U.S. Department of Agriculture
Office of Inspector General
Northeast Region

# Audit Report

## Food Safety and Inspection Service Oversight of the *Listeria* Outbreak in the Northeastern United States

Report No. 24601-02-Hy
June 2004

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250

DATE: June 9, 2004

REPLY TO
ATTN OF: 24601-02-Hy

SUBJECT: Food Safety and Inspection Service
Oversight of the *Listeria* Outbreak in the Northeastern United States

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

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

This report presents the results of our audit of Food Safety and Inspection Service's oversight of the *Listeria* outbreak in the Northeastern United States. Your response to the official draft, dated May 4, 2004, is included as exhibit A. Because the enclosures were voluminous, they were not included. Excerpts of your response and the Office of Inspector General's (OIG) position are incorporated into the Findings and Recommendations section of the report. Based on your response, management decisions have been reached on all recommendations except Nos. 1, 3, 5, 6, 7, 8, 10, 11, and 12. Please follow your agency's internal procedures in forwarding documentation for final action to the Office of the Chief Financial Officer. Management decisions for the remaining recommendations can be reached once you have provided the additional information outlined in the report section 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 implementation of the remaining recommendations. Please note that the regulation requires management decision to be reached on all recommendations within 6 months of report issuance.

//s//

ROBERT W. YOUNG
Assistant Inspector General
for Audit

# Executive Summary

***Food Safety and Inspection Service Oversight of the Listeria Outbreak In the Northeastern United States (Audit Report No. 24601-02-Hy)***

**Results in Brief**

This report presents the results of the Office of Inspector General's (OIG) audit of the Food Safety and Inspection Service's (FSIS) oversight of the *Listeria* outbreak in the Northeastern United States in 2002 and FSIS' inspection of plants that initiated recalls of product potentially contaminated with *Listeria monocytogenes*.

FSIS has the responsibility for ensuring that meat and poultry products sold in interstate commerce are safe, wholesome, and accurately labeled. FSIS is required to verify that regulations regarding food safety are being met and products are not contaminated with harmful pathogens. When products present a potential health hazard, a recall is initiated by the plant to remove the adulterated or misbranded products from commerce. FSIS is responsible for overseeing all recall activities by official meat and poultry establishments.

In late August 2002, case-control studies by the Centers for Disease Control and Prevention (CDC) implicated ready-to-eat poultry products as the likely source of illnesses associated with *Listeria monocytogenes* in the Northeastern United States. In September 2002, FSIS initiated sampling of the FSIS-regulated products. From January 1, 2002 to January 3, 2003, there were 15 recalls involving approximately 32.2 million pounds of ready-to-eat products potentially contaminated with *Listeria monocytogenes* that were produced by plants in the Northeastern United States. Our audit focused primarily on the two establishments with the largest recalls, the Pilgrim's Pride Corporation that recalled 27.4 million pounds of ready-to-eat poultry products in October 2002, and Jack Lambersky Poultry Products, Inc., that recalled 4.2 million pounds of ready-to-eat poultry products in November 2002. Our audit work for the Pilgrim's Pride Corporation was limited to FSIS' oversight of the effectiveness of the recall due to an ongoing criminal investigation.

FSIS inspection personnel did not identify material instances of noncompliance at Jack Lambersky Poultry Products, Inc., prior to the recall. This occurred because FSIS' in-plant inspection personnel did not follow inspection regulations and the circuit supervisor provided minimal supervision. For example, we determined that FSIS inspection personnel issued relatively few noncompliance records (NR) at Jack Lambersky Poultry Products, Inc. during 2001 and 2002. FSIS procedures[1] require inspectors to record findings of noncompliance on an NR each time an instance of regulatory noncompliance is found by FSIS. We determined that the plant's

[1] FSIS Directive 5400.5, "Inspection System Activities," January 1998.

quality control staff documented repetitive deficiencies in the plant's sanitation records. Those deficiencies were the same type of issues that FSIS inspection personnel documented as noncompliances at other times. They included construction dust, meat residue on equipment, and leaking ceilings. These repetitive deficiencies were noted during the period when the recalled product was produced.

We also found that plant and inspection personnel did not identify that Jack Lambersky Poultry Products, Inc., should have had a *Listeria* testing program. According to regulations,[2] plants should establish controls for a food safety hazard that is reasonably likely to occur based on plant history. Product samples taken by FSIS in 1990 and 1994 from the Jack Lambersky Poultry Products, Inc., plant tested positive for *Listeria monocytogenes*. According to the FSIS Consumer Safety Officer that reviewed plant operations in October 2002, Jack Lambersky Poultry Products, Inc., reassessed its Hazard Analysis and Critical Control Point (HACCP) plan in 1999 and incorrectly concluded that *Listeria monocytogenes* was not a hazard likely to occur.

Subsequent to the recall, FSIS inspection services did not materially improve. Along with the circuit supervisor, we observed the inspector completing his daily inspection procedures regarding product sampling, plant sanitation, product temperature monitoring, and product labeling. A scheduled inspection procedure for product temperature monitoring provides an indication of whether the plant is ensuring that processing conditions do not promote the growth of *Listeria monocytogenes*. This allows the inspector to validate that proper temperatures are maintained and documented by the plant. In performing this procedure, the inspector demonstrated that he was not aware of how the plant documented its monitoring of temperature.

FSIS did not verify the completeness of the Jack Lambersky Poultry Products, Inc., recall. Compliance officers did not obtain and verify documentation supporting the pounds of recalled products produced by the plant and the pounds returned or destroyed by customers. For example, our audit tests showed that the firm had no documentation to support the 136,067 pounds returned to the plant by customers. The firm calculated this amount by subtracting the amount held in inventory from the total amount destroyed at the landfill. As a result, FSIS could not be reasonably certain that all recalled products had been removed from commerce.

To evaluate FSIS' oversight of the recall process, we reviewed 13 of the 15 recalls of ready-to-eat product potentially contaminated with *Listeria monocytogenes.* Plants in the Northeastern United States produced the recalled product from January 1, 2002 to January 3, 2003. We found weaknesses in FSIS' management control and oversight of the recall process.

[2] 9 C.F.R. §417.2(a), January 2002.

These weaknesses were similar to those we identified in our review of the ConAgra Beef Company (ConAgra) recall[3] in that FSIS' oversight of the recalls was ineffective.

- FSIS had no assurance that the recalls of ready-to-eat product potentially contaminated with *Listeria monocytogenes* were effective. FSIS did not critically review recall final reports and other information supporting the agency's oversight of food safety recalls. FSIS' primary method for validating the completeness of recalls is the effectiveness check, a documented visit or phone call to businesses or other entities who received the recalled product. For example, the FSIS Beltsville District Office did not perform effectiveness checks to ensure that almost 279,000 pounds of product recalled by Jack Lambersky Poultry Products, Inc., were properly controlled. In 2002, there were 15 plants in the Northeastern United States that recalled approximately 32.2 million pounds of ready-to-eat poultry products potentially contaminated with *Listeria monocytogenes*. As a result, there is an increased risk that product was not removed from commerce.

- FSIS did not ensure that the recall of 1.7 million pounds of ready-to-eat poultry products distributed for use in the National School Lunch Program purchased by the U.S. Department of Agriculture from the Pilgrim's Pride Corporation was effective. We identified 351 discrepancies in the data documented on the 362 effectiveness checks. (An effectiveness check may have more than one discrepancy.) Examples of these discrepancies included instances where FSIS Compliance Officers did not accurately determine product disposition and did not perform required followup reviews. These types of discrepancies were pervasive because FSIS procedures did not require supervisory review to ensure the effectiveness checks were fully completed.

We found that in conjunction with the CDC, the FSIS Office of Public Health and Science took appropriate action in investigating the *Listeria* outbreak in 2002. FSIS performed an extensive trace-back analysis that included product sampling, plant questionnaires, and interviews with *Listeria* case patients. Using patients' shopping histories and market analysis, FSIS visited delicatessens, supermarkets, and convenience stores that sold the potentially contaminated product.

## Recommendations in Brief

FSIS needs to develop and implement a plan to address the weaknesses in inspection services provided to Jack Lambersky Poultry Products, Inc. The plan should address the level of supervision necessary for achieving an

[3] Audit Report No. 24601-2-KC, "Food Safety and Inspection Service Oversight of Production Process and Recall at ConAgra Plant (Establishment 969)," issued September 30, 2003.

acceptable level of performance by the inspector in applying HACCP requirements.

FSIS should also develop and implement procedures requiring compliance officers to validate the accuracy of recall documentation provided by the firm. These procedures should ensure that all recalled products are appropriately accounted for, with emphasis on products distributed to schools and other institutions serving vulnerable populations.

**Agency Response**

FSIS generally agreed with the report's recommendations. We have incorporated excerpts from FSIS' response in the Findings and Recommendations section of this report, along with the OIG position. FSIS' response is included as Exhibit A. Because the enclosures were voluminous, they were not included.

**OIG Position**

Based on FSIS' response, we were able to reach management decision on 3 of the report's 12 recommendations. The Findings and Recommendations section of this report provides the details of the additional information needed to reach management decision on Recommendation Nos. 1, 3, 5, 6, 7, 8, 10, 11, and 12.

## *Abbreviations Used in This Report*

| | |
|---|---|
| AMS | Agricultural Marketing Service |
| CDC | Center for Disease Control and Prevention |
| C.F.R. | Code of Federal Regulations |
| ConAgra | ConAgra Beef Company |
| CSI | Consumer Safety Inspectors |
| *E. coli* | Escherichia coli |
| EIAO | Enforcement Investigations and Analysis Officer |
| FNS | Food and Nutrition Service |
| FSIS | Food Safety and Inspection Service |
| FSRE | Food Safety Regulatory Essentials |
| HACCP | Hazard Analysis and Critical Control Point |
| NR | Noncompliance Record |
| IPPS | In-plant Performance System |
| NSLP | National School Lunch Program |
| 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 Science |
| OPPD | Office of Policy and Program Development |
| PBIS | Performance Based Inspection System |
| RTE | Ready-To-Eat |
| SSOP | Sanitation Standard Operating Procedures |
| USC | United States Code |
| USDA | U.S. Department of Agriculture |

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# Background and Objectives

## Background

The Food Safety and Inspection Service (FSIS) is the public health regulatory agency within the U.S. Department of Agriculture (USDA). FSIS is responsible for protecting consumers by ensuring that meat, poultry, and egg products are safe, wholesome, and accurately labeled.

Operating under the authority of the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, FSIS is required to inspect and regulate all raw and processed meat, poultry, and egg products sold in interstate commerce to ensure that they are not adulterated. More than 7,600 inspection personnel verify that regulations regarding food safety and other consumer protection concerns are met in over 6,500 meat, poultry, and egg processing plants.

In addition to inspection activities, FSIS has responsibilities including setting food safety standards for plant facilities and processing procedures; testing for microbiological, chemical, and other types of contamination; and conducting epidemiological investigations in cooperation with the Centers for Disease Control and Prevention (CDC) based on reports of food borne health hazards and disease outbreaks. FSIS also has responsibilities for conducting risk assessments and other scientific studies to estimate human health outcomes associated with the consumption of meat, poultry, and egg products and performing enforcement activities to address situations where unsafe, unwholesome, or inaccurately labeled products have been produced or marketed.

FSIS administers its inspection program primarily through the Office of Policy and Program Development (OPPD), Office of Public Health and Science (OPHS), and Office of Field Operations (OFO).

- The OPPD, through the Regulations and Directives Development Staff, is responsible for: (1) managing the development and drafting of Agency regulations and directives; (2) maintaining administrative records such as pubic comments and recommendations associated with regulatory issuances; (3) conducting regulatory analysis to ensure that regulations are consistent with program objectives, statutory requirements, and departmental policies; and (4) preparing and publishing notification of public hearings, meetings, and scientific conferences.

- The OPHS collects, analyzes, and reports scientific information related to meat, poultry, and egg products. The information is used to monitor production processes and identify and evaluate potential food borne hazards. OPHS and the Recall Management Division, which is part of OFO, are responsible for: (1) responding to recognized, emerging, or

potential threats to the food supply; (2) conducting trace-back or trace-forward investigations to identify product disposition and the origin of hazards; and (3) coordinating all recall activities associated with products believed to be contaminated or adulterated.

- The OFO is responsible for planning, providing leadership, formulating and coordinating policies, and directing the administration of inspection programs and activities to ensure that meat, poultry, and egg products are safe, wholesome, and properly labeled. OFO accomplishes these responsibilities through the 15 district offices. The district offices, through the circuit supervisors, are to exercise supervisory control of the inspection process performed by inspectors at plants within their jurisdictions. During a meat or poultry recall, the district offices are responsible for closely monitoring the effectiveness of the firm's recall procedures to ensure that all reasonable efforts have been made to effect the recall and that all available product has been removed from commerce.

FSIS also has responsibility for ensuring that ready-to-eat products, such as luncheon meats and deli-style products, are not contaminated with harmful pathogens such as *Listeria monocytogenes*. Ready-to-eat products are adulterated if they contain *Listeria monocytogenes* or if they come into direct contact with a food contact surface that is contaminated with the pathogen.

*Listeria monocytogenes* is a pathogenic bacterium found in the environment (e.g., soil, water, vegetation, and on the surfaces of equipment, floors and walls) and is often carried by healthy animals (including humans). It grows under low-oxygen conditions and at low refrigeration temperatures and survives for long periods of time in the environment, on foods, in processing plants, and in household refrigerators. *Listeria* can contaminate and grow in ready-to-eat products if they are not formulated or produced in a manner to destroy or suppress the growth of the organism.

In a processing plant, products can be contaminated with *Listeria monocytogenes* if the pathogen is already present in product ingredients or if there is a processing error, such as incorrect formulation or inadequate processing time or temperature. Also, a product that has undergone a successful lethality treatment to kill *Listeria monocytogenes* can be contaminated by biofilms on food-contact surfaces of equipment used for processing, handling, or packaging the product. In addition, product can be exposed to environmental contamination during post-lethality processing. This contamination could be caused by a plant's failure to take adequate precautions during construction or remodeling. This contamination could also be caused by poorly designed facilities or equipment with hard-to-reach niches that harbor the pathogen. Furthermore, product contamination can occur if raw and finished products, equipment, or plant personnel cross between raw and finished product areas.

The consumption of food contaminated with *Listeria monocytogenes* can cause listeriosis, an uncommon but potentially fatal disease. Newborns, pregnant women, elderly adults, and people with weakened immune systems are at a greater risk of becoming ill from eating foods contaminated with *Listeria monocytogenes*. The disease can cause high fever, severe headache, nausea, infections, and miscarriages and stillbirths. According to a 1999 study conducted by CDC, there are approximately 2,500 cases of listeriosis annually in the United States, resulting in approximately 500 deaths. Based on CDC's surveillance data, the number of listeriosis cases declined by 38 percent from 1996 to 2002.

From January 1, 2002 to January 3, 2003, there were 15 recalls involving approximately 32.2 million pounds of product potentially contaminated with *Listeria monocytogenes* that were produced by plants in the Northeastern United States, which led to 6 deaths and 36 illnesses in 8 States.

In September 2002, FSIS initiated sampling of FSIS-regulated products when illnesses associated with *Listeria monocytogenes* emerged. On October 12, 2002, FSIS announced that the Pilgrim's Pride Corporation was recalling approximately 27.4 million pounds of fresh and frozen ready-to-eat poultry products that were potentially contaminated with *Listeria monocytogenes*. These products were produced between May 1, 2002 and October 11, 2002, and were distributed to retail stores, restaurants, and institutions nationwide.

The Pilgrim's Pride Corporation recall included approximately 1.8 million pounds of turkey products purchased by USDA for distribution to schools and other recipient agencies. Of the 1.8 million pounds destined for schools, USDA determined that 160,000 pounds of the product was never shipped and was held at the plant, leaving approximately 1.7 million pounds to be accounted for. A total of 20 States received the product by the time the recall notification was announced. Of the 20 affected States, 14 States reported that product was sent to the school level, and 6 States reported that the product was on hold in State warehouses.

On November 2, 2002, FSIS announced that Jack Lambersky Poultry Products, Inc., voluntarily recalled approximately 200,000 pounds of fresh and frozen ready-to-eat poultry products that may have been contaminated with *Listeria monocytogenes*. FSIS' testing revealed that ready-to-eat poultry products were contaminated with a strain of *Listeria monocytogenes* that was indistinguishable from the outbreak strain, which affected victims in the Northeastern United States. In addition to the recall, the establishment voluntarily suspended its operations pending the results of additional testing. On November 20, 2002, an FSIS microbiological investigative sample collected by FSIS on November 14, 2002, returned positive for

*Listeria monocytogenes*. On November 21, 2002, the recall was expanded to approximately 4.2 million pounds of poultry products produced between May 29, 2002 and November 2, 2002.

At the request of the Senate Committee on Agriculture, Nutrition, and Forestry, we performed an audit of FSIS' oversight of the recall by the ConAgra Beef Company (ConAgra) of 18 million pounds of ground beef and beef products suspected of being contaminated with Escherichia coli *(E. coli)* O157:H7. (Audit Report No. 24601-02-KC, issued September 30, 2003.) In view of the serious conditions found during that audit, we initiated work in October 2002, to evaluate USDA's response regarding the Pilgrim's Pride recall. We made an initial assessment of activities at the establishment in Franconia, Pennsylvania and expanded our review to include FSIS' oversight of the *Listeria* outbreak in the Northeastern United States. We limited our review of the Pilgrim's Pride Corporation to FSIS' oversight of the recall due to an ongoing criminal investigation.

## Objectives

The objective of our review was to evaluate FSIS' oversight of the *Listeria* outbreak in the Northeastern United States in 2002 and FSIS' inspection of plants that initiated recalls of product potentially contaminated with *Listeria monocytogenes*. This evaluation included: (1) a review of inspector supervision, noncompliance records (NR), potential contamination, sampling procedures, *Listeria* testing, and scheduled inspection procedures at selected plants; (2) a determination of whether existing FSIS procedures were adequate and were being followed; (3) an assessment of FSIS' oversight of recalled products donated for use in the National School Lunch Program (NSLP); and (4) an assessment of FSIS' investigation and response to the *Listeria* outbreak.

To accomplish the objective, we visited FSIS headquarters, two district offices, and two circuits. Also, we conducted fieldwork at two selected plants and their respective administrative offices and facilities for storing recalled product. In addition, we performed work at the Food and Nutrition Service (FNS) and Agricultural Marketing Service (AMS) headquarters, four State education offices, and six county school districts. Our audit work primarily covered the period January 2002 through July 2003.

# Findings and Recommendations

## Section 1. Inspection Services at Jack Lambersky Poultry Products, Inc.

Jack Lambersky Poultry Products, Inc., is responsible for producing safe and wholesome products. However, on November 20, 2002, a microbiological investigative sample collected by FSIS and produced at Jack Lambersky Poultry Products, Inc., returned positive for *Listeria monocytogenes*. The strain of *Listeria monocytogenes* found in this sample matched the strain of the pathogen associated with illnesses and deaths from Listeriosis in the Northeastern United States in 2002. As a result, on November 21, 2002, the plant voluntarily recalled approximately 4.2 million pounds of ready-to-eat poultry products potentially contaminated with *Listeria monocytogenes*. The poultry products were produced between May 29, 2002 and November 2, 2002.

FSIS has the responsibility for ensuring that poultry products sold in interstate commerce are safe and wholesome. FSIS district offices, through the circuit supervisors, are to exercise supervisory control of the inspection process performed by inspectors at plants within their jurisdictions.

We found that FSIS inspection personnel did not identify material instances of noncompliance at the Jack Lambersky Poultry Products, Inc., plant preceding the recall. For example, inspection personnel failed to correct the plant's potential contamination of product, which occurred when exposed finished product passed through the raw product area. We also found that inspection personnel did not identify that the plant needed a *Listeria* testing program. These conditions occurred because inspection personnel did not follow established procedures. In October 2002, the FSIS Consumer Safety Officer also identified these conditions as part of the comprehensive assessment of the plant's operations.

FSIS' inspection services did not materially improve subsequent to the recall. For example, we observed along with the circuit supervisor, that the inspector could not complete a routine procedure for determining how the plant documents its monitoring efforts with the Hazard Analysis and Critical Control Point (HACCP) plan.

FSIS did not obtain adequate documentation from Jack Lambersky Poultry Products, Inc., to determine if the plant identified and accounted for all product subject to the recall. Consequently, FSIS cannot ensure that all reasonable efforts were made to remove from commerce the approximately 4.2 million pounds of product potentially contaminated with *Listeria monocytogenes.*

## Finding 1 Weaknesses in Inspection Services Prior to the Recall

FSIS inspection personnel did not identify some ongoing insanitary practices as defined in the Poultry Products Inspection Act at the Jack Lambersky Poultry Products, Inc., plant preceding the recall of ready-to-eat poultry products. This occurred because FSIS' in-plant inspection personnel did not follow inspection regulations and the circuit supervisor provided minimal supervision. Thus, FSIS did not enforce regulations intended to ensure that poultry products were safe and wholesome.

Because of insanitary practices at Jack Lambersky Poultry Products, Inc., in November 2002, the firm recalled approximately 4.2 million pounds of ready-to-eat poultry products potentially contaminated with *Listeria monocytogenes*.

FSIS is responsible for enforcing food safety regulations and inspecting poultry products to ensure they are safe and wholesome.[4] Field personnel are required to protect the public health by properly verifying an establishment's compliance with pathogen reduction, sanitation, and HACCP regulations.[5]

The following represent the types of inadequacies we found in the inspection services provided by FSIS at Jack Lambersky Poultry Products, Inc.

- Number of Plant Deficiencies Recorded by FSIS Inspectors was Relatively Few.

  A NR serves as FSIS' official record of noncompliance with one or more regulatory requirements by an establishment. According to FSIS procedures,[6] an inspector is required to record findings of noncompliance on an NR each time an instance of regulatory noncompliance is found by FSIS.

  During 2001 and 2002, FSIS inspection personnel issued relatively few NRs at Jack Lambersky Poultry Products, Inc. For example, only one NR was written at the plant in 2001. Furthermore, from May 29, 2002 to August 12, 2002, when recalled product was produced, FSIS issued no NRs. We shared this information with the in-plant inspection personnel and the circuit supervisor who agreed that the lack of NRs for this plant did not seem appropriate.

[4] The Poultry Products Inspection Act, 21 United States Code (U.S.C.) Chapter 10.
[5] FSIS Directive 5000.1, "Enforcement of Regulatory Requirements in Establishments Subject to HACCP System Regulations," January 1998, and FSIS Directive 5000.1, Revision 1, "Verifying an Establishment's Food Safety System," May 21, 2003.
[6] FSIS Directive 5400.5, "Inspection System Activities," January 1998.

The plant's quality control staff documented repetitive deficiencies in the plant's sanitation records. Those deficiencies were the same type of issues that FSIS inspection personnel documented as noncompliances at other times. For the period May 29, 2002 to August 12, 2002, the deficiencies included such things as construction dust, meat residue on equipment, and leaking ceilings. This was the period in which no NRs were issued and recalled product was produced.

Some deficiencies were shown to be "corrected" multiple times in a single day, according to plant records. For example, condensation was identified on the doorframe between the fry and oven room cooler on September 26, 2002, at 6 a.m. According to plant records, this condition was corrected, and identified again at 9 a.m. the same day and corrected again. In total, the same deficiency, at the same location in the plant was documented and shown to be corrected a total of five times in a single day. Further, we identified at least five additional days where this exact problem was reported and shown to be "corrected" three or more times in a single day. This led us to question whether corrective action taken by the plant was appropriate.

In discussing this issue with high-level FSIS officials, we were advised that an issue of this nature might not cause concern if it occurred in the raw product area, rather than in the finished, ready-to-eat product area. However, as described in the following section, cooked product was taken through the raw product area on the way to the cooler. Thus, we concluded that these repetitive issues were cause for concern.

According to in-plant inspection personnel, they periodically reviewed the deficiencies noted in the plant's sanitation records. However, the in-plant inspection personnel claimed that they did not record repetitive sanitation deficiencies identified by FSIS and similar to those noted by the plant on an NR because after informing the plant of the deficiency, the plant immediately took action to correct the problem. The FSIS Philadelphia District Office noted the lack of NRs written by inspectors in the District as a concern. In October 2002, District management distributed its priorities to District inspection personnel. In this document, District management emphasized that inspection personnel must write NRs. Further, District management considered it an unacceptable practice for the inspector to merely inform the plant verbally of noncompliance with regulatory requirements without documentation.

- Potential Product Contamination Not Timely Corrected

  If exposed finished product crosses through raw product areas, product contamination may occur. According to regulations,[7] plants are required to segregate exposed finished product from raw product to help prevent product contamination. At Jack Lambersky Poultry Products, Inc., FSIS inspection personnel identified that cooked product traveled through the raw product area on its way to the cooler. According to the FSIS Consumer Safety Officer who reviewed plant operations, finished product exposure to raw product areas might have contributed to the product becoming contaminated with *Listeria monocytogenes*.

  An inspector, who was at the plant from April 7, 2002 through October 8, 2002, was aware that this practice was occurring. However, the inspector issued no NRs to address this deficiency. The inspector claimed no NRs could be issued because FSIS could not control a plant's production flow. The circuit supervisor concurred with the inspector's claim. However, the FSIS Consumer Safety Officer recommended corrective action as part of the review performed in October 2002. On November 13, 2002, the plant submitted procedures to the district office for decreasing the potential product contamination.

- Plant's Need for a *Listeria* Testing Program Not Identified.

  Product samples taken by FSIS in 1990 and 1994 from the Jack Lambersky Poultry Products, Inc., plant tested positive for *Listeria monocytogenes*. According to regulations,[8] plants should establish controls for a food safety hazard that is reasonably likely to occur based on plant history. Based on the previous positive test results, plant and inspection officials should have identified *Listeria* as a food safety hazard that was likely to occur.

  According to the FSIS Consumer Safety Officer that reviewed plant operations, Jack Lambersky Poultry Products, Inc., reassessed its HACCP plan in 1999 and incorrectly concluded that *Listeria monocytogenes* was not a hazard likely to occur. Consequently, Jack Lambersky Poultry Products, Inc., had no testing program for *Listeria monocytogenes* and did not outline preventive measures to control the hazard in its HACCP plan until October 2002, when it included a testing program in response to the Consumer Safety Officer's review. *Listeria* testing is a way of indicating whether or not the pathogen is present.

[7] Title 9, Code of Federal Regulations (C.F.R.) §416.2(b)(4), January 2002.
[8] 9 C.F.R. §417.2(a), January 2002.

According to FSIS District inspection officials, inspection personnel at the plant lacked sufficient training to adequately review HACCP plans and to detect that *Listeria monocytogenes* was not identified as a potential hazard. In April 2003, FSIS initiated HACCP training for inspectors to reinforce their food safety duties. The training included such topics as HACCP verification, pathogen reduction, and food safety sampling. Unlike initial HACCP training, the training on food safety duties is tailored to an inspector's assignment based on the types of products produced at the plant where inspectors are assigned. In May 2003, FSIS issued a revised directive[9] on verifying a plant's food safety system. This directive provides comprehensive direction to inspection 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 training for the more than 400 inspectors in the Philadelphia District began in October 2003. The District plans to complete training of all inspectors in 2004. Accordingly, we are making no additional recommendations regarding training for inspectors.

As noted in our report on the ConAgra recall,[10] FSIS inspection personnel lacked the skills to critically analyze the adequacy of HACCP plans. In response to this finding, FSIS committed to hire and train a force of consumer safety officers to help review HACCP plans. Our assessment of FSIS' response disclosed that it lacked an analysis of how many qualified staff will be needed to review all HACCP plans and how much time will be needed to complete the reviews. Accordingly, we recommended the development of a written, time-phased plan for completing consumer safety officer reviews of HACCP plans. We continue to work with FSIS to reach agreement on an acceptable corrective action plan.

During the course of our review, we learned that Jack Lambersky Poultry Products, Inc., implemented a *Listeria* testing program in August 2002 to address concerns raised by a customer. The customer paid for a consultant to review the operations at the plant. Plant officials then worked with the consultant to develop its *Listeria* testing program. FSIS was aware that the plant had implemented the program and FSIS reviewed the test results. According to our analysis of the plant's test results, the percentage of environmental samples testing positive for *Listeria* had decreased since implementation of the testing program. In August 2002, 18 percent of the environmental samples tested positive for *Listeria*. In May 2003, only 0.5 percent of the environmental samples tested positive for *Listeria*.

The plant's HACCP plan now identifies *Listeria monocytogenes* as a potential food safety hazard. Furthermore, the HACCP plan now includes

[9] FSIS Directive 5000.1, Revision 1, "Verifying an Establishment's Food Safety System," May 21, 2003.
[10] Audit Report No. 24601-2-KC, "Food Safety and Inspection Service Oversight of Production Process and Recall at ConAgra Plant (Establishment 969)," issued September 30, 2003.

finished product testing on a monthly basis for *Listeria monocytogenes*. These actions are consistent with changes in inspection procedures, which require plants to have controls to prevent products from being contaminated with *Listeria monocytogenes*.[11]

- Supervision of Inspection Personnel was Minimal.

  An FSIS Circuit Supervisor oversees the work of in-plant inspection personnel by periodically observing an inspector perform his/her duties and reviewing documentation of inspection activities on file at the plant. Through an analysis of time and attendance reports, we determined the circuit supervisor did not visit Jack Lambersky Poultry Products, Inc., from June 2, 2002 through September 21, 2002, when recalled product was produced. According to the circuit supervisor, his workload at 56 plants hindered his oversight of FSIS inspection personnel at Jack Lambersky Poultry Products, Inc. The Deputy District Manager informed us that she provided minimal oversight and supervision to the circuit supervisor.

  In October 2002, FSIS' Philadelphia District Office implemented the agency procedure[12] that requires the circuit supervisor to perform and document three reviews per year for each inspector. This procedure formalized FSIS' process for evaluating inspector performance. However, the circuit supervisor informed us that he did not implement this review at the Jack Lambersky Poultry Products, Inc., plant due to the oversight being provided as part of the recall.

  In November 2002, Jack Lambersky Poultry Products, Inc., recalled approximately 4.2 million pounds of ready-to-eat poultry products that were potentially contaminated with *Listeria monocytogenes*. Because FSIS did not identify material instances of noncompliance by the plant, the agency did not take action that could have prevented the potential contamination. Further, inspection personnel did not recognize that the plant should have had a *Listeria* testing program prior to the recall. To address the deficiencies in inspection services at Jack Lambersky Poultry Products, Inc., FSIS should develop and implement a plan to strengthen inspector performance and supervisory oversight.

### Recommendation No. 1

Develop and implement a plan to address the weaknesses in inspection services provided at Jack Lambersky Poultry Products, Inc. The plan should address ways to strengthen inspector performance and supervisory oversight.

[11] FSIS Directive 10,240.3 "Microbial Sampling of Ready-to-Eat Products for the FSIS Verification Testing Program," December 9, 2002. These changes were codified in regulations in October 2003 at 9 C.F.R. §430.
[12] FSIS Directive 4430.3, "In-Plant Performance System Reviews," June 17, 2002.

**Agency Response.**

To address the issues identified at Jack Lambersky Poultry Products, Inc. (Jack Lambersky), FSIS stated that the agency took immediate and positive corrective action, to include a comprehensive food safety assessment that was performed, along with product and environmental sampling, from September 30, 2002 to October 4, 2002. As a result of that assessment, a Notice of Intended Enforcement was issued on October 7, 2002. The company responded with a written summary plan of corrective actions and preventative measures and, subsequently, a Deferral Action was issued on November 1, 2002. The firm worked under the deferral action along with a very specifically designed Verification Plan used by the inspection team at the plant to verify the various corrective actions. During the verification period, both environmental sampling and finished ready-to-eat (RTE) product sampling took place, which were used to verify the effectiveness of the corrective actions. All samples taken were reported negative for *Listeria* and subsequently, a Letter of Information dated, April 14, 2003, was issued closing the action.

The company also hired a consultant and reassessed its Sanitation Standard Operating Procedures (SSOP) and HACCP plans. The reassessment addressed product handling, product flow, and processing. The firm installed a post-pasteurization process for the fully cooked ready-to-eat items as an additional lethality step. Jack Lambersky has established an ongoing *Listeria* sampling plan for environmental and finished product. Ongoing FSIS verification sampling from November 2002 to January 2004 has been negative.

Several relief GS-10 Consumer Safety Inspectors (CSI) with knowledge of RTE fully cooked products were detailed in November 2002, to Jack Lambersky. They assisted in providing additional inspection expertise in monitoring the progress under the Verification Plan.

The two (2) CSIs that were rotating on the Jack Lambersky assignment during 2002 are no longer on the assignment. One has retired and the other is on Leave Without Pay while in the process of applying for disability retirement.

All CSIs, including relief inspectors with the Philadelphia District, have been, or are scheduled, to attend the Food Safety Regulatory Essentials (FSRE) training by June 2004. The FSRE training stresses the understanding of HACCP concepts along with production and handling of RTE fully cooked product. The CSI's currently assigned at Jack Lambersky have attended the FSRE training.

In addition, the Trenton Circuit has been restructured to more equitably distribute the workload between circuits. This allows the Circuit Supervisor to spend more time with plants encountering problems. In addition, the Circuit Supervisor has attended the Frontline Supervisor Training developed by FSIS to enhance supervisory skills.

The District Manager has restructured the Circuit reporting lines to each Deputy District Manager so that there is a more equitable distribution of supervisory workload. The responsible deputies can then give more attention to circuits and plants encountering problems within their jurisdiction.

FSIS has focused extensively during the past two years on strengthening supervisory oversight of in-plant inspection personnel. The In-plant Performance System (IPPS) is in place and circuit supervisors have clear standards and expectations for discussion with in-plant inspection personnel during their on-site visits. This system establishes a formal process so frontline supervisors can be sure that inspection personnel carry out their assigned job responsibilities. All field supervisors have been trained to use this system. The IPPS review helps the supervisor to: identify and address the need to improve an employee's knowledge about his or her responsibilities; correlate employees to ensure consistency in methods and application of methods; identify and address performance problems; and recognize and reward successful employee performance.

**OIG Position.**

FSIS' response to the recommendation summarizes a number of items we analyzed during our fieldwork and reported on in Finding No. 1 (e.g., comprehensive food safety assessment, consultant hired by Jack Lambersky Poultry Products, Inc., performance by in-plant inspection personnel, and training of inspectors on food safety duties). In addition, FSIS' response describes the restructuring of the Philadelphia District and the Trenton Circuit as well as the implementation of IPPS as the techniques used to strengthen supervisory oversight of in-plant inspection personnel. However, the response does not specify dates when actions occurred or how the agency will obtain assurance that the necessary improvements are in place at Jack Lambersky Poultry Products, Inc.

To reach management decision, FSIS needs to provide the dates that the inspectors at Jack Lambersky Poultry Products, Inc. attended the FSRE Training. FSIS needs to provide the dates when the Trenton Circuit Supervisor attended the Frontline Supervisor Training. Finally, FSIS needs to provide the dates when it expects to complete an assessment to validate that inspector performance and supervisory oversight have been strengthened and that the Trenton Circuit Supervisor is using IPPS to evaluate how inspection personnel carry out their assigned job responsibilities.

## Recommendation No. 2

Clarify, in writing, with FSIS inspection personnel the requirements for plants to segregate exposed finished product from raw product to help prevent product contamination.

### Agency Response.

It is not necessary to amend agency procedures to establish such a requirement since establishments have a responsibility to meet 9 C.F.R. 416.1. In accordance with 9 C.F.R. 416.1 each official establishment is required to operate and be maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated. Under 9 C.F.R. 430.4, "*Control of Listeria monocytogenes in post-lethality exposed ready-to-eat products*" establishments are required to maintain sanitation in the post-lethality processing environment in accordance with 9 C.F.R. 416. Further, it is not consistent with the policy framework of the Pathogen Reduction/HACCP regulation to specify to plants how to construct their control systems. FSIS procedures and regulatory requirements include an assessment of specified establishments by a trained Enforcement Investigations and Analysis Officer (EIAO) of the scientific design of industry HACCP plans and food safety systems.

Trained EIAOs are capable of conducting a complete assessment of the design of a plant's control systems. These systems include HACCP and SSOP, generic *E. coli* testing procedures, and Salmonella data. The EIAO assessment involves consideration of all food safety aspects related to the establishment and the products, processes, and environment within the establishment.

On October 2, 2003, FSIS issued FSIS Directive 10,240.4, "*Verification Procedures for Listeria monocytogenes Regulations and Microbial Sampling of Ready-to-Eat (RTE) Products for the FSIS Verification Testing Program*." This directive provides CSIs and EIAOs with instructions for verifying whether establishments are complying with regulations in 9 C.F.R. part 430, *Requirements for Specific Classes of Product*. In addition, this directive includes verification procedures for RTE products other than those applicable to 9 C.F.R. 430.

### OIG Position.

We accept FSIS' management decision. The directive issued subsequent to audit fieldwork includes detailed instruction for verifying compliance. For final action, FSIS needs to provide the Office of the Chief Financial Officer (OCFO) with documentation showing that FSIS Directive 10,240.4, issued

October 2, 2003, has been adequately implemented at Jack Lambersky Poultry Products, Inc.

## Finding 2 Weaknesses in Inspection Services Subsequent to the Recall

FSIS provided inadequate inspection services at the Jack Lambersky Poultry Products, Inc., plant following the recall of ready-to-eat poultry products. This occurred because the inspector was not able to correctly perform routine inspection procedures, as demonstrated to us during our audit. As a result, FSIS is not enforcing regulations to ensure that poultry products being produced by Jack Lambersky Poultry Products, Inc., are safe and wholesome.

According to FSIS procedures,[13] agency personnel are responsible for enforcing food safety regulations and inspecting poultry products to ensure they are safe and wholesome. Field personnel are to protect the public health by properly verifying an establishment's compliance with pathogen reduction, sanitation, and HACCP regulations.[14] FSIS is also responsible for maintaining the security and integrity of laboratory samples.[15]

The inspector at the Jack Lambersky Poultry Products, Inc., is assigned to the plant for a 6-month period. In April 2003, the inspector began his rotation, which was two weeks before our first visit to the plant. Before being assigned to Jack Lambersky Poultry Products, Inc., the inspector performed similar inspection assignments at other plants within the circuit. The following represent the types of inadequacies we found in the inspection services provided by FSIS at Jack Lambersky Poultry Products, Inc.

- Inspection Personnel Inadequately Completed Scheduled Procedures.

  Scheduled procedures are assigned by FSIS' Performance Based Inspection System (PBIS) for inspectors to verify an establishment's compliance with pathogen reduction, sanitation, and HACCP requirements. On May 14, 2003, we observed the FSIS inspector perform scheduled procedures regarding plant sanitation, product temperature monitoring, and product labeling. While being observed by the circuit supervisor, the inspector failed to properly complete the scheduled procedures. The circuit supervisor took control of the situation to ensure the procedures were correctly performed.

  A scheduled procedure for product temperature monitoring provides inspection personnel an indication of whether the plant is ensuring that

[13] The Poultry Products Inspection Act, 21 U.S.C. Chapter 10.
[14] FSIS Directive 5000.1, "Enforcement of Regulatory Requirements in Establishments Subject to HACCP System Regulations," January 1998, and FSIS Directive 5000.1, Revision 1, "Verifying an Establishment's Food Safety System," May 21, 2003.
[15] FSIS Directive 7355.1, Revision 2, "Use of Sample Seals for Laboratory Samples and Other Applications," dated December 3, 2002.

processing conditions do not promote the growth of *Listeria monocytogenes*. This is because the procedure tests how a plant monitors adherence to critical temperatures in the production process. Jack Lambersky Poultry Products, Inc., included critical control points at the cooking, cooling, and post-pasteurization phases in the production process. The plant identified these as points in the process where *Listeria monocytogenes* is a potential hazard if proper temperatures are not maintained. In performing the scheduled procedure for product temperature monitoring, the inspector demonstrated that he was not aware of how the plant documented its monitoring efforts with the HACCP plan.

- Inspection Personnel Did Not Correctly Perform Sampling Procedures.

  FSIS in-plant inspection personnel did not secure samples for pick-up by a shipping agent and did not select product samples randomly.

  Custody of Samples Not Secured. In response to the recall, the FSIS Philadelphia District Office implemented a verification-sampling regimen at Jack Lambersky Poultry Products, Inc. As instructed by the district office, this regimen consisted of one randomly selected finished product sample per week for 16 consecutive weeks. Each random sample would then be tested for *Listeria monocytogenes* at one of the three nationwide FSIS laboratories. The inspector must box and ship the sample using a shipping agent.

  On April 24, 2003, we observed the inspector select a finished product sample as part of the verification-sampling regimen. Upon selecting the sample, the inspector placed it in a box and sealed it with a shipping agent's label. The inspector then placed the sample at the loading dock entrance of the plant awaiting pick-up by the shipping agent. The sample was unsecured as the inspector departed the plant for the day. FSIS procedures do not require inspectors to maintain custody of samples before collection by a shipping agent. As noted in our report on the ConAgra recall, FSIS lacked instructions requiring inspectors to maintain custody of samples before being collected by the shipping agent. Accordingly, we recommended revising 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. We continue to work with FSIS to obtain an acceptable action plan to correct this weakness. Therefore, no additional recommendations will be made as a result of this review.

  Product Samples Not Randomly Selected. The Philadelphia District Office's verification-sampling regimen consisted of one randomly selected finished product sample per week for 16 consecutive weeks. Instead of taking the sample on varying days of the week (i.e., randomly), we found

that FSIS inspection personnel took 15 of the 16 samples on the same day of the week each week. This method of taking the sample provided the plant with the ability to predict which day of the week the sample would be taken. This method potentially allowed the plant to thoroughly clean the facility before cooking the product from which the sample would be taken.

FSIS procedures do not specify a methodology that instructs inspectors on how to take samples randomly.[16]

As noted in our report on the ConAgra recall, 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.

Due to deficiencies in the inspection services provided by FSIS at the Jack Lambersky Poultry Products, Inc. plant, FSIS had reduced assurance that the products produced are safe and wholesome. FSIS needs to develop and implement controls to ensure that inspectors adequately complete scheduled procedures and are selecting product samples in a random manner at Jack Lambersky Poultry Products, Inc.

### Recommendation No. 3

Determine whether the inspector demonstrated performance weaknesses at other plants for which he was responsible. Based on the findings of this evaluation, initiate the appropriate actions.

#### Agency Response.

Based on a review of its Quarterly 5-50 reports and feedback from the Circuit Supervisor, the Agency determined that no additional actions were warranted at other firms within the rotation. The "Quarterly 5-50 reports" are utilized to verify that none of the establishments are on any of the generated reports. Specifically, the "Summary of Establishments with Zero Non-compliances" and the "District Not Performed Summary by Procedure Code, with Comparison of Unscheduled to Not Performed Report" were reviewed. These reports are sent out to the Circuit Supervisors on a quarterly basis and then returned to the Deputy District Manager with explanation of why plants are listed on the reports. The Deputy District Manager uses the reports to decide

[16] FSIS Directive 10, 210.1, Amendment 5, "Unified Sampling Form," February 11, 2003, FSIS Directive 10,230.2, "Procedures for Collecting and Submitting Domestic Samples for Microbiological Analysis," August 6, 1992, and FSIS Directive 10,625.1, "Procedures for Evidentiary Samples," February 26, 1986.

whether there is a need for further assessment. In addition, these reports allow the Circuit Supervisors to have a "snapshot" look at the performance of plants within their circuit for a three-month period. The Circuit Supervisors can then better tailor their time to monitor plants that appear on the report more readily, find and solve problems, and provide feedback and supervision to the assigned CSI.

During the fall of 2002, the Philadelphia District Office assessed the need for reviews to be done at RTE turkey plants. Jack Lambersky was reviewed, with subsequent enforcement action instituted against the establishment. The District also performed a Performance Based Inspection System (PBIS) review of all the establishments that were under the Jack Lambersky rotation pattern. It should be noted that in the fall of 2002, the Jack Lambersky assignment was under the Philadelphia District for only one quarter, making it difficult to assess the performance of the inspection team in so short a time frame. However, the Philadelphia District did take action to react to the public health issues with RTE turkey products and increase inspection presence within the Jack Lambersky rotation.

### OIG Position.

To reach management decision, FSIS needs to provide the documentation it evaluated with respect to the specific inspector and a summary of the feedback FSIS received to determine that no additional actions were warranted at other firms within the rotation.

## Recommendation No. 4

Develop and implement a plan to ensure that inspectors are capable to adequately complete scheduled inspection procedures assigned by the PBIS.

### Agency Response.

FSIS has focused extensively during the past two years on strengthening supervisory oversight of in-plant inspection personnel. The IPPS is in place and circuit supervisors have clear standards and expectations for discussion with in-plant inspection personnel during their on-site visits. This system establishes a formal process so frontline supervisors can be sure that inspection personnel carry out their assigned job responsibilities. All field supervisors have been trained to use this system. The IPPS review helps the supervisor to: identify and address the need to improve an employee's knowledge about his or her responsibilities; encourage correlation with employees to ensure consistency in methods and application of methods; identify and address performance problems; and recognize and reward successful employee performance.

Additionally, the Philadelphia District Office has implemented a Continuous Improvement Plan that is being applied to all Circuits. The focus of the plan is to improve Non-compliance Records documentation by inspection personnel, and the review of corrective and preventive response by plant management. This will result in more consistent oversight of inspection performance in the conduct of scheduled inspection procedures, improved understanding among inspection program personnel and supervisors of the application of policies and procedures, and early identification of any potential performance problems.

FSIS is also in the second year of its initiative to upgrade the training of in-plant inspection personnel on proper application of HACCP and SSOP regulatory requirements. The FSRE training program focuses on proper understanding and effective application of regulatory requirements by in-plant inspection personnel. The training is based on the recently issued FSIS Directive 5000.1, Revision 1, "*Verifying an Establishment's Food Safety System*," which outlines the full range of inspection responsibilities in relation to the Pathogen Reduction/HACCP regulations. The FSRE training is tailored to an inspector's assignment. All persons receiving the training get the foundation training and customized training. The foundation training covers the Rules of Practice; Sanitation Performance Standards; and Sanitation Standard Operating Procedures. The customized training covers HACCP verification; Pathogen Reduction; and food safety sampling.

FSIS utilizes a number of reports generated from the PBIS database to track plant performance, such as the "Quarterly 5-50 reports," the "Summary of Establishments with Zero Non-Compliances," and the "District Not Performed Summary by Procedure Code, with Comparison of Unscheduled to Not Performed Report." These reports are sent out to the Circuit Supervisors on a quarterly basis and then returned to the Deputy District Manager with explanations of why plants are listed on the reports. The Deputy District Manager then decides whether there is a need for further assessment. These reports allow the Circuit Supervisors to have a "snapshot" look at the performance of plants within their Circuits for a three-month period. The Circuit Supervisors can then better tailor their time to target plants that show up on the report and more readily find and solve problems and provide feedback and supervision to the assigned Consumer Safety Inspector.

FSIS inspection program personnel in the Philadelphia District will have completed FSRE training by June 2004.

**OIG Position.**

We accept FSIS' management decision. For final action, FSIS needs to provide OCFO with documentation showing the dates when inspection personnel in the Philadelphia District completed the FSRE training. In

addition, FSIS needs to provide OCFO documentation that validates that the Circuit Supervisors in the Philadelphia District are using IPPS to evaluate how inspection personnel carry out their assigned job responsibilities.

### Recommendation No. 5

Develop and implement procedures to ensure that inspectors are selecting product samples in a random manner. This should include, but not be limited to, varying the days and times when samples are selected.

#### Agency Response.

FSIS Directive 10,210.1, "*Unified Sampling Form*," Amendment 6, dated December 18, 2003, specifies instructions for FSIS inspection program personnel to randomly select samples in conducting sampling procedures. To address the OIG concerns that sampling is not being conducted in a random manner, the FSIS is reaffirming through its ongoing training of inspection program personnel, the requirements for randomly selecting samples in performing sampling procedures. In particular, instructions and guidance are being provided in the Agency's ongoing FSRE training initiated in April 2003. The training reference material used in the FSRE course was provided in the response.

#### OIG Position.

We do not accept FSIS' management decision. FSIS' response addresses the development of procedures to ensure that inspectors are selecting product samples in a random manner. However, the response does not explain how the agency will make certain that this guidance is being properly implemented at the plant level. To reach management decision for this recommendation, FSIS needs to provide details of the management controls to be put in place so that the agency knows whether or not samples are being taken in accordance with the revised policy and the date by which these controls will be implemented.

## Finding 3 Inadequate Documentation on the Amount and Disposition of Recalled Product

FSIS did not obtain adequate documentation from Jack Lambersky Poultry Products, Inc., to determine if the plant identified and accounted for all product subject to the recall. This occurred because FSIS lacked specific procedures requiring compliance officers to obtain and verify documentation supporting this determination. Consequently, FSIS cannot ensure that all reasonable efforts were made to remove from commerce the approximately

4.2 million pounds of ready-to-eat products potentially contaminated with *Listeria monocytogenes*.

A recall is a voluntary action taken by a manufacturer or distributor to remove adulterated or misbranded products from commerce that may present a health hazard to consumers. According to FSIS procedures,[17] agency personnel are responsible for overseeing recall activities and verifying information provided by the firm (e.g., product distribution). Yet, the procedures do not require FSIS to validate the amount of product produced, in inventory, returned, destroyed, or consumed.

According to an FSIS District official, limited resources hindered the District's ability to validate the recall information provided by Jack Lambersky Poultry Products, Inc. Nonetheless, a review of supporting documentation, even on a test basis, would have provided FSIS a basis for determining whether the type and amount of products Jack Lambersky Poultry Products, Inc., reported as being produced, in inventory, returned, destroyed, or consumed, was accurate.

The Jack Lambersky Poultry Products, Inc. recall closeout report, which summarizes the plant's recovery efforts, was provided to FSIS on February 20, 2003. Of the 4,201,049 pounds recalled, the plant claimed that 61,713 pounds were in the plant's inventory when the recall was initiated; 136,067 pounds were returned from customers; 15,771 pounds were destroyed by customers; and 3,987,498 pounds were not returned and thus assumed to be either consumed or destroyed. The plant also reported that the recalled products in inventory and the products returned by customers were destroyed at a landfill.

We found that Jack Lambersky Poultry Products, Inc., did not have adequate documentation to support the amount of recalled products returned from customers. The firm did not implement a formal process for tracking product returns. Jack Lambersky Poultry Products, Inc., calculated the amount of recalled products that customers returned by subtracting the quantity in inventory from the total amount destroyed at the landfill (197,780 pounds), which included both products in inventory (61,713 pounds) and returned (136,067 pounds). We concluded that the amount of products returned by customers was merely a calculation, and could not be fully substantiated.

Jack Lambersky Poultry Products, Inc., reported that 21 customers destroyed 15,771 pounds of recalled product. However, we determined that this amount was not adequately supported by the credit memoranda retained by the plant. For example, one customer reported that it destroyed 237 pounds of recalled

[17] FSIS Directive 8080.1, Revision 3, "Recall of Meat and Poultry Products," issued January 19, 2000, and Compliance and Investigations Division Protocol, Section VI—Recalls, issued September 1997.

product, but Jack Lambersky Poultry Products, Inc., reported as destroyed 4 times this amount (955 pounds). Jack Lambersky Poultry Products, Inc., did not document and could not explain how they determined this number.

Due to the lack of procedures, FSIS cannot ensure that all reasonable efforts were made to remove the approximately 4.2 million pounds of product recalled by Jack Lambersky Poultry Products, Inc. from commerce. Because of the lack of documentation maintained by the company, additional follow up by FSIS is no longer likely to be effective. To prevent the recurrence of this type of situation in the future, FSIS needs to develop and implement procedures to verify the completeness of a firm's recall.

### Recommendation No. 6

Develop and implement procedures requiring compliance officers to oversee recall activities to ensure the adequacy of documentation provided by the firm and validate the completeness of the recall.

#### Agency Response.

FSIS is revising Directive 8080.1, "*Recall of Meat and Poultry Products*," to enhance the instructions and guidance given to agency personnel responsible for verifying the effectiveness of the recalling establishment in conducting the recall. The revised directive will provide a verification process to help ensure that agency personnel acquire the appropriate documentation from the recalling establishment. FSIS will issue the revised directive by June 2004.

#### OIG Position.

We do not accept FSIS' management decision. FSIS issued Directive 8080.1, Revision 4, on May 24, 2004. The Directive did not include specific direction that compliance officers obtain and verify documentation from the recalling firm to determine whether the plant identified and accounted for all product subject to recall. As reported in Finding No. 3, due to the lack of specific FSIS procedures, FSIS personnel did not obtain adequate documentation from Jack Lambersky Poultry Products, Inc., to determine if the plant identified and accounted for all product subject to the recall.

To reach management decision, FSIS needs to incorporate procedures into Directive 8080.1 that require compliance officers to ensure the adequacy of documentation provided by the firm and validate the completeness of the recall. In the interim, FSIS needs to implement compensating controls to ensure that documentation provided by the firm is adequate and that the recall is complete.

A recall is a voluntary action taken by a manufacturer or distributor to remove adulterated or misbranded products from commerce that may present a health hazard to consumers.

FSIS is responsible for overseeing all recall activities by official meat and poultry establishments, including providing scientific and technical advice. FSIS' primary role is to monitor the effectiveness of the firm's recall procedures. Compliance officers are responsible for completing a sufficient number of effectiveness checks to verify that consignees received adequate notice of the recall and the products were located, controlled, and removed from commerce. When it is determined that all reasonable efforts have been made to effect the recall and that all available product has been removed or corrected to the extent possible, the recall will be considered complete.

The deficiencies we found were similar to those identified in the ConAgra recall in that FSIS' oversight of the recalls was ineffective. In response to recommendations in the ConAgra report, FSIS agreed to strengthen recall controls and procedures, which the agency expects to finalize by July 2004.

We found that FSIS did not critically review recall reports and information supporting the agency's oversight of food safety recalls. For example, one district that received recalled products did not perform any effectiveness checks. The discrepancies, although easily identifiable, went undetected and were not followed up on by FSIS officials. From January 1, 2002 to January 3, 2003, there were 15 recalls involving approximately 32.2 million pounds of ready-to-eat products potentially contaminated with *Listeria monocytogenes* that were produced by plants in the Northeastern United States.

We also learned that FSIS did not ensure that the recall of 1.7 million pounds of ready-to-eat poultry products distributed to NSLP was effective. Due to the lack of FSIS oversight of the recall process, there were 81 effectiveness checks in which the product disposition could not be determined. For example, one effectiveness check indicated that 1,500 pounds of recalled product was temporarily on hold at a warehouse and would be returned to the Pilgrim's Pride Corporation. However, there was no record of a followup review conducted by the FSIS Compliance Officer to ensure that the products were actually returned to the recalling firm.

## Finding 4 Effectiveness of Food Safety Recalls Unknown by FSIS

FSIS had no assurance that the recalls of ready-to-eat product potentially contaminated with *Listeria monocytogenes* were effective. This occurred because FSIS officials did not critically review recall reports and information supporting the agency's oversight of food safety recalls. Due to FSIS' lack of oversight there was an increased risk that some of the 31.6 million pounds of product, recalled by 3 of the 15 plants in the Northeastern United States, was not removed from commerce.

In order to monitor the effectiveness of the recall, FSIS procedures[18] state that compliance officers are to complete a sufficient number of effectiveness checks to verify that consignees received adequate notice of the recall and the products were located, controlled, and removed from commerce. When FSIS determines that all reasonable efforts have been made to effect the recall and that all available product has been removed, the recall will be considered complete.

We selected FSIS files for 13 of the 15 recalls of product from plants in the Northeastern United States for review. We did not review the files for two of the recalls because the total pounds associated with these recalls were very minimal. We noted the following types of discrepancies that had not been resolved by FSIS officials in 3 of the 13 recalls reviewed. We found similar deficiencies in FSIS' oversight and control of the ConAgra recall.

- Prior to the recall, USDA purchased 1.7 million pounds of ready-to-eat poultry products from the Pilgrim's Pride Corporation. This product was donated to 20 States for use in the NSLP. On October 12, 2002, Pilgrim's Pride Corporation recalled approximately 27.4 million pounds of ready-to-eat poultry products potentially contaminated with *Listeria monocytogenes*. The recalled product included the 1.7 million pounds of product purchased by USDA. FSIS did not ensure that the recall of the product distributed for use in the NSLP was effective. For example, we identified 80 effectiveness checks in which compliance officers did not follow up with schools and warehouses to determine how they disposed of potentially contaminated product. (See Finding No. 5.)

- On November 2, 2002, Jack Lambersky Poultry Products, Inc., recalled approximately 200,000 pounds of ready-to-eat poultry products potentially contaminated with *Listeria monocytogenes*. On November 20, 2002, this recall was expanded to 4.2 million pounds of poultry products.

[18] FSIS Directive 8080.1, Rev. 3, "Recall of Meat and Poultry Products," dated January 19, 2000.

FSIS' Beltsville District Office did not document that it conducted effectiveness checks for the entire Jack Lambersky Poultry Products, Inc., recall. We determined that no effectiveness checks performed by the Beltsville District were dated after the expansion of the recall occurred. The FSIS Beltsville District Office did not perform effectiveness checks to ensure that almost 279,000 pounds of product recalled by Jack Lambersky Poultry Products, Inc., were properly controlled.

- On August 10, 2002, Russer Foods recalled approximately 1,300 pounds of pork products potentially contaminated with *Listeria monocytogenes*. The product was distributed in the States of New York, Pennsylvania, West Virginia, and Ohio.

  All district offices that receive recalled products are required to perform effectiveness checks. We determined that the FSIS Chicago District, which covers Ohio, did not perform effectiveness checks for stores that received approximately 76 pounds (12 cases) of products recalled by Russer Foods.

We found similar deficiencies in FSIS' oversight and control of the ConAgra recall. To address the weaknesses, we recommended that FSIS 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. We further recommended that FSIS reassess its policies and procedures for managing the recall process. This included establishing criteria to ensure that required effectiveness checks are completed and to determine whether recalls are effective. FSIS agreed with these recommendations. FSIS implemented interim guidelines in March 2003 to ensure that recall activities are effectively carried out. These interim guidelines do not establish or provide criteria for assessing recall effectiveness. FSIS also convened a workgroup to consider the overall policies and procedures for managing the recall process and the recall effectiveness checks. On May 24, 2004, FSIS issued Directive 8080.1, Revision 4, *"Recall of Meat and Poultry Products."* This Directive describes the responsibilities of industry and FSIS personnel regarding the recall of FSIS-inspected meat and poultry products. We continue to work with FSIS to obtain an acceptable action plan to correct the weaknesses identified.

FSIS needs to reassess the effectiveness checks performed and related recall reports for the Pilgrim's Pride Corporation (see Finding No. 5), Jack Lambersky Poultry Products, Inc., and Russer Foods recalls to ensure that discrepancies are resolved and the information presented is accurate and complete.

## Recommendation No. 7

Review the effectiveness checks and related recall reports submitted by the FSIS District Office for the Jack Lambersky Poultry Products, Inc., recall. Ensure that all discrepancies have been resolved and the information presented is accurate and complete.

### Agency Response.

FSIS completed the recall and officially closed it. The recall has been removed from the Agency's active list. To cost effectively address the OIG's concerns, the FSIS Office of Program Evaluation, Enforcement and Review (OPEER) will complete a review of the Jack Lambersky effectiveness checks and related recall reports to summarize the accuracy and completeness of the effectiveness checks. OPEER will complete its review by December 2004.

### OIG Position.

We generally agree with FSIS' proposed corrective action. However, we are concerned that the target date for completing the review is December 2004. To reach management decision, a timelier plan of action is needed.

Additionally, it is important that the OPEER review do more than "summarize the accuracy and completeness of the effectiveness checks." Our audit showed that the effectiveness checks were neither accurate nor complete. To reach management decision, the review should ensure the resolution of all discrepancies. To the extent that discrepancies can no longer be resolved, due to the passage of time, the review should identify specific errors and omissions and detail the actions taken to preclude their recurrence (e.g., direct feedback to the responsible compliance officers).

To reach management decision, the results of OPEER's review should be incorporated into training material for FSIS personnel. In addition, the review results should be incorporated into FSIS Directive 8080.1, *"Recall of Meat and Poultry Products,"* to strengthen FSIS' oversight of recall activities.

## Recommendation No. 8

Review the effectiveness checks and related recall reports submitted by the FSIS District Office for the Russer Foods recall. Ensure that all discrepancies have been resolved and the information presented is accurate and complete.

### Agency Response.

FSIS completed the recall and officially closed it. The recall has been removed from the Agency's active list. To cost effectively address the OIG's

concerns, OPEER will complete a review of the Russer Foods effectiveness checks and related recall reports to summarize the accuracy and completeness of the effectiveness checks. OPEER will complete its review by December 2004.

**OIG Position.**

We generally agree with FSIS' proposed corrective action. However, we are concerned that the target date for completing the review is December 2004. To reach management decision, a timelier plan of action is needed.

Additionally, it is important that the OPEER review do more than "summarize the accuracy and completeness of the effectiveness checks." Our audit showed that the effectiveness checks were neither accurate nor complete. To reach management decision, the review should ensure the resolution of all discrepancies. To the extent that discrepancies can no longer be resolved, due to the passage of time, the review should identify specific errors and omissions, and detail the actions taken to preclude their recurrence (e.g., direct feedback to the responsible compliance officers).

To reach management decision, the results of OPEER's review should be incorporated into training material for FSIS personnel. In addition, the review results should be incorporated into FSIS Directive 8080.1, *"Recall of Meat and Poultry Products,"* to strengthen FSIS' oversight of recall activities.

## Finding 5 Ineffective Oversight of Recalled Product Distributed to the NSLP

Prior to the recall, USDA purchased 1.7 million pounds of ready-to-eat poultry products from the Pilgrim's Pride Corporation. This product was donated to 20 States for use in the NSLP. On October 12, 2002, Pilgrim's Pride Corporation recalled approximately 27.4 million pounds of ready-to eat poultry products potentially contaminated with *Listeria monocytogenes*. The recalled product included the 1.7 million pounds of product purchased by USDA.

Due to FSIS' lack of control over the recall process, the agency did not ensure the product distributed for use in the NSLP and potentially served to a vulnerable population was effective. For example, we identified 80 of 362 effectiveness checks in which compliance officers did not follow up with schools and warehouses to determine how they disposed of potentially contaminated product. As a result, FSIS has no assurance that approximately 273,647 pounds of product were removed from the NSLP, and cannot fully ensure that all reasonable efforts were made to retrieve the remaining recalled product.

FSIS procedures[19] require FSIS program personnel to make a sufficient number of effectiveness checks to verify: (1) that adequate notice was provided to the consignees; and (2) that consignees located and controlled products and followed the recalling firm's instructions for removing the product. The results of the effectiveness checks performed are recorded on FSIS Form 8400-4, Report of Recall Effectiveness. These reports capture data such as the disposition of the product and whether followup reviews were performed.

We reviewed all of the effectiveness checks performed by FSIS Compliance Officers for the 1.7 million pounds of product distributed for use in the NSLP. This included checks at 202 schools where the product was distributed and at 160 warehouses where the product was stored. We identified 351 discrepancies in the data documented on the 362 forms. (An effectiveness check may have more than one discrepancy.) Examples of these discrepancies (described in more detail below) are product disposition not being accurately determined, followup reviews not being performed, and product weight not being determined. The discrepancies were similar to those we reported in our review of the ConAgra recall.

- Product Disposition Was Not Accurately Determined. FSIS Compliance Officers are required to determine the product disposition to ensure that the recalled product has been removed from commerce. We found 81 of the 362 effectiveness checks where the product disposition could not be accurately determined because the compliance officers did not accurately complete the effectiveness check form. Further, these discrepancies were not identified and corrected because FSIS procedures did not require supervisory review to ensure the forms were fully completed.

  For example, at a warehouse in Massachusetts, the effectiveness check indicated that the product was returned to Pilgrim's Pride Corporation on the form's product disposition block. However, the FSIS Compliance Officer noted in the form's remarks section that the 1,500 pounds of product was on hold in the freezer as of November 20, 2002. There was no record of a followup review by the FSIS Compliance Officer to ensure that the product was returned to Pilgrim's Pride Corporation.

- No Followup Reviews Performed. When a followup review is necessary, FSIS Compliance Officers are required to document another effectiveness check and note that it is a followup report. We found 80 of the 362 effectiveness checks where the forms indicated that product was on hold pending pickup or further instructions. However, we did not find any indication that the FSIS Compliance Officer performed a followup review to ensure that the product was removed from the schools and

[19] FSIS Directive 8080.1, Rev. 3, "Recall of Meat and Poultry Products," dated January 19, 2000.

warehouses. FSIS procedures do not adequately state the responsibilities of the compliance officer to perform followup reviews when necessary. Consequently, FSIS has no assurance that approximately 273,647 pounds of recalled products were removed from the NSLP.

For example, one effectiveness check reported 230 pounds of product was on hold at a high school in Louisiana as of November 6, 2002, pending pickup. We found that no followup review was performed by the FSIS Compliance Officer to ensure that the product was picked up. The FSIS Compliance Officer informed us that he did not follow up because the school was instructed to contact him if the product was not picked up. The compliance officer stated that no call was received from the school.

- Product Weight Was Not Determined. FSIS Compliance Officers are required to compare distribution information provided by the recalling firm with data developed during the effectiveness checks to determine the amount of product in the distribution channels. FSIS Compliance Officers are required to document the comparisons, resolve any discrepancies, and record the findings on the effectiveness check form. We found 75 of the 362 effectiveness checks where the weight of the product purchased by the consignee and the amount on hand at the time of the recall could not be determined because the amount of product was unknown or not documented on the effectiveness check form. FSIS procedures do not address the review of the effectiveness check form by the compliance officer to ensure that the form was fully completed.

  For a Head Start program in Louisiana, the effectiveness check form indicated that the amount of product in inventory was "unknown" both at the time the recall notification was issued and the time the effectiveness check was performed. In the remarks section, the FSIS Compliance Officer noted the person contacted did not know how much, if any, of the affected products were on hand when the recall notification was received. Additionally, the school cook, who was out on vacation, handled this for the firm. This effectiveness check form did not indicate whether there was a followup performed by the FSIS Compliance Officer to determine the disposition of the product.

- Other Discrepancies. We also noted additional discrepancies, which caused us to question the information presented on the effectiveness check forms. For example, firms are required to initiate sub-recalls if the recall involves distribution by distributors or wholesalers. We found 14 effectiveness checks where subaccounts were identified but sub-recalls were not initiated. We identified another 14 effectiveness checks where there was a sub-recall but no determination on the form that the sub-recall instructions were followed.

In our report on the ConAgra recall, we reported similar deficiencies in FSIS' oversight and control of the recall process. To address the weaknesses, we recommended that FSIS 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. We further recommended that FSIS reassess its policies and procedures for managing the recall process. This included establishing criteria to ensure that required effectiveness checks are completed and to determine whether recalls are effective. FSIS agreed with these recommendations. FSIS implemented interim guidelines in March 2003 to ensure that recall activities are effectively carried out. These interim guidelines do not establish or provide criteria for assessing recall effectiveness. FSIS also convened a workgroup to consider the overall policies and procedures for managing the recall process and the recall effectiveness checks. On May 24, 2004, FSIS issued Directive 8080.1, Revision 4, *"Recall of Meat and Poultry Products."* This Directive describes the responsibilities of industry and FSIS personnel regarding the recall of FSIS-inspected meat and poultry products. We continue to work with FSIS to obtain an acceptable action plan to correct the weaknesses identified.

In addition to implementing these measures to strengthen the recall process, FSIS should compile information on the effectiveness checks performed on product purchased by USDA and distributed to the NSLP. FSIS Compliance Officers should be trained on the importance of accurately and completely performing effectiveness checks for product distributed to vulnerable populations, such as school children. FSIS should also review the effectiveness checks performed for the Pilgrim's Pride Corporation recall to ensure that all discrepancies have been resolved and that a supervisory review is performed to ensure the information is accurate and complete. Finally, FSIS should implement procedures to ensure the effectiveness of checks performed on the recalled product distributed to vulnerable populations.

### Recommendation No. 9

As part of the restructuring of the recall process, FSIS should ensure that compliance officers have sufficient training to perform accurate and complete effectiveness checks on product distributed to the NSLP.

#### Agency Response.

FSIS is revising Directive 8080.1, "*Recall of Meat and Poultry Products*" to enhance the instructions and guidance given to agency personnel responsible for verifying the effectiveness of the recalling establishment in conducting the recall. The revised directive will incorporate a new risk-based approach for conducting effectiveness checks. FSIS will issue the revised directive by June 2004.

In October 2003, FSIS initiated EIAO training that included instructions and guidance on conducting effectiveness checks of establishments conducting recalls. FSIS is expanding its talent pool for conducting and following up on effectiveness checks through the use of trained EIAO and Veterinary Medical Officers in the recall verification process. FSIS conducted an EIAO training course for 250 field personnel that covered the risk-based recall effectiveness procedures during the week of April 12, 2004.

### OIG Position.

We accept FSIS' management decision. FSIS issued Directive 8080.1, Revision 4, on May 24, 2004. This Directive includes enhanced instruction to agency personnel for effectiveness checks performed on product distributed to the NSLP. For final action, FSIS needs to provide OCFO with the applicable material from the EIAO training that shows the training provided to accurately and completely perform effectiveness checks on product distributed to the NSLP.

## Recommendation No. 10

Develop and implement procedures to ensure recalled product distributed to schools and institutions that serve vulnerable populations is accounted for. FSIS should timely and accurately compile information such as the amount of recalled product: (1) sent to the school level; (2) returned or destroyed; and (3) consumed. The compiled information should also document how many schools the compliance officers visit. This information should be provided in the recall final reports submitted by each FSIS District Office to summarize the recall efforts and the findings of the effectiveness checks performed at schools.

### Agency Response.

FSIS will revise Directive 8080.1, "*Recall of Meat and Poultry Products*" to enhance the instruction and guidance given to agency personnel responsible for verifying the effectiveness of the recalling establishment in conducting the recall. The revised directive will improve the Agency's recall procedures. The revised directive will enable the collection of distribution information at the plant to begin prior to testing results becoming final to enhance the speed and effectiveness of recalls. The Agency will also increase its effectiveness checks for Class I recalls and in cases where products are distributed to at-risk groups. The risk-based effectiveness checks will help ensure that more concentrated effort is placed on timely verifying the effectiveness of recalled product from the most vulnerable population. The revised directive will include timeframes for initiating and reporting verification activities within FSIS and will include provisions for locating products at point of sale and

ensuring the proper disposition of recalled product. FSIS will issue the revised directive by June 2004.

In October 2003, FSIS initiated EIAO training that included instructions and guidance on conducting effectiveness checks of establishments conducting recalls. FSIS is expanding its talent pool for conducting and following up on effectiveness checks through the use of trained EIAO and Veterinary Medical Officers in the recall verification process. FSIS conducted an EIAO training course for 250 field personnel that covered the risk-based recall effectiveness procedures during the week of April 12, 2004.

**OIG Position.**

We do not accept FSIS' management decision. FSIS issued Directive 8080.1, Revision 4, on May 24, 2004. The Directive did not include any of the recommended actions to improve accountability over recalled product distributed to schools and institutions that serve vulnerable populations.

To reach management decision, FSIS needs to incorporate procedures into Directive 8080.1 that require FSIS personnel to account for recalled product distributed to schools and institutions that serve vulnerable populations. The procedures should require the timely and accurate compilation of information on the distribution, return, destruction, and consumption of recalled product. As part of the compilation, FSIS should document how many schools were visited. Finally, the compiled information should be included in the FSIS District Office reports that summarize the recall efforts. In the interim, FSIS needs to implement compensating controls to ensure that recalled product distributed to schools and institutions that serve vulnerable populations is accounted for.

**Recommendation No. 11**

Review the effectiveness checks performed by FSIS Compliance Officers for the Pilgrim's Pride Corporation recall to ensure that all discrepancies have been resolved and a supervisory review is performed to ensure the information is accurate and complete.

**Agency Response.**

FSIS completed the recall and officially closed it. The recall has been removed from the active list. To cost effectively address the OIG's concerns, OPEER will complete a review of the Pilgrim's Pride Corporation effectiveness checks and related recall reports to summarize the accuracy and completeness of the effectiveness checks. OPEER will complete its review by December 2004.

**OIG Position.**

We generally agree with FSIS' proposed corrective action. However, we are concerned that the target date for completing the review is December 2004. To reach management decision, a timelier plan of action is needed.

Additionally, it is important that the OPEER review do more than "summarize the accuracy and completeness of the effectiveness checks." Our audit showed that the effectiveness checks were neither accurate nor complete. To reach management decision, the review should ensure the resolution of all discrepancies. To the extent that discrepancies can no longer be resolved, due to the passage of time, the review should identify specific errors and omissions and detail the actions taken to preclude their recurrence (e.g., direct feedback to the responsible compliance officers).

To reach management decision, the results of OPEER's review should be incorporated into training material for FSIS personnel. In addition, the review results should be incorporated into FSIS Directive 8080.1, *"Recall of Meat and Poultry Products,"* to strengthen FSIS' oversight of recall activities.

**Recommendation No. 12**

Re-examine the effectiveness checks performed by FSIS Compliance Officers for the Pilgrim's Pride Corporation recall to ensure that the 273,647 pounds of product has been removed from the NSLP and the information presented is accurate and complete.

**Agency Response.**

FSIS completed the recall and officially closed it. The recall has been removed from the active list. To cost effectively address the OIG's concerns, OPEER will complete a review of the Pilgrim's Pride Corporation effectiveness checks and related recall reports to summarize the accuracy and completeness of the effectiveness checks. OPEER will complete its review by December 2004.

**OIG Position.**

We generally agree with FSIS' proposed corrective action. However, we are concerned that the target date for completing the review is December 2004. To reach management decision, a timelier plan of action is needed.

Additionally, it is important that the OPEER review do more than "summarize the accuracy and completeness of the effectiveness checks." Our audit showed that the effectiveness checks were neither accurate nor complete. To reach management decision, the review should ensure the

resolution of all discrepancies to include ensuring that the 273,647 pounds of product has been removed from the NSLP. To the extent that discrepancies can no longer be resolved, due to the passage of time, the review should identify specific errors and omissions and detail the actions taken to preclude their recurrence (e.g., direct feedback to the responsible compliance officers).

To reach management decision, the results of OPEER's review should be incorporated into training material for FSIS personnel. In addition, the review results should be incorporated into FSIS Directive 8080.1, *"Recall of Meat and Poultry Products,"* to strengthen FSIS' oversight of recall activities.

# Scope and Methodology

Our audit focused on documentation, operations, and regulations applicable to the production, distribution, and recall of ready-to-eat products primarily from January 2002 to July 2003.

FSIS Headquarters, Districts, and Circuits

To determine the adequacy of FSIS' oversight of the *Listeria* outbreak and inspection activities at selected plants, we held discussions with FSIS District, Circuit, and Inspection personnel regarding plant operations prior to, during, and subsequent to the recall and reviewed supporting documentation. At FSIS Headquarters, we concentrated on the responsibilities of the OPPD, OPHS, and OFO. Our review included an analysis of the *Listeria* outbreak investigation, FSIS Directive 10,240.3, risk assessment, ongoing research activities, recall procedures, and record keeping.

At the district offices, we familiarized ourselves with the inspection, recall, and sampling responsibilities of the inspectors and the oversight of the circuit supervisors and other district personnel including the district manager, deputy district mangers, and the inspection coordinator.

We performed audit work at the following locations:

- FSIS Headquarters in Washington, DC;
- FSIS District Offices in Philadelphia, Pennsylvania and Beltsville, Maryland; and
- FSIS Circuits in Hatfield, Pennsylvania and Trenton, New Jersey.

Selected Plants.

At the selected plants, we conducted a tour and held discussions with various corporate and plant officials such as the plant manager, recall coordinator, quality control manager, HACCP coordinator, and comptroller to obtain and understanding of their responsibilities and become familiar with the scope of the plant's operations, recall procedures, construction projects, consultants utilized during the recall, and record keeping procedures. We reviewed the plant's NRs, recall summaries, HACCP plans, SSOPs, and related documents. We also reviewed the comprehensive plant assessments performed by the consumer safety officers and the effectiveness checks completed by the compliance officers.

We performed audit work at the following locations:

- Pilgrim's Pride Corporation in Franconia, Pennsylvania and its administrative offices located in Broadway, Virginia and third party collection facilities in Crozet, Virginia and Mount Airy, Maryland; and

- Jack Lambersky Poultry Products, Inc., and its administrative office in Camden, New Jersey.

Due to an ongoing criminal investigation, our audit work for the Pilgrim's Pride Corporation was limited to FSIS' oversight of the effectiveness of the recall.

Recalled Product Distributed to the National School Lunch Program.

To determine whether FSIS adequately accounted for recalled product donated to the NSLP, we discussed recall procedures with FSIS, FNS, AMS, State Departments of Education, and local school officials. Also, we evaluated pertinent documentation, such as liability forms, commodity reports, and receiving records. We obtained a Commodity Status report from FNS and used that information to judgmentally select three States to visit, based on the volume of recalled product served in schools.

We performed audit work at the following locations:

- FNS Headquarters in Alexandria, Virginia;
- AMS Headquarters in Washington, DC;
- Georgia Department of Education in Atlanta, Georgia;
- Bartow, Forsyth, and Cherokee county school districts in Georgia;
- Michigan Department of Education in Lansing, Michigan;
- Saline, Saginaw, and Pontiac county school districts in Michigan;
- New York Office of General Services in Albany, New York; and
- New York City Board of Education in Long Island City, New York.

We reviewed the findings and recommendations included in OIG's Audit Report No. 24601-2-KC, "Food Safety and Inspection Service Oversight of Production Processes at ConAgra Plant (Establishment 969)," issued September 30, 2003.

Our audit was conducted in accordance with Generally Accepted Government Auditing Standards.

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

MAY 4 2004

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

Barbara Masters

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

**SUBJECT:** Office of Inspector General (OIG) Official Draft Audit Report – Oversight of the *Listeria* Outbreak in the Northeastern United States, Report No. 24601-2-Hy

We appreciate the opportunity to review and comment on the subject report. The Food Safety and Inspection Service (FSIS) has implemented several actions to improve the effectiveness of the recalls and further strengthen our Hazard Analysis and Critical Control Program (HACCP) approach to food safety. FSIS has strengthened 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 and protect the public health.

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

FSIS generally agrees with the report's findings and recommendations with two noted exceptions. First, FSIS believes the OIG implication in the report that FSIS was fully responsible for the recalls overstates FSIS' role. Although FSIS plays a key role in the recall process, it is the responsibility of the establishments to produce safe wholesome meat and poultry products. However, the recall did identify problems with our verification activities. Consequently, FSIS has moved to address those problems through the issuance of Directive 5000.1, improved training, and improved supervision.

Second, FSIS takes exception to the report's assertion that a successful recall is dependent on the percentage of product that is recovered. Other factors need to be considered in gauging the success of a recall including whether any epidemiological outbreak associated with the product being recalled occurred.

FSIS is revising Directive 8080.1, "*Recall of Meat and Poultry Products*." The revised directive will provide the terminology, responsibilities, and public notification procedures covering the voluntary recall of meat and poultry products. In addition, the revised directive will provide updated instructions regarding recall procedures. The directive will include the general procedures involved in determining the need for a recall, and actions FSIS expects a firm to take to ensure that the maximum amount of product is recovered in the shortest amount of time. The directive will also include effectiveness check procedures that FSIS inspection program

personnel will use to verify that the recalling firm has been diligent and successful in notifying and advising consignees of the need to retrieve and control recalled product and that the consignees have responded accordingly. Effectiveness checks procedures will be risk-based and dependent on the class of the recall as well as the number of consignees. The updated directive will also include closure procedures.

On June 6, 2003, FSIS published a regulation that requires establishments that produce certain ready-to-eat (RTE) products to prevent product adulteration by the pathogenic environmental contaminant *Listeria monocytogenes*. The regulation, 9 CFR 430, states that *Listeria monocytogenes* is a hazard that an establishment producing a RTE product that is exposed to the environment post-lethality must control through its HACCP plan or prevent in the processing environment through a Sanitation Standard Operating Procedure (SSOP) or other prerequisite program. On October 2, 2003, FSIS issued FSIS Directive 10,240.4, "*Verification Procedures for the Listeria monocytogenes Regulation and Microbial Sampling of Ready-to-Eat (RTE) Products for the FSIS Verification Testing Program.*" This directive provides FSIS inspection program personnel instructions for verifying whether establishments are complying with the regulations in 9 CFR 430, "*Requirements for Specific Classes of Product.*"

**Section 1. Inspection Services at Jack Lambersky Poultry Products, Inc.**

1. **Recommendation No. 1**

   Develop and implement a plan to address the weaknesses in inspection services provided at Jack Lambersky Poultry Products, Inc. The plan should address ways to strengthen inspector performance and supervisory oversight.

   **FSIS Response**

   To address the issues identified at Jack Lambersky Poultry Products, Inc. (Jack Lambersky), FSIS took immediate and positive corrective action. Enclosure 1 contains a comprehensive food safety assessment that was performed, along with product and environmental sampling, from September 30, 2002 to October 4, 2002. As a result of that assessment, a Notice of Intended Enforcement (NOIE) was issued on October 7, 2002. The company responded with a written summary plan of corrective actions and preventative measures and, subsequently, a Deferral Action was issued on November 1, 2002. The firm worked under the deferral action along with a very specifically designed Verification Plan used by the inspection team at the plant to verify the various corrective actions. During the verification period, both environmental sampling and finished ready-to-eat product sampling took place, which were used to verify the effectiveness of the corrective actions. All samples taken were reported negative for *Listeria* and, subsequently, a Letter of Information dated, April 14, 2003, was issued closing the action (Enclosure 2).

   The company also hired a consultant and has reassessed its Sanitation Standard Operating Procedures and HACCP plans. The reassessment addressed product handling, product flow, and processing. The firm installed a post-pasteurization process for the fully cooked ready-to-eat items as an additional lethality step. Jack Lambersky has established

an ongoing *Listeria* sampling plan for environmental and finished product. Ongoing FSIS verification sampling from November 2002 to January 2004, has been negative.

Several relief GS-10 Consumer Safety Inspectors (CSI) with knowledge of RTE fully cooked products were detailed in November 2002, to Jack Lambersky. They assisted in providing additional inspection expertise in monitoring the progress under the Verification Plan.

The two (2) CSIs that were rotating on the Jack Lambersky assignment during 2002 are no longer on the assignment. One has retired and the other is on Leave Without Pay while in the process of applying for disability retirement.

All CSIs, including relief inspectors within the Philadelphia District, have been, or are scheduled, to attend the Food Safety Regulatory Essentials (FSRE) training by June 2004. The FSRE training stresses the understanding of HACCP concepts along with production and handling of RTE fully cooked product. The CSI's currently assigned at Jack Lambersky have attended the FSRE training.

In addition, the Trenton Circuit has been restructured to more equitably distribute the workload between circuits. This allows the Circuit Supervisor to spend more time with plants encountering problems. In addition, the Circuit Supervisor has attended the Frontline Supervisor Training developed by FSIS to enhance supervisory skills.

The District Manager has restructured the Circuit reporting lines to each Deputy District Manager so that there is a more equitable distribution of supervisory workload. The responsible deputies can then give more attention to circuits and plants encountering problems within their jurisdiction.

FSIS has focused extensively during the past two years on strengthening supervisory oversight of in-plant inspection personnel. The In-plant Performance System (IPPS) is in place and circuit supervisors have clear standards and expectations for discussion with in-plant inspection personnel during their on-site visits. This system establishes a formal process so frontline supervisors can be sure that inspection personnel carry out their assigned job responsibilities. All field supervisors have been trained to use this system. The IPPS review helps the supervisor to: identify and address the need to improve an employee's knowledge about his or her responsibilities; correlate employees to ensure consistency in methods and applications of methods; identify and address performance problems; and recognize and reward successful employee performance.

**2. <u>Recommendation No. 2</u>**

Clarify, in writing, with FSIS inspection personnel the requirements for plants to segregate exposed finished product from raw product to help prevent product contamination.

**FSIS Action**
It is not necessary to amend agency procedures to establish such a requirement since establishments have a responsibility to meet 9 CFR 416.1. In accordance with 9 CFR 416.1 each official establishment is required to operate and be maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated. Under 9 CFR 430.4, "*Control of Listeria monocytogenes in post-lethality exposed ready-to-eat products*" establishments are required to maintain sanitation in the post-lethality processing environment in accordance with 9 CFR 416. Further, it is not consistent with the policy framework of the PR/HACCP regulation to specify to plants how to construct their control systems. FSIS procedures and regulatory requirements include an assessment of specified establishments by a trained Enforcement Investigations and Analysis Officer (EIAO) of the scientific design of industry HACCP plans and food safety systems.

Trained EIAOs are capable of conducting a complete assessment of the design of a plant's control systems. These systems include HACCP and Sanitation Standard Operating Procedures (SSOP), generic *E. coli* testing procedures, and *Salmonella* data. The EIAO assessment involves consideration of all food safety aspects related to the establishment and the products, processes, and environment within the establishment.

On October 2, 2003, FSIS issued FSIS Directive 10,240.4, "*Verification Procedures for the Listeria monocytogenes Regulation and Microbial Sampling of Ready-to-Eat (RTE) Products for the FSIS Verification Testing Program.*" (Enclosure 3) This directive provides CSIs and EIAOs with instructions for verifying whether establishments are complying with the regulations in 9 CFR part 430, *Requirements for Specific Classes of Product* (Attachment 5). In addition, this directive includes verification procedures for ready-to-eat (RTE) products other than those applicable to 9 CFR 430.

3. **Recommendation No. 3**
Determine whether the inspector demonstrated performance weaknesses at other plants for which he was responsible. Based on the findings of this evaluation, initiate the appropriate actions.

**FSIS Response**
Based on a review of its Quarterly 5-50 reports and feedback from the Circuit Supervisor, the Agency determined that no additional actions were warranted at other firms within the rotation. The "Quarterly 5-50 reports" are utilized to verify that none of the establishments are on any of the generated reports. Specifically, the "Summary of Establishments with Zero Non-compliances" and the "District Not Performed Summary by Procedure Code, with Comparison of Unscheduled to Not Performed Report" were reviewed (Enclosure 4). These reports are sent out to the Circuit Supervisors on a quarterly basis and then returned to the Deputy District Manager with explanations of why plants are listed on the reports. The Deputy District Manager uses the reports to decide whether there is a need for further assessment. In addition, these reports allow the Circuit Supervisors to have a "snapshot" look at the performance of plants within their circuit for a three month period. The Circuit Supervisors can then better tailor their time

to monitor plants that appear on the report more readily, find and solve problems, and provide feedback and supervision to the assigned CSI.

During the fall of 2002, the Philadelphia District Office assessed the need for reviews to be done at RTE turkey plants. Jack Lambersky was reviewed, with subsequent enforcement action instituted against the establishment. The District also performed a Performance-Based Inspection System (PBIS) review of all the establishments that were under the Jack Lambersky inspector rotation pattern. It should be noted that in the fall of 2002, the Jack Lambersky assignment was under the Philadelphia District for only one quarter, making it difficult to assess the performance of the inspection team in so short a time frame. However, the Philadelphia District did take action to react to the public health issues with RTE turkey products and increase inspection presence within the Jack Lambersky rotation.

4. **Recommendation No. 4**
Develop and implement a plan to ensure that inspectors are capable to adequately complete scheduled inspection procedures assigned by the Performance-Based Inspection System.

**FSIS Response**
FSIS has focused extensively during the past two years on strengthening supervisory oversight of in-plant inspection personnel. The In-plant Performance System (IPPS) is in place and circuit supervisors have clear standards and expectations for discussion with in-plant inspection personnel during their on-site visits. This system establishes a formal process so frontline supervisors can be sure that inspection personnel carry out their assigned job responsibilities. All field supervisors have been trained to use this system. The IPPS review helps the supervisor to: identify and address the need to improve an employee's knowledge about his or her responsibilities; encourage correlation with employees to ensure consistency in methods and applications of methods; help identify and address performance problems; and recognize and reward successful employee performance.

Additionally, the Philadelphia District Office has implemented a Continuous Improvement Plan (Enclosure 5) that is being applied to all Circuits. The focus of the plan is to improve Non-compliance Records documentation by inspection personnel, and the review of corrective and preventive responses by plant management. This will result in more consistent oversight of inspection performance in the conduct of scheduled inspection procedures, improved understanding among inspection program personnel and supervisors of the application of policies and procedures, and early identification of any potential performance problems.

FSIS is also in the second year of its initiative to upgrade the training of in-plant inspection personnel on proper application of HACCP and SSOP regulatory requirements. The FSRE training program focuses on proper understanding and effective application of regulatory requirements by in-plant inspection personnel. The training is based on the recently issued FSIS Directive 5000.1, Revision 1, "*Verifying an*

*Establishment's Food Safety System*," which outlines the full range of inspection responsibilities in relation to the Pathogen Reduction/HACCP regulations. The FSRE training is tailored to an inspector's assignment. All persons receiving the training get the foundation training and customized training. The foundation training covers the Rules of Practice; Sanitation Performance Standards; and Sanitation Standard Operating Procedures. The customized training covers HACCP verification; Pathogen Reduction; and food safety sampling.

FSIS utilizes a number of reports generated from the PBIS database to track plant performance, such as the "Quarterly 5-50 reports," the "Summary of Establishments with Zero Non-compliances," and the "District Not Performed Summary by Procedure Code, with Comparison of Unscheduled to Not Performed Report." These reports are sent out to the Circuit Supervisors on a quarterly basis and then returned to the Deputy District Manager with explanations of why plants are listed on the reports. The Deputy District Manager then decides whether there is a need for further assessment. These reports allow the Circuit Supervisors to have a "snapshot" look at the performance of plants within their Circuits for a three-month period. The Circuit Supervisors can then better tailor their time to target plants that show up on the report and more readily find and solve problems and provide feedback and supervision to the assigned Consumer Safety Inspector.

FSIS inspection program personnel in the Philadelphia District will have completed FSRE training by June 2004.

5. **Recommendation No. 5**

Develop and implement procedures to ensure that inspectors are selecting product samples in a random manner. This should include, but not be limited to, varying the days and times when samples are selected.

**FSIS Action**

FSIS Directive 10,210.1, "*Unified Sampling Form*," Amendment 6, dated December 18, 2003, specifies instructions for FSIS inspection program personnel to randomly select samples in conducting sampling procedures (Enclosure 6). To address the OIG concerns that sampling is not being conducted in a random manner, the FSIS is reaffirming, through its ongoing training of inspection program personnel, the requirements for randomly selecting samples in performing sampling procedures. In particular, instructions and guidance are being provided in the Agency's ongoing FSRE training initiated in April 2003. Provided in Enclosure 7 is training reference material used in the FSRE course.

**Section 2. FSIS Oversight of Recalls of Products Potentially Contaminated with *Listeria Monocytogenes***

6. **Recommendation No. 6**
Develop and implement procedures requiring compliance officers to oversee recall activities to ensure the adequacy of documentation provided by the firm and validate the completeness of the recall.

**FSIS Action**
FSIS is revising Directive 8080.1, "*Recall of Meat and Poultry Products*" to enhance the instructions and guidance given to agency personnel responsible for verifying the effectiveness of the recalling establishment in conducting the recall. The revised directive will provide a verification process to help ensure that Agency personnel acquire the appropriate documentation from the recalling establishment. FSIS will issue the revised directive by June 2004.

7. **Recommendation No. 7**
Review the effectiveness checks and related recall reports submitted by the FSIS District Office for the Jack Lambersky recall. Ensure that all discrepancies have been resolved and the information presented is accurate and complete.

**FSIS Action**
FSIS completed the recall and officially closed it. The recall has been removed from the Agency's active list. To cost effectively address the OIG's concerns, the FSIS Office of Program Evaluation, Enforcement and Review (OPEER) will complete a review of the Jack Lambersky effectiveness checks and related recall reports to summarize the accuracy and completeness of the effectiveness checks. OPEER will complete its review by December 2004.

8. **Recommendation No. 8**
Review the effectiveness checks and related recall reports submitted by the FSIS District Office for the Russer Foods recall. Ensure that all discrepancies have been resolved and the information presented is accurate and complete.

**FSIS Action**
FSIS completed the recall and officially closed it. The recall has been removed from the active list. To cost effectively address the OIG's concerns, OPEER will complete a review of the Russer Foods effectiveness checks and related recall reports to summarize the accuracy and completeness of the effectiveness checks. OPEER will complete its review by December 2004.

9. **Recommendation No. 9**
As part of the restructuring of the recall process, FSIS should ensure that compliance officers have sufficient training to perform accurate and complete effectiveness checks on product distributed to the National School Lunch Program.

**FSIS Action**
FSIS is revising Directive 8080.1, "*Recall of Meat and Poultry Products*" to enhance the instructions and guidance given to agency personnel responsible for verifying the effectiveness of the recalling establishment in conducting the recall. The revised directive will incorporate a new risk-based approach for conducting effectiveness checks. FSIS will issue the revised directive by June 2004.

In October 2003, FSIS initiated EIAO training that included instructions and guidance on conducting effectiveness checks of the establishments conducting recalls. FSIS is expanding its talent pool for conducting and following up on effectiveness checks through the use of trained EIAO and Veterinary Medical Officers in the recall verification process. FSIS conducted an EIAO training course for 250 field personnel that covered the risk-based recall effectiveness procedures during the week of April 12, 2004.

10. **Recommendation No. 10**
Develop and implement procedures to ensure recalled product distributed to schools and institutions that serve vulnerable populations is accounted for. FSIS should timely and accurately compile information such as the amount of recalled product: (1) sent to the school level; (2) returned or destroyed; and (3) consumed. The compiled information should also document how many schools the compliance officers visit. This information should be provided in the recall final reports submitted by each FSIS District Office to summarize the recall efforts and the findings of the effectiveness checks performed at schools.

**FSIS Action**
FSIS will revise Directive 8080.1, "*Recall of Meat and Poultry Products*" to enhance the instructions and guidance given to agency personnel responsible for verifying the effectiveness of the recalling establishment in conducting the recall. The revised directive will improve the Agency's recall procedures. The revised directive will enable the collection of distribution information at the plant to begin prior to testing results becoming final to enhance the speed and effectiveness of recalls. The Agency will also increase its effectiveness checks for Class I recalls and in cases where products are distributed to at-risk groups. The risk-based effectiveness checks will help ensure that more concentrated effort is placed on timely verifying the effectiveness of recalled product from the most vulnerable population. The revised directive will include timeframes for initiating and reporting verification activities within FSIS and will include provisions for locating products at point of sale and ensuring the proper disposition of recalled product. FSIS will issue the revised directive by June 2004.

In October 2003, FSIS initiated EIAO training that included instructions and guidance on conducting effectiveness checks of the establishments conducting recalls. FSIS is expanding its talent pool for conducting and following up on effectiveness checks through the use of trained EIAO and Veterinary Medical Officers in the recall verification process. FSIS conducted an EIAO training course for 250 field personnel

that covered the risk-based recall effectiveness procedures during the week of April 12, 2004.

11. **Recommendation No. 11**
Review the effectiveness checks performed by FSIS Compliance Officers for the Pilgrim's Pride Corporation recall to ensure that all discrepancies have been resolved and a supervisory review is performed to ensure the information is accurate and complete.

**FSIS Action**
FSIS completed the recall and officially closed it. The recall has been removed from the active list. To cost effectively address the OIG's concerns, OPEER will complete a review of the Pilgrim's Pride Corporation effectiveness checks and related recall reports to summarize the accuracy and completeness of the effectiveness checks. OPEER will complete its review by December 2004.

12. **Recommendation No. 12**
Re-examine the effectiveness checks performed by FSIS Compliance Officers for the Pilgrim's Pride Corporation recall to ensure that the 273,647 pounds of product has been removed from the NSLP and the information presented is accurate and complete.

**FSIS Action**
FSIS completed the recall and officially closed it. The recall has been removed from the active list. To cost effectively address the OIG's concerns, OPEER will complete a review of the Pilgrim's Pride Corporation effectiveness checks and related recall reports to summarize the accuracy and completeness of the effectiveness checks. OPEER will complete its review by December 2004.

If you have any questions, please call Gina Kouba, Internal Control Staff, at 202-690-0163.

Enclosures (7)