U.S. Department of Agriculture

Office of Inspector General
Southeast Region

Audit Report

Food Safety and Inspection Service
Followup Audit on the Inspector General's
Food Safety Initiative of Fiscal Year 2000

Report No. 24001-4-At
September 2004

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250

DATE: September 13, 2004

REPLY TO
ATTN OF: 24001-4-At

SUBJECT: Food Safety Initiative Followup

TO: Barbara Masters
Acting Administrator
Food Safety and Inspection Service

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

This report presents the results of our review of the Food Safety Inspection Service's (FSIS) followup of the Office of Inspector General's (OIG) Food Safety Initiative audits issued in June 2000. The Senate Committee on Agriculture, Nutrition, and Forestry requested this review. Your August 11, 2004, written response to the official draft report is included in its entirety (except for the enclosures) as exhibit E 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 Nos. 1, 2, and 3. Management decisions for all report recommendations have been accepted. Please follow your agency's internal procedures in forwarding documentation for final action to the Office of the Chief Financial Officer.

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

/s/
ROBERT W. YOUNG
Assistant Inspector General
for Audit

Executive Summary

Followup Audit on the Inspector General's Food Safety Initiative of Fiscal Year 2000 (Audit Report No. 24001-4-AT)

Results in Brief

This report presents the results of our followup review of the status of the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service's (FSIS) progress on implementing recommendations and addressing problems identified in the June 2000 Office of Inspector General's (OIG) Food Safety Initiative, Meat and Poultry Products reports[1]. The purpose of our review was to evaluate the corrective actions that were planned and taken by FSIS in order to implement the 80 recommendations contained in these reports. The current status of each recommendation is found in exhibits A through D.

We concluded that only 58 of the 80 recommendations were successfully implemented. FSIS and OIG failed to agree on the proper corrective actions for 4 recommendations, and even though agreement had been reached on the remaining 18 recommendations, FSIS did not implement all the actions it said it would. We concluded that timely implementation of corrective actions along with increased inspector's oversight could have resulted in improved safety of meat and poultry products sold since 2000.

Status of Improvements in the Hazard Analysis and Critical Control Point System

The first report in our 2000 Food Safety Initiative was on the implementation of the Hazard Analysis and Critical Control Point (HACCP) system. HACCP was designed to replace the old system of testing by touch, taste, and smell, with a system based on science and laboratory diagnostics. In our report, we proposed 20 recommendations to help FSIS improve the HACCP system. FSIS agreed to take corrective actions on 17 of these recommendations, specifically those related to ensuring that plants analyze all likely hazards, identify all critical control points, establish appropriate critical limits (temperature control, etc.), authority for oversight of all plant pathogen testing, and access to all plant testing results.

FSIS has chosen not to impose timeframes on plants to fix problems cited by FSIS. FSIS managers believe the plants will take action to avoid repeated citations, but our 2000 audit found that repeated citations were a general problem. FSIS had agreed in 2000 to establish procedures to deal with

[1] The four reports that were part of the Food Safety Initiative were: Audit No. 24001-3-At, "Implementation of the Hazard Analysis and Critical Control Point System"; Audit No. 24601-1-Ch, "Laboratory Testing of Meat and Poultry Products"; Audit No. 24099-3-Hy, "Imported Meat and Poultry Inspection, Phase I"; and Audit No. 24601-4-At, "District Enforcement Operations Compliance Activities".

repeated citations, but as of this followup audit, it had not done so. (See exhibit A for a detailed status on each recommendation.)

Status of Improvements in the Laboratory Testing Program

The second report in our 2000 Food Safety Initiative detailed our concerns about FSIS' program of laboratory testing. Laboratory testing is an integral part of the HACCP system insofar as it was designed to provide timely and accurate test results of plant samples collected by FSIS. Our report proposed 17 recommendations to help FSIS improve its testing program. FSIS implemented 15 of these recommendations, establishing a quality control system over laboratory diagnostics, improving management oversight through field visits and better check samples, and replacing defective *Salmonella* test kits.

For the other two recommendations, FSIS had begun some corrective actions but had not completed them. For one of these recommendations, FSIS had not performed the actions it had agreed to. (See exhibit B for a detailed status on each recommendation.)

The incomplete or unperformed actions relate to the methods of sampling and the timeliness of collecting the samples. During our original audit, we found that although regulations required FSIS to test for nitrosamines, a carcinogen occurring in bacon products, the agency did not do so because it had not identified bacon-producing plants in its sampling universe. FSIS has not completely remedied this condition. FSIS also continues to have problems managing nonresponses to laboratory requests for samples from plants. We had recommended that FSIS issue procedures to deal with cases in which plants subject to *Salmonella* testing have not responded to a sample request for over 30 days. Although it has moved toward controlling response time for *Salmonella* samples, it has not issued the needed procedures. In February 2002, FSIS reported that 140 plants had sample requests that were over 18 months old.

Status of Improvements in the Imported Meat and Poultry Inspection Program

FSIS has not implemented the agreed upon corrective actions for 11 of the 35 recommendations in our report on FSIS' imported meat program, the third report in our series in the 2000 Food Safety Initiative. For 1 of the remaining 24 recommendations in that report, FSIS has not agreed to corrective action. (See exhibit C for a detailed status on each recommendation.)

FSIS' imported meat program is based on the concept of equivalency of foreign food safety systems. FSIS ensures foreign meat imports are wholesome by determining that the countries' food safety systems are equivalent to ours and by reinspecting meat products on a spot-check basis to verify their purity. In response to our Food Safety Initiative, FSIS has improved its equivalency determinations by involving subject-matter experts in these determinations, by providing clearer evidence of how the determinations are made, and by performing site visits to verify the documentation submitted by the foreign countries.

The actions that have not been implemented include improving oversight and control of the program and ensuring the integrity of data entered into the information system. We found during our 2000 Food Safety Initiative that when FSIS reorganized in 1997, it did not ensure that the controls it maintained under its pre-HACCP structure were carried over into the new structure. This condition continues today. Responsibilities are not well defined: lines of authority are unclear, supervisory oversight is minimal, and internal control reviews are not conducted. Also, FSIS had agreed in 2000 to perform the following actions, but as of our current audit had not done so:

- FSIS performed no indepth assessments of its reinspection program, and

- FSIS created no system to track establishments that were removed from the list of those eligible to export to the United States.

As a result of these conditions in 2000, we recommended that the material weaknesses in FSIS' import inspection process be included in the agency's Federal Manager's Financial Integrity Act report, but FSIS would not agree to this.

Status of Improvements in FSIS' Compliance Operations

In our report on FSIS' compliance operations audit, the final report in our series in the 2000 Food Safety Initiative, we proposed eight recommendations, all of which have been satisfactorily implemented. FSIS has acted to establish and track timeframes for investigating and resolving violations, and to ensure that all consumer complaints are reviewed. FSIS has identified high-priority firms and targeted its resources to large metropolitan areas, high-risk firms, and firms with a history of violations. FSIS provided training to ensure that all managers are able to properly oversee violation case review and preparation. FSIS has also sought legislative authority to impose civil monetary penalties against violators of the meat and poultry inspection laws. (See exhibit D for a detailed status on each recommendation.)

Recommendations In Brief

We recommend that FSIS develop a plan to correct the deficiencies noted where corrective actions were agreed upon but not implemented. Individual recommendations that have not received management decision will be tracked for each individual audit. For the four unresolved recommendations, FSIS officials need to show how they plan to correct the noted conditions and what the estimated timeframes are for completion. They also need to provide any documentation that may assist in resolving these recommendations. For the imported meat audit, additional recommendations to correct the noted deficiencies have been included in the "FSIS Imported Meat and Poultry Reinpection Process Phase II" (Audit No. 24099-4-At, issued February 2003).

Agency Response

In its August 11, 2004, written response to the draft report, FSIS provided a plan showing corrective actions taken, the status of planned corrective actions, and the target date for completion of the corrective actions. The plan was developed to correct deficiencies noted in the draft 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 E.

OIG Position

We concur with FSIS' proposed corrective actions and have accepted management decisions to the three recommendations in the report.

Abbreviations Used in This Report

AIIS
Automated Import Information System 35
AOAC
Association of Analytical Chemists 28
ARS
Agricultural Research Service 19
CCP
critical control point 4
CFR
Code of Federal Regulations 27
CSO
Consumer Safety Officer 18
DEO
District Enforcement Operations 50
DO
District Office 5
FAIM
Field Automation and Information Management 38
FSIS
Food Safety and Inspection Service 1
FSSC
Food Safety Systems Correlation 18
FY
Fiscal Year 30
GAO
Government Accountability Office 6
HACCP
Hazard Analysis and Critical Control Point 1
ICS
Internal Control Staff 34
IIC
Inspector-in-Charge 21
IPD
International Policy Division 37
LM
*Listeria Monocytogene*s 2
MARCIS
Microbiological and Residue Computer Information System 38
MLG
Microbiology Laboratory Guide 28
NR
Noncompliance Records 5
OIG
Office of Inspector General 1

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Background and Objectives

Background

This review was initiated by a request from Senator Tom Harkin, Chairman, U.S. Senate Committee on Agriculture, Nutrition and Forestry; and Senator Richard Lugar, Ranking Republican Member. In a memorandum dated July 26, 2002, Senators Harkin and Lugar requested that the Office of Inspector General (OIG) examine the U.S. Department of Agriculture (USDA), Food Safety and Inspection Service's (FSIS) progress on implementing and addressing problems identified in our June 2000 Food Safety Initiative review.

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

OIG initiated a series of audits of FSIS to determine whether FSIS' meat and poultry inspection program remained effective under the science-based HACCP System. Our food safety initiative included reviews of three facets of the new inspection system – HACCP, laboratory analyses, and foreign imports – and a review of the compliance program that carried over from the previous system. OIG issued four reports from the review. The reports were: Audit No. 24001-3-At, "Implementation of the Hazard Analysis and Critical Control Point System"; Audit No. 24601-1-Ch, "Laboratory Testing of Meat and Poultry Products"; Audit No. 24099-3-Hy, "Imported Meat and Poultry Inspection, Phase I"; and Audit No. 24601-4-At, "District Enforcement Operations Compliance Activities".

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

- Implementation of the HACCP program and of sanitation standard operating procedures (SSOP), including efforts to test for pathogens and reduce their presence;

- FSIS' quality assurance programs over its laboratory facilities and operations, product sample integrity, and laboratory testing operations;

- FSIS' process to determine whether foreign countries' safety inspection systems are equivalent to that for the United States; and

- The effectiveness of FSIS' compliance review program in detecting violations of meat and poultry inspection laws at non-federally inspected firms.

The results we discovered during our June 2000 reviews demonstrated that FSIS had taken positive steps to secure the safety of meat and poultry products. However, more was needed in all four areas we reviewed. For the science-based system to reach its full potential, FSIS needed to take maximum advantage of the expanding role that science plays as a control over the meat and poultry that enters the marketplace. Some of this control was seen directly in the identification of pathogens; some was seen in the integration of scientific techniques (e.g., operational procedures, reliance on objective data) into the system being established.

Most significantly, we found that FSIS needed to command a more aggressive presence in the inspection and verification process. FSIS had not always established needed procedures or apprised itself of all areas where inspections were critical; consequently, it had reduced its oversight short of what was prudent and necessary for the protection of the consumer. More specifically, we found that FSIS needed to strengthen its oversight in all four areas we reviewed. For example:

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

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

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

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

We also concluded that FSIS should expand its own testing requirement to increase the number of tests taken of *E.coli*, *Listeria monocytogenes* (LM), and *Salmonella*, and to include other pathogens in those requirements.

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

Overall, we recommended that FSIS strengthen its procedures over the food safety system. FSIS needed to institute stronger procedures to ensure that all establishments were tested. In the case of imported meats and poultry, FSIS needed to develop and implement formal procedures over its entire equivalency process and enforce existing regulatory requirements. For compliance verification, FSIS needed to refine its existing compliance plan to establish the universe and scope of its reviews and target its resources, and it needed to seek authority to impose monetary penalties and ensure that violations of the meat and poultry inspection laws were met with these penalties and other sanctions commensurate with each violation. We also recommended that FSIS assert its authority over the HACCP system to ensure that the intent of the program was met.

Objectives

The purpose of this current audit was to evaluate the corrective actions planned and taken by FSIS to implement the 80 recommendations contained in the June 2000 Food Safety Initiative, Meat and Poultry Products audit reports.

Findings and Recommendations

Section 1: Status of Recommendations to Improve the HACCP System

Our June 2000 audit report of FSIS' Implementation of the HACCP System (Report No. 24001-3-At) contained 20 recommendations. Corrective actions for 12 of these recommendations are generally complete, although documentation for one of the 12 (Recommendation No. 16) has not yet been approved by the Office of the Chief Financial Officer.

Corrective actions that have not yet had final approval from OCFO include FSIS agreeing to evaluate the implementation of HACCP at the plants by contracting for the development of and providing inspectors with a hazard and controls guide. FSIS was also developing procedures for handling repetitive sanitation deficiencies.

FSIS and OIG agreed to corrective actions on five more recommendations, but these actions were still not completed as of the date of our followup review. FSIS would not agree to three recommendations and has not offered sufficient alternative corrective actions.

Corrective Actions Not Yet Agreed Upon

Pathogen Testing Included in the HACCP Plans

To further ensure that FSIS inspectors were given access to non-HACCP test results that showed the presence of pathogens, we recommended in our 2000 report that FSIS require plants to include in their HACCP plans all pathogen testing they perform.

FSIS officials initially stated that the HACCP regulation did not require plants to include pathogen testing in their HACCP plans, and that FSIS required inspectors to verify all corrective actions taken and documented by the plant as well as the reassessment and modification of the HACCP plan when adverse microbial test results occurred in plants. In a response (dated December 7, 2001) to the audit report, FSIS stated that they believed this recommendation was unwarranted. FSIS stated that establishments are required to meet corrective actions for adverse test results if the HACCP plan contains a critical control point (CCP) addressing *LM*, and if the HACCP plan does not address *Lysteria*, the establishment must meet corrective actions for an unforeseen hazard by reassessing their HACCP plan.

This action does not address how an establishment's official will inform FSIS inspectors of adverse microbial tests. We found that FSIS performs limited testing of establishments' products and could take weeks or months to

uncover an adverse condition that establishment personnel may have already known. In addition, we found that there are no requirements for establishments to provide test records to FSIS that are not in the HACCP plan. (See exhibit A, Recommendation No. 12.)

Monitoring of Scheduled Tasks

In our 2000 report, we reported that not all the tasks scheduled for FSIS inplant inspectors were being carried out but that it was unclear what was causing the nonperformance. Our review of reports from the Performance-Based Inspection System (PBIS) did not show whether the inspectors did not have time, whether an inappropriate task was generated based on the wrong plant profile, or whether the plant's operations rendered the task inapplicable to the shift. We recommended FSIS district personnel monitor the tasks, update the schedule when tasks become obsolete, and establish codes to identify the reason tasks are not performed.

In a response (December 7, 2001) to the audit report, FSIS officials reiterated that no new codes were needed; they would make the circuit supervisors responsible when inspectors were not performing required procedures. FSIS officials stated that they are taking steps to reinforce the usefulness of PBIS data with circuit supervisors through the circuit meetings at the district offices (DO) and through the National Supervisory Conferences.

We noted that during our 2000 audit, circuit supervisors were also responsible for ensuring that some of the scheduled tasks were performed but did not do so. FSIS officials stated that they would provide alternative corrective actions to OIG to remedy this recommendation. (See exhibit A, Recommendation No. 18.)

Timeframes for Responding to Noncompliance Records:

In our 2000 report, we reported that plants did not always respond in a timely manner to noncompliance records (NR), which are issued by FSIS to identify a violation by a plant. We found that plants did not always respond to NR's or take timely corrective action, so we recommended that FSIS establish timeframes for a response.

In a response (October 22, 2001) to the audit report, FSIS stated that NR's place the responsibility on plant management for initiating corrective actions, preventing recurrence of the noncompliance, and maintaining records. FSIS stated that they see no need to establish timeframe requirements for plant management to respond to NR's and initiating corrective action. FSIS noted that it is incumbent on plant management to take corrective actions to avoid a repeat violation of regulations. FSIS did not provide alternative corrective actions to show how the deficiency would be corrected in the future. The

Government Accountability Office (GAO) also identified the same weakness in its audit report (GAO-02-902), dated August 2002. (See exhibit A, Recommendation No. 20.)

Corrective Actions Agreed Upon But Not Implemented

Hazards and Controls Guide

During our 2000 review, we found that HACCP plans did not always identify all CCP's, all likely hazards, and all critical limits (maximum temperatures, maximum allowable defects, etc.) required of such plans. We consequently recommended that FSIS implement a system of oversight that would ensure that HACCP plans were complete and accurate. We also recommended that the system of oversight include procedures for handling products returned to the plants from buyers. HACCP plans did not include such procedures, and inspectors were not always notified of the disposition of returned products.

FSIS officials proposed a number of items to resolve these recommendations to establish procedures for inspectors that included additional oversight responsibilities for food products, including the adoption of several types of internal reviews. FSIS officials also stated that in each cited recommendation, they contracted for the development of a hazards and controls guide to provide inspection personnel with guidance on the types of hazards associated with different meat and poultry processes. This hazard and controls guide was to be completed by September 2002. At the time of our review, the hazard and controls guide had not been completed. (See exhibit A, Recommendations Nos. 1, 2, 3, and 17.)

Progressive Enforcement Procedures for Repetitive Deficiencies

We reported in our 2000 report that FSIS did not have guidelines specifying the number of times inspectors could issue the same NR to the same plant for the same reason before requiring administrative or enforcement action. We recommended that FSIS establish specific parameters for repetitive deficiencies and determine when enforcement actions should be taken.

FSIS officials stated that they would develop procedures for handling repetitive deficiencies by December 2000. At the time of our review, we found that FSIS has not developed procedures for repetitive deficiencies. FSIS officials stated that they were still determining how to address this issue. GAO also cited this issue in its current report, (GAO-02-902) dated August 2002. GAO stated, “FSIS is not consistently identifying repetitive violations. This has occurred in part because FSIS has not established specific, uniform, and clearly defined criteria for its inspectors to use in determining when a violation is repetitive." Identifying repetitive violations

and maintaining accurate documentation on those decisions is critical in deciding whether a HACCP plan is flawed and an enforcement action is needed. (See exhibit A, Recommendation No. 19.)

Recommendation No. 1

Develop a plan to implement the agreed upon recommendations to correct the deficiencies in the HAACP program. This plan should identify the officials responsible for implementing each recommendation. It should also establish reasonable timeframes for the project, as well as the individual tasks, and include periodic progress reports addressing each part of the plan. FSIS management should establish a mechanism that apprises them of the progress. (See exhibit A, Recommendations Nos. 1, 2, 3, 17, and 19.)

Agency Response. In its August 11, 2004, response, FSIS stated,

> *The corrective actions for recommendation No. 17 and 19 in the 2000 audit report were completed and the OCFO granted final action on February 17, 2004, and November 26, 2003, respectively. * * * FSIS will not pursue any further action regarding these items.*
>
> *For the three remaining recommendations, FSIS has developed an action plan aimed at correcting deficiencies in the HACCP implementation program and that addresses the remaining OIG recommendations without final action. FSIS has implemented an audit tracking system that includes bi-monthly status reports to the FSIS management council. The status report includes the recommendations where final action is incomplete, identifies the agency official responsible for addressing each recommendation, and the target date for completion of the action.*

OIG Position. We accept the management decision for this recommendation.

Section 2: Status of Recommendations to Improve FSIS' Laboratory Testing Program

Our June 2000 audit report of FSIS' Laboratory Testing of Meat and Poultry Products (Report No. 24601-1-Ch) contained 17 recommendations. Corrective actions for 15 of these recommendations have been accepted by OCFO, and FSIS has implemented them. Of the corrective actions for the remaining two recommendations, one was not implemented as agreed upon, and one was implemented but ineffective.

The recommendations already implemented largely relate to quality control issues. Specifically, FSIS has improved its onsite laboratory reviews and its proficiency checks on laboratory operations. It has also developed quality control procedures for ensuring that analytic test results are documented and that equipment is calibrated properly and operating to standards. In a separate issue, FSIS agreed to ensure that overnight deliveries of HACCP samples arrive at the laboratories promptly when mailed on a Friday or the day before a holiday.

Corrective Actions Agreed Upon But Not Implemented

Test for Nitrosamines

Our June 2000 audit found that FSIS did not test all bacon-producing plants for nitrosamines, a carcinogen occurring in bacon. We recommended the agency implement a more aggressive nitrosamines testing program.

The documentation FSIS submitted to OCFO was not sufficient to show that all establishments producing bacon products have been made subject to the required testing for nitrosamines. FSIS officials agreed to publish a regulation to incorporate the nitrosamines testing requirement into HACCP, but the regulation submitted to OCFO was still in the drafting stage. FSIS was unable to provide timeframes when the regulation would be implemented. (See exhibit B, Recommendation No. 6.)

Corrective Actions Implemented But Not Effective

Monitor Sampling Request Responses

Complementing a previous recommendation on nonresponses to laboratory requests for monitoring samples, our June 2000 report also recommended that managers provide greater oversight of sampling requests and followup at the plants to determine the reason the FSIS plant inspector failed to respond to the request.

Although the agency had implemented a monthly nonresponder report for the *Salmonella* testing program, it did not issue any supplementary procedures on how or when an FSIS inspector should respond to the new nonresponder report. The nonresponder report was developed to notify DO's on a monthly basis of instances where requested *Salmonella* samples were not provided within 30 days. When we interviewed a district official, we found that the district's followup procedures consisted of nothing more than forwarding the nonresponder report to the circuit supervisors. Lacking guidance, the circuit supervisors often did not determine why samples were not sent. Consequently, in February 2002, FSIS reported that 140 plants had ongoing *Salmonella* sample sets in excess of 18 months.

The equivalent quarterly reports covering the *E.coli* and RTE testing programs were not sent out until October 2002. As with the *Salmonella* nonresponder report, FSIS Headquarters did not provide DO's with guidance or instructions for their use. As a result, for all three reports, followup action was left to the initiative of individual district or circuit officials. The FSIS *E.coli* Random Sample Request Tracking Report showed 665 nonresponding establishments during the period March through September 2002; of these, 259 establishments appeared on the report for 7 consecutive months. Thus, the needed corrective actions for this recommendation had been only partially completed. However, on June 17, 2002, FSIS submitted documentation to OCFO on its progress, and requested final action. OCFO accepted final action on October 28, 2002. FSIS actions did not meet the intent of the recommendation, which was to monitor the responses to sampling requests on a monthly basis, identify instances where inspectors did not respond, and followup with the plant inspectors to determine the reason for their nonresponses. (See exhibit B, Recommendation No. 3.)

At the exit conference, FSIS officials stated that subsequent to our audit work, the number of non-responders had declined considerably. Figures provided to us by FSIS showed that the number of *Salmonella* sample sets open for periods of greater than 18 months had declined to 46 as of October 15, 2003. The figures provided by the agency did not include information for the *E.coli* and RTE testing program.

Recommendation No. 2

Develop a plan to implement the recommendations to correct deficiencies in the laboratory-testing program. This plan should identify the officials responsible for implementing each recommendation. It should also establish reasonable timeframes for the project as well as the individual tasks, and include periodic progress reports addressing each part of the plan. FSIS

management should establish a mechanism that apprises them of the progress. (See exhibit B, Recommendation No. 6.)

Agency Response. In its August 11, 2004, response, FSIS stated,

* * * * * * * * *

*For the remaining recommendation, FSIS has implemented an audit tracking system that includes bi-monthly status reports to the FSIS management council. The status report includes the recommendation where final action is incomplete, identifies the agency official responsible for addressing this recommendation, and the target date for completion of the action * * *.*

OIG Position. We accept the management decision for this recommendation.

Recommendation No. 3

Establish supplementary procedures for the nonresponder reports that includes controls to ensure that monitoring of sampling requests is done on a monthly basis, and followup is performed to determine reasons why plant inspectors did not respond. (See exhibit B, Recommendation No. 3)

Agency Response. In its August 11, 2004, response, FSIS stated,

As referenced in Exhibit B of the report, on August 28, 2002, the OCFO granted FSIS final action for recommendation No. 3. The OIG indicated that the corrective action was partially completed since written guidelines on the use of nonresponder reports have not been provided to the District Offices.

FSIS will issue additional guidance on the use and interpretation of the laboratory nonresponders report by October 2004.

* * * * * * * * *

OIG Position. We accept the management decision for this recommendation.

Section 3: Status of Recommendations to Improve the Imported Meat and Poultry Inspection Program

Our June 2000 audit report of FSIS' Imported Meat and Poultry Inspection Process—Phase I (Report No. 24099-3-Hy) contained 35 recommendations. For 11 of these, FSIS failed to implement the corrective actions it had agreed to take. FSIS satisfactorily implemented corrective actions for 23 recommendations. One recommendation is still in contention.

Actions properly implemented include those largely concerned with FSIS' procedures for determining whether a foreign country's food safety system is equivalent to the U.S. system—a requirement of the imported meat and poultry program. FSIS has instituted guidelines to ensure consistency in equivalency determinations, introduced subject-matter experts in the process, improved documentation of the determinations, and established management oversight of the determinations. FSIS has also strengthened its review of trading partners and of their import inspection methods.

OCFO has yet to grant approval of corrective actions for 4 of the 11 recommendations that FSIS did not implement. The corrective actions relate to FSIS' improvements in the oversight and control of the import inspection program and the integrity of data entered into the information system. (See exhibit C, Recommendations Nos. 1, 2, 14, and 18.) We reported these exceptions in February 2003[2] and FSIS agreed to develop strategies by March 2004 to address weaknesses identified in our June 2000 audit report.

Corrective Actions Not Yet Agreed Upon

Material Control Weaknesses

Our June 2000 report recommended that FSIS recognize the conditions disclosed during our audit as material management control weaknesses and report them as such in the agency's annual management control report required by the Federal Manager's Financial Integrity Act.

FSIS has not yet agreed to do this. As previously reported, basic control activities, such as documented policies, procedures, supervisory reviews and approvals, delegated responsibilities, and clear lines of authority were lacking in FSIS' operations. FSIS did not conduct the indepth assessment of its controls as it agreed to do; therefore, the agency should report the material

[2] Audit Report No. 24099-04-Hy, "Food Safety and Inspection Service Imported Meat and Poultry Reinspection Process Phase II," issued February 2003.

weaknesses in the import inspection process. (See exhibit C, Recommendation No. 6.)

Corrective Actions Agreed Upon But Not Implemented

Indepth Assessment:

During our June 2000 audit, we found that a too rapid reorganization of FSIS in 1997 left the agency's import inspection operations without an adequate system of internal controls. We recommended an indepth assessment of the division's operations as a basis for establishing such a system.

FSIS documented an assessment of the equivalence portion of import inspection operations that included the management controls for major functions (e.g., equivalence determinations and onsite audits). However, no similar assessment was performed for the reinspection portion of the operations. This assessment would have provided the agency with the opportunity to ensure the effectiveness of its operations and to address other material weaknesses. (See exhibit C, Recommendation No. 1.)

As reported in our February 2003 audit report, FSIS did not implement this recommendation but agreed to develop strategies to address it by March 2004. FSIS submitted documentation to OCFO requesting final action on this recommendation on March 20, 2002. As of May 20, 2003, OCFO had not accepted final action.

Management Oversight Functions

The June 2000 report recommended that FSIS require increased management oversight of import inspection operations and procedures and management approval of any changes to those operations and procedures.

FSIS did not prepare a summary of its management oversight functions and procedures even though the agency agreed to do so. FSIS officials claimed that reinspection activities were controlled through a multi-tiered supervisory and management oversight structure. Further, they stated that they relied on DO's to ensure that reinspection activities were well managed and properly functioning. Through discussions with district officials, we learned that DO oversight was minimal, which we confirmed at the import inspector level. Circuit supervisors were not always fully engaged in their oversight responsibilities for import reinspection operations. (See exhibit C, Recommendation No. 2.)

As reported in our February 2003 audit report, FSIS did not implement this recommendation but agreed to develop strategies to address it by March 2004. FSIS submitted documentation to OCFO requesting final action on this recommendation on March 20, 2002. As of May 20, 2003, OCFO had not accepted final action.

Management Control Training

In 2000, we recommended that FSIS provide management control training to agency managers.

FSIS did not provide management control training to all its managers responsible for the reinspection process, as it agreed to do. This training would have given agency managers knowledge for enhancing their oversight capabilities. (See exhibit C, Recommendation No. 3.)

OCFO accepted final action on this recommendation on October 28, 2002. As reported in our February 2003 audit report, FSIS did not implement this recommendation. In response to a recommendation in that report, FSIS agreed to develop strategies by March 2004 to address weaknesses identified in our June 2000 audit report.

Independent Assessments

Our 2000 report recommended that the FSIS internal control staff conduct periodic independent assessments of FSIS programs and operations, emphasizing those processes that changed during the 1997 reorganization of FSIS.

FSIS did not conduct these assessments. In response to our prior recommendation, FSIS' Executive Steering Committee for Management Controls (Committee) was charged with identifying and prioritizing selected processes for independent assessment. Members of this Committee included FSIS management officials (e.g., Associate Administrator and Associate Deputy Administrators). By September 1, 2000, the Committee was to provide guidance on the assessments performed. This guidance was not prepared until September 2001, a year later. The initial focus was to assist agency managers who requested assessments and to review programs that changed during the 1997 reorganization. The guidance also requested quarterly status reports of progress. We found that no reviews had been scheduled or performed and that no status reports had been provided to the Committee. (See exhibit C, Recommendation No. 5.)

OCFO accepted final action on this recommendation on April 3, 2002. As reported in our February 2003 audit report, FSIS did not implement this

recommendation. In response to a recommendation in that report, FSIS agreed to develop strategies by March 2004 to address weaknesses identified in our June 2000 audit report.

Entry of Test Results into the Information System

Reinspection of imported product is directed by FSIS' information system. The system may, for example, generate residue and microbiological laboratory test assignments based on the compliance histories of the plants, countries, and products being presented for reinspection. Our 2000 audit found that FSIS had no clear process for entering the results of laboratory tests into the system. Test results that show the presence of pathogens need to be available to inspectors so they may target their inspections accordingly. We recommended that FSIS establish procedures for entering data into the system and that it institute management controls to ensure the data was entered accurately.

In response to our recommendations, FSIS agreed to institute procedures to streamline the entry of residue and microbial test results into the information system. FSIS established these procedures, but did not document them. Further, no supervisory reviews were conducted to validate the entries. (See exhibit C, Recommendations Nos. 13 and 14.)

On October 28, 2002, OCFO accepted final action on Recommendation No. 13. As reported in our February 2003 audit report, FSIS did not implement this recommendation. In response to a recommendation in that report, FSIS agreed to develop strategies by March 2004 to address weaknesses identified in our June 2000 audit report.

FSIS and OIG reached management decision on Recommendation No. 14 on October 29, 2002. FSIS responded that laboratory results were transferred electronically to the new import information system. FSIS had expected to document the procedures for this process by January 2003. As of June 2003, FSIS had not requested final action from OCFO.

Integrity of Eligibility Data in the Information System

Eight recommendations in our June 2000 report concerned the annual certification of foreign establishments listed to participate in the import reinspection program, and the delistment (removal from the list) of those establishments no longer eligible to import under the program. In response to these recommendations, FSIS agreed to (1) ensure that foreign establishments met annual certification requirements and (2) establish a system for tracking delistments. Neither of these corrective actions occurred. Our June 2000 audit report included eight recommendations to address these weaknesses. FSIS took adequate action to address four of them; however, the agency's

actions were insufficient for the remaining four. (See exhibit C, Recommendations Nos. 17, 18, 19, and 21.)

OCFO accepted final action on Recommendations Nos. 17, 19, and 21 on October 28, 2002. As reported in our February 2003 audit report, FSIS did not implement these recommendations. In response to a recommendation in that report, FSIS agreed to develop strategies by March 2004 to address weaknesses identified in our June 2000 audit report.

As reported in our February 2003 audit report, FSIS did not implement Recommendation No. 18 but agreed to develop strategies to address it by March 2004. FSIS submitted documentation to OCFO requesting final action for this recommendation on March 20, 2002. As of May 20, 2003, OCFO had not accepted final action for this recommendation.

Process Control Report

In 2000, we recommended that FSIS modify its automated system to produce daily process control reports to enable verification of input.

FSIS developed a new information system to increase the efficiency and effectiveness of the system while decreasing the cost of ownership. The prior system had been brought online in 1978. However, FSIS officials did not include a daily process control report in the new information system, even though the agency agreed to do so. This control report would enable FSIS first-line supervisory personnel to timely verify the accuracy of information entered into the system. The examples of management control reports provided by FSIS personnel in April 2002 represented different ways of monitoring the system but did not enable them to verify the accuracy of information entered into the system. (See exhibit C, Recommendation No. 22.)

OCFO accepted final action on this recommendation on October 28, 2002. As reported in our February 2003 audit report, FSIS did not implement this recommendation. In response to a recommendation in that report, FSIS agreed to develop strategies by March 2004 to address weaknesses identified in our June 2000 audit report.

We included recommendations to correct the noted deficiencies in our report on "Imported Meat and Poultry Reinspection Process, Phase II" (Audit No. 24009-4-Hy, issued February 2003). Therefore, no further recommendations are made in this report.

Our June 2000 audit report of FSIS' District Enforcement Operations' Compliance Activities (Report No. 24601-4-At) contained eight recommendations. FSIS has satisfactorily implemented corrective actions on all eight recommendations.

In responding to our 2000 report, FSIS identified high-risk firms and created timeframes for monitoring and tracking violations of the meat and poultry inspection laws, and agreed to continue seeking authority to assess civil monetary penalties against the violators. FSIS established procedures to monitor the receipt and followup of all consumer complaints and reviewed 16 consumer complaints it had previously overlooked. FSIS also enhanced its plan to target resources to large metropolitan and geographic areas and high-risk firms and provide training to ensure that all managers are able to properly oversee violation case review and preparation.

Scope and Methodology

The audit fieldwork was conducted at the FSIS National Office in Washington, D.C.; OCFO in Washington, D.C.; the FSIS Technical Service Center (TSC) in Omaha, Nebraska; the Chicago DO in Lombard, Illinois; the district sub-area office in Jamaica, New York; and two judgmentally selected plants located in Alabama and South Carolina. The fieldwork was performed August 2002 through June 2003.

To assess the corrective actions taken to date by FSIS we:

- Reviewed the corrective action FSIS had taken on each recommendation made in prior cited audit reports;
- Conducted interviews with responsible FSIS and OCFO officials;
- Reviewed FSIS' regulations, instructions, procedures, studies, published reports, media releases, and other Government reviews; and
- Conducted site visits to the FSIS National Office, FSIS' TSC, DO's, and plants located in Alabama and South Carolina. These plants were judgmentally selected based on recent indepth verification reviews performed by FSIS and on travel costs.

The audit was conducted in accordance with Government Auditing Standards (1994 Revision) issued by the Comptroller General of the United States.

Exhibit A - Summary of the Status of Recommendations – Implementation of HACCP System Audit

Recommendation Number	Recommendation	Agency Response	Management Decision	Action Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
1	Implement a system of oversight, such as DO or independent reviews, to ensure HACCP plans contain minimum required CCP based on the HACCP models. Issue instructions that provide clear guidance on requirements for establishing CCP's and inspector's authority to require changes to documented CCP's. Revise checklist used to evaluate HACCP plans.	The four individual reviews will ensure necessary CCP's are identified. Created the Food Safety Systems Correlation (FSSC) Team. Established Consumer Safety Officer (CSO). Will continue to hold work unit meetings in each of district.	Yes	None	No	FSIS requested final action on February 5, 2003. OCFO requested additional information on March 4, 2003.
2	Implement a system of oversight to ensure HACCP plans contain adequate critical limits and corrective actions are proper.	FSIS implemented individual reviews to improve oversight, to ensure HACCP plans contain CCP critical limits and corrective actions for deviations are appropriate. FSIS contracted for the development of a hazard and controls guide.	Yes	None	No	FSIS requested final action on February 5, 2003. OCFO requested additional information on March 4, 2003.
3	Implement a system of oversight to ensure that the hazard analysis includes all food safety hazards that are reasonably likely to occur.	FSIS implemented several individual reviews to improve oversight, to ensure that hazard analysis identifies food safety hazards reasonably likely to occur at the establishment. FSIS contracted for the development of a hazard and controls guide.	Yes	None	No	FSIS requested final action on February 5, 2003. OCFO requested additional information on March 4, 2003.
4	Implement a system of oversight to include management reviews and/or independent reviews requiring establishments to correct flowcharts to reflect the establishments' actual operations.	FSIS implemented several individual reviews to improve oversight to ensure flowcharts incorporate the establishments' processes. Created FSSC Team and CSO positions.	Yes	None	Yes	FSIS requested final action on February 5, 2003. OCFO requested additional information on March 4, 2003.
5	Develop and implement procedures that provide FSIS employees with the authority to require HACCP plans to include pathogen testing of product environment, contact surfaces, and final products.	In January 1999, FSIS issued performance standards for the production of certain meat and poultry products. FSIS expects to issue a proposed regulation by June 2001, addressing RTE meat and poultry.	Yes	None	Yes	OCFO accepted final action for this recommendation on January 28, 2003.

Recommendation Number	Recommendation	Agency Response	Management Decision	Action Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
6	Provide clear authority in the Grant of Inspection contact for FSIS oversight of all plant pathogen testing.	On March 31, 2004, FSIS issued FSIS Directive 5000.2, *Review of Establishment Data by Inspection Program Personnel*. This directive reaffirms FSIS' authority for accessing all internal and external plant pathogen and microbial testing results. The directive specifies that inspection personnel are to be aware of all monitoring and of all food safety testing conducted by the establishment and should ask establishment management to make available for review the data that is generated by such monitoring or testing so that it is available when inspection program personnel are verifying HACCP records. Also, on at least a weekly basis, inspection personnel must review the results of any testing and of any monitoring activities that the establishment performed that may have an impact on the establishment's hazard analysis. Since the results of any testing and of any monitoring activities performed by the establishment may have an impact on the establishment's hazard analysis, records of these activities are subject to FSIS review and are to be made available to FSIS personnel.	Yes	None	Yes	FSIS has not requested final action from OCFO.
7	Develop testing programs in coordination with the Agricultural Research Service (ARS) for other pathogens that impact food safety.	FSIS continues to work closely with ARS in a variety of food and safety research and development areas. Immunomagnetic bead method implemented in all three FSIS laboratories. Projects involving *LM*, handling, transportation, and chilling of meat and poultry. Developing proposals for new research projects to develop detection methods.	Yes	None	Yes	OCFO accepted final action for this recommendation on April 7, 2003.

Recommendation Number	Recommendation	Agency Response	Management Decision	Action Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
8	Improve controls by issuing instructions for securing FSIS test samples until the samples are in the possession of the shipping agent and review security to ensure that instructions are being followed.	FSIS laboratories are revising Directive 7355.1 to reflect a more fail-safe procedure. The revised directive will provide a unified system to ensure the integrity of samples submitted to laboratories for analysis.	Yes	None	Yes	OCFO accepted final action for this recommendation on April 7, 2003.
9	Implement management controls that include (1) timely providing field office inspectors microbe testing results, (2) instructions to field offices to continue *Salmonella* testing each production day, (3) procedures to notify the DO if a field office stops submitting *Salmonella* samples prior to the completion of a testing series, and (4) procedures to ensure seasonal and products with irregular production schedules are tested in direct testing program.	Implement Pathogen Reduction Enforcement Program (PREP) RTE modules and the *E.coli* module. The Management Information Report forwarded to the DO for review will reflect that some sampling for an establishment has not been received for 30 days.	Yes	None	Yes	OCFO accepted final action for this recommendation on April 3, 2003.
10	Implement procedures that require inspectors to review and approve plants' sampling protocols for generic *E.coli* testing to ensure they are complete and being following.	FSIS implemented several individual reviews to improve oversight of the establishments' sampling protocols for genetic *E.coli*. The concerns identified in this recommendation are addressed in the four individual reviews.	Yes	None	Yes	OCFO accepted final action for this recommendation on February 17, 2004.
11	Expand the language in the Grant of Inspection agreement to include the requirements and responsibilities required of the plant under the HACCP program, FSIS authority, oversight, and access to information for plants' operation. Use Grant of Inspection as a contract, or enforceable agreement between the Government and the establishment signed by all parties and subject to review and renewal.	On March 31, 2004, FSIS issued FSIS Directive 5000.2, *Review of Establishment Data by Inspection Program Personnel*. The directive specifies that inspection personnel are to be aware of all monitoring and of all food safety testing conducted by the establishment and should ask establishment management to make available for review the data that is generated by such monitoring or testing so that it is available when inspection program personnel are verifying HACCP records. Since the results of any testing and of any monitoring activities performed by the establishment may have an impact on the establishment's hazard analysis, records of these activities are subject to FSIS review and are to be made available to FSIS personnel.	Yes	None	Yes	FSIS has not requested final action from OCFO.

Recommendation Number	Recommendation	Agency Response	Management Decision	Action Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
12	Require plants to include all pathogen testing performed by the plants in their HACCP plans, to retain test results, and to notify the Inspector-in-Charge (IIC) of adverse microbial test results.	The pathogen reduction (PR)/HACCP regulation does not require plants to include pathogen testing in their HACCP plans. FSIS will verify corrective actions when findings occur and corrective actions taken and documented by the plant as well as reassessment and modification of the HACCP plan when adverse microbial test results occur.	No	FSIS needs a description of how recommendation will be implemented and timeframe for implementation.	No	None
13	Instruct IIC's to assess the adequacy of the plants' corrective actions to eliminate harmful pathogens and to monitor those actions.	FSIS agrees to reinforce the requirement to access the adequacy of plants' corrective actions and to monitor these actions.	Yes	None	Yes	OCFO accepted final action for this recommendation on February 28, 2003.
14	Develop and implement an internal review system to provide assurances that plant level HACCP, SSOP, and microbial testing programs are operating as intended.	As mentioned in response to Recommendation No.1, FSIS is implementing the in depth verification review.	Yes	None	Yes	OCFO accepted final action for this recommendation on April 7, 2003.
15	Ensure that IIC's routinely evaluate the effectiveness of SSOP's and require changes and modifications to plants' SSOP plans when needed.	FSIS agrees to reinforce inspector's authorities in relation to the Sanitation Performance Standard regulation and SSOP's through better communication and training, National Supervisory Conferences, and work unit meetings.	Yes	None	Yes	OCFO accepted final action for this recommendation on April 9, 2003.

Recommendation Number	Recommendation	Agency Response	Management Decision	Action Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
16	Establish procedures that require that the returned product process be included in the hazard analysis and HACCP plan.	FSIS believes its current regulations require the establishment to identify any hazard related to the returned product process and include such hazards in the hazard analysis. FSIS implemented several reviews.	Yes	None	Yes	FSIS requested final action on February 5, 2003. OCFO requested additional information on March 4, 2003.
17	Establish procedures for inspectors that include their oversight responsibilities from the point of product return to product distribution.	FSIS is implementing several review processes to ensure establishments' HACCP plan(s) address regulatory requirements. FSIS implemented four individual reviews. Also, contracted for the development of hazards and control guide.	Yes	None	No	FSIS requested final action on February 5, 2003. OCFO requested additional information on March 4, 2003.
18	Require FSIS DO personnel monitor and update scheduled tasks on a continuous basis and to establish additional codes or require inspectors to document why tasks are not performed.	FSIS relies on the Inspection Systems Procedure Guide and the PBIS to schedule and record the performance of inspection procedures.	No	FSIS need details/ timeframes on how recommendation will be implemented.	No	None
19	Develop and implement progressive enforcement procedures that establish specific parameters for repetitive deficiencies and provide a basis for determining when corrective actions are inadequate and when enforcement actions should be promptly initiated.	FSIS will develop procedures for repetitive deficiencies by December 2000.	Yes	None	No	FSIS requested final action on April 3, 2003. OCFO requested additional documentation on May 12, 2003.
20	Establish timeframe requirements for responding to NR's and initiating planned corrective actions.	FSIS does not find it advisable to establish specific timeframes. FSIS believes its current regulations hold plants accountable for initiating and implementing corrective actions. FSIS does not agree to change the procedures for issuing NR's, but it does agree to reinforce inspection personnel responsibilities for monitoring and evaluating corrective actions.	No	FSIS needs a process in place to determine whether plants open NR's are due to the length of time it takes to correct deficiencies or due to the need of a description of how the recommendation will be implemented.	No	None

Exhibit B - Summary of the Status of Recommendations – Laboratory Testing of Meat and Poultry Products Audit

Recommendation Number	Recommendation	Agency Response	Management Decision	Action Needed for Mgmt. Dec	Recommendation Implemented	FSIS Requested Final Action
1	Develop a management system to track each inspector's compliance with requirements for semiannual updates to the sampling frames. Followup with establishment inspectors who do not respond to ensure that sampling information is up-to-date for all establishments.	FSIS officials responded that they would develop an approach to followup with inspectors. For *Salmonella* testing, FSIS developed the PREP that would, among its other features, allow FSIS to ensure that inspectors provide current and updated profile information for each FSIS-inspected establishment. For RTE products (*Listeria* testing) and ground beef products (*E.coli* testing) the PBIS system would be enhanced as necessary to provide the needed profile data. Corrective actions for *Salmonella* and residue testing would be in place by September 2000, and for *E.coli* and *Listeria* testing by December 2000.	Yes	None	Yes Establishment inspectors are required to update the profiles electronically. The PREP system has been implemented, to allow FSIS Headquarters or DO officials to determine whether the profile data on each establishment is current.	OCFO accepted final action on May 12, 2003.

Recommendation Number	Recommendation	Agency Response	Management Decision	Action Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
2	Develop a database that identifies and segments all establishments producing products designated for sampling under the various sampling projects. Use this information to maintain a current listing within the sampling frames for the sampling projects.	FSIS stated that it would enhance the PBIS establishment profile by December 2000, to include all product information needed for sampling programs and require inspection personnel to keep that information up to date.	Yes	None	Yes FSIS made changes to their PREP system in order to capture changes in plant profile information. The data from the PBIS system is downloaded to the PREP system as a means to update the plant profile.	OCFO accepted final action on April 17, 2003.
3	Institute procedures to monitor the responses to sampling requests on a monthly basis, and identify instances where inspectors do not respond. Where inspectors do not respond to sampling requests, require DO's to followup with the establishment inspectors to determine the reason for their failure to provide the required responses. In addition, perform immediate followup on the 197 establishments that failed to respond to 3 or more requests.	FSIS officials stated that by September 2000 their PREP system for *Salmonella* testing would be producing a quarterly report identifying nonresponding establishment inspectors. In addition, the automated e-mail system developed earlier to notify inspectors and circuit supervisors of problems with discarded samples would be enhanced to provide feedback on nonresponders under all three major testing programs, *Salmonella*, RTE, and *E.coli*. These actions would be completed by September 2000. Later, quarterly reports of nonresponders would be developed for the *E.coli* and RTE testing programs as well.	Yes	None	No FSIS now distributes the nonresponder reports for all three major testing programs (*Salmonella, E.coli*, and RTE) but has not provided DO's with written guidelines for their use. Therefore, they have only partially completed the necessary corrective actions. FSIS followup on the 197 cited establishments was completed by October 6, 2000.	FSIS requested final action for this recommendation on June 17, 2002. As of October 28, 2002, OCFO has accepted this recommendation for closure. OIG disagreed that final action has been achieved, and has verbally informed the responsible FSIS official of this.

Recommendation Number	Recommendation	Agency Response	Management Decision	Action Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
4	Implement a system, which allows FSIS to track the status of sample requests, including their receipt and disposition by inspectors at meat and poultry establishments.	FSIS agreed to modify the PBIS system to track the status and disposition of sample requests. This was to be done through the creation of a "sample log" in PBIS. As part of the implementation process, FSIS would modify Directive 10,230.5 to include instructions on maintaining the log by December 2000.	Yes	None	Yes On April 17, 2003, FSIS requested a change of management decision. OIG concurred with the change on June 5, 2003.	OCFO accepted final action on July 3, 2003.

Recommendation Number	Recommendation	Agency Response	Management Decision	Action Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
5	Determine whether it is necessary for FSIS inspectors to be able to ship product samples to the field laboratories on Fridays and on days preceding holiday. Renegotiate the existing agreement with the overnight courier to ensure next-day deliveries of such shipments, or inform the laboratories and all FSIS inspectors to discontinue shipments of product samples on these days if alternative methods are developed to test products that are produced on these days.	FSIS officials stated that they have determined that it is necessary for inspector's to ship samples on Fridays and on days preceding holidays for *Salmonella* analysis. However, the agency disagrees that further negotiation of the contract is necessary, since the General Services Administration contract with the overnight courier does require Saturday delivery of samples if these are properly labeled. FSIS officials stated that they have had Saturday delivery of HACCP samples since the initiation of the HACCP *Salmonella* Program on January 26, 1998. All laboratories receive and process samples via the overnight courier on Saturdays and selected holidays. They stated that FSIS has experienced occasional problems with Saturday deliveries only in a few remote locations. They also stated that OIG may have experienced difficulty shipping samples due to the lack of "Saturday Delivery" labels. Regarding holiday deliveries, FSIS maintains close contact with the overnight courier to determine which holidays the courier is not operating. In situations where the courier does not deliver on a particular holiday, FSIS notifies the inspectors in all HACCP establishments so that samples are not sent. Finally, FSIS officials stated that the overnight courier recently initiated a new process that does not require the use of special labels for Saturday delivery. A new flyer is being distributed to all FSIS inspectors immediately.	Yes	None	Yes FSIS now includes a flier in all boxes going out to the field, instructing the inspectors to check the Saturday Delivery box if shipping on a Friday. Also, a Saturday Delivery label must be affixed to the shipment box. In addition, inspectors are now sent flyers to remind them not to send out samples on the day preceding a holiday.	OCFO accepted final action on October 28, 2002.

Recommendation Number	Recommendation	Agency Response	Management Decision	Action Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
6	Ensure that all establishments producing bacon products are subject to required testing for nitrosamines. Implement a comprehensive program for testing for this substance, under which all bacon-producing establishments would have product subject to periodic testing over a predetermined period of time.	FSIS agreed to publish, by March 2, 2001, a rule to convert the nitrosamines testing requirements of 10 Code of Federal Regulations (CFR) 318.7(b) into performance standards under HACCP. The standard would address the nitrosamines levels as well as the potential growth of *Clostridium botulinum.*	Yes	None	No FSIS officials provided us with a copy of the proposed performance standard for bacon. The proposed rule that FSIS provided us was a draft and FSIS was unable to provide timeframes when the regulations would be implemented. FSIS did not report the draft in the Federal Register, nor could they tell us when the draft would go to the Federal Register. Therefore we believe that this recommendation has not been sufficiently implemented and that FSIS submitted documents and requested final closure prematurely.	FSIS submitted draft documentations for final action to OCFO on January 9, 2003. OCFO's decision is still pending.
7	Establish monitoring procedures to ensure that the results of proficiency check samples are reported to the laboratories in a timely manner, and that laboratories are required to provide written responses to ensure that appropriate corrective action, such as training or increased supervision, is taken.	FSIS agreed to develop procedures to assist in the review, evaluation, and reporting of check sample results. Additional mechanisms would be developed to ensure that any necessary corrective actions are implemented, recorded, and properly reported to the appropriate officials. FSIS officials stated that they had drafted standard operating procedures (SOP) to strengthen these controls. The new procedures were to be completed by September 2000.	Yes	None	Yes FSIS developed SOP's No: LW-0025.01 for laboratory proficiency testing. This SOP became effective on August 24, 2001.	OCFO accepted final action on October 28, 2002.

Recommendation Number	Recommendation	Agency Response	Management Decision	Action Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
8	Develop and implement procedures that schedule onsite laboratory reviews at regular intervals, establish guidelines for issuing reports within specified timeframes, and require the laboratories to respond to the reports' recommendations. In addition, implement procedures for Quality Assurance Branches (QAB) to track the status of both draft and issued reports to ensure that they are processed and responded to in a timely manner.	FSIS officials stated that they were in the process of instituting improvements to the management of reviews of the FSIS laboratories to include the areas of scheduling, auditing, reporting, tracking, and followup on corrective actions. They stated that QAB scientists had been assigned specific tracking and followup responsibilities. Also, QAB was developing SOP's to help ensure that reviews, responses, and corrective actions all occur in a timely, efficient, and acceptable manner. The following SOP's were under development and were expected to be completed by October 2000 (1) preparation, submission, and tracking of field service laboratory audit reports and (2) scheduling and conducting of field service and other agency laboratory audits.	Yes	None	Yes FSIS developed SOP No: L-0004.01 for FSIS laboratory system audits. This SOP became effective on January 18, 2002.	OCFO accepted final action on October 28, 2002.
9	Require the (*Salmonella* test kit) vendor to begin immediate preparation of a new production lot of *Salmonella* test kits, which meet the Microbiology Laboratory Guide (MLG) and Association of Analytical Chemists (AOAC) standards, so that the use of the test kits from the two existing lots can be discontinued at the earliest possible time.	On November 19, 1999, agency officials stated that the vendor had agreed to begin immediate preparation of a new production lot of *Salmonella* test kits, which meet the MLG and AOAC standards so that the use of tests kits from the two existing lots could be discontinued at the earliest possible time. In the response to the official draft, FSIS officials stated that they had obtained new test kits.	Yes	None	Yes	OCFO accepted final action on October 28, 2002.

Recommendation Number	Recommendation	Agency Response	Management Decision	Action Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
10	Amend FSIS contract specifications for *Salmonella* test kits to comply with the MLG.	FSIS did not believe that a change in contract specifications was needed. They believe instead that changing the MLG performance characteristics to make them more stringent would meet the intent of the recommendation. OIG agreed to this change.	Yes	None	Yes FSIS changed the MLG to state "Any screening method under consideration for *Salmonella* testing must meet or exceed the following performance characteristics: sensitivity 97%, specificity 90%, false negative rate 3%, and false positive rate 10%". The changes became effective on October 25, 2002.	OCFO accepted final action on October 28, 2002.
11	Establish an inventory reorder point to ensure that orders for new test kits are placed early enough to allow sufficient time for FSIS to verify that production lots meet requirements, or if necessary to obtain new test kits before the laboratories exhaust their existing stocks.	FSIS agreed to establish an inventory reorder point to ensure that orders for new kits are placed early enough to allow sufficient time to verify that they meet requirements before laboratories exhaust the existing supplies.	Yes	None	Yes FSIS directed the laboratories to submit purchasing orders for kits when existing inventory has been reduced to a 2-month supply. This action was completed November 4, 1999.	OCFO accepted final action on March 4, 2003.

Recommendation Number	Recommendation	Agency Response	Management Decision	Action Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
12	Establish a training program that will (1) identify required training for microbiology staff members; (2) provide formal; structured training in addition to informal on-the-job training; (3) document the training provided to each staff member; (4) assess and document the competence of each staff member to perform tests and supporting activities; and (5) monitor the continued competence of each staff member to perform laboratory tests.	FSIS officials stated that the agency had drafted new SOP's and work instructions that would address OIG's concerns. FSIS also agreed to develop more extensive checklists for on-the-job training and to implement a periodic testing program for individual analysts to further demonstrate continued competency.	Yes	None	Yes FSIS developed SOP No: LW-0040.00 for FSIS Microbiology Analyst Training and Ongoing Demonstration of Competency and SOP No: LW-0039.00 for Chemistry Analyst Training. Both SOP's became effective on November 18, 2001. FSIS has also implemented the use of Laboratory Training Worksheets, Analyst Method Training Records, and Microbiology External Training Records.	OCFO accepted final action on October 28, 2002.
13	Develop and implement a quality assurance program for the Special Project and Outbreak Support Laboratory (SPOSL).	FSIS agreed to institute a proficiency check sample program for the SPOSL. In addition, FSIS scheduled SPOSL for a laboratory review by the last quarter of fiscal year (FY) 2000.	Yes	None	Yes FSIS developed SOP No: LW-0009.01 for management reviews. This SOP became effective on November 29, 2001. FSIS instituted a proficiency check sample program during May 2002.	. OCFO accepted final action on October 28, 2002.

Recommendation Number	Recommendation	Agency Response	Management Decision	Action Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
14	Require the laboratories to implement a quality assurance system that ensures adequate documentation of analytical results, including but not limited to the methods used, and incubation times and temperatures. Require supervisory personnel at the laboratories to ensure, as part of their review, that all necessary documentation is being prepared on an ongoing basis.	FSIS agreed to take steps to review if necessary, enhance the documentation and supervisory oversight of all components of the laboratory systems by January 2001.	Yes	None	Yes FSIS developed the following SOPs to ensures adequate documentation of analytical results: SOP No: ML-0005.00 for submitting and reviewing data. This SOP became effective on June 20, 2001. SOP No: WL micro 0017.01 for data review. This SOP became effective on September 25, 2001. In addition, FSIS implemented a microbiology data and quality control review.	OCFO accepted final action on October 28, 2002.
15	Implement a quality assurance system to ensure that adequate maintenance, servicing, and calibration is both performed and documented as required for each piece of equipment used in testing.	FSIS agreed to develop additional procedures, work instructions, and forms that would further and more completely document the ongoing maintenance, servicing, and calibration of testing equipment. This was to be completed by December 2000.	Yes	None	Yes FSIS developed MLG Chapter 36, SOP LW-0008, to ensure proper maintenance and calibrations of laboratory equipment.	OCFO accepted final action on October 28, 2002.
16	Strengthen the agency's monitoring of accredited laboratories, particularly those which test official samples for FSIS, through more frequent onsite visits and/or split sampling of official product samples.	FSIS officials stated that split sampling was, based on prior experience, an ineffective means to ensure the accuracy of test results. However, the agency agreed to initiate an agreement or contract to perform more frequent accredited laboratory onsite visits. FSIS proposed to implement this action by February 2001.	Yes	None	Yes FSIS revised SOP ADMIN/PROG-1, dated November 6, 2002, which requires that accredited laboratories are reviewed on-site at least once every 2 years.	OCFO accepted final action on March 4, 2003.

Recommendation Number	Recommendation	Agency Response	Management Decision	Action Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
17	Ensure that all test results on official samples are performed only by FSIS-accredited laboratories.	FSIS officials proposed the following corrective actions by March 2001 (1) Update monthly the list of accredited laboratories, (2) develop a statement of work to upgrade the FSIS laboratory data entry software to accept only valid accredited laboratory identification numbers, (3) provide written instructions to laboratory data entry personnel dealing with laboratory identification numbers that were flagged by the computer as being valid and (4) ensure that Accredited Laboratory Program officials review relevant instructions, directives, forms etc., used by field inspection personnel for chemical analyses.	Yes	None	Yes	OCFO accepted final action on April 2, 2003.

Exhibit C - Summary of the Status of Recommendations – Imported Meat and Poultry Inspection Process - Phase I Audit

Recommendation Number	Recommendation	Agency Response	Management Decision	Action Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
1	Conduct an indepth assessment of the current organizational structure to establish a system of control objectives and processes to ensure that the goals of the import inspection process are achieved.	FSIS agreed with this recommendation and the agency planned to assess the current organizational structure and identify import inspection controls, objectives and processes. The assessment was to be completed by May 2001.	Yes	None	No	FSIS requested final action on March 20, 2002.
2	Require increased management oversight and approval of changes to import inspection operations and procedures.	FSIS believed that management oversight and approval of changes to import inspection operations and procedures were adequate. Inspection of imported meat and poultry product was controlled through a multi-tiered supervisory and management oversight structure. FSIS agreed to prepare a summary of the management oversight functions and procedures. These procedures were to outline FSIS' efforts to strengthen management controls for all import operations. The consolidated written procedures were to be developed by March 2001.	Yes	None	No	FSIS requested final action on March 20, 2002.
3	Provide management control training to agency managers.	FSIS agreed with this recommendation and stated that it believes in continuous education and refresher training for its managers in a number of areas. FSIS agreed to make arrangements for its Imported Meat and Poultry Inspection managers at Headquarters, DO's, and the TSC to receive additional training on management controls. The agency also agreed to arrange for training similar to the Management Accountability and Control (Office of Management and Budget [OMB] Circular A-123) course offered by the Government Audit Training Institute at the Graduate School, USDA by December 1, 2000. Finally, FSIS agreed to explore including a training module on management controls in its Management Leadership and Development Program, which would be available to all agency managers.	Yes	None	No	Final action accepted on October 28, 2002. OIG disagreed that final action has been achieved.

Recommendation Number	Recommendation	Agency Response	Management Decision	Action Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
4	Revise FSIS Directive 1090.1 to incorporate the provisions of OMB Circular A-123, Revised, "Management Accountability and Control," dated June 21, 1995, and to document specific program control objectives and the review procedures that will provide management reasonable assurance on the effectiveness of controls.	FSIS agreed with this recommendation and updated its Directive 1090.1 to incorporate the provisions of OMB Circular A-123, Revised, Management Accountability and Control," dated June 21, 1995. The directive outlined a process for establishing program control objectives and procedures that would provide management reasonable assurance on the effectiveness of controls.	Yes	None	Yes	Final action accepted on October 28, 2002.
5	Require the FSIS the Internal Control Staff (ICS) to conduct periodic independent assessments of FSIS' programs and operations, emphasizing those processes that changed in the reorganization.	FSIS agreed to establish selection criteria for conducting periodic independent assessment of FSIS' programs and organizations as appropriate. The Executive Steering Committee for Management Controls would identify and prioritize for independent assessment selected processes that changed during the 1997 reorganization that should be reviewed. FSIS agreed to direct the ICS, through guidance provided by the FSIS Executive Steering Committee on Management Controls, to conduct independent assessments of selected processes that changed during the 1997 reorganization. A memorandum of instruction to the ICS was to be issued by September 1, 2000, from the Executive Steering Committee on Management Controls to address this recommendation.	Yes	None	No	Final action accepted on April 3, 2002. OIG disagreed that final action has been achieved.

Recommendation Number	Recommendation	Agency Response	Management Decision	Action Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
6	Report the conditions disclosed in this audit as material management control weaknesses in the import inspection process.	FSIS strongly disagreed with the OIG recommendation that the issues outlined in this audit report constitute a material management control weakness. They acknowledged the need to strengthen management controls and procedures, but they do not believe that the findings of this audit represent a reportable material management control weakness. Although, FSIS agreed with most of the suggested management controls improvements in this audit, they do not believe they constituted a reportable material weakness of the import inspection process. FSIS would address opportunities for strengthening the management controls identified in the audit report and report them in accordance with the Agency's assessment of OMB Circular A-123 requirements.	No	Basic control activities, such as documented policies, procedures, supervisory reviews and approvals, delegated responsibilities, and clear lines of authority were lacking in FSIS' operations. In the absence of the indepth assessment of controls agreed to in response to Recommendation No. 1, FSIS should report the findings in this audit as material control weaknesses in the import inspection operations.	No	None
7	Review the roles and responsibilities of personnel involved in the equivalence determination process, the onsite review process, and the input of data to update the Automated Import Information System (AIIS), and define more specifically the authority and responsibilities of those units.	FSIS reviewed the roles and responsibilities of personnel involved in the equivalence determination process, the onsite review process, and the input of data to update the AIIS.	Yes	None	Yes	Final action accepted on October 28, 2002.

Recommendation Number	Recommendation	Agency Response	Management Decision	Action Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
8	Prior to the onsite review, ensure that the TSC reviewers are provided with all information necessary to verify data provided by foreign countries for equivalence determinations.	FSIS agreed to develop formal procedures that will continue to ensure that the TSC is provided all information necessary for the reviewers to verify data provided by foreign countries during equivalence determinations. The procedures were to be completed in December 2000.	Yes	None	Yes	Final action accepted on April 3, 2002.
9	Provide training to all inspectors responsible for conducting inspections of imported products.	FSIS developed updated import training for field inspectors who conduct import inspection activities. Training began in FY 2001 and included on-the-job training, pre-classroom CD-ROM's that cover basic import inspection procedures, and a formal training session at various United States ports of entry.	Yes	None	Yes	Final action accepted on May 20, 2003.
10	With the help of technical subject-matter experts, develop and implement comprehensive guidelines as a means of ensuring propriety and consistency in decisions involving equivalency determinations.	FSIS developed and implemented comprehensive written guidelines for equivalence determinations.	Yes	None	Yes	Final action accepted on April 3, 2002.
11	Develop written criteria and procedures for suspending the eligibility of exporting countries that do not provide sufficient documentation to support their continuing compliance with United States equivalency standards or are found to be in noncompliance based on the results of an onsite equivalency review.	FSIS agreed with this recommendation. FSIS regulations, 9 CFR 327.2, delineate criteria for both initially determining the eligibility of a foreign country to import products into the United States and for withdrawing a foreign country's eligibility to import. FSIS was to consolidate this requirement into formal procedures and guidelines by March 2001.	Yes	None	Yes	Final action accepted on October 28, 2002.

Recommendation Number	Recommendation	Agency Response	Management Decision	Action Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
12	Develop written procedures, which ensure comprehensive evaluations of foreign countries' alternative import inspection methods, and require the analysis of these systems be documented, as well as the decisions reached.	Consolidated written procedures were developed to document equivalence decisions regarding alternative import inspection methods. Effective July 1, 2000, new equivalence decision files documented (1) All FSIS correspondence with foreign countries; (2) All foreign country submissions (translated and in the originating language); (3) Summary International Policy Division (IPD) reviews of submissions; (4) Summary of all meetings and teleconferences with foreign officials; (5) Summary of all reviews by subject-matter experts; (6) Documentation of equivalence criteria; (7) Summary of all FSIS management formal reviews and approvals; and (8) decision memorandum of the equivalence determinations.	Yes	None	Yes	Final action accepted on April 3, 2002.

Recommendation Number	Recommendation	Agency Response	Management Decision	Action Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
13	Streamline the process and establish procedures that would allow expeditious entry of laboratory test results into the AIIS.	FSIS agreed that additional documentation would assist in clarifying the current system to both Agency personnel as well as outside auditors. FSIS was to be reevaluating the current system as part of the redesign of the AIIS and was to improve the documentation by December 2000 to outline the procedures for entering laboratory results into the AIIS system. As an interim measure, in March 2000, the Field Automation and Information Management (FAIM) Division instituted non-automated procedures to streamline the entry of residue and microbial results. As of March, FAIM received faxes from the TSC of laboratory Form 9770-2 for all positive residue results. The FAIM Division then documented directly on the laboratory form both the date it was received (via fax) and the date/time the lab results were entered into AIIS. Entries into the AIIS were to be made the same day they are received. Also, an internal verification process was to be established to monitor the data being entered into the AIIS. Also, FSIS was working to replace the AIIS. The new system, eventually sharing Sybase SQL tables with the Microbiological and Residue Computer Information System (MARCIS) and other agency systems will ensure real time accuracy of both negative and positive results of residue tests and microbiological tests. The FAIM Division began work on the new AIIS application in March 2000, with a test pilot planned for the first quarter of 2001. FSIS expected the system to be fully operational by December 2001.	Yes	None	No	Final action accepted on October 28, 2002. OIG disagreed that final action has been achieved.

Recommendation Number	Recommendation	Agency Response	Management Decision	Action Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
14	Require the Office of Field Operations to work with the TSC and the FAIM Division to develop management controls and a supervisory review process to ensure that all laboratory test results are promptly and accurately entered into the AIIS. Management controls must include requirements for maintaining records of when failure notifications are received and when the entries are made into the AIIS.	FSIS agreed with this recommendation. The FAIM Division was to focus on incorporating the required management controls in the replacement AIIS, which was to be completed by December 2001. The new import computer system would document when laboratory failure results are received and incorporated into the system data tables. In the interim, FSIS established a manual tracking process that documents when notification of failures is received and when the entries are made into the AIIS. Entries were to be made within 24 hours of receipt of the positive laboratory results. Negative results were to be obtained via a weekly download from MARCIS and entered that same day into the AIIS. FSIS believed that the management controls and supervisory review process could be enhanced to ensure that all laboratory results are promptly and accurately entered into the AIIS. Management controls currently included requirements for maintaining records that indicate when failure notifications are received, and when the entries are made into the AIIS. Under the new import information system, laboratory results are no longer entered manually. Test results are electronically transferred from MARCIS to the new system. A staff person has been assigned to verify the data exchange is performed successfully each day. The procedures for this process will be provided by January 2003.	Yes	None	No	FSIS had not requested final action.

Recommendation Number	Recommendation	Agency Response	Management Decision	Action Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
15	Officially notify all countries importing meat and poultry into the United States that annual certifications are due no later than the established date and that establishments that are not certified by this date may be delisted. Incorporate this requirement in regulations.	FSIS agreed that meat and poultry products exported to the United States must be produced in properly certified foreign establishments. To ensure that this occurs, the FAIM Division was to establish a Web site with search capabilities that allows import inspectors to obtain the status (certification, delistment, relistment) of foreign establishments. FSIS agreed to continue to notify all countries that certifications of establishments must be renewed annually, and if establishments are not certified annually they may be delisted. However, FSIS did not agree with the OIG's assertion that allowing countries to delay their certifications "reduces the control to prevent products from uncertified establishments from entering the United States." According to FSIS, annual certification lists are often obsolete soon after they arrive because importing countries add and delete certified establishments throughout the year. Furthermore, an additional method exists to verify that the imported product was produced in an establishment certified for export to the United States. This method is set forth in 9 CFR 327.4, "Imported products, foreign certificates required." A foreign meat inspection certificate must accompany each consignment of fresh meat, fresh meat byproducts, or meat food products. All such consignments (or lots) offered for entry into the United States from any foreign country must be reinspected by an FSIS import inspector before they are allowed into this country. An authorized foreign government official signs the certification accompanying each lot. FSIS believed that these certificates provide ample evidence that the product they accompany was produced in a foreign-certified establishment. By September 2001, FSIS planned to publish a proposed revision of Part 327, Imported Products, to eliminate the annual certification requirement. In October 2002, FSIS established a target date of January 15 as when countries will be notified that annual certifications are due. On that date each year, FSIS will notify countries that their annual certifications will be required within 120 days and the consequences if the certifications are not received by the required date.	Yes	None	Yes	Final action accepted on April 9, 2003.

Recommendation Number	Recommendation	Agency Response	Management Decision	Action Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
16	Establish a followup process to obtain the annual certification lists from the countries, which have not submitted them.	FSIS was to establish a followup process to obtain annual certification lists from countries that had not submitted them. This process was subject to change after the proposed revisions (see response to Recommendation No. 15) in Part 327 were implemented. Annual certification lists were to be sent from foreign countries to the IPD. In July 1999, effective for calendar year 2000, the FAIM Division established a procedure to notify IPD of every country for which FAIM has not received an annual certification of establishments. Starting in February 2000, and continuing on a monthly basis, the FAIM Division was to notify the IPD of outstanding certification lists. FSIS was reviewing its current procedures and would implement improvements to the followup process by December 2000.	Yes	None	Yes	Final action accepted on April 3, 2002.
17	Immediately conduct reconciliation between establishment certification information maintained by the Equivalence and Planning Branch and the AIIS to ensure that the AIIS includes only those establishments certified by their foreign governments to ship products to the United States.	FSIS agreed with the recommendation. Following the onsite portion of the OIG audit, the FAIM Division established a program of quarterly crosschecks of foreign government certification documents against the establishment listings contained in the AIIS. In addition, effective April 1999, the FAIM Division began sending to the IPD a weekly report listing all certified and decertified establishments maintained in the AIIS. IPD was to begin reconciliation of the FAIM reported data and their internal records by December 2000.	Yes	None	No	Final action accepted on October 28, 2002. OIG disagreed that final action has been achieved.
18	Establish time requirements and a management control process for reviewing and processing certification information in the AIIS.	FSIS agreed with this recommendation. The FAIM Division maintains an internal AIIS Import manual of procedures document that was to be updated by December 2000, to address time requirements and management control processes. Supervisory oversight was to be established whereby all changes to the AIIS status of establishments were to be forwarded to the Branch Chief of the FAIM Applications Systems Development Branch for review.	Yes	None	No	FSIS requested final action on March 20, 2002.

Recommendation Number	Recommendation	Agency Response	Management Decision	Action Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
19	Take immediate action to ensure that the TSC, the FAIM Division, and the Equivalence and Planning Branch coordinate efforts to verify that all delisted establishments have been timely entered into the AIIS.	FSIS agreed with this recommendation and stated that the agency would improve its system to verify that all delisted establishments are timely and properly entered into the AIIS. FSIS established and documented procedures, dated July 2001, for handling notifications of establishment certifications.	Yes	None	No	Final action accepted on October 28, 2002. OIG disagreed that final action has been achieved.
20	Establish a management control process to ensure that the TSC Director promptly forwards to the Office of Policy, Program Development and Evaluation information about foreign establishments that were delisted prior to, or because of, TSC foreign reviews.	FSIS established a management control process to address this recommendation. FSIS is notified by fax or electronic mail from the foreign country government or through the Foreign Agricultural Service about foreign country establishments delisted prior to TSC reviews. This information is shared by all of the stakeholders, and discussed at the pre-audit conference held between the TSC and the IPD. Foreign country establishments are also delisted based upon results of onsite reviews by the TSC reviewers. Reviewers report this information, by phone, to the Review Staff Director or Chief of the International Review Branch as soon as possible, but no later than the day following the onsite review. This information is also detailed in an electronic mail message immediately sent to the Chief of the Equivalency and Planning Branch, IPD and also to the Director of the Import/Export, Program Analysis, IRM Staff at the TSC. A paper copy of the electronic mail message is placed in the foreign country file at the TSC.	Yes	None	Yes	Final action accepted on October 28, 2002.

Recommendation Number	Recommendation	Agency Response	Management Decision	Action Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
21	Establish a management control process to ensure that delistment information is (a) reviewed and signed by a designated official to the FAIM Division, via a dated control number and (b) processed and verified in the AIIS.	Pursuant to the report, the FAIM Division implemented in May 2000, a management control process whereby the Branch Chief, Application Development and Support Branch, FAIM Division will be notified via e-mail of all incoming delistments received from IPD. Notification was to include the date delistments are received, the date the information was entered into the AIIS, and a printout of all establishments as they appear in the AIIS. This procedure was to be completed by October 2000.	Yes	None	No	Final action accepted on October 28, 2002. OIG disagreed that final action has been achieved.
22	Modify the AIIS to produce daily process control reports to enable verification of input.	FSIS agreed with this recommendation. The FAIM Division had begun replacing the AIIS that was first deployed in the 1970's. Available resources will be better used in continuing development of the replacement AIIS, rather than making the recommended changes to the current AIIS. The new system was to incorporate this recommendation in its design. The intent of the recommendation was to be met when the new computer system is completed by December 2001.	Yes	None	No	Final action accepted on October 28, 2002. OIG disagreed that final action has been achieved.
23	Establish procedures to ensure that all residue documents submitted by foreign countries are received, reviewed, and analyzed based on requirements outlined in regulations.	FSIS agreed with the recommendations and that it needed to strengthen its review of foreign country test plans. An interagency team was created on June 1, 2000, and expected to complete its initial review by December 2000. The team was responsible for the receipt, review, and analysis of all foreign country residue submissions. The team was also comprised of representatives of Office of Policy, Program Development, and Evaluation, Office of Field Operations, and Office of Public Health and Science. The team was to review the submissions, based on United States regulations, to determine if the information was adequate, if the documents indicated the countries met United States requirements, and if additional information was needed. FSIS questioned the need for collecting past residue plans and results because much more comprehensive information would be provided by the review performed by the interagency team. By December 2000, FSIS expected to complete its assessment of the country's controls.	Yes	None	Yes	Final action accepted on April 3, 2002.

Recommendation Number	Recommendation	Agency Response	Management Decision	Action Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
24	Obtain the residue test plans not submitted since 1998 to determine if the foreign countries have residue control standards equivalent to the United States.	See response in Recommendation No. 23.	Yes	None	Yes	Final action accepted on April 3, 2002.
25	Obtain and analyze the residue test plan results not submitted since 1998 to determine the adequacy of foreign countries' adherence to their residue test plans.	See response in Recommendation No. 23.	Yes	None	Yes	Final action accepted on April 3, 2002.
26	Develop procedures to ensure that (a) a review of residues identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants are included as part of the TSC onsite equivalency reviews and (b) appropriate action is taken in those instances where the plans are inadequate, the results vary from the plans, or violations are detected.	The IPD was to provide the Director of the Review Staff at the TSC with a summary of the information in residue questionnaires submitted by countries eligible to export to the United States. The Review Staff was part of the team that would review the submissions. The Review Staff and the IPD were to use the information, along with port-of-entry results and information from past audits, to plan upcoming reviews. FSIS planned to initiate indepth reviews of residue programs in a number of countries exporting to the United States. These reviews were to make a comprehensive evaluation of the effectiveness of the country's controls over drugs and chemicals that could contaminate meat and poultry. The reviews were expected to be completed by June 2001. FSIS planned to have these residue review procedures developed, documented, and implemented by December 2000.	Yes	None	Yes	Final action accepted on May 20, 2003.

Recommendation Number	Recommendation	Agency Response	Management Decision	Action Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
27	Develop procedures that require the participation of technical subject-matter experts, as appropriate, in equivalency determinations, and document the experts' participation, analyses, and conclusions.	FSIS developed formal procedures for participation of technical subject-matter experts, as appropriate, in equivalence determinations.	Yes	None	Yes	Final action accepted on April 3, 2002.
28	Document and implement a system of internal controls to ensure the adequacy and support for foreign equivalency determinations. This should include a formal review and approval process for the equivalence determinations made.	FSIS formalized its procedures and documentation of equivalence decisions. Effective July 1, 2000, new equivalence decision files documented (1) All FSIS correspondence with foreign countries; (2) All foreign country submissions (translated and in the originating language); (3) Summary IPD reviews of submissions; (4) Summary of all meetings and teleconferences with foreign officials; (5) Summary of all reviews by subject-matter experts; (6) Documentation of equivalence criteria; (7) Summary of all FSIS management formal reviews and approvals; and (8) Decision memorandum of the equivalence determinations.	Yes	None	Yes	Final action accepted on April 3, 2002.
29	Develop a management control process and procedures to ensure equivalence decisions are adequately documented. The procedures should require that files contain supporting evidence, including detailed analysis of information received and reviewed, resolution of issues raised during the review process, and conclusions reached.	FSIS agreed that equivalence decisions should be adequately documented and that the files must be complete. Therefore, FSIS instituted the same measures described in response to Recommendation No. 28.	Yes	None	Yes	Final action accepted on April 3, 2002.
30	Establish a time-phased plan to expedite the process for determining equivalency.	FSIS implemented time-phased plans for future equivalence determinations.	Yes	None	Yes	Final action accepted on October 28, 2002.
31	Ensure that onsite audits for current trading partners are conducted at least annually.	FSIS incorporated this into the FSIS procedures for import inspections.	Yes	None	Yes	Final action accepted on April 3, 2002.

Recommendation Number	Recommendation	Agency Response	Management Decision	Action Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
32	For current trading partners, develop and implement a policy for onsite verifications of changes in the requirements for foreign inspection systems.	FSIS revised onsite audit inspection system procedures for verification of changes in requirements.	Yes	None	Yes	Final action accepted on October 28, 2002.
33	Clarify the regulations regarding FSIS' procedures for determining equivalence for current trading partners, taking into consideration major changes such as HACCP and pathogen reduction requirements.	FSIS took into consideration major changes, such as PR/HACCP, as it documented its procedures for determining whether equivalence is maintained for current trading partners, as referenced in response to Recommendation No. 12. In addition, FSIS revised onsite audit inspection system procedures.	Yes	None	Yes	Final action accepted on April 3, 2002.
34	Ensure that reporting and evidence standards developed for equivalency verification reviews provide for appropriate documentation of all areas required to be reviewed by regulation.	At the time of the OIG audit, FSIS was in the process of developing an enhanced uniform audit format that addressed the following five risk areas (1) animal disease controls; (2) sanitation controls; (3) enforcement controls; (4) slaughter and processing controls; and (5) residue controls. These five risk areas cover all of the FSIS regulatory requirements for countries that export to the United States. Subsequent to the OIG audit, the audit format was finalized. The new audit format has been implemented for all FSIS audits conducted since FY 2000. Also, FSIS enhanced audit planning to ensure that onsite audits cover all relevant areas.	Yes	None	Yes	Final action accepted on October 28, 2002.

Recommendation Number	Recommendation	Agency Response	Management Decision.	Action Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
35	Develop procedures for timely completing reports documenting reviews of foreign inspection systems.	FSIS agreed with this recommendation. Formal procedures were to be completed by December 2000. In 2000, new foreign country reporting requirements were instituted. Draft foreign country reports are due from the reviewers within 10 working days of their return to the office. Similar timeframes are in effect throughout the process, creating a timeline that has the report completed and in "Draft Final" form to be sent to the foreign country government officials for comment within 60 days from the date of the exit conference with the foreign officials. Because of language differences, and necessary time for response, the foreign countries are allowed 60 days to submit their response to the report, which is included as an attachment to the final report.	Yes	None	Yes	Final action accepted on October 28, 2002.

Exhibit D - Summary of the Status of Recommendations – District Enforcement Operations - Compliance Activities Audit

Recommendation Number	Recommendations	Agency Response	Management Decision	Actions Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
1	Enhance FSIS' existing plan by improving the process to identify and review high-risk firms that handle meat and poultry products.	FSIS agrees with the recommendations. FSIS would proceed with enhancements to its plan and prioritize its efforts consistent with available resources. A revised plan will be completed by October 2000.	Yes	None	Yes	Final action accepted October 8, 2002.
2	Enhance and refine FSIS' existing plan by incorporating prescribed review steps for conducting compliance reviews for each of the 14 types of firms FSIS oversees. The plan should include a review checklist along with a compliance officer's certification statement that the appropriate review steps were performed.	FSIS agrees with the recommendation to work towards standardizing the scope of compliance reviews while preserving adequate flexibility to allow compliance officers to utilize their professional judgment and technical expertise to act on issues that are unusual or unique. It will develop better methods to standardize compliance reviews, such as enhancing its Investigative Protocols by including details descriptions of critical areas to review for high-risk business types. This process will be completed by December 2002.	Yes	None	Yes	Final action accepted June 16, 2003.

Recommendation Number	Recommendations	Agency Response	Management Decision	Actions Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
3	Enhance FSIS' existing plan to emphasize the targeting of resources to large metropolitan and geographical areas and to high-risk firms with a history of violations.	FSIS agrees that there is a need to improve systems for allocating resources more effectively. Its improved system will include factors such as geographical size, administrative workload, level of State and local cooperation, population density, case documentation, and complexity/density of federally-inspected establishments. Successful implementation of this system will assure that the most critical locations are adequately staffed. FSIS expects to complete this activity by December 2002.	Yes	None	Yes	Final action accepted May 16, 2003.
4	Define effective and meaningful guidelines for monitoring and tracking the progress and completion of violation cases. Establish procedures for tracking those timeframes such as investigative time, documentation time, supervisory review time, headquarters review time, etc.	FSIS agrees that much benefit would be derived from monitoring and tracking process timelines associated with the investigation and review of violation cases. FSIS is reviewing a database system to track the process timelines of violation cases from predication to referral to the U.S. attorney. FSIS stated that its new system will be fully operational prior to FY 2001.	Yes	None	Yes	Final action accepted June 13, 2002.

Recommendation Number	Recommendations	Agency Response	Management Decision	Actions Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
5	Develop a system, including written procedure to monitor receipt and followup action on all consumer complaints received at District Enforcement Operations (DEO) headquarters, district, and field office levels.	FSIS agrees with the recommendation. FSIS agrees that written procedures are needed to monitor the receipt of, and followup action on consumer complaints. FSIS plans to centralize this function under one unit that will monitor receipt and disposition of consumer complaints. Until then, FSIS is implementing an interim monitoring system for the receipt and follow up of consumer complaints from district field office staff or those referred to DEO Headquarters. FSIS intends to have newly reconstituted and reorganized system implemented by March 2001.	Yes	None	Yes	Final action accepted August 23, 2001.
6	Review the 16 consumers' complaints previously omitted from review, and perform follow up actions to satisfactorily resolve them.	FSIS agrees with the recommendation and is in the process of reviewing the 16 consumer complaints to determine if they have been resolved and perform any follow up action, if needed. FSIS will complete the review and follow up by October 2000.	Yes	None	Yes	Final action accepted October 8, 2002.

Recommendation Number	Recommendations	Agency Response	Management Decision	Actions Needed for Mgmt. Dec.	Recommendation Implemented	FSIS Requested Final Action
7	Continue to seek the authority to assess civil monetary penalties against firms that commit violations of meat and poultry inspection laws.	FSIS agrees with the recommendation that civil penalties would be an effective supplement to its current criminal and administrative authorities. Civil penalties, while having somewhat limited application, would provide it with an additional tool to deter violations of laws and would be particularly effective on preventing minor violations of law and address situations where criminal prosecution or other action is not appropriate. It will continue to work with Congress, industry, and the public to obtain this additional authority.	Yes	None	Yes	Final action accepted June 13, 2002.
8	Reinforce existing compliance Investigative Protocols for developing standard violation cases. Provide training where needed to ensure that all Assistant District Managers for Enforcement and supervisory compliance officers are able to properly oversee reviews and case preparation for appropriate sanctions and determinations.	FSIS agrees with recommendations and stated that it has already taken steps to reinforce existing protocols, procedures, and assure appropriate training of DEO personnel. FSIS has developed orientation and training protocols for newly hired compliance officers and supervisory personnel. FSIS is currently recruiting to address the 58-percent vacancy rate for the supervisory compliance officer position, which is needed to provide proper supervision of reviews and case preparation. FSIS's priority is to fill these positions as soon as possible.	Yes	None	Yes	Final action accepted May 16, 2003.

Exhibit E - FSIS Response to the Draft Report

United States Department of Agriculture

Food Safety and Inspection Service

Washington, D.C. 20250

AUG 11 2004

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

FROM: Dr. Barbara J. Masters
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Official Draft Report – Follow-up Audit on the Inspector General's Food Safety Initiative of FY 2000, Report No. 24001-4-AT

The Food Safety and Inspection Service (FSIS) appreciates the opportunity to review the subject report. FSIS is continuing to update policies and guidance and enhance supervision and oversight to improve the effectiveness of its program areas. The FSIS has reviewed the report and offers several general comments and the Agency's responses to the final audit report.

We would first, however, like to provide our perspective regarding the difficulties FSIS has had in reaching agreement on recommendations in general. We believe that the difficulties stem from inherent philosophical differences regarding the scope of OIG reviews and the acceptability of corrective actions. As a further elaboration, we believe that OIG reviews should focus on whether systems operated by FSIS are accomplishing what they were designed to accomplish, rather than on what OIG believes their functions should be. Because we are always interested in improving our systems, we appreciate having input for future planning, but the decision on whether corrective actions are needed should be based on the original intent of the systems.

In addition, OIG has been very prescriptive regarding corrective actions needed. These prescriptive recommendations do not afford FSIS the opportunity to determine the best way to rectify a deficiency identified by OIG. Once OIG identifies the problem that needs to be addressed, FSIS officials are in the best position to determine the adequacy of the methodology chosen to address the problem.

We also believe the importance OIG has placed on having every activity carried out by agency personnel documented in a notice or other issuance is unnecessary. For example, we have greatly improved our training programs recently, but evidence that inspectors are instructed through training to carry out certain tasks is not considered adequate as a management control or corrective action. Supervision is another tool we use to ensure that tasks are completed, but again OIG has been reluctant to accept this as an adequate management control. The combination of comprehensive training of the workforce and the appropriate supervisory oversight and accountability is the cornerstone for solid

employee performance and accountability. We hope you will take these comments into account as we continue to work together to improve public health.

General Comments

FSIS has implemented prudent and cost-effective corrective actions to respond to the OIG's June 2000 audit report on the Food Safety Initiative. The June 2000 Food Safety Initiative audit comprised four separate audit reports containing a combined 80 recommendations. FSIS has reached management decision on 76 of the 80 (or 95.0%) recommendations in the audit reports. As of June 30, 2004, final action was granted for 66 of the 80 recommendations by the Office of Chief Financial Officer (OCFO), which is responsible for monitoring Agency follow-up and evaluating closure and final action requests on OIG audit recommendations. Of the remaining 10 recommendations where management decision has been reached but final action has not been granted, FSIS has provided to the OCFO supporting documentation for the corrective actions it has taken to close the recommendations.

Currently, four recommendations are without resolution in that no management decision has been reached. Previously, FSIS proposed several alternative corrective actions in the form of supplemental responses to the OIG to bring to resolution these four recommendations, with no success to this point in time. A summarized status of three of the four unresolved audit recommendations is given below. The Agency is still hopeful that management decision can be reached on the fourth unresolved recommendation which requires the Agency to complete an in-depth assessment of its import reinspection operations to address the material management control weaknesses reported by the OIG in the "Imported Meat and Poultry Inspection Process, Phase 1" audit.

- The OIG recommended in the 2000 audits that FSIS require plants to include in their HACCP plans all pathogen testing they perform, including results from non-HACCP tests. In a March 30, 2004, memorandum OIG agreed that the publication of a revised FSIS Notice 54-03 would address this recommendation. However, in its June 30, 2004, memorandum accompanying the official draft audit report, OIG stated that it could not accept the Agency's proposed alternative corrective action and recommended that the Agency implement compensating controls. FSIS disagrees with the requirement for compensating controls which require establishment owners to notify FSIS about positive test results. FSIS inspection personnel are expected to complete a comprehensive review of establishment records related to food safety issues on a weekly basis and is thereby cognizant of establishments' pathogen test results.

  Further, FSIS believes the requirement for compensating controls, in this case, over regulates industry, provides no reasonable cost-benefit, and is of little to no value to FSIS or the regulated community. This requirement will not be pursued by FSIS.

- In addition, the OIG recommended in the 2000 audits that FSIS include in its Performance Based Inspection System (PBIS) a description for why scheduled tasks are not performed. FSIS agrees in principle that FSIS management and supervisors

should be apprised of why scheduled tasks are not being performed. The Agency previously indicated that supervisors currently review the PBIS data before their visits to plants and discuss the data with inspectors if there seems to be a pattern. Supervisors are instructed to do this in the In Plant Performance System (IPPS) Supervisory Guidelines. The OIG is aware that current FSIS training in IPPS covers this type of supervisory oversight but believes that this requirement should be explicitly stated in a Directive or similar document. We believe such a requirement is excessively prescriptive, and it will not be pursued by FSIS.

- Also, the OIG recommended in the 2000 audits that FSIS establish timeframes for plants to respond to noncompliance records (NRs). FSIS agrees in principle that the establishment response to the NRs should have the expected completion dates for the corrective actions. However, the Agency has noted that these NRs are discussed at weekly meetings with plant management. Due to the variable NR issues that exist across multiple establishments, it is impractical to establish specific timeframes. OIG agreed with this and instead said they wanted documentation that the Agency's inspectors are required to ask the plant to provide a timeframe, and that the inspector ensures that the plant complies with this timeframe. We believe such a requirement is excessively prescriptive, and it will not be pursued by FSIS.

The OIG implied that FSIS' failure to fully address the recommendations from the June 2000 audits resulted in less control of pathogens in meat products and contributed to the 113 recalls that were issued in 2002, including two of the largest recalls in USDA history. FSIS disagrees with this inference. No evidence of this is provided in the audit report. In fact in 2003 there was a dramatic decline in pathogen levels, leading to a dramatic decline in the number of meat and poultry product recalls during the year. The number of Class I recalls was cut almost in half from the total of the previous year (2002). This is an indicator that our scientifically-based policies and programs are working.

Finally, the OIG indicated that FSIS should expand its own testing requirements to increase the number of tests and to include other pathogens in those requirements. FSIS continues to work closely with other USDA agencies for research and development of new testing methods of foodborne pathogens, and to adapt these methods for analyses of regulatory samples.

Section 1: Status of Recommendation to Improve the HACCP System, Report No. 24001-3-At

1. **Recommendation No. 1**
   Develop a plan to implement the agreed upon recommendations to correct the deficiencies in the HACCP program. This plan should identify the officials responsible for implementing each recommendation. It should also establish reasonable timeframes for the project, as well as the individual tasks, and include periodic progress reports addressing each part of the plan. FSIS management should establish a mechanism that apprises them of the progress. (See exhibit A, Recommendations Nos. 1, 2, 3, 17, and 19)

FSIS Response
The corrective actions for recommendation No. 17 and 19 in the 2000 audit report were completed and the OCFO granted final action on February 17, 2004 and November 26, 2003, respectively (**Enclosure No. 1**). FSIS will not pursue any further action regarding these items.

For the three remaining recommendations, FSIS has developed an action plan aimed at correcting deficiencies in the HACCP implementation program and that addresses the remaining OIG recommendations without final action. FSIS has implemented an audit tracking system that includes bi-monthly status reports to the FSIS management council. The status report includes the recommendations where final action is incomplete, identifies the agency official responsible for addressing each recommendation, and the target date for completion of the action (**Enclosure No. 2**).

Section 2: Status of recommendations to Improve FSIS' Laboratory Testing Program, Report No. 24601-1-CH

2. **Recommendation No. 2**
Develop a plan to implement the recommendations to correct the deficiencies in the laboratory testing program. This plan should identify the officials responsible for implementing each recommendation. It should also establish reasonable timeframes for the project as well as the individual tasks, and include periodic progress reports addressing each part of the plan. FSIS management should establish a mechanism that apprises them of the progress. (See exhibit B, Recommendations Nos. 4 and 6)

FSIS Response
The OCFO granted FSIS final action for recommendation number 4 on July 3, 2003 (**Enclosure No. 3**). FSIS will not pursue any further action regarding this item.

For the remaining recommendation, FSIS has implemented an audit tracking system that includes bi-monthly status reports to the FSIS management council. The status report includes the recommendation where final action is incomplete, identifies the agency official responsible for addressing this recommendation, and the target date for completion of the action (**Enclosure No. 2**).

3. **Recommendation No. 3**
Establish supplementary procedures for the nonresponder reports that include controls to ensure that monitoring of sampling requests is done on a monthly basis, and followup is performed to determine reasons why plant inspectors did not respond. (See exhibit B, Recommendation No. 3)

FSIS Response
As referenced in Exhibit B of the report, on August 28, 2002, the OCFO granted FSIS final action for recommendation No. 3. The OIG indicated that the Corrective action was partially completed since written guidelines on the use of Nonresponder reports hove not been provided to the District Offices.

FSIS will issue additional guidance on the use and interpretation of the laboratory nonresponders report by October 2004.

If you have any questions, please contact [ ].

Enclosures (3)