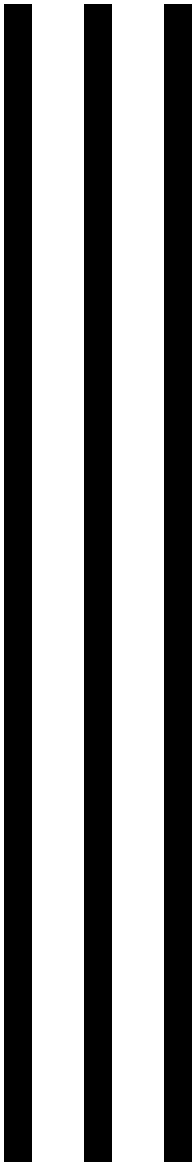

U.S. Department of Agriculture
Office of Inspector General
Food Safety Initiative
Meat and Poultry Products

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.

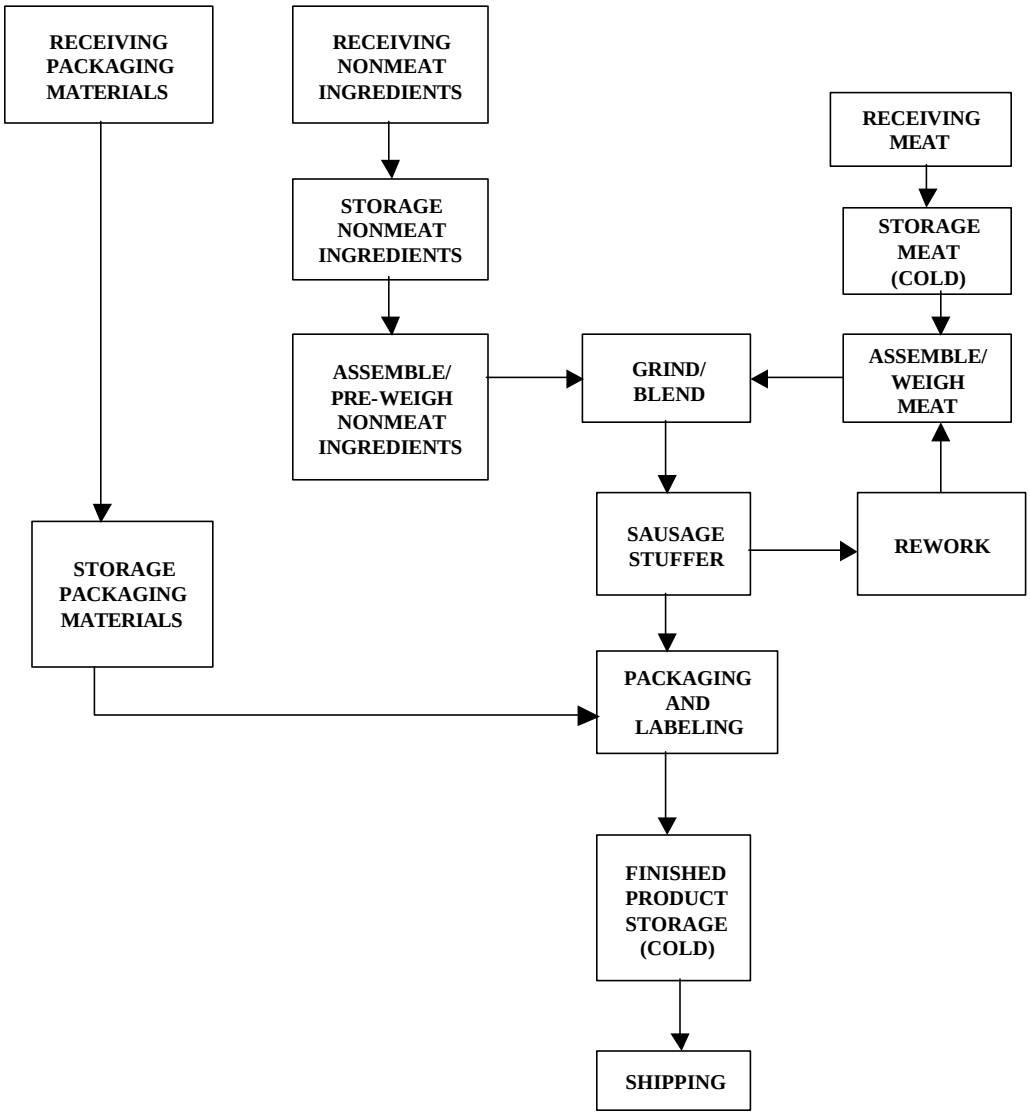
- **Principle No. 7**: ***Establish verification procedures*** - Plants must ensure that their HACCP plans accomplish their intended goal.

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