



U.S. Department of Agriculture



Office of Inspector General
Northeast Region

Audit Report

Food Safety and Inspection Service Oversight of the 2004 Recall by Quaker Maid Meats, Inc.

Report No. 24601-04-Hy
MAY 2005



UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250



May 18, 2005

REPLY TO

ATTN OF: 24601-04-Hy

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

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

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

SUBJECT: Food Safety and Inspection Service Oversight of the 2004
Recall by Quaker Maid Meats, Inc.

This report presents the results of our audit of the Food Safety and Inspection Service's oversight of the 2004 recall by Quaker Maid Meats, Inc. Your response to the official draft, dated May 5, 2005, 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, we were not able to reach management decision on the report's two recommendations. Management decision can be reached once you have provided the additional information outlined in the report section OIG Position.

In accordance with Departmental Regulations 1720-1, please furnish a reply within 60 days describing the timeframes for implementing the planned corrective actions. Please note that the regulation requires management decision to be reached on all recommendations within 6 months of report issuance.

Executive Summary

Food Safety and Inspection Service's Oversight of the 2004 Recall by Quaker Maid Meats, Inc. (Audit Report No. 24601-04-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 recall by Quaker Maid Meats, Inc. (Quaker Maid). On July 28, 2004, Quaker Maid initiated a recall of approximately 170,000 pounds of ground beef patties from U.S. commerce due to mislabeling. The ground beef patties were made, in part, from 41,000 pounds of finely textured beef trim (meat scavenged from beef taken off the bone at high pressure) from Canada. This type of product was not eligible to be imported into the United States following the detection of a Canadian cow with bovine spongiform encephalopathy in May 2003. The beef patties had been shipped to 474 distribution centers and stores in Florida, Maine, Maryland, New Jersey, New York, North Carolina, Pennsylvania, South Carolina, Virginia, and Wisconsin. According to information reported by Quaker Maid, the recall of the beef patties subsequently resulted in the recovery of over 93 percent of the ineligible product.

Establishments¹ initiate recalls to remove mislabeled products from commerce. FSIS is responsible for overseeing all recall activities by the establishments. According to procedures,² FSIS compliance officers perform a specific number of effectiveness checks to verify that the recalling establishment has been diligent and successful in notifying and advising the consignees³ of the need to retrieve and control recalled product and that the consignees have responded accordingly. The compliance officers record the results of their verifications on FSIS Form 8400-4, Report of Recall Effectiveness.

In 2003 and 2004, OIG issued three reports that were critical of FSIS' oversight of meat and poultry recalls.⁴ In response to our recommendations, FSIS agreed to implement a management control process to ensure that FSIS district managers comply with recall procedures and that compliance officers' determinations are reviewed, analyzed, and acted on. FSIS also agreed to 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.

¹ Establishments are the FSIS-regulated facilities that produce meat and/or poultry products.

² FSIS Directive 8080.1, Revision 4, Recall of Meat and Poultry Products, dated May 24, 2004.

³ Consignees are distribution centers and stores that received product from the recalling establishment.

⁴ This work included: (1) Audit Report No. 24601-02-KC, "FSIS Oversight of Production Process and Recall at ConAgra Plant (Establishment 969)," issued September 30, 2003, (2) Audit Report No. 24601-02-Hy, "FSIS Oversight of the *Listeria* Outbreak in the Northeastern United States," issued June 9, 2004, and (3) Audit Report No. 24601-03-Hy, "FSIS Effectiveness Checks for the 2002 Pilgrim's Pride Recall," issued June 29, 2004.

According to FSIS officials, these agreed upon actions were implemented through FSIS Directive 8080.1, Revision 4, Recall of Meat and Poultry Products, dated May 24, 2004.

In August 2004, we initiated actions to evaluate the adequacy of effectiveness checks performed by FSIS for the Quaker Maid recall and FSIS' oversight of this recall to include compliance with the recent revision to FSIS' recall policy. To accomplish our review, we interviewed FSIS officials and examined documentation supporting the agency's oversight of the Quaker Maid recall, to include the 58 effectiveness checks performed. We also contacted 7 of the 58 firms where FSIS performed effectiveness checks to validate information we learned from FSIS regarding the effectiveness checks performed for these firms.

Overall, we concluded that FSIS strengthened its procedures regarding the agency's oversight of meat and poultry recalls. We also found that FSIS complied with the recent revision made to the agency's recall policy. However, we noted FSIS compliance officers did not determine the amount of product purchased by consignees for 26 of the 58 effectiveness checks performed for the Quaker Maid recall. This occurred because FSIS' recall policy did not provide any specific direction on identifying and evaluating the amount of product purchased by consignees. In our opinion, FSIS had reduced assurance that mislabeled product bearing the United States Department of Agriculture seal of inspection had been retrieved from commerce. However, based on the effectiveness checks that FSIS performed, FSIS officials believed Quaker Maid's assertion that the product had been removed from the marketplace.

In November 2004, we discussed our concern with the FSIS Assistant Administrator for Field Operations and the Director of FSIS' Recall Management Division. They agreed with our concern and initiated actions in December 2004 to revise the effectiveness check form to require compliance officers to provide an explanation when they do not determine the amount of product purchased. In addition, FSIS should revise the agency's recall policy to provide specific direction on identifying and evaluating this amount and when not identifying it would be considered acceptable.

Recommendations In Brief

FSIS needs to revise FSIS Form 8400-4, Report of Recall Effectiveness, to require compliance officers to explain why the amount of product purchased by consignees was not identified. FSIS also needs to revise FSIS Directive 8080.1 to provide specific direction on identifying and evaluating the amount of product purchased by the consignees and guidance on when it is acceptable to not identify this amount.

Agency Response

FSIS 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 not able to reach management decision on the report's two recommendations. FSIS did not provide the dates when the proposed corrective actions will be implemented. The Findings and Recommendation section of this report provide the details of the additional information needed to reach management decision.

Abbreviations Used in This Report

APHIS	Animal and Plant Health Inspection Service
CFIA	Canadian Food Inspection Agency
FSIS	Food Safety and Inspection Service
OIG	Office of Inspector General
Quaker Maid	Quaker Maid Meats, Inc.
Secretary	Secretary of Agriculture
USDA	United States Department of Agriculture
U.S.	United States

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Background and Objectives

Background

As the public health regulatory agency of the United States Department of Agriculture (USDA), the 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 mislabeled, the manufacturer voluntarily removes the product from commerce, through a recall. Although recalls are voluntary, FSIS oversees all recall activities by 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,⁵ FSIS compliance officers perform a specific number of effectiveness checks to verify that the recalling firm has been diligent and successful in notifying and advising the consignees of the need to retrieve and control recalled product and that the consignees have responded accordingly. Compliance officers record the results of their verifications on FSIS Form 8400-4, Report of Recall Effectiveness.

On July 28, 2004, FSIS announced that Quaker Maid Meats, Inc. (Quaker Maid), a Reading, Pennsylvania establishment, voluntarily recalled approximately 170,000 pounds of ground beef patties due to mislabeling. In the announcement, FSIS reported that the beef patties were partially made from Canadian product that was mislabeled and ineligible for import into the United States. The ground beef patties were shipped to 474 distribution centers and retail establishments in Florida, Maine, Maryland, New Jersey, New York, North Carolina, Pennsylvania, South Carolina, Virginia, and Wisconsin.

The ineligible Canadian product was imported into the United States after the assigned Canadian meat inspector had gone on vacation and a substitute inspector accidentally approved the mislabeled product. The ineligible product included about 41,000 pounds of finely textured beef trim (meat scavenged from beef taken off the bone at high pressure) that is considered to be a higher-risk product by USDA's Animal and Plant Health Inspection Service (APHIS) and thus ineligible for import into the United States. The ineligible product was mislabeled to indicate that it was an eligible product. When the regular Canadian inspector returned from vacation, he became aware of the mislabeling, notified USDA and FSIS officials, and the recall was initiated.

On August 26, 2004, Quaker Maid officials reported to FSIS that the recall included a total of almost 313,000 pounds of ground beef patties, as opposed

⁵ FSIS Directive 8080.1, Revision 4, Recall of Meat and Poultry Products, dated May 24, 2004.

to the 170,000 pounds initially reported by Quaker Maid. The firm determined through a review of its shipping records that almost 159,000 pounds of this product had been shipped and approximately 154,000 pounds had been retained in the firm's own freezer. Quaker Maid officials reported that almost 148,000 of the 159,000 pounds distributed into U.S. commerce had been returned, just over 93 percent of the product distributed. FSIS closed the Quaker Maid recall on October 21, 2004, after the agency had completed its recall effectiveness checks and the firm had completed its plan of action to remove products from consumer channels.

In May 2003, USDA closed the border to entry of Canadian cattle and beef products after the discovery of a bovine spongiform encephalopathy positive animal in Canada. On August 8, 2003, the Secretary of Agriculture (Secretary) announced a list of low-risk products, including boneless beef from cattle less than 30 months of age, which would be allowed into the United States from Canada, under certain predetermined conditions. According to the Secretary's August 8, 2003, announcement, advanced meat recovery and mechanical separation of meat could not be used to produce boneless beef.

In June 2004, we initiated several actions in response to concerns raised by four U.S. Senators that USDA did not follow appropriate safety measures, beginning sometime in the fall of 2003, in allowing expanded Canadian beef imports into the United States. We reviewed USDA's actions pertaining to the importation of Canadian products, including the use of risk mitigation⁶ measures. Our results were included in Audit Report No. 33601-01-Hy, Oversight of the Importation of Beef Products from Canada, issued February 2005.

In 2003 and 2004, OIG issued three reports that were critical of FSIS' oversight of meat and poultry recalls.⁷ In response to our recommendations, FSIS agreed to implement a management control process to ensure that FSIS district managers comply with recall procedures and that compliance officers' determinations are reviewed, analyzed, and acted on. FSIS also agreed to 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. According to FSIS officials, these agreed upon actions were implemented through FSIS Directive 8080.1, Revision 4, Recall of Meat and Poultry Products, dated May 24, 2004.

⁶ Risk mitigations include such actions as Canadian Food Inspection Agency (CFIA) verification that calves were 36 weeks of age or less when slaughtered and CFIA verification that animals are not known to have been fed prohibited products during their lifetime.

⁷ This work included: (1) Audit Report No. 24601-02-KC, "FSIS Oversight of Production Process and Recall at ConAgra Plant (Establishment 969)," issued September 30, 2003, (2) Audit Report No. 24601-02-Hy, "FSIS Oversight of the *Listeria* Outbreak in the Northeastern United States," issued June 9, 2004, and (3) Audit Report No. 24601-03-Hy, "FSIS Effectiveness Checks for the 2002 Pilgrim's Pride Recall," issued June 29, 2004.

Objectives

Our audit objective was to evaluate FSIS' oversight of the 2004 Quaker Maid recall. Specifically we evaluated the adequacy of the effectiveness checks performed by FSIS and FSIS' oversight to include compliance with recent revisions to FSIS' recall policy.

To accomplish our objectives, we performed fieldwork at FSIS Headquarters in Washington, D.C., and the FSIS district office in Philadelphia, Pennsylvania. We examined documentation supporting the agency's oversight of the Quaker Maid recall, to include the 58 effectiveness checks performed. We also contacted seven firms that purchased the recalled product to validate information we learned from FSIS regarding the effectiveness checks performed for these firms. (See Scope and Methodology for details.)

Findings and Recommendations

Section 1. FSIS Effectiveness Checks

Finding 1

Amount of Product Purchased Not Determined

FSIS compliance officers performed 58 effectiveness checks for the recall of approximately 170,000 pounds of ground beef patties by Quaker Maid. For 26 of the 58 effectiveness checks, FSIS compliance officers did not determine the amount of product purchased by consignees, which is used by FSIS, in part, to evaluate what the recalling firm reported as entering U.S. commerce. This high error rate occurred because FSIS' procedures for overseeing the effectiveness of recalls did not provide any specific direction on identifying and evaluating this information. In our opinion, FSIS had reduced assurance that mislabeled product bearing the USDA seal of inspection had been retrieved from commerce. However, based on the effectiveness checks that FSIS performed, FSIS officials believed Quaker Maid's assertion that the product had been removed from the marketplace.

Current recall procedures⁸ explain that effectiveness checks constitute a process by which FSIS compliance officers verify that the recalling firm has been diligent in locating, retrieving, and controlling the recalled product and that product that is recalled does not remain available to consumers. One of the items that FSIS compliance officers verify when completing an effectiveness check is the amount of recalled product the consignee purchased. FSIS uses this information, in part, as a check on the amount of recalled product that entered U.S. commerce, as reported by the recalling firm.

Quaker Maid distributed the recalled ground beef patties to 474 consignees in Florida, Maine, Maryland, New Jersey, New York, North Carolina, Pennsylvania, South Carolina, Virginia, and Wisconsin. As part of FSIS' oversight of this recall, FSIS compliance officers performed a total of 58 effectiveness checks, as required by the agency's recall procedures. We analyzed the 58 effectiveness checks and interviewed responsible FSIS officials and concluded that recall procedures were followed and effectiveness checks were adequately completed. However, we found that the FSIS compliance officers did not determine and document the amount of product purchased by 26 consignees on the effectiveness check form.⁹

On the effectiveness check forms for 26 of the 58 consignees, the FSIS compliance officers recorded the amount of product purchased as "unknown"

⁸ FSIS Directive 8080.1 Revision 4, Recall of Meat and Poultry Products, dated May 24, 2004.

⁹ FSIS Form 8400-4, Report of Recall Effectiveness.

or “n/a.” According to FSIS officials at the Philadelphia district office, compliance officers could not determine the amount of product purchased, because consignees did not maintain inventory records by the lot codes associated with the recalled product. Consequently, FSIS compliance officers recorded the amount of product purchased as unknown. Through interviews with 7 of the 26 consignees, we learned that they could identify the amount of the specific lots purchased, and the FSIS compliance officers did not contact the consignee officials that keep this information. We found that the FSIS compliance officers generally contacted the consignees’ meat managers who controlled the physical inventory of product. The meat managers explained that other consignee officials, such as accounting personnel, keep the detailed records on the specific lots purchased.

FSIS officials at the Philadelphia district office explained that they did not view information on the amount of recalled product purchased by consignees as critical to evaluating the effectiveness of a recall. Accordingly, in November 2004, we met with the FSIS Assistant Administrator for Field Operations and the Director of FSIS’ Recall Management Division to solicit their views on the relevancy of this information to evaluating the effectiveness of the recall. In December 2004, these FSIS officials provided information on the importance of determining the amount of product purchased by consignees. The amounts determined by FSIS effectiveness checks can be compared to amounts reported by the recalling firm at both the start and end of the recall. Furthermore, in recalls of smaller volumes of product, this information is valuable in evaluating the accuracy of the amount of product recovered, which could range from 0 to 100 percent of the product recalled.

Our analysis of FSIS’ current recall procedures disclosed that they did not emphasize the importance of obtaining and evaluating the amount of recalled product purchased by consignees. FSIS’ Assistant Administrator for Field Operations and the Director of the Recall Management Division agreed with our assessment and initiated a revision to the effectiveness check form. FSIS compliance officers will be required to provide an explanation when they do not determine the amount of product purchased. In addition, FSIS’ procedures for overseeing the effectiveness of recalls should provide specific direction for identifying and evaluating this amount and when not identifying it would be considered acceptable.

Recommendation 1

Revise FSIS Form 8400-4, Report of Recall Effectiveness, to require compliance officers to explain why the amount of product purchased by consignees was not identified.

Agency Response.

FSIS has revised the Form, 8400-4. The revised form has specific requirements for FSIS inspection personnel to provide an explanation when they are unable to determine the amount of product purchased. The revised form must be approved by the Office of Management of Budget.

In the interim, FSIS inspection personnel will continue using FSIS Form 8400-4 dated March 3, 2004. FSIS will issue a Notice to direct inspection personnel to provide an explanation in the "Remarks" section in response to the question of "Amount of Recall Product Purchased" when the answer is unknown.

OIG Position.

We agree with FSIS' proposed corrective action; however, we cannot accept management decision for this recommendation. To reach management decision, FSIS needs to provide the date when the Notice to inspection personnel will be issued.

Recommendation 2

Develop and implement instructions to incorporate changes in the form used by compliance officers in conducting effectiveness checks; provide specific direction on identifying and evaluating the amount of product purchased by the consignees; and provide guidance on when it is acceptable to not identify this amount. Include the instructions that are implemented in the next revision of FSIS Directive 8080.1 Recall of Meat and Poultry Products.

Agency Response.

FSIS Directive 8080.1, Recall of Meat and Poultry Products, Revision 4, Amendment 1, was amended on July 29, 2004. FSIS will issue a Notice which provides specific direction to FSIS inspection personnel for identifying and evaluating the amount of product purchased by the consignee; and provides guidance on when it is acceptable to not identify this amount. The Notice will be used in the interim, and the Notice instructions will be included in the next issuance of Directive 8080.1.

OIG Position.

We agree with FSIS' proposed corrective action; however, we cannot accept management decision for this recommendation. To reach management decision, FSIS needs to provide the date when the Notice to inspection personnel will be issued.

Scope and Methodology

We performed our audit at FSIS Headquarters located in Washington, D.C., and the district office located in Philadelphia, Pennsylvania. We performed our audit fieldwork from August through December 2004.

We interviewed responsible FSIS Headquarters and district office officials to obtain an understanding of how they performed their responsibilities for the Quaker Maid recall. We also reviewed the requirements of FSIS Directive 8080.1, Revision 4, Recall of Meat and Poultry Products, dated May 24, 2004.

At the Philadelphia district office, we examined all of the 58 effectiveness checks performed and analyzed any other documentation obtained from consignees by FSIS compliance officers. Using procedures in FSIS Directive 8080.1, FSIS selected 58 firms for performing effectiveness checks from the universe of 474 firms that received recalled ground beef patties from Quaker Maid.

For 26 of the 58 effectiveness checks, the FSIS compliance officers did not determine the amount of product purchased. According to FSIS officials at the Philadelphia district office, compliance officers could not determine the amount of product purchased because consignees did not maintain inventory records by the lot codes associated with the recalled product. We contacted seven firms that had product on hand at the time of the recall. We contacted these firms to validate information we obtained from FSIS district office officials regarding the effectiveness checks performed for these firms.

We conducted the audit in accordance with Government Auditing Standards established by the Comptroller General of the United States.

To accomplish our audit objectives, we:

- Reviewed FSIS policies and procedures related to the recall of meat and poultry products;
- Interviewed responsible FSIS and consignee officials; and
- Analyzed information used by FSIS to determine the effectiveness of the Quaker Maid recall.

Exhibit A – Agency Response

Exhibit A – Page 1 of 2



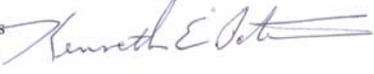
United States
Department of
Agriculture

Food Safety
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Service

Washington, D.C.
20250

MAY 05 2005

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

FROM: Dr. Barbara J. Masters
Acting Administrator 

SUBJECT: Office of Inspector General (OIG) Official Draft Audit Report -- Food
Safety and Inspection Service Oversight of the 2004 Recall by Quaker
Maid Meats, Inc., Report Number 24601-4-Hy

We appreciate the opportunity to review and comment on the subject report. The Food Safety and Inspection Service (FSIS) has implemented a number of actions to further strengthen the effectiveness of recalls. FSIS has implemented a risk-based approach to provide enhanced assurance of the effectiveness of meat and poultry recalls. The effectiveness checks verify 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.

FSIS issued a revised recall directive, FSIS Directive 8080.1, *Recall of Meat and Poultry Products*, Revision 4, Amendment 1, on July 29, 2004. The recall directive spells out the policy and procedures of FSIS for 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 will take place and provides information on the new risk-based system the Agency will use for determining the scope of effectiveness checks.

FSIS has outlined a number of positive actions that it has taken, or plans to take, to respond to the report's recommendations. Several additional procedures will be included in the next revision of Directive 8080.1, and are already in use by the Agency and have been tested in the field.

Section 1. FSIS Effectiveness Checks

1. Recommendation No. 1

Revise FSIS Form 8400-4, *Report of Recall Effectiveness*, to require compliance officers to explain why the amount of product purchased by consignees was not identified.

FSIS Response

FSIS has revised the Form 8400-4. The revised form has specific requirements for FSIS inspection personnel to provide an explanation when they are unable to determine the amount of product purchased. The revised form must be approved by the Office of Management and Budget.

In the interim, FSIS inspection personnel will continue, using FSIS Form 8400-4 dated March 3, 2004. FSIS will issue a Notice to direct inspection personnel to provide an explanation in the "Remarks" section in response to the question of "Amount of Recall Product Purchased" when the answer is unknown.

2. Recommendation No.2

Develop and implement instructions to incorporate changes in the form used by compliance officers in conducting effectiveness checks; provide specific direction on identifying and evaluating the amount of product purchased by the consignees; and provide guidance on when it is acceptable to not identify this amount. Include the instructions that are implemented in the next revision of FSIS Directive 8080.1 *Recall of Meat and Poultry Products*.

FSIS Response

FSIS Directive 8080.1, *Recall of Meat and Poultry Products*, Revision 4, Amendment 1, was amended on July 29, 2004. FSIS will issue a Notice which provides specific direction to FSIS inspection personnel for identifying and evaluating the amount of product purchased by the consignees; and provides guidance on when it is acceptable to not identify this amount. The Notice will be used in the interim, and the Notice instructions will be included in the next issuance of Directive 8080.1.