



This report was revised and reissued on May 25, 2022, to correct and clarify some narrative information. These revisions had no impact on the report's findings, conclusions, recommendations, or post audit actions.



FSIS' Compliance with Requirements for Written Recall Procedures

Audit Report 24601-0003-22

OIG audited FSIS' recall verification reviews of meat and poultry establishments to determine the sufficiency of the written recall procedures regarding product recalls.

OBJECTIVE

The objective was to determine whether FSIS' verification procedures were sufficient to ensure establishments maintain written procedures that adequately specify how the establishment will decide whether to, and how it will, conduct a product recall.

REVIEWED

We reviewed relevant laws, regulations, policies, procedures, FSIS directives, and other published guidance to understand the written recall requirements. We reviewed FSIS' organizational structure, interviewed key agency officials and inspection program personnel. In addition, we analyzed task data extracted from PHIS to identify the number of instances the inspection task was performed.

RECOMMENDS

FSIS should revise its guidance to prescribe the timeframe of when the written recall task is performed. Also, the agency should perform a reconciliation to identify establishments where the task was not performed and take corrective action.

WHAT OIG FOUND

The Food Safety and Inspection Service (FSIS) is the United States Department of Agriculture (USDA) agency responsible for ensuring that the Nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and accurately labeled and packaged. When there is reason to believe adulterated or misbranded product is in commerce, FSIS coordinates with the product's company to ensure that the product has been properly identified and removed from commerce.

Federal regulation states that each establishment must prepare and maintain written procedures for the recall of any meat, meat food, poultry, or poultry product it produces and ships. Further, the regulation states that these written procedures must specify how the establishment will decide whether to, and how it will, conduct a product recall. In addition, FSIS guidance states that inspectors are to verify that establishments have written recall procedures and to document such results in the Public Health Information System (PHIS).

FSIS' verification controls were sufficient to assess whether the establishments' written recall procedures specified how the establishment will decide to conduct a recall and how the recall will occur. However, we determined its oversight controls can be strengthened. Specifically, we found that inspectors verified only 38 percent of the 5,451 establishments required to have written recall procedures for calendar year 2017. This occurred because FSIS lacked adequate management oversight to ensure inspectors' compliance with verification requirements and that the inspectors' results were recorded in PHIS. FSIS concurred with our finding and recommendations, and we were able to accept management decision for both recommendations.



OFFICE OF INSPECTOR GENERAL

United States Department of Agriculture



DATE: May 25, 2022

AUDIT

NUMBER: 24601-0003-22

TO: Paul Kiecker
Administrator
Food Safety and Inspection Service

ATTN: Cara LeConte
Chief Financial Officer
Food Safety and Inspection Service

FROM: Gil H. Harden
Assistant Inspector General for Audit

SUBJECT: FSIS' Compliance with Requirements for Written Recall Procedures

This report presents the revised results of the subject review. We regret any inconvenience these revisions may have caused the Food Safety and Inspection Service (FSIS). Your initial written response to the official draft report, dated March 14, 2019, is included in its entirety at the end of the report. Excerpts from your response and the Office of Inspector General's (OIG) position are incorporated into the relevant sections of the report. Based on your written response, we accepted management decision for both of the audit recommendations in the report.

As part of an internal quality control process, we identified inaccuracies in the report we issued on March 26, 2019. Consequently, we revised the report to address these inaccuracies and also added clarification where we felt it was needed. Ultimately, these revisions resulted in no material impact on the reported findings, conclusions, and recommendations. Therefore, further response from FSIS is not required.

Again, we appreciate the courtesies and cooperation extended to us by members of your staff during our audit fieldwork and subsequent discussions. This report contains publicly available information and will be posted in its entirety to our website (<https://usdaoig.oversight.gov>) in the near future.

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Background and Objectives

Background

The Food Safety and Inspection Service (FSIS) is the public health agency within the United States Department of Agriculture (USDA) responsible for ensuring that the Nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and accurately labeled and packaged. FSIS ensures food safety through authorities under the Federal Meat Inspection Act (FMIA),¹ the Poultry Products Inspection Act (PPIA),² and the Egg Products Inspection Act (EPIA).³

FSIS consists of 10 district offices nationwide with about 9,600 employees stationed across the United States; the agency is responsible for 7,691 federally inspected establishments.⁴ In April 2011, FSIS began to implement the Public Health Information System (PHIS) to meet work requirements and anticipate future public health issues and trends. PHIS is a web-based application designed to automate paper-based business processes into one comprehensive, fully automated data-driven inspection system. PHIS is used to collect, consolidate, and analyze data and has four components: domestic inspection, import activities, export activities, and predictive analytics. However, only three of the four components are operational. FSIS began implementing the export component through a phased approach on June 29, 2018, with a limited number of countries. It will gradually be expanded to additional countries.

PHIS replaces several of FSIS' existing legacy systems such as the Performance-Based Inspection System (PBIS)⁵ and the Electronic Animal Disposition Reporting System (eADRS).⁶ PBIS was the system of record FSIS used to manage the Hazard Analysis and Critical Control Point (HACCP)⁷ related activities at FSIS-inspected meat and poultry establishments, while eADRS stored and recorded information about the disposition of slaughtered livestock and poultry.

When there is reason to believe adulterated or misbranded product is in commerce, FSIS coordinates with the product's company to ensure it has properly identified and removed recalled

¹ Federal Meat Inspection Act (FMIA) (21 U.S.C. Ch. 12 § 601).

² Poultry Products Inspection Act (PPIA) (21 U.S.C. Ch. 10 §451).

³ Egg Products Inspection Act (EPIA) (P.L. 91-597).

⁴ This is the total universe of meat and poultry slaughter and processing establishments based on data obtained from FSIS as of May 15, 2018. Not all establishments are required to have written recall procedures.

⁵ PBIS is no longer active and its functions have since been incorporated into PHIS.

⁶ eADRS was FSIS' system used to collect, store, and report information about the disposition of livestock and poultry presented for slaughter. Such functions of eADRS have since been integrated into PHIS and the system is no longer active.

⁷ HACCP is a food safety system that analyzes each step in the production of food for biological, physical, and chemical hazards. HACCP includes product flowcharts, hazard analysis of hazards reasonably likely to occur, and plans to control food safety hazards.

product from commerce. Essentially, FSIS and the company work together to initiate a recall. FSIS defines three classes of recalls:

- a Class 1 recall involves a health hazard situation in which there is a reasonable probability that eating the food will cause health problems or death,
- a Class 2 recall involves a potential health hazard situation in which there is a remote probability of adverse health consequences from eating the food, and
- a Class 3 recall involves a situation in which eating the food will not cause adverse health consequence.

Establishment officials are required to notify their local FSIS district office personnel within 24 hours if they have reason to believe they have shipped or received adulterated or misbranded product that has entered commerce. FSIS will then coordinate with the establishment to ensure it has properly identified and removed the recalled product from commerce by verifying the effectiveness of the firm's recall activities. In 2017, FSIS oversaw the effectiveness of 100 Class 1 recalls, which recalled over 18 million pounds of product; 22 Class 2 recalls, which recalled over 1 million pounds of product; and 9 Class 3 recalls, which also recalled over 1 million pounds of product. Of these recalls, beef represented 28 out of 131 recalls and 4.4 percent of the total amount of recalled product; pork represented 20 out of 131 recalls and 2.4 percent of the total amount of recalled product; and poultry, which includes egg products, represented 45 out of 131 recalls and 46.1 percent of the total amount of recalled product. Overall, these three products represented 93 of the 131 recalls, or approximately 71 percent of the total number of recalls.⁸

On May 8, 2012, FSIS published, by final rule, a notice in the Federal Register to implement provisions from the Food, Conservation, and Energy Act of 2008, also referred to as the 2008 Farm Bill, which amended the Federal Meat and Poultry Products Inspection Acts.⁹ The final rule requires establishments to prepare and maintain written procedures for the recall of meat and poultry products the establishment produces and ships. Specifically, the written procedures must specify how the establishment would decide whether to conduct a product recall and the procedures it would follow should it decide that a recall is necessary. Inspection program personnel (inspectors) are required to verify that establishments have written recall procedures in place. This verification task is to be performed at least once a year. Completion of the task and its results are recorded in PHIS. If the inspectors determine that the establishments do not have written recall procedures, the inspectors are to issue a noncompliance record and document the noncompliance in PHIS.¹⁰ While the establishments are not required to submit their recall procedures to FSIS management for approval, they are required to make their plans

⁸ The remaining 29 percent of the total number of recalls consists of 2 percent for Siluriformes fish (catfish) and approximately 27 percent for "mixed" product. FSIS refers to mixed product as recalled product where more than one species was involved in the recall.

⁹ Notice of Requirements for Official Establishments to Notify FSIS of Adulterated or Misbranded Product, Prepare and Maintain Written Recall Procedures, and Document Certain Hazard Analysis and Critical Control Points System Plan Reassessments, 77 Fed. Reg. 89 (May 8, 2012).

¹⁰ A noncompliance record is to be completed whenever inspection program personnel determine that an establishment has not met one or more regulatory requirements.

available to inspectors for reviewing and copying. Inspectors are required to ensure that the establishments prepare and maintain such plans.

Objectives

The objective was to determine whether FSIS' verification procedures are sufficient to ensure establishments maintain written procedures that adequately specify how the establishment will decide whether to, and how it will, conduct a product recall.

We found FSIS' verification controls were sufficient to assess whether establishments' written recall procedures specified how the establishments will decide to conduct a recall and how the recall will occur. However, we found that oversight controls should be strengthened to provide greater assurance that all establishments have developed and maintain written recall procedures.

Section 1: Oversight of Written Recall Procedure Requirements

Finding 1: FSIS Needs to Strengthen its Oversight of the Verification Process of Written Recall Procedure Requirements

Of 5,451 establishments required to have written recall procedures in calendar year 2017, we found that FSIS inspection program personnel verified only 2,095 (38 percent). This occurred because FSIS lacked adequate management oversight to ensure inspectors verified the establishments' compliance with written recall requirements and that the results of this inspection task were recorded in PHIS as directed. As a result, FSIS has reduced assurance that all establishments have developed and maintained written recall procedures.

Federal regulation states that each official establishment must prepare and maintain written procedures for the recall of any meat, meat food, poultry, or poultry product produced and shipped by establishments. Further, it states that these written procedures must specify how the establishment will decide whether to conduct a recall and how the establishment will implement the recall, should it decide one is necessary.¹¹ In addition, FSIS guidance states that inspectors are to verify that establishments have written recall procedures. If inspectors determine that an establishment has written recall procedures, they are to document the completed task in PHIS. However, if the inspectors determine otherwise, they are to document the noncompliance in PHIS and issue a noncompliance record.¹²

In June 2018, we met with FSIS national office officials to discuss the requirement for establishments' written recall procedures and to obtain an understanding of their oversight role. FSIS stated it considers the national office to function as "recall management," with the majority of the recall activities occurring at the FSIS district offices. Further, the FSIS national office official stated the national office is not directly involved with the written recall procedure requirement, but rather the inspectors—under the supervision of the district office—perform the verification task and document compliance in PHIS. FSIS indicated that, while developing its recall procedures, each establishment should assess its individual risk level with the overall goal that implementation of written recall procedures is to promote industry preparedness as it relates to food safety. Such procedures in place would provide establishments with the ability to assess their processes and procedures in the event a recall occurs to ensure efficient identification and removal of recalled product from commerce. Without such procedures in place, the agency has reduced assurance that the establishments are prepared in the event a recall occurs.

The national office assigned the written recall procedures task in PHIS as a priority level three. PHIS task priorities are based on the expected impact on public health and are ranked from one to six, with one being the highest priority. Generally, inspectors perform these tasks based on their priority so that inspectors are much less likely to complete a priority six task than a priority one.

¹¹ 9 Code of Federal Regulations (CFR) § 418.3.

¹² FSIS Directive 5000.8, *Verifying Compliance with Requirements for Written Recall Procedures* (Dec. 2013).

Based on our review of active establishments required to develop written recall procedures nationwide, we determined that, in calendar year 2017, inspectors verified the task was completed at only 2,095 of the 5,451 (38 percent) establishments required to have written recall procedures. For 2015 and 2016, inspectors verified that 38 percent and 40 percent, respectively, of the establishments met the requirement.

We non-statistically selected one district office for further review and found that inspectors did not annually perform the inspection task as required. Specifically, in 2017, we found that the inspectors performed and documented their verification of the written recall procedures task in PHIS for only 234 of 698 (34 percent) establishments.

Further, we non-statistically selected six establishments in the same district to determine whether inspection personnel completed the required task. While all of the establishments we visited had written recall procedures in place, we determined that inspection personnel at two of the six establishments completed the task and documented its results in PHIS. The frontline supervisors assigned to these establishments noted there were variances in how the inspection task was scheduled, performed, and documented in PHIS. For example, at one establishment we visited, we identified that the inspection task was scheduled on the inspector's task list; however, the task was not performed. The inspector at that establishment stated that the task was not a high priority, which was why it was not completed the prior year. At a second establishment we visited, we identified that the inspection task was not found on the task list, which prevented the inspector from being able to schedule the task in PHIS. The frontline supervisor was not aware of this occurrence until the time of our visit. Further, at a third establishment, the inspector we spoke with stated that if a task is not coded as mandatory it will not always be completed as required, due to its priority.

We discussed this further with an FSIS official, who stated the inspection task is not automatically populated in PHIS and could lead to an incomplete task. The FSIS official added that, although the inspection task is not completed, FSIS conducts other reviews that require inspectors to verify that a written recall plan exists to complete a different task. Other reviews include performing a review of the establishment profile (monthly), completing In-Plant Performance System reviews (semi-annually), food safety assessments (as needed), and a review of the Food Defense Plan (quarterly). Another official stated that all new establishments are required to ensure that they prepare and maintain written recall plans. During our review of the six establishments, inspectors at four of these establishments stated that they verified the existence of written recall procedures while conducting one of these other routine tasks. However, we could not determine whether any of these reviews satisfied the requirements outlined in the Federal regulation.

Without periodic monitoring of the inspection task, FSIS has reduced assurance that all meat and poultry product establishments have developed and continue to maintain written recall procedures. FSIS asserts that, although a recall would still occur, completing these tasks would help promote food safety industry preparedness. In addition, FSIS contends that while inspectors did not always complete the task in PHIS as required, they believe once a recall plan is developed it remains with the establishment. While we agree it may be unlikely for establishments to discard their recall plan, nevertheless, the agency should ensure it has

implemented a process to periodically monitor the establishments to ensure plans are maintained and remain in place.

Recommendation 1

Revise current guidance that prescribes a timeframe inspectors would be required to perform the written recall procedure task and document its results in PHIS. Once revised, FSIS should periodically monitor completion of the task to ensure recall plans are maintained and in place.

Agency Response

FSIS will update FSIS Directive 5000.8 “Verifying Compliance with Requirements for Written Recall Procedures” with revised instructions for inspection program personnel (IPP) to follow when verifying that official establishments that produce meat or poultry products have prepared and are maintaining written recall procedures. The updated instructions will include a process for agency officials to monitor completion of the task to ensure written recall plans are in place and maintained. FSIS District Offices will continue to ensure that establishments have written recall procedures prior to providing a Grant of Inspection and FSIS Enforcement, Investigations and Analysis Officers will continue to assess whether establishments have written recall procedures when conducting food safety assessments.

FSIS provided an estimated completion date of December 2019, for this action.

OIG Position

We accept management decision for this recommendation.

Recommendation 2

Perform a reconciliation to identify establishments where inspectors have not performed a verification of the written recall procedure task. For establishments where the written recall procedure task was not performed, take action to ensure the task is performed and documented in PHIS.

Agency Response

In its March 14, 2019, response, FSIS stated:

FSIS will perform a reconciliation to identify any establishments where IPP have not performed the task to verify that written recall plans are in place. During the course of the OIG audit, data analysts within FSIS assisted the OIG audit team by providing PHIS data on the completion of this task. FSIS will utilize this information to identify those establishments where the task needs to be conducted and instruct IPP to complete the task within the stated timeframe. The instructions will set a deadline for IPP to complete the task in those establishments identified in the reconciliation process.

FSIS provided an estimated completion date of December 2019, for this action.

OIG Position

We accept management decision for this recommendation.

Scope and Methodology

We conducted fieldwork at the FSIS national office in Washington, D.C.; one district office in Chicago, Illinois (District 50); and six meat and poultry processing plants within that district. Coverage for District 50 spans four States: Illinois, Indiana, Michigan, and Ohio. We conducted fieldwork from May 2018 through September 2018.

The scope of our review covered calendar years 2015 to 2018. To assess the sufficiency of FSIS' verification procedures and ensure establishments maintain written recall procedures, we non-statistically selected one district office and six establishments to visit. Of FSIS' 10 District Offices, we selected District 50 because it was one of the largest districts with the most establishments. To identify our sample of District 50 establishments that were required to have written recall procedures, we non-statistically selected 6 of the 698¹³ establishments primarily based on a variety of the following factors: (1) size of the establishment (large, small, or very small); (2) whether inspectors completed the inspection task to verify that the establishment developed and maintained written recall procedures; and (3) whether the establishment had a recall during calendar year 2017.

To accomplish our objective, we performed the following procedures:

- Reviewed relevant laws, regulations, policies, procedures, FSIS directives, and other published guidance to gain an understanding of the written recall procedures requirements for establishments;
- Reviewed FSIS' documented organizational structure for implementing the requirement for inspectors to verify that each establishment has prepared and maintain written recall procedures;
- Interviewed FSIS officials at the national office and District 50 to determine whether they established oversight responsibilities and verification policies related to the effectiveness and sufficiency of an establishment's written recall plan;
- Interviewed inspectors and frontline supervisors at each of the six establishments selected for review to gain an understanding of their role and responsibilities to verify if an establishment maintains a written recall plan that specifies how the establishment will decide whether to conduct a recall and how the establishment will conduct the recall; and
- Reviewed and analyzed task data that FSIS extracted from PHIS to identify the number of instances the inspection task was performed for calendar years 2015–2017.

Throughout the course of our audit, PHIS was the only FSIS system the audit team relied on for data to select our sample of a district office and establishments. We performed data validation tests from the data FSIS provided to confirm the accuracy of such information. The audit team

¹³ As of September 4, 2018, FSIS reported 698 active meat and poultry establishments required to meet written recall requirements.

did not evaluate PHIS' design and effectiveness. Further, during the course of our audit, we did not rely on or verify information in any other agency electronic information systems, and we make no representation regarding the adequacy of any other agency computer systems or the information generated from them.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Abbreviations

C.F.R.	Code of Federal Regulations
eADRS	Electronic Animal Disposition Reporting System
EPIA	Egg Products Inspection Act
FMIA	Federal Meat Inspection Act
FSIS	Food Safety and Inspection Service
HACCP	Hazard Analysis Critical Control Point
OIG	Office of Inspector General
PBIS	Performance-Based Inspection System
PHIS	Public Health Information System
PPIA	Poultry Products Inspection Act
USDA	United States Department of Agriculture

Exhibit A: FSIS District 50 Establishments Visited

This exhibit identifies the six non-statistically selected FSIS establishments we visited in the Chicago District Office (District 50).¹⁴ It describes the size of the establishment, whether inspectors at each of the establishments verified the existence of a written recall plan, OIG's verification of requirements set forth by 9 Code of Federal Regulations (C.F.R.) 418.3,¹⁵ and whether the establishment initiated a recall in calendar year 2017.

Establishment Number	Size¹⁶	IPP Verification of Recall Plan	OIG's Verification of Recall Plan Requirements	Establishment Recall in 2017
1	Large	No	Yes	No
2	Large	No	Yes	No
3	Small	Yes	Yes	Yes
4	Small	No	Yes	Yes
5	Small	No	Yes	No
6	Very Small	Yes	Yes	No

¹⁴ District 50 consists of Illinois, Indiana, Michigan, and Ohio.

¹⁵ 9 Code of Federal Regulations 418.3 states, in part, that each official establishment must prepare and maintain written procedures for the recall. These written procedures must specify how the official establishment will decide whether to conduct a product recall, and how the establishment will effect the recall, should it decide that one is necessary.

¹⁶ Large establishments are defined as all establishments with 500 or more employees. Small establishments are defined as establishments with 10 or more employees, but fewer than 500 employees. Very small establishments are defined as all establishments with fewer than 10 employees or annual sales of less than \$2.5 million.

**FOOD SAFETY AND INSPECTION
SERVICE'S
Response to Audit Report**



United States Department of Agriculture

Food Safety and
Inspection Service

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TO: Steve Rickrode
Acting Assistant Inspector General for Audit
Office of Inspector General

FROM: Carmen Rottenberg /s/ 3/14/2019
Administrator
Food Safety and Inspection Service

SUBJECT: OIG Official Draft Report: Food Safety and Inspection
Service's Compliance with Written Recall Procedures
(Audit 24601-0003-22)

The Food Safety and Inspection Service (FSIS) appreciates the opportunity to review and comment on the subject Official Draft report. FSIS reviewed the Official Draft report and responded with planned corrective actions for each of the recommendations below.

Finding 1: FSIS Needs to Strengthen its Oversight of the Verification Process of Written Recall Procedure Requirements

Recommendation 1

Revise current guidance that prescribes a timeframe inspectors would be required to perform the written recall procedure task and document its results in the Public Health Inspection System (PHIS). Once revised, FSIS should periodically monitor completion of the task to ensure recall plans are maintained and in place.

FSIS Response

FSIS will update FSIS Directive 5000.8 "Verifying Compliance with Requirements for Written Recall Procedures" with revised instructions for inspection program personnel (IPP) to follow when verifying that official establishments that produce meat or poultry products have prepared and are maintaining written recall procedures. The updated instructions will include a process for agency officials to monitor completion of the task to ensure written recall plans are in place and maintained. FSIS District Offices will continue to ensure that establishments have written recall procedures prior to providing a Grant of Inspection and FSIS Enforcement, Investigations and Analysis Officers will continue to assess whether establishments have written recall procedures when conducting food safety assessments.

Estimated Completion Date: December 2019

Recommendation 2

Perform a reconciliation to identify establishments where inspectors have not performed a verification of the written recall procedure task. For establishments

where the written recall procedure task was not performed, take action to ensure the task is performed and documented in PHIS.

FSIS Response

FSIS will perform a reconciliation to identify any establishments where IPP have not performed the task to verify that written recall plans are in place. During the course of the OIG audit, data analysts within FSIS assisted the OIG audit team by providing PHIS data on the completion of this task. FSIS will utilize this information to identify those establishments where the task needs to be conducted and instruct IPP to complete the task within the stated timeframe. The instructions will set a deadline for IPP to complete the task in those establishments identified in the reconciliation process.

Estimated Completion Date: December 2019

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