP authorities and had not established needed procedures, it had reduced its oversight beyond what was prudent and necessary for the protection of the consumer. For example, FSIS does not require plants to provide inspectors with positive environmental microbial test results although these tests could provide an indication of sanitary deficiencies in the plant.

Under the HACCP program, every meat and poultry plant must perform a hazard analysis to identity the food safety hazards likely to occur in its production process. Critical control points (CCP) also need to be documented where preventive measures need to be established to reduce or eliminate each of the hazards. In addition, the measures the plant can apply to control the hazards must be identified. In our review of 15 meat and poultry plants nationwide, we found that hazard analyses were incomplete and CCP's were not established. Although FSIS inspectors were aware of these deficiencies, they did not take corrective action because of uncertainties of their authority to do so.

- Because HACCP plans constitute the basis for FSIS oversight, plants can limit that oversight by reducing the number of CCP's identified in their plans. For example, although FSIS' model HACCP plan for fully-cooked products contained seven CCP's, most of the plants visited producing cooked products had only one or two CCP's. FSIS was consequently restricted in its oversight of the plant's products. None of the establishments audited included end-product microbial testing as a CCP in their plans, although, FSIS included such testing in its HACCP models.

- Although FSIS required a minimum of one CCP per process, we found some plants listed none. Also, there were HACCP plans that identified hazards for which no control points were listed. For example, one plant correctly showed that cold storage could introduce a hazard if the room temperature increased (to a level where hazardous microbes could grow), but it did not show that this was a CCP even though the plant itself was monitoring the temperature of the cooler. FSIS agreed that this should be

considered a control point after an OIG auditor pointed out the condition.

- HACCP plans also did not include scientific data to support the critical limits the plant had established, such as heating and cooling temperatures, and did not always document their responses to deviations from these critical limits. Critical limits established by the plants were primarily based on historical practice, not scientific data. Also, stated limits were inconsistent with practice. One plant documented "zero tolerance" for deviations from one control, but the plant's HACCP plan allowed three discrepancies before action needed to be taken.

Currently, FSIS does not review plants' microbial testing plans to ensure that sampling protocols are completed and followed, and it does not adequately secure samples sent to USDA labs for testing. One recent investigation in Florida found that samples under lax security had been tampered with, resulting in false test results. Test results from samples taken in violation of protocols could also be worthless.

FSIS also needs to assert itself more aggressively in the plants' testing programs. In the current environment with the absence of FSIS guidance, plants are not testing for pathogens in end-products, and they are not notifying FSIS of all test results, particularly those showing the potential presence of pathogens. Because FSIS requires plants to notify it only if microbial tests confirm the presence of specific pathogens causing adulterated products, plants often limit their tests when the results indicate the presence of generic microbes. Thus, plants do not test end-products for specific pathogens like *E. coli 0.157:H7* or *Listeria monocytogenes (LM) even after positive generic E. coli or Listeria tests are obtained.* We believe prudent oversight requires FSIS to be aware of all positive test results, generic or otherwise. FSIS should also expand their own testing to increase the number of tests for *E. coli 0.157:H7*, *LM*, and *Salmonella* and to include other pathogens in their testing requirements. FSIS' current testing program is primarily aimed at three main pathogens and is insufficient as a reliable assessment of individual plants. It also does not include other major foodborne pathogens, such as *Campylobacter*, that are now detectable through microbial testing.

In areas in which FSIS has asserted its oversight of the HACCP program, it has not always been effective. Although regulations

require FSIS to verify the adequacy of each plant's Sanitation Standard Operating Procedures (SSOP) of the plant environment, we found that inspectors did not ensure that plants sanitation plans contained all required elements. We also noted that FSIS had no follow-up procedures to ensure that returned products were re-inspected or destroyed.

- At 4 of the 15 plants we reviewed, the SSOP's approved by FSIS did not include plant cleaning schedules and frequencies. At one plant, violations of the standards were documented but no corrective actions were required. Unsanitary environments jeopardize the wholesomeness of the meat and poultry produced by the plant. (See Finding No. 11).

- *Salmonella* testing at one plant was never completed because the FSIS laboratory did not inform the inspector at the plant that some samples had to be discarded and additional replacement samples were needed. (See Finding No. 7).

- National office documentation showed that field personnel were not performing over 17 percent of the scheduled tasks assigned to them. We found that many assigned tasks were invalid because plant profiles had not been updated to reflect current operations. Field offices were not required to explain why the tasks were never performed. (See Finding No. 13).

- For plants with documented deficiencies, FSIS has not established when corrective action needs to be taken or when an action taken has proven inadequate. One plant we reviewed did not respond to a documented deficiency for over 4 months. Four plants had repetitive deficiencies even though they took corrective actions. One of these plants had 102 deficiency notices, one-third of which involved the same noncompliance concerning fecal contamination. Since FSIS had set no limit to the number of deficiency notices a plant could receive on the same deficiency, no long-term correction was applied. (See Finding No. 14).

We concluded that FSIS' oversight of the HACCP program would improve if FSIS established an internal review of FSIS activities at meat and poultry establishments. Although FSIS has a unit responsible to perform these reviews, it has not used that unit effectively in this area.

FSIS also needs to gain access to plant records. Under its current system of oversight, FSIS requests access only to those documents responding to HACCP requirements. Consequently, plants have limited the information they provide in their HACCP documents, and regard even those documents as proprietary. For example, during the audit, some plants initially denied both the Inspector General's and FSIS' requests for testing information. The denial of records was elevated to the FSIS Headquarters, and the plants provided the information only after extended negotiations and under restrictive terms.

We believe the key to establishing FSIS' authority over the HACCP program and gaining access to plant records is the Grant of Inspection. In order to obtain a Grant of Inspection under current procedures:

- plants must apply.
- agree to conform to Grant of Inspection regulations.
- be found to be in compliance with regulations during an FSIS' survey of the establishment.

We believe FSIS needs to enhance the Grant of Inspection so that it is a contract that stipulates exactly what is required of the plant to be recognized as operating under the HACCP assurances, and specifies what FSIS' authorities are over that plant's operations.

During the audit, we issued three management alerts that identified weaknesses in FSIS oversight procedures. We reported that one plant had not met minimum requirements for HACCP plans. We also reported that two plants own microbial testing showed the potential for pathogens in the product, but these results were not available to FSIS inspectors.

KEY RECOMMENDATIONS

We recommended that FSIS should strengthen its management controls to provide greater oversight over HACCP implementation, pathogen testing, and independent reviews of plant and inspection activities. FSIS should also expand the language contained in the Grant of Inspection agreement to include the requirements and responsibilities required of the plant under the HACCP program and FSIS' authority, oversight, and access to information regarding the plant's operation.

We also recommend that FSIS use the Grant of Inspection as a contract, or enforceable agreement between the Government and the establishment signed by all parties and subject to review and renewal.

AGENCY RESPONSE

In its May 18, 2000, written response to the draft report, FSIS was in general agreement with the findings and recommendations. However, FSIS did not always provide specific details, timeframes, and actions taken or planned for each of the recommendations. Its specific comments and OIG's position are presented in the relevant sections of the report for each finding. FSIS' entire response is shown in exhibit D of the report.

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INTRODUCTION

BACKGROUND

The Hazard Analysis and Critical Control Point (HACCP) program has been undergoing implementation since the beginning of 1998. Endorsed by the National Advisory Committee on Microbiological Criteria for Foods, HACCP offers a new approach to reducing hazards in the food supply by stressing the prevention of contamination before it occurs rather than dealing with it after its detection. Before the advent of HACCP, the U.S. Department of Agriculture's (USDA) Food and Safety Inspection Service (FSIS) monitored the meat and poultry slaughter plants under a system of continuous inspection. Under HACCP, plants monitor their own production to identify and remove the threat of contamination. FSIS is responsible for oversight to ensure that the plants have implemented an adequate HACCP program.

The HACCP program requires two types of microbial testing, Salmonella and *Escherichia coli*-Biotype 1 (generic *E. coli*). All plants are required to pass a *Salmonella* testing series administered by the agency. Slaughter facilities must also perform generic *E. coli* testing and make the testing results available to FSIS inspectors. FSIS has also developed a directed testing program, outside of HACCP, to identify harmful pathogens, such as *Listeria monocytogenes* (*LM*) and *E. coli* 0157:H7. The directed testing program administered by FSIS is designed to provide assurances on a nationwide basis that pathogen reduction measures are working.

The requirements of HACCP were contained in the Pathogen Reduction and HACCP rule, issued by USDA in July 1996. The rule requires plants to address each of seven principles in implementing their HACCP plans.

- **Principle No. 1: *Conduct a hazard analysis*** – Plants determine the food safety hazards that are likely to occur and identify the measures needed to control them. Hazards can be biological (bacteria, etc.); chemical (pesticides, etc.); and physical (metal fragments from machinery, etc.)

- **Principle No. 2**: ***Identify critical control points (CCP)*** - Plants identify a point in the production process where controls can be applied to eliminate the hazard.

- **Principle No. 3**: ***Establish critical limits for each control point*** - Plants set the maximum and/or minimum values (such as temperatures) at which a hazard (such as bacterial growth) must be controlled.

- **Principle No 4**: ***Establish monitoring requirements*** - In-plant quality control reviewers monitor the CCP's to ensure their operation.

- **Principle No. 5**: ***Establish corrective actions*** - Plants define actions to be taken when monitoring discloses a deviation from a critical limit.

- **Principle No. 6**: ***Establish record-keeping procedures*** - Plants are required to maintain documentation of their hazard analysis and HACCP plans, as well as records of their monitoring of control points and establishment of critical limits.

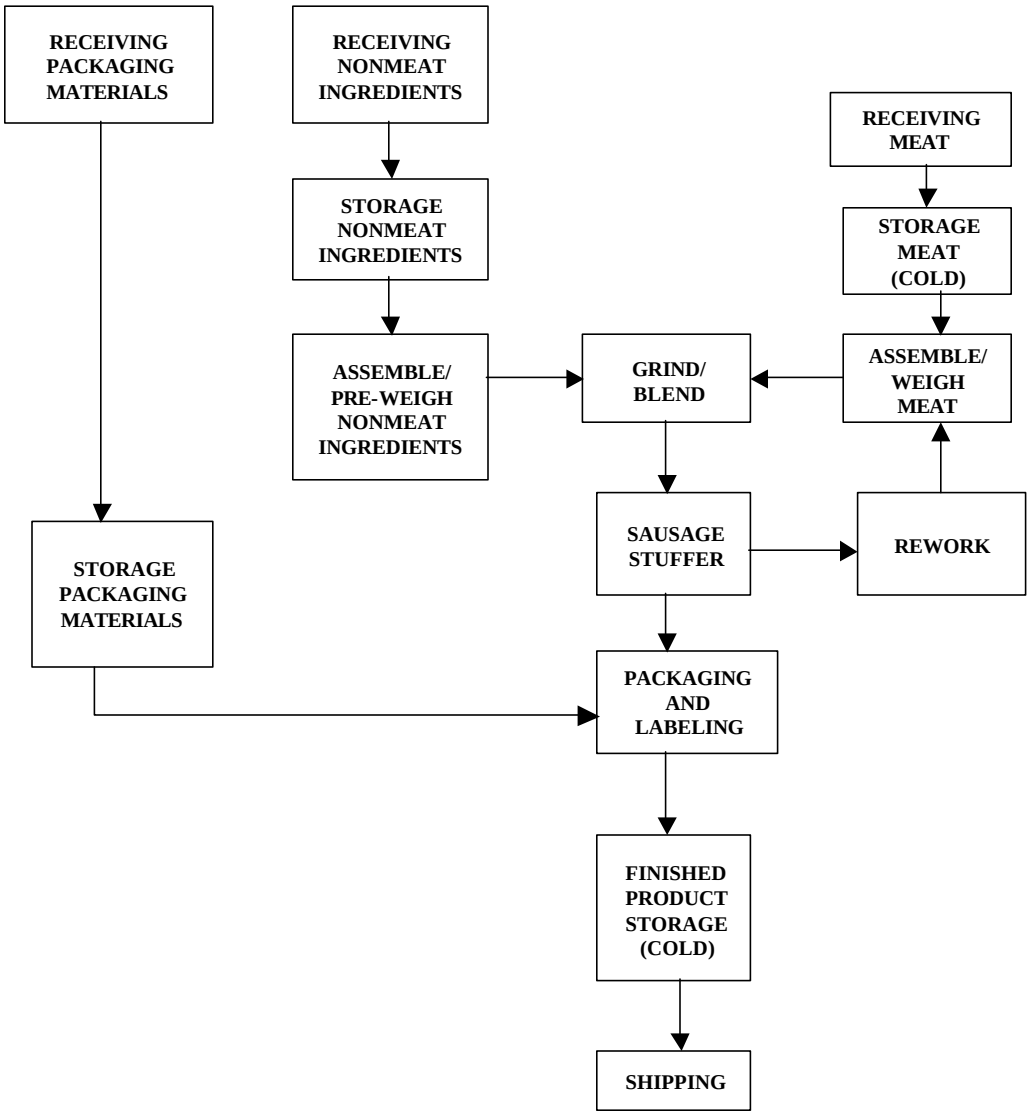
- **Principle No. 7**: ***Establish verification procedures*** - Plants must ensure that their HACCP plans accomplish their intended goal.

Since publishing the HACCP regulations in July 1996, USDA has issued several clarifications and modifications including new requirements that all HACCP plans must contain at least one CCP and must be self-contained documents that do not refer to good manufacturing practices as mechanisms for controlling hazards.

In May 1999, FSIS published a series of generic HACCP plans to assist the industry in writing their own plant specific plans. The generic plans provide guidance on the elements that should be included in the documents and recommend CCP's for the various processes covered. Examples of process flow diagrams are provided to illustrate the type of chart needed as the first step in performing the hazard analysis.

The FSIS suggested process flow diagram for making fresh pork sausage, for example, follows:

Figure 1. Process Flowchart



The models also provide examples of the recommended elements to include in the hazard analysis. One page of the FSIS suggested hazard analysis form for raw ground product follows:

Figure 2. Hazard Analysis

Process Step	Food Safety Hazard	Reasonably Likely to Occur?	Basis	If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level	Critical Control Point
Grind/ Blend	Biological – None				
	Chemical – None				
	Physical – Metal contamination	Yes	Plant records show that during the grinding process metal contamination is likely to occur.	In-line magnets are installed on the stuffing lines	3P
Sausage Stuffer	Biological – None				
	Chemical – None				
	Physical - None				
Rework	Biological - Pathogens	No	Rework left at the end is condemned or used in a cooked product at the plant.		
	Chemical – None				
	Physical – None				

The hazard analysis page illustrates the identification of a CCP (listed as "3P" in the model) for a physical hazard related to the grind/blend process. A potential biological hazard was also identified for the rework process step but was rated as not reasonably likely to occur because the reworked product was either condemned or cooked if any was left at the end of a production run. The analytical process illustrated on the form page is to be followed for every processing step shown on the process flowchart.

The FSIS model plan also shows how the CCP, or 3P, is to be documented in the HACCP plan (1) a critical limit is set for the CCP, (2) monitoring procedures are defined, (3) a system of records to document monitoring and corrective actions is specified,

(4) verification procedures are listed, and (5) corrective actions for deviations above the critical limit are shown as illustrated below.

Figure 3. Documentation of Critical Control Point

CCP # and Location	Critical Limits	Monitoring Procedures and Frequency	HACCP Records	Verification Procedures and Frequency	Corrective Actions
3P Grind/ Blend	No metal particles to exceed 1/32 inches	Maintenance personnel will check the in-line magnets every two hours.	In-Line Magnet Log Corrective Action Log	Maintenance supervisor will verify in-line magnet is functioning. QA will verify that the in-line magnets are functioning as intended by running a seeded sample through the in-line magnets twice per shift (once in the AM and once in the PM).	Stuffing line supervisor will control and segregate affected product. Maintenance personnel will identify and eliminate the problem with the in-line magnets. Preventive maintenance program will be implemented. QA will run seeded sample through in-line magnets after repair. All potentially contaminated product will be run through in-line magnets and metal detector prior to shipment.

The model HACCP plan also includes examples of other needed documents under HACCP. These include a product description showing such factors as end use, type of packing, intended customers, shelf life, labeling, handling requirements, etc., and suggested forms to use for CCP monitoring. Although the use of the model is not mandatory, it does provide an illustration of the types of documentation and records that should be available under HACCP. It also shows how the documentation flow follows the analytical process used in developing a HACCP program.

In addition to requiring the development of HACCP plans, regulations specify three other requirements that plants must comply with:

- Plants must ensure hygienic facilities. They must develop and implement written Sanitation Standard Operating Procedures (SSOP) to document such activities as plant cleaning schedules and to track adverse sanitary conditions that recur.

- Slaughter plants must maintain a microbial testing program. They must perform regular testing for generic *E. coli*, and they must meet pathogen reduction performance standards for *Salmonella* (plants producing raw Meat products also must meet the *Salmonella* performance standards).

- Plants must ensure a product-safe environment. They must implement a system of preventive controls designed to improve the safety of the product, and they must maintain records documenting that the controls are working as intended.

Although the HACCP final rule was issued in July 1996, the implementation dates for plants were based on the size of the plants. The largest plants (500 or more employees) were required to have their HACCP plans in place by January 1998, small plants by January 1999. Very small plants (nine or fewer employees) had until January 2000. SSOP and *E. coli* testing requirements became effective in January 1997. *Salmonella* pathogen reduction standards became effective with the implementation dates of HACCP.

In addition to the HACCP and SSOP programs, plants also develop their own procedures and follow the procedures and processes recommended by industry groups (Good Manufacturing Processes). These programs that are outside the documented HACCP plan are intended to provide additional controls to ensure food safety.

Food borne disease may cause an estimated 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths in the United States each year according to the Centers for Disease Control. These estimates show that certain "Known Foodborne Pathogens" cause the following health problems.

Table 1: Foodborne Pathogens

Disease/Agent	Illnesses	Hospitalizations	Deaths
Salmonella	1,341,873	15,608	553
Listeria monocytogenes	2,493	2,298	499
Toxoplasma gondii	112,500	2,500	375
Campylobacter	1,963,141	10,539	99
E. coli 0.157:H7	62,458	1,843	52

While plants are accountable under HACCP for producing safe food, FSIS is responsible for setting appropriate food safety standards, maintaining inspection oversight to ensure those standards are met,

and maintaining a strong enforcement program to deal with plants that do not meet the regulatory standards. Approximately 7,500 Federal inspectors carry out inspection law in some 6,000 plants nationwide. FSIS conducts its inspection activities through its National office in Washington, D.C.; a technical service center in Omaha, Nebraska; 17 district offices; and field offices where plants are located.

In December 1999, the General Accounting Office (GAO) issued, "Meat and Poultry – Improved Oversight and Training Will Strengthen New Food Safety System," Report No. GAO/RCED-00-16. In this report, GAO concluded that the HACCP regulations, along with implementing directives and other guidance, were consistent with the seven HACCP principles endorsed by the Advisory Committee. In addition, GAO reported that HACCP training for inspectors was generally adequate although weaknesses in the training program, such as the inspectors' authority to ask for changes in the HACCP plans, when inspectors should collect *Salmonella* samples, and when it was appropriate to issue noncompliance reports, affected their ability to ensure consistent and effective oversight of the HACCP systems. GAO also concluded that the FSIS appeal process contained inconsistent and incomplete data that precluded FSIS from effectively analyzing the HACCP-related actions that were appealed or the extent to which plants appealed inaccurate reports. We coordinated with GAO representatives to avoid duplication of efforts.

OBJECTIVES

The overall objective of this audit was to review FSIS' implementation of HACCP regulations and to determine the effectiveness of the program. Specifically, we determined whether plants (1) analyzed hazards and established CCP's, (2) implemented microbial testing and other pathogen controls, and (3) developed control procedures, including SSOP's, and maintained records of their effectiveness.

SCOPE

The audit fieldwork was performed at the FSIS National Office in Washington, D.C.; 6 district offices; and 15 field offices located at industry plants in Alabama, Arkansas, Iowa, Kansas, Minnesota, Missouri, Nebraska, and South Dakota (see exhibit A). The locations visited included 11 plants that slaughtered poultry, swine, or cattle. (Ten of the slaughter plants also processed meat products.) We also visited four plants that processed only meat products and frozen foods. We reviewed FSIS policies and procedures at the district and field offices visited. Our reviews at the plant locations included evaluations of the

plants' written SSOP's, HACCP plans, pathogen testing procedures, and responses to FSIS noncompliance reports. Our evaluation of HACCP plans included an indepth review of 57 of the 107 plans in effect at the 15 plants visited. (See exhibit B.) We also toured the plant locations and observed plant operations including pre-operational clean-up procedures and monitoring activities at the designated CCP's. FSIS provided review officers from the technical service center in Omaha, Nebraska, to assist in our reviews and ensure our conclusions were technically accurate and consistent with regulations. We judgmentally selected the districts and plants to be visited. In selecting the sites to be reviewed, we attempted to obtain a variety of operations. We selected both problem plants and plants which FSIS records showed were operating satisfactorily. In making our selections we considered the number of violations cited by inspectors, assigned tasks not performed, laboratory test results, animals slaughtered, products processed, consultations with FSIS officials, and geographical areas.

Fieldwork was conducted during the period April though December 1999. We conducted this audit in accordance with Government auditing standards.

METHODOLOGY

To fulfill our objectives, we performed the following fieldwork.

- We analyzed documents and conducted interviews with FSIS Headquarters officials.

- We contacted officials of the food industry and representatives of the Centers for Disease Control and USDA's Agricultural Research Service (ARS).

- We reviewed FSIS' regulations, instructions, procedures, and studies; published reports; media releases; and other Government reviews and studies.

- We conducted site visits to the FSIS National Office, FSIS' technical service center, district offices, and field offices located at industry plants for review and analysis.

FINDINGS AND RECOMMENDATIONS

CHAPTER 1	HACCP PLANS WERE NOT ALWAYS COMPLETE

In order to accomplish its food safety mission, we believe that everything that happens within meat and poultry establishments from the receiving dock to the shipping dock, must come under FSIS' oversight. We believe that the HACCP program is in effect an umbrella covering the plant's documented HACCP plan, its SSOP program, and its good manufacturing processes program. We believe FSIS should have access to everything that happens regarding meat and poultry from slaughter through processing - including access to all records and pathogen testing results.

Under the HACCP system, Federal regulations require every meat and poultry plant to determine the food safety hazards likely to occur in its production process, list the CCP's at which preventive measures need to be established to reduce or eliminate each of the hazards, and identify the measures the plant can apply[1]. This information is to be contained in a formal HACCP plan and must include all hazards - biological, chemical, and physical - that may cause food produced by the plant to be unsafe for human consumption. The regulations also require the HACCP plan to be a self-contained document and not refer to such extrinsic criteria as "good manufacturing practices" that cannot be evaluated[2]. Failure of any plant under HACCP to develop and implement an adequate HACCP plan and system may result in an FSIS determination that the plant is producing adulterated products[3].

We reviewed 57 HACCP plans from 15 plants nationwide, and found that at least 1 plan was incomplete at 14 of these plants. Plant officials' neither identified all CCP's nor listed all hazards to their product, or even showed all the stages of their production that might be exposed to hazards. Almost half the plans prepared by one plant indicated that no food safety hazards were likely to occur during the production process, a conclusion that FSIS does not believe possible

[1] 9 Code of Federal Regulations (CFR) § 417.2(a)(1), and 9 CFR § 417.2.

[2] Federal Register, vol. 63, No. 20, dated January 30, 1998.

[3] 9 CFR § 417.2(e).

for any production process[4]. Nevertheless, on the strength of that assertion, this plant listed no CCP's and no preventive measures. Nine other plants named their operating procedures as sufficient to control existing hazards in lieu of establishing CCP's. Most plants tended to limit the number of hazards and CCP's they reported (thereby limiting FSIS oversight), even though the number of actual controls in place was larger and generally appeared to satisfy the HACCP requirements. Representatives from FSIS' Technical Service Center visited the plants' with us and assisted us on our reviews of plants' HACCP plans.

FSIS inspectors and district office officials believed that plants abbreviated their HACCP plans as a measure to reduce FSIS oversight. Because the HACCP concept limits FSIS monitoring to only those controls declared in the HACCP plan, plants can distinguish between the controls available to Federal scrutiny and those in actual operation. In some cases, plants have even declared their HACCP plans' proprietary documents and do not allow FSIS to copy them or release their contents.

HACCP plans also failed to establish a scientifically based tolerance for all of the hazards that were identified. Maximum temperature requirements for coolers differed between plants processing similar products. One plant required beef not to exceed 45 degrees prior to boning; another plant allowed the beef to reach 55 degrees. Critical limits were established by plants primarily based on historical practice, not scientific data. Some tolerances were not even implemented. At plants that prescribed temperature limits, corrective action was not always taken when temperatures exceeded the limits.

We determined that FSIS did not enforce a greater disclosure in the HACCP plans because it was unsure of its authorities. Although FSIS had announced that it would treat failure to specify at least one CCP for each food safety hazard as a failure to implement a HACCP plan that conforms to HACCP requirements[5], it had not fully implemented this notice. Inspectors-in-Charge (IIC) at each plant review the HACCP plans using a checklist[6] that covers the minimum regulatory requirements in 9 CFR 417 but *there are no procedures for FSIS to specifically approve the HACCP plans*. Inspectors also

[4] Federal Register, vol. 63, No. 20, dated January 30, 1998.

[5] Federal Register, vol. 63, no. 20, dated January 30, 1998.

[6] FSIS Directive 5000.1, Attachment 2.

stated that plants could change their HACCP plans without notifying FSIS of the change.

The inspectors either accept the plans as written or reject them based on failure to meet regulatory requirements. The inspectors did not know if they had the authority to require specific changes in the plans. Also, district or other FSIS officials do not routinely review HACCP plans as part of management control responsibilities. Chapter 3 shows that FSIS had not performed independent reviews to ensure programs under the food safety umbrella were operating as intended. We are recommending that FSIS improve its oversight, clarify requirements for HACCP plans including mandating minimum CCP's, and provide field personnel with clear authority to enforce this mandate.

FINDING NO. 1

ALL CRITICAL CONTROL POINTS WERE NOT IDENTIFIED

Plants had not identified, documented CCP's in their food manufacturing processes or established corrective measures for all CCP's. Some of the plants visited had developed HACCP programs prior to implementation of the regulatory requirements and had revised their existing program after the regulations went into effect. We found (1) plants did not develop CCP's for key processes, (2) the number of CCP's was generally reduced (frequently to one per plan) after implementation of HACCP, (3) plants with similar processes did not have similar CCP's and were not consistent with the FSIS model HACCP plans, and (4) plants frequently showed Good Manufacturing Processes (GMP), SSOP's, USDA inspection activities, and plant operating procedures in lieu of CCP monitoring for identified hazards. Regulations require that the HACCP plans must contain a list of the CCP's for each of the identified food safety hazards[7]. FSIS IIC's cited a lack of specific guidance for identifying CCP's and lack of authority to require additional CCP's as the reasons for not requiring plants to establish needed CCP's. Inspectors also stated that plants could change their HACCP plans without notifying FSIS of the change. Establishments need to set up and monitor CCP's appropriate for their processes to ensure food safety is not compromised and prevent a loss of control over their food production processes.

[7] 9 CFR § 417.2 (c) (2).

A. Plants Did Not Develop CCP's for Key Processes

FSIS inspectors at the plants, circuit supervisors, and district managers did not always require plants to meet minimum requirements for HACCP plans. For example in August 1999, we issued Management Alert No. 3 to FSIS stating that 8 of 20 HACCP plans prepared by Plant L included no CCP's. These plans indicated that no significant food safety hazards were likely to occur during the production processes dealing with raw product. (See Finding No. 3.) Therefore, the HACCP plans did not include any CCP's where critical limits were established and monitored, and where controls could be applied to prevent or eliminate food safety hazards or reduce them to acceptable levels. For example, the plant identified no CCP's for its pork sausage, although FSIS' Generic HACCP Model, dated May 1999, lists six CCP's for raw, ground product. (See exhibit C page 56.)

Plant L's assertion that there were no significant food safety hazards likely to occur during those processes was doubtful. The plant had a history of microbial contamination of products; it had not passed established FSIS performance standards on *Salmonella* testing (more than 6 of a series of 55 samples were positive) for the first two series of tests before finally passing the standards on its third attempt.

On March 25, 1999, FSIS national office officials developed a model letter to be issued to plant management when inspection personnel identified an establishment where all food safety hazards, reasonably likely to occur, may not be addressed or controlled in the HACCP plan. The letter, referred to as a "30-day letter", gave a plant 30 days to reassess its HACCP plans, and required the plant to provide scientific and technical data to support any conclusion that it had no food safety hazards likely to occur during its production process. However, FSIS did not send plant L such a letter. The IIC said that she did not have a problem with the lack of CCP's in the plant's HACCP plans. Other inspectors at the plant said that they felt they had no authority to question the HACCP plans.

The district manager told us that he was not aware that 8 of 20 HACCP plans at this plant had no CCP’s. Although he had sent out 30-day letters to other plants in the district, the responsible circuit supervisor had not identified this plant as

requiring the letter. He said he had been told by both the IIC and plant personnel that the hazard analysis indicated there were no significant food safety hazards reasonably likely to occur during the processes covered by the eight plans. Therefore, he did not intend to take any further action concerning the lack of CCP's.

In reply to Management Alert No. 3, the agency agreed to issue a 30-day reassessment letter to the establishment. The district office was to review all HACCP plans within the circuit to determine if similar conditions existed within other establishments under HACCP. In addition, the district manager was to address failures in the execution of inspection methodology by inspection personnel and frontline supervisors through the procedures identified under the supervisory performance system.

We identified similar conditions for plants K and O. These plants had not established any CCP's for their raw, not ground products. A technical service center representative told us that at the initiation of HACCP, FSIS allowed slaughter and fabrication (cutting meat into commercial cuts, boning, etc.) to be under one HACCP plan. He said that if a plant had at least one slaughter CCP, inspectors might not have required a CCP for the raw, not ground fabrication process. It was his position now that each process should have a CCP.

Plant C had not established a CCP for cooling hot dogs after cooking. We found serious deficiencies (i.e., the plant had no documented corrective actions or preventative measures to explain how deviations from minimum/maximum temperatures would be corrected and/or prevented in the plant's chilling of hot dogs), which could pose a health threat. Without written procedures for controlling the cooling process, including corrective actions when temperature limits were exceeded, we could not readily determine whether the plant properly dealt with the food safety issues related to chilling hot dogs after cooking.

B. Plants Limited CCP's

Our observation of plant operations showed that plants actually monitored many more points in the processes than they identified as CCP's, and the HACCP plans did not appear to reflect all of the hazard controls actually in place. Also, plant F had already implemented its own HACCP program prior to implementation of the regulatory requirements, then revised that

program by reducing the number of CCP's from six to one after regulations went into effect. Therefore, although, the control processes at the other five points continued in effect, plant F was able to avoid FSIS oversight on them.

In addition, it is common for metal shavings to be incorporated into ground meat products because of fabrication and grinding operations. Only one of five plants with a raw, ground process had established a CCP for metal detection. Our review at Plant A found that metal detection was initially established as a CCP. Although the plant continued to monitor product for metal, plant management made the decision to delete this step from the HACCP plan.

C. Plants with Similar Processes Had Widely Differing CCP's

FSIS inspectors told us that they believed that some plants intentionally kept the number of CCP's low to reduce the involvement of FSIS, reduce the likelihood that FSIS could find justification to shut down the plant (i.e., withdraw inspection service) and reduce likelihood of adverse or confidential information becoming public.

Exhibit C shows that plants frequently established a minimum of CCP's in comparison to the HACCP models issued by FSIS. For example, only 2 of 11 plants producing raw, not ground product, had established more than one of the four CCP's outlined in FSIS' model for that process. In addition, four plants having fully-cooked products had established only one or two CCP's that corresponded to the seven CCP's listed in FSIS' model. (See Exhibit C.)

D. Programs and Procedures Were Used in Lieu of CCP's

Plants showed GMP, SSOP, USDA inspection activities, and plant operating procedures in lieu of establishing CCP's for identified hazards at 9 of the 15 plants. Regulations require that HACCP plans must be self-contained documents and references to programs and procedures outside of the HACCP program are not sufficient. Plants frequently identified a hazard as significant but cited programs and procedures in lieu of establishing a CCP. In other cases, plants documented a hazard as not significant and justified their decision by citing programs and procedures they believed made the hazard not

likely to occur. Consequently, inspectors found it very difficult to monitor non-CCP preventive measures in programs outside HACCP and questioned if they had the authority to require a CCP. As a result, it was unclear whether the programs and/or procedures cited in the HACCP plans were monitored by FSIS and provided effective controls or preventive measures for the associated food safety hazards.

Using prerequisite programs, such as GMP's, SSOP's, and plant operating procedures outside HACCP as justification for determining that a food safety hazard is not likely to occur (not a significant hazard) is not acceptable. It is very difficult for FSIS to determine whether the prerequisite programs are effective in reducing the likelihood that specific hazards will occur. These programs have no documentation requirements to show that they will prevent a specific hazard in the production process. We noted that plants carried out extensive monitoring activities outside of their HACCP programs, which showed that FSIS needed the authority to verify these preventive or control measures on an on-going basis. For example, plants used detection devices to control metal particles from entering their products during the fabrication or grinding processes without including a CCP in their HACCP plans that subjected it to FSIS monitoring. In addition, FSIS has no assurance that plant operating procedures have been adequately developed and implemented. For example, the hazard analysis for Plant C cited operating procedures as justification for not having a CCP to prevent the growth of pathogens during storage of perishable products. Our review disclosed that the plant had not yet developed the written operating procedures referenced in the HACCP plan.

The number of instances (processing steps) noted at the nine plants where GMP's, SSOP's, USDA inspection activities, and plant operating procedures were used in lieu of CCP's is shown below.

Table 2: Prerequisite Programs Used in Lieu of CCP's

Plant	Number of Times Program Outside HACCP Shown As Preventive Action For a Significant Hazard	Number of Times Program Outside HACCP Shown As Reason Hazard Not Considered Significant
A	82	0
B	29	0
C	0	4
E	0	1
F	0	2
H	0	7
I	32	22
M	0	4
O	6	0

The cited deficiencies occurred because the FSIS inspectors who reviewed the plant HACCP plans either were not aware of all requirements for HACCP plans or did not believe they could require the HACCP plans to be changed for issues that did not clearly constitute a failure to meet regulatory requirements. The inspectors were faced with the choice to either reject the plans on regulatory grounds or accept them as written. It should be noted that the cases cited above would constitute a violation of regulatory requirements because the HACCP plans would not meet the intent of 9 CFR 417.

However, the requirement that HACCP plans must be self-contained documents was not clearly stated in the published regulations but was added in a clarification to the regulations in the Federal Register dated January 30, 1998.[8]

RECOMMENDATION NO. 1

Implement a system of oversight, such as district office or independent reviews, to ensure HACCP plans contain minimum required CCP's based on the HACCP models. Issue instructions that provide clear guidance on requirements for establishing CCP's and inspector's authority to require changes to documented CCP's. Revise the checklist used to evaluate HACCP plans accordingly, including:

a. mandating minimum CCP requirements based on type of process, as indicated by the HACCP models,

[8] Federal Register/Vol. 63, No. 20/ Page 4562.

b. specifying that field office personnel have the authority to approve CCP's and to require additional CCP's as needed in their assigned plants, and

c. requiring the establishments to inform the IIC of any proposed change in the HACCP plan, thereby allowing FSIS review prior to the change.

Agency Response

In its May 18, 2000, response to the draft report, FSIS stated:

> *FSIS agrees that a system of oversight such as independent reviews is necessary. Development of the system of oversight i.e., the In-Depth Verification (IDV) has been underway for over one year. In Fiscal Year (FY) 2000, FSIS initiated the IDV Review. The IDV protocol is designed to evaluate the essential features of establishments' Pathogen Reduction/HACCP systems. It was developed with input from the National Advisory Committee on Meat and Poultry Inspection. It verifies Pathogen Reduction requirements and includes scientific and technical criteria drawn from the National Advisory Committee on Microbiological Criteria for Foods (NACMCF). It contains 10 checklists addressing SSOPs, E. coli testing and HACCP requirements. Each checklist has a documentation component and a system verification component.*
>
> *FSIS issued instruction to provide clear guidance to plants on requirements for establishing CCPs and inspector's authority in relation to CCPs. * * * FSIS agrees that there may be some inspectors who still may not fully understand their authority with regard to the PR/HACCP rule. * * * FSIS is conducting a series of National Supervisory Conferences to reinforce a full understanding of inspection authorities. Circuit Supervisors through work unit meetings will share the information covered in these meetings at the in-plant level. FSIS will also continue to issue policy directives and notices to explain inspection verification methods and regulatory actions.*
>
> *Furthermore, FSIS believes that PR/HACCP system implementation was conducted effectively within constraints of limited training and of a field force, which does not,*

collectively, possess all the skills necessary to perform inspection fully consistent with HACCP precepts. Now that implementation has been completed, FSIS agrees that additional instructions need to be developed for inspection program personnel to begin assessing the completeness of the HACCP plans.

FSIS will reaffirm to its inspection program personnel that the Agency has sufficient authority to accomplish its statutory mission of protecting the public health and welfare of consumers by preventing the distribution of products that are unwholesome, otherwise adulterated, or misbranded. As a first step, FSIS has begun developing a series of limited surveys, which should be completed by the end of July 2000, to ascertain if there is need to make any regulatory changes or new instructions pertaining to HACCP. Furthermore, the Agency is developing an FSIS Notice, which is intended to provide instruction to inspection program personnel regarding a three-step approach on how to verify establishment compliance with hazard analysis and HACCP Plan requirements. This Notice should be issued by October 2000.

FSIS will not approve the CCPs selected, or require notification by the plant that changes have been made to the HACCP plan. FSIS believes that its role is one of verification that the HACCP plan is being implemented as defined by the establishment, and that the scientific basis and rationale for the HACCP plan is credible. FSIS will challenge the adequacy of HACCP plans which are inadequately supported. FSIS will not serve as a quality control function for the establishment; the establishment is responsible for producing safe product.

OIG Position

Although FSIS has implemented a system of oversight with independent reviews, we cannot reach management decision on the recommendation at this time. FSIS contends that it will not approve CCPs, or require notification by the plant that changes have been made to the HACCP plan.

In verifying whether the scientific basis and rationale for the HACCP plan is credible, FSIS inspectors review CCPs and determine whether

CCPs are sufficient to reduce or eliminate food safety hazards reasonable likely to occur. If CCPs are sufficient, the inspectors have in effect approved them.

In addition, FSIS contends that it will not serve as a quality control function for the establishment. Although the establishment is required to verify its established controls, FSIS is responsible to ensure that establishments' control processes are adequate and functioning. To reach management decision, we need the results of surveys and specific decisions made to revise regulations or instructions pertaining to HACCP. We also need to review the FSIS Notice regarding verification of establish compliance with hazard analyses and HACCP plan requirements. In addition, we concluded that it is essential for plant management to notify FSIS inspectors when changes are made to HACCP plans. This could be incorporated into the Grant of Inspection agreement. Without this requirement, plants could produce food from inadequate processes for extensive time periods without FSIS knowledge or verification. FSIS inspectors are already required to review HACCP plans when reassessments occur, but unless the plant notifies the inspectors they may not be aware of it.

FINDING NO. 2

CRITICAL LIMITS AND CORRECTIVE ACTIONS WERE INADEQUATE

We found that critical limits and corrective actions identified by plants were inadequate. (Plants were to establish critical limits for each CCP identified in the HACCP plan to control food safety hazards. The critical limits were generally a numerical value, such as maximum or minimum temperature, maximum allowable defects, etc.) The critical limits were not always based on documented scientific data, prescribed corrective actions were not sufficient to control the identified hazard, and documentation was not sufficient to ensure proper actions were taken when critical limits were exceeded. In some cases, the prescribed corrective actions for deviations were either not appropriate or were not implemented. Further, FSIS established specific temperature requirements for some products but not others. FSIS inspectors did not ensure that critical limits were properly documented in the HACCP plans and that appropriate corrective actions were provided or documented when the limits were exceeded because they did not believe they had authority to require changes to HACCP plans. As a result, there was reduced assurance that hazards were properly controlled from monitoring critical limits and corrective actions for deviations from prescribed limits.

Federal regulations[9] state that the HACCP plan shall list the critical limits of each CCP and specify that those limits shall be designed to ensure that applicable targets or performance standards are met. These regulations also state that the HACCP plan shall describe the corrective action to be taken to ensure that the cause of the deviation is eliminated and measures to prevent recurrence are established.

A. Lack of Scientific Data to Support Critical Limits

There was no scientific data documented in plant files to support critical limits established for various processes at seven of the plants (Plants B, C, I, J, K, L, and M). We noted that there were wide ranges in the maximum temperatures specified for similar pork and beef processes at various locations (see exhibit C and Table 3 below).

[9] 9 CFR § 417.2 and 9 CFR § 417.3.

Table 3: Variations in Temperatures Used As Critical Limits

Product/ Plant	PROCESS
Pork	
K	**Slaughter** - Cooler temperature cannot exceed 60 degrees. **Pork sausage** - If the temperature of trimmings at the grinder exceeded 60 degrees, corrective action was to be taken.
A	**Fabrication** – Prior to cutting, carcasses cannot have a surface temperature exceeding 45 degrees nor an average internal ham temperature exceeding 45 degrees within 24 hours. **Product** - Prior to shipping variety meats, the dock temperature cannot exceed 50 degrees and the dock temperature for other products cannot exceed 41 degrees. The trailer unit cannot exceed 40 degrees.
C	**Fabrication** - Prior to cutting, carcasses cannot exceed 48 degrees, and the fabrication area room temperature cannot exceed 50 degrees. **Pork sausage** - If product temperature exceeded 45 degrees, grinding of product was to stop and corrective action taken.
Beef	
B	**Fabrication** – The surface temperature of meat was not to exceed 55 degrees prior to boning. (*Plant documentation shows the boning CCP was set at 55 degrees because it was a temperature the plant could achieve and microbial testing at or below this temperature did not indicate excessive microbial growth.)*
I	**Fabrication** – Carcass surface temperature was not to exceed 45 degrees prior to fabrication.
[1] All temperatures are in Fahrenheit (F).	

In contrast, we noted that poultry plants having similar processes also had similar maximum temperature requirements. According to technical service center personnel, FSIS had set specific requirements for poultry products.[10] Temperature requirements had been considered for raw beef and pork but never finalized.

Industry officials noted that it was very difficult and expensive (particularly for small plants) to obtain scientific data to support the establishment of critical limits.

[10] 9 CFR §381.66.

B. Corrective Actions Not Appropriate and/or Not Implemented

The prescribed corrective actions[11] to be taken for deviations from critical limits were not appropriate for the deviation and/or did not provide assurance that the problem was corrected at four plants (Plants E, J, L, and M). For example, the documented corrective action at Plant E for cases where the temperature of raw, ground products exceeded 45 degrees was to cool down the product or rework the meat into another product. The plant's HACCP coordinator said that since the growth of pathogens could occur if the raw product exceeded 45 degrees, the appropriate corrective action would be to rework (cook) the meat. The corrective measures for deviations from the critical limits for 24 of 27 CCP's at plant L and 8 of 12 CCP's at plant J were not specific procedures related to the product and process but rather were generic requirements contained in the Federal regulations. For example, the corrective action shown for a CCP in plant L was:

> *Identify and eliminate the cause of the deviation. Bring CCP under control. Establish measures to prevent recurrence. Segregate and hold any affected product.*

We also found that the prescribed corrective actions were not always followed at plants J and M. For example, in plant J, we noted three instances where a temperature limit was exceeded. The prescribed corrective action of cooling down the product was only taken in two of the cases. At plant M, the internal temperature of the product exceeded the critical limit at two separate monitoring checks during one shift. There was no documentation to show that any corrective action was taken.

C. Critical Limit Documentation Discrepancies

At plants L and J, there were 16 cases where limits were unclear or the monitoring activity occurred at a time that precluded measuring the critical limit, (i.e., temperatures were taken either before or after the time the product was required to meet the limit). The critical limit at plant F for one CCP was documented in the HACCP plan as "Zero Tolerance," but the plan stated that if more than 3 of 10 discrepancies were noted, critical limits were exceeded. At plant E, the critical limits for cooking beef

[11] 9 CFR § 417.3

for two HACCP plans did not include the time requirement associated with the specified cooking temperatures. Also, plant J's slaughter HACCP plan did not list the frequency to verify critical limits.

RECOMMENDATION NO. 2

Implement a system of oversight to ensure HACCP plans contain adequate critical limits and corrective actions are proper including:

a. issue instructions that provide clear guidance on requirements for establishing critical limits and clarify the authority of FSIS to require changes to critical limits documented in the HACCP plan,

b. provide additional guidance (such as maximum temperatures for raw beef and pork) and scientific data to assist plants in establishing critical limits for standard types of processes,

c. require plants to provide documentation of the scientific data used to support critical limits for their manufacturing processes, and

d. strengthen the supervisory and independent review process to ensure critical limits and corrective actions for deviations from critical limits are appropriate, documented, and can be verified.

Agency Response

In its May 18, 2000, response to the draft report, FSIS stated:

FSIS believes that it has issued instructions that provide clear guidance on requirements for establishing critical limits. (See 9 CFR 417.1 and 417.2.) It also believes that inspector authorities are clear, and that it is contrary to the philosophy of the PR/HACCP regulation for inspectors to "require" changes to critical limits or corrective actions documented in the HACCP plan. As stated by the NACMCF, strong plant management commitment is required for successful implementation of a HACCP plan, because it provides company employees with a sense of importance of producing safe food. FSIS believes that having inspectors "require" changes to the HACCP plan, as

*suggested by this recommendation, would undermine the effectiveness of the HACCP system within the plant. In cases of noncompliance, or at any time when inspectors have a concern about the safety or product being produced, such as inadequate critical limits or ineffective corrective actions, inspectors have effective authorities under the HACCP regulation which they can use to address the situation. * * **

With regard to recommendation (b), FSIS intends to provide additional guidance, and scientific data to assist plants in establishing critical limits for standard types of processes; however, it will not specify "maximum temperatures". FSIS will prepare appropriate guidance for inspection program personnel, and, if necessary, compliance guidance for industry to address performance standards.

FSIS has a regulatory reform initiative to convert current command-and-control regulations (which do specify things such as maximum temperatures) to performance standards (e.g., FSIS Directive 7111.1). The corresponding compliance guidance documents produced by FSIS are being made available to establishments in an effort to provide industry with specific control limits (e.g., time and temperature) to achieve the performance standards. The establishments can then incorporate the guidance procedures into their HACCP plans and demonstrate, through verification and validation, that the procedures are being implemented properly and are effective. It is the responsibility of establishments to identify specific temperatures that are necessary to ensure that safe food is produced.

Scientific data to assist plants in establishing critical limits for standard types of processes were provided through the generic HACCP models (references to scientific papers, etc.). There are also many sources of such assistance that have been widely available to plants during HACCP implementation (universities, Extension Service personnel, industry association materials). It is not the role of FSIS to be the exclusive provider of scientific data to assist plants. FSIS will continue to seek scientific information from the scientific community at large, as industry should as well, and FSIS will continue to provide scientific data as it relates to

rulemaking and policy development. However, FSIS will not take on the responsibility for providing such data to plants. FSIS' role in relation to scientific data and HACCP plans is to evaluate through verification activities the scientific and other supporting data plants use as the basis for decision-making used to develop HACCP plans.

Therefore, FSIS agrees with recommendation (c) to "ensure that plants provide documentation of the scientific data used to support critical limits." FSIS established the TSC in Omaha, Nebraska, in part to serve as a resource to inspection personnel and industry representatives when questions arose regarding such scientific data or critical limits. The TSC hosted the HACCP Implementation Technical Conference in August 1999, to reinforce plants' responsibilities relative to validating HACCP plans with documentation such as scientific data. FSIS agrees to reinforce this with field inspection personnel through avenues such as the National Supervisory Conferences.

FSIS agrees with recommendation (d) and has established the IDV review process as an independent review of plants' SSOPs and HACCP plans. The IDV protocol includes scientific and technical criteria drawn from the NACMCF.

OIG Position

FSIS inspectors can effectively require changes to the HACCP plan when inadequate food safety systems are found by withholding inspection until HACCP plan reassessment is performed to address the deviations. In reviewing HACCP plans, FSIS inspectors were either not requiring plants to provide scientific, technical, or regulatory documentation to support critical limits, or not questioning inadequate support provided by plants. Further instructions are needed for FSIS inspectors on what constitutes acceptable scientific, technical, or regulatory documentation. With regard to section (b) of the recommendation, we agree with FSIS' reform initiative to convert old regulations to new performance standards in an effort to provide industry data with specific control limits to achieve performance standards. However, to accept management decision, we need a copy of this Directive and the expected implementation date of this initiative.

With regard to sections (c) and (d), more specific details are needed on how FSIS will ensure that plants provide adequate supporting documentation and timeframes for completion.

FINDING NO. 3

HAZARD ANALYSIS DID NOT SHOW ALL LIKELY HAZARDS

Hazard analyses were not complete or were inaccurate. Specifically, the analyses did not always identify or address all microbiological, physical, and chemical food safety hazards that were reasonably likely to occur[12]. We found HACCP plans and processes where no CCP's were identified because the hazard analysis did not show existing significant food safety hazards. (See Finding No. 1.) In addition, some hazard analyses omitted products and manufacturing processes, so no evaluation of hazards or identification of CCP's was done for the products or processes left out. We also found that the description of listed hazards was not always adequate to allow evaluation of the safety risk and the appropriateness of assigned preventive measures. Some hazard analyses were also not sufficiently documented to show whether all likely food safety hazards were identified and considered.

Because plant analyses did not show all food safety hazards, there is reduced assurance that the plants properly identified and provided preventive measures for the hazards. This reduced assurance increases the possibility of contaminated or adulterated products entering the market place. FSIS IIC's cited a lack of specific guidance for hazards, along with a lack of authority to require specific hazards to be addressed, as the reasons for permitting incomplete and inaccurate hazard analyses.

We reviewed 57 of 107 HACCP plans at the 15 plants and evaluated the plants' hazard analyses with the assistance of review officers from FSIS' technical service center in Omaha, Nebraska. Based on our reviews and the opinions of the officials assisting us, we identified defects in the analyses for one or more of the plans reviewed at 4 of the 15 plants.

A. <u>All Food Safety Hazards Had Not Been Analyzed</u>

The hazard analysis deficiency we found with the most serious impact was where existing significant food safety hazards had

[12] 9 CFR § 417.2(a).

not been identified or analyzed, and a determination made on the need for additional CCP's at the plant. For example, we found product lines in plants F and L and processing steps in Plants D and H that were omitted from the hazard analyses. The manufacturing processes for the omitted products and steps had not been evaluated to determine if food safety hazards existed and if additional CCP's were needed.

B. Food Safety Hazards were not Adequately Described

The description of listed hazards in the hazard analyses of one or more HACCP plans reviewed at plant L was not sufficient to allow an evaluation of the actual risk associated with the process and appropriateness of the designated preventive measure. The hazard analysis did not describe the hazards in enough detail to determine the actual nature of the hazard. Scalding agents were listed as a chemical hazard but it was not clear if the agents were toxic, carcinogenic, or caused allergic reactions (either mild or life threatening). The appropriateness of assigned preventive measures could vary depending on the actual nature of the chemical hazard.

C. Analyses Were Not Documented to Show All Likely Hazards Were Considered

The hazard analyses at plant D did not document any physical or chemical hazards as a possibility even though other plants had considered these types of hazards. The only hazard shown in the hazard analyses for the eight HACCP plans was "microbial." The hazard analyses at the other plants visited showed that all three types of hazards were considered but physical or chemical hazards were usually shown as not applicable or not likely. The hazard analyses appeared to concentrate primarily on biological hazards.

Improvements are needed in plants' hazard analyses. All product lines and processing steps need to be evaluated to determine if food safety hazards exist. Hazard analyses also need to be described in sufficient detail to ensure that evaluation of actual risk and preventative measures assigned by the plants were appropriate. In addition, more emphasis is needed on plants' evaluation of physical and chemical hazards within the processing environment.

RECOMMENDATION NO. 3

Implement a system of oversight to ensure that the hazard analyses include all food safety hazards that are reasonably likely to occur:

a. Work with plant management to review the hazard analyses for completeness and accuracy,

b. ensure that scientific and technical data have been provided to support conclusions that processes do not pose any food safety hazards that are reasonably likely to occur.

c. provide the district office with clear authority to enforce the requirement to address identifiable hazards, as required by the HACCP regulations.

Agency Response

In its May 18, 2000, response to the draft report, FSIS stated:

> *FSIS agrees that hazard analyses must be conducted to determine the food safety hazards reasonably likely to occur in the production process (9 CFR 417.2, NACMCF Hazard Analysis and Critical Control Point Principles and Application Guidelines). FSIS disagrees with recommendation (a), "work with plant management to review the hazard analyses for completeness and accuracy," for reasons cited in earlier FSIS responses regarding the role of industry in taking responsibility for HACCP plans. Having inspection personnel review plants' hazard analyses for completeness and accuracy are tantamount to "approving" the plant's hazard analyses. However, FSIS agrees with recommendations (b) and (c). Through verification and recordkeeping activities, FSIS inspection personnel are required to ensure that scientific and technical data are provided to support conclusions in the HACCP plan. If inspection personnel have questions about the adequacy of this data, they can either contact the TSC or request the plant to provide clarification. If, as inferred by recommendation (c), the establishment has not addressed hazards that are reasonable likely to occur, inspection personnel have enforcement protocols to apply, 9 CFR 417.6.*

OIG Position

FSIS inspectors are already required to review initial HACCP plans and plans after reassessments. As part of this review, inspectors are required to review this plant's hazard analyses. We found that in many cases, these reviews were not sufficient to detect food safety hazards that were not addressed in the HACCP plans. Without more intensive reviews by FSIS inspectors, plants operating with these HACCP systems may not produce safe and wholesome meat and poultry. Therefore, to reach management decision, FSIS should provide specific plans (along with associated timeframes) that will ensure needed improvements in plants' hazard analyses.

FINDING NO. 4

FLOWCHARTS DID NOT SHOW ALL PRODUCTION PROCESSES

Flowcharts had not been prepared for all processes in the plants, and those that had been prepared did not always fully document the production process. In addition, some products produced by the plants were omitted from the HACCP plans and production flowcharts. Plants are to use the flowcharts to identify potential food safety hazards at each process. Consequently, FSIS' ability to ensure food safety was impaired because FSIS relies on the flowcharts to identify processes and points to monitor.

Federal regulations[13] state that a flowchart describing the steps of each process in the establishment shall be prepared and the intended use or consumer of the finished product shall be identified. Although these regulations support the need for accurate flowcharts, FSIS has not exercised its authority to demand them. The IIC at each plant reviews the HACCP plan and either rejects it as not complying with regulations or accepts it as written, but lacks the authority to require changes in it.

We reviewed 57 of 107 HACCP plans at the 15 plants and evaluated the production flowcharts included in the plans with the assistance of review officers from FSIS' technical service center. We identified defects in the production flowcharts for one or more of the plans reviewed at 8 of the 15 plants. Products, production processes, or individual processing steps were omitted from the flowcharts or the processing flow was not accurately documented. For example, at plant F, the production of offal products (i.e., liver, tripe, tongue) was not shown on the flowchart and the chart did not show the

[13] 9 CFR § 417.2(a)(2).

processing flow for the head boning operation. At plant L, the flowchart did not document the production of beef bacon. Other noted defects in flowcharts were:

- Steps related to receiving ingredients (including meat products from other plants) and other materials used in the production process were omitted (plants I, J, and M).

- The processing flow (including disposition or transfer of products to other processes) was unclear or not documented (plants D, I, J, and L).

- Significant steps in the processing, such as trimming carcasses and reworking product, were omitted (Plants D, F, H, I, and L).

- The location of a CCP or testing for a CCP was not accurately shown (Plants G and I).

Plant officials generally agreed to either revise the charts as needed or further study the issue. In two cases, they questioned our interpretation of how the flowcharts should be documented.

RECOMMENDATION NO. 4

Implement a system of oversight, to include management reviews and/or independent reviews requiring establishments to correct flowcharts to reflect the establishment's actual operations.

Agency Response

In its May 18, 2000, response to the draft report, FSIS stated: "FSIS believes that its role is one of verification that the HACCP plan is being implemented as defined by the establishment, and that the scientific basis and rationale for the HACCP plan is credible. FSIS will challenge the adequacy of HACCP plans."

OIG Position

FSIS' response does not address this recommendation. FSIS should provide specific details on how the inspectors' review of HACCP plans will better detect plants' incomplete flowcharts.

CHAPTER 2	FSIS NEEDS TO PLACE GREATER EMPHASIS ON PATHOGEN TESTING

One of the keys to the success of the HACCP system is the technological advance in pathogen testing. Laboratory tests are capable of identifying a host of microbiological agents whose presence in meat and poultry had thus far been undetermined. As part of our FSIS initiative, we also performed an audit to assess the adequacy of FSIS lab testing programs. Under HACCP, FSIS meat and poultry producing establishments maintain their own testing programs. Slaughter plants are required to test for generic *E. coli*. FSIS is required to test for Salmonella. In addition, FSIS' directed testing program (not part of HACCP) tests for other harmful pathogens, such as *E. coli 0157:H7* and *Listeria monocytogenes* (*LM*). Plants may voluntarily test for specific pathogens and other generic pathogens, but they are not required to do so.

The seriousness of pathogens in meat is illustrated by a case that occurred in late 1998, where 101 people became ill apparently from eating meats contaminated with *LM*. Of those who became ill, 15 died and 6 suffered a miscarriage or stillbirth. The plant that produced the meats had a history of positive tests for generic *Listeria* in the environment and on its product. However, FSIS inspectors had no knowledge of the presence of these bacteria because notification was not required. FSIS' nationwide sampling programs found that over 40 percent of raw ground chicken and 5.7 percent of sliced ham and luncheon meats tested positive for *LM*. Overall, 3 percent of cooked product tested positive.

During our review, we found that FSIS field employees needed the authority to require plants to expand their pathogen testing and to notify FSIS of positive test results. Under current procedures, plants that practice voluntary pathogen testing need not test for specific strands of *E. coli*, *even after they detect the presence of generic E. coli*, and they need not notify FSIS, *even if their generic test results are positive* (see Finding No. 9). Plants also need not test for any form of *Listeria* or any emerging pathogens, such as *Campylobacter* that causes an estimated 99 deaths and 1.9 million illnesses each year.

FSIS also needs to increase its oversight of plant testing protocols and improve its security of laboratory samples gathered. Generally, FSIS inspectors do not review the protocols to ensure they are based on

scientific standards and do not secure FSIS samples against tampering. These conditions reduce assurances that test results accurately reflect conditions at the plants. In a recent Office of Inspector General (OIG) Investigation case in Florida, officials at one plant opened FSIS' samples before they were shipped and sanitized the meat to eliminate microbial contamination.

FSIS' testing program also does not always ensure that production was subjected to testing. We found that rigid timeframes and poor communication have allowed some products to enter the market without being subjected to testing for pathogens. Tests on seasonal products did not always fall within FSIS' testing timeframes in the directed testing program, and a Salmonella series test was stopped prior to completion.

FINDING NO. 5

EXPANDED PATHOGEN TESTING WOULD INCREASE FOOD SAFETY

Pathogen reduction is achieved when HACCP performance standards are established and met. FSIS did not establish standards that required plant HACCP plans to include pathogen testing of the plant environment, product contact surfaces, or ready-to-eat products. FSIS had limited testing to *Salmonella* and generic *E. coli*. and did not require plants to test for other known pathogens, such as *E. coli. 0157:H7*, and *LM*. Although FSIS recently required plants to reassess their HACCP plans for *LM*, no documentation of the review was required and instructions did not specifically require plants to establish a CCP to test for the pathogen[14]. One of the keys to the success of HACCP is microbiological testing, and sound management practices dictate that known harmful pathogens should be monitored through an effective testing program.

Industry officials purchasing meats from HACCP plants informed us that they routinely require additional microbiological tests for pathogens as part of the purchase contracts. These tests are for pathogens, such as *E. coli 0157:H7* and *LM*, that are not required by FSIS, but are needed to meet the individual company food safety standards.

[14] Federal Register/Vol. 64, No. 101 (May 26, 1999), Pages 28351-28353; *Listeria Guidelines for Industry* (May 1999); FSIS Notice 17-99 (June 17, 1999); and FSIS Notice 23-99 (August 3, 1999).

Under HACCP, slaughter plants are only required to test for generic *E. coli*, which aids in evaluating the effectiveness of their sanitation procedures and the possible presence of pathogens. FSIS performs a testing series to ensure plants comply with established Salmonella standards. Under its directed testing program, FSIS also tests for specific pathogens, such as *E. coli 0157:H7*, and *LM* on a nationwide basis. (A test revealing the presence of a specific pathogen means that the product is regarded as adulterated, while a test revealing nonspecific microbes does not.) However, although FSIS tests are more meaningful than plant tests concerning the wholesomeness of the product, the number of directed tests FSIS obtains from an individual plant is generally not sufficient to assess reliability on an individual plant basis.

In May 1999, after the tragedy referred to earlier in which 15 people died after consuming *LM*-tainted hot dogs, FSIS advised manufacturers of ready-to-eat meat products that establishments must reassess their HACCP plans. FSIS took the position that *LM* contamination should be considered to be reasonably likely to occur in the production of products, especially if an establishment has produced products adulterated with *LM* or is producing ready-to-eat products susceptible to such contamination in an environment that is not known to be free of this pathogen.

At the time of our field visits, none of the six plants producing ready-to-eat products had included plant environmental or final product testing as a CCP. Generally, plants had established microbiological testing programs outside of HACCP, but they did not test for specific pathogens, which could result in the product being considered adulterated. For example, although plant H did not mention such testing in its HACCP plan, it tested the environment and final product, but only for the generic *Listeria* species. Plant C's HACCP plan justified not establishing a CCP by claiming that testing was done of both product and environment. However, our review showed that only environmental testing was performed.

As reported in Finding No. 9, plants did not inform FSIS when they developed a history of frequent positive generic tests on contact surfaces and products. FSIS' industry guidance[15] suggests that if positive samples are found on product contact surfaces for samples indicated in the HACCP plan for generic *Listeria*, the next lot of product produced from the line should be sampled and tested for *LM*. (If a sampled lot already in commerce test positive, it will be subject to recall.) This guidance further suggests that an end-product sampling

[15] *Listeria* Guidance for Industry (May 1999), FSIS Internet.

program for ready-to-eat products may serve as verification of the HACCP plan.

To encourage plants to take greater responsibility for the wholesomeness of their product, FSIS developed procedures that may in fact have limited its ability to identify products containing pathogens[16]. Under these procedures, FSIS inspection personnel generally may not collect raw ground beef samples to be tested for *E. coli 0157:H7* at plants that have pathogen reduction interventions on beef carcasses in place. Plants under this program are not required to notify FSIS of positive test results. In lieu of pulling a sample for FSIS testing when a request is received from the National Office's directed sampling program, inspectors are limited to reviewing plant records for positive test results within the last 6 months.

Based on data from FSIS and Centers for Disease Control (CDC), there are other known pathogens that pose danger to consumers. Foodborne disease may cause an estimated 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths in the U.S. each year according to the CDC. CDC reported that Campylobacter has been the number one pathogen causing foodborne illnesses, and *Salmonella* and *LM* cause the most foodborne deaths. In addition, significant levels of both Campylobacter and *LM* were reported for some products in baseline studies conducted by FSIS prior to the implementation of HACCP.

FSIS' testing ideology appears to be more reactive than proactive to testing for emerging foodborne pathogens. An FSIS National Office official told us that while there is a zero tolerance standard for *LM* on ready-to-eat product, there is no consensus on standards for *Listeria* on raw products including ground products. The regulations provide specific authority to impose standards on *Salmonella*. FSIS does not have standards for testing other pathogens in products or on environmental and contact surfaces. The FSIS official believed it was not FSIS' role to require plants to test ready-to-eat product for pathogens such as *Listeria* and *Campylobacter*. He believed that FSIS should focus the plant's attention on sanitation problems, and that it should be left to the plant to decide how to ensure it produces a safe and wholesome product.

[16] FSIS Directive 10,010.1 (February 1, 1998).

ARS supports FSIS in implementing HACCP by providing improved sampling protocols, user friendly pathogen identification methodology, technology to provide microbiological controls, and information to base standards for processing specific products. ARS research provides for the development of methods to ensure food safety through microbial sampling technologies to more accurately estimate the true burden of food products covered by HACCP.

We believe that FSIS is not fully addressing the danger posed by known and other new or emerging foodborne pathogens. FSIS may be placing undue reliance on plants that may be unable or unwilling to take necessary action in the face of repeated tests showing the presence of potentially harmful microbes.

For example, we issued a management alert for plant H because the plant did not notify FSIS inspectors when *Listeria* was found in their voluntary environmental and product pathogen testing programs. Inspectors became aware of the problem by questioning plant officials why some inventory had remained in the plant for an extended period. An employee informally told the inspectors of the *Listeria* problem. The product in question was subsequently destroyed after we visited the plant.

The Grant of Inspection (Form 5200-1) is the only agreement between the plant's management and FSIS. The Grant of Inspection is a one-page form that does not spell out important plant responsibilities, such as responsibilities for maintaining sanitation records and FSIS notification when a plant's pathogen testing identifies adverse conditions. Also, the Grant of Inspection does not address FSIS authority to gain access to all plant pathogen test records.

We concluded that consumer safety would be improved if plants using voluntary programs were required to immediately report positive test results and if provisions were made for routine verification testing by FSIS.

RECOMMENDATION NO. 5

Develop and implement procedures that provide FSIS employees at the appropriate level with the authority to require HACCP plans to include pathogen testing of product environment, contact surfaces, and final products, particularly if a plant has a history of positive test results for microbes such as *Listeria*.

Agency Response

In its May 18, 2000, response to the draft report, FSIS stated that:

> *FSIS has clear authority to enforce the requirements of the HACCP regulations. HACCP is an effective preventive system and a properly designed system includes microbiological validation and verification by the establishment. Moreover, FSIS believes that microbiological verification is an appropriate responsibility of FSIS. FSIS is pursuing a number of microbiological-based performance standards which would further ensure that the establishments are adequately addressing food safety. FSIS is especially concerned about the presence of pathogens on ready-to-eat products and in the production environment, and FSIS is now evaluating the response by the establishments to last year's Listeria monocytogenes reassessment (attachment 5). FSIS held a public meeting on Listeria monocytogenes on May 15, 2000, at which the agency addressed current thinking regarding further action associated with this pathogen. By December 2000, FSIS expects to issue a proposed regulation addressing ready-to-eat meat and poultry. This proposed rule is expected to contain a performance standard specifically addressing this pathogen.*
>
> *FSIS agrees that its role is to verify that the HACCP plan is being implemented as defined by the establishment, and that the scientific basis and rationale for the HACCP plan is credible. FSIS will challenge the adequacy of HACCP plans.*

OIG Position

To achieve a management decision for the recommendation, we need specific details on proposed performance standards over the production environment, and when the standards will be implemented.

RECOMMENDATION NO. 6	Provide clear authority in the Grant of Inspection contract for FSIS oversight of all plant pathogen testing.

Agency Response

In its May 18, 2000, response to the draft report, FSIS stated: "FSIS has been investigating the regulatory requirement associated with the Grant of Inspection and, if feasible, will pursue options to amend the Grant of Inspection to make clear the authority of FSIS to oversee plant pathogen testing. A conclusion will be reached by June 2001."

OIG Position

To achieve a management decision for this recommendation, we need to know FSIS' detailed plans on how the recommendation will be implemented. Departmental Regulation No. 1720-1 requires that management decisions be reached within 6 months.

RECOMMENDATION NO. 7

Develop testing programs in coordination with the ARS for other pathogens that impact food safety.

Agency Response

In its May 18, 2000, response to the draft report, FSIS stated:

> *FSIS continues to work closely with ARS in a variety of food safety research and development areas. However, ARS does not develop "testing programs" (which is the role of FSIS) but ARS does play a significant and critical role in the design and development of methods used by FSIS' laboratories for analyses of regulatory samples. A recent example of the collaborative work between FSIS and ARS is the design and development of an improved analytical method for E. coli O157:H7. ARS performed the basic research and development for the new method and then collaborated with one of FSIS' laboratories to adapt the method for analyses of regulatory samples. This joint effort resulted in FSIS' use of an improved, more sensitive testing method, allowing increased recovery of this significant pathogen to better protect public health. In September 1999, this improved immunomagnetic bead method was implemented in all three FSIS laboratories.*
>
> *Additional projects are underway including a project involving Listeria monocytogenes and a project on handling/ transportation and chilling of meat and poultry. FSIS is also developing proposals for new research projects to develop*

detection methods for foodborne viruses, the parasite Toxoplasma gondii and the foodborne pathogenic bacterium, Yersinia enterocolitica.

OIG Position

Since collaborative efforts are underway with ARS, we accept the management decision for this recommendation.

FINDING NO. 6

FSIS NEEDS TO IMPROVE SECURITY OVER LABORATORY SAMPLES

Security over samples sent by FSIS field offices to USDA labs needs improvement. Current FSIS instructions do not provide guidance for the security of test samples after packaging by inspectors until the shipping agent collects the package. In addition, instructions do not address security for samples stored in FSIS refrigerators. These test results are used by FSIS to assess the effectiveness of a plant's HACCP programs. Consequently, there is reduced assurance that FSIS' testing program reflects the actual conditions in the plants.

Instructions to inspectors cover selecting, preparing, and packaging samples for shipment to USDA labs for analysis; however, the instructions do not address sample security[17]. FSIS samples are evidence of the sanitation conditions in a plant and must be sufficient, competent, and relevant. (In the scientific community this is commonly referred to as quantitative and qualitative.)

Our review at 15 FSIS field offices found that inspectors were not required to package lab samples in tamper resistant shipping containers. The containers used had Velcro seals so that FSIS could reuse the boxes. We found that inspectors at nine field offices left their sample containers where plant officials had access to the samples prior to pickup by the shipping agent. Because the containers could be opened without detection, there is no assurance that the samples were not altered by plant officials.

For example in 1998, an OIG criminal investigation found that plant officials in Florida had tampered with FSIS samples left for the shipping agent. This was done to disguise intentional product alteration of excessive fat and water in the products. Also, the plant officials added

[17] FSIS Directive 10210.1.

sanitizer to meat samples to eliminate microbial contamination. After the tampering was discovered, several million pounds of meat products suspected of being contaminated with *E. coli* were recalled and destroyed.

Our review also found that the FSIS refrigerators at two plants, used to freeze and store FSIS samples, were not locked while inspectors were not in the room. The IIC at plant C had a lock installed on the refrigerator during our visit. (Plant personnel had access to the refrigerators when the inspection personnel were temporarily gone.) Also, carcasses selected for sampling were accessible to plant personnel while hanging in the freezer at one slaughter plant. Consequently, samples were not secured prior to shipment to the labs for analysis.

FSIS relies on their sampling program to monitor and assess plant conditions to ensure that safe and wholesome products reach consumers. However, the integrity of the sampling program was compromised because inspectors did not maintain custody of samples prior to their receipt by the shipping agent.

RECOMMENDATION NO. 8

Improve controls by issuing instructions for securing FSIS test samples until the samples are in the possession of the shipping agent and review security to ensure that instructions are being followed.

Agency Response

In its May 18, 2000, response to the draft report, FSIS stated:

> *FSIS has undertaken an effort to improve sample security. Currently, FSIS Directive 7355.1 outlines procedures for sample security. The FSIS laboratories are revising Directive 7355.1 to reflect a more fail-safe procedure, which is estimated to be completed by September 30, 2000. This will require developing new forms, educating laboratory personnel, and training inspectors.*

OIG Position

To achieve a management decision for this recommendation, we need the revised FSIS Directive 7355.1 showing the new requirements for sample security.

FINDING NO. 7

CONTROLS OVER FSIS PATHOGEN TESTING NEED IMPROVEMENT

FSIS needs to improve its monitoring of the *Salmonella* testing series and ensure that testing results are communicated to FSIS field inspectors. FSIS Technical Service Center officials were not always aware that field inspectors had stopped the *Salmonella* testing series before completion and that other required tests were not being performed. In addition, field office inspectors did not always receive test results for samples submitted. Consequently, FSIS inspectors did not know if the pathogen-testing program had revealed indications of problems in the plants which required appropriate monitoring actions to ensure that adverse conditions were eliminated.

FSIS directives[18] provide for a directed sampling program and a *Salmonella* testing series for establishments receiving inspection services. FSIS depends on its testing programs to assess a plant's compliance with established standards and to identify harmful pathogens. The FSIS technical service center is responsible for monitoring testing programs and providing inspectors testing results. FSIS' testing programs were designed to provide inspectors with a tool for monitoring to ensure that establishments complied with established standards.

A. Incomplete *Salmonella* Testing Series

At 2 of the 15 plants we visited, the *Salmonella* testing series were incomplete. FSIS field office inspectors thought the tests were completed when in fact several tests remained in the series. Inspectors stopped submitting samples when they ran out of testing materials provided instead of receiving notification from the technical service center to stop testing. The IIC stated that they were unaware the testing series was incomplete because test results were not routinely provided to the field office. In addition, the FSIS technical service center official responsible for monitoring the testing series was unaware that the inspectors had stopped testing and assumed tests were ongoing because he had not notified the IIC to stop testing. *Salmonella* testing was resumed after we brought this to the district's attention. Without our intervention, FSIS had no assurance that the plants complied with established *Salmonella* standards.

[18] FSIS Directives 10,010 and 10,240.

At one plant, we found that the IIC did not obtain samples for each day's production during the *Salmonella* testing series. The IIC excluded Saturday production because the shipping agent did not provide weekend service. The IIC was unaware that a valid sample could be taken if the selected carcass was held until the following Monday for testing. As a result, not all production was subject to random testing during the *Salmonella* series.

We also found that FSIS had not initiated a *Salmonella* testing series in a timely manner when plants entered the HACCP program. We found that FSIS had not begun its *Salmonella* testing series for two plants until 6 months had passed after the first plant implemented HACCP and until 8 months had passed after the second plant had entered the program. FSIS' *Salmonella* testing series does not specify when *Salmonella* testing should begin after a plant enters the HACCP program. Without testing, FSIS has no assurance that the plants' pathogen reduction programs were effective.

B. Production Not Included in the Directed Testing Program

FSIS' directed testing program did not ensure regular testing for establishments. The IIC at plant D had not been directed to sample for *Listeria* or *Salmonella* in over 2 years because the sampling frame form (list of products subject to the directed testing program) was incorrectly completed. The IIC did not believe that the sampling frame form contained any of the products produced at the plant, even though the sampling frame form included processed meats that were produced at the establishment. Without directed testing of the establishment's products, there is no assurance that products had not been contaminated or adulterated.

We also found that the directed sampling requests were for specific timeframes and were not linked to the times that products were produced. At plant E, the IIC did not sample raw pork sausages that were only produced on selected Fridays. Thus, seasonal or limited production-run products would not be tested unless samples were requested during production. FSIS' sampling frame form does not allow inspectors to identify seasonal products or those products with infrequent production schedules. Thus, there is no assurance that all products will be subject to testing under FSIS directed testing program.

We believe that inspectors lose a valuable tool to assess a plant's operations when testing series are incomplete, when products are not included in the directed testing program, and when test results are not communicated. FSIS field office inspectors also lose the opportunity to increase monitoring of identified problem areas. Failure to perform direct testing and complete *Salmonella* testing series increases the possibility of contaminated or adulterated product entering the market place.

RECOMMENDATION NO. 9

Implement management controls, which would include:

a. timely providing field office inspectors all microbe testing results,

b. instructions to FSIS field offices to continue *Salmonella* testing each production day, until notified by the technical service center to stop,

c. procedures to notify the district office if a field office stops submitting *Salmonella* samples prior to the completion of a testing series, and

d. procedures to ensure that seasonal and products with irregular production schedules are tested in the direct testing program.

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Agency Response

In its May 18, 2000, response to the draft report, FSIS stated:

> *With regard to recommendation 9 (a) FSIS currently uses the Biological Information Transfer E-mail System as outlined in Notice 25-99 (attachment 7) to provide timely notification to field offices of testing results. The laboratories send electronic messages to District Offices informing them of laboratory results (positive and negative). They immediately contact District Offices to notify them of potential and confirmed positive results. They also send e-mail laboratory results, with the exception of Salmonella results, to plants that have provided e-mail addresses. FSIS shares results of Salmonella testing only when the sample set is complete. In addition, FSIS is also initiating a system*

that will allow Circuit Supervisors and in-plant inspectors to obtain test results by accessing on-line electronic folders.

In response to recommendation 9 (b), (c) and (d), current procedures require FSIS in-plant personnel to continue Salmonella testing each production day until notified by the TSC to stop. FSIS acknowledges, that in some cases, inspectors did not understand that some of the samples they had submitted to the laboratory were discarded; therefore, they stopped testing prematurely. FSIS has instituted a non-responders report (attachment 8) that is sent from Headquarters monthly using the Pathogen Reduction Enforcement Program to the District Office. The report lists by district all plants that have not submitted a Salmonella sample or a reason for not submitting the sample in the last 30 days. This allows the District Office to investigate and correct the problem. Also, some inspectors reported that they exhausted their supply of sample forms, and did not know how to request additional materials. Information about how to request additional materials was included in HACCP training and in FSIS Directive 10,230.5 (attachment 9). There are also experts at the TSC to answer inspector questions. Finally, if the plant has entered the third Salmonella sample set, and they fail the sampling is discontinued and inspectors follow instructions in FSIS Directive 10,011.1 (attachment 10).

FSIS expects to issue a Notice to District Managers and Circuit Supervisors related to Salmonella performance standard testing status reports. The reports relate to the Pathogen Reduction Enforcement Program (PREP), an automated scheduling system to be used in the management of Salmonella performance standard testing. The PREP system will assist in the day-to-day scheduling, tracking, and reporting of Salmonella sample sets. The Notice is expected to be finalized by August 2000.

OIG Position

To achieve a management decision for this recommendation, we need specific details along with completion timeframes, of the system being initiated for inspectors to access test results in electronic folders. FSIS also need to address part (d) of the recommendation regarding the testing of seasonal products in the directed sampling program.

FINDING NO. 8

FSIS DOES NOT VERIFY PLANT SAMPLING PROTOCOLS FOR REQUIRED MICROBIAL TESTING

FSIS inspectors did not review plant microbial testing plans for required generic *E. coli* testing to ensure the sampling protocols were based on scientific standards and that the microbial testing was reliable. Current procedures do not require FSIS approval of plant microbial testing protocols. In addition, inspectors concentrate their review efforts on plant generic *E. coli* testing results when monitoring tasks are assigned and do not review the testing protocol. As a result, there was reduced assurance that required procedures designed to provide an indication of overall plant sanitary conditions accurately reflected conditions in the plant and identified cases where corrective action was needed.

Regulations require that pork and beef slaughter plants regularly test for generic *E. coli* (*Escherichia coli*-Biotype 1) and that the plants have written procedures for specimen collection[19]. The written procedures must identify employees designated to collect samples, the location(s) from which the samples are taken, how sampling randomness is achieved, and how sample integrity is maintained. The regulations further require that the procedures and test results be available for FSIS review. (Note: FSIS officials do not have access to test results plants perform that are not required by regulations. See Finding No. 9.) If a plant has more positive *E. coli* test results than allowed in the regulations, FSIS considers the failure to meet the standard as an indication the plant may not be maintaining process controls sufficient to prevent fecal contamination and may take further action to ensure the plant is complying with all provisions of the law.

FSIS assigns inspectors daily tasks to monitor the sanitary conditions of a plant. These tasks, in most cases, are comprised of several steps and/or areas to be reviewed. Inspectors are routinely assigned an *E. coli* testing review, task 05A01. This task requires an inspector to ensure that plants have (1) documented a written sampling protocol, (2) collected the required samples, and (3) recorded the test results on a control chart. FSIS inspectors informed us that when this task is assigned, they only review the last 13 tests for a failure and ensure that the plant implemented an appropriate corrective action.

We visited seven pork or beef slaughter plants and found the following problems with the sampling protocols and plant testing procedures at four of the plants.

[19] 9 CFR § 310.25 Contamination with microorganisms; pathogen reduction performance standards.

- Plant I was not following the written sampling procedures in that samples were not taken during every hour of production.

- Plant A had not developed any written sampling protocols for generic *E. coli*.

- The written protocols at Plants B, I, and K did not include all required information, such as location where samples were taken or how randomness was achieved.

Plant officials attributed the problems noted to a misunderstanding of the requirements in the regulations or to inaccurate documentation of the procedures followed. FSIS inspectors stated that they only reviewed the generic *E. coli* testing results and did not approve the plants' microbial testing protocols.

We concluded that management controls could be improved if FSIS required inspectors to review and approve a plant pathogen sampling protocol for all required testing.

RECOMMENDATION NO. 10

Implement procedures that require inspectors to review and approve plant's sampling protocols for generic *E. coli* testing to ensure they are complete and being followed.

Agency Response

In its May 18, 2000, response to the draft report, FSIS stated:

> *FSIS agrees that improvements can be made regarding the generic E. coli testing programs operated by the establishments and is planning a number of activities to assess the adequacy of the establishment's procedures as required by 9 CFR 310.24 and 381.94. During FY 2001 FSIS expects to begin a more complete review of HACCP implementation, which may include instructions, related to generic E. coli. FSIS expects to issue updated instructions before the second quarter of FY 2001.*

OIG Position

To achieve a management decision for this recommendation, we need a description of how the recommendation will be implemented and a timeframe for implementation.

CHAPTER 3	FSIS NEEDS TO DEFINE ITS OVERSIGHT ROLE IN THE HACCP SYSTEM AND HOLD PLANTS ACCOUNTABLE FOR NONCOMPLIANCE

As has been noted previously in this report, FSIS is uncertain of its authorities under the HACCP system and is reluctant to challenge plants that have taken measures to limit Federal oversight. We concluded that FSIS needed to define its oversight role in HACCP and ensure that industry understands the nature of its presence: to ensure that HACCP is operating as intended and that the expectations of HACCP—sanitary environment, identification and elimination of harmful bacteria on food products—are met.

To fully define its oversight role, FSIS needs to grant IIC the authority to require changes to SSOP when those procedures are inadequate, and it needs to provide guidance to IIC's when they confront plants with a history of repetitive critical deficiencies. Plant inspectors are currently unsure when to declare a plant's corrective actions unworkable. Some plants have received numerous notices of noncompliance for the same deficiency, but the inspectors had no understanding of what number, frequency, or nature of deficiencies would constitute a breakdown in the system.

FSIS procedures need to be expanded to include requirements for returned products and microbial test reporting. (See also Finding No. 6.) Plant inspectors are not always aware when returned products enter the plants and do not know how the plants dispose of them. They are also unaware of the results of a plant's internal microbial testing. FSIS instructions only require plants to provide FSIS the results of last 13 generic *E. coli* tests. When plants test for other pathogens, they are not obligated to inform FSIS of their test results and in fact do not allow FSIS access to those results. In one case, FSIS was unaware of a plant that had been testing for *Listeria* on its own initiative, and had positive tests for generic *Listeria* in its environment and *LM* in its products. FSIS did not discover the situation until it received an anonymous complaint.

Overall, FSIS could improve its oversight by performing internal reviews to evaluate the effectiveness of HACCP, and by monitoring the tasks assigned to field personnel. FSIS has not performed an internal review in the six districts we visited, and its system of tracking task

assignments could be improved to better help management monitor field level activities.

FINDING NO. 9

FSIS NEEDS ACCESS TO PLANTS' MICROBIAL TEST RESULTS

The current FSIS procedures do not require plants to provide internal microbial testing results to inspectors or require plant officials to notify inspectors when environmental testing reveals the presence or likelihood of a harmful pathogen. FSIS officials informed us that plants are not required to provide any testing results unless such tests are included in the HACCP plan or unless the plant identified an adulterated product. During our review, plant officials denied OIG access to their optional pathogen testing program records even though such testing was included in their HACCP plan. The FSIS national office intervened and the records were provided. Plants have also refused FSIS inspectors' access to records of any food safety tests not mentioned as a CCP in their HACCP plans or as a SSOP. In turn, field office personnel are not required to review plant testing results. As a result, FSIS is not aware of all food safety data generated by the plant or the overall food safety performance of the plant. It is also not aware of other historical non-HACCP foodborne hazards at the plant.

FSIS instructions[20] require establishments to maintain daily records sufficient to document the implementation and monitoring of the SSOP's and HACCP plan and any corrective actions taken. Although records required by these instructions are to be maintained and made available to FSIS upon request, FSIS' instructions do not require establishments to give inspectors access to optional pathogen test results and to products or environmental tests not specifically identified in HACCP or SSOP documents.

FSIS issues the Grant of Inspection to all plants that apply contingent on their agreement to conform to inspection regulations, and are in compliance during an FSIS survey of the establishment. The Grant of Inspection does not address FSIS authorities such as access to plant records, nor does it address penalties for noncompliance. Once attained, the Grant of Inspection is not required to be renewed and remains in place unless FSIS takes enforcement action. In our prior reports, we recommended that FSIS revise the Grant of Inspection to read and function more like a contract by placing the responsibility on

[20] 9 CFR § 416.16 and 417.2.

plant management to comply with regulations and to ensure the quality of plant operations.

None of the 15 plants reviewed had included microbial testing as a CCP, and only two plants cited microbial testing in their HACCP plans. We found that FSIS inspectors had only reviewed the plants' required *E. coli* testing records and believed that they did not have the authority to review any other plant testing records. Plant officials, in some instances, denied both OIG and FSIS inspectors access to test results even though the testing was cited in the HACCP plan. For example, even though plant C's HACCP plan cited microbial testing, corporate officials initially denied FSIS' request to review the testing records. Inspector General auditors had to leave the plant without reviewing these records. Only after negations with FSIS national office personnel did the corporate officials provide access. Our subsequent review of the plant's environmental testing records revealed the presence of *LM* in production facilities and equipment. Consumption of food contaminated with *LM* can cause listeriosis, a potentially fatal disease.

During 1999, 20 of 142 (14 percent), of the corporate lab testing forms identified the presumptive positive presence of *LM* in 28 environmental samples, 15 of which were taken from rooms with ready-to-eat products. In addition, we determined that four rooms in the plant had tested positive for *LM* two or more times, as shown on the following table. Further, plant officials stated that they did not test ready-to-eat products for the presence of *Listeria*, even after this pathogen was detected in production rooms.

Table 4: Positive *Listeria* Tests At Plant C

February Through June 1999	
Sample Site	*Number of Positive Tests*
Spiral Ham Cutting Floor	4
Ready-to-eat cooler floor	3
Hot Dog Casing peeler vacuum tube	2
Ready-to-eat Tree Drop Floor	2
Other Ready-to-eat Rooms	4
Other Areas in the Plant	13
Total	28

The IIC was unaware of the presence of *LM* in the plant until after our review. Also, the IIC and other FSIS officials were unaware that they had the authority to require the plant to share its test results because the HACCP plan included pathogen testing procedures. Consequently, the IIC did not monitor the plant's corrective actions taken or submit ready-to-eat product samples to USDA labs to ensure the products were pathogen free.

Even when plants identified the presence of generic microbes that are strong indicators of the presence of pathogens, they did not always conduct further testing. We confirmed with a national private laboratory that a *LM* confirmation test cost about $2 more than a presumptive positive *LM* test used at plant C, or a total of $28 for an additional test. At plant H, we reviewed microbial testing records voluntarily provided to us. We found that the plant had a long history of test results that suggested the presence of the general *Listeria* species. Tests showed suspect positive results from samples taken from the floor, product contact surfaces, and, in two instances, cooked product (see table 7). According to plant management, they did not perform testing to specifically determine the presence of *LM*. FSIS' current procedures do not require plants to confirm the presence of *LM*. Without such confirmation, the plants are not required to advise FSIS of positive *Listeria* test results, or product potentially adulterated with *LM*.

Table 5: Positive *Listeria* Tests At Plant H

January through June 1999		
Sample Site	*Number of Positive Tests*	*Total Number of Tests*
Work Floor	79	174
Product Contact Surfaces - Equipment	20	286

According to the IIC and other FSIS officials, FSIS did not have the authority to require the plant to share its test results if the testing was not specifically required by the regulations or included as in the HACCP plan. The IIC was not aware of the extent of suspect *Listeria* incidents and became aware of the presence of *Listeria* in the plant only after questioning plant employees as to why some finished product was held in the freezer for a number of days. He was then informally advised that the product was suspected of containing *Listeria*. The plant took action to dispose of the product after our visit.

We issued management alerts for these two plants to FSIS. FSIS advised it had issued FSIS Notice 23-99, dated August 3, 1999, which required all plants to perform a *LM* reassessment and instructed inspectors to determine if the plants reassessed their HACCP plans. However, the notice did not require the plants to maintain written documentation to support their reassessments, or require enhanced pathogen testing when adverse conditions were identified. A HACCP plan was considered reassessed when plant officials signed and dated the plan after the issuance of the FSIS Notice 23-99.

In 1998, a plant (not one of the 15 plants visited) produced *LM*-adulterated products that reached consumers and caused illnesses and deaths. The plant's environmental pathogen testing program revealed the presence of *Listeria* from product contact surfaces on the retail frank line from July to November 1998, when the plant discontinued pathogen testing. Company officials did not notify FSIS that the plant's environmental tests had detected *Listeria* on product contact surfaces or perform additional testing to confirm the presence of *LM*. After the CDC started an investigation, the company voluntarily recalled about 35 million pounds of meat. Had the IIC been informed of the plant's environmental testing results, FSIS could have increased its monitoring efforts through unscheduled monitoring tasks to help the plant eliminate its *Listeria* problem.

In 1999, at another plant (not one of the 15 plants visited), an anonymous copy of a presumptive positive *Listeria* test result was left in an IIC's mailbox. The IIC was unaware of a *Listeria* problem at the plant, and after consulting with the district office was instructed to perform directed testing of plant products for *Listeria*. FSIS' testing found the presence of *LM* in the plant's products. An investigation found that the plant had performed general *Listeria* testing for both environment and products as part of its sanitation program, even though this testing was not required by the Government. These tests demonstrated a history of generic *Listeria* in the plant, and in one instance the presence of *LM* in plant products. The IIC was not notified of the unwholesome product, even though such a notification was required. As a result, 4 to 5 million pounds of hot dogs had to be recalled because of this incident. If the IIC had access to the plant's optional testing records, FSIS could have worked with the plant to eliminate the *Listeria* problem before contaminated products reached the consumers.

Our review also disclosed that plants are not compelled to report when required *E. coli* test results exceed Federal standards. Our review of *E. coli* testing records at 11 slaughter facilities found that 9 plants had

at least one *E. coli* test failure in 1999. We found that FSIS inspectors had access to and reviewed the testing records for only the most recent 13 test results when an inspection task was assigned to review the documented corrective action. When inspectors are not informed immediately of *E. coli* failures, they cannot monitor the plant's corrective actions in progress. Consequently, inspectors do not have any assurances that the corrective actions are in fact implemented.

We concluded that, in order to improve the effectiveness of HACCP and FSIS monitoring of plant operations, inspectors need access to all plant records of pathogen testing and timely notification by plant management of all adverse testing results.

RECOMMENDATION NO. 11

Expand the language contained in the Grant of Inspection agreement to include the requirements and responsibilities required of the plant under the HACCP program and FSIS' authority, oversight, and access to information regarding the plant's operation. Use the Grant of Inspection as a contract, or enforceable agreement between the Government and the establishment signed by all parties and subject to review and renewal.

Agency Response

In its May 18, 2000, response to the draft report, FSIS stated: "FSIS has been investigating the regulatory requirements associated with the Grant of Inspection and, if feasible, will pursue options to amend the Grant of Inspection to make clear the scope of FSIS' regulatory authority over plant pathogen testing. A decision will be reached by June 2001."

OIG Position

To reach management decision for this recommendation, we need more detailed information on how the recommendation will be implemented. Departmental Regulation No. 1720-1 requires that management decisions be reached within 6 months.

RECOMMENDATION NO. 12

Require plants to include all pathogen testing performed by the plants in their HACCP plans, to retain test results, and to notify the IIC of adverse microbial test results.

Agency Response

In its May 18, 2000, response to the draft report, FSIS stated:

> *The PR/HACCP regulation does not require plants to include pathogen testing in their HACCP plans. The OIG's concern is that plants are not notifying the IIC of adverse microbial test results and how the plant reacts to the adverse test results. As discussed in Agency responses to Recommendations No. 5 and 11, based on current regulations, plants must take corrective actions when such findings occur. FSIS will verify corrective actions taken and documented by the plant as well as the reassessment and modification of the HACCP plan when adverse microbial test results occur. FSIS is taking steps to make sure that in-plant inspection personnel understand this fully through workshops conducted at the National Supervisory Conferences and through work unit meetings.*

OIG Position

The response did not address what will be done to require that plants include all pathogen testing in their HACCP plan nor explain in detail how inspectors will be informed of test results. To reach management decisions for this recommendation, we need a description of how the recommendation will be implemented and timeframe for implementation.

RECOMMENDATION NO. 13

Instruct IIC's to assess the adequacy of the plants' corrective actions to eliminate harmful pathogens and to monitor those actions.

Agency Response

In its May 18, 2000, response to the draft report, FSIS stated:

> *FSIS agrees to reinforce the requirement to assess the adequacy of plant's corrective actions and to monitor these actions. Although such instructions were provided during HACCP training, FSIS has accumulated information during HACCP implementation that can be used to create case studies that can be shared to reinforce such concepts. Case studies are being used at the National Supervisory Conference, and will be covered at local work unit meetings*

and through policy issuances. The TSC continues to be available as a resource to help answer inspectors' questions about the adequacy of plants' corrective actions.

OIG Position

We accept the management decision for this recommendation.

FINDING NO. 10

FSIS NEEDS TO PERFORM INTERNAL REVIEWS TO EVALUATE HOW WELL HACCP IS OPERATING

FSIS had not established an effective internal review process to provide assurance that plant HACCP, SSOP, and microbial testing programs are operating as intended. In the six districts we reviewed, district office personnel had not conducted any internal reviews to ensure that plants operated HACCP and other programs effectively and fully complied with regulatory requirements. In the absence of district and higher-level reviews, inspectors at each plant independently determined if the plant's HACCP plan was effective in producing a safe product. The FSIS officials attributed the lack of reviews of HACCP to a lack of resources. Without independent internal control reviews, FSIS management has reduced assurance that adequate controls are in place and functioning over HACCP as it is being implemented.

The Federal Manager's Financial Integrity Act and Office of Management and Budget Circular No. A-123 requires each agency to evaluate the adequacy of its management controls.

Although the agency published the results of a study[21] covering the initial implementation of HACCP, no additional studies have been performed to determine if the recommended corrective actions were implemented and effective at the plant level. FSIS National and district office officials told us that the agency did not have the funding for internal reviews in fiscal year (FY) 1999, but that the funding was now available and an internal review program was in the planning stage for FY 2000. Further, district office officials stated that they were working to help the very small plants prepare for the implementation of HACCP, and this effort was tying up resources.

[21] Evaluation of Inspection Activities during Phase One of HACCP Implementation (July 1998).

Currently HACCP has been implemented in approximately 2,600 (300 large and 2,300 small) plants and by January 2000 will be implemented in all (approximately 6,000) slaughter and processing plants that operate under Federal inspection. Thus, the need for internal reviews is paramount. In addition, our audit disclosed numerous instances in which HACCP, SSOP, and testing programs were not working as intended; this also suggests that internal reviews are needed immediately.

RECOMMENDATION NO. 14

Develop and implement an internal review system to provide assurances that plant level HACCP, SSOP, and microbial testing programs are operating as intended.

Agency Response

In its May 18, 2000, response to the draft report, FSIS stated:

> *As mentioned in response to Recommendation No. 1, FSIS is implementing the IDV review. The review is conducted by FSIS experts from the Office of Policy Program Development and Evaluation, Office of Public Health and Science, Office of Field Operations of a plant's SSOPs and HACCP system, including Salmonella and E. coli testing. FSIS obtained input from its Advisory Committee on Meat and Poultry Inspection during the development of the IDV protocol. It is a comprehensive review.*

OIG Position

Since FSIS has implemented In-Depth Verification (IDV) Review, we accept the management decision for this recommendation.

FINDING NO. 11

FSIS OVERSIGHT OF SSOP NEEDS IMPROVING

FSIS needs to improve its verification and oversight of SSOP to ensure that plants implement effective controls to prevent product contamination or adulteration. FSIS inspectors had not verified the adequacy of the SSOP's to ensure the plans included (1) plant cleaning schedules, (2) sanitary handling of products, and (3) identification of plant employees responsible for implementing and maintaining specific

procedures.[22] Consequently, there is reduced assurance that SSOP's implemented by plants were effective in ensuring that food safety was not compromised.

A sanitary environment is a basic prerequisite for preparing safe foods. Following established and effective SSOP's is the most basic way to ensure that a safe product is produced. FSIS inspectors are required to verify the adequacy and effectiveness of the SSOP but are not required to approve them. Thus, inspectors are not required to make changes or modifications to SSOP plans that would enhance the overall sanitation at a plant. FSIS' noncompliance monitoring records have demonstrated that many SSOP plans were in fact inadequate because repetitive conditions were never corrected (see Finding No. 14). We reviewed SSOP's from our sample plants and found that 6 of the 15 plans (40 percent) were deficient. We found the following deficiencies:

- SSOP's for plants A and B did not include cleaning schedules documenting the frequency of plant sanitation activities. Thus, we could not determine if the plant had performed the required sanitation procedures.

- Plant D did not develop effective corrective actions in its SSOP to eliminate repetitive deficiencies during pre-operational cleaning. We found that the same, or similar, sanitary conditions were documented in the plant's daily SSOP records.

- Plant M did not develop SSOP's for the sanitary handling of plastic product totes during unloading, for preventing condensation from dripping onto uncovered products, and for cleaning worker boots. We observed these conditions during our walk- through of the plant.

- Plant L's SSOP did not include procedures for addressing sanitation in peripheral areas of the plant, and it did not identify the plant employees' responsible for implementing and maintaining specific procedures. We observed plant employees, who worked in cooking areas, entering and returning from raw product and peripheral areas of the plant without changing their frock or gloves. This increased the potential for cross-contamination.

[22] 9 CFR § 416.12(d) and 416.17.

- The SSOP for plant J did not identify the plant employees responsible for implementing and maintaining the sanitation procedures.

We concluded that for FSIS to effectively perform its oversight role, the IIC needs the authority to require changes to SSOP plans which do not contain effective controls to prevent product contamination or adulteration.

RECOMMENDATION NO. 15

Ensure that IIC's routinely evaluate the effectiveness of SSOP's and require changes and modifications to plants' SSOP plans when needed.

Agency Response

In its May 18, 2000, response to the draft report, FSIS stated:

> *Under current regulations, when direct product contamination occurs, the establishment is responsible for implementing and documenting corrective action to prevent it from occurring in the future, and must prevent it from entering commerce (9 CFR 416.15). Inspection personnel have the appropriate authority to address this in case of noncompliance by the plant. In addition, 9 CFR 416.14 requires plants to routinely evaluate the effectiveness of the SSOP's. This information was covered during SSOP training, HACCP training and is addressed FSIS Directive 5000.1 In addition, some of the examples cited in this report indicate that there may be some misunderstanding on the part of inspection personnel about the newly implemented Sanitation Performance Standard regulations. FSIS held district meetings to clarify inspection personnel's responsibilities prior to issuing this regulation. FSIS agrees to reinforce through training and better communication the FSIS inspectors' authorities in relation to the Sanitation Performance Standard regulation and SSOP's through the National Supervisory Conferences and work unit meetings. It will also clarify how inspection personnel should respond in cases of repetitive noncompliance.*

OIG Position

To achieve a management decision for this recommendation, we need specific details along with completion timeframes as to your clarification of how inspection personnel will respond in cases of repetitive noncompliance.

FINDING NO. 12

FSIS PROCEDURES FOR RETURNED PRODUCTS ARE INADEQUATE

Oversight of returned products needs improvement (i.e., products that have entered commercial channels and have been returned to the plant for various reasons, such as, being rejected by the buyer due to damage in shipment, wrong quantity, etc.). FSIS does not require plant HACCP plans to include procedures for returned products, although all returned products require reinspection prior to entering the plant.[23] As a result, returned products could be reworked (sent back through the production line) and placed back into the food distribution system without FSIS having any knowledge of the returned products.

Our review disclosed that inspectors were not always notified when returned products entered the plant and were not informed of the disposition of these products. We found that HACCP plans for the 15 plants we visited did not include procedures for returned products.

At plant G, the returned product records could not account for the disposition of 56 percent (39 of 69 return forms) of the products returned. Inspectors informed us that they were not certain if they had re-inspected the returns in question or how the plant had used the products. Inspectors stated that the plant generally informed FSIS when goods were returned; however, under HACCP, the plant is no longer required to inform FSIS when goods are returned.

We also found that 3 of the 15 plants (H, K, and O) did not have procedures to account for returned goods or records of the products' disposition. Because no records were kept for returned products, we could not evaluate whether FSIS had re-inspected the returned goods or how the plants had disposed of the products.

[23] 9 CFR § 318.2 and 318.3.

In order to ensure consumer protection, FSIS needs to require HACCP plans to include procedures to account for returned products to ensure that all products are re-inspected or disposed of properly.

RECOMMENDATION NO. 16	Establish procedures that require that the returned product process be included in the hazard analysis and HACCP plan.

Agency Response

In its May 18, 2000, response to the draft report, FSIS stated:

> *FSIS agrees that establishments receiving and handling returned products should be considering the returned product process when conducting its hazard analysis and when developing its HACCP plan. The PR/HACCP regulation does not preclude this (9 CFR 417.2). The fact that plants may consider the returned product process while conducting its hazard analysis and when developing its HACCP plan doesn't mean that it will be included in the plant's HACCP plan. However, if inspection personnel have questions about the return product process not being included in the HACCP plan, they have the authority to question the plant's rationale and to request documentation indicating why the returned product process (or any other process) is not included in the plant's HACCP plan. FSIS disagrees that it needs to, "establish procedures that require," the returned product process be included in the hazard analysis and HACCP plan, but it agrees to reinforce through training and improved communication with inspection personnel the regulatory requirements and responsibilities of the establishment with regard to controlling the returned product. FSIS will also do what is necessary to ensure that official establishments are cognizant of these requirements and responsibilities and of the consequences that flow from failure to meet this.*

OIG Position

Our audit raised serious questions concerning product being returned without inspectors not always being notified or the disposition of the product, thus we continue to believe that returned product process should be addressed in the hazard analysis and HACCP plan. We are open to any alternative that FSIS may have to improve and strengthen the returned product process. However, to

reach management decision, we need a description of how the recommendation will be implemented and a timeframe for implementation.

RECOMMENDATION NO. 17

Establish procedures for inspectors that include their oversight responsibilities from the point of product return to product distribution.

Agency Response

In its May 18, 2000, response to the draft report, FSIS stated:

> *According to 9 CFR 318.1, the inspector is required to reinspect all returned products. The regulations also indicate that if at any point, returned products are suspected of being adulterated, appropriate actions will be taken. FSIS disagrees that additional procedures need to be established with regard to inspection oversight responsibilities. However, FSIS agrees to reinforce with inspection personnel their responsibilities related to returned product.*

OIG Position

We agree that reinforcing inspection personnel responsibilities related to returned products is an acceptable management decision for this recommendation. However, to reach management decision, we need to know how and when this action will be performed.

FINDING NO. 13

FSIS DISTRICT OFFICE PERSONNEL NEED TO MAINTAIN ESTABLISHMENT/SHIFT PROCEDURE PLAN

FSIS District Office personnel need to maintain, modify and update establishment/ shift plans on a continuous basis to ensure that applicable scheduled tasks are being performed. According to FSIS' Performance Based Inspection System (PBIS) computerized reports, about 17 percent of scheduled tasks were not being done by inspectors at the plants. This occurred because FSIS district office officials did not update the scheduled tasks when permanent changes occurred in the plants' operations. In addition, a lack of coding or written explanation in the report made it impossible to differentiate between when a task that was no longer valid at the plant and a task that could have been

done but was not. As a result, inspectors may not be performing tasks that carry the greatest public health significance or threat.

Inspection personnel are to develop and maintain an establishment/ shift procedure plan that reflects the current operations for shifts in an establishment. Personnel should review the form for each establishment at least annually to ensure that there is a plan for every shift and that the plan accurately reflects the operations that the establishment currently conducts during the shift.[24] District office personnel need to update scheduled tasks on a continuous basis to ensure that plant-specific tasks are being performed.

Inspection personnel complete the Establishment/Shift Inspection Procedure Worksheet (Form 5400-5) to generate daily task schedules to be performed at plants subject to HACCP system regulations. The worksheet reflects the current operations of the plant. After completing the worksheets, inspection personnel submit them to their district office where personnel enter all identified tasks into the PBIS. The PBIS schedules the in-plant tasks to be performed by inspection personnel in the plant each day on a Procedure Schedule (Form 5400-2). At four of the six district offices we visited, we found the following deficiencies in the PBIS schedules:

- **District 20 –** Two of the twenty-eight scheduled tasks assigned to inspectors at plant B were not applicable. These two tasks were for products that were no longer produced at the plant. In addition, 2 of the 33 scheduled tasks assigned to plant A were not applicable. Inspectors at the plant had given prior notice to the district office that the tasks were not applicable; however, district office personnel did not make the revisions.

- **District 25 –** Three of the seventeen scheduled tasks assigned to inspection personnel at plant E were not applicable. We also found that scheduled tasks were documented for only the first shift at plant D, although, the plant operated on two shifts.

- **District 35 –** Four of ten plants reviewed had incorrect tasks assigned based on current plant profile information.

- **District 90** – Three of thirteen plants reviewed had incorrect tasks assigned based on current plant profile information.

[24] FSIS Directive 5400.5 Section IX.

We also found that FSIS should monitor and analyze the reasons inspection tasks are not being performed and address any needed changes. We could not tell whether the inspectors were unable to perform the tasks because they did not have time, because the plant profile was incorrect (generated inappropriate tasks), or because the plant's operations simply made the task not applicable for that shift. FSIS instructions only require that the inspector circle "not performed" on the form. The instructions do not require the inspector to explain why the task was not performed. Inspectors advised that if the plant did not operate a shift, then they would code all tasks for that shift as "not performed." They noted that the form 5400-2 could include codes such as ones that indicated the plant was not operating or was not performing the process to be reviewed. We found the following at the plants we visited.

- **Plant A –** At plant A, 35 of 207 (17 percent) of scheduled monitoring tasks for February 1999 were not performed. The IIC attributed this to staff following up on noncompliance records, being unavailable due to vacation or illness, or engaging in time-consuming export duties.

- **Plant B –** At plant B, 13 of 91 (14 percent) scheduled monitoring tasks for February 1999 were not performed. Inspectors attributed this to staff shortages due to vacation, sickness, etc.

- **Plant C –** At plant C, 45 of 258 (17 percent) scheduled monitoring tasks for February 1999 were not performed. The IIC attributed this to staff shortages due to vacations, sickness, etc.

- **Plant G –** At plant G, 53 of 225 (24 percent) scheduled monitoring tasks for February 1999 were not performed. The IIC attributed this to staff shortages.

RECOMMENDATION NO. 18

Require FSIS district office personnel to monitor and update scheduled tasks on a continuous basis and to establish additional codes or require inspectors to document why tasks are not performed.

Agency Response

In its May 18, 2000, response to the draft report, FSIS stated:

> *FSIS relies on the Inspection Systems Procedure Guide and the Performance Based Inspection System (PBIS) (see FSIS Directive 5400.5 and Module 6 of HACCP training) to schedule and record the performance of inspection procedures. In-plant inspectors report the procedures they perform to the District Offices. District Offices enter the procedures performed in the PBIS. In the event that a procedure no longer applies to an establishment, in-plant inspection personnel are instructed (in FSIS Directive 5400.5) to make appropriate modifications to PBIS. In-plant inspectors are authorized to make changes to scheduled procedures based on plant conditions and their judgment (i.e., noncompliance with a scheduled 01 procedure triggers the inspector to perform an unscheduled 02 procedure, which would impact the performance of other scheduled procedures for that day). FSIS does not agree that it is necessary or beneficial to establish codes to require inspectors to document why tasks are not performed. Circuit Supervisors are responsible for reviewing PBIS reports on a regular basis and working with inspectors if they have questions about why procedures are not performed. FSIS is taking steps to reinforce the usefulness of PBIS data with Circuit Supervisors through circuit meetings at the District Offices and through the National Supervisory Conferences. The TSC is also summarizing PBIS data graphically on a national basis to indicate areas where, based on further investigation, correlation on the application of PBIS may be needed.*

OIG Position

While FSIS does have the Performance Based Inspection System (PBIS) that they rely on to schedule and record the performance of inspection procedure, neither the system nor inspection personnel ensures that the assigned scheduled tasks are applicable or determine why tasks were not performed when they are applicable. Our audit disclosed that many applicable plant -specific tasks were not performed because establishment/shift plans were not modified and updated on a continuous basis to reflect the plants current operation. Also, for applicable tasks that were not performed, we could not determine the reason why. We could not determine

whether the inspectors were unable to perform the task because (1) they did not have time, (2) the plant profile was incorrect or (3) the plant's operation made the task not applicable. Because of these issues, we believe that FSIS should document the reason why task are not being performed. Also, FSIS needs to know why tasks are not being performed so they can assess inspectors performance and staffing needs. To reach management decision, we need details and timeframes on how the recommendation will be implemented.

FINDING NO. 14

INADEQUATE RESPONSES TO NONCOMPLIANCE RECORDS

Inspection personnel perform thousands of inspection procedures each day to determine whether plants comply with regulatory requirements. Any identified instances of noncompliance are documented on a Noncompliance Record (NR). The number of NR deficiencies at any particular establishment is not always an indicator as to the safety or wholesomeness of the plant's products or an indicator of an inadequate system. Many NR's are written for regulatory violations that are not related to food safety issues. For example, labeling violations and errors in product weights will result in issuance of an NR but the public health would not be endangered by the noncompliance.

We found FSIS needs to establish specific guidelines for the number of repetitive noncompliance deficiencies that will support a determination that there has been a HACCP or SSOP system failure requiring administrative or enforcement actions. Also, we found that plants did not always promptly respond to NR or take timely corrective actions. During the audit, we found numerous repetitive critical deficiencies with the same cause, where permanent corrective action had not been taken or enforcement actions initiated. This occurred because FSIS has not issued any instructions as to how many and how frequently repetitive deficiencies can occur before corrective actions are deemed inadequate or when enforcement actions should start. In addition, procedures did not require plant management to respond to NR's in a timely manner. As a result, appropriate product control and enforcement measures to protect consumers are not in place and plants are not presenting corrective action plans to eliminate the plant sanitation or process control systems deficiencies.

There are no guidelines for the number, frequency, nature, or circumstances of repetitive critical deficiencies that constitute a breakdown in the sanitation or HACCP systems. An important part of

this determination would be the failure of previously implemented corrective measures by the plant to prevent the recurrence of direct product contamination or adulteration. In plants operating under HACCP, FSIS inspection personnel perform inspection procedures to determine whether plants comply with regulatory requirements. Each time the performance of a procedure results in a finding of noncompliance with these regulatory requirements, inspection personnel document the finding on a Noncompliance Record (FSIS Form 5400.4). These NR's are used to support, document, and notify plants of noncompliance noted in the plant's sanitation and process control systems. We found the following repetitive deficiencies with the same cause where the plant did not take long-term or permanent corrective actions to prevent recurrence of deficiencies.

- **Plant O -** From January 25, 1999, through July 2, 1999, FSIS inspectors at this plant had written 102 NR's, 31 of which (30 percent) had been written because the plant failed to comply with its own zero tolerance for fecal contamination. Also, the plant itself had identified 29 instances of noncompliance on its CCP Monitoring Log For Zero Tolerance. Although the plant took immediate action to correct the problem by rinsing the product, no permanent corrective action was taken. It appears that the plant needed to take additional measures to properly alleviate the problem. FSIS inspectors said they were unaware of any actions to take, thus they continued to allow the plant to take the same corrective action of rinsing the product.

- **Plant C -** Three (9.4 percent) of the thirty-two NR's written by the inspectors at this plant were for repetitive violations. The repetitive violations were for inadequate pre-operational cleaning and corrective actions from prior NR's that were not implemented. We also found that company officials seemed to wait for FSIS inspectors to point out deficiencies before taking corrective actions. FSIS inspectors told us that the plant management attitude was "if the inspector does not spot a problem, then the problem does not exist."

- **Plant A –** Eleven (33 percent) of the thirty-three NR's written by inspectors at this plant were for repetitive violations. Seven of the repetitive violations were for oil and grease on plant equipment that came in contact with meat product. FSIS inspectors stated that this problem had been ongoing for several years and that nothing had been done to correct the problem. The inspectors told us they wanted guidance on the "specific number" of repetitive deficiencies that were needed to

force a corrective action because they were not able to get support from the district office on this issue. District office officials told us that for a violation to be repetitive, it must be on the same piece of equipment and not the same problem on different equipment on different days. Consequently, the plant only performed minimal corrective action to appease the inspectors but did not address the specific cause or eliminate the problem.

- **Plant B –** Seven (20.5 percent) of the thirty-four NR's written by FSIS inspectors at this plant were for repetitive violations. The corrective actions were inadequate to correct the problem. The corrective actions were generally to "counsel the employees" but never to correct the real cause of the problem. Also, from January 1 through July 31, 1999, the plant was opened for work 172 days of which 38 days (22 percent) had at least one zero-tolerance failure. The FSIS technical service center representative stated that the number of zero-tolerance failures was excessive and the corrective measures taken were inadequate.

We also found that FSIS needs to establish timeframes for responding to NR's. When FSIS does not respond to NR's in a timely manner, plants do not promptly document the actions they intend to take to correct noncompliance. FSIS Directive 5400.5 Section IX. A, on NR's does not address timeframes for responding to NR's. However, the directive states that:

> *When an NR is issued, inspection personnel [should] provide plant management with a copy of the NR (as soon as possible, or by the end of the tour of duty) and an opportunity to respond either orally or in writing.*

The directive also states that:

> ** * * until an establishment has brought itself into compliance with the regulatory requirement(s) that resulted in the issuance of the NR, the NR is "open." When plant management returns the NR with their proposed immediate and further planned actions and inspection personnel determined that the actions by the plant are acceptable and have brought the plant into compliance with regulatory requirements that resulted in the issuance of the NR, the NR is then "closed."*

We found the following cases where plants had not promptly responded to NR's during our audit:

- **Plant N -** Seventeen NR's had not been closed at the time of our audit. These NR's had been open from 11 to 131 days. This occurred because inspection personnel did not review the open NR file daily and follow up with plant management on a continuous basis to determine the status of corrective actions on open NR's.
- **Plant B -** Nine NR's were not closed from 8 to 83 days.
- **Plant C -** Fourteen NR's were not closed from 8 to 29 days.
- **Plant G –** Sixteen NR's were not closed from 4 to 60 days.

In our opinion, the procedures for issuing NR's need to be changed in order to provide FSIS management with an enhanced control that can be used to identify potential problem plants requiring enforcement actions. In addition, local plant inspectors need additional guidance on how to prepare NR's, monitor corrective action and evaluate the effectiveness of corrective action on NR's.

RECOMMENDATION NO. 19

Develop and implement progressive enforcement procedures that establish specific parameters for repetitive deficiencies and provide a basis for determining when corrective actions are inadequate and when enforcement actions should be promptly initiated.

Agency Response

In its May 18, 2000, response to the draft report, FSIS stated: "FSIS will develop procedures for repetitive deficiencies by December 2000."

OIG Position

We accept the management decision for this recommendation.

RECOMMENDATION NO. 20

Establish timeframe requirements for responding to NR's and initiating planned corrective actions.

Agency Response

In its May 18, 2000, response to the draft report, FSIS stated:

> *The Noncompliance Record (NR) states that plants must respond immediately when notified by inspection personnel of noncompliance. (Also see FSIS Directive 5400.5 and HACCP training). Plants are also required to initiate planned actions to prevent reoccurrence of the noncompliance. Plants are not required to respond in writing on the NR. They are, however, required, 9 CFR 416.16 and 417.5, to document corrective actions in plant records. FSIS does not find it advisable to establish specific timeframes (i.e., minutes, hours) for a plant to initiate and implement corrective actions because of the nature and variability among plants and production processes. The nature of some corrective actions involve modifications that can be made quickly, while others (e.g., equipment changes) require longer timeframes. This may explain why, as mentioned in the report, some NR's remained open for a period of time. FSIS believes its current regulations appropriately hold plants accountable for initiating and implementing corrective actions. FSIS does not agree to change the procedures for issuing NR's, but it does agree to reinforce with inspection personnel their responsibilities for monitoring and evaluating the effectiveness of corrective actions. This is being done first through the content of the National Supervisory Conferences and then through local work unit meetings.*

OIG Position

While we agree that the length of time to initiate and implement corrective actions for NRs differs based on the nature and variability among plants and production processes, there still needs to be processes in place to determine whether plants' open NRs are due to the length of time it takes to correct deficiencies or due to the need of a description of how the recommendation will be implemented and a timeframe for implementation.

EXHIBIT A – SITES VISITED

DISTRICT NUMBER 20 - MINNEAPOLIS, MINNESOTA

Plant A
Plant B
Plant C

DISTRICT NUMBER 25 - DES MOINES IOWA

Plant D
Plant E
Plant F

DISTRICT NUMBER 30 - LAWRENCE, KANSAS

Plant G
Plant H
Plant I

DISTRICT NUMBER 35 - SPRINGDALE, ARKANSAS

Plant J
Plant K

DISTRICT NUMBER 75 - GREENBELT, MARYLAND

Plant L
Plant M

DISTRICT NUMBER 90 - JACKSON, MISSISSIPPI

Plant N
Plant O

EXHIBIT B – NUMBER OF HACCP PLANS REVIEWED

PLANT	PLANT TYPE	TOTAL HACCP PLANS	HACCP PLANS REVIEWED
A	Hog Slaughter/Processing	1	1
B	Beef Slaughter/Processing	2	2
C	Hog Slaughter/Processing	54	5
D	Processed Meat/Poultry Products	8	8
E	Processed Meat/Poultry Products	3	3
F	Beef Slaughter	1	1
G	Poultry Slaughter/Processing	2	1
H	Processed Meat/Poultry Products	1	1
I	Beef Slaughter/Processing	1	1
J	Poultry Slaughter/Processing	2	2
K	Beef Slaughter/Processing	9	9
L	Hog Slaughter/Processing	20	20
M	Processed Meat/Poultry Products	1	1
N	Poultry Slaughter/Processing	1	1
O	Poultry Slaughter/Processing	1	1
	Total HACCP Plans	**107**	**57**

EXHIBIT C – COMPARISON OF PLANT CCP'S TO FSIS MODEL

An X indicates the plant had a CCP similar to the model. The number in parentheses represents the critical limit temperature (Fahrenheit) of a process requiring heating or cooling.

MODEL HACCP-12, FULLY COOKED, NOT SHELF STABLE

PLANT	CCP 1B	CCP 2B	CCP 3P	CCP 4B	CCP 5B	CCP 6B	CCP 7B	Remarks
C				X(155°)				
D		X(40°)		X(165°)	X(40°)			
E				X(150°)	X(55°)			1/
H				X(148°)	X(50°)			2/
K				X(160°)				

1/ CCP 4B, Cooking - Temperature for poultry was 160 degrees.
2/ CCP 4B, Cooking - Temperature for poultry was 155 degrees.

Explanation of CCP's:

CCP 1B Receiving, Raw Meat
CCP 2B Storage, Cold - Raw Meat
CCP 3P Preparation of Raw Meat - Metal Detection
CCP 4B Cooking - Temperature
CCP 5B Chilling
CCP 6B Portioning (Zero tolerance for *LM*)
CCP 7B Finished Product Storage (cold)

EXHIBIT C – COMPARISON OF PLANT CCP'S TO FSIS MODEL

MODEL HACCP-4, RAW, NOT GROUND

PLANT	CCP 1B	CCP 2B	CCP 3B	CCP 4B	Remarks
A		X(45°)		X(40°)	
B		X(55°)			2/
C		X(48°)			
G		X(55°)			
I		X(45°)			
J		X(40°)	X	X(40°)	
K					1/
L					1/
M		X(40°)			
N		X(55°)			
O					1/

1/ Plant had no CCP's for this process.

2/ The plant identified food safety hazards for Refrigerated Storage and Advanced Meat Recovery where CCP's should have been established. The plant had developed, and was monitoring room temperatures in production areas; however, this control was not listed as a CCP. We also found that the plant had not established a CCP for their Advanced Meat Recovery system that produced a fine beef mixture. After our review, we were advised that CCP's were being established for both Refrigerated Storage and Advanced Meat Recovery.

Explanation of CCP's

CCP 1B	Receiving - Carcasses
CCP 2B	Storage (cold) - Carcasses
CCP 3P	Fabrication of trimmings and/or cuts - metal detection
CCP 4B	Finished Product Storage (cold)

EXHIBIT C – COMPARISON OF PLANT CCP'S TO FSIS MODEL

MODEL HACCP-3, RAW, GROUND

PLANT	CCP 1B	CCP 2B	CCP 3P	CCP 4B	CCP 5P	CCP 6B	Remarks
C		X(45°)					
E		X(45°)					
I		X(45°)			X		
K		X(60°)					
L							1/

1/ Plant had no CCP's for this process.

Explanation of CCP's

CCP 1B	Receiving Meat
CCP 2B	Storage (cold) meat
CCP 3P	Grind/Blend metal detection
CCP 4B	Packaging/labeling
CCP 5P	Packaging/labeling - metal detection
CCP 6B	Finished Product Storage (cold)

EXHIBIT C – COMPARISON OF PLANT CCP'S TO FSIS MODEL

MODEL HACCP-14, PORK SLAUGHTER

PLANT	CCP 1B	CCP 2B	CCP 3B	CCP 4B
A	X			X(45°)
C		X		
K		X		X(60°)
L			X	

Explanation of CCP's

CCP 1B	Pre-Evisceration Wash
CCP 2B	Final Trim/Final Wash
CCP 3B	Pluck/Viscera Wash
CCP 4B	Chilling/Cold Storage

MODEL HACCP-13, BEEF SLAUGHTER

PLANT	CCP 1B	CCP 2B	CCP 3B	Remarks
B	X			
I	X	X		1/
F	X			

1/ The plant installed an intervention to reduce hazards, and to qualify for a program whereby FSIS stops end-product testing (FSIS Directive 10010.1). However, the plant did not list the intervention as a CCP.

Explanation of CCP's

CCP 1B	Final Wash (Antimicrobial) - Zero Fecal
CCP 2B	Chilling (All Products)
CCP 3B	Finished Product Storage (Cold)

EXHIBIT D – FSIS' RESPONSE TO THE DRAFT REPORT

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

MAY 18 2000

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

FROM: for Thomas J. Billy
Administrator

SUBJECT: Office of Inspector General's (OIG) Draft Report on the Implementation of the Hazard Analysis and Critical Control Point System

We appreciate the opportunity to review the subject report. The Food Safety and Inspection Service (FSIS) is providing the following comments on the specific recommendations.

General Comments:

FSIS disagrees with OIG's characterization of the statutory requirements of the Federal meat and poultry inspection laws. FSIS believes that it is inaccurate to state that the Hazard Analysis Critical Control Point (HACCP) rule "…replaced FSIS' longstanding program of meat and poultry inspection." FSIS views the new Pathogen Reduction/Hazard Analysis Critical Control Point (PR/HACCP) regulations as providing a scientifically supported opportunity for improved public health protection. Since the PR/HACCP regulations require establishments operating under government inspection to analyze their process and implement procedures to ensure food safety, the new regulations provide a formal structure both for establishments in addressing potential food safety hazards and for FSIS in holding industry members accountable for fulfilling their responsibilities. In particular, the HACCP regulations complement substantive requirements already established, and they do not divest FSIS of authority.

Executive Summary

OIG Key Recommendations:

FSIS should strengthen its management controls to provide greater oversight over HACCP implementation, pathogen testing and independent reviews of plant and inspection activities. FSIS should expand the language contained in the Grant of

FSIS FORM 2530-9 (6/95) EQUAL OPPORTUNITY IN EMPLOYMENT AND SERVICES

Inspection agreement to include the requirements and responsibilities required of the plant under the HACCP program and FSIS' authority, oversight, and access to information regarding the plant's operation. FSIS should use the Grant of Inspection as a contract, or enforceable agreement between the Government and the establishment signed by all parties and subject to review and renewal.

Agency Response:

The Agency is in the process of strengthening management controls by holding National Supervisory Conferences (the first meeting was held in March 2000, the second was held May 2 to May 4, 2000, and last meeting will be held June 20 to June 22, 2000) which focus upon the supervision of the Pathogen Reduction requirements; implementing the In-Depth Verification (IDV) Review (attachment 1) which is designed to evaluate the essential features of establishments' PR/HACCP systems; and correlating inspection verification duties through policy issuances.

The Agency recognized that the Grant of Inspection was an important element of the new PR/HACCP regulations. The Agency did amend the regulations on applying for and granting inspection by adding 9 CFR 304.3 and 381.22 (Conditions for receiving inspection). These new regulations provide that before being granted Federal inspection, an establishment must have developed written Sanitation Standard Operating Procedures (SSOPs), as required by 9 CFR 416, and must have conducted a hazard analysis and developed and validated a HACCP plan, as required by 9 CFR 417.2 and 417.4. A conditional grant of inspection is issued for a period not to exceed 90 days, during which period the establishment must validate its HACCP plan. The Agency has been assessing the regulatory requirements associated with the Grant of Inspection and is interested in pursuing aspects of these recommendations. However, the Agency is concerned that the scope of the recommendation regarding the use of the Grant of Inspection as a contract may not be within the scope of FSIS statutory authority. The Agency's evaluation should be completed by June 2001.

Chapter 1 - HACCP Plans Were Not Always Complete

Recommendation No.1:

Implement a system of oversight such as district office or independent reviews, to ensure HACCP plans contain all necessary Critical Control Points (CCPs) based on known hazards likely to occur. Issue instructions that provide clear guidance on requirements for plants establishing CCPs and inspector's authority to require changes to documented CCPs.

Revise the checklist used to evaluate HACCP plans accordingly to include:

(a) that hazards and CCPs identified in the HACCP models are fully considered with decisions being documented by plant management,

(b) reinforcing that field office personnel have the authority to review CCPs and to require additional CCPs as needed in their assigned plants, and

(c) requiring the establishments to inform the IIC of any proposed change in the HACCP plan, thereby allowing FSIS review prior to the change.

Agency Response:

FSIS agrees that a system of oversight such as independent reviews is necessary. Development of the system of oversight i.e., the In-Depth Verification (IDV) has been underway for over one year. In Fiscal Year (FY) 2000, FSIS initiated the IDV Review. The IDV protocol is designed to evaluate the essential features of establishments' Pathogen Reduction/HACCP systems. It was developed with input from the National Advisory Committee on Meat and Poultry Inspection. It verifies Pathogen Reduction requirements and includes scientific and technical criteria drawn from the National Advisory Committee on Microbiological Criteria for Foods (NACMCF). It contains 10 checklists addressing SSOPs, E. coli testing and HACCP requirements. Each checklist has a documentation component and a system verification component.

FSIS issued instructions to provide clear guidance to plants on requirements for establishing CCPs and inspector's authority in relation to CCPs. This guidance can be found through the following sources: the PR/HACCP regulation (9 CFR 417.1 and 417.2); transcripts of numerous public meetings held both during the rulemaking process and after the rule became effective; clarifications issued in the Federal Register issued in January 1998; HACCP training - Modules 7 and 9B; Generic HACCP models; assistance materials provided to very small plants; and transcript of a technical conference on HACCP implementation hosted by the Technical Service Center (TSC).

It is clear from this guidance CCP's must be specified in such a manner that, at a minimum, the associated critical limits ensure performance standards established by FSIS and any other regulatory requirements pertaining to the specific process are met. This guidance also makes it clear that whenever a food safety hazard is reasonably likely to occur in the production process, even if an establishment cannot entirely prevent or eliminate occurrence of the hazard by applying control measures, it must at least reduce it to an acceptable level. The guidance also requires that a HACCP plan must be a self contained document, and that reference to good manufacturing processes is not viewed as satisfying the requirements for the contents of a HACCP plan.

The HACCP regulation provides for Agency verification (9 CFR 417.8) of food safety. In the Background section of the final PR/HACCP rule, the Agency makes it clear that a central theme of its strategy was to, "clarify and strengthen the responsibilities of the establishment for maintaining effective sanitation, following sound food safety procedures, and achieving acceptable food safety results." It was

also made clear that command-and-control regulatory requirements that were highly detailed and prescriptive and assigned to FSIS the responsibility for the means used by establishments to produce safe food in a sanitary environment would be converted to performance standards. Inspectors would no longer assume responsibility for "prior-approving production-associated decisions." FSIS responsibility is to verify establishments' compliance with food safety standards and related requirements under HACCP and pathogen reduction control.

Therefore, inspectors are to ascertain whether CCPs meet regulatory requirements through verification of a plant's reassessment and modification to the HACCP plan. FSIS agrees that there may be some inspectors who still may not fully understand their authority with regard to the PR/HACCP rule. These authorities are outlined, for example, in FSIS Directive 5000.1 (attachment 2) and the recently issued Rules of Practice (64 FR 66541, November 29, 1999) (attachment 3). FSIS is conducting a series of National Supervisory Conferences to reinforce a full understanding of inspection authorities. Circuit Supervisors through work unit meetings will share the information covered in these meetings at the in-plant level. FSIS will also continue to issue policy directives and notices to explain inspection verification methods and regulatory actions.

FSIS has provided sufficient instructions to its inspection program personnel for consistent application of the HACCP system regulations. Furthermore, FSIS believes that PR/HACCP system implementation was conducted effectively within the constraints of limited training and of a field force, which does not, collectively, possess all the skills necessary to perform inspection fully consistent with HACCP precepts. Now that implementation has been completed, FSIS agrees that additional instructions need to be developed for inspection program personnel to begin assessing the completeness of the HACCP plans.

FSIS will reaffirm to its inspection program personnel that the Agency has sufficient authority to accomplish its statutory mission of protecting the public health and welfare of consumers by preventing the distribution of products that are unwholesome, otherwise adulterated, or misbranded. As a first step, FSIS has begun developing a series of limited surveys, which should be completed by the end of July 2000, to ascertain if there is need to make any regulatory changes or new instructions pertaining to HACCP. Furthermore, the Agency is developing an FSIS Notice, which is intended to provide instruction to inspection program personnel regarding a three-step approach on how to verify establishment compliance with hazard analysis and HACCP Plan requirements. This Notice should be issued by October 2000.

FSIS will not approve the CCPs selected, or require notification by the plant that changes have been made to the HACCP plan. FSIS believes that its role is one of verification that the HACCP plan is being implemented as defined by the establishment, and that the scientific basis and rationale for the HACCP plan is credible. FSIS will challenge the adequacy of HACCP plans which are inadequately supported. FSIS will not serve as a quality control function for the establishment; the

establishment is responsible for producing safe product.

Recommendation No. 2:

Implement a system of oversight to ensure HACCP plans contain adequate critical limits and corrective actions are proper including:

(a) issue instructions that provide clear guidance on requirements for establishing critical limits and clarify the authority of FSIS inspectors to require changes to critical limits documented in the HACCP plan,

(b) provide additional guidance (such as maximum temperatures for raw beef and pork) and scientific data to assist plants in establishing critical limits for standard types of processes,

(c) ensure that plants provide documentation of scientific data used to support critical limits for their manufacturing processes, and

(d) strengthen the supervisory and independent review process to ensure critical limits and corrective actions for deviations from critical limits are appropriate, documented, and can be verified.

Agency Response:

FSIS believes that it has issued instructions that provide clear guidance on requirements for establishing critical limits. (See 9 CFR 417.1 and 417.2.) It also believes that inspector authorities are clear, and that it is contrary to the philosophy of the PR/HACCP regulation for inspectors to "require" changes to critical limits or corrective actions documented in the HACCP plan. As stated by the NACMCF, strong plant management commitment is required for successful implementation of a HACPP plan, because it provides company employees with a sense of importance of producing safe food. FSIS believes that having inspectors "require" changes to the HACCP plan, as suggested by this recommendation, would undermine the effectiveness of the HACCP system within the plant. In cases of noncompliance, or at any time when inspectors have a concern about the safety of product being produced, such as inadequate critical limits or ineffective corrective actions, inspectors have effective authorities under the HACCP regulation which they can use to address the situation. (See FSIS Directives 5000.1 and 5400.5 (attachment 4), HACCP training - Module 9B, the Rules of Practice.)

With regard to recommendation (b), FSIS intends to provide additional guidance, and scientific data to assist plants in establishing critical limits for standard types of processes; however, it will not specify "maximum temperatures". FSIS will prepare appropriate guidance for inspection program personnel, and, if necessary, compliance guidance for industry to address performance standards.

FSIS has undertaken a regulatory reform initiative to convert current command-and-control regulations (which do specify things such as maximum temperatures) to performance standards (e.g., FSIS Directive 7111.1). The corresponding compliance guidance documents produced by FSIS are being made available to establishments in an effort to provide industry with specific control limits (e.g., time and temperature) to achieve the performance standards. The establishments can then incorporate the guidance procedures into their HACCP plans and demonstrate, through verification and validation, that the procedures are being implemented properly and are effective. It is the responsibility of establishments to identify specific temperatures that are necessary to ensure that safe food is produced.

Scientific data to assist plants in establishing critical limits for standard types of processes were provided through the generic HACCP models (references to scientific papers, etc.). There are also many sources of such assistance that have been widely available to plants during HACCP implementation (universities, Extension Service personnel, industry association materials). It is not the role of FSIS to be the exclusive provider of scientific data to assist plants. FSIS will continue to seek scientific information from the scientific community at large, as industry should as well, and FSIS will continue to provide scientific data as it relates to rulemaking and policy development. However, FSIS will not take on the responsibility for providing such data to plants. FSIS's role in relation to scientific data and HACCP plans is to evaluate through verification activities the scientific and other supporting data plants use as the basis for decision-making used to develop HACCP plans.

Therefore, FSIS agrees with recommendation (c) to "ensure that plants provide documentation of the scientific data used to support critical limits." FSIS established the TSC in Omaha, Nebraska, in part to serve as a resource to inspection personnel and industry representatives when questions arose regarding such scientific data or critical limits. The TSC hosted the HACCP Implementation Technical Conference in August 1999, to reinforce plants' responsibilities relative to validating HACCP plans with documentation such as scientific data. FSIS agrees to reinforce this with field inspection personnel through avenues such as the National Supervisory Conferences.

FSIS agrees with recommendation (d) and has established the IDV review process as an independent review of plants' SSOPs and HACCP plans. The IDV protocol includes scientific and technical criteria drawn from the NACMCF.

Recommendation No. 3:

Implement a system of oversight to ensure that hazard analyses include all food safety hazards that are reasonably likely to occur:

(a) Work with plant management to review the hazard analyses for completeness and accuracy,

(b) Ensure that scientific and technical data have been provided to support conclusions that processes do not pose any food safety hazards that are reasonably likely to occur, and

(c) Ensure that the district office enforces the requirement to address identifiable hazards, as required by the HACCP regulations.

Agency Response:

FSIS agrees that hazard analyses must be conducted to determine the food safety hazards reasonably likely to occur in the production process (9 CFR 417.2, NACMCF *Hazard Analysis and Critical Control Point Principles and Application Guidelines*). FSIS disagrees with recommendation (a), "work with plant management to review the hazard analyses for completeness and accuracy," for reasons cited in earlier FSIS responses regarding the role of industry in taking responsibility for HACCP plans. Having inspection personnel review plants' hazard analyses for completeness and accuracy are tantamount to "approving" the plant's hazard analyses. However, FSIS agrees with recommendations (b) and (c). Through verification and recordkeeping activities, FSIS inspection personnel are required to ensure that scientific and technical data are provided to support conclusions in the HACCP plan. If inspection personnel have questions about the adequacy of this data, they can either contact the TSC or request the plant to provide clarification. If, as inferred by recommendation (c), the establishment has not addressed hazards that are reasonably likely to occur, inspection personnel have enforcement protocols to apply, 9 CFR 417.6.

Recommendation No. 4:

Implement a system of oversight, to include management reviews and/or independent reviews requiring establishments to correct flow charts to reflect the establishment's actual operations.

Agency Response:

FSIS believes that its role is one of verification that the HACCP plan is being implemented as defined by the establishment, and that the scientific basis and rationale for the HACCP plan is credible. FSIS will challenge the adequacy of HACCP plans.

Chapter 2 - FSIS needs to place greater emphasis on pathogen testing.

Recommendation No. 5:

Develop and implement procedures that provide FSIS employees at the appropriate level with the authority to require HACCP plans to include pathogen testing of product, environment, contact surfaces, and final products, particularly if a plant has a history of positive test results for microbes such as *listeria*.

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Agency Response:

FSIS has clear authority to enforce the requirements of the HACCP regulations. HACCP is an effective preventive system and a properly designed system includes microbiological validation and verification by the establishment. Moreover, FSIS believes that microbiological verification is an appropriate responsibility of FSIS. FSIS is pursuing a number of microbiological-based performance standards which would further ensure that the establishments are adequately addressing food safety. FSIS is especially concerned about the presence of pathogens on ready-to-eat products and in the production environment, and FSIS is now evaluating the response by the establishments to last year's *Listeria monocytogenes* reassessment (attachment 5). FSIS is held a public meeting on *Listeria monocytogenes* on May 15, 2000, at which the agency addressed current thinking regarding further action associated with this pathogen. By December 2000, FSIS expects to issue a proposed regulation addressing ready-to-eat meat and poultry. This proposed rule is expected to contain a performance standard specifically addressing this pathogen.

FSIS agrees that its role is to verify that the HACCP plan is being implemented as defined by the establishment, and that the scientific basis and rationale for the HACCP plan is credible. FSIS will challenge the adequacy of HACCP plans.

Recommendation No. 6:

Provide clear authority in the Grant of Inspection contract for FSIS oversight of all plant pathogen testing.

Agency Response:

FSIS has been investigating the regulatory requirements associated with the Grant of Inspection and, if feasible, will pursue options to amend the Grant of Inspection to make clear the authority of FSIS to oversee plant pathogen testing. A conclusion will be reached by June 2001.

Recommendation No. 7:

Develop testing programs in coordination with the ARS for other pathogens that impact food safety.

Agency Response:

FSIS continues to work closely with ARS in a variety of food safety research and development areas. However, ARS does not develop "testing programs" (which is the role of FSIS) but ARS does play a significant and critical role in the design and development of methods used by FSIS' laboratories for analyses of regulatory samples. A recent example of the collaborative work between FSIS and ARS is the design and development of an improved analytical method for *E.coli* O157:H7. ARS

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performed the basic research and development for the new method and then collaborated with one of FSIS's laboratories to adapt the method for analyses of regulatory samples. This joint effort resulted in FSIS's use of an improved, more sensitive testing method, allowing increased recovery of this significant pathogen to better protect public health. In September 1999, this improved immunomagnetic bead method was implemented in all three FSIS laboratories.

Additional projects are underway including a project involving *Listeria monocytogenes* and a project on handling/transportation and chilling of meat and poultry. FSIS is also developing proposals for new research projects to develop detection methods for foodborne viruses, the parasite *Toxoplasma gondii* and the foodborne pathogenic bacterium, *Yersinia enterocolitica*.

ARS's principle role is to conduct food safety-related research for FSIS and to work with FSIS to target science-based public health/food safety research driven by public health priorities. As the principal public health component within the Department, FSIS periodically communicates its needs for research on particular subjects to ARS. FSIS has had a long-standing relationship with ARS to coordinate food safety research. This arrangement was formalized and strengthened in 1981 when FSIS and ARS Administrators put into force a Memorandum of Understanding (attachment 6) that established an official framework to cooperate indefinitely on food safety research efforts. This arrangement allows FSIS scientific managers to steer and expand ARS research projects towards the goal of reducing foodborne illnesses associated with meat and poultry.

In 1996, to better focus on public health, FSIS formed the Office of Public Health and Science (OPHS). Additional public health professionals were hired including physicians, scientific risk analysts, epidemiologists and others. An FSIS liaison was also established at the Centers for Disease Control and Prevention (CDC). New Divisions were formed to provide pubic health and scientific expertise to support the development of meaningful Agency testing programs and to keep abreast of emerging public health issues, including pathogens that impact food safety. OPHS coordinates the development and management of laboratory testing programs for FSIS.

Recommendation No. 8:

Improve controls by issuing instructions for securing FSIS test samples until the samples are in the possession of the shipping agent and review security to ensure that instructions are being followed.

Agency Response:

FSIS has undertaken an effort to improve sample security. Currently, FSIS Directive 7355.1 outlines procedures for sample security. The FSIS laboratories are revising Directive 7355.1 to reflect a more fail-safe procedure, which is estimated to be

completed by September 30, 2000. This will require developing new forms, educating laboratory personnel, and training inspectors.

Recommendation No. 9:

Implement management controls, which would include:

(a) timely providing field office inspectors all microbe testing results,

(b) instructions to FSIS field offices to continue *Salmonella* testing each production day, until notified by the Technical Service Center to stop,

(c) procedures to notify the district office if a field office stops submitting *Salmonella* samples prior to the completion of testing series, and

(d) procedures to ensure that seasonal products with irregular production schedules are tested in the directed sampling program.

Agency Response:

With regard to recommendation 9 (a) FSIS currently uses the Biological Information Transfer E-mail System as outlined in Notice 25-99 (attachment 7) to provide timely notification to field offices of testing results. The laboratories send electronic messages to District Offices informing them of laboratory results (positive and negative). They immediately contact District Offices to notify them of potential and confirmed positive results. They also send e-mail laboratory results, with the exception of *salmonella* results, to plants that have provided e-mail addresses. FSIS shares results of *salmonella* testing only when the sample set is complete. In addition, FSIS is also initiating a system that will allow Circuit Supervisors and in-plant inspectors to obtain test results by accessing on-line electronic folders.

In response to recommendation 9 (b), (c) and (d), current procedures require FSIS in-plant personnel to continue *Salmonella* testing each production day until notified by the TSC to stop. FSIS acknowledges, that in some cases, inspectors did not understand that some of the samples they had submitted to the laboratory were discarded; therefore, they stopped testing prematurely. FSIS has instituted a non-responders report (attachment 8) that is sent from Headquarters monthly using the Pathogen Reduction Enforcement Program to the District Office. The report lists by district all plants that have not submitted a *Salmonella* sample or a reason for not submitting the sample in the last 30 days. This allows the District Office to investigate and correct the problem. Also, some inspectors reported that they exhausted their supply of sample forms, and did not know how to request additional materials. Information about how to request additional materials was included in HACCP training and in FSIS Directive 10,230.5 (attachment 9). There are also experts at the TSC to answer inspector questions. Finally, if the plant has entered the third *Salmonella* sample set, and they fail the sample set, sampling is discontinued and inspectors follow instructions in FSIS Directive 10,011.1 (attachment 10).

FSIS expects to issue a Notice to District Managers and Circuit Supervisors related to *Salmonella* performance standard testing status reports. The reports relate to the Pathogen Reduction Enforcement Program (PREP), an automated scheduling system to be used in the management of *Salmonella* performance standard testing. The PREP system will assist in the day-to-day scheduling, tracking, and reporting of *Salmonella* sample sets. The Notice is expected to be finalized by August 2000.

Recommendation 10:

Implement procedures that require inspectors to review and approve plant's sampling protocols for generic *E. coli* testing to ensure they are complete and being followed.

Agency Response:

FSIS agrees that improvements can be made regarding the generic *E. coli* testing programs operated by the establishments and is planning a number of activities to assess the adequacy of the establishment's procedures as required by 9 CRF 310.24 and 381.94. During FY 2001 FSIS expects to begin a more complete review of HACCP implementation, which may include instructions, related to generic *E. coli*. FSIS expects to issue updated instructions before the second quarter of FY 2001.

Chapter 3 - FSIS needs to define its oversight role in the HACCP system and hold plants accountable for noncompliance.

Recommendation No. 11:

Expand the language contained in the Grant of Inspection to include the statutory and regulatory requirements and the responsibilities of such plants under the HACCP program and FSIS' authority, oversight, and access to information regarding the plants operation. Use the Grant of Inspection as an enforceable agreement between the Government and the establishment, signed by all parties and subject to review and renewal.

Agency Response:

FSIS has been investigating the regulatory requirements associated with the Grant of Inspection and, if feasible, will pursue options to amend the Grant of Inspection to make clear the scope of FSIS' regulatory authority over plant pathogen testing. A decision will be reached by June 2001.

Recommendation No. 12:

Require plants to include all pathogen testing performed by the plants in their HACCP plans, to retain test results, and to notify the IIC of adverse microbial test results.

Agency Response:

The PR/HACCP regulation does not require plants to include pathogen testing in their HACCP plans. The OIG's concern is that plants are not notifying the IIC of adverse microbial test results and how the plant reacts to the adverse test results. As discussed in Agency responses to Recommendations No. 5 and 11, based on current regulations, plants must take corrective actions when such findings occur. FSIS will verify corrective actions taken and documented by the plant as well as the reassessment and modification of the HACCP plan when adverse microbial test results occur. FSIS is taking steps to make sure that in-plant inspection personnel understand this fully through workshops conducted at the National Supervisory Conferences and through work unit meetings.

Recommendation No. 13:

Instruct IIC's to assess the adequacy of the plant's corrective actions to eliminate harmful pathogens and to monitor those actions.

Agency Response:

FSIS agrees to reinforce the requirement to assess the adequacy of plant's corrective actions and to monitor these actions. Although such instructions were provided during HACCP training, FSIS has accumulated information during HACCP implementation that can be used to create case studies that can be shared to reinforce such concepts. Case studies are being used at the National Supervisory Conference, and will be covered at local work unit meetings and through policy issuances. The TSC continues to be available as a resource to help answer inspectors' questions about the adequacy of plants' corrective actions.

Recommendation No. 14:

Develop and implement an internal review system to provide assurances that plant level HACCP, SSOP, and microbial testing programs are operating as intended.

Agency Response:

As mentioned in response to Recommendation No. 1, FSIS is implementing the IDV review. The review is conducted by FSIS experts from the Office of Policy Program Development and Evaluation, Office of Public Health and Science, Office of Field Operations of a plant's SSOPs and HACCP system, including *Salmonella* and *E. coli* testing. FSIS obtained input from its Advisory Committee on Meat and Poultry Inspection during the development of the IDV protocol. It is a comprehensive review.

Recommendation No. 15:

Ensure that IIC's routinely evaluate the effectiveness of SSOP's and require changes and modifications to plants' SSOP plans when needed.

Agency Response:

Under current regulations, when direct product contamination occurs, the establishment is responsible for implementing and documenting corrective action to prevent it from occurring in the future, and must prevent it from entering commerce (9 CFR 416.15). Inspection personnel have the appropriate authority to address this in case of noncompliance by the plant. In addition, 9 CFR 416.14 requires plants to routinely evaluate the effectiveness of the SSOP's. This information was covered during SSOP training, HACCP training, and is addressed FSIS Directive 5000.1. In addition, some of the examples cited in this report indicate that there may be some misunderstanding on the part of inspection personnel about the newly implemented Sanitation Performance Standard regulations. FSIS held district meetings to clarify inspection personnel's responsibilities prior to issuing this regulation. FSIS agrees to reinforce through training and better communication the FSIS inspectors' authorities in relation to the Sanitation Performance Standard regulation and SSOP's through the National Supervisory Conferences and work unit meetings. It will also clarify how inspection personnel should respond in cases of repetitive noncompliance.

Recommendation No. 16:

Establish procedures that require the returned product process be included in the hazard analysis and HACCP plan.

Agency Response:

FSIS agrees that establishments receiving and handling returned products should be considering the returned product process when conducting its hazard analysis and when developing its HACCP plan. The PR/HACCP regulation does not preclude this (9 CFR 417.2). The fact that plants may consider the returned product process while conducting its hazard analysis and when developing its HACCP plan doesn't mean that it will be included in the plant's HACCP plan. However, if inspection personnel have questions about the return product process not being included in the HACCP plan, they have the authority to question the plant's rationale and to request documentation indicating why the returned product process (or any other process) is not included in the plant's HACCP plan. FSIS disagrees that it needs to, "establish procedures that require," the returned product process be included in the hazard analysis and HACCP plan, but it agrees to reinforce through training and improved communication with inspection personnel the regulatory requirements and responsibilities of the establishment with regard to controlling the returned product. FSIS will also do what is necessary to ensure that official establishments are

cognizant of these requirements and responsibilities and of the consequences that flow from failure to meet this.

Recommendation No. 17:

Establish procedures for inspectors that include their oversight responsibilities from the point of product return to product distribution.

Agency Response:

According to 9 CRF 318.1, the inspector is required to reinspect all returned products. The regulations also indicate that if at any point, returned products are suspected of being adulterated, appropriate actions will be taken. FSIS disagrees that additional procedures need to be established with regard to inspection oversight responsibilities. However, FSIS agrees to reinforce with inspection personnel their responsibilities related to returned product.

Recommendation No. 18:

Require FSIS district office personnel to monitor and update scheduled tasks on a continuous basis and to establish additional codes or require inspectors to document why tasks are not performed.

Agency Response:

FSIS relies on the Inspection Systems Procedure Guide and the Performance Based Inspection System (PBIS) (see FSIS Directive 5400.5 and Module 6 of HACCP training) to schedule and record the performance of inspection procedures. In-plant inspectors report the procedures they perform to the District Offices. District Offices enter the procedures performed in the PBIS. In the event that a procedure no longer applies to an establishment, in-plant inspection personnel are instructed (in FSIS Directive 5400.5) to make appropriate modifications to PBIS. In-plant inspectors are authorized to make changes to scheduled procedures based on plant conditions and their judgment (i.e., noncompliance with a scheduled 01 procedure triggers the inspector to perform an unscheduled 02 procedure, which would impact the performance of other scheduled procedures for that day). FSIS does not agree that it is necessary or beneficial to establish codes to require inspectors to document why tasks are not performed. Circuit Supervisors are responsible for reviewing PBIS reports on a regular basis and working with inspectors if they have questions about why procedures are not performed. FSIS is taking steps to reinforce the usefulness of PBIS data with Circuit Supervisors through circuit meetings at the District Offices and through the National Supervisory Conferences. The TSC is also summarizing PBIS data graphically on a national basis to indicate areas where, based on further investigation, correlation on the application of PBIS may be needed.

Recommendation No. 19:

Develop and implement procedures that establish parameters for repetitive deficiencies and provide a basis for determining when system failures have occurred, corrective actions are inadequate and when enforcement actions should be promptly initiated.

Agency Response:

FSIS will develop procedures for repetitive deficiencies by December 2000.

Recommendation No. 20:

Establish time frame requirements for responding to NR's and initiating planned corrective actions.

Agency Response:

The Noncompliance Record (NR) states that plants must respond immediately when notified by inspection personnel of noncompliance. (Also see FSIS Directive 5400.5 and HACCP training). Plants are also required to initiate planned actions to prevent reoccurrence of the noncompliance. Plants are not required to respond in writing on the NR. They are, however, required, 9 CFR 416.16 and 417.5, to document corrective actions in plant records. FSIS does not find it advisable to establish specific timeframes (i.e., minutes, hours) for a plant to initiate and implement corrective actions because of the nature and variability among plants and production processes. The nature of some corrective actions involve modifications that can be made quickly, while others (e.g., equipment changes) require longer timeframes. This may explain why, as mentioned in the report, some NR's remained open for a period of time. FSIS believes its current regulations appropriately hold plants accountable for initiating and implementing corrective actions. FSIS does not agree to change the procedures for issuing NR's, but it does agree to reinforce with inspection personnel their responsibilities for monitoring and evaluating the effectiveness of corrective actions. This is being done first through the content of the National Supervisory Conferences and then through local work unit meetings.

ABBREVIATIONS

ARS - Agricultural Research Service

CCP - Critical Control Point

CDC - Centers for Disease Control

CFR - Code of Federal Regulations

FSIS - Food Safety and Inspection Service

GAO - General Accounting Office

GMP - Good Manufacturing Processes

HACCP - Hazard Analysis and Critical Control Point

IIC - Inspector-In-Charge

LM - *Listeria monocytogenes*

NR - Noncompliance Record

OIG - Office of Inspector General

PBIS - Performance Based Inspection System

QC - Quality Control

SSOP - Sanitation Standard Operating Procedure

USDA - U.S. Department of Agriculture

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

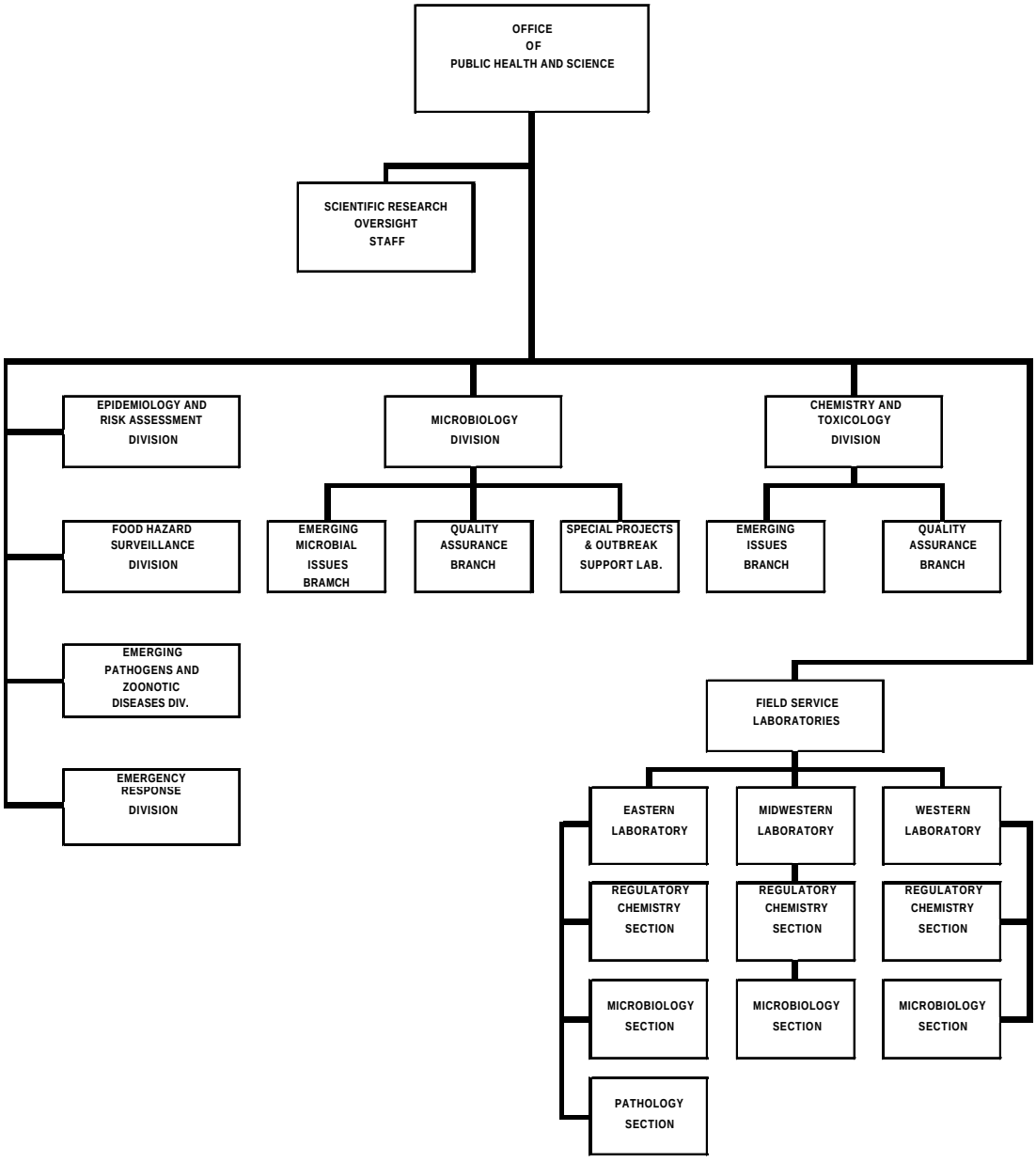
The Food Safety and Inspection Service (FSIS) was established by the Secretary of Agriculture on June 17, 1981. The mission of FSIS is to ensure that the Nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged as required by the Federal Meat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

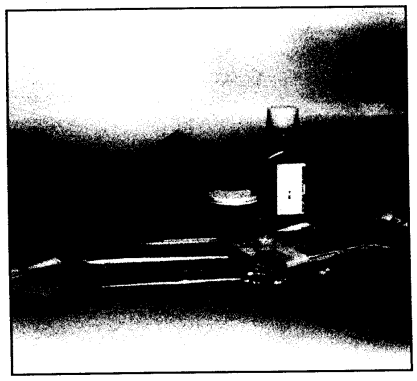
If any supplies are missing from the container, contact the designated laboratory or your district office.

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.

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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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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

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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.

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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 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

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Attachment 3 Page 13

RESERVED

Attachment 2

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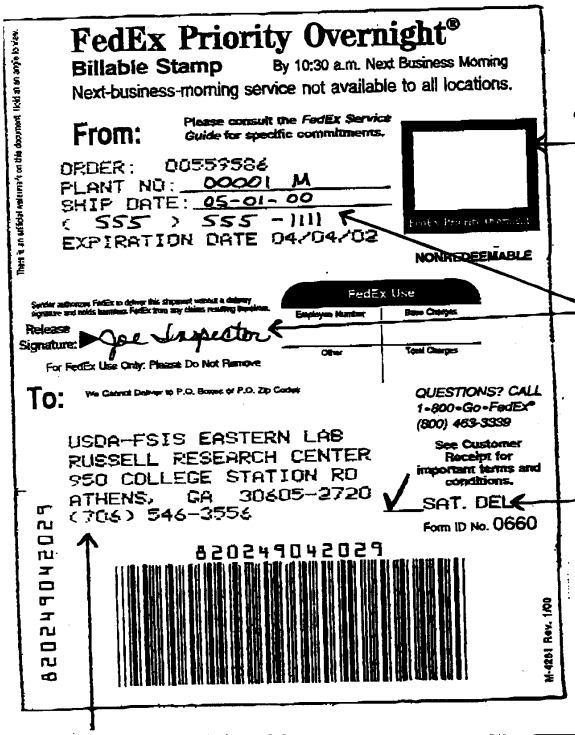
Attachment 3 Page 14

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

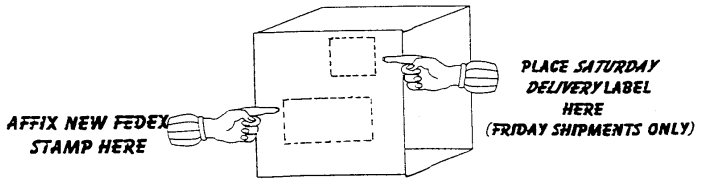
Attachment 4 Page 2

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.

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

FOOD SAFETY AND INSPECTION SERVICE

IMPORTED MEAT AND POULTRY
INSPECTION PROCESS
PHASE 1

Report No.
24099-3-Hy
June 2000

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250

DATE: June 21, 2000

REPLY TO
ATTN OF: 24099-03-Hy

SUBJECT: Imported Meat and Poultry Inspection Process

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 oversight and controls to ensure that imported meat and poultry products entering U.S. Markets are safe and wholesome. 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 procedures established for testing meat and poultry products. Your response to the official draft report, dated June 7, 2000, is included as exhibit A 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 all recommendations except Nos. 6, 14, 15, 16, 19, 26, 32, and 33. Please follow your agency' s internal procedures in forwarding documentation for final action to the Office of the Chief Financial Officer. 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

FOOD SAFETY AND INSPECTION SERVICE
IMPORTED MEAT AND POULTRY
INSPECTION PROCESS
PHASE 1
AUDIT NO. 24099-03-Hy

RESULTS IN BRIEF

This report presents the results of the first phase of our evaluation of controls to ensure that imported meat and poultry entering U.S. consumer channels is safe and wholesome. This review was part of the Office of Inspector General's food safety initiative, which also included the implementation of Hazard Analysis and Critical Control Point System, District Enforcement Operations' compliance activities, and the procedures established for U.S. Department of Agriculture laboratory testing.

The Food Safety and Inspection Service (FSIS) fulfills its responsibility for ensuring that imported meat and poultry in the U.S. marketplace is safe and wholesome by (a) determining if foreign countries and their establishments have implemented food safety systems and inspection requirements equivalent to those in the United States, and (b) reinspecting imported meat and poultry products from these countries, on a spot-check basis, to verify the purity of the imports.

FSIS administers its food imports safety program primarily through the Office of Field Operations, which reviews foreign countries' inspection systems and reinspects imported meat and poultry products at ports of entry, and the Office of Policy, Program Development and Evaluation, which makes equivalence determinations of foreign country inspection systems. These review and reinspection activities form the basis of FSIS' determinations of whether a country's systems are equivalent to U.S. standards.

Equivalency determinations are FSIS' way of applying the new requirements of the Pathogen Reduction Program and the Hazard Analysis and Critical Control Points (HACCP) Program to overseas operations. Our objective for this phase was to evaluate FSIS policies, procedures, and controls for implementing these programs in

a continuing effort to ensure that food safety systems in foreign countries are equivalent to those in the United States. As part of this objective, we assessed how effectively FSIS carried over its import inspection controls when it reorganized its operations in 1997.

During Phase II and Phase III of our review, we will examine import reinspection activities at selected U.S. ports, and initial equivalence determinations for new countries.

During a 1996 audit we performed of the import inspection program, we recommended that for purposes of reorganization, FSIS develop procedures to ensure that controls present under the pre-HACCP structure would carry over under the new structure. FSIS did not fulfill this recommendation. FSIS implemented its reorganization without developing a comprehensive, detailed plan to ensure that controls were maintained over import inspection operations. Detailed control processes and procedures for determining the equivalency or the continuing eligibility of foreign inspection programs to export meat and poultry products to the United States were not adequately developed, were not incorporated in formal agency procedures for distribution to responsible personnel, or were not functioning as required by regulation. Responsibilities were also not well defined, resulting in unclear lines of authority, minimal supervisory oversight, and training goals that had not been achieved. The absence of a strong internal control structure does not provide reasonable assurance that objectives of the import inspection program are being achieved. Nothing came to our attention during this audit, however, to indicate FSIS allowed unsafe products to enter U.S. commerce.

We found that the absence of formal procedures affected all areas of the import inspection program: requirements for annual certifications and residue test plans have gone unenforced; the eligibility status of importers has not been kept current; and FSIS' equivalency determinations of foreign countries' food safety systems have been based on insufficient documented analysis and support.

Annual certifications. Foreign governments are required to certify annually that each of the establishments in their country that export meat and poultry products to the United States continue to comply with U.S. standards. FSIS did not enforce this requirement and 19 countries were allowed to continue to export to the United States, even though they had not certified their establishments as meeting U.S. standards during 1999.

Residue test plans. Foreign inspection systems are also required to maintain residue control standards equivalent to U.S. standards in order to identify the use of such residues determined by the exporting country's meat inspection authorities or by FSIS as potential contaminants. As of April 29, 1999, 15 of 36 countries that were certified to ship meat and poultry products to the United States had not submitted their 1999 residue test plans.

Eligibility status of importers. When FSIS or foreign inspectors declared an establishment ineligible to export product to the United States, FSIS did not always timely update its reinspection system with this information. As a result, seven establishments from four foreign countries shipped over 4 million pounds of meat and poultry products and presented them for reinspection although they were delisted by their foreign inspection systems. Documentation provided by FSIS did not conclusively prove that all products were produced prior to the delistment date. Also, we could not determine whether FSIS timely updated its reinspection system with critical laboratory results of microbiological tests. These tests are used to determine if a product should be allowed to enter the United States at ports of entry. They are also used, in part, as a basis to determine how products should be sampled at ports of entry and what microbiological tests should be performed. Nothing came to our attention during this audit, however, to indicate FSIS allowed unsafe products to enter U.S. commerce.

Analysis of foreign food safety systems. FSIS cannot demonstrate that it judged the foreign food safety systems of current trading partners according to U.S. standards. At the time of our audit, FSIS had not yet determined equivalence for HACCP and *Salmonella* standards. Control procedures for equivalency determinations were not developed or adequately documented, technical subject-matter experts were not always involved in the process, and specific areas of foreign inspection systems have not yet been reviewed to verify that they are equivalent to U.S. standards. FSIS' country files did not contain sufficient evidence of FSIS' analysis of the information the country governments submitted to document their inspection systems. Moreover, FSIS granted equivalency status for six countries before it performed onsite equivalency verification reviews, and the onsite reviews that were performed were not adequately documented to support what was reviewed and what deficiencies were found. FSIS also lacked timeframes within which to make SSOP and *E. coli* equivalency determinations, and failed to meet the timeframes established for HACCP and *Salmonella* standards.

We concluded that inadequate planning for the transition to the new organization structure, as well as inadequate management oversight of the operational changes to the import inspection processes, contributed to the breakdown in controls that were designed to ensure the safety and wholesomeness of imported products entering the United States.

The weaknesses disclosed during this audit are material control weaknesses in FSIS' import inspection program. As such, they should be included in the agency's annual management control report required by the Federal Manager's Financial Integrity Act.

KEY RECOMMENDATIONS

We recommend that FSIS conduct an assessment of the current organizational structure, clarify roles and responsibilities, and establish a system of management and operating control objectives and processes to ensure the safety and wholesomeness of imported meat and poultry products. FSIS also needs to conduct independent internal control reviews, emphasizing those processes that changed in the reorganization, provide management control training, and report the conditions disclosed in this audit as material management control weaknesses in the import inspection process.

We also recommend that FSIS develop and implement formal procedures, approved by FSIS management, for all aspects of its import inspection program, most specifically those related to (1) making equivalency determinations based on an evaluation of each foreign country's food safety regulatory system, as appropriate, (2) its enforcement of sanitary measures, and (3) entering country eligibility information into FSIS' reinspection system. We also recommend that FSIS enforce the regulatory requirements for countries to submit their residue test plans and test results and establishment certifications by foreign inspection systems.

Concerning equivalency determinations, FSIS needs to establish a time-phased plan to complete each determination and ensure that technical subject-matter experts are involved, as appropriate, in determinations; the determinations are documented; and onsite verification reviews are conducted prior to granting equivalency status. For current trading partners, FSIS needs to develop and implement a policy for onsite verifications of changes in the requirements for foreign systems and ensure that onsite audits are conducted annually.

AGENCY RESPONSE

FSIS accepted 33 of the 35 recommendations in the report. However, FSIS does not believe the issues outlined in the audit report constitute a material management control weakness. FSIS also believes management oversight of import inspection operations is adequate. We have incorporated excerpts from FSIS' response in the Findings and Recommendations section of this report, along with the position of the Office of the Inspector General (OIG). FSIS' response, in its entirety, is attached as Exhibit A.

OIG POSITION

OIG disagrees with FSIS' position that the findings in this report are not material management control weaknesses and that evidence of management oversight was adequate. Basic internal control activities such as documented policies, procedures, supervisory reviews and approvals, delegated responsibilities, and clear lines of authority were lacking in FSIS' operations. OIG will continue to report our conclusion that the findings in this report are material management control weaknesses and should be reported in FSIS' internal control and management accountability reports.

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INTRODUCTION

BACKGROUND

The Federal Meat Inspection Act and the Poultry Products Inspection Act require foreign countries that export meat and poultry to the United States to establish and maintain inspection systems that are equivalent to the U.S. inspection system. Meat and poultry imported into the United States must originate in countries and plants approved to export to the United States. FSIS is responsible for (1) reviewing and assessing foreign inspection systems and facilities that export meat and poultry to the United States to ensure that standards are equivalent to those in the United States, and (2) reinspecting imported meat and poultry products at ports of entry to ensure that only safe, wholesome, unadulterated, and properly labeled products enter U.S. commerce.

Food safety equivalence evaluations are based upon provisions in the Agreement on the Application of Sanitary and Phytosanitary Measures (Agreement), which appears in the Final Act of the Uruguay Round of Multilateral Trade Negotiations, signed on April 15, 1994. The Agreement became effective in January 1995 concurrently with establishment of the World Trade Organization, which superseded the General Agreement on Tariffs and Trade (GATT), as the umbrella organization for international trade. Article 4.1 of the Agreement requires each member to accept as equivalent the food regulatory system of another country if the exporting member objectively demonstrates to the importing member that its measures achieve the importing member's appropriate level of sanitary protection. Regulations governing FSIS operations are codified in 9 Code of Federal Regulations (CFR) Chapter III, Parts 300, 416, and 417.

Under FSIS' pathogen reduction/Hazard Analysis and Critical Control Point (HACCP) regulatory proposal published in February 1995, HACCP programs would be required in meat and poultry plants, along with interim targets for pathogen reduction in slaughter establishments and microbial testing to meet those targets. In fiscal year (FY) 1996, the Final Rule was published on the pathogen reduction system and the HACCP system. Under these systems, a country's status as having controls and performance standards "equivalent" to those in the United States is determined in four areas.

HACCP. All plants must develop, adopt, and implement a HACCP plan for each of their processes. Under HACCP, plants identify critical control points during their processes where hazards such as microbial contamination can occur, establish controls to prevent or reduce those hazards, and maintain records documenting that controls are working as intended.

Mandatory Generic *Escherichia coli (E. coli)* testing in slaughter plants. All meat and poultry slaughter plants are required to conduct microbial testing of carcasses for generic *E. coli* as an indicator of the adequacy of the plant's control over fecal contamination.

Pathogen reduction performance standards for *Salmonella*. Slaughter plants and plants producing raw ground products are required to ensure that their *Salmonella* contamination rate is below the current national baseline incidence.

Sanitation Standards Operation Procedures (SSOP). As of the beginning of 1997, all plants were required to implement plant-specific operating procedures for sanitation to ensure they were meeting their responsibility to keep their facilities and equipment clean.

Prior to FSIS' reorganization, FSIS focused on individual plants and evaluated whether foreign food regulatory systems were "at least equal to" the U.S. system. The principle underlying FSIS' current import inspection activities is the "systems approach," which focuses on a country's overall inspection system rather than on individual plants. The systems approach includes an evaluation of the inspection system of each country seeking to export or already approved to export to the United States to ensure it has inspection controls equivalent to those of the United States. FSIS does not suspend trade with exporting countries while this process is underway.

Because the eligibility of countries to export meat or poultry to the United States was initially evaluated on a case-by-case basis through analysis of applications followed by onsite audits, all "at least equal to" countries that were eligible for export of meat and poultry to the United States were allowed to continue to export to the United States until their inspection systems could be determined "equivalent" under the pathogen reduction/HACCP standards. A total of 37 countries were approved under the "equal to" system. The burden for demonstrating equivalence rests with the exporting country and the importing country

is free to set any level of protection it deems appropriate to control or eliminate a food safety hazard.

Before a foreign country can initially export meat or poultry to the United States, it must apply for a determination of equivalency. Applications must contain enough technical and scientific evidence for FSIS to determine that the country's sanitary measures, oversight, and enforcement are equivalent to the U.S. system. This evaluation is to consist of a document review and an onsite equivalency verification review. The initial equivalence determination for a new trading partner is subject to notice and comment rule making when the country is listed in the Code of Federal Regulations as eligible to export to the United States.

A document review is an evaluation of laws, regulations, directives, and other written material used by the foreign country to operate its inspection program. FSIS will evaluate the country's inspection system in five risk areas which include controls over animal diseases, sanitation, residue, processing and slaughter, and enforcement. If the document review finds the country's system satisfactory, FSIS will conduct an onsite equivalency verification review to evaluate the foreign country's oversight program and practices, and to determine whether system controls are operating as represented to FSIS.

After a country is determined to have an equivalent system and is eligible to export to the United States, FSIS will rely on the country to carry out daily inspections. However, FSIS will monitor the country's activities. Besides randomly sampling meat and poultry products for reinspection as they enter the United States, FSIS will conduct onsite reviews of the country's inspection systems to ensure that its procedures and standards remain equivalent. Reviewers will visit certified plants and focus on the five areas of risk. These reviews should generally be conducted annually, but their frequency depends on the country's performance history and on the results of product reinspections at the ports of entry. A total of 30 onsite reviews were conducted in exporting countries in 1997, and a total of 24 in 1998. Based on information provided to us during the field work phase, 13 onsite reviews had been conducted in 1999.

The reinspection of imported meat and poultry products at U.S. ports of entry provides FSIS with a means of assessing the effectiveness of a foreign government's inspection system while ensuring that only safe, wholesome, unadulterated, and properly labeled products enter U.S. commerce. Reinspection is directed by FSIS' Automated Import

Information System, which stores reinspection results from all ports of entry for each country and plant. A description of each lot arriving at any of the approximately 150 official U.S. import inspection establishments is entered into the Automated Import Information System. Lots are reinspected for transportation damage, labeling, proper certification, general condition, and accurate count. The Automated Import Information System may, for example, generate residue and microbiological laboratory test assignments based on the compliance histories of the plants, countries, and products being presented for reinspection. Products that pass reinspection are allowed to enter U.S. commerce; products that do not pass are stamped "U.S. Refused Entry" and must be exported, destroyed, or converted to animal food.

FSIS administers its imported meat and poultry inspection program primarily through the Office of Policy, Program Development and Evaluation, which reviews food safety requirements imposed by foreign governments, and the Office of Field Operations, which inspects overseas plants and imported meat and poultry products. These review and inspection activities form the basis of FSIS' determinations of whether a country's inspection systems are equivalent to U.S. standards.

Within the Office of Policy, Program Development and Evaluation, the International Policy Division is responsible for providing leadership in international policy development for all programs, regulations, and activities for the agency. Within this division, the Equivalence and Planning Branch is responsible for formulating policies for determining a foreign country's eligibility to export meat and poultry products to the United States.

During 1998, the United States imported about 3 billion pounds of meat products and about 53 million pounds of poultry products. The volume of imports from Australia, Canada, New Zealand, Argentina, and Denmark totaled approximately 2.8 billion pounds during 1998. About 21 percent of the products presented to FSIS for reinspection were subjected to further examinations including laboratory analysis, product examination, and condition of containers. Approximately 1.6 percent of these reinspected products were rejected for contamination, processing defects, unsound condition, violative net weight, pathological or labeling defects, missing shipping marks, composition/standard, Animal and Plant Health Inspection Service/Veterinary Services requirements, residues, container condition, transportation, or miscellaneous reasons.

For 1999, about 3.3 billion pounds of meat and poultry products were shipped by foreign countries to the United States and presented for FSIS reinspection. The countries which shipped the greatest amount of meat and poultry products in 1999 were: Canada (1.6 billion pounds), Australia (735 million pounds), New Zealand (461 million pounds), followed by Denmark (119 million pounds), Brazil (106 million pounds), Argentina (103 million pounds), and Uruguay, (51 million pounds). These seven countries accounted for nearly 97 percent of the total meat and poultry products shipped by foreign countries to the United States during 1999. Fresh red meat represented over 85 percent of the total amount – nearly 13 percent was processed product, and the remainder was fresh poultry.

With the advent of HACCP and the pathogen reduction program, FSIS began implementing a comprehensive reorganization of the agency to streamline its operations and increase the efficient use of its resources. By 1997, FSIS substantially completed this reorganization. The new field structure unified four separate functions to carry out all inspection and compliance activities, 46 regional and area offices were reduced to 18 district offices, and a Technical Service Center was opened in Omaha, Nebraska, to provide inspection expertise for the onsite reviews and the port-of-entry reinspection process.

OBJECTIVES

The purpose of our review was to evaluate FSIS' policies and procedures to ensure that foreign countries and their establishments have adequately implemented food safety systems and inspection requirements equivalent to U.S. requirements. Our secondary objective was to determine whether controls that existed over the inspection process before FSIS reorganized had been maintained after reorganization.

SCOPE

To evaluate FSIS' policies and procedures over the food imports safety program, we focused on operations and statistical information for 1997, 1998, and 1999 through July 1999. However, we reviewed prior years' operations as deemed necessary. During the next phases of our audit, we will continue our evaluation of the reinspection process, and the initial equivalence determination process.

We performed work at FSIS' Headquarters in Washington, D.C., and the Technical Service Center in Omaha, Nebraska. Staff at FSIS' Headquarters are responsible for (a) developing international policy

for all programs, regulations, and activities, (b) formulating equivalency determination policies, (c) determining a foreign country's eligibility for importation of meat and poultry products into U.S. markets, (d) managing a program of regulatory oversight and inspection to ensure that meat and poultry products are safe, wholesome, and properly labeled, and (e) maintaining FSIS' computer data base which assigns reinspection levels for meat and poultry products imported from those countries and establishments eligible to export products to the United States. We reviewed the files for 37 countries who applied for equivalency determinations to determine whether equivalency determinations were adequately documented and whether procedures were in place to ensure regulatory requirements were met. As of April 15, 1999, 28 countries had been approved as equivalent for SSOP and *E. coli* testing procedures. During the course of our fieldwork, equivalency determinations (documentation reviews) were in process for HACCP and *Salmonella* standards; therefore, we did not comment on these areas in this report. We will review these areas in a future audit.

Staff at the Technical Service Center are responsible for (a) providing technical assistance, guidance, and advice for inspection personnel and the industry, (b) conducting foreign reviews, including the development of systems, methods, and procedures for conducting these reviews, and (c) entering laboratory test failure results into the FSIS computer data base. The review system is intended to assure consumers that foreign countries seeking eligibility to export meat and poultry products to the United States, or those already determined eligible to do so, have an inspection system equivalent to U.S. requirements.

Our work was initiated in October 1998 and was conducted in accordance with generally accepted Government auditing standards.

METHODOLOGY

To accomplish our objectives, we discussed current operations with FSIS officials and staff and reviewed supporting documentation. At FSIS Headquarters, we concentrated on the responsibilities of the Office of Policy Program, Development and Evaluation; the Office of Field Operations; and the Office of Management Internal Control Staff. Our review included analysis of records and other documents and discussions to determine if agency responsibilities are being carried out as intended by regulation.

At the Office of Field Operations' Field Automation and Information Management Division, we familiarized ourselves with FSIS' computer data base, the Automated Import Information System. We obtained a basic understanding of how information is entered into the Automated Import Information System relating to foreign country and establishment certifications and laboratory test results, and we obtained the Automated Import Information System computer printouts of products presented for FSIS reinspection by foreign countries.

At the Technical Service Center, we acquired a basic understanding of the evolving responsibilities regarding the reinspection process, particularly those related to laboratory test results. We also obtained information about the role of the Technical Service Center foreign review staff in conducting audits to ensure that the inspection systems of foreign countries comply with equivalency requirements.

At FSIS' Headquarters offices, we reviewed documentation and performed analysis of files for all 37 countries that applied for participation in the import program under the HACCP and pathogen reduction standards. We also evaluated procedures used to determine whether country inspection systems were equivalent to those in the United States. We reviewed and analyzed procedures used by FSIS to implement the requirements of the Federal Managers Financial Integrity Act. These documents included yearend management control reports and FSIS directives for management controls.

FINDINGS AND RECOMMENDATIONS

CHAPTER 1	FSIS MANAGEMENT CONTROLS OVER THE IMPORT INSPECTION PROGRAM NEED TO BE ENHANCED

Office of Management and Budget (OMB) Circular No. A-123, Management Accountability and Control, dated June 1995, states that agency managers shall incorporate management controls in the strategies, plans, guidance and procedures that govern their programs and operations. However, we found that when FSIS reorganized, management controls and written operational procedures were inadequate to assure that controls over the import inspection program were maintained under the new organizational structure. Our review disclosed: a lack of management controls over key import inspection functions; inadequate documentation to support the equivalence determination process; non-compliance with existing controls; a lack of documentation to ensure that ongoing monitoring and supervision occurred; and processes that did not reflect operating procedures as outlined in functional statements and documents provided to the Office of Inspector General (OIG) and the general public. In addition, all personnel have not received adequate training for the tasks assigned. FSIS implemented the reorganization prior to developing a comprehensive, detailed plan to ensure the effectiveness of controls over all aspects of the import inspection process. In the absence of sufficient management controls, there is reduced assurance that the goals and objectives of the import inspection program are being fulfilled.

FINDING NO. 1

COMPREHENSIVE REORGANIZATION IMPLEMENTATION PLAN WAS NOT DEVELOPED

The U.S. General Accounting Office's Standards for Internal Control in the Federal Government,[1] dated November 1999, states that internal controls should provide reasonable assurance that the objectives of the agency are being achieved. We found that program controls have not been established or are inadequate to assure that the import inspection program is operating as intended. Although FSIS had originally planned to reorganize over a 3-year period, a decision was made to make the transition to the new structure within 1 year. As a result, the transition was made without FSIS ensuring adequate controls were in place and functioning. The separation of functions that resulted from the reorganization requires considerable coordination between staffs which, in key areas, has either not occurred, or not effectively occurred. In addition, a planned retraining program for FSIS personnel has not been fully implemented.

As a result of our requests for documentation to support FSIS' transition to its current organizational structure, we were provided with a history of planning proposals that were never carried out, and a "Top-to-Bottom Review" that was self-described as a brainstorming project. This internal FSIS review recognized the need to establish and maintain a strong internal control structure within FSIS.

In February 1995, FSIS published a proposed rule, Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, which outlined its strategy to change inspection to a more scientific, industry performance-based system that would better protect the public health. In conjunction with the proposed rule, the FSIS Administrator announced that the Agency would look at itself from "top to bottom" and define an organizational structure compatible with the goals and strategies of the pathogen reduction/HACCP regulation.

FSIS prepared a report, entitled "Top-to-Bottom Review," dated August 1995, which outlined FSIS' regulatory roles and proposed an organizational structure. The review recommended that FSIS appoint an implementation team to develop a reorganization plan, assess the

[1]These standards were updated in 1999 because of revisions to OMB Circular A-123 and other laws that have prompted a renewed focus on internal control (The Government Performance and Results Act of 1993, the Federal Financial Management Improvement Act of 1996). The federal standards also recognize internal control guidance developed by the Committee of Sponsoring Organization of the Treadway Commission (COSO)).

organization on an ongoing basis, and identify complementary measures that would enhance organizational effectiveness. During our audit, we determined that many of the recommendations included in the "Top-to-Bottom Review" were not implemented by FSIS. We could not obtain information explaining why they were not.

In 1996, the U.S. Department of Agriculture (USDA) Secretary announced a comprehensive reorganization of FSIS designed to prepare for implementation of HACCP. An April 16, 1997, memorandum from the Director, Import Inspection Division, to the Deputy Administrator, Office of Field Operations, outlined a plan to provide assurance that the import inspection functions were properly controlled during the transition to the new organizational structure. The memorandum also recognized the OIG concerns about the change in management of the import inspection function and called for an assessment to be conducted after reorganization to determine what actions would be needed to properly control the reinspection of imported products for the long term. However, many of the activities outlined in this plan were never accomplished, and, again, we could not obtain information explaining why they were not.

According to an FSIS official involved in the transition, it was important that all facets of the transition connect before the reorganization was officially implemented. One important facet involved inspector retraining. Former Import Field Office Supervisors were converted to Import Coordinators and were to assist District Managers and Circuit Supervisors as they gained import inspection expertise. It was important that domestic inspectors receive import inspection training because domestic and import inspections have notable differences. For example, if the hindquarter of a carcass contains *E. coli*-causing fecal traces or some other defect, the domestic inspector can allow the affected portion to be removed. However, the import inspector would be required to reject the entire shipment.

According to the proposed transition plan, the reorganization was to be completed over a 3-year period ending September 1998. However, before it was assured that all of the components of the transition were in place, including inspector retraining, an October 23, 1997, memorandum from the Deputy Administrator, Field Operations, stated that all supervisory responsibilities for import inspection activities and personnel were to be transferred to Circuit Supervisors on October 12, 1997. USDA's 1999 Budget Explanatory Notes for Committee on Appropriations states, "although the original plan was to implement the reorganization by FY 1999, a determination

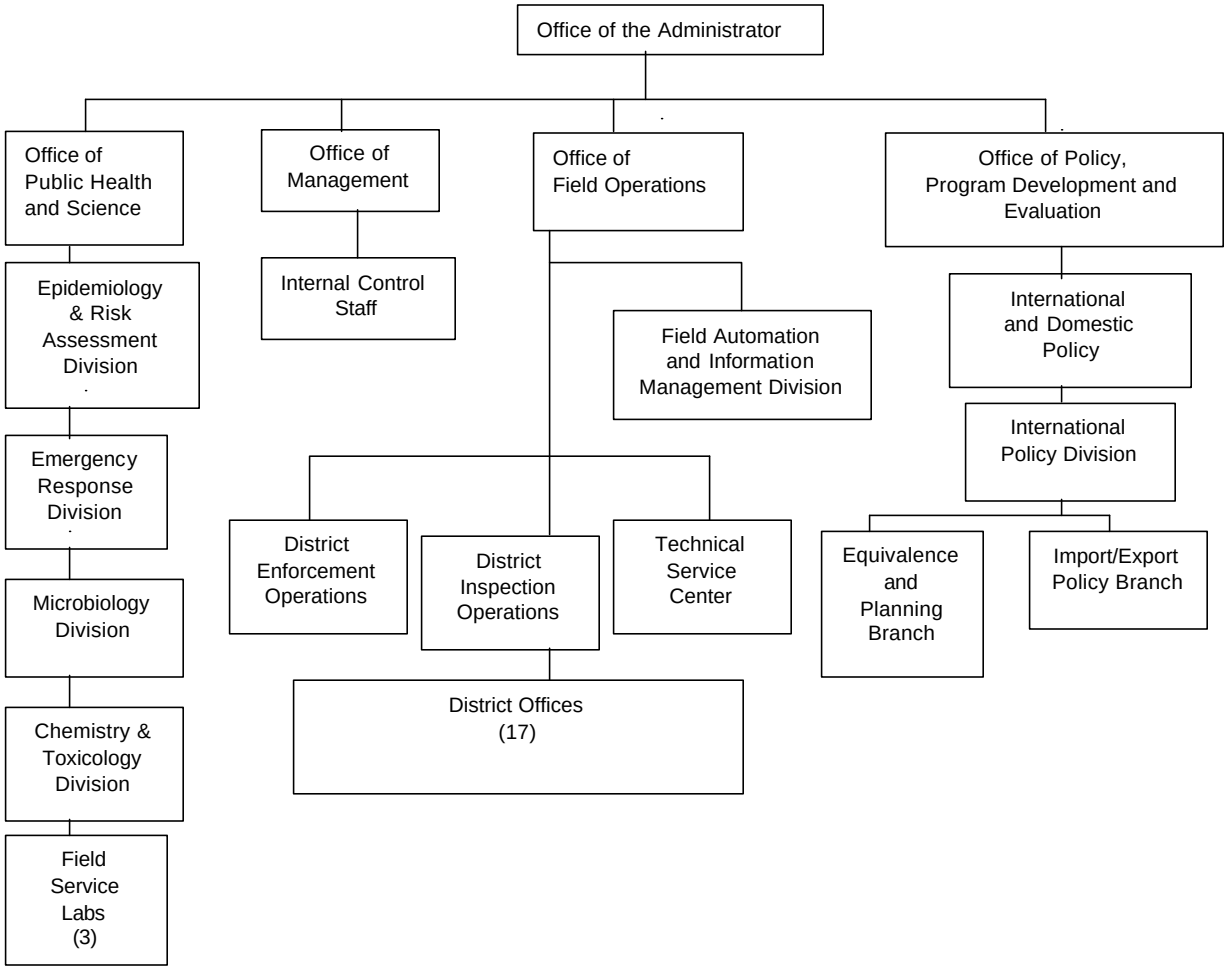
was made to move forward and complete the reorganization as quickly as practical." As a result, the reorganization went into effect before the transition plan was fully implemented.

Prior to 1985, FSIS operated under an organizational structure similar to the one currently in place. According to an FSIS official, FSIS internal reviews of this structure, as well as reviews by the OIG and the U.S. General Accounting Office, concluded that controls could be more effective. Between 1985 and 1996, the responsibility for carrying out the requirements of Federal meat and poultry inspection laws for imported products was unified within one office, FSIS' International Programs, under a single deputy administrator. FSIS consolidated its import inspection program and achieved a structure that contributed to the efficiency of the program. The import inspection function was separate from all other functions, and the unit responsible for it had both line and policy-making authority. An OIG audit performed to evaluate this organizational structure (Audit No. 38002-4-Hy, dated March 1989) concluded that controls over the import inspection process had improved since a prior (1987) audit.

An OIG audit, Audit No. 24099-01-Hy, conducted in 1996, recommended that as FSIS' reorganization was implemented, existing controls over the import meat and poultry inspection process be maintained. In response, FSIS indicated that the Director, Import Inspection Division, would ensure that accountability was in place for imported product and that inspection expertise was maintained. The response also stated that a comprehensive and detailed plan of action would be developed to maintain an effective import function. Based on our discussions with responsible FSIS officials, we found the plan was never developed.

In reorganizing, FSIS separated import inspection responsibilities between the Offices of Management; Field Operations; Public Health and Science; and Policy, Program Development and Evaluation. Under the reorganization plan, FSIS unified some functions, separated others, and reduced its office network from 46 field offices to 17 district offices. FSIS also established a Technical Service Center, located in Nebraska. Although this new field structure unified formerly separate functions to carry out inspection and compliance activities, it had the effect of fragmenting import inspection activities and increased the need for a strong internal control structure to ensure effective operations. The chart on the opposite page depicts the primary part of FSIS' reorganized structure that affects the import inspection program.

Figure 1: FSIS Organizational Structure Related to the Import Inspection Process



We found that as a result of the reorganization, the import inspection process is scattered among different entities and the operations are diffused among a number of districts. The separation of functions has required greater coordination between staffs, and has resulted in the need for retraining inspectors and the Technical Service Center foreign inspection system reviewers. However, FSIS has not developed adequate policies and procedures to facilitate this coordination, and training requirements have not been fully achieved.

OMB Circular A-123 requires managers to ensure that appropriate authority, responsibility, and accountability are defined and delegated to accomplish the mission of the organization, and that an appropriate organizational structure is established to effectively carry out program responsibilities. While we recognize there are transition difficulties in any reorganization effort, FSIS recognized the need, but did not take action, to ensure that its foreign inspection process control systems

are adequately developed, documented, and communicated to its staff. We conclude the findings in this report have occurred because FSIS did not adequately plan for the transition to the new organizational structure. In addition, there has been inadequate management oversight of the operational changes to the import inspection processes. As a result, a breakdown in controls that were designed to ensure the safety and wholesomeness of imported products entering the United States has occurred. Nothing came to our attention during this audit, however, that indicated FSIS allowed unsafe meat and poultry products to enter the United States.

According to FSIS officials, the audit failed to acknowledge the oversight in place that is responsible for managing change to import policies and procedures. However, the audit report does recognize the roles and responsibilities of these management officials. The audit disclosed weaknesses in FSIS' management control structure at various levels of the import inspection function after FSIS' reorganization. These controls include clearly defined roles and responsibilities, documented management reviews and approvals, directives/operating manuals, properly managed and maintained documentation, and a positive and supportive management attitude toward internal control. Controls over the reinspection process at U.S. ports of entry will be evaluated during Phase II of this audit.

RECOMMENDATION NO. 1

Conduct an in-depth assessment of the current organizational structure to establish a system of control objectives and processes to ensure that the goals of import inspection process are achieved.

Agency Response

FSIS agrees with this recommendation. FSIS will assess the current organizational structure and identify import inspection controls, objectives and processes. The assessment will be completed by May 2001.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 2

Require increased management oversight and approval of changes to import inspection operations and procedures.

Agency Response

FSIS believes that management oversight and approval of changes to import inspection operations and procedures is adequate. Inspection of imported meat and poultry product is controlled through a multi-tiered supervisory and management oversight structure.

FSIS will prepare a summary of the management oversight functions and procedures. These procedures will outline FSIS' efforts to strengthen management controls for all import operations. The consolidated written procedures will be developed by March 2001.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 3

Provide management control training to agency managers.

Agency Response

FSIS agrees with this recommendation. FSIS believes in continuous education and refresher training for its managers in a number of areas. FSIS will make arrangements for its Imported Meat and Poultry Inspection managers at Headquarters, District Offices, and the Technical Service Center to receive additional training on management controls. The agency will arrange for training similar to the Management Accountability and Control (OMB Circular A-123) course offered by the Government Audit Training Institute at the Graduate School, USDA by December 1, 2000. FSIS will explore including a training module on management controls in its Management Leadership and Development Program, which will be available to all agency managers.

OIG Position

We accept FSIS' management decision.

FINDING NO. 2

INDEPENDENT INTERNAL CONTROL REVIEWS HAVE NOT BEEN CONDUCTED

FSIS has not conducted independent internal control reviews of the import inspection program. According to the Director, Internal Control Staff, few resources were assigned to the staff; consequently, FSIS relied on each branch and program area to review its own activities and determine if vulnerabilities in operations exist. In the absence of independent internal control reviews, FSIS management has reduced assurance that adequate controls are in place, and functioning, over the import inspection program. These reviews are critical since FSIS has dispersed the responsibilities for the import inspection program among various operational units.

The Federal Manager's Financial Integrity Act requires each agency to evaluate the adequacy of its management controls. The correction of material weaknesses is to be considered in the agency's strategic planning, annual performance planning, and reporting processes.

As part of FSIS' reorganization, the Internal Control Staff was established and placed within the Office of Management. The Internal Control Staff is responsible for assisting management in carrying out its management control responsibilities specified in OMB Circular A-123 and FSIS Directive 1090.1, "Management Controls." To fulfill these responsibilities, the staff is empowered to independently and objectively assess the effectiveness of the agency's internal control systems, provide deputy administrators and program managers with assessments of its effectiveness, and monitor correction of any identified material weakness.

We found that the Internal Control Staff has not conducted independent assessments of import inspection activities to ensure that programs are managed effectively and comply with applicable laws and regulations. Each program office within FSIS has conducted its own assessment or evaluation of its programs to ensure compliance with management accountability and controls. The program offices responsible for the import inspection program have consistently found no areas of vulnerability during their own reviews, and the Internal Control Staff has not validated these findings.

Standards for Internal Control in the Federal Government states, in part, that qualified and continuous supervision should be provided to ensure that internal control objectives are achieved. In addition, the

"Top-to-Bottom Review" stated that FSIS' new organizational structure should have resulted in an improved supervisory span of control. However, we were unable to identify documented evidence of supervisory review or oversight over district office functions, the Technical Service Center, and the Equivalence and Planning Branch. According to an Office of Field Operations management official, if staff members are doing what they are supposed to do, then they do not need oversight. The Office of Field Operations has not conducted any reviews of the Technical Service Center and district office activity and assumed that personnel were doing a good job based on positive comments from industry and foreign governments.

The Director of the Internal Control Staff agreed that independent reviews are necessary, but noted that insufficient staff precluded his office from performing the reviews. He also noted that during the reorganization, the Internal Control Staff was assigned eight staff members and that this has proven insufficient to complete the activities mandated by FSIS Directive 1090.1.

We found, however, that some of the activities mandated by FSIS Directive 1090.1 are no longer required by OMB Circular A-123. FSIS' requirements are based on a 1986 version of the OMB circular, which has been superseded by a 1995 revision. The circular no longer requires agencies to segment themselves into assessable units, perform risk assessments of these units, rate the units, develop a 5-year management control plan, and conduct evaluations of units rated high or medium risk. It now provides a framework for integrating management control assessments with other work performed by agency managers, auditors and evaluators. In addition, the circular allows agencies to determine the appropriate level of documentation needed to support their annual assurance statements to Congress. FSIS did not incorporate any of these changes in its directive on management controls.

We were advised that the Internal Control Staff is in the process of re-engineering its internal control process. According to an FSIS official, a program management plan is being developed which will address procedures that will be used for assessing the controls and monitoring activities for programs within FSIS.

RECOMMENDATION NO. 4

Revise FSIS Directive 1090.1 to incorporate the provisions of OMB Circular A-123, Revised, "Management Accountability and Control," dated

June 21, 1995, and to document specific program control objectives and the review procedures that will provide management reasonable assurance on the effectiveness of controls.

Agency Response

FSIS agrees with this recommendation. FSIS has updated its Directive 1090.1 to incorporate the provisions of OMB Circular A-123, Revised, Management Accountability and Control," dated June 21, 1995. The draft directive outlines a process for establishing program control objectives and procedures that will provide management reasonable assurance on the effectiveness of controls. The draft document has been reviewed internally and is currently being reviewed by the National Joint Council, an employee union. We expect the directive to be finalized by October 1, 2000.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 5

Require the FSIS Internal Control Staff to conduct periodic independent assessments of FSIS' programs and operations, emphasizing those processes that changed in the reorganization.

Agency Response

FSIS agrees with the intent of this recommendation. FSIS will establish selection criteria for conducting periodic independent assessment of FSIS' programs and organizations as appropriate. The Executive Steering Committee for Management Controls will identify and prioritize for independent assessment selected processes that changed during the 1997 reorganization that should be reviewed. It should be noted that FSIS already requires the Internal Control Staff (ICS), to conduct independent assessments of FSIS' programs and operations. However, FSIS will direct the ICS, through guidance provided by the FSIS Executive Steering Committee on Management Controls, to conduct independent assessments of selected processes that changed during the 1997 reorganization. A memorandum of instruction to the ICS will be issued by September 1, 2000, from the Executive Steering Committee on Management Controls to address this recommendation.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 6

Report the conditions disclosed in this audit as material management control weaknesses in the import inspection process.

Agency Response

FSIS strongly disagrees with the OIG recommendation that the issues outlined in this audit report constitute a material management control weakness. They acknowledge the need to strengthen management controls and procedures, but they do not believe that the findings of this audit represent a reportable material management control weakness. Although FSIS agrees with most of the suggested management controls improvements in this audit, they do not believe they constitute a reportable material weakness of the import inspection process. FSIS will address opportunities for strengthening the management controls identified in this audit report and report them in accordance with the Agency's assessment of OMB Circular A-123 requirements.

OIG Position

OIG disagrees with FSIS' position that the findings in this report are not material control weaknesses. Basic control activities, such as documented policies, procedures, supervisory reviews and approvals, delegated responsibilities, and clear lines of authority were lacking in FSIS' operations. In the absence of the in-depth assessment of controls agreed to in response to Recommendation No. 1, FSIS should report the findings in this audit as material control weaknesses in the import inspection operations.

FINDING NO. 3

COORDINATION AMONG RESPONSIBLE PERSONNEL HAS NOT BEEN EFFECTIVE

Key features of the "Top-to-Bottom Review" proposed organizational model included highly integrated organizational components. We found, however, that there was a lack of effective coordination between the Office of Policy, Program Development and Evaluation and the Office of Field Operations and clear

separation of specific foreign system review (audit) tasks related to the equivalency determination process. This occurred, in part, due to unclear lines of authority and training goals that had not been achieved. As a result, there is reduced assurance that controls over the import inspection program have been maintained.

a. Roles and Responsibilities Overlap and are not Clearly Defined

The "Top-to-Bottom Review" report stated, in part, that although the current organizational structure[2] may appear to be adequate, the roles and responsibilities set out in agency functional statements have eroded over time. It also made reference to a duplication of effort and confusion about relative roles and responsibilities between specific staffs. We found this situation has occurred between the Technical Service Center and the Equivalence and Planning Branch staffs. In the absence of proactive management over the Technical Service Center and the Equivalence and Planning Branch, the two units created a working relationship, with the Equivalence and Planning Branch assuming a greater role in the equivalency verification process than specified in its functional statement.

According to a paper prepared by FSIS entitled Importing Meat and Poultry to the United States, a country must apply for a determination of equivalency before initially exporting meat or poultry to the United States. A two step evaluation consisting of a document review and an onsite equivalency verification review is conducted to determine that the country's sanitary measures, oversight, and enforcement are equivalent to the U.S. system. The Equivalence and Planning Branch maintains control over the document review process and the Technical Service Center reviewers conduct the onsite equivalency verification reviews. These reviews and inspection activities form the basis of FSIS' determinations of whether a country's inspection systems are equivalent to the United States.

The Standards for Internal Controls in the Federal Government states that key duties and responsibilities need to be divided or segregated among different people to reduce the risk of error. Agency functional statements assign the Technical Service Center responsibility for: interacting on a regular basis with other staffs to stay abreast of current issues, trends, and problems encountered, and integrating this information into onsite reviews of country

[2] The organizational structure in place prior to the 1997 reorganization.

inspection systems; designing operating systems, methods, guidelines, and processes for reviewing foreign, state, and domestic programs and conducting targeted program reviews of these operations; and, reviewing foreign programs to ensure compliance with equivalency requirements. Agency functional statements assign the Equivalence and Planning Branch responsibility for developing methods of review for foreign inspection systems and specifies that the Equivalence and Planning Branch is to maintain liaison with the Technical Service Center. However, we found that the Equivalence and Planning Branch does not routinely provide Technical Service Center reviewers with documentation provided by foreign countries to support their inspection programs prior to the Technical Service Center's onsite equivalency reviews. According to FSIS officials, copies of all incoming documents from foreign countries that export to the United States are routinely sent to the Director of the Technical Service Center Review Staff. However, we did not identify this type of documentation during our review of files maintained at the Technical Service Center. FSIS provided an April 13, 2000, document which stated, "Although EPB does not have written procedures for transmitting information to the TSC, the review staff now routinely reviews all documents received by IPD concerning the audit countries."

The Equivalence and Planning Branch has assumed a greater role in the foreign equivalence review process than outlined in functional statements and written documents prepared by FSIS. This expanded role includes reviewing and editing the foreign equivalency review (audit[3]) reports. However, the functional statements appear to provide for a separation of duties between the documentation review and the onsite verification review and subsequent audit report.

According to an FSIS paper entitled, "FSIS Process For Evaluating The Equivalence of Foreign Meat And Poultry Food Regulatory Systems," dated March 1999, equivalence decisions based on foreign food regulatory system documentation of specific sanitary measures are subsequently verified by onsite audits. However, our reviews of country files maintained at the Technical Service Center disclosed limited information on the Equivalence and Planning Branch document reviews of foreign food regulatory systems that need to be verified as part of the onsite reviews. The Equivalence

[3] While FSIS refers to these equivalency reviews as audits, they are not conducted in accordance with Government Auditing Standards.

and Planning Branch instituted a pre-audit telephone conference with the Technical Service Center reviewers to review information compiled by Equivalence and Planning Branch program analysts concerning prior audit issues, establishments known to have problems, port-of-entry violations, consumer complaints, and other matters. Equivalence and Planning Branch program analysts obtain this information from the Import/Export Policy Branch, the Automated Import Information System, country files, and other resources and divisions throughout the agency. The Technical Service Center reviewers are to use this information as a basis for planning their foreign equivalency reviews. However, documentation provided by the foreign country was not forwarded to the Technical Center Reviewers in order to ensure that all information submitted by the foreign country is verified during the onsite review. According to FSIS officials, the Technical Service Center reviewers can request that all documentation in the International Policy Division country file be sent to them.

Agency functional statements state that the Technical Service Center provides feedback on the results of its foreign inspection reviews to agency managers and the Equivalence and Planning Branch. The Technical Service Center review staff prepares a draft audit report and sends it to the Equivalence and Planning Branch for review. According to Equivalence and Planning Branch officials, the Technical Service Center reviewers are not to make recommendations because they do not determine equivalency. Recommendations for corrective actions are made by the Equivalence and Planning Branch, with input from the Technical Service Center. The Equivalence and Planning Branch staff reviews the draft reports and makes changes, primarily grammatical but sometimes substantive. In some reports we reviewed, the Equivalence and Planning Branch inserted recommendations and conclusions concerning system failures and corrective actions taken by foreign country officials. According to the Director of the Technical Service Center review staff, the Equivalence and Planning Branch is involved in the report review process due to a lack of staff, namely an Assistant Director of the review staff. He added that the reviewers are not obligated to make substantive changes, but will discuss them with the Equivalence and Planning Branch and reach an agreement. If the changes are substantive, the Equivalence and Planning Branch may request to see the report after revisions have been made.

In response to our concerns over the Equivalence and Planning Branch's role in the report process, FSIS officials provided an April 3, 2000, document which stated that the purpose of the Equivalence and Planning Branch review of the report is to ensure that all relevant information that the reviewer collected is presented in the report. While reviewing the report for substantive information, editorial comments are made for the purpose of clarifying the findings. Reviewers are not asked to change the facts. Rather, they may be asked to clarify facts so that the International Policy Division, in making equivalence determinations, can use the report.

The Equivalence and Planning Branch also maintains control over the audit resolution process. The Equivalence and Planning Branch staff sends letters to the foreign countries and receives their corrective action plans. Although the Equivalence and Planning Branch should share this information with the Technical Service Center as part of the resolution process, we found that the Technical Service Center staff was not always kept informed of agreements reached. For example, the Equivalence and Planning Branch granted a country flexibility in species testing, but the Technical Service Center reviewers were not told this prior to the onsite equivalency review.

The Equivalence and Planning Branch program analysts are to use information from the Technical Service Center audit reports to make equivalency determinations. Based on functional statements which require the Technical Service Center to provide feedback on the results of foreign inspection reviews to agency managers, the Technical Service Center audits should represent independent research upon which the Equivalence and Planning Branch can base its conclusions of equivalency or non-equivalency. However, FSIS officials believe that the issue of independence is off base, and that by organizational design the two units work closely on audits.

The position of FSIS officials is that the OIG audit should focus on outcome, not how FSIS has decided to manage this function. FSIS views the roles and working relationship between the Technical Service Center and the Equivalence and Planning Branch as very positive and harmonious, and added that the Director of the Techncial Service Center Review Staff and the Chief of the Equivalence Branch are in daily contact regarding equivalence determinations.

The Equivalence and Planning Branch must also coordinate with the Office of Field Operations' Field Automation and Information Management Division to ensure that information about delisted establishments is updated in FSIS' database, the Automated Import Information System. We found that the Equivalence and Planning Branch has not always properly coordinated with the Field Automation and Information Management Division and that some information in the Automated Import Information System on delisted establishments is inaccurate and not timely updated (see Finding Nos. 6 and 7).

This audit has raised a number of concerns regarding the coordination among several units within FSIS and identified examples of breakdowns in several processes. At the time we visited the Technical Service Center, the country files contained limited information received by the Equivalence and Planning Branch from foreign inspection systems. Also, undated administrative processing procedures developed by the Equivalence and Planning Branch did not include the Technical Service Center for distribution of incoming documents from foreign inspection systems. Our discussions with staff from the Equivalence and Planning Branch, and the Field Automation and Information Management Division disclosed confusion as to roles and responsibilities. FSIS needs to revisit its functional statements and develop procedures to clearly define the roles and responsibilities of the staffs involved.

b. Training Plan Not Fully Implemented

Standards for Internal Controls in Federal Government requires management to ensure that skill needs are continually assessed and that the organization is able to obtain a workforce that has the required skills that match those necessary to achieve organizational goals. According to recommendations outlined in the "Top-to-Bottom Review," FSIS personnel must be at least as knowledgeable as the regulated industry. Therefore, training was critical. Even though FSIS assigned new duties to personnel under its reorganized structure, it did not fully implement a training program to ensure that employees were proficient in those duties.

Under the current organizational structure, inspectors who formerly performed only domestic inspections may be required to perform import inspections. Also, import inspectors may be supervised by circuit supervisors who are only knowledgeable of domestic

inspections. Former import supervisors now serve as "import coordinators" to provide guidance to import reinspection activities in the district to which they are assigned. As previously discussed, an Import District Transition Plan was developed to ensure that district office personnel, circuit supervisors, and domestic inspectors were trained in import inspection activities during the transition to the new structure. However, FSIS officials were unable to provide adequate documentation that all personnel were trained in areas related to their current job responsibilities.

RECOMMENDATION NO. 7

Review the roles and responsibilities of personnel involved in the equivalence determination process, the onsite review process, and the input of data to update the Automated Import Information System, and define more specifically the authority and responsibilities of those units.

Agency Response

FSIS agrees to review the roles and responsibilities of personnel involved in the equivalence determination process, the onsite review process, and the input of data to update the Automated Import Information System (AIIS).

By October 1, 2000, FSIS will review and revise as necessary the functional statements of the International Policy Division (IPD) where joint and separate functional responsibilities exist in onsite equivalence audits, audit reports, and follow-up on equivalence issues raised during onsite audits.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 8

Prior to the onsite review, ensure that the Technical Service Center reviewers are provided with all information necessary to verify data provided by foreign countries for equivalence determinations.

Agency Response

FSIS agrees to develop formal procedures that will continue to ensure that the TSC is provided all information necessary for the reviewers to verify data provided by foreign countries during equivalence determinations. The procedures will be completed in December 2000.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 9

Provide training to all inspectors responsible for conducting inspections of imported products.

Agency Response

FSIS is currently developing updated import training for field inspectors who conduct import inspection activities. Training is scheduled to begin in FY 2001. This training plan is projected to include on-the-job training, pre-classroom CD-ROM's that cover basic import inspection procedures, and a formal training session at various U.S. ports of entry. The training plan will be completed in December 2000.

OIG Position

We accept FSIS' management decision.

FINDING NO. 4

WRITTEN PROCEDURES WERE NOT ADEQUATE TO ENSURE COMPLIANCE WITH REGULATORY REQUIREMENTS OR TO DOCUMENT THE PROCESS FOR DETERMINING COUNTRY EQUIVALENCY

Processes and procedures for determining equivalency were not detailed enough to ensure that all aspects of a country's regulatory system would be reviewed in accordance with applicable regulations. We also found that agency procedures were not always functioning as represented in documents provided during our review (see Chapters 2 and 3). We obtained documents (some of which were undated or in draft form), which outlined procedures for performing specific tasks related to the Equivalence and Planning Branch operations. Based on our review of these documents and discussions with FSIS officials, we determined that several of these procedures

were developed or revised on an "as-needed" basis without being subject to any formal review or approval process. In addition, no reviews were performed to determine the adequacy of the procedures. For example, procedures for reviewing documents submitted for equivalency determinations were revised during the course of our audit as a result of questions we raised about the process.

The "Top-to-Bottom Review" prepared for the pending reorganization recognized that "FSIS lacks a clearly defined and consistent approach to regulation development and is in need of a revamped process for carrying out this critical function. FSIS has developed regulations in a piecemeal fashion and issued policy memos or directives to avoid rulemaking. Not only does this approach result in implementation problems, but there is the risk of legal challenges when the agency publishes policy without rulemaking and tries to enforce a requirement that is not in the regulations." The "Top-to-Bottom Review" report recommended that a clearly established regulatory agenda process be created which would rely on subject-matter experts for input about substantive issues throughout the regulation development process. We were provided with an April 13, 2000, paper prepared by FSIS entitled: The Management Review of Equivalence Process, which outlined management's involvement in the equivalence review process; however, there was no documented evidence to support that these activities occurred.

a. Guidelines for Determining Equivalency Were Not Adequate

According to OMB Circular No. A-123, management controls include the methods and procedures adopted by management to ensure that its goals are met. Although FSIS developed basic guidelines for determining the equivalency status of a country's food inspection system, those guidelines were not detailed enough to ensure that required aspects of a country's regulatory system would be reviewed. To determine equivalency, Equivalence and Planning Branch program analysts must review the foreign government's performance standards and determine if those standards include implementation of a HACCP and pathogen reduction program, which includes SSOP, *Salmonella* testing, and *E. coli* testing. To assist the program analysts in making these determinations, procedures consisting only of a one-page document for each type of review were prepared. The guidelines described each process in very general language, and did not adequately address the processes needed to ensure compliance with federal requirements. For example, the guideline for *E. coli*

did not include an evaluation to determine whether the foreign inspection system programs maintained a process for ensuring that establishments prepare criteria for evaluating test results. The guidelines for HACCP did not include procedures for evaluating foreign inspection systems' process for ensuring that establishments validate the adequacy of HACCP plans at least annually and whenever changes occur that could affect the plan.

b. FSIS Lacks Procedures for Terminating a Foreign Country From Participating in the Import Inspection Program

FSIS actions were inconsistent when the agency handled countries that failed to timely submit required documents for equivalency determinations, or that had not implemented food regulatory systems as outlined in documents submitted for equivalency determinations. Regulations[4] outline conditions under which a foreign establishment's eligibility to import product to the United States may be terminated. However, FSIS has not developed written procedures for enforcing this regulation. There are no procedures for suspending the eligibility of exporting countries that do not provide sufficient documentation to support their continued compliance with U.S. equivalency standards, or are found to be in noncompliance based on the results of an onsite equivalency review.

An April 3, 2000, response prepared by FSIS to our draft report stated, in part, that it is not feasible to develop written procedures for terminating the eligibility of foreign establishments or an entire country's ability to export. Each situation presents itself with different factual patterns. Therefore, written procedures would have to be so general and vague, as to serve no useful purpose given that these situations require case by case assessment. However, it is our position that in the absence of written guidelines, FSIS can not be assured that each country is given due process and equal treatment.

According to FSIS' undated document on importing meat and poultry, if a country does not continue to operate an inspection system equivalent to the U.S. system, it is removed from the list of countries eligible to export to the United States. Loss of eligibility can also occur when FSIS is unable to get necessary information about a country's inspection system. Another undated document entitled, "Pathogen Reduction/HACCP Equivalence

[4] Title 9 CFR, Part 327.2, dated January 1, 1998.

Determinations," states, "three circumstances could, however, result in trade suspension. One is where an emergency sanitary measure is not implemented to address a hazard that is so severe that no product can enter the marketplace from a foreign establishment until the control is in place. The second is where an exporting country does not provide satisfactory documentary evidence of an equivalent sanitary measure. The third is where a system audit reveals that an exporting country is not implementing a sanitary measure in the manner that FSIS initially determined to be equivalent."

Based on our concerns over the equivalency determination process, the Equivalence and Planning Branch prepared a document which stated, in part, that, "in some cases, where a country failed to respond to requests for information, a draft cable was prepared which showed the country that FSIS would be forced to begin regulatory proceedings, in the form of an official action, to remove the country from the list of countries eligible to export to the United States." It also stated, "the process of initiating an official action against the importation of product from a particular country involves an extensive preparation and presentation of information to brief top executives within FSIS and USDA. Local Foreign Agricultural Service officials, agricultural attaches, U.S. Trade Representative officials, and the State Department are notified of the content of the cable or letter because of potentially serious U.S. trade considerations and political implications."

During our review of files maintained for each country eligible to export meat and poultry products to the United States, we noted that one country was immediately suspended from participation in the import inspection program when violations were found, while others with apparently similar violations continued under equivalency status without any formal deadline for corrective action. We noted this particularly in the cases of Country A and Country B.

Country A was suspended from participation in the import inspection program because it had not responded to FSIS' request for additional information for both SSOP implementation and *E. coli* testing. The Technical Service Center annual onsite equivalency reviews also revealed numerous deficiencies in the slaughter operations of three slaughter establishments in that country. These deficiencies included feces, hair, paint, dirt, and

other contaminants on the carcasses waiting to be deboned or placed in coolers. A fourth establishment showed evidence of past serious unsanitary conditions in its canning operation. None of the four establishments implemented an *E. coli* testing program.

While the conditions in Country A plants may indeed merit suspension, we noted that FSIS found several deficiencies in Country B, but did not suspend that country. An FSIS Microbiology Division document review disclosed that Country B was not complying with HACCP and pathogen reduction requirements. The review noted that Country B was not taking an appropriate sample size, did not use appropriate sampling techniques, and did not implement a formal *Salmonella* performance standard testing program. Like Country A, Country B had submitted insufficient data on its implementation of SSOP and *E. coli* testing, but in the case of Country B, FSIS continuously asked for additional information without imposing a deadline for its receipt. Those attempts continued for over a year while the country continued to export products into the United States. On one occasion, 7 months elapsed between the time FSIS requested information (February 1997) and the time Country B responded (September 1997). The data submitted was still incomplete.

FSIS and Country B reached an agreement that Country B would modify its program in relation to test site and test area, and as a result of this agreement, in November 1998, FSIS notified Country B that its *E. coli* testing was compatible with legislative requirements of equivalency. However, in contrast to the agreement, the onsite verification review conducted in March 1999 revealed numerous variances or deficiencies in Country B's testing programs that did not support documentation previously submitted to the Equivalence and Planning Branch. The onsite equivalency review found inadequate monitoring of SSOP and HACCP implementation, deviations or deficiencies in the *Salmonella* testing programs and in carcass sampling techniques, and imported meat products were not tested or included in the national residue monitoring program.

c. Procedures Used for Approving Alternative Inspection Methods Were Not Established

FSIS did not establish procedures for evaluating and documenting the assessment of alternative food safety inspection methods. Prior to 1995 when the United States implemented provisions of

the GATT Treaty, including the Sanitary Phytosanitary Agreement, all countries, which exported meat and poultry to the United States, were required to have inspection systems equal to the U.S. system. Subsequent to GATT, Congress changed the inspection laws to accept alternative, but equivalent inspection standards and procedures.

FSIS' process for evaluating different sanitary measures requires the exporting and importing countries to cooperate in a series of steps that meet mutual international obligations. The steps that countries choose depend on circumstances and trading experience between the two nations. Where sanitary measures differ, the food safety objective may need to be further explained by the importing country.

We identified four countries (Country C, Country E, Country D, and Country B) that requested to use alternative *E. coli* testing methods. Initially, FSIS determined that the four countries' alternative *E. coli* testing methods were not equivalent. Consequently, Country C decided to implement the same method used in the United States; however, the other three countries continued to seek approval for their alternative methods. During our evaluation of FSIS' process for reviewing these alternative systems, we could not determine what procedures FSIS used to approve an alternative method. Without a procedure in place, there is reduced assurance that FSIS' evaluations of alternative methods will be consistent and in accordance with U.S. standards.

An FSIS official in the Microbiology Division stated in a letter dated May 13, 1998, that during the review of Country D's submission of its microbiological testing program, there was no policy [alternative methods] in place for *E. coli* testing. Therefore, the microbiologist prepared a list of differences between the microbiological testing program in Country D and the generic *E. coli* testing program outlined in the pathogen reduction/HACCP final rule. On April 12, 2000, we were provided with documentation which outlined FSIS' Proposal For Equivalency Study, dated January 11, 1999, and a March 7, 2000, letter from FSIS to Country D's Chief Veterinary Officer concerning the equivalency of its *Enterobacteriaceae* testing program. However, these documents were not included as part of the country file during the time of our field work, and do not represent a policy for evaluating alternative methods for *E. coli* testing.

According to documentation provided to FSIS from Country E in 1997, Country E implemented the provisions of the final rule for *E. coli* testing at cattle slaughter facilities but limited its program for *Salmonella* testing on swine. It also used different sampling techniques and analytical methods. In a May 22, 1997, cable, FSIS asked Country E to provide scientific documentation that demonstrated the equivalency of these alternative techniques. Based on the onsite equivalency review, conducted between November 14, 1997, and December 18, 1997, the audit report for Country E, dated March 3, 1998, disclosed that sampling procedures, randomization, and analytical methods did not conform to U.S. requirements. In addition, pre-operational and operational SSOP's and inspection controls were not effective in most establishments reviewed.

A telefax from Country E to FSIS, dated March 27, 1998, included the raw data on the results of a study comparing the U.S. sponge technique for *E. coli* testing with Country E's gauze-tampon technique. We did not find documentation to show the analysis of this information. On April 12, 2000, we were provided with a written summary of an August 25, 1998, teleconference between FSIS and Country E's meat inspection officials to discuss deficiencies found during the 1997 onsite audit, and to address specific equivalence issues regarding Country E's *E. coli* testing program. The summary stated, in part, that International Policy and Development (IDP) presented a draft cable that determined Country E's *E. coli* testing program to be equivalent, provided they use statistical process control techniques to evaluate test results when using a method of sample collection other than the excision method. IDP asked the inspection officials to respond to the draft conditional cable by early next week (i.e., by September 1, 1998). In addition, the Country E officials agreed to address variances in their *E. coli* contamination controls.

We were also provided with a copy of a September 3, 1998, letter from FSIS to Country E's Veterinary and Food Administration that summarized prior discussions concerning deficiencies noted during the 1997 audit, and corrective actions taken by Country E. The letter included a statement that Country E officials agreed to address variances in their *E. coli* testing program regarding random sampling procedures, process control charting, and *E. coli* contamination controls, and a suggestion to reconvene to confirm upcoming corrective actions regarding issues not fully resolved. However, we were not provided with documentation to support a

subsequent meeting between FSIS and Country E officials to confirm corrective actions regarding issues not fully resolved. Also, a December 9, 1998, cable from FSIS to Country E stated that its *E. coli* testing program is "equivalent" based on its agreement to use statistical process control techniques to evaluate test results when using the gauze-tampon method of sample collection. However, we were unable to obtain documentation of information provided by Country E officials, and confirmation of agreements reached, or a subsequent analysis conducted by the Microbiology division to determine the equivalence of Country E's gauze-tampon technique to the U.S. sponge technique for *E. coli* testing.

Country B's file contained correspondence between FSIS and Country B from December 1996 to February 1999 pertaining to Country B's alternative proposal for conducting *E. coli* testing. This alternative *E. coli* testing system was found "equivalent" by FSIS as documented in a November 12, 1998, cable to Country B. Even though we were provided with documents dated from October 1997 to June 1998 to support subject-matter experts' reviews of Country B's submissions, the process for determining equivalency did not provide adequate documentation to conclude that Country B's alternative *E. coli* testing system was equivalent.

Detailed operational procedures are needed to ensure that equivalency determinations are made in accordance with regulations and that the critical areas in the five risk areas are addressed satisfactorily with respect to standards, activities, resources, and enforcement. During the course of our review, the Assistant Deputy Administrator, Office of Policy, Program Development and Evaluation, held meetings with the Equivalence and Planning Branch staff in order to conduct a comprehensive analysis of the documentation review process, along with a review of equivalency determinations previously rendered for specific countries. If this process continues, we view this as a positive step in improving the adequacy and accountability of the Equivalence and Planning Branch's equivalency determination process.

RECOMMENDATION NO. 10

With the help of technical subject-matter experts, develop and implement comprehensive guidelines as a means of ensuring propriety and consistency in decisions involving equivalency determinations.

Agency Response

FSIS agrees to develop comprehensive written guidelines for equivalence determinations by January 2001. FSIS had developed general guidelines to ensure that the foreign governments had addressed all the components of the PR/HACCP requirements. These guidelines were not the only documents used to review foreign country submissions.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 11

Develop written criteria and procedures for suspending the eligibility of exporting countries that do not provide sufficient documentation to support their continuing compliance with U.S. equivalency standards or are found to be in noncompliance based on the results of an onsite equivalency review.

Agency Response

FSIS agrees with this recommendation. FSIS regulations, 9 CFR 327.2, delineate criteria for both initially determining the eligibility of a foreign country to import products into the United States and for withdrawing a foreign country's eligibility to import. FSIS will consolidate this requirement into formal procedures and guidelines by March 2001.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 12

Develop written procedures which ensure comprehensive evaluations of foreign countries' alternative import inspection methods, and require the analysis of these systems be documented, as well as the decisions reached.

Agency Response

FSIS agrees with this recommendation. Consolidated written procedures will be developed by March 2001 to document

equivalence decisions regarding alternative import inspection methods. Effective July 1, 2000, new equivalence decision files will document: 1) All FSIS correspondence with foreign countries; 2) All foreign country submissions (translated and in the originating language); 3) Summary IPD reviews of submissions; 4) Summary of all meetings and teleconferences with foreign officials; 5) Summary of all reviews by subject-matter experts; 6) Documentation of equivalence criteria; 7) Summary of all FSIS management formal reviews and approvals; and 8) Decision memorandum of the equivalence determinations.

OIG Position

We accept FSIS' management decision.

CHAPTER 2	THE REINSPECTION PROCESS DID NOT ENSURE THAT INELIGIBLE IMPORTERS WERE PROPERLY IDENTIFIED AND THAT RECOGNIZED PATHOGEN VIOLATIONS WERE RESPONDED TO PROMPTLY

FSIS did not adequately control its resources to ensure that foreign countries importing meat and poultry products to the United States were eligible to do so. Residue test plans and eligibility certifications for foreign establishments were not always obtained and analyzed; those that were obtained were not posted to the Automated Import Information System in a timely manner. The Automated Import Information System also did not timely reflect the results of laboratory analyses performed during reinspections. Under these conditions, FSIS could not ensure that information concerning foreign imports was accurate and was available to the appropriate officials for action in a timely manner. For example, 7 establishments from 4 foreign countries shipped 4,625,363 pounds of meat and poultry products and presented them for reinspection even though the establishments were delisted (i.e., removed from the list of approved importers). This included 625,582 pounds of frozen cooked beef from an establishment that was barred from sending products because of *Listeria* violations. Discrepancies in documentation and summary information provided by FSIS raises questions about the conclusion of FSIS officials that the shipments were certified by foreign governments before the establishments were delisted. Deficiencies in FSIS' certification and delistment activities occurred largely as a result of unclear or nonexistent procedures (see Finding No. 1). FSIS officials stated that foreign countries are not required to provide information about the dates that products are produced. Therefore, we were unable to determine if foreign establishments produced products that were presented for reinspection during their delistment period. Nothing came to our attention during this audit, however, to indicate that FSIS allowed unsafe product to enter the United States.

Under FSIS' reinspection process, imported meat and poultry products from countries with equivalent status are allowed into the United States with sample testing at ports of entry. The test results are posted in the Automated Import Information System. In addition, the Automated Import Information System should include delistment information as a result of onsite equivalency reviews, as well as establishments certified/decertified by foreign countries as meeting U.S. inspection program standards. These elements form a

compliance history and the basis for assigning future inspection levels for products shipped to the United States from these establishments.

Foreign countries and establishments that have a history of noncompliance are delisted. The Office of Policy, Program Development and Evaluation is primarily responsible for ensuring that the foreign countries provide information about delistment and for promptly forwarding that information to the Field Automation and Information Management Division for timely updating of the Automated Import Information System. The Automated Import Information System is FSIS' primary means of ensuring that products from delisted establishments are refused entry.

FINDING NO. 5

INCONSISTENT REPORTING OF LABORATORY RESULTS WAS INEFFICIENT AND POTENTIALLY ERROR-PRONE

FSIS has no clear process for entering the results of laboratory tests into the Automated Import Information System. The Import Inspectors Manual (manual) does not provide adequate guidance on who is responsible for entering the information. In practice, the manner in which the results are processed and the persons responsible for processing those results vary with the type of test conducted. We also found that despite the importance of the laboratory results, neither the Technical Service Center nor the Field Automation and Information Management Division officials have established a supervisory review system for ensuring that the results are promptly and accurately entered into the Automated Import Information System. This lack of consistency could jeopardize the integrity of the Automated Import Information System data base and its ability to make appropriate reinspection assignments.

Regulations[5] state that the computerized Automated Import Information System shall be consulted for reinspection instructions. The Automated Import Information System will assign reinspection levels and procedures based on established sampling plans and established product and plant history.

When a shipment is ready to be reinspected by FSIS, the Automated Import Information System will generate an inspection assignment based solely on the compliance history of the establishment and the foreign country for the specific product. The Automated Import Information System records the results of the inspection, and can

[5] Title 9 CFR, Part 327.6 (a) (3), dated January 1, 1998.

generate reports based upon the results. The inspection assignments could include the following laboratory testing programs: residue, microbiological (*Staphylococcal aureus enterotoxin*, *Salmonella*, *Escherichia coli*, and *Listeria*), abnormal containers, food chemical, etc.

Instructions for entering laboratory test results into the Automated Import Information System are outlined in the laboratory sampling section of the manual, dated September 30, 1998. We found that procedures outlined in the manual do not reflect what is actually occurring. For example, the manual indicates that import coordinators are responsible for entering the positive (failure) results of various microbiological tests. In reality, these results are entered by Technical Service Center staff officers, who explained that they assumed this responsibility after the manual was issued. They further explained that the manual had not been revised to reflect these procedural changes because of plans to convert the manual to an FSIS Directive. Although Technical Service Center officials claimed that the Automated Import Information System is promptly updated to record laboratory test results, copies of the failure notices are not maintained at the Technical Service Center to document the reasons for, and the timeliness of their actions. Furthermore, Technical Service Center management has not instituted a system for ensuring that Technical Service Center staff are timely and accurately entering the test results into the Automated Import Information System.

The manual also states that the Field Automation and Information Management Division is responsible for entering both positive and negative residue test results into the Automated Import Information System. We learned that, in this case, the results take a circuitous route before they reach the Field Automation and Information Management Division. Positive results are conveyed to the Technical Service Center for referral to the Field Automation and Information Management Division and entry into the Automated Import Information System, while negative results are entered by the laboratories into the Microbiological and Residue Computer Information System. Because the Microbiological and Residue Computer Information System does not interface with the Automated Import Information System, the Field Automation and Information Management Division needs to download the results from the Microbiological and Residue Computer Information System into the Automated Import Information System. The timeliness of processing both negative and positive results is critical. The Automated Import Information System should reflect the most current information because inspection assignments are being

made for subsequent reinspections. Nevertheless, Field Automation and Information Management Division officials have not established a supervisory review system to ensure that all procedures are completed and that entries are made in a timely and accurate manner.

We concluded that the current system with its numerous processes for entering the various types of laboratory results (such as microbiological and residue test results) into the Automated Import Information System is prone to error and should be streamlined.

During our review, we learned that inspectors are responsible for selecting the appropriate samples and performing the tests assigned by the Automated Import Information System for products shipped from foreign establishments. The inspectors are also responsible for entering results for some test programs along with other types of data relating to the inspection process into the Automated Import Information System. Circuit supervisors have the immediate supervisory responsibility for assuring that these tasks are performed in a correct and timely manner.

We will visit inspection houses during the next audit phase to determine if the circuit supervisors and the inspectors are fulfilling these responsibilities.

RECOMMENDATION NO. 13

Streamline the process and establish procedures that would allow expeditious entry of laboratory test results into the Automated Import Information System.

Agency Response

FSIS agrees that additional documentation would assist in clarifying the current system to both Agency personnel as well as outside auditors. FSIS is reevaluating the current system as part of the redesign of the AIIS and will improve the documentation by December 2000 to outline the procedures for entering laboratory results into the AIIS system.

As an interim measure, in March 2000, the Field Automation Information Management (FAIM) Division instituted non-automated procedures to streamline the entry of residue and microbial results. As of March, FAIM receives faxes from the TSC of laboratory Form 9770-2 for all positive residue results. The FAIM Division then documents directly on the laboratory form both the date it was

received (via fax) and the date/time the lab results were entered into AIIS. Entries into the AIIS are made the same day they are received. Also, an internal verification process will be established to monitor the data being entered into the AIIS.

Also, FSIS is working to replace the AIIS. The new system, eventually sharing Sybase SQL tables with the Microbiological and Residue Computer Information System (MARCIS) and other agency systems will ensure real time accuracy of both negative and positive results of residue tests and microbiological tests. The FAIM Division began work on the new AIIS application in March 2000, with a test pilot planned for the first quarter of 2001. We expect the system to be fully operational by December 2001.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 14

Require the Office of Field Operations to work with the Technical Service Center and the Field Automation and Information Management Division to develop management controls and a supervisory review process to ensure that all laboratory test results are promptly and accurately entered into the Automated Import Information System. Management controls must include requirements for maintaining records of when failure notifications are received and when the entries are made into the Automated Import Information System.

Agency Response

FSIS agrees with this recommedation. The FAIM Division is focusing on incorporating the required management controls in the replacement AIIS, which should be completed by December 2001. The new import computer system will document when laboratory failure results are received and incorporated into the system data tables. In the interim, FSIS has established a manual tracking process that documents when notification of failures is received and when the entries are made into the AIIS. Entries are made within 24 hours of receipt of the positive laboratory results. Negative resultsare obtained via a weekly download from MARCIS and entered that same day into the AIIS.

FSIS believes that the management controls and supervisory review process can be enhanced to ensure that all laboratory results are promptly and accurately entered into the AIIS. Management controls currently include requirements for maintaining records that indicate when failure notifications are received, and when the entries are made into the AIIS.

OIG Position

To reach management decision, FSIS needs to provide a target completion date as to when the management controls and supervisory review process will be documented in agency procedures.

FINDING NO. 6

FSIS DID NOT ENSURE THAT ESTABLISHMENTS MET ANNUAL CERTIFICATION REQUIREMENTS

Foreign governments are required to certify annually that each of the establishments in their countries that export meat and poultry to the United States continue to comply with the food safety systems under which they were granted equivalent status. The FSIS Administrator may terminate the eligibility of any foreign establishment if a current certification of that establishment is not obtained[6]. We found that FSIS management did not ensure that the annual certification requirement was fulfilled. Also, FSIS is not ensuring that certification information is posted in the Automated Import Information System so that inspection officials are aware of each establishment's status. We further found that, as of April 29, 1999, FSIS had not received the 1999 annual certifications from establishments in 19 foreign countries which shipped about 2.3 billion pounds of product to the United States during 1999; or the 1998 annual certifications from establishments in 4 foreign countries which accounted for 1.4 billion of the 3 billion pounds of product shipped to the United States during 1998. Allowing countries to delay their certifications reduces the control to prevent products from uncertified establishments from entering the United States. In addition, the Secretary's annual report to Congress, "Foreign Countries and Plants Certified to Export Meat and Poultry to the United States," may not be accurate. This report is to be submitted to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture and Forestry of the Senate no later than March 1 of each year.

[6] Title 9 CFR, Part 327.2 (a) (3), dated January 1, 1998.

Regulations[7] state that only those establishments that are certified by a responsible official of the foreign meat inspection system as fully meeting U.S. requirements are eligible to have their products imported into the United States. Certifications are to be renewed annually.

The Automated Import Information System must be annually updated to reflect activity during the previous year that would affect current inspection assignments. We were advised that FSIS assigned January 1 of each year as the due date for foreign certifications. However, documentation to affirm this date could not be provided. At the beginning of 1998 and 1999, the foreign governments should have provided FSIS with comprehensive lists of establishments certified to ship meat and poultry products to the United States for those years. According to functional statements, the Assistant Deputy Administrator for International and Domestic Policy, through the Equivalence and Planning Branch, is responsible for reviewing certification information and forwarding it to the Field Automation and Information Management Division for entry into the Automated Import Information System. The Equivalence and Planning Branch is also responsible for making delistment decisions and forwarding this information for entry into the Automated Import Information System. We found that the January 1 deadline became merely a target date that few countries observed. The annual certifications were sent to FSIS at any time during the year, and were not necessarily addressed to the same FSIS official each time.

Reporting methods were inconsistent because FSIS had not established procedures to ensure that critical information, including the certification and delistment of foreign establishments, was distributed to the appropriate staff members and promptly posted in the Automated Import Information System. Staff members within the Equivalence and Planning Branch and the Field Automation and Information Management Division were unclear regarding the proper processing of the certifications. We were told that lapses began occurring after the reorganization, when related functions were parceled out to separate entities within FSIS and older procedures were abandoned.

We reviewed the Field Automation and Information Management Division's lists of annual certification information. The "Annual Certification of Plants for 1998" report shows that as of April 29, 1999, 4 of the 36 foreign countries (eligible to ship meat and poultry products to the United States) had not submitted their comprehensive annual

[7] Title 9 CFR, Part 327.2 (a) (3), dated January 1, 1998.

certification listings that had been due in January 1998. According to the Field Automation and Information Management Division officials, the status of a foreign country or establishment in the Automated Import Information System cannot be changed without first receiving authorization from the Equivalence and Planning Branch. The Field Automation and Information Management Division raised concerns that it could not update the Automated Import Information System or the Secretary's report to Congress because the comprehensive annual certification information was not provided. An Equivalence and Planning Branch official contacted the Field Automation and Information Management Division and confirmed that four countries had not provided 1998 certifications, but advised the Field Automation and Information Management Division to "go with the same establishments" certified for 1997. These four countries exported 1.4 billion pounds of meat and poultry products to the United States during 1998.

The Field Automation and Information Management Division's "Annual Certification of Plants for 1999" shows that as of April 29, 1999, only 17 of the 36 foreign countries submitted their comprehensive annual certification lists for 1999. The Automated Import Information System also continued to show that hundreds of foreign establishments from the 19 remaining countries remained eligible to ship products to the United States even though they had not been certified for 1999.

FSIS officials stated that a country's certification of its establishments never expires unless the nation removes itself from trade or unless the United States chooses to do so as a safety measure. FSIS requires that a foreign meat inspection certificate accompany each consignment. Each certificate, for each shipment, indicates that the exporting plant is certified by the foreign meat inspection system, and that the product complies with FSIS requirements. FSIS officials stated that the annual certification requirement is an "unnecessary redundancy."

Regulations currently require an annual certification of its establishments by the foreign meat inspection authority, as well as inspection certificates to accompany each shipment. OIG views these requirements as compensating controls since prior audits and investigations have identified weaknesses in controls over inspection certificates (both foreign and domestic) and concerns regarding their validity.

RECOMMENDATION NO. 15

Officially notify all countries importing meat and poultry into the United States that annual certifications are due no later than the established date and that establishments that are not certified by this date may be delisted. Incorporate this requirement in regulations.

Agency Response

FSIS agrees that meat and poultry products exported to the United States must be produced in properly certified foreign establishments. To ensure that this occurs, the FAIM Division has established a web site with search capabilities that allows import inspectors to obtain the status (certification, delistment, relistment) of foreign establishments.

FSIS agrees to continue to notify all countries that certifications of establishments must be renewed annually, and if establishments are not certified annually they may be delisted. However, FSIS does not agree with the OIG's assertion that allowing countries to delay their certifications "reduces the control to prevent products from uncertified establishments from entering the United States".

Annual certification lists are often obsolete soon after they arrive because importing countries add and delete certified establishments throughout the year. Furthermore, an additional method exists to verify that the imported product was produced in an establishment certified for export to the United States. This method is set forth in 9 CFR 327.4, "Imported products, foreign certificates required." A foreign meat inspection certificate must accompany each consignment of fresh meat, fresh meat byproducts, or meat food products. All such consignments (or lots) offered for entry into the United States from any foreign country must be reinspected by an FSIS import inspector before they are allowed into this country. An authorized foreign government official signs the certification accompanying each lot.

FSIS believes that these certificates provide ample evidence that the product they accompany was produced in a foreign-certified establishment. By September 2001, FSIS will publish a proposed revision of Part 327, Imported Products, to eliminate the annual certification requirement.

OIG Position

We agree with FSIS' response to notify all countries that certifications of establishments must be renewed annually, and if establishments are not certified annually, they may be delisted. However, we disagree that FSIS should eliminate their compensating control of requiring annual certifications from a responsible official of the foreign inspection systems. To reach management decision, FSIS needs to provide a target date as to when countries will be notified of the annual certification requirement. Also, if the annual certification requirement is discontinued, FSIS needs to develop compensating controls to ensure the validity of the foreign inspection certificate accompanying each shipment of product to the United States.

RECOMMENDATION NO. 16

Establish a followup process to obtain the annual certification lists from the countries which have not submitted them.

Agency Response

FSIS has established a follow-up process to obtain annual certification lists from countries that have not submitted them. This process is subject to change after the proposed revisions (see response to Recommendation 15) in Part 327 are implemented.

Annual certification lists are sent from foreign countries to the IPD. In July 1999, effective for calendar year 2000, the FAIM Division established a procedure to notify IPD of every country for which FAIM has not received an annual certification of establishments. Starting in February 2000, and continuing on a monthly basis, the FAIM Division has notified the IPD of outstanding certification lists.

OIG Position

To reach management decision, FSIS needs to provide a target date for developing a follow-up process to include actions to be taken by the IPD when notified of outstanding certification lists.

RECOMMENDATION NO. 17

Immediately conduct a reconciliation between establishment certification information maintained by the Equivalence and Planning Branch and the Automated Import Information System to ensure that the Automated Import Information System includes only those

establishments certified by their foreign governments to ship products to the United States.

Agency Response

FSIS agrees with the recommendation. Following the onsite portion of the OIG audit, the FAIM Division established a program of quarterly crosschecks of foreign government certification documents against the establishment listings contained in the AIIS. In addition, effective April 1999, the FAIM Division began sending to the IPD a weekly report listing all certified and decertified establishments maintained in the AIIS. IDP will begin reconciliation of the FAIM reported data and their internal records by December 2000.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 18

Establish time requirements and a management control process for reviewing and processing certification information in the Automated Import Information System.

Agency Response

FSIS agrees with this recommendation. The FAIM Division maintains an internal AIIS Import Manual of procedures document that will be updated by December 2000, to address time requirements and management control processes. Supervisory oversight will be established whereby all changes to the AIIS status of establishments will be forwarded to the Branch Chief of the FAIM Applications Systems Development Branch for review.

OIG Position

We accept FSIS' management decision.

FINDING NO. 7

FSIS DID NOT ESTABLISH A SYSTEM FOR TRACKING DELISTMENTS

Neither the Office of Policy, Program Development and Evaluation nor the Office of Field Operations had formulated supervisory review procedures to ensure that all delistment, relistment, and related information was processed for accurate and timely entry into the Automated Import Information System. Technical Service Center officials were not timely informing the Office of Policy, Program Development and Evaluation about foreign establishments that were delisted prior to, or because of, their onsite reviews. Furthermore, after the reorganization, FSIS abandoned a system for tracking delistments and did not replace it. We found that in the absence of a tracking system, establishment delistments were not timely entered in the Automated Import Information System. As a result, these delisted establishments incorrectly remained eligible to present meat and poultry products for entry to the United States. We found seven establishments from four countries shipped about 4.6 million pounds of meat and poultry products and presented them for reinspection even though the establishments were delisted. Based on documentation provided by FSIS, we were unable to determine whether product was produced prior to the delistment period. Nothing came to our attention during this audit, however, to indicate that FSIS allowed unsafe product to enter the United States.

During our review of the Technical Service Center equivalency review (audit) reports, we noted that delistment information resulting from these reviews was not being timely provided to the Field Automation and Information Management Division for entry into the Automated Import Information System. In one case, the Technical Service Center reviewers learned that a foreign establishment had been slaughtering more than one species of animal in the same slaughterhouse and delisted the slaughterhouse in October 1998. However, the Field Automation and Information Management Division was not informed of this fact. As of May 4, 1999, the establishment remained certified in the Automated Import Information System even though the foreign country's February 25, 1999, annual certification list to the Equivalence and Planning Branch excluded the establishment. As of May 6, 1999, no product from this establishment had been presented for reinspection at U.S. ports.

In another case, the Technical Service Center reviewers learned that a foreign government delisted an establishment prior to their March 1999 onsite review. As of May 4, 1999, the Field Automation

and Information Management Division had not been informed about the delistment so the Automated Import Information System was not updated to reflect the establishment's delisted status.

This lack of internal controls raises questions about the integrity of the data in the Automated Import Information System. For example, on December 29, 1998, the Office of Policy, Program Development and Evaluation received notifications from a foreign country's Bureau of Animal Industry to withdraw approval (delist) two establishments in their country. However, the Office of Policy, Program Development and Evaluation did not provide this information to the Field Automation and Information Management Division for input to the Automated Import Information System until February 8, 1999. According to handwritten notes on the notification maintained by the Field Automation and Information Management Division, the delistment was entered into the Automated Import Information System on the day that it was received, February 8, 1999. However, an Automated Import Information System report dated April 28, 1999, shows that the establishments were not delisted. From January 25, 1999 to February 23, 1999, 355,104 pounds of meat products were presented for reinspection from these two foreign establishments. Field Automation and Information Management Division personnel could not explain why the two establishments had not been delisted in the Automated Import Information System. However, because of our inquiries about the situation, the Automated Import Information System files for these two establishments were opened and these establishments were delisted. Field Automation and Information Management Division personnel made this adjustment without approval by a management official.

We reviewed delistment information for 19 establishments from 8 foreign countries. We compared this information to an Automated Import Information System printout of delisted establishments dated May 6, 1999, and to an Automated Import Information System printout of products presented for FSIS reinspection during the time these establishments should have been delisted. We found that in no instance was the information promptly provided to the Field Automation and Information Management Division to update the Automated Import Information System with the delistment status of the establishments. For example, the printout dated May 6, 1999, indicated that three establishments remained eligible to ship products to the United States even though one of the establishments was officially delisted in February 1999 and the other two in April 1999.

Most importantly, seven establishments from four countries shipped over 4.6 million pounds of meat and poultry products and presented them for reinspection even though the establishments were delisted. This included:

- 625,582 pounds of frozen cooked beef from one establishment that was delisted because *Listeria* was found in previous shipments of its frozen cooked beef;

- over 1 million pounds of meat products from an establishment that shipped 20 shipments over a 5-month period after its delistment date (December 24, 1998). [Note: we were able to determine that two of the shipments, representing about 95,000 pounds of meat products, were produced prior to the delistment date and were eligible for FSIS reinspection; however, because FSIS maintains limited information, we could not verify other shipments]; and

- 664,272 pounds of beef by a delisted establishment that had been cited for sanitation problems, *Listeria* violations, and the presence of metal fragments in previous shipments of its beef products. [Note: the limited information being maintained by FSIS shows that 55,409 pounds were produced prior to the establishment's delistment and were eligible for FSIS reinspection.]

FSIS officials provided documentation to support their conclusion that although the establishments were delisted, 4.9 million pounds of their products were eligible for FSIS reinspection because the shipments were certified by their foreign governments prior to the establishments' delistment periods. However, during our review of the documentation provided by FSIS, we found discrepancies significant enough to raise questions about the conclusion reached by FSIS officials. For example:

- the 4.9 million pounds reported by FSIS erroneously included shipments that were presented for FSIS reinspection prior to the delistment period and improperly included categories of products that were eligible for shipment to the United States. (Note: The 4.6 million pounds reported by OIG included only those products presented for FSIS reinspection while the foreign establishments should have been delisted).

- shipments reported by FSIS as being sent to the United States prior to the delistment period actually were sent during the delistment period.

- at least 20 of the documents provided by FSIS could not be matched with specific shipment information, thus limiting our ability to verify the FSIS documentation and summary information.

- FSIS used incorrect beginning delistment dates for three establishments.

- FSIS did not have documentation for at least 16 shipments and did not indicate what action will be taken to determine if the shipments were certified by the foreign governments prior to the time that the products were presented for FSIS reinspection.

According to FSIS, if the documentation has a date which coincides with the delistment period, the FSIS inspectors should have contacted FSIS headquarters or their respective district offices to verify eligibility of the shipments. The verification process should have also included contacting the foreign governments for clarification as to when the shipments were produced. However, FSIS noted in a summary of the documentation provided to OIG during April 2000, that the foreign governments will now be contacted to verify when these shipments were produced. Most of the products were shipped to the United States from December 1998 to June 1999. Thus, the verification is not occurring until 10 to 16 months have lapsed since these products were presented for FSIS reinspection. During our review of the documentation, we noted that at least 25 of these shipments had already been stamped "U.S. Inspected & Passed."

In March 1999, an official in FSIS' International Policy Division began noticing that delistments were not being adequately tracked. The official learned that a foreign establishment had not been delisted despite deficiencies in its slaughter operations and post mortem inspections, and despite failures in *E. coli* and *Salmonella* tests of its products. These deficiencies were noted by Technical Service Center staff during an onsite review of the establishment, but they were not communicated to the Equivalence and Planning Branch until about a month later. The Equivalence and Planning Branch waited another week before informing the Field Automation and Information Management Division of the deficiencies and requesting that the establishment be delisted in the Automated Import Information System.

Even after FSIS management became aware of the delays in the flow of delistment information, corrective action was not initiated until

2 months later, when we began reviewing the process. During our audit, the Equivalence and Planning Branch Chief instructed a management assistant to develop written procedures outlining how certification documentation should flow to the Field Automation and Information Management Division for entry into the Automated Import Information System, with weekly verifications between the Field Automation and Information Management Division and the Equivalence and Planning Branch. Such a procedure, however, does not seem to be efficient because the Automated Import Information System is incapable of printing a summary report of entries for a particular period. The Field Automation and Information Management Division program analyst informed us that they must download data about each separate establishment to present proof that the entries were made.

Field Automation and Information Management Division officials informed us that a document control numbering system existed prior to FSIS' reorganization. A control number log system was used to record and track all critical documents, particularly those relevant to the eligibility of a country or foreign establishment. Under this system, the Equivalence and Planning Branch would prepare a letter transmitting certification and delistment documents bearing the control number. After the Field Automation and Information Management Division received the information and made the entries into the Automated Import Information System, the transmittal letter would be signed by a Field Automation and Information Management Division official and a copy would be returned to the Equivalence and Planning Branch as evidence that the Automated Import Information System was updated. The Field Automation and Information Management Division staff suggested that the Equivalence and Planning Branch reinstate the document numbering system abandoned during reorganization.

We concluded that FSIS management needs to become more actively involved in maintaining the integrity of certification and delistment information in the Automated Import Information System. Specifically, the Office of Policy, Program Development and Evaluation needs to establish procedures for sending certification and delistment information to the Field Automation and Information Management Division and monitor those procedures to ensure compliance.

RECOMMENDATION NO. 19

Take immediate action to ensure that the Technical Service Center, the Field Automation and Information Management

Division, and the Equivalence and Planning Branch coordinate efforts to verify that all delisted establishments have been timely entered into the Automated Import Information System.

Agency Response

FSIS agrees with this recommendation. FSIS will improve its system to verify that all delisted establishments are timely and properly entered into the AIIS. FSIS will establish, by October 1, 2000, a team comprised of OFO and OPPDE personnel, responsible for examining every aspect of the issue of ensuring that only product from approved and eligible establishments gains entry into the United States.

In FY 2000, the FAIM Division expanded its Intranet Web Site with a posting of all delisted foreign establishments. This information is available to the TSC, IPD, and all field inspectors. The web site is updated when FAIM receives information from the IPD.

OIG Position

To reach management decision, FSIS needs to provide a target date for completing its review.

RECOMMENDATION NO. 20

Establish a management control process to ensure that the Technical Service Center Director promptly forwards to the Office of Policy, Program Development and Evaluation information about foreign establishments that were delisted prior to, or because of, Technical Service Center foreign reviews.

Agency Response

FSIS has established a management control process to address this recommendation. Information regarding foreign country establishments that are delisted prior to TSC reviews is received either by fax or electronic mail from the foreign country government or through the Foreign Agricultural Service. This information is shared by all of the stakeholders, and discussed at the pre-audit conference held between the TSC and the IPD.

Foreign country establishments are also delisted based upon results of onsite reviews by the TSC reviewers. Reviewers are instructed to report this information, by phone, to the Review Staff Director or Chief

of the International Review Branch as soon as possible, but no later than the day following the onsite review. This information is detailed in an electronic mail message that is sent immediately to the Chief of the Equivalency and Planning Branch, IPD and also to the Director of the Import/Export, Program Analysis, IRM Staff at the TSC. A paper copy of the electronic mail message is placed in the foreign country file at the TSC.

Both types of delistments are discussed at the post-audit exit conference held between the TSC and the IPD. The reviewer discusses the reasons given by the foreign country officials for delistment of any establishments prior to the review, and also discusses, in-depth, the reasons for any establishment delistment based upon the onsite review.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 21

Establish a management control process to ensure that delistment information is (a) reviewed and signed by a designated official to the Field Automation and Information Management Division, via a dated control number, and (b) processed and verified in the Automated Import Information System.

Agency Response

Pursuant to this report, the FAIM Division implemented in May 2000, a management control process whereby the Branch Chief, Application Development and Support Branch, FAIM Division will be notified via e-mail of all incoming delistments received from IPD. Notification will include the date delistments are received, the date the information was entered into the AIIS, and a printout of all establishments as they appear in the AIIS. This procedure will be complete by October 2000.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 22

Modify the Automated Import Information System to produce daily process control reports to enable verification of input.

Agency Response

FSIS agrees with this recommendation. The FAIM Division has begun replacing the AIIS that was first deployed in the 1970s. Available resources will be better used in continuing development of the replacement AIIS, rather than making the recommended changes to the current AIIS. The new system will incorporate this recommendation in its design. The intent of this recommendation will be met when the new computer system is completed by December 2001.

OIG Position

We accept FSIS' management decision.

FINDING NO. 8

RESIDUE TEST PLANS WERE NOT REVIEWED FOR COMPLIANCE WITH U.S. STANDARDS

We found that for 1998, 33 of 36 countries that were certified to ship meat and poultry products to the United States submitted residue test plans. However, 13 of 36 countries did not submit the corresponding test plan results to FSIS. Also, as of April 29, 1999, 15 of the 36 certified countries did not submit their 1999 test plans. We could find no evidence that FSIS followed up with countries to obtain either their residue plans or test plan results. The residue test plans received were not reviewed by the Equivalence and Planning Branch, and the test results were not provided to the Technical Service Center for verification and followup during onsite reviews. Also, notes of entrance conference discussions between the Equivalence and Planning Branch and Technical Service Center staffs for 7 of the 12 foreign inspection system reviews conducted during the first 3 months of 1999 showed that residue test plans were discussed for only 2 of the 7 countries.

Foreign countries that ship products to the United States are required to have residue control standards equivalent to those of the United States. These standards include (a) random sampling of animals at slaughter, (b) approved testing methods, (c) testing of appropriate target tissues, and (d) testing for compounds identified as potential contaminants of meat exported to the United States.

Each foreign country is required to submit annually a residue test plan, which identifies the drugs and chemical residues that will be its

monitoring focus during the year. Foreign countries are also required to provide the results of tests performed during the previous year. FSIS should be using this information to monitor how well the countries and their establishments are adhering to their residue test plans. Furthermore, the Technical Service Center's foreign review staff should be using residue test plans and results as they prepare for their foreign onsite equivalency reviews.

Regulations[8] state that the foreign inspection system must maintain a program to ensure that equivalency requirements are being met. The program as implemented must provide for "random sampling of internal organs and fat of carcasses at the point of slaughter and the testing of such organs and fat, for such residues having been identified by the exporting country's meat inspection authorities or by [FSIS] as potential contaminants, in accordance with sampling and analytical techniques approved by the Administrator."

Although a number of countries submitted residue test plans and results, nothing much was done with the information, according to one FSIS official, because it was not made part of a data base. The official added that comparisons were not made to determine if the countries actually performed the tests outlined in their plans for the previous year. In this regard, we also noted that two of the 1998 residue test plans and one of the residue test plan results submitted by three foreign countries had not yet been translated into the English language for review by FSIS officials.

On May 7, 1999, the Office of Policy, Program Development and Evaluation sent a questionnaire to the foreign countries to update residue information originally provided during their pre-HACCP initial eligibility determinations. An official advised that because this questionnaire is comprehensive, the countries are still preparing their responses.

RECOMMENDATION NO. 23

Establish procedures to ensure that all residue documents submitted by foreign countries are received, reviewed, and analyzed based on requirements outlined in regulations.

Agency Response

See Recommendation No. 25.

[8] Title 9 CFR, Part 327.2 (a) (2) (iv), dated January 1, 1998.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 24

Obtain the residue test plans not submitted since 1998 to determine if the foreign countries have residue control standards equivalent to the United States.

Agency Response

See Recommendation No. 25.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 25

Obtain and analyze the residue test plan results not submitted since 1998 to determine the adequacy of foreign countries' adherence to their residue test plans.

Agency Response to Recommendation Nos. 23, 24 and 25

FSIS agrees with the recommendations. FSIS agrees that it needs to strengthen its review of foreign country test plans. An interagency team was created on June 1, 2000, and expects to complete its initial review by December 2000. The team is responsible for the receipt, review, and analysis of all foreign country residue submissions. The team is comprised of representatives of OPPDE, OFO, and OPHS. The team will review the submissions based on U.S. regulations to determine if the information is adequate, if the documents indicate the countries meet U.S. requirements, and if additional information is needed.

The test plans and results are only a part of the basis for assessing a foreign country's residue program. FSIS onsite audits include reviews of the country's laboratory testing capability and FSIS annually collects more than 8,000 statistically selected samples at the port of

entry for laboratory analysis. Consequently, FSIS questions the need for collecting past residue plans and results because much more comprehensive information has been requested from every country through a lengthy questionnaire, which negates the value of the earlier submissions.

Responses to the questionnaire will provide this information along with other information such as production practices, veterinary drug usage, agricultural chemicals and incidence of environmental contaminants and pesticides, basis for the residue plan, and actual implementation and operation of the program. By December 2000, FSIS will have a more complete and current assessment of the country's controls. If, upon reviewing the responses, FSIS determines that required information is missing, it will be requested from the country. FSIS believes that focusing on in-depth reviews is a more productive use of its resources.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 26

Develop procedures to ensure that (a) a review of residues identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants are included as part of the Technical Service Center onsite equivalency reviews, and (b) appropriate action is taken in those instances where the plans are inadequate, the results vary from the plans, or violations are detected.

Agency Response

The IPD will provide the Director of the Review Staff at the TSC with a summary of the information in residue questionnaires submitted by countries eligible to export to the United States. The Review Staff will be part of the team that will review the submissions. The Review Staff and the IPD will use this information, along with port-of-entry results and information from past audits, to plan upcoming reviews.

This year, FSIS is initiating in-depth reviews of residue programs in a number of countries exporting to the United States. These reviews will make a comprehensive evaluation of the effectiveness of the country's controls over drugs and chemicals that could contaminate meat and poultry. This will include a review of documents, an assessment of whether the country is testing for the appropriate

compounds, whether the plan is implemented as designed, laboratory capability, and enforcement. The reviews are expected to be completed by June 2001.

OIG Position

Management decision can be reached when FSIS provides a targeted completion date for developing, documenting, and implementing residue review procedures.

CHAPTER 3	FSIS DOCUMENTATION OF APPROVED FOREIGN FOOD SAFETY SYSTEMS NEEDS TO BE ENHANCED

FSIS cannot demonstrate compliance with regulatory requirements for determining foreign countries as having equivalent inspection systems and, thus, eligible to export meat and poultry products to the United States. The involvement of technical subject-matter experts in the process for determining equivalency was not always documented and process control procedures were not developed and/or adequately documented. In some cases, FSIS' timeframes within which to make equivalency determinations were inconsistent; in other cases, FSIS did not meet the timeframes it established.

We also found that FSIS' documentation reviews and foreign equivalency review (audit) reports did not always provide a sound basis for equivalency determinations.

- The Equivalence and Planning Branch's analysis of foreign countries' import inspection systems was poorly documented, offering inadequate support that the Equivalence and Planning Branch reviewed all of the information submitted by foreign countries for equivalency determinations.

- Data needed to track equivalency determinations was incomplete.

- FSIS reports for equivalency verification audits did not contain evidence that all equivalency requirements had been fully addressed. FSIS analysts made equivalency decisions in cases where audit reports provided insufficient details of the tests made, and where onsite equivalency verification audits had not been conducted.

Regulations[9] require that the determination of the acceptability of foreign countries to import meat and poultry products to the United States include an evaluation that the foreign country inspection program is equivalent to U.S. standards. To be equivalent, the inspection system must require (1) a process similar to HACCP, (2) mandatory *E. coli* testing, (3) pathogen reduction standards for *Salmonella* and other pathogens, and (4) operating procedures for sanitation, referred to as SSOP. The foreign inspection system must

[9] Title 9 CFR, Part 327 (a) (2), dated January 1, 1998.

have a program that is adequately staffed by qualified inspectors, that is controlled by the national government, and that is provided with adequate administrative and technical support. It also needs to demonstrate that it maintains a program of inspection, sanitation and quality species verification. [10]

FINDING NO. 9

TECHNICAL SUBJECT-MATTER EXPERTS DID NOT ALWAYS PARTICIPATE IN EQUIVALENCY DETERMINATIONS

Contrary to documents provided by FSIS to support their equivalency determination process, technical experts are not always made a part of determining whether a country's food safety regulatory system is equivalent to the U.S. system. Also, when they were involved, their participation was not always adequately documented (see Finding No. 10). According to FSIS officials, all equivalence determinations, where a country proposes to adopt alternative sanitary measures, are made after review and consultation with agency subject-matter experts. If the foreign country adopted the identical *E. coli* testing approach, there was no need for the Microbiology Division to review those documents. However, we believe FSIS' equivalence determinations could be subject to adverse publicity if evidence does not exist that appropriate technical experts participated in the review and approval process for all determinations that foreign country inspection systems are equivalent to U.S. standards.

The determination of whether a foreign country's import inspection system is equivalent to U.S. standards involves the review of highly technical documentation. According to an FSIS paper entitled, "FSIS Process for Evaluating the Equivalence of Foreign Meat and Poultry Food Regulatory Systems," dated March 1999, FSIS developed a process to conduct equivalence evaluations of foreign food regulatory systems or of individual sanitary measures that vary from U.S. requirements. These evaluations employ evolving international concepts of the linkage between a sanitary measure designed to protect life or health, and the appropriate level of protection it is intended to achieve. Stressing the degree to which sanitary measures require a technical knowledge of food hazard controls, FSIS procedures state that "FSIS experts [should] review the country's program to assure that approved analytical methods are used, that foreign officials are knowledgeable about the use of chemical compounds in their country, and that the country tests for those compounds with potential for getting into the U.S. food supply."

[10] Title 9 CFR, Part 327.2 (a) (2) (i), dated January 1, 1998.

FSIS provided us various documents which purportedly documented their procedures for determining equivalency. An undated paper entitled "Importing Meat and Poultry to the United States," states, that for initial equivalence determinations, "FSIS technical experts evaluate information to assure that critical areas in the five risk areas (contamination, disease, processing, residues, and compliance and economic fraud) are addressed satisfactorily with respect to standards, activities, resources, and enforcement. This review is conducted by a multi-disciplinary team composed, typically of a veterinarian, chemist, microbiologist, statistician, compliance officer, and food technologist." However, we found that this multi-disciplinary team was not always used during equivalency determinations.

The Standards for Internal Control in the Federal Government states that management should ensure that skill needs are continually assessed and that the organization is able to obtain a workforce that has the required skills that match those necessary to achieve organizational goals. We question whether the Equivalence and Planning Branch, collectively, has the technical expertise to make equivalency determinations, in the absence of technical subject-matter experts. According to FSIS, the Equivalence and Planning Branch's function is not to do technical reviews of equivalence issues, but to facilitate the equivalence determinations with Agency technical experts. However, if a country chose to adopt, in its entirety, the FSIS requirements, then equivalence determinations were made by the Branch.

The Equivalence and Planning Branch's operating procedures for determining equivalence were developed by the Equivalence and Planning Branch Chief and are outlined in an undated document entitled "Procedures for Review of Documents Submitted for Equivalence Determination." These procedures state that the Chief, Equivalence and Planning Branch, determines whether the document review should be undertaken by the Equivalence and Planning Branch, or if a special review team is needed. Based on discussions with the Equivalence and Planning Branch Chief, we found that this special review team consists of the Equivalence and Planning Branch program analysts. The procedures also state that, if necessary, portions of the documents are provided to subject-matter experts for additional review. Comments from these experts are reviewed and considered during the equivalence meetings. According to the Equivalence and Planning Branch Chief, assistance from FSIS

microbiologists, chemists, or other experts is requested if a country wants to use an alternative system.

Once documents are reviewed and additional information is requested and received, team reviews are conducted only for what the Equivalence and Planning Branch Chief regards as complex cases. In response to questions that we raised concerning the Equivalence and Planning Branch's internal procedures, the Equivalence and Planning Branch Chief wrote in a July 16, 1999, memo that, "if the equivalence determination is complex or particularly difficult, a team review will be initiated. If the issue is reasonably simple to address, a team review may not be initiated.... I have the discretion to make a decision as to whether I have a team review a document, I review the document, or I assign someone else to review a document."

According to our discussions with Equivalence and Planning Branch staff, Equivalence and Planning Branch's determination of equivalency is based on a roundtable discussion by the program analysts after they review the documents submitted by the foreign countries under consideration. In many instances, along with the branch chief, the program analysts reviewed documents related to a foreign country's inspection system without the involvement of a technical subject-matter expert. Based on our review, we found correspondence from technical subject-matter experts in only 19 of 37 foreign country files reviewed.

According to FSIS officials, FSIS employs a multi-disciplinary team for initial equivalence determinations, but not for ongoing equivalence decisions about specific measures adopted by countries that have already been found to have equivalent systems. FSIS officials also stated that "…each *E. coli* equivalence determination of any sanitary measure that differed from FSIS requirements was fully vetted and reviewed by… five levels of management." FSIS officials acknowledged that this review process, however, was not documented.

FSIS officials disagree with OIG concerns regarding the qualification of the Equivalence and Planning Branch staff to make equivalence decisions, and stated that the positions in this Branch have not been classified as having a specific educational degree requirement; the staff collectively possess the knowledge, skills, and ability necessary for their position.

FSIS recognized the importance of, and the technical expertise needed in, making sound equivalence determinations. An undated document prepared by the Equivalence and Planning Branch entitled "Pathogen Reduction/HACCP Equivalence Determinations," states that, "FSIS' process for evaluating the equivalency of foreign meat and poultry food regulatory systems is both pathfinding and precedence setting. No other food regulatory system in the world, to our knowledge, is actively engaged in applying the concepts of equivalence to the degree and extent as is FSIS. The matter of exactly how an importing country judges, and determines equivalence is controversial. The world is watching how FSIS carries out its equivalence process." On April 14, 2000, FSIS provided copies of e-mails, memos, and other correspondence to show subject-matter experts' participation in reviews of *E. coli* testing programs. These documents, however, were not maintained in the country files. FSIS needs to implement procedures to ensure that technical subject-matter experts are involved in equivalency determinations, as appropriate, and that their equivalency determinations are adequately documented.

RECOMMENDATION NO. 27

Develop procedures that require the participation of technical subject-matter experts, as appropriate, in equivalency determinations, and document the experts' participation, analyses, and conclusions.

Agency Response

FSIS agrees to develop formal procedures by October 2000, for participation of technical subject-matter experts, as appropriate, in equivalence determinations. FSIS will apply this approach, in making equivalence determinations, where a foreign country proposes to adopt requirements that are *different* from FSIS requirements. When a country proposes to adopt an *identical* requirement, then it is not necessary to involve subject-matter experts in those determinations. This is often the case during FSIS' evaluation of foreign country documents submitted in response to the HACCP/pathogen reduction regulation.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 28

Document and implement a system of internal controls to ensure the adequacy and support for foreign equivalency determinations. This should include a formal review and approval process for the equivalence determinations made.

Agency Response

FSIS agrees with this recommendation. FSIS will formalize its procedures and documentation of equivalence decisions. By December 2000, FSIS will complete the implementation of an internal controls system for foreign equivalency determinations. Effective July 1, 2000, new equivalence decision files will document: 1) All FSIS correspondence with foreign countries; 2) All foreign country submissions (translated and in the originating language); 3) Summary IPD reviews of submissions; 4) Summary of all meetings and teleconferences with foreign officials; 5) Summary of all reviews by subject-matter experts; 6) Documentation of equivalence criteria; 7) Summary of all FSIS management formal reviews and approvals; and 8) Decision memorandum of the equivalence determinations.

OIG Position

We accept FSIS' management decision.

FINDING NO. 10

EQUIVALENCE DETERMINATIONS WERE NOT ALWAYS SUPPORTED BY FILE DOCUMENTATION

The Standards for Internal Control in the Federal Government states that internal controls and all transactions and other significant events need to be clearly documented, and documentation should be readily available for examination. As part of the "Top-to-Bottom Review" for the pending reorganization, FSIS identified the increased need for clear and concise documentation, along with the ability to explain the results of various tests and findings. We found that the Equivalence and Planning Branch's files containing the results of documentation reviews of foreign inspection systems did not always include adequate documentation to support equivalence determinations for SSOP's and *E. coli* testing. (FSIS was in the process of determining the equivalence of foreign systems for HACCP and *Salmonella* testing during our field work. Therefore, we were not able to evaluate the

support for equivalence determinations for these areas.) In all instances, the Equivalence and Planning Branch did not document how it determined that a country's SSOP and *E. coli* testing requirements were equivalent to U.S. standards, while in some instances, the files did not contain the information the Equivalence and Planning Branch would have needed to make a determination. Procedures had not been developed to ensure that this type of documentation was prepared and maintained to support equivalency determinations. In one case, the Equivalence and Planning Branch conferred "provisional equivalency" on a country even though available documentation, including an onsite equivalence verification review, suggested the country's alternative system was not equivalent.

In August 1996, the Equivalence and Planning Branch sent foreign countries a copy of the requirements for pathogen reduction and HACCP, along with an implementation schedule. In October of that year, the Equivalence and Planning Branch provided additional information on the new requirements and requested information on country plans to implement the SSOP and *E. coli* testing requirements. Foreign countries wishing to be approved for equivalency status were requested to submit responses to questionnaires and documentation to support that the requirements of HACCP and pathogen reduction have been met. Countries were also requested to provide copies of all statutes, regulations, directives, circulars, manuals, and other written instructions that implement the HACCP and SSOP requirements, and *Salmonella* and *E. coli* testing program requirements. In addition, the country governments' plans for meeting these requirements by adopting the same or an equivalent set of sanitary measures were also required. Countries were to submit their SSOP and *E. coli* testing plans no later than December 31, 1996.

We evaluated the Equivalence and Planning Branch's process and procedures for making equivalence determinations and reviewed the country files for the 37 countries that applied for eligibility to import to the United States under the new standards. Documents in the files included the countries' submission of their SSOP and *E. coli* testing programs, telegrams sent by the Equivalence and Planning Branch to the countries, Equivalence and Planning Branch minutes of their review of countries' submissions, microbiology laboratory results, and other internal correspondence.

a. Equivalence Analysis Was Not Adequately Documented

Documentation was not always sufficient to show how the Equivalence and Planning Branch determined the equivalency of the 37 countries reviewed for SSOP and *E. coli* testing. According to the Equivalence and Planning Branch Chief, information provided by the foreign countries was copied and distributed to members of the Equivalence and Planning Branch review team for an evaluation of each country's inspection system. After each evaluation, the team arrived at a consensus on each issue of equivalence, which was summarized in minutes of its discussions of foreign country submissions. However, based on our review of these summaries, they are very broad and do not describe what information was reviewed, the events that occurred, or the results of the Equivalence and Planning Branch's analysis which led to the equivalency conclusion.

The following represent examples of instances in which we were unable to determine the process used by FSIS to evaluate the adequacy of foreign countries' food inspection systems.

Country F. The file on Country F contained insufficient documentation to explain how the Equivalence and Planning Branch determined the adequacy of Country F's *E. coli* testing program. There was no evidence in the file to show that Country F had responded to all of FSIS' requests for documentation. Summaries of Equivalence and Planning Branch's discussions on what Country F had submitted were prepared for January, February, and July 1997. The July summary stated that the SSOP information was sufficient, but the summary showed no analysis that resulted in this conclusion. The summary also stated that the Equivalence and Planning Branch would wait for the Microbiology Division to review Country F's *E. coli* sampling submissions, but there were no follow-up summaries on this issue.

An onsite equivalency review of Country F's inspection system was conducted from November 20 through December 10, 1997. The review report concluded that Country F's inspection system did not have effective controls in place to consistently prevent, detect, control, and correct product adulteration. The one slaughterhouse did not have *E. coli* testing procedures in place.

In April 1998, the Microbiology Division completed its analysis of Country F's *E. coli* testing procedures. The results stated that

Country F needed to revise information it provided about its sampling techniques. The file shows no additional information between April and August 1998, when an Equivalence and Planning Branch memorandum was sent to the FSIS Administrator stating that Country F had implemented an equivalent *E. coli* testing program. As of the completion of our field work, a subsequent onsite equivalency review had not been conducted to verify the equivalency of the *E. coli* testing program.

Country D. An August 1998 Office of Policy, Program Development and Evaluation memorandum stated that Country D's *E. coli* system was not equivalent, but as of April 15, 1999, Country D is shown as "provisionally equivalent." However, we were unable to identify information in Country D's file that would support this determination. A comparison study between the *E. coli*-based system of the United States and the *Enterobacteriaceae*-based system of Country D was not completed, and issues related to the collection of indicator organisms had not been resolved as of the completion of our field work.

An onsite review performed at the end of 1997 identified significant operational and systems deficiencies pertaining to in-plant inspection system controls and *E. coli* testing requirements. It is unclear, however, whether Country D's use of an alternative system of *E. coli* testing was reviewed. The report stated, "*E. coli* testing was not performed in any establishments that slaughtered swine and bovine." However, Technical Service Center reviewers asked managers in Country D the same series of questions asked in the United States to determine if U.S. requirements are being met.

Even though FSIS maintained concerns over Country D's *E. coli* testing, an onsite equivalency review was not conducted in 1998. The Microbiology Division's January 28, 1998, review of information submitted by Country D concluded that none of the documents pertained to generic *E. coli* testing, and that the bacteriological testing procedures submitted were not equivalent to the generic *E. coli* testing program required under HACCP and pathogen reduction. As stated in FSIS' April 21, 1998, telegram to Country D requesting additional information, "Country D's testing program establishes Aerobic Colony Counts and *Enterobacteriaceae* Colony Counts as the indicator organisms for validating and verifying the process control of fecal contamination.

The pathogen reduction/HACCP final rule establishes generic *E. coli* as the indicator organism." Also, a May 13, 1998, memorandum from a Microbiology Division staff member to the Equivalence and Planning Branch states, "The pathogen reduction/HACCP final rule specifies that generic *E. coli* is the most effective measure of process control for fecal contamination. Since we do not yet have a policy statement on generic *E. coli* testing, I have simply prepared a list of differences, between the generic *E. coli* testing outlined in pathogen reduction/HACCP and Country D's system."

Even though the Microbiology Division had determined that the alternative sampling method that Country D wanted to adopt was not equivalent to generic *E. coli* as the indicator organism, a September 10, 1998, letter from Country D's government to FSIS' stated, "I am pleased that you agree to Country D's proposal to use Aerobic Plate Counts and *Enterobacteriaceae* bacterial counts as test indicators." Subsequent to this, Country D sent the Equivalence and Planning Branch an equivalence assessment plan (for alternative *E. coli* testing) dated September 30, 1998. The Microbiology Division's October 7, 1998, assessment of this plan stated that parts of the draft submission were unclear and confusing, and suggested improvements to the plan. Of note was the choice of a different indicator organism, indicating that Country D would need to provide a comparative study between the United States' *E. coli* testing program and Country D's *Enterobacteriaceae* testing program. In response to FSIS' request for clarification and additional information to be added to Country D's plan, Country D resubmitted the same information that was previously found lacking by the Microbiology Division, and dated it October 27, 1998.

Country D drafted a November 5, 1998, "Experimental Plan" in order to conduct a comparative study analysis between Aerobic Plate Counts *Enterobacteriaceae* and generic *E. coli* testing and the differences in the size of the surface areas sampled. However, a November 9, 1998, memorandum from the microbiologist reviewing the "Experimental Plan" stated that it should be resubmitted with a more detailed protocol because it was unclear as to exactly what the researchers would be doing in each part of the study. The memorandum also stated that FSIS hoped to resolve the issues in an upcoming meeting in January 1999.

As a result of the January 12 and 13, 1999, conference with Country D officials in Washington, DC, a "Proposal for Equivalency Study" was adopted. The study was to be completed by May 1; however, the Technical Service Center onsite equivalency review performed from January 25 to February 26, 1999, concluded that Country D had not fully implemented pathogen reduction and HACCP requirements. Therefore, at the time of the onsite review, Country D was not in compliance with the pathogen reduction/HACCP requirements for generic *E. coli* testing.

To respond to our questions concerning missing documentation, the Equivalence and Planning Branch Chief prepared a chronology, dated July 14, 1999, which outlined events related to Country D's equivalency determination. According to the chronology, on December 3, 1998, FSIS advised Country D that testing for *Enterobacteriaceae* was equivalent to *E. coli* testing provided that they initiate a study comparing the two testing programs in those areas where they differed. On December 15, 1998, a document listing two of the remaining issues outstanding from the documentation and outlining the comments raised by the Microbiology Division and the Equivalence and Planning Branch were faxed to Country D for comment. Subsequently, a December 21, 1998, letter was sent to the Equivalence and Planning Branch thanking FSIS for accepting *Enterobacteriaceae testing*.

The chronology noted that most of the document review deficiencies were resolved between FSIS and Country D officials at the January 12-13, 1999, meeting. On March 10, 1999, a meeting with Country D officials was initiated to address the remaining document review issues and each finding as a result of the Technical Service Center onsite review. On April 21, 1999, a letter was faxed by Country D, which satisfactorily addressed the document review issues. On June 1, 1999, the Microbiology Division provided a favorable evaluation of the results of Country D's research comparing *E. coli* testing to *Enterobacteriaceae* testing.

None of the additional information included in the July 1999 chronology prepared by the Equivalence and Planning Branch was documented in the country file for Country D.

Country G. A Technical Service Center onsite equivalency review completed in June 1998 found that Country G (1) was not

performing species verification testing, (2) had not developed actions to take if establishments failed to implement pathogen reduction and HACCP requirements, (3) did not follow U.S. standards in sampling for *E. coli*, and (4) did not monitor for *Listeria* and *Salmonella* in ready-to-eat products. We noted that the approval date for the 1998 onsite review report was March 9, 1999, 9 months after it was completed and 4 months after the FSIS cable confirming Country G's equivalency status. The review report recommended that Country G outline the procedures it planned to implement to correct the deficiencies noted in the report.

Country G's *E. coli* testing program was determined equivalent based on a November 1998 cable from FSIS to the Agriculture Counselor for Warsaw that stated that Country G has agreed to use an equivalent, internationally recognized method to analyze *E. coli*. We were unable to locate documentation in the country file to support this agreement. However, on April 14, 2000, FSIS provided documentation of an October 6, 1998, cable from Country G to FSIS which stated that Country G Veterinary Officials confirmed that they would be able to comply with the conditions required by FSIS for *E. coli* testing by October 8, 1999.

The November 1998 cable also stated that FSIS was unsure if Country G took the required 12 months to complete its baseline study to establish performance criteria for *E. coli* testing, and noted that unless Country G met the baseline study qualification, FSIS would **assume** (emphasis added) it was using the statistical process control techniques it had agreed to implement. Based on the inadequacy of information to clarify FSIS' uncertainties about Country G's performance criteria and corrective actions taken to address the deficiencies found in the 1998 onsite review, we question FSIS' equivalency determination.

According to the July 14, 1999, chronology for Country G prepared by the Equivalence and Planning Branch in response to our questions, the May/June 1999 onsite equivalency review of Country G found that statistical process control techniques for *E. coli* testing were implemented in all but one establishment. However, we continue to have concerns over the Equivalence and Planning Branch's equivalency determination process since Country G was determined to be equivalent in November 1998, which was prior to the results of the May/June 1999 onsite review.

b. The Equivalence and Planning Branch Did Not Adequately Track the Data Involved in Equivalence Determinations

The Standards for Internal Control in the Federal Government states, in part, that control activities include the creation and maintenance of related records which provide evidence of execution of activities, as well as appropriate documentation. As part of our review, we requested the Equivalence and Planning Branch to provide all documentation related to equivalence determinations for each country approved to export meat and poultry products to the United States. We were informed that all information would be included in documentation review files maintained for each foreign country. However, we found that the Equivalence and Planning Branch documentation review files did not include all information pertaining to equivalence for each country. During our evaluation of the countries' files, we identified information for 17 countries that was missing from the files. The type of information that could not be located included Microbiology Division analysis results and telegrams sent to countries regarding their SSOP's and *E. coli* testing.

Of those 17 countries where there was insufficient data in the country file, 15 were approved as having an SSOP and *E. coli* testing program equivalent to U.S. requirements.

For example, based on a March 13, 1998, cable from FSIS to the chief meat and/or poultry inspection official for Country H, information dated February 2, 1997, April 1997, June 19, 1997, and July 15, 18, 19, and 21, 1997, regarding the implementation of *E. coli* testing was submitted by Country H. However, our review of the country file for Country H did not identify any of these documents in the files. In addition, the file for Country I contained a September 10, 1997, response to an August 4, 1997, request from FSIS concerning their implementation of SSOP and *E. coli*. However, the file did not include FSIS' August 4, 1997, request for information in order to determine the adequacy of Country I's response.

We conclude that FSIS needs to strengthen internal controls relating to its documentation of the processes used and analyses made in reaching equivalence determinations.

RECOMMENDATION NO. 29

Develop a management control process and procedures to ensure equivalence decisions are adequately documented. The procedures should require that files contain supporting evidence, including detailed analysis of information received and reviewed, resolution of issues raised during the review process, and conclusions reached.

Agency Response

FSIS agrees with this recommendation. FSIS agrees that equivalence decisions should be adequately documented and that the files must be complete. Therefore, FSIS will institute the same measures described in response to Recommendation 28.

The examples that OIG cites to demonstrate their concern with the equivalence determination process is misplaced and erroneously concludes that the equivalence process was incomplete. The process was complete, but not all of the documents were in the country files at the time of the audit.

OIG Position

We accept FSIS' management decision.

FINDING NO. 11

EQUIVALENCE DETERMINATIONS WERE NOT MADE IN A TIMELY MANNER

At the time of our audit (July 1999), FSIS had not completed reviews to determine the equivalency status for foreign countries that continue to export meat and poultry products into the United States under HACCP and pathogen reduction standards. FSIS did not establish timeframes for completing reviews of *E. coli* and SSOP submissions from foreign countries, and it did not meet the timeframes it established for completing reviews of *Salmonella* and HACCP submissions. These reviews are critical in determining the adequacy of foreign country food safety systems.

During the implementation of HACCP and pathogen reduction requirements for imported meat and poultry, establishments in the 37 countries that had been approved for importing these products into the United States under the pre-HACCP system were allowed to continue their importations pending the Equivalence and Planning

Branch's approval of their governments' food safety systems and its determination that those systems are equivalent to U.S. standards. According to regulations,[11] establishments with 500 or more employees were required to have an equivalent system in place by January 1998, and establishments with between 10 and 500 employees were required to have a system in place by January 1999. (Establishments with fewer than 10 employees had until January 2000 to implement a system.) An FSIS official stated that a decision was made to review country SSOP and *E. coli* testing programs before reviewing HACCP and *Salmonella* because the SSOP and *E. coli* requirements were to be in effect as of January 27, 1997.

The Equivalence and Planning Branch is responsible for ensuring that eligible countries implement both systems by the established dates. However, a formal plan for completing the equivalency determinations for SSOP and *E. coli* testing was never established. The Equivalence and Planning Branch prepared a plan to complete the HACCP and *Salmonella* equivalency determinations and notify all 14 countries by June 30, 1999. However, as of July 1999, the documents were still under review by Equivalence and Planning Branch officials.

RECOMMENDATION NO. 30

Establish a time-phased plan to expedite the process for determining equivalency.

Agency Response

FSIS agrees with this recommendation. FSIS will implement time-phased plans for future equivalence determinations, effective October 1, 2000.

OIG Position

We accept FSIS' management decision.

[11] Title 9 CFR, Part 304 et al., dated July 25, 1996.

FINDING NO. 12

EQUIVALENCY DETERMINATIONS WERE MADE WITHOUT ONSITE REVIEWS FOR CURRENT TRADING PARTNERS

The Equivalence and Planning Branch made HACCP and pathogen reduction equivalency determinations for current trading partners in cases where Technical Service Center reviewers had not performed onsite equivalency verification reviews. Regulations[12] state, in part, that maintenance of eligibility of a country for importation of products into the United States depends on the results of periodic reviews of the foreign meat inspection system in operation by a representative of the Department. According to documentation provided by FSIS, these periodic reviews are generally repeated annually. In addition, each equivalency decision should be based, in part, on an onsite verification review. However, we found that for current trading partners, onsite reviews of foreign food regulatory systems were not being conducted on an annual basis. FSIS did not place a high enough priority on the reviews to prevent budgetary constraints from restricting overseas travel. In addition, we found that six countries were approved equivalent for SSOP and *E. coli* without onsite reviews to verify the country inspection program was operating as represented by documentation submitted to FSIS.

In response to our concerns over the equivalence determination process, FSIS prepared a document which stated, in part, that OIG has incorrectly interpreted that audit (onsite review) findings have an impact on document review equivalence decisions, and that the timing of an audit must impact on the equivalence decision. In addition, an April 3, 2000, document prepared by FSIS, in response to our draft report, states that the regulations do not require that an onsite review must be made before equivalence determinations regarding new FSIS requirements that must be implemented by current trading partners to maintain equivalence. However, without the onsite equivalency verification review, there is no validation that the foreign country's food regulatory system is operating as represented to FSIS.

The Equivalence and Planning Branch made equivalency decisions for current trading partners after completing their documentation reviews, but without the results of onsite verification reviews. In these cases, the Technical Service Center had not conducted onsite reviews to validate the equivalency of the foreign country's food regulatory system. In 1997 and 1998, 37 countries were subject to review, but only 30 onsite reviews were conducted in 1997 and 24 in 1998. A

[12] Title 9 CFR, Part 327 (a) (2), dated January 1, 1998.

Technical Service Center management official stated that reviews were postponed because of a 40-percent cut in the International Review Staff's budget. However, FSIS had not developed a contingency plan for cases where a country had not received an onsite review as part of the equivalency determination process, or as part of the maintenance of eligibility requirement.

Documents prepared by the Equivalence and Planning Branch for determining equivalency state that the onsite review is conducted after the Equivalence and Planning Branch completes its documentation review. However, for six countries, the Equivalence and Planning Branch granted equivalency status for SSOP and *E. coli* testing programs prior to an onsite review. The Equivalence and Planning Branch's documents for determining equivalence also state that before a final equivalency determination is made, another onsite audit is completed, and the findings and subsequent documents are thoroughly reviewed. We found that for five countries, the Equivalence and Planning Branch granted equivalency status after completion of the documentation review, but before the onsite verification. Country B was granted equivalency in November 1998 and was not subject to an onsite verification review in either 1997 or 1998. A March 1999 onsite review of this country’s inspection system identified variances in their testing programs.

Table 1: Foreign Countries Determined "Equivalent" Prior to an Onsite Review

Country	Type of Approval Per Foreign Country Cable	Date of Approval	Date Documentation Review Completed	Date of Onsite Audit	Comments
B	Equivalent	Nov. 12, 1998	Nov. 12, 1998	None	No audit conducted in 1997 or 1998.
E	Equivalent	Dec. 9, 1998	Dec. 9, 1998	Dec. 1997	No audit conducted in 1998. Cable stated equivalent for *E. coli.*
G	Equivalent	*E.coli* Nov. 13, 1998 SSOP Feb. 20, 1998	Nov. 13, 1998	June 1998	No audit conducted after documentation review. Cable stated equivalent for *E. coli*.
J	Fully Equivalent	Dec. 2, 1998	June 23, 1998	Apr. 1998	No audit conducted after documentation review.
K	Fully Equivalent	Dec. 9, 1998	Sept. 4, 1998	June 1998	No audit conducted after documentation review.
L	Fully Equivalent	Dec. 2, 1998	June 11, 1998	Mar. 1998	No audit conducted after documentation review.

Country E received an onsite review as early as 12 months before the documentation review was completed. Countries G, J, K, and L received onsite reviews as early as 2 to 5 months before the documentation reviews were completed. FSIS has not established any procedures that would allow use of the results of onsite reviews that had been performed prior to the completion of the documentation review. Specific areas reviewed during the onsite review may not be sufficient to verify information submitted by foreign countries for use in determining equivalency with U.S. requirements.

RECOMMENDATION NO. 31

Ensure that onsite audits for current trading partners are conducted at least annually.

Agency Response

FSIS agrees with this recommendation. This issue will be incorporated into the FSIS procedures for import inspections by December 2000.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 32

For current trading partners, develop and implement a policy for onsite verifications of changes in the requirements for foreign inspection systems.

Agency Response

FSIS agrees with this recommendation. The equivalence process begins with a document review, to determine if the foreign country's written submission documents how its sanitary measures meet the United States' appropriate level of protection. This evaluation is then verified by an onsite audit to confirm that the foreign country has in fact implemented its sanitary measures, as described in its written submission.

However, the finding for this recommendation reflects a misinterpretation of 9 CFR 327.2. The misinterpretation is evidenced by a statement: "We found that the food regulatory systems of six countries were determined "equivalent" by the Equivalence and Planning Branch without verification by an onsite review."

This statement is incorrect. The six countries (cited later in a table) have food regulatory systems that were found fully equivalent to the U.S. system many years ago. Each of these countries has undergone initial equivalence evaluations to include an extensive onsite audit and are listed as equivalent at 9 CFR 327.2(b) Additionally, each of these countries has been audited onsite many times since their food regulatory systems were initially found equivalent.

When an eligible country proposes an alternative sanitary measure to FSIS for an equivalence decision, FSIS conducts a full document analysis of only that component of the foreign food regulatory system that is affected by the change. A final determination of equivalence for a proposed sanitary measure is verified by onsite audit. Trade continues in the interim. Three circumstances could result in an interruption of trade. One, where an emergency sanitary measure is implemented by FSIS to address a hazard that is so severe that no product can enter the marketplace from a foreign establishment until the control is in place. Two, where an exporting country does not provide satisfactory documentary evidence of an equivalent sanitary measure. Three, where a system audit reveals that an exporting country is not implementing a public health sanitary measure in the manner that FSIS initially determined to be equivalent. None of these three conditions applied during FSIS evaluations of PR/HACCP alternative sanitary measures proposed by foreign countries.

OIG Position

To reach management decision, FSIS needs to provide a target date for the development and implementation of a policy for onsite verifications of changes in the requirements for foreign inspection systems.

RECOMMENDATION NO. 33

Clarify the regulations regarding FSIS' procedures for determining equivalence for current trading partners, taking into consideration major changes such as HACCP and pathogen reduction requirements.

Agency Response

FSIS has been properly applying its regulations regarding equivalence determinations. In the future, FSIS will take into consideration major changes, such as PR/HACCP, as it documents its procedures for determining whether equivalence is maintained for current trading partners, as referenced in our response to Recommendation No. 12.

OIG Position

To reach management decision FSIS needs to provide a target date for the development and implementation of a policy for onsite verifications of changes in the requirements for foreign inspection systems.

FINDING NO. 13

ONSITE EQUIVALENCY VERIFICATION REVIEWS NEED TO BE BETTER DOCUMENTED

Technical Service Center onsite equivalency verification review (audit) reports and their supporting notes do not provide documented evidence that U.S. equivalent inspection requirements were verified as functioning. In addition, we found inconsistency in the information included in the audit reports and supporting review notes. Reporting and evidence standards had not been established to support the adequacy of the onsite reviews and subsequent equivalency determinations. Although FSIS refers to their onsite verification reviews as audits, these reviews are not conducted and/or reported in accordance with Generally Accepted Government Auditing Standards. FSIS does not maintain sufficient, competent evidence to support the scope of the verification work or the conclusion that foreign systems were equivalent to U.S. inspection standards.

Documentation provided by FSIS on April 3, 2000, states, in part, that "The annual ongoing equivalence onsite reviews are not required to cover all aspects of a country's inspection system on each visit. Prior to becoming eligible to export to the United States, all countries had previously been subjected to an onsite team audit by Agency experts. These annual audits focus primarily on new FSIS inspection requirements and sampling of inspection requirements on other risk areas on a case by case basis."

We reviewed audit reports for 31 countries and determined that none of the reports or supporting review notes included sufficient information to be used as a basis for making equivalency determinations. Many of the reports and supporting review notes lacked sufficient information about deficiencies identified during the review. Therefore, there is a risk that equivalency determinations are not supported and that adequate followup on corrective actions will not occur during subsequent reviews.

The Technical Service Center staff is responsible for conducting onsite equivalency reviews to verify whether a country's food safety regulatory inspection system meets U.S. standards. The review seeks evidence that the exporting country has instituted sanitary measures that will provide the same level of protection for American consumers that is ensured by the domestic system.

The audit reports are provided to the Equivalence and Planning Branch and, according to FSIS procedures, are used as a basis for making equivalency decisions. However, according to subsequent documentation provided by FSIS, the audit reports are not the only basis for making equivalence determinations. Prior to the equivalency decision, the Equivalence and Planning Branch staff members review the reports to determine if the country's system of oversight and compliance, as represented in their laws, regulations, and other documentation, is in place and functioning. Regulations[13] require that FSIS review country documentation to ensure that foreign inspection programs meet U.S. requirements. Those requirements identify an "equivalent" system as a national food safety program that meets U.S. standards with regard to organization and staffing, supervision of employees, qualification of inspectors, enforcement authority, and national sanitation and residue standards. Regulations further identify an "equivalent" inspection program as one that provides periodic inspections, random sampling, and written reports.

We reviewed audit reports performed of establishments in foreign countries during 1997 and 1998 and found that none of the reports specifically addressed U.S. equivalent elements relating to HACCP and pathogen reduction requirements, as outlined in Federal regulations. We could not determine if required elements were reviewed by the Technical Service Center staff. For example, the reports for Country H, Country N, and Country O make no reference to inspector qualifications and supervision. The reports for Country H, Country N, and Country O also make no reference to any review of the enforcement authority the national governments claimed to have over meat and poultry establishments. The reports for Country A, Country P, Country Q, Country R, Country G, Country S, Country T, Country U, Country V, and Country J include a general statement that a visit was made with foreign national inspection officials to discuss their oversight program and practices. However, neither the reports or supporting review notes provide sufficient information to document that U.S. requirements relating to organizational structure, staffing, and qualifications of inspectors were validated.

According to FSIS officials, the organizational structure, staffing, and qualifications of inspectors had not changed since the prior audit, and reviewers had verified this through discussions with the country inspection officials during the entrance conference.

[13] Title 9 CFR, Part 327.2, dated January 1, 1998.

For Country P, we noted the report stated that residue control and processed product control were adequate at the sites visited. However, neither the report nor supporting review notes gave details concerning what was reviewed. The report for Country R stated that controls over laboratory reviews, disease, residue, and compliance fraud were in place but provided no information about the methodology used to arrive at this conclusion. The reports for Country A and Country E both noted that deficiencies were present at several establishments visited, but did not include the specific establishments where the deficiencies were disclosed.

In some cases, the sufficiency of the review work performed could not be determined due, in part, to lack of adequate documentation of the work performed and any deficiencies disclosed. For example, as part of the 1997 audit report for Country P, the Technical Service Center reviewer offered no details of what was reviewed under residue control, compliance/economic fraud control, and processed product control. In addition, Country P's national residue laboratory was not reviewed because according to the reviewer's notes, it had been reviewed the previous year. However, based on our analysis of the 1996 report for Country P, we could not conclude that the national residue laboratory had been reviewed. For residue, the report stated only that "sampling and analysis is done per a residue national program, complying with USDA requirements." No other documentation was provided to substantiate a review of the national residue laboratory. According to FSIS officials, the Agency followed up its 1998 onsite review with a review of one national residue control laboratory that was found satisfactory.

We also noted in the audit report for Country P that no formal exit meeting was held with Country P's meat inspection officials. The exit meeting section of the report stated, "the Head of the Meat Hygiene Unit accompanied the reviewer and was aware of findings and review results." However, the report did not identify any findings, so we were unable to determine the nature of the findings and review results of which the Head of the Meat Hygiene Unit was made aware.

Based on our discussions with Technical Service Center staff, we concluded that the reviewers possess the competence and expertise needed to conduct onsite equivalency reviews of foreign food regulatory systems. Guidelines need to be developed to provide both reporting and evidence standards to support the adequacy of the onsite reviews and the resulting equivalency determinations. Based

on discussions with TSC officials on April 6, 2000, a new reporting format has been developed to improve the reporting process.

RECOMMENDATION NO. 34

Ensure that reporting and evidence standards developed for equivalency verification reviews provide for appropriate documentation of all areas required to be reviewed by regulation.

Agency Response

According to 9 CFR 327.2 (a) (2) (iii) "Maintenance of eligibility of a country for importation of products into the United States depends on the results of periodic reviews of the foreign meat inspection system…" The regulatory requirement of periodic reviews does not mandate that each review encompass all aspects of a country's inspection system.

Nevertheless, FSIS is committed to ensuring that these reviews are consistent and thoroughly documented. At the time of the OIG audit, FSIS was in the process of developing an enhanced uniform audit format that addressed the following five risk areas: 1) animal disease controls; 2) sanitation controls; 3) enforcement controls; 4) slaughter and processing controls; and 5) residue controls. These five risk areas cover all of the FSIS regulatory requirements for countries that export to the United States. Subsequent to the OIG audit, the audit format was finalized.

The new audit format has been implemented for all FSIS audits conducted in fiscal year 2000. Also, audit planning has been enhanced to ensure that onsite audits cover all relevant areas.

OIG Position

We accept FSIS' management decision.

FINDING NO. 14

EQUIVALENCY REVIEW REPORTS WERE NOT ISSUED IN A TIMELY MANNER

We found that equivalency review reports were not issued in a timely manner. For almost half the reports that bore a date and were released for onsite reviews performed in 1997 and 1998, the elapsed time between the completion of the fieldwork and the issuance of the report was 4 months or longer.

We conducted a comparison between the completion date for a foreign country's onsite review and the date of the final audit report for that country and noted that a substantial length of time had elapsed between these dates. As noted in Finding No. 3, the draft report is forwarded from the Technical Service Center to the Equivalence and Planning Branch for review and comment prior to issuance. In 1997 and 1998, 37 foreign countries were subject to review as part of the HACCP and pathogen reduction requirements. In 1997, 30 onsite reviews were conducted by the Technical Service Center reviewers, but only 24 audit reports were issued. Reports were not issued for Country H, Country N, Country M, Country W, Country X, and Country Y. In 1998, 24 onsite reviews were conducted, but only 17 reports were approved as final. As of July 1999, four reports were still in draft. These draft reports are for Country H (onsite review conducted in November 1998), for Country M (onsite review conducted in October 1998), and for Country Z and Country AB (both onsite reviews conducted in April 1998). Reports had not been issued for Country I, Country P, and Country Y as of the end of our field work.

Of the 41 final reports that were issued in 1997 and 1998, seven reports were undated. Of the remaining 34 reports that included a date, we found delays ranging up to 15 months between the date the onsite review was completed and the date the final report was issued. Of these reports, 15, or 44 percent, were completed 4 to 15 months after the onsite review.

According to an April 3, 2000, document prepared by FSIS, the major reason that these reviews were not released within a shorter timeframe was that the Director of the Review Staff had to perform the functions of three positions: the Director of the Review Staff, the Branch Chief for Domestic Review, and the Branch Chief for International Review which precluded him from focusing only on the reports. In addition the document stated that the length of time for audit reports to be finalized does not preclude the agency from taking action on findings, and that depending on the seriousness of

the finding, the Equivalence and Planning Branch initiates immediate action prior to the completion of the audit report.

RECOMMENDATION NO. 35

Develop procedures for timely completing reports documenting reviews of foreign inspection systems.

Agency Response

FSIS agrees with this recommendation. Formal procedures will be completed by December 2000. In 2000, new foreign country reporting requirements were instituted. Draft foreign country reports are due from the reviewers within 10 working days of their return to the office. Exceptions to the 10-day rule must be requested in writing, with justification, through the Branch Chief of the International Review Branch or Director of the Review Staff. Similar timeframes are in effect throughout the process, creating a timeline that has the report completed and in "Draft Final" form to be sent to the foreign country government officials for comment within 60 days from the date of the exit conference with the foreign officials. This 60-day commitment is also detailed in the cable that each reviewer sends to the foreign country prior to each audit. Because of language differences, and necessary time for response, the foreign countries are allowed 60 days to submit their response to the report. The foreign country response is then added to the report as an attachment, and the report is finalized.

OIG Position

We accept FSIS' management decision.

GENERAL COMMENTS

We noted that as part of the pre-audit process, FSIS transmits a copy of its audit plan to the foreign country at least 30 days before implementation. The plan identifies each establishment that the Technical Service Center reviewers will visit during the onsite review. A document entitled FSIS Process for Evaluating the Equivalence of Foreign Meat and Poultry Food Regulatory Systems, dated March 1999, states, "the audit protocol is sufficiently detailed to inform the exporting country of the audit objectives, scope, and criteria, who they will be visiting, what they wish to see, where they wish to go, and when they wish to do so." We found that in one instance, a foreign country delisted an establishment that was known by the government to be in noncompliance with U.S. inspection requirements after receipt of the audit plan but prior to initiation of the onsite review. Therefore, another establishment was selected since delisted establishments are not reviewed. Having advance knowledge of the establishments selected for review may have been the reason that the foreign government delisted the establishment. We were provided with a copy of a letter sent to all countries concerning FSIS' delistment policy. However, in order to validate the true condition of a foreign country's food regulatory inspection system during its onsite equivalency verification reviews. FSIS should reconsider the benefits of providing advance notice to the foreign countries of the establishments to be reviewed.

EXHIBIT A – FSIS RESPONSE TO THE DRAFT REPORT

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

JUN 7 2000

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

FROM: for Thomas J. Billy
Administrator

SUBJECT: Office of Inspector General's (OIG) Draft Report on the Imported Meat and Poultry Inspection Process Phase 1, Audit Number 24099-03-Hy

We appreciate the opportunity to review the subject report. The Food Safety and Inspection Service (FSIS) offers the following responses to the recommendations. FSIS recognizes the need to make improvements in the current program. While we have accepted many of the report's recommendations, nevertheless, there are a number of areas in which we disagree. The actions that FSIS will take to enhance the imported meat and poultry inspection process are outlined in our responses.

Key Recommendations:

We recommend that FSIS conduct an assessment of the current organizational structure, clarify roles and responsibilities, and establish a system of management and operating control objectives and processes to ensure the safety and wholesomeness of imported meat and poultry products. FSIS also needs to conduct independent internal control reviews, emphasizing those processes that changed in the reorganization, provide management control training, and report the conditions disclosed in this audit as material management control weaknesses in the import inspection process.

We also recommend that FSIS develop and implement formal procedures, approved by FSIS management, for all aspects of its import inspection program, most specifically those related to (1) making equivalency determinations based on an evaluation of each foreign country's food safety regulatory system, as appropriate, (2) its enforcement of sanitary measures, and (3) entering country eligibility information into FSIS' inspection system. We also recommend that FSIS enforce the regulatory requirements for countries to submit their residue test plans and test results and establishment certifications by foreign inspection systems.

Concerning equivalency determinations, FSIS needs to establish a time phased plan to complete each determination and ensure that technical subject-matter experts are involved in determinations, the determinations are documented, and onsite verification reviews are conducted prior to granting equivalency status. For current trading partners, FSIS needs to develop and implement a policy for onsite verifications of changes in the requirements for foreign systems and ensure that onsite audits are conducted annually.

Agency Response:

We agree with the key recommendations with the exception that FSIS does not believe the issues outlined in this audit report constitute a material management control weakness. FSIS expects to complete the recommendations outlined in this report by March 2002.

FSIS firmly believes that enhanced internal controls will help in managing change from shifting environments and evolving demands and priorities in the import arena. FSIS will employ a comprehensive and continuous effort to ensure that the imported meat and poultry inspection processes use a system and a risk management approach in applying management controls in its operations.

Recommendation No. 1:

Conduct an in-depth assessment of the current organizational structure to establish a system of control objectives and processes to ensure that the goals of import inspection process are achieved.

Agency Response:

FSIS agrees with this recommendation. FSIS will assess the current organizational structure and identify import inspection controls, objectives and processes. The assessment will be completed by May 2001.

Recommendation No. 2:

Require increased management oversight and approval of changes to import inspection operations and procedures.

Agency Response:

FSIS believes that management oversight and approval of changes to import inspection operations and procedures is adequate. Inspection of imported meat and poultry product is controlled through a multi-tiered supervisory and management oversight structure. The port of entry import inspections are conducted in 15 of the 17 FSIS Districts. The Circuit Supervisor, Assistant District Manager, District Manager, Assistant Deputy Administrator and Deputy Administrator, Field Operations all serve to provide progressive levels of supervisory/management oversight and controls to inspectors conducting imported product inspections.

Additionally, the Technical Service Center (TSC) provides technical guidance and support to Agency inspection personnel, including supervisors and managers, with regard to all aspects of the import process. The TSC also works directly with Office of Policy, Program Development and Evaluation (OPPDE) in order to achieve clarity and changes to Agency policy issues as needed. When changes in policy occur that impact import inspection operations and procedures, this information is conveyed to all FSIS personnel involved with import inspection through electronic generated import messages and through changes to the import manual of procedures. FSIS will prepare a summary of the management oversight functions and procedures. See item 7 of the response to recommendation 12. These procedures will outline FSIS' efforts to strengthen management controls for all import operations. The consolidated written procedures will be developed by March 2001.

Recommendation No. 3:

Provide management control training to agency managers.

Agency Response:

FSIS agrees with this recommendation. FSIS believes in continuous education and refresher training for its managers in a number of areas. FSIS will make arrangements for its Imported Meat and Poultry Inspection managers at Headquarters, District Offices, and the Technical Service Center to receive additional training on management controls. The agency will arrange for training similar to the Management Accountability and Control (OMB Circular A-123) course offered by the Government Audit Training Institute at the Graduate School, USDA by December 1, 2000. FSIS will explore including a training module on management controls in its Management Leadership and Development Program, which will be available to all agency managers.

Recommendation No. 4:

Revise FSIS Directive 1090.1 to incorporate the provisions of OMB Circular A-123, Revised, Management Accountability and Control," dated June 21, 1995, and document specific program control objectives and review procedures that will provide management reasonable assurance on the effectiveness of controls.

Agency Response:

FSIS agrees with this recommendation. FSIS has updated its Directive 1090.1 to incorporate the provisions of OMB Circular A-123, Revised, Management Accountability and Control," dated June 21, 1995. The draft directive outlines a process for establishing program control objectives and procedures that will provide management reasonable assurance on the effectiveness of controls. The draft document has been reviewed internally and is currently being reviewed by the National Joint Council, an employee union. A copy of the draft Directive 1090.1 is attached. We expect the directive to be finalized by October 1, 2000.

Recommendation No. 5:

Require the FSIS Internal Control Staff to conduct periodic independent assessments of FSIS' programs and operations, emphasizing those processes that changed during the reorganization.

Agency Response:

FSIS agrees with the intent of this recommendation. FSIS will establish selection criteria for conducting periodic independent assessment of FSIS' programs and organizations as appropriate. The Executive Steering Committee for Management Controls will identify and prioritize for independent assessment selected processes that changed during the 1997 reorganization that should be reviewed. The Executive Steering Committee for Management Controls was established in July 1999 with the purpose to:

- Provide Agency policy direction for management accountability, controls, and prioritizing of oversight activities.
- Emphasize management accountability and effective use of management controls.
- Implement and facilitate a corporate framework for improving management controls by identifying and eliminating critical vulnerabilities in Agency systems in ways that stress problem prevention as well as problem resolution.
- Ensure reliable, timely and complete analysis of documentation in support of the Agency's management control system.

It should be noted that FSIS already requires the Internal Control Staff (ICS) to conduct periodic independent assessments of FSIS' programs and operations. However, FSIS will direct the ICS, through guidance provided by the FSIS Executive Steering Committee on Management Controls, to conduct independent assessments of selected processes that changed during the 1997 reorganization. A memorandum of instruction to the ICS will be issued by September 1, 2000, from the Executive Steering Committee on Management Controls to address this recommendation.

ICS was established as a result of the 1997 reorganization. ICS has conducted several independent reviews since the beginning of this audit in October 1998. In October 1998, ICS had four full time employees (FTEs) (i.e., the Director, two GS-9 management analysts, and a secretary). ICS currently has 10 FTEs (including three vacancies). ICS positions currently consists of the Director, a secretary, an operations research analyst, two investigators, a physical scientist, a veterinarian and vacancies for a financial management analyst and two program analysts.

Recommendation No. 6:

Report the conditions disclosed in this audit as material management control weaknesses in the import inspection process.

Agency Response:

FSIS strongly disagrees with the OIG recommendation that the issues outlined in this audit report constitute a material management control weakness. We acknowledge the need to strengthen our management controls and procedures, but we do not believe that the findings of this audit represent a reportable material management control weakness. Although FSIS agrees with most of the suggested management controls improvements in this audit, we do not believe they constitute a reportable material weakness of the import inspection process. FSIS will address opportunities for strengthening the management controls identified in this audit report and report them in accordance with the Agency's assessment of OMB Circular A-123 requirements.

Recommendation No. 7:

Review the roles and responsibilities of personnel involved in the equivalence determination process, the onsite review process, and the input of data to update the AIIS, and define more specifically the authority and responsibilities of those units.

Agency Response:

FSIS agrees to review the roles and responsibilities of personnel involved in the equivalence determination process, the on-site review process, and the input of data to update the Automatic Import Information System (AIIS).

By October 1, 2000, FSIS will review and revise as necessary the functional statements of the International Policy Division (IPD) where joint and separate functional responsibilities exist in on-site equivalence audits, audit reports, and follow-up on equivalence issues raised during on-site audits.

The sharing of information between the IPD and the TSC has evolved since the Agency's reorganization, and has matured into a very efficient and effective system. All foreign country documents and correspondence received by the IPD are copied and forwarded to TSC for inclusion in their country files. This information is available to the reviewers as they prepare for foreign reviews. The reviewer's independent assessment of these documents is discussed with the Review Staff Director, Chief of the International Review Staff, and with various IPD personnel during the pre-audit conference conducted prior to each foreign country audit. Any recent updates or questions regarding supporting documentation are discussed at these pre-audit conferences. All relevant information needed for the reviewer to verify that a foreign country is adhering to written procedures or policies is made available to the reviewer prior to his departure to the foreign country.

During the 1997 reorganization, FSIS determined as a matter of policy to have the on-site audit function separated. Prior to the reorganization, significantly less emphasis was placed on either audit preparation or audit follow-up. In addition, the Agency did not have a uniform audit report that could be easily understood by foreign governments and U.S. consumers. As a result of the reorganization, controls over on-site audits have been significantly strengthened. OPPDE and the TSC have developed a thorough, in-depth reporting format for foreign country audits.

Included in this process was the development of a series of "checklists" that detailed the Pathogen Reduction/Hazard Analysis Critical Control Points (PR/HACCP) requirements. Although reviewers had been verifying these requirements during the foreign country audits, they had very limited written documentation to verify the process. The new report format, including checklists, is now in place and being used by the reviewers during their foreign country audits and as they prepare their report documenting their observations and findings.

The TSC provides the results of on-site foreign inspection system review to the OPPDE so that it can make on-going equivalence determinations. It is imperative that the on-site audits include collecting information on specific equivalence subjects in order that OPPDE can make sound equivalence determinations.

The evaluation and analysis of the FSIS audit findings and the resultant course of action is a policy matter that is managed by the OPPDE. Management in this situation includes, but is not limited to: (1) determining the severity and meaning of the audit findings in the scope of the overall foreign country's inspection system; (2) determining what is expected of the foreign country's inspection system in regards to correcting the deficiencies, both short term and long term, both establishment specific and system specific; and (3) communicating with the foreign inspection officials.

Recommendation No. 8:

Prior to the onsite review, ensure that the Technical Service Center reviewers are provided with all information necessary to verify data provided by foreign countries for equivalence determinations.

Agency Response:

FSIS agrees to develop formal procedures that will continue to ensure that the TSC is provided all information necessary for the reviewers to verify data provided by foreign countries during equivalence determinations. The procedure will be completed in December 2000.

Recommendation No. 9:

Provide training to all inspectors responsible for conducting inspections of imported products.

Agency Response:

FSIS is currently developing updated import training for field inspectors who conduct import inspection activities. Training is scheduled to begin in FY 2001. This training plan is projected to include on-the-job training, pre-classroom CD-ROM's that cover basic import inspection procedures, and a formal training session at various U.S. ports of entry. The training plan will be completed in December 2000.

Recommendation No. 10:

With the help of technical subject-matter experts, develop and implement comprehensive guidelines as a means of ensuring propriety and consistency in decisions involving equivalency determinations.

Agency Response:

FSIS agrees to develop comprehensive written guidelines for equivalence determinations by January 2001.

FSIS had developed general guidelines to ensure that the foreign governments had addressed all the components of the PR/HACCP requirements. These guidelines were not the only documents used to review foreign country submissions.

When reviewing the foreign country submissions, FSIS used the specific detailed regulatory requirements listed in the Code of Federal Regulations (CFR), documents published in the Federal Register, FSIS directives and guidelines prepared by the Microbiology Division. The following Federal Register documents were used in the review of foreign submissions:

- Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems Rule, Volume 61, Federal Register, pages 38806-38989, published on July 25, 1996.
- Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Technical Corrections and Amendments Rule, Volume 62, Federal Register, pages 26211-26220, published on May 13, 1997.
- Pathogen Reduction; Hazard Analysis and Critical Control Point Systems-Sample Collection-Technical Amendments and Corrections Rule, Volume 62, Federal Register, pages 61007-61009, published on November 14, 1997.

When reviewing submissions from foreign governments concerning Sanitation Standard Operating Procedures (SSOP), FSIS used the specific detailed regulatory requirements set forth in 9 CFR 416.12 through 416.17. When reviewing the individual submissions concerning generic *Escherichia coli* (*E. coli*) testing, FSIS used the specific detailed regulatory requirements set forth in 9 CFR 310.25(a) and 9 CFR 381.94. In addition, FSIS used the following guidelines for reviewing SSOP and generic *E. coli* testing programs that were developed by program experts within the Agency and were published as appendixes to the PR/HACCP rule on July 24, 1996:

- Appendix A—Guidelines for Developing a Standard Operating Procedure for Sanitation (Sanitation SOP's) in Federally Inspected Meat and Poultry Establishments;
- Appendix B—Model of a Standard Operating Procedure for Sanitation;
- Appendix F—Guidelines for *Escherichia coli* Testing for Process Control Verification in Cattle and Swine Slaughter Establishments; and

- Appendix G—Guidelines for *Escherichia coli* Testing for Process Control Verification in Poultry Slaughter Establishments.

Other guidelines used in the review of generic *E. coli* submissions included Agency directives and a three page summary guideline prepared by the Microbiology Division for use in reviewing foreign submissions.

When reviewing PR/HACCP submissions, FSIS used the specific detailed regulatory requirements set forth in 9 CFR Part 417. When reviewing the individual submissions concerning generic *Salmonella* testing, FSIS used the specific detailed regulatory requirements set forth in 9 CFR 310. 25 (b) and 9 CFR 381.94. In addition, FSIS used the following guidelines to review HACCP and *Salmonella* testing submissions that were developed by program experts within the Agency and were published as appendixes to the PR/HACCP rule on July 24, 1996:

- Appendix C—Guidebook for the Preparation of HACCP Plans;
- Appendix D—Hazards and Preventive Measures Guide; and
- Appendix E—FSIS Sample Collection Guidelines and Procedure for Isolation and Identification of *Salmonella* from Raw Meat and Poultry Products.

Other guidelines used in the review of generic *Salmonella* testing submissions included a six page summary guideline prepared by the Microbiology Division for use in reviewing foreign submissions. This document incorporated all of the regulatory requirements and the procedures used by FSIS in *Salmonella* testing.

Although many countries elected to adopt the identical requirements as stated in the regulations, some countries chose to adopt different requirements as permitted under the Agreement On The Application Of Sanitary And Phytosanitary Measures (SPS Agreement) and 9 CFR 327.2 and 381.196. In those cases, the countries had to provide sufficient scientific evidence to demonstrate equivalence. The appropriate subject-matter experts within FSIS reviewed the foreign country submissions. In some cases, FSIS subject-matter experts worked with the scientific experts from other countries to develop scientific protocols for comparative studies. In addition, all equivalence determinations were reviewed within the Agency and criteria for each decision was developed with the assistance of the subject-matter experts. The decisions and the criteria used were announced and discussed at a public meeting on December 14, 1999. A document summarizing the guidelines, the criteria, and the equivalence determinations for each country for the PR/HACCP rule was provided at the public meeting.

Recommendation No. 11:

Develop written criteria and procedures for suspending the eligibility of exporting countries that do not provide sufficient documentation to support their continuing compliance with U.S. equivalency standards or are found to be in noncompliance based on the results of an onsite equivalency review.

Agency Response:

FSIS agrees with this recommendation. FSIS regulations, 9 CFR 327.2.[1] , delineate criteria for both initially determining the eligibility of a foreign country to import products into the United States and for withdrawing a foreign country's eligibility to import. FSIS will consolidate this requirement into internal procedures and guidelines by March 2001.

Initial determinations of eligibility and withdrawals of eligibility require notice and comment rulemaking under the Administrative Procedure Act (APA).[2] The APA contains provisions that ensure all interested parties receive equal treatment and due process under the laws and regulations of the United States. Full public participation occurs at each stage in this process. Specific regulatory criteria exist both for initial determinations of eligibility and for subsequent withdrawals. For example, FSIS may publish a proposed regulation to withdraw the eligibility of a foreign country under any of three clearly stated regulatory criteria:[3]

1. The system of meat inspection maintained by such foreign country does not ensure compliance with requirements equivalent to all the inspection, building construction standards, and other requirements of the Act and the regulations...as applied to official establishments in the United States.

2. Reliance cannot be placed upon certificates required under 9 CFR Part 327 from authorities of such foreign country.

3. For lack of current information concerning the system of meat inspection being maintained by such foreign country.

FSIS may withdraw but may not suspend the eligibility of any country to import meat or meat products into the United States. The Agency may, however, take action to ensure that *products* from a particular country are not admitted into the United States if they are adulterated or misbranded.[4] USDA regulations, the Federal Meat Inspection Act, and the Poultry Products Inspection Act define the term "adulteration" to mean any product if it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.[5]

FSIS has established three criteria under which it would suspend the importation of product:

1. An emergency sanitary measure is not implemented to address a hazard that is so severe that no product can enter the marketplace from a foreign establishment until the control is in place.

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[1] Imported poultry products are regulated by 9 CFR Part 381, Subpart T. This discussion pertains to both meat and poultry as the imported product regulations are virtually identical.
[2] 5 U.S.C. 551 et seq.
[3] 9 CFR 327.2(a)(4)
[4] 9 CFR 327.3 (a)
[5] 9 CFR 301.2 See definition (4) of "adulterated.", 21 U.S.C. 453 (g)(4), and 601 (m)(4)

2. Where an exporting country does not provide satisfactory documentary evidence of an equivalent sanitary measure.

3. Where a system audit reveals that an exporting country is not implementing a sanitary measure in the manner that FSIS initially determined to be equivalent.

During the audit, OIG saw evidence of FSIS taking action to suspend the importation of product from Country A because serious sanitation problems had been discovered in establishments located in that country. That action, in itself, did not affect the eligibility of Country A to export meat products to the United States. Only notice and comment rulemaking can do that. Rather it served to protect American consumers from products that were adulterated under U.S. law because they were produced in establishments that had serious sanitation problems. The situation in Country A could, however, lead to the loss of its eligibility under criteria 1 or 2 above if the problems in its establishments were judged to be systemic.

The situation in Country B was entirely different. FSIS had engaged Country B in a lengthy discussion of alternative sanitary measures proposed by that country to meet the U.S. level of protection under our PR/HACCP requirements. With Country B, the issues were wholly procedural and methodological—different ways to reach the same safe food goal. At no time was there a question about the safety of Country B products. Consequently, FSIS took no action to stop the importation of Country B products even when it was found during on-site audit that some of the agreed upon procedures and methodologies had not yet been fully implemented.

FSIS encountered several similar type situations during the document analysis portion of its PR/HACCP equivalence evaluations. Trade did not stop while discussions continued in good faith because no product safety issues were involved. In the end, FSIS made equivalence decisions in every case that became import requirements for the foreign country. In the event that a foreign country ultimately fails to adopt equivalent sanitary measures, FSIS would be obliged to propose rulemaking under criterion 1 above to withdraw its eligibility status.

Recommendation No. 12:

Develop written procedures, which ensure comprehensive evaluations of foreign countries' alternative import inspection methods and require the analysis of these systems be documented, as well as the decisions reached.

Agency Response

FSIS agrees with this recommendation. Consolidated written procedures will be developed by March 2001 to document equivalence decisions regarding alternative inspection methods. These procedures will reflect and strengthen the Agency's management controls. Effective July 1, 2000, new equivalence decision files will document:

1. All FSIS correspondence with foreign countries;

2. All foreign country submissions (translated and in the originating language);

3. Summary IPD reviews of submissions;

4. Summary of all meetings and teleconferences with foreign officials;

5. Summary of all reviews by subject-matter experts;

6. Documentation of equivalence criteria;

7. Summary of all FSIS management formal reviews and approvals; and

8. Decision memorandum of the equivalence determinations.

FSIS has existing procedures for reviewing countries' alternative inspection methods, including an internal IPD review; a referral to the appropriate subject-matter experts within the Agency; development of equivalence criteria with subject-matter experts; and, discussion and review by senior Agency management officials. In addition, on-site audits are used to verify that countries have implemented the programs properly, and if not, resolve differences and clarify requirements.

In the case of the submission of different inspection methods for the implementation of requirements under the PR/HACCP requirements, appropriate subject-matter experts within FSIS reviewed the submissions from the countries. In some cases, FSIS subject-matters experts worked with experts from other countries to develop scientific protocols for comparative studies. In addition, all equivalence determinations were reviewed within the Agency and criteria for each decision was developed with the assistance of Agency subject-matter experts. Because FSIS had procedures and applied them in the review of these submissions, FSIS was assured that the evaluations were consistent and in accordance with the U.S. standards.

For example, all PR/HACCP requirement decisions and the criteria used to make them were announced and discussed at a public meeting on December 14, 1999. A document summarizing the guidelines, the criteria, and the equivalence determinations for each country for the PR/HACCP requirements was provided at the public meeting.

An example of how the procedure was applied is Country D's submission on generic *E. coli* testing. The original submission was reviewed by the IPD and sent to the Microbiology Division for review. The Microbiology Division correctly determined that Country D's submission had a number of differences and that at the time there had been no policy decision with respect to those differences. As a result, the Microbiology Division worked with the IPD to develop a protocol for a comparative study that would compare Country D's program with the U.S. generic *E. coli* program. Analyzing and developing criteria is one of the steps in developing the protocol. During the development of the protocol, scientists from Country D met in Washington, D.C. with representatives of the Agency to finalize the study. The reason that these documents were not in the Country File at the time of the OIG audit was that a staff officer was using the documents and they had not been consolidated into the Country File.

Another example is the implementation of generic *E. coli* testing and *Salmonella* testing in Country E. Approximately one year after generic *E. coli* testing was implemented, in cattle establishments, Animal and Plant Health Inspection Service (APHIS) imposed a ban on importation of cattle from Country E and other European countries because of BSE outbreaks. As a result, Country E did not need to implement *Salmonella* testing in cattle establishments. The APHIS restrictions on the importation of cattle are still in place. Although Country E has provided documentation that *Salmonella* testing is being conducted in cattle establishments, until the restrictions are lifted, Country E does not need to implement *Salmonella* testing in cattle establishments.

In addition, the Agency has recognized the gauze tampon (pad) that Country E and other countries use as an equivalent sampling tool. The Agency is familiar with this sampling tool and it is generally recognized as an appropriate sampling tool within the scientific community. The merits of this sampling tool was further discussed with the Microbiology Division, criteria developed, and the sampling tool was found to be equivalent. A memorandum summarizing the decision was reviewed within the Agency. FSIS agrees to make certain that this memorandum and the criteria for different sampling tools published at the public meeting December 14, 2000 will be filed in the Country File.

Further, the on-site audit of Country E revealed that Country E had some implementation problems with Sanitation Standard Operating Procedures (SSOP) and generic *E. coli* testing. As often the case when implementing programs that are based on English documents that have been translated into another language, dialogue is needed to clarify requirements and improve implementation. Country E and the Agency entered into such a dialogue and corrective actions were taken to improve the implementation of the SSOP and generic *E. coli* testing programs. Country E was subsequently audited in May 1999. The auditor found that SSOP, generic *E. coli* testing, HACCP, and *Salmonella* testing programs met the basic requirements. FSIS will document those areas that have not been documented in the Country Files.

FSIS determined that Country B's implementation of generic *E. coli* testing is equivalent, based on a thorough scientific review of the documentation provided by Country B. There were differences in Country B's program, some of which FSIS found to be equivalent and others that were not found to be equivalent because of insufficient scientific evidence. Although an audit in March 1999 raised some implementation issues, Country B has resolved the issues. An FSIS on-site audit in April 2000 confirmed that SSOP, generic *E. coli* testing, HACCP, and *Salmonella* testing have been implemented.

Recommendation No. 13:

Streamline the process and establish procedures that would allow expeditious entry of laboratory test results into the Automated Import Information System.

Agency Response:

FSIS agrees that additional documentation would assist in clarifying the current system to both Agency personnel as well as outside auditors. FSIS is reevaluating the current system as part of

the redesign of the AIIS and will improve the documentation by December 2000 to outline the procedures for entering laboratory results into the AIIS system.

As an interim measure, in March 2000, the Field Automation Information Management (FAIM) Division instituted non-automated procedures to streamline the entry of residue and microbial results. As of March, FAIM receives faxes from the TSC of laboratory Form 9770-2 for all positive residue results. The FAIM Division then documents directly on the laboratory form both the date it was received (via fax) and the date/time the lab results were entered into AIIS. Entries into the AIIS are made the same day they are received. Also, an internal verification process will be established to monitor the data being entered into the AIIS.

Also, FSIS is working to replace the AIIS. The new system, eventually sharing Sybase SQL tables with the Microbiological and Residue Computer Information System (MARCIS) and other agency systems will ensure real time accuracy of both negative and positive results of residue tests and microbiological tests. The FAIM Division began work on the new AIIS application in March 2000 with a test pilot planned for the first quarter of 2001. We expect the system to be fully operational by December 2001.

Recommendation No. 14:

Require the Office of Field Operations to work with the Technical Service Center and the Field Automation and Information Management Division to develop management controls and a supervisory review process to ensure that all laboratory test results are promptly and accurately entered into the Automated Import Information System. Management controls must include requirements for maintaining records of when failure notifications are received and when the entries are made into the Automated Import Information System.

Agency Response:

FSIS agrees with this recommendation. The FAIM Division is focusing on incorporating the required management controls in the replacement AIIS, which should be completed by December 2001. The new import computer system will document when laboratory failure results are received and incorporated into the system data tables. In the interim, FSIS has established a manual tracking process that documents when notification of failures is received and when the entries are made into the AIIS. Entries are made within 24 hours of receipt of the positive laboratory results. Negative results are obtained via a weekly download from MARCIS and entered that same day into the AIIS.

FSIS believes that the management controls and supervisory review process can be enhanced to ensure that all laboratory results are promptly and accurately entered into the AIIS. Management controls currently include requirements for maintaining records that indicate when failure notifications are received, and when the entries are made into the AIIS.

Recommendation No. 15:

Officially notify all countries importing meat and poultry into the United States that annual certifications are due no later than the established date and that establishments that are not certified by this date may be delisted. Incorporate this requirement in regulations.

Agency Response:

FSIS agrees that meat and poultry products exported to the United States must be produced in properly certified foreign establishments. To ensure that this occurs, the FAIM Division has established a web site with search capabilities that allows import inspectors to obtain the status (certification, delistment, relistment) of foreign establishments.

FSIS agrees to notify all countries that certifications of establishments must be renewed annually, and if establishments are not certified annually they may be delisted. However, FSIS does not agree with the OIG's assertion that allowing countries to delay their certifications "reduces the control to prevent products from uncertified establishments from entering the United States".

Annual certification lists are often obsolete soon after they arrive because importing countries add and delete certified establishments throughout the year. Furthermore, an additional method exists to verify that imported product was produced in an establishment certified for export to the United States.

This method is set forth in 9 CFR 327.4, "Imported products; foreign certificates required."[6] A foreign-meat-inspection certificate must accompany each consignment of fresh meat, fresh meat byproducts, or meat food products. All such consignments (or "lots") offered for entry into the United States from any foreign country must be reinspected by an FSIS import inspector before they are allowed into this country.[7] For example, every lot of product is routinely given a visual inspection by an FSIS import inspector for appearance and condition, and checked for certification and label compliance.

An authorized foreign government official signs the certification accompanying each lot. Each foreign certificate contains information such as kind of product, species of livestock it was derived from, number of pieces or containers in the lot, shipment weight, shipping marks, and the producing establishment number. FSIS believes that these certificates provide ample evidence that the product they accompany was produced in a foreign-certified establishment.

The value of an annual list as proof of establishment certification diminishes quickly, however, and must be supplemented by prompt notifications from foreign governments of changes—additions and deletions of establishments—as soon as they occur. Thus, the focus of FSIS management controls should be on receipt and posting of updates rather than the annual compilation of changes. By September 2001, FSIS will publish a proposed revision of Part

[6] Imported poultry products are regulated by 9 CFR Part 381, Subpart T. This discussion pertains to both meat and poultry as the imported product regulations are virtually identical.
[7] 9 CFR 327.6 (a)(1)

327—Imported Products to eliminate the annual certification requirement.

Recommendation No. 16:

Establish a follow-up process to obtain the annual certification lists from the countries which have not submitted them.

Agency Response:

FSIS has established a follow-up process to obtain annual certification lists from countries that have not submitted them. This process is subject to change after the proposed revisions (see response to Recommendation 15) in Part 327 are implemented. Attachment 1 is a copy of our current follow-up process.

Annual certification lists are sent from foreign countries to the IPD. In July 1999, effective for calendar year 2000, the FAIM Division established a procedure to notify IPD of every country for which FAIM has not received an annual certification of establishments. Starting in February 2000, and continuing on a monthly basis, the FAIM Division has notified the IPD of outstanding certification lists.

Recommendation No. 17:

Immediately conduct reconciliation between establishment certification information maintained by the Equivalence and Planning Branch and the Automated Import Information System to ensure that the Automated Import Information System includes only those establishments certified by their foreign governments to ship products to the United States.

Agency Response:

FSIS agrees with the recommendation. Following the on-site portion of the OIG audit, the FAIM Division established a program of quarterly crosschecks of foreign government certification documents against the establishment listings contained in the AIIS. In addition, effective April 1999, the FAIM Division began sending to the IPD a weekly report listing all certified and decertified establishments maintained in the AIIS. IPD will begin reconciliation of the FAIM reported data and their internal records by December 2000.

Recommendation No. 18:

Establish time requirements and a management control process for reviewing and process certification information in the Automated Import Information Certification System.

Agency Response:

FSIS agrees with this recommendation. The FAIM Division maintains an internal AIIS Import Manual of procedures document that will be updated by December 2000, to address time requirements and management control processes. Supervisory oversight will be established

whereby all changes to the AIIS status of establishments will be forwarded to the Branch Chief of the FAIM Applications Systems Development Branch for review.

Recommendation No. 19:

Take immediate action to ensure that the Technical Service Center, the Field Automation and Information Management Division, and the Equivalence and Planning Branch coordinate efforts to verify that all delisted establishments have been timely entered into the Automated Import Information System.

Agency Response:

FSIS agrees with this recommendation. FSIS will improve its system to verify that all delisted establishments are timely and properly entered into the AIIS. FSIS will establish, by October 1, 2000 a team comprised of OFO and OPPDE personnel, responsible for examining every aspect of the issue of ensuring that only product from approved and eligible establishments gains entry into the United States.

In FY 2000, the FAIM Division expanded its Intranet Web Site with a posting of all delisted foreign establishments. This information is available to the TSC, IPD, and all field inspectors. The web site is updated when FAIM receives information from the IPD.

Recommendation No. 20:

Establish a management control process to ensure that the Technical Service Center Director promptly forwards to the Office of Policy, Program Development and Evaluation information about foreign establishments that were delisted prior to, or because of, Technical Service Center foreign reviews.

Agency Response:

FSIS has established a management control process to address this recommendation. Information regarding foreign country establishments that are delisted prior to TSC reviews is received either by fax or electronic mail from the foreign country government or through the Foreign Agriculture Service. This information is shared by all of the stakeholders, and discussed at the pre-audit conference held between the TSC and the IPD.

Foreign country establishments are also delisted based upon results of on-site reviews by the TSC reviewers. Reviewers are instructed to report this information, by phone, to the Review Staff Director or Chief of the International Review Branch as soon as possible, but no later that the day following the on-site review. This information is detailed in an electronic mail message that is sent immediately to the Chief of the Equivalency and Planning Branch, IPD and also to the Director of the Import/Export, Program Analysis, IRM Staff at the TSC. A paper copy of the electronic mail message is placed in the foreign country file at the TSC.

Both types of delistments are discussed at the post-audit exit conference held between the TSC and the IPD. The reviewer discusses the reasons given by the foreign country officials for delistment of any establishments prior to the review, and also discusses, in-depth, the reasons for any establishment delistment based upon the on-site review.

Recommendation No. 21:

Establish a management control process to ensure that delistment information is (a) reviewed and signed by a designated official to the Field Automation and Information Management Division, via a dated control number and (b) processed and verified in the Automated Import Information System.

Agency Response:

Pursuant to this report, the FAIM Division implemented in May 2000 a management control process whereby the Branch Chief, Application Development and Support Branch, FAIM Division will be notified via e-mail of all incoming delistments received from IPD. Notification will include the date delistments are received, the date the information was entered into the AIIS, and a printout of all establishments as they appears in the AIIS. This procedure will be complete by October 2000.

Recommendation No. 22:

Modify the Automated Import Information System to produce daily process control reports to enable verification of input.

Agency Response:

FSIS agrees with this recommendation. The FAIM Division has begun replacing the AIIS that was first deployed in the 1970s. Available resources will be better used in continuing development of the replacement AIIS, rather than making the recommended changes to the current AIIS. The new system will incorporate this recommendation in its design. The intent of this recommendation will be met when the new computer system is completed by December 2001.

Recommendation No. 23:

Establish procedures to ensure that all residue documents submitted by foreign countries are received, reviewed, and analyzed based on requirements in regulations.

Agency Response:

See Rec. No. 25

Recommendation No. 24:

Obtain the residue test plans not submitted since 1998 to determine if the foreign countries have residue control standards equivalent to the United States.

Agency Response:

See Rec. No. 25

Recommendation No. 25:

Obtain and analyze the residue test plan results not submitted since 1998 to determine the adequacy of foreign countries' adherence to their residue test plans.

Agency Response to Rec. Nos. 23, 24 and 25:

FSIS agrees with these recommendations. FSIS agrees that it needs to strengthen its review of foreign country test plans. An interagency team was created on June 1, 2000, and expects to complete its initial review by December 2000. The team is responsible for the receipt, review, and analysis of all foreign country residue submissions. The team is comprised of representatives of OPPDE, OFO, and OPHS. The team will review the submissions based on U.S. regulations to determine if the information is adequate, if the documents indicate the countries meets U.S. requirements, and if additional information is needed.

The test plans and results are only a part of the basis for assessing a foreign country's residue program. FSIS on-site audits include reviews of the country's laboratory testing capability and FSIS annually collects more than 8,000 statistically selected samples at the port of entry for laboratory analysis. Consequently, FSIS questions the need for collecting past residue plans and results because much more comprehensive information has been requested from every country through a lengthy questionnaire, which negates the value of the earlier submissions.

Responses to the questionnaire will provide this information along with other information such as production practices, veterinary drug usage, agricultural chemicals and incidence of environmental contaminants and pesticides, basis for the residue plan, and actual implementation. and operation of the program. By December 2000, FSIS will have a more complete and current assessment of the country's controls. If, upon reviewing the responses, FSIS determines that required information is missing, it will be requested from the country. FSIS believes that focusing on in-depth reviews is a more productive use of its resources.

Recommendation No. 26:

Develop procedures to ensure that (a) a review of residues identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants are included as part of the Technical Service Center on-site equivalency reviews, and (b) appropriate action is taken in those instances where the plans are inadequate, the results vary from the plans, or violations are detected.

Agency Response:

The IPD will provide the Director of the Review Staff at the TSC with a summary of the information in residue questionnaires submitted by countries eligible to export to the United States. The Review Staff will be part of the team that will review the submissions. The Review Staff and the IPD will use this information, along with port-of-entry results and information from past audits, to plan upcoming reviews.

This year, FSIS is initiating in-depth reviews of residue programs in a number of countries exporting to the United Sates. These reviews will make a comprehensive evaluation of the effectiveness of the country's controls over drugs and chemicals that could contaminate meat and poultry. This will include a review of documents, an assessment of whether the country is testing for the appropriate compounds, whether the plan is implemented as designed, laboratory capability, and enforcement. The reviews are expected to be completed by June 2001.

Recommendation No. 27:

Develop procedures that require the participation of technical subject-matter experts, as appropriate, in equivalency determinations, and document the experts' participation, analyzes, and conclusions.

Agency Response:

FSIS agrees to develop formal procedures by October 2000 for participation of technical subject-matter experts, as appropriate, in equivalence determinations. FSIS will apply this approach in making equivalence determinations, where a foreign country proposes to adopt requirements that are *different* from FSIS requirements. When a country proposes to adopt an *identical* requirement, then it is not necessary to involve subject-matter experts in those determinations. This is often the case during FSIS' evaluation of foreign country documents submitted in response to the HACCP/pathogen reduction regulation.

As a matter of policy, FSIS has determined that the best way to facilitate equivalence determinations was to establish a Branch within IPD responsible for equivalence judgements. The personnel in that Branch possess the necessary expertise to make equivalence judgement when a country is proposing to adopt *identical* requirements. Whenever an equivalence decision involves alternative measures then, subject-matter experts participate in the equivalence decision making.

The OIG noted that a "multi-disciplinary team was not always used during equivalency determinations". That statement is correct because FSIS makes equivalence determinations in two areas: initial equivalence determinations and equivalence maintenance determinations. When making an initial equivalence determination as to whether a country is eligible to export meat, poultry, or egg products to the United States, the country is subject to a multi-disciplinary team audit. Once a country has been approved to export product to the United States the Agency normally conducts annual audits by a veterinary medical officer. In the case of SSOP and generic *E. coli* testing programs, the individual auditors possess the necessary training and skills

to verify that these programs had been implemented. It is unnecessary for FSIS, on a routine basis, to assign multi-disciplinary teams to conduct on-going equivalence audits. However, there have been a number of instances in which FSIS has expanded its audits of current trading partners to include subject-matter experts.

Recommendation No. 28:

Document and implement a system of internal controls to ensure the adequacy and support for foreign equivalency determinations. This should include a formal review and approval process for the equivalence determinations made.

Agency Response:

FSIS agrees with this recommendation. FSIS will formalize its procedures and documentation of equivalence decisions. By December 2000, FSIS will complete the implementation of an internal controls system for foreign equivalency determination. Effective July 1, 2000, new equivalence decision files will document:

1. All FSIS correspondence with foreign countries;
2. All foreign country submissions (translated and in the originating language);
3. Summary IPD reviews of submissions;
4. Summary of all meetings and teleconferences with foreign officials;
5. Summary of all reviews by subject-matter experts;
6. Documentation of equivalence criteria;
7. Summary of all FSIS management formal reviews and approvals; and
8. Decision memorandum of the equivalence determinations.

Recommendation No. 29:

Develop a management control process and procedures to ensure equivalence decisions are adequately documented. The procedures should require that files contain supporting evidence, including detailed analysis of information received and reviewed, resolution of issues raised during the review process, and conclusions reached.

Agency Response:

FSIS agrees with this recommendation. FSIS agrees that equivalence decisions should be adequately documented and that the files must be complete. Therefore, FSIS will institute the same measures described in response to Recommendation 28.

The examples that OIG cites to demonstrate its concern with the equivalence determination process is misplaced and erroneously concludes that the equivalence process was incomplete. The process was complete, but not all of the documents were in the Country files at the time of the audit.

OIG states that there is inadequate information regarding FSIS's equivalence determination for Countries F, D, and G. With respect to the documentation of the generic *E. coli* implementation in Country F, the OIG report neglects to state that there are currently no approved Country F slaughter establishments certified to export product to the United States. During the on-site audit of County F, the only certified slaughter establishment was voluntarily delisted by Country F because generic *E. coli* was not properly implemented in that establishment. Until Country F wishes to certify a slaughter establishment to export to the United States, Country F does not need to implement generic *E. coli* testing.

In addition, the OIG notes a lack of documentation regarding the equivalence determination for generic *E. coli* for Country D. FSIS provided OIG evidence of additional documentation prior to the final draft of the audit report. That documentation was not in the Country Files, but still in the program officer's working files.

Furthermore, OIG's concerns about Country G are based on a misunderstanding of the equivalence process. The equivalence process involves both a document review and an on-site review. Normally, but not always, the on-site audit follows the document review process. Based on the document review, discussions with representatives from Country G, and a previous on-site audit, FSIS sent Country G a cable telling Country G that their generic *E. coli* program was equivalent and reminding them that it was based on their agreement to use statistical process control.

Recommendation No. 30:

Establish a time-phased plan to expedite the process for determining equivalency.

Agency Response:

FSIS agrees with this recommendation. FSIS will implement time-phased plans for future equivalence determinations, effective October 1, 2000.

Recommendation No. 31:

Ensure that onsite audits for current trading partners are conducted at least annually.

Agency Response:

FSIS agrees with this recommendation. This issue will be incorporated into the FSIS procedures for imported inspections by December 2000.

Recommendation No. 32:

For current trading partners, develop and implement a policy for onsite verifications of changes in the requirements for foreign inspection systems.

Agency Response:

FSIS agrees with this recommendation. The equivalence process begins with a document review, to determine if the foreign country's written submission documents how its sanitary measures meet the United States' appropriate level of protection. This evaluation is then verified by an onsite audit to confirm that the foreign country has in fact implemented its sanitary measures, as described in its written submission.

However, the finding for this recommendation reflects a misinterpretation of 9 CFR 327.2. The misinterpretation is evidenced by a statement on page 60: "We found that the food regulatory systems of six countries were determined "equivalent" by the Equivalence and Planning Branch without verification by an onsite review".

This statement is incorrect. The six countries (cited later in a table on page 62) have food regulatory systems that were found fully equivalent to the U.S. system many years ago. Each of these countries has undergone initial equivalence evaluations to include an extensive on-site audit and are listed as equivalent at 9 CFR 327.2 (b). Additionally, each of these countries has been audited on-site many times since its food regulatory system was initially found equivalent.

When an eligible country proposes an alternative sanitary measure to FSIS for an equivalence decision, FSIS conducts a full document analysis of only that component of the foreign food regulatory system that is affected by the change. A final determination of equivalence for a proposed sanitary measure is verified by on-site audit. Trade continues in the interim. Three circumstances could result in an interruption of trade. One, where an emergency sanitary measure is implemented by FSIS to address a hazard that is so severe that no product can enter the marketplace from a foreign establishment until the control is in place. Two, where an exporting country does not provide satisfactory documentary evidence of an equivalent sanitary measures. Three, where a system audit reveals that an exporting country is not implementing a public health sanitary measure in the manner that FSIS initially determined to be equivalent. None of these three conditions applied during FSIS evaluations of PR/HACCP alternative sanitary measures proposed by foreign countries.

Recommendation No. 33:

Clarify the regulations regarding FSIS' procedures for determining equivalence for current trading partners, taking into consideration major changes such as HACCP and pathogen reduction requirements.

Agency Response:

FSIS has been properly applying its regulations regarding equivalence determinations. FSIS

makes two types of equivalence determinations: (1) determinations of initial equivalence (termed "eligibility" in current regulations) for countries that are not yet trading partners; and (2) determinations of whether equivalence is being maintained by countries that are now trading partners.

Regulatory authority for all equivalence determinations is at 9 CFR 327.2, "Eligibility of foreign countries for importation of products into the United States." Imported poultry products are regulated by 9 CFR Part 381, Subpart T. This discussion pertains to both meat and poultry, as the imported product regulations are virtually identical.

The criteria for initial country equivalence are set forth at 9 CFR 327.2 (a) (2) (i) and (ii). The process through which a foreign country may request an initial determination of equivalence and the manner in which FSIS makes these determinations are described at 9 CFR 327.2 (a) (2) (iii).

Mention is also made in 9 CFR 327.2(a)(2)(iii) of two criteria for maintaining country equivalence. They are as follows: (1) the result of periodic reviews of the foreign meat inspection system; and (2) the timely submission of documents and other information related to the conduct of the foreign inspection system. Additional criteria for maintaining equivalence are provided at 9 CFR 327.2(a)(2)(iv).[8] All FSIS activities in connection with verification that foreign countries have implemented equivalent PR/HACCP sanitary measures were conducted in full accordance with the regulatory provisions cited in this paragraph.

In the future, FSIS will take into consideration major changes, such as PR/HACCP, as it documents its procedures for determining whether equivalence is maintained for current trading partners, as referenced in our response recommendation No. 12.

Recommendation No. 34:

Ensure that reporting and evidence standards developed for equivalency verification reviews provide for appropriate documentation of all areas required to be reviewed by regulation.

Agency Response:

According to 9 CFR 327.2 (a) (2) (iii) "Maintenance of eligibility of a country for importation of products into the United States depends on the results of periodic reviews of the foreign meat inspection system..." The regulatory requirement of periodic reviews does not mandate that each review encompasses all aspects of a country's inspection system.

Nevertheless, FSIS is committed to ensuring that these reviews are consistent and thoroughly documented. At the time of the OIG audit, FSIS was in the process of developing an enhanced uniform audit format that addressed the following five risk areas: (1) animal disease controls; (2) sanitation controls; (3) enforcement controls; (4) slaughter and processing controls; and (5) residue controls. These five risk areas cover all of the FSIS regulatory requirements for countries that export to the United States. Subsequent to the OIG audit, the audit format was

[8] FSIS would add that the results of port-of-entry product reinspections are also critical to the maintenance of equivalence.

finalized. The new audit format has been implemented for all FSIS audits conducted in Fiscal Year 2000. Also, audit planning has been enhanced to ensure that on-site audits cover all relevant areas.

Recommendation No. 35:

Develop procedures for timely completing reports documenting reviews of foreign inspection systems.

Agency Response:

FSIS agrees with this recommendation. Formal procedures will be completed by December 2000. In Fiscal Year 2000, new foreign country reporting requirements were instituted. Draft foreign country reports are due from the reviewers within 10 working days of their return to the office. Exceptions to the 10-day rule must be requested in writing, with justification, through the Branch Chief of the International Review Branch or Director of the Review Staff. Similar timeframes are in effect throughout the process, creating a timeline that has the report completed and in "Draft Final" form to be sent to the foreign country government officials for comment within 60 days from the date of the exit conference with the foreign officials. This 60-day commitment is also detailed in the cable that each reviewer sends to the foreign country prior to each audit. Because of language differences, and necessary time for response, the foreign countries are allowed 60 days to submit their response to the report. The foreign country response is then added to the report as an attachment, and the report is finalized.

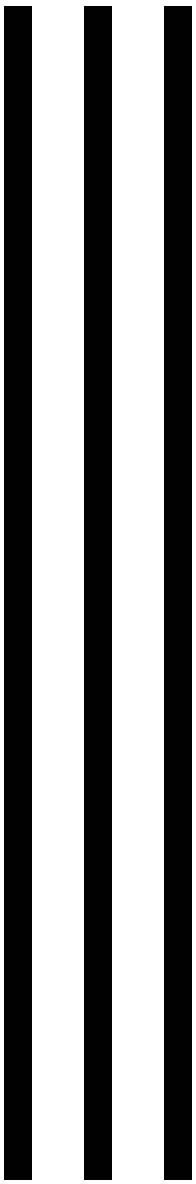
EXHIBIT B – COUNTRIES ALLOWED TO CONTINUE EXPORTING TO THE UNITED STATES PRIOR TO IMPLEMENTATION OF HACCP.

Argentina
Australia
Austria
Belgium
Brazil
Canada
Costa Rica
Croatia
Czech Republic
Denmark
Dominican Republic
Finland
France
Germany
Guatemala
Honduras
Hong Kong
Hungary
Iceland
Israel
Italy
Japan
Mexico
Netherlands
New Zealand
Nicaragua
Northern Ireland
Poland
Republic of Ireland
Romania
Slovenia
Spain
Sweden
Switzerland
United Kingdom
Uruguay

NOTE: Paraguay was delisted as an eligible exporter of meat products to the United States as of September 5, 1997.

ABBREVIATIONS

E. coli	-	Escherichia coli
FSIS	-	Food Safety and Inspection Service
FY	-	Fiscal Year
GATT	-	General Agreement on Tariffs and Trade
HACCP	-	Hazard Analysis and Critical Control Point
OIG	-	Office of Inspector General
OMB	-	Office of Management and Budget
SSOP	-	Sanitation Standards Operation Procedures
USDA	-	U.S. Department of Agriculture



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

FOOD SAFETY AND INSPECTION SERVICE
DISTRICT ENFORCEMENT
OPERATIONS
COMPLIANCE ACTIVITIES

Report No.
24601-4-At
June 2000

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250

DATE: June 21, 2000

REPLY TO
ATTN OF: 24601-4-At

SUBJECT: District Enforcement Operations Compliance Activities

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 compliance review program. This review is part of the Office of Inspector General' s food safety initiative, which also included the implementation of the Hazard Analysis Critical Control Point System, imported meat and poultry inspection process, and the agency' s procedures established for testing meat and poultry products. Your June 6, 2000, response to the official draft report is included as exhibit I 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, 4, 5, 6 and 7. 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 yet been reached on Recommendations Nos. 2, 3, and 8. 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

FOOD SAFETY INSPECTION SERVICE
DISTRICT ENFORCEMENT OPERATONS
COMPLIANCE ACTIVITIES

AUDIT REPORT NO. 24601-4-AT

RESULTS IN BRIEF

This report represents the results of our audit of the Food Safety and Inspection Service (FSIS) District Enforcement Operations (DEO) compliance activities[1]. 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 (HACCP) system, the controls over imported meats, and the procedures established for laboratory testing of meat and poultry products. The objective of the audit was to determine whether FSIS' policies, procedures, and controls were adequate to provide an effective compliance review program to detect and prevent food safety violations and to ensure industry compliance with the provisions of meat and poultry inspection laws and regulations.

9 Code of Federal Regulations, Part 300, gives FSIS the responsibility of ensuring that meat and poultry entering consumer channels is wholesome. To meet the responsibility, FSIS performs compliance reviews of non-federally inspected firms, such as warehouses, processors, distributors, transporters, and retailers. Compliance reviews are initiated for a variety of reason. For example, FSIS may initiate a compliance review to respond to a consumer complaint, to carry out its random reviews of firms, or to followup its reviews of previous violators. Violators of meat and poultry inspection laws can be cited, imposed with administrative sanctions, or even prosecuted for criminal actions.

Several systemic deficiencies are having an impact on FSIS' ability to meet its compliance obligations. Most importantly, FSIS needs to enhance its existing plan to ensure compliance reviews are sufficient to detect and prevent major food safety violations and ensure industry

[1] The audit scope was limited to FSIS compliance and enforcement activities at non-federally inspected firms. We did not assess compliance with HACCP by federally inspected establishments and FSIS' administrative enforcement actions such as fitness determinations and consent and plea agreements.

compliance with the provisions of meat and poultry inspection laws and regulations.

- FSIS' compliance reviews were not systematic and did not have review steps for 13 of the 14 types of firms the agency is responsible for overseeing. FSIS' plan should, at a minimum, define the universe of high-risk firms it is required to review within each district's jurisdiction and the scope of the reviews (what areas to inspect, records review to perform, etc,). FSIS' plan should also emphasize the targeting of resources to heavy populated areas, and those areas that are geographically large. For example, FSIS' data shows for the Albany, New York, district, that the majority of violations occur in the New York City metropolitan area. However, the majority of FSIS random reviews are conducted in the Albany, New York area, where far fewer violations occur. We found that under the agency's existing plan, compliance officers did not know the number of firms subject to a compliance review in their districts, did not review the same processes at similar firms, or in several instances, did not document cases for minor violations of the meat and poultry inspection laws.

- FSIS does not have timeframes and procedures for monitoring and tracking the progress and completion of violation cases at the headquarters, district, and field office levels. The timeliness of processing case reviews was at the discretion of headquarters, district, and field offices. The average number of days cases have remained open indicates that FSIS' existing plan could be enhanced, if the agency sets goals and tracks the time it takes to process violation cases.

FSIS also needs to remove systemic weaknesses in three other areas to improve the effectiveness of its investigations of consumer complaints and food safety violations.

- FSIS does not have an effective system to provide reliable information regarding the number, status, and disposition of all consumer complaints received by their offices. Other than consumer complaints received through the U.S. Department of Agriculture's meat and poultry hotline, FSIS could not readily identify all consumer complaints that had been received nationwide.

- FSIS' enforcement actions taken against 197 (11 percent) of 1,873 firms did not deter them from committing additional

violations. Several firms were cited as many as 4 times for the same violation within a 24-month period. Currently, FSIS does not have the authority to impose monetary fines for violations. Consequently, FSIS' enforcement actions consisted of a letter of warning or similar letter for these cases. Several compliance officers we spoke with stated that the agency should have the authority to fine firms to deter further violations. We support FSIS' ongoing efforts to seek authority to impose monetary fines on firms that violate the meat and poultry inspection laws.

- DEO determined that over half of the cases received from the districts did not require referral for prosecution. District offices refer standard cases to DEO headquarters for possible prosecution action by the U.S. attorney, through the Office of the General Counsel (OGC). We found that DEO headquarters determined 27 of the 41 cases (66 percent) referred from October 1, 1997, through February 28, 1999, did not require referral for prosecution. DEO officials stated that the cases did not have prosecutable merit or some assistant district managers for enforcement (ADME) and supervisory compliance officers did not have enough training or supervisory experience to properly prepare and submit violation cases. As a result, enforcement actions against these violators were delayed.

During our audit fieldwork, we also detected a potential conflict of interest between a compliance officer and a firm that he was responsible for conducting compliance reviews. FSIS took immediate action and reassigned the compliance officer to other duties. The issue is currently under investigation.

KEY RECOMMENDATIONS

We recommend that FSIS further refine its plan to incorporate prescribed procedures for conducting compliance reviews at 13 of the 14 types of firms it is required to oversee (FSIS currently has review steps only for warehouses). FSIS' plan should also define the universe of high-risk firms requiring review and determine the review steps to be performed at each type of firm. FSIS' plan needs to emphasize the targeting of resources to those areas that are geographically large and heavily populated, as well as to firms that are considered high risk. FSIS' plan could be further enhanced by establishing timeframes and procedures for monitoring and tracking the progress and completion of violation cases. FSIS should ensure that all ADME's and supervisory compliance officers receive training to adequately prepare and submit violation cases for prosecution.

We recommend that FSIS develop an effective system to monitor the receipt and processing of all consumer complaints. We are also recommending that FSIS continue to seek authority to fine firms that violate the meat and poultry inspection laws.

AGENCY RESPONSE

In its response to the draft report, dated June 6, 2000, FSIS stated that for the past several years, it has placed strong emphasis on developing and applying appropriate enforcement support for the HACCP system and pathogen reduction regulations * * *. Nevertheless, FSIS acknowledged that this additional emphasis has required it to delay certain needed improvements in traditional compliance activities. FSIS stated that the report comes at an excellent time as it considers ways to strengthen its coverage of distribution channels and to assure timely and appropriate actions in response to violations that put consumers at risk. FSIS also stated that implementation will be contingent on available resources.

FSIS' response to the official draft report is included as exhibit I of the audit report.

OIG POSITION

We agree with FSIS' response to the report. Based on FSIS' response, we achieved management decision on five of the report's eight recommendations.

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INTRODUCTION

BACKGROUND

The Food Safety and Inspection Service's (FSIS) mission is to ensure that the Nation's commercial supply of meat, poultry, and egg products are safe, wholesome, and properly labeled and packaged as required by the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act. Throughout this report, we will refer to the cited Acts as meat and poultry inspection laws. FSIS' District Enforcement Operations (DEO) plays a key role in carrying out this mission.

The DEO compliance Investigative Protocols (formerly the compliance officer's manual and training guidelines) states that

> DEO policies, procedures, and traditions date from May 1966, when meat law investigators and poultry regulatory officers were merged into one staff. The formation of a central compliance unit was stimulated after a series of scandals among non-federally inspected firms received widespread publicity. These scandals involved insanitary conditions in meat and poultry slaughter and processing facilities, and adulteration of meat and poultry products. The U.S. Department of Agriculture (USDA) recognized the need for regular and continuing surveillance of the meat and poultry industry outside of federally inspected plants. The compliance and evaluation staff, as it was known then, was established to meet this need by extending regulatory functions carried out in inspected plants by food inspectors to compliance officers in the meat and poultry allied industries. Non-federally inspected firms, such as warehouses, processors, distributors, transporters, retailers, and other businesses that handled meat and poultry products for human consumption and/or animal food, became the working environment of the compliance officer.

In 1995, FSIS restructured its headquarters and field operations to focus its resources on Hazard Analysis and Critical Control Point (HACCP) system verification tasks, and increase microbial sampling and oversight of the transportation, storage, and retail stages of the food system. In order to help ensure the successful implementation of HACCP, FSIS changed its field operations structure in 1997. This

restructuring resulted in the formation of 18 district offices from 5 area offices in 1997[1]. Also, FSIS had 179 compliance officers on board at the time of our review. (See exhibit A for a listing of the district offices and locations.) FSIS officials stated that the new FSIS organization integrates inspection monitoring resources and regulatory enforcement resources into a unified district structure and assigns a new role to compliance officers. Specifically, FSIS uses the training and expertise of compliance officers to assist in-plant inspectors in documenting HACCP failures and to ensure appropriate due process when enforcement actions are needed.

DEO, headquartered in Washington, D.C., plans and administers an enforcement and compliance program, which is an integral part of FSIS' overall farm-to-table safety strategy. DEO's organizational function statement states that DEO "provides guidance and direction to the 17 district offices relating to the monitoring of businesses engaged in distribution of food products; manages and oversees criminal investigations and case development; and takes appropriate administrative, civil, and criminal sanctions on cases referred from the field." The district offices conduct compliance reviews to monitor businesses engaged in production, and distribution of food products. The district manager oversees the entire district operations; however, the assistant district manager for enforcement (ADME) directs all compliance reviews.

According to DEO's compliance Investigative Protocols, DEO, through its headquarters, district, and field offices, uses five major approaches to carry out the compliance function. DEO:

- Conducts Planned Compliance Program (PCP) reviews to prevent and detect violations in the distribution chain of meat and poultry products.

- Conducts random examination of products at various stages of the distribution chain.

- Documents meat and poultry inspection law violations and recommends criminal, civil, and administrative sanctions.

- Establishes cooperative programs with other Federal, State, and local authorities for product control throughout the distribution chain, and

[1] FSIS currently has 17 district offices due to the July 1999 closure of the Boston, Massachusetts, district office.

- ❖ Identifies program deficiencies that could result in the distribution of adulterated or misbranded products.

DEO's compliance Investigative Protocols state that "either a standard (significance 1) or streamline (significance 2 or 3) case can be developed against firms that may be in violation of the meat and poultry inspection laws. A significance 1 case requires very detailed, highly structured formal reports of violations that indicate critical impact involving likely harm to consumers, either physical or financial. Examples may include (1) gross negligence in handling, storage or distribution of meat and poultry products that cause contamination or rodent infestation, (2) adulterated product found in human food channels, (3) species misrepresentation, (4) misbranding that would likely bring substantial monetary gain, (5) violator(s) engaged in criminal conspiracy, scheme or evasion, (6) record of past violations by the firm or principle officer(s) suggesting the need for legal action, (7) sale of meat or poultry from animals slaughtered without inspections, (8) retail sale of meat or poultry in excess of the firm's dollar limitation,[2] and (9) violations involving HACCP failures."

"Significance 2 cases are those that indicate a definite violation of the meat and poultry inspection laws, but no serious threat to the consumer. These are violations where it is unlikely that the product would be harmful and there is no serious economic fraud. These cases are generally closed with a letter of warning. Examples might include (1) transactions involving either non-federally inspected or improperly labeled product, (2) small amount of product involved, and (3) improper handling of inedible product resulting in opportunity for diversion into human food channels."

"Significance 3 cases are minor impact cases involving no obvious threat to the consumer and only a minor or technical violation of meat and poultry inspection laws. In most cases, placing the firm in the PCP is sufficient for a first-time occurrence. Examples might include (1) reuse of meat or poultry containers bearing the official marks of inspection, when there seems to be no intent to misrepresent meat or poultry product as inspected and passed, (2) inedible meat and poultry product improperly labeled or inadequately denatured found in non-human food channels, and (3) incidents involving products not consumed by most Americans and not apt to be diverted into processed human food products."

[2] In order to remain exempt from Federal inspection, a retail stores' annual amount of meat and poultry product sales to non-household consumers must not exceed a dollar limit established by the FSIS administrator.

Detected violations of the meat and poultry inspection laws can result in detentions, seizures, letters of warning, letters of information, criminal or civil prosecutions, and injunctions. If evidence is found that, an individual or business has engaged in violations of the meat and poultry inspection laws, FSIS through the Office of the General Counsel (OGC) and/or OIG can refer the case to the appropriate U.S. attorney to pursue criminal or civil prosecution, seizures, and injunctions.

From January 1, 1998, through December 31, 1999, FSIS' quarterly compliance activity reports show that the agency detained over 37 million pounds of meat and poultry products from 1,748 incidents of noncompliance with meat and poultry inspection laws. FSIS' data shows that 27.5 million pounds (68 percent) of meat and poultry products were related to 731 incidents at 5 district offices. In addition, FSIS issued 4,693 letters of warnings, obtained 64 criminal actions, had 2 injunctions (currently 29 firms are under injunctions), and obtained 4 seizures for violations of the meat and poultry inspection laws.

FSIS also maintains the USDA meat and poultry hotline to which consumers may report their concerns regarding meat and poultry products. These concerns can involve the unwholesomeness of products, or the discovery of product tampering. FSIS' Office of Public Health and Science (OPHS), reviews consumer complaints regarding health and safety matters received through the USDA meat and poultry hotline and refers specific complaints to DEO for their review. Also, specific consumer complaints received through OIG's fraud hotline are referred to DEO. In addition, consumer complaints concerning meat and poultry products are received and reviewed by the district offices.

FSIS has a memorandum of agreement with OIG-Investigations. This agreement requires FSIS to refer cases meeting specific criteria to OIG-Investigations for their investigative determination.

OBJECTIVES

The objective of the audit was to determine whether FSIS' policies, procedures, and controls were adequate to provide an effective compliance review program overseeing non-federally inspected firms for the purpose of detecting and preventing food safety violations and ensuring industry compliance with the provisions of meat and poultry inspection laws and regulations.

SCOPE

The fieldwork was performed at DEO headquarters in Washington, D.C., at five judgmentally selected district offices (Alameda, California; Albany, New York; Atlanta, Georgia; Jackson, Mississippi; and Pickerington, Ohio) and at five judgmentally selected field offices, one in each of the five selected districts (Diamond Bar, California; Jamaica, New York; Fort Lauderdale, Florida; Knoxville, Tennessee; and Lexington, Kentucky). (See exhibit A.)

We selected the Alameda, Albany, and Atlanta district offices and the Diamond Bar, Jamaica, and Fort Lauderdale field offices based on the high level of compliance activities during fiscal year (FY) 1998. The Jackson and Pickerington district offices and Knoxville and Lexington field offices were selected based on the low level of compliance activities and possible staffing-level problems.

We also visited 90 firms (retailers, custom slaughter facilities, warehouses, distributors, etc.) that handle meat and poultry products in the 5 selected districts. Fifty-five of the 90 firms were in the PCP. These firms were selected because of prior violation(s), repeat violations, or the nature of their business. The remaining 35 firms were randomly selected and visited. (See exhibit B.)

The initial fieldwork began in July 1998. In March 1999, the scope of the audit was increased from three district offices to five district offices. Also, we increased our review and analysis of agency data from 2 months to about 2 years. The fieldwork was completed in December 1999, and covered compliance activities from October 1, 1997, through February 28, 1999. We extended our review period through September 30, 1999, to review enforcement actions pertaining to repeat violators of the meat and poultry inspection laws and processing timeframes for standard cases.

The audit was performed in accordance with generally accepted government auditing standards. The auditors examined, on a judgmental sample basis, evidence supporting FSIS' compliance activities. (See exhibit C.)

We assessed (1) the adequacy of action taken in conducting, documenting, and resolving standard and streamline cases, performing PCP and random reviews, and investigating consumer complaints and (2) the maintenance and reliability of recordkeeping systems for violation cases and consumer complaints.

- We judgmentally selected 111 of 656 standard and streamline cases for review at the 5 district offices visited. We primarily selected violations cases for firms that were repeat violators.

- We also selected 41 of 102 standard cases at DEO headquarters that were referred from district offices for further action. The 41 violation cases were closed or referred to OGC for possible prosecution actions as of February 28, 1999.

- For our analysis of processing timeframes for violation cases, we reviewed all 116 standard cases (35 closed and 81 open) at DEO headquarters that were referred from district offices for possible prosecution action as of September 30, 1999. We relied on violation case information obtained from DEO's headquarters database. However, a cursory review of this information disclosed instances of conflicting data or missing dates. We obtained missing data from the case files in those instances.

- We judgmentally selected 5 compliance officers from each district office visited (25 in total) and reviewed the 2,085 random reviews they conducted over a 6-month period. Selection was based on the number of random reviews conducted. At each district, we selected some compliance officers who conducted a high number of random reviews and some compliance officers who conducted a low number of reviews.

- We also judgmentally selected and reviewed the status of 57 firms that were on the PCP for the 5 district offices. Our selection process placed emphasis on firms with a history of prior violations or firms, which, based on the nature of their business operations, may lead to violations, such as custom slaughter facilities.

- We identified 858 consumer complaints received by the 5 district offices we visited. We did not identify the total number of consumer complaints because the five district offices lacked a system to document the initial receipt of complaints. We also assessed whether all 74 consumer complaints referred by OPHS to DEO were assigned to compliance officers and reviewed, as appropriate.

See exhibit C for FSIS' compliance activity from October 1, 1997, through February 28, 1998.

METHODOLOGY

To accomplish our audit objectives, we:

- Reviewed meat and poultry inspection laws, regulations, policies, and procedures;
- Analyzed the process and supporting documentation for violation case reviews, PCP, random reviews, and consumer complaints;
- Analyzed FSIS' tracking systems for violation cases and consumer complaints;
- Interviewed FSIS and OGC officials;
- Obtained and reviewed information regarding DEO's organizational structure, including training and experience of compliance staff;
- Joined compliance officers on their compliance reviews of non-federally inspected firms; and
- Observed and photographed potential violations committed by non-federally inspected firms while accompanying compliance officers on their compliance reviews.

FINDINGS AND RECOMMENDATIONS

CHAPTER 1	EFFECTIVENESS OF PLANNED COMPLIANCE REVIEWS AND RANDOM REVIEWS COULD BE ENHANCED

FSIS' compliance activities could be enhanced with refinements to the existing plan. DEO's compliance Investigative Protocols, which serve as the agency's plan for conducting compliance reviews and preparing violation cases, do not include all the key elements of an effective and systematic approach. Of the 14 types of firms FSIS has identified as subject to its compliance oversight (see exhibit D), FSIS has review steps for only 1—warehouses. Also, compliance officers:

- were not aware of the number of high-risk firms subject to review,
- did not adequately document compliance reviews and identify the scope of work performed,
- did not follow the same processes at each firm visited, did not document minor violations, and in many instances did not indicate they reviewed any processes at all,
- did not plan reviews taking into account the population or geographic size of the areas needing review or the risk posed by the types of operations in the areas, and
- did not have timeframes and procedures for monitoring violation cases.

We concluded that FSIS' plan should identify the number of high-risk firms within each district's jurisdiction, define the scope of compliance reviews (what areas to inspect, what record reviews to perform, etc.), and establish timeframes and procedures for violation cases. The plan should also emphasize the targeting of compliance resources to heavily populated areas, those areas that are geographically large, and those firms that historically have been shown to pose a high-risk to consumer health and safety.

FINDING NO. 1

DEO NEEDS TO IDENTIFY ALL HIGH RISK FIRMS AND BETTER DEFINE THE SCOPE OF ITS REVIEWS

FSIS has not identified all high risk firms within each FSIS district's jurisdiction that may be subject to a compliance review, or defined the scope of the review to be performed at each type of firm (what areas to inspect, record reviews to perform, etc.). No instructions require compliance officers to identify all firms or provide systematic review coverage of firms selected for review. Several DEO officials stated that more defined instructions would restrict their flexibility for conducting these reviews. However, under existing review plans, compliance officers risk letting some firms go uninspected while providing inadequate coverage of some firms visited.

FSIS conducts both planned compliance program (PCP) reviews, as well as random reviews of firms to detect and prevent violations of meat and poultry inspection laws. PCP reviews are planned reviews conducted of firms that previously violated meat and poultry inspection laws, or lend themselves to possible violations. Random reviews are generally carried out through unannounced visits to firms. A typical compliance review may include, but is not limited to, review coverage of areas such as product inventory, product handling, pest management, housekeeping, and record retention. FSIS has identified 14 types of firms that process or handle meat and poultry products for which it has compliance oversight responsibility. (See exhibit D.)

In reviewing the universe of firms subject to FSIS compliance reviews, we determined that districts were not aware of all firms within their jurisdictions. FSIS Directive 8100.1, Rev. 1, dated April 2, 1993, provides that the purpose of the PCP review is to obtain and maintain current data on handlers of meat and poultry products. However, compliance officers for the five districts reviewed were not aware of the number of high-risk firms in their districts that were subject to compliance reviews. Consequently, it is possible that not all high-risk firms are being reviewed. (Our review also determined that not all high-risk firms *known* to FSIS were being reviewed. See Finding No. 2).

State and local agencies (such as business licensing offices) could serve as reliable sources to obtain universe information regarding firms that handle meat and poultry products.

We reviewed 2,085 random reviews and 57 PCP reviews performed by compliance officers in 5 district offices, and we joined compliance officers on 55 PCP reviews and 35 random reviews of meat and poultry firms. For the compliance reviews already performed, supporting documentation was insufficient and did not identify the scope of the reviews. We also noted some inconsistencies in the coverage provided by the compliance officers we joined on the compliance reviews.

During our review, we found the following.

a. Review Steps Were Not Documented

FSIS has not implemented operating procedures to establish documentation requirements for random reviews. Compliance officers typically documented their random reviews by notating "NNC" on their daily activity reports, which signified "no noncompliance" if no violation was identified. If a violation was identified, the compliance officer documented a brief description of the violation(s). However, from this documentation, we were unable to determine the scope and methodology used to conduct the reviews. For example:

In the Pickerington, Ohio, district office, we found that compliance officers often documented only the name of the firm and a contact person to serve as the record of the random review if no deficiency was identified. One compliance officer we reviewed performed a total of 219 random reviews during the period of September 1, 1998, through February 28, 1999. The compliance officer documented only "NNC" and the name of the firm and the contact person for 181 of the 219 random reviews he conducted which had no deficiencies.

In the Albany, New York, field office, we reviewed 1,022 random reviews conducted by two compliance officers from September 1, 1998, through February 28, 1999. We were unable to identify the review steps performed by the two compliance officers, including meat and/or poultry inventory observations and record reviews. The compliance officers did not document whether assessments of controls relative to product storage and handling, pest management, and housekeeping were made. Without documentation of the reviews, there was no record that key components of the reviews were performed.

Of the 57 PCP's we reviewed, the majority of firms had at least one previous violation. Although the PCP reviews generally contained more documentation than the random reviews, the compliance officers seemed to focus only on the issue(s) relative to the previous violation(s) committed by the firms. Consequently, we could not determine the extent of the reviews, even when violations were identified.

DEO's compliance Investigative Protocols for random reviews need improvement by requiring compliance officers to perform specific review steps at firms. Although a detailed report may not be necessary when no violations are identified, the use of a checklist to document that sufficient review steps are performed, along with a compliance officer certification, would better assure that an adequate review was conducted.

b. Inconsistencies In Review Coverage

Scope of compliance reviews needs to be better defined. Compliance officers did not always review the same processes at similar firms, did not document streamline cases for minor violations and in many cases, did not indicate that they reviewed any processes at all. Although FSIS does have review steps for conducting compliance reviews of warehouses, it has not developed similar review steps for the other 13 types of firms subject to review.

We noted some inconsistencies in review coverage by several compliance officers we joined on the 55 PCP reviews and the 35 random reviews.

The following table summarizes the number of visits made in each of the five field offices visited.

Table 1: Number of Compliance Reviews Attended by OIG

District Office	Field Office	Number of PCP reviews	Number of Random Reviews
Alameda, CA	Diamond Bar, CA	11	6
Albany, NY	Jamaica, NY	14	5
Atlanta, GA	Fort Lauderdale, FL	10	7
Jackson, MS	Knoxville, TN	9	8
Pickerington, OH	Lexington, KY	11	9
		55	35

For example, during our visits to meat and poultry firms in the Fort Lauderdale, Florida, area, the compliance officer examined

(1) storage areas (e.g., coolers/freezers, shelves), (2) processing areas, and (3) records for meat and poultry products at each firm.

However, during our visits to two firms located in the Lexington, Kentucky, area, the compliance officer did not examine meat and poultry products stored in the coolers/freezers. Both firms were in the PCP due to previous violations for preparing and selling non-federally inspected meat products. During a subsequent visit to one of the firms, the compliance officer noted that the firm was preparing and selling a meat-based chili that had not been inspected. Because of these previous violations, we concluded that the compliance officer should have at least examined the products in the coolers/freezers. The two compliance officers had comparable years of experience.

Also, during our visits we found that compliance officers did not follow FSIS' policy to document streamline cases for minor violations of the meat and poultry inspection laws. For example, on June 30, 1999, we joined a compliance officer from the Diamond Bar, California, field office on a compliance review of a food distributor. The compliance officer found four packages of unlabeled meat products in a storage cooler. The products were stored with other meat products that were being offered for sale. The owner stated that the unlabeled products were not for sale and he intended to return them to the supplier. The owner then voluntarily destroyed the four packages of unlabeled meat products in our presence. However, the compliance officer did not document a streamline case for this violation. DEO's compliance Investigative Protocols stipulate that a streamline case (significance 2) should be documented for transactions involving either non-federally inspected or **improperly labeled** products. FSIS previously issued a LOW to this firm on March 11, 1999, for reuse of containers bearing the official marks of meat and poultry inspection, without removing or defacing the marks in question.

FSIS officials stated that the compliance officer handled this situation in accordance with its policy because the compliance officer did not find evidence that adulterated or misbranded product was prepared, transported, or offered for sale. However, we concluded that the compliance officer should have documented a streamline case because of this firm's history of violations and the fact that unlabeled product was stored among other products being offered for sale.

In addition, the compliance officer recommended that the firm remain in risk category 2. Risk category 2 criteria includes (1) violation(s) of the meat and poultry inspection laws by the firm within the past 12 months, (2) indications that the firm has placed unsound meat, meat food products, poultry, or poultry products into human food channels within the past 12 months, or (3) past operations of the firm demonstrate that they constitute a constant or intermittent risk in regard to 1 and 2 above.

We joined another compliance officer assigned to the same field office on a compliance review of a processor/retailer on June 29, 1999. The compliance officer observed 29 pounds of beef products that were dark in color and had evidence of slime. The meat products were located in a cooler/freezer along with other meat products that the firm was planning to process. The owner, in the presence of the compliance officer and OIG auditors, voluntarily denatured the products. However, the compliance officer did not document a streamline case for this violation. DEO's compliance Investigative Protocols stipulate that a streamline case (significance 2) should be documented for improper handling of inedible product resulting in opportunity for diversion into human food channels.

FSIS officials stated that the product was not in the retail display area and no evidence of preparation, transportation, or sale of the product was found. Also, FSIS officials stated that the product was properly controlled and the compliance officer notified the county health department that had primary jurisdiction over sanitation and product handling for this retail exempt firm. We concluded that a streamline case should have been documented for this violation because the firm could have processed the meat for its retail business if the compliance officer had not disclosed the violation. Also, the county health department was contacted regarding the poor sanitation problems, not the improper handling of the 29 pounds of inedible meat product.

In another example, we joined a compliance officer assigned to the Lexington field office on a PCP review of a meat and poultry distributor on June 24, 1999. At this firm, we observed the reuse of boxes (re-boxing broken bulk) bearing the official marks of inspection for shipment of meat and poultry products to retail stores. This was a violation of meat and poultry inspection laws. The compliance officer discussed the defacement of the empty boxes with the firm's management. However, the compliance officer recommended that the firm be placed on inactive PCP

status (this would cease reviews) even though an official of the firm admitted to the violation.

FSIS officials stated that the compliance officer handled this situation correctly and in accordance with its policy. However, two different compliance officers from the same district developed two streamline cases on two separate occasions against another firm for reusing shipping boxes that bore the official marks of inspection. FSIS officials also stated that the compliance officer did not observe used boxes bearing the inspection legend being used to pack un-inspected meat products.

According to 9 Code of Federal Regulations, Chapter III, Part 317.10, paragraph (a) states that no official inspection legend or other official mark which has been previously used shall be used again for the identification of any product, except as provided for in paragraph (b) of this section. Paragraph (b) states that all stencils, marks, labels, or other labeling on previously used containers, whether relating to any product or otherwise, shall be removed or obliterated before such containers are used for any product, unless such labeling correctly indicates the product to be packed therein and such containers are refilled under the supervision of a program employee. This regulation is applicable to inspected products.

According to DEO's compliance Investigative Protocols for significance 3 cases a streamline case should have been documented for the "reuse of meat or poultry containers bearing the official mark of inspection, when there seems to be no intent to misrepresent meat or poultry products as inspected and passed." In addition, an ADME from another district office advised us that it would be improper for a firm to reuse boxes without defacing the official marks of inspection even if the meat or poultry product was federally inspected. We concluded that this firm should have been cited for the violation.

We also found that several compliance officers made questionable determinations regarding what constitutes a random review. For example, we joined a Fort Lauderdale, Florida, based compliance officer on a compliance review of a laundry equipment business. The compliance officer counted this visit on his daily activity report as a random review. FSIS officials stated that the compliance officer was following up on a firm that had a history of non-compliance due to activity observed at the address. FSIS officials also stated that this type of visit is within their broad

definition of a random review. We concluded that this visit should not had been counted as a random review for the following reasons (1) the compliance officer did not perform a review, he only conversed with the owner and (2) the firm did not handle meat or poultry products (the compliance officer noted on his daily activity report that this location was **formerly** occupied by a firm that handled meat and poultry products).

Further, in May 1999, our review of a compliance officer's daily activity report from the Albany, New York, district revealed that he counted, as a random review, a visit to a retail firm (sandwich shop) even though the owner did not allow him to review the firm. FSIS officials advised that the compliance officer, who had been refused entry into the sandwich shop on September 4, 1998, took credit for the review in error.

A DEO official stated that DEO's compliance Investigative Protocols provide the necessary guidelines for the effective and consistent execution of prescribed enforcement activities. We found that DEO's compliance Investigative Protocols describe how to document internal FSIS forms upon conducting a compliance review, but they do not provide sufficient instruction for compliance officers to identify all high-risk firms in their jurisdictions or what storage and product areas to examine, which records to review, etc.

We concluded that FSIS should enhance its existing plan by improving its systematic approach to its compliance reviews. The plan should be enhanced to (1) define the universe (number) of high-risk firms subject to compliance reviews in each district and (2) standardize the scope of reviews to identify what should be reviewed, record reviews to perform, etc.

RECOMMENDATION NO. 1

Enhance FSIS' existing plan by improving the process to identify and review high-risk firms that handle meat and poultry products.

FSIS Response

FSIS agrees with the recommendation to enhance its existing plan by improving the process to identify and review high-risk firms. FSIS stated that it would proceed with these enhancements to its plan and prioritize its efforts consistent with available resources. A revised plan will be completed by October 2000.

OIG Position

We accept FSIS' management decision for this recommendation.

RECOMMENDATION NO. 2

Enhance and refine FSIS' existing plan by incorporating prescribed review steps for conducting compliance reviews for each of the 14 types of firms the agency oversees (FSIS has review steps for warehouses). The plan should also include a review checklist along with a compliance officer's certification statement that the appropriate review steps were performed.

FSIS Response

FSIS agrees with the recommendation to work towards standardizing the scope of compliance reviews while preserving adequate flexibility to allow compliance officers to utilize their professional judgment and technical expertise to act on issues that are unusual or unique. FSIS stated that it will develop better methods to standardize compliance reviews, such as enhancing its Investigative Protocols by including detail descriptions of critical areas to review for high-risk business types. FSIS also stated that it will establish a review policy to assure that personnel follows all critical procedures. FSIS further stated that this process will be completed by December 2002.

OIG Position

We agree with FSIS' proposed action. However, to reach management decision, FSIS needs to amend its December 2002 completion date to comply with Departmental Regulation (DR) 1720-1, which requires final action within 1 year of management decision.

FINDING NO. 2

DEO NEEDS TO BETTER TARGET ITS RESOURCES

DEO does not target its resources to provide appropriate coverage of major metropolitan and geographical areas and high-risk firms. No procedures require DEO to plan its reviews according to such a strategy, even though the recent restructuring of FSIS, which centralized many of its compliance officers away from locations that need greater coverage, requires targeting to ensure the appropriate reviews are performed. In the absence of targeted coverage, those areas and firms with a greater frequency of violations are receiving a lesser frequency of reviews. In the State of

New York, for example, violations were found during only 2 percent of the 1,167 random reviews performed upstate, while in New York City itself, violations were found during 25 percent of the 89 random reviews performed there.

Once DEO establishes an accurate universe of high-risk firms (see Finding No. 1), it should emphasize that districts need to target their resources to ensure coverage is provided proportionately throughout major metropolitan and geographical areas, and that reviews of areas and firms are commensurate with the risks they have historically posed to consumers' health and safety.

FSIS officials stated that it needs additional funding and resources to fill critical vacancies in major metropolitan and geographical areas. FSIS officials advised that its employment ceiling for compliance officers is 179. However, based on a DEO assessment, they need 245 compliance officers to fulfill their compliance function. FSIS officials also stated that it should continue to enhance its assessment of allocating and adjusting available staffing resources in response to changing levels of activity.

FSIS officials estimate there are 1 million firms that handle meat and poultry products. In addition, FSIS officials advised that with the implementation of HACCP, the role of the compliance officer has expanded; specifically, to assist in-plant inspectors in documenting HACCP failures and to ensure appropriate due process when enforcement actions are needed. FSIS officials also advised that compliance officers are used to investigate foodborne illness outbreaks and to monitor judicial decrees and orders.

a. FSIS' Compliance Review Coverage May Not Be Sufficient In Certain Major Metropolitan and Geographical Areas

FSIS needs to assess its review coverage in certain major metropolitan and geographical areas. In 1997, FSIS reorganized from 5 area offices to 18 district offices (there are currently 17 district offices) nationwide. (See exhibit A.) FSIS officials stated that the agency is now more geographically flexible with the establishment of the district office structure. However, we found that FSIS needs to assess its coverage in certain major geographical areas.

For instance, the Pickerington, Ohio, district had seven compliance officers and compliance oversight responsibility over the States of Ohio, Kentucky, and West Virginia. However, the

Pickerington district had compliance officers based in Ohio and Kentucky, but not in West Virginia. As a result, West Virginia received the least compliance review coverage. Compliance officers performed 587 random reviews between September 1, 1998, and February 28, 1999, of which 486 reviews were in Ohio and 87 reviews were in Kentucky. However, only 14 random reviews were performed in West Virginia within this same 6-month period. Ten of the 14 random reviews occurred over a 2-day span, September 29 and 30, 1998.

We also found that only nine firms in West Virginia were undergoing PCP reviews. (Ohio had 134 firms and Kentucky had 36 undergoing PCP reviews.) During 1998, West Virginia had a reported foodborne illness at an elementary school. The ADME acknowledged that there was a need for better compliance coverage in West Virginia. He stated that compliance officers go there only for mission-critical purposes.

Also, a compliance officer from the Pickerington, Ohio, field office stated that it takes 6 hours to commute one way to some parts of West Virginia. The 6-hour commute may be significant because it could require overnight lodging. ADME's from the five district offices all expressed concerns regarding the availability of travel funds for compliance activities.

Likewise, the Jackson, Mississippi, district, which had six compliance officers and compliance oversight responsibility over the States of Mississippi, Tennessee, and Alabama, provided minimal compliance coverage in the Memphis, Tennessee, area (the heaviest populated city in the district). The nearest compliance officer to Memphis was located approximately 3 hours away in Nashville, Tennessee. There were no random reviews performed in Memphis between September 1, 1998, and February 28, 1999. The area compliance case report showed only one violation case in Memphis. The violation case had a case date of April 1997, which was prior to the reorganization from the area offices to district offices. Also, at the time of our review, there was only one compliance officer responsible for covering the entire State of Mississippi. Only two compliance officers were responsible for the entire State of Alabama. The three compliance officers combined conducted only 35 random reviews between September 1, 1998, and February 28, 1999.

The Atlanta, Georgia, district had 17 compliance officers and compliance oversight responsibility over the States of Georgia

and Florida, the Commonwealth of Puerto Rico, and the Virgin Islands. We found that the three compliance officers were primarily responsible for reviewing north and central Georgia, including metropolitan Atlanta, performed only three random reviews between September 1, 1998, and February 28, 1999. Forty-two violation cases were identified in Georgia between October 1, 1997, and September 30, 1999. Twenty-two of those (52 percent), occurred in metropolitan Atlanta.

In addition, we found that the two compliance officers in the Tallahassee, Florida, field office, who are responsible for northern Florida and South Georgia, performed only two random reviews in South Georgia between September 1, 1998, and February 28, 1999. Also, the two compliance officers did not perform any random reviews in Valdosta, Georgia; Panama City, Florida; and Pensacola, Florida during the same period.

b. Review Coverage Needs To Be Targeted At High-Risk Areas

We found that FSIS' overall plan or strategy to target high-risk areas needs improvement. For example, the New York City area has a high concentration of custom exempt slaughtering facilities.

Historic data shows that for the Albany, New York, district, the majority of the standard and streamline cases were disclosed in the New York City metropolitan area. In comparison, the Albany, New York, area had far fewer violations. However, compliance officers assigned to the Albany, New York, field office performed 1,260 random reviews between September 1, 1998, and February 28, 1999, while compliance officers assigned to the New York City metropolitan area (Jamaica, New York and Bogota, New Jersey) performed only 162 random reviews.

In addition, our analyses of compliance reviews conducted by five compliance officers assigned to the Albany, New York, district showed that three of the five compliance officers from the Albany, New York, field office performed 1,167 random reviews and identified violations at 20 firms (2-percent). In contrast, two compliance officers from the Jamaica, New York, field office performed 89 random reviews and identified violations at 22 firms (25-percent). This data indicates that FSIS may have a greater need for compliance activity in the New York City metropolitan areas as opposed to the Albany, New York, area where violations appear to be less prevalent.

c. Review Coverage Also Needs To Be Targeted To High-Risk Firms

We found that FSIS may need to target their compliance reviews at high-risk firms. We found that transporters, warehouses, and processors could be considered as high-risk firms. We characterize a high-risk firm[3] as one that (1) handles large volumes of meat and poultry products that may be one or two distribution levels from the household consumer and/or (2) exposes large groups of consumers to meat and poultry products when the consumers may have factors (age, health, limited options, etc.) that make them more susceptible to foodborne illness and/or injury.

We reviewed 2,085 random reviews in the 5 district offices conducted by 25 compliance officers between September 1, 1998, and February 28, 1999. Fewer random reviews were performed at transporters, warehouses, and processors. We concluded that FSIS should assess the need for increased coverage of these types of firms. The following table provides the number of reviews performed at these types of firms.

Table 2: FSIS' Least Reviewed Firms

DISTRICT OFFICE	NUMBER OF COMPLIANCE REVIEWS	PROCESSORS	TRANSPORTERS	WAREHOUSES
Alameda	188	15	3	5
Albany	1,256	12	34	10
Atlanta	76	2	0	3
Jackson	156	6	0	3
Pickerington	409	8	1	3
TOTAL	2,085	43	38	24

We also found that firms such as schools, senior citizen and childcare centers and homes, hospitals, correctional institutions, and military bases may be considered as high-risk because of the nature of their operations. These firms serve meat and poultry products to large numbers of people on a daily basis. We found that only a few of these types of firms were in the PCP. The table on the following page shows the number of these types of firms that had active status in the PCP at the time of our fieldwork.

[3] Our definition for high-risk firms was solely based on our observations during the audit.

Table 3: FSIS' Least Reviewed Firms that Serve Food Directly to Consumers

DISTRICT	UNIVERSE OF PCP FIRMS [1/]	SCHOOLS	CHILD/ADULT CARE CENTERS/ HOMES	HOSPITALS	CORRECTIONAL INSTITUTIONS	MILITARY BASES
Alameda	496	2	0	3	1	1
Albany	1,072	3	9	10	12	5
Atlanta	510	2	0	1	7	10
Jackson	231	1	0	4	3	5
Pickerington	179	0	0	3	3	0
Total	**2,488**	**8**	**9**	**21**	**26**	**21**

[1/] This information was obtained during the audit fieldwork for the respective district offices between March 1999, and August 1999.

A review of violation cases and consumer complaints disclosed that adulterated products had reached firms such as schools, senior citizen and childcare centers and homes, correctional institutions, and military bases. For example, a firm prepared and sold more than 2 million pounds of adulterated and/or unwholesome products that reached 34 states, including schools located in Mississippi and West Virginia. The products caused injury/illness to some consumers, and as a result, were recalled. Another firm prepared and sold adulterated, off-condition (putrid), and/or noncompliance products to a school district in Florida, a correctional institution in Texas, and a military base in Puerto Rico. More of these types of firms should be on the PCP because of the large number of people they serve meat and poultry products on a daily basis, along with the age factors and health concerns of the elderly and children.

We concluded that FSIS needs to emphasize the targeting of reviews to large metropolitan and geographical areas and firms that pose a high-risk to consumer health and safety. We are recommending that FSIS enhance their existing plan to emphasize these risks.

RECOMMENDATION NO. 3

Enhance FSIS' existing plan to emphasize the targeting of resources to large metropolitan and geographical areas and to high-risk firms with a history of violations.

FSIS Response

FSIS agrees that there is a need to improve systems for allocating resources more effectively. FSIS stated that its improved system will include factors such as geographical size, administrative workload, level of State and local cooperation, population density, case documentation, and complexity/density of federally-inspected establishments. FSIS stated that successful implementation of this

system will assure that the most critical locations are adequately staffed. FSIS expects to complete this activity by December 2002.

OIG Position

We agree with FSIS' proposed action. However, to reach management decision, FSIS needs to amend its December 2002 completion date to comply with DR 1720-1, which requires final action within 1 year of management decision.

FINDING NO. 3

DEO NEEDS TO ESTABLISH TIMEFRAMES FOR PROCESSING CASE REVIEWS

DEO's compliance Investigative Protocols does not have timeframes and procedures for monitoring and tracking the progress and completion of violation cases at its headquarters, district, and field office levels. FSIS officials stated that prescribed timeframes could interfere with the quality of the processing; consequently, it left timeliness of processing to the discretion of each level involved. We found that FSIS could enhance its existing plan with procedures for monitoring and tracking the timeframes for processing violation cases. In the absence of established timeframes, cases may encounter lengthy delays. In one 2-year-old case in which putrid meat was delivered to a child care center, a letter of warning to the meal caterer was drafted and forwarded to headquarters for review, but as of the date of our audit, it has not been issued.

Each district office maintained a database for standard and streamline cases. The district offices forwarded these cases to DEO headquarters when their involvement was warranted (review of prosecution case, etc.). Headquarters maintains a database for cases forwarded to them by the district offices.

Between October 1, 1997, and September 30, 1999, DEO headquarters' "Evaluation and Enforcement Division Case Tracking System" showed 116 violation cases that were forwarded to them by the district offices for possible prosecution or other enforcement actions. DEO headquarters took the following enforcement actions on these cases (1) referrals for prosecution, (2) letters of warnings or similar letters, and (3) referral to the States for sanctions. For several cases, no action was taken.

Of the 116 prosecution cases forwarded to DEO headquarters, 35 were closed and 81 were still open as of September 30, 1999. To

process the 35 closed cases, headquarters and the district offices took an average of 249 days. The cases were closed with either a letter of warning or similar letter issued to the firm, referral to the appropriate State for administrative action, or no action at all. These cases remained in the districts an average of 121 days before being submitted to DEO headquarters, which took an average of an additional 127 days to complete the case reviews and take enforcement actions. (See exhibit E.)

The remaining 81 cases that were still open, had been open an average of 395 days through September 30, 1999. These cases were in various stages of being reviewed by DEO headquarters staff. The cases had been in the districts an average of 182 days before being submitted to DEO headquarters, where they averaged 213 days in open status. (See exhibit F.)

FSIS officials stated that it would be inappropriate to prescribe timeframes for each phase since quality and completeness are dependent on adequate time. We found that the number of days these cases have remained open indicate that FSIS' existing plan could be enhanced if they set goals and track the time it takes to process the cases. We identified two serious instances where inadequate monitoring resulted in lengthy delays in completing the cases.

- On February 10,1998, the executive director of a childcare center in West Palm Beach, Florida, made a consumer complaint (referred to DEO through a USDA official from Washington, D.C.) that meals were received from a catering company to serve about 71 children contained "off condition" (putrid) meat products. This catering company also had contracts to provide meals to four senior citizen centers. The same day the childcare center received the putrid meals, 50 individuals became ill after consuming meals provided by the same caterer at the 4 senior citizen centers.

  FSIS initiated a case review on February 13, 1998. A compliance officer observed putrid meat products received from the same catering company on a subsequent visit to the childcare center. Additionally, the Florida Department of Health was notified and reported that laboratory results were inconclusive and did not explain the outbreak, but it did say that the outbreak was consistent with Bacillus cereus food poisoning. In June 1998, the Atlanta, Georgia, district office drafted a letter of warning addressed to the firm. However, the letter was never issued.

According to FSIS officials, since the letter addresses alleged violations that pertain to a catering company which could qualify for an exemption e.g., as a retail store or restaurant under the FMIA, PPIA, and applicable regulations, it was sent to DEO for review. As of January 11, 2000, almost 2 years later, no action has been taken regarding this case.

The lack of action is especially serious because the owners of the catering company also owned a federally inspected plant, an in-house catering facility, and five other satellite catering facilities. These satellite catering facilities had also contracted with the Florida Department of Health, Child Care Food Service Program, Meals on Wheels, and other government-sponsored feeding programs to provide meals. An official from the catering company commented that they feed over 5,000 people per day at 40 centers.

FSIS officials advised that their investigation did not document a health or safety violation of USDA statues and the pathogen in question is not likely to be related to a FSIS source. Further, FSIS officials stated that their concern for the health and safety of consumers was brought to the attention of the catering company during the investigation and by telephone conversations with the Atlanta, Georgia, district office. In addition, FSIS stated that the Florida Department of Health's April 16, 1998, report pertaining to the illnesses of the 50 individuals was provided to the catering company. Further, FSIS officials stated that their report did not support any enforcement action.

- In another instance, a school district was the source of a complaint, referred to FSIS that reported a federally inspected plant delivered them "beef patties" that had a "strong, rancid odor, along with shrinkage, moisture, and fat." The beef patties, approximately 31,000 pounds, were supposed to be of a single ingredient product, but were also found to contain other undeclared ingredients, such as chicken and soy. The product was returned to the plant between September and December 1997. The plant extended credit memos to the school district as resolution for the incident.

  Approximately one year later, in November 1998, this same plant prepared, sold, and transported to the U.S. Department of Justice 700 pounds of beef cubed steaks that were soured. We were told by the compliance officer that the 700 pounds of products were destroyed under his supervision. Less than 5 months later,

(in March 1999, under a U.S. Department of Defense contract) the plant filled a top sirloin butt steak order with beef round knuckle steak. A USDA Agricultural Marketing Service official reported that the beef knuckle steak commanded a significantly lower price in the market. As of January 11, 2000, FSIS was still processing this case. FSIS officials stated that the actions taken to date are monitoring product disposition and investigations as to why the product emitted a strong, rancid and sour odor or was misbranded.

We concluded that FSIS needs to establish procedures to monitor and track the timeframes for processing and completion of violation cases.

RECOMMENDATION NO. 4

Define effective and meaningful timeframe guidelines for monitoring and tracking the progress and completion of violation cases. Establish procedures for tracking those timeframes such as investigative time, documentation time, supervisory review time, headquarters review time, etc.

FSIS Response

FSIS agrees that much benefit would be derived from monitoring and tracking process timeliness associated with the investigation and review of violation cases. FSIS is reviewing a database system to track the process timeliness of violation cases from predication to referral to the U.S. attorney. FSIS stated that its new system will be fully operational prior to FY 2001.

OIG Position

We accept FSIS' management decision for this recommendation.

CHAPTER 2	FSIS DID NOT HAVE AN EFFECTIVE SYSTEM TO MONITOR CONSUMER COMPLAINTS

FINDING NO. 4

FSIS did not have an effective system to monitor consumer complaints. FSIS is responsible for reviewing consumer complaints received through the USDA meat and poultry hotline, the OIG fraud hotline, and directly to its headquarters, district, and field offices. However, DEO's compliance Investigative Protocols for consumer complaints do not prescribe a method for monitoring. As a result, FSIS could not provide reliable information concerning the number, status, and disposition of all consumer complaints received by its offices. After an extensive record review, we identified 858 consumer complaints for the five district offices we visited. FSIS has no assurance that all consumer complaints were reviewed and appropriately resolved. Also, the 5 district offices visited had no record of receipt or followup action on 16 consumer complaints (22 percent of the 74 complaints) referred to them by OPHS that was received through the USDA meat and poultry hotline.

Consumer complaints may involve the discovery of unwholesome meat and poultry products, or they may disclose incidents of product tampering. DEO's compliance Investigative Protocols provide guidance on where to forward specific types of consumer complaints for followup and completion of supporting documents, but they do not address monitoring by headquarters, district, or field offices. Further, these offices were not required to maintain a log or other record of consumer complaints received. Also, the district and field offices were not required to keep DEO headquarters or some designated centralized location informed of all consumer complaints received and the results of reviews conducted.

Consumers may report their concerns regarding meat and poultry products in several ways (1) over the USDA meat and poultry hotline, (2) over the OIG fraud hotline, or (3) directly to DEO headquarters, districts, or field offices. Agencies such as the Food and Drug Administration and local health departments also are sources for reporting complaints that are forwarded to FSIS.

For consumer complaints received through the USDA meat and poultry hotline, OPHS is responsible for forwarding certain complaints to DEO for review. Consumer complaints received through the USDA meat and poultry hotline involving foreign objects

should be referred to DEO. Consumer complaints involving product tampering should be referred to OIG for review. Consumer complaints made directly to the OIG fraud hotline are reviewed by OIG-Investigations and either investigated (e.g., product tampering) or referred to FSIS for handling. District and field offices also initiate reviews of those consumer complaints made directly to them.

DEO did not have an effective system in place to monitor consumer complaints received by district and field offices. With the exception of those consumer complaints referred to DEO by OPHS that came through the USDA meat and poultry hotline and those complaints referred by OIG received through the fraud hotline[4], DEO could not readily identify all consumer complaints received. A DEO headquarters official informed us that consumer complaints received directly by his office are referred to the applicable district or field office for handling. However, headquarters did not maintain a system to record the initial receipt of consumer complaints and thus did not have the means to monitor all consumer complaints

We encountered similar problems at the district and field offices visited. The district offices forwarded consumer complaints received to the applicable field offices for followup without documenting receipt of the complaint. None of the five district offices reviewed had a system to document the **initial receipt** of a consumer complaint or to track complaints once received. Although the Albany, New York; Jackson, Mississippi; and Pickerington, Ohio, district offices each maintained a log of consumer complaints received, their logs were not kept up to date. Consumer complaints were routinely documented after followup action by the field offices had been completed and submitted to the district. Also, entries for data fields on the logs--such as the date received, status, and disposition--were missing.

In order to determine the number of consumer complaints received by the five district offices for the purpose of constructing a universe, we either relied on numbers provided by the offices, including the logs, or conducted a search of district offices' files to locate and identify each case record (i.e., consumer complaint information sheet). According to the DEO's compliance Investigative Protocols, the consumer complaint information sheet is completed following a visit to the consumer to discuss the complaint and to examine the product involved.

[4] FSIS' OPHS provided us with a listing of USDA meat and poultry hotline complaints. OIG fraud hotline complaints were provided by OIG–Investigations.

The following table shows the number of consumer complaints that we identified as received by the five district offices during our audit period (October 1997-February 1999).

Table 4: Number of Consumer Complaints for the Five District Offices Visited

DISTRICT OFFICE	NO. OF CONSUMER COMPLAINTS
Alameda	204
Albany	143
Atlanta	236
Jackson	132
Pickerington	143
Total	**858**

We found that these numbers were not reliable because, although in many cases, they support complaints where there was a record of followup action, they do not support the **initial receipt** of all complaints, including instances where no followup action took place.

Likewise, the five field offices reviewed did not have a formal system to document the initial receipt of a consumer complaint or a tracking mechanism. Compliance officers from the five field offices informed us that they were responsible for initiating followup on consumer complaints received directly by them, including those from DEO headquarters, but that they were not required to document receipt of the complaints or report the results of the followup action to the district offices for all complaints (e.g., unfounded complaint).

DEO headquarters officials stated they did not need a tracking system because they assumed the field offices were tracking consumer complaints. The officials stated that they had been relying on "on-the-job training" instead of written guidelines or procedures to ensure that consumer complaints were properly received and reviewed. However, they conceded that written procedures might be appropriate to ensure the integrity of the resolution of consumer complaints. They noted that the reorganization contributed to procedures not being developed.

In addition, we noted that OPHS referred 74 consumer complaints to DEO that were received through the USDA meat and poultry hotline from October 1, 1997, through February 28, 1999, for the 5 selected district offices. Our review disclosed that 4 of the 5 district offices had no record of receipt for 16 of the 74 (22 percent) consumer complaints, as shown on the table on the next page.

Table 5: Number of Consumer Complaints with No Record of Receipt

DISTRICT OFFICE	NO. OF CONSUMER COMPLAINTS REFERRED BY OPHS	NO RECORD OF RECEIPT
Alameda	18	3
Albany	11	2
Atlanta	13	5
Jackson	9	0
Pickerington	23	6
TOTAL	**74**	**16**

Consumer complaints were not followed up on because DEO did not have an effective system to document and monitor consumer complaints received by its offices. OPHS officials stated that once a complaint (foreign objects) is referred to DEO, all responsibility for the complaint is assumed by DEO. There was no further involvement by OPHS to ensure that DEO received, reviewed, and appropriately resolved the complaints.

Without a tracking system to monitor consumer complaints, FSIS is not able to readily provide the number or status of consumer complaints or ensure consumer complaints are investigated and, when warranted, conditions corrected.

FSIS is currently piloting a consumer complaint database in its Philadelphia, Pennsylvania, district office. FSIS officials stated that the database will monitor receipt and follow up action on all consumer complaints received at both the headquarters and district levels. FSIS is also developing written procedures and guidelines for the consumer complaint system prior to its September 1, 2000, expected nationwide implementation date.

RECOMMENDATION NO. 5

Develop a system, including written procedures, to monitor receipt and followup action on all consumer complaints received at DEO headquarters, district, and field office levels.

Agency Response

FSIS agrees with this recommendation that an improved system should be developed to monitor receipt and followup action on all consumer complaints. FSIS also agrees that written procedures are needed to monitor the receipt of, and followup action on consumer complaints. FSIS stated that it plans to centralize this function under one unit that will monitor receipt and disposition of consumer complaints. Until then, FSIS stated that it is implementing an interim

monitoring system for the receipt and follow up of consumer complaints from district field staff or those referred to DEO headquarters. FSIS further stated that it intends to have the newly reconstituted and reorganized system implemented by March 2001.

OIG Position

We accept FSIS' management decision for this recommendation.

RECOMMENDATION NO. 6

Review the 16 consumer complaints previously omitted from review, and perform followup action to satisfactorily resolve them.

Agency Response

FSIS agrees with this recommendation and is in the process of reviewing the 16 consumer complaints to determine if they have been resolved and perform any followup action, if needed. FSIS stated that it will complete the review and followup by October 2000.

OIG Position

We accept FSIS' management decision for this recommendation.

CHAPTER 3	FSIS' ENFORCEMENT ACTIONS TO DETER REPEAT VIOLATORS OF MEAT AND POULTRY INSPECTION LAWS COULD BE IMPROVED BY USE OF CIVIL PENALTIES

FINDING NO. 5

FSIS' enforcement actions taken against 197 (11 percent) of 1,873 firms were not effective to deter them from committing additional violations of meat and poultry inspection laws. Within 24 months of the initial violation, several firms were cited again by FSIS for as many as 4 additional violations of meat and poultry inspection laws. In each instance, where final enforcement action had been taken, FSIS issued a letter of warning or similar letter for the violation. We found that FSIS does not have sufficient enforcement actions available to it to deter these firms from committing additional violations. Specifically, FSIS could make effective use of civil penalties for repeat violations that do not lend themselves to criminal prosecution.

FSIS can issue letters of warning to firms for both streamline and standard cases for violations of the meat and poultry inspection laws. The letters of warning typically advise firms of their expectancy to "voluntarily compliance" with the meat and poultry inspection laws. These letters also inform firms that FSIS could seek legal actions for continuous violations. From January 1, 1998, through September 30, 1999, FSIS issued 4,131 letters of warning to violators.

A DEO headquarters official stated that a letter of warning may be sent to a firm for a first-time violation of meat and poultry inspection laws if there were no public health risks involved (streamline case). However, recommendations for prosecution can be made for first time or repeat violations depending on the nature of the offense, severity of the violation and the extent to which the evidence supports intent or gross negligence. The official also stated that in some cases, multiple letters of warning may be sent if the cases involve different offenses, if violations are over a period of time, or chronic noncompliance that typically would not rise to the level of criminal prosecution. In these cases, FSIS may develop adequate documentation to seek a Federal injunction, exercise some limited administrative authorities, or refer the matter to State or local health authorities. In addition, FSIS has supported statutory change to authorize civil penalties for cases that do not rise to the level of warranting criminal prosecution.

The area compliance case records (listing of violation cases) for the 5 districts reviewed, showed that FSIS cited 1,873 firms for violating meat and poultry inspection laws between October 1, 1997, and September 30, 1999. Our review disclosed that 197 (11 percent) of these firms had a second violation case during this same period. Thirty-nine of these firms, primarily in the Albany, New York, district (mostly in the New York City area), had from 3 to 5 violation cases during the 2-year period. The number of firms with violations is shown in the table below (Note: more than one firm can be included in the same violation case.)

Table 6: Violations from October 1, 1997, through September 30, 1999, for Five District Offices

DISTRICT	NUMBER OF VIOLATION CASES	NUMBER OF FIRMS WITH VIOLATION CASES	NUMBER OF FIRMS WITH TWO OR MORE VIOLATION CASES	PERCENT
Alameda	330	434	39	9%
Albany	747	854	110	13%
Atlanta	302	412	31	8%
Jackson	94	93	10	11%
Pickerington	78	80	7	9%
Totals	**1,551**	**1,873**	**197**	**11%**

One Atlantic City, New Jersey, firm (the Albany, New York, district) was cited by FSIS in five separate violation cases between October 9, 1997, and September 9, 1999. The firm's violations involved the offering for sale and the sale of misbranded meat and poultry products in four of the five instances. The fifth instance pertained to the sale of non-federally inspected meat products. FSIS issued a letter of warning to the firm as final enforcement action for each of the violation cases.

Also, in the Albany district, we identified one other firm that had 5 violation cases and 6 firms that had 4 violation cases against them within the 24 months. The violations committed included (1) intimidation and assault against FSIS' compliance officers, (2) sale of non-federally inspected products, (3) failure to identify custom slaughter product as "Not for Sale," (4) failure to maintain custom exempt records, (5) offering for sale misbranded meat and poultry products, and (6) failure to maintain and operate facility in a sanitary manner. FSIS issued a letter of warning as final enforcement action for each of these violation cases.

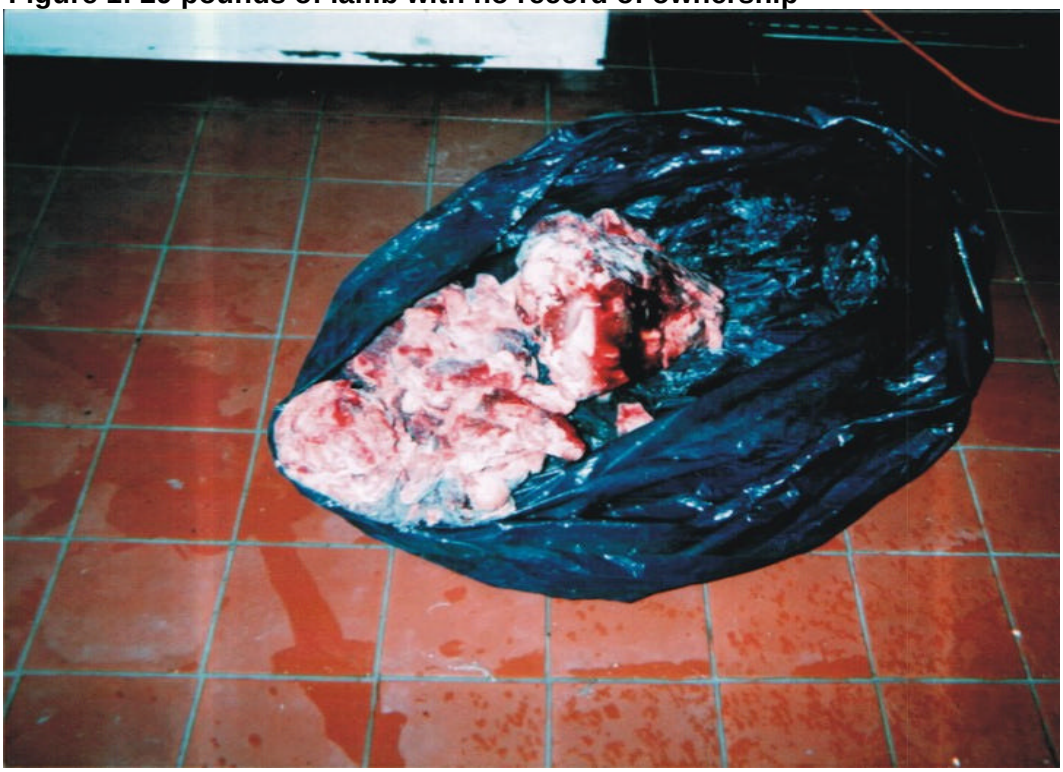
During our fieldwork, we joined compliance officers in visiting 55 firms that were cited by FSIS for previous violations of the meat and poultry inspection laws during FY's 1998 and 1999. Nine of

these firms had two or more violation cases within this timeframe. During our visits, additional violations were disclosed at 2 of the 9 (22 percent). In total, 8 of the 55 firms we visited had additional violations (14.5 percent). (See exhibit G.) The two firms that were cited for their fourth or fifth violation during our audit period (Business No. 1 and Business No. 2) were custom slaughter facilities located in Jamaica, New York.

During our May 20, 1999, visit to Business No. 1, we observed unidentifiable products and insanitary conditions as follows.

There were no supporting records for the ownership of 29 pounds of lamb.

Figure 1: 29 pounds of lamb with no record of ownership



Blood, meat scraps, and other debris were on the processing table, band saws, and floors from the previous day.

Figure 2: Processing table covered with debris

Figure 3: Band saw with debris

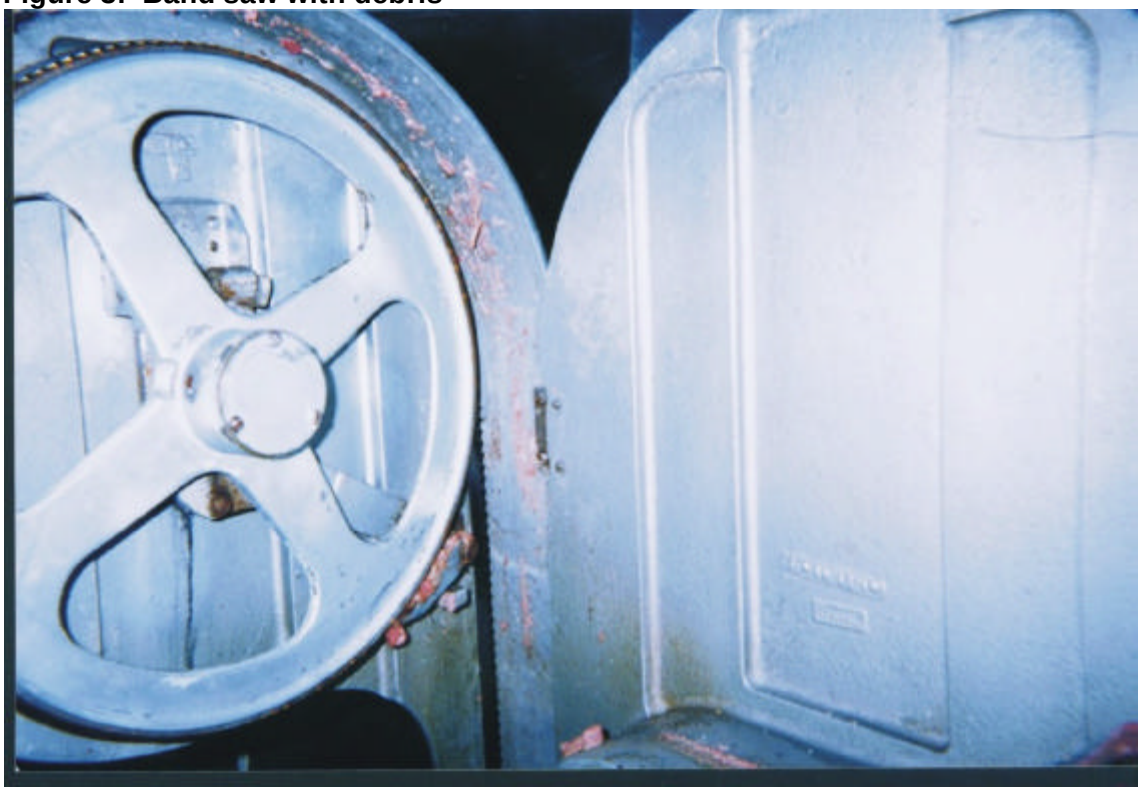


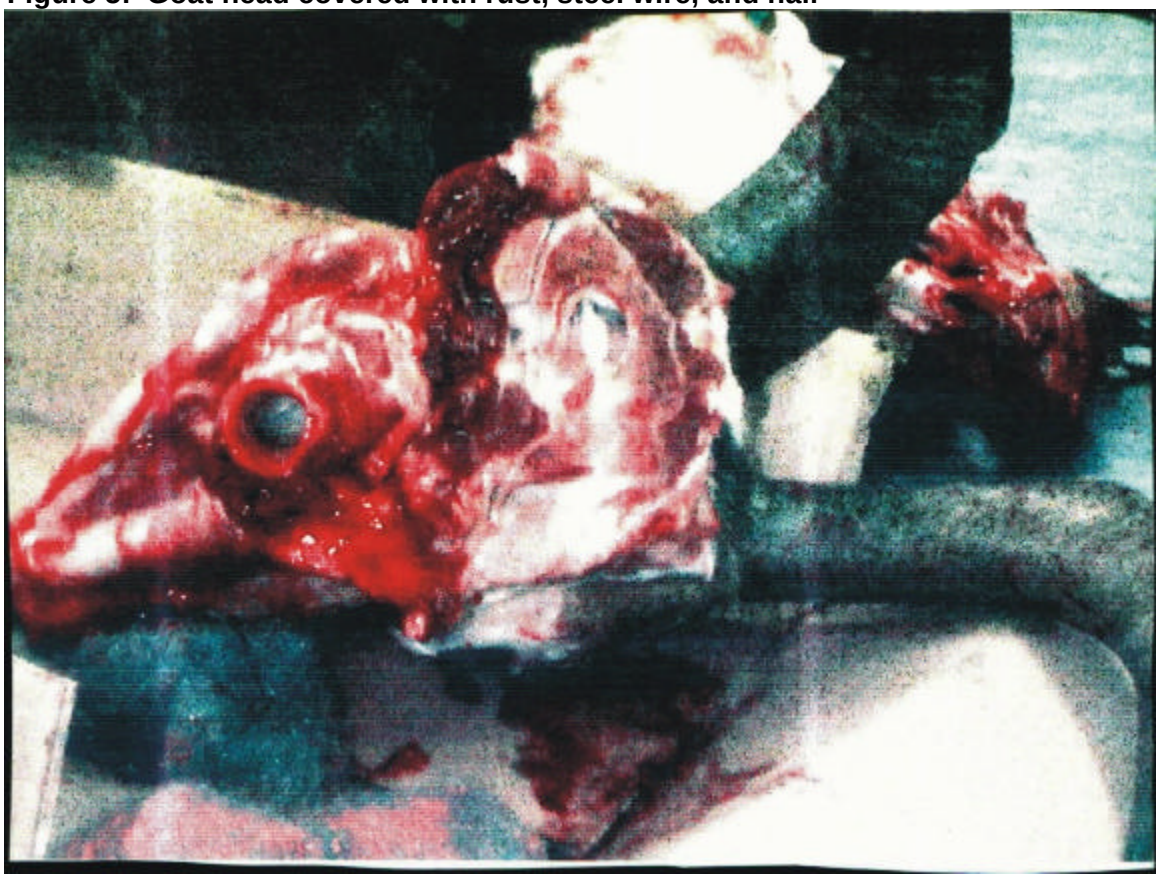
Figure 4: Floor showing dirt and cuttings

Also, unlabeled meats were found at the firm. Business No. 1 had four violation cases between November 10, 1997, and July 13, 1999. The firm received another letter of warning from FSIS for these violations. FSIS acknowledged that this firm was a repeat violator but believes that the violations disclosed were not something they would refer for criminal prosecution. FSIS noted that additional reviews conducted during our audit period do not reveal any irregularities at this firm.

During our May 21, 1999, visit to Business No. 2, we observed insanitary conditions and adulterated products on hand as follows.

A goat head lay in a cardboard box on top of a rusty steel wool pad. The goat head was adulterated with rust, rusty steel wire, and hair. It also had been sold to a customer.

Figure 5: Goat head covered with rust, steel wire, and hair



Goat intestines were placed in a bowl that sat on the floor of the kill room. The floor had blood and other debris on it.

Figure 6: Goat Intestines exposed to debris on the kill room floor

We also observed rodent droppings on (1) a rusty band saw, (2) plastic bags used for packaging meats for customers, and (3) floors of the kill and processing rooms.

The firm's history included six violation cases from August 1995 to May 21, 1999. Two of the violation cases, dated November 24, 1997, and January 25, 1999, were still open, even though the firm twice violated a November 27, 1996, stipulation and consent agreement that allowed the firm to operate despite the previous violations committed. Business No. 2 was issued another letter of warning for the violations disclosed during the May 21, 1999, visit.

FSIS officials stated that it would not recommend criminal prosecution based on the adulteration of one 5-pound goat heat. FSIS officials also informed us that on February 7, 2000, they issued the firm a Notice of Summary Termination of Custom Eligibility and on or about February 9, 2000, the custom exempt operations at this

firm were terminated. However, a subsequent compliance review at this firm on March 15, 2000, found that the firm had continued its custom slaughter operations. The compliance officer observed and detained a whole dress lamb (90 pounds) in the firm processing room. The animal had apparently been slaughtered. In a signed statement on March 16, 2000, the owner claimed that he did not believe the Notice of Summary Termination of Custom Eligibility dated February 7, 2000, still applied. The owner stated that he discarded the detained lamb and thus violated the detention. The owner further denied slaughtering any other animals and could not account for three lambs and one goat that were missing. FSIS is currently processing a violation case.

The two cases we illustrated above serve as good examples for why we support FSIS in their efforts to obtain authority to fine firms for violations of meat and poultry inspection laws, that do not warrant criminal prosecution. The following represents the firms visited and the number of violations observed during the audit. (See Exhibit G.)

Table 7: Number of Firms Visited and Number of Violations Observed

FIELD OFFICE LOCATION	FIRMS VISITED	FIRMS VISITED WITH TWO OR MORE VIOLATIONS	VIOLATION CASES ESTABLISHED AS RESULT OF VISITS	FIRMS VISITED WITH ONE VIOLATION	VIOLATION CASES ESTABLISHED AS RESULT OF VISITS
Diamond Bar, CA	11[1]/	2	0	8	4
Jamaica, NY	14[2]/	4	2	6	2
Fort Lauderdale, FL	10	2	0	8	0
Knoxville, TN	9	1	0	8	0
Lexington, KY	11	0	0	11	0
Totals	**55**	**9**	**2**	**41**	**6**

[1]/ One firm was visited because of the nature of its business (rendering plant).
[2]/ Four firms were visited because of the nature of their businesses (distributor, transporter, wholesaler, and custom exempt slaughtering facility).

Since 1997, bills have been introduced in Congress to give the Secretary the authority to assess monetary penalties against firms that violate meat and poultry inspection laws. None of the bills have become law.

ADME's and supervisory compliance officers from the Alameda, Albany, and Jackson district offices stated that the agency should have the authority to fine firms or individuals that violate meat and poultry inspection laws. A DEO headquarters official commented

that fines for violations could have a negative economic impact against firms but, if implemented, fines should be severe enough to deter further violations.

We concluded that FSIS should continue to seek the authority to assess monetary penalties against firms that commit repeat violations of meat and poultry inspection laws. Additionally, FSIS should be more aggressive in utilizing the authorities it currently has, including seizures, injunctions, withdrawal of custom exempt status, and prosecutions, against repeat violators of the meat and poultry inspection laws.

RECOMMENDATION NO. 7

Continue to seek the authority to assess civil monetary penalties against firms that commit violations of meat and poultry inspection laws.

Agency Response

FSIS agrees with this recommendation that civil penalties would be an effective supplement to its current criminal and administrative authorities. FSIS stated that civil penalties, while having somewhat limited application, would provide it with an additional tool to deter violations of USDA laws and would be particularly effective in preventing minor violations of law and address situations where criminal prosecution or other action is not appropriate. FSIS stated that it will continue to work with Congress, industry, and the public to obtain this additional authority.

OIG Position

We accept FSIS' management decision for this recommendation.

CHAPTER 4	DEO DETERMINED THAT MOST CASES REFERRED BY DISTRICTS WERE NOT RPOSECUTABLE

FINDING NO. 6

DEO determined that over half of the cases received from district offices did not require referral for prosecution. District offices refer standard cases to DEO headquarters for possible prosecution action by the U.S. attorney, through OGC. We found that DEO headquarters determined 27 of the 41 cases (66 percent) referred from October 1, 1997, through February 28, 1999, did not require referral for prosecution. DEO officials stated that the cases did not have prosecutable merit or some ADME's and supervisory compliance officers did not have enough training or supervisory experience to properly prepare and submit violation cases. As a result, enforcement actions against these violators were delayed.

DEO's compliance Investigative Protocols provides for establishing standard cases for violations involving likely harm to consumers, either physical or financial. These cases are forwarded to DEO headquarters for their review and for possible referral to OGC so the appropriate civil, administrative, or criminal actions can be taken.

Between October 1, 1997, and February 28, 1999, 41 standard cases were developed by compliance officers in the FSIS' district and field offices and submitted to DEO headquarters for review and possible referral to OGC for further action. Our review disclosed that DEO headquarters determined 27 of the 41 (66 percent) cases received from the districts did not require referral. DEO headquarters officials stated the cases did not have prosecutable merit or were not fully developed by compliance officers. According to the officials (1) 21 of the cases did not have sufficient evidence for prosecution, (2) 3 cases were not fully developed by the compliance officers, (3) the firms for 2 cases were no longer in business, and (4) 1 firm had been previously prosecuted by the state for the same violation. (See exhibit H for more details.) Instead, the agency issued letters of warning to 24 of the firms and took no action for the remaining 3 firms.

In one example of a case not being fully developed, the Beltsville, Maryland, district office prepared a Report of Apparent Violation, dated December 9, 1998, that reported a federally inspected plant sold and transported via interstate commerce approximately

479,470 pounds of adulterated and misbranded pork bacon ends and pieces from Virginia to a food processing company in Kansas. The shipments were contaminated with various foreign materials such as metal, cardboard, paper, and rubber. The compliance officer became aware of the adulteration during a random review visit to the Virginia plant. He examined the plant's records and found several credit memos and nonconformance reports that showed the plant may have been aware of these possible violations.

The responsible ADME referred the case to DEO headquarters for prosecution. However, headquarters officials stated that the documentary evidence was not sufficient to prove that the plant knowingly sold adulterated and misbranded products and the products did not appear to have been tampered with. The officials stated that the case was not prosecutable because the compliance officer had not proven criminal intent on the part of the Virginia plant. The ADME responded by obtaining additional information. However, headquarters officials decided that the additional information did not enhance the case. The ADME and headquarters officials agreed to issue a letter of warning as final enforcement action.

In another example where a case was not fully developed, the Springdale, Arkansas, district office prepared a Report of Apparent Violation, dated October 13, 1997, that reported a firm sold and transported approximately 1,150 pounds of adulterated and misbranded frozen pork ribs into commerce from Minnesota to Louisiana. The 39 boxes of ribs had no labeling or marks of inspections, were "slimy," and had a "soured putrid" odor. The product was detained and destroyed on May 6, 1997.

On June 5, 1998, (235 days following the date of the Report of Apparent Violation) DEO headquarters made a decision to close the case with a letter of warning. A headquarters official stated that the evidence was inconclusive based on the following.

- The product was repacked at a federally inspected plant after being resorted.

- The product was sold sight unseen.

- The firm never acknowledged knowing there was a problem with the product.

The DEO headquarters official stated that the compliance review was not sufficiently documented to show the firm had knowledge of

the product being adulterated and misbranded. The ADME agreed with the headquarters decision on the case and questioned why the compliance officer and the supervisor compliance officer thought the case was prosecutable. FSIS issued a letter of warning to the firm.

Another DEO headquarters official stated that many of the cases sent to headquarters for review were not fully developed. He said that some compliance officers, supervisors, and ADME's were not experienced or trained to properly develop standard violation cases. The official further stated that when DEO reorganized from 5 area offices to 18 district offices, DEO did not have enough supervisory experience in the field to properly prepare and submit standard violation cases. He said that several ADME's had little or no experience in preparing standard violation cases.

RECOMMENDATION NO. 8

Reinforce existing compliance Investigative Protocols for developing standard violation cases. Provide training where needed to ensure that all ADME's and supervisory compliance officers are able to properly oversee reviews and case preparation for appropriate sanctions and determinations.

Agency Response

FSIS agrees with the recommendation and stated that it has already taken steps to reinforce existing protocols, procedures, and assure appropriate training of DEO personnel. FSIS stated that it has developed orientation and training protocols for newly hired compliance officers and supervisory personnel. FSIS also stated that it is currently recruiting to address the 58 percent vacancy rate for the supervisory compliance officer position, which is needed to provide proper supervision of reviews and case preparation. FSIS further stated it is the agency's priority to fill these positions as soon as possible.

OIG Position

We agree with FSIS' proposed action. However, to reach management decision, FSIS needs to provide us with its newly developed orientation and training protocols for new hires. Also, FSIS needs to provide its plan for recruiting compliance officers and the estimated timeframe for when these position will be filled.

EXHIBIT A – DISTRICT OFFICES VISITED

	DISTRICT OFFICE	OVERSIGHT RESPONSIBILITY	FIELD OFFICE	NO. OF [1/] COMPLIANCE OFFICERS
1	Alameda, CA	California	Alameda, CA	6
			Diamond Bar, CA	5
			Fresno, CA	2
			Sacramento, CA	2
			San Diego, CA	1
	District Total			**16**
2	Albany, NY	New Jersey	Bogota, NJ	3
			Moorestown, NJ	4
		New York	Albany, NY	5
			Jamaica, NY	6
			Rochester, NY	2
		Connecticut	Hartford, CT	3
		Maine	Augusta, ME	1
		Massachusetts	Waltham, MA	6
		New Hampshire		
		Rhode Island		
		Vermont		
	District Total			**30**
3	Atlanta, GA	Florida	Fort Lauderdale, FL	4
			Orlando, FL	3
			Tallahassee, FL	2
		Georgia	Atlanta, GA	3
		Puerto Rico	Guaynabo, PR	4
			Ponce, PR	1
		Virgin Islands		
	District Total			**17**

[1/] According to "Meat and Poultry Inspection Directory," dated July 1999.

Note: The Boston, MA district office was closed in July 1999 and its oversight responsibility was transferred to the Atlanta, GA district office (Puerto Rico and the Virgin Islands) and the Albany, NY district office (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island and Vermont).

EXHIBIT A – DISTRICT OFFICES VISITED (CONT')

	DISTRICT OFFICE	OVERSIGHT RESPONSIBILITY	FIELD OFFICE	NO. OF [1/] COMPLIANCE OFFICERS
4	Jackson, MS	Alabama	Gadsden, AL	1
			Montgomery, AL	1
		Mississippi	Ridgeland, MS	1
		Tennessee	Knoxville, TN	2
			Nashville, TN	1
	District Total			**6**
5	Pickerington, OH	Kentucky	Lexington, KY	2
		Ohio	Middleburg Heights, OH	2
			Pickerington, OH	3
		West Virginia		
	District Total			**7**
	Total			**76**

[1/] **According to "Meat and Poultry Inspection Directory," dated July 1999.**

EXHIBIT A – LIST OF OTHER FSIS DISTRICT OFFICES

	DISTRICT OFFICE	OVERSIGHT RESPONSIBILITY	FIELD OFFICE	NO. OF [1/] COMPLIANCE OFFICERS
6	Boulder, CO	Arizona	Phoenix, AZ	
		Colorado	Boulder, CO	6
		New Mexico	Albuquerque, NM	1
		Utah	Salt Lake City, UT	2
	District Total			**9**
7	Lombard, IL	Illinois	Lombard, IL	5
			Springfield, IL	3
		Indiana	Indianapolis, IN	3
	District Total			**11**
8	Dallas, TX	Texas	Dallas, TX	4
			Lubbock, TX	2
			Houston, TX	2
			San Antonio, TX	3
	District Total			**11**
9	Des Moines, IA	Iowa	Des Moines, IA	3
		Nebraska	Lincoln, NE	3
	District Total			**6**
10	Greenbelt, MD	Delaware		
		District of Columbia		
		Maryland	Baltimore, MD	2
			Beltsville, MD	3
		Virginia	Richmond, VA	2
	District Total			**7**
11	Lawrence, KS	Kansas	Lawrence, KS	3
		Missouri	Florissant, MO	1
			Springfield, MO	1
	District Total			**5**
12	Madison, WI	Michigan	Oak Park, MI	7
			Grandville, MI	2
		Wisconsin	Madison, WI	3
	District Total			**12**

[1/] According to "Meat and Poultry Inspection Directory," dated July 1999.

EXHIBIT A – LIST OF OTHER FSIS DISTRICT OFFICES (CONT')

	DISTRICT OFFICE	OVERSIGHT RESPONSIBILITY	FIELD OFFICE	NO. OF [1/] COMPLIANCE OFFICERS
13	Minneapolis, MN	Minnesota	S. St. Paul, MN	4
		Montana	Billings, MT	1
		North Dakota	Bismarck, ND	1
		South Dakota	Sioux Falls, SD	
		Wyoming		
	District Total			**6**
14	Philadelphia, PA	Pennsylvania	Philadelphia, PA	4
			Pittsburgh, PA	4
			Scranton, PA	2
	District Total			**10**
15	Raleigh, NC	North Carolina	Raleigh, NC	2
		South Carolina	Columbia, SC	3
	District Total			**5**
16	Salem, OR	Alaska		
		American Samoa		
		Guam		
		Hawaii	Honolulu, HI	2
		Idaho	Boise, ID	1
		Northern Mariana Islands		
		Oregon	Salem, OR	3
		Washington	Bothell, WA	2
			Spokane, WA	2
	District Total			**10**
17	Springdale, AR	Arkansas	Little Rock, AR	3
			Springdale, AR	3
		Louisiana	New Orleans, LA	4
		Oklahoma	Oklahoma City, OK	1
	District Total			**11**
	FSIS Total			**179**

[1/] **According to "Meat and Poultry Inspection Directory, " dated July 1999**.

EXHIBIT B – PCP AND RANDOM REVIEW FIRMS VISITED

DISTRICT OFFICE	FIELD OFFICE	LOCATION	TYPE OF FIRM	TYPE OF REVIEW
Alameda, CA	Diamond Bar, CA.	Montebello, CA	Distributor	PCP
Alameda, CA	Diamond Bar, CA	Los Angeles, CA	Retailer	PCP
Alameda, CA	Diamond Bar, CA	Corona, CA	Custom Slaughter	PCP
Alameda, CA	Diamond Bar, CA	Los Angeles, CA	Retailer	PCP
Alameda, CA	Diamond Bar, CA	Riverside, CA	Warehouse	PCP
Alameda, CA	Diamond Bar, CA	Los Angeles, CA	Distributor	PCP
Alameda, CA	Diamond Bar, CA	Chino, CA	Processor	PCP
Alameda, CA	Diamond Bar, CA	Ontario, CA	Retailer	PCP
Alameda, CA	Diamond Bar, CA	Ontario, CA	4-D	PCP
Alameda, CA	Diamond Bar, CA	Chino, CA	Distributor/Retailer	PCP
Alameda, CA	Diamond Bar, CA	Corona, CA	Custom Slaughter	PCP
Alameda, CA	Diamond Bar, CA	Bell Garden, CA	Distributor	Random
Alameda, CA	Diamond Bar, CA	N. Hollywood, CA	Distributor	Random
Alameda, CA	Diamond Bar, CA	Rancho Cucamonga, CA	Transporter	Random
Alameda, CA	Diamond Bar, CA	Chino, CA	Retailer	Random
Alameda, CA	Diamond Bar, CA	Ontario, CA	Distributor	Random
Alameda, CA	Diamond Bar, CA	Sun Valley, Ca	Retailer	Random
Albany, NY	Jamaica, NY	Jamaica, NY	Custom Slaughter	PCP
Albany, NY	Jamaica, NY	New York, NY	Distributor	PCP
Albany, NY	Jamaica, NY	Bronx, NY	Custom Slaughter	PCP
Albany, NY	Jamaica, NY	Avenel, NJ	Transporter	PCP
Albany, NY	Jamaica, NY	Jamaica, NY	Retailer	PCP
Albany, NY	Jamaica, NY	New York, NY	Distributor	PCP
Albany, NY	Jamaica, NY	Jamaica, NY	Retailer	PCP
Albany, NY	Jamaica, NY	Wappingers, NY	Distributor	PCP
Albany, NY	Jamaica, NY	Greenwich Village, NY	Retailer	PCP
Albany, NY	Jamaica, NY	Brooklyn, NY	Distributor	PCP
Albany, NY	Jamaica, NY	Richmond Hill, NY	Retailer	PCP
Albany, NY	Jamaica, NY	Jamaica, NY	Custom Slaughter	PCP
Albany, NY	Jamaica, NY	Ozone Park, NY	Abattoir	PCP
Albany, NY	Jamaica, NY	Jamaica, NY	Processor	PCP
Albany, NY	Jamaica, NY	New York, NY	Distributor	Random
Albany, NY	Jamaica, NY	New York, NY	Retailer	Random
Albany, NY	Jamaica, NY	New York, NY	Distributor	Random
Albany, NY	Jamaica, NY	Laurelton, NY	Retailer	Random
Albany, NY	Jamaica, NY	Jersey City, NJ	Distributor	Random
Atlanta, GA	Fort Lauderdale, FL	Miami Gardens, FL	Warehouse	PCP
Atlanta, GA	Fort Lauderdale, FL	North Miami Beach, FL	Broker/Salvage	PCP
Atlanta, GA	Fort Lauderdale, FL	Miami Lakes, FL	Retailer	PCP
Atlanta, GA	Fort Lauderdale, FL	Delray Beach, FL	Distributor	PCP

EXHIBIT B – PCP AND RANDOM REVIEW FIRMS VISITED (CONT.)

DISTRICT OFFICE	FIELD OFFICE	LOCATION	TYPE OF FIRM	TYPE OF REVIEW
Atlanta, GA	Fort Lauderdale, FL	Hollywood, FL	Distributor	PCP
Atlanta, GA	Fort Lauderdale, FL	Miami, FL	Distributor	PCP
Atlanta, GA	Fort Lauderdale, FL	Miami, FL	Retailer	PCP
Atlanta, GA	Fort Lauderdale, FL	Hollywood, FL	Retailer	PCP
Atlanta, GA	Fort Lauderdale, FL	Miami, FL	Retailer	PCP
Atlanta, GA	Fort Lauderdale, FL	Miami, FL	Broker	PCP
Atlanta, GA	Fort Lauderdale, FL	Fort Lauderdale, FL	Correctional Institution	Random
Atlanta, GA	Fort Lauderdale, FL	Fort Lauderdale, FL	Retailer	Random
Atlanta, GA	Fort Lauderdale, FL	Fort Lauderdale, FL	Distributor	Random
Atlanta, GA	Fort Lauderdale, FL	Fort Lauderdale, FL	Retailer	Random
Atlanta, GA	Fort Lauderdale, FL	Miami, FL	Processor/Distributor	Random
Atlanta, GA	Fort Lauderdale, FL	West Palm Beach, FL	Child Care Center	Random
Atlanta, GA	Fort Lauderdale, FL	Delray Beach, FL	Distributor	Random
Jackson, MS	Knoxville, TN	Chattanooga, TN	Distributor	PCP
Jackson, MS	Knoxville, TN	Alcoa, TN	Salvage	PCP
Jackson, MS	Knoxville, TN	Knoxville, TN	Retailer	PCP
Jackson, MS	Knoxville, TN	Clinton, TN	Retailer	PCP
Jackson, MS	Knoxville, TN	Knoxville, TN	Retailer	PCP
Jackson, MS	Knoxville, TN	Chattanooga, TN	Processor	PCP
Jackson, MS	Knoxville, TN	Knoxville, TN	Warehouse	PCP
Jackson, MS	Knoxville, TN	Knoxville, TN	Retailer	PCP
Jackson, MS	Knoxville, TN	Knoxville, TN	Retailer	PCP
Jackson, MS	Knoxville, TN	Chattanooga, TN	Warehouse	Random
Jackson, MS	Knoxville, TN	Clinton, TN	Retailer	Random
Jackson, MS	Knoxville, TN	Sevierville, TN	Medical Center	Random
Jackson, MS	Knoxville, TN	Chattanooga, TN	Mental Institution	Random
Jackson, MS	Knoxville, TN	Sevierville, TN	Retailer	Random
Jackson, MS	Knoxville, TN	Alcoa, TN	Retailer	Random
Jackson, MS	Knoxville, TN	Knoxville, TN	Public School	Random
Jackson, MS	Knoxville, TN	Clinton, TN	Retailer	Random
Pickerington, OH	Lexington, KY	Louisville, KY	Retailer	PCP
Pickerington, OH	Lexington, KY	Lexington, KY	Hospital	PCP
Pickerington, OH	Lexington, KY	Walton, KY	Processor/Custom Slaughter	PCP
Pickerington, OH	Lexington, KY	Shelbyville, KY	Retailer	PCP
Pickerington, OH	Lexington, KY	Lancaster, KY	Retailer/Restaurant	PCP
Pickerington, OH	Lexington, KY	Mt. Sterling, KY	Warehouse	PCP
Pickerington, OH	Lexington, KY	Shelbyville, KY	4-D	PCP
Pickerington, OH	Lexington, KY	Bellevue, KY	Retailer	PCP
Pickerington, OH	Lexington, KY	Louisville, KY	Distributor/ Retailer	PCP

EXHIBIT B – PCP AND RANDOM REVIEW FIRMS VISITED (CONT.)

DISTRICT OFFICE	FIELD OFFICE	LOCATION	TYPE OF FIRM	TYPE OF REVIEW
Pickerington, OH	Lexington, KY	Lancaster, KY	Custom Slaughter	PCP
Pickerington, OH	Lexington, KY	Louisville, KY	Restaurant	PCP
Pickerington, OH	Lexington, KY	Louisville, KY	Renderer	Random
Pickerington, OH	Lexington, KY	Covington, KY	Retailer	Random
Pickerington, OH	Lexington, KY	Lexington, TN	Retailer	Random
Pickerington, OH	Lexington, KY	Louisville, KY	Renderer	Random
Pickerington, OH	Lexington, KY	Covington, KY	Restaurant	Random
Pickerington, OH	Lexington, KY	Covington, KY	Retailer	Random
Pickerington, OH	Lexington, KY	Lexington, TN	Distributor	Random
Pickerington, OH	Lexington, KY	Louisville, KY	Renderer	Random
Pickerington, OH	Lexington, KY	Covington, KY	Retailer	Random

EXHIBIT C – COMPLIANCE ACTIVITY REVIEWED FROM OCTOBER 1, 1997 THROUGH FEBRUARY 28, 1999

ACTIVITY				
	Violation Cases	**PCP**	**Random Reviews**	**Consumer Complaints**
ALAMEDA				
District Total	191	1304	1150	204
Reviewed by OIG	20	10	188	55
ALBANY				
District Total	262	2528	5120	143
Reviewed by OIG	20	10	1256	115
ATLANTA				
District Total	106	1558	581	236
Reviewed by OIG	22	14	76	25
JACKSON				
District Total	54	578	732	132
Reviewed by OIG	28	11	156	132
PICKERINGTON				
District Total	43	303	935	143
Reviewed by OIG	21	12	409	17

TOTAL COMPLIANCE ACTIVITY				
	Violation Cases	**PCP**	**Random Reviews**	**Consumer Complaints**
Total for Eighteen Districts	2605	9901	25122	1654
Total for Five Districts Visited	656	6271	8518	858
Total Reviewed by OIG	111*	57	2085	344
Percent Reviewed by OIG	17%	1%	24%	40%

***We reviewed 111 violation cases at the 5 district offices visited. We also reviewed an additional closed 41 violation cases at DEO headquarters for enforcement actions and 116 violation cases at DEO headquarters for processing timeframes.**

EXHIBIT D - TYPES OF FIRMS

BUSINESS CODE NO.	TYPE OF FIRM	INCLUDES
01	Processor	Boner, Fabricator, Cannery, Packer, Country Hams
02	Distributor	Peddler, Route, Sales
03	Renderer	
04	Broker	
05	4-D (dead, dying, disabled, or diseased)	Collector
06	Retailer	Farmers Market, Lease Arrangements
07	Transporter	Trucker, Railroad, Airlines, Ships
08	Custom	Locker Plant
09	Restaurant	Caterer, Commissary, Central, Kitchen
10	Abattoir	
11	Animal Food	Mink Farm, Pet Food Manufacturer
12	Warehouse	Freezer, Cold Storage Warehouse
13	Salvage	
14	Miscellaneous	Consumer, Auction

EXHIBIT E – PROCESSING TIMEFRAMES FOR CLOSED VIOLATION CASES

NUMBER	(A) PREDICATION DATE	(B) DATE RECEIVED DEO HQ	(B-A) ELAPSED DAYS AT DO	(C) DATE CASE CLOSED	(D) CLOSURE ACTION	(C-B) ELAPSED DAYS AT DEO-HQ	(C-A) TOTAL ELAPSED DAYS
1	27-May-98	24-Jun-98	28	06-Aug-98	OTH	43	71
2	16-May-97	11-Feb-98	271	24-Jun-98	LOW	133	404
3	03-Apr-98	10-Nov-98	221	15-Mar-99	LOW	125	346
4	11-Jun-97	29-Oct-97	140	18-Nov-97	LOI	20	160
5	03-Mar-97	11-Feb-98	345	05-Aug-98	NOA	175	520
6	29-May-98	02-Sep-98	96	06-Apr-99	LOW	216	312
7	06-Nov-97	27-Feb-98	113	06-Aug-98	LOW	160	273
8	03-Jun-98	20-Oct-98	139	13-Jan-99	LOW	85	224
9	06-Oct-98	26-Jan-99	112	06-Apr-99	LOW	70	182
10	05-Feb-98	05-Mar-98	28	13-May-98	NOA	69	97
11	14-Oct-97	20-Aug-98	310	29-Jan-99	STADM	162	472
12	26-Sep-97	28-Jan-98	124	28-May-98	LOW	120	244
13	11-Jun-98	31-Jul-98	50	07-Aug-98	LOW	7	57
14	01-Oct-97	01-Oct-97	0	07-Oct-97	STINJ	6	6
15	29-Jul-98	11-Dec-98	135	19-Apr-99	LOW	129	264
16	10-Aug-98	29-Oct-98	80	05-May-99	LOW	188	268
17	24-Mar-98	24-Apr-98	31	22-Jul-98	LOW	89	120
18	21-Sep-98	19-Oct-98	28	10-Dec-98	LOW	52	80
19	03-Feb-98	13-Feb-98	10	12-May-98	NOA	88	98
20	15-Dec-98	29-Jan-99	45	06-Apr-99	LOW	67	112
21	20-Jul-98	17-Aug-98	28	30-Dec-98	LOW	135	163
22	16-Jun-98	15-Sep-98	91	25-Aug-99	LOW(2)	344	435
23	24-Feb-98	23-Jun-98	119	18-Aug-98	LOW	56	175
24	07-Mar-98	23-Jun-98	77	29-Dec-98	NOA	189	266
25	12-Mar-98	23-Jun-98	103	10-Aug-98	LOW	48	151

Key: LOW = Letter of Warning, LOI = Letter of Information, STADM = State Administrative Action STINJ = State Injunction, OTH = Other, NOA= No Action, DO=District Office, DEO-HQ=District Enforcement Operations - Headquarters

EXHIBIT E – PROCESSING TIMEFRAMES FOR CLOSED VIOLATION CASES (CONT')

NUMBER	A PREDICATION DATE	B DATE RECEIVED DEO HQ	B-A ELAPSED DAYS AT DO	C DATE CASE CLOSED	D CLOSURE ACTION	C-B ELAPSED DAYS AT DEO-HQ	C-A TOTAL ELAPSED DAYS
26	10-Jun-98	31-Aug-98	82	29-Mar-99	LOW	210	292
27	30-Sep-98	08-Feb-99	131	21-Jul-99	LOW	163	294
28	17-Mar-98	16-Apr-98	30	24-Jul-98	NOA	99	129
29	26-Jan-98	08-Apr-98	72	14-May-99	STADM	401	473
30	25-Aug-97	03-Apr-98	221	14-Dec-98	LOW	255	476
31	14-Dec-98	21-Jan-99	38	27-Jan-99	LOW	6	44
32	06-Feb-98	25-Feb-98	19	20-Aug-98	LOW	176	195
33	07-Apr-98	17-Sep-98	163	01-Dec-98	LOW	75	238
34	05-May-98	29-Sep-98	147	02-Mar-99	LOW	154	301
35	18-Apr-96	27-Dec-97	618	18-May-98	LOW	142	760
Totals			4,245			4,457	8,702
Count			35			35	35
Average Days			121			127	249

Note: These violation cases were predication on or after October 1, 1997, and closed by September 30, 1999.

EXHIBIT F – PROCESSING TIMEFRAMES FOR OPEN VIOLATION CASES AS OF SEPTEMBER 30, 1999

NUMBER	(A) PREDICATION DATE	(B) DATE RECEIVED DEO HQ	(B-A) ELAPSED DAYS AT DO	(C) CASE OPEN AS OF	STATUS	(C-B) ELAPSED DAYS AT DEO-HQ	(C-A) TOTAL ELAPSED DAYS
1	30-Dec-98	05-Feb-99	37	30-Sep-99	DEO	237	274
2	01-Sep-98	12-Mar-99	192	24-Aug-99	OGC	165	357
3	21-Mar-97	24-Oct-97	217	31-Jul-99	USA	280	497
4	21-Mar-97	24-Oct-97	217	30-Sep-99	USA	280	497
5	03-Jul-97	02-Dec-97	152	30-Sep-99	USA	127	279
6	29-Aug-98	22-Dec-98	115	30-Sep-99	DEO	282	397
7	13-Aug-98	26-Jan-99	166	30-Sep-99	DEO	247	413
8	16-Jun-98	18-May-99	336	10-Aug-99	OGC	84	420
9	21-Jan-99	04-Aug-99	195	30-Sep-99	DEO	57	252
10	02-Sep-97	25-Aug-98	357	28-Jan-99	USA	156	513
11	09-Oct-98	24-Feb-99	138	30-Sep-99	DEO	218	356
12	19-Aug-98	02-Aug-99	348	30-Sep-99	DEO	59	407
13	02-Apr-98	22-Sep-98	173	30-Sep-99	DEO	373	546
14	02-Oct-98	22-Jan-99	112	30-Sep-99	DEO	251	363
15	16-Dec-98	24-Feb-99	70	30-Sep-99	DEO	218	288
16	28-Oct-98	23-Jul-99	268	30-Sep-99	DEO	69	337
17	10-Mar-99	27-Aug-99	170	30-Sep-99	DEO	34	204
18	07-May-98	16-Sep-99	497	30-Sep-99	DEO	14	511
19	08-Sep-98	30-Aug-99	356	30-Sep-99	DEO	31	387
20	24-Nov-97	29-Sep-98	309	05-Apr-99	OGC	188	497
21	18-May-99	18-May-99	0	30-Sep-99	DEO	135	135
22	21-Jul-98	30-Dec-98	162	29-Apr-99	USA	120	282
23	11-Aug-98	19-Nov-98	100	30-Sep-99	DEO	315	415
24	02-Apr-98	07-Aug-98	127	30-Sep-99	DEO	419	546
25	04-Aug-98	30-Oct-98	87	30-Mar-99	OGC	151	238
26	28-Jul-98	08-Jan-99	164	17-Sep-99	OGC	252	416
27	28-Jul-98	08-Jan-99	164	17-Sep-99	OGC	252	416
28	28-Jul-98	19-Nov-98	114	17-Sep-99	OGC	302	416
29	03-Nov-97	28-Apr-99	541	30-Sep-99	DEO	155	696
30	02-Oct-98	20-Jul-99	291	30-Sep-99	DEO	72	363
31	06-Jun-97	09-Oct-97	125	24-Nov-98	USA	411	536

EXHIBIT F - PROCESSING TIMEFRAMES FOR OPEN VIOLATION CASES AS OF SEPTEMBER 30, 1999 (CONT')

NUMBER	(A) PREDICATION DATE	(B) DATE RECEIVED DEO HQ	(B-A) ELAPSED DAYS AT DO	(C) CASE OPEN AS OF	STATUS	(C-B) ELAPSED DAYS AT DEO-HQ	(C-A) TOTAL ELAPSED DAYS
32	21-Jul-98	13-Oct-98	84	30-Sep-99	DEO	352	436
33	16-Feb-99	26-May-99	99	30-Sep-99	DEO	127	226
34	05-Aug-97	27-Oct-97	83	30-Sep-99	DEO	703	786
35	28-May-97	09-Oct-97	134	30-Sep-99	DEO	721	855
36	16-Jul-98	30-Nov-98	137	30-Sep-99	DEO	304	441
37	25-Jun-98	10-Dec-98	168	30-Sep-99	DEO	294	462
38	02-Nov-98	13-Jul-99	253	30-Sep-99	DEO	79	332
39	15-Jul-98	21-Jan-99	190	30-Sep-99	DEO	252	442
40	18-Dec-98	13-Jan-99	26	30-Sep-99	DEO	260	286
41	20-Nov-98	19-Jan-99	60	30-Sep-99	DEO	254	314
42	01-Mar-99	12-Mar-99	11	30-Sep-99	DEO	202	213
43	08-Mar-99	15-Apr-99	38-	30-Sep-99	DEO	168	206
44	08-Jun-99	18-Jun-99	10	30-Sep-99	DEO	104	114
45	20-Aug-98	29-Oct-98	70	30-Sep-99	DEO	336	406
46	30-Sep-98	29-Oct-98	29	30-Sep-99	DEO	336	365
47	01-Dec-98	18-Feb-99	79	30-Sep-99	DEO	224	303
48	11-Mar-99	19-May-99	69	30-Sep-99	DEO	134	203
49	13-Mar-99	04-May-99	52	30-Sep-99	DEO	149	201
50	09-Jun-98	19-Jul-98	40	30-Sep-99	DEO	438	478
51	22-Apr-99	09-Jul-99	78	22-Jul-99	OGC	13	91
52	29-Apr-99	29-Jul-99	91	30-Sep-99	DEO	63	154
53	04-May-99	17-Aug-99	105	30-Sep-99	DEO	44	149
54	22-May-97	23-Jun-98	397	30-Sep-99	DEO	464	861
55	23-Feb-99	29-Apr-99	65	10-Aug-99	OGC	103	168
56	25-Nov-98	01-Jul-99	218	30-Sep-99	DEO	91	309
57	17-Dec-98	29-Apr-99	133	30-Sep-99	DEO	154	287
58	18-Sep-98	17-Aug-99	333	30-Sep-99	DEO	44	377
59	30-Jul-98	30-Nov-98	123	30-Sep-99	DEO	304	427
60	30-Jun-98	04-Jun-99	339	30-Sep-99	DEO	118	457
61	11-Mar-98	23-Sep-98	196	30-Sep-99	DEO	372	568
62	15-Jan-98	20-Oct-98	278	30-Sep-99	DEO	345	623
63	05-Apr-99	23-Jun-99	79	30-Sep-99	DEO	99	178

EXHIBIT F - PROCESSING TIMEFRAMES FOR OPEN VIOLATION CASES AS OF SEPTEMBER 30, 1999 (CONT')

NUMBER	(A) PREDICATION DATE	(B) DATE RECEIVED DEO HQ	(B-A) ELAPSED DAYS AT DO	(C) CASE OPEN AS OF	STATUS	(C-B) ELAPSED DAYS AT DEO-HQ	(C-A) TOTAL ELAPSED DAYS
64	13-Jan-98	08-Oct-98	268	04-Jun-99	USA	239	507
65	25-Jan-98	4-Aug-99	556	30-Sep-99	DEO	57	613
66	24-May-99	23-Sep-99	122	30-Sep-99	DEO	7	129
67	19-Nov-97	16-Apr-98	148	30-Sep-99	DEO	532	680
68	12-Mar-98	08-Jul-98	118	22-Jun-99	USA	349	467
69	08-Oct-98	17-Feb-99	132	30-Sep-99	DEO	225	357
70	06-Feb-98	19-Aug-99	559	30-Sep-99	DEO	42	601
71	24-Feb-99	25-May-99	90	20-Jul-99	USA	56	146
72	05-Dec-95	31-Jul-98	969	19-Nov-99	USA	111	1080
73	20-Feb-98	17-Sep-98	209	30-Sep-99	DEO	378	587
74	21-Jul-97	28-Jul-98	372	30-Sep-99	DEO	429	801
75	12-Jun-97	10-Dec-97	181	18-Mar-98	USA	98	279
76	30-Apr-97	10-Dec-97	224	10-Mar-98	USA	90	314
77	20-Jul-98	29-Sep-98	71	30-Sep-99	DEO	366	437
78	08-Oct-98	26-Feb-99	141	14-Sep-99	OGC	200	341
79	14-Jan-99	09-Apr-99	85	30-Sep-99	DEO	174	259
80	26-Aug-99	03-Sep-99	8	30-Sep-99	DEO	27	35
81	06-Apr-98	14-Jul-98	99	08-Apr-99	OGC	268	367
Totals			14,719			17,259	31,972
Count			81			81	81
Average Days			182			213	395

Note: The column titled "CASE OPEN AS OF" is either the date the case was currently being reviewed at DEO-headquarters through September 30, 1999, or the date the case was transferred out of DEO-headquarters for review at OGC and subsequently to the USA, if appropriate.

Key – USA=United States Attorney, OGC=Office of General Counsel, DO=District Offices, DEO=District Enforcement Operations

EXHIBIT G – VIOLATIONS DISCLOSED DURING OIG VISITS

TYPE OF FIRMS	LOCATION	DATE VISITED	ENFORCEMENT ACTION	DATE	HISTORY ACTION	DATE
Custom Exempt Slaughter	Chino, CA	6/29/99	LOW	8/2/99	LOW	5/5/97
FINDING: Found 28 pounds (one beef head, one hog head, and one goat head) of products that was not associated with an owner. The custom slaughter records were incomplete. **VIOLATIONS:** Failure to maintain custom exempt records and failure to identify custom exempt meat products as "Not for Sale."						
Custom Exempt Slaughter	Corona, CA	6/29/99	LOW	8/2/99	LOW	9/11/96
FINDING: Observed five pounds of pork lungs and liver not associated with an owner. Also records did not account for animals slaughtered on June 27, 28, and 29, 1999. **VIOLATIONS:** Failure to maintain custom exempt records and failure to identify custom exempt meat products as "Not for Sale."						
Retailer	Ontario, CA	7/1/99	LOW	8/2/99	LOW	3/19/99
FINDING: Retailer sold beef and pork tacos and chile verde dinners to another retailer in a catering truck. **VIOLATION:** Sale of non-Federally inspected meat products.						
Custom Exempt Slaughter	Corona, CA	6/30/99	LOW	8/11/99	LOW	9/4/97
FINDING: Failed to maintain accurate records. Compliance officer detained 2,400 pounds of products, of which 1,570 pounds were destroyed. Also, the firm failed to maintain control of persons who threatened, intimidated, and interfered with USDA employees in performing their duties. **VIOLATION:** Failure to maintain custom exempt records.						
NOTES: Violations cases were established by FSIS compliance officers based on the violations disclosed during the OIG visits with compliance officers.						

EXHIBIT G – VIOLATIONS DISCLOSED DURING OIG VISITS (CONT')

TYPE OF FIRMS	LOCATION	DATE VISITED	ENFORCEMENT ACTION	DATE	HISTORY ACTION	DATE
Custom Exempt Slaughter	Bronx, NY	5/20/99	LOW	6/11/99	[1]	
FINDING: Slaughtered and cut goats and failed to mark product "Not for Sale." **VIOLATION:** Failure to identify custom meat products as "Not for Sale."						
Distributor	Brooklyn, NY	5/20/99	LOW	6/11/99	LOW	4/4/99
FINDING: Had in possession 29 pounds of unlabeled or unidentified product from unnamed source. Some of the product was sold to customers. **VIOLATION:** Failure to identify custom meat products as "Not for Sale."						
Custom Exempt Slaughter	Jamaica, NY	5/20/99	LOW	8/9/99	LOW LOW LOW	11/14/97 8/10/98 1/14/99
FINDING: Slaughtered and cut lamb and failed to mark product "Not for Sale." Also, failed to maintain proper records. **VIOLATIONS:** Failure to maintain custom exempt records and failure to identify custom exempt meat products as "Not for Sale."						
Custom Exempt Slaughter	Jamaica, NY	5/21/99	[2] RAV	6/21/99	LOW [3] PYV [4] NOI [5] RAV	8/1/95 1/5/96 11/24/97
FINDING: Observed unsanitary conditions and adulterated products. **VIOLATION:** Failure to maintain and operate facility in a sanitary manner causing meat products to become adulterated.						

NOTES:

[1] **The firm at this location, operated by a different owner, had a history of noncompliance**.
[2] **"Report of Apparent Violation."**
[3] **Firm was ordered to report to DEO HQ to "Present Your Views."**
[4] **Firm was issued a "Notice of Ineligibility" for custom exempt slaughter practices.**
[5] **"Report of Apparent Violation" case pending.**

Key: LOW – Letter of Warning

EXHIBIT H – VIOLATION CASES RECEIVED FROM DISTRICT OFFICES THAT WERE NOT REFERRED FOR PROSECUTION

NUMBER	REASONS NOT REFER FOR PROSECUTION			ENFORCEMENT ACTION	COMMENT
	INSUFFICIENT EVIDENCE	NOT PROPERLY DEVELOPED	OTHER		
1	X			LOW	
2		X		LOW	
3	X			LOW	
4	X			LOW	
5			X	LOW	Firm no longer in business
6	X			LOW	
7	X			NOA	
8			X	LOW	Firm prosecuted By State
9	X			LOW	
10	X			LOW	
11		X		LOW	
12	X			LOW	
13	X			LOW	
14	X			LOW	
15	X			NOA	
16	X			LOW	
17	X			LOW	
18	X			LOW	
19	X			LOW	
20	X			LOW	
21	X			LOW	
22	X			NOA	
23		X		LOW	
24	X			LOW	
25	X			LOW	
26	X			LOW	
27			X	LOW	Firm no longer in business
Totals	**21**	**3**	**3**		

KEY: LOW = Letter of Warning, NOA = No Action

EXHIBIT I – FSIS RESPONSE TO THE DRAFT REPORT

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

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

FROM: Thomas J. Billy
Administrator

SUBJECT: FSIS Response to Office of Inspector General (OIG) Draft Report on District Enforcement Operations Compliance Program, Audit Number 24601-4-At

Thank you for the opportunity to submit Agency comments on your audit of the "Food Safety and Inspection Service (FSIS), District Enforcement Operations, Compliance Program." FSIS has reviewed the draft report and offers the following enclosed responses to the findings and recommendations for your addition to the final audit report.

OIG Key Recommendations:

We recommend that FSIS further refine its plan to incorporate prescribed procedures for conducting compliance reviews at 13 of the 14 types of establishments it is required to oversee (FSIS currently has review steps only for warehouses). FSIS' plan should also define the universe of high risk establishments requiring review and determine the review steps to be performed at each type of establishment. FSIS' plan needs to emphasize the targeting of resources to those areas that are geographically large and heavily populated, as well as to establishments that are considered high risk. FSIS' plan could be further enhanced by establishing timeframes and procedures for monitoring and tracking the progress and completion of violation cases. FSIS should ensure that its assistant district managers for enforcement (ADME) and supervisory compliance officers receive training to adequately prepare and submit violation cases for prosecution.

We recommend that FSIS develop an effective system to monitor the receipt and processing of all consumer complaints. We are also recommending that FSIS continue to seek authority to fine establishments that violate the meat and poultry laws.

Agency Response:

We agree with the general recommendations. For the past several years, FSIS has placed strong emphasis on developing and applying appropriate enforcement support for the Hazard Analysis Critical Control Point (HACCP) system and pathogen reduction regulations, and we believe the results have strengthened our public health protections. Nevertheless, we acknowledge that this

additional emphasis has required us to delay certain needed improvements in traditional compliance activities. Your report comes at an excellent time as we consider ways to strengthen our coverage of distribution channels and to assure timely and appropriate actions in response to violations that put consumers at risk.

We are concerned, however, that page iii of the report may give an incorrect impression of the Agency's position concerning training and supervisory experience of Assistant District Manager for Enforcement's (ADME's) and supervisory compliance officers. While FSIS has identified a need for additional supervision and training of some field supervisors, there is little or no connection between these training needs and the percentage of cases that lack merit for prosecution. The comments by District Enforcement Operations (DEO) officials to which you refer were a one-time, temporary concern (shortly after the 1997 reorganization) about a small number of supervisors. New supervisors were lacking case review experience and were encouraged to submit cases to headquarters for advice and assistance. This concern would certainly not apply to all supervisors at the time, nor to the current mix of field supervisors. Current enforcement records show that a high percentage of cases submitted to headquarters are successfully prosecuted. Further, it is useful to point out that the process of oversight and scrutiny by headquarters officials is to assure the best quality case documentation and decisionmaking. Central case review promotes consistent interpretations across the country and is in keeping with an effective enforcement program. Occasionally this scrutiny will result in cases being returned.

Also, page i of the Executive Summary should reflect that FSIS authorities derive from the Federal Meat Inspection Act, the Poultry Products Inspection Act and the Egg Products Inspection Act, not just from the Code of Federal Regulations.

Chapter 1 Effectiveness of Planned Compliance Reviews and Random Reviews Could Be Enhanced

Recommendation No. 1:

Enhance FSIS' existing plan by improving the process to identify and review high risk establishments that handle meat and poultry products.

Agency Response:

We agree with the recommendation to enhance our existing plan by improving the process to identify and review high-risk firms. We will proceed with these enhancements to our plan and prioritize our efforts consistent with available resources. Traditionally, FSIS has focused the vast majority of its resources on providing inspection at official establishments. We are currently in transition to a system that focuses more resources on food safety across the entire "farm-to-table" continuum. Plans for our "workforce of the future" are being developed and include current testing of ways to improve methods to identify and review high risk-firms in product distribution channels and ways to strengthen partnerships with State and local authorities and with other Federal food safety and public health agencies. We believe that our plans to improve FSIS monitoring of handlers of meat and poultry products will be responsive to the audit findings and serve to assure a continued high level of protection to the public. A revised plan will be completed by October 2000. Implementation of the plan will be contingent on

available resources.

Recommendation No. 2:

Enhance and refine FSIS' existing plan by incorporating prescribed review steps for conducting compliance reviews for each of the 14 types of establishments the agency oversees (FSIS has review steps for warehouses). The plan should include a review checklist along with a compliance officer's certification statement that the appropriate review steps were performed.

Agency Response:

We agree with the recommendation to work towards standardizing the scope of compliance reviews while preserving adequate flexibility to allow compliance officers to utilize their professional judgement and technical expertise to act on issues that are unusual or unique. However, please note that FSIS does not concur with the findings in this section of the report as they relate to interpretations of the law and regulations. DEO will develop better methods to standardize compliance reviews, such as enhancing the Investigative Protocols by including detailed descriptions of critical areas to review for high-risk business types, such as warehouses; distributors; dead, dying, disabled or diseased (4D) operators; renderers; salvage operators and other business types. DEO will also establish a review policy to assure that FSIS personnel followed all critical procedures, if not otherwise noted on Agency review or reporting records. We will also enhance our enforcement database capabilities to provide management reports to aid in increasing the level and effectiveness of supervisory oversight. Further, we plan to improve training methods by developing computer based training modules for conducting reviews and case development, increasing the use of on-the-job training assignments to field and headquarters locations, and other means. This process will be completed by December 2002, if adequate resources are provided.

Recommendation No. 3:

Enhance FSIS' existing plan to emphasize targeting of resources to large metropolitan and geographic areas and to high risk establishments with a history of violations.

Agency Response:

FSIS agrees that there is a need to improve systems for allocating resources more effectively. The audit highlighted the resource limitations that FSIS is under due to budget constraints. We have applied Office of Personnel Management (OPM) reviewed criteria, the "Internal Classification Criteria for Evaluating Compliance Work" (matrix), informally to assist in targeting resources, along with other factors. As DEO is provided with additional resources, a more formalized system to target resources will be necessary. This improved system will include factors such as geographical size, administrative workload, level of State and local cooperation, and the factors identified in the matrix – population density, case documentation, and complexity/density of Federally inspected establishments. Successful implementation of this system will assure that the most critical locations are adequately staffed and require time to make the required reallocations. We expect to complete this activity by December 2002.

Recommendation No. 4:

Define effective and meaningful timeframe guidelines for monitoring and tracking the progress and completion of violation case. Establish procedures for tracking those timeframes such as investigative time, documentation time, supervisory review time, headquarters review time, etc.

Agency Response:

The Agency agrees that much benefit would be derived from monitoring and tracking process timeliness associated with the investigation and review of violation cases. In that regard, DEO is currently reviewing a draft database system created to track the process timeliness of violation cases from predication to referral to the U. S. Attorney. This new system will be fully operational prior to fiscal year (FY) 2001. After sufficient information is collected from the tracking system, the data will be assessed to help develop effective timeframe guidelines for case documentation and review. It is expected that this new system will help the Agency identify areas where improvements can be made to ensure that all cases are processed in a timely manner.

Chapter 2 FSIS Did Not Have an Effective System to Monitor Consumer Complaints

Recommendation No. 5:

Develop a system, including written procedures, to monitor receipt and follow up action on all consumer complaints received at DEO headquarters, district and field level offices.

Agency Response:

We agree with this recommendation. An improved system can be developed to monitor receipt and follow up action on all consumer complaints. FSIS's electronic system (Consumer Surveillance Information System) for receiving and tracking consumer complaints currently does not extend to all areas of FSIS. As the Audit Report points out, consumer and other complaints are received from a wide variety of sources within FSIS, other agencies within USDA and other Federal, State and local public health and food safety agencies. FSIS agrees that written procedures are needed to monitor the receipt of, and follow up action on, consumer complaints. The Agency plans to centralize this function under one Agency unit that will monitor receipt and disposition of each complaint. This staff will evaluate each complaint to determine its validity based on its public health implications and risk to consumers. Matters requiring investigatory follow up would be referred to DEO and tracked and monitored. Until this occurs, we will continue to use the current system. Until then, DEO is implementing an interim monitoring system for the receipt and follow up of consumer complaints from District field staff or those referred to DEO headquarters. FSIS will also continue to operate its current Consumer Surveillance Information System and coordinate information exchange between that system and DEO. We intend to have the newly reconstituted and reorganized system implemented by March 2001, if resources are available.

Recommendation No. 6:

Review the 16 consumer complaints previously omitted from review and perform follow up action to satisfactorily resolve them.

Agency Response:

We agree with this recommendation. FSIS is in the process of reviewing the 16 consumer complaints to determine if they have been resolved and perform any follow up action, if needed. It is important to note that the Consumer Surveillance Information System database shows that 13 of the 16 consumer complaints did not involve illness or injury. We will complete our review and follow up, as appropriate, by October 2000.

Chapter 3 FSIS' Enforcement Actions Did Not Deter Repeat Violators of Meat and Poultry Inspection Laws

Recommendation No. 7:

Continue to seek the authority to assess civil monetary penalties against establishments that commit violations of meat and poultry inspection laws.

Agency Response:

We agree with this recommendation that civil penalties would be an effective supplement to the Agency's current criminal and administrative authorities. FSIS has sought or supported for many years legislation in Congress to give the Secretary additional authorities to ensure food safety. In 1997, Secretary Glickman transmitted to Congress a draft bill to improve public health and food safety by providing USDA with enhanced enforcement powers, including the authority to impose civil penalties for violations of the meat and poultry inspection laws. The legislation was introduced in the 105th Congress, but no action was taken. The legislation was again introduced in the 106th Congress, as the "Safe and Fair Enforcement and Recall (SAFER) for Meat and Poultry Act."

The authority to impose civil penalties would provide a timely and effective remedy against those who violate USDA meat and poultry laws. Civil penalties, while having somewhat limited application, would provide the Agency with an additional tool to deter violations of USDA laws and would be particularly effective in preventing minor violations of law and address situations where criminal prosecution or other action is not appropriate. We will continue to work with Congress, the industry and the public to obtain this additional authority.

Agency enforcement data regarding the number of letters of warning issued nationwide for the two year period of the audit show that out of 4,404 letters of warning issued, only 374 involved repeat violators (about 8%). Our systems are designed to focus enforcement resources on the further monitoring of high risk businesses and individuals that are known violators. Detection of repeat violations is expected and supports the conclusion that our current enforcement system is effective. Moreover, focusing on letters of warning fails to capture the full range of enforcement tools – product control actions, detentions, seizures, administrative suspension and withdrawals, injunctions, and criminal prosecutions – that FSIS effectively uses to minimize recidivism by industry and individuals.

Chapter 4 FSIS' Process for Investigating Violation Cases Needs Improvement

Recommendation No. 8:

Reinforce existing compliance Investigative Protocols for developing standard violation cases. Provide training where needed to ensure that all ADMEs and supervisory compliance officers are able to properly oversee reviews and case preparation for appropriate sanctions and determinations.

Agency Response:

The Agency agrees with the recommendation and has already taken steps to reinforce existing protocols, procedures, and assure appropriate training of DEO personnel.

DEO has developed orientation and training protocols for newly hired compliance officers and supervisory personnel. An orientation and training checklist is being used to assure that new employees are exposed to all tasks and functions that compliance officers currently perform. Since October 1997, DEO has provided basic and advanced compliance officer training to over 200 employees. DEO also intends to establish a position to work with Agency training officials on compliance officer basic and advanced courses, computer based training (CBT) courses, enforcement supervisory training and the proposed training of inspectors and inspection managers in enforcement techniques.

While budget constraints have curtailed some of our training and developmental activities in the last two years, we are committed to giving enforcement a high priority and assuring that sufficient funds are allocated to train and equip Agency enforcement personnel.

FSIS is currently recruiting to address the 58 percent vacancy rate for supervisory compliance officer positions. Recruitment for these positions is needed to provide proper supervision of reviews and case preparation. It is an Agency priority to fill these positions as soon as possible.

Also, the audit points out that a high number of cases forwarded to DEO headquarters were not referred to OGC or DOJ for action. DEO headquarters is responsible for making determinations as to what case actions meet Agency goals and policies. The headquarters review process is intended to assure that cases are adequately supported, represent serious non-compliance and otherwise warrant referral to the U.S. Attorneys for criminal prosecution or other action. Cases involving minor violations of law are not referred for prosecution, though repetitive violations may be referred for civil injunctive action. During the audit period, the ADME's were encouraged to submit cases to headquarters with recommended dispositions. It also is not unusual for cases to be sent to headquarters for special review or issuance of a headquarters letter of warning. It should not be construed that every case entered in the DEO system for injunction or prosecution should be referred to the U.S. Attorney. Coding cases in this manner enables the Agency to effectively track field activities and aids the various reporting media, i.e., Quarterly Regulatory and Enforcement Reports, Reports to Congress, and other management reports. We would note that during the 15-month period prior to initiation of the audit, less than 25 percent of the cases submitted to DEO for criminal or civil action were closed with a letter of warning. Since March of 1999, less than 9 percent of violation cases submitted to DEO headquarters have been closed with letters of warning.

EXHIBIT I – FSIS RESPONSE TO THE DRAFT REPORT

Exhibits

Agency Comment:

We believe that all references to actual DEO case file numbers should be deleted from any exhibits to the report. We did not raise this during our exit meeting, but have now advised your Atlanta office and understand they concur. In Exhibit B the names of specific businesses should be deleted.

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ABBREVIATIONS

ADME	-Assistant District Manager for Enforcement
DEO	-District Enforcement Operations
DR	-Departmental Regulation
FMIA	-Federal Meat Inspection Act
FSIS	-Food Safety and Inspection Service
FY	-Fiscal Year
HACCP	-Hazard Analysis and Critical Control Point
OGC	-Office of General Counsel
OIG	-Office of Inspector General
OPHS	-Office of Public Health and Science
PCP	-Planned Compliance Program
PPIA	-Poultry Products Inspection Act
USDA	-U.S. Department of Agriculture