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Northeast Region

Audit Report

Followup Review of Food and Safety Inspection Service's Controls Over Imported Meat and Poultry Products

Report No. 24601-08-Hy
August 2008

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington, D.C. 20250

August 4, 2008

REPLY TO
ATTN OF: 24601-08-Hy

TO: Alfred V. Almanza
Administrator
Food Safety and Inspection Service

ATTN: William C. Smith
Assistant Administrator
Office of Program Evaluation, Enforcement and Review

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

SUBJECT: Followup Review of Food Safety and Inspection Service's Controls Over Imported Meat and Poultry Products

This report presents the results of the subject audit. Your response to the official draft, dated July 16, 2008, is included as exhibit B. Excerpts of your response and the Office of Inspector General's position are incorporated into the Findings and Recommendations section of the report. Based on your response, we accepted management decision on 18 of the report's 19 recommendations. Please follow your agency's internal procedures in forwarding documentation for final action to the Office of the Chief Financial Officer.

In accordance with Departmental Regulation 1720-1, please furnish a reply within 60 days describing the interim procedures and timeframes for implementing Recommendation 15. Please note that the regulation requires management decision to be reached on all findings and recommendations within 6 months from report issuance and final action to be taken within 1 year of the date of management decision.

We appreciate the courtesies and cooperation extended to us by members of your staff during this audit.

Executive Summary

Followup Review of the Food Safety and Inspection Service's Controls Over Imported Meat and Poultry Products (Audit Report No. 24601-08-Hy)

Results in Brief

In April 2007, the Chairman of the Committee on Agriculture, Nutrition, and Forestry of the United States Senate requested that we evaluate the adequacy of the Food Safety and Inspection Service's (FSIS) inspection processes for meat and poultry imports to ensure the integrity of the U.S. food supply. These processes included: (1) determinations that foreign countries' food safety systems are equivalent to U.S. standards, (2) periodic (generally annual) onsite, in-country audits[1] to verify that the systems remain equivalent, and (3) reinspection of products at the U.S. ports of entry. We also agreed to determine whether FSIS took appropriate and timely actions to implement prior Office of Inspector General (OIG) audit recommendations regarding the imported meat and poultry inspection program.[2]

FSIS administers its imported meat and poultry inspection program through the Office of International Affairs (OIA). OIA is responsible for formulating policies, determining a foreign country's eligibility to export meat and poultry products into the United States, and reinspecting imported meat and poultry products. OIA is also responsible for conducting system audits (also referred to as onsite audits) of a foreign government's food regulatory program, which include a review of (1) establishments certified to export to the United States, (2) laboratories conducting analytical testing of products being exported to the United States, and (3) government controls and oversight to ensure that products are produced under requirements equivalent to U.S. inspection requirements. These review and reinspection activities form the basis of FSIS' determinations of whether a country's inspection system is equivalent to U.S. standards.

In our prior reports, OIG made 51 recommendations to strengthen FSIS' regulatory oversight of imported meat and poultry products. For these 51 recommendations, FSIS provided the Office of the Chief Financial Officer (OCFO) with evidence that the agreed upon corrective actions had been implemented. We found that FSIS adequately implemented the corrective actions reported to OCFO for 49 of the 51 recommendations. For the remaining two recommendations, FSIS had not documented the protocols provided to OCFO in OIA's management controls. We also noted additional areas of FSIS' equivalence and reinspection processes that could be enhanced.

[1] FSIS' audits of foreign countries' food safety systems are designed to ensure compliance with the regulatory requirements of the Federal Meat *Inspection* Act and the Poultry Products Inspection Act. These audits are not conducted in accordance with *Government Auditing Standards*.

[2] Since June 2000, OIG has issued four reports: (1) *FSIS Imported Meat and Poultry Inspection Process Phase I*, Audit Report No. 24099-03-Hy, June 2000; (2) *FSIS Imported Meat and Poultry Reinspection Process Phase II*, Audit Report No. 24099-04-Hy, February 2003; (3) *FSIS Imported Meat and Poultry Equivalence Determinations Phase III*, Audit Report No. 24099-05-Hy, December 2003; and (4) *FSIS Assessment of the Equivalence of the Canadian Inspection System*, Audit Report No. 24601-05-Hy, December 2005.

- **Equivalence of Foreign Food Inspection Safety Systems**

  We found that FSIS needs to strengthen the agency's controls for assessing the equivalence of foreign countries' food safety systems, specifically, the controls concerning the methodology used to select foreign establishments for review. In addition, FSIS should document the management controls implemented in response to two of our prior recommendations and the agency's policy to perform onsite audits prior to receiving product from a new country (i.e., initial equivalence) or a suspended country (i.e., did not maintain an inspection system equivalent to the United States).

  Sample of Foreign Establishments Selected for Review. As one part of its onsite audits in a foreign country, FSIS selects a sample of establishments (if there are more than 10 establishments certified by the foreign government to export to the United States) to validate that the country's inspection system is equivalent to the United States. If a foreign government has certified 10 or less establishments, then FSIS is to review all certified establishments. As designed, FSIS' sample selection methodology is composed of two parts. The first part, a random sample of establishments, is derived from a statistical sample table based on the number of certified establishments in an exporting country. The second part, a targeted-judgmental sample, includes establishments with known problems based on findings from prior onsite audits, consumer complaints, or reinspection results at U.S. ports of entry recorded in FSIS' information system. FSIS' review of foreign establishments is one-third of the agency's process to determine whether a country is maintaining an equivalent inspection system. The remaining two-thirds are a review of laboratories and government controls.

  - FSIS' random sample selection methodology is designed to provide the agency with the statistical assurance, at the 95 percent confidence level, that FSIS will find at least one deficient establishment if 20 percent of the universe of eligible establishments are deficient (i.e., a 20 percent error rate). FSIS officials could not provide information or documentation on how the agency decided that a 20 percent error rate was reasonable and acceptable. For three of the four countries we reviewed, FSIS officials did not select the minimum number of establishments to review as part of the random sample in the onsite reviews performed in 2006 and 2007. FSIS officials could not explain why FSIS reviewers did not visit the minimum number of establishments in 2006. For 2007, FSIS officials explained that they

used a draft, risk-based approach to select establishments.[3] Since the minimum number of establishments was not reviewed, we questioned whether FSIS had sufficient data to conclude that these countries' food safety systems were equivalent to the U.S. system.

- FSIS could not demonstrate that it performed an adequate sample of foreign establishments. FSIS officials explained that they do not document the basis (i.e., random versus judgmental) for including specific establishments in the sample. In addition, FSIS does not have criteria for evaluating reinspection results at U.S. ports of entry to determine which establishments should be judgmentally selected for review.

As implemented, FSIS' sample selection methodology provides the agency with reduced assurance that FSIS has a sufficient basis for assessing the equivalence of a country's food safety system.

Prior OIG Recommendations. We previously reported that FSIS did not timely address serious concerns with a country's inspection system because FSIS did not have protocols for evaluating deficiencies that could jeopardize a country's overall equivalence determination. We also found that FSIS did not conduct an enforcement audit[4] of this country's food safety system to ensure noted deficiencies were corrected. As part of our current review, we found that FSIS implemented protocols to address these two weaknesses based on actions FSIS took in response to equivalency concerns raised regarding the Danish inspection system in 2007. However, agency officials confirmed that FSIS did not document the protocols in the agency's management controls. The protocols were explained in documentation FSIS provided to OCFO to demonstrate FSIS' planned corrective action. However, FSIS did not make a priority of documenting these protocols as part of its management controls. Accordingly, FSIS has reduced assurance that correct decisions will be consistently made when enforcement audits are delayed or a country's equivalence is in question. FSIS officials agreed that these protocols should be documented, and in January 2008, the agency hired an intern to assist with this process.

Onsite Audit Procedures Need Documenting. FSIS officials explained that the agency's policy is to perform an onsite audit to ensure a country's inspection system is equivalent to U.S. standards prior to (1) a new

[3] Agency officials explained that this approach was not finalized; therefore, we did not perform a detailed examination of the risk-based approach. According to the January 30, 2007, draft "Guidelines for a Risk-Based Program for Verifying the Equivalence of Foreign Inspection Systems," FSIS planned to use a variety of inputs in selecting foreign establishments for review. These inputs included such things as types and volume of product exported to the United States, past performance of an establishment's food safety controls of public health significance, and delistments of or recommendations to delist foreign establishments.

[4] FSIS currently refers to these audits as "followup" or "special emphasis" audits. Enforcement audits can lead to a determination that a country's inspection system is not equivalent to U.S. standards and, thus, not eligible to export to the United States.

country's first shipment and (2) a suspended country resuming trade with the United States. Agency officials confirmed that this policy is not documented as part of FSIS' management controls but could not explain why. Documented procedures in these areas are critical because an extended period of time can transpire (e.g., over 2 years) between FSIS' onsite audit to determine that a country's inspection system is equivalent to U.S. standards and the date of the country's first shipment. In addition, countries may be suspended for extended periods of time. For example, FSIS suspended Austria's ability to export product from 2003 to 2007 for not maintaining an equivalent inspection system. To mitigate the risk that ineligible product is potentially exported to the United States or a country's food safety system is not equivalent, FSIS should document procedures to conduct onsite audits prior to the first shipments of new countries or countries that had been suspended.

- **Reinspection of Imported Meat and Poultry Products**

  FSIS needs to strengthen agency controls for reinspecting[5] meat and poultry products at U.S. ports of entry. Specifically, FSIS should determine the number of intensified inspections for physical and laboratory failures that provide the appropriate level of protection to ensure the safety and wholesomeness of imported products. In addition, FSIS needs to strengthen procedures for: (1) specifying the order of performing reinspection activities, (2) verifying a lot's production date, (3) analyzing data in FSIS' import information system, and (4) managing noncompliance records.

  When products are presented to FSIS, the FSIS information system assigns one of four levels of reinspection to the product presented: skipped, normal, intensified, or increased. Skipped inspection signifies the lot[6] will be subjected to the evaluations for transportation damage, labeling, proper certification, general condition, and accurate count. Under normal inspection, the lot has been randomly selected for physical reinspection, which can include laboratory analyses. Physical reinspection activities determine such things as whether the product is contaminated (e.g., fecal, metal) or otherwise not in good condition (e.g., spoiled). Laboratory analyses test for microbial violations (e.g., *Escherichia coli* O157:H7) or residues (e.g., drugs and chemicals) above tolerable limits. Intensified inspection signifies a previous failure to meet U.S.

[5] The reinspection of imported meat and poultry products at U.S. ports of entry by FSIS inspection personnel helps assess the effectiveness of a foreign government's food safety system. To that end, FSIS is given the responsibility to randomly select samples of imported meat and poultry products and perform the following types of reinspection activities, as appropriate: product examinations, net weight compliance, condition of container, incubation of shelf-stable products, special examinations, and laboratory analyses. The random selection of product is based on compliance histories of the establishment, countries, and product being presented for reinspection.

[6] A lot is a group of similarly processed and packaged products (e.g., boxed, frozen boneless beef) from one establishment in a country.

requirements. Under intensified level of inspection,[7] lots are held by FSIS pending results for the type of inspection in question. If the level of inspection is increased, FSIS management officials have decided to perform reinspection activities above the normal level of inspection for the lot based on problems associated with the specific product, foreign establishment, or country.

Basis Needed for Intensified Inspection. When product from an eligible foreign establishment fails reinspection (i.e., physical and laboratory failures) at U.S. ports of entry, FSIS intensifies the reinspection of subsequent shipments of the same type of product from that establishment. For example, FSIS reinspects 10 subsequent shipments when inspectors find that product is contaminated with fecal material. FSIS has used this practice for 25 years. The foundation of this practice was traced to the June 1983 report by FSIS' Import Inspection Task Force. FSIS could not demonstrate that the number of intensified inspection for physical and laboratory failures provided the appropriate level of protection to ensure the safety and wholesomeness of imported products. According to FSIS officials, when the agency reprogrammed the information system in 2002, statisticians evaluated the number of intensified inspections for physical and laboratory failures.

Specify Order for Performing Reinspection Activities. When shipments contained multiple lots of the same type of product that included both normal and skipped levels of reinspection, FSIS inspection personnel performed the skip assignments before the physical reinspection. This occurred because FSIS procedures did not require the physical reinspection to be performed first. According to FSIS officials, skips are done first because these assignments can be completed quickly. As a result, FSIS has reduced assurance that the appropriate actions were taken prior to imported products being allowed to enter U.S. commerce. We identified 35 shipments that contained 43 lots of the same type of product that had a physical failure for such things as fecal contamination, processing defects (e.g., blood clots), excess hair, and labeling defects. Of these 35 shipments, 12 had skipped lots that contained approximately 325,000 pounds of lamb, mutton,[8] beef, and goat from Australia and Brazil that was released into U.S. commerce without the same type of reinspection as those lots that failed physical reinspection.

Document Procedures to Verify a Lot's Production Date. According to FSIS officials, when product is received from a previously delisted establishment, import inspection personnel have been verbally instructed

[7] Intensified inspections are triggered after a product fails to pass reinspections for physical and laboratory testing. According to the programming of the information system a certain number of shipments (e.g., 10 consecutive shipments for physical failures) of the same types of product must pass reinspection before the level of reinspection returns to normal.

[8] Mutton is a mature sheep.

that the production date must be verified before they enter this date into the information system. FSIS inspection personnel have been told that if the date of the foreign health certificate or production data information on the shipping carton is not within an eligible time period for the foreign establishment, they are to consult with their supervisor or FSIS headquarters. However, FSIS has not documented this in procedures to guide inspectors' decision on what data sources to use to verify a lot's production date and did not provide a reason for not documenting this procedure.

By analyzing data in FSIS' information system, we identified 38 shipments from a delisted foreign establishment that did not appear to follow the verbal instruction.[9] We found that a Brazilian establishment was recertified as eligible to export product on June 29, 2005. The establishment then exported 39 lots[10] of beef product totaling almost 1.6 million pounds from September 19, 2005 to January 10, 2006. According to data in FSIS' information system, all 39 lots were produced by the establishment on June 29, 2005, which was not consistent with the establishment's export history. Data in FSIS information system indicated that an average day's production from this establishment totaled approximately 100,000 pounds.

FSIS regulation does not require production dates to be certified by the foreign countries; however, FSIS inspection personnel have the authority to hold shipments until the eligibility of the product is verified. This includes requesting the foreign government to provide productions dates for specific shipments. FSIS should determine whether foreign establishments should be required to provide the lot's production date(s).

Establish Procedures to Analyze Data. FSIS' information system contained incomplete and erroneous data. For example, we identified that FSIS' information system did not have a record of the reinspection results for 400 lots of product (approximately 7.4 million pounds of meat and poultry products) presented for reinspection from January 1, 2005 to August 31, 2007. This occurred because FSIS did not have documented procedures for analyzing data in the information system or other edit checks to determine that data were reasonable, complete, and accurate. FSIS officials explained that their analyses of data in the information system are often performed on an ad hoc basis. FSIS officials explained that the information system does not alert users (i.e., import inspectors, their supervisors, and Headquarters staff) that inspection results have not been recorded. We also found that inspection personnel could enter rejected weights that exceeded the weight of product presented for

[9] FSIS could not provide source documentation that we could use to validate the date in the information system. This source documentation was deleted according to FSIS record retention requirements.

[10] One of the shipments contained more than one lot.

reinspection. As previously noted, we found that FSIS also does not have criteria for evaluating reinspection results at U.S. ports of entry. This type of analysis would assist in identifying foreign establishments to select for onsite review. As a result, FSIS' has reduced assurance that its data provide reliable information for monitoring program operations.

Strengthen Management of Noncompliance Records. FSIS inspection personnel did not always follow established procedures for resolving the deficiencies noted in noncompliance records.[11] For example, FSIS inspection personnel had not documented the resolution of deficiencies noted in January 2007 (e.g., build up of blood and debris on the bottom of a band saw) in a California import inspection establishment.[12] In addition, FSIS' database[13] of noncompliance records may not be complete. We found a noncompliance record in the files at a Pennsylvania import inspection establishment that was not in FSIS' database. As a result, there is reduced assurance that import inspection establishments are adequately correcting identified deficiencies.

We identified a similar finding in our review of issues impacting the development of the risk-based inspection.[14] In response to one of our prior recommendations, FSIS agreed to reassess the effectiveness of its training programs. FSIS should include the training of import inspection personnel in the agency's reassessment.

FSIS needs to address the weaknesses in the agency's imported meat and poultry inspection program identified in this report. By addressing these concerns, FSIS will put in place a more robust system of controls for evaluating the equivalency of foreign countries' food safety systems and reinspecting product at U.S. ports of entry.

Recommendations In Brief

To enhance controls for assessing the equivalence of foreign food safety systems FSIS should strengthen the agency's methodology for selecting foreign establishments for review. The agency should document in its management controls the protocols implemented in response to our prior recommendations for evaluating deficiencies that question the equivalence of a foreign food safety system and performing enforcement audits. FSIS should also document the policy for performing onsite audits for new countries and countries that resumed trade with the United States.

[11] FSIS inspection personnel issue a noncompliance record to an establishment that is not complying with regulatory requirements. FSIS inspection personnel provide the noncompliance records to the management of the establishment for response and are required to document their verification of the establishment's corrective action (i.e., resolution).

[12] At the exit conference to discuss the draft report in June 2008, FSIS provided documentation these deficiencies were adequately resolved.

[13] Noncompliance records are recorded in FSIS' Performance Based Inspection System, the system currently used to record inspection results.

[14] *Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments*, Audit Report No. 24601-07-Hy, issued December 2007

To strengthen controls over the reinspection of meat and poultry products at U.S. ports of entry, FSIS should determine the number of intensified inspections for physical and laboratory failures that provide the appropriate level of protection to ensure the safety and wholesomeness of imported product. FSIS should also require physical reinspection, which includes laboratory analyses, of imported product be conducted prior to skip assignments to ensure skip assignments receive the same type of inspection if a lot fails reinspection. The agency should also assess whether foreign establishments should be required to provide the lot's production date(s). FSIS needs to implement standard procedures for analyzing agency data to ensure the data is reasonable, accurate and complete. Data from the information system should provide a basis for selecting foreign establishments for onsite reviews.

Agency Response

FSIS agreed with the report's 19 recommendations. We have incorporated FSIS' response in the Findings and Recommendations section of this report, along with the OIG position. FSIS' response is included as Exhibit B.

OIG Position

Based on FSIS' response, we were able to reach management decision on 18 of the report's 19 recommendations. Management decision on Recommendation 15 can be reached once FSIS provides us with the additional information outlined in the report section, "OIG Position."

Abbreviations Used in This Report

C.F.R.	Code of Federal Regulations
FSIS	Food Safety and Inspection Service
HACCP	Hazard Analysis and Critical Control Point
OCFO	Office of the Chief Financial Officer
OIA	Office of International Affairs
OIG	Office of Inspector General
PHIS	Public Health Information System
Secretary	Secretary of Agriculture
SSOP	Sanitation Standard Operating Procedures
USDA	U.S. Department of Agriculture

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Background and Objectives

Background

U.S. food safety legislation[15] requires foreign countries that export meat and poultry products to the United States to establish and maintain systems that are equivalent to the U.S. inspection system. Meat and poultry products must originate in countries and establishments approved to export to the United States. The U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) is responsible for monitoring foreign countries and exporters to ensure the countries' food safety systems are equivalent to U.S. standards.

FSIS administers its imported meat and poultry inspection program primarily through the Office of International Affairs (OIA). OIA is responsible for formulating policies, determining a foreign country's eligibility to export meat and poultry products to the United States, reviewing food safety requirements imposed by foreign governments, and reinspecting imported meat and poultry products. OIA is also responsible for conducting system audits (also referred to as onsite audits) of a foreign government's food regulatory program, which include a review of (1) establishments certified to export to the United States, (2) laboratories conducting analytical testing of products being exported to the United States, and (3) government controls and oversight to ensure that products are produced under requirements equivalent to U.S. inspection requirements. These review and reinspection activities form the basis of FSIS' determinations of whether a country's inspection system is equivalent to U.S. standards.

Food safety equivalence evaluations are based on provisions of the Agreement on the Application of Sanitary and Phytosanitary Measures, which became effective in January 1995. Prior to this agreement, FSIS focused on individual establishments and evaluated whether foreign food safety systems were "at least equal to" the U.S. system. The principle underlying FSIS' current import inspection activities is the "systems approach," which evaluates the equivalence of the inspection system controls of each country. Regulations[16] codify FSIS' responsibilities for evaluating foreign meat and poultry inspection systems. The burden for demonstrating equivalence rests with the exporting country and the importing country is free to set any level of protection it deems appropriate to control or eliminate a food safety hazard.

FSIS evaluates the ongoing equivalency of foreign meat and poultry inspection systems through a process that consists of (1) document analysis, (2) onsite audit, and (3) port-of-entry product reinspection. Judgments of

[15] The Federal Meat Inspection Act and Poultry Products Inspection Act.
[16] Title 9, Code of Federal Regulations (C.F.R.) § 327, Imported Products, and 9 C.F.R.§ 381, Subpart T, Imported Poultry Products.

system equivalence are necessary for FSIS and the American public to develop and maintain trust in imported meat and poultry products.

A foreign country must apply for and receive a determination of equivalency before it can export meat and poultry products to the United States. To make this determination, FSIS reviews documentation provided by the country and performs an onsite audit. After a country is determined to have an equivalent system and is eligible to export to the United States, FSIS relies on the country to provide effective oversight of food inspection activities and enforcement of U.S. requirements. However, FSIS continues to monitor the country's activities. In addition to randomly sampling imported meat and poultry products, FSIS conducts onsite audits of the country's inspection system to ensure that its procedures and standards remain equivalent. Reviewers visit certified establishments and focus on five areas of risk (i.e., animal disease, sanitation, enforcement, residue, and slaughter/processing) to determine if the country's inspection system remains equivalent.[17] These audits are generally conducted annually.

If the monitoring audits identify critical weaknesses in the implementation and enforcement of key provisions, FSIS officials take a number of immediate actions to ensure that products from the country are consistent with FSIS' public health requirements. These actions include compensating controls at ports of entry (e.g., increased reinspections and product sampling), and may include delistment of individual establishments, suspension of product categories from the country, or suspension of the entire country. These actions would remain in place until corrective actions have been completed and verified by the foreign government's inspection officials. FSIS would then schedule a followup audit to confirm that the corrective actions implemented were effective to address the identified problems and the public health requirements are being maintained.

The reinspection of imported meat and poultry meat and poultry products at U.S. ports of entry provides FSIS with a means of assessing the effectiveness of a foreign government's inspection system while ensuring that only safe, wholesome, unadulterated, and properly labeled products enter U.S. commerce. A description of each lot arriving at any the official U.S. import inspection establishments is entered into the information system. Lots are routinely reinspected for transportation damage, labeling, proper certification, general condition, and accurate count. Further, in-depth reinspection is directed by FSIS' information system, which stores reinspection results from all ports of entry for each country and establishment. The system may, for example, generate product examinations[18] or residue and microbial

[17] As FSIS reviewers evaluate the certified establishments they determine whether they are acceptable or should be recommended for delistment.

[18] A product examination is an organoleptic type of inspection in which an inspector feels, smells, and visually examines exposed product samples to discover defects such as blood clots, bruises, bone fragments, ingesta, extraneous materials (wood, glass, chemicals, insects, etc.), hair/wool, hide, stains, pathologic lesions, and off condition.

laboratory test assignments based on the compliance histories of the establishments, countries, and products being presented for reinspection. Products that pass reinspection are allowed to enter U.S. commerce; products that do not pass are stamped "U.S. Refused Entry" and must be exported, destroyed, relabeled or converted to animal food within 45 days.

In April 2007, the Chairman of the Committee on Agriculture, Nutrition, and Forestry of the U.S. Senate requested that we evaluate the adequacy of FSIS' inspection processes for meat and poultry imports to ensure the integrity of the U.S. food supply. We also agreed to determine whether FSIS took appropriate and timely actions to implement 51 prior Office of Inspector General (OIG) audit recommendations regarding the imported meat and poultry inspection program. Since 2000, OIG has issued four reports:

- *FSIS Imported Meat and Poultry Inspection Process Phase I,* Audit Report No. 24099-03-Hy, June 2000 containing 35 recommendations;

- *FSIS Imported Meat and Poultry Reinspection Process Phase II*, Audit Report No. 24099-04-Hy, February 2003 containing 11 recommendations;

- *FSIS Imported Meat and Poultry Equivalence Determinations Phase III*, Audit Report No. 24099-05-Hy, December 2003 containing no recommendations; and

- *FSIS Assessment of the Equivalence of the Canadian Inspection System*, Audit Report No. 24601-05-Hy, December 2005 containing 5 recommendations.

In September 2007, FSIS awarded a contract to build the agency's new Public Health Information System (PHIS) in order to better integrate and consolidate its numerous applications that collect information on activities to ensure the safety of meat, poultry, and egg products. FSIS plans to have the export and import functions of this system ready for user acceptance testing by the third quarter of 2009. The proposed system FSIS is developing for these functions is to be a consolidated, interactive system that replaces the current import information system and establishes an electronic certification capability for exports. This system is also being proposed as the electronic link for obtaining data from the Animal and Plant Health Inspection Service and the Customs and Border Protection of the U.S. Department of Homeland Security on import entries of meat, poultry, and egg products.

Objectives

The objective of our review was to evaluate the adequacy of FSIS' inspection processes (i.e., equivalence determinations, onsite audits, and product reinspection at U.S. ports of entry) for meat and poultry imports to ensure the integrity of the U.S. food supply. We also determined whether FSIS took appropriate and timely actions to implement prior OIG audit recommendations.

Findings and Recommendations

Section 1. Equivalence of Foreign Food Safety Systems

OIA is responsible for determining a foreign country's eligibility to export meat and poultry products to the United States and conducting system audits, which include reviewing a sample of exporting establishments. Fulfillment of these responsibilities assists the agency in ensuring that products are produced under requirements equivalent to U.S. inspection requirements.

FSIS needs to strengthen the agency's controls for assessing the equivalence of foreign countries' food safety systems, specifically, the controls concerning the methodology used to select foreign establishments for review. In addition, FSIS should document the management controls implemented in response to two of our prior recommendations for evaluating deficiencies that question the equivalence of a foreign food safety system and performing enforcement audits. FSIS should also document the policy to perform onsite audits prior to receiving product from a new country (i.e., initial equivalence) or a suspended country (i.e., inspection system not equivalent to the United States).

Finding 1 — Methodology for Selecting Foreign Establishments to Review Needs Strengthening

FSIS' sample selection methodology is designed to find at least one deficient establishment if 20 percent of the universe of eligible establishments are deficient (i.e., a 20 percent error rate). However, FSIS officials could not provide information or documentation on how the agency decided that a 20 percent error rate was reasonable and acceptable. We found that for three of the four countries we reviewed, FSIS did not follow the established methodology for selecting the minimum number of establishments to review as part of the routine onsite audits in 2006 and 2007. Because OIA does not have requirements for documenting deviations from its prescribed guidance, FSIS officials could not justify why FSIS reviewers did not visit the minimum number of establishments. As a result, FSIS has reduced assurance that it has a sufficient basis for assessing the equivalence of a country's food safety system.

According to FSIS' established controls,[19] FSIS reviewers select a random sample that provides the agency with the statistical assurance, at the 95 percent confidence level, that FSIS will find at least one deficient

[19] FSIS OIA's Management Control Manual, November 2003

establishment if 20 percent of the universe of eligible establishments are deficient.[20]

In response to our inquiries, FSIS officials could not specifically explain or provide documentation on how the agency decided that a 20 percent error rate was reasonable and acceptable. FSIS officials described that the policy was based on sampling performed for State Cooperative Inspection Programs in 1992. FSIS officials explained that the 1992 policy for reviewing State programs included a sampling table similar to the one currently used for imports. FSIS needs to determine if the current 20 percent error rate provides a sound basis for evaluating the equivalence of a country's inspection system and document the basis for the error rate accepted as reasonable.

As designed, FSIS' sample selection methodology is composed of two parts. The first part, a random sample of establishments, is derived from a statistical sample table based on the number of certified establishments in an exporting country. The second part, a targeted-judgmental sample, includes establishments with known problems based on findings from prior onsite audits, consumer complaints, or reinspection results at U.S. ports of entry recorded in FSIS' information system.

To provide statistical assurance that a country's food safety system is equivalent to the U.S. standards, FSIS reviewers should visit the number of establishments identified in the sampling methodology. If there are more than 10 establishments certified by the foreign government to export to the United States, then FSIS selects a sample of establishments to validate that the country's inspection system is equivalent. If a foreign government has certified 10 or less establishments, the FSIS is to review all certified establishments. As noted in the following table, FSIS review officials did not visit the minimum number of establishments in Australia, Brazil, and Chile during the audits performed in 2006 and 2007. FSIS officials could not explain why FSIS reviewers did not always visit the minimum number of establishments in 2006. For 2007, FSIS officials explained that they used a draft, risk-based approach to select establishments.[21] Since the minimum number of establishments was not reviewed, we question whether FSIS had sufficient data to conclude that these countries' food safety systems are equivalent to the U.S. system. FSIS' review of foreign establishments is one-third of the agency's process to determine whether a country is maintaining an equivalent inspection system. The remaining two-thirds are a review of laboratories and government controls.

[20] Through consultation with our statistician, we confirmed that the design of FSIS sample selection methodology provides the agency with this statistical assurance.

[21] Agency officials explained that this approach was not finalized; therefore, we did not perform a detailed examination of the risk-based approach. According to the January 30, 2007, draft "Guidelines for a Risk-Based Program for Verifying the Equivalence of Foreign Inspection Systems," FSIS planned to use a variety of inputs in selecting foreign establishments for review. These inputs included such things as types and volume of product exported to the United States, past performance of an establishment's food safety controls of public health significance, and delistments of or recommendations to delist foreign establishments.

Country	Number of Establishments 2006/2007	Minimum Random Sample for 2006/2007	Random Sample Reviewed in 2006	Random Sample Reviewed in 2007
Australia	130/127	13/13	10	8
Brazil	22/23	11/11	8	8
Chile	3/5	All/All	3	3

FSIS officials explained that they do not document the basis for the selected sample of establishments (i.e., random statistical versus judgmental). This occurred because FSIS did not have protocols for documenting which establishments are selected for review. In addition, FSIS does not have criteria for evaluating reinspection results to determine which establishments should be judgmentally selected for review. FSIS also did not have a process for analyzing how information from a country should be considered in the judgmental sample of establishments (e.g., establishments with a pattern of being decertified and subsequently recertified). This occurred because FSIS did not have criteria for judgmentally selecting foreign establishments for review. Accordingly, we could not validate that FSIS selected a sufficient number of establishments randomly to assess the equivalence of the country's food safety system or corroborate the propriety of FSIS' decisions for judgmentally selecting specific establishments.

At the time FSIS was planning the 2007 audit of Chile, five establishments were certified as eligible to export product to the United States. According to established controls,[22] FSIS should have reviewed all of the establishments. However, FSIS only included three establishments in the sample. Of the three establishments reviewed, only one was exporting product to the United States,[23] approximately 1.3 million pounds of beef products (e.g., boneless cuts and trimmings) through August 2007. According to data in FSIS' information system, the other two establishments not reviewed exported approximately 1.4 million pounds of beef and pork products (e.g., bone-in and boneless cuts) through August 2007. FSIS did not visit these two establishments as part of the April 2007 audit. The prior audit of Chile in 2006 reported deficiencies in the operations of these two establishments. For example, according to the 2006 audit report, FSIS had noted deficiencies in both establishments' implementation and enforcement of HACCP requirements. According to FSIS officials, the scope of the deficiencies noted in 2006 was not sufficient to require that these two establishments be a part of the 2007 audit (e.g., the establishments were not recommended for delistment). FSIS officials also explained that they used a risk-based approach to select establishments in 2007.

[22] FSIS OIA's Management Control Manual, November 2003
[23] The other two plants were included in the review because they were eligible to export product to the United States.

FSIS needs to develop and implement the necessary protocols to ensure the methodology used for selecting establishments is consistently followed, deviations from the established methodology are justified, and the basis for the selected sample is documented.

Recommendation 1

Determine whether the current 20 percent error rate provides a sound basis for evaluating the equivalence of a country's food safety system and document the basis for the error rate accepted as reasonable.

Agency Response.

The establishment selection tool is just one of the many tools currently in use as part of the annual equivalence audit process. Using OIA's well-documented "triad" approach, prior to each audit International Audit Staff auditors collect and analyze all available information related to the particular country to be audited. Port of entry results, consumer complaints, prior audit history, historical and pending equivalence determination, and any other available information is used to determine the scope of the upcoming audit. All of this information is documented in the agenda for the "Pre-Audit Conference." Therefore, the establishment selection chart is not considered to be a "stand alone" instrument to determine equivalence, but as a guide to be used along with all other available information to determine the appropriate number of establishments to visit during the onsite audit in consideration of the overall risk related to the products produced, amount exported to the U.S., and other historical information. On occasion the number of establishments selected will be greater than the number recommended in the establishment chart, and on other occasions the number of establishments selected will be less. FSIS will develop and implement a process to document the reasons for the number of establishments selected for onsite audit as part of the agenda for the Pre-Audit Conference. A description of this process will be included in the OIA Management Control Manual. FSIS expects to complete these actions by October 31, 2008.

OIG Position.

We accept FSIS' management decision.

Recommendation 2

Develop and implement protocols for documenting deviations from the guidelines on visiting the minimum number of establishments as part of the onsite audit. The documentation should provide sufficient, competent evidence that the establishments visited provide a reasonable basis for

concluding that the country's food safety system remains equivalent to the U.S. system.

Agency Response.

FSIS will develop and implement a process to document the reasons for the number of establishments selected for onsite audit as part of the agenda for the Pre-Audit Conference. A description of this process will be included in the OIA Management Control Manual. FSIS expects to complete these actions by October 31, 2008.

OIG Position.

We accept FSIS' management decision.

Recommendation 3

Develop and implement protocols for documenting which establishments are selected for review as part of the: (a) random sample and (b) judgmental sample. The protocols should also specify where this information will be documented (e.g., in the onsite audit report).

Agency Response.

FSIS will develop and implement a protocol for documenting the reasons for each establishment that is included as part of the onsite audit. This information will be documented as part of the agenda for the Pre-Audit Conference. A description of this process will be included in the OIA Management Control Manual. FSIS expects to complete these actions by October 31, 2008.

OIG Position.

We accept FSIS' management decision.

Recommendation 4

Develop and implement criteria for judgmentally selecting foreign establishments for onsite review. The selection criteria should consider such information as (a) reinspection results from FSIS' information system, or any subsequent system, (b) deficiencies noted in prior onsite audits, (c) establishments with a pattern of being decertified and subsequently recertified, and (d) and any other appropriate evaluation factors.

Agency Response.

FSIS will develop and implement a protocol for judgmentally selecting foreign establishments for onsite review. A description of this process will be included in the OIA Management Control Manual. FSIS expects to complete these actions by October 31, 2008.

OIG Position.

We accept FSIS' management decision.

Finding 2 Prior Recommendations Not Fully Implemented

FSIS did not fully implement two of the five recommendations from one of our prior reports,[24] which were intended to strengthen the overall equivalence determination process. These recommendations required FSIS to implement protocols for: (1) determining which equivalence deficiencies would question a country's overall equivalence determination and (2) postponing and cancelling a scheduled enforcement audit.[25] This occurred because FSIS did not make a priority of documenting these protocols in OIA's management controls. We found that the protocols (see Exhibit A) were implemented through actions that the agency took (e.g., increased port-of-entry testing and enforcement audits scheduled) in response to equivalence concerns regarding the Danish food safety system in 2007. However, since the protocols are not documented in OIA's management controls, FSIS has reduced assurance that correct decisions will be consistently made when enforcement audits are delayed or a country's equivalence is in question.

In our prior reports, OIG made 51 recommendations to strengthen FSIS' regulatory oversight of imported meat and poultry products. For these 51 recommendations, FSIS provided the Office of the Chief Financial Officer (OCFO) with evidence that the agreed upon corrective actions had been implemented. We found that FSIS adequately implemented the corrective actions reported to OCFO for 49 of the 51 recommendations. For the remaining two recommendations, FSIS had not documented the protocols provided to OCFO in OIA's management controls.

We previously reported that FSIS did not timely address serious concerns with a country's food safety system even though high-level agency officials documented the potential for compromising public health. Timely action had not been taken because FSIS did not have protocols or guidelines for evaluating deficiencies in a country's food safety system that could

[24] *Assessment of the Equivalence of the Canadian Inspection System*, Audit Report No. 24601-05-Hy, December 2005.
[25] FSIS currently refers to these audits as "followup" or "special emphasis" audits.

jeopardize a country's overall equivalence determination. We also found that FSIS did not conduct an enforcement audit of a country's food safety system to ensure noted deficiencies were corrected. Enforcement audits can lead to a determination that a country's inspection system is not equivalent to U.S. standards and, thus, not eligible to export to the United States.

In FSIS' response to our prior report, the agency agreed to develop and implement these protocols by March 31, 2006. In the documentation provided to OCFO to close these recommendations, FSIS provided a detailed description of how these protocols would be implemented (see Exhibit A). However, FSIS did not follow through to include these protocols in OIA's Management Control Manual. (The most recent version of this manual is dated November 2003 with updates to certain chapters in March 2004.) An FSIS official explained that documenting the protocols in the management controls was not a priority due to OIA staff shortages. FSIS officials agreed that these protocols should be documented, and in January 2008, the agency hired an intern to assist with this process.

In our review of the protocol to postpone or cancel an enforcement audit, we found that FSIS included a description of the documentation that would be prepared to support the decisions made. Similar direction was not found in the protocol on questioning a country's equivalence. FSIS should include in this protocol a description of how FSIS officials will document and justify the decisions made. This would provide a basis for understanding decisions to increase port of entry testing as compared to suspending trade with a country.

In response to our inquiries, FSIS demonstrated that the two recommended protocols were implemented through equivalency concerns FSIS raised regarding the Danish food safety system in 2007. In May 2007, FSIS performed a routine audit of the Danish inspection system. For the seven slaughter and processing establishments reviewed,[26] FSIS recommended that Danish officials issue each establishment a Notice of Intent to Delist because of potential product contamination, issues with HACCP systems and SSOPs, and insufficient government oversight. The issuance of a Notice of Intent to Delist means that no direct product contamination was observed, but all documented deficiencies must be corrected by the establishment and verified by the government inspection program no later than 30 days after the initial audit. This corrective action and verification information must then be provided to FSIS, or action is taken to remove the establishment(s) from the list of establishments approved to export product to the United States.

[26] FSIS reviewed a total of eight establishments. The eighth establishment was a cold storage facility.

As a result of the findings from the May 2007 audit, FSIS began to perform product examinations[27] on 100 percent of the product presented for reinspection. This increased level of reinspection continued until the Danish Government submitted sufficient documentation that adequate corrective actions had been taken.[28] As a result of this action, FSIS stopped performing product examinations on 100 percent of the product presented on June 20, 2007. However, to confirm implementation of the corrective actions, FSIS required the Danish Government to provide evidence of supervisory review of the eligible establishments. According to data we obtained from FSIS information system through August 2007, just over 1,600 lots[29] of Danish pork products totaling over 34 million pounds were presented for reinspection from May 1 through August 31, 2007.

In September 2007, FSIS notified the Danish Government that FSIS would perform a followup (i.e., enforcement) audit to verify that the corrective actions were implemented. The Danish Government requested that this audit be postponed[30] to allow additional time for it to satisfactorily address all issues from the previous audit. FSIS honored this request and completed the followup audit during 2008.[31] As a compensating control, FSIS continued to require the Danish Government to provide evidence of supervisory review of the eligible establishments.[32]

In order to ensure that the protocols will be followed, when needed, FSIS should document them as part of its management controls. The protocol for questioning a country's equivalence should also describe how FSIS officials will document and justify the decisions made.

Recommendation 5

Revise OIA's Management Control Manual to include the protocols for (1) determining which equivalence deficiencies would question a country's overall equivalence determination and (2) postponing and cancelling a scheduled enforcement audit. The protocol for questioning country equivalence should also describe how FSIS officials will document and justify the decisions made.

[27] A product examination is an organoleptic type of inspection in which an inspector feels, smells, and visually examines exposed product samples to discover defects such as blood clots, bruises, bone fragments, ingesta, extraneous materials (wood, glass, chemicals, insects, etc.), hair/wool, hide, stains, pathologic lesions, and off condition.

[28] Data in FSIS' information system confirmed that FSIS performed product examinations on all shipments from Denmark from May 15 to June 20, 2007.

[29] Of these lots, seven were rejected for such reasons as transportation damage and missing shipping marks. The amount rejected totaled more than 70,000 pounds.

[30] The decision to postpone the followup audit in order to allow Denmark to satisfactorily address prior issues is consistent with information FSIS provided to OCFO on why an enforcement audit would be postponed **(**see Exhibit A**)**.

[31] FSIS issued this report in final in July 2008.

[32] The additional testing of Danish product subsequent to the May 2007 findings and compensating controls that were in effect prior to the followup review are decisions that are consistent with information FSIS provided to OCFO for determining deficiencies that question overall equivalence **(**see Exhibit A**)**.

Agency Response.

FSIS has developed a protocol for determining the equivalence of a countries foreign inspection system (see Exhibit A). Upon completion of every audit, FSIS personnel review the findings of the audit team. In the event that problems are identified, the OIA management team will consider the audit findings as well as other variables such as audit history, products exported, etc., to determine whether or not an enforcement measure is warranted. FSIS also has developed a protocol for postponing or cancelling a scheduled enforcement audit (see Exhibit A). FSIS will include these protocols in the revised OIA management controls manual. FSIS expects to complete these actions by October 31, 2008.

OIG Position.

We accept FSIS' management decision.

Finding 3 — Policy for Performing Onsite Audits for New and Suspended Countries Not Documented

FSIS officials explained that the agency's policy is to perform an onsite audit to ensure a country's food safety system remains equivalent to U.S. standards prior to (1) a new country's first shipment and (2) a suspended country resuming trade with the United States. However, FSIS officials also confirmed that this policy was not part of their written procedures but could not explain why. Documented procedures in these areas are critical because an extended period of time can transpire (e.g., over 2 years) between FSIS' onsite audit of a country's equivalence and the date of the country's first shipment. In addition, countries may be suspended for extended periods of time (e.g., 4 years). As a result, FSIS does not have current information to mitigate the risk that product not meeting U.S. standards may be exported and a country's food safety system may not remain equivalent to the United States.

Departmental regulation requires agencies to ensure controls for processes supporting agency programs and operations are documented and commensurate with program risk.[33]

To mitigate the risk that ineligible product is potentially exported to the United States or a country's food safety system is not equivalent, FSIS should document procedures to conduct onsite audits prior to the first shipments of

[33] Departmental Regulation 1110-002, Management Accountability and Control, dated April 14, 2004.

new countries or countries that had been suspended. We noted 16 countries[34] currently approved as equivalent to U.S. standards are not currently exporting product to the United States. According to FSIS officials, one country has not exported product to the United States since 1999.

- **New Countries**

  FSIS determines the equivalency of foreign meat and poultry inspection systems through a process that consists of document analysis and onsite audit. After a country is determined to have an equivalent system and is eligible to export to the United States, FSIS relies on the country to provide effective oversight of food inspection activities and enforcement of U.S. requirements.

  In April 2006, FSIS published a rule[35] concluding that China was eligible to export processed poultry products to the United States "only if they are processed in certified establishments in the People's Republic of China from poultry slaughtered in certified slaughter establishments in other countries eligible to export poultry to the United States." FSIS performed an onsite audit to determine that China had an equivalent inspection system for processing poultry products in December 2004. In response to our inquiries, FSIS officials explained that they followed their established processes for assessing the equivalence of the Chinese food safety system; they did not intend to do anything special regarding this assessment in an effort to treat China in a manner consistent with other countries.

  China has not certified any establishments as eligible to export processed poultry products to the United States. Accordingly, no product from China has been presented to FSIS for reinspection. However, an extended period of time has transpired since FSIS' onsite audit (December 2004) to determine China's food safety system for processed poultry products is equivalent to U.S. standards. To ensure onsite audits are performed prior to a new country's first shipment, such as China, FSIS should document this policy in the agency's procedures. The procedures should specify the timeframe in which this onsite audit should be performed.

  In June 2006, FSIS determined that China's system for slaughtering domestic poultry was equivalent to U.S. standards. FSIS based this determination, in part, on an onsite audit of slaughter operations performed in August 2005. As a next step, FSIS would issue a proposed rule that requests public comment on whether China's poultry slaughter operations should be considered equivalent. However, additional

[34] The 16 countries include: (1) the Czech Republic, (2) Slovenia, (3) Romania, (4) Austria, (5) Slovakia, (6) Switzerland, (7) Hong Kong, (8) Paraguay, (9) Belize, (10) El Salvador, (11) Guatemala, (12) Norway, (13) Taiwan, (14) Venezuela, (15) Yugoslavia, and (16) the Dominican Republic.

[35] *Federal Register*, Volume 71, Number 78, April 24, 2006.

measures currently prevent the import of poultry from China (i.e., processed product or product from domestic Chinese poultry). According to information maintained by the Animal and Plant Health Inspection Service, domestic Chinese poultry and poultry products cannot be imported into the United States due to the country's disease status (i.e., currently infected with highly pathogenic avian influenza, subtype H5N1). Further, the Committee Report[36] for the appropriations authorized for FSIS for fiscal year 2008 prohibits the use of appropriated funds to establish or implement any rule allowing poultry products from China into the United States.

- **Suspended Countries**

  According to FSIS officials, suspended countries would receive an onsite audit before the country resumes exporting product to the United States. OIA's Assistant Administrator verbally communicated this policy to staff; however, the policy has not been documented in OIA's management controls.

  FSIS demonstrated that it correctly implemented this policy based on actions the agency took before allowing Austrian establishments to export product to the United States. In 2003, FSIS suspended Austria's ability to export product because the Austrian government did not maintain an inspection system equivalent to the United States. In December 2007, FSIS withdrew its suspension of imports of Austrian meat products based, in part, on an onsite audit performed in September 2007. According to data we obtained from FSIS' information system, Austria did not export product to the United States from January 2005 through August 2007.

  The policy for performing onsite audits before suspended countries resume exporting product to the United States is not documented. As a result, FSIS may not be appropriately mitigating the risk that product not meeting U.S. standards is exported and a country's inspection system remains equivalent to the United States.

Because of changes in conditions that can occur in new and suspended countries, FSIS should formalize procedures for conducting onsite audits within established timeframes prior to the first shipments from new countries and countries that had been suspended. The procedures for suspended countries should define the period of time that would cause an onsite audit to be performed before the country resumes exporting product to the United States.

[36] House of Representatives Report 110-258, Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, 2008.

Recommendation 6

Formalize procedures to conduct onsite audits, within a specified timeframe, prior to the first shipments from new countries in OIA's Management Control Manual.

Agency Response.

FSIS agrees with this recommendation. All countries that are eligible to ship are audited on a regular basis according to a protocol currently outlined in the manual. However, OIA had not specifically identified this circumstance in the protocol. Therefore, FSIS will include a revised protocol in the manual. FSIS expects to complete these actions by October 31, 2008.

OIG Position.

We accept FSIS' management decision.

Recommendation 7

Formalize procedures to conduct onsite audits, within a specified timeframe, prior to the first shipments from countries that had been suspended in OIA's Management Control Manual. These procedures should define the period of time that would cause an onsite audit to be performed before the country resumes exporting product to the United States.

Agency Response.

FSIS agrees with this recommendation. Currently, FSIS does ensure that a country has been audited prior to lifting a suspension that has been put in place to ensure that product will not enter the United States. A written protocol will be added to the manual. FSIS expects to complete these actions by October 31, 2008.

OIG Position.

We accept FSIS' management decision.

The reinspection of imported meat and poultry products at U.S. ports of entry by FSIS inspection personnel helps assess the effectiveness of a foreign government's food safety system and ensures that only wholesome, unadulterated, and properly labeled products enter U.S. commerce. To that end, FSIS is given the responsibility to randomly select samples of imported meat and poultry products and perform the following types of reinspection activities, as appropriate: product examinations, net weight compliance, condition of container, incubation of shelf-stable products, special examinations, and laboratory analyses.

When products are presented to FSIS, the FSIS information system assigns one of four levels of reinspection to the product presented: skipped, normal, intensified, or increased. Skipped inspection signifies the lot will be reinspected for transportation damage, labeling, proper certification, general condition, and accurate count. Under normal inspection, the lot has been randomly selected for physical reinspection, which can include laboratory analyses. Physical reinspection activities determine such things as whether the product is contaminated (e.g., fecal, metal) or otherwise not in good condition (e.g., spoiled). Laboratory analyses test for microbial violations (e.g., *Escherichia coli* O157:H7 (*E. coli*)) or residues (e.g., drugs and chemicals) above tolerable limits. Intensified inspection signifies a previous failure to meet U.S. requirements. Under intensified level of inspection, lots are held by FSIS pending results for the type of inspection in question. If the level of inspection is increased, FSIS management officials have decided to perform reinspection activities above the normal level of inspection for the lot based on problems associated with the specific product, foreign establishment, or country.

FSIS needs to strengthen agency controls for reinspecting meat and poultry products at U.S. ports of entry. Specifically, FSIS should determine the number of intensified inspections for physical and laboratory failures that provide the appropriate level of protection to ensure the safety and wholesomeness of imported products. In addition, FSIS needs to strengthen procedures for: (1) specifying the order of performing reinspection activities, (2) verifying a lot's production date, (3) analyzing data in FSIS' import information system, and (4) managing noncompliance records.

Finding 4 Basis for the Number of Intensified Inspections Needed

When product from an eligible foreign establishment fails reinspection at U.S. ports of entry, FSIS intensifies the reinspection of subsequent shipments

of the same type of product from that establishment. FSIS' information system is programmed to select a certain number of subsequent shipments from that establishment to perform the same type of inspection. For example, FSIS reinspects 10 subsequent shipments when product is contaminated with fecal material. FSIS has used this practice for 25 years. The foundation of the practice was traced to the June 1983 report by FSIS' Import Inspection Task Force. As a result, FSIS has reduced assurance that intensified inspections provide the appropriate level of protection to ensure the safety and wholesomeness of imported products entering the United States.

Intensified inspections are triggered after a product fails to pass reinspections for physical and laboratory testing. According to the programming of the information system, if a product fails during the intensified inspection period, the counter is reset. According to FSIS officials, when the agency reprogrammed the information system in 2002, statisticians evaluated the number of intensified inspections for physical and laboratory failures.

- For physical failures, the FSIS information system triggers the same type of inspection for 10 consecutive shipments of the same type of product. Physical failures occur when FSIS finds the product to be contaminated (e.g., fecal, metal, grease), be of unsound condition (e.g., spoiled) or contain processing defects (e.g., blood clots, lung tissue, bones).

- For laboratory failures, the level of inspection will return to normal after 15 consecutive shipments (and 15 times the weight of the failed lot) pass the same type of laboratory analysis.[37] Laboratory failures occur when FSIS finds the product positive for microbial violations (e.g., *E.-coli*, *Salmonella*, *Listeria monocytogenes*) or contains residues (e.g., drugs and chemicals) above tolerable limits.

FSIS needs to determine the number of intensified inspections for physical and laboratory failures that provide the appropriate level of protection to ensure the safety and wholesomeness of imported products. As part of this determination, FSIS should also document any needed revisions to procedures for intensified inspections.

We confirmed that FSIS' information system does trigger intensified inspections for physical and laboratory failures as described; however, documentation of this intensified testing in the system is not clear. We found that some lots that were subject to intensified testing were not recorded as receiving an intensified inspection assignment but were counted toward the required number of shipments for intensified inspection. For example, as part of one physical failure, the information showed nine lots labeled as

[37] To return to the normal level of inspection, 15 consecutive shipments must pass the same the type of analysis. If the weight of these 15 shipments is not equal to 15 times the weight of the lot that originally failed, additional shipments must be tested.

"intensified status" and one lot (i.e., the seventh lot) labeled as "scheduled inspection." FSIS officials acknowledged that this could be confusing and agreed with the need to accurately document the level of reinspection being performed in the agency's information system. FSIS officials plan to clarify this in the new import information system that is currently being developed. As part of the new import information system, FSIS should ensure that scheduled inspections are suspended when the level of inspection is intensified.

Recommendation 8

Determine the appropriate number of intensified inspections for physical and laboratory failures that ensure the safety and wholesomeness of imported products and document the necessary revisions to procedures for intensified inspections.

Agency Response.

FSIS concurs with this recommendation. FSIS will determine the appropriate number of intensified inspections following physical and laboratory failures needed to ensure the safety and wholesomeness of imported products and will document the necessary revisions to procedures for intensified inspections. FSIS expects to complete these actions by October 31, 2008.

OIG Position.

We accept FSIS' management decision.

Recommendation 9

Clearly document the level of reinspection being performed on imported product in FSIS' information system and ensure that scheduled inspections are suspended when the level of inspection is intensified.

Agency Response.

FSIS concurs with this recommendation. In the forthcoming PHIS, FSIS will clearly document the level of reinspection being performed on imported product and ensure that scheduled inspections are suspended when the level of inspection is intensified. FSIS expects to complete these actions by December 31, 2009.

OIG Position.

We accept FSIS' management decision.

Finding 5 — Physical Reinspections Not Required to be Performed Before Skipped Assignments

When shipments contain multiple lots[38] of the same type of product that include both normal and skipped levels of reinspection, FSIS inspection personnel perform the skip assignments before the physical reinspection. This occurred because FSIS procedures did not require the physical reinspection to be performed first. According to FSIS officials, skipped assignments are done first because they can be completed quickly. These lots of product are then released into U.S. commerce and would not be available for additional inspections. As a result, FSIS has reduced assurance that the appropriate actions were taken prior to imported products being allowed to enter U.S. commerce.

During a skipped reinspection, product from the lot is not physically examined; only the outside of the box is examined for general condition (e.g., transportation damage, labeling). However, during a physical reinspection, the FSIS inspector conducts such tests as product examinations, which requires the inspector to feel, smell, and visually examine the exposed product for things like blood clots, hair, bruises, and fecal material on the product. When an inspector discovers defects during a physical reinspection, the lot is refused entry into the U.S. and the inspector can perform additional physical reinspection (i.e., an unscheduled inspection) on the skipped lots. However, because FSIS processes skipped lots first and immediately releases them into U.S. commerce, the inspectors lack assurance that the skipped lots from the same shipment are free of defects.

We randomly selected 94 lots associated with 73 shipments from Australia, Canada, Brazil, and Chile that had been rejected between January 1, 2005 and August 31, 2007, at the 9 import inspection establishments we visited.[39] Of the 73 shipments, 35 shipments contained 43 lots[40] that had a physical failure for such things as fecal contamination, processing defects (e.g., blood clots), excess hair, and labeling defects.[41] Of these 35 shipments, 12 had skipped lots that contained approximately 325,000 pounds of lamb, mutton, beef, and goat from Australia and Brazil of the same type of product that was rejected. These 12 lots were released into U.S. commerce without the same type of reinspection as those lots that failed physical reinspection.

[38] A shipment can contain one or more lots of product. A lot is a group of similarly processed and packaged products (e.g., boxed, frozen boneless beef) from one establishment in a country.

[39] We randomly selected 10 rejected lots for each country per import inspection establishments in our sample. If 10 lots had not been rejected during the scope of our review, we reviewed all that had been rejected. See the Scope and Methodology section of this report for further explanation of our sampling methodology.

[40] The other 51 physical failures were for such things as labeling defects, missing or incorrect shipping marks, and transportation damage.

[41] This is based on information recorded in FSIS' information system and documentation available at the import inspection establishments we visited.

Recommendation 10

Develop and implement procedures that require inspectors to perform physical reinspections first and for FSIS import inspection personnel to perform unscheduled inspections on skipped lots associated with lots that failed reinspection.

Agency Response.

FSIS concurs with this recommendation and has taken steps to implement it. Instructions to field personnel have been issued directing them to hold all assignments associated with lots of product presented for inspection from a single establishment, and to perform all physical inspection assignments before skip lot assignments are processed. In this manner, results of physical inspection decisions can determine the need to perform a physical inspection of skip lot assignments. The Import Inspection Division is documenting these instructions as a procedural change within the Import Manual of Procedures. FSIS expects to complete these actions by October 31, 2008.

OIG Position.

We accept FSIS' management decision.

Recommendation 11

Take the appropriate action on the approximately 325,000 pounds of product from the 12 skipped lots associated with lots that failed physical reinspection.

Agency Response.

FSIS requests that OIG identify the 43 lots of imported product that it found to have been recorded for physical examination failure, in order to determine if product associated with the corresponding 12 skip lots represents a food safety hazard, or constitutes misbranding or economic adulteration, and to determine whether follow-up action is needed. FSIS will organize a recall committee to determine the requirements for a recall action on the 12 skip lots if analysis of the data on the 43 failed lots indicates a need. FSIS expects to complete these actions by October 31, 2008.

OIG Position.

We accept FSIS' management decision. We will provide the identity of the 43 lots in a separate memorandum.

Finding 6 Procedures to Assist Inspectors' Validation of a Lot's Production Date Not Documented

FSIS does not have documented procedures to guide inspectors' decisions on what data sources to use for a lot's production date. According to FSIS officials, when product is received from a delisted establishment,[42] import inspection personnel have been verbally instructed to use the health certificate, product label, or shipping carton to verify that the lot's production dates are within the eligible period. If these items do not substantiate the product's eligibility, import inspection personnel are to consult with their supervisor or FSIS headquarters.[43] If the production date cannot be verified or if the product was produced during an ineligible period the shipment will be refused. Without documented procedures, FSIS has reduced assurance that the appropriate data sources are used to ensure that only eligible products are imported into the United States.

When FSIS inspection personnel receive product from a delisted establishment, FSIS inspection personnel must enter the lot's date of production to ensure that product was produced during an eligible period. However, foreign establishments are not required to provide the lot's production date(s). FSIS regulation does not require production dates to be certified by the foreign countries; however, FSIS inspection personnel have the authority to hold shipments until the eligibility of the product is verified. This includes requesting the foreign government to provide productions dates for specific shipments. A lot's production date, however, could facilitate trace back for such things as product recalls. FSIS should conduct an assessment, including any other appropriate FSIS units, to determine whether foreign establishments should be required to provide the lot's production date(s).

By analyzing data in FSIS' information system,[44] we identified 38 shipments from a delisted foreign establishment that did not appear to follow this verbal instruction. We found that a Brazilian establishment was delisted from May 6, 2005 to June 28, 2005. This establishment exported 39 lots of beef product totaling almost 1.6 million pounds to the United States from September 19, 2005 to January 10, 2006. According to data in FSIS' information system, all 39 lots were produced by the establishment on June 29, 2005. We question whether this establishment would produce 1.6 million pounds of product in a single day based on its export history. According to data in FSIS' information system, an average day's production from this establishment totaled approximately 100,000 pounds.

[42] A delisted establishment is one that is ineligible to export product to the United States. The information system is coded to notify inspectors that the establishment is delisted.

[43] FSIS officials did not have an explanation as to why this instruction was not documented.

[44] FSIS could not provide source documentation that we could use to validate the date in the information system. This source documentation was deleted according to FSIS record retention requirements.

Recommendation 12

Document the procedures to guide inspectors' decisions on what data sources to use for a shipment's production date.

Agency Response.

FSIS has already taken steps related to this recommendation. On February 28, 2008, an import notice was issued to field personnel that provided instructions on what information from shipping documentation and containers can and cannot be used to identify product production dates, and what procedures to follow to document that information in the Automated Import Information System, and to generate an inspection assignment for a delisted or delisted and relisted foreign establishment.

OIG Position.

We accept FSIS' management decision.

Recommendation 13

Implement an edit check in the information system, or any subsequent revision, to validate that inspectors used an adequate data source to verify a shipment's production date.

Agency Response.

FSIS concurs with this recommendation. FSIS will implement an edit check in the PHIS to validate that inspectors used an adequate data source to verify a shipment's production date. FSIS expects to complete this action by December 31, 2009.

OIG Position.

We accept FSIS' management decision.

Recommendation 14

Perform an assessment, including any other appropriate FSIS units, to determine whether foreign establishments should be required to provide the lot's production date.

Agency Response.

FSIS regulations do not require domestic establishments to identify lots of product according to production dates. According to the national treatment provisions of the World Trade Organization Agreement on Sanitary and Phytosanitary Measures, to which the United States is a signatory, no Member State may maintain standards for imported products that exceed requirements for domestic product. The establishment of a lotting policy for imported products that identifies a lot of product by production date would necessitate a corresponding domestic policy change. FSIS will consider the establishment of such a policy in the context of its entire food safety and inspection program. FSIS expects to complete this action by October 31, 2008.

OIG Position.

We accept FSIS' management decision.

Finding 7 FSIS Needs Procedures for Analyzing Data

FSIS' information system contained incomplete and erroneous data. For example, we identified that FSIS' information system did not have a record of the reinspection results for 400 lots of product presented for reinspection from January 1, 2005 to August 31, 2007.[45] We also found that inspection personnel could enter rejected weights that exceeded the weight of product presented for reinspection. This occurred because FSIS did not have documented procedures for analyzing data in the information system or other edit checks to determine that data were reasonable, complete, and accurate. FSIS officials could not explain why the errors were not detected and corrected. In addition, they explained that their analyses of data in the information system are often performed on an ad hoc basis. As a result, FSIS' has reduced assurance that its information system is a reliable tool for monitoring program operations.

Departmental regulation requires agencies to implement sufficient controls for collecting reliable information.[46]

As noted in Finding 1, we found that FSIS does not have criteria for evaluating reinspection results at U.S. ports of entry. This type of analysis would assist in identifying foreign establishments to select for onsite review. Accordingly, we recommended that FSIS develop and implement criteria for judgmentally selecting foreign establishments for onsite review. This criteria

[45] During this timeframe more than 597,000 lots were presented for reinspection.
[46] Departmental Manual 1110-002, USDA Management Control Manual, dated November 29, 2002.

should consider, among other factors, the reinspection results from FSIS' information system.

We also identified several areas in which FSIS could improve the integrity of data in the agency's information system. Improvements in these areas could assist in making the information system a more reliable tool for monitoring program operations.

- FSIS' information system did not have a record of the reinspection results for 400 lots of product presented for reinspection from January 1, 2005 to August 31, 2007. The meat and poultry products associated with these lots totaled approximately 7.4 million pounds. FSIS officials explained that regional supervisory personnel are expected to monitor inspection results; however, there are no standard analyses to ensure that the data recorded are reasonable, complete, and accurate. In addition, FSIS officials explained that the information system also does not alert system users (i.e., import inspectors, their supervisors, and Headquarters staff) that inspection results have not been recorded.

- FSIS' information system allowed inspection personnel to enter rejected weights for rejected portions of a lot that exceeded weight of the product presented for reinspection. We identified 5 lots where the amount presented for reinspection totaled almost 28,000 pounds and the amount rejected totaled more than 450,000 pounds. We also identified two lots where the amount of product reinspected and rejected were negative numbers. FSIS should modify the information system to ensure that only appropriate amounts are entered into the information system.

- FSIS' information system prompted inspection personnel to perform inspection tasks (e.g., physical reinspection and laboratory analysis) that were not suitable to the product presented. We identified over 18,000 reinspection tasks that were not performed by inspection personnel from January 1, 2005 to August 31, 2007. For example, the information system assigned certain types of residue tests to product that did not have a sufficient fat content to perform the required test. Detailed analysis of the reinspection tasks were hampered because no reason was recorded for not performing the inspection tasks for almost 30 percent of the entries. We also noted that entries for the exempt reasons were not standardized (i.e., no effective drop down menus). FSIS should modify the information system to require that the reason for not performing an inspection task be recorded in a standard way. FSIS should develop and implement a standard analysis to evaluate the reasons inspection tasks are not performed in order to revise the types of inspections assigned.

- FSIS' information system did not prevent inspection personnel from entering erroneous production dates. We tested the system to determine if

it would prevent or reject the entry of a date in the future for a lot's production date. We found that if an inspector entered a production date of December 21, 2012, the system did not reject or otherwise question this entry. Our examination of FSIS' data from January 1, 2005 to August 31, 2007 showed that the date of the lot's inspection assignment preceded the production dates entered for 133 lots. The products in these lots totaled approximately 2.1 million pounds from a variety of product types and countries.

In September 2007, FSIS awarded a contract to build the agency's new PHIS in order to better integrate and consolidate its numerous applications that collect information on activities to ensure the safety of meat, poultry, and egg products. FSIS plans to have the export and import functions of this system ready for user acceptance testing by the third quarter of 2009. FSIS should develop and implement procedures for analyzing data in the agency's new information system to determine that data are reasonable, complete, and accurate. The analytical procedures implemented should also ensure that only appropriate amounts are entered into the system and the reasons for not performing scheduled reinspection tasks are valid.

Recommendation 15

Develop and implement procedures for performing standard analyses of data in the new information system to determine that data were reasonable, complete, and accurate. The procedures should identify the FSIS officials responsible for performing the analyses and following up on discrepancies noted.

Agency Response.

FSIS concurs with this recommendation. FSIS will develop and implement standard operating procedures for performing analyses of data in the PHIS to determine that data were reasonable, complete, and accurate. FSIS expects to complete these actions by December 31, 2009.

OIG Position.

Although we agree that the standard analyses of data should be a part of the new PHIS, the procedures for performing these analyses should be in place before the PHIS is put into operation. To reach management decision, FSIS should specify the timeframe for developing the procedures for performing standard analyses of data in the PHIS. In addition, FSIS should develop and implement interim procedures for performing standard analyses of data until the PHIS is operational.

Recommendation 16

In the new information system, implement an edit check to alert users when inspection results have not been recorded. As part of this analytical tool, FSIS should also establish the expected timeframes for recording inspection results.

Agency Response.

FSIS concurs with this recommendation and has established requirements for the development of this capability within the PHIS. FSIS expects to complete these actions by December 31, 2009.

OIG Position.

We accept FSIS' management decision.

Recommendation 17

In the new information system, implement an edit check to ensure that only appropriate amounts are entered into the information system (e.g., negative amounts are not entered, rejected weights do not exceed the presented weight, and valid production dates are entered).

Agency Response.

FSIS concurs with this recommendation and has established requirements for the development of this capability within PHIS. FSIS expects to complete these actions by December 31, 2009.

OIG Position.

We accept FSIS' management decision.

Recommendation 18

In the new information system, require that the reason for not performing an inspection task be recorded in a standard way (e.g., pick the reason from a drop down menu). FSIS should also develop and implement a standard analysis to evaluate the reasons inspection tasks are not performed in order to revise the types of inspections assigned.

Agency Response.

FSIS concurs with this recommendation and has established requirements for the development of this capability within PHIS. FSIS expects to complete these actions by December 31, 2009.

OIG Position.

We accept FSIS' management decision.

Finding 8 Procedures for Managing Noncompliance Records Not Followed

FSIS inspection personnel did not always follow established procedures for resolving the deficiencies noted in noncompliance records and could not explain why the procedures were not followed. For example, FSIS inspection personnel did not document on the noncompliance records the resolution of deficiencies noted in January 2007 (e.g., build up of blood and debris on bottom of band saw) in a California import establishment. In addition, FSIS' database of noncompliance records may not be complete. We noted that a noncompliance record in the files at a Pennsylvania import establishment that was not in FSIS' database. FSIS could not provide explanations for these discrepancies. As a result, there is reduced assurance that import inspection establishments are adequately correcting identified deficiencies.

We noted a similar finding as part of our assessment of the issues impacting the development of risk-based inspection.[47] In that review, we recommended that FSIS reassess the effectiveness of training programs for inspection personnel and frontline supervisors and revise the program, as appropriate. FSIS agreed with this recommendation and expected to initiate the revision of its training programs by September 2008. Based on issues we identified at the import inspection establishments, FSIS should include the training of import inspection personnel in the agency's reassessment of the effectiveness of its training programs. Examples of the types of issues we identified include the following.

- In January 2007, the inspector at a California import inspection establishment found the build up of blood and debris on bottom of band saw, dust and debris at bottom of the defrost tank, and debris in bottom of Cryovac machine as part of the pre-operational sanitation review on two consecutive days. The inspector did not document how these deficiencies were resolved on the NR, as required. At the exit conference to discuss

[47] *Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments*, Audit Report No. 24601-07-Hy, issued December 2007.

the draft report in June 2008, FSIS provided documentation that these deficiencies were adequately resolved.

- In August 2007, the inspector at another California import inspection establishment noted that an outside contractor inappropriately picked up an unsanitary white coat off the floor and put it on in the processing room, stepped out of the room and returned carrying in a wooden pallet. The same contractor also used an unsanitary knife that had residue on it from the previous day's work. At the time of our review at this establishment in November 2007, there was no resolution of these issues. At the exit conference to discuss the draft report in June 2008, FSIS provided documentation that these deficiencies were adequately resolved.

- FSIS' database of noncompliance records may not be complete. We found a noncompliance record in the files at the import inspection establishment that was not in FSIS' database. In addition, review of noncompliance records in FSIS' database for an import inspection establishment in California disclosed records in FSIS' database that were not found in the files at the import inspection establishment

Recommendation 19

Include the training of import inspection personnel in FSIS' reassessment of the effectiveness of the agency's training programs that is currently scheduled to be completed by September 2008.

Agency Response.

FSIS agrees. As part of the ongoing comprehensive evaluation of FSIS training programs being conducted in response to recommendation 34 of OIG Audit 24601-7-Hy, FSIS is examining the training of import inspection personnel. FSIS expects to complete this action by September 30, 2008.

OIG Position.

We accept FSIS' management decision.

Scope and Methodology

We performed our audit at FSIS Headquarters in Washington, D.C., the office of the International Audit Staff in Omaha, Nebraska, two import field offices and selected import inspection establishments from August 2007 to January 2008. To accomplish our objectives, we discussed current operations with FSIS officials, reviewed supporting documentation to evaluate how the agency implemented its responsibilities regarding the imported meat and poultry inspection program, and became familiar with FSIS' import information system. Our review was concentrated on three divisions of OIA: (1) international equivalence, which makes the determinations on the equivalence of foreign food safety system, (2) international audit, which performs the onsite audits to verify that the food safety systems are equivalent, and (3) import inspection, which reinspects meat and poultry products at U.S. ports of entry. We also assessed FSIS' implementation of prior OIG audit recommendations related to the scope of this audit.

To examine the procedures and controls associated with FSIS' imported meat and poultry inspection program, we judgmentally selected five countries to review: China, Chile, Canada, Brazil, and Australia. We selected China and Chile because they represent two countries for which FSIS has made recent decisions on the equivalency of the country's food safety system. In April 2006, FSIS determined that China was eligible to export certain processed poultry products to the United States. In November 2005, FSIS determined that Chile was eligible to export meat products to the United States. We selected Canada, Brazil and Australia for review because of the high volume of product these countries annually export to the United States; they are generally in the top five countries that export products.

We visited the import field offices located in Philadelphia, Pennsylvania and Diamond Bar, California, and nine import inspection establishments overseen by these offices. These locations were selected for review based on the volume of products reinspected by FSIS' import inspection personnel for the four countries we selected to review. Almost 9 million pounds of product was presented to FSIS for reinspection at the nine import inspection establishments from January 2005 through August 2007. The nine import inspection establishments were located in Carson, California; Vernon, California (2 establishments); Dominguez Hills, California; Elizabeth, New Jersey; Mullica Hill, New Jersey (2 establishments); Woodstown, New Jersey; and Kennet Square, Pennsylvania.

Equivalency

To assess FSIS' equivalence determinations, we focused on operations and decisions made from November 2005 through December 2007. As of 2007, FSIS had approved 33 countries as eligible to import meat and poultry into United States. We evaluated FSIS' procedures for making the initial determination of equivalence by examining the determinations made for Chile and China.

We also evaluated the annual audits that were conducted during fiscal years 2005, 2006, and 2007 for the four countries selected for review. Our review included an analysis of FSIS' methodologies for scheduling the audits and for selecting the foreign establishments to review. China was excluded from this analysis because it currently does not export product to the United States.

Reinspection

To examine FSIS processes related to reinspecting product at U.S. ports of entry, we visited nine import inspection establishments and analyzed data in FSIS' import information system. Our analysis included data recorded in the system from January 2005 to August 2007.

At the import inspection establishments, we familiarized ourselves with the responsibilities of import inspectors and the oversight role of the regional supervisors. We also examined the supporting documentation for a judgmental sample of 192 lots of meat and poultry products presented to FSIS for reinspection from January 2005 through August 2007. We selected the sample of lots for review based on the quantity and variety of products reinspected, the type of reinspections performed, and the reinspection results.

We conducted our audit in accordance with *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.

Exhibit A – Equivalence Protocols

In March and April 2006, FSIS provided the following information to OCFO to close two of the recommendations from our prior report.[48] In response to these recommendations, FSIS agreed to develop and implement protocols for: (1) postponing and cancelling a scheduled enforcement audit and (2) determining which equivalence deficiencies would question a country's overall equivalence determination. In June 2006, OCFO notified FSIS that it accepted FSIS' proposed actions and closed the recommendations.

The following was taken from the information FSIS provided to OCFO in March and April 2006.

- **FSIS Protocol for Postponing or Canceling a Scheduled Enforcement Audit**

  FSIS has developed a process for evaluating when a scheduled enforcement audit should be postponed or cancelled. FSIS schedules enforcement audits when findings from a routine audit(s) demonstrate a considerable weakness in the oversight and enforcement of the U.S. import inspection requirements by the national government regarding its country's inspection system relative to producing meat, poultry, or egg products for export to the United States. On very rare occasions, a scheduled enforcement audit will be postponed or cancelled, even though compensating controls, when enacted, will remain in effect until FSIS has absolute assurance of corrective actions being implemented. FSIS' compensating controls include increased port-of-entry testing of all products from those establishments identified with potential or serious public health concerns.

  FSIS uses the following process to evaluate when a scheduled enforcement audit should be postponed or cancelled. When an enforcement audit is postponed or cancelled, the Director of FSIS' International Equivalence Staff, OIA, documents the proposed action in a memo for evaluation and concurrence by the OIA Assistant Administrator and FSIS Administrator. FSIS follows the criteria listed below in postponing or canceling an enforcement audit:

  - Postponement of an Enforcement Audit

    One or any combination of the following criteria would lead to a postponement of an enforcement audit.

    - Security issues in country preventing safe traveling.
    - Natural disaster in country.
    - Additional time required for FSIS auditors to satisfactorily prepare for the audit.
    - Sudden unavailability of an auditor(s) due to health problems or audit scheduling.
    - Foreign country requires additional time to satisfactorily address all issues from previous audit.

[48] *Assessment of the Equivalence of the Canadian Inspection System*, Audit Report No. 24601-05-Hy, December 2005.

- Foreign country disallows the enforcement audit, which results in FSIS suspending imports from the country.
- FSIS budget restrictions.

▪ Cancellation of an Enforcement Audit

FSIS will cancel an enforcement audit only in the following circumstance:

- Sufficient evidence that the country has taken the necessary steps of implementing corrective actions, thus, changing the scheduled enforcement audit to a routine audit. FSIS will make this decision based on supporting documentation from the country detailing the corrective actions by the establishment(s) and verification of corrective actions by the national government.

- **FSIS Protocol for Determining Deficiencies that Question Overall Equivalence**

FSIS' determination of the equivalence of a foreign country's system of inspection is based on an evaluation of various requirements and procedures put into effect by the national government with respect to establishments preparing products for export to the United States. FSIS questions a country's equivalence when there is evidence that the requirements and procedures are not being implemented and enforced on a system-wide basis by confirmation of one or more of the following conditions:

▪ The inability by the national government to ensure uniform enforcement of the requisite laws and regulations in establishments resulting in the production of adulterated or misbranded product for export to the United States as evidenced by one or more of the following circumstances:

- Foreign establishment deficiencies identified on the FSIS auditor's checklist likely to result in product contamination, adulteration or misbranding, and resulting in a trend of such occurrences in a significant number of the audited establishments. Examples of deficiencies of public health concern could include negative findings involving HACCP, SSOP, labeling, microbiological or chemical sampling and testing programs, and ante-mortem and post-mortem inspection issues.
- U.S. port-of-entry violations resulting in trend indicators of adulterated product or misbranding in a significant number of the establishments exporting to the United States.

▪ The lack of control and supervision by the national government over official activities of employees including inspection personnel assigned to establishments as evidenced by:

- Payment of inspectors by sources other than government.

- Non-enforcement of regulatory requirements and procedures resulting in product being contaminated, adulterated or misbranded.

- Failure of a country to implement a national residue program to prevent the exportation of product with potential contaminants as evidenced by (1) lack of infrastructure of national government to control residue contaminants in meat, poultry, or egg products or (2) the exportation to the United States of product having contaminants.

FSIS will make a decision regarding whether a foreign inspection system is maintaining equivalence within 30 days of the conclusion of the audit. In situations where a country's equivalence is questioned, FSIS takes one or more of the following measures:

- Conducts follow-up enforcement audit to substantiate the equivalence of the foreign inspection system;

- Suspends the imports of products until the exporting country demonstrates that its sanitary measures attain the same level of public health protection as the U.S. system of inspection; or

- Establishes compensating controls to ensure product safety. Compensating controls may include increased port-of-entry testing of products from all exporting establishments until product in pipeline is exhausted.

One or more of these measures would remain in effect until question of equivalence is no longer an issue

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

JUL 16 2008

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

FROM: Alfred V. Almanza
Administrator
Food Safety and Inspection Service

SUBJECT: Office of Inspector General (OIG) Official Draft Audit Report – Followup Review of Food Safety and Inspection Service's Controls Over Imported Meat and Poultry Products, Report number 24601-08-Hy

We appreciate the opportunity to review and comment on this report. The Food Safety and Inspection Service (FSIS) has reviewed the draft report and has responded to each of the audit's 19 recommendations, which can be organized into three groups:

- Seven recommendations related to changes in documentation of activities (2, 3, 5, 9, 12, 18, 19)
- Eleven recommendations related to re-examination of current standards and procedures (1, 4, 6, 7, 8, 10, 13, 14, 15, 16, 17) and
- One recommendation related to a potential food safety issue (11)

FSIS has agreed to implement all of the recommendations. We believe the FSIS approach to ensuring the safety of imported meat, poultry, and egg products is the best system in the world. This audit will help us to strengthen the protections already in place.

Recommendation 1
Determine whether the current 20 percent error rate provides a sound basis for evaluating the equivalence of a country's food safety system and document the basis for the error rate accepted as reasonable.

Agency Response
The establishment selection tool is just one of the many tools currently in use as part of the annual equivalence audit process. Using the Office of International Affairs' (OIA) well-documented "triad" approach, prior to each audit International Audit Staff auditors collect and analyze all available information related to the particular country to be audited. Port of entry results, consumer complaints, prior audit history, historical and pending equivalence

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determinations, and any other available information is used to determine the scope of the upcoming audit. All of this information is documented in the agenda for the "Pre-Audit Conference." Therefore, the establishment selection chart is not considered to be a "stand alone" instrument to determine equivalence, but as a guide to be used along with all other available information to determine the appropriate number of establishments to visit during the onsite audit in consideration of the overall risk related to the products produced, amount exported to the U.S., and other historical information. On occasion the number of establishments selected will be greater than the number recommended in the establishment chart, and on other occasions the number of establishments selected will be less. FSIS will develop and implement a process to document the reasons for the number of establishments selected for onsite audit as part of the agenda for the Pre-Audit Conference. A description of this process will be included in the OIA Management Control Manual.

Estimated Completion Date: October 31, 2008

Recommendation 2

Develop and implement protocols for documenting deviations from the guidelines on visiting the minimum number of establishments as part of the onsite audit. The documentation should provide sufficient, competent evidence that the establishments visited provide a reasonable basis for concluding that the country's food safety system remains equivalent to the U.S. system.

Agency Response

FSIS will develop and implement a process to document the reasons for the number of establishments selected for onsite audit as part of the agenda for the Pre-Audit Conference. A description of this process will be included in the OIA Management Control Manual.

Estimated Completion Date: October 31, 2008

Recommendation 3

Develop and implement protocols for documenting which establishments are selected for review as part of the: (a) random sample and (b) judgmental sample. The protocols should also specify where this information will be documented (e.g., in the onsite audit report).

Agency Response

FSIS will develop and implement a protocol for documenting the reasons for each establishment that is included as part of the onsite audit. This information will be documented as part of the agenda for the Pre-Audit Conference. A description of this process will be included in the OIA Management Control Manual.

Estimated Completion Date: October 31, 2008

Recommendation 4
Develop and implement criteria for judgmentally selecting foreign establishments for onsite review. The selection criteria should consider such information as (a) reinspection results from FSIS' information system, or any subsequent system, (b) deficiencies noted in prior onsite audits, (c) establishments with a pattern of being decertified and subsequently recertified, and (d) any other appropriate evaluation factors.

Agency Response
FSIS will develop and implement a protocol for judgmentally selecting foreign establishments for onsite review. A description of this process will be included in the OIA Management Control Manual.

Estimated Completion Date: October 31, 2008

Recommendation 5
Revise OIA's Management Control Manual to include the protocols for (1) determining which equivalence deficiencies would question a country's overall equivalence determination and (2) postponing and cancelling a scheduled enforcement audit. The protocol for questioning country equivalence should also describe how FSIS officials will document and justify the decisions made.

Agency Response
FSIS has developed a protocol for determining the equivalence of a countries foreign inspection system (See Attachment A). Upon completion of every audit, FSIS personnel review the findings of the audit team. In the event that problems are identified, the OIA management team will consider the audit findings as well as other variables such as audit history, products exported, etc., to determine whether or not an enforcement measure is warranted. FSIS also has developed a protocol for postponing or cancelling a scheduled enforcement audit (see Attachment A). FSIS will include these protocols in the revised OIA management controls manual.

Estimated Completion Date: October 31, 2008

Recommendation 6
Formalize procedures to conduct onsite audits, within a specified timeframe, prior to the first shipments from new countries in OIA's Management Control Manual.

Agency Response
FSIS agrees with this recommendation. All countries that are eligible to ship are audited on a regular basis according to a protocol currently outlined in the manual. However, OIA had not specifically identified this circumstance in the protocol. Therefore, FSIS will include a revised protocol in the manual.

Estimated Completion Date: October 31, 2008

Recommendation 7
Formalize procedures to conduct onsite audits, within a specified timeframe, prior to the first shipments from countries that had been suspended in OIA's Management Control Manual. These procedures should define the period of time that would cause an onsite audit to be performed before the country resumes exporting product to the United States.

Agency Response
FSIS agrees with this recommendation. Currently, FSIS does ensure that a country has been audited prior to lifting a suspension that has been put in place to ensure that product will not enter the United States. A written protocol will be added to the manual.

Estimated Completion Date: October 31, 2008

Recommendation 8
Determine the appropriate number of intensified inspections for physical and laboratory failures that ensure the safety and wholesomeness of imported products and document the necessary revisions to procedures for intensified inspections.

Agency Response
FSIS concurs with this recommendation. FSIS will determine the appropriate number of intensified inspections following physical and laboratory failures needed to ensure the safety and wholesomeness of imported products and will document the necessary revisions to procedures for intensified inspections.

Estimated Completion Date: October 31, 2008

Recommendation 9
Clearly document the level of reinspection being performed on imported product in FSIS' information system and ensure that scheduled inspections are suspended when the level of inspection is intensified.

Agency Response
FSIS concurs with this recommendation. In the forthcoming Public Health Information System (PHIS), FSIS will clearly document the level of reinspection being performed on imported product and ensure that scheduled inspections are suspended when the level of inspection is intensified.

Estimated Completion Date: December 31, 2009

Recommendation 10
Develop and implement procedures that require inspectors to perform physical reinspections first and for FSIS import inspection personnel to perform unscheduled inspection on skipped lots associated with lots that failed reinspection.

Agency Response
FSIS concurs with this recommendation and has taken steps to implement it. Instructions to field personnel have been issued directing them to hold all assignments associated with lots of product presented for inspection from a single establishment, and to perform all physical inspection assignments before skip lot assignments are processed. In this manner, results of physical inspection decisions can determine the need to perform a physical inspection of skip lot assignments. The Import Inspection Division is documenting these instructions as a procedural change within the Import Manual of Procedures.

Estimated Completion Date: October 31, 2008

Recommendation 11
Take the appropriate action on the approximately 325,000 pounds of product from the 12 skipped lots associated with lots that failed physical reinspection.

Agency Response
FSIS requests that OIG identify the 43 lots of imported product that it found to have been recorded for physical examination failure, in order to determine if product associated with the corresponding 12 skip lots represents a food safety hazard, or constitutes misbranding or economic adulteration, and to determine whether follow-up action is needed. FSIS will organize a recall committee to determine the requirements for a recall action on the 12 skip lots if analysis of the data on the 43 failed lots indicates a need.

Estimated Completion Date: October 31, 2008

Recommendation 12
Document the procedures to guide inspectors' decisions on what data sources to use for a shipment's production date.

Agency Response
FSIS has already taken steps related to this recommendation. On February 28, 2008, an import notice was issued to field personnel that provided instructions on what information from shipping documentation and containers can and cannot be used to identify product production dates, and what procedures to follow to document that information in the Automated Import Information System, and to generate an inspection assignment for a delisted or delisted and relisted foreign establishment.

Estimated Completion Date: February 28, 2008

Recommendation 13
Implement an edit check in the information system, or any subsequent revision, to validate that inspectors used adequate data source to verify a shipment's production date.

Agency Response
FSIS concurs with this recommendation. FSIS will implement an edit check in the PHIS to validate that inspectors used adequate data source to verify a shipment's production date

Estimated Completion Date: December 31, 2009

Recommendation 14
Perform an assessment, including any other appropriate FSIS units, to determine whether foreign establishments should be required to provide the lot's production date.

Agency Response
FSIS regulations do not require domestic establishments to identify lots of product according to production dates. According to the national treatment provisions of the World Trade Organization Agreement on Sanitary and Phytosanitary Measures, to which the United States is a signatory, no Member State may maintain standards for imported products that exceed requirements for domestic product. The establishment of a lotting policy for imported products that identifies a lot of product by production date would necessitate a corresponding domestic policy change. FSIS will consider the establishment of such a policy in the context of its entire food safety and inspection program.

Estimated Completion Date: October 31, 2008

Recommendation 15
Develop and implement procedures for performing standard analyses of data in the new information system to determine that data were reasonable, complete, and accurate. The procedures should identify the FSIS officials responsible for performing the analyses and following up on discrepancies noted.

Agency Response
FSIS concurs with this recommendation. FSIS will develop and implement standard operating procedures for performing standard analyses of data in the PHIS to determine that data were reasonable, complete, and accurate.

Estimated Completion Date: December 31, 2009

Recommendation 16
In the new information system, implement an edit check to alert users when inspection results have not been recorded. As part of this analytical tool, FSIS should also establish the expected timeframes for recording inspection results.

Agency Response
FSIS concurs with this recommendation and has established requirements for the development of this capability within the PHIS.

Estimated Completion Date: December 31, 2009

Recommendation 17
In the new information system, implement an edit check to ensure that only appropriate amounts are entered into the information system (e.g., negative amounts are not entered, rejected weights do not exceed the presented weight, and valid production dates are entered).

Agency Response
FSIS concurs with this recommendation and has established requirements for the development of this capability within PHIS.

Estimated Completion Date: December 31, 2009

Recommendation 18
In the new information system, require that the reason for not performing an inspection task be recorded in a standard way (e.g., pick the reason from a drop down menu). FSIS should also develop and implement a standard analysis to evaluate the reasons inspection tasks are not performed in order to revise the types of inspections assigned.

Agency Response
FSIS concurs with this recommendation and has established requirements for the development of this capability within PHIS.

Estimated Completion Date: December 31, 2009

Recommendation 19
Include the training of import inspection personnel in FSIS' reassessment of the effectiveness of the agency's training programs that is currently scheduled to be completed by September 2008.

Agency Response
FSIS agrees. As part of the ongoing comprehensive evaluation of FSIS training programs being conducted in response to recommendation 34 of OIG audit 24601-7-Hy, FSIS is examining the training of import inspection personnel.

Estimated Completion Date: September 31, 2008

If you have any questions, please contact William C. Smith, Assistant Administrator, Office of Program Evaluation, Enforcement and Review, at (202) 720-8609.