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Office of Inspector General
Northeast Region

Audit Report

Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments

Report No. 24601-07-Hy
December 2007

December 4, 2007

REPLY TO
ATTN OF: 24601-07-Hy

TO: Alfred V. Almanza
             Administrator
             Food Safety and Inspection Service

ATTN: William C. Smith
             Assistant Administrator
             Office of Program Evaluation, Enforcement and Review

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

SUBJECT: Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry
             Processing Establishments

This report presents the results of our audit concerning the issues impacting the development of risk-based inspection at meat and poultry processing establishments. Your response to the official draft, dated November 26, 2007, is included as Exhibit I and the supplemental response for seven of the report's recommendations, dated November 30, 2007, is included as Exhibit J. Excerpts of your response and the Office of Inspector General's position are incorporated into the Findings and Recommendations section of the report. Based on your responses, we were able to reach management decision on all of the report's 35 recommendations. Please follow your agency's internal procedures in forwarding documentation for final action to the Office of the Chief Financial Officer.

We appreciate the courtesies and cooperation extended to us by members of your staff during this audit.

Executive Summary

Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments (Audit Report No. 24601-07-Hy)

Results in Brief

In 2004, the U.S. Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS), began the process of developing a risk-based inspection program that would assign more inspection resources at processing establishments that posed a greater food safety risk. FSIS has invested considerable time and effort into building a foundation for implementing a risk-based inspection program and has sought input from a number of external stakeholders[1] through public meetings and expert elicitations[2] as it developed and refined its conceptual model for risk-based inspection. FSIS recognized that development of a risk-based inspection model would be a continuous process as it learned more about the risk associated with particular products and the hazards associated with food processing operations, as well as predictive data indicators for risk.

In February 2007, FSIS announced its plans to implement a pilot risk-based inspection program because the agency believed it had "sound, comprehensive, and reliable" data and that "real and immediate" improvements could be made to the effectiveness of inspection operations. Congress and other stakeholders became concerned that FSIS was beginning to implement risk-based inspection before it had corrected deficiencies reported in prior USDA Office of Inspector General (OIG) audits and that known limitations and concerns with its methodology for determining risk had not been addressed. The Committees on Appropriations of the U.S. House of Representatives and the U.S. Senate were concerned that food safety may be compromised if risk-based inspection proceeded at that time. Therefore, they included language in Public Law 110-028, signed May 25, 2007, that prevented FSIS from using funds to implement risk-based inspection in any location until OIG studied the program, including the data in support of its development and design, and FSIS addressed and resolved the issues identified.

When FSIS proposed to proceed with risk-based inspection in February 2007, it based risk assessments of processing establishments predominately on data contained in their various information systems.[3] Because these data were

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[1] Stakeholders include representatives from such entities as States, academia, consumers, interest groups, industry, Federal agencies and foreign countries.

[2] An expert elicitation pulls together a panel of experts, carefully assesses the uncertainties in each of their views, and then mathematically combines their risk estimates along with the accompanying uncertainties.

[3] See the Background section in this report for a description of the risk-based inspection methodology, as originally envisioned by FSIS.

limited,[4] OIG's audit was designed to determine whether FSIS currently has the infrastructure and management controls in place to support a comprehensive, timely, and reliable data-driven risk-based inspection program. Based on our audit results, we question whether FSIS has the systems in place, at this time, to provide reasonable assurance that risk can be timely or fully assessed, especially since FSIS lacks current, comprehensive assessments of establishments' food safety systems.

We could not assess FSIS' plan for evaluating the risk-based inspection pilot project, as requested by the Committees, because an evaluation plan had not been developed at the time of our review. FSIS ceased its efforts to develop an evaluation plan when the legislation was signed into law in May 2007.

In prior audits, OIG had reported concerns with FSIS' information technology (IT) systems and other processes that collect, process, and analyze data; we concluded in these audits that FSIS could not, on an ongoing basis, timely identify and react to indicators of problems that could impact food safety. Prior audits also identified the lack of basic building blocks and adequate management controls to provide proper oversight and management of inspection operations. In those audits, we recommended that FSIS consider scientific, risk-based approaches (through trend analysis, base-line studies, etc.) for inspection and pathogen testing activities. In addition to evaluating FSIS' infrastructure and management controls, this report presents an assessment of FSIS' progress in implementing agreed-to corrective actions in those areas that would have a direct impact on FSIS' ability to effectively implement a risk-based inspection program.

Throughout this review, we discussed concerns with and provided our recommendations to FSIS so that the agency could immediately initiate actions to address weaknesses we identified in the development and design of the risk-based inspection program. The concerns related to FSIS' (1) assessments of establishments' food safety systems, (2) security over IT resources and application controls, (3) data management infrastructure and analyses, and (4) management control structure. FSIS provided responses to our recommendations, which are included as Exhibits C through G. This report summarizes the findings previously reported to FSIS and presents a number of observations and concerns that FSIS should consider and address as it moves forward with the development of a risk-based inspection program.

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[4] Our analysis of FSIS' data to support the development of risk-based inspection and establishments' risk rankings was limited to data covering plant operations from October 1, 2005 through September 30, 2006. According to FSIS officials, the agency calculated risk rankings only once and did not update its assessments since the risk-based inspection program was deferred due to Public Law 110-028. Therefore, OIG was unable to determine the reasonableness and relevance of FSIS data to support the design of risk-based inspection, as requested.

FSIS' Approach to the Design of Risk-Based Inspection

In our review, we found FSIS planned to begin implementation of risk-based inspection before completing an assessment of, and determining the data needed for, a comprehensive risk determination at processing establishments. FSIS planned to implement an initial phase of risk-based inspection using available data, and to continue collecting and refining data and data needs in subsequent phases. FSIS has also accelerated implementation of initiatives and improvements to its sampling methodology to respond to concerns related to two large recalls of ground beef product potentially contaminated with *Escherichia coli (E. coli)* O157:H7 (see Section 1 of this report).

- In the initial risk-based inspection algorithm,[5] FSIS did not incorporate the results of the agency's assessments of an establishment's food safety systems (i.e., food safety assessments). FSIS recognized that these assessments are the agency's best evidence of the establishment's ability to control risk. However, FSIS currently reports food safety assessment-related data in an inconsistent, text format that cannot be easily used to estimate risk. During our audit, FSIS developed and initiated an action plan for enhancing food safety assessment-related data.

- FSIS chose to move forward with a pilot risk-based inspection program recognizing that there were limitations and uncertainties that impact the interpretation and use of the available data. During the course of our audit, FSIS began a critical in-depth examination of the data used as the components of its risk-based inspection algorithm with a view to refine and expand the data used in future versions of risk-based inspection. FSIS expects to finalize the results of this review by March 2008. In addition to these limitations and uncertainties, we identified weaknesses in the design of the risk-based inspection algorithm. For example, FSIS did not conduct analyses to support that the window of data[6] used to determine how well an establishment controlled risk was appropriate.

- In June 2007, FSIS identified an increased number of *E. coli* O157:H7 positive tests in beef, as well as a larger number of recalls and illnesses caused by this pathogen than in recent years. In October 2007, FSIS accelerated implementation of initiatives and improvements to its sampling methodology scheduled for Spring 2008 to respond to concerns related to two large recalls of ground beef product potentially adulterated (i.e., contaminated) with *E. coli* O157:H7. At that time, FSIS also accelerated its plans to review the control of this pathogen by beef suppliers and processors. Pathogen test results are a critical component of FSIS' risk-based inspection model.

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[5] A precise rule (or set of rules) specifying how to solve some problem.
[6] A window of data is a baseline time period for data collection.

FSIS' Infrastructure to Control and Oversee Regulated Activities

Currently, FSIS does not have adequate management control processes or an integrated IT system in place to support a timely, reliable risk-based inspection program. Building a solid foundation for shifting to a risk-based environment that focuses inspection resources on improving FSIS' ability to protect public health should be a process that uses (1) science and statistical analysis based on high-quality, relevant data that focus on risk analysis and prevention, (2) effective integration of FSIS' data management systems, and (3) strong IT and management controls over inspection activities (see Section 2 of this report).

- In response to two prior OIG reports, FSIS agreed to strengthen security over IT resources and application controls. Our current work confirmed that vulnerabilities continue to expose FSIS systems to unnecessary risks and that access (physical and logical) and application controls need improvement. FSIS provided detailed responses to address these weaknesses (see Exhibits D and E). Instituting the appropriate oversight and control in these areas is critical to developing and implementing a reliable, data-driven risk-based inspection program.

- Since June 2000, we have recommended that FSIS implement a system of oversight for Hazard Analysis and Critical Control Point (HACCP) plans[7] that establishments develop. In response, FSIS initiated the use of food safety assessments to evaluate these controls. Our current work confirmed, however, that FSIS had not completed food safety assessments at all processing establishments and did not have procedures for prioritizing and scheduling assessments or following up on assessment findings. Food safety assessments are a fundamental building block for assessing establishment risk.

- FSIS does not currently have a comprehensive, agency-wide data analysis and distribution system in place to inform decision makers of all the relevant food safety and food defense issues. Only in the current year has FSIS begun initial steps to specifically define and implement data management controls to ensure: (1) necessary types of information are collected, (2) required standard reports are produced, (3) relevant analyses are performed and fully used by all program areas and district offices, and (4) corrective actions are taken when problems are identified. During our audit, FSIS initiated actions to strengthen data management controls so that the agency will be in a better position to provide all

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[7] In 2000, FSIS completed implementation of the Pathogen Reduction and HACCP system, which required meat and poultry processing establishments to target and reduce harmful bacteria in their products. Establishments must develop and implement HACCP plans that systematically address all significant hazards associated with its products.

management levels with information to identify and correct food safety concerns.

- We previously recommended that FSIS establish a management control process for accumulating and analyzing food safety data and for strengthening its monitoring of inspection activities. FSIS responded by implementing the In-Plant Performance (IPPS) and AssuranceNet systems[8] as a means of providing management oversight of public health activities of FSIS inspection personnel. These systems are important components in the implementation of a management control structure, in that they provide valuable performance data both to supervisors and to higher-level managers. However, FSIS is still in the process of fully and effectively refining and implementing both systems. While the management control structure is not an actual component of FSIS' risk-based inspection determination, it directly affects the accuracy of recorded risk factors such as microbial test results and food safety-related noncompliance records (NRs).[9]

- We assessed FSIS' progress in implementing 94 prior audit recommendations, which OIG considered to be the most critical to the development and implementation of risk-based inspection. Although recent improvements have been made, we found FSIS did not timely address deficiencies noted in prior OIG audit reports. For 3 of the 94 recommendations, no agreement has been reached on the actions needed to correct reported deficiencies; agreements should be reached no later than 6 months after the audit report is issued. One of these recommendations was made in June 2000.[10] For an additional 34 recommendations, FSIS did not implement the agreed upon corrective actions within 1 year. According to FSIS officials, the amount of time it takes to close a recommendation varies and is due to the (1) difficulty and complexity of the corrective action, (2) emerging public health problems that compete for agency resources, and (3) the continuous evolution of agency programs and industry practices.

To further assess the development of risk-based inspection, we conducted site visits at 15 processing establishments. We also reviewed certain data and

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[8] FSIS implemented IPPS in October 2002. AssuranceNet did not become fully functional until approximately February 2007.

[9] FSIS inspection personnel issue an NR to an establishment that is not complying with regulatory requirements. In the NR, the inspector cites one or more applicable regulatory requirements from a list of over 500 citations. NRs are also recorded in FSIS' Performance Based Inspection System, the system currently used to record inspection results.

[10] In our report on the Implementation of HACCP (Audit Report No. 24001-03-At, June 2000), we recommended that FSIS establish timeframe requirements for responding to NRs and initiating planned corrective actions. FSIS does not agree with establishing specific timeframes but has not proposed an alternative approach to address this recommendation. NRs are critical to FSIS' risk-based inspection model.

information for the two establishments with large recalls[11] of ground beef products potentially contaminated with *E. coli* O157:H7: (1) United Food Group, LLC (Establishment No. 1241) and (2) Topps Meat Company, LLC (Establishment No. 9748).[12]

- At the 15 establishments visited, FSIS inspection personnel did not document that they were reviewing the results of establishment pathogen testing on at least a weekly basis.[13] Inspection personnel were not subject to sufficient supervisory oversight to ensure they are fulfilling this requirement. Documenting that inspection personnel review establishment testing on at least a weekly basis assists in validating that food safety concerns that require additional followup are recognized in a timely manner.

- We reviewed inspection data associated with the two establishments with recent recalls of ground beef products potentially contaminated with *E. coli* O157:H7. As a result, we found FSIS inspection personnel did not always link[14] NRs identifying recurring sanitary deficiencies. However, even when NRs were linked, FSIS inspection personnel did not have guidance on when to take further enforcement actions when addressing repetitive noncompliance violations. This occurred because FSIS had not issued the necessary criteria for evaluating repetitive noncompliance violations to establish when further enforcement action must be taken as recommended and agreed to in prior OIG audit reports. As a result, there is reduced assurance FSIS personnel are effectively identifying food hazards caused by unsanitary practices. Linkage of related NRs and associated evaluation criteria would provide a basis for determining when an establishment's corrective actions were inadequate and when additional enforcement actions should be initiated. NRs and enforcement actions are two critical components of FSIS' risk-based inspection model.

In September 2007, FSIS awarded a contract to build the agency's new Public Health Information System (PHIS) in order to better integrate and consolidate its numerous applications that collect information on activities to ensure the safety of meat, poultry, and egg products. FSIS plans to have a functional domestic inspection module ready for limited deployment in the third quarter of calendar year 2008 with full production implementation scheduled for the second quarter of calendar year 2009. The sub-modules currently identified for the domestic inspection module include: in-plant inspection activity, food safety assessments, laboratory sample scheduling,

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[11] We did not evaluate what FSIS processes may have broken down for these recalls because FSIS' internal investigations were still in process at the end of our fieldwork.

[12] We did not visit this Topps Meat Company, LLC due to FSIS' ongoing investigation.

[13] FSIS initiated the review of establishment pathogen testing in response to a recommendation from our report on the Oversight of the Production Process and Recall at ConAgra Plant, Audit Report No. 24601-02-KC, September 2003.

[14] Linking refers to documenting in an NR that similar deficiencies were noted in a previous NR or NRs.

in-plant data and data from other sources, reporting, and predictive modeling and analysis (see Exhibit A). As FSIS moves forward with development of risk-based inspection, the agency should institute the appropriate oversight and control during the development of critical IT systems such as PHIS.

We believe that FSIS needs to address the deficiencies in the agency's infrastructure and processes identified in this report. By addressing these elements, FSIS will take significant, critical steps to support a comprehensive, timely, and reliable data-driven risk-based inspection program.

Recommendations In Brief

FSIS should complete its plan for improving the use of food safety assessment-related data and determine how the assessment results will be used in estimating establishment risk. As the agency moves forward with the development and implementation of a risk-based inspection program, FSIS should ensure that components of the selected algorithm are thoroughly documented and evaluated with limitations mitigated and are transparent (i.e., clear and understandable) to all stakeholders. The agency should conduct analyses to support the data windows selected for assessing an establishment's ability to control risk. FSIS should also institute appropriate oversight and control over the development of critical IT systems needed to support risk-based inspection. In various sections of this report, we have recommended actions aimed at strengthening FSIS' training programs for its supervisory and inspection personnel.

FSIS should develop and implement procedures to ensure sufficient, timely followup work is performed in response to findings in food safety assessments. FSIS should continue with efforts begun during the course of our audit to prioritize and schedule food safety assessments. FSIS should also continue its efforts to complete a comprehensive, agency-wide examination of its information needs and establish a process for periodically reassessing these needs. This will include management controls to identify the specific types of information to collect, the standard reports to produce, and analyses to perform by program areas and district offices. FSIS should continue its increased diligence to resolve prior audit recommendations.

FSIS needs to provide written procedures and guidance on the use of the AssuranceNet system, to ensure that its data are being used in the most effective manner and to allow the system to be used in the context of a larger management control structure. In addition, FSIS needs to implement procedures to ensure that IPPS data being input to AssuranceNet are properly supported, and to strengthen AssuranceNet's monitoring over the IPPS process.

FSIS needs to develop and implement requirements for inspection personnel to document their reviews of establishment testing results and for supervisory officials to ensure that this requirement is met. FSIS should expedite the development of criteria for progressive enforcement actions inspection personnel should follow when repetitive deficiencies are noted.

**Agency
Response**

FSIS agreed with the report's 35 recommendations. We have incorporated FSIS' response in the Findings and Recommendations section of this report, along with the OIG position. FSIS' responses to the draft report are included in Exhibits I and J. FSIS' earlier responses to issues reported during our audit fieldwork are included as Exhibits C through G.

**OIG
Position**

Based on FSIS' responses, we were able to reach management decision on all of the report's 35 recommendations.

Abbreviations Used in This Report

AMR	Advanced Meat Recovery
ANSI	American National Standards Institute
APHIS	Animal and Plant Health Inspection Service
CDC	Center for Disease Control and Prevention
C.F.R.	Code of Federal Regulations
COTR	Contracting Officer's Technical Representative
DAIG	Data Analysis and Integration Group
DCC	Data Coordination Committee
E. coli	*Escherichia coli*
EARO	Executive Associate for Regulatory Operations
EIAO	Enforcement, Investigation, and Analysis Officer
FSIS	Food Safety and Inspection Service
HACCP	Hazard Analysis and Critical Control Point
IPPS	In-Plant Performance System
IT	Information Technology
Lm	*Listeria monocytogenes*
OFO	Office of Field Operations
OIG	Office of Inspector General
OMB	Office of Management and Budget
OPEER	Office of Program Evaluation, Enforcement and Review
OPPED	Office of Policy, Program, and Employee Development
NACMPI	National Advisory Committee on Meat and Poultry Inspection
NR	Noncompliance Record
PBIS	Performance Based Inspection System
PEIS	Program Evaluation and Improvement Staff
PHICP	Public Health Information Consolidation Project
PHIS	Public Health Information System
RTE	Ready-to-Eat
SRM	Specified Risk Material
SSOP	Sanitation Standard Operating Procedure
TSC	Technical Service Center
USDA	U.S. Department of Agriculture

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Background and Objectives

Background
The Food Safety and Inspection Service (FSIS) is the public health regulatory agency of the U.S. Department of Agriculture (USDA). As such, the agency protects consumers by ensuring that meat, poultry, and egg products are safe, wholesome, and accurately labeled. Under the Federal Meat Inspection Act and the Poultry Products Inspection Act, FSIS inspects all meat and poultry products sold in interstate commerce to ensure that they meet U.S. food safety standards.

For more than 90 years, meat inspection was based on organoleptic[15] methods, using sight, touch, and smell. However in 1993, a deadly outbreak of the *Escherichia coli (E. coli)* O157:H7 strain signaled the need for greater controls based on science to prevent food-borne illness and protect consumers. In 2000, FSIS completed implementation of the Pathogen Reduction and Hazard Analysis and Critical Control Point (HACCP) system, which required meat and poultry establishments to target and reduce harmful bacteria in their products. Under the regulations, establishments must develop and implement a written plan for meeting their sanitation responsibilities, as well as develop and implement a HACCP plan that systematically addresses all significant hazards associated with their products. Establishments also must meet pathogen reduction performance standards for *Salmonella*, and verify process control through generic *E. coli* testing. FSIS is responsible for verifying that establishments' HACCP systems are working and that they prevent adulterated (i.e., contaminated) meat and poultry products from entering commerce.

In February 2007, FSIS proposed a risk-based inspection algorithm[16] to rank the potential risks at processing establishments for allocating more inspection resources to riskier plants. This algorithm combined an estimate of the potential risk that was considered inherent to the establishment (inherent risk measure) and an estimate of how well the establishment controlled those potential risks (risk control measure). The inherent risk measure included factors for the different types of processed products and the volume of the products produced by the establishment. The risk control measure considered the following seven factors, as applicable to the establishment: (1) public health significant noncompliance records (NRs), (2) enforcement actions, (3) control of *Listeria monocytogenes* (*Lm*) in Ready-to-Eat (RTE) products, (4) control of *Salmonella* in raw meat and poultry products, (5) microbial testing program results, (6) food safety recalls, and (7) food safety consumer complaints.

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[15] Organoleptic methods relate to the senses (taste, color, odor, feel). Traditional USDA meat and poultry inspection techniques are considered organoleptic because inspectors perform a variety of procedures that involve visually examining, feeling, and smelling animal parts to detect signs of disease or contamination. These inspection techniques are not adequate to detect food-borne pathogens that are of growing concern.
[16] A precise rule (or set of rules) specifying how to solve some problem.

FSIS had planned to begin using this algorithm in 30 locations, which included 254 of the more than 5,000 meat and poultry processing establishments, in April 2007.[17] Each location represented samples of establishments in close geographic proximity. By November 2007, FSIS expected to complete policy development and programming for the risk-based algorithm and to revise it, as necessary. The agency then planned to test the algorithm in 150 additional locations. Full implementation was originally scheduled to begin in June 2008. The following briefly summarizes each component of FSIS' original risk-based inspection algorithm. FSIS' methodology for using this algorithm to determine an establishment's level of inspection[18] is detailed in documentation posted on FSIS' website.

Inherent Risk Measure

- Species/Process Values- In order to rank the potential hazards inherent in the meat and poultry products regulated by FSIS, the agency used an expert elicitation[19] conducted in 2005. The experts ranked the risks associated with the species processed (i.e., beef, pork, or poultry) and the production processes used (e.g., raw ground product, RTE product, etc.) by establishment.

- Production Volume- FSIS inspection personnel estimated production volume using a range of pounds produced in a typical day over a period of days in a 30-day period.

Risk Control Measure

- Public Health Significant NRs- FSIS inspection personnel document when an establishment is noncompliant by recording an NR in the agency's Performance Based Inspection System (PBIS). When inspectors issue an NR, they cite one or more applicable regulatory requirements from a list of over 500 citations. The rate at which an establishment fails to meet these requirements and receives an NR is considered by FSIS to be an indication of the establishment's ability to control risk. For the

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[17] FSIS provided OIG with establishment listings that originated from each district office. Because each district office did not provide its listing using the same format, we were unable to confirm the completeness of the number provided as to the total number of meat and poultry processing establishments.

[18] An establishment's level of inspection defines the type of inspection procedures FSIS would perform under its risk-based inspection model. The risk-based inspection measure determined the level of inspection. The risk-based inspection measure is an average of the inherent risk and risk control measures. The higher the risk-based inspection measure for a given establishment the higher the level of risk. FSIS proposed three levels of inspection: Level 1 would be less intense inspection for establishments with lower risk, Level 3 would be more intense inspection for establishments with higher risk, and Level 2 would be about the same intensity of inspection as under the current system for all establishments that fall between Level 1 and 3. Regardless of the level of inspection, FSIS planned to be in each processing establishment at least once per shift, per day.

[19] An expert elicitation pulls together a panel of experts, carefully assesses the uncertainties in each of their views, and then mathematically combines their risk estimates along with the accompanying uncertainties.

purpose of calculating the risk control measure, FSIS ranked[20] each of the regulatory requirements in one of four categories based on how strongly each indicated a loss of an establishment's food safety system process control. This provided a point score that could be used as a weighting factor in the risk control measure calculation.

- Enforcement Actions- Enforcement actions are a measure of an establishment's ability to implement and maintain corrective action once a noncompliance is observed and documented. FSIS can take a variety of enforcement actions (e.g., notice of intended enforcement, suspension, and inspection under consent order) against establishments that fail to sufficiently comply with applicable requirements. In order to calculate the risk control measure, FSIS assigned points to each type of enforcement action.

- Control of *Lm* in RTE Product- Establishments that produce RTE products that are exposed to the environment subsequent to the lethality step[21] must classify its products into one of three possible alternatives used for controlling *Lm*.[22] FSIS assigned points to an establishment based on its *Lm* alternative in order to calculate the risk control measure.

- Control of *Salmonella*- Establishments that produce certain types of raw meat and poultry products are subject to *Salmonella* performance standards. These establishments are classified into one of several *Salmonella* verification categories based on the results of recent *Salmonella* test sets. FSIS assigned a higher score to establishments in higher verification categories as these establishments' controls were less effective for controlling *Salmonella*.

- Microbial Test Results- Establishments that produce RTE and/or raw ground beef products are subject to pathogen testing programs. RTE products are tested for *Lm, Salmonella*, and *E. coli* O157:H7 and raw ground beef products are subject to *E. coli* O157:H7 testing. The agency considers establishments that test positive for these pathogens as demonstrating a loss of food safety system process control and increases its risk control measure. FSIS assigned points for this portion of the calculation based on the frequency of positive test results.

- Food Safety Recalls- Establishments that recall meat or poultry product demonstrate a loss of food safety system process control. FSIS assigned

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[20] OIG did not evaluate the methodology used by FSIS for determining these rankings because FSIS used subject matter experts to perform the rankings.

[21] A lethality step is a successful treatment to kill *Lm* on product.

[22] Under Alternative 1, the establishment uses a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms on the product and an antimicrobial agent or process that suppresses or limits the growth of *Lm*. Under Alternative 2, the establishment uses either the post-lethality treatment or antimicrobial agent or process that limits the growth of *Lm* described in Alternative 1. Under Alternative 3, the establishment relies on sanitation measures to control *Lm*.

points to the risk control measure for recalls with the probability that eating the food could cause health problems or death.

- Food Safety Consumer Complaints- FSIS assigned a point value based on the number of verified food safety consumer complaints. These verified complaints are evidence of an establishment's loss of food safety system process control.

In response to questions raised[23] on March 1, 2007, we initiated a review to obtain an understanding of FSIS' approach and timeline for designing and implementing risk-based inspection. We intended to identify any matters that needed to be reported immediately and to develop a strategy and approach for more detailed reviews of risk-based inspection. However, the Committees on Appropriations of the U.S. House of Representatives and the U.S. Senate were concerned that food safety may be compromised if risk-based inspection proceeded at this time. Therefore, they included language in Public Law 110-028, signed May 25, 2007, that prevented FSIS from using funds to implement risk-based inspection in any location until the USDA Office of Inspector General (OIG) studied the program, including the data in support of its development and design, and FSIS addressed and resolved the issues identified.

Objectives

We evaluated FSIS' plan for implementing a risk-based inspection program at meat and poultry processing establishments. Specifically, we evaluated the overall effectiveness of FSIS' management control processes, as well as assessed the FSIS data to support the development and design of risk-based inspection, including whether FSIS determined product risk and establishment risk utilizing an unbiased, logical system based on timely, comprehensive, accurate, and scientific data. In addition, we determined whether FSIS had fully implemented prior OIG audit recommendations considered the most critical to the development and implementation of risk-based inspection.

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[23] The questions were raised by the Chairwoman of the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies of the Committee on Appropriations of the U.S. House of Representatives during our fiscal year 2008 appropriations hearing.

Findings and Recommendations

In 2004, FSIS began the process of developing a risk-based inspection program that would assign more inspection resources at processing establishments that posed a greater food safety risk. FSIS planned to begin implementation of risk-based inspection in February 2007 before completing an assessment of, and determining the data needed for, a comprehensive risk determination. At that time, FSIS officials believed their data were "sound, comprehensive, and reliable" and they saw the "potential to make real and immediate improvements" to inspection operations. FSIS planned to implement an initial phase of risk-based inspection using available data, and to continue collecting and refining data and data needs in subsequent phases. FSIS chose to move forward with a pilot risk-based inspection program[24] even though it recognized there were limitations and uncertainties that impacted the interpretation and use of the available data.[25] Prior audits issued since 2000 (see Exhibit B) also raised concerns regarding FSIS' systems and processes for validating establishment food safety systems and for accumulating, analyzing, and reporting inspection and microbial test data.

Public Law 110-028 was signed on May 25, 2007, and it included language that prevented FSIS from using funds to implement a risk-based inspection program in any location until OIG studied the program, including a review of the data in support of its development and design, and whether FSIS had addressed and resolved the issues identified. This Section presents our observations on the process used to develop risk-based inspection. It also highlights concerns and limitations with FSIS' approach that the agency should consider as it moves forward with the development and implementation of a risk-based inspection program.

Finding 1	**FSIS Did Not Include Assessments of Establishments' Risk Control Effectiveness**

In the pilot program, FSIS planned to implement risk-based inspection without incorporating the results of FSIS' assessments of establishments' risk control effectiveness (i.e., food safety assessments). In a concept paper for measuring establishment risk control for risk-based inspection, dated July 2006, FSIS recognized that a food safety assessment yields the agency's best evidence about the design of an establishment's food safety system. FSIS, however, chose to move forward without considering this most basic

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[24] FSIS intended to implement the pilot in April 2007 in 30 prototype locations, which included 254 processing establishments.

[25] The data limitations and uncertainties are outlined in the current draft of FSIS' Risk-Based Inspection for Processing Technical Report, dated August 27, 2007. FSIS plans to have this report peer reviewed by a third party before issuing it in final, which is expected to be in March 2008.

assessment of establishment risk because food safety assessment data were not in a format that could be easily used for estimating risk. FSIS did, however, plan to incorporate a measurement for food safety assessments into risk-based inspection calculations after the pilot. Currently, food safety assessments are reported in an inconsistent, text format, which FSIS recognizes does not allow them to use the data in their methodology for determining risk. FSIS also recognizes that the format does not allow them to analyze food safety assessment results fully for policy development, to compare establishments, and to track changes at an establishment over time. During our audit, FSIS developed and initiated an action plan for enhancing food safety assessment-related data.

Under final regulations published in 1996, all meat and poultry slaughter and processing establishments are required to implement a system of process controls, called HACCP, for preventing food safety hazards. FSIS is responsible for verifying that each establishment's HACCP system is operating in compliance with these regulations in a way that will result in the production of safe meat and poultry products.

We discussed this concern and our recommendations in an issue paper provided to FSIS on August 23, 2007. FSIS provided its response on September 18, 2007 (see Exhibit C).

Recommendation 1

Implement an action plan with specific milestone dates for capturing the results of food safety assessments in an appropriate configuration that allows for effective analysis.

Agency Response.

On September 26, 2007, FSIS awarded a contract to build the agency's new Public Health Information System (PHIS). FSIS plans to have a functional domestic inspection module, including the new electronic food safety assessment module, ready for limited deployment in April 2008. Full production implementation should be in August 2008, based on a 10 month period of performance. PHIS will facilitate effective analyses by capturing similar types of information for all establishments, capturing those findings in quantifiable terms, storing detailed food safety assessment findings in an electronic format, and interacting with the replacement for PBIS (see Exhibit C).

In the response to the draft report, dated November 26, 2007, FSIS also agreed to establish unique tracking numbers for each food safety assessment recorded in the PHIS (see Exhibit I).

OIG Position.

We accept FSIS' management decision.

Recommendation 2

Perform food safety assessments, using the new configuration, in all establishments that will be in the universe of establishments where risk-based inspection may be used. The food safety assessments should be comprehensive assessments of the establishment's current operations.

Agency Response.

In the supplemental response to the draft report dated November 30, 2007, FSIS agreed that prior to implementing a redesigned processing risk-based inspection system via the domestic inspection module of the PHIS, FSIS will have performed food safety assessments under the new configuration in all of the largest processing establishments, i.e. those that produce approximately 95 percent of meat and poultry products annually. FSIS will use the results from these food safety assessments, along with other data, to estimate the levels of risk posed by these establishments' products to the public health. Inspection then will be allocated in consideration of these estimated levels of risk.

After the new risk-based inspection system is implemented, to estimate risk for establishments that have not yet had food safety assessments under the new configuration, FSIS will use data from the establishments' profile in PHIS, inspection and micro-testing results, and enforcement and other data. PHIS "profile" and "event" data will represent a significant expansion over the data currently contained in PBIS, and will include establishment testing results, production volume, and other data.

Further, PHIS will raise "flags" based on establishment profile and other data indicating the possible need for a food safety assessment in these establishments, regardless of their production volume. So, immediately after the implementation of the PHIS, PHIS profile and other data will be used not only to estimate risk and allocate inspection resources but also to prioritize food safety assessments for smaller volume establishments that have not yet had food safety assessments under the new configuration.

The Data Analysis and Integration Group (DAIG) risk-based inspection technical paper and the business process documents for the new food safety assessments and the "in-plant inspection area" of the PHIS will detail the content of the new food safety assessments; the range of data to be contained in the domestic inspection module of PHIS; the PHIS flags, which are raised based on establishment "profile" and "event" data and that indicate the possible need for a food safety assessment; and the algorithm used for calculating establishment risk.

FSIS officials have established a timeline for initiating the domestic inspection module of PHIS nationwide. As noted in the timeline, many milestones must be met to put this module in production, which is expected to be during the second quarter of calendar year 2009 (see Exhibit J).

OIG Position.

We accept FSIS' management decision.

Recommendation 3

Determine how the results of food safety assessments will be used by FSIS in estimating establishment risk.

Agency Response.

In the supplemental response to the draft report dated November 30, 2007, FSIS stated that the agency is developing a new, more comprehensive food safety assessment configuration and will incorporate it into the domestic inspection module of the PHIS. Food safety assessments conducted under the new configuration will be scheduled, in part, using "flags" in PHIS data that show public health risks indicating the possible need for a food safety assessment at an individual establishment. The food safety assessment results, in turn, will be fed into PHIS to help FSIS managers to better estimate the risks posed by an establishment's products and allocate inspection resources accordingly.

In addition, FSIS is creating a new food safety assessment instrument consisting of sections containing a series of data gathering and data analysis questions tailored to the specific food safety hazards and regulatory requirements associated with each HACCP 03 process (e.g., 03B Raw Product-Ground). The new food safety assessment reporting instrument will be web-based; interactive with the new domestic inspection system to obtain needed profile data; consist of questions to help structure an EIAOs investigation reporting, as well as prompt the EIAO to explain their findings; provide consistent information for analysis purposes to inform policy and inspection resource allocation; and contain a tracking system to ensure food safety assessments for cause are getting performed and that all relevant establishments are assessed at least every four years.

The DAIG is developing an algorithm for estimating risk posed by the products from establishments, which can be used to allocate inspection resources based on risk. The DAIG will publish a peer-reviewed risk-based inspection technical paper by March 17, 2008, and will develop the method for incorporating food safety assessment results data into the risk-based inspection algorithm by December 1, 2008.

FSIS officials have established a timeline for initiating the domestic inspection module of PHIS nationwide. As noted in the timeline, many milestones must be met to put this module in production, which is expected to be during the second quarter of calendar year 2009 (see Exhibit J).

OIG Position.

We accept FSIS' management decision.

Finding 2	**Data Limitations in the Algorithm for Risk-Based Inspection**

FSIS has recognized that to effectively make risk management decisions for protecting the U.S. food supply, sound science based on high quality data is needed. Several external groups, including OIG, stakeholders,[26] and the National Advisory Committee on Meat and Poultry Inspection (NACMPI) have provided comments to FSIS regarding deficiencies in agency data. To address these concerns, in April 2007, FSIS formed the DAIG to improve agency data by identifying data needs and by analyzing and integrating the data.

During the course of our audit, FSIS' DAIG began a critical in-depth examination[27] of the data used in the nine components of the risk-based inspection algorithm with a view to refine and expand the data used in future versions of risk-based inspection. According to FSIS officials, some of the limitations the DAIG identified had been acknowledged in the development of the initial phase of risk-based inspection and FSIS intended to mitigate them in future versions of risk-based inspection. This review is still in process, but the agency has already disclosed limitations and uncertainties regarding each of these components. Our audit tests verified the limitations and uncertainties of various components of the algorithm. We also found FSIS could not provide documentation of analyses it performed to support that the window of data[28] used to determine how well an establishment controlled risks was appropriate. FSIS needs to ensure the basis for decisions made regarding the components included in the risk-based inspection program are thoroughly documented and evaluated with limitations mitigated and are transparent (i.e., clear and understandable) to all stakeholders.

In February 2007, FSIS proposed a risk-based inspection algorithm to rank the potential risks across different establishments for allocating inspection resources. This algorithm combined an estimate of the potential risk that was

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[26] Stakeholders include representatives from such entities as States, academia, consumers, industry, Federal agencies, and foreign countries.

[27] We reviewed the most current draft of FSIS' Risk-Based Inspection for Processing Technical Report, dated August 27, 2007. FSIS plans to have this report peer reviewed by a third party before issuing it in final, which is expected to be in March 2008.

[28] A window of data is a baseline time period for data collection.

considered inherent to the establishment (inherent risk measure) and an estimate of how well the establishment controlled those potential risks (risk control measure). The inherent risk measure included factors for the different types of processed products and the volume of the products produced by the establishment. The risk control measure considered the following seven factors, as applicable to the establishment: (1) public health significant NRs, (2) enforcement actions, (3) control of *Lm* in RTE products, (4) control of *Salmonella* in raw meat and poultry products, (5) microbial testing program results, (6) food safety recalls, and (7) food safety consumer complaints.

In October 2007, FSIS accelerated implementation of initiatives originally scheduled for Spring 2008 to respond to concerns related to two large recalls of ground beef product potentially contaminated with *E. coli* O157:H7. At that time, FSIS also accelerated its plans to review the control of this pathogen by beef suppliers and processors. In June 2007, FSIS identified an increased number of *E. coli* O157:H7 positive tests in beef, as well as a larger number of recalls and illnesses caused by this pathogen than in recent years.

Data Window for Components of the Risk Control Measure

During the development of risk-based inspection, FSIS requested input from stakeholders on the appropriate window of data (i.e., period of time) to be used for determining an establishment's risk control measure. Stakeholders suggested periods of 6 months or 1 year as possible choices. FSIS officials made the determination to use a 6 month rolling data window for NRs, consumer complaints, and recalls; and a 1 year window for microbial test results and for the control of *Salmonella*.[29] In response to our inquiries during audit fieldwork, FSIS officials explained that the agency did not conduct analyses to support that these data windows were appropriate; FSIS based the windows on internal discussions and stakeholder input.

Analysis Planned for Inherent Risk Measure

The proposed inherent risk measure is based on the types of processed products and the volume of these products produced by an establishment. FSIS used an expert elicitation conducted in 2005 to rank risks associated with species (i.e., meat, pork, or poultry) and type of processing (e.g., raw, ground, ready-to-eat). This ranking was then weighted based on the proportion of product volume for each product. FSIS is examining the relative importance of the two components of inherent risk, as well as how much weight each factor should be given. Multivariate analyses are also being conducted to examine how changing the weight does and should impact the final inherent risk measure.

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[29] Data for the other factors used in the risk control measure, enforcement actions and the control of *Lm* in RTE products, were to be based on the day an establishment's level of inspection was computed.

Potential Limitations of the Expert Elicitation Data

In order to rank the potential hazards inherent in the products regulated by FSIS relative to risk-based inspection, the agency has sought the opinion of experts in two similar elicitations—one in 2005 and another in 2007.[30] Because varying amounts of data on risk from the different types of processed meat and poultry products were available, FSIS conducted the expert elicitations in an effort to organize existing data and expert judgment into a ranking of relative public health risks posed by each product type. During the course of our audit, FSIS acknowledged the following limitations, among others, related to its expert elicitation data.

- Experts were asked to consider only bacterial hazards, not viral, chemical, or physical hazards. The inclusion of those hazards would raise the rankings of some products.

- FSIS assumed that the establishments were establishments with typical food safety controls. Including consideration of food safety control failures could have raised the ranking of some products with a higher incidence of control failures.

Analyses Related to Expert Elicitations

FSIS has recognized that when considering the use of the results from expert elicitations, it is important to analyze additional factors that were not previously considered in its interpretation of this data. The following analyses are in various stages of completion.

- FSIS is comparing the consistency of the 2005 and 2007 elicitations across the various experts, both within a given elicitation and across the different elicitations. There was variability in the absolute ratings of products across experts for some products (although the relative rankings were consistent both within each elicitation and between the 2005 and 2007 rankings). FSIS believes a strong correlation between the two elicitations of different experts would provide confidence in the results of each expert elicitation.

- The agency is analyzing its own microbial sampling results to determine if those products and processes that were ranked in the expert elicitations as having the highest likelihood of illness are the most likely to have a contamination event. FSIS will compare the incidence of *E. coli* O157:H7, *Salmonella*, and *Lm* in various end products with the expert elicitation risk rankings.

- FSIS is examining the context of published literature on food-borne illness and the food products associated with those illnesses. FSIS will summarize relevant literature and the results of the expert elicitation will be interpreted in the context of that literature.

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[30] FSIS did an initial elicitation in 2001which ranked processes, but not species type. Because of this limitation, the 2001 elicitation is not compared with the ones performed in 2005 and 2007. Stakeholder concerns with the 2005 elicitation led FSIS to conduct another elicitation in 2007.

Potential Limitations of the Production Volume Data

Another component of the inherent risk measure in the risk-based inspection algorithm is production volume. According to FSIS, higher production volumes are riskier because establishments that produce larger volumes of product have a greater potential to impact public health. FSIS did not have production volume data for all processing establishments in its inspection database. Because FSIS would need Office of Management and Budget (OMB) approval to request volume data from industry, which would take considerable time, FSIS directed inspectors to estimate production volume for the establishments in which they worked.[31]

During our fieldwork in August 2007, we visited 15 processing establishments. As part of this work, we obtained production volume data from each establishment and compared it to the estimates from inspectors.[32] The production volume provided by 13 of the 14 establishments changed the inherent risk measure; the change for 2 of them was significant enough to change the level of inspection calculated by FSIS. This occurred because FSIS inspectors inaccurately estimated production volume and incorrectly identified the types of product produced by these establishments. Prior to implementing risk-based inspection, FSIS should validate the accuracy of data used in calculating an establishment's level of inspection.

FSIS has acknowledged the following limitations, among others, related to its production volume data.

- The FSIS inspection force is not able to precisely collect production volume information.

- The annual production volume collected from industry might misrepresent the 6-month period analyzed for risk-based inspection due to seasonal variations.

- Production volume estimates by inspection program personnel can be inaccurate when compared to establishment records.

As FSIS moves forward to develop and implement a risk-based inspection program, the agency should develop a process to obtain more accurate, verifiable production data (e.g., pounds of product produced by product types) and regularly update the data from FSIS-regulated establishments.

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[31] As explained at the April 2007 public meeting on volume, collection of volume data from industry would require OMB approval due to requirements of the Paperwork Reduction Act of 1995. FSIS noted that the OMB approval process takes multiple months to complete and requires substantial justification.

[32] FSIS was unable to provide the production volume estimate for 1 of the 15 establishments we visited because inspection personnel had not yet collected this information. Therefore, we were only able to review FSIS volume data for 14 establishments. During our fieldwork, we found that FSIS had not yet estimated production volume for 285 of the more than 5,000 meat and poultry processing establishments.

Analyses Related to Volume Data

Stakeholders have questioned whether inspection program personnel can accurately estimate an establishment's production volume. The stakeholders also argued that large volume establishments might have better control measures in place and, therefore, pose less risk to public health. FSIS has recognized the need to perform additional analyses, not only to address these stakeholders' questions, but also to consider production volume in its interpretation of the data. The following analyses are underway, although not complete.

- Comparisons are being made between inspector-generated estimates of volume and other available industry data on production volume. FSIS is also looking at potential methods or additional means to compare the data; including having Enforcement, Investigation, and Analysis Officers (EIAO) report more detailed information on volume as part of food safety assessments.

- FSIS is comparing production volume to microbial sampling results, and other indicators of an establishment's food safety performance. The other indicators include those proposed previously for use in risk-based inspection; namely, NRs, consumer complaints, recalls, and enforcement actions.

Potential Limitations of Public Health Significant NR Data

FSIS inspection personnel issue NRs based upon an observed noncompliance during an inspection task and associate them with a certain regulatory citation. NRs, as a component of the proposed risk control measure, were given different weights relevant to an establishment's loss of control of its food safety system, and subsequent potential public health significance.

During our fieldwork in August 2007, we obtained the NR data used in the risk-based inspection calculation for 14 of 15 establishments visited[33] to verify that the data properly reflected the number of NRs filed for these establishments.[34] We found one occasion where the same NR was counted twice towards an establishment's risk-based inspection calculation. This establishment had 23 NRs in the calculation period. This occurred because an FSIS inspector entered an NR into PBIS and then revised it. Although the NR was revised, PBIS counted this NR twice. In response to our inquiries during fieldwork, FSIS did not provide an explanation as to why PBIS counted this NR twice.

For another establishment, FSIS did not include all the public health significant NRs in the risk-based inspection calculation. The calculation only included five NRs when six NRs had been issued. As FSIS moves forward with the development of risk-based inspection, the agency needs to research this type of error to ensure that data are accurately processed. The 14

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[33] As noted previously, FSIS had not collected volume information for one establishment. Therefore, we could not verify the risk-based inspection calculation for this establishment including the NR component.

[34] The data window for NRs in the risk-based inspection calculation was April 1 to September 30, 2006.

establishments had a total of 122 NRs during the period used for the risk-based inspection calculation. Prior to implementing risk-based inspection, FSIS should validate the accuracy of data used in calculating an establishment's level of inspection.

The following data limitations related to public health significant NRs have been recognized by FSIS.

- The issuance of NRs could vary nationwide. For example, high vacancy rates among inspectors in some districts may reduce the rate of NR issuances due to fewer inspector resources. Also, there could be an increase in a particular NR following the release of an FSIS directive or notice due to increased awareness.

- Stakeholders have commented that there could also be potential food safety issues occurring at an establishment that may on occasion not be written in an NR because FSIS personnel does not recognize them as a noncompliance. FSIS conducts ongoing training of its inspection force to limit such events.

- The impact of appeals of an NR by an establishment on the risk-based inspection algorithm should be examined.

Analyses Related to Public Health Significant NRs

FSIS is evaluating whether the individual experts categorized public health NRs consistently in their evaluation of each of the 564 regulations cited in NRs.[35] This analysis will aid in evaluating if the categorization of citations by FSIS' experts was appropriate or should be re-evaluated due to a wide variation in viewpoint of the public health significance.

Potential Limitations of Consumer Complaint Data

Consumer complaints could be an indication of an establishment's ability to maintain an effective food safety system. The risk control measure is based on consumer complaints that are related to a food safety issue and have been verified to be connected to a specific establishment. During the course of our audit, FSIS identified the following limitations in consumer complaint data.

- FSIS' consumer complaint monitoring was not designed to assign blame or pinpoint losses of process control; rather, it was designed to alert FSIS and establishment personnel that there have been reports of incidents that might benefit from further evaluation.

- The complaint database does not reflect the total number of food-borne illnesses in the United States due to underreporting. A large number of

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[35] One way FSIS is determining what types of NRs may be more predictive of adverse outcomes is by ranking NRs. Ranking of NRs based on their significance to adverse public health outcomes was performed by nine FSIS subject matter experts using four categories, which related to a food safety system's loss of process control. According to FSIS officials, each expert had a diverse background of work with related regulatory experience in the meat, poultry, and egg products industries. OIG did not evaluate the methodology used by FSIS for determining these rankings.

illnesses might never be captured because consumers do not contact FSIS. In 1999, CDC estimated that food-borne diseases caused approximately 76 million illnesses in the United States, yet there have been less than 6,000 consumer complaints reported to FSIS over the past 6 years.

- FSIS consumer complaint data, although always associated with an inspected establishment, cannot always definitively attribute an illness to consumption of a particular product (attribution data has been identified by nearly all stakeholders as critical for implementing a successful risk-based inspection program). This lack of definite attribution is due, in part, to the difficulties consumers have in identifying the sources of food-borne illnesses.

Potential Limitations of Food Safety Recall Data

The food safety recall component of the risk control measure is intended to assess whether an establishment can effectively implement a food safety plan and control product risk before its products reach commerce. During the course of our audit, FSIS identified the following limitations in food safety recall data.

- Recall data do not capture every instance of a food safety system failure in an establishment. The fact that an establishment has not been linked to a recall is not evidence that it has not produced and shipped contaminated product.

- There may be a significant lag time (possibly a couple of months) between when a product is distributed and when it is determined that it is contaminated and a recall is necessary.

Potential Limitations of Enforcement Actions Data

There are a variety of enforcement actions the agency can take against establishments that fail to sufficiently comply with applicable requirements – both food safety and non-food safety. Enforcement actions were given different weights in the risk control measure depending on FSIS' determination of severity.

During our review, we found that FSIS inadvertently omitted the enforcement action of Notice of Intended Enforcement (NOIE) Under Deferral[36] from the risk control measure. FSIS officials had not detected this omission because the algorithm and supporting data had not been tested to ensure that all enforcement actions were considered in the calculation. As FSIS moves forward in the development and implementation of risk-based inspection, this type of enforcement action should be included in the risk control measure.

In addition, FSIS identified the following limitations in enforcement actions data as they relate to the risk-based inspection algorithm.

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[36] The NOIE Under Deferral category is where the NOIE has been issued and the establishment has adequately responded to FSIS. Thus, temporarily the suspension does not go into effect, which allows the establishment to operate and demonstrate the effectiveness of its response.

- Stakeholders in public meetings have raised a concern regarding inconsistencies in the issuance of enforcement actions that may occur across FSIS regions and personnel. FSIS has a number of controls, including detailed directives and notices, and training to guide enforcement actions, and management controls, such as AssuranceNet, to monitor field activities and help ensure that its actions are consistent nationwide. There is no data that FSIS is aware of that indicates that this has occurred, but FSIS will analyze its inspection data further to determine if any such inconsistencies occur in different areas of the country or in particular districts. It also continues to reinforce to its field personnel the importance of issuing enforcement actions in a consistent manner.

- Not all enforcement actions are equally related to immediate food safety concerns. Some enforcement actions may result from administrative procedures or be related more to food wholesomeness than food safety. Therefore, if using enforcement actions for risk-based inspection to better protect public health, consideration should be given to ranking them based on how related they are to food safety concerns.

Potential Limitations of Data for Salmonella Verification Testing

Establishments that produce one or more types of raw meat or poultry products are classified into a *Salmonella* verification category based on the results of recent *Salmonella* test sets. The categories are given different weights in the risk control measure based upon which category an establishment is in. During the course of our audit, FSIS identified the following limitations in data for *Salmonella* verification testing.

- Current FSIS procedures allow only one product to be tested at a time per establishment. Depending on the frequency of production, the time needed to complete a *Salmonella* test set could range from two months to more than a year. In low volume establishments, it can take years to obtain data for each product produced.

- The design of the random sample gives all products equal likelihood of being tested, despite information from baseline studies and indications from regulatory samples that not all products have the same likelihood of testing positive for *Salmonella*.

- The sample designs do not take into account the consumption patterns across FSIS-regulated product. A product that is consumed less frequently than another product and, therefore, has less potential for affecting public health (because fewer people will eat it to be exposed to *Salmonella*) has the same likelihood of being tested as a more heavily consumed product.

- FSIS informs establishments in advance that *Salmonella* testing will occur, which could influence the activities of an establishment, biasing the results.

Potential Limitations of Data on the Control of Lm in RTE Products

Lm performance standards only apply to those establishments that produce RTE products that are exposed to the environment subsequent to a lethality step. FSIS requires these establishments to choose one of three alternatives for controlling *Lm*.[37] Establishments are required to report this information to FSIS at least annually and whenever there is a significant change in the alternative used or volume of production. However, FSIS does not have oversight procedures to ensure that this is done. Scores for the risk control measure are assigned based on which methods, or combinations thereof, an establishment has in place to control *Lm* in RTE products.

FSIS identified the following limitation regarding the control of *Lm* in RTE product data.

- All establishments required to control *Lm* have not submitted the required forms describing their processes for controlling *Lm*, and FSIS does not verify the accuracy of the information, including the alternative. Thus, this data element is not captured, or incorrectly captured, in the algorithm and the level of inspection calculated for these plants would not consider how well the establishment controls the risk associated with *Lm* in RTE products. Also, it is left to the establishment to determine when to report a significant change in its operation, including the possibility of falling into a different alternative.

Our fieldwork in August 2007 confirmed that this is a valid concern; we found seven of nine establishments did not submit current information (for over 2 years) on how they controlled *Lm* in RTE product or the volume of product they produced under each alternative. This also has a potential adverse effect on FSIS' risk-based *Lm* testing program, which is based, in part, on the control methods used and production volume. In March 2007, FSIS began collecting this information electronically, as opposed to relying on paper-based forms; four of the seven establishments submitted the information electronically in 2007. If FSIS monitors this data and follows up with non-responders, the data used in the risk-based inspection calculation may be more accurate and complete. Prior to implementing risk-based inspection, FSIS should validate the accuracy and completeness of data used in calculating an establishment's level of inspection.

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[37] Under Alternative 1, the establishment uses a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms on the product and an antimicrobial agent or process that suppresses or limits the growth of *Lm*. Under Alternative 2, the establishment uses either the post-lethality treatment or antimicrobial agent or process that limits the growth of *Lm* described in Alternative 1. Under Alternative 3, the establishment relies on sanitation measures to control *Lm*.

Potential Limitations of Data from Microbial Testing Programs

Establishments that produce RTE or raw ground beef products are subject to pathogen testing programs. The testing programs considered relevant to the proposed risk-based inspection algorithm include RTE products tested for *Lm*, *Salmonella,* and *E. coli* O157:H7, and raw ground beef products subject to tests for *E. coli* O157:H7. Scores for the risk control measure were assigned based on the number of positive samples an establishment had for these pathogens. During the course of our audit, FSIS identified the following limitations in microbial data as they relate to the risk-based inspection algorithm.

- There are lower numbers of *E. coli* O157:H7 samples analyzed than are scheduled.[38] There are a number of reasons why not all scheduled samples are analyzed, including that the product scheduled to be sampled at a given establishment is not being made at that point in time, or samples are damaged or lost during shipment to the FSIS laboratory. A difference between the number of samples planned and analyzed could affect the reliability of the data collection if the drop-off occurred more in one type of establishment or one location.

- There is a concern whether contamination by an organism such as *Lm*, *E. coli* O157:H7, and *Salmonella* is uniformly distributed within and among lots of meat and poultry products. This could affect, for a given lot, the probability that a test will be positive if the lot is contaminated, and the probability that sampling one lot will find contamination if contamination is not uniform among lots.

- *E. coli* O157:H7 sampling currently does not include beef components such as head meat, cheek meat, organ meat, and advanced meat recovery (AMR) products.[39] FSIS announced plans to expand testing to these products in October 2007.

- The *Salmonella* verification test must be interpreted cautiously because the sampling protocols were not designed to assess the national prevalence of *Salmonella* in FSIS-regulated products and did not take into account the production volume. Therefore, the results do not provide a good estimate of the prevalence of *Salmonella* in the nation's supply of those products tested.

- Although the randomization of a sampling plan helps decrease biases, it also limits certain interpretations or conclusions that can be drawn from the data. Randomization is not adjusted for production volume, and

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[38] During calendar year 2006, 72.1 percent of scheduled samples were analyzed. Samples requested from very small establishments are the least likely to be tested (large establishments 88.1 percent tested; small establishments 78.5 percent tested; very small establishments 68 percent tested).

[39] AMR technology removes muscle and other edible tissue from the bones of beef carcasses under high pressure without incorporating the bone. AMR machinery separates meat by scraping, shaving, or pressing the muscle and edible tissue away from the bones.

therefore, establishments with large production volumes are not sampled more frequently than those with smaller production volumes. Establishments producing smaller volumes, therefore, are sampled more frequently on a per volume basis than those producing larger volumes. That results in some limitations in the interpretation of the data (e.g., does not present an accurate picture of the national prevalence rate of *E. coli* O157:H7).

In a prior audit,[40] we recommended FSIS perform the necessary baseline studies to define the goals, objectives, and performance measurements and develop a scientific, risk-based sampling plan to include relevant factors, such as individual plant volume of production and effectiveness of interventions that will provide reasonable assurance that HACCP systems in place are effective. In response, FSIS agreed to publish the results of baseline studies on generic *E. coli* and *Salmonella*. FSIS also agreed to report the results of the beef trim *E. coli* O157:H7 baseline program once the baseline was completed, which FSIS expects to publish by the end of 2007.

Analyses Related to Components of the Risk Control Measure

FSIS has recognized the need to perform additional analyses on the relative importance of the seven components of the risk control measure, as well as how much weight each factor should be given. Multivariate analyses are being conducted to examine how changing the weight does and should impact the final risk control measure and how the individual components should be weighted in the overall risk-based inspection algorithm to determine resource allocation.

FSIS has also recognized the need to perform analyses to examine the relationships between the components of the risk control measure and the relationships between the components and other indicators of performance of an establishment's food safety system. FSIS will conduct analyses to examine these correlations.

Potential Limitations of Other Possible Components

FSIS has also recognized the importance of focusing not only on the data previously used, but also on other data that it has that could be used and data that could possibly be available to it for use in the future. Other possible components that have been considered and their potential limitations are listed below.

- The age of an establishment may influence an establishment's pathogen performance. Older establishments might use older production technology or might not have adequate personnel coverage for pathogen control. Alternatively, newer establishments may not have experienced staff or adequate training programs to manage food safety issues. On the basis of the survey data for slaughter establishments, a strong single predictor of pathogen results was the percentage of establishment space that is older than 20 years of age.

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[40] Oversight of Production Process and Recall at ConAgra Plant, Audit Report No. 24601-02-KC, September 2003.

- Whether establishment square footage might also influence performance on pathogen tests was explored by the Research Triangle Institute.[41] In its analysis of slaughter establishments, the establishment production space and age were interdependent, but production space was not an important characteristic associated with performance on pathogen tests.

- The number of employees may influence an establishment's performance on pathogen tests because it could be related to providing adequate personnel coverage for food safety quality assurance programs and production areas. The number of employees will be highly variable among establishments. The number of employees may not be an independent variable but interdependent with other variables such as HACCP training and the size of establishment production area.

- In food-handling operations, chemical sanitizers are used as rinses, sprayed onto surfaces, or circulated through equipment in clean-in-place operations. In certain applications the chemicals are foamed on a surface or fogged into the air to reduce airborne contamination. The extent to which an establishment uses chemical sanitizers in its food processing area could affect its performance on pathogen tests.

Data from the Centers for Disease Control and Prevention

FSIS works with the Center for Disease Control and Prevention (CDC) to be able to better make associations between the products that FSIS regulates and the illnesses reported on by CDC. To obtain CDC's perspectives, FSIS provided CDC's Enteric Diseases Epidemiology Branch with information related to risk-based inspection. In addition, CDC officials attended the FSIS' public meeting on attribution in April 2007.

FSIS has requested access to data from food-borne disease outbreaks as collected and compiled by CDC. FSIS plans to compare the human illness data from the CDC with the expert elicitation data. Both sets of data will be used to better allocate FSIS inspection resources to specific products that pose more risk to the public health. FSIS believes this work will provide valuable information to enhance existing attribution and severity data.

Use of Non-FSIS Data

FSIS intends to use non-FSIS data to supplement FSIS data to develop effective risk management strategies. The use of data from industry, as well as other sources, could fill important data gaps. NACMPI has also agreed that supplementing FSIS' data with data from interested stakeholders could maximize the agency's ability to safeguard meat and poultry products. Specifically, NACMPI has recommended that FSIS explore ways that industry, academia, and other stakeholders can transfer data to FSIS, including incentives for participation.

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[41] The Research Triangle Institute is an independent, nonprofit organization that serves clients in government, industry, academia, and public service throughout the United States and abroad. The Food and Agriculture Policy Program at the Research Triangle Institute has been conducting analyses of the economic effects of food safety and nutrition regulations for USDA for more than 15 years.

FSIS has previously used non-FSIS data in such ways as risk assessments and economic impact analyses. However, most of the data submitted and used by FSIS has been aggregate data, not specific to individual establishments. A primary focus of risk-based inspection relates to the degree of process control exhibited by individual establishments and allocating an appropriate level of inspection by FSIS in that establishment. FSIS has recognized that one concern for using non-FSIS data is to assure the data are validated and reliable.

FSIS Actions to Combat E. coli O157:H7 in Raw Beef Products

In June 2007, FSIS identified an increased number of *E. coli* O157:H7 positive tests in beef, as well as a larger number of recalls and illnesses caused by this pathogen than in recent years. In response, FSIS immediately increased the number of tests of ground beef for *E. coli* O157:H7 by more than 75 percent in July and began planning for a new followup testing program for Federally inspected beef plants that had positive tests for *E. coli* O157:H7. In October 2007, after a series of large recalls, FSIS announced that the agency was accelerating implementation of initiatives originally scheduled for Spring 2008 to respond to concerns about increased positives of *E. coli* O157:H7. Lessons learned from a number of recent recalls emphasized the need for FSIS to further strengthen its policies and programs. The agency realized that to make risk-based inspection in processing establishments more effective, FSIS needed to strengthen its data that will support that system. In October 2007, FSIS announced the following initiatives targeting Federally inspected plants that produce raw beef products.

- **Testing and analysis of trim**. Based on preliminary data from the agency's beef trim baseline and scientific literature indicating that contamination of trim is related to contamination of ground beef, FSIS began trim testing in March 2007. FSIS believes that by testing earlier in the production chain to identify contaminated beef trim intended for ground beef, this source will be prevented from contaminating the ground beef available to consumers. FSIS believes this also gives the agency more data to analyze in determining and implementing the most appropriate actions to reverse upward trends.

- **Verifying control of *E. coli* O157:H7**. FSIS notified the beef industry that, as of November 2007, all beef plants will be expected to verify that they are effectively controlling *E. coli* O157:H7 during slaughter and processing.[42] The agency also provided the industry specific examples of

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[42] In October 2002, FSIS advised establishments to reassess their HACCP plans for potential contamination of raw beef products with *E. coli* O157:H7. According to FSIS officials, since this announcement, the agency focused on whether establishments have controls in place. FSIS personnel determined whether the establishment (1) reassessed its operations or (2) identified controls. FSIS officials explained that the verification efforts announced in October 2007 will evaluate the underlying support for an establishment's controls to prevent potential contamination of raw beef products with *E. coli* O157:H7.

minimum controls that would meet the minimum criteria for a well-controlled process. Identifying which establishments achieve the minimums, and which establishments do not, will provide FSIS the critical information on establishments with vulnerabilities.

- **New checklist for verifying control**. FSIS inspection program personnel will review both suppliers and processors based on a new checklist, once they complete specialized training that was scheduled to begin the week of October 29, 2007. Data from the checklists will be completed in November and will be updated quarterly to help the agency more quickly identify significant changes in establishments' production controls and ensure the companies take corrective action. FSIS will analyze the checklist data and use them to adjust programs or policies as needed.

- **Testing more domestic and imported ground beef components**. FSIS will begin testing materials that are used as components in raw ground beef, in addition to the beef trim already tested, which is the primary component. FSIS is also requiring countries whose beef is imported to the United States to conduct the same sampling or an equivalent measure.

- **More rapid recalls**. FSIS now takes into account a broader, more complete range of evidence when evaluating whether to seek a recall or take regulatory action. This gives the agency a credible approach to more rapidly taking action when certain types of evidence are available. In two recent cases, FSIS acted upon epidemiological evidence that linked illness to opened, FSIS-inspected product found in consumers' freezers.

- **Targeting routine testing**. In January 2008, FSIS will begin routine targeted sampling for *E. coli* O157:H7 at slaughter and grinding facilities. Currently, all plants have an equal chance of being tested. Under this new verification testing program, FSIS will test larger volume operations more frequently than in the past. Data from the checklists will be used to determine testing frequency for establishments.

- **Ensuring safety of imported beef products**. FSIS notified countries that export raw beef product to the United States of new policies and programs and is working with them to ensure they implement the same or equivalent measures to protect the public from *E. coli* O157:H7 risks.

Decisions for Risk-Based Inspection

Without proper consideration and evaluation of these and other data and structural limitations, FSIS cannot yet confidently demonstrate in a transparent and proactive manner that it has adequately considered all the potential challenges it faces in implementing a data driven, scientifically based risk-based inspection system. FSIS should ensure the basis for decisions made regarding the components included in the risk-based inspection program are thoroughly documented and evaluated with limitations mitigated and be transparent to all stakeholders.

FSIS intended to create a plan for evaluating risk-based inspection in the 254 establishments included in the pilot program. However, FSIS did not finalize its evaluation plan because legislation delayed the pilot risk-based inspection program. Therefore, OIG was unable to assess the adequacy of FSIS' plan.

Recommendation 4

As FSIS moves forward to develop and implement risk-based inspection, conduct and document analyses that support the data windows selected for each of the components in the risk control measure, which assesses an establishment's ability to control risk.

Agency Response.

In the response to the draft report, dated November 26, 2007, FSIS stated that in developing its risk-based inspection technical paper, the DAIG is conducting a number of analyses to determine the temporal relationships among the factors they are considering for use in a risk-based algorithm. These analyses will provide information regarding an appropriate data window for use in risk-based inspection. That is, by examining the relationships in time among food safety events, FSIS can determine what amount of data is needed to develop an accurate characterization of an establishment's food safety controls. Such analysis has begun on the relationship between NRs and positive *Salmonella* results. Similar analyses will be conducted to examine the temporal relationships between other components of a risk-based algorithm. The results of those analyses will be used, in conjunction with other considerations such as availability of data, to determine the most appropriate data window to be used. The rationale and analyses underlying the decision will be presented in a technical plan in support of risk-based inspection to ensure transparency. The risk-based inspection technical report will be made final and available to stakeholders, following review by NACMPI and by peer reviewers, by March 17, 2008 (see Exhibit I).

OIG Position.

We accept FSIS' management decision.

Recommendation 5

Ensure that the basis for decisions made regarding the components included in the risk-based inspection program are thoroughly documented and evaluated with limitations mitigated and are transparent to all stakeholders.

Agency Response.

In the supplemental response to the draft report, dated November 30, 2007, FSIS stated the agency is developing a technical report that will outline, in detail, the basis for decisions made regarding the components included in the risk-based inspection program. The report will outline the limitations of the data, and how those limitations affect the use of the data in risk-based inspections. All effort will be made to decrease the limitations in the data, including incorporating data analysis plans into directives and notices to emphasize the importance of the data, and training. (However, it is important to note that all data has limitations, the limitations must be stated and the subsequent uncertainty resulting from those limitations should be discussed, but not all limitations preclude the use of data.) The technical paper will be peer reviewed according to OMB's peer review guidelines, shared with stakeholders, including NACMPI, and modified in response to comments prior to implementation of risk-based inspection in processing. The technical report will be made final and available to stakeholders, following review by NACMPI and by peer reviewers, by March 17, 2008 (see Exhibit J).

OIG Position.

We accept FSIS' management decision.

Recommendation 6

Develop a process to obtain more accurate, verifiable production data (e.g., pounds of product produced by product type) and regularly update the data from FSIS-regulated establishments.

Agency Response.

In the response to the draft report, dated November 26, 2007, FSIS agreed that production data, including volume of pounds of product produced by product type, is critical and that FSIS needs to account for this information in the design of its verification activity. Consequently, through the new PHIS, FSIS expects to implement a mechanism for inspection program personnel to identify specific production records upon which such information is based, and to provide the establishment management an opportunity to review the collected information. Collection of such information in this manner provides FSIS a means to verify the source and accuracy of the information.

FSIS took steps to collect information on raw beef products in this manner with FSIS Notice 65-07 (regarding control of *E. coli* 0157:H7) and will assess the process to ensure that it is refined and enhanced in order to be effective. Until PHIS is fully implemented, FSIS will repeat the collection of verifiable volume data begun with FSIS Notice 65-07 at a frequency determined by analysis of the initial results and changing data needs. Also before PHIS is fully implemented, FSIS will begin collecting verifiable

volume data on products other than raw beef. Once implemented, the PHIS is expected to prompt inspection program personnel to regularly verify that the collected information remains accurate.

A prototype for domestic inspection within PHIS will run in a test environment during the third quarter of calendar year 2008 to selected users. The nationwide production readiness for PHIS with the domestic module is currently scheduled for the second quarter of calendar year 2009 (see Exhibit I).

OIG Position.

We accept FSIS' management decision.

Recommendation 7

Determine why NRs were not correctly accounted for (i.e., one counted twice and one omitted) when calculating an establishment's level of inspection. Implement the necessary controls to ensure that these types of errors do not occur and that data are complete and accurately processed.

Agency Response.

In the response to the draft report, dated November 26, 2007, FSIS stated that the two errors identified by OIG were human errors on the part of inspection program personnel. Further, PBIS does not have automated functions to check for such errors and they were missed during the manual error checks during the single calculation of levels of inspection for the planned "prototype" risk-based inspection establishments. The PHIS will include constraints on data entry to better prevent the erroneous duplication of NRs and other information.

FSIS will include in its technical plan for risk-based inspection that prior to implementing any risk-based inspection algorithm, it will check that the correct data is being processed and that it is being processed accurately. That check will include pulling, for a subset of the establishments, the individual data sets and independently calculating the values for those establishments to ensure that any automated algorithm is accurately processing the data. In addition, FSIS will further emphasize to its personnel the importance of having the data input correctly in its system by, for example, including information on how the data being collected will be analyzed and used in its directives and notices. Also, FSIS will conduct extensive performance and functional testing of PHIS during user acceptance testing to ensure that the system operates as designed. The testing will be derived from the business processes, scenarios, and use cases defined during the Requirements Phase of the project.

A prototype for domestic inspection within the PHIS will run in a test environment during the third quarter of calendar year 2008 to selected users. The nationwide production readiness for PHIS with the domestic module is currently scheduled for the second quarter of calendar year 2009. The risk-based inspection technical report will be made final and available to stakeholders, following review by NACMPI and by peer reviewers, by March 17, 2008 (see Exhibit I).

OIG Position.

We accept FSIS' management decision.

Recommendation 8

Develop and implement at least an annual process to verify how establishments control *Lm* in RTE product and that establishments report when there is a significant change in the method they use to control *Lm* or volume of product they produce.

Agency Response.

In the response to the draft report, dated November 26, 2007, the agency stated that the FSIS headquarters personnel will incorporate information currently captured on the industry-submitted 10,240 form regarding *Lm* controls into the PHIS establishment profile and by September 2008, FSIS will have inspection program personnel collect and input this information in the PHIS. By having inspection program personnel collect such information, FSIS will have a built-in mechanism to verify that the information is current, accurate, and verifiable.

A prototype for domestic inspection within the PHIS will run in a test environment during the third quarter of calendar year 2008 to selected users. The nationwide production readiness for PHIS with the domestic module is currently scheduled for the second quarter of calendar year 2009 (see Exhibit I).

OIG Position.

We accept FSIS' management decision.

Recommendation 9

As FSIS moves forward to develop and implement risk-based inspection, include the enforcement action NOIE Under Deferral in the calculation.

Agency Response.

In the response to the draft report, dated November 26, 2007, FSIS stated that the agency is considering a number of potential components in a risk-based algorithm and evaluating the data on those components. One of those components is data on enforcement actions. FSIS agrees that enforcement actions are important indicators that there has been a loss of food safety controls at an establishment, and provided that the analyses do not indicate that the data are inappropriate for use in an algorithm, this and other enforcement actions would be included in a risk-based algorithm. The factors to be used in the algorithm will be outlined in the risk-based inspection technical report. The risk-based inspection technical report will be made final and available to stakeholders, following review by NACMPI and by peer reviewers, by March 17, 2008 (see Exhibit I).

OIG Position.

We accept FSIS' management decision.

Recommendation 10

Prior to implementation, validate the accuracy of the risk-based inspection data (e.g., species, product type, public health NRs, and control of *Lm* in RTE product) used for calculating an establishment's level of inspection.

Agency Response.

In the response to the draft report, dated November 26, 2007, FSIS stated the agency will conduct extensive performance and functional testing of PHIS during user acceptance testing to ensure that the system operates as designed. The testing will be derived from the business processes, scenarios, and use cases defined during the requirements phase of the project.

A prototype for domestic inspection within the PHIS will run in a test environment during the third quarter of calendar year 2008 to selected users. The nationwide production readiness for PHIS with the domestic module is currently scheduled for the second quarter of calendar year 2009 (see Exhibit I).

OIG Position.

We accept FSIS' management decision.

Currently, FSIS does not have adequate management control processes or an information technology (IT) system in place to support a timely, reliable, risk-based inspection program. Prior audits have reported deficiencies in the basic building blocks of oversight and inspection activities used to verify HACCP food safety systems, as well as the IT systems used to support those processes. FSIS has recognized the current processes are error-prone and are not efficient towards effective delivery of timely, accurate data. On September 26, 2007, FSIS awarded a contract to develop the PHIS that is to provide the means to implement an effective food safety system that can collect, assess, and respond to hazards and risks. According to the contract, the PHIS is to provide the capabilities to mine and analyze inspection, surveillance, and investigative data; predict hazards and vulnerabilities; communicate or report analysis results; and target resources to prevent or mitigate the risk of food-borne illness and threats to the food supply. The domestic inspection module is targeted for implementation in June 2008; a predictive analytics and modeling component will be deployed around the same time.

FSIS has invested considerable time and effort into building a foundation for implementing a risk-based inspection program. The objective of such a modified inspection system is to focus inspection resources on those establishments that pose the greatest food safety risk, improving FSIS' ability to protect public health while maintaining the necessary level of inspection at all Federally-regulated establishments.

FSIS' original risk-based inspection strategy combined what it believed to be the best available data with the best expert judgment that was then available. However, FSIS has received comments and criticisms from a number of external sources (e.g., NACMPI and public stakeholder meetings) regarding FSIS data and its methodology for ranking the potential risks across different establishments. FSIS continues to consider this input in refining its approach to risk-based inspection.

As FSIS moves forward, its methodologies will need to be refined and improved. FSIS has already identified many areas for potential refinement and improvements; some are already in process and others are still planned for the future. Building a solid foundation for shifting to a risk-based environment that focuses inspection resources on improving FSIS' ability to protect public health lies in a process that uses (1) science and statistical analysis based on high-quality data that focus on risk analysis and prevention; (2) effective integration of FSIS' data management systems; and (3) strong IT and management controls.

| **Finding 3** | **FSIS Needs to Strengthen Security Over IT Resources and PBIS Application Controls** |

In fiscal year 2003, we issued our report on the security of IT resources at FSIS.[43] This report identified weaknesses in the agency's ability to adequately protect its IT resources from potential disruptions. During our current audit, we determined to what extent the agency had implemented the agreed upon corrective actions, and if implemented, to assess the effectiveness of these actions.

In fiscal year 2005, we issued our report on FSIS' PBIS.[44] The objective of this audit was to evaluate whether FSIS had adequate and effective controls over the input, processing, and output of PBIS data. FSIS relies on PBIS to manage its inspection activities. Overall, we found that FSIS had not implemented adequate controls to ensure the integrity of PBIS data. We reported that this ultimately may affect FSIS' ability to adequately manage its inspection activities and to ensure that the nation's commercial supply of meat, poultry, and egg products is safe and wholesome.

This audit confirmed that vulnerabilities continue to expose FSIS systems to unnecessary risks and that access (physical and logical) and application controls need improvement. Strengthening controls in these areas is critical to developing and implementing a reliable, data-driven risk-based inspection program that can produce information timely and accurately.

Security Over IT Resources

As a result of the 2003 IT security audit, FSIS immediately moved forward to correct and/or mitigate the high and medium vulnerabilities[45] noted. However, the agency was not diligent in continuing to scan its infrastructure on a timely basis and to correct or mitigate noted vulnerabilities. As a result, FSIS' servers, workstations, and network devices are unnecessarily vulnerable to attack and penetration, placing production data at risk. During our current audit, we received a related hotline complaint alleging that FSIS had not adequately mitigated vulnerabilities, patched systems, and scanned all required IT equipment. Also, FSIS had incorrectly reported its security status to the Department. We incorporated the allegations into the scope of our current audit and determined that the complaint was valid. FSIS management attributed the problems found to a lack of resources, poor communications within the agency, and the unique nature of the FSIS infrastructure.[46] As a result, the data residing on the FSIS IT infrastructure

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[43] Security Over the IT Resources at FSIS, Audit Report No. 24099-01-FM, August 2003.

[44] FSIS Application Controls—Performance Based Inspection System, Audit Report No. 24501-01-FM, November 2004.

[45] High risk vulnerabilities are those that provide access to the computer, and possibly the network of computers. Medium risk vulnerabilities are those that could provide this access if exploited.

[46] Distributed processing, remote locations, and lack of high speed communication.

are at risk of potential compromises to their availability, confidentiality, and integrity.

Physical/Logical Access Controls over Networks and Databases

We found that FSIS had not developed and implemented policies and procedures for granting access to the headquarters computer facility. As a result, FSIS could not ensure that only authorized employees have access to the computer facility, and that security measures were taken to protect systems and related supporting infrastructures against threats associated with the computer facility's physical environment. We noted that while a card key access system was installed to track employee's access FSIS was not reviewing or updating the computer facility access list. Therefore, employees that no longer required access or required restricted access (i.e., left the agency or changed job responsibilities) remained on the list as having access to the facility.

Noncompliance with Federal Information Security Requirements

Although FSIS had completed the required security plans in response to our prior recommendations, it had not ensured the plans were appropriately updated on an annual basis. We noted that the plans were dated August 2004, and had not been updated since that time. FSIS procedures incorrectly allowed the plan to be updated every 3 years instead of annually as required by OMB and Departmental guidance.

PBIS Application Controls

Our prior audit identified deficiencies in FSIS' controls over the input, processing, and output of PBIS data. During our current audit, we determined to what extent the agency had implemented the agreed to corrective actions, and if implemented, to assess the effectiveness of these actions. Overall, we concluded that corrective actions have yet to be initiated on all prior deficiencies identified. FSIS has not yet developed and effectively implemented policies and procedures to:

- Restrict access to only authorized users and ensure that legitimate users had access to only that information needed to perform their job functions.

- Provide reasonable assurance that only authorized and allowable data were entered into PBIS. FSIS relied on notices, directives, and user training instead of written policies and procedures. However, FSIS was not verifying that all users had completed training. As of June 2007, over 1,000 PBIS users had not completed IT training.

- Provide proper segregation of duties over the PBIS system development, testing, and production environments. In the agency response to our prior report, FSIS stated it would reorganize the IT structure to achieve separation of duties. The FSIS Plan of Action and Milestones, dated August 2005, states that FSIS would "establish a policy to ensure the proper segregation of duties over the PBIS system development, testing, and production environment." The status of this action was shown as

"completed" as of September 30, 2005. During this review we requested these policies and were informed by FSIS that they did not exist.

- Improve the timeliness and completeness of PBIS data to include appropriate synchronization[47] between headquarters and field operations. Incomplete, untimely data may impair analysis and impact timely identification of a problem establishment.

On August 23, 2007, we provided these concerns to FSIS. We did not make additional recommendations because FSIS had not effectively implemented our prior recommendations. On September 18, 2007, FSIS provided detailed responses on the agency's actions to address the weaknesses in IT security and access and application controls (see Exhibit E). FSIS provided an update of the actions they plan to take on IT security and access controls on October 19, 2007 (see Exhibit D).

In September 2007, FSIS awarded a contract to build the agency's new PHIS in order to better integrate and consolidate its numerous applications that collect information on activities to ensure the safety of meat, poultry, and egg products. FSIS plans to have a functional domestic inspection module ready for limited deployment in April 2008 with full production implementation scheduled for August 2008. The sub-modules currently identified for the domestic inspection module include: in-plant inspection activity, food safety assessments, laboratory sample scheduling, in-plant data and data from other sources, reporting, and predictive modeling and analysis (see Exhibit A). As FSIS moves forward with development of risk-based inspection, the agency should institute the appropriate oversight and control during the development of critical IT systems such as PHIS.

Recommendation 11

Institute the appropriate oversight and control during the development of critical IT systems needed to support risk-based inspection.

Agency Response.

In the response to the draft report, dated November 26, 2007, FSIS stated that the agency, with the contractor, is developing a project management plan. Certified agency project managers will assert appropriate project control using American National Standards Institute (ANSI) earned value management standards to measure and control costs and schedule. The PHIS will be developed using standard software development life cycle practices. The first version of the project management plan will be developed by December 31, 2007 (see Exhibit I).

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[47] Inspection data at an establishment should be uploaded to the main data warehouse on a daily, or at least weekly, basis.

OIG Position.

We accept FSIS' management decision.

Finding 4   **FSIS Needs to Further Enhance Controls Concerning Food Safety Assessments**

Since June 2000, we have recommended that FSIS implement a system of oversight for HACCP plans that establishments develop. In response, FSIS initiated the use of food safety assessments to evaluate these controls. In a concept paper for measuring establishment risk control for risk-based inspection, dated July 2006, FSIS recognized that food safety assessments are the agency's best evidence regarding the design of an establishment's food safety system. However, FSIS has not fully incorporated this fundamental building block for assessing establishment risk.

This audit confirmed that FSIS had not completed food safety assessments at all processing establishments, had not established a process for periodically reassessing establishments' food safety assessments, and does not have procedures in place to ensure timely followup in response to food safety assessment findings. We also question whether prior assessments fully analyzed food safety risks based on recent recalls of ground beef product potentially contaminated with *E. coli* O157:H7.

Food Safety Assessments Not Completed for All Establishments

FSIS developed a risk-based inspection program that estimated establishment risk; however, they had not performed food safety assessments of HACCP systems in all meat and poultry processing establishments. This occurred because the FSIS national office did not establish management controls to prioritize, schedule, and analyze food safety assessments, which prevented the agency from including all of the results in its estimate of establishment risk. As a result, FSIS has less assurance that consumers are protected from adulterated meat and poultry products.

As of June 2007, FSIS had not completed food safety assessments at 485 of the more than 5,000 meat and poultry processing establishments.[48] According to an FSIS official, all except one district office were instructed to complete food safety assessments for all establishments that have yet to have one completed by September 30, 2007.[49] In addition, FSIS had not established a process to periodically reassess establishments' food safety systems.

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[48] FSIS provided OIG with establishment listings that originated from each district office. Because each district office did not provide its listing using the same format, we were unable to confirm the completeness of the number provided as to the total number of meat and poultry processing establishments.

[49] The Alameda District Office, which inspects over 500 establishments, was given until December 31, 2007, to complete its food safety assessments due to the large amount of establishments within its district.

In June 2000,[50] OIG recommended that FSIS implement a system of oversight concerning the hazard analyses and HACCP plans that establishments developed. The food safety assessment process evolved in response to OIG's recommendation that FSIS assess the completeness of HACCP plans. In a 2003 audit,[51] OIG recommended that FSIS develop a time-phased plan for completing its reviews of HACCP plans, which numbered more than 5,000 at the time. In addition, OIG recommended that FSIS develop a periodic review program for reassessing HACCP plans every one to two years. FSIS responded that it could not conduct food safety assessments at all 7,500 establishments; however, it agreed to complete food safety assessments at the 2,500 establishments where they were most needed, by 2005.

FSIS has agreed to develop and implement criteria for prioritizing the scheduling of food safety assessments and to conduct periodic reevaluations of an establishment's food safety system. We discussed the concern that food safety assessments had not been completed for all establishments and our recommendations in an issue paper to FSIS on August 23, 2007. FSIS provided its response on September 18, 2007 (see Exhibit C).

Followup Needed on Food Safety Assessment Findings

As part of our fieldwork, we visited 15 establishments to help us assess FSIS' oversight of food safety systems. We obtained the food safety assessments for the 15 establishments and determined that each addressed the elements listed in FSIS directive;[52] however, we identified certain issues related to the control of *E. coli* O157:H7 in ground beef products that appeared to require followup action. However, the FSIS procedure did not provide guidance on actions to take to followup on food safety assessment findings.

A 2002 Federal Register Notice required all establishments to reassess their HACCP plans for the risk of *E. coli* O157:H7 contamination in their raw beef products.[53] FSIS Notice 44-02 instructed inspection personnel to perform verification procedures on *E. coli* O157:H7 reassessments. This FSIS Notice was the reason FSIS conducted the food safety assessments in 6 of the 15 establishments we visited. For these, we reviewed the food safety assessments to determine whether they were compliant with FSIS Notice 44-02. These six food safety assessments were performed from April 2003 to January 2007. In four of the food safety assessments, we noted six issues that appear to require followup action.

- Two found that establishments did not adequately reassess their HACCP plans based on requirements in the Federal Register Notice.

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[50] Implementation of the HACCP, Audit Report No. 24001-03-At, June 2000.

[51] Oversight of Production Process and Recall at ConAgra Plant, Audit Report No. 24601-02-KC, September 2003.

[52] FSIS Directive 5000.1, Verifying an Establishments Food Safety System, Revision 2, Amendment 1, July 18, 2006.

[53] Large establishments were to reassess their HACCP plans for *E. coli* O157:H7 by December 6, 2002; small establishments were required to perform this reassessment by February 4, 2003; and very small establishments were to accomplish this by April 7, 2003.

- Two identified that establishments did not verify that suppliers' *E. coli* O157:H7 specifications were being met. In December 2004, FSIS completed a food safety assessment at one of these establishments and identified that the establishment did not verify supplier specifications. Subsequently, FSIS conducted another food safety assessment in December 2005 because a product sample tested positive for *E. coli* O157:H7. This assessment again found that the establishment was not verifying supplier specifications, as identified in the first food safety assessment.

- Two of the food safety assessments noted inconsistencies in the establishments' HACCP plans. It was unclear whether *E. coli* O157:H7 was a hazard likely to occur based on information in the food safety assessments.

We requested additional information from FSIS officials to determine whether FSIS performed followup work for the issues we identified. During our audit fieldwork, FSIS only provided a response describing their followup actions for the establishment that did not verify supplier specifications. In response to this finding in December 2005, FSIS issued the establishment an NR. The establishment then provided FSIS with a verification plan that closed the NR. This same establishment was one of the establishments that did not clearly identify E. *coli* O157:H7 as a hazard likely to occur. FSIS needs to implement procedures to ensure that sufficient, timely followup work is performed on the remaining issues identified and for all other findings that FSIS documents in food safety assessments.

Recommendation 12

Develop and implement criteria for prioritizing the scheduling of food safety assessments.

Agency Response.

In the response dated September 18, 2007, FSIS agreed that public health would be better served by a transparent food safety assessment scheduling system that considers establishment food safety risk. FSIS determined it prudent to conduct recurring food safety assessments in all establishments on a pre-determined cycle, and its intention is to conduct a food safety assessment in every establishment at least once every 4 years. By January 1, 2008, FSIS will complete an analysis of past "for-cause" food safety assessments and project what to expect in 2008. This will be the basis for both allocating a "target" number of "not for cause" food safety assessments to be conducted in 2008, and for projecting the number of food safety assessments (two types) FSIS might conduct in 2009 and beyond.

The prioritization process for "not-for-cause" food safety assessments will take the form of a decision tree that each District Manager is expected to consult as he/she schedules food safety assessments in 2008 and beyond. This decision tree will consider the primary pathogens of public health concern (*E. coli* O157:H7, *Lm,* and *Salmonella*), establishment activities and production volumes, inspection findings, and other risk-management considerations. FSIS also expects to conduct some "not-for-cause" food safety assessments annually for processes of special concern (e.g., specified risk material control (SRM)). FSIS expects to post the "not-for-cause" food safety assessment prioritization plan to the FSIS web page by July 2008 (see Exhibit C).

In the response to the draft report, dated November 26, 2007, FSIS stated that the 4-year cycle used to schedule food safety assessments was based on resource availability and estimates regarding food safety assessments needed to be performed "for cause." FSIS is currently developing a risk-based approach to prioritize food safety assessments that will be outlined in the risk-based inspection technical paper. The risk-based inspection technical report will be made final and available to stakeholders, following review by NACMPI and by peer reviewers, by March 17, 2008 (see Exhibit I).

OIG Position.

We accept FSIS' management decision.

Recommendation 13

Develop and implement criteria for conducting periodic reevaluations of an establishment's food safety system to assess its progress after an initial food safety assessment.

Agency Response.

In the response dated September 18, 2007, FSIS stated that the current plans for the domestic inspection system address this recommendation with a procedure to be conducted annually by each inspector-in-charge to review each establishment's latest food safety assessment as part of the annual reassessment verification procedure. If the inspector-in-charge documents any changes, an alert will be sent to the frontline supervisor who then could decide to address the issue at his/her level or to elevate it to the district office which may decide to send out an EIAO for review. FSIS issued Notice 64-07, Scheduling Food Safety Assessments and Intensified Verification Testing, on October 12, 2007. This Notice requires that a food safety assessment be scheduled within 30 days of an *Lm* FSIS positive sample or an *E. coli* O157:H7 positive sample. These requirements will be built into the domestic inspection system.

Also, the new domestic inspection system will have the ability to use inspection verification data at all levels (field, team, district, headquarters) to establish trends and direct verification activities where needed (e.g., multiple sanitation performance standard noncompliance to generate a food safety assessment).

FSIS believes that risk-based daily inspection and verification activities, coupled with a risk-prioritized food safety assessment scheduling system (Recommendations 12 and 14), will ensure continuous feedback on establishment risk controls (see Exhibit C).

OIG Position.

We accept FSIS' management decision.

Recommendation 14

Develop and implement a system to track changes at an establishment over time and determine which changes would trigger FSIS to conduct a food safety assessment at an establishment prior to its periodic reevaluation.

Agency Response.

In the response dated September 18, 2007, FSIS agreed that a critical feature of the new food safety assessment system will be its ability to interact with the PBIS replacement system. Like the current PBIS system, the PBIS replacement system is the primary means by which FSIS tracks changes at establishments over time. A system will be developed by August 2008 that monitors the PBIS replacement system for significant changes in establishment characteristics, inspection findings, and other information. The system will also flag establishments for which food safety assessments might be in order using a set of criteria that will consider such things as changes in noncompliance rates, changes in the types or quantities of products produced, and establishment start-ups after a prolonged period of inactivity. This flag would alert the district office to the possible need for a food safety assessment, but it would be the prerogative of the district manager and staff about how this flagged establishment should fit into their prioritized food safety assessment schedule. FSIS will fully implement the system as part of the new public health system (see Exhibit C).

In the supplemental response to the draft report, dated November 30, 2007, FSIS stated that the agency fully intended to carefully track its execution on an ongoing basis. FSIS will conduct an assessment of the "flags" in PHIS to determine a process and a hierarchy for their use in scheduling food safety assessments. Prior to the implementation of PHIS, Office of Field Operations will communicate the process for following up on any PHIS flags to district managers and other field employees. FSIS also will establish management controls for the Executive Associate for Regulatory Operations (EARO) to

review the district manager's management of food safety assessment scheduling (see Exhibit J).

OIG Position.

We accept FSIS' management decision.

Recommendation 15

Develop and implement procedures to ensure sufficient, timely followup work is performed in response to findings in food safety assessments.

Agency Response.

In the supplemental response to the draft report, dated November 30, 2007, FSIS officials stated that FSIS directive 5100.1, EIAO Comprehensive Food Safety Assessment Methodology, will be updated to include a work method for verification plans. Currently, that information is only contained in the EIAO training material. The updated directive will also describe a work method to address other food safety assessment findings that do not become part of a formal enforcement action. FSIS intends to publish this revision to this directive by May 2008 (see Exhibit J).

OIG Position.

We accept FSIS' management decision.

Finding 5   **A Comprehensive Agency-wide Data Analysis and Distribution System is Needed**

FSIS does not currently have a comprehensive, agency-wide data analysis and distribution system in place to inform decision-makers of all the relevant food safety and food defense issues, which may be of importance to the agency, in the most timely and effective manner. Until last year, FSIS had not focused its resources on developing a public health data infrastructure with automated analytical tools for integrating agency data to rapidly identify events, trends, and anomalies. Only in the current year has FSIS begun initial steps to specifically define and implement data management controls to ensure: (1) necessary types of information are collected, (2) required standard reports are produced, (3) relevant analyses are performed and fully used by all program areas and district offices, and (4) corrective actions are taken when problems are identified. With strong data management controls in place and fully functioning, FSIS is much better positioned to provide all management levels the information needed to identify and correct food safety concerns and effectively implement a risk-based inspection program.

Prior Audit
Concerns
Prior audits have disclosed that FSIS does not always have data management control systems in place, which consistently ensure that the agency is able to detect trends in serious food safety issues and inspection activities. Our 2004 report[54] disclosed that FSIS had not developed an effective management control process for ensuring that it used its information systems and important data to the fullest extent possible through information sharing and trend analysis. A subsequent 2006 report[55] disclosed that FSIS management information systems were not designed to allow the agency to readily monitor and identify trends or weaknesses in establishments' compliance with specific regulatory requirements, such as controlling SRM. Our 2003 report[56] concerning the ConAgra recall pointed out that FSIS needed to be more proactive in its oversight by seeking access to available sources of data and analyzing, on an ongoing basis, the data's importance as indicators of problems that could impact food safety. FSIS has worked with OIG to reach agreement on the corrective actions that need to be taken on the data management control issues detailed in these reports. However, these reports, as well as other OIG reports, demonstrate the agency's continuous struggle to collect, review, and analyze available information necessary to rapidly identify events, trends, and anomalies that may indicate issues that could adversely affect food safety.

The agency has not completed a formal, comprehensive, agency-wide examination of its information needs or established a process to periodically reassess these needs. The agency also has not fully implemented management controls to identify the specific types of information to collect, the standard reports to produce, or the analyses to perform, on an ongoing basis, by all program areas and district offices. In about April 2007, the agency began a process to formally analyze some of its data information streams; however, the evaluations are not yet complete. The agency is also actively pursuing how to conduct sophisticated statistical analyses of FSIS data and data from other sources to provide indicators of potential food safety or food defense related concerns in the future. In the past, FSIS had not dedicated adequate resources toward building a consolidated, agency-wide, comprehensive, and top-down data analysis and distribution system.

During our fieldwork in August 2007, we determined what data analysis activities were currently in place at the agency-wide and local (district) levels. We found that FSIS prepared a limited number of standard analytical reports and those that were prepared were not fully used or shared with all appropriate program managers. In addition, the agency has not provided training or direction on specific analyses to be performed.

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[54] Use of Food Safety Information Systems, Audit Report No. 24601-03-Ch, September 2004.
[55] Animal and Plant Health Inspection Service (APHIS) Bovine Spongiform Encephalopathy (BSE) Surveillance Program – Phase II and FSIS Controls Over BSE Sampling, Specified Risk Materials, and Advance Meat Recovery Products – Phase III, Audit Report No. 50601-10-KC, January 2006.
[56] Oversight of Production Process and Recall at ConAgra Plant, Audit Report No. 24601-02-KC, September 2003.

Existing Management Reports Are Not Fully Used

From interviews with FSIS national and district office officials, we found that FSIS program offices do not fully use routine data extracted and analyzed by the Office of Policy, Program, and Employee Development (OPPED).[57] Also, FSIS has not thoroughly considered if modifications could be made to the data extracted to make them more useful to other program areas, including the Office of Field Operations (OFO).[58] This occurred because FSIS had not implemented management controls to ensure effective distribution and full use of the results of all data analyses. Strengthening management controls over data analysis and distribution would allow affected program areas to initiate actions to correct problems identified by analyses performed by other areas.

Beginning in mid-2005, OPPED began to focus on data analyses that enhance policy development. OPPED began assessing the ongoing effectiveness of the implementation of SRM regulations and related NRs. The identification of the need to assess these specific NRs led OPPED to consider other possible analyses for determining the need for new policy development. However, in our discussions, we determined that neither OPPED, nor other senior managers within the agency, have fully evaluated whether the information in these and other analyses routinely performed by OPPED could have broader applications. This is because these analyses were intended to serve OPPED primarily as an active means for enhancing policy issuances and training materials, and for more timely correcting misapplication of policy.

OFO officials at the national and district levels indicated that they would find reviewing some of the other OPPED analyses useful to help identify trends and issues in their districts and circuits. However, the reports would need modification to offer the same analysis on a specific district and circuit basis.

FSIS Had No Process for Sharing Results of Analyses

We reviewed a sample of other analyses prepared by OPPED. However, we found there were various types of information indicating concerns or problems that field management officials may have found useful. The following are examples of the types of issues that could be shared if FSIS had in place a routine systematic process for sharing results or conclusions presented in the current analyses[59] with interested users.

- Inspectors entered incorrect procedure codes in PBIS over 50 percent of the time, which hindered the data analysis that could be performed on establishment noncompliances with SRM requirements;

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[57] OPPED develops and makes recommendations concerning all domestic policy.

[58] OFO manages the national program of inspection and enforcement activities.

[59] The conditions shown in these reports may not have actually been problems or may not have been as serious as shown. The authors of these reports relied strictly on the data extracted from FSIS systems and their professional judgment as to their meaning and relevance. These OPPED staff did not validate their conclusions with other sources of data or discussions with appropriate FSIS personnel.

- Food safety assessments and intensive verification testing were not always being done promptly[60] when positive biological test results were found in a plant. One intensive verification testing was completed over 8 months after a positive biological test result;
- Inspection staff in some States were shown as having performed none of the required food defense procedures;
- Inspectors recorded performing a task over 7,000 times under a procedure code that was retired by FSIS;
- A high percentage of slaughter NRs were linked,[61] which may indicate that a number of HACCP plans appear to be inadequate;
- A large number of establishments' sanitation standard operating procedures (SSOP) may be inadequate due to plants not routinely evaluating the effectiveness of their SSOPs and revising their sanitation program as necessary; and
- A large number of establishments were not being operated and maintained in a manner sufficient to prevent the creation of unsanitary conditions.

Because FSIS lacked a routine systematic process to distribute these reports within FSIS, the validity of these issues was not substantiated or, ultimately, corrective actions may not have been implemented to enhance food safety. FSIS' data management controls should ensure effective distribution and full use of the results of all data analyses and reports to other affected program areas, including field operations. Specifically, FSIS should perform an analysis of all the reports currently available to determine if any would be beneficial to other management levels in improving compliance and operations, or if modifications would make them more useful at the district or circuit levels.

Factors Adversely Affecting District Analysts' Performance

From our work at district offices, we found that (1) district analysts had not been provided with adequate guidance on standard types of data management and analysis they were to perform, (2) at least 3 district analyst position vacancies had not been promptly filled, (3) district analysts spend a significant portion of their time performing tasks unrelated to their data management and analysis functions, (4) district analysts did not always review pathogen testing reports or receive the reports in a format that is useful, and (5) district analysts had not received ongoing technical training.

Below the headquarters level, FSIS maintains a field structure of 15 district offices that provide regulatory and inspection oversight in a State or several

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[60] Until recently, specific requirements were not established for performing food safety assessments and intensive verification testing followup on positive biological test results. On October 12, 2007, FSIS issued Notice 64-07, Scheduling Food Safety Assessments and Intensive Verification Testing. This Notice requires the district office to schedule a food safety assessment within 30 days of being notified of a positive *Lm*, *E. coli* O157:H7, or *Salmonella* test result. The Notice also requires the district office to schedule intensive verification testing only with positive *Lm* test results.

[61] Linking NRs refers to documenting in an NR that similar deficiencies were noted in a previous NR or NRs.

States. Within the district office are employees who are responsible for analyzing various agency data and ensuring that districts are tracking and following up on establishments with food safety issues. One such employee is the district analyst, who aids district managers in analyzing data and reports generated from the agency's information systems and noting trends, problem establishments, or emerging issues involving food safety. The district analyst, in particular, monitors information systems with vast amounts of food safety and inspection data like PBIS and the pathogen reduction enforcement program.

FSIS Did Not Provide Standardized Guidance or Training

There is no ongoing standardized national training provided to district analysts on manipulating, analyzing, correlating, or interpreting data available from each of the agency's information systems. As a result, FSIS management and supervisory personnel may lack some of the analytical tools necessary to recognize problems at meat and poultry establishments and take appropriate action that may prevent serious food safety problems.

While we recognize that field managers may need the latitude to perform their own type of data analysis, some basic system of standard reports and analysis is needed to assist district managers, as well as headquarters officials, in performing critical reviews of operational activities and assure that oversight at the district office level is sufficient and effective across the nation.

Currently, the OFO has plans to provide the district offices with a new predictive model, being developed in conjunction with the Office of Public Health and Science by the end of calendar year 2007. OFO intends to mandate that district analysts collect the required data, analyze the results, and act upon any adverse trends that are identified. Further, FSIS plans to provide training to district analysts on the proper use of the new model and software.

DA Vacancies Have Created Problems for District Offices

Three of the districts reviewed experienced significant delays in filling district analyst positions. The Albany and Des Moines districts had vacancies that lasted over 6 months and the vacancy in Madison lasted over 1 year. As a consequence of having these extended vacancies, district office personnel informed us that they had difficulties accomplishing needed work. As an example, the Albany district analyst did not follow up on management reports that indicated that numerous scheduled samples were not submitted to FSIS laboratories for testing.

Critical Reports Were Not In Searchable Formats

District analysts could not readily perform historical analysis of pathogen testing results within their districts because recorded information was presented in text or other non-searchable formats. Five district analysts stated that they would like to either receive sampling results in a spreadsheet format or have read only access to the sampling databases in order to be able to look at data on a long term basis. One deputy district manager noted that when she wanted more than one month of testing data on a particular

establishment she had to go into monthly or quarterly reports individually and see if the establishment in question was listed. The deputy district manager stated that she could go back several years but she could not readily search the text documents for the information she needed. In another case, the district analyst manually converted the information from monthly and quarterly reports into a spreadsheet, which could be analyzed in various ways. Another district analyst stated that if information is in a sortable format he could do analysis by circuit, by inspector, or by the class of facility (e.g., red meat slaughter verses poultry processing).

The DAIG Has Been Formed To Monitor FSIS' Data

Within the last year, agency managers have taken action to improve their data collection and analyses processes. On an agency-wide basis FSIS intends to improve overall situational awareness and better inform decision-makers about food safety and defense issues through the newly formed DAIG, whose mission is to characterize, coordinate, analyze, and integrate data within and across program areas.

The DAIG is responsible for ensuring the agency uses a transparent process, based on sound science and inclusive of all stakeholders' perspectives, to improve the agency's ability to effectively protect the food supply and public health. The DAIG has developed standard procedures to be followed when a data analysis project is initiated. The procedures consist of standard steps, including problem definition, development of a technical plan (e.g., identifies, reviews, and discusses limitations of available data; discusses the data collection and analysis strategy; and includes an evaluation plan), and development of a technical paper that summarizes the results of the analyses. The procedures included places for stakeholder input and peer review, which would allow the technical paper to be used in agency decision-making.

FSIS Is Now Considering Using Advanced Analyses Techniques

Along with the agency's recent efforts on risk-based inspection, the DAIG has been tasked with focusing its activities on how the agency can conduct sophisticated statistical analyses of FSIS data. FSIS plans to develop a set of predictive tools capable of identifying patterns and trends within FSIS data and using data from other sources to provide indicators of potential food safety or food defense related concerns. According to FSIS, the new predictive analysis may include:

- Using existing FSIS and USDA systems that support public health, such as the FSIS data warehouse and AssuranceNet;
- Incorporating self-learning algorithms into the system to allow FSIS data analysis to evolve as more information is gathered;
- Providing a mechanism that could subsequently integrate FSIS data with Animal and Plant Health Inspection Service (APHIS) data for rapid recognition and containment of animal disease; and
- Developing a mechanism to link FSIS data with the Department of Homeland Security's National Biosurveillance Integration System once developed.

It is important that a predictive model use information and data generated by FSIS, as well as other agencies (such as APHIS) and departments. The model should be capable of combining internal and external data from inspection, pathogen sampling, surveillance, imports, exports, health, disease, consumer complaints, and other food safety and food defense sectors to perform automated predictive analysis to efficiently and effectively eliminate or reduce food safety issues. The contract for developing the predictive analysis tool was awarded September 26, 2007, and is scheduled for deployment into nationwide production by June 2008.

Data Information Sheets Are Incomplete

In conjunction with the DAIG, the Data Coordinating Committee (DCC) working group was established in April 2007. The DCC acts as a liaison between the various FSIS program offices and DAIG and provides the DAIG with information and feedback on data analysis issues in FSIS. As their first initiative, the DCC began a process of identifying key systems that will be needed to compile information for risk-based inspection. These systems include the administrative enforcement reporting system, various subparts of the microbiology and residue computer information system, consumer complaints monitoring system, and pathogen reduction enforcement program.

The DAIG team has started a process of preparing information data sheets on all of the key systems identified, about 15 systems. We recognize this as a significant move in the right direction; however, considerable work remains.

We found the data sheets were incomplete. Most of the data sheets do not include critical information such as key functions and data elements, user requirements, or reports to generate routinely or ad hoc. The DAIG has not completed most of the information data sheets. As of September 2007, the DAIG had focused only on those systems critical to risk-based inspection, which is only a first step. The group will still have considerable work to perform in analyzing all of the agency's information systems and data needs, how data from these systems can be linked to identify problems, and how the agency can develop predictive models and apply these analyses across the entire agency. Already, the DAIG's limited analysis of the data systems critical to risk-based inspection has identified a number of potential data limitations (see Finding 2).

FSIS has not yet fully defined or implemented data management controls to ensure, that specific types of information are collected, necessary analyses are performed on an ongoing basis, standard reports are produced, and that needed followup actions are taken to correct problems identified. Establishing effective data management controls is a continuous, dynamic process of assessing and reassessing the data needs of the agency at all levels to keep abreast of changes in the industry and revisions to laws and regulations related to food safety. Effective data management controls places FSIS in a better position for effective implementation for a risk-based inspection program.

FSIS is Developing New Inspection System

FSIS is developing PHIS to replace existing domestic, export, and import inspection systems, which will include new modeling and analysis modules. The new system is intended to allow FSIS personnel to know and report what requirements were verified and that the appropriate requirements were verified and recorded for each establishment. Further, FSIS plans for the new system to guide inspectors on the frequency of performing critical verification procedures based on the establishment's level of inspection for risk-based inspection. FSIS is currently in the developmental phase of this major infrastructure change and we believe the agency must closely monitor the development, testing, and implementation of this new system to attain satisfactory assurance that it can support the operations necessary to carry out a complex scientifically-based, risk-based inspection system. It is critical that risk-based inspection data requirements are established and incorporated into the developmental phase of this PHIS endeavor.

To assure that national and district managers have all the tools they need to properly manage program operations, controls need to be strengthened to provide district analysts with (1) specific guidance on the types of data to collect and analyses to perform, as well as data pathogen testing systems that are searchable and are adaptable to various types of analysis, and (2) ongoing training on new or modified software and specific analytical techniques. In addition, focusing the activities of district analysts primarily on data management, analysis, followup, and filling vacant district analyst positions as soon as possible should increase the expediency with which food safety issues will be identified and brought to the attention of management for action.

We discussed our concerns and recommendations in an issue paper to FSIS on September 20, 2007. FSIS provided its response on October 18, 2007 (see Exhibit F). In developing our findings from our visits to the district offices, we found that providing pathogen test result data in a searchable format would assist analyses performed by district office personnel.

Recommendation 16

Closely monitor the administration of the PHIS contract and the development, testing, and implementation of the new system to ensure it is progressing as intended and to attain satisfactory assurance that it can support the operations necessary to carry out a complex, scientifically-based risk-based inspection program.

Agency Response.

In the response dated October 18, 2007, FSIS agreed to appoint a Contracting Officer's Technical Representative (COTR) to play a critical role during all phases of the acquisition process: pre-solicitation, solicitation and award, and post-award. The COTR, with assistance from program staff, writes the

statement of work, establishes tasks, deliverables and timelines for the project, monitors technical performance, compares progress with delivery schedules and cost objectives, reviews and critiques contractor's deliverables, and obtains Agency review from subject matter experts. In the case of the PHIS contract, the COTR specifically will ensure the timely delivery of a system that meets the goals outlined in the PHIS business requirements (see Exhibit F).

In the response to the draft report, dated November 26, 2007, FSIS stated that the agency, in conjunction with the contractor, is also developing a project management plan. Certified agency project managers will assert appropriate project control using ANSI earned value management standards to measure and control costs and schedule. PHIS will be developed using standard software development life cycle practices. The first version of the project management plan will be developed by December 31, 2007 (see Exhibit I).

OIG Position.

We accept FSIS' management decision.

Recommendation 17

Complete a comprehensive, agency-wide examination of national, divisional, and district level analytical and informational needs and establish a process to periodically reassess needs. This should include implementing management controls to specifically define what analysis and information is needed, who should perform the analysis and collect the information, who needs to be provided the analysis or information (customers), how often the information needs to be collected and analyzed, what is the most useful format to present the information or analysis to the final users, and, finally, who is responsible to ensure followup actions are taken to correct problems identified. The study should also include an action plan for making the necessary changes to the agency's operating procedures and the estimated timeframes for implementing these changes.

Agency Response.

In the response dated October 18, 2007, FSIS agreed that a comprehensive examination of analytical and informational needs and a process for periodic reassessment of those needs is essential. The DAIG, within the FSIS Office of Food Defense and Emergency Response, was formed to lead a range of activities, including those recommended by OIG. Specifically, the DAIG is evaluating individual data streams and integrating data analyses across FSIS program offices; ensuring that data analyses are relevant to program offices' business processes and the agency mission; and ensuring that data analyses are consistent and of high quality. The DAIG has a number of projects either underway or soon to be initiated to identify and reassess analytical and informational needs within the agency.

The DAIG will be developing a data analysis plan for identifying systemic problems and positive outcomes in food safety or inspection associated with identifiable trends in noncompliance or other data collected in OPPED reports. A thorough review of all OPPED-generated reports will be completed by December 30, 2007. Until then, OPPED will continue to create the current reports and share each with all the senior managers in each program area, and document the process for sending the reports to them and capturing any comments received from them.

Also, during the initial phase of development for all modules of the PHIS (i.e., predictive analytics, domestic inspection, import, and export) the contractor and the agency will be refining the system's business requirements. That will involve meeting with all program areas to determine and prioritize their analytical needs, including report generation. The information will be used to determine and prioritize program office analysis and report needs, and will be summarized in a report for future reference.

As for an action plan for changing the agency's operating procedures, the development of the PHIS already set the action plan in motion. Through the incorporation of analytical needs into the IT system, the agency's operating procedures will be changed. The DAIG, as part of coordinating data analysis for the agency, will meet monthly with the DCC, comprised of senior representatives from each program area. One purpose of these meetings will be to review and update analytical needs (see Exhibit F).

In the response to the draft report, dated November 26, 2007, FSIS provided estimated timeframes for when DAIG will complete the various types of analysis and projects noted in the response to our issue paper. The requirements gathering phase of PHIS, during which the DAIG and the contractors developing the system will meet with all program areas to identify and prioritize analytical and reporting needs will be completed January 31, 2008. The DAIG's report on its survey of district analysts and their roles, including recommendations on reports that they should be generating, will be completed by February 28, 2008.

The DAIG has been working with DCC members from FSIS programs to complete an FSIS data analysis project matrix. That matrix, in combination with the data stream and data sub-stream information sheets being prepared by DAIG in conjunction with the DCC, will summarize what data analysis projects are being conducted by each program office, what reports are being generated, who the audience is for the reports, the distribution method used for the reports, and followup tracking methods (e.g., emailed to relevant individuals, posted on the FSIS website, etc.). The DAIG and DCC meet monthly, at which time the DCC members will be asked to provide any updates to the matrix and data stream/sub-stream information sheets. The initial matrix will be completed by December 31, 2007 (it will be continually

updated based on projects being initiated and completed), and initial information sheets will be completed by April 15, 2008 (see Exhibit I).

OIG Position.

We accept FSIS' management decision.

Recommendation 18

Complete the in-depth analysis of all the data information streams within FSIS. Also, establish a mechanism to assure that once the analysis is performed for a system it is updated on a regular basis and that new systems are fully analyzed before they come on line.

Agency Response.

In the response dated October 18, 2007, FSIS stated that the DAIG is completing data information sheets to catalogue and characterize data within the agency. A subset of the data sheets, which includes those streams of potential use in a risk-based algorithm, will be completed by mid-October 2007. Completion of the remaining information sheets has been incorporated into the DAIG's project schedule for completion by April 15, 2008. As part of the process, the information sheets will be reviewed by the DCC before being finalized so that the DCC is responsible for reporting to the DAIG on any updated or new datasets, analysis projects, or reports. In addition, the DCC will conduct an annual review of all data sheets beginning April 15, 2009 (see Exhibit F).

OIG Position.

We accept FSIS' management decision.

Recommendation 19

Implement management controls to ensure effective distribution and full use of the results of all data analyses and reports to other affected program areas, including field operations, in order to allow for followup actions to correct problems identified and to establish performance goals for inspectors.

Agency Response.

In the response dated October 18, 2007, FSIS agreed to implement effective distribution and full use of the results of all data analyses and reports to document attainment of department and agency strategic plan goals. Agency management controls that define control activities, information dissemination and reporting, and monitoring functions will be used to document data analysis and reports as part of the program assessment rating tool (see Exhibit F).

In the response to the draft report, dated November 26, 2007, FSIS stated that the DAIG has undertaken a number of activities to identify, characterize, coordinate, analyze, and integrate data collection and analysis needs within the agency. Specific projects conducted in anticipation of the implementation of risk-based inspection and PHIS will be completed in the Spring of 2008. Upon reviewing the results of these DAIG projects, FSIS programs will determine what management controls are necessary for the distribution and review of data analyses.

The requirements gathering phase of PHIS, during which the DAIG and the contractors developing the system will meet with all program areas to identify and prioritize analytical and reporting needs, will be completed January 31, 2008. The DAIG's report on its survey of district analysts and their roles, including recommendations on reports that they should be generating, will be completed by February 28, 2008.

The DAIG has been working with DCC members from FSIS programs to complete an FSIS data analysis project matrix. That matrix, in combination with the data stream and data sub-stream information sheets being prepared by DAIG in conjunction with the DCC, will summarize what data analysis projects are being conducted by each program office, what reports are being generated, who the audience is for the reports, the distribution method used for the reports, and followup tracking methods (e.g., emailed to relevant individuals, posted on the FSIS website, etc.). The DAIG and DCC meet monthly, at which time the DCC members will be asked to provide any updates to the matrix and data stream/sub-stream information sheets. The initial matrix will be completed by December 31, 2007 (it will be continually updated based on projects being initiated and completed), and initial information sheets will be completed by April 15, 2008 (see Exhibit I).

OIG Position.

We accept FSIS' management decision.

Recommendation 20

Perform an analysis of all reports currently generated (including those generated by the OPPED) and determine if any would be beneficial to other divisions/levels in improving compliance and operations. Further, determine if modifications could be made to the reports to make them more beneficial to other program areas, including field operations.

Agency Response.

In the response dated October 18, 2007, FSIS stated that as discussed in response to Recommendation 17, FSIS is initiating a number of major projects that include current reports and reporting needs. Through these

efforts, modifications of reports will be made to make them more beneficial to all relevant program areas, and ensure dissemination to all offices (see Exhibit F).

In the response to the draft report, dated November 26, 2007, FSIS provided estimated timeframes for when DAIG will complete the various types of analysis and projects noted in the response to our issue paper. The requirements gathering phase of PHIS, during which the DAIG and the contractors developing the system will meet with all program areas to identify and prioritize analytical and reporting needs will be completed January 31, 2008. The DAIG's report on its survey of district analysts and their roles, including recommendations on reports that they should be generating, will be completed by February 28, 2008.

The DAIG has been working with DCC members from FSIS programs to complete an FSIS data analysis project matrix. That matrix, in combination with the data stream and data sub-stream information sheets being prepared by DAIG in conjunction with the DCC, will summarize what data analysis projects are being conducted by each program office, what reports are being generated, who the audience is for the reports, the distribution method used for the reports, and followup tracking methods (e.g., emailed to relevant individuals, posted on the FSIS website, etc.). The DAIG and DCC meet monthly, at which time the DCC members will be asked to provide any updates to the matrix and data stream/sub-stream information sheets. The initial matrix will be completed by December 31, 2007 (it will be continually updated based on projects being initiated and completed), and initial information sheets will be completed by April 15, 2008 (see Exhibit I).

OIG Position.

We accept FSIS' management decision.

Recommendation 21

Provide ongoing training to district analysts on new or modified software and specific analytical techniques, including the type of data to collect, standard types of analysis to perform, format to present data, frequency of reporting the results, and followup actions the analysts are expected to take on any adverse issues noted. Also, establish a system to track when training is taken, the type of training taken, and a system to alert the appropriate managers if the minimal levels of training are not being achieved.

Agency Response.

In the response dated October 18, 2007, FSIS stated that as part of its efforts to identify the analyses currently being conducted by the district offices and to help determine what analyses should be conducted at the district offices or at headquarters, the DAIG and the Center for Learning in OPPED will

develop a component to train district analysts. The training will include the use of new or modified software and specific analytical techniques, how to generate standard reports, the frequency of generating reports, and followup actions that appropriate program officials are expected to take on any potential adverse issues identified by the tools. The Center for Learning currently tracks when training is taken thru AgLearn, where the learning history of all courses for each employee is stored. The type of training also is recorded in AgLearn. By the end of 2008, FSIS will be fully implementing the feature in AgLearn that allows managers to detect if minimal levels of training are not completed (see Exhibit F).

In the response to the draft report, dated November 26, 2007, FSIS agreed to complete the training of district analysts by June 30, 2008 (see Exhibit I).

OIG Position.

We accept FSIS' management decision.

Recommendation 22

To the extent feasible, focus the activities of district analysts primarily on their data management and analysis responsibilities and promptly fill vacant district analyst positions.

Agency Response.

In the response dated October 18, 2007, FSIS stated that the key grade-determining duty of the district analyst involves their support for the technical and scientific basis of district-wide enforcement actions. Other key duties include serving as a subject matter expert and coordinator concerning a variety of food safety regulatory and inspection matters. FSIS agrees that to the extent feasible, the district analysts should focus their activities on data analysis and management. We believe that the DAIG activities described in response to Recommendation 20 will assist them in accomplishing this goal. In addition, FSIS will revise the district analyst position description by January 2008 to better clarify their primary data analysis role, especially as that relates to enforcement activity.

As a result of non-frontline hiring restrictions during 2006, several district analyst positions were, by necessity, left vacant. Currently there is one vacant district analyst position in the Atlanta District. The announcement to fill this position closed on October 19, 2007 (see Exhibit F).

OIG Position.

We accept FSIS' management decision.

Recommendation 23

Provide pathogen test results data in a searchable format to the appropriate district office personnel.

Agency Response.

In the response to the official draft report, dated November 26, 2007, FSIS stated that the PHIS will provide lab data in a more user-friendly format, allowing inspection program personnel to run reports providing the details of samples collected during a user-specified timeframe. A prototype for domestic inspection within the PHIS will run in a test environment during the third quarter of calendar year 2008 to selected users. The nationwide production readiness for PHIS with the domestic module is currently scheduled for the second quarter of calendar year 2009 (see Exhibit I).

OIG Position.

We accept FSIS' management decision.

Finding 6	**Progress Made on Management Control Structure, But Improvements are Still Needed**

Prior OIG audit reports[62] recommended, and FSIS officials agreed, to establish a management control process for accumulating and analyzing food safety data and to strengthen monitoring of inspection activities. FSIS responded to our recommendations by implementing the In-Plant Performance (IPPS) and AssuranceNet systems as a means of providing management oversight of public health activities carried out by OFO. These systems are important components in the implementation of a management control structure, in that they provide valuable performance data both to supervisors and to higher-level managers. However, FSIS is still in the process of getting them fully and effectively implemented. A fully functioning management control structure should provide the means to accumulate, review, and analyze all data available to the agency, and to assign responsibilities and provide guidance for performing these functions. FSIS' management control structure directly affects the accuracy of recorded risk factors such as microbiological test results and food safety-related NRs, and is thus integral to FSIS' risk-based inspection program.

FSIS implemented the IPPS system in October 2002 as its first step in creating a management control structure. IPPS is a tool used by supervisors to assess the work of non-supervisory in-plant inspection program personnel. The IPPS review process provides a framework and guidelines for

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[62] Oversight of Production Process and Recall at ConAgra Plant, Audit Report No. 24601-02-KC, September 2003, and Use of Food Safety Information Systems, Audit Report No. 24601-03-Ch, September 2004.

supervisors to use in evaluating employee performance. It also allows higher-level officials such as district managers and EAROs[63] to review and evaluate the adequacy of the performance assessments. IPPS is a critical building block in any management control structure because it provides assurances to management that FSIS' in-plant inspection personnel are performing their inspection duties in accordance with agency policies and instructions. However, a 2006 OIG audit of the IPPS process[64] revealed that better guidance was needed for the supervisors, as well as stronger controls to ensure that IPPS reviews were being performed in a complete and consistent manner. This was provided in the form of a new FSIS directive while the audit work was still ongoing.[65]

In July 2006, FSIS implemented the second and broader component of its management control process, AssuranceNet.[66] This system tracks and monitors the performance of FSIS personnel in eight key functional areas[67] related to food safety and security. Each functional area contains one or more monitored performance measures in which current performance is measured against predetermined thresholds, some of which are based on average performance measures from prior years. For example, some performance measures assess whether a sufficient percentage of scheduled tasks is being performed by FSIS inspectors.

AssuranceNet draws information from various sources and databases, including PBIS, laboratory data systems, animal disposition systems, IPPS assessment reports, and entries made to AssuranceNet directly, to determine the current level of performance. This information can be displayed at various organizational levels. In all, AssuranceNet monitors 61 performance measures in the 8 functional areas related to food safety and provides this to FSIS managers in the form of standard reports for each performance measure. It also allows Headquarters and district-level managers to view a special

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[63] EAROs report to the Assistant Administrator for Field Operations. Each of the four EAROs, working through their assigned district offices, is responsible for assuring that regulated meat, poultry, and egg establishments meet regulatory requirements for food safety, food security, and other consumer protection activities. In AssuranceNet, the EARO has view access to data from every functional area, and also has the ability to enter comments to the IPPS record in AssuranceNet, following his/her review of an IPPS assessment. EAROs are responsible for reviewing at least 2 percent of the IPPS forms reviewed by their subordinate District Manager teams.

[64] In-Plant Performance System, Audit Report No. 24601-06-Ch, March 2006.

[65] FSIS Directive 4430.3, In-Plant Performance System, Rev. 1, issued November 18, 2005.

[66] Although implemented in July 2006, FSIS officials stated that the system did not become fully functional until approximately February 2007.

[67] These are: (1) Ante Mortem/Post Mortem Inspection; (2) HACCP Pathogen Reduction Execution; (3) HACCP Pathogen Reduction Design; (4) Recall System Management; (5) Enforcement; (6) Food Security/Reporting of Non-Routine Events; (7) IPPS; and (8) Exports. In early 2007, AssuranceNet was expanded to include monitoring in an additional 8 areas involving such areas as financial management and employee relations.

Dashboard Manager screen that provides a broad "snapshot" of current performance.[68]

AssuranceNet Does Not Fully Address Prior Audit Recommendations

Prior OIG audits have identified several functions which FSIS' management control structure would need to perform in order to address conditions that were noted during our audit work. As presently designed, AssuranceNet addresses only some of these areas, as described below.

1. FSIS agreed to define the responsibilities of each management and operating level associated with meat and poultry establishment inspection.[69] Except for specific requirements for reviewing IPPS, food safety assessment review forms, and administrative enforcement reports, however, AssuranceNet does not define the responsibilities of officials at various organizational levels and functional areas for using the system or following up on the performance information it provides.

2. FSIS agreed to implement procedures for regular communication and coordination between units.[70] AssuranceNet, while providing important information to its users, does not ensure that various levels and units are adequately communicating with one another except in specific areas.[71]

3. Finally, FSIS agreed to provide a process for the Technical Service Center (TSC) to perform independent analyses of inspection and establishment data collected through the agency's IT systems, and to provide the results of such analyses to appropriate users both at headquarters and in the field.[72] Although AssuranceNet's own generated reports are accessible to all designated officials from the frontline supervisor level to upper management, it does not address the need for sharing of other information (e.g., the OPPED Reports) to all identified users. (FSIS officials are also addressing this issue in their response to Recommendation 17, where they agreed to implement effective distribution and full use of the results of all data analyses and reports).

Specific issues we noted with the AssuranceNet application, as well as with IPPS, are noted in the upcoming paragraphs.

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[68] Along with Headquarters users, the District Manager, Deputy District Manager, and District Analyst in each district have access to the Dashboard Manager screen. This tool is intended to allow managers to see if there are any performance measures within their area of responsibility that are currently not meeting the target expectations. On this screen, the performance measures are depicted in the form of color-coded speedometer gauges, with red indicating the performance measures that are not meeting the assigned targets.

[69] Use of Food Safety Information Systems, Audit Report No. 24601-03-Ch, Recommendation 1; and Oversight of Production Process and Recall at ConAgra Plant, Audit Report No. 24601-2-KC, Recommendation 5.

[70] Use of Food Safety Information Systems, Audit Report No. 24601-03-Ch, Recommendation 1.

[71] Performance measures under two of the eight functional areas, food safety assessments and IPPS, monitor the number of reviews by EAROs, district managers, deputy district managers, and district case specialists, as applicable.

[72] Use of Food Safety Information Systems, Audit Report No. 24601-03-Ch, Recommendation 2.

FSIS Needs to Strengthen Its Written Procedures to Supplement AssuranceNet

In 2004, we reported[73] that the agency had not developed a set of written procedures to specify the responsibilities of each organizational level – including headquarters, the district offices, Office of Program Evaluation, Enforcement and Review (OPEER), and the TSC – for data collection, analysis, and monitoring. In addition, we noted that the agency needed to develop procedures to ensure regular communication and coordination between these various groups to ensure the most effective use of the agency's inspection and managerial resources. Agency officials agreed with the need to implement a management control system that incorporated these features, and AssuranceNet is a significant step in that direction. However, by itself AssuranceNet does not constitute a management control structure which would ensure that data – such as food safety NRs and microbial test results – are completely and accurately recorded for use in the risk-based inspection process. Rather, AssuranceNet is a tool for FSIS managers to use in implementing a management control structure. The agency still needs to issue written policies and procedures to ensure that AssuranceNet is used in a consistent and comprehensive manner at all organizational levels.

Clear Written Instructions Needed

When the system was implemented, FSIS issued the AssuranceNet Users Guide to describe how the system operated from a functional perspective. The guide instructed users in technical matters such as site navigation and the permission levels of various users to input, review, and update data. Also, certain performance measures specifically required designated officials to perform specific actions – such as the requirement that district management teams, district case specialists, and EAROs review set percentages of completed IPPS forms and food safety assessments. However, the guide did not outline policies and procedures to specify the responsibilities of agency officials for collecting, monitoring, and analyzing the data which the system produces.

Managers Not Consistently Using AssuranceNet

OFO officials stated that it was their expectation that officials at all levels would access and review key system data pertinent to their areas of responsibility (e.g., the dashboard screens) on at least a monthly basis. However, we found that there was little uniformity in how district managers and their deputies used the system at the five district offices we visited. One district had independently issued written instructions to the district staff, specifying responsibilities of deputy district managers, frontline supervisors, and the district analyst for following up on identified problems and reporting these to the appropriate management level; these instructions were amended to incorporate AssuranceNet as a management tool. Officials from another district, by contrast, stated that they made little use of AssuranceNet beyond normal data entry and the required management reviews of IPPS forms and food safety assessments. Other districts we visited used the system to varying degrees, alongside other monitoring practices employing both manual reviews and other IT systems such as PBIS.

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[73] Use of Information Technology Systems, Audit Report No. 24601-03-Ch, September 2004.

AssuranceNet Reviews Not Performed Below Circuit Level

FSIS has not defined how the AssuranceNet performance measures are applied to each organizational level. We generally found that the district offices and frontline supervisors viewed the system's performance measures only at the circuit level and higher. They did not use AssuranceNet to review the performance of individual establishments unless the entire circuit failed to meet a particular performance measure. However, we found instances in which a circuit's overall performance could conceal poor performance at individual establishments in key areas such as the completion of PBIS-assigned inspection tasks or the submission of microbial samples. This could also potentially impact the performance measure that monitors the submission of product samples for microbial testing by FSIS laboratories.

Followup Action Not Consistently Taken

FSIS had not issued guidance as to when followup action should be initiated once a performance measure in AssuranceNet drops below the target thresholds. In addition, guidance had not been issued on how to document the actions taken. We found that the EAROs, who monitor the performance of the districts, did not follow a specified process in determining at what point a particular AssuranceNet measure indicated the need for supervisory intervention. Contacts with district offices to followup on supervisory contacts initiated due to AssuranceNet were not consistently documented, a condition we had found in our previous audit before the system was implemented. There was considerable variation at the district offices as well; while some districts stated that they followed up promptly when the performance targets were not met, officials at one district stated that the timing of their followup was largely dictated by their overall workload at the time the AssuranceNet reports were reviewed. Without clear written procedures to guide FSIS officials in the use of the AssuranceNet system, previously reported issues related to the management control structure may continue to exist. In their response to an issue paper on this subject, issued in August 2007, FSIS officials agreed and stated that more comprehensive procedures would be issued (see Exhibit G).

To be successful, a risk-based inspection program depends upon the work of FSIS inspectors in identifying and documenting health and safety issues at inspected establishments; it also depends on this data being properly recorded and used in the risk calculations for each inspected establishment. A management control structure based on AssuranceNet could provide reasonable assurance this is done, but only when the necessary policies, procedures, and controls have been put into place to ensure that the system is being used in a prescribed and consistent manner by users at all organizational levels.

Lack of Controls to Ensure that IPPS Reviews Cover All Required Elements

Our prior audit found that supervisors were not consistently assessing inspectors on their proficiency in all performance elements critical to food safety oversight during each annual rating period. Although FSIS improved its guidance to supervisory personnel in performing IPPS reviews, we found that employees are still not being consistently assessed on all performance elements. The IPPS reviews we analyzed for 24 of 46 (52 percent) non-supervisory employees did not document that all required performance elements were assessed. The agency's response to our prior audit stated that the AssuranceNet system would monitor performance on an ongoing basis.

As presently designed, the system captures the necessary data from the IPPS review forms to monitor whether employees are being rated on all elements and sub-elements applicable to their positions during each 1-year rating period. However, AssuranceNet is not currently used to perform this function.

Unless FSIS inspectors are consistently evaluated on all of their applicable performance elements as part of the IPPS process, FSIS has reduced assurance that inspection tasks at the establishment level are being performed in such a way as to provide complete and accurate information for its risk based inspections.

Lack of Controls to Ensure that IPPS Reviews Are Performed as Required

In our prior audit on the IPPS process, we reported that for a significant number of the inspectors reviewed – 13 percent – supervisors did not perform the required minimum of two IPPS reviews per year. Since implementation of AssuranceNet, we found that improvements have been made. However, for the 2006-2007 rating year, for the 46 employees we reviewed, 4 (9 percent) received only one documented IPPS review. Although FSIS' primary emphasis is to ensure that employees are rated on each performance element and sub-element at least once a year, the agency also requires that at least two reviews be done – one in each 6-month period – as a means of ensuring that employees are receiving supervision throughout the year and are adequately performing their duties on an ongoing basis. AssuranceNet's performance measure 8.1.1 (IPPS) analyzes whether the number of IPPS reviews performed in a given year is equal to or greater than the number of reviews needed to provide two to each employee the system is monitoring. However, it does not monitor whether individual employees are receiving the required number of IPPS reviews because the system was not initially designed as a tracking mechanism for the IPPS reviews. FSIS has since concluded that it should design a component of the system that could be used for this purpose, and should adjust the calculations for the measure 8.1.1 to more truly reflect the percentage of employees who have (or have not) received the required two IPPS assessments per year. Currently, the system only counts employees who have had at least one IPPS review in the current rating year. An employee who had not received even a single IPPS review, or for whom no reviews had been entered in the system, would not be factored into the AssuranceNet analysis.

At present, the only other IPPS-related controls built into AssuranceNet are the five performance measures that monitor reviews of completed IPPS forms by district management and the EAROs. These reviews are not necessarily effective, however, in assuring that the required numbers of IPPS reviews are performed for each employee, or that all performance elements have been addressed.[74]

IPPS Reviews Do Not Support AssuranceNet Performance Elements

AssuranceNet monitors 24 performance measures that are based entirely on data from the IPPS review forms that are entered into the system. These include all of the measures for two of AssuranceNet's functional areas (Food Security/Reporting of Non-Routine Incidents, and Exports) and approximately half of the performance measures for two other functional areas (Ante Mortem/Post Mortem Inspection and HACCP Pathogen Reduction Execution).

For instance, one performance measure[75] uses data from IPPS forms to assess whether all noncompliances at inspected establishments are documented using NRs. AssuranceNet performs this analysis by scanning the IPPS forms for instances in which a "followup" block has been checked, indicating a performance deficiency on the part of the employee being assessed.[76]

The FSIS Directive[77] on IPPS instructs the supervisor to check the followup block when deficiencies are noted and provide comments and feedback. Comments must clearly describe what was reviewed or observed.

We found that supervisors were not consistently following this guidance. Of the 98 IPPS forms we reviewed, 13 contained "followup" blocks that were either checked when there was no supporting documentation to describe the deficiency the supervisor was reporting, or else where the blocks were not checked when the narrative clearly described a performance deficiency.[78] If the information being input to AssuranceNet from the IPPS review forms cannot be relied on, then AssuranceNet's analyses based on this data will be of limited value.

We believe FSIS officials need to review on an agency-wide basis the overall design of the existing management control structure and determine whether

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[74] This is because EAROs and District Manager teams generally review only a single IPPS form as part of their review for any given employee. To verify either the number of reviews performed, or that all of the required measures were addressed, it would be necessary for them to review all of the IPPS reviews performed on a particular employee during a given rating year. There is no requirement that this level of review be performed.

[75] Performance measure 2.1.2, under HACCP/Pathogen Reduction Execution

[76] For instance, sub-element 5a of the consumer safety inspector IPPS form asks whether the inspector "Describes each noncompliance in clear, concise terms," while sub-element 5b asks whether the inspector "Cites specific regulatory requirements that were not met."

[77] Directive 4430.3 In-Plant Performance System, Revision 1, section X.C.3, dated November 18, 2005.

[78] Note that we would not have been able to identify any instances where a deficiency was not reflected either by checking the "followup" box or through narrative on the IPPS form.

the supplemental controls we are recommending as part of this report are sufficient to address these needs.

Recommendation 24

Provide officials at each level with written guidance on the use of the AssuranceNet system, particularly with regard to followup actions and adherence to the established system thresholds.

Agency Response.

In the response dated September 18, 2007, FSIS agreed to provide additional, comprehensive written guidance for managers at all levels on reviewing, analyzing, and responding to AssuranceNet results. This guidance will be published as an FSIS directive or notice by December 2007 (see Exhibit G).

OIG Position.

We accept FSIS' management decision.

Recommendation 25

Establish procedures to ensure that warning "flags" provided by AssuranceNet are timely and effectively followed up on, particularly in cases in which deficiencies are repeatedly noted at the same establishment, circuit, or district.

Agency Response.

In the response to the draft report, dated November 26, 2007, FSIS agreed with the need for timely and effective followup on "flags." They agreed to provide additional, comprehensive written guidance for managers at all levels on reviewing, analyzing, and responding to AssuranceNet results. FSIS anticipated issuing this guidance in January 2008 (see Exhibit I).

OIG Position.

We accept FSIS' management decision.

Recommendation 26

Provide guidance to officials, particularly at the district level, to use AssuranceNet to view performance data down to the establishment level, as well as the circuits and districts.

Agency Response.

In the response to the draft report, dated November 26, 2007, FSIS stated that they would issue instructions by January 2008 for "drilling down" into data below the circuit level in AssuranceNet. They noted that while this was normally done in cases where an entire circuit failed to meet a target, drilling down to the establishment level in circuits that did meet their targets would identify any outliers that might require further investigation (see Exhibit I).

OIG Position.

We accept FSIS' management decision.

Recommendation 27

Modify AssuranceNet to monitor the completion and results of all required elements and sub-elements assessed during IPPS reviews.

Agency Response.

In the response to the draft report, dated November 26, 2007, FSIS stated that it would be impossible to program AssuranceNet to make the determination that all applicable elements were covered for each of the 6,000 employees to which IPPS applies. However, FSIS agreed that they needed to better monitor the completion of all applicable elements and sub-elements, and proposed instead to develop additional guidance to supervisors reviewing IPPS assessments, instructing them to specifically focus on the extent to which these are being covered over the course of the year. This guidance will be contained in an updated version of the AssuranceNet User's Guide in January 2008 (see Exhibit I).

OIG Position.

We accept FSIS' management decision.

Recommendation 28

Implement features within AssuranceNet that will allow the system to (1) identify employees who have not worked in an IPPS-rated position for an entire rating period (e.g., retired or new employees), and (2) identify, for corrective action, instances in which employees have not received the required IPPS reviews.

Agency Response.

In the response to the draft report, dated November 26, 2007, FSIS expressed agreement with the recommendation and noted that this had also been identified as a concern by FSIS district management teams. They stated that

design and implementation of an AssuranceNet feature for tracking completion of IPPS assessments has been incorporated into a contract the agency currently has in place to build onto AssuranceNet, and they are working with the contractor to finalize the requirements. The tracking feature, planned for implementation in May 2008, will allow users to generate reports displaying lists of individuals who have outstanding IPPS reviews, including individuals who have not yet received an IPPS assessment in the current rating period (see Exhibit I).

OIG Position.

We accept FSIS' management decision.

Recommendation 29

Implement procedures and controls as needed to ensure that supervisors limit their use of the "followup" box on the IPPS review forms to instances involving documented performance deficiencies.

Agency Response.

In the response to the draft report, dated November 26, 2007, FSIS agreed that the importance of accurately using the followup box needs to be re-emphasized. As a result, FSIS Directive 4430.3 will be updated by February 2008 to make more explicit the instructions on using the followup box. In addition, FSIS will develop guidance for use by reviewers of IPPS assessments to ensure that their oversight reviews include a determination of whether there is a match between the narrative comments and what is in the followup boxes, whether checked or un-checked. This will either be included in the guidance to be issued to managers at all levels, or will be reflected in the updated version of the AssuranceNet User's Guide, both of which will be issued in January 2008 (see Exhibit I).

OIG Position.

We accept FSIS' management decision.

Finding 7   FSIS Did Not Timely Address Prior Audit Recommendations

Although recent improvements have been made, we found FSIS did not timely address deficiencies noted in prior OIG audit reports. According to FSIS officials, the amount of time it takes to close a recommendation varies and is due to the (1) difficulty and complexity of the corrective action, (2) emerging public health problems that compete for agency resources, and (3) the continuous evolution of agency programs and industry practices.

OMB Circular A-50 requires agreement to be reached between the agency and OIG (i.e., management decision) on the corrective actions to address recommendations within 6 months of report issuance. In addition, Departmental Regulation 1720-01 states agencies will implement agreed-upon corrective actions that are associated with audit recommendations in a timely manner. The regulation further instructs agency liaison officials to ensure that (1) corrective actions on audits without final action 1 year after the management decision date are proceeding as intended and (2) the corrective action associated with each management decision is completed as scheduled.

We reviewed 278 prior recommendations OIG made since 2000. Including the 6 recommendations still without management decision, there are 66 prior OIG audit recommendations where the corrective actions (i.e., final action) have not yet been implemented. FSIS has made recent progress in achieving management decision and final action on prior OIG audit recommendations. Over the last 2 years, FSIS has worked closely with OIG to reduce the number of unresolved audit recommendations. In 2005, there were 36 recommendations without management decision; FSIS has reduced that number to 6. During the same time period, the percentage of recommendations where final action was achieved increased from 54 to 76 percent.

As part of this audit, we selected 94 prior audit recommendations that OIG considered to be the most critical to the development and implementation of risk-based inspection. Of these 94 recommendations, 3 were without management decision and an additional 40 were without final action. One of the recommendations without management decision was made in our June 2000 report.[79] We recommended that FSIS establish timeframe requirements for responding to NRs and initiating planned corrective actions. FSIS does not agree with establishing specific timeframes but has not proposed an alternative approach to address this recommendation. NRs are critical to FSIS' risk-based inspection model.

We found 34 out of 40 recommendations without final action have been without final action for more than 1 year since the management decision date. During our fieldwork, we also found that FSIS did not adequately implement the actions they proposed in response to the recommendations made. We have incorporated the status of FSIS' actions to implement prior audit recommendations, where appropriate, throughout this report.

Recommendation 30

Continue the increased diligence for achieving management decision and final action on the remaining prior recommendations. In addition, apply this increased diligence to future recommendations to ensure timeframes are met.

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[79] Implementation of HACCP, Audit Report No. 24001-03-At, June 2000.

Agency Response.

In the response to the draft report, dated November 26, 2007, FSIS agreed to continue its expedited efforts to resolve and achieve final action (close) on OIG recommendations. FSIS notes that since September 2007, it has closed an additional 20 recommendations and requested closure for 2 more. Additionally, the Program Evaluation and Improvement Staff (PEIS) in FSIS-OPEER, which serves as the agency's liaison to OIG and the Government Accountability Office, is implementing a new system to notify FSIS programs monthly about their obligations to respond to and take final action on OIG recommendations, to track the results, and to produce a variety of reports for FSIS management and USDA's Office of the Chief Financial Officer. PEIS will add the maintenance of this system to its own management controls. PEIS will have the new system in place and will have amended its management controls by February 1, 2008 (see Exhibit I).

OIG Position.

We accept FSIS' management decision.

Finding 8	**Inspection Personnel Did Not Document Their Review of Establishment Test Results**

At the 15 establishments visited, FSIS inspection personnel did not document that they were reviewing the results of establishment pathogen testing on at least a weekly basis. IPPS reviews of inspectors conducted prior to our site visits did not specifically identify this because FSIS personnel were not required to document their reviews of establishment testing. Documenting that inspection personnel review establishment testing on at least a weekly basis assists in validating that food safety concerns that require additional followup are recognized in a timely manner.

In a prior audit,[80] we concluded that if FSIS personnel had reviewed and analyzed all test results at the establishment, the progressive increase in positive *E. coli* O157:H7 results could have been noted and acted upon by FSIS. In response, FSIS instructed[81] inspection personnel to review the results of any testing that may have an impact on the establishment's hazard analysis on at least a weekly basis.

Recommendation 31

Develop and implement requirements for inspection personnel to document their reviews of establishment testing results. At a minimum, the inspection

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[80] Oversight of Production Process and Recall at ConAgra Plant, Audit Report No. 24601-02-KC, September 2003.
[81] FSIS Directive 5000.2, Review of Establishment Data by Inspection Program Personnel, dated March 31, 2004.

personnel should document when they reviewed the test results, the type(s) of results they looked at (*E. coli* O157:H7, *Salmonella*, etc.) and the time period reviewed.

Agency Response.

In the response to the draft report, dated November 26, 2007, FSIS agreed to provide instructions to inspection program personnel concerning which types of industry data they should review for which types of products. They will also provide a work method for reviewing the data, for example trends over time, and also describe documentation procedures to track the specific data, and time window, in which it was reviewed (see Exhibit I).

In the supplemental response to the draft report, dated November 30, 2007, FSIS agreed, before the high prevalence season for *E. coli* O157:H7 (i.e., prior to April 2008), to either issue a new FSIS Directive or a new FSIS Notice specific to *E. coli* O157:H7; and by July 2008, for *Lm* in product subject to testing under 9 Code of Federal Regulations (C.F.R.) 430, to either issue a new FSIS Directive or a new FSIS Notice. FSIS will also address other test results (e.g., zero tolerance, generic *E. coli*, *Salmonella*) by September 30, 2008 (see Exhibit J).

OIG Position.

We accept FSIS' management decision.

Recommendation 32

Ensure that the inspection personnel's reviews of establishment testing are periodically verified by responsible supervisory officials and noncompliance is specifically identified in IPPS.

Agency Response.

In the response to the draft report, dated November 26, 2007, FSIS agreed to add a sub-element to the IPPS form to capture this responsibility. This new sub-element will be available for use in May 2008. FSIS also will revise instructions to inspection program personnel concerning when they should alert their supervisor that trends indicate that the establishment may not be responding appropriately to a trend of increasing positive pathogen test results. In addition, FSIS will include instructions for how supervisors, including district office personnel, should respond to such information from inspection program personnel. Scheduling of food safety assessments may be part of the district office response (see Exhibit I).

In the supplemental response to the draft report, dated November 30, 2007, FSIS agreed, before the high prevalence season for *E. coli* O157:H7 (i.e., prior to April 2008), to either issue a new FSIS Directive or a new FSIS

Notice specific to *E. coli* O157:H7; and by July 2008, for *Lm* in product subject to testing under 9 C.F.R. 430, to either issue a new FSIS Directive or a new FSIS Notice. FSIS will also address other test results (e.g., zero tolerance, generic *E. coli*, *Salmonella*) by September 30, 2008 (see Exhibit J).

OIG Position.

We accept FSIS' management decision.

Finding 9   **FSIS Needs to Provide Guidance on Progressive Enforcement Actions**

FSIS inspection personnel did not always follow instructions[82] and link NRs identifying recurring sanitary deficiencies. However, even when NRs were linked, FSIS inspection personnel did not have guidance on when to take further enforcement actions when addressing repetitive noncompliance violations. This occurred because FSIS had not issued the necessary criteria for evaluating repetitive noncompliance violations to establish when further enforcement action must be taken as recommended and agreed to in prior OIG audit reports.[83] FSIS personnel also cited the staffs' lack of sufficient expertise or supervision to determine when to link NRs indicating that a trend is developing. As a result, there is reduced assurance of FSIS personnel effectively identifying food hazards caused by unsanitary practices. Linkage of related NRs and associated evaluation criteria would provide a basis for determining when an establishment's corrective actions were inadequate and when additional enforcement actions should be initiated.

In the months preceding large recalls by two establishments that produced ground beef products potentially contaminated with *E. coli* O157:H7, FSIS inspection personnel issued multiple NRs for sanitary deficiencies.[84] At United Food Group LLC (Establishment No. 1241), inspection personnel did not follow instructions to link the deficiencies noted on five separate NRs. At Topps Meat Company LLC (Establishment No. 9748), inspection personnel linked the recurring deficiencies in eight NRs, and on six occasions rejected the non-compliant equipment (i.e., FSIS action that prevents the establishment from using equipment in production). Stronger enforcement actions were not taken due to the lack of guidance. As a result of these recalls, FSIS should reassess the effectiveness of training programs for inspection personnel and frontline supervisors and revise these programs, as appropriate. At a minimum, refresher training should be provided to

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[82] FSIS Directive 5000.1, Verifying an Establishment's Food Safety System, dated July 18, 2006.

[83] Implementation of HACCP, Audit Report No. 24001-03-At, June 2000 and Oversight of Production Process and Recall at ConAgra Plant, Audit Report No. 24601-02-KC, September 2003.

[84] We did not evaluate what FSIS processes may have broken down for these recalls because FSIS' internal investigations were still in process at the end of our fieldwork.

inspection personnel and frontline supervisors assigned to United Food Group LLC and Topps Meat Company LLC.

United Food Group, LLC Establishment No. 1241

In the three months prior to the recall of approximately 5.7 million pounds of fresh and frozen ground beef products by United Food Group LLC, FSIS personnel issued 5 separate NRs with the same cause. However, none of the five were linked with a previous NR. For example, on March 27, 2007, when performing a review of the plant's pre-operational sanitary procedures, the FSIS inspector noticed a piece of meat/fat in a blender. The plant cleaned the blender and stated that an official training session was planned for March 30, 2007. On April 19, 2007, a similar situation was reported with several small pieces of fat particle beneath a stacker. Again, on April 27, May 3, and May 29, FSIS inspectors generated NRs for observation of meat or fat particles on product contact surfaces during pre-operational sanitation reviews.

Using these repetitive violations as an example, we asked FSIS officials what threshold of noncompliance needed to be reached before an inspector would be required to write an NR questioning the establishment's SSOPs' ability to provide sanitary food contact surfaces. The official stated that, in his view, the average inspector did not have the technical expertise to develop that type of NR because he/she lacked sufficient training and expertise. Additionally, he was not sure that frontline supervisors had sufficient expertise either. Rather, he thought it would require the technical expertise of an EIAO to develop the type of NR that would support an enforcement action.

Topps Meat Company LLC Establishment No. 9748

In the 10 months prior to the recall of approximately 21.7 million pounds of frozen ground beef products by Topps Meat Company LLC, FSIS inspection personnel issued 8 separate NRs with the same violations. The NRs described equipment with meat/fat particles/residue from the prior shift or prior day's production that were noted during FSIS' pre-operational sanitation review. FSIS inspection personnel linked six of the NRs citing previous NRs with similar violations. In all six instances, FSIS initiated the required regulatory control action to reject the non-compliant equipment but did not initiate stronger enforcement actions. We determined that FSIS directives were not clear on when inspection personnel should initiate progressive enforcement actions beyond retention of product (e.g., withholding marks of inspection or suspension).

OIG recommended additional guidance in separate reports issued in 2000 and 2003.[85] In September 2005, FSIS responded that they were revising FSIS Directive 5000.1 to contain additional criteria to specifically use in making decisions on repetitive noncompliance violations. To date, FSIS has not issued these additional criteria.

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[85] Implementation of HACCP, Audit Report No. 24001-03-At, June 2000 and Oversight of Production Process and Recall at ConAgra Plant, Audit Report No. 24601-02-KC, September 2003.

Recommendation 33

Expedite the development of the specific criteria to inspection personnel that provide a basis for establishing when corrective actions are inadequate and appropriate enforcement actions should be initiated for repetitive deficiencies. The criteria should also define when progressive enforcement actions should be taken.

Agency Response.

In the response to the draft report, dated November 26, 2007, FSIS agreed to revise Directive 5000.1 to include additional instructions concerning linking NRs and initiating enforcement actions. The revised directive will provide for more consistent and coordinated action if noncompliance is not corrected, persists, or recurs. FSIS intends to issue the revised directive in May 2008. In addition to a revision of Directive 5000.1, more focus will be given to the section in the food safety regulatory essentials training for linking of NRs and evaluating corrective actions (see Exhibit I).

OIG Position.

We accept FSIS' management decision.

Recommendation 34

Reassess the effectiveness of training programs for inspection personnel and frontline supervisors and revise the programs, as appropriate.

Agency Response.

In the response to the draft report, dated November 26, 2007, FSIS agreed to conduct a comprehensive review of the effectiveness of its training programs for inspection personnel and frontline supervisors and revise the programs as appropriate. FSIS will be conducting IPPS related activities or surveys of inspection program personnel and their supervisors following training to verify that inspectors are performing key job duties as instructed in FSIS policies and training. FSIS also anticipates developing further refresher training to reinforce inspection duties. FSIS expects to complete the comprehensive review and to initiate the revision of its training programs by September 2008 (see Exhibit I).

OIG Position.

We accept FSIS' management decision.

Recommendation 35

Provide refresher training, at a minimum, to the inspection personnel and frontline supervisors assigned to the establishments with the recalls (i.e., United Food Group LLC and Topps Meat Company LLC).

Agency Response.

In the response to the draft report, dated November 26, 2007, FSIS detailed the retraining of personnel at Topps and United Food Group completed from October to December 2007 (see Exhibit I).

OIG Position.

We accept FSIS' management decision.

Scope and Methodology

We performed our audit at FSIS Headquarters in Washington, D.C. and at selected FSIS district offices and meat and poultry processing establishments between June and October 2007. To accomplish our objectives, we interviewed appropriate FSIS officials, examined pertinent documentation, and reviewed applicable policies and procedures for the agency's plan for implementing risk-based inspection at meat and poultry processing establishments.

FSIS Headquarters and District Offices

At FSIS Headquarters, we reviewed the responsibilities of the following offices as they related to risk-based inspection.

- Program Evaluation, Enforcement and Review—assesses FSIS program functions and operations
- Field Operations—manages the national program of inspection and enforcement activities
- Policy, Program, and Employee Development—develops and makes recommendations concerning all domestic policy
- Food Defense and Emergency Response—prepares, prevents, and coordinates a response to intentional or suspected deliberate acts and major events threatening the U.S. food supply
- Public Health and Science—provides scientific analysis, advice, data, and recommendations regarding matters involving public health and science that are of concern to FSIS

Our reviews included an analysis of FSIS' data to support the development and design of risk-based inspection, food safety assessments, FSIS' data management, and AssuranceNet. We also assessed FSIS' implementation of prior OIG audit recommendations related to the scope of this audit.

Our analysis of FSIS' data to support the development of risk-based inspection and establishments' risk rankings was limited to data covering plant operations from October 1, 2005 through September 30, 2006. According to FSIS officials, the agency calculated risk rankings only once and did not update its assessments since the risk-based inspection program was deferred due to Public law 110-028. Therefore, OIG was unable to determine the reasonableness and relevance of FSIS data to support the design of risk-based inspection, as requested by Congress.

At the district offices, we further evaluated the data supporting the risk-based inspection formula and FSIS' procedures for conducting food safety assessments. In addition, we reviewed the responsibilities of the district

managers, deputy district mangers, district analysts, and other district personnel for using management reports and AssuranceNet.

We performed audit work at the following five FSIS district offices. They were selected because they oversee almost 50 percent of the Federally inspected meat and poultry processing establishments in the United States.

- Alameda, California
- Albany, New York
- Chicago, Illinois
- Philadelphia, Pennsylvania
- Dallas, Texas

During our initial audit fieldwork, we also visited the FSIS district offices in Beltsville, Maryland; Lawrence, Kansas; and Madison, Wisconsin to familiarize ourselves with district office procedures.

Selected Processing Establishments

To further assess the development of risk-based inspection, we conducted site visits at 15 of the approximately 2,700 processing establishments that are inspected by personnel from the 5 district offices selected for analysis.[86] The 15 establishments are listed in Exhibit H. We selected these establishments using data FSIS compiled for the pilot program for risk-based inspection. While visiting these establishments, we conducted a tour of the operations and held discussions with plant officials, FSIS front-line supervisors, and FSIS inspectors to obtain an understanding of their responsibilities and to become familiar with the scope of the establishments' operations. We also reviewed the establishments' volume data, NRs, and food safety assessments completed by FSIS EIAOs.

Establishments with Food Safety Recalls

We also reviewed certain data and information for two establishments with large recalls of ground beef product potentially contaminated with *E. coli* O157:H7: (1) United Food Group, LLC (Establishment No. 1241) and (2) Topps Meat Company, LLC (Establishment No. 9748). However, we did not evaluate what FSIS processes may have broken down for these recalls because FSIS' internal investigations were still in process at the end of our fieldwork.

United Food Group, LLC recalled approximately 5.7 million pounds of fresh and frozen ground beef products in June 2007. Based on the timing of this recall, this establishment was included in our sample of 15 establishments to visit. Accordingly, while visiting this establishment, we conducted a tour of

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[86] As of June 2007, FSIS provided inspection services to approximately 5,400 meat and poultry processing establishments nationwide.

the operations and held discussions with plant officials, FSIS front-line supervisors, and FSIS inspectors to obtain an understanding of their responsibilities and to become familiar with the scope of the establishment's operations. We also reviewed the establishment's volume data, NRs, and food safety assessments completed by FSIS' EIAOs before and after the recall.

We added Topps Meat Company LLC to our review subsequent to its recall of approximately 21.7 million pounds of frozen ground beef products in October 2007. We did not visit this establishment due to FSIS' ongoing investigation. We reviewed information on NRs issued to the establishment as well as the food safety assessments completed by FSIS EIAOs before and after the recall.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Exhibit A *–Public Health Information System*

FSIS is re-aligning its systems into the Public Health Information Consolidation Project (PHICP) to better integrate and consolidate its numerous applications that collect information regarding its primary activities of ensuring the safety of meat, poultry, and egg products. The FSIS PHICP will use a web-based system design to augment and replace current IT systems used to support mission critical FSIS business functions such as inspection, surveillance, auditing, enforcement, scheduling, modeling and analysis. Some of the FSIS mission critical applications contained in PHICP include the Public Health Information System (PHIS), AssuranceNet, and laboratory systems. The major business functions\modules of PHIS include Domestic Products, Imported Products, Exported Products, and Modeling and Analysis.

PHIS is being developed, in part, to predict hazards and vulnerabilities, communicate or report analysis results, and target resources to prevent or mitigate the risk of food-borne illness and threats to the food supply. Another planned key benefit of PHIS is the ability to exchange data with key external stakeholders – organizations that FSIS has no current electronic connection with, but with which future interfaces are essential in order for the agency to satisfactorily perform its mission and to operate within the law. Such organizations would include the Department of Homeland Security, Customs and Border Protection.

Other key goals of PHIS are to build a Domestic Inspection Module for use by field inspectors and headquarters staff and predictive models to analyze real time data. The domestic inspection module is targeted for implementation in June 2008; a predictive analytics and modeling component will be deployed around the same time.

Inspection Functions for the Domestic Inspection Module

The functions identified for the domestic inspection module include:

- In-plant Inspection Activity;

- Food safety assessments;

- Laboratory Sample Scheduling;

- In-Plant data and data from other public health systems and external information sources;

- Reporting - including the ability to feed data from the Domestic Inspection Module transaction system to the Corporate Data Warehouse; and

- Integration with Predictive Analytics and Modeling and other FSIS transaction database systems (including those needed to conduct domestic inspection).

Primary goals for the system are to:

- Improve timeliness of data collection and analysis by providing an easy to use application and accessible tools;

- Continually improve the capacity of FSIS to respond to and implement policy changes;

- Incorporate risk based procedures, including predictive modeling, into the business processes for inspection operations;

- Enhance the capability of FSIS to anticipate hazards by thoroughly analyzing data obtained from FSIS' regulatory sampling and other data sources; and

- Enhance the capability of FSIS to respond in a timely manner to emerging or existing threats to public health.

Predictive Modeling and Analysis

PHIS is being developed to use predictive models to analyze near real time data from FSIS and other Federal, State, and local agencies and deliver critical reports to Agency program personnel and managers. The Predictive Analytics and Modeling module is intended to help FSIS analyze relevant public health and other data to achieve its mission. The module will encompass information/data generated by FSIS, as well as other agencies (such as USDA's APHIS) and departments. Specifically, it will combine data from inspection, pathogen sampling, surveillance, meat and poultry product importing and exporting, disease, consumer complaints, and other food safety and food defense sectors to perform automated predictive analysis to more efficiently and effectively eliminate or reduce intentional and unintentional food-borne illness.

The module will use existing FSIS and USDA systems that support its public health infrastructure, such as the FSIS data warehouse (the repository that stores FSIS data in a single accessible location) and AssuranceNet (the tool FSIS uses to enter and retrieve data, and create standard and custom reports, and report management control performance data). It will also incorporate self-learning algorithms into the system to allow FSIS data analysis to evolve as more information is gathered; provide a mechanism that could subsequently integrate FSIS data with APHIS data for rapid recognition and containment of animal diseases that could impact public health (e.g., Bovine Spongiform Encephalopathy, Avian Influenza); and develop a mechanism to link FSIS data with the Department of Homeland Security's National Biosurveillance Integration System once developed.

Exhibit B *–Prior OIG Audit Reports with Recommendations that Impact the Development of Risk-Based Inspection at Processing Establishments*

Exhibit B – Page 1 of 1

Audit Report Number	*Title*	*Date Issued*
24001-03-At	Implementation of the Hazard Analysis and Critical Control Point System	June 2000
24601-01-Ch	Laboratory Testing of Meat and Poultry Products	June 2000
24601-01-FM	Review of FSIS Inspector Staffing Shortages and Anti-Deficiency Act Violations	April 2001
24601-02-KC	Food Safety and Inspection Service Oversight of Production Process and Recall at ConAgra Plant	September 2003
24601-02-Hy	Food Safety and Inspection Service Oversight of the Listeria Outbreak in the Northeastern United States	June 2004
24001-04-At	Food Safety and Inspection Service Followup Audit on the Inspector General's Food Safety Initiative of Fiscal Year 2000	September 2004
24601-03-Ch	Food Safety and Inspection Service Use of Food Safety Information Systems	September 2004
24501-01-FM	Food Safety and Inspection Service Application Controls – Performance Based Inspection System	November 2004
24601-05-At	Hazard Analysis and Critical Control Point Implementation at Very Small Plants	June 2005
24601-06-Ch	Food Safety and Inspection Service's In-Plant Performance System	March 2006
24601-07-Ch	Review of Pathogen Reduction Enforcement Program Sampling Procedures	September 2006

Exhibit C *–FSIS Response to Issues Regarding Food Safety Assessments*

Exhibit C – Page 1 of 4

United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

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

SEP 1 8 200/

FROM: Alfred V. Almanza
Administrator

SUBJECT: Office of Inspector General (OIG) Issue Paper – Food Safety and
Inspection Service Application Controls – Food Safety Assessments (Audit No. 24601-
07-HY, Issue No. 07-01)

The Food Safety and Inspection Service appreciates the opportunity to review and
comment on this issue paper. In this document we respond to the OIG recommendations
and provide clarification on several points in your "Description" Section.

Responses to Recommendations

Recommendation No. 1
"Implement an action plan with specific milestone dates for capturing the results of FSAs
in an appropriate configuration that allows for effective analysis."

Agency Response
The Agency is currently in negotiations with a contractor under an IRS TIPSS-3
competitive procurement to build the Agency's new Public Health Information System
(PHIS). It is planned to have a functional Domestic Inspection System, including the
new electronic FSA system, ready for limited deployment in April 2008. Full production
implementation should be in August 2008, based on a 10 month period of performance
and an anticipated contract start date o/a October 1, 2007.

The design features and capabilities of the new Food Safety Assessment Reporting
System are described in detail on pages 93-200 of the *Public Health Information System
Business Requirements* (PHIS-BR) document that FSIS has already transmitted to OIG.
The new FSA Reporting System, for which funds are available and obligated in the first
phase of the contract, will replace the existing paper-based FSA system with a web-based
FSA application that:

- captures FSA information electronically (p. 93 PHIS-BR)
- interacts with the PBIS replacement system (which is also part of the Domestic
  Inspection System module in the new contract) (p. 93 PHIS-BR)
- Guides EIAO FSA activities with structured questions to be answered in all FSAs
  about Sanitation Performance Standards and Sanitation Standard Operating
  Procedures (pp. 100-101 PHIS-BR)

- Contains structured questions tailored to specific products (e.g. beef, pork, poultry) for each HACCP 03 category that collect pertinent data for each type of process in an establishment provides (pp. 102-162)
- Contains structured food safety system questions for establishments that produce pasteurized egg products or dual jurisdiction (FSIS/FDA products) (pp. 185-192)
- Contains structured questions to be answered in all FSAs about Food Defense (pp. 193-200 PHIS-BR)
- develops a quantification aspect using questions pertaining to an establishment's controls and validation for incorporation into the risk control portion of the RBI algorithm (p. 94 PHIS-BR)
- allows ample free text areas associated with questions for an EIAO to explain their findings and reference establishment documents as support for those findings (p. 93 PHIS-BR)
- incorporates an annual inspection procedure so that an FSA report can be periodically reevaluated for accuracy every year by the IIC (p. 94 PHIS-BR)
- establishes clear criteria for prioritizing FSA scheduling (p. 94 PHIS-BR)
- includes an automated FSA tracking system (p. 94 PHIS-BR) so that the Agency will be able to instantaneously determine the date and findings of the most recent FSA conducted in any establishment.

FSIS believes the design, features, and capabilities of the new system *directly* addresses OIG recommendations 1, 4, 5, and 6, and *indirectly* supports other Agency activities that address recommendations 2 and 3. **Specifically related to Recommendation 1**, the new system will facilitate effective analyses by capturing similar types of information for all establishments, capturing those findings in quantifiable terms, storing detailed FSA findings in an electronic format, and interacting with the PBIS replacement system.

Recommendation No. 2
"Perform FSAs, using the new configuration, in all establishments that will be in the universe of establishments where risk-based inspection may be tested. The FSAs should be comprehensive assessments of the establishment's current operations."

Agency Response
FSIS agrees. FSIS will have the new electronic FSA system ready for limited deployment in April 2008. At this time, we can begin using the new system in establishments that comprise the RBI establishment universe.

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Recommendation No. 3

"Determine how the results of FSAs will be used by FSIS in estimating establishment risk."

Agency Response

FSIS agrees with this recommendation and will determine how we use the results of FSAs in estimating establishment risk by January 1, 2008. The Agency's Data Analysis and Integration Group (DAIG) and OPPED's FSA workgroup are currently considering the types of findings from FSAs that should factor in the measure of establishment risk, which findings should be factored into "inherent risk" vs. "risk control," how much "weight" should be given to each individual finding and to FSA findings in total, and how "recent" FSAs need to be to validly factor into the establishment risk measure(s).

Recommendation No. 4

"Develop and implement criteria for prioritizing the scheduling of FSAs."

Agency Response

The Agency agrees with OIG that public health would be better served by a transparent FSA scheduling system that considers establishment food safety risk. We have already determined that it is prudent to conduct recurring FSAs in all establishments on a pre-determined cycle, and our intention is to conduct an FSA in every establishment at least once every four years. By January 1, 2008, FSIS will complete an analysis of past "for cause" FSAs and project what to expect in 2008. This will be the basis of allocating a "target" number of FSAs conducted "not for cause" in 2008, and for projecting how many of the two types of FSAs we might conduct in 2009 and beyond.

The prioritization process for "not for cause" FSAs will take the form of a decision tree that each District Manager is expected to consult as they schedule FSAs in 2008 and beyond. This decision tree will consider the primary pathogens of public health concern (*E. coli* O157:H7, *Listeria monocytogenes*, and *Salmonella*), establishment activities and production volumes, inspection findings, and other risk-management considerations. FSIS also expects to appropriate some "not-for-cause" FSAs annually to processes of special concern (e.g., SRM control). FSIS expects to post the "Not-For-Cause" FSA prioritization plan to the FSIS web page by July, 2008.

Recommendation No. 5

"Develop and implement criteria for conducting periodic reevaluations of an establishment's food safety system to assess its progress after an initial FSA."

Agency Response

The current plans for the Domestic Inspection System address this recommendation with a procedure to be conducted annually by each IIC to review each establishment's latest FSA as part of the annual reassessment verification procedure (p. 94). If the IIC documents any changes, an alert will be sent to the FLS which then could decide to address the issue at their level or to elevate it to the District Office which may decide to send out an EIAO for review. A draft Notice is in clearance now that says an FSA must

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be scheduled within 30 days of an LM FSIS positive sample or an E. coli O157:H7 positive sample. These requirements will of course be built-into the Domestic Inspection System.

Also, the new Domestic Inspection System will have the ability to utilize inspection verification data at all levels (field, team, District, HQ) to establish trends and direct verification activities where needed (e.g. multiple SPS noncompliance to generate FSAs) (p 6 PHIS-BR).

We believe that risk-based daily inspection and verification activities, coupled with a risk-prioritized FSA scheduling system (Recommendations 4 and 6), ensure *continuous* feedback on establishment risk controls.

Recommendation No. 6
"Develop and implement a system to track changes at an establishment over time and determine which changes would trigger FSIS to conduct an FSA at an establishment prior to its periodic reevaluation."

Agency Response
FSIS agrees with this recommendation. A critical feature of the new FSA system will be its ability to "interact" with the PBIS replacement system (pp. 6 and 94 PHIS-BR). Like the current PBIS system, the PBIS replacement system is the primary means by which FSIS tracks changes at establishments over time. A system will be developed by August, 2008 that monitors the PBIS replacement system for significant changes in establishment characteristics, inspection findings, and other information. The system will also "flag" establishments for which FSAs might be in-order using a set of criteria that will consider such things as changes in noncompliance rates, changes in the types or quantities of products produced, and establishment start-ups after prolonged period of inactivity. This "flag" would alert the District Office to the *possible* need for an FSA, but it would be the prerogative of the DM and staff about how this "flagged" establishment should fit into their prioritized FSA schedule. FSIS will fully implement the system as part of the new public health system.

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October 19, 2007

Interim Update on FSIS Activities in Response to Office of Inspector General (OIG) Issue Paper 07-01: *Security over the Information Technology Resources at the Food Safety Information Service,* **Audit No. 24501-2-FM**

1. Open Vulnerabilities not corrected or mitigated

Supporting the IT infrastructure at FSIS, as everywhere, includes the continual challenge of staying ahead of the stream of new system exploits, attacks, and vulnerabilities. An essential component of meeting the challenge is constant vigilance and awareness of the state of all IT assets in the enterprise. This is accomplished through a continuous scanning and mitigation program of discovered and open vulnerabilities for all servers, routers, switches, and workstations.

<u>Current Activities:</u>

The server vulnerabilities are being tracked and corrected in the following multiple, tiered ways (what is commonly referred to as defense-in-depth):

- The first line of defense is[   ]which is a package that tracks and automates the patching/correcting of production servers through a centralized console. Since February 2007, the third Sunday of each month is scheduled for the routine patching of servers.
- Second, if a critical vulnerability is either announced by[   ]or identified through the FSIS internal weekly scans, then unscheduled maintenance is announced and the servers are taken off-line for immediate updating.
- A tertiary level of scanning is accomplished through the central management console of [   ]which correlates the data reported from all of the individual workstation weekly anti-virus scans, and alerts the administrator to those scans which indicate a potential problem with the clients.
- In addition, there is a weekly scan of all workstations that tracks and alerts the FSIS Service Desk to vulnerabilities. The service desk then reviews the issues raised with the desktop configuration team, to determine the best means and methods of addressing the vulnerability.
- FSIS is also annually re-examining its contingency plans to identify actions to mitigate potential large-scale vulnerabilities.
- Additionally, FSIS communicates with counterparts in other Agencies and continually re-evaluate lessons learned as part of our self-improvement.

<u>Ongoing Activities:</u>

FSIS is establishing new processes, procedures, and management controls to monitor the scanning program and to identify vulnerabilities associated with servers, switches, routers, and workstations, and ensure mitigation of the vulnerabilities. The thrust of these activities is to provide an automated capacity to supplement the current manual processes. These include:

- [   ]systems provide live monitoring and correlation of security events generated by disparate systems and appliances. *Completion Date: 04/30/07*

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October 19, 2007

- Operational Awareness software. FSIS is procuring[   ]to provide a new level of awareness capacity so that the entire network activity and status can be seen in a single live dashboard. *Completion Date: 07/30/08*

10/19/07 Update: Since our original submission, the contract for this software was awarded on 9/26/07, and we are waiting for receipt of the software. A Request For Change (RFC) for the internal FSIS change management process has been prepared for the installation and testing.

- Security Operations Center (SOC) to coordinate response to issues identified as well as develop an incident response capacity. *Completion Date: 11/01/07*

10/19/07 Update: Since our original submission, the contract support for this activity has been procured and been active for the last month. One contractor FTE has come on board to begin supporting the SOC activities. Written procedures for the SOC are being developed, and will be signed off and implemented within the next 60 days. Incident response escalation rules are being developed in conjunction with[   ]the OCIO task tracking system, and should be in place within the next 90 days.

2. **FSIS was not scanning all workstations**

   FSIS has implemented numerous corrective actions to develop a scanning process that will effectively cover all of the client desktops and laptops nationwide that comprise the enterprise. Each end-user computer, or workstation, is a potential entry point to the FSIS network, through dial-up or broadband connections at the office or in the field, and each must be continuously reviewed to ensure that it remains secure. The remedies include the following ongoing activities, which are already in place, as well as developing process improvements and planned future implementations.

   Current Activities:

   - FSIS scans all servers and network appliances with[   ] software. This software, the current scanning standard set by the Department's Office of CyberSecurity, systematically probes every machine at every network address, and all 65,000 available ports at each address, and compares the results to a continuously updated database of known vulnerabilities. As of May 2007, this scanning has been set to the most aggressive level[   ]in order to guarantee that all possible vulnerabilities can be detected.
   - [   ]is active on all FSIS servers.[   ]continuously scans the state of the software configuration on each server, and logs all changes attempted and enacted.

   Ongoing Activities:
   Much of the improvements in scanning are dependant upon the broadband connectivity rollout and the[   ]standard software rollout. These activities are described in depth under section four, but basically call for FSIS to complete high-speed network access to all field assignments, and to bring all computers to a common installed base of software. When complete, these will provide a standard baseline and configuration against which the scans can be conducted and measured in a meaningful way.

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- Upgrade all client computers to [   ] *Completion Date: 11/30/2007*

10/19/07 Update: This activity is still on track to meet the completion date. Since our original submission, 1,204[ ] upgrades have been successfully completed.

- Roll out broadband to field sites on dial-up. *Completion Date: 12/31/2007*

10/19/07 Update: This activity is still on track to meet the completion date. Since our original submission, 1,964 broadband connections have been installed and are in use.

- Scan Headquarters client computers with [ ] scanner, to ensure the same quality of vulnerability awareness that the servers and network appliances provide. Because of the extensive network traffic that scanning activity generates, this will occur every other Thursday (alternating weeks with the agency's time and attendance activities, which create their own spike in demand for network service). The network load is being tuned and a schedule developed in order to minimize the impact to the network services and not disrupt FSIS users or business processes. *Completion Date: 02/29/2008*

10/19/07 Update: Since our original submission, FSIS has built two stand-alone [ ] scanner servers to handle the increased load (previously [ ] was run on a client computer in the Server Operations Branch). These servers will be placed into production in order to help balance the processing and network loads and allow us to meet the scheduled completion date.

- Conduct regular scanning of enterprise client base image: To occur in PC lab monthly, and upon changes to the software base image. As we continuously patch and improve our standard software load, all changes need to be re-evaluated from a security perspective. A configuration management process has been put into place, and each potential change requirement will be tested to ensure that it does not create a conflict with existing software or hardware. Even changes/patches urgently recommended by US-CERT and/or the Department must be evaluated to ensure that they do not create unintended consequences. *Completion Date: 05/31/2008*

10/19/07 Update: Because FSIS has migrated to the department's UTN network for all backbone services, a Network Impact Assessment must be developed and approved for the scanning activities. Since our original submission, a preliminary scanning methodology (using [ ] software at [ ] the most rigorous scanning level) has been developed, and is being tested, and a production schedule identified that will enable us to meet the anticipated completion date.

Planned Activities
- Creation of a scanning practice for all field clients. The challenge of a 100% complete scanning solution is largely one of inadequate bandwidth. Currently, FSIS is engaged in the deployment of broadband to all field assignments. Once in place, a methodology will be developed that adequately examines the state of the client. This will be predicated in part upon the use Network Access Controls (NAC) that regulate client requests to connect to the network based on a live evaluation of the computer's security state. Because of the irregular patterns of FSIS field computer traffic, traditional

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October 19, 2007

scanning methods will also have to be augmented with client-based auditing software, similar to the typical anti-virus scans. *Completion Date: 05/31/2008*

10/19/07 Update: This activity schedule will slip, because of newly mandated USDA requirement for client two-factor authentication. The department has issued a memo requiring the use of HSPD-12 compliant Personal Identity Verification (PIV) cards by all laptop computers to begin production by March 3rd, 2008, and FSIS will need to focus significant attention on this project to attempt to meet the aggressive timeline. There are multiple critical path dependencies for this task that are outside FSIS control, presenting real operational risks to successful completion.

- Create a Security Operations Center (SOC) functionality, and a corresponding cross-matrixed Incident Response Team (IRT) within the Computer Network and Support Division (CNSD). The SOC will provide the continuous human review and assessment of the results of the continuous scanning activities, resolving those issues they can, and escalating other issues to the IRT as open security incidents to be escalated and tracked until successfully mitigated or eliminated. FSIS is contracting to initially staff and develop the procedures and tools needed to integrate the SOC activities into its operations. *Completion Date: 06/30/2008*

10/19/07 Update: Since our original submission, contract support for this activity has been procured and been active for the last month. The department recently released an updated directive, DM3505, which redefined Incident Response (IR) requirements for the agency. A cross-cutting team has been established within OCIO to develop the procedures necessary to implement these IR requirements, as activated by the activities of the Security Operations Center. One contractor FTE has come on board to begin supporting the SOC activities.

3. Patches are not being managed

As an organization entirely based upon⌐   ⌐ software, our homogenous operating environment means that any ⌐   ⌐ vulnerability creates risk for the entire enterprise. Any patches to be applied thus also present the same risk profile, and must be rigorously evaluated and tested before deployment. FSIS is developing its activities in accordance with the National Institute of Standards and Technologies (NIST) Special Publication 800-40, *Procedures for Handling Security Patches*.

Current Activities:
- In the last ten months, FSIS has created a functional testing laboratory with dedicated resources in response to the requirements of the Change Control Board (CCB), which is a management review team approves all change patch requests. The CCB management has been explicit and adamant that formal patch testing must take place in order to receive approval for deployment. All patches are first thoroughly reviewed in the test environment, and then upon approval, a deployment package is prepared.
- The server patch vulnerabilities are tracked and mitigated through the use of⌐   ⌐ ⌐   ⌐ a package that tracks and automates the patching of production servers through a centralized console. The third Sunday of each month is scheduled for the routine patching of servers; however, if a critical vulnerability is either announced by ⌐   ⌐ or identified through the FSIS internal weekly scans, then once the patches are

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tested, an unscheduled maintenance window is announced and the servers taken off-line for immediate updating.

- The client computer software configuration is managed by ⌐ ⌐ Each month's patches are integrated into a distribution package that is sent out to the FSIS enterprise. For directly connected clients, the update is installed almost immediately. For field clients with intermittent, dial-up connections, the update is transmitted in the background of the connection, and the transmission restarts for each dial-up session until the entire package is received. Upon receipt, the installation automatically runs without user or administrator intervention.

<u>Ongoing Activities:</u>

FSIS is developing better processes and procedures to ensure the management of patches on workstations.
- FSIS is procuring a configuration management tool called ⌐ ⌐ a tool that, once installed on each client computer, enforces standard configuration policies, and can scan for and automatically correct unauthorized configuration changes. *Completion Date: 09/30/2007*

10/19/07 Update: Since our original submission, the contract for this procurement was awarded on 9/25/07, meeting the original deadline. We are currently awaiting software delivery, and, once received, testing and configuration is expected to take several months. Development will include the incorporation of several security mandates, with the system targeted for production deployment in August of 2008.

- FSIS also is improving its management controls and audit functions to provide review of the patching and scanning activities and the reporting of those activities to the department and to the annual FISMA security review. *Completion Date: 03/31/2008*

10/19/07 Update: Since our original submission, FSIS has made several procedural changes to incorporate improved management controls. As of the September report submission, the OCIO signed off on the validated report. The scanning and patching reports were validated by creating to reports from separate solutions, and the full disclosure of the data to the department by inclusion in the monthly submission. As of October 1st, the Management Controls Technology Staff (MCTS) has been moved into the Office of the CIO, providing an internal resource to efine and improve the management controls that govern the security reporting. This task is still on schedule to meet the estimated completion date.

- In addition, the previously mentioned Security Operations Center will create a real-time use of and response to scanning activities and data in its daily operational demand that will far surpass any paper report or monthly validation activities. *Completion Date: 06/30/2008*

10/19/07 Update: This task is still on schedule to meet the estimated completion date. Preliminary Standard Operating Procedures (SOP) for security data monitoring and scanning activities will be submitted to the CIO for approval and signature within the next 90 days.

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October 19, 2007

4. Patches for the Big Yellow Worm virus are not complete.

In responding to the Yellow worm outbreak, the Office of Chief Information Officer (OCIO) wrote a comprehensive SOW and then awarded a contract for the upgrade of all client operating systems and [   ] software in June 2007. Because of the complexity of this install, each user that (1) contains the new software, and (2) backs up the existing user data receives a [   ] hard drive. The new process of an externally-contracted and managed, nation-wide upgrade of all FSIS computers to the most recent and secure versions of [   ] and various supporting software packages and patches officially began July 9, 2007, with the field offices. Simultaneously, we have been upgrading the headquarters and district office computers, and anticipate completing all activities within the same timeframe.

Current Activities:

To prepare for the upgrade, OCIO:
*   Developed and tested the new standard image;
*   Completed a pilot rollout with 21 field users to test the image and process, with the average time ranging from 3-5 hours;
*   Increased the number of personnel on the Help Desk to anticipate increased phone support;
*   Used the Help Desk ticketing system [   ] to send out the advance notice, verify the user's address and automate reminders to each recipient;
*   Informed employees that laptop users would have 2 weeks to complete the installation whereas desktop users would have 3 weeks to complete the installation due to the sharing of equipment; and
*   Contacted representatives in the programs areas to discuss the rollout for the ISLO's, OIA Inspectors, OPEER Investigators and Headquarter offices.
*   Sent each computer user the following:
    *   [   ] hard drive pre-loaded with the new load image files, including [   ]
    *   [   ] and supplemental utilities CD;
    *   Instructions and Checklist for the [   ] upgrade; and
*   Met with OFO RMA's to determine the schedule for each district.

To date, OCIO has distributed 421 drives to the Beltsville, Jackson and Minneapolis Districts. Of the 421 recipients 88 upgrades have been completed and 302 are in progress. This effort is targeted to be complete by November 30, 2007.

10/19/07 Update: This task is still on schedule to meet the estimated completion date. Since the last update, 3,082 inspectors have been contacted and 1,204 upgrades completed.

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Exhibit D – *FSIS Response to Issues Regarding IT Security*

October 19, 2007

5. **Develop and implement procedures for performing and monitoring patches and vulnerability scanning to ensure compliance with Departmental requirements.**

   The USDA CyberSecurity office does not provide guidance for the agencies as to which patches are considered critical. Not all "critical" patches are relevant to the FSIS enterprise.

   - The Agency CIO will require automated documentation to verify scores before signing monthly reports to USDA beginning September 2007.

   10/19/07 Update: This target was met with the September scorecard submission.

   - A dedicated CyberSecurity staff will be created during the OCIO realignment and a separate auditing function will be retained outside of the operations division. The plan is targeted to be delivered to the Associate Administrator for review by 12/31/07.

   10/19/07 Update: This activity is still on schedule to meet the anticipated completion date.

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United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

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

SEP 1 8 2007

FROM: Alfred V. Almanza
                Administrator

SUBJECT: Office of Inspector General (OIG) Issue Paper – Food Safety and
Inspection Service Application Controls - Performance Based Inspection System (PBIS)
Audit No. 24501-2-FM

The Food Safety and Inspection Service appreciates the opportunity to review and
comment on this issue paper. In this document we respond to the OIG findings and
conclusions as follows:

OIG Finding:

FSIS has not yet developed and effectively implemented policies and procedures to:

- Restrict access to only authorized users and that legitimate users had access to only
  that information needed to perform their job functions.

FSIS Response:

In practice, FSIS does "restrict access to only authorized users and that legitimate users
had access to only that information needed to perform their job functions." FSIS
acknowledges that written policies and procedures (Agency issuances) are needed to
document existing practice to restrict access to authorized users and ensure that only
legitimate users have access to the information needed to perform their job functions.
Under existing practice, designated individuals at the district level grant access to PBIS
users within the district. Field inspectors only have access to establishments to which
they are assigned, or likely to be assigned in the event that temporary coverage is
necessary. Frontline Supervisors have access only to establishments under their
supervision. Designated District users have access to all establishments in the district.
Headquarters users who require additional access receive access from a superuser who
oversees all PBIS management. Written policies and procedures documenting the
existing practices will be developed in issuances by the end of January, 2008.

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

<u>OIG Finding:</u>

FSIS has not yet developed and effectively implemented policies and procedures to:

- Provide reasonable assurance that only authorized and allowable data was entered into PBIS.

<u>FSIS Response:</u>

FSIS acknowledges that existing policies and procedures need to be documented in Agency issuances that provide reasonable assurance that only authorized and allowable data is entered into PBIS. PBIS tracks the specific inspection system procedures performed at each establishment to ensure that only results for allowable procedures are entered. Validation and edit checks are performed on the procedure results as the results are entered to ensure that only allowable results are entered. The validation and edit checks will be documented by the end of January, 2008.

PBIS requires justification to change certain critical data to ensure that only allowable data is entered. Examples include modifications to noncompliance records, inspection system procedures, and certain establishment data. The justification procedure is documented in the *PBIS User Guide for Inspectors*. PBIS also provides reports to allow users to review data for errors which are also documented in the *PBIS User Guide for Inspectors*. FSIS will implement the aforementioned procedures described in the *PBIS User Guide for Inspectors* as policy by the end of January, 2008.

<u>OIG Finding:</u>

FSIS has not yet developed and effectively implemented policies and procedures to:

- Provide proper segregation of duties over the PBIS system development, testing, and production environments. In the agency response to the report, FSIS stated they would reorganize the IT structure to achieve separation of duties. In the FSIS Plan of Action and Milestones (POA&M) document dated August 2005, there is a line item specifying "establish a policy to ensure the proper segregation of duties over the PBIS system development, testing, and production environment," which shows a status of "completed" and the date completed is September 30, 2005. During this review we requested these policies and were informed by FSIS that they did not exist.

<u>FSIS Response:</u>

FSIS acknowledges that written policies and procedures are needed to document the segregation of duties. However, there is proper separation of duties in the organizational structure. The OCIO organizational structure, as outlined in the official functional statements, effective November 2004, separates application testing from application development by placing each in a separate branch. Development and database administration are currently under one branch, but assigned to separate teams within that

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branch. The OCIO functional statements are under review as the organization looks to enhance its support of the Agency's mission. Written policies and procedures documenting the existing practices will be developed in issuances by the end of March, 2008.

FSIS acknowledges that a separate development environment is needed for the PBIS application. FSIS recognizes that separate development, test, and production environments are necessary to ensure application quality control and availability. FSIS already maintains a development environment for the PBIS database and has procured the necessary software licenses and hardware to create development and test environments for its databases. FSIS will implement a development environment for the PBIS application by the end of March, 2008. Effective July 2007, OCIO set up an isolated test environment for client server applications such as PBIS that is available for use.

FSIS has entered into a contract to develop an improved domestic inspection system. The contract requires the creation of separate development, test, pre-production, and production environments to ensure the availability of the production system and improve software quality.

OIG Finding:

- FSIS relied on notices, directives, and user training instead of policies and procedures.

FSIS Response:

FSIS requests clarification regarding this finding. Policies and procedures are communicated to FSIS personnel through notices and directives. Notices and directives are vetted through an official clearance process prior to release.

OIG Finding:

- However, FSIS was not verifying that all users had completed training. As of June 2007, over 1,000 PBIS users had not completed the online training.

FSIS Response:

FSIS acknowledges, that although 3,500 PBIS users had completed the PBIS version 5.1.3 online training by June 2007, approximately 1,000 had not. FSIS will identify inspection program personnel who still need to complete PBIS training by the end of December, 2007. Once the exact number of users is identified, FSIS will notify those who require training and set a deadline for completion.

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OIG Finding:

- We also continued to note that FSIS needed to improve the timeliness and completeness of PBIS data to include appropriate synchronization between headquarters and field operations. FSIS stated in its management decision letter that "FSIS is able to utilize data effectively from PBIS when the database is synchronized less frequently than daily." But then went on to say that "Guidance has been provided in the PBIS Users' Guide for inspection program personnel to conduct daily synchronization." FSIS will determine whether the guidance provided in the PBIS Users' Guide should be updated. FSIS will issue a policy and update the guide, if necessary, establishing the time requirements for synchronization." We were provided both the current PBIS Users' Guide and the one in draft. Both stated that users should synchronize daily. FSIS stated that it had a draft policy to not synchronize on a daily basis, but it was not provided to us.

FSIS Response:

In regard to the discussion of PBIS synchronization, FSIS notes that there is an open audit recommendation in which OIG recommended that FSIS establish policy and controls to ensure that inspection program personnel "synchronize inspection results daily" (OIG Audit 24501-1-FM, Recommendation No. 5). FSIS responded that the Agency is able to use data effectively from PBIS when the database is synchronized less than daily, but that it would issue a policy on time requirements for PBIS synchronization by March 2005. OIG granted management decision and FSIS issued FSIS 4-05 on January 13, 2005, which encouraged inspection program personnel to synchronize daily but required them to synchronize weekly. More recently, FSIS has issued guidance in its PBIS Users Guide (version 5.1.3) encouraging inspection program personnel to synchronize daily. And, by the end of 2007, FSIS will issue a new Notice again encouraging inspection program personnel to synchronize daily but requiring them to synchronize at least weekly. FSIS will announce that users who fail to synchronize during a 21-day period will be locked out of the system. The application changes needed to implement this policy also will be completed by the end of 2007.

Daily synchronization is not feasible for all inspectors. Many Federally inspected establishments do not produce product on a daily basis. Furthermore, many small establishments do not have readily available access to allow inspectors who are on rotational assignments to connect and synchronize.

FSIS is unaware of any draft policy instructing inspection program personnel "not to synchronize on a daily basis."

The improved domestic inspection system will move away from the synchronization model by utilizing broadband connectivity to reduce the need to synchronize data. FSIS is currently implementing 2000 broadband installations either to establishments and/or patrol assignments in preparation for this effort. The implementation of broadband connectivity is to be completed by the end of December, 2007.

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<u>OIG Finding:</u>

During our current audit FSIS provided us 20 of its daily synchronization logs for the period February 1, 2007 through June 01, 2007 for selected inspectors. We reviewed the activity for 24 individuals on the logs to determine whether the report supported successful daily synchronization. The documentation provided by FSIS did not support that the 24 individuals were performing daily synchronization. For example, activity ranged from 8 to 77 successful daily updates for the 85 working days included in the time period. As a result, the data may not be accurate, reliable, and timely. In addition, FSIS may not be able to quickly detect and address problems with the nation's food supply.

<u>FSIS Response:</u>

FSIS responded previously that the Agency is able to use data effectively from PBIS when the database is synchronized less than daily. FSIS recognizes that synchronization could affect the timeliness, accuracy, and reliability of data if synchronization is not performed each day that a federally inspected establishment operates. As the logs reviewed constituted a sample of synchronization patterns, FSIS would need to review the establishments assigned to the inspectors in the logs to determine if the establishments were in operation each day.

FSIS' upcoming Notice will describe procedures by which inspectors will be notified if weekly synchronization does not occur. The procedures will instruct inspectors to seek technical support upon notification.

The improved domestic inspection system will increase the timeliness, accuracy, and reliability of inspection data by reducing the need for synchronization. Inspectors, to the extent that technology allows, will be able to enter inspection data directly into FSIS' central database rather than synchronizing periodically.

<u>OIG Finding:</u>

Furthermore, FSIS had not yet documented the application, data flow, and data elements of the PBIS system to provide the foundation of operational and security planning, and ensure the continual operation of the system in the event of a disruption of service or turnover in staff.

<u>FSIS Response:</u>

In response to OIG's finding that "FSIS had not yet documented the application, data flow, and data elements of the PBIS system," FSIS notes that it has completed some of these items and provided them to OIG. FSIS provided OIG documentation via email of PBIS data elements on May 18, 2007, in response to item 6 of Data Request List for the "IT track" audit. Specifically, FSIS provided the following, attached again here in this document:

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- Names of each PBIS table
- Purpose for each table
- Separate charts for each table with field names and detailed descriptions for each field
- FSIS Data Warehouse Physical Model – Version 4.0 dated November 14, 2006 which not only provides a visual of how the data for each table in PBIS is connected but also entails how data is connected throughout each FSIS system in the Data Warehouse.

FSIS will have a finalized data dictionary for the Data Warehouse completed by the end of October, 2008. FSIS will have a draft data dictionary of the PBIS database completed by the end of October, 2008.

FSIS acknowledges that it has not documented the data flow for PBIS. FSIS is currently working on developing the dataflow documentation that will be completed by December 2007.

The contract for the improved domestic inspection system requires the contractor to produce all necessary documentation to support the system including the system design and data flows.

<u>OIG Finding:</u>

FSIS officials stated that a general lack of resources (both human and technical) and high turnover of information technology (IT) staff caused much of the delays in their ability to achieve final actions. In addition, during our fieldwork we observed a general lack of communication between various IT branches/staffs.

<u>FSIS Response:</u>

In FY07, FSIS increased the numbers of IT contractors to augment application support, documentation, and configuration management. FSIS is currently in the process of filling 7 FTE vacancies on hold due to a prior hiring freeze. Additionally, OCIO is undergoing a realignment to more effectively utilize our human resources, with a draft realignment plan due to OPEER management December 31, 2007.

FSIS anticipates that the improved domestic inspection system will require less support. Most data will be entered directly into the central database, reducing the need to ensure frequent synchronization and reducing the effort required to support synchronization.

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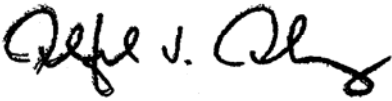
United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

OCT 18 2007

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

From: Alfred V. Almanza
         Administrator

Subject: Office of Inspector General (OIG) Issue Paper –FSIS Data Management
         Infrastructure and Analysis (Audit No. 24601-07-HY, Issue No. FSIS-07-
         02)

We appreciate the opportunity to review and comment on this issue paper. The Food
Safety and Inspection Service has responded to each of the seven specific
recommendations has provided clarification of and general comments on the issue paper.

Responses to Recommendations

Recommendation 1: Closely monitor the administration of the PHIS contract and the
development, testing and implementation of the new system to ensure it is progressing as
intended and to attain satisfactory assurance that it can support the operations necessary
to carry out a complex scientifically-based RBI system.

FSIS Response: The Agency uses best practices of contract administration in the
acquisition, management, and administration of contracts. The focus is on obtaining
supplies and services, of requisite quality, on time, and within budget to ensure the
government gets what it paid for. To this end, the Agency appoints a Contracting
Officer's Technical Representative (COTR) to play the critical role during all phases of
the acquisition process: pre-solicitation, solicitation and award, and post-award. The
COTR, with assistance from program staff, writes the statement of work, establishes
tasks, deliverables and timelines for the project, monitors technical performance,
compares progress with delivery schedules and cost objectives, reviews and critiques
contractor's deliverables and obtains Agency review from subject matter experts. In the
case of the PHIS contract, the COTR specifically will ensure the timely delivery of a
system that meets the goals outlined in the PHIS business requirements:

- Ensures that inspected establishments' food safety systems are meeting regulatory
  requirements and operating at an optimal level of process control to protect public
  health.
- Collects and facilitates analysis of verification and compliance data to direct the
  allocation of Agency resources toward verification activities with the most benefit
  to public health.

- Allows FSIS to correlate plant-level data with broader public health data to ensure that risk-based inspection activities are effective in improving public health and to identify and address emerging issues.

Recommendation 2: Complete a comprehensive, agency-wide examination of the national, divisional and district level analytical and informational needs and establish a process to periodically reassess needs. This should include implementing management controls to specifically define what analysis and information is needed, who should perform the analysis and collect the information, who needs to be provided the analysis or information (customers), how often the information needs to be collected and analyzed, what is the most useful format to present the information or analysis to the final users, and, finally, who is responsible to ensure follow-up actions are taken to correct problems identified. The study should also include an action plan for making the necessary changes to the agency's operating procedures and the estimated timeframes for implementing these changes.

FSIS Response: The agency agrees with OIG that a comprehensive examination of analytical and informational needs and a process for periodic reassessment of those needs is essential. The Data Analysis and Integration Group (DAIG) within the FSIS Office of Food Defense and Emergency Response, was formed to lead a range of activities, including those recommended by OIG. Specifically, the DAIG is evaluating individual data streams and integrating data analyses across FSIS program offices; ensuring that data analyses are relevant to program offices' business processes and the agency mission; and ensuring that data analyses are consistent and of high quality. The DAIG has a number of projects either underway or soon to be initiated to identify and reassess analytical and informational needs within the Agency.

The DAIG will be developing a data analysis plan for identifying systemic problems and positive outcomes in food safety or inspection associated with identifiable trends in noncompliance or other data collected in OPPED reports. The thorough review of all OPPED-generated reports will be completed by December 30, 2007. Until then, OPPED will continue to create the current reports and share each with all the senior managers in each program area, and document the process for sending the reports to them and capturing any comments received from them.

Also, during the initial phase of development for all modules of the PHIS (i.e., Predictive Analytics, Domestic Inspection System, Import System, and Export System) the contractor and the Agency will be refining the system's business requirements. That will involve meeting with all program areas to determine and prioritize their analytical needs, including report generation. The information will be used to determine and prioritize program office analysis and report needs, and will be summarized in a report for future reference.

As for an action plan for changing the agency's operating procedures, the development of the PHIS already set the action plan in motion. Through the incorporation of analytical needs into the IT system, the agency's operating procedures will be changed. The DAIG,

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as part of coordinating data analysis for the agency, will meet monthly with the Data Coordinating Committee (DCC), comprised of senior representatives from each program area. One purpose of these meetings will be to review and update analytical needs.

Recommendation 3: Complete the in-depth analysis of all data information streams within FSIS. Also, establish a mechanism to assure that once the analysis is performed for a system it is updated on a regular basis and that new systems are fully analyzed before they come on line.

FSIS Response: The DAIG is completing data information sheets to catalogue and characterize data within the agency. A subset of the data sheets, which includes those streams of potential use in a risk-based algorithm, will be completed by mid-October 2007. Completion of the remaining information sheets has been incorporated into the DAIG's project schedule for completion by April 15, 2008. As part of the process, the information sheets will be reviewed by the DCC before being finalized so that The DCC is responsible for reporting to the DAIG on any updated or new datasets, analysis projects or reports. In addition, the DCC will conduct an annual review of all data sheets beginning April 15th, 2009.

Recommendation 4: Implement management controls to ensure effective distribution and full utilization of the results of all data analyses and reports to other affected program areas, including field operations, in order to allow for follow-up actions to correct problems identified and to establish performance goals.

FSIS Response: The Agency will implement effective distribution and full use of the results of all data analyses and reports to document attainment of Department and Agency Strategic Plan Goals. Agency management controls that define control activities, information dissemination and reporting, and monitoring functions will be used to document data analysis and reports as part of the Program Assessment Rating Tool (PART).

Recommendation 5: Perform an analysis of all reports and determine if any would be beneficial to other divisions/levels in improving compliance and operations. Further, determine if modifications could be made to the reports to make them more beneficial to other program areas, including field operations.

FSIS Response: As discussed in response to Recommendation #2, FSIS is initiating a number of major projects that include current reports and reporting needs. Through these efforts, modifications of reports will be made to make them more beneficial to all relevant program areas, and ensure dissemination to all offices.

Recommendation 6: Provide ongoing training to DAs on new or modified software and specific analytical techniques, including the type of data to collect, standard types of analysis to perform, format to present data, frequency of reporting the results and follow-up actions the analysts are expected to take on any adverse issues noted. Also, establish a

system to track when training is taken, the type of training taken, and a system to alert the appropriate managers if the minimal levels of training are not being achieved.

FSIS Response: As part of its efforts to identify the analyses currently being conducted by the District Offices and to help determine what analyses should be conducted at the District Offices or at FSIS HQ, the DAIG and the Center for Learning (CFL) in OPPED will develop a component to train District Analysts. The training will include the use of new or modified software and specific analytical techniques, how to generate standard reports, the frequency of generating reports, and follow-up actions that appropriate program officials are expected to take on any potential adverse issues identified by the tools. The CFL currently tracks when training is taken thru AgLearn, where the learning history of all courses for each employee is stored. The type of training also is recorded in AgLearn. By the end of 2008, we will be fully implementing the feature in AgLearn that allows managers to detect if minimal levels of training are not completed.

Recommendation 7: To the extent feasible, focus the activities of DAs primarily on their data management and analysis responsibilities and promptly fill vacant DA positions.

FSIS Response: The key grade-determining duty of the District Analyst involves their support for the technical and scientific basis of district-wide enforcement actions. Other key duties include serving as a subject matter expert and coordinator concerning a variety of food safety regulatory and inspection matters. FSIS agrees that to the extent feasible, the DAs should focus their activities on data analysis and management. We believe that the DAIG activities described above will assist them in accomplishing this goal. In addition, FSIS will revise the DA position description by January 2008 to better clarify their primary data analysis role, especially as that relates to enforcement activity.

As the PHIS is developed and implemented, much of the data analysis needed by District Offices will be automated, including predictive analyses that help target Agency resources toward developing food safety problems that pose the most risk to the public health. District analysts' roles will change accordingly, as they are required to perform less data analysis and instead ensure that analytical results are used to appropriately allocate District inspection and other resources. Their role in using data to support enforcement actions also should change somewhat, although the goal will remain the same: to ensure that data supports enforcement actions to keep adulterated or misbranded meat and poultry products out of commerce.

As a result of non-frontline hiring restrictions during 2006, several DA positions were, by necessity, left vacant. Currently there is one vacant DA position in the Atlanta District. The announcement to fill this position closes on October 19, 2007.

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United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

To: Robert W. Young
           Assistant Inspector General for Audit   **SEP 18 200/**
           Office of Inspector General

From: Alfred V. Almanza
           Administrator

Subject: Office of Inspector General (OIG) Issue Paper – Management Control
           Structure (Audit No. 24601-07-HY, Issue No. FSIS-07-03)

We appreciate the opportunity to review and comment on this issue paper. The Food
Safety and Inspection Service has responded to each of the five specific
recommendations has provided clarification of and general comments on the issue paper.

Responses to Recommendations

Recommendation 1:
Officials at each level are provided with guidance on the use of the AssuranceNet system,
particularly with regard to follow-up actions and adherence to the established system
thresholds.

FSIS Response:
FSIS has implemented its management control system, of which AssuranceNet is a key
part, in phases. Phased implementation has allowed us to test the system and make it
fully operational, populate the system with data, and introduce users to the system and
allow time for them to learn its features. Preliminary guidance on using AssuranceNet
has been provided throughout these phases at workshops, correlations and through the
FSIS Intranet. FSIS agrees now to provide additional, comprehensive written guidance
for managers at all levels on reviewing, analyzing and responding to AssuranceNet
results. This guidance will be published as an official FSIS Issuance (Directive or
Notice) by December 2007.

The planned guidance will detail the type and depth of analysis of AssuranceNet data
each level of FSIS manager must undertake. Required analysis will be commensurate
with the organizational level of the individual manager, i.e., managers at FSIS
headquarters will perform broader analysis of national or District performance while a
District Manager might analyze results across Circuits. And importantly, the planned
guidance also will describe how FSIS managers are to document findings and determine
risks (consequences) associated with not achieving goals and objectives.
FSIS is committed to following management control standards of assessing
vulnerabilities and adjusting control and monitoring activities to reduce vulnerabilities in

compliance with Departmental regulation DM 1110-02, governing the application of management control systems. The Agency's work in developing and implementing Assurance Net, including the forthcoming guidance on using the system, applies the Department's policies to use management controls to reasonably ensure that:

(1) programs achieve their intended results;
(2) resources are used consistently with agency mission;
(3) programs and resources are protected from waste, fraud, and mismanagement;
(4) laws and regulations are followed; and
(5) reliable and timely information is obtained, maintained, reported and used for decision making.

More specifically, the forthcoming guidance to FSIS managers will direct them, consistent with USDA management control policy, on how to use AssuranceNet results and other data to conduct systematic analyses of their programs to identify their vulnerability to failing to achieve Agency missions or goals and to producing erroneous reports or data. Identifying and responding to vulnerabilities using AssuranceNet results will involve comparative analysis of rates of performance in meeting management control targets over time (the response to Recommendation 3 contains more detail). And importantly, the guidance will instruct FSIS managers on how to respond to these identified vulnerabilities.

Recommendation 2:
Data entering the system, whether by direct input or from other systems, is subject to accuracy checks.

FSIS Response:
Much of the data in AssuranceNet is generated by other FSIS systems (PBIS, eADRS, and M2K) and imported from the FSIS data warehouse. Because it is imported electronically and automatically from the data warehouse, there is little or no opportunity for the introduction of error. Otherwise, the accuracy of this data is checked within the other originating systems and through its continued use for comparative analyses by AssuranceNet users (e.g. a manager might compare eADRS results to IPPS results to look for consistency).

With regard to measures that are calculated using data imported from the data warehouse, the District Analysts actively correlate what they are seeing in AssuranceNet with the data and reports they use from those feeder systems, like PBIS. It is through their efforts that we discovered some programming errors, when data for the same time period from PBIS did not correlate with what should have been matching data in AssuranceNet. These issues have been corrected, but the District Analysts continue to use the ~~other~~ tools they have available to correlate with the data in AssuranceNet to ensure it is accurate and valid.

In regard to data entered directly into AssuranceNet by FSIS managers, FSIS has mechanisms in place for ensuring its quality and accuracy. There are several functional

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areas in our management control system on which reviews are required by higher levels in the organization, and on which the findings/comments of the higher level officials are captured in AssuranceNet. District management teams are required to review 20% of Food Safety Assessments per year (measure 3.1.5) and 10% of Administrative Enforcement Reports quarterly (measure 5.1.9), and to record their findings in AssuranceNet. The purpose of these reviews is to verify that the entries made by the District Case Specialist are an accurate assessment of the FSA or AER, and to ensure that feedback is given when the expectations regarding FSA's and AER's themselves are not being met.

IPPS reviews are an important example of management control data entered directly into AssuranceNet. To ensure accuracy and quality, all supervisory levels are required to review a set percentage of IPPS assessments conducted at lower levels in the supervisory chain, to enter their comments on the IPPS assessment form in the space provided, and to send the report and/or other feedback to those in the supervisory chain to which the comments are directed. The relevant measures are 8.1.2a, 8.1.2b, 8.1.3a, 8.1.3b, and .8.1.4. The purpose of these reviews is to determine whether the IPPS assessments are being performed according to Agency policy and procedure, the reporting on the IPPS assessments is comprehensive, and follow-up on deficient performance is clearly indicated (see attached IPPS assessment form)

Recommendation 3:
Warning "flags" provided by AssuranceNet are timely and effectively followed-up on, particularly in cases in which deficiencies are repeatedly noted at the same establishment, circuit, or district.

FSIS Response:
We agree with the need for timely and effective follow-up on "flags." And, as stated in the response to recommendation 1, FSIS will provide official direction to FSIS managers at all levels on reviewing, analyzing and responding to AssuranceNet results by December 2007.

Keep in mind, however, that the fact that a target is exceeded or not met means vulnerability exists and that that vulnerability presents a risk to be assessed. A target not met in and of itself does not mean there has been a failure that requires immediate attention – the actual performance shown on a measure in AssuranceNet must be put in perspective of what the measure is, where it comes from, the period of time involved, the degree to which actual performance varies from the target, and what the trend has been over time. For example, the target for measure 1.4.1 is 100% of condemned animals and inedible product is identified and properly disposed. This measure relies on IPPS assessments in AssuranceNet. If the actual performance for a District on this measure, for a quarter was 95%, this would not be cause for alarm. It would mean that some supervisors are finding that their employees are not properly carrying out the related inspection activities, but the vast majority of them are finding acceptable performance on this element. The target is 100%, but realistically, with hundreds of employees performing these functions, the expectation would be that some employees would show

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the need for additional training and instruction at any given time. This is the purpose of IPPS; to identify the need for additional training, instruction or coaching, or to take a personnel action, to make sure the vast majority of inspection personnel are competently carrying out their assigned functions.

Notably, we have been working towards more systematic review and follow-up since the spring of this year, when the enhanced version of AssuranceNet was launched and there was ample data in the system for meaningful reporting and analysis. We agree that we need to ensure that follow up actions are taken and documented, as evidence that the controls we have in place are working. At the July 2007 District Manager's meeting, we reiterated the expectation that AssuranceNet comment fields provided on both AssuranceNet screens used by the District Analysts be fully utilized to document findings and follow-up actions. The District Managers were also reminded to set up a system for documenting their follow up activities outside of AssuranceNet, where necessary. Again however, we will develop an FSIS issuance providing direction for each organizational level, outlining the requirements regarding follow-up and the documentation of follow-up activities, by December 2007.

Recommendation 4:
Officials, particularly at the district level, are using AssuranceNet to view performance data down to the establishment level, as well as the circuit and districts.

FSIS Response:
AssuranceNet has very little data that reflects on what is going on at the establishment level, because the system focuses on organizational performance (circuit/district) and not on the establishment itself or the work done at the establishment level. AssuranceNet focuses on measuring our success in carrying out our regulatory functions. Although the data is captured at an establishment level for many performance measures so that it can be aggregated to reflect circuit and district level performance, it would be inappropriate to ensure that each "establishment level" is meeting the performance measure set for a circuit or higher level. When targets are not met at the circuit level, then drilling down to the establishment level may show that performance of inspection personnel at certain establishments is lower than expected and may be contributing disproportionately to the circuit level not meeting the performance target. Drilling down is not to see if the performance target was met at the establishment level, but to narrow down where there might be performance issues that need to be addressed. For that reason, if the circuit is meeting the performance target, it is not necessary to drill down further in AssuranceNet for the purpose of organizational performance assessment.

However, the Districts are expected to monitor activities carried out at the establishment level, using PBIS and other tools, such as supervisory oversight, designed for this purpose. During 2004 and 2005, three training and correlation sessions were provided to the District Analysts on PBIS and the other systems they utilize for data analysis for their Districts. This included training on how to use these systems to monitor activities at the establishment level and target areas not meeting expectations for further review or supervisory intervention. The guidance that FSIS will be developing by December 2007,

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will make it clear the levels at which performance measures must be reviewed and the "drilling down" that should be done and how it should be interpreted, when warranted.

Recommendation 5:
A higher priority is placed on addressing prior audit recommendations at the earliest possible time.

FSIS Response:

Since 2000, OIG has made 278 recommendations to FSIS for revising its programs and policies. So, although it is true that corrective actions for 19 of 30 audit recommendations identified in the issue paper remain open, FSIS has closed the majority (192 of 278 or 69%) of all OIG audit recommendations from the same period (2000-2007).[1] The chart below shows the status of all recommendations issued by OIG since June 2000 as of January 1 of each year and starting on January 1, 2001.

Status Breakdown of OIG Recommendations Issued Since 2000
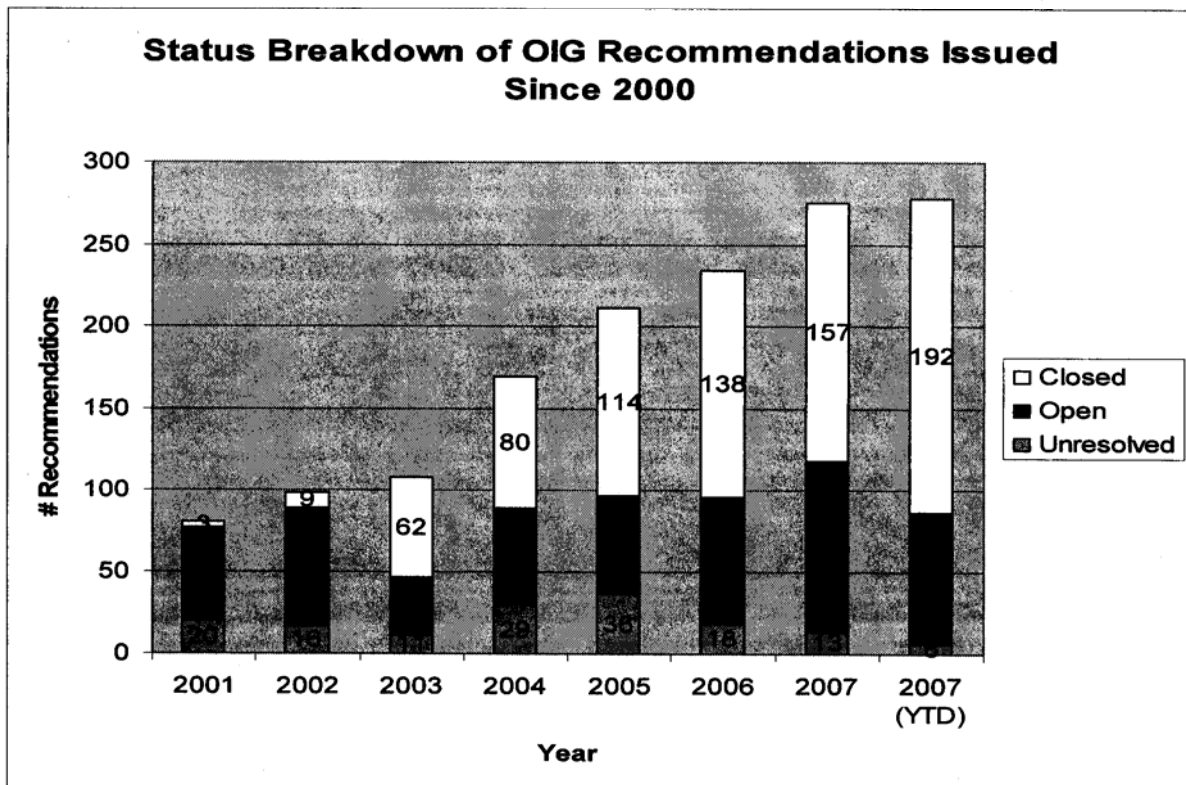
FSIS places a priority on closing all OIG audit recommendations. But, the amount of time it takes to close an individual audit recommendation varies considerably owing to a number of factors, including: the difficulty and complexity of the corrective action;

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[1] FSIS submitted actions for 10 more recommendations to USDA-OCIO in August, 2007.

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emerging public health problems that compete for Agency resources; and the continuous evolution of Agency programs and industry practices. Further, given the volume of audit recommendations and the fact that OIG does not prioritize recommendations for management decision and closure, FSIS has closed recommendations in a manner and order it has seen to be most expedient, taking into account the factors listed above. So again, although it is true that FSIS has closed only 11 of the cited 30 audit recommendations, the Agency has had significant success in reducing the total number of open recommendations. Also, FSIS and OIG have made recent improvements in streamlining the resolution and closure of audits.

Specifically over the last two years, the Program Evaluation and Improvement Staff (PEIS) in FSIS has worked closely with USDA-OIG to reduce the number of unresolved audit recommendations. The chart above shows the significant success we have had working together to achieve management decision on unresolved recommendations (from 36 to 6 unresolved recommendations since 2005). PEIS and USDA-OIG also have cooperated to reduce the number of open recommendations by streamlining the closure process. Notably in May, 2007, at the request of PEIS, OIG sent a letter to USDA-OCFO informing them that they could accept electronic copies of materials as evidence that final action had been taken on audit recommendations. USDA-OCFO changed their policies accordingly and the closure process has been streamlined dramatically.

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FSIS FORM 4430-8C

INSTRUCTIONS FOR
FSIS 4430-8C, N-PLANT PERFORMANCE SYSTEM ASSESSMENT SHEET
For Consumer Safety Inspector and Consumer Safety Inspector with Unique Duties

Name of Employee - Enter name of employee *(Last Name, First)*

Assessment Number - Enter the Assessment Number 1, 2, 3 (At least 2 IPPS Assessments are required per rating cycle)

Assessment Date - Enter MM/DD/YYYY

District Name - Enter District Name *(alpha e.g. Alameda)*

District Code - Enter District Code *(numerical e.g. 0500)*

Circuit Name - Enter Circuit Name *(alpha e.g. Vernon)*

Circuit Code - Enter Circuit Code *(numerical e.g. 03)*

Name of Supervisor - Enter the Name of the Supervisor *(Last Name, First)*

Unique Duties - Check the appropriate Unique Duties Block *(If applicable)*

Consumer Safety Inspectors - Elements:
Complete items 1 through 7 under the Mission Support Element and complete the Communication, Personal Contacts, and Individual Contribution to the Team Elements.

Consumer Safety Inspectors with Unique Duties - Elements:
Complete items 1 through 7 and the appropriate Unique Duties under the Mission Support Element and complete the Communications, Personal Contacts, and Individual Contribution to the Team Elements. Complete only the elements that apply to the duties you are assessing.

Management Control Item - Leave Blank

Assessment Block - Enter the Assessment Code: Y = Yes, Blank = Not Observed, N/A = Not Applicable

Method of Assessement - Check the appropriate Method of Assessment: Records Review, Discussion, Observation
(More than one method of Assessment can be used)

Follow-Up - Check block, if follow-up is required

Comments/Feedback - NOTE: Your comments should clearly describe what you reviewed, observed and discussed; what you concluded; and what indications demonstrated why the performance was on target, off target or noteworthy. When applicable, your comments should also include what remedial action should be taken to improve performance.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

IN-PLANT PERFORMANCE SYSTEM ASSESSMENT SHEET
Consumer Safety Inspector *(with/without unique duties)*

DISTRICT NAME	DISTRICT	CIRCUIT NAME	NAME OF EMPLOYEE	ASSESSMENT NO.	ASSESSMENT DATE
NAME OF SUPERVISOR					CIRCUIT CODE

☐ AM/PM   ☐ EXPORT   ☐ EGG PRODUCTS

ELEMENT	Mgmt. Control Item (Check)	UNIQUE DUTIES Assessed Y = Yes Blank= Not observed NA = Not applicable	Method of Assessment Record Review (Check)	Method of Assessment Discussion (Check)	Method of Assessment Observation (Check)	Follow-up (Check if required & provide comments)	COMMENTS/FEEDBACK (If more space is needed, use "Additional Comments" provided on Pages 3-5)
MISSION SUPPORT							
1. Verifies SPS/SSOP Procedures							
a. Implements SSOP verification activities to ensure production in a sanitary environment							
b. Observes plant conditions and verifies compliance with SPS regulations							
2. Verifies HACCP Regulatory Compliance							
a. Determines that the plant HACCP plan meets regulatory requirements							
b. Assures that plant HACCP plan includes documented hazard analysis, verification, monitoring, record keeping systems that include supporting data							
c. Conducts HACCP verification activities on plant's execution of it's HACCP system							
3. Assures that HACCP plan is reassessed at least annually and/or to reflect changes in production processes/equipment							
4. Initiates additional verification procedures, as necessary in response to specific problems							
5. Identifies and Documents Noncompliance							
a. Describes each noncompliance in clear, concise terms							
b. Cites specific regulatory requirements that were not met							
c. Implements regulatory control actions							
d. Monitors verification of the plant's corrective actions/preventative measures							
6. Sampling							
a. Sample collection							
b. Reviews results and documents findings.							
7. Verification of Food Security Procedures							
a. Implements Food security verification activities							
b. Records and documents findings							
c. Reports non-routine incidents							

FSIS FORM 4430-8C CSI (10/13/2005)

FSIS FORM 4430-8C (Page 2)

ELEMENT	Mgmt. Control Item (Check)	Assessed (Y = Yes, Blank = Not observed, NA = Not applicable)	Method of Assessment			Follow-up (Check if required & provide comments)	COMMENTS/FEEDBACK (If more space is needed, use "Additional Comments" provided on Pages 3-5)
			Records Review (Check)	Discussion (Check)	Observation (Check)		
AM/PM DUTIES							
8. Performs AM Inspection							
a. Id and holds suspects for PHV disposition							
b. Performs PM Inspection							
- Identifies abnormal conditions							
- Rejects, condemns or hold suspects for examination by PHV							
c. Identifies and/or tag carcasses requiring further action by plant							
d. Assures condemned products are disposed of in accordance with regulations							
e. Monitors operational sanitation to ensure sanitary handling and dressing procedures are in accordance with regulations							
f. Monitors slaughter activities for conformance with humane handling regulations and procedures							
EXPORT DUTIES							
8. Evaluates and certifies products for export by assuring that products approved for export are in compliance with laws, regulations and foreign requirements							
a. Verifies the accuracy of labels and inspection certificates							
b. Examines product and containers to determine wholesomeness and that export requirements are met.							
c. Performs product reinspection in accordance with applicable laws, rules, and regulations							
d. Assures the security of export stamps and monitors the marking of products							
e. Notifies parties of product refused for export; explains and interprets requirements							
f. Prepares required export records and certificates							
g. Completes and verifies accuracy of export documents							
h. Assures that authorized export inspection sites meet general sanitation and facility requirements							
EGG PRODUCTS DUTIES							
8. Egg Processing activities							
a. Assures facilities and equipment are properly maintained							
b. Assures operating procedures are in compliance with regulations							
c. Assures approved chemicals, etc. are used							
d. Assures approved labels are used to identify product							
e. Assures inedible product is segregated, identified and controlled							
9. Conducts egg product inspection to assure products are in full compliance with regulations							
10. Monitors the shipping and receiving of tanker egg products							

FSIS FORM 4430-8C (Page 3)

ELEMENT	Mgmt. Control Item (Check)	Assessed Y=Yes Blank=Not observed N/A = Not applicable	Method of Assessment — Record Review (Check)	Method of Assessment — Discussion (Check)	Method of Assessment — Observation (Check)	Follow-up (Check if required & provide comments)	COMMENTS/FEEDBACK (If more space is needed, use "Additional Comments" provided on Pages 3 - 9)
COMMUNICATIONS							
1. Keeps supervisor informed of work activities and critical issues in accordance with established protocols							
2. Documents Noncompliance and Regulatory Control Actions							
a. Describes condition relating to the noncompliance							
b. Describes the significance of the noncompliance from a sanitation or public health perspective							
c. Identifies applicable regulatory requirements							
d. Required documentation is produced, disseminated and maintained as required							
3. Communicates with inspection personnel and industry representatives on policies and procedures							
4. Affords industry due process by informing them of the basis of regulatory decisions and providing information that is technically sound, reliable, and clear							
5. Consults with supervisor and/or other experts to ensure effective response to non-compliance or other problems.							
PERSONAL CONTACTS							
1. Makes regulatory decisions in a non-discriminatory and impartial manner							
2. Meets Agency standards for professionalism							
3. Works cooperatively with other agency teams and organizations							
4. Conforms to Agency's EO/CR policies							
INDIVIDUAL CONTRIBUTIONS TO THE TEAM							
ADDITIONAL COMMENTS:							

Exhibit H – *Selected Processing Establishments*

Establishment Name	Location
Thumann, Inc.	Carlstadt, New Jersey
E.G. Food, Inc.	Brooklyn, New York
Sandridge Food Corporation	Medina, Ohio
Plains Meat Co, LTD	Lubbock, Texas
United Food Group, LLC	Vernon, California
Sara Lee Foods U.S.	Chicago, Illinois
Owens Country Sausage, Inc.	Richardson, Texas
American Foodservice Corp.	King of Prussia, Pennsylvania
Moy's Meat Market, Inc.	Brooklyn, New York
A to Z Kosher Meat Prod's, Inc.	Brooklyn, New York
Bierig Brothers, Inc.	Vineland, New Jersey
Trinity Valley Foods, Inc.	Irving, Texas
D&S Meats, Inc.	Oak Forest, Illinois
Kohler Freda, LLC	Philadelphia, Pennsylvania
Texas Best Beef Jerky, Inc.	Wichita Falls, Texas

Exhibit I– *Agency Response to the Draft Report*

Exhibit I – Page 1 of 18

United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

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

NOV 2 6 2007

FROM: Alfred V. Almanza
        Administrator
        Food Safety and Inspection Service

SUBJECT: Audit Resolution

On November 7, 2007, the Office of Inspector General (OIG) reported on audit 24601-0007-Hy, *Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments*. This audit report contains 35 recommendations, four of which already have been resolved by responses to OIG issue papers during the course of the audit, and 31 unresolved. Responses for the 31 unresolved recommendations follow, consisting of 12 supplemental responses to recommendations contained in the OIG issue papers and 19 responses to new recommendations.

Recommendation No. 1

Implement an action plan with specific milestone dates for capturing the results of food safety assessments in appropriate configuration that allows for further analysis.

FSIS Response

FSIS agrees to OIG's specific recommendation subsequent to the initial FSIS response, i.e. FSIS will establish unique tracking numbers for each FSA recorded in the Public Health Information System (PHIS).

Expected Completion Date:

A prototype for domestic inspection within the PHIS will run in a test environment in Q3CY08 to selected users. The nationwide production readiness for PHIS with the Domestic Module is currently scheduled for Q2CY09.

Recommendation No. 2

Perform food safety assessments, using the new configuration, in all establishments that will be in the universe of establishments where risk-based inspection may be used. The food safety assessments should be comprehensive assessments of the establishment's current operations.

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

USDA/OIG-A/24601-07-Hy   Page 107

Exhibit I – *Agency Response to the Draft Report*

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<u>FSIS Response</u>

Risk-based inspection (RBI) for meat and poultry processing will encompass thousands of inspected establishments. It will not be possible to conduct FSAs under the new configuration in all meat and poultry processing establishments prior to RBI and also to implement RBI in a timely manner. FSIS will determine means for incorporating new FSA data from establishments, collected by the PHIS, into its calculations of risk, while adjusting calculations for establishments that have yet to have FSAs under the new configuration. It also is important to note that an FSA is not the sole determinant of regulatory compliance. Most regulated establishments operate under full compliance with the statutes and regulations and are subject to daily inspectional oversight by inspection personnel.

<u>Expected Completion Date</u>:

FSIS will have determined how to use FSA results in risk-based inspection by December 1, 2008, after analyzing data collected during the test run of the PHIS, scheduled to begin in 3QCY2008.

Recommendation No. 3

Determine how the results of food safety assessments will be used by FSIS in estimating establishment risk.

<u>FSIS Response</u>

The electronic food safety assessments (FSAs) will contain detailed information on all food safety aspects that relate to the establishment and its products, the nature and source of all materials received, the establishment's processes, and the environment of the establishment. While conducting an FSA, the Enforcement, Investigations and Analysis Officer (EIAO) assesses the design and validity of the hazard analysis, HACCP plan, SSOP, pre-requisite programs, testing programs, and any other programs that constitute the establishment's HACCP system, and records the findings. Once available, that information will be used as a component of a risk-based algorithm. However, as discussed by OIG in this report, and by FSIS in other responses, data must be evaluated and analyzed, including examining relevant time windows, prior to establishing its exact use in an RBI algorithm. Therefore, with respect to the FSAs, exact details on how they will be used to estimate establishment risk cannot be determined until the electronic data from the FSAs are available for analysis to determine how best to incorporation the information into a risk-based algorithm.

<u>Expected Completion Date</u>:

FSIS will have determined how to use FSA results in risk-based inspection by December 1, 2008, after analyzing data collected during the test run of the PHIS, scheduled to begin in 3QCY2008.

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Exhibit I – *Agency Response to the Draft Report*

Exhibit I – Page 3 of 18

Recommendation No. 4

As FSIS moves forward to develop and implement risk-based inspection, conduct and document analyses that support the data windows selected for each of the components in the risk control measure, which assesses an establishment's ability to control risk.

FSIS Response

In developing its RBI Technical paper, the DAIG is conducting a number of analyses to determine the temporal relationships among the factors they are considering for use in a risk-based algorithm. These analyses will provide information regarding an appropriate data window for use in risk-based inspection. That is, by examining the relationships in time among food safety events, we can determine what amount of data this needed to develop an accurate characterization of an establishment's food safety controls. Such analysis has begun on the relationship between noncompliance records (NRs) and positive *Salmonella* results. Similar analyses will be conducted to examine the temporal relationships between other components of a risk-based algorithm. The results of those analyses will be used, in conjunction with other considerations such as availability of data, to determine the most appropriate data window to be used. The rationale and analyses underlying the decision will be presented in any technical plan in support of RBI to ensure transparency.

Expected Completion Date:

The RBI technical report will be made final and available to stakeholders, following review by NACMPI and by peer reviewers, by March 17, 2008.

Recommendation No. 5

Ensure the basis for decisions made regarding the components included in the risk-based inspection program are thoroughly documented and evaluated with limitations mitigated and be transparent to all stakeholders.

FSIS Response

FSIS is developing a technical report that will outline, in detail, the basis for decisions made regarding the components included in the risk-based inspection program. The report will outline the limitations of the data, and how those limitations affect the use of the data in risk-based inspections. The technical report will be peer reviewed according to OMB's peer review guidelines, shared with stakeholders, including NACMPI, and modified in response to comments prior to implementation of RBI in processing.

Expected Completion Date:

The RBI technical report will be made final and available to stakeholders, following review by NACMPI and by peer reviewers, by March 17, 2008.

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Exhibit I – *Agency Response to the Draft Report*

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Recommendation No. 6

Develop a process to obtain more accurate, verifiable production data (e.g., pounds of product produced by product type) and regularly update the data from FSIS-regulated establishments.

<u>FSIS Response</u>

FSIS agrees that production data, including volume of pounds of product produced by product type, is critical and that FSIS needs to account for this information in the design of its verification activity. Consequently, through the new PHIS, FSIS expects to implement a mechanism for inspection program personnel to identify specific production records upon which such information is based, and to provide the establishment management an opportunity to review the collected information. Collection of such information in this manner provides FSIS a means to verify the source and accuracy of the information.

FSIS took steps to collect information on raw beef products in this manner with FSIS Notice 65-07 (regarding control of *E. coli* O157:H7) and will assess the process to ensure that it is refined and enhanced in order to be effective. Until PHIS is fully implemented, FSIS will repeat the collection of verifiable volume data begun with FSIS Notice 65-07 at a frequency determined by analysis of the initial results and changing data needs. Also before PHIS is fully implemented, FSIS will begin collecting verifiable volume data on products other than raw beef. Once implemented, the PHIS is expected to prompt inspection program personnel to regularly verify that the collected information remains accurate.

<u>Expected Completion Date</u>:

A prototype for domestic inspection within the PHIS will run in a test environment in Q3CY08 to selected users. The nationwide production readiness for PHIS with the Domestic Module is currently scheduled for Q2CY09.

Recommendation No. 7

Determine why NRs were not correctly accounted for (i.e., one counted twice and one omitted) when calculating an establishment's level of inspection. Implement the necessary controls to ensure that these types of errors do not occur and that data is accurately processed.

<u>FSIS Response</u>

The two errors identified by OIG were human errors on the part of inspection program personnel. Further, PBIS does not have automated functions to check for such errors and they were missed during the manual error checks during the single calculation of levels of inspection for the planned "prototype" RBI establishments. The PHIS will include constraints on data entry to better prevent the erroneous duplication of NRs and other information.

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Exhibit I – *Agency Response to the Draft Report*

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FSIS will include in its technical plan for risk-based inspection that prior to implementing any risk-based inspection algorithm, it will check that the correct data is being processed and that it is being processed accurately. That check will include pulling, for a subset of the establishments, the individual data sets and independently calculating the values for those establishments to ensure that any automated algorithm is accurately processing the data. In addition, FSIS will further emphasize to its personnel the importance of having the data input correctly in its system by, for example, including information on how the data being collected will be analyzed and used in its directives and notices.

Also, FSIS will conduct extensive performance and functional testing of PHIS during user acceptance testing to ensure that the system operates as designed. The testing will be derived from the business processes, scenarios, and use cases defined during the Requirements Phase of the project.

Expected Completion Date:

A prototype for domestic inspection within the PHIS will run in a test environment in Q3CY08 to selected users. The nationwide production readiness for PHIS with the Domestic Module is currently scheduled for Q2CY09. The RBI technical report will be made final and available to stakeholders, following review by NACMPI and by peer reviewers, by March 17, 2008.

Recommendation No. 8

Develop and implement an annual process to verify how establishments control Lm in RTE product and when there is a significant change in the method they use or volume of product they produce.

FSIS Response

FSIS headquarters personnel will incorporate information currently captured on the industry-submitted 10,240 form regarding *Listeria monocytogenes* controls into the PHIS establishment profile and by September 2008, FSIS will have inspection program personnel to collect and input this information in the PHIS. By having inspection program personnel collect such information, FSIS will have a built-in mechanism to verify that the information is current, accurate, and verifiable.

Expected Completion Date:

A prototype for domestic inspection within the PHIS will run in a test environment in Q3CY08 to selected users. The nationwide production readiness for PHIS with the Domestic Module is currently scheduled for Q2CY09.

Recommendation No. 9

As FSIS moves forward to develop and implement risk-based inspection include the enforcement action NOIE with deferral in the calculation.

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Exhibit I – *Agency Response to the Draft Report*

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FSIS Response

FSIS is considering a number of potential components in a risk-based algorithm and evaluating the data on those components. One of those components is data on enforcement actions. FSIS agrees that enforcement actions are an important indicators that there has been a loss of food safety controls at an establishment, and provided that the analyses do not indicate that the data are inappropriate for use in an algorithm, this and other enforcement actions would be included in a risk-based algorithm. The factors to be used in the algorithm will be outlined in the RBI technical report.

Expected Completion Date:

The RBI technical report will be made final and available to stakeholders, following review by NACMPI and by peer reviewers, by March 17, 2008.

Recommendation No. 10

Prior to implementation, validate the accuracy of the risk-based inspection data (e.g., species, product type, publish health NRs, and control of *L. monocytogenes* in RTE product) used for calculating an establishment's level of inspection.

FSIS Response

FSIS will conduct extensive performance and functional testing of PHIS during user acceptance testing to ensure that the system operates as designed. The testing will be derived from the business processes, scenarios, and use cases defined during the Requirements Phase of the project.

Expected Completion Date:

A prototype for domestic inspection within the PHIS will run in a test environment in Q3CY08 to selected users. The nationwide production readiness for PHIS with the Domestic Module is currently scheduled for Q2CY09.

Recommendation No. 11

Institute the appropriate oversight and control during the development of critical IT systems needed to support risk-based inspection.

FSIS Response

FSIS, with the contractor, is developing a project management plan. Certified Agency project managers will assert appropriate project control using American National Standards Institute (ANSI) Earned Value Management standards to measure and control costs and schedule. The PHIS will be developed using standard software development life cycle (SDLC) practices.

Expected Completion Date:

The first version of the project management plan will be developed by December 31, 2007.

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Exhibit I *– Agency Response to the Draft Report*

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Recommendation No. 12

Develop and implement criteria for prioritizing the scheduling of food safety assessments.

<u>FSIS Response</u>

The 4-year cycle used to schedule FSAs was based on resource availability and estimates regarding FSAs needed to be performed "for cause." FSIS is currently developing a risk-based approach to prioritize FSAs that will be outlined in the RBI technical paper.

<u>Expected Completion Date</u>:

The RBI technical report will be made final and available to stakeholders, following review by NACMPI and by peer reviewers, by March 17, 2008.

Recommendation No. 14

Develop and implement a system to track changes at an establishment over time and determine which changes would trigger FSIS to conduct a food safety assessment at an establishment prior to its periodic evaluation.

<u>FSIS Response</u>

The PHIS will contain detailed data on establishment practices and performance that will be reviewed regularly and updated as needed by inspection program personnel. Data such as that which is currently being collected in the *E. coli* O157H:7 Checklist by inspection program personnel or from industry in FSIS Form 10,240, regarding an establishment's controls for *L. monocytogenes*, will be entered by inspection program personnel into the PHIS. By having inspection program personnel collect such information, FSIS will have a built-in mechanism to verify that the information is current, accurate, and verifiable. The data, analogous in purpose but greater in scope than the data in the PBIS "profile," will be considered when scheduling FSAs.

<u>Expected Completion Date</u>:

A prototype for domestic inspection within the PHIS will run in a test environment in Q3CY08 to selected users. The nationwide production readiness for PHIS with the Domestic Module is currently scheduled for Q2CY09.

Recommendation No. 15

Develop and implement procedures to ensure sufficient, timely follow-up work is performed in response to findings in food safety assessments.

<u>FSIS Response</u>

Several directives and management controls have been issued since many of the food safety assessments that were conducted under FSIS Notice 44-02 were conducted. By January 2006, approximately 2400 FSAs had been conducted in direct response to FSIS

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Exhibit I – *Agency Response to the Draft Report*

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Notice 44-02. The September 2005 FSIS directive 5100.1, EIAO comprehensive food safety assessment (FSA) methodology, instructs the EIAO to make one or more recommendations upon completion of an FSA: (1) No action needed, (2) 30-day reassessment letter, (3) NRs written by in-plant inspection team, (4) Notice of Intended Enforcement Action (NOIE), (5) Suspension/withdrawal. A recommendation is required whenever a report is complete, even if the facts do not support an enforcement action. The March 2006 FSIS directive 5100.3, Administrative Enforcement Reporting, describes the recordkeeping requirements for FSAs generated enforcement actions. The AssuranceNet management control, Function 5, documents and tracks various FSA factors, including the sufficiency of the documentation to support an enforcement action.

Expected Completion Date:

Completed.

Recommendation No. 16

Closely monitor the administration of the PHIS contract and the development, testing, and implementation of the new system to ensure it is progressing as intended and to attain satisfactory assurance that it can support the operations necessary to carry out a complex, scientifically-based risk-based inspection program.

FSIS Response

FSIS, in conjunction with the contractor, is developing a project management plan. Certified Agency project managers will assert appropriate project control using ANSI Earned Value Management standards to measure and control costs and schedule. PHIS will be developed using standard software development life cycle (SDLC) practices.

Expected Completion Date:

The first version of the project management plan will be developed by December 31, 2007.

Recommendation No. 17

Complete a comprehensive, agency-wide examination of the national, divisional and district level analytical and informational needs and establish a process to periodically reassess needs. This should include implementing management controls to specifically define what analysis and information is needed, who should perform the analysis and collect the information, who needs to be provided the analysis or information (customers), how often the information needs to be collected and analyzed, what is the most useful format to present the information or analysis to the final users, and, finally, who is responsible to ensure follow-up actions are taken to correct problems identified. The study should also include an action plan for making the necessary changes to the agency's operating procedures and the estimated timeframes for implementing these changes.

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Exhibit I – *Agency Response to the Draft Report*

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<u>FSIS Response</u>

The requirements gathering phase of PHIS, during which the Data Analysis and Integration Group (DAIG) and the contractors developing the system will meet with all program areas to identify and prioritize analytical and reporting needs will be completed January 31st, 2008.

The DAIG's report on its survey of district analysts and their roles, including recommendations on reports that they should be generating, will be completed by February 28, 2008.

The DAIG has been working with Data Coordinating Committee (DCC) members from FSIS programs to complete an FSIS Data Analysis Project Matrix. That matrix, in combination with the Data Stream and Data Sub-Stream Information Sheets being prepared by DAIG in conjunction with the DCC, will summarize what data analysis projects are being conducted by each program office, what reports are being generated, who the audience is for the reports, the distribution method used for the reports, and follow-up tracking methods (e.g., emailed to relevant individuals, posted on the FSIS website, etc.). The DAIG and DCC meet monthly, at which time the DCC members will be asked to provide any updates to the matrix and datastream/substream information sheets. The initial matrix will be completed by December 31st, 2007 (it will be continually updated based on projects being initiated and completed), and initial information sheets will be completed by April 15, 2008.

<u>Expected Completion Date</u>:

January 31, February 28, and April 15, 2008 (see above).

Recommendation No. 19

Implement management controls to ensure effective distribution and full use of the results of all data analyses and reports to other affected program areas, including field operations, in order to allow for follow-up actions to correct problems identified and to establish performance goals for inspectors.

<u>FSIS Response</u>

The DAIG has undertaken a number of activities to identify characterize, coordinate, analyze and integrate data collection and analysis needs within the Agency. Specific projects listed below and conducted in anticipation of the implementation of RBI and PHIS will be completed in the spring of 2008. Upon reviewing the results of these DAIG projects, FSIS programs will determine what management controls are necessary for the distribution and review of data analyses.

The requirements gathering phase of PHIS, during which the DAIG and the contractors developing the system will meet with all program areas to identify and prioritize analytical and reporting needs, will be completed January 31, 2008.

The DAIG's report on its survey of district analysts and their roles, including recommendations on reports that they should be generating, will be completed by February 28, 2008.

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The DAIG has been working with DCC members from FSIS programs to complete an FSIS Data Analysis Project Matrix. That matrix, in combination with the Data Stream and Data Sub-Stream Information Sheets being prepared by DAIG in conjunction with the DCC, will summarize what data analysis projects are being conducted by each program office, what reports are being generated, who the audience is for the reports, the distribution method used for the reports, and follow-up tracking methods (e.g., emailed to relevant individuals, posted on the FSIS website, etc.). The DAIG and DCC meet monthly, at which time the DCC members will be asked to provide any updates to the matrix and datastream/substream information sheets. The initial matrix will be completed by December 31, 2007 (it will be continually updated based on projects being initiated and completed), and initial information sheets will be completed by April 15th, 2008.

Expected Completion Date:

January 31, February 28, and April 15, 2008 (see above).

Recommendation No. 20

Perform an analysis of all reports currently generated (including those generated by OPPED) and determine if any would be beneficial to other divisions/levels in improving compliance and operations. Further, determine if modifications could be made to the reports to make them more beneficial to other program areas, including field operations.

FSIS Response

The requirements gathering phase of PHIS, during which the DAIG and the contractors developing the system will meet with all program areas to identify and prioritize analytical and reporting needs will be completed January 31, 2008.

The DAIG's report on its survey of district analysts and their roles, including recommendations on reports that they should be generating, will be completed by February 28, 2008

The DAIG has been working with DCC members from FSIS programs to complete an FSIS Data Analysis Project Matrix. That matrix, in combination with the Data Stream and Data Sub-Stream Information Sheets being prepared by DAIG in conjunction with the DCC, will summarize what data analysis projects are being conducted by each program office, what reports are being generated, who the audience is for the reports, the distribution method used for the reports, and follow-up tracking methods (e.g., emailed to relevant individuals, posted on the FSIS website, etc.). The DAIG and DCC meet monthly, at which time the DCC members will be asked to provide any updates to the matrix and datastream/substream information sheets. The initial matrix will be completed by December 31, 2007 (it will be continually updated based on projects being initiated and completed), and initial information sheets will be completed by April 15, 2008.

Expected Completion Date:

January 31, February 28, and April 15, 2008 (see above).

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Recommendation No. 21

Provide ongoing training to DAs on new or modified software and specific analytical techniques, including the type of data to collect, standard types of analysis to perform, format to present data, frequency of reporting the results and follow-up actions the analysts are expected to take on any adverse issues noted. Also, establish a system to track when training is taken, the type of training taken, and a system to alert the appropriate managers if the minimal levels of training are not being achieved.

<u>FSIS Response</u>

FSIS agrees and will complete the training of DAs by June 30, 2008.

<u>Expected Completion Date:</u>

June 30, 2008.

Recommendation No. 23

Provide pathogen test results data in a searchable format to the appropriate district office personnel.

<u>FSIS Response</u>

The PHIS will provide lab data in a more user-friendly format, allowing inspection program personnel to run reports providing the details of samples collected during a user-specified timeframe.

<u>Expected Completion Date:</u>

A prototype for domestic inspection within the PHIS will run in a test environment in Q3CY08 to selected users. The nationwide production readiness for PHIS with the Domestic Module is currently scheduled for Q2CY09.

Recommendation No. 25

Establish procedures to ensure that warning "flags" provided by AssuranceNet are timely and effectively followed-up on, particularly in cases in which deficiencies are repeatedly noted at the same establishment, circuit, or district.

<u>FSIS Response</u>

We agree with the need for timely and effective follow-up on "flags." FSIS will provide additional, comprehensive written guidance for managers at all levels on reviewing, analyzing and responding to AssuranceNet results. The guidance will explain which levels of performance require follow-up. Specifically, for each performance measure or grouping of "like" performance measures, we will identify performance levels at which follow-up is definitely required. This guidance will include the nature of the follow-up required, which would vary depending on the activity being measured, and the expectation for documenting the follow-up action taken and in what form. We will also provide guidance on how to use the performance measure data to identify performance

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trending downwards, and how to use the data to determine if there are "warning flags" that need attention or follow-up.

The AssuranceNet Dashboard Manager, available to the District and headquarters levels, already displays data for each measure with a "red zone", "yellow zone" and "green zone" on a speedometer-like display. If performance level is in the green zone, it is clearly meeting the performance measure threshold; if it is in the yellow zone it is meeting but trending towards not meeting the threshold; and if it is in the red zone it is clearly not meeting. These ranges were established when the system was originally designed.

In addition to providing guidance on how to use and react to the Dashboard Manager indicators, we will be providing guidance on how to interpret and react to the data displayed in the Standard Reports, which are the primary tools for determining whether or not performance measures are met, and which allow for "drilling down" further into the data to help pinpoint where the weaknesses might be. For example, there are three measures that reflect the "percent scheduled PBIS procedures performed." We expect the District to be reviewing these measures every month to ensure that each circuit is meeting the performance measure threshold. If a circuit is not meeting the measure, a review of the establishment data for that circuit would indicate which establishments are contributing to the failure. In addition, we plan to explain that that circuit performance on these measures should be compared over time to determine if one or more circuits consistently perform near or below the threshold.

As we are now looking at more detailed guidance than we had previously planned, we anticipate issuing the guidance in January 2008 rather than December 2007.

Expected Completion Date:

January 2008.

Recommendation No. 26

Provide guidance to officials, particularly at the district level, to use AssuranceNet to view performance data down to the establishment level, as well as the circuit and districts.

FSIS Response

In the additional AssuranceNet guidance to be published in January 2008, we will issue instructions in regard to "drilling down" into data below the circuit level in AssuranceNet. It should be noted that establishment level data available in AssuranceNet is captured primarily so that it can be aggregated to reflect circuit and district level performance. It is not appropriate to ensure that each "establishment level" is meeting the performance measure developed and set for a circuit or higher level. When targets are not met at the circuit level, drilling down to the establishment level may show that performance of inspection personnel at certain establishments is lower than expected, and may be contributing to the circuit level not meeting the performance target. Drilling down to the establishment level data when circuits are meeting the establishment targets is to determine if there appear to be any outliers that may require further investigation. This

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would be particularly important if a circuit's performance was just barely meeting the standard and/or was substantially different from most other circuits.

<u>Expected Completion Date</u>:

January 2008.

Recommendation No. 27

Modify AssuranceNet to monitor the completion and results of all required elements and sub-elements assessed during IPPS reviews.

<u>FSIS Response</u>

FSIS must rely on its supervisors to make the determination as to which elements and sub-elements apply to employees and to determine which elements and sub-elements they will review when they conduct IPPS visits. With regard to this recommendation specifically, we believe it would be impossible to program the AssuranceNet system to make the determination that all applicable elements were covered in the rating year for each of the 6,000 employees to which IPPS applies. Further, as inspection program personnel assignments change over time, their required elements and sub-elements change. We have designed the IPPS forms so that all possible elements/sub-elements are available for use on an IPPS assessment. The elements used depend on whether or not the employee's assignment requires performance of a given element or sub-element at that time. That is, inspection personnel may not be required to perform all of the possible elements in a given year. As such, what constitutes a complete set of elements/sub-elements for an inspector is tailored to his/her assignment at that time, and can even change during the rating year, and would certainly change if he/she changed positions in the middle of the rating year.

However, we agree that we should better ensure monitoring of all applicable elements and sub-elements each rating year. We will develop additional guidance for supervisors reviewing IPPS assessments that will instruct them to specifically focus on the extent to which elements and sub-elements are covered over the course of the year by supervisors conducting IPPS assessments. Although reviewers at higher levels would not know for certain every sub-element that would be applicable to a given employee's assignment, such a review would highlight situations in which certain commonly assigned elements may not have been covered, or where it is clear that a full complement of elements was not assessed.

<u>Expected Completion Date</u>:

This guidance will publish in an updated version of the AssuranceNet User's Guide in January 2008.

Recommendation No. 28

Implement features within AssuranceNet that will allow the system to (1) identify employees who have not worked in an IPPS-rated position for an entire rating period, and (2) identify, for corrective action, instances in which employees have not received the required IPPS reviews.

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FSIS Response

We agree with this recommendation, which has also been identified by FSIS District Office management teams as a desired feature of the AssuranceNet system. Design and implementation of a feature for tracking accomplishment of the required IPPS assessments on employees subject to IPPS is a one of several enhancements which we have established as requirements in a contract that we currently have in place to build onto AssuranceNet. The Agency and the contractor are currently working to finalize the requirements. The tracking feature will be built out and ready for implementation by May 2008. Specifically, the tracking feature will allow the user to generate a report displaying the list of individuals who have outstanding IPPS reviews. Once this feature is available, we will be able to issue instructions as to when we expect these reports to be reviewed and what action should be taken as a result of incomplete IPPS reviews.

Expected Completion Date:

May 2008.

Recommendation No. 29

Implement procedures and controls as needed to ensure that supervisors limit their use of the "follow-up" box on the IPPS review forms to instances involving documented performance deficiencies.

FSIS Response

Instructions on how to use the follow-up column on the IPPS form have been in place since 2002, when IPPS was first established. And, updated guidance is available in the AssuranceNet User's Guide and use of the follow-up box has been discussed at various meetings with supervisory field personnel. However, as a result of questions we received concerning the use of the follow-up box in AssuranceNet and reviews of AssuranceNet results, we agree that the importance of accurately using the follow-up box needs to be re-emphasized.

So, we are planning to update the FSIS Directive 4430.3, issued prior to the launch of AssuranceNet, to make more explicit the instructions on using the follow-up box. We will issue the updated Directive by February 2008.

We also plan to develop guidance for use by reviewers of IPPS assessments (Front line Supervisors (FLS), the District Management Team, and Executive Associate for Regulatory Operations (EARO)), to ensure that these oversight reviews are focused on the same factors, one of which is to determine if there is a match between the narrative comments associated with an element for which the follow-up column is checked (or not checked). This will either become a part of the guidance to be issued to managers at all levels or will be reflected in the updated version of the AssuranceNet User's Guide, both to be issued in January 2008.

Expected Completion Date:

January and February 2008.

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Recommendation No. 30

Continue the increased diligence for achieving management decision and final action on the remaining prior recommendations. In addition, apply this increased diligence to future recommendations to ensure that timeframes are met.

FSIS Response

FSIS agrees and will continue its expedited efforts to resolve and achieve final action (close) OIG recommendations. FSIS notes that since September 2007, it has closed an additional 20 recommendations and requested closure for 2 more. Additionally, the Program Development and Improvement Staff (PEIS) in FSIS-OPEER, which serves as the Agency's liaison to OIG and GAO, is implementing·a new system to notify FSIS programs monthly about their obligations to respond to and take final action on OIG recommendations, to track the results, and to produce a variety of reports for FSIS management and USDA-OCFO. PEIS will add the maintenance of this system to its own management controls.

Expected Completion Date:

OPEER-PEIS will have the new system in place and will have amended its management controls by February 1, 2008.

Recommendation No. 31

Develop and implement requirements for inspection personnel to document their reviews of establishment testing results. At a minimum, the inspection personnel should document when they reviewed the results, the type(s) of results they looked at (*E. coli* O157:H7, *Salmonella*, etc.) and the time period reviewed.

FSIS Response

FSIS will revise Directive 5000.2 to provide instructions to inspection program personnel concerning which types of industry data they should review for which types of products. The directive will provide a work method for reviewing the data, for example trends over time, and also describe documentation procedures to track the specific data, and time window, in which it was reviewed.

Expected Completion Date: ·

FSIS will revise Directive 5000.2 by September 30, 2008.

Recommendation No. 32

Ensure that inspection personnel's reviews of establishment testing are periodically verified by responsible supervisory officials and noncompliance in specifically identified in IPPS.

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<u>FSIS Response</u>

FSIS agrees and will add a sub-element to the IPPS form to capture this responsibility. This new sub-element will be available for use in May 2008. FSIS also will revise Directive 5000.2 to provide instructions to inspection program personnel concerning when they should alert their supervisor that trends indicate that the establishment may not be responding appropriately to a trend of increasing positive pathogen test results. In the revised Directive, FSIS will include instructions for how supervisors, including District Office personnel, should respond to such information from inspection program personnel. Scheduling of FSAs may be part of the District Office response.

<u>Expected Completion Date</u>:

FSIS will establish a sub-element relating to the review of establishment data in May 2008. FSIS will revise Directive 5000.2 by September 30, 2008.

Recommendation No. 33

Expedite the deployment of specific criteria to inspection personnel that provide a basis for establishing when corrective actions are inadequate and enforcement actions should be initiated for repetitive deficiencies. The criteria should also define when progressive enforcement actions should be taken.

<u>FSIS Response</u>

FSIS will revise Directive 5000.1 to include additional instructions concerning linking NRs and initiating enforcement actions. The revised directive will provide for more consistent and coordinated action if noncompliance is not corrected, persists, or recurs. FSIS intends to issue the revised directive in May 2008. In addition to a revision of Directive 5000.1, more focus will be given to the section in FSRE training for linking of NRs and evaluation of corrective actions.

<u>Expected Completion Date</u>:

May 2008.

Recommendation No. 34

Reassess the effectiveness of training programs for inspection personnel and frontline supervisors and revise the programs, as appropriate.

<u>FSIS Response</u>

FSIS will conduct a comprehensive review of the effectiveness of its training programs for inspection personnel and frontline supervisors and revise the programs as appropriate. FSIS will be conducting IPPS related activities or surveys of inspection program personnel and their supervisors following training to verify that inspectors are performing key job duties as instructed in FSIS policies and training. FSIS also anticipates developing further refresher training to reinforce inspection duties. FSIS expects to complete the comprehensive review and to initiate the revision of its training programs by the end of FY 08.

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<u>Expected Completion Date</u>:

September 2008.

Recommendation No. 35

Provide refresher training, at a minimum, to the inspection personnel and frontline supervisors assigned to establishments with the recalls (i.e., United Food Group LLC and Topps Meat Company LLC).

<u>FSIS Response</u>

Retraining/Correlation of Personnel associated with Topps: Immediately following the Topps recall, extensive "retraining" on the job was given to the FLS and the three inspectors involved. The week of October 1, 2007, a Deputy District Manager (DDM) and EIAO discussed the enforcement actions that occurred at Topps, explaining the issues and findings that led to the recall and enforcement actions. The FLS and inspectors were brought into the Philadelphia District office during the week of October 9, and sent out with high-performing FLS and CSIs who shadowed them and provided a refresher on how to perform the procedures and document findings. In the case of the FLS, not only did he receive "retraining" from the FLS on how to review establishment documentation and perform verifications of prerequisite programs and company test results, but he was also retrained on how to assess and document the performance of inspection personnel on an IPPS assessment and how to use data from AssuranceNet, PBIS and the sampling databases to determine where inspection activities/performance may not be on track. The week of November 14, the District Manager and DDM visited the Elizabeth circuit to observe the FLS conducting IPPS assessments on the three inspectors involved and observed the FLS extract and analyze data from the applicable systems and to discuss with them his interpretation of the data.

Retraining/Correlation of Personnel associated with United Food Group (UFG): The Frontline Supervisor has recently conducted three separate work unit meetings with inspection personnel at UFG. Discussion topics included: a review of the establishment's microbiological testing records; a review of the establishment's adherence to its prerequisite programs (COA's and Audit reports); a review of FSIS verification procedures; as well as a review of FSIS Notices 62-07, 65-07, 66-07, and 68-07. On October 30, 2007, the FLS conducted an IPPS assessment for the second shift inspector, and IPPS assessments are planned in the near term for all inspectors at UFG. The FLS also will be regularly reviewing reports on PBIS, LEARN and AssuranceNet to ensure that all inspection personnel at UFG are performing verification procedures as required, appropriately taking product samples, reviewing plant microbiological findings, and taking all appropriate enforcement actions. The FLS will complete training on AgLearn on FSIS Notice 65-07 by November 30, 2007. A refresher training and correlation session will be conducted by the Deputy District Manager in December 2007 for the FLS and all inspection personnel at UFG. Topics will include: verification of the prerequisite programs; proper performance of verification procedures; documentation of inspection findings; as well as a review of the FSIS Notices 62-07, 65-07, 66-07 and 68-07. In addition, the Alameda District Office has recently removed a second processing facility from the UFG assignment which will permit additional inspector time at the UFG facility.

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The lessons learned from both of these situations were incorporated into the training on FSIS Notice 65-07: specifically, a discussion on prerequisite programs and supporting documentation such as certificates of analysis and letters of guarantee.

Expected Completion Date:

October through December 2007.

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November 30, 2007

Supplemental Information in Response to Seven Recommendations from Audit 24601-0007-Hy, *Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments*

Recommendation #2

Prior to implementing a redesigned processing RBI system via the Domestic Inspection module of the PHIS, FSIS will have performed FSAs under the new configuration in all of the largest processing establishments, i.e. those that produce approximately 95% of meat and poultry products annually.   FSIS will use the results from these FSAs, along with other data, to estimate the levels of risk posed by these establishments' products to the public health. Inspection then will be allocated in consideration of these estimated levels of risk.

After the new RBI system is implemented, to estimate risk for establishments that have not yet had FSAs under the new configuration, FSIS will use data from the establishments' profile in PHIS, inspection and micro-testing results, and enforcement and other data. PHIS "profile" and "event" data will represent a significant expansion over the data currently contained in PBIS, and will include:

- information on establishment interventions and other controls from the *E. coli* O157: H7 and *Listeria monocytogenes* Checklists;
- establishment testing results
- consumer complaints;
- food borne illness investigations;
- production volume;
- other data.

Further, PHIS will raise "flags" based on establishment profile and other data indicating the possible need for an FSA in these establishments, regardless of their production volume. So, immediately after the implementation of the PHIS, PHIS profile and other data will be used not only to estimate risk and allocate inspection resources but also to prioritize FSAs for smaller volume establishments that have not yet had FSAs under the new configuration.

The DAIG RBI Technical Paper and the business process documents for the new FSAs and the "in-plant inspection area" of the PHIS will detail the content of the new FSAs; the range of data to be contained in the Domestic Inspection module of PHIS; the PHIS flags, which are raised based on establishment "profile" and "event" data and that indicate the possible need for an FSA; and the algorithm used for calculating establishment risk.

November 30, 2007

Timeline

1/4/08	Report to NACMPI Subcommittee on RBI Technical Paper
1/25/08	Receive NACMPI comments on RBI Technical Paper
2/4/08	Revise RBI Technical Paper to address NACMPI comments
2/5/08	Post RBI Technical Paper for stakeholder comment
2/5/08	Send RBI Technical Paper to peer review
2/28/08	Delivery (by contractor) of Systems Requirement Documents to FSIS containing the business processes for the new FSA configuration and "in-plant inspection," which includes the establishment profiles and "flags" indicating the possible need for FSAs (FSIS will be able to request modifications, based on pilots of the new FSA configuration and other Agency work, as the contractor develops use cases for PHIS software development.)
2/28/08	Receive peer review comments on RBI Technical Paper
3/5/08	Receive stakeholder comments on RBI Technical Paper
3/17/08	Revise RBI Technical Paper to address peer review and stakeholder comments and finalize
3/21/08	Delivery (by contractor) of the "Requirements Definition" for the PHIS system
3QCY2008	Implement PHIS Test environment for selected users
12/1/2008	Determine method for using FSA results in RBI algorithm
Q2CY2009	Put Domestic Inspection Module of PHIS in nationwide production readiness

Recommendation #3

FSIS is developing a new, more comprehensive FSA configuration and will incorporate it into the Domestic Inspection module of the PHIS. FSAs conducted under the new configuration will be scheduled, in part, using "flags" in PHIS data that show public health risks indicating the possible need for an FSA at an individual establishment. The FSA results, in turn, will be fed into PHIS to help FSIS managers to better estimate the risks posed by an establishment's products and allocate inspection resources accordingly.

New FSA Instrument

The new FSA reporting instrument consists of sections containing a series of data gathering and data analysis questions tailored to the specific food safety hazards and regulatory requirements associated with each HACCP 03 process (e.g. "03B Raw Product-Ground"). Below is a list of key enhancements of the new FSA reporting instrument.

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November 30, 2007

- The new FSA instrument will be web based and interact with the new Domestic Inspection System to obtain needed profile data. Information obtained during the FSA such as process flow diagram, CCP's, identified hazards, pre-requisite programs, interventions, validation strength, sampling programs, testing programs, and other valuable data can be imported into the Domestic Inspection System plant profile. This will consolidate valuable plant data.
- The FSA instrument will consist of questions to both help structure an EIAO's investigation reporting but also provide consistent information for analysis purposes to inform policy and inspection resource allocation.
- Sections consist of questions for each HACCP 03 category and additional agency needs (food defense, dual jurisdiction and sanitation) to collect pertinent data for each type of process that can be incorporated into the plant profile.
- The new FSA will have questions that are data gathering and also questions that prompt the EIAO to analyze the collected data and explain their findings, referencing establishment documents as support for potential enforcement actions. This structure will facilitate enhanced critical thinking by EIAOs.
- There will be a quantification aspect using questions pertaining to an establishment's controls and validation incorporated into the new Domestic Inspection System to inform the Predictive Analytics Module on how to prioritize future inspection and other verification activities with in the Domestic Inspection Module.
- The most current FSA report information will be incorporated into the new Domestic Inspection System profile making it possible for inspection program personnel to periodically reevaluate the information for accuracy and alert the District Office when changes occur, potentially triggering an EIAO visit to follow up on a specific aspect of the food safety system
- The new Domestic Inspection Module will also contain criteria for prioritizing FSA scheduling and a tracking system to ensure FSAs for cause are getting performed and that all relevant plants are assessed at least every 4 years.

The programming of the new FSA configuration will begin in February, as business requirements for the FSA instrument will be made final with the contractor on or by January 31, 2008. As programming of the FSA instrument progresses, refinements to the configuration, suggested by pilot testing, will be made by the contractor. FSIS is currently testing the new FSA configuration in the Philadelphia District. Because the PHIS is not yet implemented, the test is being conducted using paper forms. Review of the FSAs conducted using the new instrument in the Philadelphia District and related refinements of the paper instrument will be completed by February 15, 2008. FSIS will continue to pilot the paper FSAs in the Districts and will have piloted it in all Districts by the time the prototype for domestic inspection within the PHIS runs in a test environment in Q3CY08. As a result, District Offices and EIAOs will be familiar with the new FSA configuration and, again, any refinements suggested by the pilot can be passed on to the contractor.

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November 30, 2007

FSA Flags

The PHIS Domestic Inspection Module will contain triggers, or "flags," that alert District Office personnel that an FSA may be necessary in an establishment. The flags could be data driven from the inspection transaction data from PHIS, data from the data warehouse such as sampling results, or establishment profile data. Events that could indicate the need for an FSA will likely include:[1]

- Scheduled RLM Sampling
- CCMS Complaint
- Produced and Shipped Adulterated Product that impacts public health. This information could come from the establishment, inspection program personnel, or other state, federal, local or foreign government agency[2]
- Positive first LM FSIS (ALLRTE and RTE001) or other Federal, State, local, or foreign government Agency Sample on RTE (ALLRTE and RTE001)
- Positive first *E. coli* O157:H7 FSIS or other Federal, State, local, or foreign government Agency Sample on RTE, raw ground beef, raw ground beef component, tenderized beef, marinated beef, or injected beef (03B)
- Positive *Salmonella* FSIS (ALLRTE or RTE001) or other Federal, State, local, or foreign government Agency Sample on RTE product
  Salmonella FSIS PR/HACCP Sample set with medium (M) or high (H) number of positive samples with serotypes of human health significance according to the product class
- Inspector generated recommendation for an FSA due to Repetitive NR's citing regulations associated with public health or recurring issues that indicate a food safety concern
- New establishment
- SRM Violation
- Foodborne Illness Investigation
- DO discretion due to an event not addressed above that may lead to the production and shipment of adulterated product which may come from another federal, state, local or foreign agency
- FSIS HQ directed due to policy change or event of public health impact

The business requirements for the in-plant inspection portion of the Domestic Inspection modules, which will contain these flags, will be made final with the contractor on February 28, 2008.

Using FSA Results to Calculate Establishment Risk

The FSIS Data Analysis and Integration Group (DAIG) is developing an algorithm for estimating risk posed by the products from establishments, which can be used to allocate inspection resources based on risk. The algorithm ultimately will be part of a module of the PHIS containing predictive analytic tools. The DAIG will publish a peer-reviewed RBI Technical Paper

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[1] Note that the events triggering flags and the method for interpreting them are still under development.
[2] Linking to external sources of pathogen test result information will be an incremental process. PHIS will be programmed to collect data first from existing links first, such as data from other agencies in USDA, and programmed to collect data from other sources as the links are completed.

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November 30, 2007

by March 17, 2008, which will outline the algorithm. In regard to FSA results data, the paper will discuss:

- the FSA results data under the new configuration;
- DAIG plans for using it an algorithm to estimate establishment risk;
- the limitations of FSA results data in calculating establishment risk and DAIG plans to mitigate those limitations; and
- DAIG plans to test FSA results data during the operation of PHIS in a test environment in 3QCY2008.

The DAIG will have developed the method for incorporating those results into the RBI algorithm, after testing FSA data, by December 1, 2008.

Timeline

1/4/08	Report to NACMPI Subcommittee on RBI Technical Paper
1/25/08	Receive NACMPI comments on RBI Technical Paper
2/4/08	Revise RBI Technical Paper to address NACMPI comments
2/5/08	Post RBI Technical Paper for stakeholder comment
2/5/08	Send RBI Technical Paper to peer review
2/15/08	Review of FSA results from test in Philadelphia District complete
2/28/08	Delivery (by contractor) of Systems Requirement Documents to FSIS containing the business processes for the new FSA configuration and "in-plant inspection," which includes the establishment profiles and "flags" indicating the possible need for FSAs (FSIS will be able to request modifications, based on pilots of the new FSA configuration and other Agency work, as the contractor develops use cases for PHIS software development.)
2/28/08	Receive peer review comments on RBI Technical Paper
3/5/08	Receive stakeholder comments on RBI Technical Paper
3/17/08	Revise RBI Technical Paper to address peer review and stakeholder comments and finalize
3/21/08	Delivery (by contractor) of the "Requirements Definition" for the PHIS system
3QCY2008	Implement PHIS Test environment for selected users
12/1/2008	Determine method for using FSA results in RBI algorithm
Q2CY2009	Put Domestic Inspection Module of PHIS in nationwide production readiness

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November 30, 2007

Recommendation #5

FSIS is developing a technical report that will outline, in detail, the basis for decisions made regarding the components included in the risk-based inspection program. The report will outline the limitations of the data, and how those limitations affect the use of the data in risk-based inspections. All effort will be made to decrease the limitations in the data, including incorporating data analysis plans into directives and notices to emphasize the importance of the data, and training. (However, it is important to note that all data has limitations, the limitations must be stated and the subsequent uncertainty resulting from those limitations should be discussed, but not all limitations preclude the use of data.) The technical report will be peer reviewed according to OMB's peer review guidelines, shared with stakeholders, including NACMPI, and modified in response to comments prior to implementation of RBI in processing.

Recommendation #14

We agree on the need for this recommendation item, and fully intend to carefully track its execution on an ongoing basis. FSIS will conduct an assessment of the "flags" in PHIS to determine a process and a hierarchy for their use in scheduling FSAs. Prior to the implementation of PHIS, OFO will communicate the process for following-up on any PHIS flags to District Managers and other field employees. FSIS also will establish management controls for the EAROs to review the DM management of FSA scheduling.

Recommendation #15

FSIS will update FSIS directive 5100.1 to include a work method for verification plans. Currently, that information is only contained in the EIAO training material. The updated directive will also describe a work method to address other FSA findings that do not become part of a formal enforcement action. FSIS intends to publish this revision to this directive by May 2008.

Recommendations #31 and #32

FSIS can incrementally move up the dates for instructing inspectors to document plant test result reviews. Before the high prevalence season for *E. coli* O157:H7 (i.e., prior to April 2008), we will either issue a new FSIS Directive or a new FSIS Notice specific to O157. By July 2008, for *L. monocytogenes* in product subject to 9 CFR 430, we will either issue a new FSIS Directive or a new FSIS Notice. We will address other test results (e.g., zero tolerance, generic *E. coli*, *Salmonella*) by September 30, 2008.

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