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Southeast Region

Audit Report

Hazard Analysis and Critical Control Point Implementation at Very Small Plants

Report No. 24601-5-AT
June 2005

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington, D.C. 20250

June 24, 2005

TO: Barbara Masters
Acting Administrator
Food Safety and Inspection Service

ATTN: Ronald F. Hicks
Assistant Administrator
Office of Program Evaluation, Enforcement and Review

FROM: Robert W. Young /S/
Assistant Inspector General
for Audit

SUBJECT: HACCP – Implementation at Very Small Plants (24601-5-At)

This report presents the results of our review of the Food Safety Inspection Service's (FSIS) Hazard Analysis and Critical Control Point (HACCP) Implementation at Very Small Plants. Your June 1, 2005, written response to the official draft report is included in its entirety (except for the enclosures) as exhibit D with excerpts and the OIG position incorporated into the Findings and Recommendations section of the report, where applicable.

We accept the management decisions for Recommendations 1, 2, 4, 6, 7, 10, 11, 12, and 13. Management decisions have not been accepted for Recommendations 3, 5, 8, 9, and 14. Please follow your agency's internal procedures in forwarding documentation for final action to the Office of the Chief Financial Officer.

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 those recommendations for which management decisions have not yet been reached. Please note that the regulation requires that management decisions be reached on all recommendations within a maximum of 6 months from report issuance.

We appreciate the cooperation and assistance provided to our staff during the audit.

Executive Summary

Hazard Analysis and Critical Control Point Implementation for Very Small Plants (Audit Report No. 24601-5-AT)

Results in Brief

This report presents the results of our audit of the Hazard Analysis and Critical Control Point (HACCP) system at very small plants,[1] administered by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS). FSIS implemented the final rule on HACCP systems effective January 25, 2000, at approximately 3,400 very small federally inspected plants. The purpose of our audit was to evaluate FSIS' implementation of the HACCP program at very small plants and to determine whether the program was effective in ensuring the wholesomeness of the meat and poultry sold to consumers.

We found that FSIS timely implemented HACCP systems at very small plants; however, the systems need improvement to ensure the wholesomeness of the meat and poultry produced for consumers. We continued to find a number of deficiencies that need correction before FSIS can consider the HACCP implementation at very small plants to be in total compliance. We concluded that management controls for monitoring both plant operations and inspectors' performance need improvement to further reduce the number of deficiencies. Although food safety assessments (FSA) performed by consumer safety officers (CSO) were useful in identifying and correcting many plant HACCP, Sanitation Standard Operating Procedures (SSOP) and pathogen reduction deficiencies, further improvements in this process are also needed. We found that the national office had not developed written criteria regarding how districts should select plants to receive FSA's, did not readily know which plants had received one, or how many complete FSA's had been performed to ensure that coverage was adequate and in the most needy plants. More importantly, plant deficiencies noted in FSA's were not linked to FSIS In-Plant Performance System (IPPS) reviews to determine which inspectors had not noted many of the HACCP, SSOP or pathogen reduction noncompliances that CSO's found, and why.

We reviewed 36 HACCP plans at 15 plants (see exhibit B) and found HACCP plan deficiencies at 9 of these plants. This is an improvement since our prior audit[2] reported HACCP plan deficiencies at 14 of the 15 plants we visited. We attribute these improvements, in part, to a number of reviews currently being performed by FSIS, particularly the FSA's that reviewed the scientific basis of HACCP plans. FSIS had FSA's performed at 6 of 15 plants we visited. The agency issued a 30-day reassessment letter to each of the plants requiring them to reassess their HACCP plans and initiate corrective

[1] The Food Safety and Inspection Service (FSIS) define "very small plants" as all plants with fewer than 10 employees or annual sales of less than $2.5 million.

[2] "Implementation of the HACCP System," Audit No. 24001-3-At, dated June 21, 2000.

actions on all of the findings identified in their reviews. These reviews helped reduce the number of deficiencies found at these plants during our review.

However, we continued to find deficiencies with HACCP plans in that they were incomplete. Specifically, we found that (1) hazard analyses did not address all food safety hazards,[3] (2) production process steps were omitted from process flowcharts, and (3) changes that occurred in production processes were not always being updated in the HACCP plans. Many of these deficiencies occurred because FSIS inspectors or plant management either overlooked or were not aware of HACCP plan requirements.

FSIS oversight and verification of SSOP also needs to be improved to ensure that meat and poultry products are free from adulteration and contamination. FSIS records and our visual inspections showed that 6 of 15 plants did not have adequate SSOP procedures, or did not maintain proper records to show that SSOP procedures were followed. FSIS had also found repetitive noncompliance deficiencies that were not adequately corrected at 7 of 15 plants. This occurred because (1) FSIS inspectors did not verify the adequacy of the SSOP plans, (2) plant management did not follow the SSOP plans, or (3) plant management did not develop adequate corrective action to resolve noncompliances. Consequently, there is reduced assurance that SSOPs implemented by the plants were effective in ensuring that food safety was not compromised. During our review of FSIS and plant records, and visual inspection at 15 very small plants, we found some of the same repetitive SSOP noncompliances the inspectors and plant management found in the past. The noncompliances included: food particles left in machinery and equipment, dripping condensation, flaking paint over product processing areas, and improper storage of product. In one plant, we observed live rodents on two occasions in a 2-day period. The inspectors had cited this plant for rodent problems on two other occasions during the past year.

In the prior HACCP audit report (Audit No. 24001-3-At, dated June 2000), we reported deficiencies in both plants' HACCP plans and SSOPs. We recommended that FSIS ensure that inspectors routinely evaluate the sufficiency and effectiveness of HACCP plans and SSOPs, and require changes and modifications to plants' HACCP and SSOP plans when needed. FSIS agreed to reinforce inspector's authorities through better communication and training, national supervisory conferences, and work unit meetings. However, further actions are necessary to correct deficiencies noted in this audit.

In addition, further guidance is needed over inspection activities, specifically with the accuracy and reviews of plants' profiles and the timelines of corrective actions taken on noncompliance records (NR). Because of

[3] Plant operators are required to identify the biological, physical, and chemical hazards that may be encountered for each process in the production of a food product.

incorrect plant profiles and eligibility reports,[4] FSIS did not perform sufficient microbiological sampling at 1 of 15 plants; and, at a second plant, sampling tasks were generated which were not required at the plant. We also found that at 3 of the 15 plants, plant management had not timely responded to NR's to show corrective actions were taken and/or adequate, even though NR's had been opened for over 30 days. FSIS Directive 5400.5 requires inspectors to review "open" FSIS NR files daily. At a fourth plant, the inspector did not write NR's because the inspector said it was not an effective method of addressing plant deficiencies.

We also reviewed the security procedures at the 15 very small plants we visited and found that none had developed or implemented a formal security plan. We questioned plant managers about their security procedures and some of them said that they have a heightened awareness of security issues, but had not developed a formal plan. Although FSIS issued security guidelines for food processors in May 2002, they have not mandated minimum security procedures that plants must implement. During our visits, we observed the security practices of the plants and found the following vulnerabilities:

- The main receiving door at one plant was left open and unattended for extended periods of time.

- Unprocessed product was left on the loading dock at another plant. This product was unattended and could have been accessed by anyone.

FSIS recently revised Directive 5420.1 to require inspectors to monitor plants' security measures when the Department of Homeland Security issues a red, orange, or yellow alert. However, FSIS has not mandated that plants develop and implement written security plans.

Recommendations in Brief

We recommend that FSIS develop a system to ensure that FSA's are conducted at the most high-risk and needed areas, and establish procedures to link FSA's to IPPS reviews to determine why inspectors were not able to identify causes of plant noncompliances.

We also recommend that FSIS include as a scheduled task in the Performance Based Inspection System for inspectors to review HACCP and SSOP plans to ensure timely reviews are being conducted, and require inspectors to review the HACCP training of plant employees who prepare the HACCP plans, particularly off-site contractors.

[4] Inspectors complete plant profiles that contain codes that identify inspection tasks to be performed at each plant. If incorrect codes are input into the plant profiles, all applicable inspection tasks will not be scheduled at the plant.

FSIS should also establish definitive guidelines to ensure that adequate corrective action is required and implemented at plants when repetitive deficiencies are found, and improve guidance over inspector reviews of plant profiles. We further recommend that FSIS establish minimum security requirements at all plants.

Agency Response

In its June 1, 2005, written response to the draft report, FSIS stated that the findings in the Office of Inspector General (OIG) report are not representative of small and very small plants across the country because our field visits to 15 plants represented less than 0.3 percent of the total small and very small plants in the United States. However, FSIS provided a plan showing corrective actions taken, the status of planned corrective actions, and the target dates for completion of the corrective actions for each recommendation in the report. We have incorporated FSIS' response along with our position in the Findings and Recommendations section of this report. The agency's entire response is included in exhibit D.

OIG Position

We disagree with FSIS' assertion that our findings were not representative of the conditions at small and very small plants in the United States. Although we visited only 15 plants in our audit, we reviewed and analyzed management reports with noncompliance data and FSA's of hundreds of plants nationwide. Items found in FSIS' management reports and FSA's were consistent with the conditions noted in our findings. We concur with FSIS' proposed corrective actions and have accepted management decisions for Recommendations 1, 2, 4, 6, 7, 10, 11, 12, and 13. However, FSIS did not provide specific actions planned, or estimated timeframes for implementation, to correct the conditions noted for Recommendations 3, 5, 8, 9, and 14. Therefore, we cannot accept management decisions for these recommendations.

Abbreviations Used in this Report

CCP
Critical Control Point 1
CFR
Code of Federal Regulations 10
CSI
Consumer Safety Inspector 4
CSO
Consumer Safety Officer 4
E. coli
Escherichia coli 2
FMIA
Federal Meat Inspection Act 1
FSA
Food Safety Assessment 4
FSIS
Food Safety and Inspection Service 1
FSRE
Food Safety Regulatory Essentials 16
GAO
Government Accountability Office 1
HACCP
Hazard Analysis and Critical Control Point 1
IPPS
In-Plant Performance System 4
ISP
Inspection System Procedure 30
NR
Noncompliance Record 4
OIG
Office of Inspector General 6
PBIS
Performance Based Inspection System 11
PPIA
Poultry Products Inspection Act 1
PREP
Pathogen Reduction Enforcement Program 30
RTE
Ready-to-Eat 2
SSOP
Sanitation Standard Operating Procedure 2
USDA
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Background and Objectives

Background

The mission of the Food Safety and Inspection Service (FSIS) is to ensure that the nation's commercial supply of meat, poultry, and egg products are safe, wholesome, and correctly labeled and packaged. Under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), FSIS inspects all meat and poultry sold in interstate and foreign commerce, including imported products. Approximately 7,400 Federal inspectors carry out inspection laws in some 6,200 plants. FSIS conducts its inspection activities through its national office in Washington, D.C.; a technical service office in Omaha, Nebraska; 15 district offices; and field offices where plants are located.

Outbreak of foodborne illnesses and studies conducted over the past decade established the need for fundamental changes and improvement in meat and poultry inspection. To improve the safety of meat and poultry products and in response to recommendations from the Government Accountability Office (GAO) and the National Academy of Sciences, FSIS implemented additional regulatory requirements for meat and poultry plants. These requirements were intended to ensure that plants operate food safety systems that are prevention-oriented and science-based. These systems, called Hazard Analysis and Critical Control Point (HACCP) systems, were established in July 25, 1996, when FSIS issued its final rule.

The HACCP final rule was based on seven principles adopted by the National Advisory Committee on Microbiological Criteria for Food in its March 20, 1992, publication, Hazard Analysis and Critical Control Point System. While the seven principles were not explicitly listed in regulatory text, they are embodied in the regulatory requirements. The rule required plants to address each of the 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 a 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 recordkeeping 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 goals.

In addition to requiring the development of HACCP plans, regulations specified 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 *Escherichia coli* (*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 the effectiveness of the controls.

Although the HACCP final rule was issued in July 1996, the implementation dates for plants were based on the size of the plants. The very small plants (fewer than 10 employees) had until January 2000 to implement HACCP. SSOP and *E. coli* testing requirements became effective in January 1997. Salmonella pathogen reduction standards became effective with the implementation dates of HACCP. Since publishing the HACCP regulations, FSIS has issued several directives, clarifications, and modifications such as: a directive for controlling *Listeria monocytogenes* in ready-to-eat (RTE) products; a series of generic HACCP plans to assist plants in writing their own plant-specific plan; and notices for *E. coli* reassessments.

FSIS prepared for the implementation of HACCP in very small plants (approximately 3,400 federally-inspected and 2,300 State-inspected plants) by providing extensive technical assistance and guidance to help them meet HACCP requirements. FSIS recognized that very small plants had fewer resources to draw on and their familiarization with HACCP was limited; for these reasons, FSIS continues to assist very small plants. For example, FSIS established:

- A national coordinator for HACCP in small and very small plants to coordinate the Very Small Plant Outreach Initiative;
- A network of State HACCP contacts and coordinators, including the District of Columbia and United States' territories, who are disseminating information on HACCP and providing technical guidance to very small plants;
- Language assistance (translators) for Asian-Pacific American and Hispanic plant owners and operators;
- Handbooks and guidebooks to assist very small plant owners and operators in developing their own HACCP plans, tailored to their operations; and
- A HACCP hotline (1-800-233-3935) at the FSIS Technical Service Center to respond to HACCP technical and implementation questions and concerns.

Objectives

The overall objective of the audit was to determine the effectiveness of FSIS' implementation of HACCP regulations at very small plants, and to determine whether the HACCP program was effective in ensuring the wholesomeness of meat and poultry products produced for consumers. Because of concerns that the nation's food supply could be the next target of terrorists, we also determined if security measures were implemented at plants.

Findings and Recommendations

Section 1. FSIS Management Controls Need Improvement

Finding 1 Controls Over FSIS Inspection Procedures Need Improvement

FSIS' management controls for monitoring plant operations and inspector performance need improvement. FSIS implemented a series of reviews to better monitor plant and inspector activities after our previous HACCP audit of large and small plants. The most abundant of these reviews are the food safety assessments (FSA). Our analysis of these reviews at very small plants found them to be useful in identifying HACCP, SSOP, and other deficiencies in plant operations. Also, FSIS initiated the In-Plant Performance System (IPPS) to assess its inspectors' performance. However, these reviews were not linked in a manner so as to provide FSIS with a means to determine the relationship between plant deficiencies noted in the FSA's and deficiencies in the inspectors' performance noted in the IPPS. Additionally, the national office had not developed written criteria regarding how districts should select plants to receive FSA's, and did not readily know which plants had received a FSA, or how many complete FSA's had been done. This information was kept at each district office. Improving how FSIS utilizes these management controls will result in its inspectors being more effective in identifying and correcting deficiencies at their assigned plants, thereby improving the deficiencies cited in Findings 2 through 4.

FSIS Directive 5000.1, Revision 1, dated May 21, 2003, provides comprehensive direction to FSIS field personnel on how they are to protect the public health by properly verifying a plant's compliance with the pathogen reduction, sanitation, and HACCP regulations. In this policy, FSIS describes that consumer safety inspectors (CSI) focus on the execution or implementation of the HACCP plan while consumer safety officers (CSO) focus more on the design of the HACCP plans when they conduct an assessment of the HACCP system. However, our analysis of the FSA's performed at our selected very small plants found that CSO's were finding numerous noncompliance issues with pathogen reduction, sanitation, and HACCP regulations. This directive also states that when a CSI determines that an establishment does not meet one or more of the regulatory requirements, they should document this finding on a noncompliance record (NR).

In addition to the changes FSIS made to inspectors' duties, and as a result of our prior HACCP audit issued in June 2000, FSIS initiated a series of additional controls to ensure that inspectors were properly verifying that plants had implemented successful HACCP and pathogen reduction systems. FSIS initiated (1) Food Safety Correlation reviews to improve the effectiveness of inspection activities at all federally inspected plants (over

400 at the time of our audit); (2) In-Depth Verification reviews to examine plants' compliance with HACCP plan design and implementation requirements (over 80 at the time of our audit); and (3) FSA's to review the scientific basis of HACCP plans (over 1,640 at the time of our audit). The CSO's were trained in microbiological hazards, HACCP plan design, epidemiology, and statistics. In addition, FSIS provided additional HACCP training, held National Supervisory Conferences, and implemented the IPPS reviews.[5] The IPPS review system was developed over the concerns of the knowledge and abilities of inspectors to fulfill their public health assurance responsibilities when applying HACCP, SSOP, and other regulatory requirements.

Our review found that the national office had no directive on conducting FSA's or requirement to review all plants. FSIS Directive 5000.1 included a section on FSA's but it only consisted of instructions on how to complete the assessment form. There were no FSIS procedures showing that high-risk plants were or should be targeted for FSA's, or which high-risk indicators to use. FSIS had no centralized database to show the number of FSA's that had been performed, or whether the assessments were comprehensive or special (comprehensive assessments generally lasted for about a week whereas a special assessment could last only 1 day). FSIS Notice 44-02 dated November 4, 2002, required that all plants that produce raw beef products reassess their HACCP plans for *E. coli* 0157:H7 by February 4, 2003. Therefore, comprehensive FSA's performed after February 2003 included a review of the *E. coli* reassessment as part of their in-depth review of current HACCP and SSOP plans, while special assessments included only an *E. coli* reassessment. The national office could not readily determine the number of each type. Also, the national office did not have policies to direct districts to target high-risk plants or to determine whether all plants were scheduled to receive FSA's. Each district planned its own assessments and maintained copies of the assessments.

During our review, 6 of the 15 very small plants we selected had received a FSA prior to our visit. Three of these assessments appeared to be comprehensive (3 to 8 days) while the other three assessments were only one-day assessments to include a review of the plants' *E. coli* reassessment. We found that the FSA's were detailed and noted many exceptions that the FSIS inspectors had not previously noted. Details of the FSA's at the six plants follow:

> Plant A: District office personnel were unable to locate Form 5000-8, Comprehensive Assessment of the Execution and Design of an Establishments Food Safety Systems, which documented the FSA. The district office did provide a 30-day reassessment letter showing that a

[5] FSIS Directive 4430.3, issued June 17, 2002.

3-day assessment was conducted about 10 months prior to our review and resulted in 13 items of HACCP system noncompliance.

Plant D: A 4-day FSA was conducted about 9 months prior to our review. This assessment detailed numerous deficiencies with the HACCP and SSOP requirements and Sanitation Performance Standards. The assessment resulted in a Notice of Intended Enforcement Action being issued. FSIS deferred enforcement action after the plant agreed to make all necessary changes and, about 3 months later, the CSI at the plant verified that the establishment made all necessary changes.

Plant E: An 8-day FSA was performed about 5 months prior to our review. The assessment detailed several SSOP record noncompliances and numerous HACCP noncompliances, even though it was noted on the assessment that there were only two NR's written at this plant for the last 7 months, and none were for SSOP or HACCP deficiencies.

Plant F: A 1-day FSA was performed about 4 months prior to our review. The assessment detailed eight HACCP deficiencies, four SSOP deficiencies, and an *E. coli* 0157:H7 reassessment deficiency. These items were subsequently corrected and we found no HACCP or SSOP deficiencies at this plant.

Plant G: A 1-day FSA was performed about 4 months prior to our review. This assessment detailed four HACCP system deficiencies and one *E. coli* 0157:H7 deficiency.

Plant O: A 1-day FSA was performed about 13 months prior to our review. This assessment noted 2 SSOP deficiencies and 13 HACCP deficiencies, even though the FSIS plant inspector had not documented any plant noncompliances prior to the FSA.

Although our audit disclosed several exceptions at these plants, we believe we would have found many more exceptions if FSA's had not been performed. The FSIS inspectors have been trained in HACCP principles, but did not identify many plants' noncompliance with HACCP and SSOP regulations, as evidenced by subsequent CSO and our current Office of Inspector General (OIG) reviews of the plants' operations.

We assessed the IPPS reviews conducted at the plants we visited. During an individual IPPS review, supervisors could choose to review any of five main areas of the inspector's duties (verification of HACCP plan, verification of SSOPs, inspections and sampling, maintains liaison, administrative duties, and performs Am/Pm inspections) or parts thereof. Supervisors were instructed to review all main areas of the inspector's duties during the annual review period. We found that 13 of the 15 plants visited were processing

facilities where inspectors would be at the plant on a part-time basis only. They inspected several other plants during their daily inspection duties. Therefore, IPPS reviews were not performed for inspectors at some plants they were responsible for during their inspection duties. In addition, FSIS would rotate inspection duties for many inspectors, changing plants for each inspector every 4 to 6 months. The inspector on duty at a plant we visited may not have been the same inspector assessed for the last IPPS review at the plant. FSIS officials emphasized that IPPS reviews were only an evaluation of the FSIS inspector's performance and not an evaluation of the plant's performance. We found that the IPPS reviews were not effective in identifying why the inspectors were not able to identify HACCP and SSOP deficiencies that existed at the plants. Several examples follow:

Plant E: Two IPPS reviews were documented for the inspector at this plant during our review. The first IPPS review covered only procedures for the verification of SSOPs, and did not disclose any deficiencies. The second review performed 2 months later covered only procedures for the verification of HACCP plans. The supervisor noted on the IPPS Assessment Sheet that the inspector met the standards for reviewing HACCP plans and taking regulatory action, but that followup actions were needed for reviewing/verifying records, determining appropriate corrective action by plant, and determining regulatory compliance/noncompliance by the plants. The supervisor did not provide any narrative on the assessment to explain or describe the specific deficiencies. About 5 months later, a FSA on the plant disclosed several SSOP deficiencies and numerous HACCP plan and *E. coli* testing deficiencies. The inspector at the plant had not written any NR's at this plant for these types of deficiencies for the prior 7 months. Therefore, the IPPS reviews at this plant did not appear to improve the inspector or plant's performance, as evidenced by the subsequent FSA.

Plant O: The supervisor documented one IPPS review at this plant during our audit period. He covered parts of four main areas of inspector's duties during this review, and documented that he reviewed the inspector's verification of HACCP and SSOPs, including whether the inspector documents regulatory noncompliance. The supervisor found no deficiencies with the inspector in these areas and documented that the inspector was keeping a tight inspection regime on his patrol. During our review, we found that this inspector did not document NR's at this plant when he found noncompliance because the plant agreed to correct the deficiencies. This condition was in violation of FSIS policy but was not noted by the supervisor performing the IPPS review.

We concluded that IPPS reviews were not always an accurate measure of inspectors' performance at the plants we visited. Even if a supervisor noted deficiencies in an IPPS review, when the supervisor followed up on the

deficiency during the next review, the inspector may have been at a different, well-managed plant without any problems. The inspector's deficiencies could still exist, but go undetected. FSIS should consider the IPPS reviews to determine how to tie the plant's performance more closely with the inspector's performance (i.e., a poor performing plant should have more NR's and enforcement action documented than a good plant). In addition, FSIS needs to determine why inspectors are not documenting more HACCP and SSOP deficiencies when FSA's are finding many of these deficiencies.

Recommendation 1

Develop a system to ensure that FSA's are conducted at the most high-risk and needed areas, and maintain a centralized database of these assessments to ensure that coverage is adequate and conducted in the most needed areas.

Agency Response. In its June 1, 2005, response, FSIS stated:

> *FSIS conducts * * * FSAs based on risk to public health. In accordance with the food safety objectives outlined in Healthy People 2010, which include reducing infection caused by foodborne pathogens and reducing outbreaks of foodborne pathogens, FSIS targets * * * [FSA's] at high risk operations. For example, FSA's are conducted at plants that have been associated with an outbreak of foodborne illness or identified with risk associated with E.coli 0157:H7. Also, as part of its Management Control System, FSIS has documented and implemented a control activity for FSA's that establishes specific levels of performance for all assessments. * * *. Additionally, FSIS will implement a control activity and information system within its Management Control System with standard procedures for FSA's. As part of this process, FSIS is developing procedures for identifying the inherent risk of a product or process that will be used to further target all FSA's to the highest risk establishments. These standard procedures will further improve FSIS' ability to focus FSA's as the most high-risk and needed areas.*
>
> *Timeframe*
> *FSIS will establish additional control activities, including the standard procedures for Enforcement, Investigations, and Analysis Officers * * * [FSA's], by September 30, 2005.*

OIG Position. We concur with FSIS' proposed corrective actions and have accepted management decision for this recommendation.

Recommendation 2

Establish procedures to link FSA results to IPPS reviews. Utilize the results to better identify the causes of inspectors not identifying noncompliances with HACCP, SSOP, and pathogen reduction requirements.

Agency Response. In its June 1, 2005, response, FSIS stated:

> *FSIS will develop a control activity that uses information from the IPPS to align it with key food safety and food security functions. As part of this activity, supervisors will consider the results from FSA's, in addition to other measures of compliance with inspection system activities, in preparation for IPPS reviews. As part of the more fully documented Management Control System * * *, IPPS reviews are used to hold supervisors accountable for specific levels of performance in monitoring the conduct of in-plant inspection and verification activities.*
>
> *FSIS has established specific levels of performance (performance measures) for its key food safety and food security functions, to be monitored by FSIS managers through the use of an automated database. Supervisory personnel in Circuits and Districts failing to meet the established performance levels for key functions will be given feedback for improvement during performance reviews.*
>
> *Timeframe*
> *FSIS will implement control activities for the IPPS to align them with key food safety* and food security functions by September 30, 2005.

OIG Position. We concur with FSIS' proposed corrective actions and have accepted management decision for this recommendation.

Section 2. HACCP Plans Are Not Meeting Regulatory Requirements

Under the HACCP system, each establishment determines the food safety hazards that are likely to occur in their production process and establishes preventive measures to reduce or eliminate the hazards. One of the major steps in developing a HACCP plan is to develop a process flowchart. The chart should show all steps in the production process from the receipt to the distribution of the product and should be verified to ensure its accuracy. Failure of any establishment under HACCP to develop and implement an adequate HACCP plan and system may result in an FSIS determination that the plant may be producing adulterated products.[6]

During our audit, we reviewed 36 HACCP plans at 15 plants (see exhibit B) and found HACCP plan deficiencies in 9 of these plants. This is an improvement from our prior audit in which we found HACCP plan deficiencies at 14 of the 15 plants we visited. We attribute these improvements, in part, to the reviews currently being performed by FSIS.

In our review of 9 of 15 very small meat and poultry plants, we found that HACCP plans were incomplete because (1) hazard analyses did not address all hazards, (2) production process steps were omitted from process flowcharts, (3) changes that occurred in production processes were not always being included in the plans, or (4) plants were not properly monitoring CCP's in their food production processes. Many of these deficiencies occurred because FSIS inspectors, plant management, or contractors were not aware of HACCP plan requirements or inadvertently overlooked the deficiencies, and supervisory and other reviews did not identify these deficiencies. (See Finding No. 1.)

Finding 2 HACCP Plans Need Improvement

Although improvements and efforts have been made, FSIS needs to continue aggressive monitoring of HACCP implementation at the very small plants because we found that HACCP plans needed improvement. We found that plants did not meet the regulatory requirements as (1) 6 of the 15 plants visited omitted at least 1 process step from their hazard analysis, even though these steps had been listed on their flowcharts, (2) 2 of the 15 plants we reviewed had not reassessed their HACCP plans when required; and (3) at 3 of the 15 plants visited, the hazard analyses did not identify or address if food safety hazards were reasonably likely to occur in their process steps. Plant management was not always aware of HACCP plan requirements. In addition, FSIS inspectors did not thoroughly review HACCP plans. Because

[6] Title 9, Code of Federal Regulations (CFR) 417.2 (e)

hazard analyses did not always identify likely hazards or omitted process steps, there is reduced assurance that plants properly identified and provided preventive measures for the hazards.

Our review noted that in the 15 plants visited, FSIS inspectors wrote only 1 NR for actual HACCP plan deficiencies within a 1-year period. Two inspectors acknowledged that they had not reviewed their plants' HACCP plans since they had been assigned responsibility for the plants. One inspector had been at the plant for over a year and the other inspector had rotated into the plant 3 months earlier. FSIS procedures require inspectors to review plants' HACCP plans at least once a year or upon rotation, but inspectors must perform an unscheduled task to review the plans when needed. FSIS' Performance Based Inspection System (PBIS) does not assign a specific scheduled task for inspectors to assess HACCP plans on a periodic basis.

A. Production process steps were omitted from the hazard analysis and flowchart

Six of the 15 plants visited omitted at least one process step from their hazard analysis, even though these steps had been listed on their flowcharts. In addition, we found three plants with process steps listed on their hazard analysis that were omitted from their flowcharts. At two of these plants, a contractor had developed the HACCP plan for the plants without being properly trained. This occurred because FSIS inspectors had not verified the plant operations process flow to the flowchart and to the hazard analysis, and had not verified that a contractor who prepared HACCP plans had adequate training. The inspectors inadvertently overlooked these deficiencies, and supervisory and other reviews did not identify these deficiencies. FSIS officials also stated that inspectors do not certify or verify the training of HACCP plan preparers. As a result, plant management overlooked food safety hazards that existed in their production process, and failed to apply preventive measures to these hazards that increased the risk of producing adulterated products.

Federal regulations[7] state that a flowchart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified. FSIS provided a training and technical guidance manual to very small plants entitled *Your Self Study Guide to Understanding How to Develop a HACCP Plan*. As part of the training materials, plant employees are to prepare a flowchart that shows all the steps in the production process (everything from receiving through distribution), verify the flowchart's accuracy, and perform a hazard analysis for each process step. It is critical that process steps depicted in the flowchart be analyzed in the hazard analysis. FSIS inspectors

[7] 9 CFR 417.2 (a)(2)

are required[8] to verify the adequacy of the HACCP plan(s) by determining that each HACCP plan meets requirements and all other applicable regulations.

As stated in 9 CFR 417.7, only an individual who has successfully completed a course of instruction in the application of the seven HACCP principles to applicable meat or poultry product processing, including segments on the development of a HACCP plan for a specific product and record review, shall be permitted to develop a HACCP plan.

The number of plants noted with process steps omitted from either their hazard analysis or flowchart is shown below:

Table 1: Plants with process steps omitted from hazard analysis or flowchart.

Plant	Process steps omitted from hazard analysis	Process steps omitted from flowchart
A		5
C	1	
D	1	
E	4	1
I	1	
K	3	1
M	6	
Totals	16	7

Several examples of the deficiencies we noted follow:

At plant E, we found four process steps identified on the flowchart, but not addressed in their "Fully Cooked Not Shelf Stable" hazard analysis for turkey and pork products. These process steps included receiving non-meat ingredients, storage of non-meat ingredients, brine mixing, and catering. In addition, in their hazard analysis "Fully Cooked Not Shelf Stable" for cured sausage products, we found one process step (hanging) for cured beef and sausage products was addressed in the hazard analysis, but not listed on the flowchart. Plant managers agreed with these deficiencies and stated they were overlooked during their latest reassessment of the HACCP plan. The FSIS inspector had not been trained in the principals of HACCP as he had been on extended sick leave.

Plant K had two process steps (receiving and storage of meat and non-meat products) listed on their flowchart, but not addressed in their hazard analysis.

[8] 9 CFR 417.8

In addition, a third process step (returned/reworked product) was not listed on their flowchart or included in their hazard analysis. Plant management agreed with our analysis and said they would adjust their flowcharts and hazard analyses. FSIS had not conducted a FSA at this plant at the time of our audit.

We found that 4 of 15 plants had their HACCP plans developed by a contractor. In two of these plants (plants A and C), the same contractor developed the HACCP plans, SSOPs, and pathogen sampling procedures. Our review of plant records and discussions with the contractor for these two plants revealed that the contractor had not obtained the required training. The contractor stated that their knowledge of FSIS regulations and experience was the only training needed for developing HACCP plans. The contractor added that she attended a 3-day HACCP Train-the-Trainer course conducted by industry officials, but this training did not cover developing HACCP plans, SSOPs, or sampling procedures. In addition, the contractor stated that they contract with over 100 other plants.

During our review, we found deficiencies at these two plants (plants A and C) that used the same contractor. Based on our review, both HACCP plans at the two plants needed to be reassessed due to changes in the hazard analysis. Plant A had a FSA performed February 24, 2003. The review disclosed numerous deficiencies and a 30-day reassessment letter was issued to the plant on February 27, 2003. The inspectors at these two plants had not inquired whether the HACCP plan was developed by an individual with adequate HACCP training.

Our review also revealed that plant management at both plants were apparently not aware of the contents included in their HACCP plans. Plant managers said that the contractor performed a one-day "walk through", observing the plant's food processing operations, and then mailed the HACCP plan back to the plant.

B. Plant hazard analyses did not address food safety hazards

In 3 of the 15 plants visited, the hazard analyses did not identify or address whether food safety hazards were reasonably likely to occur in all of their production processes. In two cases, plant management overlooked this discrepancy during their HACCP plan reassessment. In the other case, plant management inadvertently omitted these items when they revised their HACCP plan after a FSA had been performed at the plant. FSIS inspectors did not properly review the HACCP plans. As a result, there was reduced assurance that the plants could properly identify and provide preventive measures for food safety hazards.

FSIS regulations[9] state that,

> *Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.*

Identifying and addressing food safety hazards is a critical process in ensuring that plants are not producing adulterated products. At plant D, although plant management had identified a "biological" (pathogen growth) food safety hazard in the hazard analysis for its production process step for "repackage," plant management had not identified whether the food safety hazard was likely to occur; determined if corrective measures could be applied to prevent, eliminate, or reduce the hazard to an acceptable level; or decided if a CCP was needed to control this hazard. This occurred because plant management inadvertently overlooked this discrepancy during a reassessment and revision of their HACCP plan after a FSA had been performed.

At plant F, plant management correctly identified a potential biological food safety hazard during processing, but did not establish critical limits for two of four products (pork and lamb) that the plant produces. The plant's hazard analysis showed that finished raw product maximum temperatures of 45°F and 40°F were established for beef and chicken only.

Management at plant E did not identify food safety hazards (chemical or physical) in their beef slaughter hazard analysis, or address whether these hazards were likely to occur in the "split breast and pelvis" production process step. Plant management stated that they were not aware that these food safety hazards had not been addressed in this production process step. As a result, the hazard analysis was incomplete for this process. Also, plant management identified a "biological" hazard (pathogen) for the production process step "packing and labeling," but did not address whether it was likely to occur. If it was likely to occur, plant management did not provide any corrective measures to prevent, eliminate, or reduce the hazard to an acceptable level, and therefore, a CCP would be required. The FSIS inspector had not performed an adequate review of the hazard analysis to detect any food safety hazards that were not addressed. This inspector had been on

[9] 9 CFR 417.2(a)(1)

extended sick leave and did not receive HACCP training. The circuit supervisor said he had performed numerous visits to the plant in addition to a FSA that was performed on the plant prior to our visit. However, we found none of these deficiencies were noted in the food safety report, or by the circuit supervisor in his visits.

C. Plants are not reassessing HACCP plans for *E. coli* 0157:H7 and other plant process changes

Two of the 15 plants we reviewed had not reassessed their HACCP plans as required by FSIS regulations. One of the plants had not reassessed its HACCP plan for *E. coli* 0157:H7, even though this plant produced beef and should have reassessed its HACCP plan by April 7, 2003, as required by FSIS Notice 44-02. Another plant had not reassessed their HACCP plan after a change in the implementation of product process design. At one plant, the inspector had been recently trained in the principles of HACCP, but had not received on-the-job training or close supervision. At the other plant the FSIS inspector did not ensure that the HACCP plan had been reassessed after changes in the plant's production process. As a result, FSIS could not determine whether plants have systems and controls in place designed to ensure safety of food products.

FSIS issued Notice 44-02 (November 4, 2002) that required very small plants producing raw beef to reassess their HACCP plans for *E. coli* 0157:H7 by April 7, 2003. In addition, the notice stated that plants must determine whether *E. coli* 0157:H7 contamination was a hazard reasonably likely to occur in their production process. The notice stated that, upon receipt, inspectors were to discuss its requirements with plant managers in order to verify that they understood the obligation to reassess and the timeframe in which to complete the reassessment. Plants were also required[10] to reassess the adequacy of their HACCP plan annually and whenever any changes occurred that would affect the hazard analysis or alter their HACCP plan.

During our review, we found one plant (plant A) that came under the auspices of Notice 44-02, but did not comply with its provisions. This plant, which produces beef and poultry products, had reassessed its HACCP plan, but not to determine if *E. coli* was likely to occur in their production process. The inspector (a new inspector on his first assignment) was neither aware of the notice nor was he aware that a reassessment for *E. coli* 0157:H7 had to be made on the plant's HACCP plan. The inspector had recently been assigned to the plant and, although trained in the principles of HACCP, did not understand the requirements of Notice 44-02. The inspector felt that prior reassessments performed at the plant met the requirement of reassessment for *E. coli* 0157:H7. According to this notice, if a plant failed to reassess its

[10] 9 CFR 417.4 (a)(3)

HACCP plan, the inspector should issue an NR on FSIS Form 5400-4, which was not done.

We also found that plant M should have reassessed its HACCP plan because of a production process change that occurred in its RTE products. Plant management implemented a production process to have its products marinated overnight under refrigeration before cooking. This process was occurring in 4 of the plant's 25 RTE products. We found that neither the plant's hazard analysis nor its HACCP plan was reassessed in order to identify any food safety hazards that might be likely to occur, the existence of any pathogens, or whether a CCP was necessary in order to control the pathogens. Federal regulations[11] require reassessment of the adequacy of the hazard analysis whenever a change occurs that could reasonable affect whether a food safety hazard exists. Plant managers agreed with the deficiency and noted that it was due to an oversight on their part. The FSIS inspector did not ensure that the HACCP plan had been reassessed to include the change in the plant's production process.

Recommendation 3

Include as a specific scheduled task in PBIS for inspectors to assess HACCP plans annually, or upon rotation, to ensure that timely reviews are being performed.

Agency Response. In its June 1, 2005, response, FSIS stated:

> *FSIS proposes an alternative approach in order to meet the concern identified. Establish management controls to ensure that inspectors assess HACCP plans annually, or upon rotation, and that timely reviews are being performed.*
>
> *FSIS Directive 5000.1, Revision 1, Amendment 1, Verifying an Establishment's Food Safety System * * *, addresses timely HACCP plan assessments. It is neither necessary nor practical to schedule reviews of plants' HACCP plans by Consumer Safety Inspectors because reviews are ongoing. FSIS Directive 5000.1 establishes that HACCP plan reviews are conducted on an ongoing basis as part of scheduled inspection verification procedures.*
>
> *Regular HACCP plan reviews are also reinforced in Food Safety Regulatory Essentials (FSRE) training. FSRE training covers the full range of inspection responsibilities in relation to the HACCP/Pathogen Reduction; Rules of Practice; Sanitation Performance Standards; and SSOP. CSI are*

[11] 9 CFR 417.4 (b)

trained in HACCP verification; Pathogen Reduction; and food safety sampling. CSI are instructed to use the basic compliance checklist (FSIS Form 5000-1) to review an establishment hazard analysis assessing compliance with Part 417 when in a new establishment, when an establishment adds a new product or process, or when the CSI becomes aware that a modification to an existing HACCP plan has been made. The directive and training provide instruction to CSI on actions that should be taken based on the findings of the review. In addition, CSI are instructed to review establishments' HACCP plans each time they perform HACCP verification procedures as a primary means of gathering information regarding a plant's processes and determining regulatory compliance.

*Additionally, FSIS has linked control activities and performance measures under its Management Control System * * *. The four critical constituent control activities for HACCP/Pathogen Reduction Executive are: 1) sanitation performance standards; 2) SSOPs; 3) HACCP-03 procedures; and 4) pathogen sampling. FSIS, as part of its Management Control System, has established performance measures associated with the execution of all critical control activities in order to improve accountability and strengthen public health.*

Timeframe
FSIS will implement control activities for the IPPS to align them with HACCP/Pathogen Reduction Execution by September 30, 2005.

OIG Position. We cannot accept management decision for this recommendation. FSIS Directive 5000.1, requiring inspectors to review HACCP plans annually or upon rotation, which FSIS proposes as its basis to correct the cited deficiencies, was already in effect during our fieldwork but was not adhered to by the inspectors. FSIS' response regarding the Management Control System was not specific enough to correct the cited deficiencies. In addition, FSIS' response to implement controls to align IPPS to HACCP/Pathogen Reduction execution did not specifically address a review of HACCP plans. FSIS needs to implement specific controls to ensure that required reviews of HACCP plans are conducted.

Recommendation 4

Ensure that the inspector who was at plant E, and at least one employee responsible for HACCP at each plant, has been adequately trained in the seven principles of HACCP.

Agency Response. In its June 1, 2005, response, FSIS stated:

> *FSIS will verify that the inspector who was at plant E has been adequately trained in the seven principles of HACCP. FSIS personnel responsible for inspection verification at establishments have been adequately trained in the seven principles of HACCP. Inspection program personnel are required to demonstrate proficiency in "Verification of HACCP Plans" during at least one of two mandatory IPPS assessments carried out annually by the Frontline Supervisor under the IPPS. In addition, most inspection program personnel have received or will receive FSRE training which covers responsibilities related to the HACCP/Pathogen Reduction.*
>
> *FSIS has established a control activity and performance measures under its Management Control System * * * that will enable senior managers to monitor the appropriate execution of IPPS assessments by Frontline Supervisors. This includes review by each supervisory level up to and including the Assistant Administrator of the Office of Field Operations.*
>
> *Timeframe*
> *FSIS will provide evidence that FSIS inspection personnel have been adequately trained in the seven principles HACCP by July 30, 2005.*

OIG Position. We concur with FSIS' proposed corrective actions and have accepted management decision for this recommendation.

Recommendation 5

Require the inspectors to review the HACCP training received by individual plant employees who develop HACCP plans to ensure they have been trained in the principles of HACCP in accordance with 9 CFR 417.7.

Agency Response. In its June 1, 2005, response, FSIS stated:

> *FSIS proposes an alternative approach in order to meet the concern identified: Require FSIS to verify that the plant design*

and execution of HACCP plans and SSOPs meet the principles of HACCP.

*FSIS Directive 5000.1, Revision 1, Amendment 1, Verifying and Establishment's Food Safety System * * *, contains the criteria for comprehensive verifications and assessments of all food safety systems.*

*FSIS has established a control activity and performance measures under its Management Control System * * * that will enable senior managers to monitor the appropriate executive of IPPS assessments by Frontline Supervisors. This includes review by each supervisory level up to and including the Assistant Administrator of the Office of Field Operations.*

OIG Position. We cannot accept management decision for this recommendation. FSIS' proposed corrective actions were not specific and would not resolve the noted condition. When FSIS inspectors identify noncompliances with HACCP plans, and do not review the training received by the individual who developed the HACCP plan, then the inspector may not identify the root cause of deficiencies noted in these plans. This could result in inadequate corrective actions and repetitive noncompliances. To reach management decision, FSIS officials should specifically address the recommendation.

Finding 3 — Plants' Monitoring of CCP's and Other Processes Need Improvement

Four of the 15 plants were not properly monitoring the CCP's in their food production processes. Monitoring is a fundamental part of any HACCP system and it consists of observations or measurements. Although the plants had identified CCP's in their hazard analysis and established corrective actions to be taken, we found instances where plant employees (1) did not monitor CCP's, (2) could not locate monitoring logs, and (3) did not follow monitoring frequencies as established. We identified these same conditions in our previous HACCP audit (Audit Report 24001-3-At, dated June 2000) of large and small plants, and recommended that FSIS implement a system of oversight reviews. Although these reviews, when conducted, noted numerous HACCP deficiencies, less than half of all 6,200 plants have received a review. We found plant managers and staff that were not properly trained in the principles of HACCP, and in many instances, relied on the inspector or a paid contractor to ensure that their plans and procedures complied with regulatory requirements. In addition, FSIS inspectors did not verify the adequacy of the plants' HACCP plans and CCP records, nor did they perform

adequate on-site observations or records reviews. As a result, FSIS inspectors and plant management at these four plants could not always ensure if plant's HACCP plans were effective in controlling food safety hazards, nor could they provide adequate written documentation to ensure the plant was in compliance with HACCP requirements.

Under the HACCP system, 9 CFR 417.5 requires every meat and poultry plant to maintain records that contain the actual values and observations obtained during their CCP monitoring. This information is to be contained in a formal HACCP plan and the plan should list the frequencies with which each procedure will be performed in accordance with the validation, verification, and reassessment of the HACCP plan. It also requires plants to maintain records documenting their monitoring of CCP's and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the plant's HACCP plans.

In addition, 9 CFR 417.8 requires FSIS to verify the adequacy of the plant's HACCP plan by determining that each HACCP plan meets the requirements of FSIS regulatory guidance. Such verification includes reviewing HACCP plans, CCP records, critical limits, direct observation or measurement at a CCP, or onsite observations and records review.

At plant A, we found that plant employees were not currently performing any monitoring (temperature) of the three CCP's identified in their process steps for chilling, cooking/frying, and chilling and freezing. We found many of the plant's monitoring records missing from the files and many reflecting the initials of an employee who had left the plant 3 months before our review. The inspector acknowledged that the employee had left the plant and that the records reflecting the employee's initials were not valid. Plant management also agreed that this employee left the plant 3 months prior and that these logs were not accurate. We found that the employee who recently assumed the duties and responsibilities for HACCP had not been properly trained in monitoring requirements and procedures. The recently hired inspector stated that he was unaware that monitoring checks were not being performed. The inspector visited the plant only on days in which the plant processed meat, which was only 1 or 2 days per week. In addition, we found that this plant was not performing weekly calibration of their thermometers, as required by their HACCP plan.

We found that monitoring checks were not consistently performed at plant B. Additionally, one CCP was missing from the plant's hazard analysis, and the plant's HACCP plan did not address the frequencies of verification activities, supporting decision-making documents for established critical limits, or corrective actions that should be taken for any of its three CCP's. In addition, we found very few records for any of its CCP's showing that monitoring or verification was done. The plant owner admitted that he was not able to

maintain accurate and updated files as he has no paid administrative staff. In addition, we found that the inspector had not reviewed the plant's HACCP plan in order to verify the plant was adhering to the monitoring and verification frequencies for each of the plant's CCP's. We observed that the FSIS inspector spent most of his time performing and overseeing the plant's slaughter activities instead of verifying HACCP requirements.

At plant C, monitoring logs for four CCP's were missing. On one HACCP plan "Raw Not Ground," plant officials retained monitoring logs for two CCP's for only the 2 most recent months. In another HACCP plan, "Fully Cooked Not Shelf Stable," monitoring records for process steps (cooking/smoking and cooling) were only available for one out of the past 6 months. In addition, we found that HACCP plan "Raw Ground" contained one CCP (grind meat) for which we found no monitoring logs being maintained. The plant manager noted that new forms had been recently developed in order to monitor this CCP. We also found no calibration procedures or weekly calibration forms being used to calibrate one of the plant's four thermometers. The monitoring log indicates that this thermometer was being used to monitor temperature frequencies for two of the plant's CCP's for HACCP plan "Raw Not Ground." The plant manager stated that the plant has been operating at this facility since November 2003 and files had been misplaced during their move to this new facility. The plant manager added that staff members were not trained in HACCP systems, and that he relied on the FSIS inspector and a paid contractor to keep them informed of HACCP requirements. The FSIS inspector said this was an oversight during his reviews of the HACCP plan. Supervisory and other reviews also did not identify these deficiencies. (See Finding No. 1.)

At plant I, the plant's HACCP plan did not clearly distinguish between products that do and do not fall under the monitoring requirements of the CCP. For example, the hazard analysis for the "shipping" process step stated that the product temperature should be less than or equal to 40°F prior to shipping, but product temperature was not being measured at this step. The plant manager stated that monitoring was only performed for the CCP when product was processed, not when previously processed product just passed through the plant. Our review of the plant's monitoring log found it was very difficult to determine which products just passed through the plant and which products were processed by the plant. The dates listed on the CCP monitoring log also were not legible for all temperatures taken at the receiving step. A CSO performed a review at this plant approximately 3 weeks after our review. The CSO noted deficiencies similar to our findings. The CSO issued a 30-day letter after the assessment.

Recommendation 6

Review CCP monitoring records at plant A and determine if records were accurate. If not, take appropriate administrative or enforcement actions.

Agency Response. In its June 1, 2005, response, FSIS stated:

> *FSIS will review CCP monitoring records at plant A, determine if records were accurate, and take appropriate administrative or enforcement actions if necessary.*
>
> *Timeframe*
> *FSIS will complete the review of CCP monitoring records at plant A and take appropriate administrative or enforcement actions by July 30, 2005.*

OIG Position. We concur with FSIS' proposed corrective actions and have accepted management decision for this recommendation.

Recommendation 7

Review cited plants' monitoring of CCP's and require changes at each plant to ensure they meet regulatory requirements.

Agency Response. In its June 1, 2005, response, FSIS stated:

> *FSIS will review the cited plants' monitoring of CCP's and require changes at each plant to ensure they meet regulatory requirements.*
>
> *Timeframe*
> *FSIS will complete the review of the cited plants' monitoring of CCP's and require changes at each plant to ensure they meet regulatory requirements by July 30, 2005.*

OIG Position. We concur with FSIS' proposed corrective actions and have accepted management decision for this recommendation.

Section 3. FSIS Oversight of SSOPs Needs Improvement

FSIS oversight and verification over SSOP needs to be improved to make certain that meat and poultry products are free from adulteration and contamination. FSIS records, and our visual inspections, showed that plants (1) did not have adequate SSOP procedures, (2) did not maintain proper records to show that SSOP procedures were followed, and (3) had repetitive noncompliance deficiencies that were not corrected. This occurred because (1) FSIS inspectors did not verify the adequacy of the SSOP plans, (2) plant management did not follow the SSOP plans, or (3) plant management did not develop adequate corrective action to resolve noncompliances. Consequently, there is reduced assurance that SSOPs implemented by the plants were effective.

In the prior HACCP audit report (Audit No. 24001-3-At, dated June 2000, Finding 11), we reported that at 6 of the 15 plants, the SSOP plans were deficient. We recommended that FSIS ensure that inspectors routinely evaluate the effectiveness of SSOPs, and require changes and modifications to plants' SSOP plans when needed. FSIS agreed to reinforce inspector's authorities in relation to the SSOPs through better communication and training, national supervisory conferences, and work unit meetings.

During our review of FSIS and plant records, and visual inspection at the 15 very small plants, we found some of the same repetitive SSOP noncompliances the inspectors and plant management found in the past. The noncompliances included food particles left in machinery and equipment, dripping condensation, flaking paint over product processing areas, improper storage of product, and live rodents.

A sanitary environment is a basic prerequisite for preparing safe foods. Following an established and effective SSOP 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. We reviewed SSOPs at the 15 plants we visited and found that 10 of these plants contained deficiencies.

Finding 4 Plants' SSOP Plans and Monitoring Records Were Inadequate

At 6 of the 15 plants, we found that SSOP plans or monitoring records were inadequate. At 3 of these plants, SSOP plans did not address needed sanitation operation procedures, specify the frequency of procedures, or have suitable forms for recording deficiencies. Another three plants did not adequately document their monitoring of these procedures. The inspectors did not sufficiently review the SSOP plans before the plants put them into

effect, or sufficiently review the plant's monitoring records. The FSIS inspectors overlooked performing tasks to review the SSOP plans or monitoring records, and supervisory or other reviews did not identify these deficiencies. (See Finding No. 1.) Without adequate procedures or monitoring records, there were few assurances that plants were effective in producing meat or poultry products in a sanitary environment.

Title 9, CFR 416.17 provides that FSIS shall verify the adequacy and effectiveness of the SSOPs and the procedures specified therein by determining that they meet the requirements of this part.

FSIS Directive 5000.1, chapter I, part XVII states, in part, that plants shall maintain daily records sufficient to document the implementation and monitoring of SSOPs and any corrective actions taken. The SSOP plans require the plants to document their monitoring of the sanitation procedures performed before and during the processing of the product. Properly maintained monitoring records would indicate that the plant is following the procedures, as outlined in the SSOP plan.

Details of inadequate SSOP procedures follow:

At plant A, the SSOP plan pre-operational procedures did not adequately address the cleaning of surfaces, equipment, and utilities. The cleaning and sanitizing procedure annotated in the SSOP procedure was "Remove heavy meat pieces from equipment as much as possible." This procedure was not specific enough to meet regulations. The inspector had issued two NR's during the three months prior to our review involving the inadequate pre-operational cleaning of equipment. Although plant management agreed to clean the affected equipment, there was no corrective action to address the SSOP procedures.

At plant I, the pre-operational inspection form did not provide for or instruct the plant employees to monitor overhead structures and walls and did not have entry spaces for preventive measures. The plant did not report any deficiencies involving overhead structures and walls. However, the inspector reported on NR 27-2003-2139, dated June 9, 2003, that the upper part of the rails used to hold exposed product had a moderate to heavy buildup of flaking and chipping paint. Exposed product was directly below this condition. The plant responded to the NR by stating that the rails would be checked weekly and flaking paint would be removed; however, the pre-operational inspection form was not revised to show the stated preventive measure. Therefore, plant management had no documentation to support that these reviews were performed.

At plant K, the SSOP plan did not specify the frequency of each SSOP procedure. For example, the walk-in freezer is to be cleaned with approved cleaning agents and rinsed with potable water. However, the SSOP plan does not provide how often the freezer should be cleaned. There was no indication as to how often the plant management cleaned the freezer.

During our review of NR's written by FSIS inspectors at the 15 plants we visited, we found that FSIS inspectors documented only 1 NR for inadequate SSOP plans. One FSIS official stated that assessing SSOP plans is not a scheduled task in PBIS and inspectors may have overlooked performing this task on a regular basis. FSIS Directive 5000.1, part XII, states, in part, that the plant is responsible for developing, maintaining, and implementing written SSOPs, and the inspector performs procedures to verify that SSOPs meet regulatory requirements. However, the Directive adds that the inspector determines when it is necessary to perform this procedure.

Plants Are Not Maintaining Adequate SSOP Monitoring Records

Details of plants not maintaining adequate SSOP monitoring records follow:

Plant B did not properly maintain documentation for its recordkeeping system for monitoring the SSOP. There were only 12 Operational Sanitation of Facilities, Equipment, and Personal Hygiene forms on file for the monitoring tasks performed each day between January 28, 2003, and November 25, 2003. The documentation for the monitoring of tasks performed on the other dates was missing. In addition, records do not identify the corrective actions taken on deficiencies or whether any deficiencies were corrected. Plant C did not identify the employees who were to maintain or perform the SSOP procedures. Plant E did not have a log to document the changes the plant made in its monitoring of the SSOPs.

Recommendation 8

Include a scheduled task in the PBIS system for assessing SSOP plans to ensure this task is performed on a regular basis.

Agency Position. In its June 1, 2005, response, FSIS stated:

> *FSIS proposes an alternative approach in order to meet the concern identified: Establish management controls to ensure that SSOP plans are assessed on a regular basis.*
>
> *FSIS Directive 5000.1 * * * addresses regular assessments for SSOP plans. Regular SSOP plan reviews are also reinforced in FSRE training. CSI perform PBIS Procedure 01A01 to verify that an establishment's written sanitation SSOP meet regulatory*

requirements. Establishments are required to have adequate SSOP in place at the time inspection is granted. Thereafter, CSIs may perform procedure 01A01 as needed to verify SSOPs and any modifications to them. Inspection program personnel are also instructed to review the SSOPs to become knowledgeable of the plants' written procedures each time they perform verification procedures associated with SSOPs.

*Additionally, FSIS has established under its Management Control System * * * the control activity "SSOP-PBIS 01 and 02 Procedures," as well as specific performance measures for inspection program personnel to: (1) monitor the review of SSOP plans, (2) ensure that all deficiencies are documented on a noncompliance record and, (3) verify that an establishment has made an appropriate response to the deficiencies noted. Specific emphasis is placed on the verification of 9 CFR 416.4 requirements*

Timeframe
FSIS will implement control activities for the IPPS to align them with regular assessments of SSOP plans by September 30, 2005.

OIG Position. We cannot accept management decision for this recommendation. FSIS Directive 5000.1, requiring inspectors to review SSOP plans as needed, was in effect during our fieldwork but was not adhered to by the inspectors. FSIS' response regarding the Management Control System was not specific enough to correct the cited deficiencies. In addition, FSIS' response to implement controls to align IPPS to assessments of SSOP plans did not specifically address the cited deficiencies. FSIS needs to implement specific controls to ensure that required reviews of SSOP plans are conducted.

Finding 5 — FSIS Continues to Issue Repetitive NR's Without Requiring Adequate Corrective Action or Taking Further Enforcement Actions

Plants did not make effective changes in their SSOPs to reduce repetitive deficiencies reported by FSIS inspectors and plant management. In 7 of the 15 plants, we found the same, or similar, SSOP deficiencies that were previously documented in NR's and plant's preoperational and operational inspection records. Plant management did not develop effective corrective actions in their SSOP to eliminate the deficiencies. FSIS inspectors continued to issue NR's for the same deficiencies, without requiring adequate corrective action, and did not implement further enforcement actions. The repeated

deficiencies could result in contamination and adulteration of the meat and poultry products and place consumers at risk.

The FMIA and PPIA both established that a meat or poultry product is adulterated if it has "been prepared, packed, or held under unsanitary conditions whereby it may become contaminated with filth, or whereby it may have been rendered injurious to health." When FSIS personnel inspect the grounds, facilities, and equipment at meat and poultry plants they are looking for these unsanitary conditions. Each time unsanitary conditions are disclosed, inspectors are to document the noncompliance on the NR (FSIS Form 5400.4).

FSIS Directive 5000.1, chapter IV, part 1 provides that the inspector should describe each noncompliance in clear, concise terms, including the exact problem, its location, and the effect on product. If there is a trend of noncompliance developing, and the current NR is linked to previous NR's, the inspector should list the previous NR's with the similar noncompliance from the same cause. The NR should state which corrective actions were proposed, and that these actions were ineffective or not implemented. If this developing trend has been discussed with the plant management, this information should also be documented on the NR form.

We found the following conditions:

At plant A, we observed a repetitive non-compliance condition in that a live rat was on the plant's floor. We pointed the rat out to a plant employee who promptly trapped and killed it. We informed the inspector when he arrived what had happened. The inspector immediately stopped production at the plant based on instructions from the circuit supervisor. The inspector tagged the plant and required plant management to examine all products, packages, boxes, and containers and to have the plant exterminated, and determine how the rodents were getting into the plant.

The next day, while conducting the exit conference, we noted another rat on a light fixture. The circuit supervisor, who was also in the meeting, informed the plant owner that the plant would remain closed until the rodent problem was corrected.

Upon our visit, we reviewed the NR's for this plant. FSIS inspectors previously reported that the plant had rodent problems. The inspector issued two NR's during the current year citing rodent droppings and dead mice in both cases. In the previous year, two other NR's were issued for mice infestation. The inspector's records showed that neither the inspector's monitoring nor the plant's corrective actions had resolved the rodent problem.

The inspector on duty at the plant had little experience as an inspector. He completed his inspector's training and reported to the plant just three months prior to our visit. This was his first assignment.

We noted the following during our review of six other plants:

Plant	No. of NR's Issued in 2003	No. of Repetitive NR's Issued	Conditions Disclosed
F	77	7	Repetitive NR's were issued for unsanitary conditions that included inadequate cleaning and monitoring practices. Our walk-through at the plant disclosed some of the same unsanitary conditions previously reported by the inspectors. The inspectors previously issued six similar NR's during 2003.
H	22	3	Three NR's were issued in calendar year 2003, identifying meat particles that had been repeatedly left in saws, drains, and floors. Our walk-through of the plant disclosed fat residue on saws and tables, as reported on previous occasions. We also observed product on pallets on the loading dock being surrounded by birds. The inspector had cited similar conditions twice during 2003.
I	22	4	The inspector issued an NR for flaking paint on a fixture in the processing area during our preoperational review. The inspector had previously issued three similar NR's during 2003.
J	28	10	The inspector issued 10 NR's identifying meat particles being repeatedly left in saws, drains, and on floors.
K	28	4	The inspector issued NR's related to meat particles on equipment, utensils, and machinery.
N	35	10	The inspector issued NR's identifying grease, mold, and food particles located in the belts of equipment and utensils.

Recommendation 9

Establish definitive guidelines to ensure that both short-term and permanent corrective action is required and implemented when repetitive deficiencies are found at plants, and take further enforcement actions on repetitive deficiencies.

Agency Response. In its June 1, 2005, response, FSIS stated:

> *FSIS has already established official policy in the form of FSIS Directive 5000.1 to verify corrective action. * * * As evidenced by over 400 administrative actions taken within the*

last year, FSIS does implement further enforcement action on violations of law including repetitive deficiencies. The standard for determining that further enforcement action are necessary is proof that product has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health. In-plant inspection program personnel, frontline supervisors and District personnel all have a role in this determination. Repeating deficiencies of a low hazard nature that are acted upon at the time of occurrence do not meet the burden identified above for further enforcement action.

*FSIS, as part of its Management Control System * * * has established a performance measure associated with all documented noncompliance records that requires "100% verification of establishment's responses to an NR."*

OIG Position. We cannot accept management decision of this recommendation. FSIS Directive 5000.1 was in effect during our audit review and did not resolve the deficiencies noted. In addition, the cited performance measure in the Management Control System will only ensure that the plant responds to an NR, not the adequacy of the response.

Section 4. FSIS Should Improve Guidance Over Inspector Activities

FSIS needed to provide additional guidance to inspectors over inspection activities, specifically with the accuracy and reviews of plants' profiles and the timelines of corrective actions taken on NR's. Because of incorrect plant profiles and Pathogen Reduction Enforcement Program (PREP) eligibility reports, FSIS inspectors did not perform sufficient sampling at 1 of the 15 plants, and at a second plant, plant profiles generated sampling tasks which were not required at the plant. We also found that at 3 of the 15 plants, plant management had not timely responded to NR's to show corrective actions were taken and/or adequate.

Finding 6 Improvements Needed in Codes on Plant Profiles

FSIS did not perform sufficient sampling at 1 of the 15 plants, and at a second plant, sampling tasks were generated for inspectors that did not apply to the plant. This occurred because FSIS officials were not ensuring that accurate Inspection System Procedures (ISP) codes for FSIS sampling were included in the plant profile. The inspectors overlooked performing a task to review plant profiles at least annually or upon rotation, as required, or had not adequately reviewed and updated an eligibility report to accurately reflect the plants operations. As a result, a plant produced meat products without being subjected to sufficient testing. Further, FSIS scheduled sampling tasks at a plant that were not required at this plant.

Inspectors complete plant profiles that generate ISP codes that identify the inspection tasks to be performed by inspection personnel. These codes are part of FSIS' PBIS. One component of PBIS schedules and generates ISP codes that identify work to be performed by inspectors. The 05 series relates to microbiological sampling, and in some instances the codes listed on the plant profiles were not accurate based on the plant's operation. ISP codes for each plant were listed on the establishment/shift inspection procedure worksheet (FSIS Form 5400-5). These codes were fed into FSIS' PREP database where Salmonella sampling units were selected. FSIS Directive 5400.5 states that "Inspection program personnel are to review the preprinted FSIS Form 5400-5 for each establishment at least annually and upon rotation to assure that there is a plan for every shift and that the plan accurately reflects the operations that the establishment currently conducts during that shift."

Title 9 CFR 310.25(b) and 381.94(b) requires that plants that produce the following raw meat products (steers/heifers, cows/bulls, ground beef, hogs, broilers, ground chicken, ground turkey) are subject to the pathogen

reduction performance standards for Salmonella. These standards provide a direct measure of progress in controlling and reducing the most significant hazards connected with raw meat and poultry products.

We found that the plant profile for one plant we visited should have shown that it was subject to Salmonella testing. However, the ISP code was not included in the plant profile worksheet to generate the task that instructed inspection personnel to perform the Salmonella tests. Plant J produces ground beef and the plant profile for the plant did not include the 05A03 code. This code specifies that inspectors are to collect samples from applicable products for Salmonella testing. Our review of plant and FSIS records and interviews with plant and inspection personnel disclosed that the Salmonella testing was not performed at this plant.

At plant J, the inspector stated that the plant profile worksheet did not list the ISP code requiring Salmonella testing. He said that he is responsible for two other plants that grind beef and that Salmonella testing is performed at those plants. He added that he did not know why the testing was not performed at this plant, but he felt that there was no reason to perform testing at this plant because it was well maintained and clean. He also said that he did not closely review the plant profile for accuracy upon his rotation to this plant.

Plant F received and processed raw meat, mainly hamburger patties, but did not conduct slaughter activities. The plant profile worksheet indicated that the plant was subject to ISP code 05A01. This code was used in slaughter facilities to verify that plants have written procedures in place for collecting samples for *E. coli* testing and were following these procedures. Plant F was not required to test for *E. coli*; therefore, this code should not have been included in the plant's profile. The FSIS inspector responsible for this plant agreed that the profile should not list this code. The inspector added that the plant profile was not reviewed for accuracy since they had assumed responsibility for this plant approximately 3 months earlier because they overlooked performing this task.

At the exit conference, FSIS officials stated that the plant profile is used for testing of Listeria and Salmonella in RTE products, and for *E. coli* 0517:H7 in raw ground beef. However, they added that Salmonella testing for raw meat products is driven by their PREP database, which is updated by an eligibility report that is generated from the database and sent to the field for verification. FSIS officials did not provide information on how the original entries are entered into the PREP databases, or if the plant profile information is used for this purpose.

Recommendation 10

Review the testing deficiencies noted at the cited plants and determine the causes of the deficiencies noted. Develop and implement guidance to ensure that plant profiles and any other documents causing the deficiencies are reviewed at least annually and upon rotation (within the first month).

Agency Response. In its June 1, 2005, response, FSIS stated:

> *Plant profiles do not determine microsampling scheduling for Salmonella in raw products. Sample scheduling is based on inspector input on eligibility reports. FSIS Directive 5400.5, Inspection System Activities, implements a policy to ensure that plant profiles are reviewed at least annually and upon rotation (within the first month). * * *.*
>
> *Timeframe*
> *FSIS will complete the review and correct an identified deficiencies by September 30, 2005.*

OIG Position. We concur with FSIS' proposed corrective actions and have accepted management decision for this recommendation.

Finding 7 FSIS Inspectors Are Not Reviewing Open NR's on a Daily Basis to Ensure Prompt and Adequate Corrective Action

During our review of 15 plants, we found that 3 inspectors did not review open NR's on a daily basis, as required. Plant management did not respond to the NR's as to the corrective actions or further planned actions they would take to bring the NR deficiencies into compliance in a timely manner. The inspectors said that they did not timely follow up on the open NR's because they overlooked these reviews. Subsequent supervisory or other reviews also did not identify these deficiencies. This condition was noted in a prior HACCP audit report, dated June 2000, and remains unresolved. We also found at one plant that the inspector had not written any NR's in calendar year 2003 because the inspector did not feel that writing NR's was an effective method of addressing problems at the plant. As a result, timely actions may not have been taken on deficiencies that could result in processing products that could be harmful to consumers.

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 an NR (FSIS Form 5400.4). There are no specific timeframes in place that instruct plant management to respond to NR's. However, FSIS Directive 5400-5 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. FSIS Directive 5400.5, XI.A.2 states that until an establishment has brought itself into compliance with the regulatory requirement(s) that resulted in issuance of an FSIS Form 5400-4, the form is "open." Inspection program personnel are to review the file of "open" FSIS Form 5400-4's daily.

In the prior HACCP audit report (Audit No. 24001-3-At, dated June 2000, Finding 14) we found that plants did not always promptly respond to NR's or take timely corrective actions. We also found numerous repetitive critical deficiencies with the same cause, where permanent corrective actions had not been taken or enforcement actions initiated. We recommended that FSIS 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. Also, we recommended that FSIS establish timeframe requirements for responding to NR's and initiating planned corrective actions. FSIS replied that it did not find it advisable to establish specific timeframes. FSIS believed its current regulations hold plants accountable for initiating and implementing corrective actions. FSIS did not agree to add timeframes for responding to NR's, but it agreed to reinforce inspection personnel responsibilities for monitoring and evaluating corrective actions.

Details of our current observations follow:

At plant A, the plant management did not timely respond to 3 of the 12 NR's issued during our audit period (Nos. 4-2003-48, 9-2003-4485, and 10-2003-4485). Plant management had not responded to two of the NR's (over 45 days) when we left the plant, and it took plant management over 30 days to respond to the other NR. The inspector said that the NR's were not immediately responded to because he forgot to follow up on, and track, the open NR's**.**

NR No. 4-2003-48 described numerous sanitation deficiencies in the Description of Noncompliance Section; it described that a chill cabinet in the kitchen was in need of repair and had some old residue. The plant's immediate action was to correct the noted sanitation deficiencies. The packaging operation line was stopped until employees cleaned the area. Management replied that it would do its best to take care of the deficiencies and make sure they did not happen again. They added the chilling cabinet would be fixed but did not show a target date. Plant management did not

respond to the NR until 31 days later. However, the inspector did not subsequently sign the NR showing that he approved the corrective actions taken by plant management.

The other two NR's were as follows:

Date	Deficiency	Plant Action
October 17, 2003	NR Record No. 9-2003-4485 reported that (1) The inspector had not seen evidence of any environmental or product testing or trends, (2) Ready-To-Eat product was not easily distinguished, (3) Ready-To-Eat and Not Ready-To-Eat had similar, if not identical cooking instructions, (4) the plant layout was not clearly defined, and (5) raw traffic and cooked traffic were not clearly defined.	The NR was still open as of December 1, 2003, and no corrective actions had been documented.
October 31, 2003	NR Record No. 10-2003-4485 reported that the inspector reviewed the plant's HACCP plan for the weekly calibration of thermometers and noted that the last entry on the form was made on September 22, 2003. The inspector noted that this was a 5-week period where no thermometer checks were performed or recorded.	The NR did not show a response from plant management. The NR was still open as of December 3, 2003, and no corrective actions had been documented.

The inspector documented that he informed plant management in writing and verbally of the deficiencies. He said that he did not follow up on the three open NR's because of his lack of knowledge due to his having been only recently hired as an inspector.

At plant B, plant management had not timely responded to five of the nine NR's written by the inspector. These NR's were still open at the time of our review on December 10, 2003. There were no indications that corrective actions were taken on any of the deficiencies. The five NR's are listed below:

Date	NR Number	Deficiency
September 3, 2003	4-2003-3407	The NR reported that the inspector observed a hog carcass in the freezer without markings. The carcass should have been marked "Not For Sale."

Date	NR Number	Deficiency
October 1, 2003	5-2003-3407	The NR reported that the inspector observed the owner wipe down water that had splashed on the ceiling and rail from the legging area to the carcass wash area after the preoperational inspection and did not record on the sanitation record the corrective actions taken. The inspector said that plant management should record any corrective actions taken as a result of the preoperational sanitation inspection.
October 17, 2003	6-2003-3404	The NR reported that the inspector observed condensation dripping from the refrigeration unit in the carcass cooler. No adulteration was detected. The inspector reported that he observed the same condition days prior and reported that corrective action given by plant management at the time was ineffective.
November 4, 2003	7-2003-3314	The NR reported that the inspector observed the SSOP preoperational inspection log form being re-used 3 or 4 times and the results were not always entered.
November 6, 2003	8-2003-3314	The NR reported that the inspector noticed that the ceiling of the door entrance that connected the kill floor to the edible room was crumbling when touched.

The inspector at plant O did not write any NR's during calendar year 2003. The inspector at this plant said that writing NR's would not improve on how well the plant manages its HACCP plans. He added that he found some noncompliances and orally told them to plant management who then immediately took appropriate corrective action. He said that he did not see the need to write NR's in such cases. The supervisory veterinarian medical officer, acting for the circuit supervisor, said that NR's should be written to document all noncompliances.

FSIS officials stated that plants are not currently required to respond to NR's; that plants are only required to respond to regulatory deficiencies in a timely manner. FSIS needs to improve controls to ensure that ongoing deficiencies are corrected and documented in a timely manner.

Recommendation 11

Establish and implement policies to assure that inspectors timely monitor plants' corrective actions to NR's and document NR's when the plant management has taken appropriate actions to address the noted deficiencies.

Agency Response. In its June 1, 2005, response, FSIS stated:

> *FSIS Directive 5000.1 defines procedures to verify compliance with regulations 417.3, 416.15, and the sanitation performance standards. Although it is the plant's*

responsibility to respond to a noncompliance, FSIS, as part of its Management Control System, has established a performance measure associated with all documented noncompliances that requires "100% verification of establishment's responses to an NR." This system ensures that inspectors timely verify plants' corrective actions to NR's and document NR's when the plant management has not taken appropriate actions to address the noted deficiencies.

Timeframe
FSIS will implement control activities for the IPPS to align them with key food safety and food security functions by September 30, 2005.

OIG Position. We concur with FSIS' proposed corrective actions and have accepted management decision for this recommendation.

Recommendation 12

Require district or supervisory personnel to conduct trend analysis and review of the timeliness of NR's under their purview.

Agency Response. In its June 1, 2005, response, FSIS stated:

*District Analysts' responsibilities include trend analysis of establishment compliance with regulatory requirements. The District Analyst position was established in July 2004. The position description * * * [has been] provided * * *. Verification of corrective action including timeliness is a performance expectation for Public Health Veterinarians and CSI that is assessed as part of the performance of IPPS.*

OIG Position. We concur with FSIS' proposed corrective actions and have accepted management decision for this recommendation.

Recommendation 13

Direct the cited inspector at plant O to document instances of noncompliance so that a written history is developed for all noncompliance, and corrective actions taken on the noncompliance. Also, FSIS should implement supervisory oversight sufficient to ensure the cited inspector is properly performing inspection duties.

Agency Response. In its June 1, 2005, response, FSIS stated:

> *FSIS, as part of its Management Control System, has established a performance measure associated with all documented noncompliances that requires "100% verification of establishment's responses to an NR."*
>
> *FSIS is revising IPPS to align it with key food safety and food security functions of the Management Control System. FSIS will conduct IPPS Reviews to hold supervisors accountable for specific levels of performance through IPPS reviews. Performance measures for the key food safety and food security functions have been established and will be monitored by senior managers through the use of an automated database.*
>
> *Additionally, FSIS will direct the cited inspector at plant O to document instances of noncompliance so that a written history is developed for all noncompliance, and corrective actions are taken on the noncompliance.*
>
> *Timeframe*
> *FSIS will review all instances of noncompliance at plant O and ensure that necessary corrective actions are taken by September 30, 2005.*

OIG Position. We concur with FSIS' proposed corrective actions and have accepted management decision for this recommendation.

Section 5. FSIS and Plant Management Need to Place Greater Emphasis on Plant Security

Finding 8 Plant Security Measures Need Improvement

During our review of the 15 plants, we found that none of them had developed or implemented formal security plans. FSIS has issued and distributed security guidelines to meat and poultry processing plants, but has not mandated required procedures that plants must implement. A failure to provide adequate security over meat and poultry products could result in accidental or intentional contamination of the food supply.

Since the terrorist attacks on September 11, 2001, there is increased concern regarding the security and safety of our nation's food supply. It is believed that terrorists could attempt to attack our nation by introducing chemical or biological agents into the food supply system. Meat and poultry processing plants are one point of entry at which terrorists could access the system. A publication issued by the World Health Organization stated that a terrorist attack aimed at our food supply system is a real and current threat.

One of the most concerted efforts made by FSIS to ensure a safe food supply was the implementation of FSIS Directive 5420.1, "Homeland Security Threat Condition Response – Food Security Monitoring Procedures." The directive provides inspectors with specific tasks to perform based upon heightened threat conditions as issued by the Department of Homeland Security. These actions are substituted in place of regular scheduled tasks, and provide inspectors with tasks aimed directly at ensuring that there are no breaches in the security of a plant that could lead to threatening conditions.

Along with this directive, FSIS issued "FSIS Security Guidelines for Food Processors." These guidelines were provided to meat and poultry plants. The suggestions made in this publication were not mandated by FSIS, but offered some guidance for processors who wanted to take a proactive approach to food safety.

Examples of suggestions made to the plants were:

- Identify a food security management team and a food security management coordinator.
- Develop and implement a food security plan using established risk management principles.
- Conduct regular food security inspections of the facility.

- Post “No Trespassing” signs at the plant boundaries.

- Restrict access to production and holding areas to plant employees and FSIS personnel.

In February 2003, GAO issued a report (Report No. GAO-03-342) on Food-Processing Security: Voluntary Efforts Are Under Way, but Federal Agencies Cannot Fully Assess Their Implementation. This report details how existing food safety statutes do not specifically authorize the Food and Drug Administration or the U.S. Department of Agriculture (USDA) to require food processors to implement any type of security measures designed to prevent the intentional contamination of the food they produce. USDA’s general counsel did conclude that to the extent that security precautions pertain to activities closely related to sanitary conditions in the food preparation process, FSIS has the authority to require food processors to implement certain security measures. The general counsel concluded that FSIS could require facilities to develop and maintain a food security management plan concerning their response to an actual threat involving product tampering, since this is directly related to food adulteration.

In our review of very small plants, we evaluated the level of security employed at each of the plants. Our goal was to determine what additional security measures, if any, the plants and FSIS had implemented since the attacks. Based on our review of procedures, FSIS had not imposed any requirements on plants to develop and implement formal security plans and procedures.

We requested the security procedures at the 15 very small plants we visited and found that none had developed or implemented a formal security plan. We questioned plant managers about their security procedures and some of them said that they have a heightened awareness of security issues, but had not developed a formal plan.

At 8 of the 15 plants, plant management had implemented at least one effective security measure. Five plants secured plant entrances at all times. Three of these plants, along with three others, are secured by fences. Of the five plants with secured plant entrances, two plants also had signs posted prohibiting trespassers; and one plant was using security cameras. The general manager at plant C stated that he was in the process of developing a security plan that would include security cameras and security guards positioned at the entrances. He hoped to have this plan implemented next year. None of the plants we visited were using security guards or dogs (see exhibit C).

During our visit we observed the security practices of the plants and found these vulnerabilities:

- The main receiving door at plant F was left opened and unattended for extended periods of time.

- Unprocessed product was left unattended on the loading dock at plant H, and could have been accessed by anyone.

Figure 1 - OIG photo of product left on dock at plant H.

Based on our review of FSIS and plant security practices, FSIS has made valuable recommendations to plants; however, they did not require plants to implement these recommendations. We understand that FSIS' security guidelines must be weighted against the cost/benefit of the plants' production processes; however, FSIS should establish minimum security requirements that plants must meet to more adequately protect our food supply.

FSIS recently revised Directive 5420.1 in January 2005 to include specific procedures for inspectors to perform when a threat condition of yellow, orange, or red is declared by the Department of Homeland Security, even when a specific food safety threat was not made. While we acknowledge FSIS' proactive measures in this area, we continue to assert that plants should be required to develop and implement written security plans to prevent deliberate product adulteration.

Recommendation 14

Establish minimum security requirements for plants that include a written security plan and actions to prevent deliberate product adulteration.

Agency Response. In its June 1, 2005, response, FSIS stated:

> *A proposed rule that would mandate food security plans in all official establishments and provide for special verification activity by FSIS during a heightened food threat event is on FSIS' regulatory agenda. Meanwhile, FSIS is encouraging voluntary development of food security plans. To assist establishments, especially small and very small establishments, in developing food security plans, FSIS will conduct a series of training workshops throughout the nation by May, June, and July 2005. The workshops will assist plants with food security awareness and in the development of their food security plans. Tools such as the Model Food Security Plans, FSIS Industry Self-Assessment Checklist for Food Security, and FSIS Directive 5420.1, Revision 1, Food Security Verification Procedures * * * will be addressed during the workshops.*

OIG Position. We cannot accept management decision for this recommendation. FSIS officials state that a proposed rule mandating food security plans is on their regulatory agenda, however, no estimate timeframes were given for when this action will be pursued and completed. To accept management decision for this recommendation, we will need estimated timeframes for implementing the proposed rule.

Scope and Methodology

OIG performed the audit work at the FSIS national Office in Washington, D.C.; three district offices (Albany, New York; Atlanta, Georgia; and Philadelphia, Pennsylvania); and 15 plants located in Connecticut, Florida, Georgia, Massachusetts, New Jersey, New York, Pennsylvania, and Rhode Island (see exhibit A). The plants visited included 14 plants that processed meat products and 2 plants that slaughter livestock (1 of these 2 plants also processed meat products). We reviewed FSIS policies and procedures at the national and district offices visited. Our reviews at the plant locations included evaluations of the plants' written SSOPs, HACCP plans, pathogen testing procedures, and responses to FSIS NR's. Our evaluation of HACCP plans included an indepth review of all plans in effect at the 15 plants visited (see exhibit A). We also toured the plant locations and observed plant operations, including operational cleanup procedures and monitoring activities at the designated CCP's. 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 by selecting plants that FSIS records showed were both problem plants and ones that were operating satisfactorily. In making our selections we considered the number of noncompliances cited by inspectors, assigned tasks not performed, animals slaughtered, products processed, and geographical areas.

Fieldwork was conducted during the period October 2003 through July 2004. We conducted this audit in accordance with Government Auditing Standards.

To accomplish our audit objectives, we performed the following fieldwork.

- We analyzed documents and conducted interviews with FSIS Headquarters officials, district office officials, inspectors, and plant management.

- We reviewed FSIS' regulations, instructions, procedures, studies, published reports, media releases, FSA, IPPS reviews, *E. coli* reassessments, and GAO audits.

- We conducted site visits to the FSIS national Office, district offices, and industry plants for review and analysis.

Exhibit A – Plants Selected for Review

District Number 60 – Philadelphia, Pennsylvania

Plant A	Pennsylvania
Plant B	New Jersey
Plant C	New Jersey
Plant D	Pennsylvania
Plant E	Pennsylvania

District Number 65 – Albany, New York

Plant F	New York
Plant G	New York
Plant H	Connecticut
Plant I	Massachusetts
Plant J	Rhode Island

District Number 85 – Atlanta, Georgia

Plant K	Georgia
Plant L	Georgia
Plant M	Florida
Plant N	Florida
Plant O	Florida

Exhibit B – Number of HACCP Plans Reviewed

HACCP Category	Number of HACCP Plans Reviewed
Raw - Ground	9
Raw - Not Ground	10
Thermally Processed - Commercially Sterile	0
Not Heat Treated - Shelf Stable	0
Heat Treated - Shelf Stable	3
Fully Cooked - Not Shelf Stable	9
Heat Treated not Fully Cooked - Not Shelf Stable	3
Secondary Inhibitors - Not Shelf Stable	0
Slaughter	2
Total	**36**

Exhibit C – Security Measures at Very Small Plants

Plant	Formal Plan	Secured Doors	Security Cameras	Fences/ Gates	Security Guards	Signs Prohibiting Trespassers	Guard Dogs
A		X		X			
B							
C				X			
D							
E							
F				X			
G							
H							
I							
J		X		X		X	
K		X					
L		X					
M				X			
N		X	X	X		X	
O							

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

JUN - 1 2005

TO: Robert W. Young
Assistant Inspector General for Audit
Office of Inspector General

FROM: Barbara J. Masters
Barbara J. Masters
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Official Draft Audit Report – Hazard Analysis and Critical Control Point Implementation at Very Small Plants, Report No. 24601-5-AT

We appreciate the opportunity to review and comment on this report. The Food Safety and Inspection Service (FSIS) has continued to strengthen its Hazard Analysis and Critical Control Point (HACCP) system. FSIS has updated its policies, procedures, and guidelines; provided supplemental training for inspection program personnel; and established performance measures to increase accountability and oversight to ensure a safe and wholesome food supply and protect the public health.

The report identified several establishments where improvements could be made based on an audit conducted from October 2003 to July 2004. Since this time, the Agency has strengthened management controls for monitoring plant operations and inspection program personnel performance in order to better ensure public health.

The findings in the OIG report are not representative of small and very small plants across the country. Two of the 15 plants selected for the audit were slaughter facilities, and the rest were processing facilities. Together, the two plants slaughtered 7850 animals in fiscal year 2003. All small and very small plants slaughtered a total of 1,151,565 animals during fiscal year 2003, so the two plants selected for the audit represent approximately 0.7 percent of the total number of animals slaughtered at small and very small plants that year. We are concerned that the audit findings presented in this report are derived from a limited and unrepresentative sample of small and very small plants. The 15 plants reviewed by the OIG represent less than 0.3 percent of the total small and very small plants in the U.S.

FSIS recognizes the unique needs of small and very small plants. FSIS has met the goals of the Small Business Regulatory Enforcement Act of 1996 and has continuously demonstrated its commitment to assist these plants. In FY 2004, FSIS received an "A" rating in the SBA's Small Business Regulatory Enforcement Fairness Criteria for compliance assistance, training, technical assistance and communications. FSIS has an extensive outreach and education program to actively support food safety regulatory compliance and public health by small and very small plants.

FSIS FORM 2630-9 (6/86) EQUAL OPPORTUNITY IN EMPLOYMENT AND SERVICES

FSIS provides technical assistance and compliance guidance to small and very small plants when major rules, policies, or directives are issued. For example, in 2004, FSIS held eleven instructive workshops to help industry better understand the impact of the revised *E. coli* O157:H7 directives on plant operations. These workshops, which were held in areas of the country where beef slaughter and processing plants are concentrated, are part of FSIS' continuing effort to protect public health by enhancing technical expertise and providing up-to-date information and clarification about new and revised FSIS regulations to small and very small plants. Workbooks were developed in an easy-to-understand format and were given to participants. These workbooks were also mailed to all affected plants. FSIS utilized new technology, web casting, for two of the *E. coli* O157:H7 workshops, to reach an even greater number of people who were not able to travel to one of the workshop locations. FSIS also held five workshops in 2004 to explain the new rules designed to prevent human exposure to Bovine Spongiform Encephalopathy (BSE). Additionally, FSIS is conducting six workshops, scheduled for May through July of this year, on food security. The workshops will assist plants with food security awareness and in the development of their food security plans. FSIS will web cast several of the workshops.

FSIS continued its use of cooperative agreements to develop partnerships with universities to provide small and very small plants with a more in-depth understanding of HACCP systems and emerging food safety concerns. The universities, in cooperation with FSIS, offer low-cost training to small and very small plant owners/operators to help these small businesses improve their food safety systems and produce safer products. Classes include, but are not limited to: Introductory HACCP, Advanced HACCP, *Listeria monocytogenes*, *E. coli* O157:H7 and BSE.

FSIS maintains a network of established HACCP contacts and coordinators in all 50 states, Puerto Rico, the Virgin Islands, and the District of Columbia. Partners include representatives from state-inspected programs, academia and extension offices. Small and very small plant operators can access these local resources for help in developing HACCP plans, to locate training, and to seek food safety advice or locate other food safety information. Through the State contacts and coordinators and Land Grant colleges and universities, FSIS has expanded its distribution of materials aimed at assisting small establishments. FSIS HACCP documents and other food safety materials, such as closed-captioned videos and computer disks, are offered to all at no charge. Most materials are offered in both English and Spanish. In FY 2004, the program filled approximately 19,000 requests for educational materials, which included three direct mailings of specific materials that were sent to approximately 4,000 meat and poultry establishments. To date in FY 2005, FSIS has filled approximately 7,500 individual requests for resource materials. The Agency plans to do direct mailings to approximately 10,000 meat, poultry, and egg establishments on food security guidance material.

FSIS maintains a Small and Very Small Plant Outreach focus on its website featuring workshops, compliance guidance, resource materials, a listing of State contacts and coordinators for HACCP information, and links to the Small Business Administration website and the National Ombudsman's website. FSIS is also working on an outreach video to provide information about Agency resources to small and very small plants that are not already aware of what it does and provide valuable contact information. The anticipated release of the video is

positive actions that it has taken, or plans to take, to respond to the report's recommendations. Agency corrective actions that extend beyond the current fiscal year will be dependent upon available funding.

Section 1. FSIS Management Controls Need Improvement

1. **Recommendation No. 1**
Develop a system to ensure that Food Safety Assessments are conducted at the most high-risk and needed areas, and maintain a centralized database of these assessments to ensure that coverage is adequate and conducted in the most needed areas.

FSIS Response
FSIS conducts food safety assessments (FSAs) based on risk to public health. In accordance with the food safety objectives outlined in *Healthy People 2010*, which include reducing infection caused by foodborne pathogens and reducing outbreaks of foodborne pathogens, FSIS targets food safety assessments at high risk operations. For example, FSAs are conducted at plants that have been associated with an outbreak of foodborne illness or identified with risk associated with *E. coli* O157:H7. Also, as part of its Management Control System, FSIS has documented and implemented a control activity for FSAs that establishes specific levels of performance for all assessments. (See **Enclosure 1**, *Office of Field Operations: Management Control Program Description*.) Additionally, FSIS will implement a control activity and information system within its Management Control System with standard procedures for FSAs. As part of this process, FSIS is developing procedures for identifying the inherent risk of a product or process that will be used to further target all FSAs to the highest risk establishments. These standard procedures will further improve FSIS' ability to focus FSAs at the most high-risk and needed areas.

Timeframe
FSIS will establish additional control activities, including the standard procedures for Enforcement, Investigations, and Analysis Officers Food Safety Assessments, by September 30, 2005.

2. **Recommendation No. 2**
Establish procedures to link food safety assessment results to In-Plant Performance System (IPPS) reviews. Utilize the results to better identify the causes of inspectors not identifying noncompliances with HACCP, Sanitation Standard Operating Procedures, and pathogen reduction requirements.

FSIS Action
FSIS will develop a control activity that uses information from the IPPS to align it with key food safety and food security functions. As part of this activity, supervisors will consider the results from FSAs, in addition to other measures of compliance with inspection system activities, in preparation for IPPS reviews. As part of the more fully documented Management Control System **(Enclosure 1)**, IPPS reviews are used to hold

supervisors accountable for specific levels of performance in monitoring the conduct of in-plant inspection and verification activities.

FSIS has established specific levels of performance (performance measures) for its key food safety and food security functions, to be monitored by FSIS managers through the use of an automated database. Supervisory personnel in Circuits and Districts failing to meet the established performance levels for key functions will be given feedback for improvement during performance reviews.

Timeframe
FSIS will implement control activities for the IPPS to align them with key food safety and food security functions by September 30, 2005.

Section 2. HACCP Plans Are Not Meeting Regulatory Requirements

3. **Recommendation No. 3**
Include as a specific scheduled task in Performance Based Inspection System for inspectors to assess HACCP plans annually, or upon rotation, to ensure that timely reviews are being performed.

FSIS Response
FSIS proposes an alternative approach in order to meet the concern identified: *Establish management controls to ensure that inspectors assess HACCP plans annually, or upon rotation, and that timely reviews are being performed.*

FSIS Directive 5000.1, Revision 1, Amendment 1, *Verifying an Establishment's Food Safety System* **(Enclosure 2),** addresses timely HACCP plan assessments. It is neither necessary nor practical to schedule reviews of plants' HACCP plans by Consumer Safety Inspectors because reviews are ongoing. FSIS Directive 5000.1 establishes that HACCP plan reviews are conducted on an ongoing basis as part of scheduled inspection verification procedures.

Regular HACCP plan reviews are also reinforced in Food Safety Regulatory Essentials (FSRE) training. FSRE training covers the full range of inspection responsibilities in relation to the HACCP/Pathogen Reduction; Rules of Practice; Sanitation Performance Standards; and SSOP. CSI are trained in HACCP verification; Pathogen Reduction; and food safety sampling. CSI are instructed to use the basic compliance checklist (FSIS Form 5000-1) to review an establishment hazard analysis assessing compliance with Part 417 when in a new establishment, when an establishment adds a new product or process, or when the CSI becomes aware that a modification to an existing HACCP plan has been made. The directive and training provide instruction to CSI on actions that should be taken based on the findings of the review. In addition, CSI are instructed to review establishments' HACCP plans each time they perform HACCP verification procedures as a primary means of gathering information regarding a plant's processes and determining regulatory compliance.

Additionally, FSIS has linked control activities and performance measures under its Management Control System **(Enclosure 1).** The four critical constituent control activities for HACCP/Pathogen Reduction Execution are: 1) sanitation performance standards; 2) SSOPs; 3) HACCP-03 procedures; and 4) pathogen sampling. FSIS, as part of its Management Control System, has established performance measures associated with the execution of all critical control activities in order to improve accountability and strengthen public health.

Timeframe
FSIS will implement control activities for the IPPS to align them with HACCP/Pathogen Reduction Execution by September 30, 2005.

4. **Recommendation No. 4**
Ensure that the inspector who was at plant E, and at least one employee responsible for HACCP at each plant, has been adequately trained in the seven principles of HACCP.

FSIS Response
FSIS will verify that the inspector who was at plant E has been adequately trained in the seven principles of HACCP. FSIS personnel responsible for inspection verification at establishments have been adequately trained in the seven principles of HACCP. Inspection program personnel are required to demonstrate proficiency in "Verification of HACCP Plans" during at least one of two mandatory IPPS assessments carried out annually by the Frontline Supervisor under the IPPS. In addition, most inspection program personnel have received or will receive FSRE training which covers responsibilities related to the HACCP/Pathogen Reduction.

FSIS has established a control activity and performance measures under its Management Control System **(Enclosure 1)** that will enable senior managers to monitor the appropriate execution of IPPS assessments by Frontline Supervisors. This includes review by each supervisory level up to and including the Assistant Administrator of the Office of Field Operations.

Timeframe
FSIS will provide evidence that FSIS inspection personnel have been adequately trained in the seven principles of HACCP by July 30, 2005.

5. **Recommendation No. 5**
Require the inspectors to review the HACCP training received by individual plant employees who develop HACCP plans to ensure they have been trained in the principles of HACCP in accordance with 9 CFR 417.7.

FSIS Action
FSIS proposes an alternative approach in order to meet the concern identified: *Require FSIS to verify that the plant design and execution of HACCP plans and SSOPs meet the principles of HACCP.*

FSIS Directive 5000.1, Revision 1, Amendment 1, *Verifying an Establishment's Food Safety System* **(Enclosure 2)**, contains the criteria for comprehensive verifications and assessments of all food safety systems.

FSIS has established a control activity and performance measures under its Management Control System **(Enclosure 1)** that will enable senior managers to monitor the appropriate execution of IPPS assessments by Frontline Supervisors. This includes review by each supervisory level up to and including the Assistant Administrator of the Office of Field Operations.

6. **Recommendation No. 6**
Review Critical Control Point (CCP) monitoring records at plant A and determine if records were accurate. If not, take appropriate administrative or enforcement actions.

FSIS Action
FSIS will review CCP monitoring records at plant A, determine if records were accurate, and take appropriate administrative or enforcement actions if necessary.

Timeframe
FSIS will complete the review of CCP monitoring records at plant A and take appropriate administrative or enforcement actions by July 30, 2005.

7. **Recommendation No. 7**
Review cited plants' monitoring of CCPs and require changes at each plant to ensure they meet regulatory requirements.

FSIS Action
FSIS will review the cited plants' monitoring of CCPs and require changes at each plant to ensure they meet regulatory requirements.

Timeframe
FSIS will complete the review of the cited plant's monitoring of CCPs and require changes at each plant to ensure they meet regulatory requirements by July 30, 2005.

Section 3. FSIS Oversight of SSOPs Needs Improvement

8. **Recommendation No. 8**
Include a scheduled task in the PBIS system for assessing SSOP plans to ensure this task is performed on a regular basis.

FSIS Action
FSIS proposes an alternative approach in order to meet the concern identified: *Establish management controls to ensure that SSOP plans are assessed on a regular basis.*

FSIS Directive 5000.1 **(Enclosure 2)** addresses regular assessments for SSOP plans. Regular SSOP plan reviews are also reinforced in FSRE training. CSI perform PBIS

Procedure 01A01 to verify that an establishment's written sanitation SSOP meet regulatory requirements. Establishments are required to have adequate SSOP in place at the time inspection is granted. Thereafter, CSIs may perform procedure 01A01 as needed to verify SSOPs and any modifications to them. Inspection program personnel are also instructed to review the SSOPs to become knowledgeable of the plants' written procedures each time they perform verification procedures associated with SSOPs.

Additionally, FSIS has established under its Management Control System **(Enclosure 1)** the control activity "SSOP—PBIS 01 and 02 Procedures," as well as specific performance measures for inspection program personnel to: (1) monitor the review of SSOP plans, (2) ensure that all deficiencies are documented on a non compliance record and, (3) verify that an establishment has made an appropriate response to the deficiencies noted. Specific emphasis is placed on the verification of 9 CFR 416.4 requirements.

Timeframe
FSIS will implement control activities for the IPPS to align them with regular assessments of SSOP plans by September 30, 2005.

9. **Recommendation No. 9**
Establish definitive guidelines to ensure that both short-term and permanent corrective action is required and implemented when repetitive deficiencies are found at plants, and take further enforcement actions on repetitive deficiencies.

FSIS Action
FSIS has already established official policy in the form of FSIS Directive 5000.1 to verify corrective action. **(Enclosure 2)** As evidenced by over 400 administrative actions taken within the last year, FSIS does implement further enforcement action on violations of law including repetitive deficiencies. The standard for determining that further enforcement actions are necessary is proof that product has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health. In-plant inspection program personnel, frontline supervisors and District personnel all have a role in this determination. Repeating deficiencies of a low hazard nature that are acted upon at the time of occurrence do not meet the burden identified above for further enforcement action.

FSIS, as part of its Management Control System **(Enclosure 1)**, has established a performance measure associated with all documented noncompliance records that requires "100% verification of establishment's responses to an NR."

Section 4. FSIS Should Improve Guidance Over Inspector Activities

10. **Recommendation No. 10**
Review the testing deficiencies noted at the cited plants and determine the causes of the deficiencies noted. Develop and implement guidance to ensure that plant profiles and

any other documents causing the deficiencies are reviewed at least annually and upon rotation (within the first month).

FSIS Action
Plant profiles do not determine microsampling scheduling for Salmonella in raw products. Sample scheduling is based on inspector input on eligibility reports. FSIS Directive 5400.5, *Inspection System Activities*, implements a policy to ensure that plant profiles are reviewed at least annually and upon rotation (within the first month). **(Enclosure 3).**

FSIS will review the testing history at the cited plants to determine the cause of any deficiencies that are identified.

Timeframe
FSIS will complete the review and correct any identified deficiencies by September 30, 2005.

11. **Recommendation No. 11**
Establish and implement policies to assure that inspectors timely monitor plants corrective actions to Noncompliance Records (NR) and document NRs when the plant management has taken appropriate actions to address the noted deficiencies.

FSIS Action
FSIS Directive 5000.1 defines procedures to verify compliance with regulations 417.3, 416.15, and the sanitation performance standards. Although it is the plant's responsibility to respond to a noncompliance, FSIS, as part of its Management Control System, has established a performance measure associated with all documented noncompliances that requires "100% verification of establishment's responses to an NR." This system ensures that inspectors timely verify plants' corrective actions to NRs and document NRs when the plant management has not taken appropriate actions to address the noted deficiencies.

Timeframe
FSIS will implement control activities for the IPPS to align them with key food safety and food security functions by September 30, 2005.

12. **Recommendation No. 12**
Require district or supervisory personnel to conduct trend analysis and review the timeliness of NRs under their purview.

FSIS Action
District Analysts' responsibilities include trend analysis of establishment compliance with regulatory requirements. The District Analyst position was established in July 2004. The position description is provided in **Enclosure 4**. Verification of corrective action including timeliness is a performance expectation for Public Health Veterinarians and CSI that is assessed as part of the performance of IPPS.

13. **Recommendation No. 13**
Direct the cited inspector at plant O to document instances of noncompliance so that a written history is developed for all noncompliance, and corrective actions taken on the noncompliance. Also, FSIS should implement supervisory oversight sufficient to ensure the cited inspector is properly performing inspection duties.

FSIS Action
FSIS, as part of its Management Control System, has established a performance measure associated with all documented noncompliances that requires "100% verification of establishment's responses to an NR."

FSIS is revising IPPS to align it with key food safety and food security functions of the Management Control System. FSIS will conduct IPPS Reviews to hold supervisors accountable for specific levels of performance through IPPS reviews. Performance measures for the key food safety and food security functions have been established and will be monitored by senior managers through the use of an automated database.

Additionally, FSIS will direct the cited inspector at plant O to document instances of noncompliance so that a written history is developed for all noncompliance, and corrective actions are taken on the noncompliance.

Timeframe
FSIS will review all instances of noncompliance at plant O and ensure that necessary corrective actions are taken by September 30, 2005.

Section 5. FSIS and Plant Management Need to Place Greater Emphasis on Plant Security

14. **Recommendation No. 14**
Establish minimum security requirements for plants that include a written security plan and actions to prevent deliberate product adulteration.

FSIS Action
A proposed rule that would mandate food security plans in all official establishments and provide for special verification activity by FSIS during a heightened food threat event is on FSIS' regulatory agenda. Meanwhile, FSIS is encouraging voluntary development of food security plans. To assist establishments, especially small and very small establishments, in developing food security plans, FSIS will conduct a series of training workshops throughout the nation in May, June and July of 2005. The workshops will assist plants with food security awareness and in the development of their food security plans. Tools such as the Model Food Security Plans, FSIS Industry Self-Assessment Checklist for Food Security, and FSIS Directive 5420.1, Revision 1, *Food Security Verification Procedures* **(Enclosure 5)** will be addressed during the workshops.

If you have any questions, please call Ronald F. Hicks, Assistance Administrator, Office of Program Evaluation, Enforcement and Review on (202) 720-8609.

Enclosures (5)

Informational copies of this report have been distributed to:

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