U.S. Department of Agriculture

Office of Inspector General
Northeast Region

Audit Report

Food Safety and Inspection Service Effectiveness Checks for the 2002 Pilgrim's Pride Recall

Report No. 24601-03-Hy
June 2004

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250

DATE: June 29, 2004

REPLY TO
ATTN OF: 24601-03-Hy

SUBJECT: Food Safety and Inspection Service
Effectiveness Checks for the 2002 Pilgrim's Pride Recall

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 effectiveness checks for the 2002 Pilgrim's Pride recall. Your response to the official draft, dated May 20, 2004, is included as exhibit A. 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 decision has been reached on Recommendation No. 4. Please follow your agency's internal procedures in forwarding documentation for final action to the Office of the Chief Financial Officer. Management decisions for Recommendation Nos. 1, 2, 3, and 5 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.

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ROBERT W. YOUNG
Assistant Inspector General
for Audit

Executive Summary

Food Safety and Inspection Service Effectiveness Checks for the 2002 Pilgrim's Pride Recall (Audit Report No. 24601-03-Hy)

Results in Brief

In October 2002, the Pilgrim's Pride Corporation (Pilgrim's Pride) recalled approximately 27.4 million pounds of ready-to-eat poultry products potentially contaminated with *Listeria monocytogenes*, the largest recall in 2002. Pilgrim's Pride had distributed this product nationwide and exported it to foreign countries. Because of the recall's magnitude, the Office of Inspector General (OIG) evaluated the Food Safety and Inspection Service's (FSIS) efforts to verify the effectiveness of the recall. Although FSIS determined in July 2003 that the recall was successful, we found an overwhelming number of significant discrepancies on the agency's effectiveness check forms that call this conclusion into question.

To verify the effectiveness of a recall, FSIS compliance officers contact a sufficient number of customers to ensure that: (1) the product manufacturer or distributor provides adequate notice of the recall to all customers, and (2) customers locate and control the recalled product. The compliance officers record the results of their verifications on FSIS Form 8400-4, Report of Recall Effectiveness. Although FSIS based its conclusion that the Pilgrim's Pride recall was effective on these forms, we found 389 discrepancies on the 582 FSIS effectiveness check forms we examined.[1]

We attributed this high error rate to the careless approach FSIS compliance officers and supervisory personnel took in overseeing the recall. Specifically, some FSIS compliance officers failed to obtain pertinent data while many others did not fully analyze and act on the information they collected. Furthermore, FSIS supervisors did not adequately review the effectiveness check forms for completeness and accuracy or to ensure that all problems had been resolved. This type of supervisory oversight would have detected many of the discrepancies we noted, which fell into several categories:

- No Reconciliation. For 166 of the 582 effectiveness check forms we reviewed, FSIS compliance officers did not reconcile the amount of product purchased by customers with the amount recorded on the Pilgrim's Pride distribution list. For example, a food distributor in Virginia purchased almost 22,000 pounds of recalled product according to the Pilgrim's Pride distribution list. When the compliance officer visited this distributor, he recorded the amount of product purchased as "?" or unknown. Similar problems occurred in each of the four FSIS districts we reviewed. Although the compliance officers explained that they normally reconcile the amount of product purchased by the customer with the

[1] Some of the effectiveness check forms contained more than one discrepancy.

amount recorded as sold by Pilgrim's Pride, the effectiveness check forms did not support this.

- No Evidence of Followup. For 93 of the 582 effectiveness checks, compliance officers did not document their followup to ensure that customers had located and controlled recalled product. In one case, an FSIS compliance officer visited a Delaware detention center where eight pieces of recalled turkey breast were defrosting in the sink to be served that night. The compliance officer wrote on his effectiveness check form, "The eight pieces were taken out of the water and [the center's food service supervisor] stated that they would be returned." According to the compliance officer, he contacted the center 2 days later and determined that the primary customer had picked up the product. While we confirmed that the product had been picked up, the compliance officer did not document this information as a followup effectiveness check.

We reported similar weaknesses in our reports on FSIS' oversight of the ConAgra recall[2] and FSIS' oversight of the *Listeria* outbreak in the Northeastern United States.[3] In response to our recommendations, FSIS agreed to strengthen recall controls and procedures. Until it corrects the problems we identified, FSIS' conclusions regarding the effectiveness of food safety recalls may be based on inaccurate and incomplete information.

To further strengthen the recall process, FSIS needs to correct three other problems we identified during the present review:

- Information Used in Assessment Not Documented. According to FSIS officials, the agency relies on information other than effectiveness checks to determine whether a recall is effective. However, agency procedures do not describe what information is considered or how the information is assessed.

- Not Performed Timely. Compliance officers performed 72 of the 582 effectiveness checks more than 30 days after customers received notice of the recall.

- No Selection Methodology. Compliance officers conducted effectiveness checks at businesses that did not purchase any of the recalled product because FSIS does not have a process for selecting customers for effectiveness checks.

[2] 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.
[3] Audit Report No. 24601-2-Hy, "Food Safety and Inspection Service Oversight of the *Listeria* Outbreak in the Northeastern United States," issued June 9, 2004.

In addition to the FSIS effectiveness checks, we analyzed 40 of the 784 effectiveness checks conducted by Pilgrim's Pride personnel, which we found were adequately performed.

Recommendations In Brief

We recommend that FSIS document the information used to assess whether a recall is effective. Further, FSIS needs to implement controls to ensure that it adequately supports its conclusions regarding future recalls. FSIS needs to examine all of the effectiveness check forms for the Pilgrim's Pride recall to ensure that the information recorded is accurate and complete. Finally, FSIS needs to implement a process for selecting customers for effectiveness checks and establish timeframes for completing and reviewing effectiveness checks.

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.

OIG Position

Based on FSIS' response, we were able to reach management decision on one of the report's five 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, 2, 3, and 5.

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Background and Objectives

Background

As the public health regulatory agency of the U.S. Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) is responsible for ensuring that meat and poultry products are safe, wholesome, and accurately labeled. When there is reason to believe that product may be adulterated (i.e., injurious to health or unfit for human consumption), the manufacturer voluntarily removes the product from commerce, through a recall. Although recalls are voluntary, FSIS oversees all recall activities by official establishments. If a company refuses to recall a meat or poultry product that may cause health problems or death, FSIS has legal authority to detain and/or seize those products in commerce.

According to FSIS procedures,[4] FSIS compliance officers must perform a sufficient number of checks on the effectiveness of a product recall. These checks verify that: (1) the firm conducting the recall provides adequate notice about the recall to all customers, and (2) customers locate and control products according to the recalling firm's instructions. Compliance officers record the results of their verifications on FSIS Form 8400-4, Report of Recall Effectiveness.

When illnesses associated with *Listeria monocytogenes* began appearing in the Northeastern United States in September 2002, FSIS initiated a vigorous sampling of ready-to-eat poultry products. These products included luncheon and deli-style meats. In a press release dated October 2, 2002, FSIS stated that the agency, in cooperation with the Centers for Disease Control and Prevention and State health officials, was continuing its aggressive investigation into the origins of the outbreak of *Listeria monocytogenes*, which had led to 6 deaths and 36 illnesses in 8 States.

On October 9, 2002, FSIS announced that the Pilgrim's Pride Corporation, doing business as Wampler Foods Inc., a Franconia, Pennsylvania establishment, voluntarily recalled approximately 295,000 pounds of fresh and frozen ready-to-eat poultry products possibly contaminated with *Listeria monocytogenes*. In this announcement, FSIS reported that it had collected a microbiological investigative sample at the plant on October 2, 2002, which returned with positive results for *Listeria monocytogenes*. However, FSIS reported that there was no link between the recalled products and the *Listeria monocytogenes* illnesses in the Northeastern United States.

On October 12, 2002, FSIS announced that Pilgrim's Pride was expanding the voluntary recall to approximately 27.4 million pounds of fresh and frozen

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

ready-to-eat poultry products produced between May 1, 2002 and October 11, 2002. Pilgrim's Pride had distributed these products to retail stores, restaurants, and institutions nationwide as well as overseas; USDA purchased approximately 1.7 million pounds for distribution to schools and other recipient agencies. As part of this announcement, FSIS reported that, while product samples from various days of production were all negative, environmental sampling in the plant demonstrated the presence of the *Listeria monocytogenes* strain matching the October 9, 2002, recalled product. Pilgrim's Pride voluntarily suspended operations of the plant in Franconia, Pennsylvania. Production resumed on November 14, 2002, when Pilgrim's Pride proposed an adequate corrective action plan to eliminate potential *Listeria* contamination. FSIS also concurrently initiated finished product sampling to ensure that the corrective action plan was adequately implemented.

FSIS terminated the Pilgrim's Pride recall on July 11, 2003, after concluding that the recall had been effective. At that time, Pilgrim's Pride had reported the recovery of more than 5.5 million pounds of recalled product, which was either stored at several warehouses pending FSIS-approved disposition or destroyed by customers. According to Pilgrim's Pride, the rest of the recalled product, almost 21.9 million pounds, was consumed in the marketplace or otherwise disposed of.

Objectives

Our objective was to evaluate the adequacy of the effectiveness checks performed for the Pilgrim's Pride recall. This included an evaluation of the effectiveness checks performed by FSIS District Offices and Pilgrim's Pride personnel.

To accomplish this objective, we obtained an understanding of FSIS' procedures for performing effectiveness checks and analyzed the 582 effectiveness checks performed by 4 FSIS District Offices. We also obtained an understanding and analyzed a sample of the effectiveness checks performed by Pilgrim's Pride. Our audit work covered the period from when the Pilgrim's Pride recall began in October 2002 through August 2003. We performed fieldwork from April 2003 through August 2003.

Findings and Recommendations

Section 1. FSIS Effectiveness Checks

On July 11, 2003, FSIS concluded that the Pilgrim's Pride recall of 27.4 million pounds of ready-to-eat poultry products had been effective. To make this determination, the agency relied on effectiveness checks completed by FSIS compliance officers from its 15 District Offices. However, we noted a significant number of discrepancies in the data recorded on the 582 effectiveness check forms we reviewed. Accordingly, we concluded that these forms did not provide a reliable basis for evaluating the recall's effectiveness.

On March 16, 2004, we held an exit conference with FSIS officials to discuss the draft report. At this meeting, FSIS officials explained that the agency's conclusion that a recall is effective is based on more than the compliance officers' completion of effectiveness checks. Other information considered includes such things as consumer notification and epidemiological data regarding the product being recalled. However, FSIS' documented methodology for assessing the effectiveness of a recall only describes the agency's use of effectiveness checks. FSIS did not provide documentation to support the other information considered.

Finding 1 — FSIS Oversight of the Pilgrim's Pride Recall Was Ineffective

Of the 582 FSIS effectiveness check forms we reviewed, 319 contained discrepancies in information. This high error rate occurred because FSIS compliance officers did not adequately assess and act on the information they collected. In some cases, compliance officers did not obtain the information necessary to complete the forms. Furthermore, FSIS supervisory personnel did not review the effectiveness check forms to ensure they were properly completed and that all problems had been resolved, which would have detected many of the 389 discrepancies we noted.[5] As a result, FSIS did not have reasonable assurance that potentially adulterated product bearing the USDA seal of inspection had been retrieved from commerce.

According to FSIS procedures, compliance officers perform checks on the effectiveness of a product recall to verify that: (1) the firm conducting the recall provides adequate notice about the recall to all customers, and (2) customers locate and control products according to the recalling firm's instructions. In the event that effectiveness checks disclose that customers have not been notified of the product recall or have not acted as requested by

[5] Some of the effectiveness check forms contained more than one discrepancy.

the recalling firm, FSIS program personnel must detain any products posing a health risk and notify the recalling firm.

Amount of Product Purchased Not Reconciled

Of the 582 effectiveness checks we reviewed, 103 were of primary customers (i.e., customers that purchased product directly from Pilgrim's Pride). The remaining 479 effectiveness checks were of secondary customers (i.e., customers that purchased product from the primary customers). For the primary customers, FSIS compliance officers did not always reconcile the amount of product purchased with the Pilgrim's Pride distribution list. Compliance officers also did not obtain sufficient information from the primary customers in order to reconcile the amount of product purchased by secondary customers. As a result, FSIS had no assurance that the recalled product was properly accounted for and removed from commerce.

For 50 of the 103 effectiveness checks of primary customers, compliance officers did not reconcile the amount of recalled product purchased by the customer with the amount shown on the Pilgrim's Pride distribution list. For these 50 customers, the amount not reconciled totaled over 846,000 pounds. In one case, a food distributor in Virginia purchased almost 22,000 pounds of recalled product according to the Pilgrim's Pride distribution list. When the compliance officer visited the distributor, he recorded the amount of product purchased as "?" or unknown. The compliance officer explained that he normally compares the amount of product purchased as stated by the customer with the amount of product shown on the Pilgrim's Pride distribution list. However, he could not explain why he did not follow this process for the Virginia distributor. While compliance officers in all of the four districts we reviewed stated that they reconciled the purchase amounts, the effectiveness check forms for the 50 customers in question indicated that none of them did so.

In addition, we determined that FSIS compliance officers did not reconcile the amount of product purchased by secondary customers. For 116 of the 479 secondary effectiveness checks, compliance officers did not document the amount of product purchased on the form or recorded it as unknown. Although we attempted to reconcile the amount of product purchased, the compliance officers had not retained sufficient information. Specifically, the compliance officers either did not obtain distribution information from primary customers or obtained information irrelevant to the amount of product purchased by secondary customers.

For example, we found that the compliance officer who visited the Virginia food distributor did not retain the firm's distribution list in order to reconcile the amount of product purchased by secondary customers. Instead, he noted on the effectiveness check form that the firm sold product to 58 secondary

customers, 5 of which he selected for effectiveness checks. For two of the five secondary customers, the amount the compliance officer recorded on the effectiveness check forms did not agree with the amount on the firm's distribution list; the compliance officer overstated the amount purchased by approximately 13 pounds. For two of the other secondary customers, the compliance officer reported the amount of product purchased as unknown. According to the firm's distribution list, these customers purchased approximately 403 pounds. The fifth customer the compliance officer selected for review, a Virginia public school district, did not purchase any of the recalled product. (See page 7 for details on problems with selecting customers for effectiveness checks.)

No Evidence of Followup

FSIS compliance officers did not always document followup effectiveness checks on product being held by customers pending further instructions. We noted this problem on 93 of the 582 effectiveness check forms we reviewed, further diminishing the agency's assurance that customers controlled potentially contaminated product.

In one case, a compliance officer did not document the followup visit he made to ensure that a Delaware detention center returned recalled product to a primary customer. At the time of the initial visit, October 24, 2002, the center had four cases of recalled product in inventory, approximately 70 pounds. The compliance officer noted on the effectiveness check form that eight pieces of recalled turkey breast were defrosting in a sink of water, to be served that night. According to the form, the eight pieces were taken out of the water and the center's food service supervisor stated that the product would be returned. The compliance officer told us that he did not detain the recalled product because the customer agreed to return it. He stated that he contacted the center 2 days later and determined that the primary customer had picked up the product. While we confirmed this with the center, the compliance officer did not document this information as a followup effectiveness check. He explained that he overlooked documenting the followup in his haste to complete his assigned effectiveness checks.

Initial Corrective Actions Underway, Further Strengthening Needed

In our report on the ConAgra recall, we reported similar weaknesses in FSIS oversight of the recall process. To address these issues, 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. Specifically, we recommended that FSIS establish criteria for completing effectiveness checks and for determining recall effectiveness.

FSIS agreed with these recommendations and implemented interim guidelines in March 2003. While these new guidelines do not establish criteria for assessing recall effectiveness, FSIS has convened a workgroup to consider the agency's overall policies and procedures for managing the recall process and 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 the agency to reach agreement on an acceptable corrective action plan.

We also reported related weaknesses in our report on FSIS oversight of the *Listeria* outbreak in the Northeastern United States. To improve FSIS oversight of recall effectiveness checks, we recommended that FSIS train compliance officers on the importance of accurately performing and documenting effectiveness checks. FSIS agreed with this recommendation and initiated training in October 2003. This training included instructions and guidance on conducting effectiveness checks. In addition, FSIS expanded its talent pool for conducting and following up on effectiveness checks through the use of trained enforcement officers and veterinarians. According to FSIS, 250 field personnel were trained on risk-based recall effectiveness procedures in April 2004.

Accordingly, we are not making additional recommendations in regard to reconciliation and followup at this time. However, to further strengthen the recall process, FSIS needs to document the factors considered and the methodology used to conclude whether a recall is effective. FSIS also needs to ensure that it conducts effectiveness checks in a timely manner and with appropriate customers.

Process for Assessing the Effectiveness of a Recall Not Documented

According to documentation closing the Pilgrim's Pride recall, dated July 11, 2003, FSIS relied on the effectiveness checks completed by the agency's compliance officers to conclude that the recall was effective. However, at the exit conference for this audit on March 16, 2004, FSIS officials explained that they relied on other information including such things as consumer notification and epidemiological data to conclude the recall was effective. FSIS officials explained that consumers are notified of the recall in a variety of ways including media reports, press releases, and websites of the agency and the recalling firm. FSIS officials also explained that they monitor epidemiological data maintained by the Centers for Disease Control and Prevention and State health officials for additional illnesses associated with the recalled product.

Subsequent to the exit conference, we re-reviewed FSIS' recall policy in place at the time of the Pilgrim's Pride recall. We also reviewed FSIS

Directive 8080.1, Revision 4, *"Recall of Meat and Poultry Products,"* issued May 24, 2004. Both of these documents described FSIS' sole reliance on effectiveness checks to determine whether a recall is effective. FSIS' recall procedures should document all the information the agency considers for assessing the effectiveness of a recall and how this assessment is completed. The procedures should also include controls to ensure that FSIS adequately supports its conclusions regarding the effectiveness of future recalls.

Effectiveness Checks Not Performed in a Timely Manner

Compliance officers performed 72 of the 582 effectiveness checks more than 30 days after the customers received notice of the recall—25 of these were up to 40 days after customers received the recall notice, and the remaining 47 were as many as 53 days after the customers received notice. While FSIS procedures do not specify the timeframes required for conducting effectiveness checks, the agency must be responsible for ensuring that potentially contaminated product is identified and removed from commerce in a timely manner.

We noted that one compliance officer performed 68 of the 72 untimely effectiveness checks. The compliance officer acknowledged that the checks were not performed in a timely manner. He explained that other work priorities, such as performing effectiveness checks for the ConAgra recall and collecting samples from product returned to Pilgrim's Pride, prevented him from completing the checks sooner. He added that other compliance officers were unavailable to assist him due to their own workloads for Pilgrim's Pride recall.

Additionally, seven of the forms we reviewed did not state the date of the effectiveness check. As a result, we could not determine whether compliance officers performed those effectiveness checks in a timely manner.

Inappropriate Customers Selected for Effectiveness Checks

In our followup on the Virginia public school district mentioned previously, we verified that the school district did not purchase any of the recalled product. The compliance officer who visited the district for a secondary effectiveness check explained that he used a list of the primary distributor's customers to select a sample of secondary customers. However, the compliance officer did not narrow down the list of secondary customers to include only those that purchased recalled product. This occurred because FSIS had not developed a method for selecting customers for effectiveness checks.

We found that this was not an isolated instance. In Puerto Rico, two FSIS compliance officers performed effectiveness checks at 29 entities that did not

purchase any of the recalled product. In addition to reducing public confidence in FSIS recall activities, these misguided selections meant that other customers that did purchase recalled product went unchecked.

On May 24, 2004, FSIS issued Directive 8080.1, Revision 4, *"Recall of Meat and Poultry Products."* This Directive included information on: (1) the timeframes for performing effectiveness checks, and (2) the process to be used for selecting customers to contact.

Recommendation No. 1

Document all information considered by FSIS for assessing the effectiveness of a recall and how this assessment is made.

Agency Response.

Effectiveness checks are conducted by FSIS inspection program personnel to verify that recalling firms have been diligent and successful in notifying and advising the consignees of the need to retrieve and control recalled product and the consignees have responded accordingly. Recalling firms are responsible for developing and implementing effective recall strategies used to notify all consignees and to remove recalled product from commerce. Through effectiveness checks, FSIS verifies that the recall actions are being conducted in an effective manner.

FSIS is revising FSIS Directive 8080.1, *"Recall of Meat and Poultry Product."* In the revised directive, FSIS will provide definite criteria the Agency will use in considering the effectiveness of a recall. In particular, the revised directive will note that recalls will be deemed effective when the number of consignee checks that are found to have the product available to the public is less than the critical number in the sampling plan applied to the effectiveness check.

The revised FSIS Directive 8080.1 will be issued by June 2004.

OIG Position.

FSIS' response did not address the recommendation. At the exit conference on March 16, 2004, FSIS officials explained that they relied on other information in addition to effectiveness checks to conclude the recall was effective. This other information included such things as consumer notification and epidemiological data. On May 24, 2004, FSIS issued Directive 8080.1, Revision 4, *"Recall of Meat and Poultry Products."*

FSIS' response to the recommendation and the recently issued Directive 8080.1 continue to describe the agency's sole reliance on

effectiveness checks to determine whether a recall is effective. To reach management decision, FSIS needs to incorporate into Directive 8080.1 all of the information it considers for assessing the effectiveness of a recall and how this assessment is made. In the interim, FSIS needs to implement compensating controls to ensure all relevant information is considered when the agency assesses the effectiveness of a recall.

Recommendation No. 2

Implement controls to ensure that FSIS adequately supports its conclusions regarding the effectiveness of future recalls.

Agency Response.

FSIS is revising FSIS Directive 8080.1, *Recall of Meat and Poultry Products."* In the updated directive, the role and responsibility of the Deputy District Managers (DDMs) during a recall is specifically identified. Each DDM will serve as the District Recall Officer (DRO) in his or her district and be responsible for coordinating the recall activities. The revised directive will outline the criteria the DRO will use in order to determine the effectiveness of a recall. The DRO will conduct on-site reviews of the recalling firm's effectiveness checks including confirmed recall notices, receipts of returned product, telephone call reports, and email confirmations.

The revised FSIS Directive 8080.1 will be issued by June 2004.

OIG Position.

We do not accept FSIS' management decision. FSIS issued Directive 8080.1, Revision 4, on May 24, 2004. This Directive did not identify the controls FSIS would implement to ensure that its conclusions regarding the effectiveness of future recalls are adequately supported. The Directive continues to describe the agency's sole reliance on effectiveness checks to determine whether a recall is effective. The Directive did not describe the reliance on consumer notification and epidemiological data to determine the effectiveness of the recall. To reach management decision, FSIS needs to incorporate these controls into Directive 8080.1. In the interim, FSIS needs to implement compensating controls to ensure that FSIS adequately supports its conclusions regarding the effectiveness of future recalls.

Recommendation No. 3

Examine all of the effectiveness checks performed for the Pilgrim's Pride recall to ensure that the information recorded on the forms is accurate and complete. Provide feedback to individual compliance officers when patterns of errors and omissions are noted.

Agency Response.

FSIS completed the Pilgrim's Pride recall and officially closed it. To cost effectively address the OIG's concerns, the FSIS Office of Program Evaluation, Enforcement and Review (OPEER) will complete a review of the Pilgrim's Pride effectiveness checks and related recall reports to summarize the accuracy and completeness of the effectiveness checks. OPEER will complete its review and provide feedback to the FSIS Office of Field Operations 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. 4

Develop and implement a process for selecting customers for effectiveness checks.

Agency Response.

FSIS is revising FSIS Directive 8080.1, *"Recall of Meat and poultry Products."* In the revised directive, FSIS will implement a risk-based process for selecting customers for effectiveness checks. Under a new, three-tiered classification system for recalls, the number of effectiveness checks inspection program personnel will conduct will be based on risk, dependent on the class of recall and the number of customers. Upon notice of the recall, the DRO will immediately request information and records, in accordance with Title 9 of the Code of Federal Regulations § 320.1, of the

recalling firm and the subsequent consignees regarding the distribution of recalled product. The information is expected to contain sufficient details to allow FSIS personnel to understand the distribution patterns and make contacts without further delay. The DRO will sort the information according to geographical location and coordinate field personnel to contact the consignees.

The revised FSIS Directive 8080.1 will be issued by June 2004.

OIG Position.

We accept FSIS' management decision. FSIS issued Directive 8080.1, Revision 4, on May 24, 2004, which incorporated the cited improvements into the agency's recall procedures. For final action, FSIS needs to provide Office of the Chief Finance Officer with documentation that the agency has implemented the procedures for selecting customers for effectiveness checks.

Recommendation No. 5

Develop and implement timeframes in which effectiveness checks must be completed and reviewed.

Agency Response.

FSIS is revising FSIS Directive 8080.1, *"Recall of Meat and poultry Products."* In the updated directive, timeframes are specified for initiating and reporting verification activities within FSIS. Recall activities by firms will start immediately after a decision has been made that a recall should be initiated or when notification of a recall is received. The directive outlines the timetable for both beginning and completing FSIS verification activities. FSIS verification activities will begin as soon as possible within a period of 3 days for a Class I recall, 5 days for a Class II recall, and 10 days for a Class III recall. Similarly, FSIS verification activities will be substantially completed within a period of 10 days for a Class I recall, 12 days for a Class II recall, and 17 days for a Class III recall.

The revised FSIS Directive 8080.1 will be issued by June 2004.

OIG Position.

We do not accept FSIS' management decision. FSIS issued Directive 8080.1, Revision 4, on May 24, 2004. This Directive did not identify the timeframes in which a second party (i.e., DRO) will review the accuracy of effectiveness checks. To reach management decision on this recommendation, FSIS needs to incorporate this into Directive 8080.1. In the

interim, FSIS needs to implement compensating controls to ensure that effectiveness checks are reviewed.

Scope and Methodology

We focused our audit on regulations and documentation applicable to the Pilgrim's Pride recall of ready-to-eat poultry products. Our audit work covered the period October 2002, when the Pilgrim's Pride began, through August 2003. We conducted fieldwork from April 2003 through August 2003, including visits to FSIS Headquarters, FSIS District Offices, the Pilgrim's Pride administrative office, and selected primary and secondary Pilgrim's Pride customers.

To evaluate the adequacy of FSIS effectiveness checks performed for the Pilgrim's Pride recall, we identified and reviewed the policies and procedures for conducting a recall of meat and poultry products. These included FSIS Directive 8080.1, Revision 3 *"Recall of Meat and Poultry Products,"* dated January 2000, and the Recall Protocol, dated September 1997. We also interviewed appropriate FSIS personnel to gain an understanding of the effectiveness check process. We compared these procedures to those used by compliance officers for the Pilgrim's Pride recall to identify weaknesses in the process.

We selected for review the effectiveness checks performed by compliance officers at 4 of the 15 FSIS District Offices involved in the recall:

- The Philadelphia District Office, because it was the lead district;
- the Beltsville District Office, because it was the district where the primary Pilgrim's Pride collection center was located; and
- the Albany and Atlanta District Offices, due to the large number of effectiveness checks they performed.

We examined all 582 effectiveness check forms completed by compliance officers in these four districts to determine if they were complete and accurate. When necessary, we contacted compliance officers to resolve discrepancies noted on the effectiveness checks.

We validated the information recorded by FSIS compliance officers on the effectiveness checks by visiting two primary customers (located in Virginia and Maryland), reviewing their records, and contacting a sample of secondary customers (located in Virginia, Maryland, and Delaware). We judgmentally selected these primary and secondary customers based on the discrepancies noted in the effectiveness check forms.

At the Pilgrim's Pride administrative office located in Broadway, Virginia, we obtained an understanding of the process used to notify customers of the recall. We also reviewed the documentation on file to substantiate that Pilgrim's Pride notified its customers of the recall.

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

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

MAY 20 2004

FROM: Barbara J. Masters
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Official Draft Audit Report – FSIS Effectiveness Checks for the 2002 Pilgrim's Pride Recall, Report Number 24601-03-Hy

We appreciate the opportunity to review and comment on the subject report. The Food Safety and Inspection Service (FSIS) has implemented actions to improve the effectiveness of the recalls the Agency oversees. FSIS has made substantial changes to its recall process, strengthened verification activities, and established clearer lines of authority to ensure that potentially contaminated products are removed from commerce and that consumers receive information promptly.

FSIS is committed to public health protection by developing and implementing new risk-based approaches to effectiveness checks of meat and poultry recalls. FSIS field compliance officers conduct effectiveness checks of meat and poultry recalls ensuring that proper and adequate customer notification is made by the recalling firm and that the firm makes all reasonable efforts to retrieve and appropriately dispose of the recalled products. Effectiveness checks allow the Agency to verify that the actions of the recalling firm are made swiftly and accurately in the best interest of public health.

FSIS is currently updating and revising its recall directive, FSIS Directive 8080.1, *Recall of Meat and Poultry Products*. The issues raised in this report are addressed in the revised directive.

The recall directive spells out the policy and procedures FSIS will take in cases of meat and poultry recalls. It describes how recalls are to be conducted by the establishment and the role of FSIS throughout the recall process. The directive discusses how public notification of recalls is to take place and provides information on the new risk-based system the Agency will use for determining the scope of effectiveness checks.

The new recall effectiveness check verification process will be based on risk, dependent on the class of the recall and the number of customers. This risk-based system will allow the Agency to better target its resources to protect public health. New statistically-based guidance will direct the number of effectiveness checks conducted. Effectiveness checks will be most intensive for Class I recalls when they are related to school lunch, outbreaks or illnesses. The guidance will also address the recommended time frames for initiating and reporting the verification process

which will be based on the class of the recall. An objective procedure will be used to verify appropriate recall product disposition or destruction by consignees.

Several procedures which will be included in the revised directive are already in use by the Agency and have been tested in the field. We expect the directive to be issued by June 2004.

Section 1. FSIS Oversight of the Pilgrim's Pride Recall Was Ineffective

1. **Recommendation No. 1**
Document all information considered by FSIS for assessing the effectiveness of a recall and how this assessment is made.

FSIS Response
Effectiveness checks are conducted by FSIS inspection program personnel to verify that recalling firms have been diligent and successful in notifying and advising the consignees of the need to retrieve and control recalled product and the consignees have responded accordingly. Recalling firms are responsible for developing and implementing effective recall strategies used to notify all consignees and to remove recalled product from commerce. Through effectiveness checks, FSIS verifies that the recall actions are being conducted in an effective manner.

FSIS is revising FSIS Directive 8080.1,"*Recall of Meat and Poultry Products.*" In the revised directive FSIS will provide definite criteria the Agency will use in considering the effectiveness of a recall. In particular, the revised directive will note that recalls will be deemed effective when the number of consignee checks that are found to have the product available to the public is less than the critical number in the sampling plan applied to the effectiveness check.

The revised FSIS Directive 8080.1 will be issued by June 2004.

2. **Recommendation No. 2**
Implement controls to ensure that FSIS adequately supports its conclusions regarding the effectiveness of future recalls.

FSIS Action
FSIS is revising FSIS Directive 8080.1, "*Recall of Meat and Poultry Products.*" In the updated directive, the role and responsibility of the Deputy District Managers (DDMs), during a recall, is specifically identified. Each DDM will serve as the District Recall Officer (DRO) in his or her district and be responsible for coordinating the recall activities. The revised directive will outline the criteria the DRO will use in order to determine the effectiveness of a recall. The DRO will conduct on-site reviews of the recalling firm's effectiveness checks including confirmed recall notices, receipts of returned product, telephone call reports, and e-mail confirmations.

The revised FSIS Directive 8080.1 will be issued by June 2004.

3. **Recommendation No. 3**
Examine all of the effectiveness checks performed for the Pilgrim's Pride recall to ensure that the information recorded on the forms is accurate and complete. Provide feedback to individual compliance officers when patterns and omissions are noted.

FSIS Response
FSIS completed the Pilgrim's Pride recall and officially closed it. To cost effectively address the OIG's concerns, the FSIS Office of Program Evaluation, Enforcement and Review (OPEER) will complete a review of the Pilgrim's Pride effectiveness checks and related recall reports to summarize the accuracy and completeness of the effectiveness checks. OPEER will complete its review and provide feedback to the FSIS Office of Field Operations by December 2004.

4. **Recommendation No. 4**
Develop and implement a process for selecting customers for effectiveness checks.

FSIS Response
FSIS is revising FSIS Directive 8080.1, "*Recall of Meat and Poultry Products.*" In the revised directive, FSIS will implement a risk-based process for selecting customers for effectiveness checks. Under a new, three-tiered classification system for recalls, the number of effectiveness checks inspection program personnel will conduct will be based on risk, dependent on the class of recall and the number of customers. Upon notice of the recall, the DRO will immediately request information and records, in accordance with 9 CFR 320.1, of the recalling firm and the subsequent consignees regarding the distribution of recalled product. The information is expected to contain sufficient details to allow FSIS personnel to understand the distribution patterns and make contacts without further delay. The DRO will sort the information according to geographical location and coordinate field personnel to contact the consignees.

The revised FSIS Directive 8080.1 will be issued by June 2004.

5. **Recommendation No. 5**
Develop and implement timeframes in which effectiveness checks must be completed and reviewed.

FSIS Action
FSIS is revising FSIS Directive 8080.1, "*Recall of Meat and Poultry Products.*" In the updated directive, timeframes are specified for initiating and reporting verification activities within FSIS. Recall activities by firms will start immediately after a decision has been made that a recall should be initiated or when notification of a recall is received. The directive outlines the timetable for both beginning and completing FSIS verification activities. FSIS verification activities will begin as soon as possible within a period of 3 days for a Class I recall, 5 days for a Class II recall, and 10 days for a Class III recall. Similarly, FSIS verification activities will be substantially completed within a period of 10 days for a Class I recall, 12 days for a Class II recall, and 17 days for a Class III recall.

The revised FSIS Directive 8080.1 will be issued by June 2004.