U.S. Department of Agriculture

Office of Inspector General
Midwest Region

Audit Report

Food Safety and Inspection Service
Use of Food Safety Information Systems

Report No. 24601-0003-Ch
SEPTEMBER 2004

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington, D.C. 20250

DATE: September 30, 2004

REPLY TO
ATTN OF: 24601-0003-Ch

SUBJECT: Food Safety and Inspection Service - Use of Food Safety Information Systems

TO: Dr. Barbara J. Masters
Acting Administrator
Food Safety and Inspection Service

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

This report presents the results of our audit of the Food Safety and Inspection Service's Use of Food Safety Information Systems. The response to the official draft report is included in its entirety as exhibit A, with excerpts and the Office of Inspector General's position incorporated into the Findings and Recommendations section of the report.

Based on the response, we have reached management decisions on Recommendations Nos. 6 and 10. Please follow your agency's internal procedures in forwarding documentation for final action to the Office of the Chief Financial Officer. We have not reached management decisions on Recommendations Nos. 1, 2, 3, 4, 5, 7, 8, and 9. Management decisions on these recommendations can be reached once you have provided us with the additional information outlined in the report sections OIG Position following each recommendation.

In accordance with Departmental Regulation 1720-1, please furnish a reply within 60 days describing the corrective actions taken or planned and the timeframes for implementation of those recommendations for which management decisions have not yet been reached. Please note that the regulation requires that management decisions be reached on all recommendations within a maximum of 6 months from report issuance.

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

Attachment

Executive Summary

Use of FSIS Food Safety Systems

Results in Brief

Information systems are critical to the Food Safety and Inspection Service's (FSIS) oversight of meat and poultry establishments. These systems house a vast amount of food safety data, which FSIS uses to monitor establishments' compliance with Federal health and safety regulations. The systems alone, however, cannot ensure that FSIS will detect serious problems that could lead to product recalls. Our review disclosed that FSIS has not developed an effective management control process for making sure that it uses its information systems and the important data they store to the fullest extent.

Following the massive ConAgra recall in 2002, OIG pointed out FSIS' need to establish an effective management control process for handling food safety data. FSIS responded that inspectors have real-time access to all available inspection data generated for their respective establishments. However, we identified the need for more effective coordination and information sharing between FSIS Headquarters, the agency's Technical Service Center (TSC), and the district offices. At the time of our fieldwork at the districts, Headquarters had not issued instructions to the TSC regarding its responsibility to distribute important monthly exception reports to the districts. Furthermore, Headquarters had not communicated with the TSC regarding how it could improve the reports**.** Thus, even after the ConAgra recall, the absence of an effective management control process inhibited the flow of food safety information and feedback.

In addition, FSIS has provided little in the way of hands-on training or written procedures on how to analyze food safety data to those responsible for using that data to recognize trends and take action that could prevent a recall. At the district level, FSIS has not adequately instructed personnel to use the extensive information available through the Performance-Based Inspection System (PBIS), the agency's inspection scheduling and result reporting system. We determined that inspection personnel relied on their own judgment to interpret and act on compliance data presented in the PBIS standard reports, meaning that inspectors' opinions of what is acceptable and unacceptable at FSIS-inspected establishments may differ. In addition, many front-line supervisors and district officials we interviewed did not know how to operate ProClarity, a data-mining software tool for creating specialized reports with PBIS data. Although FSIS has made the Corporate Sybase database and the accompanying software available to inspection personnel, it needs to make a greater effort to ensure they use those resources consistently and effectively.

Also of concern, FSIS has not provided a comprehensive plan for the Office of Program Evaluation, Enforcement, and Review's (OPEER) to monitor the agency's development of a management control process as was stated in response to earlier audit reports. For 2004, FSIS has directed OPEER to review the agency's In-Plant Performance System (IPPS), a personnel management tool for front-line supervisors and the inspectors they oversee**.** By not including Headquarters, the district offices, and the TSC in its reviews, OPEER cannot obtain a comprehensive picture of the agency's progress in developing a management control process or making effective use of its food safety data. Furthermore, FSIS has not developed any written plans or procedures detailing how OPEER will accomplish this assignment.

We also found several ways in which FSIS could improve the information systems themselves. For example, FSIS' District Early Warning System (DEWS) often failed to issue "early warnings" before product recalls and did not issue followup alerts if a problem identified by the system was not resolved promptly. Since FSIS implemented DEWS in April 2002, the agency had not reviewed or modified the system. Although DEWS generated numerous alerts that may have prevented serious health and safety problems at inspected establishments, the 11 product recalls that were not preceded by DEWS alerts between April 2002 and October 2003 indicate the need to review the system's effectiveness. At the exit conference, FSIS officials informed us that the DEWS system had been taken out of service because the information it provided was available through PBIS and PREP, and could be accessed directly through other means. However, the officials we interviewed concurred with our observation that, unlike DEWS, the measures currently in place do not provide automatic warnings of potential problems, but rather require system users to perform their own reviews.

FSIS' principal system, PBIS, also needs additional controls for tracking serious noncompliance records (NRs), such as fecal material on carcasses. None of the PBIS reports specifically categorizes fecal material NRs, which are associated with *E. coli* O157:H7 contamination, allowing inspectors to easily pinpoint them. Because of the lack of this capability, PBIS is not as effective as it could be in identifying serious noncompliance trends at inspected establishments. Also, due to a limited data exchange with PBIS, the agency's Pathogen Reduction Enforcement Program (PREP) does not increase *E. coli* O157:H7 testing when inspectors report problems with fecal material contamination at meat and poultry establishments. Until PREP is able to draw noncompliance information directly from the main PBIS database, this problem could increase the risk of products contaminated with dangerous pathogens entering commerce.

Finally, to preserve the continuity of its IT operations, FSIS needs to develop all required system documentation, such as data dictionaries and system flowcharts, to support PBIS and the agency's other systems. Without such documentation, some employees may not be able to perform risk assessments and other analyses to evaluate the systems' effectiveness, and new employees may come to an incomplete or incorrect understanding of the systems' operations.

Recommendations In Brief

To establish an effective management control process for accumulating and analyzing food safety data, we recommend that FSIS:

- Develop a comprehensive management control process that defines the responsibilities of each management and operating level and provides guidelines for regular communication and coordination.

- Provide guidelines and hands-on training to FSIS inspectors and supervisors to use in analyzing data available through PBIS and other systems.

Additionally, to improve the effectiveness of its information systems (particularly their ability to identify problems that could lead to product recalls), FSIS should:

- Periodically review the effectiveness of FSIS' early-warning system, and implement a system to track the status of unresolved system alerts;
- Code noncompliances in PBIS by type so that inspectors and supervisors can more readily identify the most hazardous NRs, such as fecal material contamination;
- Establish data exchange between PBIS and PREP to allow PREP to increase sampling based on fecal material noncompliances; and
- Develop all required system documentation, particularly data dictionaries and system flowcharts.

Agency Response

In their response to the official draft report dated September 30, 2004, FSIS officials stated that they are in the process of updating FSIS' management control program. They also described several other actions they are taking to increase their oversight of inspectors' activities, such as creating District Analyst and Case Management Specialist positions.

Regarding the use of key information systems, FSIS officials stated that each system was developed and implemented with a specific purpose in mind and, as such, they believed that OIG reviews should evaluate them on that basis

rather than on what additional functions the systems should be accomplishing. They also stated that their systems were not designed to predict product recalls; however, agency officials stated that they are establishing an analytical capacity within the recall management function to review and analyze product recall cases. Their response is provided in its entirety as exhibit A of the report.

OIG Position:

Section 1 of this report describes our issues with FSIS' management control process. We concur with FSIS officials regarding the need to update their management control program, and we will continue working with them as we have over the past several months to ensure that controls over inspection activities are strengthened.

Section 2 of the report describes our review of the guidance and training provided to FSIS inspectors and front-line supervisors. We believe that creating District Analyst positions within each district will provide additional support to field managers and supervisors in their oversight of inspection activities. However, we do not agree that this eliminates the need for additional written guidelines, to assist managers and supervisors in determining whether information appearing in PBIS and other reports could be indicative of serious problems. We believe that such guidelines are needed to assist managers and supervisors in performing critical reviews of inspection activities using the information systems.

Section 3 of the report describes the results of our review of FSIS' own use of key information systems to oversee inspection activities. We cannot agree with FSIS officials' position that we should evaluate the systems only in terms of the functions they were originally designed to perform, particularly where opportunities clearly exist for the systems to provide needed support to the agency in its oversight of meat and poultry establishments.

Abbreviations Used in This Report

DEWS	District Early Warning System
FSIS	Food Safety and Inspection Service
GAO	Government Accountability Office
HACCP	Hazard Analysis and Critical Control Point
IPPS	In-Plant Performance System
IT	Information Technology
LEARN	Laboratory Electronic Application for Results Notification
NOIE	Notice of Intent to Enforcement
NOS	Notice of Suspension
NR	Noncompliance Record
OIG	Office of Inspector General
OPEER	Office of Program Evaluation, Enforcement and Review
PAIT	Program Analysis and Information Technology
PBIS	Performance Based Inspection System
PREP	Pathogen Reduction Enforcement Program
TSC	Technical Service Center
USDA	United States Department of Agriculture

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Background and Objectives

Background

The Secretary of Agriculture established FSIS to ensure that the Nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged. Over 7,600 full-time FSIS inspectors monitor the slaughter and processing of meat and poultry products at approximately 6,500 establishments nationwide.

Implemented in 1989, PBIS provides FSIS personnel a risk-based method of scheduling and reporting on inspection tasks at meat and poultry establishments. After inspectors enter results of each onsite inspection into the system, PBIS generates establishment performance reports that FSIS can use to evaluate the establishment's sanitation level and other factors. FSIS' adoption of the landmark Hazard Analysis and Critical Control Point (HACCP) system on July 25, 1996, changed the agency's overall operations and required a new version of PBIS. FSIS issued the PBIS 5.0 user's manual for inspectors in March 2002.

In addition to PBIS, FSIS uses several other information systems to produce analytical sample results and establishment testing reports. PREP is designed to schedule, track, and report testing information on raw and ready-to-eat (RTE) products in relationship to *Salmonella* performance standards, *E.coli* O157:H7 and RTE testing programs. The Office of Public and Science (OPHS) generates PREP reports that are distributed through its Laboratory Sample Management Reports. In addition, OPHS generates ad hoc reports that are sent to the Technical Service Center for distribution. DEWS (which the agency removed from service following the end of our fieldwork) was designed to alert Headquarters and district managers of changes in establishments that might need further investigation. The system's purpose was to retrieve pertinent information from the PBIS and PREP systems, and then issue an e-mail alert to Headquarters and district managers.

The TSC opened in May 1997 to provide technical assistance and guidance to FSIS inspection employees. The TSC generates a series of monthly exception reports using PBIS data, which show establishments' compliance with Federal meat and poultry regulations.

OIG recently completed an audit (Audit No. 24601-2-KC,[1] issued September 2003) that assessed FSIS' actions in response to the large ConAgra recall. This audit, as well an audit by the Government Accountability Office (GAO-

[1] [1] Audit Report No. 24601-2-KC, "Food Safety and Inspection Service Oversight of Production Process and Recall at ConAgra Plant," dated September 2003

02-902, issued August 2002), highlighted the need for FSIS to improve its management controls over the inspection process. FSIS agreed to strengthen its policies and controls, citing its IT systems as key elements in addressing the audit recommendations.

Objectives

The objectives of this audit were to identify the information systems FSIS uses in conducting its domestic inspection programs at meat, poultry and egg establishments, and to evaluate (1) the effectiveness of the agency's policies, procedures, and instructions for utilizing the systems, and (2) the adequacy of the systems as designed to perform their assigned tasks, particularly in identifying problems at inspected establishments. We also assessed the applicable controls and procedures in relation to FSIS' responses to the GAO and OIG audits.

Findings and Recommendations

Section 1. Management Control Process

Finding 1 — FSIS Needs To Establish A Management Control Process For Effective Coordination Between Headquarters And Field Units

In its report on the ConAgra recall, OIG recommended that FSIS establish a management control process to provide FSIS inspectors with all available data necessary to perform their monitoring functions at meat and poultry establishments. Although FSIS agreed with OIG's recommendation, we found that the agency had not established the controls or oversight essential for a truly effective management control process. As a result, even with the aid of the IT systems cited in its response to the ConAgra audit, FSIS may not always be able to identify significant noncompliance trends at inspected establishments before they escalate into situations that could threaten public health and safety.

In its initial and followup responses to the ConAgra report, FSIS named several groups that would play a role in accumulating and analyzing compliance data: inspection personnel, front-line supervisors and district officials, the TSC, and Headquarters officials. FSIS also assigned its OPEER to monitor the management control process, specifically the agency's IPPS. However, FSIS has not developed a set of written procedures to specify each group's responsibilities for data collection, analysis, and monitoring. FSIS also needs to develop procedures to ensure regular communication and coordination between these groups to ensure the most effective use of the agency's IT systems. In discussions held in December 2003, an agency official generally agreed with the need for a system of controls but could not provide any specific plans or timeframes for implementation.

FSIS Needs To Improve Coordination Between Headquarters, the TSC, and the Districts

Although the TSC was preparing a series of monthly exception reports based on PBIS data at the time of our review, it was providing the reports to FSIS Headquarters only, without distributing them to the district offices. FSIS Headquarters had not issued written instructions to the TSC regarding its responsibilities for report distribution, nor had it established a process to review the exception reports and offer feedback to either the TSC or the district offices directly affected by the reports. Without an effective process

for sharing and reviewing important food safety data, FSIS may not detect and avoid problems such as those that resulted in the ConAgra recall.

In its response to OIG's ConAgra report, FSIS wrote that it had "judiciously implemented this process [the TSC's distribution of reports to Headquarters and the districts] to make decision-support information available to the inspection personnel."

Reports Not Distributed to Key Personnel

In its response to OIG's ConAgra report, FSIS officials stated, "the Technical Service Center collects and analyzes…data from a number of sources, including PBIS. They provide reports to senior officials in Headquarters and at the district level. The reports include non-compliance summaries, sample results, trend analyses, and various operational data summaries."

We found that the TSC, as directed by FSIS Headquarters, produces a series of eight monthly reports based on PBIS data. Unlike the standard PBIS reports generated in the districts, these are "exception reports," intended to identify areas that may require immediate attention or followup action by FSIS managers. For instance, one of the reports lists the 5 establishments in each district with the highest percentages of noncompliances, while a similar report identifies the 50 establishments with the highest noncompliance percentages nationwide. Another example is the "Zero-Noncompliance" report, which identifies establishments for which FSIS has issued no noncompliance reports (NRs) during the past three months.

Although district and field personnel could have benefited from some of the exception reports, the TSC had been distributing them only to FSIS Headquarters at the time of our audit. Managers at the two district offices we visited had not received the TSC exception reports, and prior to our visits one was unaware they existed. One district office, in fact, had used a time-consuming manual process to prepare its own equivalent to the Zero-Noncompliance report because district officials believed it could indicate problems at operating meat and poultry establishments. As noted in Finding 3, district office personnel could have produced the report more quickly and efficiently if they had greater familiarity with the ProClarity data-mining software. However, in this instance, it should not have been necessary for the district office to produce its own version of a report that was already being prepared monthly by the TSC.

We interviewed four of the Headquarters officials who received the TSC reports every month. One of these officials stated that the reports were not used; the remaining three stated that they reviewed the reports every month

and provided feedback as needed to the district offices. However, the officials did not maintain documentation of that feedback.

No formal procedures existed to require the TSC to share reports with the districts, or Headquarters officials to document their communications with the districts regarding potential problems presented in the reports. Consequently, the district officials who could have most directly benefited from the reports did not even know of their existence, and thus could not take action to follow up on any information they contained regarding establishments in their districts.

FSIS officials noted that, following our visits to the districts, the TSC had been instructed to include the district offices in its distribution of the eight exception reports.

Additional Analysis Needed

As noted above, FSIS' response to the ConAgra report stated that the TSC was "analyzing" data obtained from PBIS. However, we found that while the TSC was using PBIS data to produce monthly exception reports, TSC personnel did not routinely perform their own analysis of the information except to collate and summarize the reports. TSC officials stated that Headquarters had not offered them feedback on how they could improve the monthly reports or make them more beneficial to users in Headquarters and in the field. According to the TSC officials, they did provide such services to the districts when requested, but this was not a frequent occurrence.

In our own reviews of the TSC exception reports, we noted instances where the reports could have been enhanced for greater effectiveness. For example, we noted that the TSC's Zero-Noncompliance report included all inspected establishments in a particular district that had received no NR's in the last 3 months. However, in discussions with district office personnel, we found that while it was considered unusual for a slaughtering or processing establishment to meet this criterion, it was not unusual for an inspected warehouse. In reviewing some of the Zero-Noncompliance reports with district personnel, we found that a significant portion of the listed establishments were in fact warehouses. District personnel or front-line supervisors would thus need to manually review the report to identify establishments that required followup. This process could be eliminated if the TSC produced a version of the report that excluded warehouses, an idea that might have been brought to the attention of TSC officials through regular analysis and feedback.

While FSIS has the resources to form the basis of a working management control process, the agency needs to ensure that all units are communicating information to one another as needed and coordinating their actions to achieve the maximum benefit. To do this, the agency needs to develop written procedures that specify the roles and responsibilities of each level.

Role Of OPEER Needs To Be Enhanced

Although FSIS officials stated that they had designated OPEER to monitor the agency's progress in developing a management control system, little oversight has been exercised to date. We attributed this to the fact that FSIS has not developed written procedures defining exactly what the proposed management control system will entail, or the process by which it will be implemented. Until FSIS addresses these challenges, OPEER cannot adequately fulfill its monitoring responsibilities. Although OPEER will be reviewing IPPS in 2004, this is only one aspect of the overall system that FSIS needs to develop and which OPEER would need to monitor.

OPEER's mission is to enhance FSIS' evaluation, review, assessment, investigation, enforcement, and audit capacity in order to improve management effectiveness, efficiency, and decision-making. OPEER has five units, four located at FSIS Headquarters and the other co-located with the TSC in Omaha, Nebraska. In the agency's initial response to OIG's ConAgra report, FSIS officials stated that OPEER had been assigned to monitor the agency's progress in developing a management control process through audits, evaluations, and reviews.

However, FSIS has not developed written procedures to define the recommended management control process or timeframes for implementing it. As a result, we question the effectiveness of any evaluations or reviews OPEER might conduct at this point. We interviewed OPEER officials both at Headquarters and at the Omaha office to determine what assignments FSIS management had given to them. We found that the OPEER's Headquarters office has been assigned to complete a review of the IPPS guidelines by the end of FY 2004, while the Omaha office has been assigned the task of performing State-equivalency reviews.

The IPPS guidelines, which FSIS described in its response to the ConAgra report as "integral to the Agency's management control system in the field," were designed for front-line supervisors to follow in overseeing and evaluating the job performance of FSIS establishment inspectors. However, the IPPS guidelines do not describe any management control process above the front-line supervisor level. They do not address the problems of communication and coordination between the various operating units as

described in Finding 1, nor do they contain guidelines for higher management levels to ensure that FSIS' inspection programs are working effectively.

As discussed with FSIS officials in December 2003, the IPPS guidelines by themselves do not constitute the management control process that previous OIG and GAO audits have strongly indicated a need for, and an OPEER review of these guidelines in 2004 would therefore address only one aspect of what is needed overall. One FSIS official agreed with this, while another explained that their written response pertained solely to the circumstances surrounding the ConAgra recall rather than to FSIS operations nationwide.

FSIS officials noted at the exit conference that the statements they made in response to the ConAgra report applied to that audit alone, and questioned their relevance to this audit. The comments OIG has made in this report as they relate to our prior audit of ConAgra are relevant to the issues being reported herein because FSIS has represented the PBIS and other systems, as well as monitoring by OPEER, as critical elements of its management controls over field inspection operations. This audit has disclosed that these functions, as represented by FSIS, have not been adequately established, documented, or effectively implemented.

In order for OPEER to perform a meaningful oversight role, FSIS must first develop written procedures and timeframes for developing a comprehensive management control process as described in Finding 1. FSIS will then need to expand OPEER's oversight role to include monitoring of all aspects of the new system's implementation, which may entail reviews at Headquarters, the districts, the TSC, and inspected meat and poultry establishments.

Recommendation No. 1

Develop a comprehensive management control system that defines the responsibilities of each management and operating level associated with meat and poultry establishment inspections, including procedures for regular communication and coordination between units.

Agency Response.

FSIS officials agreed with the need for enhancing management controls in certain areas, and for better defining their program of oversight. They stated that they would establish a management control accountability model that will produce clear performance standards and measures for both individual and organizational performance. Once these standards are developed, the agency will define the key functions to be addressed by each district office, and describe how each function is to be verified. After establishing key

functions, FSIS will document the details for monitoring and measuring the function, implement the model for organizational performance, and evaluate the model to determine if it is functioning as intended. Work is underway to define the key functions, and agency officials expect to complete the design of the accountability model by April 2005. The target date for full implementation of the Field Operations management control system is fiscal year 2006.

In addition, the agency will revise FSIS Directive 1090.1, revision 2, *Management Controls*, to include detailed instructions for FSIS programs to apply a more rigorous and comprehensive management control system that will encompass administrative controls to ensure operational efficiency and adherence to managerial policies and applicable laws. The revised directive will incorporate GAO's Standards for Internal Control in the Federal Government and the Internal Control Management and Evaluation Tool, and will provide explicit instructions for use by program managers. The revised directive will be issued by April 2005.

OIG Position.

We concur with the agency's plan of action. However, before management decision can be reached, we need to review the draft procedures. We remain available to work with FSIS during the development of the agreed-upon processes.

Recommendation No. 2

Include provisions in the management control system for the TSC to perform independent analyses of inspection and establishment data collected through the IT systems, and to provide the results of its analyses and exception reports as appropriate to Headquarters and the field.

Agency Response.

FSIS officials stated that the comprehensive management control system will pay close attention to the key components for information, communications, and monitoring in order to strengthen communications and foster continuous improvement. They stated that the agency will include provisions for formal reporting of analysis to Headquarters, the TSC, and district offices. The management control system will also provide timely feedback to program managers. FSIS officials expect to implement the management control system in fiscal year 2006.

OIG Position.

We agree with the agency's plan of action. However, before management decision can be reached, we need to review the draft procedures related to the role of the TSC.

Finding 2 FSIS Needs To Improve Guidance and Training of Field Personnel

Although the agency's IPPS guidelines state that both establishment inspectors and front-line supervisors should be performing trend analyses using data available through PBIS 5.0, the guidelines do not indicate how this should be accomplished. In addition, the front-line supervisors and district officials we interviewed generally did not consider themselves proficient in using FSIS' data-mining software. These problems existed because FSIS had provided inspectors and supervisors with little guidance for interpreting PBIS data and insufficient training for using the ProClarity data-mining software. As a result, FSIS personnel may not be able to recognize problems at meat and poultry establishments and take appropriate action that could prevent a product recall or other serious health and safety problems.

In response to OIG's ConAgra report, FSIS officials stated that their inspectors "have real-time access to all available inspection data generated for the respective establishment that they are working on. This data is in the PBIS database. Inspection personnel use this data and other sources in their verification activities." The response further stated that FSIS personnel "…have regular access to the PBIS database and related reports."

In addition to scheduling tasks for inspectors to perform at meat and poultry establishments, the PBIS 5.0 system collects significant quantities of inspection data and organizes the results into a series of five "standard reports." These reports document information such as the numbers of scheduled inspection tasks (including how many were performed and not performed), unscheduled tasks, acceptable results, and noncompliances. FSIS inspectors are trained to enter specific information into PBIS and to produce the five standard reports. Depending on the user's level of authorization, these reports can cover operations at an individual establishment, or at the circuit, district, and national levels.

The inspectors and front-line supervisors we interviewed routinely printed out the standard reports and used them, as one inspector told us, to "keep track of establishments' performance." However, the agency had not developed guidance for interpreting the reports or numerical ranges to help inspectors and supervisors identify potential problems. For example, FSIS personnel could use additional guidance when reviewing the PBIS "Trend Indicator Summary," which presents data on a variety of inspection activities

for a particular establishment or establishments over a given period of time. Specifically, the report shows numbers and percentages of noncompliances issued by the inspector for sanitation and HACCP activities and sorts them into general noncompliance trend indicator categories such as Monitoring, Recordkeeping, Implementation, and Verification. According to FSIS, the report "allows inspection personnel to easily monitor plant trends."

However, we found that the Trend Indicator Summary could be both complex and time-consuming to interpret and use. For instance, while the report lists the number of NR's issued under each category, it is not an "exception report" and thus does not automatically guide an inspector or front-line supervisor to areas where the number or type of NRs would indicate a particular problem. For instance, in one district-level Trend Indicator Summary we reviewed, the percent of scheduled inspection tasks not performed by the inspectors varied from 1.2 percent at one establishment to 20.9 percent at another establishment. On the same report, the number of inspection procedures for which the inspectors had failed to report any feedback totaled 58 at one establishment and 212 at another establishment. Without prescribed ranges to indicate acceptable and unacceptable values or percentages for a given inspection category, FSIS personnel must rely on their judgment to interpret the reports and determine areas that may require additional monitoring or other followup action.

In most cases, FSIS field personnel were provided with only the PBIS user's manual and basic training on using the system. This training concentrated on how to input information correctly into the system, and the inspectors we interviewed told us they were comfortable with their level of knowledge in this regard. However, both inspectors and supervisors stated that they had to rely on their own judgment to assess and act on information in the Trend Indicator Summary and the other standard reports. One inspector told us that he had developed his own guidelines for interpreting such data over the course of his career. Other inspectors' criteria for interpreting the reports could be very different. One supervisor told us that, although he had looked at Trend Indicator Summaries, he was "unable to get much out of the report."

While FSIS personnel indicated that they knew how to work with the PBIS 5.0 standard reports to a certain extent, three of the four front-line supervisors we interviewed stated that they did not know how to use ProClarity, FSIS' standard data-mining tool for narrowing down and analyzing the vast amount of information stored in PBIS. Provided to both front-line supervisors and district-level staff, ProClarity allows users to produce summary reports and charts designed to help them identify trends and problems in individual establishments or circuits.

In response to a GAO audit in August 2002, FSIS stated that it would train district staff and front-line supervisors to use ProClarity by October 7, 2002. We found that although FSIS had demonstrated the software's capabilities and provided supervisors with user's manuals, the agency had not provided any hands-on training or training that specifically related ProClarity to FSIS' inspection environment.

During our visits to the district offices, most supervisors said they were only minimally competent with ProClarity because they had not received sufficient training. Specifically, the supervisors told us: (1) very few people at the districts knew how to use the software; (2) personnel could not relate the demonstration or the manual to FSIS procedures; (3) the manual was confusing; and (4) they did not have time to learn ProClarity on their own. As a result, one district office we visited used a time-consuming manual process to produce a report that it could have generated quickly and easily with ProClarity.

According to an FSIS Headquarters official, field and district office personnel have the tools they need to perform their duties. He said that personnel know how to use the PBIS reports without Headquarters "micro-managing" them. Given the diverse types of operations being inspected, the official also expressed concern at using a "cookie-cutter" approach to guide personnel in interpreting the reports**.** FSIS officials further stated that since the implementation of the HACCP-based inspection system, the agency's frontline inspectors need to be "critical thinkers" and they questioned the usefulness of providing guidelines and parameters for interpreting the system reports since inspectors should be capable of using their own judgment in making such interpretations.

Our review disclosed, however, that inspectors and supervisors armed only with user's manuals, basic technical training, and the IPPS guidelines are not equipped to make the most effective use of the PBIS systems. While we concur with the officials' position that inspectors need to be capable of using independent judgment, this does not preclude the agency from providing additional guidance to assist them in performing data mining and trend analyses. The provision of such training would further be consistent with the assurances provided by FSIS officials in their responses to previous audit reports.

To effectively and consistently analyze the PBIS system, FSIS field personnel need guidance for interpreting the PBIS standard reports and hands-on training for using the ProClarity data-mining software. Until it provides such guidance and training, FSIS has only limited assurance that

field personnel are satisfactorily carrying out the measures cited in its response to the ConAgra report.

Recommendation No. 3

Develop written guidelines for FSIS inspectors and supervisors to use in analyzing and interpreting PBIS data and provide them to district offices, front-line supervisors, and inspectors.

Agency Response.

FSIS officials stated that to aid field inspection personnel in analyzing PBIS data, the agency established District Analyst (DA) positions in all districts. The DAs are responsible for analyzing data and reports generated from FSIS' information systems. They will be responsible for noting trends, problem plants, or emerging issues involving food safety and consumer protection. Their work will include reviewing NRs, Food Safety Assessment Reports, plant profile information, and various other data. They will also identify findings and observations that require more in-depth technical or scientific analysis to assess public health impact, and recommend appropriate action to district officials. FSIS has begun to implement the DA positions within the districts. Initial training on the new position responsibilities will begin in November 2004, and is expected to be completed by April 2005.

OIG Position.

We agree that FSIS' action in establishing the DA positions should provide needed technical support to managers and front-line supervisors. However, we also believe that additional written guidance is needed, not only for the managers and supervisors, but for the DAs as well. This would assist them in performing their analyses and also to provide some degree of uniformity in the types of reviews that are being performed nationwide. To reach a management decision on this recommendation, FSIS officials need to provide us with a response that addresses this need. This could be done as part of the overall process of developing a management control process.

Recommendation No. 4

Provide hands-on ProClarity training to district officials and front-line supervisors to ensure they are able to systematically review all pertinent food safety data. Work with inspectors and front-line supervisors to determine the need for additional training, or changes in assignment structure.

Agency Response.

FSIS officials stated that in addition to training provided to front-line supervisors at conferences in 2002 and 2003, the Program Analysis and Information Technology (PAIT) staff at the TSC had conducted ProCarity training sessions at front-line supervisor meetings in multiple districts.

OIG Position.

We concur with the actions being taken by FSIS to provide training to its front-line supervisors. To reach management decision, FSIS needs to provide us with its timeframes for providing hands-on training to all its front-line supervisors.

Although FSIS' principal IT systems (DEWS, PBIS, and PREP) provided worthwhile or useful information to agency inspectors, supervisors, and managers regarding inspection operations, we found that the systems were not used in the most effective way. For example, although DEWS has generated numerous alerts that may have prevented serious health and safety problems, the 11 product recalls that occurred during an 18-month period at the 2 districts we visited were not preceded by any alerts. We also noted a loophole that could reduce the effectiveness of DEWS by allowing inspectors to avoid reporting sanitation procedures that were not performed. In addition, when the systems were developed, the agency had not prepared all of the required system documentation such as data dictionaries and flowcharts, thus limiting the ability of anyone not closely associated with the systems to perform risk assessments and other analyses.

Finding 3 DEWS Needs To Be Strengthened

Although the DEWS system was designed to provide FSIS officials with advance warning of impending problems at inspected establishments, we noted that the system had often not alerted FSIS in situations that later resulted in product recalls. Although this could have indicated a need to review the parameters of the system's warning "triggers," the agency had neither updated the system since its inception in April 2002, nor determined if adjustments were needed. Instead, agency officials stated at the exit conference that the system had been taken out of service since the conclusion of our fieldwork.

DEWS' purpose was to extract inspection, sampling, and enforcement data from various FSIS databases and was intended to issue an "early warning" when a trigger is activated—that is, when a combination of factors reached a pre-determined threshold. FSIS personnel were alerted to such situations by automatic e-mails that the system generates. To trigger a DEWS alert, an establishment must exceed the thresholds in two or more of the following areas:

DEWS Factors	Pre-Established Thresholds (Triggers)
HACCP noncompliance	8 %
Sanitation noncompliance	10%

Sanitation procedures not performed	35%
Failure of a pathogen sample	1
Failure of *Salmonella* B and C set	1
Issuance of enforcement action	1

We attempted to evaluate the appropriateness of the thresholds shown above. According to FSIS officials, the threshold percentages assigned to the HACCP and sanitation triggers were arrived at using past experience as a guide. For example, we questioned why the threshold for "Sanitation Procedures Not Performed" was set at 35 percent. However, agency officials were unable to provide any documentation of how the thresholds were determined.

As one measure of the system's effectiveness, we reviewed all 11 product recalls for pathogen contamination that occurred between April 2002 (when DEWS went into service) and October 2003. None of these recalls was preceded by a DEWS alert. Agency officials stated that FSIS had not performed an analysis of product recalls to determine whether PBIS or PREP data from these establishments contain identifiable trends that might be found to precede product recalls. Such an analysis could provide FSIS with data to refine the DEWS triggers and allow FSIS inspectors to respond to problems at establishments before recalls become necessary.

Although FSIS officials stated that they were reviewing DEWS, they stated that the review was in draft; as of the time of the exit conference, no results had been provided to us; officials were also unable to provide us with details of the review itself, such as whether or not the trigger values were being studied.

We noted instances in which the effectiveness of DEWS might have been reduced because of conditions we noted in the PBIS system. The DEWS trigger for "Sanitation Procedures Not Performed" was keyed to instances where FSIS inspectors report in PBIS that they did not perform assigned sanitation procedures. This trigger was designed to identify instances where inspectors may not be performing a sufficient number of assigned sanitation tasks at their establishments. However, a loophole in PBIS allows inspectors to simply not report whether or not they performed a particular task. A large number of non-responses could lower the percentage of not-performed tasks below the DEWS trigger threshold. (See Finding 4 for further details on this problem.)

In addition, because of the known association between fecal material contamination and *E.coli* O157:H7, we believe DEWS could have benefited from a trigger to key on noncompliance reports related to such contamination

(or other types of noncompliance reports involving higher-risk situations). However, as noted in Finding 4, PBIS does not incorporate codes that allow the system to separately track noncompliance reports related to the presence of fecal material contamination.

We also noted a specific instance in which the DEWS system could have been strengthened to increase its effectiveness. Although FSIS requires its personnel to follow up on DEWS alerts, the system does not track the status of corrective actions resulting from previously generated DEWS alerts. There is no provision for the system to generate additional alerts unless the same triggers are activated by new information from the databases.

At one district office we found that DEWS alerts at two establishments, generated on June 2, 2003, were not followed up on until the date of our visit 22 days later. The initial DEWS reports for both establishments were triggered by the same combination of factors: (1) A district office issued an enforcement action (a Notice Of Intent To Enforce, or NOIE) because the establishments' sanitation standard operating procedures and HACCP plans failed to meet regulatory requirements; and (2) scheduled sanitation procedures not performed exceeded the 35 percent threshold. The delay in followup occurred because e-mails from the district office were not timely opened by one of the front-line supervisors. This district's policy was to follow up on DEWS alerts within 3 days of issuance.

District officials noted that if, as in this case, the district office has already issued an NOIE, a subsequent DEWS warning would not be helpful because an enforcement action is already in progress at the affected establishment. However, as noted above, the initiation of an enforcement action is only one of several factors that can trigger a DEWS alert. The officials agreed that in other circumstances a tracking feature in DEWS could be useful.

We were informed at the exit conference that since the completion of our fieldwork, the DEWS system had been discontinued. FSIS officials stated that the information provided by DEWS was available from other systems through the use of the ProClarity data-mining software. However, the officials we interviewed concurred with our observation that ProClarity and Laboratory Electronic Application for Results Notification (LEARN, a computer application that transmits laboratory results such as microbiological, food chemistry, and residue analyses performed at FSIS laboratories) do not generate automated alerts as DEWS was designed to do, but instead are dependent on the initiative of individual users to perform the necessary queries. And, as noted in Findings 1 and 2, insufficient training of personnel and the lack of a documented management control process could reduce the effectiveness of such a system.

We believe that the concept of an early-warning system such as DEWS is a valid one, and it should also be noted that the DEWS system was put forward by the agency as part of its response to two different recommendations from GAO's report. Thus, we believe FSIS continues to have a need for a system of this type, as well as a process to review and evaluate its effectiveness on a continuous basis. This process should include analyses of product recalls to determine why the system triggers were not activated. Finally, we continue to believe that FSIS should explore the possibility of incorporating a tracking feature into whatever system is used to replace DEWS, or take other steps to ensure timely followup action when the system identifies situations that require corrective action.

Recommendation No. 5

Develop and implement procedures to periodically review the effectiveness of the agency's new early-warning system, including analyses of product recall cases that did not trigger system alerts.

Agency Response.

FSIS officials stated that DEWS was redundant in that it flagged problems that had already been identified by district personnel using data from other applications that was being provided on a near real-time basis. As a result, FSIS has discontinued the use of DEWS. FSIS instead established the District Analyst (DA) positions in each district.

The DAs will be responsible for managing and overseeing each district's verification sampling process, and will follow up on samples not taken, discards, and potential positive results when products are shipped or to confirm product holds. In the case of *Salmonella* sampling, the DAs will monitor sample results daily and provide notification to front-line supervisors on full sets, early warnings, and initiation of action on failed sets. The DAs are expected to be trained and in place by April 2005.

In addition, FSIS officials stated that with respect to product recall cases, the agency is establishing an analytical capacity within the recall management function to review and analyze product recall cases to determine if product sampling, epidemiological evidence, and food safety systems compliance contribute to the timeline for recall.

OIG Position.

Although we agree that the same data that was used by DEWS is also available through PBIS and PREP, the absence of an automated early warning system means that this data must now be reviewed by a District Analyst or other FSIS employee in order for potential problems to be discovered. This results in reduced assurance that problems will be detected at all plants, or detected on a timely basis.

We believe that the concept of an early warning system was valid and needs to be continued. The analytical capacity within the recall management function that is being established could provide the basis for such a system. To reach a management decision, FSIS officials need to provide us with additional information on this system, along with information on how it will relate to the management control process as a whole, and timeframes for implementation.

Recommendation No. 6

Implement a system to track the status of unresolved system alerts to ensure timely followup.

Agency Response.

Although agency officials discontinued DEWS, they agreed that it was important to be able to track and follow up on districts' enforcement actions. Consequently, in fiscal year 2004, FSIS implemented the Case Management Specialist (CMS) position in each district. The CMS' responsibilities include analyzing enforcement case files to ensure that the statutory and regulatory basis of enforcement actions are supported by documentation. The CMS is also responsible for initiating data collection or analysis needed to strengthen enforcement cases, and for following up with front-line supervisors and inspectors to ensure that proper administrative enforcement actions have been taken, including suspensions, withdrawals seizures, and detentions of unsafe or improperly labeled meat and poultry products. FSIS implemented the CMS positions within the districts during fiscal year 2004.

OIG Position.

We accept FSIS' management decision, and believe that this should constitute final action as well, as soon as documentation of the establishment of the CMS positions in each district has been forwarded to OCFO.

Finding 4 PBIS Needs Additional Controls for Tracking High-Risk Noncompliance Reports and Inspection Tasks

We noted several modifications that could make the system more effective. Specifically, FSIS needs to develop identification codes to enable inspectors to more easily track specific noncompliance records (NRs). It also needs to establish tighter built-in controls over online reports of inspection tasks. FSIS had not undertaken these improvements because it considers them unnecessary. As a result, PBIS is not as effective as it could be in identifying serious noncompliance trends and other problems at inspected establishments.

As FSIS acknowledged in its response to OIG's ConAgra report, the system's purpose is to facilitate the inspection process and to aid district and front-line supervisors in overseeing inspection activities.

We found that PBIS users cannot readily identify certain types of NRs, particularly fecal material contamination, in order to identify trends and recurring problems. After entering inspection results into PBIS, inspectors at each establishment are responsible for reviewing and linking related types of NRs by common causes. Since fecal material noncompliances can result from many different causes, inspectors do not always link them. And because PBIS does not capture fecal material NRs in a unique inspection procedure code, front-line supervisors and district managers have no way of monitoring the total number of occurrences of fecal material contamination without reading the entire, lengthy "NR Summary Report." Although FSIS considers fecal material contamination a zero tolerance noncompliance matter because of its association with *E. coli* O157:H7 the agency has not taken steps to make such serious NR trends easier to spot.

FSIS also needs to develop stricter controls over the information inspectors enter into PBIS. As currently programmed, PBIS does not require inspectors to account for all scheduled procedures when entering inspection results into the system. When an inspector fails to report on an inspection task, PBIS counts the omission as a "no feedback" response and allows the inspector to continue inputting information on other tasks. This system shortcoming makes it difficult for supervisors to determine if inspectors have or have not performed a scheduled task, and thus casts doubt on the effectiveness of the inspection process. Potentially, the "no feedback" response also reduces the effectiveness of DEWS, as noted in Finding 3. Furthermore, FSIS Headquarters has not given district managers any instructions on how to handle "no feedback" responses. Managers at one district we visited

considered the "no feedback" response unacceptable. In another district, however, managers expressed little concern that as many as 15 percent of all scheduled tasks at some establishments appeared in the system with "no feedback."

Finally, even if inspectors input that they did not complete an inspection task, the most recent version of PBIS does not ask them to give the reason for doing so. Without this information, district managers cannot immediately determine if the reason for not performing a scheduled task was legitimate (i.e., the task was not relevant to the particular establishment) or if the unperformed task may leave potential problems undiscovered. FSIS Headquarters officials believed that tracking the reasons was unnecessary and deleted this capability when they implemented PBIS 5.0. However, district personnel told us they would prefer that the system require inspectors to document their reasons for not performing scheduled procedures.

FSIS officials expressed concerns that our report was citing the need for PBIS to perform functions for which it was not designed. They stated that PBIS was designed to schedule inspection tasks for inspectors, not to be a management information system. They also disagreed that adding additional codes would be useful, since they expected their frontline inspection personnel to identify critical problems at their establishments rather than depending on an IT system to do so.

While we agree that PBIS initial purpose is to schedule inspection procedures and collect inspection results, it was agency officials themselves who determined that it should also be used as a management information system, as revealed by their responses to both the GAO report and OIG's report on the ConAgra recall. We also agree that establishment inspectors should be aware of problems occurring at that level; however, higher level managers from the circuit supervisors upward also have monitoring responsibilities, which can only be achieved through the use of an automated information system functioning as part of an overall management control process.

Recommendation No. 7

Modify PBIS 5.0 to eliminate the "no feedback" response to require inspectors to report on all scheduled inspection tasks.

Agency Response.

FSIS officials stated that the agency would incorporate, in its management control system, guidance covering the appropriate use and application of the

"no feedback" responses in PBIS. The target date for full implementation of the IPPS management control system document is FY 2006.

OIG Position.

We concur with the agency's plan of action. However, before management decision can be reached, we need to review FSIS' draft procedures regarding the handling of no-feedback responses.

Recommendation No. 8

Code NRs in PBIS by type so that inspectors and supervisors can more readily identify the most hazardous NR's, such as those involving fecal material on product.

Agency Response.

FSIS officials stated that attempting to identify the most hazardous types of NRs was impractical because of the variety of pathogens, processes, and operational conditions in the various establishments. They indicated that OIG's concerns were addressed by their revision of FSIS Directive 5000.1, *Verifying an Establishment's Food Safety System,* which was issued on May 21, 2003. The revised Directive provides specific guidance to inspection program personnel on how to link related NRs and how to detect or discern when the establishment is proposing inadequate or ineffective preventive or corrective measures.

OIG Position.

We concur that an efficient process to link NRs would largely address our concerns in this regard. However, the current process as described in Directive 5000.1 requires manual linking by in-plant inspection personnel or front-line supervisors. This can be a time-consuming process for these personnel, and we have concerns about how district managers or DAs could apply management controls to such a process. To reach a management decision, FSIS officials need to clarify whether there is an intent to automate this process as part of the new management control process, and if so, to provide us with draft procedures.

Finding 5 PREP May Not Be Scheduling *E. coli* O157:H7 Testing As Often As Necessary

At present, the PREP system is not designed to increase *E.coli* O157:H7 testing in cases where FSIS inspectors report a high incidence of problems relating to fecal material contamination, even though this is a known factor in the presence of *E.coli* O157:H7 We attributed this, in part, to the fact that the PBIS and PREP systems use separate databases, and the information needed for such a procedure is not contained in PREP's database. In addition, as noted in Finding 4, PBIS does not record information on NRs in a readily accessible format. This problem could increase the risk of *E.coli* O157:H7 contaminated products entering commerce.

The purpose of PREP is to schedule, track, and report testing information on *E. coli* O157:H7 and *Salmonella* in raw ground products. However, FSIS policy does not require increased *E. coli* O157:H7 testing based on fecal material NR's.

PREP does not increase scheduled *E. coli* O157:H7 testing based on fecal material NR's because FSIS did not set up the system to do so. Currently, PREP, which uses its own database, cannot draw noncompliance information directly from the main corporate database. Although data is manually transferred from the Corporate Sybase database into the PREP database at regular intervals, information on NRs issued by FSIS inspectors at specific establishments is not included. FSIS personnel indicated that the agency plans to consolidate the databases used by PREP and PBIS eventually, but no definite date has been slated for completing the project. Besides consolidating the databases, we believe that FSIS should make provisions to specifically identify fecal material NR's in PBIS, as detailed in Finding 4, to ensure that PREP increases *E. coli* O157:H7 testing at high-risk establishments.

Recommendation No. 9

Establish data exchange between PBIS and PREP and a trigger in PREP to allow PREP to increase sampling based on fecal material noncompliances.

Agency Response.

FSIS officials stated that under revised Directive 10,010.1, effective May 17, 2004, FSIS is developing a risk-based verification program for sampling raw products in Federally inspected establishments. The number of fecal NRs is one of many risk factors what will be considered, but is not a factor available

for most establishments that produce raw ground beef. The risk-based sampling model that is developed will determine the data needed and the required interaction between FSIS information systems. The new DAs will monitor district sampling procedures and follow up with results, samples not taken, discards, potential positives when product is shipped, presumptive positives to confirm product holds or acquire shipping information, and to assure overall uniform application of procedures. For *E. coli* 0157.H7 testing, the DAs will recommend to the district managers the appropriate number of follow-up samples required for verifying the corrective actions taken by establishments in responding to prior positive test results.

OIG Position.

Although the corrective actions proposed by FSIS are different then those recommended, they could be sufficient to achieve the necessary level of control. Before reaching a management decision, we need additional information describing the risk-based verification program referenced in the agency's response.

Finding 6 FSIS Has Not Developed Required System Documentation

Although FSIS has been using PBIS and its other IT systems for several years, the agency has not developed all the required system documentation, such as data dictionaries and system flowcharts, necessary to support them. FSIS officials agreed that the documentation should have been prepared at the time the systems were created, but limited time and resources during system development prevented them from doing so. The lack of this documentation could potentially limit the effectiveness and usefulness of the IT systems. It also limits the ability of anyone not highly familiar with the systems to perform risk assessments and other analyses to evaluate the systems' effectiveness.

At a minimum, USDA Departmental manuals require agencies, at the beginning of a computer application's lifecycle, to identify the information needed to perform the system processes and to chart the system's information flow.[2] The Departmental manuals also require agencies to build a data dictionary, or a directory of current system data and reporting requirements, for new computer applications.[3]

The main IT application systems - PBIS, PREP, and DEWS - used by FSIS to monitor compliance at meat and poultry establishments, use three separate databases. PBIS operates using a "Corporate Sybase" database, which consists of approximately 1,000 data fields grouped into 128 data tables. PREP operates using a separate, smaller database, which consists of approximately 730 data fields grouped into 66 tables. The DEWS system, on which FSIS depended for early warnings of potential health and safety problems at inspected establishments, used information from both the Corporate Sybase and PREP databases, plus information from the enforcement database. The Corporate Sybase database provides the data that the TSC uses to prepare its monthly exception reports, and which ProClarity and PBIS Reader use to perform trend analyses.

We found that FSIS had not created flowcharts to detail the workings of its various information systems, such as PBIS and DEWS, and chart their relationship to each other and to the Corporate Sybase database. FSIS also had not created data dictionaries for its systems to identify precisely what

[2] U.S. Department of Agriculture Departmental Manual, 3200-002, The Application System Life Cycle Management, Chapter 1, 1.1B. (3)(d), dated March 3, 1998
[3] U.S. Department of Agriculture Departmental Manual, 3200-002, The Application System Life Cycle Management, Chapter 1, 1.2 A. (2)(c), dated March 3, 1998

type of information each data field contains, which we discovered when we attempted to perform an analysis of the Corporate Sybase database. We had planned to determine, for those establishments at which product recalls had taken place, whether additional database analysis would reveal trends that might allow FSIS to anticipate and correct problems before a recall would be required. However, the lack of a data dictionary to document the contents of the database limited our ability to perform such a review, just as it would limit FSIS personnel who are not highly familiar with the system.

While they acknowledged that a data dictionary should have been prepared, FSIS officials stated that the lack of one had never been a problem because the IT staff is highly familiar with the system and did not need a data dictionary to work with the database. They said they could verbally provide the OIG auditors with the necessary information on each data field, but this would take an excessive amount of time. Given the audit team's inability to obtain specific details on the data fields and tables in a timely manner, we question if new employees joining the FSIS-IT staff could readily acquire this information or ensure that the knowledge passed on to them by other employees is fully accurate. The lack of system documentation could, in the long term, affect the continuity of the agency's IT operations.

Agency officials stated that they plan to create a data dictionary for the Corporate Sybase database now that funding is available. However, they estimated that this would take at least 3 months, and longer if other priorities needed to be addressed. In order to ensure that all IT staff have the necessary knowledge and information to perform their duties in an efficient and effective manner, FSIS needs to prioritize completion of the system documentation required by the Departmental manuals.

Recommendation No. 10

Create the necessary system documentation, particularly system flowcharts and data dictionaries, for the databases and system applications currently used to monitor compliance at inspected establishments.

Agency Response.

FSIS officials stated that they would follow the Department's standard System Development Life Cycle (SDLC) process for documenting their information systems. The agency will utilize a contractor to document the SDLC process currently being used, and this process will be used on all major system developments and modifications. The SDLC will include a security study, feasibility study, requirements study, requirements definition, detailed design, programming, testing, installation, and post implementation review. A contact to implement the SDLC process will be awarded by October 2004, and the contractor is expected to complete the design and implementation of the SDLC by September 2005.

OIG Position.

We accept FSIS' management decision. Final action can be reached when the agency provides documentation that the SDLC has been implemented.

Scope and Methodology

The audit fieldwork was conducted at the FSIS Headquarters in Washington, D.C.; the TSC in Omaha, Nebraska; two of the 15 districts offices, District 45 office in Madison, Wisconsin; and District 50 suboffice in Pickerington, Ohio. We also visited five FSIS-inspected meat, poultry and egg establishments in Wisconsin. The districts offices and the meat and poultry establishments were judgmentally selected. We performed our fieldwork from April through September 2003.

In December 2003, we began meeting FSIS Headquarters officials to discuss our results. We continued to meet with them up to and after the exit conference while the agency prepared its response, which is attached as exhibit A.

At FSIS Headquarters, we interviewed the assistant administrator, directors, staff members, and IT technical personnel. We reviewed available documentation and created flowcharts for the PBIS, PREP, and DEWS databases. We evaluated the adequacy of these information systems as well as the policies and procedures governing their use.

At the TSC we interviewed key personnel in PAIT and OPEER divisions. Specifically, we inquired about the purpose of each division, how it functions within the TSC, and any problems or concerns regarding FSIS information systems. We also reviewed eight TSC exception reports.

At the District 45 office, the District 50 suboffice, and the five FSIS–inspected establishments, we evaluated the effectiveness of the information systems at the field level as well as the districts' and inspectors' compliance with existing policies and procedures. In addition, we reviewed the five standard PBIS reports, DEWS reports, NOIE, and NOS.

We evaluated the agency's internal controls for ensuring that FSIS personnel at all levels are receiving the data they require from the IT systems to perform their assigned inspection and enforcement tasks, and that they possess the necessary training and guidance to effectively and efficiently use this information.

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

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

TO: Robert W. Young
Assistant Inspector General
for Audit

SEP 30 2004

FROM: Dr. Barbara J. Masters
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Official Draft Report – Use of Food Safety Information Systems, Report No. 24601-3-Ch

The Food Safety and Inspection Service (FSIS) welcomes the opportunity to provide comments on its use of food safety information systems. We appreciate the chance to work with OIG to enhance the operation and oversight of our programs to improve their effectiveness. FSIS has reviewed the OIG official draft report and offers its responses to the recommendations. In addition, we are providing several general comments.

FSIS is updating its management controls system to improve the effectiveness of its program operations, ensure full accountability of personnel, achieve the Agency's mission and goals, and ensure that all levels of the organization are in compliance with applicable laws and regulations. FSIS will continue to review its programs and policies and implement prudent and cost-effective corrective actions to ensure the highest level of efficiency and excellence that will improve the safety and wholesomeness of meat and poultry products.

General Comments

We recognize the important contribution and vital role played by FSIS' key information systems in assisting the Agency in carrying out its mission. Each system was developed and implemented with a specific purpose in mind. We recognize that information systems can be redesigned to enhance their functionality or other uses of the systems can be explored to increase their effectiveness, but the decision to make major changes needs to include consideration of the costs and benefits that will result from changes. Our focus should be to make major system changes that provide a clear benefit, are cost effective, or are required for the Agency to carry out its mission. We believe that OIG reviews on information systems should report on whether the systems are achieving the functions they were designed to perform, rather than on what additional functions the systems should be accomplishing. Nevertheless, we appreciate having your input for future planning.

We noted that a significant amount of OIG's audit work was devoted to the District Early Warning System (DEWS), which was an application designed to integrate selective pieces of information from several other systems and provide an "early warning" to district management of potentially emerging food safety problems. Even though FSIS found the system useful early on, as time went on, DEWS did not function as an early warning system because it was flagging

potential problems after those problems had already been identified by district management officials. Thus, on April 1, 2004, FSIS discontinued use of the DEWS system. We want to ensure that there is no misunderstanding about the status of DEWS since parts of this report implies that it is still operational.

In addition, FSIS is concerned that the intent and function of certain of its information management systems may not have been clearly understood. In particular, the official draft report notes, in several places, that the purpose of the information management systems is to provide the capability "to recognize trends and take action to prevent a recall." In our professional opinion, given the nature and cause of recalls, it is not clear how a data system could be sophisticated enough to predict recalls. FSIS, however, is evaluating other policies to determine if recalls, especially related to pathogens, can be further decreased.

Finding 1. FSIS Needs to Establish a Management Control Process for Effective Coordination Between Headquarters and Field Units.

1. **Recommendation No. 1**
   Develop a comprehensive management control system that defines the responsibilities of each management and operating level associated with meat and poultry establishment inspections, including procedures for regular communication and coordination between units.

   FSIS Response
   We agree with the need to enhance management controls in certain areas and better define our program oversight responsibilities. As part of an overall FSIS management control system, FSIS will establish a management control accountability model that will produce clear performance standards and performance measures for both individual and organizational performance. Individual performance standards will be defined by the requirements of the Department of Agriculture (USDA) performance management system and have clear ties to the USDA and FSIS strategic plans. Organizational performance will be defined in terms of an accountability model that establishes clear responsibilities for each management and operating level.

   Once the performance standards are developed, FSIS will then define key functions to be addressed by each district office and describe how each function is to be verified (e.g., how the district office will be held accountable). After establishing key functions, FSIS will document the details for monitoring and measuring the function, implement the model for organizational performance, and evaluate the model to determine if it is functioning as intended. Work is currently underway to define the key functions, and we expect to have the design of the accountability model completed by April 2005. The target date for full implementation of the FSIS' Field Operations management control system is fiscal year (FY) 2006.

   FSIS Directive 1090.1, revision 2 "*Management Controls*" prescribes Agency standards and organizational responsibilities for the accountability and efficient use of sound management control systems to ensure that programs comply with applicable laws and regulations. FSIS will revise the Directive to instruct FSIS programs to apply a more rigorous and comprehensive management control system. The management control system will

encompass administrative controls that ensure the operational efficiency and adherence to managerial policies and applicable laws. The revised directive will incorporate the Government Accountability Office (GAO) Standards for Internal Control in the Federal Government, November 1999 (GAO/AIMD-00-21.3.1) and provide instructions for use by program managers. In addition, the Directive will incorporate, as appropriate, GAO's Internal Control Management and Evaluation Tool, August 2001, GAO-01-1008G.

The revised Directive will be issued by April 2005.

2. **Recommendation No. 2**
Include provisions in the management control system for the Technical Service Center (TSC) to perform independent analyses of inspection and establishment data collected through the Information Technology (IT) systems, and to provide the results of its analyses and exception reports as appropriate to Headquarters and the field.

FSIS Response
FSIS agrees that it is important to utilize skilled analysts for objectively evaluating and analyzing the information provided by the Agency's information systems. FSIS established the Program Analysis and Information Technology (PAIT) staff at the TSC to provide program support, including the analysis of data from the Agency's information systems. The various programs specify to PAIT their data analyses requirements consistent with the accountability model and the management control system. In FY 2004, FSIS reorganized the TSC under the Office of Policy, Program and Employee Development (OPPED). This reorganization affords the PAIT staff greater opportunity to analyze trends and to evaluate the effectiveness of the food safety systems in plants.

The FSIS comprehensive management control system will pay close attention to the key components for information, communications, and monitoring in order to strengthen communications and foster continuous improvement. We recognize the need for more effective coordination and information sharing between Headquarters, the TSC, and district offices, and will include provisions for formal reporting of analysis to headquarters and district offices. The FSIS management control system will provide timely feedback to program managers. The management control system in Field Operations should be fully implemented by FY 2006.

Finding 2. FSIS Needs to Improve Guidance and Training of Field Personnel.

3. **Recommendation No. 3**
Develop written guidelines for FSIS inspectors and supervisors to use in analyzing and interpreting Performance Based Inspection System (PBIS) data and provide them to district offices, front-line supervisors, and inspectors.

FSIS Response
FSIS agrees that it is important that its inspection program personnel understand and comprehend information provided by the PBIS. FSIS also recognizes the important and vital role its inspection personnel play in reviewing and taking into account all food safety-related data within the plant that may not be captured in the information system. Our objective,

consistent with the newly defined management control system, is to define clear descriptions of the system of data and reports, their formats, reporting frequency, expected actions, etc. to be used by supervisors and inspectors nationwide. FSIS requires its skilled inspection personnel to use their judgment, based on their training, to carry out their regulatory responsibilities. We recognize that the information provided by the PBIS reports represents one tool in the inspection personnel toolbox. Our goal is not to make data analysts out of trained inspection personnel, but rather to assist them in best using the tools that are available to them.

To aid FSIS field inspection personnel in analyzing PBIS data, the Agency established District Analyst (DA) positions in all districts. The DAs are responsible for analyzing data and reports generated from the Agency's information systems, noting trends, problem plants, or emerging issues involving food safety and other consumer protection. The DAs recommend action to district officials as needed. The DAs are also responsible for reviewing non-compliance records (NRs), Food Safety Assessment Reports, plant profile information, and input and/or feedback from front-line supervisors, inspectors, or Enforcement Investigations and Analysis Officers to determine the need for additional training, change in assignment structure, or scheduling verification actions. The DAs also interface with the PAIT staff in acquiring standards and ad hoc analytical reports for use by the District Managers. The DAs identify findings or observations that require more in-depth technical or scientific analysis to assess the public health impact and to ensure appropriate follow-up action is taken.

FSIS has begun to implement the DA positions within the districts. Initial training on their new position responsibilities will begin in November 2004 and is expected to be completed by April 2005.

4. **Recommendation No. 4**
Provide hands-on ProClarity training to district officials and front-line supervisors to ensure they are able to systematically review all pertinent food safety data.

FSIS Response
FSIS agrees that it is important that its inspection program personnel understand and comprehend information provided by the PBIS. FSIS also recognizes the important and vital role its inspection personnel play in reviewing and comprehending the full depth of all food safety-related issues within the plant that may not be captured in the information system. FSIS requires its skilled inspection personnel to use their judgment, based on their training, to carry out their regulatory responsibilities. We recognize that the information provided by the PBIS reports represents one tool in the inspection personnel toolbox. Our goal is to not make data analysts out of trained inspection personnel, rather to assist them in using the tools that are available to them.

In October 2002, FSIS held a ProClarity training session as part of its front line supervisory conference in Dallas, Texas. The Dallas training was given to all front-line supervisors. A separate training session was given to the inspection coordinators (now called the District Analysts) from each district in October 2002. In October 2003, FSIS provided additional hands-on training to front-line supervisors at its supervisory conference in Nashville,

Tennessee. Further, the PAIT staff of the Technical Service Center has conducted ProClarity training sessions at the front line supervisor meetings in multiple districts.

Finding 3. DEWS Needs to be Strengthened.

5. **Recommendation No. 5**
Develop and implement procedures to periodically review the effectiveness of the Agency's new early-warning system, including analyses of product recall cases that did not trigger system alerts.

FSIS Response
As previously stated, FSIS has discontinued the use of the DEWS application. The DEWS system was discontinued because DEWS was flagging potential problems after those problems had already been identified by district management officials. Inspection personnel have access to data and are required to use that data for regulatory decision-making.

FSIS established the District Analyst position in each district. The DA supports the District Manager by analyzing data and assuring that district responsibilities based on analyses associated with microbial sampling programs are carried out. The DAs are responsible for managing and overseeing the district's verification sampling processes. The DAs serve as the district points of contact. In addition, the DAs monitor district sampling procedures and follow up with results, samples not taken, discards, potential positives when product is shipped, presumptive positives to confirm hold or acquire shipping information, and assure overall uniform application of procedures. In the case of *Salmonella* sampling, the DAs monitor sample results daily and provide notification to Front-Line Supervisors on full sets, and early warnings and they initiate actions on failed sets.

FSIS has begun to implement the DA positions within the districts. Initial training on their new position responsibilities will begin in November 2004 and is expected to be completed by April 2005.

With respect to product recall cases, FSIS is establishing an analytical capacity within the recall management function to review and analyze product recall cases to determine if product sampling, epidemiological evidence, and food safety systems compliance contribute to the timeline for recall.

6. **Recommendation No. 6**
Implement a system to track the status of unresolved system alerts to ensure timely follow-up.

FSIS Response
As we stated in response to Recommendation No. 5, FSIS has discontinued the use of the DEWS system because it was flagging potential problems after those problems had already been identified by district management officials.

FSIS agrees that it is important to be able to track and follow-up on enforcement actions in the districts. We believe the OIG's concerns have to do with the Agency's controls for ensuring that the districts are tracking and following-up on establishments with multiple enforcement actions. FSIS established the Case Management Specialist (CMS) positions within each district. The CMS is responsible for analyzing enforcement case files, including documentation and data collected, to ensure that the statutory and regulatory basis of enforcement actions are supported by the documentation. The CMS initiates data collection or analyses by appropriate experts as required to strengthen enforcement cases. The CMS is also responsible for following-up with front-line supervisors and in-plant inspection personnel to ensure proper administrative enforcement actions have been taken, including suspensions, withdrawals, seizures and detentions of unsafe or improperly labeled meat and poultry products.

FSIS implemented the CMS positions within the districts during fiscal year 2004.

Finding 4. PBIS Needs Additional Controls for Tracking High-Risk Noncompliance Reports and Inspection Tasks.

7. **Recommendation No. 7**
Modify PBIS 5.0 to eliminate the "no feedback" response to require inspectors to report on all scheduled inspection tasks.

FSIS Response
FSIS believes the OIG's concerns relate to a need for FSIS to establish controls to ensure that inspection program personnel are accountable for completing scheduled PBIS tasks, and that the application of PBIS is consistent. FSIS has focused extensively during the past 2 years on strengthening supervisory oversight of its in-plant inspection personnel through the use of the In-plant Performance System (IPPS). This system was designed to establish a formal process to ensure that inspection personnel are carrying out their assigned job responsibilities. The IPPS reviews hold employees accountable for their actions in addressing the scheduled inspection procedures assigned by PBIS and provide for performance improvement.

The IPPS management control system should be fully implemented by FY 2006.

8. **Recommendation No. 8**
Code NRs in PBIS by type so that inspectors and supervisors can more readily identify the most hazardous NRs, such as those involving fecal material on product.

FSIS Response
FSIS inspection personnel are required to verify potential food safety concerns in accordance with Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) regulations. While recognizing that fecal contamination is a key food safety concern, it is only one indicator of a problem in a plant. Attempting to identify the most hazardous NRs is

impractical because of the variety of pathogens, processes, and operational conditions in the various establishments. Because the Agency's focus is on the actions taken by the plant in response to the findings, HACCP is designed to alert an inspector or supervisor to a food safety concern in a plant.

FSIS has previously addressed the OIG's concern about ensuring that its inspection personnel are able to link and connect related NRs by revising FSIS Directive 5000.1 *Verifying an Establishment's Food Safety System,* which was issued on May 21, 2003. The revised Directive provides specific guidance to inspection program personnel on how to link related NRs and how to detect or discern when the establishment is proposing inadequate or ineffective corrective or preventive measures. Chapter IV of the Directive specifically defines the process for linking NRs.

It should be noted that every inspection procedure is identified as being focused on food safety, food security, or other consumer protection (wholesomeness and economic adulteration). It is not necessary for NRs to be coded, because the inspection procedure noted on the NR is, by definition, either food safety, food security or other consumer protection. FSIS believes this is adequate for identifying food safety concerns.

Finding 5. PREP May not be Scheduling *E. coli* O157:H7 Testing as Often as Necessary.

9. **Recommendation No. 9**
Establish data exchange between PBIS and PREP and a trigger in PREP to allow PREP to increase sampling based on fecal material noncompliances.

FSIS Response
FSIS' sampling program is one component of the Agency's overall verification program as specified in 9 CFR 417.8. We understand the OIG's concern that adequate sampling be done at the establishments. However, there is no scientific information or analysis to support the assertions in the official draft report that link findings of visible fecal contamination as a basis to intensify sampling for *E. coli* O157:H7. Under revised Directive 10, 010.1 effective May 17, 2004, FSIS is developing a risk-based verification program for sampling raw products in federally inspected establishment. The number of fecal NRs is one of many risk factors that will be considered, but it is not a factor available for most establishments that produce raw ground beef operations. The risk-based sampling model that is developed will determine the data needed and the required interaction between FSIS information systems.

When visible fecal contamination occurs, we expect inspection program personnel to react to the event, document the regulatory non-compliance, and require that the plant respond with appropriate corrective and preventive measures.

The OIG issue pertains to a need for FSIS to implement controls to ensure that sampling results are monitored and the information is incorporated into the decision-making process. The DAs monitor district sampling procedures and follow-up with results, samples not taken, discards, potential positives when product is shipped, presumptive positives to confirm hold or acquire shipping information, and assure overall uniform application of procedures. Regarding *E. coli* O157:H7 testing, the DAs recommend to the District Manager the

appropriate number of follow-up samples required for verifying the corrective actions taken by establishments in responding to prior positive test results.

Finding 6. FSIS Has Not Developed Required System Documentation

10. Recommendation No. 10

Create necessary system documentation, particularly system flowcharts and data dictionaries, for the databases and system applications currently used to monitor compliance at inspected establishments.

FSIS Response

FSIS agrees that system documentation, such as system flowcharts and data dictionaries, are important to assure the continuity of the Agency's information systems. FSIS will follow the Department's standard System Development Life Cycle (SDLC) process for documenting its information systems. A standard SDLC, in accordance with Department requirements, will be adopted for major system development and modifications. FSIS will utilize a contractor to document the SDLC process currently being used. The SDLC process will be used on all major system development and modifications. The SDLC will include: a security study, feasibility study, requirements study, requirements definition, detailed design, programming, testing, installation, and post implementation review. A contract to implement the SDLC process will be awarded by October 2004. The contractor is expected to complete the design and implementation of the SDLC by September 2005.

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