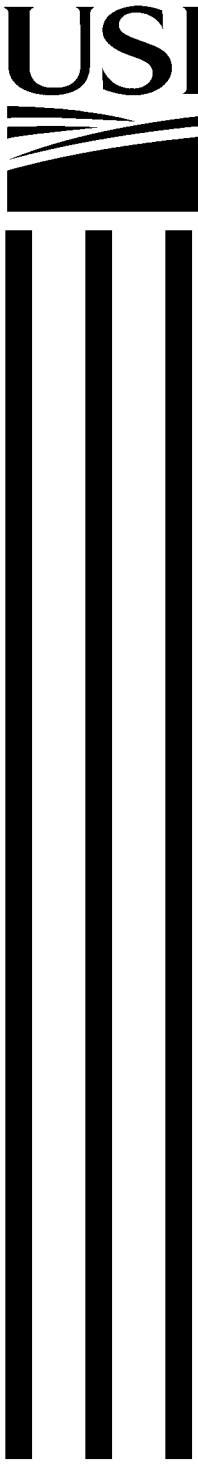

U.S. Department of Agriculture
Office of Inspector General
Great Plains Region
Audit Report

FOOD SAFETY AND INSPECTION SERVICE
OVERSIGHT OF PRODUCTION PROCESS AND RECALL AT CONAGRA PLANT (ESTABLISHMENT 969)

Report No.
24601-2-KC
September 2003

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250

DATE: September 30, 2003

REPLY TO
ATTN OF: 24601-2-KC

SUBJECT: Oversight of Production Process and Recall at ConAgra Plant

TO: Dr. Garry L. McKee
Administrator
Food Safety and Inspection Service

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

This report presents the results of our audit of the Food Safety Inspection Service's (FSIS) oversight of the recall by the ConAgra Beef Company of its ground beef and beef products suspected of being contaminated with *E. coli* O157:H7. This review was requested by the Senate Committee on Agriculture, Nutrition, and Forestry. Your August 18, 2003, written response to the official draft report is included in its entirety (except for the enclosures) as exhibit G with excerpts and the Office of Inspector General's (OIG) position incorporated into the Findings and Recommendations section of the report, where applicable. Exhibit E included references to proprietary production information of the three establishments cited therein. In order to protect this information from unauthorized disclosure, we have withheld the contents of this exhibit from presentation in our final audit report.

We accept the management decisions for Recommendations Nos. 3, 4, 6, 7, 10, 11, 18, 19, 23, and 26. Please follow your agency's internal procedures in forwarding documentation for final action to the Office of the Chief Financial Officer. Based on the information provided in the response, we were unable to reach management decisions for Recommendations No. 1, 2, 5, 8, 9, 12-17, 20-22, 24, 25, and 27-31. For Recommendation No. 9, please note that we have revised the recommendation based on your response. In order for us to consider the management decisions for these recommendations, we will need additional information and/or action by your agency. The additional information and/or actions needed are outlined in the report sections, OIG Position.

In accordance with Departmental Regulation 1720-1, please furnish a reply within 60 days describing the corrective actions taken or planned and the timeframes for implementing the corrective actions on the recommendations for which management

decisions have not yet been reached. Please note that the regulation requires a management decision to be reached on all findings and recommendations within a maximum of 6 months from report issuance, and final action to be taken within 1 year of each management decision.

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

/signed/

RICHARD D. LONG
Assistant Inspector General
for Audit

EXECUTIVE SUMMARY

FOOD SAFETY AND INSPECTION SERVICE OVERSIGHT OF PRODUCTION PROCESS AND RECALL AT CONAGRA PLANT (ESTABLISHMENT 969)

AUDIT NO. 24601-2-KC

RESULTS IN BRIEF

At the request of the Senate Committee on Agriculture, Nutrition, and Forestry, we performed an audit of the Food Safety and Inspection Service's (FSIS) oversight of the recall by the ConAgra Beef Company[1] (ConAgra) of 18 million pounds[2] of ground beef and beef products suspected of being contaminated with *E. coli* O157:H7. ConAgra, Establishment 969, is located in Greeley, Colorado. The Committee requested that we review the effectiveness of the U.S. Department of Agriculture's (USDA) recall system as it was put in practice during the recall at ConAgra.

The Federal meat inspection program is operated under the Hazard Analysis and Critical Control Point (HACCP) system that was adopted in 1998.[3] Under the HACCP program, FSIS is responsible for verifying that each establishment's food safety system is operating in compliance with the regulations and in a way that will result in safe and wholesome meat products. FSIS is also responsible for verifying that each plant's food safety system is properly designed. Each establishment, in turn, is responsible for designing a food safety system that complies with sanitation performance standards, requirements for sanitation standard operating procedures (SSOP), HACCP requirements, and pathogen reduction activities. As part of HACCP, the establishment must identify and control (1) physical, chemical, and biological hazards to the production process, and (2) conduct a program of ongoing microbial testing to verify that the food safety system is working. The establishment is also responsible for monitoring meat production at every stage of the process to ensure the safety of meat products.

[1] The ConAgra Beef Company was sold to Swift Foods Company in September 2002, after the recall, and the Greeley, Colorado, production facility became known as Swift and Company. This report will refer to the company only as ConAgra.
[2] The USDA press release reported a figure of 19 million pounds, but that was an estimate only. The actual number of pounds recalled was 18,048,361.
[3] Code of Federal Regulations (CFR), 9 CFR Part 417.

Beginning in mid-June 2002, at least 46 people in 16 States became ill from contaminated meat. About 1 month earlier, FSIS' microbiological tests of ground beef at a meat grinder that used product supplied by ConAgra identified the presence of *E. coli* O157:H7. Testing, conducted by the Colorado Department of Public Health and Environment and the Centers for Disease Control and Prevention (CDC), confirmed that about 23 individual *E. coli* illnesses around the State of Colorado were from the same genetic strain of *E. coli*. ConAgra officials agreed to an initial voluntary recall of 354,200 pounds of ground beef produced in late May of that year. A subsequent FSIS review of ConAgra records showed that beef product from that plant had been testing positive for *E. coli* O157:H7 as early as April 12, 2002, and as late as July 11, 2002. At that time, ConAgra, Establishment 969, produced over 1 million pounds of beef a day. The recall was consequently expanded to include 18 million pounds of beef product.

We evaluated the effectiveness of USDA's management and oversight of the recall of ConAgra product. We also determined whether FSIS was aware of potential problems at ConAgra prior to the recall and whether FSIS and ConAgra operated in accordance with HACCP requirements. Our audit found that neither ConAgra nor FSIS effectively fulfilled their responsibilities under HACCP. ConAgra did not design or reassess its food safety system to ensure it operated in compliance with SSOP and HACCP requirements. Data was available to both ConAgra and FSIS in the period prior to the recall (January 2001 to the expanded recall) that indicated *E. coli* O157:H7 contamination was becoming a continuous problem at ConAgra. FSIS inspectors did not recognize and/or respond to these indicators and followed FSIS policies that effectively limited the documents the inspectors could review and the enforcement actions they were allowed to take.

FSIS needs to be more proactive in its oversight by seeking access to available sources of data and analyzing, on an ongoing basis, the data's importance as indicators of problems that could impact food safety. Also, FSIS needs to reassess its management and oversight of the recall process. The recall was ineffective and inefficient because adequate controls and processes were not in place to timely identify the source (establishment) of the contaminated product or provide reasonable assurance that recovery of the recalled product was maximized or enforcement actions taken, as necessary. As of the end of January 2003, only about 3 million pounds of the 18 million pounds of recalled product has been recovered. The majority of the beef was not returned or accounted for.

Pre-Recall Indicators Showed Problems

Pathogen testing and HACCP. The HACCP program was designed to rely on scientific, microbial testing to determine the wholesomeness of meat products. The program generally requires FSIS to test for *E. coli* O157:H7 at plants producing ground beef. We found that FSIS inspectors at ConAgra did not perform their own tests and did not review other test results that were available to them.

- Under FSIS policy, plants such as ConAgra that performed their own pathogen tests as a part of HACCP were exempt from FSIS testing,[4] and those tests ConAgra performed apart from HACCP were not directly presented to FSIS for review. None of the tests taken by ConAgra for HACCP purposes in 2001 and 2002 showed the presence of *E. coli* O157:H7, while at least 63 of the tests taken for non-HACCP purposes in 2002 did. The tests taken for HACCP purposes were on carcasses; the non-HACCP tests were taken on beef trim. Trimmings from meat cuts are used as ingredients in the production of many meat products, including ground beef.

- FSIS inspectors did not pursue the non-HACCP test results because they determined FSIS had no clear authority to review non-Government tests even though they knew those tests showed the presence of the *E. coli* pathogen. Test summaries, to which FSIS had access after the recall, showed an increasing frequency of *E. coli* O157:H7 contamination at ConAgra. Officials from FSIS' Technical Service Center (TSC) advised us that it is FSIS' policy not to require plants to provide their own testing results to inspectors.

Reanalysis of hazards. In designing its HACCP system, ConAgra management assumed that *E. coli* O157:H7 contamination was not a hazard that was likely to occur. Consequently, the ConAgra HACCP system was unprepared to respond to the actual hazards that could and did present themselves. FSIS regulations require that a plant reassess its HACCP system when food safety hazards are found in the finished product.

- ConAgra did not perform a reassessment of its HACCP system, even though its tests were showing an increasing presence of *E. coli* O157:H7 contamination.

[4] This exemption was provided for by FSIS Directive 10,010.1 (Microbiological Testing Program for *E. coli* in Raw Ground Beef), dated February 1, 1998. This exemption was discontinued by FSIS effective September 24, 2002.

- FSIS plant inspectors were aware of some of ConAgra's tests, but they believed that because the tests were not part of the HACCP program, they could not use the test results to force ConAgra to reassess its HACCP system.

Enforcement actions. Before the recall, FSIS issued multiple noncompliance notifications to ConAgra for fecal contamination of product (the source of *E. coli*), but FSIS took no decisive enforcement action. Instead, it continually allowed ConAgra to introduce superficial stopgap measures, such as increasing supervision or retraining an employee. The actions taken by ConAgra did not provide assurance that the physical and biological hazards to the production process had been identified and controlled. No FSIS policy stipulates what level of noncompliance should result in enforcement action.

Although inspectors at ConAgra raised concerns regarding the increasing level of fecal contamination and positive testing results, we could find no evidence that FSIS managers responded to the concerns raised. Before the recall, FSIS instituted a number of management reviews to provide FSIS managers with oversight mechanisms to better manage field operations, but ConAgra was never selected for any of these reviews.

Both FSIS and Beef Processors Were Unprepared for a Recall

Neither FSIS nor the processing plants involved in the ConAgra recall were prepared for the possibility of a recall. Although FSIS encourages all establishments to prepare recall plans, HACCP plans for two of the grinders using ConAgra beef did not address recall procedures. One of these grinders was unable to readily determine from its records which of its customers received the recalled product.

FSIS policies added to the inefficiency of the recall by impeding the inspectors' ability to trace a contaminant from the grinder's establishment back to the supplier. FSIS inspectors discovered the pathogen at a meat grinding plant that used ConAgra product, but they could not test traceback samples because FSIS policy required concurrence from its TSC before the samples could be drawn, and the district office could not get this concurrence. FSIS policy held grinders accountable for ensuring that the product from their suppliers was wholesome. This policy, and the need for TSC concurrence for traceback samples, contributed to a 7-day delay in the recall and added to the quantity of beef product recalled.

- FSIS had imposed no specific requirement that plants keep production or distribution records. Poor records at the establishments that used ConAgra beef increased the difficulty FSIS had in tracking the further disbursement of the ground meat.

- Reviews designed by FSIS to determine the effectiveness of the recall were not used to exercise control over the recall process. After a recall, FSIS conducts effectiveness checks to determine if all distributors of the recalled product were notified of the recalled product and if all recalled product had been withheld from further distribution. These reviews were not performed in time to maximize the amount of ConAgra product recovered, and problems found during the reviews received limited management attention.

- Even though 67 of the 490 effectiveness checks we reviewed indicated that distributors and others in the distribution chain had not been notified of the recall, FSIS district managers determined the recall was a success because, to their knowledge, no one consuming the unrecovered product became ill.

During the recall, ConAgra altered its HACCP process by introducing lactic acid into the production of ground beef to control the *E. coli* O157:H7 contaminant. FSIS approved the use of the acid but did not adequately document how it determined that lactic acid was an appropriate antimicrobial intervention in ground beef. We found scientific evidence that the use of lactic acid in ground beef may raise the cooking temperature necessary to destroy the *E. coli* O157:H7 contaminant. Thus, the pathogen may not be destroyed using current cooking temperature guidelines.

Monitoring Needs To Be Proactive

The recall of ConAgra beef products might have progressed more effectively if FSIS had provided closer monitoring of ConAgra and the establishments that processed its beef. Primarily, FSIS needed to ensure the establishments' HACCP plans were technically sufficient to ensure compliance with HACCP and SSOP requirements. HACCP plans at all three of the plants we reviewed for this audit did not adequately address all food safety hazards.

FSIS officials stated that the FSIS in-plant personnel performing most of the reviews of HACCP plans were not sufficiently trained and, therefore, not technically competent to make accurate assessments of the plans. In 2000, FSIS started a program to hire and train a staff of technically competent personnel, and by the end of 2002, it had about 105 individuals available to review the more than 5,000 HACCP plans at federally inspected plants. However, even with the program in place, FSIS does not want or plan to have approval authority over establishment HACCP plans.

FSIS oversight needed strengthening in other key areas:

- FSIS guidance to reinspect carcasses when fecal contamination is observed is not clearly announced in FSIS' written policy. We noted at least one case where 175 beef carcasses at ConAgra may have been contaminated with fecal matter and were not reinspected.

- FSIS' current random nationwide sampling of plants for the presence of *E. coli* O157:H7 does not verify the effectiveness of HACCP systems and does not measure the extent of a hazard. We concluded that the sampling should be based on the risk posed by individual plants.

- FSIS has no written procedures that require FSIS personnel to take control of or monitor beef that has tested positive for *E. coli* O157:H7. FSIS allowed ConAgra to resell contaminated beef without verifying that the buyers would not reuse it as raw ground.

The Office of Inspector General issued a series of food safety audits in 2000 that reported our assessment as to whether FSIS' meat and poultry inspection program remained effective under HACCP. In that food safety initiative summary report, we concluded that while FSIS had taken positive steps in its implementation of the science-based HACCP program, FSIS needed to command a more aggressive presence in the inspection and verification process; it had reduced its oversight short of what was prudent and necessary for the protection of the consumer. The conditions noted in our review of the ConAgra recall have again led us to question the adequacy of establishment HACCP plans and FSIS' oversight and verification programs that identify and control hazards to the production process.

Two of the conditions we noted during this review are, in our judgment, material internal control weaknesses—namely (1) that FSIS lacked a process to accumulate, review, and analyze all data available to assess the adequacy of food safety systems and (2) that accurate assessments of HACCP plans had not been made because FSIS lacked sufficient, competent staff to make those assessments. As material weaknesses, these conditions should be included in the agency's Federal Manager's Financial Integrity Act (FMFIA) report.

During the recall and audit, FSIS took a number of actions to strengthen their inspection procedures. Also, in October 2002, FSIS informed establishments producing raw beef products of the need to reassess their HACCP plans, based on the assumption that *E. coli* O157:H7 is a hazard reasonably likely to occur at all stages of the process. FSIS has also begun comprehensive food safety assessments to evaluate the adequacy

of HACCP plans and food safety systems. These assessments are critical to the success of HACCP.

On March 19, 2003, the Secretary of Agriculture issued a challenge to FSIS calling for creative and effective ways to modernize FSIS' ability to continue to improve the safety of U.S. meat, poultry, and egg products to better protect public health. On July 10, 2003, the Department released a food safety vision document titled "Enhancing Public Health: Strategies for the Future." This document articulated five core goals: (1) improve the management and effectiveness of regulatory programs; (2) ensure that policy decisions are based on science; (3) improve coordination of food safety activities with other public health agencies; (4) enhance public education efforts; and (5) protect meat, poultry, and egg products against intentional contamination. The vision statement, as well as portions of FSIS' response to the recommendations made in this report, describes the agency's accomplishments to date in meeting these goals. FSIS' response to this report, as well as exhibit B, presents other actions under consideration to correct the problems reported herein.

KEY RECOMMENDATIONS

We are recommending that FSIS provide clear authority for FSIS' access to all internal and external plant pathogen and microbial testing results, including tests performed for customers, and ensure plants notify FSIS of test results, especially when those results show the presence of pathogens. We had made a similar recommendation in our prior report of 2000, but FSIS determined not to amend the Grant of Inspection. We are reiterating the recommendation because we believe events have shown that FSIS needs to revisit its authorities and establish operating procedures to address the weaknesses disclosed in this audit.

We are recommending that FSIS reassess its management control process over the recall operations. FSIS should make recall activities more effective by ensuring that ground beef is traceable from manufacturing to point-of-sale and that adequate production records are maintained to facilitate traceback. Regulations need to be issued to provide clear directions on when traceback samples are to be collected and how the samples are to be processed.

We are also recommending that FSIS:

- establish a management control process to accumulate, review, and analyze all data available to the agency;

- establish criteria when enforcement action should be taken for repetitive violations and/or ineffective corrective action;

- increase supervision and oversight of ConAgra, Establishment 969, until the plant demonstrates it is capable of sanitary and wholesome production;

- strengthen its monitoring of inspector activities to ensure the inspectors achieve an acceptable level of performance in applying HACCP requirements; and

- define the goals, objectives, and methods of its *E. coli* O157:H7 testing program and ensure that the program is risk-based and includes performance measures.

Finally, we are recommending that FSIS instruct FSIS inspection personnel to take control of *E. coli* O157:H7 adulterated product and verify that product is properly processed or destroyed.

AGENCY RESPONSE

In its August 18, 2003, written response to the official draft report, FSIS was in agreement with the findings and recommendations presented therein, except for Recommendations Nos. 2, 9, 12, 15, and 24. Based on FSIS' response, we revised Recommendation No. 9. We have incorporated applicable portions of FSIS' response, along with our position, in the Findings and Recommendations section of this report. The agency's response is included in its entirety (except for the enclosures) as exhibit G.

OIG POSITION

We concur with FSIS' proposed corrective actions and have accepted management decisions for Recommendations Nos. 3, 4, 6, 7, 10, 11, 18, 19, 23, and 26. However, FSIS did not provide the specific actions planned, and estimated timeframes for implementation, to correct the conditions noted for Recommendations Nos. 1, 2, 5, 8, 9, 12-17, 20-22, 24, 25, and 27-31. FSIS, for these recommendations, generally responded that a directive will be issued or that a working group will be convened to study and recommend changes to its policies and procedures. Since FSIS has not provided the specific actions it will take to correct the conditions noted, we cannot accept management decisions for these recommendations.

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INTRODUCTION

BACKGROUND

A request from the Senate Committee on Agriculture, Nutrition, and Forestry, dated July 26, 2002, asked the Office of Inspector General (OIG) to examine the effectiveness of the response by the U.S. Department of Agriculture (USDA) to the recall of 18 million pounds[1] of ground beef and beef products by the ConAgra Beef Company (ConAgra)[2] after beef product from that company was found to contain the pathogen *Escherichia coli (E. coli*) O157:H7.[3] At the time of this request, OIG had an audit survey in process to evaluate Food Safety and Inspection Service (FSIS) recall program. This work was put in abeyance to address the ConAgra recall.

Beginning in mid-June 2002, at least 46 people in 16 States consumed ConAgra ground beef products and became ill. It was subsequently determined that these illnesses were caused by ground beef that was adulterated with *E. coli* O157:H7. Testing, conducted by the Colorado Department of Public Health and Environment and the Centers for Disease Control and Prevention (CDC), confirmed that about 23 individual *E. coli* illnesses around the State of Colorado were from the same genetic strain of *E. coli*. In mid-June, FSIS microbiological tests of ground beef at a Denver meat grinder identified the presence of the *E. coli* O157:H7 pathogen. Later testing of the raw materials used in the ground beef that tested positive for the pathogen identified the source of the contamination as beef products coming from the ConAgra plant in Greeley, Colorado.

On June 30, 2002, ConAgra officials agreed to an initial voluntary recall of 354,200 pounds of ground beef, which they identified as being produced on May 31, 2002, and the probable source of the adulterated product. At

[1] For the USDA press release, 19 million pounds was estimated. The actual number of pounds recalled was 18,048,361.

[2] The recalled product was produced at the ConAgra plant in Greeley, Colorado. According to press reports, the plant is one of the largest in the Nation, employing about 2,500 people. The plant slaughters about 1.2 million cattle a year and processes, on average, at least 350 cattle per hour.

[3] *E. coli* O157:H7 is one of hundreds of strains of the bacterium *Escherichia coli*. Although, most strains are harmless and live in the intestines of healthy humans and animals, this strain produces a powerful toxin and can cause severe illness. *E. coli* O157:H7 was first recognized as a cause of illness in 1982; the outbreak was traced to contaminated hamburgers. Since then, most infections have come from eating undercooked ground beef. The combination of letters and numbers in the name of the bacterium refers to the specific markers found on its surface and distinguishes it from other types of *E. coli*. The organism can be found on a small number of cattle farms and the organism can live in the intestines of healthy cattle. Meat can become contaminated during slaughter, and organisms can be thoroughly mixed into beef when it is ground. Eating meat, especially ground beef that has not been cooked sufficiently to kill *E. coli* O157:H7, can cause infection (CDC Disease Information, *Escherichia coli* O157:H7, website).

the direction of the Secretary, FSIS conducted an indepth review of ConAgra plant practices and company records. The review revealed multiple positive company sample results of its beef trim on various dates during the period April 12 through July 11, 2002.

On July 18, 2002, because of the FSIS review, the company decided that the recall needed to be expanded to include about 18 million pounds of ground beef and beef trim. On the same day, FSIS issued a Notice of Intended Enforcement (NOIE) to ConAgra that allowed the company 3 days to respond in writing to demonstrate why an inadequacy determination should not be made against its sanitation standard operating procedure (SSOP) and its Hazard Analysis and Critical Control Point (HACCP) system. Based on the company's response and planned corrective actions, the NOIE was held in abeyance and the plant continued to operate from July through mid-November. However, on November 15, 2002, FSIS suspended inspection services, effectively closing the plant. Inspection services were suspended because of repeated "zero tolerance" violations that occurred following the issuance of the NOIE. (FSIS policy tolerates no amount of fecal material, ingesta, or milk in beef.) Zero tolerance failures had been a recurring problem at the plant for several years. The plant was allowed to resume operations on November 20, 2002, after the company presented FSIS with planned corrective actions that were deemed sufficient to correct the problems with zero tolerance failures.

USDA's actions in carrying out the recall received widespread publicity and criticism in the Press and from Congress. These critics noted that the recall did not start until the end of June even though contaminated product was first produced in April and that the recall had to be expanded because not all potentially contaminated product had been identified until July. The critics also took FSIS procedures to task because they did not stipulate that FSIS should notify suppliers that their products were potentially the cause of contamination in ground beef found at meat grinders. The *E. coli* O157:H7 contamination was first identified at a Denver meat grinder – Galligan Wholesale Meat Company (Galligan) – that used ConAgra beef. Shortly thereafter, a Montana meat grinder, Montana Quality Foods & Processing, Inc., (Montana Quality Foods), claimed to have suffered *E. coli* O157:H7 contamination from ConAgra beef as early as January 2002.

Food Safety and the HACCP System

To improve the safety of meat and poultry products, FSIS implemented regulatory requirements intended to ensure that plants operate food safety systems that are prevention-oriented and science-based. These systems, called HACCP systems, were phased in from January 1998 through

January 2000 at all meat and poultry slaughter and processing plants. Under the HACCP system, plants are responsible for developing plans that identify all of the contamination hazards that are reasonably likely to occur in a plant's production environment, establish the steps needed to control these hazards, and have valid scientific evidence to support their decisions.

Because the HACCP system relies on scientific standards, rather than the earlier sight-touch-smell inspections by FSIS inspectors, processing plants assume more control over the wholesomeness of their product. In turn, FSIS assumes a less obvious presence and relies, in part, on the pathogen test results to determine the effectiveness of the plants' HACCP controls.

FSIS, through its 15 district offices across the country, oversees the activities of about 7,500 Federal inspectors who review the operations of about 5,000 plants subject to the HACCP requirements nationwide. As a part of their oversight, inspectors ensure that the plants' HACCP plans respond to the seven criteria established by regulation. The generic HACCP plan calls for the plant to:

- Conduct an analysis of the potential hazards that could threaten the safety of the product;

- Identify critical points where controls can be applied to prevent, eliminate, or reduce a food safety hazard to an acceptable level;

- Establish critical limits (e.g., minimum temperatures) at which the hazard is controlled;

- Establish monitoring procedures to ensure that the measured values (temperatures, foreign particles, etc.) are within critical limits;

- Establish corrective actions to be taken if critical limits are violated;

- Establish recordkeeping procedures to document the monitoring of critical control points (CCP); and

- Establish verification procedures to ensure the HACCP plan is effective.

When FSIS inspectors find a violation of the HACCP requirements, such as a plant's failure to control fecal contamination, they document the violation on a noncompliance record (NR) and advise the plant. If the plant does not correct the violation, FSIS may take an enforcement action, such as slowing one or more production lines or withholding the "USDA

Inspected" stamp. From a sample of 14 large[4] cattle slaughter plants like ConAgra, we found that FSIS issued an average of 89 NRs in 2001 and an average of 44 through August 2002. By contrast, ConAgra received 103 NRs in 2001 and 43 through August 2002.

Prior Criticisms of FSIS' Oversight of HACCP

In 1999, the General Accounting Office (GAO) reported that weaknesses in FSIS' training for its inspectors affected its ability to ensure consistent and effective oversight of HACCP.[5] The following year, an OIG report identified shortcomings in plants' HACCP plans and deficiencies in FSIS' oversight of HACCP's implementation.[6]

To help address these problems, FSIS stepped up its inspector training and initiated reviews of inspection practices in selected districts and of HACCP plans in plants with serious safety problems. In addition to the food safety system correlation reviews and indepth verification reviews, FSIS conducts seven other types of internal reviews to ensure their programs are functioning effectively. These reviews include reviews of agency programs, processes, and related management controls and reviews to assist in program planning, implementation, improvement, and accountability. FSIS also introduced consumer safety officers (CSO) into its workforce with the expertise to review the scientific soundness of HACCP plans. As of December 31, 2002, about 105 individuals were trained as CSOs.

Science Testing and *E. Coli*

According to CDC, *E. coli* O157:H7 is an emerging cause of foodborne illness.[7] An estimated 73,000 cases of infection and 61 deaths occur in the United States each year. Most illness has been associated with eating undercooked, contaminated ground beef. Although the number of organisms required to cause the disease is not known, it is suspected to be very small. *E. coli* O157:H7 is one of hundreds of strains of the bacterium *Escherichia coli*. Although most strains are harmless and live in the intestines of healthy humans and animals, the O157:H7 strain produces a powerful toxin and can cause severe illness.

On October 17, 1994, FSIS began a microbiological testing program for *E. coli* O157:H7 in raw ground beef. The objective of the testing program

[4] FSIS defines large plants as those employing 500 or more employees.
[5] GAO/RCED-00-16, Meat and Poultry: Improved Oversight and Training Will Strengthen New Food Safety System, dated December 8, 1999.
[6] OIG Report No. 24001-3-At, Implementation of the Hazard Analysis and Critical Control Point System, dated June 2000.
[7] CDC Disease Information, *Escherichia coli* O157:H7, website.

was to detect *E. coli* O157:H7 and to "stimulate industry action to reduce the presence of the pathogen in raw ground beef." In 1998, when the HACCP program was initiated, FSIS expanded the objectives of the testing program to include verification that the plant's HACCP system was effective. Under the testing program, 600 tests are randomly scheduled at establishments producing raw ground beef each month.

ConAgra was generally exempted from the testing program because it used its own validated pathogen reduction interventions on beef carcasses.[8] ConAgra routinely verified the effectiveness of the interventions by testing for *E. coli* O157:H7 on carcasses and prevented the use of boneless beef or carcasses from outside sources. Consequently, since 1998 there were only four FSIS tests of raw ground beef taken at ConAgra before the recall. One sample was discarded and three tested negative. ConAgra did not test for *E. coli* O157:H7 in its ground beef products.

The Recall Process

If an HACCP system fails and adulterated or misbranded products are identified in commerce, FSIS will seek voluntary recalls of the affected products. Although recalls are voluntary, FSIS oversees all recall activities by official meat and poultry firms. FSIS also has the authority to detain and seize adulterated or misbranded products, if necessary.

When determining the need for a recall, the FSIS Recall Management Division (RMD) assembles a recall committee. The committee is made up of representatives of various FSIS divisions who oversee the recall. Typically, recalls include a hazard evaluation, a recall classification, a recall recommendation, a public notification, and a recall notice report. The recall is followed by effectiveness checks, during which FSIS compliance officers determine if all distributors of the recalled product had been notified of the recall and if all recalled product had been withheld from further distribution. The recall ends when the plant that initiated the recall reports that the recall is completed, and when FSIS compliance and RMD concur that the recalling firm has made all reasonable efforts to recall product, and that the firm has either disposed of the product or the product is under company or FSIS control. FSIS then notifies the firm in writing that the recall is closed.

In 2002, FSIS added regulations that call for an information-sharing process between Federal and State governments during a recall. Under these new regulations, FSIS would give States a distribution list of the

[8] This exemption was provided for by FSIS Directive 10,010.1 (Microbiological Testing Program for *E. coli* O157:H7 in Raw Ground Beef), dated February 1, 1998.

customers of a firm that is recalling meat products in those States. Such a list would help State health authorities locate and sequester recalled products. Because the distribution lists are confidential commercial information, State agencies requesting the lists are to provide a written agreement not to disclose such information without the firm's written permission. The new regulations were proposed in an April 2002 Federal Register, and the accompanying memorandums of understanding between FSIS and the six participating States were not signed until September 2002.

The Federal Manager's Financial Integrity Act (FMFIA) requires that agencies evaluate their systems of management controls and report any material weaknesses identified in its fiscal year 2002 report to the Office of the Chief Financial Officer. FSIS reported that they had no material weaknesses and their management control systems generally complied with the FMFIA.

OBJECTIVES

Our overall audit objective was to respond to a Congressional request to evaluate FSIS' recall system in light of widespread publicity and criticism related to the recent ConAgra recall and to identify potential threats to consumers. Specifically, our objectives were to:

- Determine whether FSIS was aware of potential problems at ConAgra that could lead to a recall;

- Determine the effectiveness of FSIS' response regarding the ConAgra recall, specifically whether FSIS followed its existing procedures (see exhibit B); and

- Identify any improvements needed to better protect consumers.

The Congressional request also asked us to examine two other areas: USDA's program for recalling meat and poultry products, and the Department's progress in addressing problems identified in our 2000 review of the implementation of the HACCP program, FSIS' determinations of U.S.-equivalency of food safety systems in foreign countries, FSIS' program for testing pathogens, and the effectiveness of FSIS' compliance activities. These two additional areas of the Congressional request are being addressed in separate audits and our conclusions about them will be reported under separate covers.

SCOPE

The audit fieldwork was conducted at the FSIS National Office in Washington, D.C.; the Boulder, Colorado, and Minneapolis, Minnesota, District Offices; and three plant locations. Other sites were visited as needed (see exhibit A for a complete list of the locations visited). We reviewed FSIS policies and procedures at the National Office and district offices visited. We focused our review on regulations and procedures related to production of beef products.

Records we reviewed at ConAgra generally covered the period April through August of 2002, but longer periods were reviewed when deemed necessary.

The fieldwork was conducted during the period August 2002 through March 2003. We conducted this audit in accordance with Government Auditing Standards.

METHODOLOGY

To accomplish our audit objectives we performed the following fieldwork:

- We analyzed documents and conducted interviews with FSIS Headquarters officials;

- We contacted officials of the food industry and representatives of USDA's Agricultural Research Service (ARS);

- We reviewed FSIS' regulations, instructions, procedures, and studies; published reports; media releases; and other Government reviews and studies; and

- We conducted site visits to the FSIS National Office, FSIS Technical Service Center (TSC), district offices, and industry plants for review and analysis.

Our reviews at the plant locations included evaluation of the plants' written SSOPs, HACCP plans, pathogen testing procedures, responses to FSIS NRs, procedures followed for the recalls, and returned product procedures. Our evaluation of the HACCP plans included an indepth review with the assistance of technical experts from the FSIS TSC. We also toured the plant locations and observed plant operations, including pre-operational cleanup procedures and monitoring activities at the designated CCPs. We made a detailed review of the HACCP processing records, production records, NRs, microbiological testing records from both ConAgra and Warren Analytical Laboratory, and records associated

with the recall at ConAgra. Recall related records reviewed included customer notifications, records of recovered product, and effectiveness checks.

The sites selected for review included the ConAgra plant involved in the recall and two meat grinding facilities that used ConAgra products in their process, specifically Galligan and Montana Quality Foods. The following table provides the most important statistics about these establishments:

Figure 1: Vital Statistics of Sites Visited

Plant	Estimated Production
ConAgra Establishment No. 969 Greeley, Colorado	An average of 5,200 head of fat cattle are slaughtered and fabricated each day. This produces about 2.1 million pounds of boxed beef and 1 million pounds of boneless beef trim daily. Of this 1 million pounds of boneless beef trim, 350,000 pounds is used for ground beef production within the establishment, 100,000 pounds is rendered for technical fat, and 550,000 pounds is sold to other processors. Variety meat production (hearts, livers, head meat items, tripe, etc.) adds an additional 270,000 pounds of production each day.
Galligan Wholesale Meat Company, Establishment No. 6475 Denver, Colorado	The plant does not have a slaughter operation. During a month, it processes about 10,000 pounds of ground beef, 10,000 pounds of ham product, 1,000 pounds of sausage, and smaller amounts of beef patties, Salisbury Steaks, and chicken.
Montana Quality Foods & Processing, Inc. Establishment No. 7679 Miles City, Montana	The plant normally slaughters 12-15 head per day and, during busy times, slaughters 20-25 head per day. Slaughter operations are conducted only 1 day per week. The plant produces about 700,000 pounds of product annually.

FINDINGS AND RECOMMENDATIONS

CHAPTER 1	AVAILABLE INDICATORS BEFORE THE RECALL SHOWED THAT *E. COLI* O157:H7 CONTAMINATION WAS A PROBLEM AT CONAGRA

Neither ConAgra nor FSIS effectively fulfilled their responsibilities under HACCP. Data existed prior to the recall that showed *E. coli* O157:H7 contamination was a continuing problem at ConAgra. ConAgra did not design or reassess its food safety system to ensure it operated in compliance with SSOP and HACCP requirements. FSIS lacks a process to accumulate, review, and analyze all data available to them to monitor and assess plant compliance. We consider this a material weakness in FSIS' inspection and verification activities. FSIS needs to be more proactive in seeking access to all available sources of plant data and in analyzing the data's importance as indicators of problems. Also, FSIS' written and unwritten policy to defer to the plant to detect and control any contamination precluded FSIS' inspectors from making their own early detection of the contaminant and limiting any recall.

Under the science-based HACCP system, FSIS tests for pathogens, such as *E. coli* O157:H7, at establishments that purchase and process beef. FSIS schedules 600 random nationwide *E. coli* pathogen tests on ground beef each month, and some meat processors, like ConAgra, perform their own pathogen tests on carcasses. We found several weaknesses in FSIS' role in the pathogen testing and in implementing the HACCP system at ConAgra.

FSIS tests at ConAgra. FSIS had relinquished its testing of most of the beef production process at ConAgra and determined it had no clear authority to review non-Government testing results even though it knew the tests showed the presence of the *E. coli* O157:H7 pathogen. Under FSIS policy, plants like ConAgra were encouraged to perform their own pathogen tests on beef carcasses, allowing them to be exempt from FSIS random testing.[9] Moreover, FSIS did not test beef trim (an ingredient in ground beef) and did not ask ConAgra to share

[9] During the recall, FSIS revoked its policy of exempting plants from random testing. Ground beef products from all plants, including ConAgra, are now tested routinely for *E. coli* O157:H7.

its test results on trim because FSIS' policy was unclear on whether to consider contaminated trim as adulterated.

ConAgra tests for generic *E. coli*. FSIS requires plants like ConAgra to routinely monitor the presence of generic *E. coli* on beef carcasses. (Generic *E. coli* is naturally occurring, but large amounts of the microbe indicate a potential problem with the plant's control of fecal contamination.) For 2002, ConAgra increased the amount of generic *E. coli* it would tolerate in its product, but FSIS did not question this increase.

ConAgra's HACCP plan. ConAgra managers designed their HACCP plan under the flawed assumption that the *E. coli* O157:H7 pathogen was unlikely to occur in their product, and they did not alter this assumption in spite of growing evidence that the pathogen was contaminating their beef and that their HACCP system was not controlling the contamination. Although aware that there was a contamination problem, FSIS inspectors did not ask to see evidence of the contamination to determine how severe the problem was.

Recurring fecal contamination. Although animal feces on product was repeatedly observed during production at ConAgra, and although FSIS notified ConAgra of these repeated violations, FSIS took no enforcement action. (Animal feces is one source of the *E. coli* O157:H7 pathogen.) FSIS has issued no guidance on what constitutes an excessive number of violations and requires enforcement.

FSIS management and supervision of the ConAgra inspection team was inadequate. Supervisors were not always responsive to the inspectors' concerns relating to increasing levels of fecal contamination and positive *E. coli* testing results. FSIS management reviews could have been used to determine that the contamination problem at ConAgra was severe, but FSIS did not perform any of these reviews at ConAgra.

FINDING NO. 1

FSIS DID NOT REVIEW TEST DATA AT CONAGRA THAT SHOWED *E. COLI* O157:H7 CONTAMINATION

As a result of unclear FSIS policy and regulations, FSIS had relinquished its testing of most of the ground beef production process at ConAgra and determined it had no clear authority to review non-HACCP test results that it knew showed the presence of *E. coli* O157:H7. FSIS' policy was not to test the beef cuts used in the production of ground beef, and it did not exercise its prerogative to test the ground beef itself during processing. Because of these policy decisions on the part of FSIS, the agency was forced to rely solely on ConAgra to identify the presence of *E. coli* O157:H7 in its product and to eliminate the pathogen.

Also, ConAgra was able to claim proprietary interest in many other test results. Without access to the ConAgra test results, FSIS could not ensure that all potentially adulterated products had been recalled from commerce.

Pathogen testing can take several forms: FSIS can test samples of its own selection; plants can test samples either for HACCP purposes or for in-plant purposes; and trim beef buyers (processors, distributors, etc.) can have tests performed at their own expense. ConAgra owned and operated its own testing laboratory and used it for its own test samples, for HACCP test samples, and for tests requested by its customers.

a. FSIS Had Not Clarified Requirements For Testing Beef Trim

Beef trim. FSIS had not clarified the actions field inspectors are to take when trim containing *E. coli* O157:H7 is considered adulterated (used in making ground beef). In 1994, FSIS notified the public that raw ground beef products contaminated with the pathogen *E. coli* were adulterated unless the ground beef was further processed to destroy the pathogen. On January 19, 1999, FSIS announced that the policy on ground beef would be expanded to all non-intact beef product, including beef trim that would subsequently be used to produce raw ground beef.[10] However, in its March 15, 1999, publication, Constituent Update, FSIS explained the agency would not act on its January 19, 1999, policy statement until it had an opportunity to consider the comments received. This information was also included in a notice in the Federal Register.[11]

We found no subsequent instructions addressing the agency's proposed policy that beef trimmings contaminated with *E. coli* O157:H7 would be considered adulterated. The agency did not develop any nationwide system to test beef trim for *E. coli* O157:H7, and it did not provide inspectors-in-charge (IIC), circuit supervisors, and district office personnel with instructions for implementing the policy specified in the Federal Register. Also, on October 7, 2002, the agency stated in a Federal Register Notice (Vol. 67, No. 194) that the agency's policy regarding beef trim had been in effect since January 1999.

[10] Federal Register Vol. 64, No. 11, 2803, (Beef Products Contaminated with *E. coli* O157:H7), dated January 19, 1999.
[11] Federal Register Vol. 65, No. 29, 6881, (Recent Developments Regarding Beef Products Contaminated with *E. coli* O157:H7; Public Meeting), dated February 11, 2000.

Ground beef. As a result of an FSIS policy to encourage plants to take greater responsibility for the wholesomeness of their product, FSIS developed procedures[12] that may have limited its ability to identify products containing pathogens.[13] Under these procedures, FSIS inspection personnel typically did not collect raw ground beef samples to be tested for *E. coli* O157:H7 at plants, such as ConAgra, that have pathogen reduction interventions of their own (see Finding No. 11). In lieu of pulling a sample for FSIS testing when a sampling request was received, FSIS policy limited inspectors to reviewing plant records for positive test results on carcasses within the last 6 months. If a positive test result had occurred on carcasses, FSIS would then perform its own test on ground beef for *E. coli* O157:H7. Since testing of carcasses is considered to be performed under the HACCP plan, the test results were available to FSIS. FSIS' sampling plan prohibits the inspectors from drawing ground beef samples on their own. Since ConAgra had no positive test results on carcasses for 2 years prior to the recall, this accounts for the low number of FSIS ground beef tests (only two were performed since September 2000) performed at ConAgra.

b. Under Existing FSIS Policy, ConAgra's HACCP Tests Did Not Need To Reflect the Information Derived From non-HACCP Sources

ConAgra normally produced about 1 million pounds of boneless beef trim[14] each day yet, under its HACCP plan, it was required to test only beef carcasses. These tests (available to the inspectors) had not disclosed any positive *E. coli* O157:H7 results for 2 years before the recall. By contrast, non-HACCP tests of beef trim taken by ConAgra in 2002 alone showed at least 63 positives before the expanded recall and 115 total positives (in trim, one ground beef sample tested by FSIS, and the plant environment) through October 21, 2002.

Regulations do not specifically require plants to share the results of tests that are not called for in the HACCP plan. The IIC at ConAgra said the plant voluntarily shared positive test information with him from both its tests and its customers' tests, but this was usually oral information or summary information, never detailed laboratory test results. The IIC took no action on the positive test information because he understood it was FSIS' policy not to monitor or rely on non-HACCP

[12] FSIS Directive 10,010.1, (Microbiological Testing Program For *E. coli* O157:H7 in Raw Ground Beef), dated February 1, 1998.
[13] This condition was reported in our prior report (Finding No. 5), Audit Report No. 24001-3-At, Implementation of the Hazard Analysis and Critical Control Point System, dated June 2000.
[14] This 1 million pounds of boneless beef trim is used for ground beef production (350,000 pounds) within the establishment, rendered for technical fat (100,000 pounds), or sold to other further processors (550,000 pounds) per day.

tests conducted by plants. Such tests posed problems, foremost of which was FSIS' inability to establish a chain of custody to verify the samples had not been tampered with. The IIC also noted that during an October 2000 work meeting at the Boulder Office, a representative of FSIS' TSC told the group that if a plant tests on its own, finds problems, and takes appropriate action then FSIS will not become involved. The district office gave similar instructions.

c. FSIS Did Not Require ConAgra to Disclose Non-HACCP Test Results

Current FSIS policy and regulations do not require ConAgra to provide information on internal test results to FSIS inspectors at the plant. In cases where a plant's HACCP plan contains provisions that would allow an inspector to see non-HACCP test results, FSIS would have the authority to review them. But there is currently no requirement that HACCP plans contain this provision and, under current policy, the inspectors would not request the information.

FSIS National Office officials said a change to the regulations might be possible but questioned the need for it. One official said the Federal Meat Inspection Act (Act) was sufficiently broad to give FSIS access to all records of a plant pertinent to food safety, including non-HACCP internal test results. Another official said that he believed the Act allowed FSIS to require plants to make their test results available to FSIS personnel. National Office officials noted that compliance officers had access to more plant records than inspectors did and that FSIS also had subpoena authority. Headquarters officials questioned if knowing plant test results would be of value and noted such requirements could hamper FSIS' efforts to have plants do more testing on their own.

We believe FSIS needs to have immediate access to all data necessary to evaluate the adequacy of a plant's implementation of HACCP and the effectiveness of the plant at reducing or eliminating contaminants. Had FSIS reviewed and analyzed all test results at ConAgra, the increase in positive *E. coli* O157:H7 results may have been noted and acted upon.

d. Guidance Is Needed on FSIS Access to "Customer Tests"

Officials of two nationwide fast food chains informed us that they require microbiological tests as part of their normal purchasing process. These tests include *E. coli* O157:H7, *Listeria*, and *Salmonella*. From June 1, 2001, through August 30, 2002, ConAgra's customers paid for about 1,400 of these tests, which ConAgra calls

"customer tests." No policy offers guidance on FSIS access to these tests.

The scope of our audit at ConAgra was initially impaired because we were unable to review detailed laboratory beef trim microbiological test results performed for customers. ConAgra stated the test results could not be provided because they were considered the property of customers and disclosure was prohibited by corporate policy. The laboratory that performed the tests also refused to provide the test results. Laboratory officials stated that customer test results were considered confidential and could only be obtained through or with the permission of the customers. Officials further stated that maintaining the confidentiality of test results was a condition of their International Organization for Standardization (ISO) 17025 accreditation.

We were subsequently able to review the test results after obtaining written permission from the customers. The test results showed that over the 3-month period of the expanded recall (April 12 through July 11, 2002) there were 63 positive test results for *E. coli* O157:H7 in ConAgra beef trim. In addition, during the recall period, there were three additional environmental *E. coli* O157:H7 positive results found at the plant. Since the end of the recall period (July 12 through October 21, 2002), we were provided information showing that there had been an additional 49 *E. coli* O157:H7 positives in its trim and ground beef.

Other sources showed variable results. FSIS cited in the NOIE that tests over the 5-week period May 20 through June 29, 2002, the ConAgra plant had 33 positive *E. coli* O157:H7 tests in its trim. An FSIS food safety inspection team found that over the 3-month period of the expanded recall, there were 59 positive *E. coli* O157:H7 tests in its customers' trim. From April 12, 2002, through October 21, 2002, OIG noted at least 115 *E. coli* O157:H7 positives (including food contact surfaces) at the ConAgra plant.

When FSIS does not have access to customer test results, it cannot ensure that contaminated product is removed from commerce if those test results show the presence of the *E. coli* pathogen in the product. We encountered one condition under which contaminated product was redirected by ConAgra and FSIS was unable to verify its disposition because it was unaware of the movements of the product. Regulations require that if a consignee of allegedly adulterated product, which bears an official inspection legend, refuses to accept delivery of the product on the grounds that it is adulterated, the consignee shall notify

the IIC of the kind, quantity, source, and present location of the product.[15]

ConAgra considered test results of beef trim leaving its plant to be the property of the customers. The customers considered that the title of product did not pass until a negative test result was provided. If the test was positive, the product was considered to remain the property of ConAgra, even if the product was located on a truck parked on the customer's premises. Accordingly, neither ConAgra nor the customer believed they were obliged to notify FSIS of the adulterated product.

To illustrate, we noted from ConAgra's returned products log, during the period covered by the recall, that there were 10 instances totaling about 118,000 pounds of beef trim where product was rerouted because of positive test results. Instead of having the products returned to its plant, ConAgra redirected the questionable lots of beef trim products to other processors and warehouses. According to ConAgra's records, the products for these 10 instances were shown to have been ultimately sent to processors for rendering, even though there was no evidence that FSIS was notified of their contamination or that it verified the products were handled properly. In addition, we further noted from ConAgra's returned product logs that there were 12 instances between July 12, 2002, and July 25, 2002 (after the period covered by the recall), where ConAgra had approximately 204,000 pounds of beef products reboxed at a warehouse for distribution to cookers because of positive test results. Again, there was no evidence that FSIS was notified and, therefore, it did not verify the disposition of the product.

FSIS' access to pathogen tests performed by establishments has been a continuing concern of OIG.[16] In our prior report, we recommended that FSIS expand the Grant of Inspection (1) to provide clear authority for Government oversight of all plant pathogen testing and (2) to include the requirements and responsibilities of the plant under the HACCP program and FSIS' oversight authority. In a December 7, 2001, response, FSIS stated that it did not believe that changing the Grant of Inspection to provide FSIS with clear authority or to include the plant's responsibilities was the most practical approach to enforcement. FSIS officials stated that they would provide OIG with an alternative action, but to date no alternative action has been proposed.

[15] 9 Code of Federal Regulations (CFR) 320.7, Reports By Consignees Of Allegedly Adulterated Or Misbranded Products; Sale Or Transportation As Violations. (All citations of 9 CFR are as of January 1, 2002, unless otherwise noted.)
[16] Audit Report No. 24001-3-At, Implementation of the Hazard Analysis and Critical Control Point System, dated June 2000.

After the recall, FSIS announced plans to initiate corrective action on some of the conditions described above (see exhibit B). We concluded that more needs to be done. FSIS can only meet its food safety responsibilities by being fully aware of all microbial problems that plants are experiencing, whether through its own tests or those taken by the plant for HACCP or non-HACCP purposes. FSIS needs to emphasize, either through its Grant of Inspection or through regulations and policy, that FSIS has an oversight responsibility in the production of beef products and has significant authority in fulfilling that responsibility, including the authority to access any and all pathogen tests taken by the establishment.

RECOMMENDATION NO. 1

Provide clear authority for FSIS access to all internal and external plant pathogen and microbial testing results, including tests performed for customers or where title has not passed.

FSIS Response

The Federal Meat Inspection Act provides authority for FSIS to access all plant generated pathogen testing results. On October 7, 2002, Federal Register Notice 62325, "*E. coli O157:H7 Contamination of Beef Products,*" was issued (Enclosure No. 1), which reminded establishments of their responsibility to keep records, including records concerning plant testing, and other pre-requisite program data, as part of ongoing verification of the plant's hazard analysis and 9 CFR Part 417.5, Records. FSIS inspection personnel have access to external testing results, which are available via the records associated with the establishment's shipping and receiving plans. Inspection personnel are expected to review records as they perform daily inspection procedures to verify whether HACCP regulatory requirements are being met. Establishments' shipping and receiving plan will identify the testing requirements that must be met. FSIS inspection personnel can review the results. It is also expected that FSIS inspection personnel will initiate appropriate action if records are not made available to FSIS.

In the event that enforcement is initiated, plant generated data become an important indicator of whether and how well the plant is executing corrective actions. As such, when the decision is made to defer enforcement or hold a suspension in abeyance based on an establishment's proposed corrective measures, as part of FSIS' verification activities, Compliance Officers (CO) and CSOs will review plant data bi-weekly, or monthly, in collaboration with in-plant personnel and provide recommendations to the District Manager as to whether further enforcement is warranted.

During the week of April 28-May 2, 2003, a compliance training session was held in Dallas, Texas. All COs and CSOs who are being cross utilized to carry out compliance duties received training regarding verifying plant data associated with enforcement actions. Participants were also advised that FSIS will issue an administrative subpoena to access records when a plant is unwilling to share testing data. As such, participants were instructed to contact their supervisor for further direction if they encounter plants unwilling to share their testing results with FSIS. Enclosure No. 2 contains the agenda for the compliance training session.

OIG Position

We cannot accept management decision because FSIS has not addressed the issue of inspector access to external test results performed for customers. Also, the corrective actions described, as related to enforcement action and administrative subpoenas, are applicable to situations where violations have already occurred. Our recommendation is intended to ensure that inspectors have ready access to all microbial and pathogen tests conducted by establishments on a routine basis as part of normal inspection procedures, not just when enforcement actions are initiated. During the audit, it was the position of ConAgra and its testing laboratory that test results for tests performed for customers were confidential, and could not be disclosed without the customer's permission. To determine the recall period, FSIS was provided only a summary of such test results prepared by ConAgra; FSIS was not provided the actual test results. OIG obtained the test results after getting a written release from the customers. To reach management decision for this recommendation, FSIS needs to provide clarification on how FSIS inspectors will gain access to actual customer test results on a routine basis, without the need for a written customer release or administrative subpoena.

RECOMMENDATION NO. 2

Require plants to notify FSIS of internal and external test results, especially positive test results for *E. coli* O157:H7. Instruct establishments to notify FSIS when adulterated *E. coli* O157:H7 product enters the plant, regardless of whether title to the product did or did not pass, and when the product is disposed of rather than returned to the plant.

FSIS Response

FSIS has informed beef establishments that their food safety systems for controlling *E. coli* O157:H7 must be reassessed. On October 7, 2002, Federal Register Notice 62325, "*E. coli O157:H7 Contamination of Beef Products,*" (Enclosure No. 1) was issued to advise establishments of their

obligation to reassess their HACCP plans for raw beef products. The Federal Register Notice also announced the availability of guidance materials for industry. In the Notice, FSIS advised establishments about disregarding the testing results of trim from one product lot to another. FSIS noted that it expects establishments to have a scientific basis that justifies why any raw ground product produced from trim that was found to be positive for *E. coli* O157:H7 should not be considered to be adulterated. The Notice provided a notification to establishments that FSIS will be increasing its scrutiny of food safety systems that test product. FSIS does not believe that further evaluation of the issue of notification of FSIS about positive results is warranted.

Consequently, FSIS disagrees that the notification is needed. FSIS believes that the recommendation should be restated to require specific instructions for FSIS personnel to effectively monitor and verify the establishment's handling of *E. coli* O157:H7 contaminated beef products. Specifically, 9 CFR Part 417.5, Records, outlines all record-keeping requirements. FSIS inspection personnel have access to internal and external testing results, which are available via the records associated with the establishment's shipping and receiving plans. Inspection personnel are required to review records as they perform daily inspection procedures to verify whether HACCP regulatory requirements are being met. Establishments' shipping and receiving plan will identify the testing requirements that must be met. FSIS inspection personnel can review all sampling results. It is also expected that FSIS inspection personnel will initiate appropriate action if records are not made available to FSIS.

FSIS will provide further guidance to industry and instructions to inspection program personnel on prudent measures to ensure that this product is diverted to other ready-to-eat product or for cooking. FSIS will address this issue in the new 10,010.1 Directive to be issued by October 2003.

By December 2003, FSIS will fully implement guidelines that address the responsibility of FSIS personnel to take control and monitor product that has tested positive, from both internal and external test results, for *E. coli* O157:H7. This will enhance the utilization of existing regulatory authorities pertaining to pre-shipment reviews, returned goods, hazard analysis and assessing the plant's decision-making documents related to these activities.

OIG Position

We agree with the actions proposed by FSIS to develop and implement guidelines that address the responsibility of FSIS personnel to take control and monitor product that has tested positive for *E. coli* O157:H7.

However, we cannot reach management decision because FSIS has not addressed the need to require plants to notify FSIS of internal and external test results, especially internal and external positive test results for *E. coli* O157:H7. FSIS is placing sole responsibility on the inspector to identify product that tested positive for *E. coli* O157:H7 by increasing scrutiny of food safety systems through periodic monitoring of shipping and receiving documents. The principles of HACCP assign dual responsibility for ensuring the safety of meat products. Therefore, OIG continues to believe that FSIS must place responsibility on the plant to timely notify FSIS when testing results identify the presence of a pathogen in the product, especially shipped lots. To reach management decision, FSIS needs to provide its rationale for why plants should not be held responsible for notifying FSIS when positive test results occur. Also, without routine access to external test results (see OIG Position, Recommendation No. 1) FSIS needs to provide a detailed description of the control processes that will be implemented to assure that positive test results are reflected in plant shipping and receiving documents.

RECOMMENDATION NO. 3

Issue policies that clarify to inspectors the authority for FSIS to consider *E. coli* O157:H7 in beef trim destined for grinding to be adulterated. Devise a risk-based sampling plan to select and test beef trim for pathogens.

FSIS Response

FSIS will address the issue of sampling trim in the revised Directive 10,010.1 to be issued by October 2003. The revised Directive provides for FSIS sampling of trim at Federal establishments.

On October 7, 2002, Federal Register Notice 62325, "*E. coli O157:H7 Contamination of Beef Products,*" (Enclosure No. 1) was issued to direct establishments to reassess their HACCP plans for raw beef products. The Federal Register Notice also announced the availability of guidance materials for industry and discussed revisions to be made to FSIS Directive, 10,010.1, "*Microbiological Testing Program For Escherichia coli O157:H7 in Raw Ground Beef*." In the Notice, FSIS provided notification that establishments that receive product for grinding must address *E. coli* O157:H7. Establishments were instructed to employ validated CCPs in their HACCP plans to address *E. coli* O157:H7. On November 4, 2002, FSIS issued FSIS Notice 44-02 (Enclosure No. 3), "*Instructions for Verifying E. coli O157:H7 Reassessment*." This Notice provided inspection personnel instructions for performing verification of *E. coli* O157:H7 reassessments. These documents clarify FSIS' position that *E. coli* O157:H7 in beef trim destined for grinding is considered to be adulterated.

OIG Position

We accept the management decision.

FINDING NO. 2

HACCP PLANS WERE NOT REASSESSED WHEN *E. COLI* PATHOGEN BECAME AN INCREASING PROBLEM

FSIS did not enforce a requirement that ConAgra reassess its HACCP plan even though evidence showed that fecal contamination was becoming an increasing problem at the plant. ConAgra managers concluded that the amount of *E. coli* O157:H7 being detected did not warrant their revising the HACCP plan or making significant operational changes. FSIS inspectors were aware that a problem existed, but they did not pursue the issue to apprise themselves of the full extent of the contamination because they believed the product tested (beef trim) was not within their authority under HACCP (see Finding No. 1). As a result, ConAgra's HACCP plan remained largely unchanged, and the plant continued to operate under ConAgra's assumption that contamination of its product by the *E. coli* O157:H7 pathogen was unlikely to occur.

Regulations require plants to conduct reassessments of their HACCP plans when food safety hazards are found in their finished product.[17]

Prior to the recall, ConAgra did not design or reassess its food safety system to ensure it operated in compliance with SSOP and HACCP requirements. In response to the recall and subsequent enforcement actions by FSIS, ConAgra reassessed its HACCP plans and with concurrence of FSIS, implemented a number of interventions (e.g., the use of lactic acid in ground beef) to reduce the occurrence of *E. coli* O157:H7. The actions taken by ConAgra both prior to and after the recall, however, did not provide assurance that physical and biological hazards to the production process had been identified and controlled.

We reviewed ConAgra's HACCP records for the period April through August 2002—before and during the recall. These records showed that the company's acceptable quality level checks were identifying fecal contamination in products on a regular basis. For the 5-month period we reviewed, fecal contamination was found in 23 instances in the slaughter department and in 187 instances in the variety meat department. ConAgra HACCP records also showed that *E. coli* O157:H7 was being found at an increasing rate at ConAgra beginning in April 2002. The record of fecal contamination in the HACCP logs combined with the

[17] 9 CFR 417.4(a)(3), Reassessment of the HACCP plan, dated January 1, 2002.

increasing number of positive test results for the *E. coli* O157:H7 pathogen found in the beef trim indicates that the company should have reassessed its HACCP plans before the recall.

Figure 2: ConAgra Tests for Customers Showing the Presence of *E. coli* O157:H7

Week of:	Number of Lots Tested	Number of Positive Tests	Percent Positive Tests
April 2	112	0	0.00%
April 8	107	1	0.93%
April 15	105	4	3.81%
April 22	152	0	0.00%
April 29	131	2	1.53%
May 6	105	0	0.00%
May 13	110	1	0.91%
May 20	124	6	4.84%
May 28	92	5	5.43%
June 3	139	3	2.16%
June 10	156	13	8.33%
June 17	152	3	1.97%
June 24	155	9	5.81%
July 1	268	3	1.12%
July 8	269	17	6.32%
July 15	305	11	3.61%
July 22	348	7	2.01%
July 29	491	2	0.41%

By contrast, the positive test results from FSIS' nationwide testing program was less than 1 percent.[18]

HACCP records showed that ConAgra reassessed one of its HACCP plans on February 11, 2002, when a new CCP was added to the process. The records also showed that in April 2002, at the time the problems with fecal contamination and positive tests for *E. coli* O157:H7 were starting to increase, company officials did their annual review of four of their HACCP plans (variety meats, advanced meat recovery, ground beef, and edible rendering) and signed the plans to show no changes were needed. Instead of reassessing the HACCP plans, the company officials chose to consider each occurrence of the pathogen as a hazard that was unlikely to occur and determined there was no need to alter any operations at the plant. This determination was questionable based on the *E. coli* O157:H7

[18] In 2001, FSIS tested 5514 samples and found that 0.87 percent tested positive. In 2002, the year of the recall, FSIS tested 5430 samples (through October 10, 2002) and found that 0.88 percent tested positive.

testing results. ConAgra could not demonstrate that it fully analyzed why the *E. coli* O157:H7 problem continued to occur.[19]

FSIS' in-plant inspectors advised us that they were aware there were some positive tests for *E. coli* O157:H7 before the recall because product was returned to the plant. The inspectors were informed of the contamination in the returned product by ConAgra officials and observed the product being repackaged and labeled "for cooking only." However, the positive tests were for samples of beef trim and, as noted in Finding No. 1, the inspectors did not ask to review the test results because they believed tests on beef trim were not part of the HACCP program. Consequently, the plant inspectors believed they could not require ConAgra to reassess its HACCP plans.

Company officials said they would have made test results available for any tests taken for internal company use, if asked, and later provided the information to the FSIS Food Safety Investigation team and to OIG. If the inspectors had reviewed the test results and been fully aware of the scope of the problem, they may have been in a better position to take prompt action to enforce the relevant sections of the HACCP regulations.

In response to the recall and subsequent enforcement actions by FSIS, ConAgra is reassessing its HACCP plans and validating the effectiveness of its proposed corrective actions. The process of reassessing the HACCP plans does not require that the underlying cause of processing problems be identified. The reassessment only requires that critical points be identified where controls can be applied to reduce or eliminate food safety hazards that are deemed likely to occur.

We are making no recommendation related to reassessment of HACCP plans as these actions are underway as part of ConAgra's response to FSIS' intended enforcement action. Also, FSIS published a Federal Register notice,[20] on October 7, 2002, that required all establishments that produce raw beef products and that have not reassessed their HACCP plans in light of new scientific information[21] to do so and consider whether

[19] The FSIS Notice of Intended Enforcement Action, dated July 18, 2002, references 9 CFR 417.2; 417.3(b); 417.4(a)(2); 417.4(a)(3); 417.5(a)(2) (Hazard Analysis and Critical Control Point Systems); and 416.12 and 416.14 (Sanitation). 9 CFR 417.4(a)(3), dated January 1, 2002, provides that "every establishment shall reassess the adequacy of the HACCP plan whenever any changes occur that could affect the hazard analysis…"

[20] Federal Register, Vol. 67, No. 194, 62325 (*E. coli* O157:H7 Contamination of Beef Products), dated October 7, 2002.

[21] On September 3, 1999, FSIS began using new testing procedures to detect the presence of *E. coli* O157:H7, which were four times more sensitive than the previous testing method. FSIS found that these new procedures showed that the *E. coli* pathogen was significantly more prevalent in raw ground beef samples than the previous testing method indicated. Also, some studies have found more animals within specific herds to be positive for *E. coli* O157:H7. See the Federal Register for October 7, 2002.

E. coli O157:H7 is a hazard reasonably likely to occur. On November 4, 2002, FSIS issued instructions to their inspectors[22] for verifying that all establishments affected had performed the required reassessment of their HACCP plans to determine if *E. coli* O157:H7 contamination was a hazard likely to occur.

RECOMMENDATION NO. 4

Provide training to in-plant inspectors to increase their awareness as to the availability of and their access to microbiological test results and to take appropriate action, such as issuing an NR when HACCP records indicate CCP failures that could allow contaminated product to enter commerce.

FSIS Response

FSIS agrees with this recommendation. On April 29, 2003, FSIS instituted new Food Safety Regulatory Essentials (FSRE) training designed to better equip inspection personnel in verifying an establishment's food safety system. Unlike initial HACCP training, the FSRE training is tailored to an inspector's assignment. All trainees receive foundation training, covering the Rules of Practice, Sanitation Performance Standards, and Sanitation Standard Operating Procedures (SSOP). Customized HACCP training is provided based on the types of products being produced at the establishments where inspectors are assigned. One of the modules was designed specifically to address the production of raw beef products in a HACCP environment at plants such as ConAgra. This specialized training is now being offered at the FSIS Training and Education Center in College Station, Texas. The training will improve FSIS' ability to effectively monitor and verify food safety controls at plants such as ConAgra and at the establishments that purchase and process its beef. All inspection program personnel with primary duties for verification of the HACCP pathogen reduction program activities will be trained on the FSRE. FSIS expects the FSRE training to be completed for field personnel by the end of September 2004. Enclosure No. 4 contains the course description and training agendas.

In addition, during the week of April 28-May 2, 2003, a compliance training session was held in Dallas, Texas (Enclosure No. 2). All COs and CSOs who are being cross utilized to conduct compliance duties attended the training session. One of the topics discussed at this session was the review and analysis of plant records and testing data and the expectation that COs and CSOs who have been trained in enforcement, to review plant data bi-weekly, or monthly, in collaboration with the in-plant

[22] FSIS Notice 44-02 (Instructions for Verifying *E. coli* O157:H7 Reassessment), dated November 4, 2002.

personnel when enforcement at a plant has been deferred, or when a plant is operating under a suspension held in abeyance. Plant generated data is an important indicator of whether and how well the plant is executing its corrective actions.

FSIS issued revised Directive 5000.1 (Enclosure No. 5), "*Verifying an Establishment's Food Safety System*," on May 21, 2003. Attachment 1 to the Directive is FSIS Handbook 5000.1, which provides comprehensive direction to field personnel on how they are to protect the public health by properly verifying an establishment's compliance with pathogen reduction, sanitation, and HACCP regulations. The handbook provides additional guidance to inspection personnel on their authority in accessing a plant's microbiological test results and the appropriate actions to be taken to ensure adulterated product does not enter commerce, such as reviewing the establishment's corrective action to determine if it is appropriate and addressing proper product disposition.

OIG Position

We accept the management decision.

RECOMMENDATION NO. 5

Develop a management control process that will provide FSIS inspectors with all available data necessary to monitor compliance with HACCP requirements.

FSIS Response

FSIS agrees that a process is required to ensure that inspection personnel have all available data necessary to monitor compliance with HACCP requirements. FSIS inspectors have real-time access to all available inspection data generated for the respective establishment that they are working in. This data is in the PBIS database. Inspection personnel use this data and other sources in their verification activities.

Each level of FSIS supervision has responsibilities to review data of operational and compliance activities. The review covers individual establishment's compliance records to aggregate compliance records for establishments within a circuit, within a District and nationally. The Technical Service Center (TSC) collects and analyzes this 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 analysis, and various operational data summaries.

FSIS has judiciously implemented this process to make decision-support information available to the inspection personnel. FSIS field personnel have regular access to the PBIS database and related reports. The most recent version of the PBIS database system (version 5.0) allows inspection personnel to enter and access specific non-compliance records (NRs) that have been issued to a plant for PR/HACCP, Sanitation Standard Operating Procedures (SSOP), Sanitation Performance Standards (SPS), and Other Consumer Protections (OCP) non-compliances. FSIS inspection personnel also have access to the Laboratory Electronic Application for Results Notification (LEARN) database system. The LEARN database contains laboratory testing results, including potential, presumptive, and positive sample results for raw ground and ready to eat products. These systems allow inspectors to monitor an establishment's compliance with PR/HACCP requirements.

Also, FSIS has issued Directive 4430.3, "*In-Plant Performance System Reviews,*" (IPPS) and a comprehensive Supervisory Guideline (Enclosure No. 6). IPPS was designed to hold inspection program personnel accountable and ensures that inspectors are applying the appropriate inspection methods, using effective regulatory decision-making, and documenting findings appropriately and when warranted, implementing enforcement actions properly.

The Office of Program Evaluation, Enforcement and Review (OPEER) will monitor the Agency's progress in the area. Audits, evaluations, and reviews will be conducted to verify implementation and measure the effectiveness of the corrective actions.

OIG Position

Based on the information provided, we cannot reach management decision. In its response, FSIS states that inspectors have real-time access to various databases that contain inspection data and laboratory testing results. Also, FSIS states that each level of supervision has the responsibility to review the data and monitor operations and that OPEER will monitor the Agency's progress. FSIS has not provided a documented management control program that specifies the actions required at each level in the organization to analyze data on a plant, district, or national basis, including the procedures and processes to be used by OPEER to "…monitor the Agency's progress." To reach management decision, FSIS needs to provide a description of its management control program to include details as to what actions are required at each level of the organization, including OPEER, and a description of the controls put in place to ensure the expected analysis takes place and is acted on.

FINDING NO. 3

INDICATORS OF INCREASING LEVELS OF GENERIC *E. COLI* WERE NOT MONITORED OR ANALYZED

FSIS did not review or monitor ConAgra's process control criteria to determine if it was effective in controlling generic *E. coli.* Although ConAgra raised its tolerance level for generic *E. coli* between 2001 and 2002, neither ConAgra nor FSIS personnel critically analyzed the increase to determine why it occurred and if it was acceptable. Also, FSIS guidance to inspectors does not specifically require them to verify a plant's methodology for determining a tolerance level. High levels of generic *E. coli* are indicative of problems in the plant's controls over fecal contamination. As a result of the change in tolerance, the generic *E. coli* testing done by ConAgra to comply with its HACCP plan provided erroneous results, which affected the ability of plant management and FSIS personnel to accurately monitor the plant's operations.

In order to verify that an establishment's manufacturing processes are controlling generic *E. coli*, FSIS requires each establishment that slaughters livestock to routinely test for the generic strain of the microbe. Establishments like ConAgra, which base their tests on a carcass-sponging technique, are to evaluate generic *E. coli* test results using statistical process control techniques.[23] These techniques involve upper control limits to the amount of generic *E. coli* measured in a tested sample. If routine test results show amounts of generic *E. coli* beyond this upper limit, FSIS plant inspectors need to increase their surveillance of plant operations.

FSIS in-plant personnel are tasked with reviewing the generic *E. coli* testing by their establishments. As appropriate, FSIS inspectors are to review procedures and record keeping and make a determination about the plant's compliance with regulatory requirements.[24] FSIS Directive 5000.1 directs the inspectors to examine the establishment's process control chart to determine if the plant is analyzing its test data against a baseline level "to ensure the process is in control and variations are within normal and acceptable limits."[25] At ConAgra, the process control chart depicted each test result as a point and the upper control limit as a horizontal line running above the points (or under them, if test results should begin to exceed the upper limit). The FSIS directive does not require the inspectors to validate the plant's methodology for arriving at its upper control limit.

[23] 9 CFR 310.25 (Contamination with Microorganisms; Process Control Verification Criteria and Testing; Pathogen Reduction Standards), dated January 1, 2002.
[24] FSIS, Regulatory Process for HACCP-Based Inspection Reference Guide, dated January 1998.
[25] FSIS Directive 5000.1 (January 1998), Part Four-*E. Coli* Testing and Criteria.

ConAgra chose to monitor and track its generic *E. coli* results by shift (shift A and B). ConAgra measured the amount of generic *E. coli* on a scale of 0 to 21. For calendar year 2001, the plant's generic *E. coli* upper control limits were low on the scale (less than 6.0) for both the "A" shift and the "B" shift. At the beginning of calendar year 2002, the plant recomputed the upper control limits for both shifts based on the results from the 2001 sampling. When the results were recomputed, the upper control limit for the "A" shift was increased by 50 percent, while the upper control limit for the "B" shift was decreased by 33 percent. The horizontal line on the "A" shift control chart was higher than before and the line on the "B" shift control chart was lower. Beef worked on the "A" shift was therefore allowed to have more than twice the amount of generic *E. coli* than the "B" shift before any further tests were taken.

We questioned plant management as to why, in 2002, there was such a pronounced difference in upper control limits between the two shifts. The plant managers, after some analysis, explained that upon closer review they concluded that their methodology for tracking the generic *E. coli* was flawed. They observed that livestock killed on both shifts ended up in data for both the "A" and "B" shifts. This mixing of sample results from different shifts invalidated their results for both shifts. The plant management stated that they were immediately reviewing and correcting their generic *E. coli* sampling methodology.

FSIS in-plant inspection personnel did not identify this problem in the generic *E. coli* sampling methodology. They also did not notice or question plant managers about why there was a dramatic change in the generic *E. coli* upper control limits between the two shifts during calendar year 2002. The increase in upper limit on the "A" shift allowed ConAgra to process beef carcasses with greater amounts of generic *E. coli* without triggering additional FSIS scrutiny.

RECOMMENDATION NO. 6

Verify ConAgra's methodology for establishing the upper control limit for generic *E. coli.* Require FSIS personnel to review and monitor all control limits established by ConAgra.

FSIS Response

FSIS is continuing to review and monitor Est. 969's control limits, as well as other operations in the plant as part its ongoing regulatory duties. FSIS has completed a verification of ConAgra's (now Swift's) methodology for establishing the upper control limit for generic *E. coli* to ensure compliance with §310.25(a)(5)(i), Table 1 of 9 CFR. On May 7, 2003, FSIS conducted a review and analysis of Est. 969's generic *E. coli* testing process, including design, execution, and test results reporting. The review was

aimed at determining the establishment's regulatory compliance with §310.25(a).

Est. 969 now determines baseline standards yearly, reflecting previous yearly data averages. Est. 969 reviews and revises, as necessary, its Standard Operating Procedure (SOP) # 1128 detailing sample collection procedures and SOP # 1802 detailing data sampling reporting procedures.

FSIS in-plant inspection team oversight and verification was accomplished by reviewing information from the PBIS procedures performed at Est. 969. PBIS verification procedures conducted from June 1, 2002, to May 1, 2003, included:

- Procedure 05A01= 61 scheduled and 61 performed.
- Procedure 05A02= 49 scheduled, 43 performed and 6 not performed.
- A total of 104 procedures were performed.
- No noncompliance was observed for the 104 performed procedures during the specified time frame.

The review of Est. 969's current documentation and operations found them to be in compliance with Regulation 310.25 (a). During the July 2002, FSIS Food Safety Investigation (FSI) at Est. 969, the FSI team reviewed the generic *E. coli* testing program, but primarily focused on the *E. coli* O157:H7 carcass program utilized by Est. 969 at that time because it was determined by the team to be more indicative of the health risk associated with the product recall. The generic *E. coli* testing program is required by regulation as an indicator of process control. However, the specific *E. coli* O157:H7 carcass program was thought to be more plant and program specific.

OIG Position

We accept the management decision.

RECOMMENDATION NO. 7

Revise FSIS Directive 5000.1 (January 1998) to require qualified FSIS personnel to periodically review the methodology used for setting generic *E. coli* upper control limits in all beef establishments.

FSIS Response

FSIS issued revised FSIS Directive 5000.1 (Enclosure No. 5), "*Verifying an Establishment's Food Safety System*." The Directive provides instructions to consumer safety personnel on verifying that generic *E. coli*

upper control limits in all beef establishments have been implemented as required by the regulation. The revised Directive was issued on May 21, 2003.

In addition, CSOs are assigned to District Offices to conduct comprehensive assessments to verify that establishment control systems are well-documented, supported by scientific information, and validated. Currently, CSOs are conducting comprehensive assessments of HACCP plans at beef product establishments. These comprehensive assessments are being conducted as part of an October 7, 2002, Federal Register Notice, "*E. coli O157:H7 Contamination of Beef Products*," that required all beef slaughter establishments to reexamine their food safety strategies in light of evidence that *E. coli* was more prevalent in live animals than previously thought. The comprehensive examination of HACCP plans by CSOs at raw beef product establishments was a proactive step to strengthen pathogen prevention practices. Eventually all beef plants will be reassessed.

OIG Position

We accept the management decision.

FINDING NO. 4

RECURRING CITATIONS FOR FECAL CONTAMINATION OF PRODUCTS AT CONAGRA DID NOT LEAD TO FSIS ENFORCEMENT ACTIONS

FSIS did not take enforcement action against ConAgra even though it continued to cite the plant for HACCP violations involving visible fecal contamination of products. The inspectors continued to issue citations because FSIS has not established criteria for determining when repeat violations warrant taking additional enforcement action or require a plant to reassess its HACCP plan. As a result, animal feces continued to be observed contaminating ConAgra product and likely contributed to the adulteration of product that was the subject of the recall.

Because animal feces is the source of the *E. coli* O157:H7 pathogen and because it can be observed during production and removed, FSIS follows a "zero tolerance" policy on a plant's compliance with this sanitation requirement. FSIS issues an NR for each "zero tolerance failure" on the part of a plant.

To determine the number of repeated NRs written at ConAgra for fecal contamination, we reviewed and summarized the NR logs for 2001 and 2002 (through November 14, 2002), as shown in exhibit D. The logs showed that the in-plant inspectors had written a total of 66 NRs for zero tolerance failure for the period. We were told that the number of observed

zero tolerance failures actually exceeded the number of NRs written for that particular deficiency because in many cases plant inspectors preferred to discuss the problems with ConAgra management rather than write the NRs. This indicates that zero tolerance failures had been an ongoing problem at this plant and continued to be a problem after the recall period. We completed our fieldwork at the plant in September 2002. On November 15, 2002, FSIS suspended inspection services at the plant because of repetitive zero tolerance failures since August 2002. Records showed that FSIS had issued 16 NRs for zero tolerance failures after the recall. This shows that the corrective actions that were taken by the company were not fully effective in correcting the problem with fecal contamination at the plant.

We interviewed the IIC concerning the NRs for HACCP failures at ConAgra, especially those involving fecal contamination. He said that he had been concerned about the high frequency of tests showing the *E. coli* pathogen in product that had occurred in the fall of 2001. By way of impressing on plant officials that additional action could be taken by FSIS, the IIC referred in each new NR to the previous NRs that reported zero tolerance violations. Although the IIC was not required to take a monitoring sample for *E. coli* O157:H7 testing, even under the circumstances, he did anyway. (The sample tested negative.) He said he discussed these issues weekly with plant management and had impressed on them that enforcement action could be taken for repetitive noncompliance violations.

The IIC told us, however, that as far as he knew there was no magic number of NRs that would result in FSIS enforcement action. He said he had consulted the district office on what actions to take but could get no guidance on whether there were too many NRs for the same problem. He also consulted the TSC and, in the end, the district and TSC decided that because the plant was responsive to the NRs and because the IIC's monitoring sample tested negative, they would take no enforcement action.

In our earlier audit of HACCP, we noted that FSIS was repeatedly issuing NRs for the same violation,[26] and we recommended that the agency establish guidelines on what was an acceptable number of NRs for repetitive violations. In response to our audit, FSIS said they would develop procedures for repetitive deficiencies by December 2000. In September 2001,[27] FSIS issued a notice providing general guidelines on the types of enforcement actions that may be taken and the general circumstances under which they would be appropriate. However, the

[26] Audit Report No. 24001-3-At, Implementation of the Hazard Analysis and Critical Control Point System, dated June 2000.
[27] FSIS Notice 36-01, Rules of Practice, dated September 5, 2001.

procedures do not provide specific criteria for determining when enforcement action is needed based on repetitive NRs. Also, FSIS needs to develop alternative enforcement actions, within its existing authorities, for when establishments fail to comply with established pathogen reduction benchmarks and/or when they are cited for repetitive food safety violations.

More recently, GAO[28] reported that in 16 plants reviewed, the most common repetitive deficiency reported in NRs was for violation of the zero tolerance standard for fecal contamination. The GAO study showed that FSIS had not taken enforcement action on any of the repetitive violations identified. GAO further noted that FSIS had not established criteria for inspectors to consider when assessing whether repetitive violations warrant enforcement action. GAO recommended that FSIS "establish clear, consistent criteria for inspectors to use when considering whether to recommend suspension because of repetitive violations." The report stated that FSIS officials recognized the need to establish such criteria and were in the process of updating a policy directive to include it. The report further stated FSIS expected to implement this directive in early 2003. However, the written response to the report did not provide specific timeframes for the planned directive changes cited.

RECOMMENDATION NO. 8

Develop and implement criteria to evaluate repetitive noncompliance violations that provide a basis for determining when corrective actions are inadequate and enforcement actions should be initiated. Establish specific criteria when further enforcement action must be taken based on criteria established for repetitive violations.

FSIS Response

On June 17, 2002, FSIS issued Directive 4430.3, "*In-Plant Performance System Reviews,*" (IPPS) and a comprehensive Supervisory Guideline (Enclosure No. 6). These documents provide specific instructions and guidance on how to assess the performance of inspection personnel in the PR/HACCP system environment and for verifying that inspection personnel are carrying out their responsibilities. These include having supervisors ensure that inspection personnel are evaluating trend indicators over time to determine whether to take regulatory action based on the establishment's performance and having supervisors assess from inspection records that inspection personnel are determining whether a trend of noncompliance that warrants the withholding of inspection is

[28] GAO Report No. GAO-02-902, Better USDA Oversight and Enforcement of Safety Rules Needed to Reduce Risk of Foodborne Illnesses, dated August 2002.

occurring. IPPS holds inspection personnel accountable and ensures that the significance of repetitive noncompliance violations is not being overlooked.

FSIS also revised FSIS Directive 5000.1 (Enclosure No. 5), "*Verifying an Establishment's Food Safety System*." The revised Directive provides guidance for the field on how to identify repetitive deficiencies and what action to take in response. The revised Directive was issued on May 21, 2003. The Directive 5000.1 is used along with the Rules of Practice, 9 CFR 416 and 9 CFR 417 by the District Offices to determine when enforcement actions are warranted. This process has been implemented.

On April 29, 2003, FSIS implemented new FSRE (Enclosure No. 4) training designed to better equip inspection personnel in verifying an establishment's food safety system. The training provides guidance to inspection personnel for evaluating repetitive noncompliance and furnishes a basis for determining when corrective actions are inadequate and enforcement should be initiated.

In addition, during the week of April 28-May 2, 2003, a compliance training session was held in Dallas, Texas. The Deputy District Managers of each District Office and several District Managers attended the session. At the training, FSIS stressed the importance of ensuring that FSIS verification plans are developed and carried out for all deferral actions and suspensions held in abeyance. A presentation was given which covered the development of FSIS verification plans and the procedures that should be utilized to ensure that a plant's corrective and preventive measures are effectively carried out.

Furthermore, in August 2002, FSIS implemented a procedure that requires that whenever FSIS defers enforcement following the issuance of a Notice of Intended Enforcement (NOIE), or hold a suspension in abeyance, a written FSIS verification plan will be developed and attached to the deferral or suspension held in abeyance letter. The verification plan is also discussed with plant officials. The verification plan identifies the specific procedures that an FSIS in-plant inspection team will carry out to ensure that the establishment implements the corrective and preventive actions proffered to the Agency in response to a NOIE or suspension. The procedures in the verification plan are carried out until such time that the establishment can demonstrate it is capable of eliminating unsanitary conditions and practices and is producing product that is safe and sanitary. If FSIS verification activities reveal that the establishment's corrective and preventive measures are effective, the deferral or suspension being held in abeyance will be closed. On the other hand, if FSIS verification activities show that the plant's food safety controls are

ineffective, further enforcement will be initiated.

The Office of Program Evaluation, Enforcement and Review (OPEER) will monitor the Agency's progress in the area. Audits, evaluations, and reviews will be conducted to verify implementation and measure the effectiveness of the corrective actions.

OIG Position

We cannot accept the management decision. We agree, in principal, that the issued directives and training will be beneficial for inspectors in analyzing whether a trend of noncompliance or repetitive violations has occurred. These procedures do not, however, provide specific criteria for determining when enforcement action is needed. The instructions provide for referring cases of trends/repetitive violations to supervisors and/or the district office but do not provide guidance as to when enforcement actions should be initiated and/or accelerated. FSIS also states that OPEER will monitor the Agency's progress in this area, verify implementation, and measure the effectiveness of corrective actions. To reach management decision, FSIS needs to establish criteria to ensure consistent application of its enforcement actions, describe the process to be used by OPEER in its evaluation, and provide an estimated timeframe for implementing the specific actions proposed.

RECOMMENDATION NO. 9

Develop and implement alternative enforcement tools, within existing authorities, when establishments fail to comply with established pathogen reduction benchmarks and/or when they are cited for repetitive food safety violations.

FSIS Response

FSIS believes that the concerns raised by the OIG should be directed at the Agency's need for improving its management controls and supervision of its inspection personnel to ensure effective enforcement of regulatory requirements. FSIS does not have the authority to implement civil penalties; however, the judicial system has imposed civil penalties for statutory violations. FSIS believes that the OIG recommendation should encourage better use of existing authorities for enforcement. Federally inspected establishments are required to take appropriate and effective corrective actions to address identified deficiencies. Further, when serious deficiencies are noted at establishments, FSIS will begin preparing an Administrative Enforcement Report (AER) that compiles all serious non-compliances. The AER will support the Agency's basis for actions taken, ensure uniformity and consistency, and become a part of the formal record for action.

To enhance the supervision of inspection program personnel and improve management controls, FSIS has issued Directive 4430.3, "*In-Plant Performance System Reviews,*" (IPPS) and a comprehensive Supervisory Guideline (Enclosure No. 6). IPPS holds inspection program personnel accountable and ensures that inspectors are applying the appropriate inspection methods, using effective regulatory decision-making, and documenting findings appropriately and when warranted, implementing enforcement actions properly.

Also, FSIS instituted new Food Safety Regulatory Essentials (FSRE) training designed to better equip inspection personnel in verifying an establishment's food safety system. Unlike initial HACCP training, the FSRE training is tailored to an inspector's assignment. All trainees receive foundation training, covering the Rules of Practice, Sanitation Performance Standards, and Sanitation Standard Operating Procedures (SSOP).

The Office of Program Evaluation, Enforcement and Review (OPEER) will monitor the Agency's progress in the area. Audits, evaluations, and reviews will be conducted to verify implementation and measure the effectiveness of the corrective actions.

OIG Position

Based on FSIS' response, we revised this recommendation. However, we cannot reach management decision. OIG believes FSIS needs additional enforcement tools to ensure compliance with regulatory requirements. FSIS, in its response, has proposed the development of an Administrative Enforcement Report that compiles all serious non-compliances. The Administrative Enforcement Report is to support the Agency's basis for actions taken, ensure uniformity and consistency, and become part of the formal record for action. FSIS has also proposed that OPEER will monitor the Agency's progress in this area. The intent of OIG's original recommendation was for FSIS to consider alternative enforcement actions for plants that have repetitive violations and/or take ineffective corrective actions. To reach management decision, FSIS needs to identify the options or alternatives available under its existing authority to address these situations, how it will implement them, and the timeframes for doing so.

FINDING NO. 5

FSIS INSPECTORS AT CONAGRA DID NOT RECEIVE ADEQUATE SUPERVISION

ConAgra's long history of production containing *E. coli* O157:H7 demonstrates the need for FSIS managers to strengthen oversight and training of both FSIS and plant staff and to achieve a culture and environment adequate to assure food safety. We found few instances before the recall in which FSIS managers responded to inspector concerns at ConAgra or contacted the FSIS staff there. More recent food safety problems at the plant occurred in the absence of the circuit supervisor, who was on extended sick leave during our audit.

Some of the instances and results of poor FSIS supervision at ConAgra are summarized below.

- Although the plant's testing records between 2001 and 2002 showed an increasing presence of *E. coli* O157:H7 and a failing HACCP system, the IIC did not take any action because he could not get support from the TSC or the district office. (The district office could provide no evidence to dispute this.) The IIC wanted to perform additional testing for *E. coli* O157:H7 but, under FSIS Directive 10,010.1, ConAgra was exempt from testing unless inspectors received permission through supervisory channels. Furthermore, several of ConAgra's positive tests were from beef trim, and procedures required FSIS action only if the adulteration were found in ground beef. According to district office officials, since TSC and FSIS headquarters advised against approving the IIC's request for testing, the district office denied permission. Both the IIC and district office officials understood that it was the TSC's policy that FSIS would not get involved if a plant was testing on its own, found problems, and corrected them;

- In October of 2000, the IIC was denied permission to ignore ConAgra's *E. coli* O157:H7 testing exemption in an effort to conduct some FSIS testing of ground product, even though he advised that the plant had increasing numbers of positive *E. coli* O157:H7 tests. An August 2001 NR linked eight instances of fecal contamination in the processing area. Finally, in September 2001, the IIC advised a staff member of the district office and the circuit supervisor that the plant had encountered several positive tests for *E. coli* O157:H7. The circuit supervisor said he would be in the plant the following week. Although the circuit supervisor did arrive at the plant, he gave no instructions to the inspectors and no actions were taken on the plant's operations;

- Before the recall, the plant's own quality assurance staff identified

serious problems with meat sanitation but did not reassess the HACCP plan to prevent future HACCP failures;

- FSIS inspectors wrote 66 NRs from January 1, 2001, through November 14, 2002, for fecal contamination (see exhibit D) but took no enforcement action. (See Finding No. 4.) We noted that sanitation deficiencies were sometimes handled informally; no NRs were written; and

- ConAgra inspectors did not write an NR, as required, after FSIS tested a sample of ground beef on September 10, 2002, and found it positive for *E. coli* O157:H7. The IIC said he was aware of the requirement but could not explain why an NR was not prepared. No one was held accountable.

FSIS has in place an array of reviews aimed at improving agency operations and inspector performance. Most significant among these are the Program Assessments and Internal Audits, which are performed in response to actual or perceived problems, and the Management Control Reviews, which are conducted to determine if agency controls are in compliance with GAO and Office of Management and Budget requirements. Although any of these reviews, properly performed, may have resulted in tighter standards at ConAgra, none were conducted there over the period before the recall. In April and May of 2001, FSIS conducted the first of a series of reviews known as Food Safety Systems Correlations, designed to identify the range of food safety practices within an FSIS district and share these practices with FSIS personnel in that district. Although the first district selected for a correlation review was the one in which ConAgra resided, ConAgra itself was not included in the review sample.

Indepth verification reviews could have helped draw the attention of both the inspectors and FSIS management to the poor practices at ConAgra. Verification reviews allow supervisors and managers to concentrate oversight of operations at problem plants. However, because ConAgra was not considered a problem plant, an indepth verification review was never performed there.

We believe the FSIS inspection staff at ConAgra could benefit from greater management guidance. For example, when the results from the correlation reviews were shared with the ConAgra inspectors, none of them, including the IIC, appeared to draw the appropriate correlations, even though the poor practices disclosed by the reviews (incomplete analysis of hazards, weak controls, poor records) mirrored the operation at ConAgra. We also observed during our audit that both plant and FSIS inspection personnel engaged in numerous unhygienic practices. We saw

the cleaning crew, plant quality assurance personnel, and FSIS inspectors touching unsanitary surfaces and then touching food contact surfaces without washing or disinfecting their hands (see exhibit F). The IIC took the position that because the plant used disinfectant foam on food contact surfaces just before the start of operations, the practices we observed affected only nonfood contact surfaces.

We concluded that FSIS supervision of the inspection team at ConAgra, both before and during the recall, was too limited and ineffective. Conditions at the plant clearly warranted additional oversight. We also concluded that FSIS managers should be ready to support enforcement actions under the conditions that prevailed at ConAgra. Earlier enforcement may have limited the scope of the recall or eliminated the need for it entirely.

RECOMMENDATION NO. 10

Increase supervision and oversight to the plant until it demonstrates it is capable of eliminating unsanitary conditions and practices and producing product that is sanitary and wholesome.

FSIS Response

FSIS agrees that greater oversight over the inspection program at Est. 969 is beneficial and has done so. The Agency has taken several personnel actions to immediately address the problems at the plant. A new acting Circuit Supervisor (CS) has been assigned to the establishment. The new acting CS is actively involved in oversight activities.

In addition, the District Office placed a Supervisory Veterinary Medical Officer (SVMO) in the position as acting Inspector In Charge (IIC). He is actively involved in all supervision and oversight functions. Supervisory oversight has increased dramatically at all levels. In-plant staffing has remained a constant priority to facilitate adequate inspectional oversight activities.

The FSIS monitoring of the in-plant sampling of ground beef for *E. coli* O157:H7 has continued since the initial recall of product began. In addition, Est. 969 has continued its daily in-plant sampling of all beef trim.

OIG Position

We accept the management decision.

RECOMMENDATION NO. 11	Strengthen monitoring of inspector activities at the plant to achieve an acceptable level of performance in applying HACCP requirements.

FSIS Response

The FSIS inspection activities have been strengthened and increased at Est. 969 since the initiation of the enforcement action. As a result of the November 2002 enforcement action, an in-plant FSIS Verification Plan was developed detailing FSIS in-plant activities to monitor the plant's actions in response to the enforcement action taken. A copy of the FSIS Verification Plan was provided to and discussed with plant management. The plan is designed to ensure that the establishment fully implements and executes the revisions of the SSOP and HACCP plan(s) and other corrective actions as indicated and can be modified to reflect any necessary changes. The FSIS Verification Plan identifies the establishment's actions, the relevant regulatory requirement the actions meet and the Inspection System Procedure (ISP) code under which the inspection task will be performed. It identifies and establishes timelines to which the plant committed. The plan also has to be initialed and dated by the in-plant inspection team member completing the task and identifying plant actions, responses, or non-compliances documented. The completed copies of the plan are mailed or faxed to the Boulder District Office for review bi-weekly.

In addition, the in-plant inspection team, both day and night shifts, generate daily e-mail reports detailing the plant operations, NR's documented or other problems. The e-mail reports are sent to the opposite shift FSIS supervisor, the CS, and the District Office.

In addition, on June 17, 2002, FSIS issued Directive 4430.3, "*In-Plant Performance System Reviews,*" (IPPS) and a comprehensive Supervisory Guideline (Enclosure No. 6). These documents provide specific instructions and guidance on how to assess the performance of inspection personnel in the PR/HACCP system environment and for verifying that inspection personnel are carrying out their responsibilities. These include applying the appropriate inspection methods, using effective regulatory decision making and documenting findings appropriately, and when warranted, implementing enforcement actions properly.

FSIS will complete an internal assessment of IPPS to ensure that the reviews are accomplishing their objectives. The internal assessment at Est. 969 will be completed by October 2003.

OIG Position

We accept the management decision.

CHAPTER 2	RECALL OF CONAGRA BEEF PRODUCTS NEEDED MORE PROACTIVE INVOLVEMENT BY FSIS

The recall of ConAgra beef products was not effective or efficient. FSIS' management of the recall process, as well as the manner in which it is conducted, needs to be reassessed. Traceback policy impeded the timely identification of the source of the adulterated product and the product (production period) that should be recalled. FSIS' monitoring of the recall process through its effectiveness checks was not timely to maximize the product recovered. Also, problems and/or discrepancies identified in its checks were not subject to management review, analysis, and/or action. Although all recalls are voluntary on the part of industry, we concluded in the case of ConAgra that FSIS should strengthen its oversight role to provide increased assurance that recall measures are rapid and timely notice of the recall and recovery of the product is made. As of January 2003, FSIS recovered no more than 17 percent of the 18 million pounds of beef recalled.

Inefficient trace back policies. Identification of the specific amount of product to be recalled was complicated by FSIS delays in identifying the source of the contamination and by plant records that did not help track the disbursements of the product to its purchasers. FSIS was slow to react to evidence of *E. coli* O157:H7 contamination at Galligan and Montana Quality Foods because FSIS had no clear policy on when to take a traceback sample to identify the source of the contamination. FSIS technicians refused to approve traceback sampling, but the district office persisted until National Office managers approved it. Because of this unclear FSIS policy, the ConAgra recall was delayed 7 days. During the 7-day period, under its normal operation, ConAgra could have produced up to 3.75 million pounds of recalled beef.

No record requirements to quickly identify purchasers of beef. Galligan managers could not readily identify from their records which of their purchasers received product made from ConAgra beef and how much of their product made from other sources may have been cross-contaminated by the ConAgra beef. FSIS does not require firms to keep records that can readily trace raw or finished product to all suppliers and/or purchasers.

Little preparation for a recall. Industry managers were not always prepared for a recall. Although ConAgra had procedures in place for a potential recall, there were no plans at Galligan and Montana Quality

Foods. FSIS directives ask establishment operators to take measures to ensure a rapid and effective recall but, because recalls are voluntary, FSIS does not have the authority to mandate recall provisions in the HACCP plans.

Ineffective FSIS oversight. FSIS conducted effectiveness checks of ConAgra's recall from the time of the initial recall to up to 4 months later (about 50 percent of the effectiveness checks occurred more than 30 days after the recall). To date, there has been limited management review, analysis, and/or action on the findings disclosed. In one district, FSIS compliance officers documented in 67 of the 490 effectiveness checks we reviewed that distributors and others in the distribution chain had not been properly notified of the recall. District compliance officers did not always resolve the problems encountered during the reviews and did not initiate any enforcement actions. Moreover, they did not always verify information provided by the distributors.

During the recall, FSIS dispatched an inspection team to ConAgra to determine if its HACCP systems and other controls were adequate to prevent adulterated product from entering commerce and if future production from ConAgra posed a health risk to consumers. In response to FSIS' demands for improvement, ConAgra attempted to control the *E. coli* O157:H7 contamination of its ground beef by offering to add lactic acid to the ground beef to destroy the contaminant. This process had not been tried, but FSIS approved it without performing a well documented and systematic review of the scientific evidence submitted by ConAgra that showed the process would work.

To date, only about 3 million pounds of the 18 million pounds of recalled product have been returned and the remaining pounds were not returned or accounted for.

FINDING NO. 6

HACCP PLANS DID NOT RECOGNIZE A NEED FOR RECALL

Although ConAgra had procedures in place (external to its HACCP plan) to address a potential recall, there were no plans at Galligan and Montana Foods. ConAgra followed its plan during the recent recall; neither of the other establishments had considered what they would do in the event of a recall. FSIS policy recommends but does not require that establishments have a recall plan, and a recall plan is not considered part of an establishment's overall HACCP plan. The absence of recall plans can impact the timely and efficient identification and recovery of potentially contaminated product. During this recall, one of the establishments lacking a recall plan had difficulty in identifying all product subject to the recall.

FSIS Directive 8080.1,[29] states that establishment operators should take measures that will ensure rapid and effective recall of products. To achieve this goal, the operator should prepare and maintain a detailed, written recall plan. This plan should describe, step-by-step, the procedures (which include scope of recall, effectiveness checks, and returned product control) the firm will follow in case it becomes necessary to recall a product. Because recalls are considered a voluntary action on the part of industry, FSIS has no regulatory requirement that an establishment have a recall plan or that the recall plan be included in its HACCP plan.

Galligan did not have a written recall procedure and did not see a need for one because sampled product never leaves the facility. The product is always held until the results of FSIS microbiological tests are completed. When Galligan did experience a recall from its supplier, the only way the company could determine what customers had received the recalled product was to review its sales records. However, incomplete sales records, ground beef production records, and SSOP records complicated the identification of the product requiring recall as well as the customers who purchased the recalled product.

According to a Montana Quality Foods official, the company did not have a recall plan because it is a small plant. The FSIS circuit supervisor advised us that no plant in the circuit had a recall plan.

The USDA Office of the General Counsel informed us that since recalls are done voluntarily by industry, some type of Congressional action would be required before FSIS can mandate that recall provisions be incorporated in HACCP plans. However, FSIS officials informed us this was unnecessary because FSIS would be involved in any recall and they would follow their own procedures, not a company's plan. We found, however, that FSIS procedures were not always effective (see Finding No. 8).

Based on the inefficiencies experienced during this current recall, we concluded that recall operations can be improved if a recall plan is required as part of each plant's HACCP plan.

RECOMMENDATION NO. 12

Seek legislation and issue regulations requiring that all establishments include in their HACCP plan the steps that would be necessary to conduct an effective recall of product and provide for its proper disposition.

[29] FSIS Directive 8080.1, Revision 3, (Recall of Meat and Poultry Products), dated January 19, 2000.

FSIS Response

FSIS has strongly encouraged establishments to incorporate a recall plan in their HACCP plans through direction provided in FSIS Directive 8080.1 (Enclosure No. 7), "*Recall of Meat and Poultry Products*." As part of the Directive, FSIS provided "Product Recall Guidelines for Firms." The guideline outlines the actions that FSIS expects a firm to take in the event that the establishment decides to recall product.

FSIS does not have authority to make it mandatory for establishments to include plans for a recall in their HACCP plans. On December 12, 2002, FSIS held a public meeting to discuss improving the overall recall process. As a result of that meeting, FSIS is considering ways to further encourage plants to incorporate effective recall plans into their HACCP plans. FSIS expects to update this guidance on planning for recalls by March 2004.

OIG Position

We cannot reach management decision based on this response. Since recalls are currently voluntary by industry and FSIS states it cannot mandate that plants incorporate recall plans in their HACCP plans, FSIS must develop compensating controls to ensure that recalls are effectively performed so that recovery of contaminated product is maximized. To reach management decision, in the absence of authority to require plants to develop and implement recall plans, FSIS needs to provide a description of the compensating controls it will put in place, and timeframes for implementation, to ensure recalls are timely and efficient to maximize the recovery of contaminated product. This is especially critical for those plants that have not established recall plans.

FINDING NO. 7

UNCLEAR POLICY AND PROCEDURES FOR TRACEBACK SAMPLES DELAYED RECALL

When *E. coli* O157:H7 was detected at Galligan, FSIS did not take timely traceback samples to identify the source of the contamination, even though Galligan officials complained that their suppliers' beef was the source, not the Galligan operation itself. FSIS also took no traceback samples from Montana Quality Foods, which made the same complaint. FSIS was slow to react, in part, because it did not have a clear written policy on when to take a traceback sample to identify the source of *E. coli* O157:H7 in product at meat processors (grinders). Existing policy stated that the grinders should be held accountable for ensuring the product they purchased from their suppliers was wholesome. Moreover, some FSIS officials interpreted the guidance and regulations to restrict or eliminate any sampling for traceback purposes. As a result of uncertainty

over procedure, the traceback sample that resulted in the ConAgra recall was delayed 7 days, in part, because FSIS field personnel were required to obtain concurrence from the FSIS TSC before taking the sample. During the 7-day period, under its normal operation, ConAgra could have produced up to 3.75 million pounds of recalled beef. We concluded that this and other product may have been consumed when clearer traceback procedures could have either kept it out of commerce or ensured that it was identified and returned.

In 1994,[30] FSIS defined *E. coli* O157:H7 in raw ground beef as an adulterant. Accordingly, ground beef shipped by beef processors (grinders) that was contaminated was to be considered adulterated and the grinder held responsible for a violation of the Federal Meat Inspection Act.[31] In January 1999, FSIS extended the definition to include contaminated beef trim and coarse-ground beef. Therefore, raw materials received by beef grinders that contained the *E. coli* pathogen were also to be considered adulterated and the supplier was in violation of the Federal Meat Inspection Act.[32]

The January 1999 definition of adulteration appeared to make traceback essential since a violation of law would have occurred. However, in March 1999,[33] FSIS requested comments on the new definition of what constituted adulteration and stated they would not take action to enforce the change pending evaluation of the comments. Inspectors inferred from this action that FSIS had suspended the new definition of trim and coarse-ground beef as adulterated if contaminated by *E. coli* O157:H7.[34] Remaining in place was FSIS' verbal policy to hold meat grinders responsible for the products processed at their establishments and for ensuring meat products they purchased from suppliers were wholesome.

[30] 9 CFR III (FSIS, USDA).
[31] 21 U.S.C. 601, *et seq.*
[32] Federal Register, dated January 19, 1999
[33] Federal Register, dated February 11, 2000.
[34] It should be noted that the original Federal Register Notice stated that the agency was soliciting input from the public about regulatory requirements that may be appropriate to prevent distribution of products adulterated with *E. coli* O157:H7. The Notice specified that any changes made to the regulations would have to be consistent with the agency's view that *E. coli*-contaminated intact cuts (e.g., trim) that are to be further processed into non-intact products (e.g., ground beef) will be considered adulterated unless conditions of handling can ensure they will not be distributed until they have been processed into ready-to-eat products. However, constituent guidance provided to the industry after a March 8, 1999, public meeting to accept comments on the policy, stated that FSIS would not take action to enforce their determination that trim products were adulterated, pending evaluation of the public comments.

Unwritten[35] FSIS policy that had not been clearly communicated to field personnel provided that traceback samples could be conducted when *E. coli* O157:H7 was identified in product produced by meat grinders. However, for a traceback to be attempted, FSIS required two conditions to be met:

- The contaminated ground beef had to have been produced from a "clean-grind" (i.e., the establishment had to demonstrate a documented cleanup of their facilities and equipment immediately before the production of the contaminated lot); and

- The contaminated ground beef had to have come from a single source supplier (i.e., the establishment had to prove to the satisfaction of FSIS inspectors that the contaminated ground beef did not contain product from more than one supplier).

Thus, traceback sampling would only be attempted if the plant could already establish the likely outside source of the contamination. The decision itself to take traceback samples further required FSIS inspectors to gain the concurrence of the TSC.

Galligan Wholesale Meat Company

A routine monitoring sample of ground beef (MT03) taken at Galligan first identified the presence of the *E. coli* pathogen on May 14, 2002. An NR was issued and the company reassessed its HACCP plan, as required. A traceback sample was not taken because the sampled product (ground on May 9) contained beef from more than one supplier. As part of the corrective action taken on the NR, the company stated they would minimize suppliers to one or two per lot.

FSIS began its verification series of 15 consecutive samples (MT04) at Galligan on May 31. It collected samples on May 31, June 4, 5, 7, 11, 12, and 14. On June 17, the FSIS Western Laboratory reported that the sample taken on June 12 tested positive for *E. coli* O157:H7. The IIC at the plant immediately retained the lot containing the product that tested positive. Company officials reported that all of the beef used in the contaminated lot had come from ConAgra in Greeley. At this point, no recall was considered necessary by FSIS because the lot that tested positive had been held at Galligan.

[35] FSIS Directive 10,010.1, dated February 1, 1998, provides the instructions for the microbiological testing program for *E. coli* O157:H7 in raw ground beef. The directive provides for collecting samples under three project codes, MT03 (monitoring program at grinding facilities), MT04 (15 consecutive verification samples taken after a positive MT03 test), and MT05 (samples taken at retail level establishments). The directive does not address traceback sampling.

On June 18, the district manager instructed the IIC to stop the company from producing product and to retain any raw materials remaining in the plant that had been used in the lot that tested positive. At the same time, the district manager contacted the TSC to obtain their agreement to take a traceback sample from raw materials available at Galligan. An e-mail response, dated June 18, stated:

> The TSC cannot recommend or support any decision to collect a sample as part of MT04 follow-up sampling prior to the product being ground at the establishment where the initial positive occurred under the MT03 project. It is the establishment's [Galligan][36] responsibility under the regulations to address the source of the food safety hazard…. It does not appear that this company [Galligan] is trying to do this, but instead to point fingers at other companies [ConAgra] not meeting their responsibilities…. In regards to the other plant [ConAgra], where the adulterant is being alleged to be coming from, you may want to have your in-plant inspection team verifying the adequacy of the HACCP-Based Inspection System, looking at their program and current documentation.

After the TSC refused to support the district office request to take the sample on, or about, June 19 or 20, the district contacted FSIS' Office of Public Health and Safety (OPHS) in Washington for permission to take the sample. Permission was given by OPHS on June 24, and a compliance officer immediately obtained the traceback sample at Galligan. The product sampled was ConAgra coarse-ground beef produced on May 31, 2002, and was in chubs[37] labeled sell or use by June 18, 2002. In all, 7 days were lost in obtaining permission to take the traceback sample (June 17-24). The traceback sample was confirmed positive for the *E. coli* pathogen on June 29; the recall process was initiated that resulted in the June 30 recall at ConAgra.

Montana Quality Foods

Company officials allege that positive *E. coli* O157:H7 samples in their products, detected in January and February 2002, were made from beef supplied by the ConAgra plant at Greeley. Company records showed that at the time of the first positive test result in January 2002 Montana Quality Foods had products on hand from both ConAgra and another supplier. When an FSIS compliance officer arrived at the plant after the first positive result (MT03 test), a Montana Quality Foods official said he offered both products to the compliance officer for testing. The Montana Quality Foods

[36] All entries in brackets added for clarification and were not included in the original message.
[37] A chub is processed meat packaged in a tube.

official said the compliance officer declined and said the procedures did not allow FSIS to sample incoming product that bore the mark of inspection. District office officials said FSIS did not collect a traceback sample of raw materials at Montana Quality Foods because the contaminated product could not be linked to a single source.

Montana Quality Foods returned products from both ConAgra and the other supplier. It subsequently received additional ConAgra product, which a Montana Quality Foods official later said was the source of the positive verification (MT04) test results at the plant. The contaminated ConAgra beef bore the same batch number and date of production as the ConAgra product previously returned; however, the Montana Quality Foods official said he was unaware of this at the time. The official said that when Montana Quality Foods learned of the three positive test results on verification samples, no source product was left in the plant to fulfill an FSIS request for the source product. FSIS tried but could not find any remaining ConAgra product from the same batch and production date to test.

FSIS officials informed us that a project code and sample collection and processing procedures for traceback samples have been developed, although the written procedures have not yet been issued. In addition, FSIS issued guidance in July 2002 that provided for in-plant inspection personnel to identify the firms supplying the raw materials when presumptive positive test results are reported in raw ground beef. These requirements were contained in a notice in November 2002.[39] Upon notification that there is a confirmed positive test result, the district office is now required to notify the affected suppliers that product from their establishment was used in raw ground beef that tested positive for the *E. coli* O157:H7 pathogen. In addition, FSIS' RMD has been instructed to follow a similar procedure to notify suppliers when their raw materials are included in adulterated product subject to recall.

RECOMMENDATION NO. 13

Expedite issuance of the regulations and/or written directives, as necessary, to provide clear directions on when traceback samples are to be collected and how the samples are to be processed. Incorporate the cited notice requiring notification of suppliers into the FSIS Directive System.

FSIS Response

FSIS will provide clear directions on when traceback samples are to be

[39] FSIS Notice 47-02, dated November 20, 2002.

collected and how the samples are to be processed in the updated FSIS Directive 10,010.1, "*Microbiological Testing Program For Escherichia coli O157:H7 in Raw Ground Beef*." In the interim, FSIS issued Notice 11-03, "Update to FSIS Directive 10,010.1, Microbiological Testing Program For Escherichia coli O157:H7 in Raw Ground Beef," dated April 18, 2003. This notice updates instructions to inspection personnel on planned changes to the Directive including providing more comprehensive procedures, requirements for notification of suppliers, and increased verification needs. The revised Directive will be issued by October 2003 and incorporate the instructions of the notice.

OIG Position

We cannot accept the management decision. The notice cited by FSIS does not contain requirements or procedures for notifying suppliers when positive MT03 sample test results are found. To reach management decision, FSIS needs to incorporate such procedures into the cited directive when issued.

FINDING NO. 8

FSIS' OVERSIGHT REVIEWS OF THE CONAGRA RECALL WERE NOT USED TO CONTROL THE RECALL PROCESS

FSIS' management control and oversight of the recall process does not provide reasonable assurance that recovery of the recalled product is maximized and enforcement actions, when necessary, are taken. Effectiveness checks by compliance officers were not reviewed by management, analyzed, and/or problems always resolved. We found that effectiveness checks were made up to 4 months after the initial recall, which limits the potential recovery of product, such as ground beef. Also, our review of the effectiveness checks disclosed incomplete and inconsistent reviews and lack of documented enforcement actions when problems were disclosed. In one district, although FSIS confirmed that ConAgra notified all primary distributors of the recall, in 67 cases, FSIS found that those distributors had not notified others in the commercial chain. There was no evidence that FSIS took enforcement action in these cases. As a result, FSIS' oversight of the recall process was not always effective in ensuring that the objectives of its management control process are met. According to FSIS Directive 8080.1 (Rev. 3), the primary purpose of effectiveness checks is to verify (1) that adequate notice about the recall has been provided to all consignees by the firm conducting the recall and (2) that consignees have located and controlled the recalled product and have followed the recalling firm's instructions for removing it.

FSIS officials stated that resource constraints have limited how quickly it can complete its effectiveness checks. However, we believe that FSIS

needs to reassess how it conducts and manages this process to ensure that recall notice is timely provided and recalled product is removed from commerce.

a. Effectiveness Checks Had Not Been Monitored

We reviewed FSIS management control over the effectiveness check process in one district. We found limited evidence of supervisory review over the checks to be performed or the adequacy of those checks. Supervisory reviews were not completed until March 2003, after OIG requested documentation of the effectiveness checks. We found evidence of supervisory review for only 37 of 490 effectiveness checks we reviewed.

Enforcement Protocol VI, *Recalls*, specifies that compliance officers in all districts involved in the recall should conduct recall effectiveness checks to verify that the recall action is conducted in an efficient manner. There are no specific criteria in the instructions for determining the optimum number of checks to be performed.

FSIS National Office officials informed all affected districts that effectiveness checks would be conducted on 100 percent of the primary distributors, 20 to 25 percent of the secondary distributors, 5 to 10 percent of the tertiary distributors, and 5 percent of the distributors beyond tertiary. In one district reviewed, about 20 compliance officers were responsible for effectiveness checks. The district's Recall Effectiveness Progress Reports reported that all primary distributor effectiveness checks had been completed.[40] Furthermore, the district reported that no problems had been encountered during the effectiveness check process. The district provided OIG 490 effectiveness checks for analysis (37 primary, 436 secondary, 13 tertiary, 4 beyond). Our review disclosed the following concerns:

FSIS did not ensure it performed a sufficient number of checks. We found that individual FSIS compliance officers were responsible for contacting the required number of distributors outlined in the FSIS plan and for determining the number of secondary, tertiary and beyond reviews to be done. However, the individual compliance officers did not formally document how they determined the number of checks to be performed, and there was no reconciliation of the number of reviews conducted to those planned. We could not determine if all planned reviews were performed because the data had not been accumulated. FSIS officials stated

[40] As of March 25, 2003, FSIS had made (nationwide) about 250 primary checks, 5,000 secondary checks, and 250 checks at the tertiary level and beyond.

it would be too labor intensive to collect this information after the fact. There is no requirement for FSIS at any level to document that FSIS accomplished its plan for completing its effectiveness checks.

Effectiveness checks were inconsistent and incomplete. We found at least 266 discrepancies in the data collected and documented on the effectiveness check forms completed by district compliance officers. Examples follow:

- 10 cases where disposition of product on hand at the time of the effectiveness check was not documented;
- 6 cases where the number of subaccounts was not documented;
- 2 cases where the firm had a sub-recall but there was no notation as to whether sub-recall instructions were followed;
- 2 cases where the form showed the firm did not comply with recall instructions but there was no documentation of the problem;
- 1 case where the form showed no sub-recall but 5 sub-accounts were noted;
- 3 cases where the form indicated a sub-recall was instituted but the box indicating the sub-recall instructions were followed was marked “NA”;
- 97 cases where the weight of recalled product purchased was not shown; and
- 145 cases where key dates were omitted.

Checks were not always timely. Some effectiveness checks were not timely performed. Effectiveness checks were conducted between July 8, 2002 and November 2002. For the effectiveness checks we reviewed, we found about 31 percent were done in July, 42 percent in August, 20 percent in September, and 7 percent in October. Two checks were performed in November (0.4 percent).

FSIS procedures do not specify the timeframes required for conducting effectiveness checks. To provide reasonable assurance that recalled product is timely identified and removed

from commerce, FSIS needs to establish timeframes for completing and acting on its reviews.

b. Managers Did Not Follow-Up on Problems Disclosed by Effectiveness Checks

Enforcement Protocol VI, *Recalls*, states that if effectiveness checks disclose that consignees have not been notified of the product recall or have not acted as requested by the recalling firm, FSIS personnel are to detain any product posing a health risk and notify the recalling firm. Communication breakdowns that cause a failure to recall product should result in FSIS compliance personnel notifying the recalling firm so corrective actions can be taken. District offices are to notify the compliance officer in headquarters and they are to follow-up with the firm and document the corrective actions taken. Logs are to be maintained of these reported problems and how the problems were resolved. If the firm does not take prompt action to contact the consignees with recall instructions or the consignee fails to act on the product as requested by the firm, compliance personnel may initiate other enforcement actions.

In 19 cases, we found that the district office did not follow up to ensure that compliance officers resolved situations where they documented that the firm had not been notified of the recall. District office personnel stated that they were convinced at the time that all product was out of commerce and therefore, it was not necessary to resolve all these issues.

For example, effectiveness checks for 4 of 37 primary distributors, 1 secondary distributor, and 4 tertiary distributors showed that some secondary and tertiary distributors were either not notified or were notified in an untimely manner.

Figure 3: Secondary Distributors Not Notified of Recall

Primary Distributor	Number of Secondary Distributor Effectiveness Checks	Number of Secondary Distributors Not Notified of the Recall
A	24[1]	0
B	10	0
C	65	4[2]
D	15	14

[1] Six effectiveness checks showed that the stores were notified from 8 to 10 days following the recall.
[2] In addition, three other secondary distributors did not know whether they had been notified of the recall.

Figure 4: Tertiary Distributors Not Notified of Recall

Secondary Distributor	Number of Tertiary Distributor Effectiveness Checks	Number of Tertiary Distributors Not Notified of the Recall
E[3]	4	4
[3] Distributor E is a secondary distributor for primary Distributor D.		

District compliance officers documented the reasons some notifications were not made, but did not always verify the information provided, and they did not take enforcement actions where needed. We question whether information provided to District managers by these effectiveness checks was sufficient to allow the managers to conclude that the recall was effective.

Distributor A. The primary effectiveness check for distributor A showed that distributor personnel would not be able to trace product to any particular retail store because the product was given a new lot code when it was received at the distribution center. Therefore, all similarly packaged product that was purchased from more than one supplier would have the same lot number. The distributor's representative stated that the only way to trace product to the individual stores would be through the grinding logs. It is FSIS' policy not to take exception to this practice, even though the recall process would be delayed.

Distributor D. A representative of distributor D stated to the compliance officer that his firm had received verbal and written recall notification of the original recall but not of the expanded recall. The FSIS compliance officer documented that the distributor purchased 80,084 pounds of ground beef that was included in the expanded recall. Distributor D's representative told the compliance officer that the company did not institute a "sub-recall" during the original recall because it sold the product lines to high-volume end-users who would have likely used the ground beef in a short timeframe. The representative stated, "I am sure the product had been used up but our sales staff has begun notifying people by phone."

From our review of the effectiveness checks for 15 secondary distributors, we could not verify that primary distributor D had notified 14 of its customers as stated. The FSIS compliance officer did not resolve this issue, and FSIS National Office officials informed us that no enforcement actions were taken against any of the firms that failed to make the proper notifications. However, we noted that although current procedures require compliance officers to take enforcement actions if a customer is not notified, they do not make clear what those actions should be if the distributor is down line. FSIS has not

established criteria for assessing penalties when such recall notifications are not done.

FSIS National Office officials informed us that the district office notified them once of a specific distributor (on the island of Guam) that was not notified of the recall.[41] According to FSIS officials, other districts have referred cases to FSIS headquarters, which monitors the districts' pursuit of the cases to resolution. For example, one district reported that one tertiary firm was not informed of the recall, and the National Office instructed the district to trace the chain of companies from this firm. Ultimately, the district located one remaining case of product that should have been recalled. Another district reported that a distributor refused to notify customers of a sub-recall because it assumed all the meat had been eaten. FSIS instructed this district to verify this assumption. The district contacted 13 of the customers, who verified that the product had been consumed onsite, with only one consumer complaint of an "off odor" to the beef.

c. Effectiveness Checks Were Not Analyzed by Management

The recall is considered for closure after (1) the recalling firm has submitted a final closeout letter and (2) FSIS determines that the recalling firm has made all reasonable efforts to recall the product and that the product has either been disposed of, been retained by FSIS, or been taken under documented control by the company. A recommendation for closure would be prepared and submitted to the RMD for its review and approval, and the recall case would be removed from active status on the FSIS web site. However, no desired timeframe for completing these actions is contained in FSIS procedures, and no criteria are provided for evaluating the effectiveness of the recall, such as the amount of product accounted for, the number of consignees contacted, etc.

As of March 1, 2003, ConAgra had not issued a recall closeout letter to FSIS showing the disposition of all recalled product. In addition, the company had about 900,000 pounds of recalled ground beef in storage whose disposition FSIS has not approved. FSIS has no evidence that validated the proper disposition of this product.

In its draft closeout memorandum to the FSIS National Office, the district reviewed showed that a total of 497 effectiveness checks were done. The draft conclusion reached by the district office on the recall was, "It would appear that the recall was conducted in an effective

[41] We discovered that a district compliance officer provided the notification without the knowledge of district office management.

manner. No problems were noted or encountered. This letter will close the recall for the district." The district office determined that the ConAgra recall was effective because district personnel were convinced that all product had been taken out of commerce. Even though all the notifications were not made, compliance officers found no cases of additional illness that they could directly relate to the absence of a specific notification. Therefore, they believe that it could be concluded that the absence of notifications had no adverse public health effects.

We question the determination made by the district office. We found that neither the district nor National Office analyzed the effectiveness checks to determine whether ConAgra and its distributors made all reasonable efforts to recall and dispose of the product. The district office based its conclusion that the recall was effective on the abatement of reported cases of food poisoning.

Documentation showed that in 67 effectiveness checks reviewed, distributors and others in the distribution chain were not notified of the ConAgra recall. When FSIS notified the firms during the effectiveness checks, the firms were able to take control of about 1,600 pounds of recalled product that may have otherwise been consumed. One firm's manager told the FSIS compliance officer that he found out about the recall on the Internet. He searched his freezer and identified a case of recalled product, but he could not get the distributor to pick it up until he insisted it had to be removed.

FSIS National Office officials stated that resource constraints limit what they can do in a set time period. However, FSIS needs to re-examine their process for completing effectiveness checks; they serve a limited purpose if they are not timely and/or enforcement action taken when needed. FSIS needs to strengthen its procedures for completing, reporting, and analyzing the results of its management control reviews over the effectiveness of the recall. Although FSIS procedures suggest that the recalling firm conduct effectiveness checks of its primary distributors' notification to others in the commercial chain, ConAgra's recall plan did not provide for this control. FSIS assumed sole responsibility to evaluate whether the primary distributors properly notified others in the distribution chain and disposed of the recalled product. FSIS needs to place the responsibility for conducting effectiveness checks on the firm conducting the recall and take enforcement action whenever necessary when product has not been timely identified and disposed of. FSIS can then direct its resources to providing management oversight over the adequacy of the recalling firm's actions.

RECOMMENDATION NO. 14

Implement a management control process to ensure that district managers comply with recall procedures and that compliance officers' determinations are reviewed, analyzed, and acted on.

FSIS Response

In March 2003, the District Offices were provided draft guidelines to be immediately implemented to ensure that recall activities are effectively carried out. These guidelines clarify CO responsibilities associated with recalls and require that each District Office designate an individual to manage recall activities during working hours, as well as after hours, weekends, and holidays. The guidelines also address the responsibilities of the Deputy District Manager and COs pertaining to recalls. The responsibilities of Deputy District Managers and COs were also addressed at the FSIS Compliance Training session that was held in Dallas, Texas, during the week of April 28-May 2, 2003 (Enclosure No. 2).

FSIS also plans to convene an internal workgroup to provide recommendations as to how to improve the recall effectiveness checks process. The workgroup will also provide recommendations so FSIS has a mechanism in place to ensure that, on an ongoing basis, District Managers comply with recall procedures and assure that COs' determinations are reviewed, analyzed and acted on. The workgroup will also consider the overall policies and procedures for managing the recall process and the recall effectiveness checks and will make recommendations for improvement.

As part of the recall process improvement effort, FSIS will examine and include in directives, as appropriate, provisions to establish criteria to assess the overall effectiveness of a recall, to reconcile planned effectiveness checks to those checks actually performed, to identify corrective actions to be taken when deficiencies are noted, etc. This information will be assembled and formalized in a directive. The management controls, responsibilities, and oversight roles for this process will be clearly delineated.

The workgroup will provide a report outlining recommendations by October 2003. The draft guidelines issued to District Offices in March 2003 will be updated and finalized by March 2004. The final FSIS recommendations will be implemented by July 2004.

OIG Position

The planned actions are not sufficiently described to reach management

decision. Our review of the interim guidelines of March 3, 2003, and information contained in the response, do not detail what provisions will be put in place for reconciling planned effectiveness checks to those checks that were actually performed. Also, the guidelines and reply do not specify what actions will be initiated when deficiencies are found with vendor notifications. Moreover, they do not establish or provide the criteria for assessing recall effectiveness. To reach management decision for this recommendation, FSIS needs to provide details of the management controls to be put in place to improve the recall activities and estimated timeframes for implementation.

RECOMMENDATION NO. 15

Reassess the policies and procedures for managing the recall process. Require the recalling firm to conduct effectiveness checks on those below the primary distribution level. Perform sufficient oversight over the recall to ensure that notifications have been timely made and appropriate actions taken to dispose of the recalled product.

FSIS Response

FSIS does not have the statutory authority to require that establishments conduct effectiveness checks. FSIS believes the recommendation should be restated to ask that FSIS work with industry to improve the recalling firms' effectiveness checks.

FSIS has convened a workgroup to provide recommendations as to how to improve the recall effectiveness checks process. The workgroup will also provide recommendations designed to ensure that FSIS has a mechanism in place to ensure that on an ongoing basis, District Managers comply with recall procedures and assure that COs' determinations are reviewed, analyzed, and acted on.

In addition to providing recommendations to ensure that District Offices are properly carrying out their recall responsibilities, the workgroup will provide recommendations regarding what action should be taken in the event that the recalling firm has failed to conduct effectiveness checks below the primary level, and/or has not provided timely notifications to its consignees regarding the recalled product, or has not taken appropriate action to dispose of recalled product. FSIS intends to include as workgroup participants, persons who are familiar with the recall process and who have knowledge of problems that are encountered in the course of conducting recall effectiveness checks.

As part of the recall process improvement effort, FSIS will examine and include in a directive, as appropriate, provisions to establish criteria to

assess the overall effectiveness of a recall, to reconcile planned effectiveness checks to those checks actually performed, to identify corrective actions to be taken when deficiencies are noted, etc. This information will be assembled and formalized in a directive. The management controls, responsibilities, and oversight roles for this process will be clearly delineated in a directive.

The workgroup will provide a report outlining recommendations by October 2003. The draft guidelines entitled, "*Office of Field Operations District Office Recall Responsibilities*" which was issued to District Offices in March 2003 will be finalized by March 2004. The final FSIS recommendations will be implemented by July 2004.

OIG Position

We cannot reach management decision until FSIS provides details as to the changes that will be implemented to improve recall policies and procedures. Since product recalls are voluntary actions by the recalling firm, verification that proper notice has been provided to those in the distribution chain should be the responsibility of the recalling firm. FSIS, as part of its oversight responsibility, should monitor the process and provide additional oversight, where warranted.

RECOMMENDATION NO. 16

Establish a system of specific enforcement actions to be taken against those processors or distributors where effectiveness checks disclose proper notifications of the consignees/customers have not been made.

FSIS Response

Under 9 CFR 500.3 FSIS has authority to take enforcement action against any establishment that has been found to have produced and shipped adulterated product. When effectiveness checks disclose that proper notification of the consignee/customers has not been given, FSIS has the authority to detain and, if necessary, seize products that have been determined to be adulterated. FSIS has prior precedent in applying its enforcement authority.

FSIS is working closely with industry and is providing guidance on the proper and appropriate actions that should be taken during recalls. On December 12, 2002, FSIS held a public meeting to discuss improving the recall process. The Agency is considering ideas presented at the public meeting for increasing industry's involvement in managing recalls.

Also, during the week of April 28-May 2, 2003, an Office of Field Operations (OFO) Compliance training session was held in Dallas, Texas (Enclosure No. 2). As part of the training, OFO COs were provided training on their expected roles and responsibilities regarding recall activities. OFO COs will play a greater role in recalls. These COs will collect information to demonstrate that processors or distributors have either met or failed to disclose proper notifications to consignees or customers regarding recalled product. This information will be used as a basis for further strengthening and improving the recall process.

As part of the recall process improvement effort, FSIS will examine and include as appropriate, provisions to establish criteria to assess the overall effectiveness of a recall, to reconcile planned effectiveness checks to those checks actually performed, to identify corrective actions to be taken when deficiencies are noted, etc. This information will be assembled and formalized in a directive. The management controls, responsibilities, and oversight roles for this process will be clearly delineated within the directive.

The workgroup will provide a report outlining recommendations by October 2003. The draft guidelines entitled, "*Office of Field Operations District Office Recall Responsibilities*" which was issued to District Offices in March 2003 will be finalized by March 2004. The final FSIS recommendations will be implemented by July 2004.

OIG Position

The proposed action is not sufficient to reach management decision. We do not consider detention and seizure of adulterated product to be sufficient enforcement action against firms that do not fulfill their recall notification responsibilities. To reach management decision, FSIS needs to provide the details of the changes that will be implemented in recall policies and procedures and the timeframe for implementation.

RECOMMENDATION NO. 17

Develop effectiveness check criteria for monitoring the universe of potential effectiveness checks and documenting the number of required individual checks completed, as well as establishing substantive and quantitative criteria for determining whether recalls are effective.

FSIS Response

FSIS plans to convene an internal workgroup to provide recommendations as to how to improve the recall effectiveness checks process. The workgroup will also provide recommendations designed to ensure that

FSIS has a mechanism in place to ensure that on an ongoing basis, District Managers comply with recall procedures and assure that COs' determinations are reviewed, analyzed and acted on. In addition to providing recommendations to ensure that District Offices are properly carrying out their recall responsibilities, the workgroup will be expected to develop recommendations for effectiveness check criteria, including establishing substantive and quantitative criteria for determining whether recalls are effective. The workgroup will provide a report outlining recommendations by October 2003. The recommendations will be finalized by March 2004. The final FSIS recommendations will be implemented by July 2004.

As part of the recall process improvement effort, FSIS will examine and include as appropriate, provisions to establish criteria to assess the overall effectiveness of a recall, to reconcile planned effectiveness checks to those checks actually performed, to identify corrective actions to be taken when deficiencies are noted, etc. This information will be assembled and formalized in directives. The management controls, responsibilities, and oversight roles for this process will be clearly delineated in the directive.

OIG Position

The proposed action is not sufficient to reach management decision. To reach management decision, FSIS needs to provide the details of the changes that will be implemented in recall policies and procedures and the timeframe for implementation.

FINDING NO. 9

PLANT PRODUCTION RECORDS WERE NOT DETAILED ENOUGH TO TRACK PRODUCT DISBURSEMENT

Galligan records pertaining to production, distribution, and sanitation activities were either inadequate or nonexistent. Galligan itself had no company policies for production records of any kind, and FSIS had not codified specific record requirements to ensure that pertinent manufacturing activities were documented for regulatory review. While most companies keep the transaction records required by FSIS regulations, the production records needed are those that allow a company to trace the source and distribution of product that is later identified as contaminated with *E. coli* O157:H7. The lack of adequate production records diminished the ability of FSIS to exercise appropriate oversight and contributed to the untimely removal of potentially contaminated ground beef product from commerce.

Regulations require companies to maintain records that will fully and correctly disclose all transactions in the business subject to the Act[42] and require that SSOPs describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).[43] SSOPs shall specify the frequency with which each procedure in the SSOP is to be conducted and identify the establishment employees responsible for the implementation and maintenance of such procedures. However, regulations do not require that production records be kept. HACCP record keeping principles require the plant to record its monitoring of CCPs, but they do not specify any requirements for production records.

The plant sales manager at Galligan said that there are no internal company policies or requirements that specify the preparation of production records of any kind. A plant production employee did maintain limited unofficial records of ground beef production in a notebook. This notebook showed the products, day, lot number, amount of product, raw meat ingredients, and the source (company) of the raw product. However, the sales manager pointed out that the entries in the notebook may not accurately reflect the production sequence. He told us plant personnel had performed a cleanup after production of product (later known to be contaminated with *E. coli* O157:H7) and before the production of beef pepper patties. The notebook did not corroborate this statement.

FSIS officials stated that there are no FSIS requirements regarding whether establishments must maintain production records. Therefore, there are no policies specifying the content of plant production records. At our request, the supervisory compliance officer (SCO) analyzed the establishment's available ground beef production records. Of the 20 sample cases he reviewed, the SCO found no instances where plant personnel recorded enough production information to immediately identify the specific supplier's product that was used. In addition, the TSC personnel who assisted us confirmed that the establishment's HACCP plan had no record keeping requirements. We also noted that there were no production records maintained for the chicken, pork, or other beef products.

We reviewed the available production and distribution records for Galligan in an attempt to determine whether this plant removed from commerce all contaminated product they produced from contaminated raw product that they received from ConAgra. The available production records for June 14, 2002, showed that Galligan produced (1) ground beef patties, (2) ground beef pepper patties, and (3) bulk ground beef, in that order.

[42] 9 CFR 320.1, Records Required to be Maintained, dated January 1, 2002.
[43] 9 CFR 416.12, Development of Sanitation SOPs, dated January 1, 2002.

Both the ground beef patties and the bulk ground beef were produced with product from ConAgra that was contaminated with *E. coli* O157:H7. According to production records, the pepper patties were produced from product received from another plant, but they were nevertheless produced between two rounds of production that were confirmed positive for *E. coli* O157:H7, and there was no documentation to show that plant employees cleaned the equipment after producing the contaminated ground beef patties. As a result, it was questionable whether the ground beef patties did not also contaminate the pepper patties.

We attempted, in conjunction with plant management, to identify and account for the distribution of 49 boxes of beef pepper patties that were potentially contaminated. We could only account for 11 boxes that available records showed had been shipped. Thirty-eight boxes were not accounted for with available records. On August 30, 2002, following our visit, the plant voluntarily recalled about 980 pounds of pepper patties, based on our review at the plant.

Following our review, an FSIS Office of Program Evaluation, Enforcement, and Review (OPEER) team initiated a review at Galligan at the request of the FSIS National Office. The OPEER draft report concluded that:

- The voluntary recall of the pepper patties might have occurred earlier if inspection personnel had recognized the establishment's production record limitations;

- The compliance officer could have questioned the pepper patty production further by not accepting oral statements that a proper cleanup was made before production of the pepper patties;

- The circuit supervisor provided minimal involvement and oversight of the circumstances that led to the voluntary recall of the pepper patties; and

- The nature of the establishment records contributed to a slow response to initiate a voluntary recall.

The review team's draft report noted that an FSIS compliance officer was dispatched to the establishment on June 19, 2002. The compliance officer reviewed plant production records for June 14, 2002, as well as incoming raw product and sales invoices. The draft report stated:

> The production records for June 14, 2002, show that three types of ground products were produced on that day. The records do not show that a cleanup was performed between the different products; however, plant management orally stated that there was a cleanup.

The OPEER draft report indicated that the inspector at Galligan satisfied the compliance officer that a proper cleanup was done before the pepper patties were produced. The report also showed that the compliance officer found no record of production for June 12, 2002. On this date, another ground beef sample had been taken and was found to be contaminated with *E. coli* O157:H7. The report showed that plant personnel later furnished an addendum to the production records for June 12, 2002, that appeared to be documented some time after the June 12 production.

The draft OPEER report supports our conclusion that company records were insufficient to allow for an adequate accounting for products produced at the plant. It reported that records were not adequate to show the source of the raw product used in finished product, the dates of production, or the locations where finished products were shipped. It also reported that there was no documented evidence of cleanup on June 14, 2002, after the contaminated production and before production of the pepper patties.

In Finding No. 8, we detail additional problems concerning production records. We noted that the primary effectiveness check for distributor A showed that distributor personnel would not be able to trace product to any particular retailer because the product was given a new lot code when it was received at the distribution center.

RECOMMENDATION NO. 18

Establish minimum acceptable requirements for an establishment's production records. Ensure that these production record requirements are adequate to facilitate tracebacks; direct that these requirements be incorporated into each establishment's HACCP plan; and periodically verify the records for sufficiency.

FSIS Response

FSIS Directive 8080.1 (Enclosure No. 7), "*Recall of Meat and Poultry Products,*" provides guidance to industry on developing a recall plan. FSIS recommends that the recall plan specify that product production and distribution records be maintained by establishments such that they can facilitate identification and location of products that may need to be recalled. FSIS will revise Directive 8080.1 to provide additional guidance on the establishments' production records. Also, FSIS will work to issue additional guidance through a Federal Register Notice that details how language in 9 CFR 320.1 "*Records required to be kept,*" would be utilized to ensure the establishment records are adequate to facilitate tracebacks.

FSIS will revise and issue an updated FSIS Directive 8080.1 by October 2003. FSIS will issue a Federal Register Notice by December 2003.

OIG Position

We accept the management decision.

RECOMMENDATION NO. 19

Verify that sanitation procedures at Galligan are always properly documented by the plant.

FSIS Response

On May 7, 2003, FSIS conducted a confirmation and verification review at the Galligan Wholesale Meat, Est. 6475, Denver, Colorado, to review deficiencies and needed improvements identified during the OIG audit. The review specifically focused on verifying the corrective actions required to improve the plant's SSOP plan and the production documents for ground beef and other ground products at the establishment.

As a result of the review, new record-keeping practices have been instituted at the establishment to more closely monitor all products used in the production of ground beef. The establishment's sanitation procedures have been documented. A log book is being kept with all fresh beef suppliers listed for each batch of ground product, lot numbers, production dates and all pertinent information on the labeled products. Finished product identification including total box count, total weight and finished product lot numbers is also recorded in the log.

In addition, on June 17, 2002, FSIS issued Directive 4430.3, "*In-Plant Performance System Reviews,*" (IPPS) and a comprehensive Supervisory Guideline (Enclosure No. 6). These documents provide specific instructions and guidance on how to assess the performance of inspection personnel in the PR/HACCP system environment and for verifying that inspection personnel are carrying out their responsibilities. These include applying the appropriate inspection methods using effective regulatory decision making, documenting findings appropriately, and when warranted, implementing enforcement actions properly.

The Office of Program Evaluation, Enforcement and Review (OPEER) will monitor the Agency's progress in the area. Audits, evaluations, and reviews will be conducted to verify implementation and measure the effectiveness of the corrective actions.

OIG Position

We accept the management decision.

FINDING NO. 10

FSIS VIOLATED POLICY WHEN IT APPROVED THE POST-RECALL USE OF LACTIC ACID

During the recall, ConAgra offered to control the *E. coli* O157:H7 contamination of its ground beef by introducing lactic acid into the product during production. In approving this use of lactic acid, FSIS reviewers did not regard the process as a new technology; even though FSIS' technical staff was unaware it had ever been tried before. Whenever establishments intend to introduce a new technology, FSIS must document its analysis of the scientific validity of the process. In the case of ConAgra, however, the reviewers lacked sufficient evidence showing how they concluded the use of lactic acid in ground beef would produce a safe and wholesome product. The FSIS review team did not thoroughly document its analysis of the data ConAgra provided because it was trying to expedite its decisions to allow ConAgra to take corrective action in response to an NOIE. Although it was finally determined that ConAgra ground beef processed with lactic acid was safe, FSIS' initial, undocumented approvals were open to challenge and raised questions within FSIS about the need to relabel the product. We found, however, scientific studies that documented that the use of lactic acid may raise the cooking temperature necessary to destroy the *E. coli* O157:H7 contaminant.

FSIS' Approval Process for the Use of Lactic Acid

On July 18, 2002, FSIS informed ConAgra in an NOIE letter that it intended to withhold the marks of inspection and suspend the assignment of inspectors at the plant. In an effort to prevent implementation of the enforcement action, ConAgra submitted a plan to FSIS outlining what corrective and preventive measures the plant intended to implement. One of the corrective actions proposed by ConAgra was to add lactic acid to its ground beef.

Before its 2002 recalls, the ConAgra plant was spraying lactic acid on carcasses as an antimicrobial intervention during slaughter operations. This intervention is commonly used by facilities that slaughter beef, and was included in ConAgra's HACCP plan. However, TSC officials who assisted us during the audit informed us that they were not aware of any beef processor adding lactic acid to its ground beef at the time the beef was ground. ConAgra submitted its support for the use of lactic acid as an

[45] 21 CFR 184.1061 (Lactic Acid), dated April 1, 2002.

intervention against *E. coli* O157:H7 as part of its effort to satisfy FSIS that the enforcement measures stipulated in the NOIE were unnecessary.

FSIS assembled a Technical Assessment Group team to review ConAgra's proposals. The team reviewed the plant's documentation, including the use of lactic acid treatment in ground beef. FSIS' overall conclusion was that the documents supporting the HACCP plan revisions were scientifically sound. ConAgra subsequently started incorporating lactic acid in its ground beef.

We asked FSIS to provide us with support for its decision to approve the plant's use of lactic acid in ground beef. FSIS National Office officials told us that the information submitted by ConAgra was reviewed, but that FSIS did not formally document its analysis on the use of lactic acid. The officials stated that ConAgra submitted a considerable amount of documentation on a variety of topics at various times, and the review team was charged with reviewing all the information and making a decision within a month. These factors limited the amount of formal documentation FSIS could prepare to support its review.

FSIS officials explained that their approval was based on the Food and Drug Administration's (FDA) acceptance of lactic acid as generally safe when it is used as an antimicrobial agent.[45] Antimicrobial agents are defined as substances used to preserve food by preventing growth of microorganisms and subsequent spoilage.[46] Because lactic acid is considered generally safe by the FDA, FSIS considered it safe for use as an antimicrobial agent in ground beef.

With assistance from the TSC, we examined the use of lactic acid in ground beef and we identified the following concerns:

- We could not locate any evidence to show that the *E. coli* O157:H7 pathogen in ground beef acts as a spoilage organism;

- We could not locate any evidence to show that lactic acid aids in preserving ground beef through a material reduction in the numbers of the *E. coli* O157:H7 pathogen;

- We found two studies that indicate that exposure of *E. coli* O157:H7 to moderately acidic conditions (lactic acid) can increase the pathogen's ability to survive cooking;[47] and

[46] 21 CFR 170.3 (Definitions), dated April 1, 2002.
[47] Agricultural Research Service, Effect of PH-Dependent, Stationary Phase Acid Resistance on the Thermal Tolerance of *Escherichia Coli* O157:H7, January 26, 1998. Also see Food Technology, Foodborne Disease Significance of *Escherichia coli* O157:H7 and Other Enterohemorrhagic *E. coli*, October 1997.

- We found one study that concluded that lactic acid, individually or in combination with other treatments (fast freezing, pulsed electric field, sodium lactate, and citric acid), did not significantly reduce *E. coli* O157:H7 numbers when applied at different stages throughout the beef burger manufacturing process.[48]

Absent FSIS' written analysis of ConAgra's use of lactic acid as an additive to ground beef, it is not clear to what extent FSIS thoroughly considered all the available scientific data concerning the use of lactic acid, including studies that indicate a counter-hygienic effect of that use.

ConAgra applied about 440 gallons of 2 percent lactic acid solution to about 1 million pounds of raw ground beef over 13 days between August 12 and September 11, 2002. FSIS National Office officials informed us that ConAgra intends to discontinue use of lactic acid in its ground beef.

Labeling Requirements

Missing from ConAgra's documentation for using the lactic acid was information that showed the acid had no technical effect on the product after processing. As an antimicrobial intervention, the acid was intended to have a technical effect during processing only. If it continued to have a technical effect in the finished product, ConAgra would have to re-label its beef to declare the presence of the lactic acid.[49] Federal regulations define a misbranded product as one whose labeling is false or misleading in any particulars.[50]

At the time ConAgra proposed to use lactic acid in its ground beef, FSIS officials stated that the process would likely result in a labeling requirement. An internal FSIS memorandum, dated August 13, 2002, noted, in part, that:

> The study provided by ConAgra as scientific support for the use of lactic acid indicates that the treatment does not significantly alter the color or odor of the product. However, the use would trigger labeling requirements to declare a descriptive statement of the product and the water/moisture gain or retention, if any remains after processing. In addition, there may be other technical effects to be considered, e.g., change in pH of the final product that would need consideration.

[48] Irish Agriculture and Food Development Agency, Control of *Escherichia coli* O157:H7 in Beefburgers, April 2001.
[49] Section on Incidental Additives, 2c, FSIS' Food Standards and Labeling Policy Book, August 1996.
[50] 9 CFR 301.2 (Definitions).

An FSIS e-mail on August 15, 2002, from a National Office official to the Boulder District Office stated, in part, that:

> The presence of the lactic acid would be required to appear as a part of the identity statement unless the company can provide information that shows that there is no sustained technical effect in the ground beef.

FSIS National Office officials informed us that ConAgra's ground beef label did not declare the lactic acid and that the company never provided FSIS with any documentation to show that the lactic acid did not remain after processing or that it had no technical effect. This, according to the National Office e-mail, caused the product to be misbranded, as defined by regulations.[51] In a conference call on November 4, 2002, between FSIS National Office officials and OIG, FSIS officials agreed that use of the lactic acid should have been declared on ConAgra's packaging label for the affected ground beef.

FSIS officials at all levels were aware that in the absence of any company documentation proving lactic acid had no residual effects in ground beef, ConAgra was required to declare the lactic acid in its labeling. However, FSIS did not take action to ensure the company either provided the required documentation or made the necessary disclosures. We concluded that the agency's decisions regarding both the safety of the product and its labeling should have been more thoroughly documented.

ConAgra officials noted at the time of our review that the ground beef with the lactic acid additive was being held at the plant and that it would not be released for sale until the plant received approval from FSIS. Company officials subsequently informed us that FSIS gave their approval for sale of the product in late November or early December 2002. According to the company officials, FSIS concluded that ConAgra had satisfactorily demonstrated that no residual lactic acid was present in the finished ground beef, that the acid had no effect on the product's shelf-life, and that the additive made no changes in the appearance of the product. These three characteristics allowed ConAgra to release the product without a label declaration.

RECOMMENDATION NO. 20

Document the analysis and determinations made for the suitability of new ingredients used in meat or poultry products. This documentation should include details on the review process and the factors considered, how conclusions will be

[51] 9 CFR 301.2 (Definitions).

communicated to the establishment, and who will be responsible for ensuring that FSIS decisions are properly implemented, in particular those relating to product labeling requirements. Coordinate with FDA on the safety concerns related to the use of lactic acid in ground beef.

FSIS Response

On December 23, 1999, the Food Safety and Inspection Service (FSIS) published in the Federal Register a final rule on "Food Ingredients and Sources of Radiation Listed or Approved for Use in the Production of Meat and Poultry Products." The final rule streamlined the process for approving the use of food ingredients and sources of radiation in meat and poultry products to provide for the simultaneous review, by FSIS and the Food and Drug Administration (FDA), of petitions for new uses of food and color additives and notifications for new uses of generally recognized as safe (GRAS) substances that are submitted to FDA.

Subsequent to the publication of the final rule in January 2000, FDA and FSIS entered into a Memorandum of Understanding (MOU) that outlines the procedures that are followed by FDA and FSIS regarding the joint review of requests and petitions for the use of food ingredients and sources of radiation in meat and poultry products with regard to safety and suitability determinations. The final rule and the MOU explain that, except in limited circumstances, FDA will now (1) list in its regulations (21 CFR) food additives and sources of radiation that are safe and suitable for use in the production of meat or poultry products and (2) document the generally recognized as safe (GRAS) substances that are both safe and suitable for use in meat and poultry products that are the subject of GRAS Notices they receive.

With regard to new uses of substances that are GRAS, the MOU explains the process that FSIS operates jointly with FDA to perform acceptability (suitability) determinations. The Federal Register notice entitled "*E. coli O157:H7 Contamination of Beef Products*" (67 FR 62325) and related documents, such as "*Guidance on Ingredients and Sources of Radiation Used to Reduce Microorganisms on Carcasses, Ground Beef, and Beef Trimmings,*" and "*Guidance on the Procedures for Joint Food Safety and Inspection (FSIS) and Food and Drug Administration (FDA) – Approval of Ingredients and Sources of Radiation Used in the Production of Meat and Poultry Products,*" provided additional guidance. The information contained in these documents clearly specifies the data, documentation, and related requirements to support how FSIS makes suitability determinations. In order to document the results of suitability determinations, FSIS also issued Directive 7120.1, Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products, dated December 2002, to communicate with inspectors and provide field personnel and establishments with an up-to-date list of approved

substances for use in the production of meat and poultry products. The Directive is updated every few months as needed. FSIS regularly evaluates and updates its guidance documents as required. FSIS will coordinate with FDA in performing an updated acceptability determination on the use of lactic acid in ground beef by March 2004.

OIG Position

FSIS cites various agreements with FDA and processes that should be used to approve ingredients used to reduce microorganisms on carcasses, ground beef, and beef trimmings. During the audit, however, we found that FSIS did not document its determinations on the acceptability (suitability) determination for using lactic acid in ground beef. Of further concern, are the studies OIG found that questioned this practice, one of which was done by another USDA agency. While we concur with FSIS' proposed action to coordinate with FDA in performing an updated acceptability determination on the use of lactic acid in ground beef, to reach management decision, FSIS needs to provide the requirements that will be put in place that describe when acceptability determinations will be required and the documentation necessary to support the results of these internal determinations, as well as approvals needed.

CHAPTER 3	MONITORING AND SUPERVISION OF FOOD SAFETY PROCEDURES AT BEEF PRODUCTION PLANTS NEED TO BE IMPROVED

Some methods and procedures practiced by FSIS and industry could be improved to ensure that contaminated product does not enter channels of commerce. In the case of ConAgra, Galligan, and Montana Quality Foods, we identified four areas in which controls needed strengthening or where managers needed to reexamine systems in place.

Testing samples. FSIS' *E. coli* O157:H7 testing program cannot be used to measure the effectiveness of HACCP on either a company or a nationwide basis. The sampling program, as designed, does not provide scientific, risk-based data to measure the extent of an existing hazard. Also, FSIS needs to strengthen controls over the samples it selects for laboratory testing. Managers at both Galligan and Montana Quality Foods knew when FSIS was going to take samples for *E. coli* O157:H7 testing and adjusted their production accordingly. Packaged samples also remained unsealed and accessible by plant personnel.

HACCP plans. HACCP plans for ConAgra, Galligan, and Montana Quality Foods contained the seven principles required by regulation but were technically inadequate. Hazards were not properly analyzed and controls were not always established. The plants need to reassess their plans and correct the deficiencies.

Carcass reinspections. When animal feces were observed on ConAgra beef carcasses during production, the plant did not reinspect an adequate number of carcasses to ensure the contamination was not also present on them. FSIS policy on such reinspections is too obscure to provide adequate guidance to the plants.

Disposal of contaminated product. Beef trim that was returned to ConAgra after customer tests found the presence of *E. coli* O157:H7 was repackaged and resold for cooking. FSIS did not attempt to verify the actual disposition of the repackaged trim because FSIS officials did not believe it was necessary for the agency to monitor the disposition of all beef product that tested positive for the *E. coli* O157:H7 pathogen.

We also noted that FSIS' random sample testing of plants for pathogens and other contaminants does not provide meaningful performance data. Although the testing is intended to verify the effectiveness of the HACCP

systems, it has not been designed to measure the extent of an existing hazard. A risk-based sampling plan that ultimately targets testing toward those plants with the greatest risk of contamination would be more effective.

FINDING NO. 11

FSIS' *E. COLI* O157:H7 TESTING PROGRAM CAN BE IMPROVED TO PROVIDE MORE MEANINGFUL PERFORMANCE DATA

FSIS' *E. coli* O157:H7 testing program cannot be used to measure the effectiveness of HACCP on either a company or a nationwide basis. The sampling program, as designed, does not provide scientific, risk-based data to measure the extent of an existing hazard. The data that is produced does not reflect industry performance because a) plants like ConAgra, that performed their own *E. coli* O157:H7 testing on carcasses were exempt from sampling of ground beef, b) sampling plans do not take into account all relevant plant operational or processing factors, and c) samples taken at the plants that are selected for testing are not always representative of the lot of production or final product. As a result, FSIS cannot rely on its random sampling program to detect plants like ConAgra nor can it conclude whether HACCP, as a program, is effective in controlling product contamination by the *E. coli* O157:H7 pathogen.

FSIS' sampling program consists of two projects, designated MT03 and MT04. The MT03 project is designed to test for the *E. coli* pathogen and to stimulate industry to reduce the presence of the pathogen in raw ground beef.[52] The MT04 project is designed to verify that plant operations are back under control after an MT03 test has shown the presence of the *E. coli* pathogen in beef.

One of the objectives of FSIS' sampling program is to verify the effectiveness of HACCP systems.[53] We concluded that the random sampling program is not achieving this objective or measuring the nature, scope, or extent of an existing hazard.

a. <u>Verifying the Effectiveness of HACCP Systems at Plants Like ConAgra</u>

FSIS' sampling program, as designed, is not functioning to verify the effectiveness of HACCP systems at federally inspected plants. The program design, which was not designed to allow generation of statistical results to the entire universe of plants, is to consist of about

[52] FSIS Directive 10,010.1, dated February 1, 1998.
[53] "FSIS Sampling Programs," FSIS, USDA, Washington, D.C.

7,000 samples per year.[54] The samples are divided between manufacturers of ground beef products in retail stores and federally inspected plants. Within the sample of approximately 1,700 federally inspected plants producing ground beef, there was a further division into random selection and target selection. The target sample is to be collected from the plants that have been identified through management reviews as performing below average.[55] For 2002, FSIS targeted only 60 samples, largely because pathogens had already been identified in the plants where the samples were taken. While this method of plant selection provided some risk-based data with which to measure performance, it did not take into account plant factors such as volume of production and effectiveness of interventions in determining sampling frequencies.

OIG understands a risk-based sampling system is one that bases testing on the risk a plant poses to the wholesomeness of its product and the number of consumers endangered by contaminated product originating from that plant. OIG understands a statistically-based sample is one that bases testing on the assumption that the test results will have enough scientific validity to be projected over a universe to identify the probable magnitude of those results. OIG further recognizes that the random testing used in the program is neither risk-based nor sufficiently scientific to produce results that may be projected.

For its random selections, FSIS planned its sample size with the knowledge that a number of establishments selected for sample testing would not be sampled. FSIS Directive 10,010.1[56] provides exemptions from microbiological testing for the *E. coli* pathogen if an establishment meets one of three criteria:[57] (1) it conducts routine daily testing of raw ground beef products for *E. coli* O157:H7; (2) it requires suppliers of boneless beef to certify that each lot received has been tested and found negative for *E. coli* O157:H7; or (3) it uses validated pathogen reduction interventions on beef carcasses, routinely verifies the interventions' effectiveness through testing for *E. coli* O157:H7, and prevents the use of boneless beef or carcasses from outside sources. (ConAgra was granted an exemption under the third criteria.)

[54] The sampling is limited by the capacity of FSIS' laboratories and has recently been expanded to about 7,000 samples per year.
[55] FSIS Notice 50-94 (Microbiological Testing Program for *E. coli* O157:H7 in Raw Ground Beef), dated December 23, 1994.
[56] FSIS Directive 10,010.1 (Microbiological Testing Program For *E. coli* O157:H7 in Raw Ground Beef), dated February 1, 1998.
[57] This exception is not valid unless the establishment has had no positive test results (related to required HACCP testing) within the last 6 months.

Thus, prior to the recall, FSIS' tests for *E. coli* O157:H7 were neither risk-based, statistical, nor truly random and were not designed to detect HACCP failures in some individual plants, like ConAgra, or to determine the extent of the *E. coli* O157:H7 hazard industrywide.

FSIS managers stated that when the sampling program was developed, they understood it to be risk-based rather than statistically based. They emphasized that FSIS considered plants that performed their own interventions as low risk and that by exempting these from testing, FSIS was testing only the higher risk establishments. One manager stated that FSIS had no evidence the self-testing plants did not present a low risk and that the ConAgra recall did not provide any such evidence.

Subsequent to the recall, FSIS announced its intention to discontinue its practice of exempting plants from MT03 sampling. An FSIS manager stated that implementation of the exemptions was not uniform or adequate nationwide. We concluded that a testing program based on risk assessments would provide greater uniformity of results and greater protection to the consumer.

b. Measuring the Extent of the Hazard

Once a positive MT03 sample is found, FSIS procedures call for the collection of subsequent routine samples at the establishment where the positive is found, in accordance with the instructions for MT04 testing found in FSIS Directive 10,210.1. The MT04 sampling must continue until 15 consecutive ground beef samples have tested negative for the *E. coli* O157:H7 pathogen.[58] FSIS officials appeared uncertain about the scientific basis for collecting 15 consecutive negative ground beef samples but were able to find support for it in the International Commission on Microbiological Specifications for Foods.[59]

We determined, however, that while the International Commission on Microbiological Specifications for Foods supports collecting 15 negative verification samples, it does not provide the timeframe or the sampling techniques for the 15 samples. According to FSIS instructions, one sample is to be taken from each of the 15 consecutive lots produced by an establishment. A lot is defined

[58] FSIS Directive 10,010.1 (Microbiological Testing Program For *E. coli* O157:H7 in Raw Ground Beef), dated February 1, 1998.
[59] Case 13 sampling plan in the International Commission on Microbiological Specifications for Foods, Microorganisms in Food 7.

as the period of time from cleanup to cleanup. The sample is described as a 1-pound sample selected at a random time.[60]

We concluded that the sampling timeframe and technique set forth in FSIS instructions may not produce a sample that is indicative of the extent of the hazard. The 1-pound sample from a lot of raw ground beef product may not be representative if the entire lot is not subject to sampling. Also, in our opinion, a 1-pound sample, per lot, for an establishment the size of ConAgra that produces 500,000 pounds of raw ground beef per lot is not as representative of the lot as a 1-pound sample from a lot produced at an establishment that produces only 5,000 pounds per lot. In other words, the sample size should be proportionate to the relative size of the lot. More samples should be taken for a 500,000-pound lot than for a 5,000-pound lot. For large producers, a sampling technique can be employed that allows the inspector to take smaller samples at various times in the production day. One industry leader as part of its regular microbiological testing program is currently using this procedure.

To improve the usefulness of its sampling program, FSIS managers need to determine what they want the program to do and design it accordingly. They need to define specific goals, objectives, and performance measures for the program and incorporate them into a sampling plan design. We have been advised by FSIS officials that FSIS is currently undertaking a baseline study to develop a general microbiological description of all types of raw ground beef components for selected microorganisms of various degrees of public health concern. The microorganisms of concern for which quantitative data will be collected are pathogenic *E. coli* and *Salmonella*, which produce severe illness in humans. Other microorganisms for which qualitative data will be collected are generic *E. coli*, Coliforms, and Mesophilic aerobic plate counts. We believe the data from baseline studies like these can help give direction to the testing program.

RECOMMENDATION NO. 21

Perform the necessary baseline studies to define the goals, objectives, and performance measurements and develop a scientific, risk-based sampling plan to include relevant factors, such as individual plant volume of production and effectiveness of interventions that will provide reasonable assurance that HACCP systems in place are effective.

[60] FSIS Directive 10,210.1, Amendment 3 (Unified Sampling Form), effective July 1, 2002.

FSIS Response

FSIS agrees that baseline studies on different raw ground beef components can be useful in making the allocation of verification samples more risk-based, measuring the national prevalence, providing a marker for measuring future change in pathogens, and providing input for risk assessments. Subject to available funding provided through appropriations, FSIS will conduct baseline studies to complement and enhance its sampling program. FSIS' sampling program is one component of the Agency's overall verification program as specified in 9 CFR 417.8.

FSIS will update FSIS Directive 10,010.1, "*Microbiological Testing Program for Escherichia coli O157:H7 in Raw Ground Beef,*" with more comprehensive procedures. These procedures will address various sampling scenarios such as those based on estimates of production volume, production types (e.g., trim), statistical process data feedback, and technical interventions. FSIS' new *E. coli* O157:H7 verification testing program will be more risk-based than the current program and will place added emphasis on collecting more than one sample from higher risk operations. By increasing the number of samples FSIS collects from higher risk operations, FSIS will have greater confidence that the sampled lot is negative for *E. coli* O157:H7. In addition, no official establishment will be exempted from FSIS *E. coli* O157:H7 verification testing. Under the revised Directive, FSIS intends to sample at grinding establishments. When FSIS finds a positive sample at the grinding operation, FSIS then intends to collect subsequent samples of product from suppliers (at the supplying establishment). FSIS expects this new Directive to be issued by October 2003. FSIS expects full implementation to commence December 2003.

OIG Position

We cannot reach management decision. To reach management decision, FSIS needs to provide the details as to goals, objectives, and performance measures to be established, and timeframe for implementation, of a risk-based sampling program to provide assurance that HACCP programs are operating effectively. Also, FSIS needs to provide an estimated date for completing the baseline studies.

RECOMMENDATION NO. 22	Strengthen sampling procedures so that samples are either representative of lots being sampled or of production operations.

FSIS Response

FSIS will continue to consider all options for strengthening its verification strategies, of which sampling is one component. FSIS will update FSIS Directive 10,010.1, "*Microbiological Testing Program for Escherichia coli O157:H7 in Raw Ground Beef,*" with more comprehensive procedures. These procedures will address various sampling scenarios such as those based on estimates of production volume, production types (e.g., trim), statistical process data feedback, and technical interventions.

The revised Directive will be issued by October 2003. FSIS expects full implementation to commence December 2003.

OIG Position

Although FSIS has concurred with the need to update its sampling directive, we cannot reach management decision. To reach management decision, FSIS needs to provide details as to how the sampling procedures will be strengthened to ensure the samples are representative of the lot being sampled or production operations.

RECOMMENDATION NO. 23

Issue the planned revision to FSIS directives to eliminate the current procedure that exempts plants performing their own testing from being tested by FSIS.

FSIS Response

This has been completed by FSIS. On April 18, 2003, FSIS issued FSIS Notice 11-03 (Enclosure No. 8), "*Update to FSIS Directive 10,010.1, Microbiological Testing Program For Escherichia Coli O157:H7 in Raw Ground Beef.*" The Notice provides updated instructions to inspection program personnel on some of the issues covered by FSIS Directive 10,010.1, "*Microbiological Testing Program For Escherichia Coli O157:H7 in Raw Ground Beef."* In addition, the Notice provides notification that FSIS will be revising Directive 10,010.1.

In the Notice, updated procedures that immediately went into effect were given to inspection program personnel that instructed them to collect raw ground beef samples whenever they received an FSIS Form 10,210-3 for microbiological sampling project MT03. Samples are to be collected regardless of whether the establishment had met criteria set forth in FSIS Directive 10,010.1, VI.B. All raw ground beef, hamburger, ground veal, veal or beef patties, or other products meeting the standard of identity in 9 CFR 319.15, are eligible for verification sampling by FSIS. Thus, plants

are no longer exempted from sampling based on conducting their own testing.

OIG Position

We accept the management decision.

FINDING NO. 12

STRONGER CONTROLS NEEDED TO ENSURE INTEGRITY OF LABORATORY SAMPLES

FSIS' process before the recall for taking test samples did not provide assurance that *E. coli* O157:H7 would be detected if present in the sample. Plant officials at Galligan and Montana Quality Foods were aware of the timing of the samples, and FSIS personnel were willing to accommodate the plants' preferred sampling time rather than sample during unannounced times. Under conditions like these, where sample-taking is partially controlled by the establishments, there is an increased risk that production can be manipulated and the sample integrity compromised.

A positive test result at a plant can have substantial financial impact. The plant may have to conduct a recall and divert the entire lot of sampled product to be cooked, rendered, or in some cases destroyed. Therefore, there can be an incentive for plants to provide samples that are free of contaminants. FSIS directives[61] provide that inspection program personnel should ensure that sample integrity and security is maintained at all times for samples of the *E. coli* O157:H7 pathogen. FSIS' sampling procedures, however, do not ensure either sample integrity or sample security.

Sampling Controlled by the Plant

Plant management at Galligan and Montana Quality Foods informed us that they knew when FSIS was going to take samples for *E. coli* O157:H7 testing and adjusted their production accordingly. An official of Montana Quality Foods stated that he was aware that FSIS had to pull samples by about noon on the appointed day in order to have the sample ready for the carrier. This official stated that since the sampling is not random, he could protect his own product from ever being sampled. This could be done by delaying the start of the grinding operation to just before the time to take the sample and by switching at that time to product from another source.

Although a change in directives allowed FSIS inspectors to take a monitoring sample of raw ground beef at any time, including during late

[61] FSIS Directive 10,210.1, Amendment 3 (Unified Sampling Form), effective July 1, 2002.

shifts and weekends,[62] we found that the inspectors were not aware of this change or were not taking advantage of it. Instead, they accommodated plant management by limiting the time when samples could be taken. FSIS personnel believed they were limited by carrier pickup times. They were not aware that under revised procedures, *E. coli* O157:H7 samples could be refrigerated or frozen for later pickup by the carrier; thus, samples could be taken any time during the day.

At Galligan, after being notified that an FSIS sample would be collected, the plant would grind product for sampling at the beginning of the day. If the inspector was not present, the plant held the product and designated this lot for *E. coli* O157:H7 sampling. The plant conducted a cleanup and continued to process other ground product. The inspector then sampled from the lot designated by the plant for sampling, rather than taking a random sampling.

While FSIS policy requires a plant to be notified in time for product to be held for sampling, FSIS must protect and control the integrity of the sample. In recall situations, such as that experienced by ConAgra, FSIS' procedure could delay identification of the source of the *E. coli* O157:H7 contamination.

Samples Were Not Secure

We found that inspectors at all three plants—Galligan, Montana Quality Foods, and ConAgra—left their packaged samples where plant personnel had access to the samples before pickup by the shipping agent. The containers had Velcro seals to allow FSIS to reuse the container. As a result, there is reduced assurance that integrity can be maintained.

During our visit to the FSIS Western Laboratory, we observed nine boxes that contained product to be tested for *E. coli* O157:H7. Only two of these had intact security seals. A laboratory official estimated that only about 25 percent of *E. coli* O157:H7 samples received for testing had intact security seals.[63]

A similar condition was reported in our prior report.[64] We recommended that FSIS improve controls by issuing instructions for securing FSIS test samples until the samples are in the possession of the shipping agent and review security to insure instructions are being followed. FSIS stated in its May 18, 2000, response to the draft report that:

[62] FSIS Directive 10,210.1, Amendment 3 (Unified Sampling Form), effective July 1, 2002.
[63] FSIS Directive 7355.1, Sample Seals for Program Samples, dated October 20, 1992.
[64] Audit Report No. 24001-3-At, Implementation of the Hazard Analysis and Critical Control Point System, dated June 2000.

FSIS has undertaken an effort to improve sample security. Currently, FSIS Directive 7355.1 outlines procedures for sample security. The FSIS laboratories are revising Directive 7355.1 to reflect a more fail-safe procedure, which is estimated to be completed by September 30, 2000. This will require developing new forms, educating laboratory personnel, and training inspectors.

The directive strengthening security over samples was issued on December 3, 2002. We reviewed the new procedures and determined that although they strengthened requirements for sealing laboratory samples, they did not ensure that FSIS would maintain custody and control of the samples until an approved carrier picked up the shipment. We are therefore recommending that the December 2002 directive be revised to include instructions concerning the chain of custody of the samples.

RECOMMENDATION NO. 24

Revise current instructions to require that laboratory samples be under the direct custody and control of FSIS personnel until the sample can be provided directly to the delivery service.

FSIS Response

FSIS disagrees with the recommendation as written. The recommendation should be restated to ask FSIS to ensure the integrity of its sample delivery service. The requirement to have samples remain under the direct custody and control of FSIS personnel has significant resource implications with marginal or limited additional assurances to be gained. Idling personnel waiting for the handoff of samples to delivery personnel would result in workforce inefficiencies.

FSIS agrees that appropriate measures should be taken to ensure chain of custody for samples. Consequently, on December 3, 2002, FSIS issued Directive 7355.1 (Enclosure No. 9), Revision 2, "*Use of Sample Seals for Program Samples and Other Applications."* This Directive ensures the integrity of samples submitted to laboratories for analysis or held for incubation in the establishment as agar plate. The revision provides guidelines for proper sealing of samples and shipping boxes. All sample packages (with the exception of investigation samples) shipped to FSIS laboratories are sealed and identified using a three-part system. This system identifies and links the sample with the submission form and the shipping container. When properly sealed, each laboratory sample package will have three separate but identically numbered/bar-coded identification labels, as follows:

1. One small bar-coded label is affixed to the sample submission form.
2. A medium-sized bar-coded label, the "*FSIS Laboratory Sample Identification Label*" is placed on the primary container.
3. A large bar-coded label, the "*FSIS Laboratory Sample Container Seal,*" is placed on the shipping container.

The inspector retains a record of the seal packet used for each sample sent to the laboratory. An additional, small bar-coded label may be placed on the inspector's file copy of the submission form or on a log sheet indicating to which sample the seal corresponds. For shipping the samples to the laboratories, the inspection personnel choose the carrier that assures the least time in transit.

OIG Position

We cannot reach management decision. While we agree that the revised directive strengthened requirements for sealing laboratory samples, the intent of the recommendation is to provide adequate physical security over the sample. Adequate physical security is essential to deter deliberate breach of the packaging; the new security procedures do nothing to protect the samples from parties who wish to prevent any testing of the sample at all. OIG's visit to an FSIS laboratory during the audit disclosed that an estimated 25 percent of the samples arrived for testing with broken seals. FSIS officials told us that the in-plant inspector is not instructed to take a replacement sample. To reach management decision, FSIS needs to provide acceptable alternative actions to mitigate the cited vulnerabilities and a timeframe for completing its actions.

RECOMMENDATION NO. 25

Require district offices to conduct periodic reviews to ensure compliance with sampling procedures.

FSIS Response

To enhance management controls and oversight of its field inspection personnel, FSIS issued Directive 4430.3, "*In-Plant Performance System Reviews,*" (IPPS) and a comprehensive Supervisory Guideline (Enclosure No. 6). These documents provide specific instructions and guidance on how to assess the performance of inspection personnel in the PR/HACCP system environment and for verifying that inspection personnel are carrying out their responsibilities. These include applying the appropriate inspection methods, using effective regulatory decision making, documenting findings appropriately and when warranted, and implementing enforcement actions properly. This would also include ensuring compliance with sampling procedures.

The Office of Program Evaluation, Enforcement and Review (OPEER) will monitor the Agency's progress in the area. Audits, evaluations, and reviews will be conducted to verify implementation and measure the effectiveness of the corrective actions.

OIG Position

We cannot reach management decision. To reach management decision, FSIS needs to provide additional information on the procedures OPEER will use to verify compliance with sampling procedures and a timeframe for implementation.

FINDING NO. 13

FSIS DOES NOT REVIEW HACCP PLANS FOR REGULATORY COMPLIANCE

FSIS did not determine whether ConAgra and the two grinding operations had scientific evidence in support of the processes they announced in their HACCP plans to prevent or eliminate food safety hazards. FSIS reviews HACCP plans to determine if the plans address the seven principles of HACCP (see the Background section of this report), but FSIS has acknowledged that their in-plant staff lacks the necessary skills to critically analyze the adequacy of the HACCP plans. We consider the lack of adequate technical assessments of HACCP plans and sufficient, competent staff to make that assessment, a material weakness in FSIS' oversight of HACCP implementation. As a result, there is reduced assurance that the HACCP systems were controlling food safety hazards in the three establishments.

FSIS inspection personnel are responsible to ensure the establishment's initial HACCP plan is apparently responding to all regulatory requirements. FSIS inspection personnel also perform ongoing basic compliance checks that focus on whether an establishment has failed to institute the system features required by FSIS regulations (e.g., when an HACCP plan does not identify the corrective action to be taken in response to a control failure at a CCP).

FSIS periodically schedules reviews to examine elements of an establishment's HACCP plan. The inspections may include reviews to determine:

- if the establishment is maintaining records documenting the monitoring of CCPs;

- if the establishment is verifying implementation of its HACCP plan by performing verification activities;

- if the HACCP plan assigns responsibility for taking corrective action when a control (e.g., temperature) deviates from its critical limits;

- if the establishment reassesses its HACCP plan when an unforeseen hazard arises; and

- if the establishment maintains documentary support for its HACCP plan.

For part of our review, FSIS technical representatives assisted us in reviewing HACCP records for technical adequacy and correlation with pertinent FSIS regulations. These FSIS representatives found that the HACCP plans at ConAgra, Galligan, and Montana Quality Foods contained all seven required basic principles but were technically inadequate. There were problems with the plants' hazard analyses, critical limits, records, and monitoring and verification procedures. These problems continued to exist even though FSIS in-plant inspection personnel periodically reviewed the HACCP plans. We found that these reviews did not contain adequate documentation to support the analyses made by the inspection personnel. See exhibit E for a summary of deficiencies identified by the FSIS technical representatives.

FSIS technical representatives noted the following deficiencies in the HACCP plans at the three plants visited for this audit:

- At ConAgra, three HACCP plans (slaughter, fabrication, and raw-ground) had deficiencies in their hazard analysis; CCP determinations; critical limits; corrective actions; and monitoring, validation, verification, and reassessment procedures. There was no indication that ConAgra reassessed its fabrication HACCP plan, even though the plant continued to have numerous positive *E. coli* O157:H7 test results for its beef trimmings. The FSIS representatives concluded that the HACCP plan no longer met regulatory requirements;

- At Galligan, two HACCP plans (raw-ground and raw not-ground) were deficient in their hazard analysis; CCP determinations; critical limits; corrective actions; and monitoring, validation, verification, and reassessment procedures. In January 2002, when the company reassessed two of its plans—for raw-ground product and raw not-ground product—it eliminated the freezing and storage step as a CCP. A Galligan company official stated that the CCP was removed, in part, because an FSIS inspector recommended it no longer be considered a CCP for HACCP purposes. The FSIS technical representative noted during our audit that freezing and storage meets the definition of a CCP. Galligan also did not conduct a reassessment

of its HACCP plan, as required, each time the regulatory samples collected from its final ground beef product tested positive for the *E. coli* O157:H7 pathogen; and

- At Montana Quality Foods, five HACCP plans (slaughter, raw not-ground, and three raw-ground) had deficiencies in their hazard analysis, critical limits, records, and monitoring and verification procedures. Documents were not provided to support most of the critical limits established for the temperature of the product, and records did not indicate which type of verification procedure was conducted or what the results of the verification were.

Prior reviews by both GAO[65] and OIG[66] found deficiencies similar to those identified during this audit. GAO reported that FSIS verification reviews at 47 plants considered as having potentially serious food safety risks found significant violations of regulatory requirements in HACCP plans at 44 of the plants. In our report, we recommended that FSIS implement a system of oversight to ensure that hazard analyses include all food safety hazards that are reasonably likely to occur and that HACCP plans contain correctly identified CCPs, adequate critical limits, and corrective actions. In response to that audit, FSIS maintained that it would not approve the CCPs selected but that it would challenge the adequacy of HACCP plans that were inadequately supported. FSIS also recognized that additional instructions needed to be developed for inspection personnel to begin assessing the completeness of the HACCP plans.

District office personnel advised that FSIS personnel assigned to the ConAgra plant had not received any HACCP-related training since the fall of 1997. FSIS National Office officials also noted that FSIS inspection personnel do not have the technical expertise to assist companies in developing their HACCP plans and they have been directed by the FSIS National Office not to provide plants any technical guidance.

It is FSIS' policy not to approve HACCP plans; however, FSIS National Office officials indicated that they have hired and properly trained a force of CSOs[67] to help review HACCP plans. Furthermore, they indicated that there are plans to hire and train more CSOs and to train some veterinary medical officers on how to evaluate HACCP plans and supporting documentation. We reviewed FSIS' written proposal for hiring and training qualified staff to review HACCP plans, and we found that the proposal lacks an analysis of how many qualified staff will be needed to review all

[65] GAO Report No. GAO-02-902, Better USDA Oversight and Enforcement of Safety Rules Needed to Reduce Risk of Foodborne Illnesses, dated August 2002.
[66] OIG Audit Report No. 24001-3-At, Implementation of the Hazard Analysis and Critical Control Point System, dated June 2000.
[67] As of December 31, 2002, there were about 105 CSOs.

HACCP plans and how much time will be needed to complete the reviews. GAO had previously noted that only about 6 percent of the officers that FSIS needs are currently on staff, and that FSIS managers in two large districts expressed concern that it may take years to assess the plans for all plants in the district.

It is evident from the deficiencies disclosed during this audit that the current system of in-plant inspectors monitoring an establishment's compliance with FSIS regulatory requirements cannot ensure that major shortcomings in an establishment's HACCP plan will be identified and corrected. Implementation of the CSO program may fill the need for a staff trained in HACCP principles, but we question whether the CSOs or other trained employees will be available in a timely manner and in sufficient numbers to review the more than 5,000 HACCP plans in use and the supporting documentation on a continuing basis.

RECOMMENDATION NO. 26

Require the three plants to revise their HACCP plans to correct the cited deficiencies noted during our reviews.

FSIS Response

FSIS took immediate action to ensure that the establishments' HACCP plans were corrected to address the deficiencies uncovered in the audit. As a result of FSIS' immediate actions, several changes were made by the establishments including:

- ConAgra made major modifications to its slaughter floor. Additional major improvements are planned over the next several months.

- Galligan Wholesale Meat, Est. 6475, Denver, Colorado modified its SSOP and HACCP plans to correct the deficiencies noted during the OIG audit.

- Montana Quality Foods, Est. # 7679, Miles City, Montana plant management reassessed its HACCP plan. FSIS inspection personnel have reviewed the HACCP plans and activities as required verifying that Montana Quality is meeting all of its obligations with respect to both the original part of its HACCP plan as well as the new CCP, which was added as a result of the enforcement action.

Concerning ConAgra, the changes made and incorporated into the SSOP programs for the entire plant were re-evaluated and modified this year to improve the company's documentation of corrective actions in meeting 9 CFR 416.15 in addition to tracking and resolving trends of unsanitary conditions.

The changes made and incorporated into the HACCP program were because of numerous reassessments as a result of the enforcement actions taken by FSIS at the plant, circuit, and District levels. In addition, the plant reassessed its HACCP plan as required by FSIS Notice 44-02 for *E. coli* O157:H7 (Enclosure No. 3).

OIG Position

We accept the management decision.

RECOMMENDATION NO. 27

Develop a written, time-phased plan for completing CSO reviews of HACCP plans. The time-phased plan should include a strategy for hiring and training staff.

FSIS Response

The determination as to whether a comprehensive food safety assessment is needed at an establishment can be based on several factors. As such, District Offices regularly review PBIS data, including NRs, FSIS sampling results, and other available information to determine if a CSO assessment is needed. Also, often a triggering event occurs, such as a consumer complaint, a food borne illness outbreak, or a specific food safety issue, that warrants conducting a comprehensive food safety assessment. Presently, there are 104 persons trained in the CSO methodology, making it impossible to conduct comprehensive food safety assessments at every federally inspected facility. There are approximately 7500 establishments operating under a grant of inspection. Because of this, District Managers are expected to monitor activities in their districts and to use discretion in determining where comprehensive food safety assessments are most needed.

As of June 24, 2003, there have been 677 comprehensive food safety assessments completed by CSOs to verify *E. coli* O157:H7 reassessments at establishments that conduct beef slaughter and ground beef operations, and we estimate that by year 2005, CSOs will conduct such assessments at 2,500 establishments. FSIS has focused its initial food safety assessments at those plants that produced the largest volumes of product.

FSIS has asked for an additional $5.7 million in its fiscal year 2004 budget request to retool training, to accomplish our public health goals, and ensure that our CSO methodology continues to be carried out. Over the next several years, we will continue to train additional employees in the CSO methodology, including training 1000 VMOs in the CSO and

enforcement methodology by year 2007.

OIG Position

The adequacy of establishment HACCP plans is a critical control necessary to meet the goals of HACCP and pathogen reduction. Based on the information contained in the response, we cannot reach management decision. We agree that the current number of persons trained is inadequate to conduct comprehensive food safety assessments at every facility. However, to reach management decision for this recommendation, FSIS needs to provide a time-phased plan for targeting and reviewing establishment HACCP plans. The plan should include an analysis of how many qualified staff are needed, as well as a viable strategy for hiring and training.

RECOMMENDATION NO. 28

Develop an FSIS review program that includes a periodic (1 to 2-year) reassessment of HACCP plans.

FSIS Response

On October 7, 2002, Federal Register Notice 62325, "*E. coli O157:H7 Contamination of Beef Products,*" (Enclosure No. 1) was issued to advise establishments of their obligation to reassess their HACCP plans for raw beef products. On November 4, 2002, FSIS issued FSIS Notice 44-02, "*Instructions for Verifying E. coli O157:H7 Reassessment*." This Notice provided inspection personnel instructions for performing verification of *E. coli* O157:H7 reassessments. These documents will help ensure that establishments are reassessing their HACCP plans in accordance with 9 CFR 417.4, which requires that HACCP plans be reassessed at least annually.

In addition, in 2002 CSOs were assigned to District Offices to conduct comprehensive assessments to verify that establishment control systems are well-documented, supported by scientific information, and validated. Currently, CSOs are conducting comprehensive assessments of HACCP plans at all large raw beef product establishments. These comprehensive assessments are being conducted as part of the October 2002 directive from FSIS that required all beef slaughter establishments to reexamine their food safety strategies in light of evidence that *E. coli* O157:H7 was more prevalent in live animals than previously thought. The comprehensive examination of HACCP plans by CSOs at raw beef product establishments was a proactive step to strengthen pathogen prevention practices, and will expand to include smaller establishments in the future.

As of June 24, 2003, there have been 677 comprehensive food safety assessments completed by FSIS' 107 CSOs to verify *E. coli* O157:H7 reassessments at federally inspected establishments that conduct beef slaughter and ground beef operations. FSIS estimates that by the year 2005, comprehensive assessments to verify *E. coli* O157:H7 reassessments will be completed for approximately 2500 remaining establishments. These reviews will be conducted on a recurring basis.

Additionally, the Office of Program Evaluation, Enforcement, and Review will establish an annual review plan to conduct regular reviews of in plant inspection activities and facility compliance with PR/HACCP. The domestic reviews are expected to begin March 2004.

OIG Position

We cannot accept the management decision. To reach management decision, FSIS needs to provide the details of a requirement for recurring reassessments of establishment HACCP plans. Also, FSIS needs to provide information as to the scope of OPEER's reviews of inspection activities and facility compliance.

RECOMMENDATION NO. 29

Develop a technical assistance program using properly trained and qualified employees that could provide guidance to establishments on HACCP plans development and maintenance requirements.

FSIS Response

FSIS recognizes that effective training of both FSIS and industry employees is vital to the success of the Pathogen Reduction and HACCP Systems final rule. Consequently, FSIS is assessing the viability of conducting joint training with industry. Various kinds of establishments, including small and very small plants, must have access to training, technical assistance, and other resources that will facilitate HACCP implementation. Therefore, FSIS has developed and implemented an approach to training and technical assistance that is designed to support HACCP implementation within available resource constraints.

FSIS has designed several guidance documents to help industry reduce the occurrence of *E. coli* O157:H7. On October 7, 2002, Federal Register 62325, "*E. coli O157:H7 Contamination of Beef Products*" (Enclosure No. 1) was published with related guidance documents. In particular, the following documents were published as guidance to industry:

- "*Guidance for Minimizing the Risk of Escherichia coli O157:H7 and Salmonella in Beef Slaughter Operations*,"
- "*Guidance for Beef Grinders and Suppliers of Boneless and Trim Products – Guide for Minimizing Impact Associated with Food Safety Hazards in Raw Ground Meat and Other FSIS Regulated Products*,"
- "*Guidance on Ingredients and Sources of Radiation Used to Reduce Microorganisms on Carcasses, Ground Beef, and Beef Trimmings,*" and
- "*Guidance on the Procedures for Joint Food Safety and Inspection Service (FSIS) and Food and Drug Administration (FDA) – Approval of Ingredients and Sources of Radiation Used in the Production of Meat and Poultry Products*."

In May 1997, FSIS opened the Technical Service Center (TSC), in Omaha, Nebraska, to provide technical assistance and guidance to FSIS meat, poultry, and egg products inspection employees, industry representatives, plant owners and operators, other government agencies, and others on the implementation and enforcement of regulations and policies for both domestic and imported products. The technical assistance and guidance provided daily by the TSC comes from a team of FSIS experts comprised of veterinarians, microbiologists, food technologists, statisticians, management analysts, and others.

In addition, FSIS continuously conducts HACCP demonstration projects to show how HACCP systems are supposed to work for various products and product categories under actual operating conditions in small and very small plants. These demonstration projects began during the 2-year period following the issuance of the final rule, at a number of sites around the country. The HACCP demonstration projects provided the opportunity to answer a number of industry questions and reduced the costs incurred by small establishments in developing HACCP systems.

FSIS has made available guidance materials to assist plants in conducting their hazard analyses and developing HACCP plans. They include a *Guidebook for the Preparation of HACCP Plans*, which was designed to provide the small establishments with a step-by-step approach for developing a HACCP plan; it included examples and sample forms for each step.

The USDA/FDA "*Foodborne Illness Education Information Center*," was developed and maintains the *HACCP Training Programs and Resources Database*, which provides up-to-date listings of HACCP training programs, resources, and consultants offering training programs or resources. The database can be accessed through the Internet at

http://www.nalusda.gov/fnic/foodborne/haccp/index.shtml.

OIG Position

Based on the information contained in the response, we cannot reach management decision. The intent of this recommendation is to establish a proactive technical assistance program when HACCP plans are found to be technically deficient, rather than a passive program of making guidance documents available to industry. To reach management decision, FSIS needs to establish a technical assistance program, in conjunction with HACCP reviews.

FINDING NO. 14

FSIS' POLICY ON REINSPECTING CARCASSES FOR FECAL CONTAMINATION IS TOO OBSCURE TO OFFER REASONABLE GUIDANCE

ConAgra did not always reexamine an acceptable number of beef carcasses when zero tolerance violations (animal feces on product) were noted. FSIS' written policy does not state in a clear and obvious place how far back plant production should be held and reinspected from the point the defect is recorded. FSIS technicians have advised that all carcasses back to the last verification should be reinspected. Because this procedure is not written into generally available FSIS policy, ConAgra did not hold and reinspect 175 beef carcasses on July 10, 2002, after fecal contamination was observed on beef product. The carcasses, which may have been contaminated, were released for production.

FSIS has no clear specific written guidance on what actions are to be taken when there is a deviation from the zero tolerance's critical limit. We did find an obscure reference in the model generic Beef[68] Slaughter HACCP plan which shows that, "All affected carcasses back to the last acceptable check will be visually inspected and reworked if visible fecal contamination is observed." The model generic Pork[69] Slaughter HACCP plan contains a similar provision. Also, the TSC has advised both industry and FSIS inspection personnel that when an establishment's critical control point monitoring check shows the critical limit for the control point was exceeded, the plant should retain product back to the last acceptable monitoring/verification check for product disposition.

[68] USDA FSIS Generic HACCP Model for Beef Slaughter, dated September 1999, page 30.
[69] USDA FSIS Generic HACCP Model for Pork Slaughter, dated September 1999, page 34.

When there was a deviation from the zero tolerance's critical limit, ConAgra did not always retain carcasses back to the last acceptable monitoring or verification check. According to the plant's SOP, SOP 1804A and 1804, "carcasses processed since the last passed check shall be retained for any necessary zero tolerance reconditioning and reinspected by quality assurance." However, the two procedures go on to state, "carcasses processed since last passed check shall be defined as those carcasses of *the present hour* of production at the final trim rail area" [emphasis added]. In other words, the group of carcasses retained by the establishment go back 1 hour of production, but may not always include carcasses back to the last acceptable monitoring or verification check, if that check occurred more than 1 hour before the deviation. For example, when FSIS found fecal contamination during an HACCP check at 9:15 a.m. on July 10, 2002, ConAgra held 272 carcasses produced during the period of 8:15 a.m. to 9:15 a.m. In this instance, there were 175 carcasses unaccounted for between the plant's last acceptable zero tolerance verification check at 7:48 a.m. and the production lot of carcasses they actually retained.

ConAgra officials stated that their rationale for retaining carcasses back only 1 hour was based on the premise that the checks were made randomly during a 1-hour production lot (this determines if that specific production lot was subject to contamination). The officials believed that the random check did not determine that the previous hour's production lot was subject to contamination if the random check conducted during the previous hour was acceptable. The IIC at ConAgra had the same understanding as the company official as to what would be the appropriate group of carcasses to be retained for production disposition.

FSIS needs to clarify the actions necessary when there is a deviation from the zero tolerance critical limit. A TSC official indicated that ConAgra's carcass reinspection process may have been adequate if (1) the company had properly documented the scientific basis of their approach and (2) the company had sufficient control of fecal contamination in the plant. In the TSC official's opinion, the fact that ConAgra had numerous instances of fecal contamination being discovered in all areas of the plant (areas of the plant outside of the slaughter operation) indicated that the plant's carcass reinspection process was inadequate.

RECOMMENDATION NO. 30

Issue clear written policy on how contaminated carcasses are to be handled when a zero tolerance violation occurs, including the circumstances under which it is appropriate to hold and reinspect all carcasses produced since the last acceptable check.

FSIS Response

FSIS Directive 6420.1, "*Livestock Post-Mortem Inspection Activities-Enforcing the Zero Tolerances for Fecal Material, Ingesta, and Milk*," directs FSIS inspection program personnel on how to enforce the zero tolerance standards. The instructions provided in this directive will ensure that the circumstances for holding and reinspecting all carcasses are clearly defined and in accordance with acceptable and established statistical methodology. FSIS will update this policy with more explicit instructions for handling and re-inspecting contaminated carcasses by December 2003.

OIG Position

Based on the information provided in the response, we cannot reach management decision. To reach management decision, FSIS needs to provide details as to how contaminated carcasses will be handled.

FINDING NO. 15

FSIS CANNOT PROVIDE ASSURANCE THAT ALL CONTAMINATED PRODUCT IS PROPERLY DISPOSED OF

FSIS has no written procedures that require FSIS personnel to monitor the disposition of ground beef or beef trim that has tested positive for the *E. coli* O157:H7 pathogen. Contaminated beef products were returned to ConAgra periodically and resold to be used in pet foods or canned or frozen precooked meals, but FSIS inspectors did not verify that the buyers of the contaminated beef were in business to make pet food or precooked meals. Nor is FSIS always notified when beef products are found to be contaminated. FSIS officials believe that it is not necessary or practical for the agency to monitor the final disposition of all ground beef or beef trim that has tested *E. coli* O157:H7 positive. We believe that FSIS' mission obligates it to implement controls to protect the public health and that failing to monitor the final disposition of raw ground beef contaminated with *E. coli* O157:H7 is inconsistent with this mission. Although we found no instances in which contaminated raw ground beef was not disposed of properly, the absence of FSIS procedures to ensure this disposition presents a weakness in the food safety inspection system.

Before the recall, ConAgra beef trim that tested positive for the *E. coli* O157:H7 pathogen, as a result of customer testing, was often returned to the plant for reprocessing. ConAgra officials said that they would notify FSIS in-plant inspection personnel when product was returned. ConAgra personnel would then transfer the trim from its original bins into smaller boxes. They said the small-boxed trim would then be labeled "for cooking only" and would be resold. FSIS inspectors would sometimes observe the

repackaging but would make no effort to verify the actual disposition of the product and ensure it was not resold to an outlet that handled only raw ground beef.

With the assistance of FSIS compliance personnel, we reviewed the sales of this boxed trim for the period June 2001 through August 2002. We did not find any instances where the distributors sold the boxed trim to any operations that intended to use the trim for raw ground beef. However, our reviews did disclose instances where recalled beef trim was not always returned to the plant. For example, about 118,000 pounds of trim that tested positive during the recall period was reportedly rendered and not returned to the plant. There is no requirement that customers of meat slaughter plants or processors notify FSIS when their tests of raw beef products disclose the presence of *E. coli* O157:H7.

In order to control and monitor the final disposition of adulterated products, FSIS would have to be notified of the location of these products, and it would have to seal shipments of the adulterated product to prevent any amount from being diverted. On three occasions, FSIS' *E. coli* O157:H7 testing indicated positive results in Galligan ground beef. Galligan personnel informed us that the finely ground beef associated with the first positive was destroyed and that the finely ground beef from the other two positives were returned to ConAgra. FSIS policy did not require that the finely ground beef be transported from Galligan to ConAgra under FSIS seal. However, in this case, a seal was used. FSIS compliance personnel stated that the truck transporting the finely ground beef to ConAgra was also carrying intact ConAgra course ground beef chubs on which FSIS intended to perform traceback *E. coli* O157:H7 testing. Consequently, the compliance personnel sealed the entire truckload of meat products. Compliance personnel informed us that if the chubs had not been on the truck, the cargo would not have been sealed. We believe all trim that is destined for grinding and ground beef that tests positive for *E. coli* O157:H7 should be sealed or monitored in some manner.

FSIS National Office officials stated that it is unnecessary and impractical for FSIS to monitor the disposition of all ground beef and beef trim that tests positive for the *E. coli* pathogen. These officials said that it is the establishment's responsibility to ensure that *E. coli* O157:H7 positive product is destroyed or diverted to acceptable uses such as cooking or rendering. They also said that monitoring all *E. coli* O157:H7 positive trim and ground beef would involve complex issues (although they did not elaborate on what these issues were), and would consume considerable FSIS resources. Consequently, there is no requirement that FSIS be informed of these positive test results.

We realize that FSIS' resources are limited; however, once FSIS is aware microbiological testing has indicated there is *E. coli* O157:H7 in raw trim or ground beef, it seems prudent for FSIS to intensify its surveillance of contaminated product known to contain a potentially deadly pathogen. Although our review did not show that any trim or ground beef contaminated with *E. coli* O157:H7 was used in an unacceptable manner, there is no assurance that it was all disposed of properly.

We concluded that FSIS needs to reevaluate its operations to consider the risks to the public by its decision not to monitor the disposition of product contaminated with *E. coli* O157:H7. Establishments may be financially liable for any contaminated product reaching the consumer, but FSIS has a larger responsibility to protect the public's health and safety. It should be FSIS' responsibility to ensure that products contaminated with *E. coli* O157:H7 are always used in an acceptable manner or destroyed.

RECOMMENDATION NO. 31

Reevaluate FSIS operations in terms of the risks posed to the public by the agency decision not to monitor the disposition of product contaminated with *E. coli* O157:H7 and consider the need to issue regulations that require FSIS to take control of such product and verify that it has been properly processed or destroyed.

FSIS Response

On April 18, 2003, FSIS issued FSIS Notice 11-03 (Enclosure No. 8), "*Update to FSIS Directive 10,010.1, Microbiological Testing Program For Escherichia Coli O157:H7 in Raw Ground Beef.*" The Notice provides updated instructions to inspection program personnel on some of the issues covered by FSIS Directive 10,010.1, "*Microbiological Testing Program For Escherichia Coli O157:H7 in Raw Ground Beef."*

FSIS will provide clear directions on the disposition of product contaminated with *E. coli* O157:H7 in the updated FSIS Directive, 10,010.1, "*Microbiological Testing Program For Escherichia coli O157:H7 in Raw Ground Beef*." The revised Directive will be issued by October 2003.

The FSIS Notice 11-03, updates and implements procedures that immediately went into effect and were given to inspection program personnel that instructed them to collect raw ground beef samples whenever they received an FSIS Form 10,210-3 for microbiological sampling project MT03. Samples are to be collected regardless of whether the establishment had met criteria set forth in FSIS Directive 10,010.1, VI.B. All raw ground beef, hamburger, ground veal, veal or beef

patties, or other products meeting the standard of identity in 9 CFR 319.15, are subject to verification sampling by FSIS. Thus, plants are no longer exempted from sampling based on conducting their own testing.

Under 9 CFR 500.3 FSIS has authority to take enforcement action against any establishment that has been found to have produced and shipped adulterated product. When effectiveness checks disclose that proper notification of the consignee/customers has not been given, FSIS has the authority to detain and, if necessary, subsequently seize products that have been determined to be adulterated. FSIS has prior precedent in applying its enforcement authority.

FSIS is working closely with industry and is providing guidance on the proper and appropriate actions that should be taken during recalls. On December 12, 2002, FSIS held a public meeting to discuss improving the recall process. The Agency is considering ideas presented at the public meeting for increasing industry's involvement in managing recalls.

As part of the recall process improvement effort, FSIS will examine and include as appropriate, provisions to establish criteria to assess the overall effectiveness of a recall, to reconcile planned effectiveness checks to those checks actually performed, to identify the corrective actions to be taken when deficiencies are noted. This information will be assembled and formalized in a directive. The management controls, responsibilities, and oversight roles for this process will be clearly delineated in a directive.

The workgroup will provide a report outlining recommendations by October 2003. The draft guidelines entitled, "*Office of Field Operations District Office Recall Responsibilities*" which was issued to District Offices in March 2003 will be finalized by March 2004. The final FSIS recommendations will be implemented by July 2004.

OIG Position

Based on the information provided in the response, we cannot reach management decision. To reach management decision, FSIS needs to provide information as to the processes and procedures to be put in place to improve the recall process, including inspector responsibilities to monitor the disposition of contaminated products.

GENERAL COMMENTS

Laboratories, which are not accredited by USDA for microbiological testing, are conducting microbiological tests for HACCP purposes. USDA certifies laboratories for food chemistry testing, such as moisture, protein, fat, and salt, but it no longer certifies laboratories for microbiological testing. ConAgra uses Warren Analytical Laboratory for its testing, and laboratory officials maintained that they are qualified to perform microbiological testing by the laboratory's ISO 17025 accreditation. The American Association for Laboratory Accreditation is the accrediting body for ISO 17025 in the United States, and the ISO 17025 accreditation is recognized as the highest international standard for food testing laboratories. Since there is no consistency of standards from laboratory to laboratory, we do not know what standards, if any, other laboratories follow for conducting microbiological tests for HACCP purposes.

Further, laboratories may have inherent conflicts of interest when the processing plants, for which they do testing, own them. ConAgra owns Warren Analytical Laboratory, but laboratory officials maintain that firewalls (a letter instructing that communications were to be limited between plant and laboratory personnel) were established to prevent plants they do testing for from influencing test results.

However, the European Union questioned Warren Analytical Laboratory's ability to function independently. The European Union insisted USDA prohibit Warren Analytical Laboratory from running additional residue tests as part of the trade agreement with the United States on the grounds the laboratory has a conflict of interest with ConAgra. USDA was not concerned with Warren Analytical Laboratory's independence, as it believed it could maintain a significant amount of control over the sampling, and falsification of test results would destroy a laboratory's reputation. However, USDA did not select Warren Analytical Laboratory to conduct testing under the trade agreement because the laboratory did not meet projected deadlines to submit method validation information.

FSIS needs to address the need for uniformity in testing completed for HACCP purposes, as well as the conflicts of interest between laboratories and the processing plants that own them.

EXHIBIT A – LOCATIONS VISITED

FSIS National Office – Washington, D.C.

FSIS District Number 20 – Minneapolis, Minnesota

FSIS District Number 15 – Boulder, Colorado

ARS Roman L. Hruska Meat Animal Research Center – Clay Center, Nebraska

FSIS Western Laboratory – Alameda, California

Montana Quality Foods & Processing, Inc. – Miles City, Montana

Galligan Wholesale Meat Company – Denver, Colorado

ConAgra Beef Company – Greeley, Colorado

Warren Analytical Laboratory – Greeley, Colorado

ConAgra Customer (Grinder for Nationwide Fast Food Restaurant)

Two Nationwide Fast Food Restaurant Corporations

EXHIBIT B – PROCEDURES, POLICIES, AND REGULATIONS CHANGED AFTER THE CONAGRA RECALL

Regulation/ Directive	Procedure Before the Recall	Changes to the Procedures	Changes Under Consideration
Pathogen Testing			
Federal Register 9 CFR, Chapter III Federal Register Notice: January 19, 1999, Docket No. 97-068N Federal Register Notice: October 7, 2002, Docket No. 00-022N	Raw ground beef not intended for ready-to-eat products was considered adulterated if it was contaminated with *E. coli* O157:H7. This policy was expanded in 1999 to include beef trim and similar products. March 15, 1999, Constituent Update, FSIS explained the Agency would not act on its January 19, 1999, policy statement until it had an opportunity to consider the comments received. We could not identify any subsequent instructions to the field implementing the policy that beef trimmings could be adulterated.	Agency officials recalled beef trim products as part of the ConAgra recall. Federal Register Notice: October 7, 2002, Docket No. 00-022N restated the January 1999 policy determination that beef trim and similar products that were not destined for cooking, i.e., would be used in raw product, are considered adulterated if contaminated with *E. coli* O157:H7.	
FSIS Directive 10,010.1, Microbiological Testing Program for *Escherichia coli* O157:H7 in Raw Ground	The testing program was limited to raw ground beef. Establishments meeting certain criteria were exempt from the testing program. If a sample of ground beef from an establishment tested positive for *E. coli* O157:H7, FSIS continued to collect samples until the Agency obtained 15 consecutive samples with negative test results.		A testing program for beef trimmings is under development. No establishments producing raw ground beef will be exempt from the sampling and testing program. FSIS will exercise discretion in determining the number of follow-up test samples to take, based on the suspected cause of the contamination and the establishment's corrective action.

Regulation/ Directive	Procedure Before the Recall	Changes to the Procedures	Changes Under Consideration
	Sampled lot was defined as all raw ground beef products produced between performance of complete cleaning and sanitization procedures.		FSIS will recognize the establishment's defined lot size, provided the establishment has a scientific or other supportable basis for defining the sampled lot.
	No provisions were included in the Directive for traceback samples.	A project code and sample collection and processing procedures for traceback samples have been developed.	The new provisions have not been codified in the Directive, as it has not been revised yet.
	District offices were instructed to inform the affected plant or retail outlet when positive *E. coli* O157:H7 test results were confirmed.	No Change.	
Traceback			
FSIS Notice 47-02, dated November 20, 2002	No provisions in prior procedures to cover the affected area.	Procedures in notice provide for in-plant personnel to identify the firms supplying the raw materials when presumptive positive test results are reported. Upon notification that there was a confirmed positive test result, the district office now notifies suppliers that product from their establishment was used in raw ground beef that tested positive for *E. coli* O157:H7. In addition, the RMD follows a similar procedure to notify suppliers.	
HACCP			
9 CFR 417 HACCP, Federal Register Vol. 67, No. 194, dated October 7, 2002	Establishments producing raw beef products were required to reassess their HACCP plans at least annually. Based on scientific evidence at the time the regulation was issued, it was considered	Based on new scientific evidence, all establishments producing raw beef products that have not reassessed their HACCP plans in light of the new information must do so and consider whether *E. coli* O157:H7 is a hazard	

Regulation/ Directive	Procedure Before the Recall	Changes to the Procedures	Changes Under Consideration
	acceptable for plants to consider *E. coli* O157:H7 as a hazard not likely to occur.	reasonably likely to occur.	
FSIS Notice 44-02, dated November 4, 2002, Instructions for Verifying *E. coli* O157:H7 Reassessment		Instructions were issued to verify the required reassessment was performed according to a specified timeline.	
	The automated inspection system periodically generates task assignments to inspectors to perform record review for HACCP verification.		
FSIS Notice 29-02, dated August 9, 2002, HACCP Verification Procedures and the 30-day Reassessment Letter		Notice issued to clarify the difference between a deviation from a critical limit and the conditions where such a deviation results in noncompliance. Notice provides guidance on when an NR should be written when inspectors are performing the 01 and 02 assigned tasks.	
FSIS Directive 5000.1 Revision 1, dated May 21, 2003	Duties and responsibilities of FSIS personnel with respect to HACCP monitoring, verification, and reassessment were generally not specified.	Procedures have been clarified with respect to the duties of Consumer Safety Investigators (CSI) and Consumer Safety Officers (CSO). Items clarified by the procedures related to the verification or reassessment of the following for CSIs: • HACCP procedure verification methodology; • hazard analysis by the establishment;	

Regulation/ Directive	Procedure Before the Recall	Changes to the Procedures	Changes Under Consideration
		• monitoring; • verification of the establishment's plan verification requirement; • recordkeeping requirements; • corrective actions taken by establishment personnel in response to a deviation from a critical limit; • HACCP plan reassessment requirement. Items related to HACCP pertaining to the duties and responsibilities of CSOs were clarified for: • HACCP assessment; • hazard analysis review; • assessing the establishment's HACCP monitoring procedures; • assessment of whether the establishment's on-going verification activities comply with regulatory requirements; • assessment of the establishment's recordkeeping activities; • corrective actions assessment; and	

Regulation/ Directive	Procedure Before the Recall	Changes to the Procedures	Changes Under Consideration
		• reassessment activities for the hazard analysis or the HACCP plan.	
Recall Activities			
FSIS Directive 8080.1, Rev. 3, Recall of Meat and Poultry Products	Public notification of recalls was limited to press releases with no provision for directly notifying State public health departments. There were no provisions for notifying suppliers when a recall was made at a grinding facility that used the supplier's product in the affected grind.	The RMD now notifies affected State public health departments by e-mail or telephone contact when recalls are initiated. The RMD now notifies affected suppliers by e-mail or telephone contact when a recall is initiated at a grinding facility that used the supplier's product in the recalled product.	The new provisions have not been codified in the Directive, as it has not been revised as yet. The new provisions have not been codified in the Directive, as it has not been revised as yet.
FSIS Directive 7355.1, Use of Sample Seals for Program Samples and Other (Replaced) FSIS Directive 7355.1 Revision 2, Use of Sample Seals for Laboratory Samples and Other Applications	These are the basic procedures used by FSIS for collecting, securing, and shipping microbiological and other product samples.	New procedure was issued to provide improved security over samples and ensure the integrity of samples on December 3, 2002.	

Overall Program Areas			
Regulation/ Directive	Procedure Before the Recall	Changes to the Procedures	Changes Under Consideration
No Specific Regulation or Directive	Food Safety Investigations.	The Secretary directed FSIS to conduct an unprecedented investigation of food safety issues at the ConAgra plant. A team of experts headed by the Deputy Administrator, Field Operations, conducted the investigation.	The new procedure has not been codified.
	Baseline study of the prevalence of *E. coli* O157:H7 in raw beef products.		FSIS is considering conducting a scientifically valid study (testing program) to determine the prevalence of the pathogen in raw beef products and identifying risk factors that increase the chance of the pathogen being present in products. Based on the results of this study, the microbiological testing program for *E. coli* O157:H7 could be changed to target sampling to high-risk areas/plants.
9 CFR 390.9, Rule Making, Effective July 31, 2002	Due to considerations related to trade secrets, product distribution lists for recalled products were not shared with State public health officials.	A Memorandum of Understanding has been developed. Any State public health organization willing to sign the Memorandum of Understanding with FSIS will be provided with product distribution lists for Class I and II recalls in their area that occur subsequent to signing the agreement.	

EXHIBIT C – CONAGRA RECALL TIMELINE

Sample or Other Action Date	Establishment	Action
January 2002		
Jan 23	Montana Quality Foods	Random (MT03) sample was reported **positive** for *E. coli* O157:H7 on January 28 from random monitoring sample. The contaminated product was destroyed. FSIS scheduled 15 verification samples. FSIS issued 2 NRs and issued a voluntary recall press release announcing that the establishment was recalling about 270 pounds of fresh ground beef. Establishment held an additional 100 pounds.
February 2002		
Feb 11	Montana Quality Foods	A Montana Senator and Congressman faxed a letter to the Minneapolis FSIS District Office regarding the recall. The letter included a note from Montana Quality Foods demanding that USDA "publicly clear/exonerate the name of my firm and its exemplary reputation."
Feb 12	Montana Quality Foods	Verification sample (MT04) 1 of 15 was reported negative on February 14.
Feb 15	Montana Quality Foods	Verification sample 2 of 15 was reported negative on February 17.
Feb 19	Montana Quality Foods	Verification sample 3 of 15 was reported **positive** on February 24. No product from the lot was shipped. The contaminated product was destroyed.
Feb 20	Montana Quality Foods	Verification sample 1 of 15 following the positive sample was reported **positive** on February 25. No product from this lot was shipped. The contaminated product was destroyed.
Feb 21	Montana Quality Foods	Verification sample 1 of 15 following the positive sample was reported **positive** on February 26. No product from this lot was shipped. The contaminated product was destroyed.
Feb 22	Montana Quality Foods	Verification sample 1 of 15 following the positive sample was reported negative on February 24.
Feb 25	Montana Quality Foods	FSIS issued 6 NRs for the reported positive sample results.
Feb 26	Montana Quality Foods	NRs were amended by FSIS. FSIS issued an NOIE to notify the company of intent to withhold the marks of inspection and suspend the assignment of inspectors for its raw ground process. This was based on an inadequate HACCP system for its raw ground process and three positive *E. coli* O157:H7 samples. Verification sample 2 of 15 was reported negative on February 28.
Feb 28	Montana Quality Foods	Verification sample 3 of 15 was reported negative on March 2.

March 2002

Mar 1	Montana Quality Foods	Responded to FSIS' NOIE. Response was considered inadequate because it (1) did not address how the CCP would be under control after corrective action was taken, (2) did not identify *E. coli* as a hazard likely to occur, and (3) did not indicate that the facility would only use sampled or intervention-certified product.
Mar 5	Montana Quality Foods	FSIS issued Notice of Suspension for the establishment's Raw Ground Process.
Mar 8	Montana Quality Foods Galligan Wholesale Meat Co.	Submitted a reassessed Raw Ground HACCP process to FSIS for review. This included a CCP for sampled or intervention-certified incoming product for coarse-ground product, and sampling and lab analysis of incoming coarse-ground product for *E. coli* O157:H7. Random sample was reported negative on March 10.
Mar 12	Montana Quality Foods	FSIS issued a Notice of Suspension Held in Abeyance. Establishment agreed to reassess its HACCP plan for its own trimmings used in the process, and to keep its own trimmings out of the process until the reassessment was complete. FSIS gave the company 45 days to complete this reassessment.
Mar 14	Montana Quality Foods	Verification samples 4 and 5 of 15 were reported negative on March 16.
Mar 15	Montana Quality Foods	Verification samples 6 and 7 of 15 were reported negative on March 17.
Mar 18	Montana Quality Foods	Verification samples 8 and 9 of 15 were reported negative on March 20.
Mar 19	Montana Quality Foods ConAgra	Verification samples 10, 11, and 12 of 15 were reported negative on March 21. Random sample was reported negative on March 23.
Mar 21	Montana Quality Foods	Verification samples 13 and 14 of 15 were reported negative on March 23.
Mar 22	Montana Quality Foods	Verification sample 15 of 15 was reported negative on March 24.

April 2002

Apr 2-5	ConAgra	112 beef trim lots tested by ConAgra – 0 confirmed positive for *E. coli* O157:H7.[1]
Apr 8-12	ConAgra	107 beef trim lots tested by ConAgra – 1 confirmed **positive** for *E. coli* O157:H7.
Apr 15-19	ConAgra	105 beef trim lots tested by ConAgra – 4 confirmed **positive** for *E. coli* O157:H7.
Apr 16	Montana Quality Foods	Random sample was reported negative on April 18.
Apr 18	Montana Quality Foods	Requested an extension to the 45-day timeline for the reassessment of its trimmings in its raw ground process. This was granted because the establishment was not using its own trimmings.
Apr 22-27	ConAgra	152 beef trim lots tested by ConAgra – 0 confirmed positive for *E. coli* O157:H7.

[1] Samples of beef trim that were taken at ConAgra were not tested by FSIS. Company records showed that FSIS personnel were informed of the positive beef trim test results for the product that was returned to ConAgra.

Apr 29-May 3	ConAgra	131 beef trim lots tested by ConAgra – 2 confirmed **positive** for *E. coli* O157:H7.

May 2002

May 6-10	ConAgra	105 beef trim lots tested by ConAgra – 0 confirmed positive for *E. coli* O157:H7.
May 9	Galligan Wholesale Meat Co.	Random sample was reported **positive** May 14. Establishment held product pending sample results. Establishment officials asserted they later destroyed the contaminated product.
May 13-17	ConAgra	110 beef trim lots tested by ConAgra – 1 confirmed **positive** for *E. coli* O157:H7.
May 14	Galligan Wholesale Meat Co.	Sample taken May 9 was confirmed **positive**. No recall was necessary because the company held the entire product. FSIS scheduled 15 verification samples for testing at the establishment.[2]
May 20	Galligan Wholesale Meat Co.	FSIS issued an NR for **positive** result reported on May 14 and directed the establishment to reassess its HACCP plan.
May 20-24	ConAgra	124 beef trim lots tested by ConAgra – 6 confirmed **positive** for *E. coli* O157:H7.
May 23	Montana Quality Foods Galligan Wholesale Meat Co.	Random sample was reported negative on May 25. Establishment responded to its NR. HACCP plan was reassessed. Establishment minimized suppliers of raw product to 1 or 2 per lot.
May 28	Galligan Wholesale Meat Co.	Verification sample was reported negative on May 30.
May 28-Jun 1	ConAgra	92 beef trim lots tested by ConAgra – 5 confirmed **positive** for *E. coli* O157:H7.
May 31	ConAgra	Date of production of original ConAgra ground beef implicated in June 30 recall.

June 2002

Jun 3-7	ConAgra	139 beef trim lots tested by ConAgra – 3 confirmed **positive** for *E. coli* O157:H7.
Jun 4	Galligan Wholesale Meat Co.	Verification sample reported potential positive on June 6. Sample reported negative June 8.
Jun 5	Galligan Wholesale Meat Co.	Verification sample was reported potential positive on June 7, but reported negative June 9.
Jun 10	Galligan Wholesale Meat Co.	Laboratory reported sample collected June 10 was discarded because the sample was too warm.
Jun 10-15	ConAgra	156 beef trim lots tested by ConAgra – 13 confirmed **positive** for *E. coli* O157:H7.
Jun 11	Galligan Wholesale Meat Co.	Random sample was reported negative on June 15. Verification sample was reported as potential positive on June 13 and was reported negative on June 15.
Jun 12	Galligan Wholesale Meat Co.	Verification sample was reported **positive** June 17. Product sampled was supplied solely by ConAgra, according to establishment records. Sampled product was held at the plant.
Jun 13	Galligan Wholesale Meat Co.	Verification sample reported negative on June 15. ConAgra did not supply product sampled.

[2] The verification sample sequence for Galligan could not be definitely determined due to the absence of documentation.

Jun 14	Galligan Wholesale Meat Co.	Verification sample was reported **positive** on June 19. According to FSIS, allegedly, only product purchased from ConAgra was sampled (produced by ConAgra on May 31); however, other sources may have been incorporated into the ground beef. Establishment records showed that only ConAgra-supplied product was sampled. Sampled product was held at the plant.
Jun 17	Galligan Wholesale Meat Co.	Verification sample taken on June 12 reported **positive**. This was product obtained solely from ConAgra. FSIS sent two compliance officers to the establishment.
Jun 17-22	ConAgra	152 beef trim lots tested by ConAgra – 3 confirmed **positive** for *E. coli* O157:H7.
Jun 18	ConAgra Galligan Wholesale Meat Co.	FSIS district manager contacted the FSIS TSC for permission to do traceback sample on product that was produced by ConAgra on May 31. TSC advised that a traceback sample would not be proper. FSIS issued an NR for positive results from June 12 sample. IIC retained two boxes of chubs–course ground beef purchased from ConAgra.
Jun 19	Galligan Wholesale Meat Co. ConAgra	NR issued for positive result from June 14 sample. Establishment continued to allege that only ConAgra-supplied product had been used. An FSIS compliance team was dispatched to initiate an investigation. Compliance personnel from the district office visited the establishment and determined that the **positive** sample was from a single source: ConAgra. Galligan pledged daily *E. coli* testing and set July 12 as the date for completing HACCP reassessment. Safeway launched a buy-1-get-1-free sale on ground beef for 6 days, until June 24.
Jun 20	Galligan Wholesale Meat Co.	Of 160 pounds of course ground beef located at the plant, FSIS detained 2 10-pound chubs, and 140 pounds were returned to ConAgra and held by the company. District office compliance personnel contacted FSIS Headquarters to obtain permission to take a traceback sample. Compliance personnel obtained additional documentation, photographed the remaining source product, and verified that the source of the product contamination was from course ground beef from ConAgra with a pack date of May 31. Advised FSIS Headquarters officials of their findings and requested permission from FSIS OPHS to take a traceback sample.
Jun 21	Galligan Wholesale Meat Co.	Verification sample was reported negative on June 23. The district office Assistant District Manager for Enforcement contacted an FSIS Headquarters compliance specialist concerning traceback authority. District office personnel provided background information to the compliance specialist.

Jun 24	Galligan Wholesale Meat Co.	Boulder District Office personnel received authority from FSIS Headquarters to take traceback samples. Traceback samples were collected by a district office compliance officer and taken from the unopened product detained on June 20 (two 10-pound chubs that Galligan purchased from ConAgra with a May 31 production date). Samples were sent to the FSIS Western Laboratory. FSIS scheduled 15 verification samples. Samples reported **positive** on June 29. Verification sample was reported negative June 26.
Jun 24-29	ConAgra	155 beef trim lots tested by ConAgra – 9 confirmed **positive** for *E. coli* O157:H7.
Jun 25	Galligan Wholesale Meat Co.	Verification sample was reported negative on June 27.
Jun 26	Galligan Wholesale Meat Co.	Verification sample was reported negative on June 28.
Jun 27	Galligan Wholesale Meat Co. ConAgra	Verification sample was reported negative on June 29. FSIS Western Laboratory informed ConAgra of potential positive test from the traceback sample taken at Galligan on June 24.
Jun 29	Galligan Wholesale Meat Co. ConAgra	Traceback samples taken June 24 at Galligan were confirmed **positive** for *E. coli* O157:H7. Positive results were transmitted about 7:10 a.m. Mountain Standard Time. FSIS initiated 15 verification samples from ground beef produced by ConAgra. Boulder District Office received notification at 8:30 a.m. that the traceback samples collected on June 24 were **positive**. A recall worksheet was faxed to ConAgra corporate officials in Greeley with instructions to start gathering distribution data for product produced on May 31, 2002. Recall committee meeting was scheduled for June 30. FSIS requested a voluntary recall.
Jun 30	ConAgra	Recall Committee met. ConAgra agreed to a voluntary recall of ground beef products. Nationwide recall release was issued by FSIS for about 354,000 pound of fresh and frozen ground beef products produced on May 31.

July 2002

Jul 1	Galligan Wholesale Meat Co.	Western Laboratory faxed a copy of the positive *E. coli* O157:H7 results to the Boulder District Office. FSIS compliance officer and supervisory compliance officer met with ConAgra. Safeway Stores in Colorado issued a recall for ground beef. Verification sample was reported negative on July 3.
Jul 1-6	ConAgra	268 beef trim lots tested by ConAgra – 3 confirmed **positive** tests for *E. coli* O157:H7.
Jul 2	Galligan Wholesale Meat Co. ConAgra	Verification sample was reported negative on July 4. The June 30 ConAgra recall triggered the dispatch of FSIS compliance officers to conduct recall effectiveness checks. FSIS dispatched a CSO to work with in-plant inspection personnel to review the company's reassessment of its HACCP plan. Safeway announced it sold some of the recalled ground beef.
Jul 5	Galligan Wholesale Meat Co.	Verification sample was reported negative on July 7.

Jul 8	Galligan Wholesale Meat Co.	Verification sample was reported negative on July 10.
Jul 8-13	ConAgra	269 beef trim lots tested by ConAgra – 17 confirmed **positive** for *E. coli* O157:H7.
Jul 10		Colorado State health officials reported an outbreak of 12 cases of *E. coli* O157:H7 in 9 counties and informed the public to return product from Safeway stores that was sold from June 7 to June 18. Colorado Department of Public Health and Environment notified the CDC of a cluster of 18 culture-cured confirmed cases of *E. coli* O157:H7 infections possibly related to recalled ground beef.
	ConAgra	FSIS determined the need for a full food safety investigation and a review team was dispatched to the ConAgra plant.
Jul 11	ConAgra	Verification sample discarded on July 13 due to inconsistency with the chain of custody requirements.
	Galligan Wholesale Meat Co.	Responded to two NRs. Galligan will do daily *E. coli* O157:H7 testing in beef trimmings or ground beef. Establishment will change supplier from ConAgra. Establishment will complete HACCP plan reassessment by July 26. Retained product recalled to ConAgra and shipped under seal to ConAgra.
Jul 12	ConAgra	Colorado State health officials announced there were an additional 5 cases associated with the current illness outbreak, bringing the total to 17 cases. Colorado Health Department reported that epidemiological case interviews found that 17 of 18 patients were reported purchasing ground beef from the same grocery store chain. Colorado Health Department review of grocery store chain grinding logs indicated that ConAgra produced the ground beef repackaged by the store chain on May 31. Sample discarded on July 13 because of inconsistency with chain of custody requirements.
Jul 13	ConAgra	Verification sample 1 was reported negative on July 17.
Jul 15	Galligan Wholesale Meat Co.	Verification sample was reported negative on July 19. CDC informed FSIS that pulsed-field gel electrophoresis (PFGE) pattern of patients' isolates in Colorado matched pattern of ConAgra chub isolate. Food Safety Review Team, led by FSIS Deputy Administrator for Field Operations, arrived at ConAgra. FSIS released statement on change in its recall policy. FSIS will inform meat suppliers of positive *E.coli* O157:H7 test results for products sampled at plants to which the supplier shipped raw product for further processing. Staff members from a Congressional representative and a senator contacted the Office of Congressional and Public Affairs requesting information regarding the July 14 *Denver Post* article concerning the ConAgra beef recall.

		A senator sent a letter to USDA Secretary expressing concern about the USDA procedures and guidelines that do not require inspectors, upon a positive *E-coli* O157:H7 test, to contact suppliers so that they may initiate aggressive voluntary testing and recall procedures. PFGE patterns from Colorado patient isolates were found to be indistinguishable from the same isolates for ConAgra ground beef produced on May 31. At least 3 additional cases of *E. coli* O157:H7 in Arkansas and California are potentially associated epidemiologically with the consumption of ground beef produced by ConAgra on May 31.
	ConAgra	Verification sample 2 was reported negative on July 18.
Jul 15-19	ConAgra	305 beef trim lots tested by ConAgra – 11 confirmed **positive** for *E. coli* O157:H7.
Jul 16	Montana Quality Foods	FSIS closed out establishment's suspension with a Notice of Warning because FSIS accepted the establishment's completed reassessment of its hazard analysis of its own trimmings.
	ConAgra	Verification sample 3 was reported negative on July 19.
Jul 17	Galligan Wholesale Meat Co.	Verification sample was reported negative on July 19. FSIS Food Safety Review Team briefed Recall Committee of findings at ConAgra.
	ConAgra	Verification sample 4 was reported negative on July 19.
Jul 18	ConAgra	Recall Committee recommended ConAgra expand recall beyond the 354,200 pounds (May 31 production) to include product produced between April 12 and July 11 (about 18 million pounds). ConAgra accepted this determination. NOIE action was submitted to ConAgra, which had 72 hours to respond. Verification sample 5 was reported negative on July 20.
Jul 19	ConAgra	Recall of 26 production days of product was announced by FSIS – about 19 million pounds. Verification sample 6 was reported negative on July 24.
Jul 20	ConAgra	Verification sample 7 was reported negative on July 26.
Jul 22	ConAgra	Conference call with the CDC reported 21 confirmed cases of *E. coli* O157:H7 that share the Colorado/ConAgra PFGE pattern. There were 17 cases in Colorado, with 1 each from 4 other states. Verification sample 8 was reported negative on July 24.
Jul 22-26	ConAgra	348 beef trim lots tested by ConAgra – 7 confirmed **positive** for *E. coli* O157:H7.
Jul 23	Galligan Wholesale Meat Co.	Verification sample was reported negative on July 25.
	ConAgra	Verification sample 9 was reported negative on July 26.
Jul 24	ConAgra	Verification sample 10 was reported negative on July 27.
Jul 25	Galligan Wholesale Meat Co.	Verification sample was reported negative on July 27.
	ConAgra	Verification sample 11 was reported negative on July 28.

Jul 26	Galligan Wholesale Meat Co. ConAgra ConAgra	Deadline for completing reassessment per response to 2 NRs. Verification sample was reported negative on July 28. Letter from 2 senators to the Acting Inspector General requested information concerning the effectiveness of USDA's recall system for meat and poultry products, and the effectiveness of USDA's response regarding the ConAgra recall. Verification sample 12 was reported negative on July 31.
Jul 27	ConAgra	Verification sample 13 was reported negative on July 31.
Jul 29-Aug 2	ConAgra	491 beef trim lots tested by ConAgra – 2 confirmed **positive** for *E. coli* O157:H7.
Jul 29	ConAgra	Verification sample 14 was reported negative on August 1.
Jul 30	ConAgra	Verification sample 15 was reported negative on August 1.

August 2002

Aug 2	Galligan Wholesale Meat Co. ConAgra	Random sample was reported negative on August 27. Sample was discarded on August 7 because of sample collection irregularities.
Aug 5-9	ConAgra	478 beef trim lots tested by ConAgra – 2 confirmed **positive** tests for *E. coli* O157:H7.
Aug 7	ConAgra	Verification samples 16-22 were reported negative on August 9.
Aug 8	ConAgra	Verification sample 23 was reported negative on August 11.
Aug 9	ConAgra	The CDC reported 46 confirmed cases in 16 states of *E. coli* O157:H7 that shared the Colorado/ConAgra PFGE pattern. Verification sample 24 was reported negative on August 13.
Aug 12-16	ConAgra	357 beef trim lots tested by ConAgra – 5 confirmed **positive** for *E. coli* O157:H7.
Aug 12	ConAgra	Verification sample 25 was reported negative on August 15.
Aug 13	ConAgra	Verification sample 26 was reported negative on August 15.
Aug 14	ConAgra	Verification sample 27 was reported negative on August 17.
Aug 15	ConAgra	Verification sample 28 was reported negative on August 17.
Aug 16	ConAgra	Verification sample 29 was reported negative on August 21.
Aug 19	ConAgra	Verification sample 30 was reported negative on August 21.
Aug 19-23	ConAgra	349 beef trim lots tested by ConAgra – 10 confirmed **positive** for *E. coli* O157:H7.
Aug 20	Galligan Wholesale Meat Co. ConAgra	Verification sample was reported negative on August 23. Verification sample 31 was reported negative on August 23. Notice of Deferral is issued to ConAgra placing the NOIE in abeyance.
Aug 21	Galligan Wholesale Meat Co. ConAgra	Verification sample was reported negative on August 26. Verification sample 32 was reported negative on August 23.
Aug 22	ConAgra	Verification sample 33 was reported negative on August 24.
Aug 23	ConAgra	Verification sample 34 was reported negative on August 28.
Aug 26	ConAgra	Verification sample 35 was reported negative on August 29.
Aug 27	ConAgra	Verification sample 36 was reported negative on August 30.

Aug 26-30	ConAgra	336 beef trim lots tested by ConAgra – 5 confirmed **positive** for *E. coli* O157:H7.
Aug 28	ConAgra	Verification sample 37 was reported negative on August 30.
Aug 30	Galligan Wholesale Meat Co.	Recalled about 980 pounds of ground beef pepper patties that were potentially contaminated on June 14 with *E-coli* O157:H7 from product recalled by ConAgra. OIG audit team discovered the problem.
	ConAgra	Verification sample 38 was reported negative on September 5.

September 2002

Sep 10	ConAgra	Sample for Wolf Brand product was taken. Results were reported **positive** on September 16. The contaminated product was cooked. FSIS inspection personnel had not written an NR as of September 25 (the final day of OIG's in-plant review). Random sample was reported negative on September 16.
Sep 11	ConAgra	Verification sample 39 was reported negative on September 14.

November 2002

Nov 15	ConAgra	FSIS withdrew inspection.
Nov 20	ConAgra	FSIS again provided inspection personnel to ConAgra to allow the plant to continue full operations.

EXHIBIT D – REPETITIVE NRs WRITTEN FOR ZERO TOLERANCE VIOLATIONS

Calendar Years 2001 and 2002

NR		Department with Violation		
Number	Date	Slaughter	Fabrication	Var. Meats
00001-01	01/02/01		**X1**	
00003-01	01/08/01	**X1**		
00006-01	01/11/01		**X2**	
00009-01	01/16/01	**X2**		
00010-01	01/17/01	**X3**		
00011-01	01/17/01		**X3**	
00012-01	01/24/01	**X4**		
00013-01	01/29/01		**X4**	
00014-01	01/30/01		**X5**	
00019-01	02/26/01		**X6**	
00020-01	03/06/01	**X5**		
00021-01	03/13/01	**X6**		
00030-01	05/08/01		**X7**	
00035-01	05/16/01		**X8**	
00045-01	07/02/01		**X9**	
00053-01	07/13/01		**X10**	
00057-01	07/30/01		**X11**	
00058-01	07/30/01	**X7**		
00059-01	07/31/01		**X12**	
00060-01	08/01/01		**X13**	
00061-01	08/01/01	**X8**		
00066-01	08/10/01	**X9**		
00067-01	08/14/01		**X14**	
00068-01	08/15/01		**X15**	
00072-01	08/25/01		**X16**	
00075-01	09/04/01	**X10**		
00077-01	09/08/01	**X11**		
00079-01	09/13/01	**X12**		
00080-01	09/15/01	**X13**		
00081-01	09/15/01	**X14**		
00083-01	10/09/01			**X1**
00084-01	10/11/01			**X2**
00086-01	10/24/01	**X15**		
00088-01	11/07/01	**X16**		
00093-01	12/05/01		**X17**	
00095-01	12/05/01	**X17**		
00101-01	12/17/01	**X18**		

Calendar Years 2001 and 2002				
NR		Department with Violation		
Number	Date	Slaughter	Fabrication	Var. Meats
00102-01	12/21/01		X18	
00103-01	12/28/01	X19		
Total 2001	**39**	**19**	**18**	**2**
00009-02	01/22/02	X1		
00010-02	01/25/02	X2		
00012-02	01/29/02		X1	
00016-02	02/18/02			X1
00019-02	02/19/02		X2	
00020-02	02/20/02		X3	
00021-02	03/05/02		X4	
00022-02	03/06/02			X2
00025-02	04/09/02		X5	
00026-02	04/11/02	X3		
02-2002	06/06/02			X3
Recall	06/30/02			
Expanded	07/18/02			
06-2002	07/25/02	X4		
12-2002	09/04/02	X5		
14-2002	09/10/02	X6		
15-2002	09/10/02	X7		
18-2002	09/16/02	X8		
21-2002	09/27/02		X6	
24-2002	10/02/02	X9		
26-2002	10/07/02	X10		
33-2002	10/28/02	X11		
38-2002	11/04/02	X12		
40-2002	11/06/02	X13		
43-2002	11/12/02		X7	
44-2002	11/13/02	X14		
45-2002	11/13/02		X8	
46-2002	11/14/02		X9	
47-2002	11/14/02	X15		
Total 2002	**27**	**15**	**9**	**3**
Total for 2001-2002	**66**	**34**	**27**	**5**

EXHIBIT E – DETAILS OF FLAWS IN HACCP PLANS

The above exhibit can be requested pursuant to the Freedom of Information Act (FOIA), 5 U.S.C. § 552(a)(3)(A) by contacting:

Freedom of Information Act Officer
Food Safety and Inspection Service
U.S. Department of Agriculture
1400 Independence Avenue SW.
Washington, D.C. 20250
Telephone: (202) 690-3881

EXHIBIT F – EXAMPLES OF UNSANITARY PRACTICES AND VIOLATIONS OF PROCEDURES AT CONAGRA

Observations on USDA Inspection Personnel

1. An FSIS inspector was observed walking on the moving viscera table after all pre-operational procedures and sanitization of the surfaces had been performed by the plant. The boots the inspector was wearing were the same boots that he had used to walk on the contaminated floor.

2. Lock Out/Tag Out procedures as defined in FSIS directives were not followed.

3. No documentation was kept for noncompliance found by FSIS GS-7 inspectors while conducting pre-operational sanitation verifications on the slaughter floor. The noncompliances were orally passed to a GS-9 inspector. The GS-9 inspector then notified the establishment of the noncompliances found orally at a weekly sanitation meeting. No record of the meeting was made by FSIS and no documentation of the noncompliances observed by FSIS personnel was made on an FSIS Form 5400-4, Noncompliance Record. There were no NRs issued for the year 2002 for pre-operational sanitation verifications by FSIS. This is not indicative of SSOP's pre-operational sanitation verification methodology, as illustrated by FSIS Directive 5400.5, XI, A, or as outlined in the regulations.

4. FSIS inspection personnel did not follow the personal hygiene rules of the establishment. We noted beard nets were not worn by one inspector and one veterinary medical officer and hairnets were improperly worn by three FSIS inspectors because they were completely under their issued helmets. (ConAgra SOP 213 requires that the hairnet must cover all of the hair.)

5. Inspectors did not hold samples under security until shipped.

6. The local inspectors did not write an NR, as required by procedure, after FSIS tested a sample of ground beef on September 10, 2002, and found it to be positive for *E. coli* O157:H7 on September 16, 2002. An NR had not been written as of September 25, 2002. The IIC said he was aware the procedure required an NR, but could not explain why an NR was not prepared.

Observations on ConAgra Production Areas

1. Cleaning crew from the contracted cleaning service followed each monitor in a "bucket brigade." That is, the contract cleaning personnel followed the official SSOP monitors with green rags, with and without buckets of soap, and attempted to clean the noncompliances as they were pointed out by the official SSOP monitor. In many instances, the residual meat, fat, or blood was simply rinsed off with potable water or wiped off with a rag. (In general, inspection personnel were of the opinion that the conditions we cited would be corrected by the plant using a sanitizing foam that killed bacteria before the start of operations.)

2. The SSOP monitor crawled on top of edible contact surfaces so that the top of her contaminated boot rested on an edible product contact surface. The area was not identified by the monitor as needing to be recleaned after she contaminated the surfaces through unhygienic practices. (When the GS-9 inspector was questioned as to whether he saw a problem with the unhygienic practices of the plant's SSOP monitor, the inspector answered, "No, they sanitize everything before they start.")

3. A large overhead refrigeration drip pan was observed draining out what appeared to be water onto the edible product cutting boards below.

4. Standing water was observed in an overhead drip pan suspended over a belt. No drain was apparent. A later walk through the area revealed that the water had not been drained out.

5. A drain from a catch pan for overhead frosted-over pipes was noted bent so that the angle of the drain would force water above the lowest point in the pan. This lowest point of the drain pan was bent down directly over an edible product belt.

6. Large amounts of condensation were observed on numerous uncleaned overhead structures. The condensation was wiped down so that the excess contaminated condensate dripped/fell directly onto food product contact and nonfood product contact surfaces.

7. Black grease observed on two belts.

8. Packaging material for products observed being loaded and staged into the fabrication room before the room being released by the official SSOP monitor or FSIS.

9. Spinal cord tissue observed in neck bones being prepared for advanced meat recovery. (NOTE: The audit team was informed later in the day that the combo-bin of product was plant-condemned.)

10. Residual droplets of clear fluid identified by the quality assurance manager as sanitizer (200 ppm of quaternary ammonia) were observed on the stainless steel chutes above the boneless beef trimmings. The droplets of sanitizer were observed falling directly into the combo-bin of edible beef trimmings destined for

grinding into raw ground beef. Similar droplets were observed on other stainless steel overhead structures in the grinding area. According to the quality assurance manager, this is the same concentration level used on direct product contact surfaces without a potable water rinse.

11. In one case, the official SSOP monitor pointed out dried blood to a contract sanitation worker for correction and went on with her inspection. The sanitation worker did not clean the noncompliant area. In a similar case, the official monitor did not observe an approximately 3.5 inches by 1 inch area of blood on the automated hind quarter deboning drop in fabrication. It was then pointed out to the contract cleaning crew by the quality assurance manager. The quality assurance manager, the SSOP monitor, and the cleaning crew all left the area. A contract-cleaning crewmember tried to correct the noncompliance. He jumped up to try to reach the noncompliance with a rag to wipe it off, but could not reach it. He then shrugged his shoulders and left the area.

12. Related to the contract cleaning crew, there were uncleaned overhead structures and the porous concrete ceilings were wet with condensate and beaded condensation. Pressurized air is used to dry the surfaces. Workers use air hoses equipped with about 6-foot copper piping to focus air directly onto the overhead surfaces to dry the wet, porous concrete ceiling and overhead surfaces. This practice potentially spreads overhead debris, dust, organic matter; condensate contaminated by formation on the uncleaned surfaces, and microorganisms onto the food product contact surfaces below.

13. Squeegees and poles wrapped with rags darkened by contamination are used to wipe condensate from unclean overhead structures. The condensate was observed falling onto food product contact surfaces (belts, cutting boards, etc.). These surfaces were previously cleaned by the cleaning contractors. This practice potentially contaminates the food product contact surfaces below.

14. Hoses from the floor were observed being dragged over edible product contact belts and other food product contact surfaces. Workers routinely picked up hoses and other equipment from the floor with their hands and then touched product contact surfaces after the cleaning procedure was completed.

15. The contract cleaning crew was observed using metal rods to prop up edible product contact belts to aid in the inspection by the official SSOP monitors. The rods were observed being routinely dragged, dropped, and temporarily stored on the contaminated floor before, during, and after their use to aid inspection of edible food product contact surfaces. The food product contact surfaces, on which the rods were used, were previously cleaned by the cleaning contractors as the room was presented to the official SSOP monitors for monitoring.

16. Hoses were used to rinse down meat, fat, etc., on food product contact and nonfood product contact surfaces of equipment and utensils with potable water without further cleaning.

17. The official SSOP monitors observed (about three of five) concentrated monitoring procedures on nonfood product contact surfaces, equipment, and utensils rather than on direct food product contact surfaces.

18. The official SSOP monitors were observed using unsanitary hygienic practices during their monitoring procedures. For example, the monitors examined the undersides of perforated treads on ladders and other contaminated nonfood product contact surfaces through organoleptic "touch" methodology. The official SSOP monitors then organoleptically examined direct food product contact surfaces through "touch" methodology without washing and/or sanitizing their hands. A monitor was noted wiping her nose on her forearm and then proceeding to resume her SSOP monitoring of direct food product contact surfaces without washing or sanitizing her hands or forearm. A monitor was observed adjusting and putting on her personal protective gear and then proceeding to resume her SSOP monitoring of direct food product contact surfaces without washing or sanitizing her hands. A monitor was seen scratching her head through a hairnet and then proceeding to resume her SSOP monitoring of direct food product contact surfaces without washing or sanitizing her hands. An official SSOP monitor was observed walking on the movable viscera table in the slaughter department to inspect equipment. The moving table had previously been cleaned as it was released by the cleaning contractor for the ConAgra monitoring. The SSOP monitor wore the same boots used to walk on the contaminated floor. The table was not recleaned or reinspected. The official SSOP monitors either ignored or were not cognizant of the numerous incidences of direct product contact surface contamination by the contracted cleaning crew or themselves through improper equipment handling, employee hygiene practices, or cleaning methodology.

19. Large sections of mold (12 feet by 2 feet) and chipping and flaking paint were observed on the overhead structures and ceilings of the offal room in the slaughter department. Mold was noted in two other production areas.

20. Cracks in welds were also observed on stainless steel chutes that connect to the ceiling in the offal department and on one wash table for the offal.

21. During line operation in fabrication, an employee was noted trimming fecal material and not sanitizing her knife before trimming the next item.

22. Contract cleaning personnel observed using a hose to fill the sanitizer pump. The hose was submerged in the sanitizer and overflowing. The other end of the hose was placed over the nozzle of a faucet of a hand wash sink without an air gap, thus covering the entire faucet head. This could lead to possible back-siphoning of nonpotable materials into the water supply.

EXHIBIT G – FSIS RESPONSE TO THE DRAFT REPORT

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

AUG 18 2003

TO: Richard D. Long
Assistant Inspector General for Audit
Office of Inspector General

FROM: Dr. Garry L. McKee
Administrator

SUBJECT: Office of Inspector General (OIG) Official Draft Report – Oversight of Production Process and Recall at ConAgra Plant, Report No. 24601-2-KC

The Food Safety and Inspection Service (FSIS) appreciates the opportunity to review the subject report. The Agency has already recognized many of the issues you raise, and is committed to making cost-effective improvements throughout our programs. FSIS is continuing to strengthen its programs with updated policies and guidance, supplemental training for field personnel, increased accountability, and better supervision and oversight to ensure a safe and wholesome food supply. We believe these efforts will continue to ensure American consumers the safest food source in the world.

Overview

With regards to the recall at ConAgra Establishment 969 in Greeley, Colorado, FSIS acted swiftly to protect public health when microbiological testing determined on June 29, 2002, that meat produced by ConAgra was contaminated with *E. coli* O157:H7. The initial recall of ConAgra products began 10 days before the first cases of illness were reported and 15 days before the Centers for Disease Control and Prevention (CDC) confirmed a linkage to ground beef.

In addition, FSIS immediately sent a scientific and technical team to the ConAgra facility to examine production practices and plant records. That investigation led to an expansion of the recall on July 19, 2002. No illnesses were ever linked to the expanded recall; however, FSIS took the action due to concerns that product destined to become ground beef that was produced at the Greeley plant during those days had a heightened probability of containing *E. coli* O157:H7.

FSIS has had an ongoing effort to review and improve its policies and procedures. The Agency's own investigation began long before the Office of Inspector General (OIG) began its audit into the ConAgra recall. The FSIS investigation has resulted in improved operations at every facility in America that slaughters or processes beef products. Consequently, while acknowledging many of the comments contained in the audit report, FSIS has either implemented new policies to address them or is well on its way toward that end.

In the past 6 years, according to the CDC, the rate of foodborne illness in America has declined by 16 percent. At the same time, our Nation's meat food safety system has evolved from a regulatory program with visual inspection as its cornerstone to one in which a science-based framework is used to identify and prevent food safety problems. This framework is known as the Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) system. CDC has attributed part of the credit for the reduction in foodborne illness directly to HACCP.

Under HACCP, plants must address hazards presented by pathogens that cannot be detected through visual inspection. Plants have to demonstrate to FSIS through HACCP plans that they are addressing all hazards likely to occur, and the Agency verifies that plant practices are effective and are being carried out faithfully and consistently.

Clearly, the ConAgra recall revealed opportunities to improve HACCP enforcement. The Agency has aggressively targeted those areas to reduce the possibility of the repetition of a similar situation at that plant or any other. We believe the initiatives FSIS has implemented in the past year will contribute to continued reduction in illnesses associated with meat, poultry, and egg products and provide American consumers added confidence that our food supply remains the safest in the world.

For example, FSIS now regularly reviews all plant generated testing data and other information to assess the status of food safety systems and anticipate possible problems. Confusion as to inspectors' access to this information has been eliminated. Further, inspection reports are continually analyzed by district officials in order to spot trends and areas needing additional attention. FSIS has also developed new management systems to help gauge and improve the performance of inspectors. Clearly, FSIS has systems in place to review and analyze all available data and is doing so.

During the past 12 months, the former ConAgra plant, now known as Swift, has been testing 100 percent of its meat trim destined to become ground beef for the presence of *E. coli* O157:H7. Evidence indicates that other large and small beef establishments have dramatically increased their testing as well. A 1990's policy that exempted some facilities from FSIS random testing for *E. coli* O157:H7 in ground beef has been eliminated. FSIS is also developing a random testing program for beef trim and adjusting its ground beef testing program to focus on high volume and high-risk establishments.

FSIS has instituted a policy of notifying the original supplier of any ground beef that is, further in the distribution chain, found by the Agency to be positive for *E. coli* O157:H7, so that food safety effectiveness checks can be initiated by the originating establishment. FSIS has also begun compiling a database that is being used to plan in-depth food safety assessments at establishments by Consumer Safety Officers (CSOs) or Agency scientific teams.

In October 2002, FSIS informed all establishments producing raw beef products that they must reassess their HACCP plans, based on new scientific evidence that E. *coli* O157:H7 is a hazard reasonably likely to occur at all stages of the process. If establishments determine from these reassessments that *E. coli* O157:H7 is a hazard reasonably likely to occur, they (or for grinders, their suppliers) must incorporate one or more critical control points (CCPs) critical control points designed to prevent or eliminate contamination with this pathogen. As of July 2003, there have been approximately 700 comprehensive food safety assessments conducted by CSOs, personnel specially trained in the science of HAACP, at establishments that conduct beef slaughter and at ground beef establishments. The Swift plant has made a number of changes based on that reassessment.

In 2003, FSIS expects to train an additional 140 Veterinary Medical Officers (VMO)/Compliance Officers (CO) in the CSO methodology from among current staff. The VMOs will retain their classification as VMOs. By 2005, CSOs will have conducted 2,500 assessments at beef plants.

FSIS has also made substantial changes to its recall process, strengthened verification activities, and established clearer lines of authority to ensure that potentially tainted products are removed from commerce and that consumers receive information promptly. FSIS has also strengthened training for those inspectors whose job it is to verify that plant processes vital to prevent contamination are being carried out faithfully and consistently.

General Comments

FSIS has the following general comments.

1. The report would be more helpful to readers and reflect a better understanding of the requirements if the background and finding sections clearly identify the relevant standards and regulations that are being used as a basis to assess Agency and industry compliance. The report's findings should focus on program implementation based on the scientific principles of HACCP, the implementing regulations, and relevant performance-based standards versus the prescriptive, command and control-oriented type of internal controls.

2. FSIS disagrees with the OIG claim in the report that under HACCP the Agency assumes a less obvious presence and relies, in part, on the pathogen test results to determine the effectiveness of the plants' HACCP controls. HACCP did not change the presence of inspectors, who are inspecting products in every plant, everyday. FSIS expects its inspection personnel to understand: a) the regulations in 9 CFR 417, as well as Part 416 (Sanitation), b) how to apply the regulations in the plant environment, and c) what methodology to use in verifying compliance with the regulations. As documented by FSIS' Performance Based Inspection System (PBIS) data, inspection personnel regularly perform HACCP record keeping procedures and HACCP review and observation procedures to determine the effectiveness of the plant's food safety controls.

3. FSIS agrees that the Agency's sampling program is designed to verify the effectiveness of HACCP systems at federally inspected plants. A fundamental premise of the regulations is that verification is through generic *E. coli* testing. However, our experience has shown us that the Agency's *E. coli* O157:H7 testing should be used as a verification tool as well. A new directive that is under development will ensure that this is the case. Nonetheless, we would point out that sampling is not the only verification tool that the Agency employs. As stated in 9 CFR 417.8, sampling is one of eight different activities or procedures used by FSIS to verify the adequacy of HACCP plans. Sampling was never intended to be the sole method used by the Agency to verify the effectiveness of HACCP. Sampling is a component of FSIS' overall verification system. The report seems to intimate that sampling alone is supposed to be verifying the HACCP plan.

Chapter 1. Available Indicators Before the Recall Showed that *E. Coli* O157:H7 Contamination was a Problem at ConAgra

1. **Recommendation No. 1**
Provide clear authority for FSIS access to all internal and external plant pathogen and microbial testing results, including tests performed for customers or where title has not passed.

FSIS Response
The Federal Meat Inspection Act provides authority for FSIS to access to all plant generated pathogen testing results. On October 7, 2002, Federal Register Notice 62325, "*E. coli O157:H7 Contamination of Beef Products,*" was issued (Enclosure No. 1), which reminded establishments of their responsibility to keep records, including records concerning plant testing, and other pre-requisite program data, as part of ongoing verification of the plant's hazard analysis and 9 CFR Part 417.5, Records. FSIS inspection personnel have access to external testing results, which are available via the records associated with the establishment's shipping and receiving plans. Inspection personnel are expected to review records as they perform daily inspection procedures to verify whether HACCP regulatory requirements are being met. Establishments' shipping and receiving plan will identify the testing requirements that must be met. FSIS inspection personnel can review the results. It is also expected that FSIS inspection personnel will initiate appropriate action if records are not made available to FSIS.

In the event that enforcement is initiated, plant generated data become an important indicator of whether and how well the plant is executing corrective actions. As such, when the decision is made to defer enforcement or hold a suspension in abeyance based on an establishment's proposed corrective measures, as part of FSIS' verification activities, COs and CSOs will review plant data bi-weekly, or monthly, in collaboration with in-plant personnel and provide recommendations to the District Manager as to whether further enforcement is warranted.

During the week of April 28-May 2, 2003, a compliance training session was held in Dallas, Texas. All COs and CSOs who are being cross utilized to carry out compliance duties received training regarding verifying plant data associated with enforcement actions. Participants were also advised that FSIS will issue an administrative subpoena to access records when a plant is unwilling to share testing data. As such, participants were instructed to contact their supervisor for further direction if they encounter plants unwilling to share their testing results with FSIS. Enclosure No. 2 contains the agenda for the compliance training session.

2. **Recommendation No. 2**

Require plants to notify FSIS of internal and external test results, especially positive test results for *E. coli* O157:H7. Instruct establishments to notify FSIS when adulterated *E. coli* O157:H7 product enters the plant, regardless of whether title to the product did or did not pass, and when the product is disposed of rather than returned to the plant.

FSIS Response

FSIS has informed beef establishments that their food safety systems for controlling *E. coli* O157:H7 must be reassessed. On October 7, 2002, Federal Register Notice 62325, "*E. coli O157:H7 Contamination of Beef Products,*" (Enclosure No. 1) was issued to advise establishments of their obligation to reassess their HACCP plans for raw beef products. The Federal Register Notice also announced the availability of guidance materials for industry. In the Notice, FSIS advised establishments about disregarding the testing results of trim from one product lot to another. FSIS noted that it expects establishments to have a scientific basis that justifies why any raw ground product produced from trim that was found to be positive for *E. coli* O157:H7 should not be considered to be adulterated. The Notice provided a notification to establishments that FSIS will be increasing its scrutiny of food safety systems that test product. FSIS does not believe that further evaluation of the issue of notification of FSIS about positive results is warranted.

Consequently, FSIS disagrees that the notification is needed. FSIS believes that the recommendation should be restated to require specific instructions for FSIS personnel to effectively monitor and verify the establishment's handling of *E. coli* O157:H7 contaminated beef products. Specifically, 9 CFR Part 417.5, Records, outlines all record-keeping requirements. FSIS inspection personnel have access to internal and external testing results, which are available via the records associated with the establishment's shipping and receiving plans. Inspection personnel are required to review records as they perform daily inspection procedures to verify whether HACCP regulatory requirements are being met. Establishments' shipping and receiving plan will identify the testing requirements that must be met. FSIS inspection personnel can review the all sampling results. It is also expected that FSIS inspection personnel will initiate appropriate action if records are not made available to FSIS.

FSIS will provide further guidance to industry and instructions to inspection program personnel on prudent measures to ensure that this product is diverted to other ready-to-eat product or for cooking. FSIS will address this issue in the new 10,010.1 Directive to be issued by October 2003.

By December 2003, FSIS will fully implement guidelines that address the responsibility of FSIS personnel to take control and monitor product that has tested positive, from both internal and external test results, for *E. coli* O157:H7. This will enhance the utilization of existing regulatory authorities pertaining to pre-shipment reviews, returned goods, hazard analysis and assessing the plant's decision-making documents related to these activities.

3. **Recommendation No. 3**
Issue policies that clarify to inspectors the authority for FSIS to consider *E. coli* O157:H7 in beef trim destined for grinding to be adulterated. Devise a risk-based sampling plan to select and test beef trim for pathogens.

FSIS Response
FSIS will address the issue of sampling trim in the revised Directive 10,010.1 to be issued by October 2003. The revised Directive provides for FSIS sampling of trim at Federal establishments.

On October 7, 2002, Federal Register Notice 62325, "*E. coli O157:H7 Contamination of Beef Products,*" (Enclosure No. 1) was issued to direct establishments to reassess their HACCP plans for raw beef products. The Federal Register Notice also announced the availability of guidance materials for industry and discussed revisions to be made to FSIS Directive, 10,010.1, "*Microbiological Testing Program For Escherichia coli O157:H7 in Raw Ground Beef.*" In the Notice, FSIS provided notification that establishments that receive product for grinding must address *E. coli* O157:H7. Establishments were instructed to employ validated CCPs in their HACCP plans to address *E. coli* O157:H7. On November 4, 2002, FSIS issued FSIS Notice 44-02 (Enclosure No. 3), "*Instructions for Verifying E. coli O157:H7 Reassessment.*" This Notice provided inspection personnel instructions for performing verification of *E. coli* O157:H7 reassessments. These documents clarify FSIS' position that *E. coli* O157:H7 in beef trim destined for grinding is considered to be adulterated.

4. **Recommendation No. 4**
Provide training to in-plant inspectors to increase their awareness as to the availability of and their access to microbiological test results and to take appropriate action, such as issuing an NR when HACCP records indicate CCP failures that could allow contaminated product to enter commerce.

FSIS Response

FSIS agrees with this recommendation. On April 29, 2003, FSIS instituted new Food Safety Regulatory Essentials (FSRE) training designed to better equip inspection personnel in verifying an establishment's food safety system. Unlike initial HACCP training, the FSRE training is tailored to an inspector's assignment. All trainees receive foundation training, covering the Rules of Practice, Sanitation Performance Standards, and Sanitation Standard Operating Procedures (SSOP). Customized HACCP training is provided based on the types of products being produced at the establishments where inspectors are assigned. One of the modules was designed specifically to address the production of raw beef products in a HACCP environment at plants such as ConAgra. This specialized training is now being offered at the FSIS Training and Education Center in College Station, Texas. The training will improve FSIS' ability to effectively monitor and verify food safety controls at plants such as ConAgra and at the establishments that purchase and process its beef. All inspection program personnel with primary duties for verification of the HACCP pathogen reduction program activities will be trained on the FSRE. FSIS expects the FSRE training to be completed for field personnel by the end of September 2004. Enclosure No. 4 contains the course description and training agendas.

In addition, during the week of April 28-May 2, 2003, a compliance training session was held in Dallas, Texas (Enclosure No. 2). All COs and CSOs who are being cross utilized to conduct compliance duties attended the training session. One of the topics discussed at this session was the review and analysis of plant records and testing data and the expectation that COs and CSOs who have been trained in enforcement, to review plant data bi-weekly, or monthly, in collaboration with the in-plant personnel when enforcement at a plant has been deferred, or when a plant is operating under a suspension held in abeyance. Plant generated data is an important indicator of whether and how well the plant is executing its corrective actions.

FSIS issued revised Directive 5000.1 (Enclosure No. 5), "*Verifying an Establishment's Food Safety System*," on May 21, 2003. Attachment 1 to the Directive is FSIS Handbook 5000.1, which provides comprehensive direction to field personnel on how they are to protect the public health by properly verifying an establishment's compliance with pathogen reduction, sanitation, and HACCP regulations. The handbook provides additional guidance to inspection personnel on their authority in accessing a plant's microbiological test results and the appropriate actions to be taken to ensure adulterated product does not enter commerce, such as reviewing the establishment's corrective action to determine if it is appropriate and addressing proper product disposition.

5. **Recommendation No. 5**

Develop a management control process that will provide FSIS inspectors with all available data necessary to monitor compliance with HACCP requirements.

FSIS Response

FSIS agrees that a process is required to ensure that inspection personnel have all available data necessary to monitor compliance with HACCP requirements. FSIS inspectors have real-time access to all available inspection data generated for the respective establishment that they are working in. This data is in the PBIS database. Inspection personnel use this data and other sources in their verification activities.

Each level of FSIS supervision has responsibilities to review data of operational and compliance activities. The review covers individual establishment's compliance records to aggregate compliance records for establishments within a circuit, within a District and nationally. The Technical Service Center (TSC) collects and analyzes this 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 analysis, and various operational data summaries.

FSIS has judiciously implemented this process to make decision-support information available to the inspection personnel. FSIS field personnel have regular access to the PBIS database and related reports. The most recent version of the PBIS database system (version 5.0) allows inspection personnel to enter and access specific non-compliance records (NRs) that have been issued to a plant for PR/HACCP, Sanitation Standard Operating Procedures (SSOP), Sanitation Performance Standards (SPS), and Other Consumer Protections (OCP) non-compliances. FSIS inspection personnel also have access to the Laboratory Electronic Application for Results Notification (LEARN) database system. The LEARN database contains laboratory testing results, including potential, presumptive, and positive sample results for raw ground and ready to eat products. These systems allow inspectors to monitor an establishment's compliance with PR/HACCP requirements.

Also, FSIS has issued Directive 4430.3, "*In-Plant Performance System Reviews,*" (IPPS) and a comprehensive Supervisory Guideline (Enclosure No. 6). IPPS was designed to hold inspection program personnel accountable and ensures that inspectors are applying the appropriate inspection methods, using effective regulatory decision-making, and documenting findings appropriately and when warranted, implementing enforcement actions properly.

The Office of Program Evaluation, Enforcement and Review (OPEER) will monitor the Agency's progress in the area. Audits, evaluations, and reviews will be conducted to verify implementation and measure the effectiveness of the corrective actions.

6. **Recommendation No. 6**

Verify ConAgra's methodology for establishing the upper control limit for generic *E. coli.* Require FSIS personnel to review and monitor all control limits established by ConAgra.

FSIS Response
FSIS is continuing to review and monitor Est. 969's control limits, as well as other operations in the plant as part its ongoing regulatory duties. FSIS has completed a verification of ConAgra's (now Swift's) methodology for establishing the upper control limit for generic *E. coli* to ensure compliance with §310.25(a)(5)(i), Table 1 of 9 CFR. On May 7, 2003, FSIS conducted a review and analysis of Est. 969's generic *E. coli* testing process, including design, execution, and test results reporting. The review was aimed at determining the establishment's regulatory compliance with §310.25(a).

Est. 969 now determines baseline standards yearly, reflecting previous yearly data averages. Est. 969 reviews and revises, as necessary, its Standard Operating Procedure (SOP) # 1128 detailing sample collection procedures and SOP # 1802 detailing data sampling reporting procedures.

FSIS in-plant inspection team oversight and verification was accomplished by reviewing information from the PBIS procedures performed at Est. 969. PBIS verification procedures conducted from June 1, 2002, to May 1, 2003, included:

- Procedure 05A01= 61 scheduled and 61 performed.
- Procedure 05A02= 49 scheduled, 43 performed and 6 not performed.
- A total of 104 procedures were performed.
- No noncompliance was observed for the 104 performed procedures during the specified time frame.

The review of Est. 969's current documentation and operations found them to be in compliance with Regulation 310.25 (a). During the July 2002, FSIS Food Safety Investigation (FSI) at Est. 969, the FSI team reviewed the generic *E. coli* testing program, but primarily focused on the *E. coli* O157:H7 carcass program utilized by Est. 969 at that time because it was determined by the team to be more indicative of the health risk associated with the product recall. The generic *E. coli* testing program is required by regulation as an indicator of process control. However, the specific *E. coli* O157:H7 carcass program was thought to be more plant and program specific.

7. **Recommendation No. 7**
Revise FSIS Directive 5000.1 to require qualified FSIS personnel to periodically review the methodology used for setting generic *E. coli* upper control limits in all beef establishments.

FSIS Response
FSIS issued revised FSIS Directive 5000.1 (Enclosure No. 5), "*Verifying an Establishment's Food Safety System*." The Directive provides instructions to consumer safety personnel on verifying that generic *E. coli* upper control limits in all beef establishments have been implemented as required by the regulation. The revised Directive was issued on May 21, 2003.

In addition, CSOs are assigned to District Offices to conduct comprehensive assessments to verify that establishment control systems are well-documented, supported by scientific information, and validated. Currently, CSOs are conducting comprehensive assessments of HACCP plans at beef product establishments. These comprehensive assessments are being conducted as part of an October 7, 2002, Federal Register Notice, "*E. coli O157:H7 Contamination of Beef Products*," that required all beef slaughter establishments to reexamine their food safety strategies in light of evidence that *E. coli* was more prevalent in live animals than previously thought. The comprehensive examination of HACCP plans by CSOs at raw beef product establishments was a proactive step to strengthen pathogen prevention practices. Eventually all beef plants will be reassessed.

8. Recommendation No. 8

Develop and implement criteria to evaluate repetitive noncompliance violations that provide a basis for determining when corrective actions are inadequate and enforcement actions should be initiated. Establish specific criteria when further enforcement action must be taken based on criteria established for repetitive violations.

FSIS Response

On June 17, 2002, FSIS issued Directive 4430.3, "*In-Plant Performance System Reviews,*" (IPPS) and a comprehensive Supervisory Guideline (Enclosure No. 6). These documents provide specific instructions and guidance on how to assess the performance of inspection personnel in the PR/HACCP system environment and for verifying that inspection personnel are carrying out their responsibilities. These include having supervisors ensure that inspection personnel are evaluating trend indicators over time to determine whether to take regulatory action based on the establishment's performance and having supervisors assess from inspection records that inspection personnel are determining whether a trend of noncompliance that warrants the withholding of inspection is occurring. IPPS holds inspection personnel accountable and ensures that the significance of repetitive noncompliance violations is not being overlooked.

FSIS also revised FSIS Directive 5000.1 (Enclosure No. 5), "*Verifying an Establishment's Food Safety System*." The revised Directive provides guidance for the field on how to identify repetitive deficiencies and what action to take in response. The revised Directive was issued on May 21, 2003. The Directive 5000.1 is used along with the Rules of Practice, 9 CFR 416 and 9 CFR 417 by the District Offices to determine when enforcement actions are warranted. This process has been implemented.

On April 29, 2003, FSIS implemented new FSRE (Enclosure No. 4) training designed to better equip inspection personnel in verifying an establishment's food safety system. The training provides guidance to inspection personnel for evaluating repetitive noncompliance and furnishes a basis for determining when corrective actions are inadequate and enforcement should be initiated.

In addition, during the week of April 28-May 2, 2003, a compliance training session was held in Dallas, Texas. The Deputy District Managers of each District Office and several District Managers attended the session. At the training, FSIS stressed the importance of ensuring that FSIS verification plans are developed and carried out for all deferral actions and suspensions held in abeyance. A presentation was given which covered the development of FSIS verification plans and the procedures that should be utilized to ensure that a plant's corrective and preventive measures are effectively carried out.

Furthermore, in August 2002, FSIS implemented a procedure that requires that whenever FSIS defers enforcement following the issuance of a Notice of Intended Enforcement (NOIE), or hold a suspension in abeyance, a written FSIS verification plan will be developed and attached to the deferral or suspension held in abeyance letter. The verification plan is also discussed with plant officials. The verification plan identifies the specific procedures that an FSIS in-plant inspection team will carry out to ensure that the establishment implements the corrective and preventive actions proffered to the Agency in response to a NOIE or suspension. The procedures in the verification plan are carried out until such time that the establishment can demonstrate it is capable of eliminating unsanitary conditions and practices and is producing product that is safe and sanitary. If FSIS verification activities reveal that the establishment's corrective and preventive measures are effective, the deferral or suspension being held in abeyance will be closed. On the other hand, if FSIS verification activities show that the plant's food safety controls are ineffective, further enforcement will be initiated.

The Office of Program Evaluation, Enforcement and Review (OPEER) will monitor the Agency's progress in the area. Audits, evaluations, and reviews will be conducted to verify implementation and measure the effectiveness of the corrective actions.

9. **Recommendation No. 9**

Consider implementing civil penalties when companies fail to comply with established pathogen reduction benchmarks and/or when they are cited for repetitive food safety violations.

FSIS Response

FSIS believes that the concerns raised by the OIG should be directed at the Agency's need for improving its management controls and supervision of its inspection personnel to ensure effective enforcement of regulatory requirements. FSIS does not have the authority to implement civil penalties; however, the judicial system has imposed civil penalties for statutory violations. FSIS believes that the OIG recommendation should encourage better use of existing authorities for enforcement. Federally inspected establishments are required to take appropriate and effective corrective actions to address identified deficiencies. Further, when serious deficiencies are noted at establishments, FSIS will begin preparing an Administrative Enforcement Report (AER) that compiles all serious non-compliances. The AER will support the Agency's basis for actions taken, ensure uniformity and consistency, and become apart of the formal record for action.

To enhance the supervision of inspection program personnel and improve management controls, FSIS has issued Directive 4430.3, "*In-Plant Performance System Reviews,*" (IPPS) and a comprehensive Supervisory Guideline (Enclosure No. 6). IPPS holds inspection program personnel accountable and ensures that inspectors are applying the appropriate inspection methods, using effective regulatory decision-making, and documenting findings appropriately and when warranted, implementing enforcement actions properly.

Also, FSIS instituted new Food Safety Regulatory Essentials (FSRE) training designed to better equip inspection personnel in verifying an establishment's food safety system. Unlike initial HACCP training, the FSRE training is tailored to an inspector's assignment. All trainees receive foundation training, covering the Rules of Practice, Sanitation Performance Standards, and Sanitation Standard Operating Procedures (SSOP).

The Office of Program Evaluation, Enforcement and Review (OPEER) will monitor the Agency's progress in the area. Audits, evaluations, and reviews will be conducted to verify implementation and measure the effectiveness of the corrective actions.

10. Recommendation No. 10

Increase supervision and oversight to the plant until it demonstrates it is capable of eliminating unsanitary conditions and practices and producing product that is sanitary and wholesome.

FSIS Response

FSIS agrees that greater oversight over the inspection program at Est. 969 is beneficial and has done so. The Agency has taken several personnel actions to immediately address the problems at the plant. A new acting Circuit Supervisor (CS) has been assigned to the establishment. The new acting CS is actively involved in oversight activities.

In addition, the District Office placed a Supervisory Veterinary Medical Officer (SVMO) in the position as acting Inspector In Charge (IIC). He is actively involved in all supervision and oversight functions. Supervisory oversight has increased dramatically at all levels. In-plant staffing has remained a constant priority to facilitate adequate inspectional oversight activities.

The FSIS monitoring of the in-plant sampling of ground beef for *E. coli* O157:H7 has continued since the initial recall of product began. In addition, Est. 969 has continued its daily in-plant sampling of all beef trim.

11. Recommendation No. 11

Strengthen monitoring of inspector activities at the plant to achieve an acceptable level of performance in applying HACCP requirements.

FSIS Response

The FSIS inspection activities have been strengthened and increased at Est. 969 since the initiation of the enforcement action. As a result of the November 2002 enforcement action, an in-plant FSIS Verification Plan was developed detailing FSIS in-plant activities to monitor the plant's actions in response to the enforcement action taken. A copy of the FSIS Verification Plan was provided to and discussed with plant management. The plan is designed to ensure that the establishment fully implements and executes the revisions of the SSOP and HACCP plan(s) and other corrective actions as indicated and can be modified to reflect any necessary changes. The FSIS Verification Plan identifies the establishment's actions, the relevant regulatory requirement the actions meet and the Inspection System Procedure (ISP) code under which the inspection task will be performed. It identifies and establishes timelines to which the plant committed. The plan also has to be initialed and dated by the in-plant inspection team member completing the task and identifying plant actions, responses, or non-compliances documented. The completed copies of the plan are mailed or faxed to the Boulder District Office for review bi-weekly.

In addition, the in-plant inspection team, both day and night shifts; generate daily e-mail reports detailing the plant operations, NR's documented or other problems. The e-mail reports are sent to the opposite shift FSIS supervisor, the Circuit Supervisor (CS), and the District Office.

In addition, on June 17, 2002, FSIS issued Directive 4430.3, "*In-Plant Performance System Reviews,*" (IPPS) and a comprehensive Supervisory Guideline (Enclosure No. 6). These documents provide specific instructions and guidance on how to assess the performance of inspection personnel in the PR/HACCP system environment and for verifying that inspection personnel are carrying out their responsibilities. These include applying the appropriate inspection methods, using effective regulatory decision making and documenting findings appropriately, and when warranted, implementing enforcement actions properly.

FSIS will complete an internal assessment of IPPS to ensure that the reviews are accomplishing their objectives. The internal assessment at Est. 969 will be completed by October 2003.

Chapter 2. Recall of ConAgra Beef Products Needed More Proactive Involvement by FSIS

12. Recommendation No. 12

Seek legislation and issue regulations requiring that all establishments include in their HACCP plan the steps that would be necessary to conduct an effective recall of product and provide for its proper disposition.

FSIS Response
FSIS has strongly encouraged establishments to incorporate a recall plan in their HACCP plans through direction provided in FSIS Directive 8080.1 (Enclosure No. 7), "*Recall of Meat and Poultry Products*." As part of the Directive, FSIS provided "Product Recall Guidelines for Firms." The guideline outlines the actions that FSIS expects a firm to take in the event that the establishment decides to recall product.

FSIS does not have authority to make it mandatory for establishments to include plans for a recall in their HACCP plans. On December 12, 2002, FSIS held a public meeting to discuss improving the overall recall process. As a result of that meeting, FSIS is considering ways to further encourage plants to incorporate effective recall plans into their HACCP plans. FSIS expects to update this guidance on planning for recalls by March 2004.

13. **Recommendation No. 13**
Expedite issuance of the regulations and/or written directives, as necessary, to provide clear directions on when traceback samples are to be collected and how the samples are to be processed. Incorporate the cited notice requiring notification of suppliers into the FSIS Directive System.

FSIS Response
FSIS will provide clear directions on when traceback samples are to be collected and how the samples are to be processed in the updated FSIS Directive 10,010.1, "*Microbiological Testing Program For Escherichia coli O157:H7 in Raw Ground Beef*." In the interim, FSIS issued Notice 11-03, "Update to FSIS Directive 10,010.1, Microbiological Testing Program For Escherichia coli O157:H7 in Raw Ground Beef," dated April 18, 2003. This notice updates instructions to inspection personnel on planned changes to the Directive including providing more comprehensive procedures, requirements for notification of suppliers, and increased verification needs. The revised Directive will be issued by October 2003 and incorporate the instructions of the notice.

14. **Recommendation No. 14**
Implement a management control process to ensure that district managers comply with recall procedures and that compliance officers' determinations are reviewed, analyzed, and acted upon.

FSIS Response
In March 2003, the District Offices were provided draft guidelines to be immediately implemented to ensure that recall activities are effectively carried out. These guidelines clarify CO responsibilities associated with recalls and require that each District Office designate an individual to manage recall activities during working hours, as well as after hours, weekends, and holidays. The guidelines also address the responsibilities of the Deputy District Manager and COs pertaining to recalls. The responsibilities of Deputy District Managers and COs were also addressed at the FSIS Compliance Training session that was held in Dallas, Texas, during the week of April 28-May 2, 2003 (Enclosure No. 2).

FSIS also plans to convene an internal workgroup to provide recommendations as to how to improve the recall effectiveness checks process. The workgroup will also provide recommendations so FSIS has a mechanism in place to ensure that, on an ongoing basis, District Managers comply with recall procedures and assure that COs' determinations are reviewed, analyzed and acted on. The workgroup will also consider the overall policies and procedures for managing the recall process and the recall effectiveness checks and will make recommendations for improvement.

As part of recall process improvement effort, FSIS will examine and include in directives, as appropriate, provisions to establish criteria to assess the overall effectiveness of a recall, to reconcile planned effectiveness checks to those checks actually performed, to identify corrective actions to be taken when deficiencies are noted, etc. This information will be assembled and formalized in a directive. The management controls, responsibilities, and oversight roles for this process will be clearly delineated.

The workgroup will provide a report outlining recommendations by October 2003. The draft guidelines issued to District Offices in March 2003 will be updated and finalized by March 2004. The final FSIS recommendations will be implemented by July 2004.

15. Recommendation No. 15

Reassess the policies and procedures for managing the recall process. Require the recalling firm to conduct effectiveness checks on those below the primary distribution level. Perform sufficient oversight over the recall to ensure that notifications have been timely made and appropriate actions taken to dispose of the recalled product.

FSIS Response

FSIS does not have the statutory authority to require that establishments conduct effectiveness checks. FSIS believes the recommendation should be restated to ask that FSIS work with industry to improve the recalling firms' effectiveness checks.

FSIS has convened a workgroup to provide recommendations as to how to improve the recall effectiveness checks process. The workgroup will also provide recommendations designed to ensure that FSIS has a mechanism in place to ensure that on an ongoing basis, District Managers comply with recall procedures and assure that COs' determinations are reviewed, analyzed, and acted on.

In addition to providing recommendations to ensure that District Offices are properly carrying out their recall responsibilities, the workgroup will provide recommendations regarding what action should be taken in the event that the recalling firm has failed to conduct effectiveness checks below the primary level, and/or has not provided timely notifications to its consignees regarding the recalled product, or has not taken appropriate action to dispose of recalled product. FSIS intends to include as workgroup participants, persons who are familiar with the recall process and who have knowledge of problems that are encountered in the course of conducting recall effectiveness checks.

As part of recall process improvement effort, FSIS will examine and include in a directive, as appropriate, provisions to establish criteria to assess the overall effectiveness of a recall, to reconcile planned effectiveness checks to those checks actually performed, to identify corrective actions to be taken when deficiencies are noted, etc. This information will be assembled and formalized in a directive. The management controls, responsibilities, and oversight roles for this process will be clearly delineated in a directive.

The workgroup will provide a report outlining recommendations by October 2003. The draft guidelines entitled, "*Office of Field Operations District Office Recall Responsibilities*" which was issued to District Offices in March 2003 will be finalized by March 2004. The final FSIS recommendations will be implemented by July 2004.

16. Recommendation No. 16

Establish a system of specific enforcement actions to be taken against those processors or distributors where effectiveness checks disclose proper notifications of the consignees/customers have not been made.

FSIS Response

Under 9 CFR 500.3 FSIS has authority to take enforcement action against any establishment that has been found to have produced and shipped adulterated product. When effectiveness checks disclose that proper notification of the consignee/customers has not been given, FSIS has the authority to detain and, if necessary, seize products that have been determined to be adulterated. FSIS has prior precedent in applying its enforcement authority.

FSIS is working closely with industry and is providing guidance on the proper and appropriate actions that should be taken during recalls. On December 12, 2002, FSIS held a public meeting to discuss improving the recall process. The Agency is considering ideas presented at the public meeting for increasing industry's involvement in managing recalls.

Also, during the week of April 28-May 2, 2003, an Office of Field Operations (OFO) Compliance training session was held in Dallas, Texas (Enclosure No. 2). As part of the training, OFO COs were provided training on their expected roles and responsibilities regarding recall activities. OFO COs will play a greater role in recalls. These COs will collect information to demonstrate that processors or distributors have either met or failed to disclose proper notifications to consignees or customers regarding recalled product. This information will be used as a basis for further strengthening and improving the recall process.

As part of recall process improvement effort, FSIS will examine and include as appropriate, provisions to establish criteria to assess the overall effectiveness of a recall, to reconcile planned effectiveness checks to those checks actually performed, to identify corrective actions to be taken when deficiencies are noted, etc. This information will be assembled and formalized in a directive. The management controls, responsibilities, and oversight roles for this process will be clearly delineated within the directive.

The workgroup will provide a report outlining recommendations by October 2003. The draft guidelines entitled, "*Office of Field Operations District Office Recall Responsibilities*" which was issued to District Offices in March 2003 will be finalized by March 2004. The final FSIS recommendations will be implemented by July 2004.

17. **Recommendation No. 17**
Develop effectiveness check criteria for monitoring the universe of potential effectiveness checks and documenting the number of required individual checks completed, as well as establishing substantive and quantitative criteria for determining whether recalls are effective.

FSIS Response
FSIS plans to convene an internal workgroup to provide recommendations as to how to improve the recall effectiveness checks process. The workgroup will also provide recommendations designed to ensure that FSIS has a mechanism in place to ensure that on an ongoing basis, District Managers comply with recall procedures and assure that COs' determinations are reviewed, analyzed and acted on. In addition to providing recommendations to ensure that District Offices are properly carrying out their recall responsibilities, the workgroup will be expected to develop recommendations for effectiveness check criteria, including establishing substantive and quantitative criteria for determining whether recalls are effective. The workgroup will provide a report outlining recommendations by October 2003. The recommendations will be finalized by March 2004. The final FSIS recommendations will be implemented by July 2004.

As part of recall process improvement effort, FSIS will examine and include as appropriate, provisions to establish criteria to assess the overall effectiveness of a recall, to reconcile planned effectiveness checks to those checks actually performed, to identify corrective actions to be taken when deficiencies are noted, etc. This information will be assembled and formalized in directives. The management controls, responsibilities, and oversight roles for this process will be clearly delineated in the directive.

18. **Recommendation No. 18**
Establish minimum acceptable requirements for an establishment's production records. Ensure that these production record requirements are adequate to facilitate tracebacks; direct that these requirements be incorporated into each establishment's HACCP plan; and periodically verify the records for sufficiency.

FSIS Response

FSIS Directive 8080.1 (Enclosure No. 7), "*Recall of Meat and Poultry Products,*" provides guidance to industry on developing a recall plan. FSIS recommends that the recall plan specify that product production and distribution records be maintained by establishments such that they can facilitate identification and location of products that may need to be recalled. FSIS will revise Directive 8080.1 to provide additional guidance on the establishments' production records. Also, FSIS will work to issue additional guidance through a Federal Register Notice that details how language in 9 CFR 320.1 "*Records required to be kept,*" would be utilized to ensure the establishment records are adequate to facilitate tracebacks.

FSIS will revise and issue an updated FSIS Directive 8080.1 by October 2003. FSIS will issue a Federal Register Notice by December 2003.

19. Recommendation No. 19

Verify that sanitation procedures at Galligan are always properly documented by the plant.

FSIS Response

On May 7, 2003, an FSIS conducted a confirmation and verification review at the Galligan Wholesale Meat, Est. 6475, Denver, Colorado, to review deficiencies and needed improvements identified during the OIG audit. The review specifically focused on verifying the corrective actions required to improve the plant's SSOP plan and the production documents for ground beef and other ground products at the establishment.

As a result of the review, new record-keeping practices have been instituted at the establishment to more closely monitor all products used in the production of ground beef. The establishment's sanitation procedures have been documented. A log book is being kept with all fresh beef suppliers listed for each batch of ground product, lot numbers, production dates and all pertinent information on the labeled products. Finished product identification including total box count, total weight and finished product lot numbers is also recorded in the log.

In addition, on June 17, 2002, FSIS issued Directive 4430.3, "*In-Plant Performance System Reviews,*" (IPPS) and a comprehensive Supervisory Guideline (Enclosure No. 6). These documents provide specific instructions and guidance on how to assess the performance of inspection personnel in the PR/HACCP system environment and for verifying that inspection personnel are carrying out their responsibilities. These include applying the appropriate inspection methods using effective regulatory decision making, documenting findings appropriately, and when warranted, implementing enforcement actions properly.

The Office of Program Evaluation, Enforcement and Review (OPEER) will monitor the Agency's progress in the area. Audits, evaluations, and reviews will be conducted to verify implementation and measure the effectiveness of the corrective actions.

20. Recommendation No. 20

Document the analysis and determinations made for the suitability of new ingredients used in meat or poultry products. This documentation should include details on the review process and the factors considered, how conclusions will be communicated to the establishment, and who will be responsible for ensuring that FSIS decisions are properly implemented, in particular those relating to product labeling requirements. Coordinate with FDA on the safety concerns related to the use of lactic acid in ground beef.

FSIS Response

On December 23, 1999, the Food Safety and Inspection Service (FSIS) published in the Federal Register a final rule on "Food Ingredients and Sources of Radiation Listed or Approved for Use in the Production of Meat and Poultry Products." The final rule streamlined the process for approving the use of food ingredients and sources of radiation in meat and poultry products to provide for the simultaneous review, by FSIS and the Food and Drug Administration (FDA), of petitions for new uses of food and color additives and notifications for new uses of generally recognized as safe (GRAS) substances that are submitted to FDA.

Subsequent to the publication of the final rule in January 2000, FDA and FSIS entered into a Memorandum of Understanding (MOU) that outlines the procedures that are followed by FDA and FSIS regarding the joint review of requests and petitions for the use of food ingredients and sources of radiation in meat and poultry products with regard to safety and suitability determinations. The final rule and the MOU explain that, except in limited circumstances, FDA will now (1) list in its regulations (21 CFR) food additives and sources of radiation that are safe and suitable for use in the production of meat or poultry products and (2) document the generally recognized as safe (GRAS) substances that are both safe and suitable for use in meat and poultry products that are the subject of GRAS Notices they receive.

With regard to new uses of substances that are GRAS, the MOU explains the process that FSIS operates jointly with FDA to perform acceptability (suitability) determinations. The Federal Register notice entitled "*E. coli O157:H7 Contamination of Beef Products*" (67 FR 62325) and related documents, such as "*Guidance on Ingredients and Sources of Radiation Used to Reduce Microorganisms on Carcasses, Ground Beef, and Beef Trimmings,*" and "*Guidance on the Procedures for Joint Food Safety and Inspection (FSIS) and Food and Drug Administration (FDA) – Approval of Ingredients and Sources of Radiation Used in the Production of Meat and Poultry Products,*" provided additional guidance. The information contained in these documents clearly specifies the data, documentation, and related requirements to support how FSIS makes suitability determinations. In order to document the results of suitability determinations, FSIS also issued Directive 7120.1, Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products, dated December 2002, to communicate with inspectors and provide field personnel and establishments with an up-to-date list of approved substances for use in the production of meat and poultry products. The Directive is updated every few months as needed. FSIS regularly evaluates and updates its guidance documents as required. FSIS will coordinate with FDA in performing an updated acceptability determination on the use of lactic acid in ground beef by March 2004.

Chapter 3. Monitoring and Supervision of Food Safety Procedures at Beef Production Plants Need to be Improved

21. Recommendation No. 21

Perform the necessary baseline studies to define the goals, objectives, and performance measurements and develop a scientific risk-based sampling plan to include relevant factors, such as individual plant volume of production and effectiveness of interventions that will provide reasonable assurance that HACCP systems in place are effective.

FSIS Response

FSIS agrees that baseline studies on different raw ground beef components can be useful in making the allocation of verification samples more risk-based, measuring the national prevalence, providing a marker for measuring future change in pathogens, and providing input for risk assessments. Subject to available funding provided through appropriations, FSIS will conduct baseline studies to complement and enhance its sampling program. FSIS' sampling program is one component of the Agency's overall verification program as specified in 9 CFR 417.8.

FSIS will update FSIS Directive 10,010.1, "*Microbiological Testing Program for Escherichia coli O157:H7 in Raw Ground Beef,*" with more comprehensive procedures. These procedures will address various sampling scenarios such as those based on estimates of production volume, production types (e.g., trim), statistical process data feedback, and technical interventions. FSIS' new *E. coli* O157:H7 verification testing program will be more risk-based than the current program and will place added emphasis on collecting more than one sample from higher risk operations. By increasing the number of samples FSIS collects from higher risk operations, FSIS will have greater confidence that the sampled lot is negative for *E. coli* O157:H7. In addition, no official establishment will be exempted from FSIS *E. coli* O157:H7 verification testing. Under the revised Directive, FSIS intends to sample at grinding establishments. When FSIS finds a positive sample at the grinding operation, FSIS then intends to collect subsequent samples of product from suppliers (at the supplying establishment). FSIS expects this new Directive to be issued by October 2003. FSIS expects full implementation to commence December 2003.

22. Recommendation No. 22

Strengthen sampling procedures so that samples are either representative of lots being sampled or of production operations.

FSIS Response

FSIS will continue to consider all options for strengthening its verification strategies, of which sampling is one component. FSIS will update FSIS Directive 10,010.1, "*Microbiological Testing Program for Escherichia coli O157:H7 in Raw Ground Beef,*" with more comprehensive procedures. These procedures will address various sampling scenarios such as those based on estimates of production volume, production types (e.g., trim), statistical process data feedback, and technical interventions.

The revised Directive will be issued by October 2003. FSIS expects full implementation to commence December 2003.

23. Recommendation No. 23

Issue the planned revision to FSIS directives to eliminate the current procedure that exempts plants performing their own testing from being tested by FSIS.

FSIS Response

This has been completed by FSIS. On April 18, 2003, FSIS issued FSIS Notice 11-03 (Enclosure No. 8), "*Update to FSIS Directive 10,010.1, Microbiological Testing Program For Escherichia Coli O157:H7 in Raw Ground Beef.*" The Notice provides updated instructions to inspection program personnel on some of the issues covered by FSIS Directive 10,010.1, "*Microbiological Testing Program For Escherichia Coli O157:H7 in Raw Ground Beef.*" In addition, the Notice provides notification that FSIS will be revising Directive 10,010.1.

In the Notice, updated procedures that immediately went into effect were given to inspection program personnel that instructed them to collect raw ground beef samples whenever they received an FSIS Form 10,210-3 for microbiological sampling project MT03. Samples are to be collected regardless of whether the establishment had met criteria set forth in FSIS Directive 10,010.1, VI.B. All raw ground beef, hamburger, ground veal, veal or beef patties, or other products meeting the standard of identity in 9 CFR 319.15, are eligible for verification sampling by FSIS. Thus, plants are no longer exempted from sampling based on conducting their own testing.

24. Recommendation No. 24

Revise current instructions to require that laboratory samples be under the direct custody and control of FSIS personnel until the sample can be provided directly to the delivery service.

FSIS Response

FSIS disagrees with the recommendation as written. The recommendation should be restated to ask FSIS to ensure the integrity of its sample delivery service. The requirement to have samples remain under the direct custody and control of FSIS personnel has significant resource implications with marginal or limited additional assurances to be gained. Idling personnel waiting for the handoff of samples to delivery personnel would result in workforce inefficiencies.

FSIS agrees that appropriate measures should be taken to ensure chain of custody for samples. Consequently, on December 3, 2002, FSIS issued Directive 7355.1 (Enclosure No. 9), Revision 2, "*Use of Sample Seals for Program Samples and Other Applications.*" This Directive ensures the integrity of samples submitted to laboratories for analysis or held for incubation in the establishment as agar plate. The revision provides guidelines for proper sealing of samples and shipping boxes. All sample packages (with the exception of investigation samples) shipped to FSIS laboratories are sealed and identified using a three-part system. This system identifies and links the sample with the

submission form and the shipping container. When properly sealed, each laboratory sample package will have three separate but identically numbered/bar-coded identification labels, as follows:

1. One small bar-coded label is affixed to the sample submission form.
2. A medium-sized bar-coded label, the "*FSIS Laboratory Sample Identification Label*" is placed on the primary container.
3. A large bar-coded label, the "*FSIS Laboratory Sample Container Seal,*" is placed on the shipping container.

The inspector retains a record of the seal packet used for each sample sent to the laboratory. An additional, small bar-coded label may be placed on the inspector's file copy of the submission form or on a log sheet indicating to which sample the seal corresponds. For shipping the samples to the laboratories, the inspection personnel choose the carrier that assures the least time in transit.

25. **Recommendation No. 25**
Require district offices to conduct periodic reviews to ensure compliance with sampling procedures.

FSIS Response
To enhance management controls and oversight of its field inspection personnel, FSIS issued Directive 4430.3, "*In-Plant Performance System Reviews,*" (IPPS) and a comprehensive Supervisory Guideline (Enclosure No. 6). These documents provide specific instructions and guidance on how to assess the performance of inspection personnel in the PR/HACCP system environment and for verifying that inspection personnel are carrying out their responsibilities. These include applying the appropriate inspection methods, using effective regulatory decision making, documenting findings appropriately and when warranted, and implementing enforcement actions properly. This would also include ensuring compliance with sampling procedures.

The Office of Program Evaluation, Enforcement and Review (OPEER) will monitor the Agency's progress in the area. Audits, evaluations, and reviews will be conducted to verify implementation and measure the effectiveness of the corrective actions.

26. **Recommendation No. 26**
Require the three plants to revise their HACCP plans to correct the cited deficiencies noted during our reviews.

FSIS Response
FSIS took immediate action to ensure that the establishments' HACCP plans were corrected to address the deficiencies uncovered in the audit. As a result of FSIS' immediate actions, several changes were made by the establishments including:

- ConAgra made major modifications to its slaughter floor. Additional major improvements are planned over the next several months.

- Galligan Wholesale Meat, Est. 6475, Denver, Colorado modified its SSOP and HACCP plans to correct the deficiencies noted during the OIG audit.

- Montana Quality Foods, Est. # 7679, Miles City, Montana plant management reassessed its HACCP plan. FSIS inspection personnel have reviewed the HACCP plans and activities as required verifying that Montana Quality is meeting all of its obligations with respect to both the original part of its HACCP plan as well as the new CCP, which was added as a result of the enforcement action.

Concerning ConAgra, the changes made and incorporated into the SSOP programs for the entire plant were re-evaluated and modified this year to improve the company's documentation of corrective actions in meeting 9 CFR 416.15 in addition to tracking and resolving trends of unsanitary conditions.

The changes made and incorporated into the HACCP program were because of numerous reassessments as a result of the enforcement actions taken by FSIS at the plant, circuit and District levels. In addition, the plant reassessed its HACCP plan as required by FSIS Notice 44-02 for *E. coli* O157:H7 (Enclosure No. 3).

27. **Recommendation No. 27**

Develop a written, time-phased plan for completing consumer safety officer reviews of HACCP plans. The time-phased plan should include a strategy for hiring and training staff.

FSIS Response

The determination as to whether a comprehensive food safety assessment is needed at an establishment can be based on several factors. As such, District Offices regularly review PBIS data, including NRs, FSIS sampling results, and other available information to determine if a CSO assessment is needed. Also, often a triggering event occurs, such as a consumer complaint, a food borne illness outbreak, or a specific food safety issue, that warrants conducting a comprehensive food safety assessment. Presently, there are 104 persons trained in the CSO methodology, making it impossible to conduct comprehensive food safety assessments at every federally inspected facility. There are approximately 7500 establishments operating under a grant of inspection. Because of this, District Managers are expected to monitor activities in their districts and to use discretion in determining where comprehensive food safety assessments are most needed.

As of June 24, 2003, there have been 677 comprehensive food safety assessments completed by CSOs to verify *E. coli* O157:H7 reassessments at establishments that conduct beef slaughter and ground beef operations, and we estimate that by year 2005, CSOs will conduct such assessments at 2,500 establishments. FSIS has focused its initial food safety assessments at those plants that produced the largest volumes of product.

FSIS has asked for an additional $5.7 million in its fiscal year 2004 budget request to retool training, to accomplish our public health goals, and ensure that our CSO methodology continues to be carried out. Over the next several years, we will continue to train additional employees in the CSO methodology, including training 1000 VMOs in the CSO and enforcement methodology by year 2007.

28. **Recommendation No. 28**

Develop an FSIS review program that includes a periodic (1 to 2 year) reassessment of HACCP plans.

FSIS Response

On October 7, 2002, Federal Register Notice 62325, "*E. coli O157:H7 Contamination of Beef Products,*" (Enclosure No. 1) was issued to advise establishments of their obligation to reassess their HACCP plans for raw beef products. On November 4, 2002, FSIS issued FSIS Notice 44-02, "*Instructions for Verifying E. coli O157:H7 Reassessment.*" This Notice provided inspection personnel instructions for performing verification of *E. coli* O157:H7 reassessments. These documents will help ensure that establishments are reassessing their HACCP plans in accordance with 9 CFR 417.4, which requires that HACCP plans be reassessed at least annually.

In addition, in 2002 CSOs were assigned to District Offices to conduct comprehensive assessments to verify that establishment control systems are well-documented, supported by scientific information, and validated. Currently, CSOs are conducting comprehensive assessments of HACCP plans at all large raw beef product establishments. These comprehensive assessments are being conducted as part of the October 2002 directive from FSIS that required all beef slaughter establishments to reexamine their food safety strategies in light of evidence that *E. coli* O157:H7 was more prevalent in live animals than previously thought. The comprehensive examinations of HACCP plans by CSOs at raw beef product establishments was a proactive step to strengthen pathogen prevention practices, and will expand to include smaller establishments in the future.

As of June 24, 2003, there have been 677 comprehensive food safety assessments completed by FSIS' 107 CSOs to verify *E. coli* O157:H7 reassessments at federally inspected establishments that conduct beef slaughter and ground beef operations. FSIS estimates that by the year 2005, comprehensive assessments to verify *E. coli* O157:H7 reassessments will be completed for approximately 2500 remaining establishments. These reviews will be conducted on a recurring basis.

Additionally, the Office of Program Evaluation, Enforcement, and Review will establish an annual review plan to conduct regular reviews of in plant inspection activities and facility compliance with PR/HACCP. The domestic reviews are expected to begin March 2004.

29. **Recommendation No. 29**

Develop a technical assistance program using properly trained and qualified employees that could provide guidance to establishments on HACCP plans development and maintenance requirements.

FSIS Response

FSIS recognizes that effective training of both FSIS and industry employees is vital to the success of the Pathogen Reduction and HACCP Systems final rule. Consequently, FSIS is assessing the viability of conducting joint training with industry. Various kinds of establishments, including small and very small plants, must have access to training, technical assistance, and other resources that will facilitate HACCP implementation. Therefore, FSIS has developed and implemented an approach to training and technical assistance that is designed to support HACCP implementation within available resource constraints.

FSIS has designed several guidance documents to help industry reduce the occurrence of *E. coli* O157:H7. On October 7, 2002, Federal Register 62325, "*E. coli O157:H7 Contamination of Beef Products*" (Enclosure No. 1) was published with related guidance documents. In particular, the following documents were published as guidance to industry:

- "*Guidance for Minimizing the Risk of Escherichia coli O157:H7 and Salmonella in Beef Slaughter Operations*,"
- "*Guidance for Beef Grinders and Suppliers of Boneless and Trim Products – Guide for Minimizing Impact Associated with Food Safety Hazards in Raw Ground Meat and Other FSIS Regulated Products*,"
- "*Guidance on Ingredients and Sources of Radiation Used to Reduce Microorganisms on Carcasses, Ground Beef, and Beef Trimmings,*" and
- "*Guidance on the Procedures for Joint Food Safety and Inspection Service (FSIS) and Food and Drug Administration (FDA) – Approval of Ingredients and Sources of Radiation Used in the Production of Meat and Poultry Products*."

In May 1997, FSIS opened the Technical Service Center (TSC), in Omaha, NE, to provide technical assistance and guidance to FSIS meat, poultry, and egg products inspection employees, industry representatives, plant owners and operators, other government agencies, and others on the implementation and enforcement of regulations and policies for both domestic and imported products. The technical assistance and guidance provided daily by the TSC comes from a team of FSIS experts comprised of veterinarians, microbiologists, food technologists, statisticians, management analysts, and others.

In addition, FSIS continuously conducts HACCP demonstration projects to show how HACCP systems are supposed to work for various products and product categories under actual operating conditions in small and very small plants. These demonstration projects began during the 2-year period following the issuance of the final rule, at a number of sites around the country. The HACCP demonstration projects provided the opportunity to answer a number of industry questions and reduced the costs incurred by small establishments in developing HACCP systems.

FSIS has made available guidance materials to assist plants in conducting their hazard analyses and developing HACCP plans. They include a *Guidebook for the Preparation of HACCP Plans*, which was designed to provide the small establishments with a step-by-step approach for developing a HACCP plan; it included examples and sample forms for each step.

The USDA/FDA "*Foodborne Illness Education Information Center,*" was developed and maintains the *HACCP Training Programs and Resources Database*, which provides up-to-date listings of HACCP training programs, resources, and consultants offering training programs or resources. The database can be accessed through the Internet at http://www.nalusda.gov/fnic/foodborne/haccp/index.shtml.

30. Recommendation No. 30

Issue clear written policy on how contaminated carcasses are to be handled when a zero tolerance violation occurs, including the circumstances under which it is appropriate to hold and reinspect all carcasses produced since the last acceptable check.

FSIS Response

FSIS Directive 6420.1, "*Livestock Post-Mortem Inspection Activities-Enforcing the Zero Tolerances for Fecal Material, Ingesta, and Milk*," directs FSIS inspection program personnel on how to enforce the zero tolerance standards. The instructions provided in this directive will ensure that the circumstances for holding and reinspecting all carcasses are clearly defined and in accordance with acceptable and established statistical methodology. FSIS will update this policy with more explicit instructions for handling and re-inspecting contaminated carcasses by December 2003.

31. Recommendation No. 31

Reevaluate FSIS operations in terms of the risks posed to the public by the agency decision not to monitor the disposition of product contaminated with *E. coli* O157:H7 and consider the need to issue regulations that require FSIS to take control of such product and verify that it has been properly processed or destroyed.

FSIS Response

On April 18, 2003, FSIS issued FSIS Notice 11-03 (Enclosure No. 8), "*Update to FSIS Directive 10,010.1, Microbiological Testing Program For Escherichia Coli O157:H7 in Raw Ground Beef.*" The Notice provides updated instructions to inspection program personnel on some of the issues covered by FSIS Directive 10,010.1, "*Microbiological Testing Program For Escherichia Coli O157:H7 in Raw Ground Beef."*

FSIS will provide clear directions on the disposition of product contaminated with *E. coli* O157:H7 in the updated FSIS Directive, 10,010.1, "*Microbiological Testing Program For Escherichia coli O157:H7 in Raw Ground Beef.*" The revised Directive will be issued by October 2003.

The FSIS Notice 11-03, updates and implements procedures that immediately went into effect and were given to inspection program personnel that instructed them to collect raw ground beef samples whenever they received an FSIS Form 10,210-3 for microbiological sampling project MT03. Samples are to be collected regardless of whether the establishment had met criteria set forth in FSIS Directive 10,010.1, VI.B. All raw ground beef, hamburger, ground veal, veal or beef patties, or other products meeting the standard of identity in 9 CFR 319.15, are subject to verification sampling by FSIS. Thus, plants are no longer exempted from sampling based on conducting their own testing.

Under 9 CFR 500.3 FSIS has authority to take enforcement action against any establishment that has been found to have produced and shipped adulterated product. When effectiveness checks disclose that proper notification of the consignee/customers has not been given, FSIS has the authority to detain and, if necessary, subsequently seize products that have been determined to be adulterated. FSIS has prior precedent in applying its enforcement authority.

FSIS is working closely with industry and is providing guidance on the proper and appropriate actions that should be taken during recalls. On December 12, 2002, FSIS held a public meeting to discuss improving the recall process. The Agency is considering ideas presented at the public meeting for increasing industry's involvement in managing recalls.

As part of recall process improvement effort, FSIS will examine and include as appropriate, provisions to establish criteria to assess the overall effectiveness of a recall, to reconcile planned effectiveness checks to those checks actually performed, to identify the corrective actions to be taken when deficiencies are noted. This information will be assembled and formalized a directive. The management controls, responsibilities, and oversight roles for this process will be clearly delineated in a directive.

The workgroup will provide a report outlining recommendations by October 2003. The draft guidelines entitled, "*Office of Field Operations District Office Recall Responsibilities*" which was issued to District Offices in March 2003 will be finalized by March 2004. The final FSIS recommendations will be implemented by July 2004.

Enclosures (9)

ABBREVIATIONS

Act	-	Federal Meat Inspection Act
AER	-	Administrative Enforcement Report
ARS	-	Agricultural Research Service
CCP	-	Critical Control Point
CDC	-	Centers for Disease Control and Prevention
ConAgra	-	ConAgra Beef Company
CFR	-	Code of Federal Regulations
CO	-	Compliance Officer
CS	-	Circuit Supervisor
CSO	-	Consumer Safety Officer
E. coli	-	*Escherichia coli*
FDA	-	Food and Drug Administration
FMFIA	-	Federal Manager's Financial Integrity Act
FSI	-	Food Safety Investigation
FSIS	-	Food Safety and Inspection Service
FSRE	-	Food Safety Regulatory Essentials
Galligan	-	Galligan Wholesale Meat Company
GAO	-	General Accounting Office
GRAS	-	Generally Recognized as Safe
HACCP	-	Hazard Analysis and Critical Control Point
IIC	-	Inspector-In-Charge

IPPS	-	In-Plant Performance System Reviews
ISO	-	International Organization for Standardization
ISP	-	Inspection System Procedure
LEARN	-	Laboratory Electronic Application for Results Notification
Montana Quality Foods	-	Montana Quality Foods & Processing, Inc.
MOU	-	Memorandum of Understanding
NOIE	-	Notice of Intended Enforcement
NR	-	Noncompliance Record
OCP	-	Other Consumer Protections
OCFO	-	Office of the Chief Financial Officer
OFO	-	Office of Field Operations
OIG	-	Office of Inspector General
OPEER	-	Office of Program Evaluation, Enforcement, and Review
OPHS	-	Office of Public Health and Safety
PBIS	-	Performance Based Inspection System
PFGE	-	Pulsed-field Gel Electrophoresis
PPM	-	Parts Per Million
RMD	-	Recall Management Division
SCO	-	Supervisory Compliance Officer
SOP	-	Standard Operating Procedure
SPS	-	Sanitation Performance Standards
SSOP	-	Sanitation Standard Operating Procedures
SVMO	-	Supervisory Veterinary Medical Officer

TSC	-	Technical Service Center
USDA	-	U. S. Department of Agriculture
VMO	-	Veterinary Medical Officer

GLOSSARY OF TERMS

Chub	A tube type package containing processed meat.
Combo	A bin or box containing either 1,000 or 2,000 pounds of beef products.
Fabrication Department	The section of the plant devoted to processing carcasses into primal cuts and other non-intact beef products, such as trim and raw ground beef.
Slaughter Department	The section of the plant devoted to slaughtering cattle and dressing out beef carcasses.
Small Boxing	Procedure of re-packaging beef trim from combo boxes into smaller boxes for re-sale to processing plants that produce fully cooked products. This procedure was followed when combo boxes were rejected at grinding facilities due to positive tests for *E. coli* O157:H7.
Variety Meats Department	The section of the plant devoted to processing offal products.

Informational copies of this report have been distributed to:

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Office of the Chief Financial Officer
Director, Planning and Accountability Division (1)