FAV—Implementation of the Public Health Information System for Domestic Inspection

United States Department of Agriculture

Office of Inspector General

Washington, D.C. 20250

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FAV
NUMBER: 24026-0001-22

TO: Stanley McMichael
                             Associate Chief Financial Officer
                             Office of the Chief Financial Officer

FROM: Gil H. Harden
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SUBJECT: FAV—Implementation of the Public Health Information System for
                             Domestic Inspection

The Office of Inspector General (OIG) completed a final action verification (FAV) of all
eight recommendations for audit report 24601-0001-23, *Implementation of the Public
Health Information System for Domestic Inspection*, Audit published in August 2015.
The purpose of the FAV was to determine whether the documentation the Food Safety
and Inspection Service (FSIS) provided to the Office of the Chief Financial Officer
(OCFO) was sufficient to close the recommendations made in audit report 24601-0001-
23.[1,2]

In a memorandum dated July 16, 2018, OCFO reported to FSIS that it closed all eight
recommendations, and we concur with this decision.

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[1] *Final action* is the completion of all actions that management has concluded, in its management decision, are
necessary with respect to the finding and recommendations included in an audit report. DR1720-001, 6g(1), *Audit
Follow-up and Management Decision* (Nov 2, 2011).
[2] *Management decision* is an agreement between agency management and OIG on the action(s) taken or to be taken
to address a finding and recommendations cited in an audit report. The management decision must include the
agreed-upon dollar amount affecting the recommendations and an estimated completion date unless all corrective
action is completed by the time agreement is reached. DR1720-001, 6i, *Audit Follow-up and Management Decision*
(Nov 2, 2011).

Background

Our report, *Implementation of the Public Health Information System for Domestic Inspection*,[3] made eight recommendations for improving FSIS controls to effectively monitor and evaluate the performance of the Public Health Information System (PHIS), and ensure that the system is accessible, is operating as designed, and contains complete and accurate information.

OIG and FSIS reached management decision on all eight recommendations in memoranda dated August 20, 2015, and December 9, 2015. The memoranda detailed what FSIS needs to implement in order to achieve final action on the recommendations.

In accordance with Departmental Regulation 1720-001, OCFO has the responsibility to determine final action for recommendations where OIG has agreed to management decision.[4] As such, OCFO evaluates agency-provided documentation to support planned corrective actions and to determine if final action has occurred.

Scope and Methodology

The scope of this final action verification was limited to determining whether FSIS' plan of action for all of the recommendations in the subject report was completed in accordance with the management decisions reached on August 20, 2015, and December 9, 2015. To accomplish our objective, we reviewed the documentation FSIS submitted to OCFO. We did not perform internal control testing or make site visits to determine whether the underlying deficiencies that were initially identified had been corrected. In addition, we did not provide an opinion on the results of the implementation or effectiveness of each recommendation. This FAV was conducted in accordance with our internal guidance IG-7710, *Nonaudit Work* and *Final Action Verification Guidance and Procedures*. As a result, this FAV was not conducted in accordance with *Generally Accepted Government Auditing Standards*, issued by the Comptroller General of the United States or the *Quality Standards for Inspection and Evaluation*, issued by the Council of the Inspectors General for Integrity and Efficiency. However, before we performed the non-audit service, we determined that it would not impair our independence to perform audits, inspections, attestation engagements, or any other future or ongoing reviews of the subject.

Results of Final Action Verification

We determined that FSIS provided sufficient documentation to OCFO to close the eight recommendations we made in our audit report, *Implementation of the Public Health*

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[3] Audit Report 24601-0001-23, *Implementation of the Public Health Information System for Domestic Inspection*, Aug. 2015.

[4] DR1720-001, 7d(1-9), *Audit Follow-up and Management Decision* (Nov 2, 2011).

Information System for Domestic Inspection. The following table summarizes the actions FSIS took with respect to each recommendation.

We informed FSIS officials of the results of this final action verification.

Table 1. Recommendations with Sufficient Documentation to Achieve Final Action.

Rec. No.	Recommendation	Action Taken
1	Complete a written assessment of the current status of PHIS implementation that includes prioritized corrective actions with specific timeframes for completion. Also, implement a process to verify that the corrective actions are completed within the established timeframes.	FSIS' response provided details for the short- and long-term actions it has completed and the timeframes for completing future corrective actions based on the recommendations in the top-to-bottom assessment of PHIS. FSIS stated that representatives of its Office of Chief Information Officer (OCIO) and the Office of Field Operations (OFO) meet on a periodic basis to review and monitor the action items and progress made on each item. These action items cover five areas: (1) architecture and design, (2) processing layers, (3) shared infrastructure, (4) user experience, and (5) governance. FSIS provided a detailed action plan for each area, including a contract to incorporate an integrated process for monitoring PHIS infrastructure operations; a comprehensive plan for capacity planning; the creation of two new information technology (IT) specialist positions; upgrading communication devices and improving connectivity through MiFI devices, T1 connections and DSL; upgrading inspection personnel to Windows 10 laptops; and formalizing the structure and operations for the PHIS Change Control Board, which is responsible for providing oversight and leadership of PHIS development.
2	Enhance internal controls by ensuring management oversight of PHIS encompasses ongoing monitoring and periodic evaluation of PHIS to ensure the system is accessible, operating as	FSIS highlighted the following enhanced internal controls it implemented to strengthen PHIS: • FSIS oversight of the PHIS

	designed, and includes both complete and accurate information.	investment is included as part of FSIS' Annual PortfolioStat review. The review is briefed to the FSIS Management Council, which consists of the agency's senior leadership, as part of the agency's enterprise governance process. • Quarterly investment reviews are conducted in collaboration with FSIS OCIO, FSIS OCFO, FSIS stakeholders, and USDA OCIO to review PHIS investment, including project activities, earned value management, issues, and risks. • FSIS, in conjunction with USDA, performs monthly investment reviews for PHIS. Monthly investment reviews are posted on the Office of Management and Budget Federal IT Dashboard. • FSIS project managers provide status briefings on a weekly basis to OCIO senior staff. These briefings include reports on the health and operating status of PHIS. • PHIS software releases follow the agency's system development life cycle. PHIS releases go through eight different phase gates, which are comprised of technical subject matter experts and business area representatives. • FSIS reported that all PHIS enhancements are approved by the agency's IT Investment Review Board. PHIS is managed by a certified program manager, and the development contract is managed by a certified contracting officer's representative.

3	Develop and implement a plan to review and correct the data in PHIS' establishment profiles. This should include procedures for FSIS supervisors to conduct ongoing reviews of data in establishment profiles.	On October 19, 2016, FSIS issued Directive 5300.1, *Managing the Establishment Profile in the Public Health Information System*, to be implemented on November 21, 2016. The directive provides instructions to inspection program personnel in FSIS-inspected facilities on how to maintain and update the establishment profile in PHIS. To ensure the appropriate inspection tasks are generated, inspection personnel are to dedicate time each month to verify that the establishment profile is accurate and to update the establishment profile as soon as any change occurs. Inspection personnel are to present updated establishment profile reports to FSIS management and establishment management officials during weekly meetings.
4	Develop instructions that define the specific data fields, such as product produced, that are required for an establishment to be included in a sampling project.	FSIS provided the Sampling Project Algorithm Documentation (Manual) as support. FSIS reported that the documentation is a centralized reference on all domestic sampling projects that includes a sampling algorithm that identifies eligible establishments and assigns sampling tasks. The document also describes how the sampling algorithms are implemented and the applicable data elements selected for each project code. The project names, product groups and finished product categories are all taken directly from PHIS.
5	FSIS needs to strengthen its procedures to ensure that a separated employee's user role, user account, and system access is promptly disabled and/or removed, in accordance with Federal guidance.	FSIS issued Directive 2410.1, *FSIS Employee Separation or Transfer Clearance*, on April 3, 2018. The directive provides instructions for clearing employees who separate or transfer from FSIS. The directive also specifies the responsibilities of the separating or transferring employees,

		supervisors, and clearance officials.
6	Review and evaluate the tasks PHIS currently generates for inspectors, as well as the inspectors' workload. Develop and begin implementing a plan that ensures the inspectors are assigned a manageable number of tasks and that the most important tasks are routinely performed at each establishment. The plan should require the front-line supervisors to: monitor the inspectors' completion of the tasks and to document the results of this review, take corrective actions needed to ensure compliance, and monitor the status of those corrective actions.	FSIS issued Directive 13,000.1, *Scheduling In-Plant Inspection Tasks in the Public Health Information System (PHIS)*, on August 31, 2012. This directive instructs in-plant personnel (IPP) to adjust or rearrange scheduled tasks as necessary to adapt to changes in establishment operations. Those who cannot complete all assigned tasks are to ensure they complete the tasks based on the priority rating, which is based on the expected impact on public health. To accompany this directive, the 2016 revision of FSIS Directive 4430.3, *In-Plant Performance System (IPPS)*, states that the front-line supervisor is to review PHIS reports and data in preparation for each inspector's IPPS assessment. Specifically, the front-line supervisor identifies the review of the establishment task list, verifies task regulations, reviews inspection verification results, and assesses Public Health Regulation (PHR) noncompliance for the establishment as part of the preparation for the assessment. Additionally in May 2017, FSIS will implement a national circuit realignment. This realignment will redistribute the inspection workload in impacted circuits and is expected to reduce the number of daily inspection tasks distributed per inspector in these circuits. Finally, FSIS issued the revised Directive 4430.3 on January 6, 2016. This directive provides procedures for OFO supervisors who conduct, document, and report on IPPS assessments. The supervisors will assess employees' knowledge of job requirements, appropriate regulatory decision making, and ability to execute

		inspection and verification procedures. As part of the IPPS review, supervisors review PHIS reports and data to determine whether IPP responsible for maintaining PHIS at the plant level are keeping the establishment profile current, completing routine inspection tasks, and properly entering data concerning whether scheduled procedures are performed or not performed.
7	Develop an action plan with specific timeframes for implementing the actions agreed to in Recommendations 1, 3, and 13 of Audit Report 24601-0007-Hy.	FSIS stated that the PHIS food safety assessment (FSA) reporting system was fully implemented by February 2014. Additionally, FSIS contracted data analysis work to analyze FSA data housed in non-PHIS systems. The agency (1) conducted analysis for its ongoing accomplishment reports, and (2) performed research for policy or to revise the questions Enforcement, Investigations, and Analysis Officers (EIAO) use to document the FSA. All FSAs are now in a configuration that allows for effective analysis. FSIS continues to make enhancements to the FSA procedures, as exhibited by the publication of the updated *PHIS Food Safety Assessment Reference Guid*e. Additionally, FSIS issued Directive 5100.4, *Enforcement, Investigations and Analysis Officer Public Health Risk Evaluation (PHRE) Methodology*, on May 22, 2015. This directive sets forth instructions on prioritizing FSAs. PHRE is a decision-making process that is to be used by an EIAO to determine whether the district office needs to schedule an FSA. The FY 2016 Public Health Regulations report updates the current list of public health regulations FSIS uses for prioritizing FSAs. The updated list of PHRs is based on 2014 verification

| | | inspection results and were to be implemented in FY 2016. The list of PHRs contains both regulations and specific provisions of regulations. The inclusion of provisions of regulations in the PHR list allows FSIS to focus on specific, health-related provisions of regulations that may be most informative for prioritizing FSAs. Additionally, FSIS issued Notice 02-15, which provided updated instructions on how PHRs are used in scheduling FSAs and FSA entrance meetings.

FSIS issued Directive 5100.1, *Enforcement, Investigations, and Analysis Officer (EIAO) Food Safety Assessment (FSA) Methodology*, on May 29, 2015. This directive sets forth instructions on the new FSA procedures in PHIS. The directive provides instructions to EIAOs regarding how to conduct FSAs using a new work methodology, so an EIAO can complete the in-plant portion of most FSAs in 5 to 7 production days. This directive also provides instructions on how to document FSAs using the FSA tools, which are a series of questionnaires that an EIAO uses to gather information.

Both FSIS Directives 5100.4 and 5100.1 provide instructions outlining the risk-based decision making process FSIS began using in June 2015 to determine whether to conduct an FSA or to take enforcement action. PHREs use a risk-based decision-making process to determine whether to conduct an FSA or take enforcement action.

The new FSA procedures outlined above demonstrate FSIS' implementation of the corrective actions agreed to in Recommendations 1, 3, and 13 of OIG |
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		audit report 24601-0007-HY.
8	Develop an action plan with specific timeframes to ensure the effective implementation of the corrective actions put in place to address Recommendations 6 and 16 of Audit Report 24601-0007-Hy.	FSIS issued Directive 5300.1, *Managing the Establishment in the Public Health Information System*, on October 19, 2016. This directive provides instructions to inspection program personnel in FSIS-inspected facilities on how to maintain and update the establishment profile in PHIS. FSIS uses the establishment profile information to ensure the correct tasks are assigned to each establishment. FSIS also uses the establishment profile information to assign both routine and directed inspection tasks; manage inspection assignments; determine eligibility for sampling; and generate FSIS sample requests, automated reporting, and ad-hoc data analysis. Additionally, when an establishment begins production of a new product, there is a significant change in product volume. There may also be establishment address changes or jurisdiction changes. IPP are expected to update the establishment profile as soon as changes occur to ensure the appropriate inspection tasks are generated. Finally, IPP are to dedicate time each month to verify the accuracy of the establishment profile. FSIS has also ensured that the establishments identified in Exhibit C of the audit report were updated and their accuracy verified by FSIS' management. The establishment profiles were reviewed by OFO officials, and documentation was forwarded to FSIS' OCFO to certify this activity.

Cc: Cara LeConte, Chief Financial Officer, Food Safety and Inspection Service

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