USDA
United States Department of Agriculture

Evaluation of Food Safety and Inspection Service's Equivalency Assessments of Exporting Countries

Audit Report 24601-0002-21

September 2017

OFFICE OF INSPECTOR GENERAL

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OBJECTIVE

Our objectives were to evaluate: (1) FSIS' determinations that the exporting countries' food safety systems were equivalent to U.S. standards, and (2) FSIS' oversight to ensure that foreign systems remain equivalent. We also evaluated the effectiveness of corrective actions implemented by FSIS in response to prior OIG audits in 2005 and 2008.

REVIEWED

We observed two ongoing equivalence verification audits; we reviewed relevant laws, regulations, guidance, and prior audits; and we interviewed FSIS officials.

RECOMMENDS

We recommend that FSIS strengthen its oversight of the equivalence process and revise its guidance and management control manual for conducting ongoing equivalence verification audits.

OIG reviewed FSIS' equivalency assessments of exporting countries' food safety systems.

WHAT OIG FOUND

Federal legislation requires foreign countries that export meat, poultry, and egg products to the United States to establish and maintain systems equivalent to the U.S. inspection system. The Food Safety and Inspection Service (FSIS) is responsible for ensuring these products meet all safety standards applied to foods produced in the United States. The Office of Inspector General (OIG) found that equivalent countries were not consistently audited in compliance with agency policy, and that policies and procedures did not contain sufficient guidance for conducting ongoing equivalence verification audits. First, we found that FSIS did not consistently audit equivalent countries because officials did not follow policies and procedures when selecting countries for ongoing equivalence verification audits. Next, we found that FSIS officials had not consistently performed, completed, or documented audit procedures when conducting ongoing equivalence verification audits of foreign countries' food safety systems. We also found FSIS did not have adequate policy to monitor, classify, evaluate, or determine equivalence of individual sanitary measures. Lastly, we found that FSIS does not obtain details identifying the actual date or reason why certified foreign establishments were removed from the program because after they were deemed no longer eligible to export product to the United States.

Furthermore, we found that FSIS procedures for conducting ongoing equivalence verification audits did not include corrective actions in response to prior audit recommendations. Specifically, FSIS did not incorporate new procedures into agency guidance. FSIS did initially implemented corrective actions by updating its management control manual, but these procedures were not incorporated into subsequent guidance issued in 2015.

FSIS generally agreed to take corrective actions based on our recommendations and we accepted management decision on five of our eight recommendations.

United States Department of Agriculture
Office of Inspector General
Washington, D.C. 20250

DATE: September 27, 2017

AUDIT NUMBER: 24601-0002-21

TO: Paul Kiecker
Acting Administrator
Food Safety and Inspection Service

ATTN: Steven Fisher
Chief Financial Officer
Office of the Chief Financial Officer

FROM: Gil H. Harden
Assistant Inspector General for Audit

SUBJECT: Evaluation of FSIS' Equivalency Assessments of Exporting Countries

This report presents the results of the subject audit. Your written response to the official draft report, dated August 23, 2017, is included in its entirety at the end of the report. Excerpts from the response and the Office of Inspector General's (OIG) position are incorporated into the relevant sections of the report. Based on your written response, we have accepted management decision for Recommendations 1, 2, 3, 5, and 6. Please follow your internal agency procedures in forwarding final action correspondence to the Office of the Chief Financial Officer (OCFO).

Based on your written response, management decision has not been reached for Recommendations 4, 7, and 8. To reach management decision on these recommendations, please see the relevant OIG Position sections in the audit report. In accordance with Departmental Regulation 1720-1, please furnish a reply within 60 days describing the corrective actions taken or planned, and timeframes for implementing the recommendations for which management decision has not been reached. Please note that the regulation requires management decision to be reached on all recommendations within 6 months from report issuance, and final action to be taken within 1 year of each management decision to prevent being listed in the Department's annual Agency Financial Report.

Your written response to the official draft report expressed concerns with some aspects of our report. The audit team met with Food Safety Inspection Service (FSIS) officials on multiple occasions to discuss our findings and recommendations, and provided FSIS the opportunity to comment on our work. FSIS provided both written and oral revisions to the proposed report and recommendation language. We implemented those changes that we agreed with because they were factual and based on the results of our audit. In other areas, we did not make changes because the suggested revisions were based on opinion, and did not alter the facts presented in

the report. Some of the suggested revisions were based on new guidance issued by FSIS that was not in place during the scope of our review, but may be used as your response to the report recommendations.

Your additional concerns, along with our comments on your concerns, are listed below:

1. FSIS Stated - Throughout the report, OIG appears to characterize directives as providing guidance to inspection program personnel (IPP). FSIS would like to clarify that directives are official communications and instructions to agency personnel.

OIG Comment – We did not make any changes to the report. We used FSIS' documented policies and procedures related to agency personnel to characterize directives of the equivalence program. The citations used in the report are not related to agency policies and procedures for inspection program personnel.

2. FSIS Stated - Additionally, OIG states throughout the report that FSIS provides oversight of a foreign country's food system. FSIS would like to clarify that the agency does not provide oversight, rather FSIS monitors and assesses whether a foreign country's system maintains equivalent standards to the U.S. food system on an ongoing basis through a three-part process that includes the following: 1) document reviews, 2) on-site audits, and 3) point-of-entry re-inspection.

OIG Comment – We reviewed the report and did not identify any references to FSIS' oversight of a foreign country's food system. The references in our report refer specifically to FSIS' oversight controls and structure for monitoring the overall equivalence program.

3. FSIS Stated - On page 4, paragraph 2, OIG describes the process FSIS takes for products that are imported from a country that has been deemed equivalent. FSIS would like to clarify that FSIS performs point-of-entry (POE) re-inspections on all shipments of imported meat, poultry, or egg products offered for import into the United States. During re-inspection, FSIS inspectors verify that all certifications and applications of imported meat, poultry, and egg products are complete and accurate and that the products are not adulterated or misbranded. FSIS does not sample every shipment of meat, poultry, and egg products and instead relies on the Public Health Information System (PHIS) randomly assigning sampling tasks as products enter the United States. In addition to sampling, other types of inspection that the PHIS can assign include net weight checks of retail packages; examination of the containers' condition; examination for product defects; and incubation of canned goods. For newly equivalent countries, FSIS performs increased sampling and product examination in order to gain confidence in the foreign country's inspection system.

OIG Comment - We did not make any additional changes to the report. Based on your agency's request at the exit conference, we had already included the information regarding point-of-entry re-inspections in a footnote on page 4 of the report. The

information in footnote 7 is verbatim from the document agency officials provided to us at the exit conference.

4. FSIS Stated - Additionally, OIG states, "the purpose of the re-inspection is to ensure that exporting country certificates are authentic and accurate, and that products meet U.S. food safety and quality standards." FSIS does not determine the "quality" of any food product.

OIG Comment – We did not make any changes to the report because this statement, including the word "quality," was quoted directly from FSIS' *Process for Evaluating the Equivalence of Foreign Meat and Poultry Food Regulatory System*, dated July 2011 (pdf page 15) and in the earlier version of guidance, dated October 2003 (page 16).

5. FSIS Stated - On page 5, paragraph 2, OIG does not accurately describe the role of FSIS's Office of International Coordination (OIC). OIC serves as the agency's point of contact for foreign government officials on all regulatory matters and is responsible for coordinating international activities among program areas related to the public health and food safety mission of FSIS. Part of that mission includes ensuring that criteria used for measuring equivalence of a foreign food safety system align with existing and emerging domestic food safety regulations and policies.

OIG Comment - We did not make any changes to the report because we took this information directly from FSIS' webpage identifying the agency's structure and organization. (https://www.fsis.usda.gov/wps/portal/informational/aboutfsis/structure-and-organization/oa/oa)

6. FSIS Stated - On page 9, paragraph 1, OIG makes a statement indicating it had to complete additional analysis to ensure information provided by FSIS was accurate and complete. It is FSIS' understanding that OIG's audit responsibilities include assessing, verifying, and further analyzing information from audited agencies as part of its documentation review process. It is unclear why OIG would include such a statement in its report, one that seems to criticize FSIS for providing additional documentation for OIG to assess, verify, and analyze.

OIG Comment - We did not make any changes to the report. We included the statement because we had to request documents multiple times, and requested several follow-up meetings with FSIS officials, to obtain complete and accurate information. The statement in our report represents the actions we took, which were required to obtain complete and accurate information, and support our audit conclusions.

7. FSIS Stated - On page 9, paragraph 3, OIG makes a statement that FSIS acknowledges that we have not audited all countries eligible to export at least once every 3 years. This is a misleading statement, since the list of eligible countries may include countries that are not currently shipping product to the United States. FSIS currently has a system in place to manage when it has been more than 3 years since a country has shipped a specific commodity. FSIS requires the country to request a reinstatement of equivalence

determination. As part of FSIS' equivalence determination, FSIS assesses the country's documentation, and may perform an on-site verification audit before FSIS reinstates equivalence and allows the country to export the product to the United States.

OIG Comment – We did not make any changes to the report because we took this information directly from the public notice in the Federal Register - 2015 Fed Reg Vol. 80 No. 89 Friday May 8, 2015 (page 4).

8. FSIS Stated - On page 11, paragraph 4, OIG describes FSIS's on-site verification audit process. It fails to indicate that FSIS tailors each audit to the country to ensure each audit is based on on-site conditions and observations conducted. As described in FSIS Directive 9780.1, Verifying the Ongoing Equivalence of Foreign Food Safety Systems, FSIS uses its procedure, the Component Analysis Verification Form (CAVF), to form the basis, objectives, scope, and verification activities tailored to the unique situation for each country. The audit methods are neither inconsistent nor insufficient, and while some on-site audits are more detailed than other on-site audits, they are all adequate for agency purposes. It is not appropriate for OIG to determine that the standard that agency experts have established for conducting on-site verification audits is not adequate simply based on the level of detail in reporting.

OIG Comment - We did not make any changes to the report. We agree that FSIS can tailor each audit to a particular country. However, FSIS did not consistently complete or document why audit procedures were not completed for certain countries.

We appreciate the courtesies and cooperation extended to us by members of your staff during our audit fieldwork and subsequent discussions. This report contains publically available information and will be posted in its entirety on our website (http://www.usda.gov/oig) in the near future.

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Background and Objectives

Background

Federal legislation requires foreign countries that export meat, poultry, and egg products to the United States to establish and maintain systems equivalent to the U.S. inspection system.[1] The Food Safety and Inspection Service (FSIS) is responsible for ensuring that meat, poultry, and egg products imported from another nation provide an equivalent level of public health protection as applied to foods produced in the United States. Federal regulations govern FSIS' responsibilities for reviewing and assessing foreign meat, poultry, and egg inspection systems.[2]

Since 1995, food safety equivalence evaluations have been based on provisions of the World Trade Organization's Agreement on the Application of Sanitary and Phytosanitary Measures (Agreement). This Agreement adopted the term "equivalent," meaning that different sanitary measures can achieve the same level of public health protection. U.S. laws were then amended to require foreign food regulatory systems to be "equivalent to" the U.S. system. Under equivalence, food regulatory systems in exporting countries may employ sanitary measures that differ from those applied domestically by the importing country as long as these sanitary measures provide the same level of protection against food safety hazards. Determinations of system equivalence are necessary for FSIS to develop and maintain the American public's trust in imported meat, poultry, and egg products.

FSIS conducts four types of equivalence determinations: (1) initial equivalence, (2) ongoing equivalence verification, (3) reinstatement of equivalence, and (4) individual sanitary measure (ISM).[3] Initial equivalence determinations are for countries seeking to export meat, poultry, or egg products to the U.S. for the first time. FSIS evaluates a country's food safety inspection system to make an initial equivalence determination before a country can export products to the United States. Ongoing equivalence verifications involve countries that have an equivalence determination and are exporting meat, poultry, or egg products to the United States, and are used to ensure that countries maintain equivalence. Reinstatement of equivalence determinations are for countries that FSIS determined to have an equivalent food safety inspection system and stopped exporting to the United States for an extended period of time, but want to be reinstated. Finally, ISM determinations consist of countries that have an equivalence determination and want to change a procedure in their food safety inspection system. FSIS will assess the new procedure before the country can implement the ISM for products it exports to the United States.[4]

[1] 21 United States Code (U.S.C.) §§ 601-695, the Federal Meat Inspection Act; 21 U.S.C. §§ 451-472, the Poultry Products Inspection Act; and 21 U.S.C. §§ 1031-1056, the Egg Products Inspection Act.
[2] 9 Code of Federal Regulations (C.F.R.) § 327.2, meat products (Jan. 1, 2012), 9 C.F.R. § 381.196, poultry products (Jan. 1, 2010), and 9 C.F.R. § 590.910, egg products (Jan. 1, 2012).
[3] ISMs are measures applied to eliminate or abate food safety hazards.
[4] FSIS will also review ISMs during an initial equivalence determination if the applicant country were to propose alternative sanitary measures as part of its initial equivalence submission.

FSIS determines initial equivalence of a foreign food regulatory system through a process that consists of (1) document analysis, (2) an on-site initial equivalence audit, and (3) point-of-entry (POE) re-inspections.[5] For document analysis, foreign countries apply for eligibility to export meat, poultry, or egg products to the United States. The countries submit an application to FSIS, and FSIS conducts an analysis to compare the foreign inspection system to the U.S. system. Then, if FSIS determines that the foreign country's food regulatory system documentation meets all U.S. import requirements in the same or equivalent manner, and the foreign country's system cumulatively provides the same level of public health protection as attained domestically, FSIS schedules an on-site initial equivalence audit of the foreign country's food system. The on-site initial equivalence audit is to verify that the foreign country's food system has satisfactorily implemented all requirements that FSIS found to be equivalent during its analysis of the country's documents.

Once both the document analysis and on-site initial equivalence audit have been successfully completed, FSIS publishes a proposed rule in the *Federal Register* to propose adding the applicable country to its list of eligible exporters in the C.F.R. After soliciting and receiving public comments, FSIS makes a final decision on the system's equivalence and publishes a final rule in the *Federal Register* that announces the country's eligibility.[6] No meat, poultry, or egg products are accepted from a foreign country until its initial equivalence determination has been established through document analysis, an on-site initial equivalence audit, and rulemaking—the process that executive and independent agencies use to create, or promulgate, regulations. FSIS performs POE re-inspection to sample meat, poultry, and egg products randomly as they enter the United States.[7] The purpose of the re-inspection is to ensure that exporting country certificates are authentic and accurate, and that products meet U.S. food safety and quality standards. FSIS' POE activities monitor the effectiveness of exporting countries' inspection system and overall food safety programs.

FSIS conducts an evaluation of ISMs when an exporting country proposes an alternative sanitary measure different from one initially determined equivalent by FSIS. The exporting country develops a written submission to demonstrate that its ISM will still achieve the same level of protection as achieved by FSIS in the United States. FSIS evaluates the evidence provided by the exporting country and notifies the country of its decision. If determined equivalent, FSIS will verify the application of the ISM during an ongoing equivalence verification audit to confirm that the measure is being implemented in the manner found to be equivalent. FSIS retains the right to decide if the exporting country's ISM is equivalent to its own, provided that

[5] Document analysis includes review of laws, regulations, inspection procedures, and enforcement protocols submitted to FSIS by foreign countries. Ongoing initial equivalence audits are conducted to assess countries' implementation of laws, regulations, inspection procedures, and enforcement protocols identified during the document analysis process. POE re-inspection includes product examination of imported product, condition-of-container reinspection, and collection of product samples for laboratory analysis.

[6] As of July 2015, 31 countries were eligible to export to the United States. However, the number of countries determined equivalent by FSIS to export to the United States can change at any time.

[7] Product re-inspection at U.S. points-of-entry refers to the inspection by FSIS inspectors of all meat, poultry, and egg products offered for import into the United States. FSIS inspectors verify that the certification and application of imported meat, poultry, and egg products, whether paper or electronic, are complete and accurate, and that the products are not adulterated or misbranded.

the process is fair, transparent, and based on the best available science. Exporting countries should seek FSIS equivalence determinations well before an ISM is implemented.

FSIS also uses a three-part process to verify that foreign countries' food regulatory systems exporting meat, poultry, and egg products to the United States continue to be equivalent. The first part is a recurring document analysis, which includes a review of the laws, regulations, and policies of foreign countries' food regulatory systems. The second part is a system verification audit of the food regulatory system for every country that exports meat, poultry, or egg products to the United States. Based on current FSIS policy, system verification audits are to be conducted at least once every three years within each country to assess the delivery of inspection services by each foreign country's inspection service.[8] The final part is the continuous POE re-inspection of products shipped from exporting countries.

FSIS' Office of International Coordination (OIC) is responsible for managing the equivalence process. OIC's mission is to enhance compliance of domestic and foreign produced products with safety regulations and guidance. OIC also ensures that criteria for measuring the equivalence of a foreign food safety system will be more closely aligned with existing and emerging domestic food safety regulations and policies. Prior to a May 2013 reorganization of FSIS, the Office of International Affairs (OIA) was responsible for administering the equivalence program. OIC also relies on other FSIS offices to assist with the equivalence program. The Office of Policy and Program Development (OPPD) completes the document analyses for initial equivalence determinations and for recurring equivalence verification. OPPD also ensures policies that are required internationally of exporting countries are aligned with those policies for domestic inspection. The Office of Investigation, Enforcement, and Audit (OIEA) conducts the ongoing equivalence verification audits and issues the related audit report from each visit.

In September 2007, FSIS awarded a contract to design the Public Health Information System (PHIS). PHIS was designed to replace many of FSIS' older systems and automate the agency's paper-based business processes into one comprehensive and fully automated data-driven inspection system. PHIS is a web-based application that requires internet connection and an eAuthentication account in order to obtain system access,[9] and it was designed to include four inspection modules: domestic, import, export, and predictive analytics. The import module includes FSIS' responsibilities for reviewing and assessing foreign meat, poultry, and egg inspection systems. On May 29, 2012, FSIS began employing PHIS for its import module.

PHIS enhances FSIS' ability to receive, process, and track import certificates while also communicating with the U.S. Customs and Border Protection's (CBP) Automated Commercial Environment (ACE).[10] PHIS also automates the POE re-inspections of import shipments, increases the level of inspection for follow-up testing of failed re-inspections, targets specific

[8] Ongoing Equivalence Verifications of Foreign Food Regulatory Systems, 78 Fed. Reg. No. 17 (Jan. 25, 2013).
[9] A web-based application is an application in which all or some parts of the software are downloaded from the web each time it is run. The system called "eAuthentication" is a password-based system used by USDA employees that allows them access to web-based applications and services through the internet.
[10] ACE is CBP's automated system to facilitate the electronic importing and exporting of goods.

products for testing, and automates the notification of rejected product. PHIS was also designed to include a Self-Reporting Tool (SRT) to collect information from foreign governments.

Prior Audits

OIG completed audits in 2005 and 2008 related to FSIS' foreign equivalence process.[11] The objective of the 2005 audit was to evaluate FSIS' assessment of the equivalence of the Canadian inspection system. The evaluation included determining whether FSIS took appropriate and timely actions on identified concerns and whether FSIS ensured that Canadian processing plants exporting meat and poultry products to the United States received daily inspection. OIG reported that FSIS did not have protocols or guidelines for evaluating deficiencies for any country's inspection system.

The objective of the audit completed in 2008 was to evaluate the adequacy of FSIS' inspection processes (i.e., equivalence determinations, on-site audits, and product re-inspection at U.S. POE) for meat, poultry, and egg imports to ensure the integrity of the United States food supply. OIG found that FSIS needed 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.

Objectives

Our objectives were to evaluate: (1) FSIS' determinations that the exporting countries' food safety systems were equivalent to U.S. standards, and (2) FSIS' oversight to ensure that foreign systems remain equivalent. We also evaluated the effectiveness of corrective actions implemented by FSIS in response to prior OIG audits in 2005 and 2008.

[11] Audit Report 24601-05-Hy, *Food Safety and Inspection Service Assessment of the Equivalency of the Canadian Inspection System*, Dec. 2005, and Audit Report 24601-08-Hy, *Follow-up Review of Food Safety and Inspection Service's Controls over Imported Meat and Poultry Products*, Aug. 2008.

Finding 1: FSIS Needs to Strengthen Its Oversight of the Equivalence Process

FSIS is responsible for ensuring that U.S. imported meat, poultry, and processed egg products are safe, wholesome, unadulterated, and properly labeled and packaged. To fulfill this responsibility, the agency is required to develop and maintain effective internal controls. Our audit concluded that FSIS has a robust system for determining initial equivalence, and found no public health concerns related to FSIS' ongoing equivalence. However, we found weaknesses in the agency's oversight structure for monitoring ongoing equivalence. Our audit disclosed that FSIS did not consistently audit equivalent countries in compliance with the agency's performance assessments, and that policies and procedures for conducting ongoing equivalence verification audits contained insufficient guidance for performing those audits consistently and completely. We also concluded that FSIS lacked management controls over the process of determining equivalence of ISMs as well as adequate documentation detailing the delistment of foreign establishments. Without more robust controls over ongoing equivalence evaluations of foreign countries' food safety systems, we concluded that FSIS' inspection program is vulnerable to weaknesses that increase the risk of adulterated or unsafe meat, poultry, or egg products being imported into the United States.

Office of Management and Budget (OMB) Circular A-123 states, "management has a fundamental responsibility to develop and maintain effective internal controls." It further states that "effective internal control provides assurance that significant weaknesses in the design or operation of internal control, that could adversely affect the agency's ability to meet its objectives, would be prevented or detected in a timely manner."[12] Additionally, Federal standards affirm that appropriate internal controls help agencies achieve their goals and minimize operational problems. These controls comprise the plans, methods, and procedures used to meet the agency's mission, goals, and objectives.[13]

In general, FSIS officials agreed that oversight controls of the program could be strengthened. Specifically, officials agreed that policies and procedures should be updated to reflect the implementation of the equivalence program as it relates to ongoing equivalence oversight. We recognize and commend FSIS for agreeing that oversight control policies and directives could be strengthened. However, FSIS needs to ensure that updated guidance adequately addresses the following weaknesses we identified in the agency's management controls:

FSIS Needs to Strengthen and Document Controls Over Ongoing Equivalence Verification Audit Scheduling

FSIS did not consistently audit equivalent countries in compliance with the agency's performance assessments. This occurred because FSIS did not follow its established policies and procedures when selecting equivalent countries for ongoing equivalence verification audits based on established performance categories. FSIS' policy also generally prohibits conducting ongoing equivalence verification audits within a year of

[12] OMB, *Management's Responsibility for Internal Control*, Circular A-123, (Dec. 2004, last amended in Oct. 2014).
[13] United States Government Accountability Office (GAO), *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1 (Nov. 1999) and GAO-14-704G (Sept. 2014).

publishing an audit report. While we agree that this is a logical policy, it conflicts with FSIS' annual on-site audit policy for "adequately" performing countries. Further, FSIS officials used, but did not consistently document, non-performance-related factors to select countries for ongoing equivalence verification audits.[14] As a result, FSIS officials did not audit equivalent countries on an adequate basis in compliance with policy. Therefore, we concluded that there is reduced assurance that ongoing equivalence is consistently maintained in equivalent countries, which increases the risk to public health within the United States.

FSIS policy published in the *Federal Register* says that "FSIS determines the scope and frequency of on-site system audits…through analysis of the results of its document reviews and an assessment of a country's performance. This performance-based approach allows FSIS to direct its resources to foreign food regulatory systems that pose greater risk to public health compared to others."[15] In fiscal year (FY) 2011, "FSIS transitioned from an annual on-site audit to less frequent on-site audits based on performance."[16] Under this approach, FSIS identified three category rankings for equivalent countries: (1) "adequate," (2) "average," and (3) "well-performing." Adequately performing countries would be audited every year, average performing countries every two years, and well-performing countries every three years. FSIS currently "schedule(s) on-site systems audits at a minimum frequency of once every three years." [17]

We determined that FSIS officials did not consistently maintain and adhere to country performance ratings as identified in their policy; therefore, the scheduling of ongoing equivalence verification audits was not in compliance with agency procedures. As of July 31, 2015, FSIS identified 31 equivalent countries eligible to export products to the United States. Per FSIS' policy, each of the 31 countries should have been identified as adequate, average, or well-performing to identify their audit frequency. However, FSIS was unable to provide a comprehensive list tracking the performance rating for all 31 countries. Initially, FSIS was only able to provide performance ratings for 22 of the 31 equivalent countries. FSIS did not provide performance ratings for the nine remaining countries, stating that those countries had not been assigned a performance category within an audit report.[18] In response to OIG follow-up, FSIS provided additional documentation to identify the performance rating for each country. However, we had to

[14] Non-performance related factors include FSIS officials' professional judgment based on their working knowledge of a country. For example, a country may be selected for audit because it updated a sanitary measure or because of disease concerns within the region. Additionally, FSIS officials stated that they work with the countries on an ongoing basis and may know additional details not specific to performance, which could impact on-site audit decisions.
[15] Ongoing Equivalence Verifications of Foreign Food Regulatory Systems, 78 Fed. Reg. No. 17 (Jan. 25, 2013).
[16] In July 2011, FSIS issued a process document reflecting the change from annual to performance-based auditing. Prior to this update, FSIS policy required annual on-site audits of all equivalent countries.
[17] Ongoing Equivalence Verifications of Foreign Food Regulatory Systems, 78 Fed. Reg. No. 17 (Jan. 25, 2013).
[18] These countries included England/United Kingdom, Finland, Germany, Mexico, Republic of Korea, Poland, and Spain. Also, FSIS did not provide a performance rating for China, which had not shipped product to the United States. Additionally, the Netherlands was assigned an undefined rating of satisfactory, which FSIS later corrected.

complete additional analysis to clarify and ensure all information provided by FSIS was accurate and complete.

According to FSIS officials, the classification of performance was defined in *Federal Register* documents because they wanted the equivalence program to categorize countries based on performance in three areas: prior audits, POE re-inspections, and document review. An FSIS official explained that policies referencing well-performing, average, and adequate country categorizations were implemented. However, FSIS officials determined that the classifications were misleading because they provided only a reference to a country's status at a specific point in time, and its rating could change after a report was issued. As a result, FSIS stopped posting the rating in audit reports. Per an FSIS official, performance ratings were to be documented in a country's audit records, such as the Component Analysis Verification Form (CAVF). Removing the rating from audit reports was not intended as a means to discard the rating itself, but was intended simply to document the rating information in a different location. An FSIS official stated that, currently, all countries have performance ratings documented in either past audit reports or country records (i.e., CAVF); however, another official stated that performance ratings are not updated frequently. As a result, we determined that FSIS is unable to accurately track or ensure that countries are accurately categorized and scheduled for ongoing equivalence verification audits in compliance with policy.

With performance rating information obtained from FSIS, we compiled a list of the 31 eligible countries and their applicable performance ratings. Of the 31 equivalent countries eligible to export to the United States, 24 were categorized as adequately performing,[19] another 7 were categorized as average performing,[20] and none were identified as well-performing. We found that none of the 24 adequately performing countries were audited annually between FYs 2012 and 2015. Additionally, only three of the seven average performing countries were audited every two years during the same period.[21] Based on FSIS' policy, the adequately performing countries should have been audited annually, and the average performing countries should have been audited every two years. Further, in a public notice released in May 2015, FSIS acknowledged that it had not audited all countries eligible to export at least once every three years. Thus, we determined that FSIS did not follow its policies and procedures in the selection of equivalent countries for ongoing equivalence verification audits between FYs 2012 and 2015. If FSIS' intent is to audit each equivalent country at least once every three years, agency policy needs to be updated to reflect that change and correspondingly document the performance ratings and decision process used in order to move from completing audits annually or every two or three years. Without clearly defined policy and support

[19] Countries identified as adequate included: (1) Argentina, (2) Australia, (3) Brazil, (4) Canada, (5) Chile, (6) China, (7) Costa Rica, (8) Croatia, (9) Denmark, (10) Finland, (11) France, (12) Germany, (13) Ireland, (14) Italy, (15) Japan, (16) Republic of Korea, (17) Mexico, (18) Netherlands, (19) New Zealand, (20) Northern Ireland, (21) Poland, (22) Spain, (23) United Kingdom, and (24) Uruguay.
[20] Countries identified as average included: (1) Austria, (2) Honduras, (3) Hungary, (4) Iceland, (5) Israel, (6) Nicaragua, and (7) San Marino.
[21] Per 78 Fed. Reg. No. 17 (Jan. 25, 2013), average performing countries would be audited every two years.

for that decision, we determined that there is reduced assurance that FSIS is directing its resources to foreign food regulatory systems that pose the greatest risk to public health.

We also determined that FSIS' policy generally prohibits conducting ongoing equivalence verification audits within a year of publishing an audit report. While we agree that this is a logical policy, it conflicts with the annual ongoing equivalence verification audit policy for "adequately" performing countries. FSIS' policy states that FSIS "is not to schedule on-site equivalence verification audits within one year of the posting of the preceding final audit report for that country unless special circumstances arise that establish a special need for such action."[22] FSIS officials stated that they do not want to re-audit a country before the previous audit report has been issued. While we agree that this is a logical policy it conflicts with FSIS' policy of auditing "adequately" performing countries annually and could impact the scheduling of further audits if an audit report is not published timely. We found that for one country, FSIS performed an audit in June 2014, but did not post the results of the audit until January 2016. This country was assigned a performance category of adequate, indicating the need for annual ongoing equivalence verification audits. However, this policy generally precludes the country from being scheduled for audit again until at least January 2017—more than two and a half years after the preceding audit. Based on the assigned performance category, the country should have been audited again in FY 2015. We determined that this policy generally precludes those countries rated as "adequate" from being audited annually, as prescribed in FSIS policy. As such, FSIS officials should design their internal policies to be consistent with each other.

Additionally, we determined that FSIS officials utilized, but did not consistently document, non-performance related factors or the impact those factors had on the selection of equivalent countries for ongoing equivalence verification audit. According to FSIS' policy, the country performance assessment—hereafter referred to as the "algorithm"—ranking was to be used as the basis for the on-site audit schedule.[23] FSIS' policy does not identify that non-performance related factors can be considered when planning the ongoing equivalence verification audit schedule, nor does FSIS identify what those factors could entail, or require that they be documented. We determined that the algorithm was developed and implemented because an FSIS official told us "the agency felt that the scheduling process for ongoing equivalence verification audits should be formalized." However, algorithm rankings are not used exclusively to select equivalent countries for ongoing equivalence verification audit. Per FSIS, "the algorithm output was not the final determination of the countries selected for audit; equivalence staff also used professional judgment, based on their working knowledge of countries, when selecting countries for ongoing equivalence verification audit." For example, a country that is ranked high by the algorithm may be added to the ongoing equivalence verification audit schedule because it had not been audited recently. Additionally, FSIS

[22] FSIS Directive 9780.1, *Verifying the Ongoing Equivalence of Foreign Food Safety Systems*, Oct. 7, 2015.
[23] "Country performance assessment" is an algorithm-based tool that compares the food safety performance of export eligible countries. The assessment includes a statistical analysis of compliance data from POE re-inspection and the results from FSIS' previous on-site audits of the country's government offices, establishments, and laboratories.

management may decide that a lower ranking country be audited based on other factors, such as a country updating a sanitary process or a disease concern. However, FSIS officials did not consistently identify and document the analysis.

While we agree that FSIS officials should take into account non-performance related factors when determining their ongoing equivalence verification audit schedule, FSIS' policy does not identify that those factors can be considered when planning the ongoing equivalence verification audit schedule, nor does it identify what those factors could entail. The policy also does not require that those factors be documented. Therefore, FSIS officials do not consistently document their judgmental analysis or the impact those factors play in deviating from the performance-based analysis provided by the algorithm. As a result, we determined that FSIS officials did not audit equivalent countries on an adequate basis.

Without clearly identifying ongoing equivalence verification audit requirements and the process used to select countries for ongoing equivalence verification audit, there is reduced assurance that FSIS is auditing equivalent countries on an adequate basis to ensure that they remain equivalent to U.S. food safety standards.

FSIS Needs to Strengthen and Document Policy and Procedures for Conducting Ongoing Equivalence Verification Audits

FSIS officials had not consistently performed, completed, or documented audit procedures when conducting ongoing equivalence verification audits of foreign countries' food safety systems. Specifically, FSIS auditors did not complete all steps listed within the audit plan, CAVF, or establishment checklists as prescribed by FSIS policy.[24] In addition, FSIS auditors used inconsistent methods for record review sampling and completion of audit documentation. This occurred because FSIS' policy for completion of ongoing equivalence verification audits was not detailed or specific; further, the guidance instructions overestimated the level of activity actually performed while on-site and did not provide adequately detailed policy to ensure procedures were consistently completed. Moreover, there was no formal training required for FSIS auditors to prepare them for conducting ongoing equivalence verification audits. As a result, we determined that there is increased risk that ongoing equivalence verification audits will not be consistently or adequately completed to ensure that foreign food safety systems remain equivalent, which we determined could increase the risk that adulterated or unsafe products could be exported to the U.S.

Federal standards state that a routinely and consistently performed control activity is generally more precise than one performed sporadically.[25] Per policy, FSIS ensures that countries maintain equivalence through a three-part process, one of which is a periodic

[24] The CAVF is a tool used by FSIS equivalence officers and auditors to evaluate foreign inspection systems. The CAVF forms the basis for audit planning, scope, and reporting, and identifies the records and processes that an auditor is to assess during an on-site equivalence audit. IAS auditors also use the CAVF to record the results of on-site audit verification activity and to develop a draft foreign audit report.
[25] GAO-14-704G, *Standards for Internal Control in the Federal Government*, Sept. 2014.

on-site equivalence verification audit in exporting countries. FSIS policy further states that the CAVF functions as the workspace for FSIS auditors to inventory the aspects of a country's inspection system that need to be verified during an on-site audit and to document the evidence collected during the audit to verify the equivalence of the country's inspection system.[26]

We observed FSIS officials conducting their ongoing equivalence verification audits of Northern Ireland and Denmark during our audit. Through our observations, we identified that specific areas of the CAVF, such as requesting and reviewing procedures and records, were not completed by FSIS auditors while conducting the ongoing equivalence verification audits. When questioned about completing the CAVF, one FSIS auditor stated that they did not perform a few CAVF procedures, such as verifying that scales had been calibrated at laboratories, due to lack of time. Moreover, the FSIS auditor stated that the CAVF can be confusing and added that training for ongoing equivalence verification audits is limited and/or informal. Additionally, FSIS Directive 9780.1 is limited in nature and does not provide enough direction about consistently conducting ongoing equivalence verification audits. To verify our observations, we asked FSIS officials to explain why the auditors did not complete actions outlined in the CAVF while on-site. According to FSIS, "The scope of verification activities depends on the auditor's judgment and the extent of the confirmation needed." Since FSIS relies on its auditors to determine the scope of verification activities and does not require any written documentation to justify the auditor's determination, there is no assurance that the scope of activities outlined in the CAVF will be adequately completed or consistently documented to justify deviations from planned verification activities.

We also noted that the FSIS auditors did not clearly document the work completed at establishments on FSIS' establishment checklist. The checklist required FSIS auditors to identify any anomalies at an establishment. If no anomalies were noted, the checklist was left blank. We noticed that the auditors did not complete items on the checklists due to time constraints. Those items were also left blank on the checklist; therefore, it appeared that the FSIS auditor had reviewed those items and did not identify any issues or anomalies. The practice of leaving the checklist blank is confusing because it does not clearly represent that all of the work identified on the checklist was completed. As such, we concluded that FSIS needs to change the way the checklist is used so it is clear which sections are completed while FSIS auditors are on-site. Additionally, FSIS' policy should identify which items on the checklist are a top priority and must be addressed when the auditor is facing time constraints.

Through our observations in Northern Ireland and Denmark, we also identified that auditors used inconsistent methods for record review sampling and completion of audit documentation. We noted that FSIS auditors inconsistently obtained documentation to verify oversight activities at certified establishments and laboratories. One FSIS auditor requested a specific timeframe of 6 months when requesting documentation to verify, while another auditor requested a variable timeframe, such as 30 or 90 days. When asked

[26] FSIS Directive 9780.1, *Verifying the Ongoing Equivalence of Foreign Food Safety Systems*, Oct. 7, 2015.

why a specific timeframe was selected, the auditor stated that, based on past experience, that period of time was what he felt was necessary. When we questioned the other FSIS auditor, he stated that he usually asks for 90 days of records, but on other occasions he could ask for 30 days of records. The auditor explained that it was up to each individual auditor to determine the appropriate number of records to review, and if issues are identified, additional records could be requested. When we asked if document review was a part of FSIS policy, the auditors stated they had not been provided specific direction on sampling, and the total number of documents reviewed depended entirely on the individual auditor's judgment. We also reviewed FSIS policy and confirmed that no direction was given on sampling during ongoing equivalence verification audits.

To confirm that inconsistencies existed within FSIS' ongoing equivalence verification audit process, we conducted interviews with additional FSIS auditors to identify the methods they used for completing ongoing equivalence verification audits. Specifically, we interviewed four auditors responsible for conducting ongoing equivalence verification audits in six equivalent countries.[27] Through this process, we confirmed inconsistencies when FSIS conducted ongoing equivalence verification audits in prior fiscal years. Specifically, we identified that two of the four auditors did not always complete every step of the CAVF at every establishment; one of the four auditors did not always complete every item on the establishment checklist; and three of the four auditors collected 90 days' worth of records for review and could expand the sample size if issues were identified. Additionally, all of the auditors stated no FSIS guidance existed for collecting records for review. One auditor stated that he collects 60 to 90 days' worth of records. Another auditor, who stated that he collected 90 days' worth of records, previously stated that he could request as few as 30 days' records while conducting on-site audits.

FSIS' policy should be updated to include more detailed instructions for FSIS auditors when conducting ongoing equivalence verification audits to increase the level of consistency and to ensure that the FSIS auditors are appropriately completing the assigned tasks. Additionally, FSIS should implement a formal training program to ensure auditors are consistently trained in completing FSIS ongoing equivalence verification audits.

FSIS Needs to Strengthen and Document Policies and Procedure for Monitoring, Assessing, and Determining Equivalence of ISMs

We determined that equivalent countries may have implemented ISMs not considered equivalent to U.S. safety standards. This occurred because FSIS did not have adequate policy to monitor, classify, evaluate, or determine equivalence of ISMs prior to implementation by countries. Additionally, FSIS policy does not identify the difference between "major" and "minor" ISMs or the impact that designation has on FSIS' required review and determination of equivalence prior to implementation. As a result, we determined that countries could potentially produce and export products that do not

[27] The six countries were: Australia, Canada, Chile, China, Honduras, and Northern Ireland.

comply with FSIS equivalence standards, therefore increasing food safety risks for U.S. consumers.

Federal regulations state, "No carcasses, parts of carcasses, meat or meat food products of cattle, sheep, swine, goats, horses, mules, or other equines which are capable of use as human food, shall be imported into the United States if such articles are adulterated or misbranded[28] and unless they comply with all the inspection, building, construction standards, and all other provisions of this chapter and regulations issued thereunder applicable to such articles in commerce within the United States."[29] Sanitary measures include laws, decrees, regulations, requirements, and procedures related to food safety as measures applied to eliminate or abate food safety hazards to a degree that achieves the appropriate level of protection, and "protect human life or health from foodborne hazards that involve an additive, contaminant, toxin, or disease-causing organism."[30]

Through our review of FSIS' policies, we determined that the process for making an ISM equivalence determination was not clearly or concisely documented. First, we determined that FSIS did not have a documented process to monitor the ISM equivalence determination process. An FSIS official stated that during the scope of our audit, FSIS employed a project status tracking chart in SharePoint® to track the ISM equivalence determination process. However, the official stated that that process was no longer in effect. Another FSIS official stated that project plans were created to monitor the ISM equivalence determination process. We obtained a copy of a project plan and identified that it contained pertinent information related to monitoring and determining equivalence of an ISM request. Specifically, it included the name of the country requesting an ISM, a description of the ISM, as well as sections outlining dates and reviews conducted by FSIS, along with the equivalence determination date. However, when we reviewed two project plans, initiated by that FSIS official, we identified that they were incomplete. Additionally, there was no guidance outlining what was required to be documented in the project plan that the FSIS official identified as being used to monitor and determine the equivalence of ISM requests.

We also identified that one ISM request, which originated in 2011, was not completed or closed. This led to a new project plan for the same ISM in 2014, when the country resubmitted the ISM request for an equivalence determination. When we questioned FSIS officials about the current process for monitoring and determining equivalence of ISMs, one FSIS official explained that they currently used an Excel® spreadsheet for ISM project monitoring and equivalence determination purposes. However, the official stated that the Excel® process was new and was currently maintained on an FSIS official's desktop. However, only the individual with access to the desktop can view the Excel® spreadsheet and, additionally, there is no FSIS guidance identifying what is required to be documented and retained on the spreadsheet, or how that data are to be retained after

[28] "Misbranded" means to label in violation of statutory requirements.
[29] 21 U.S.C. § 620(a), Federal Meat Inspection Act.
[30] FSIS Directive 9780.1, *Verifying the Ongoing Equivalence of Foreign Food Safety Systems*, October 7, 2015, and USDA FSIS, *Process for Evaluating the Equivalence of Foreign Meat, Poultry, and Egg Products Food Regulatory Systems,* July 2011.

ISMs have been determined equivalent. Although FSIS officials stated that they are currently using Excel,® FSIS has no formal policy or procedure in place for monitoring the ISM equivalence determination process. As a result, we determined that there is reduced assurance that ISMs are adequately monitored and determined equivalent prior to a country's implementation.

We also identified deficiencies in FSIS' classification of ISM equivalence requests submitted by countries. We requested all ISM equivalence requests submitted by countries during the scope of our audit. FSIS officials provided two lists in which they identified a total of 10 ISM requests. Through our review of the lists provided by FSIS, we identified a total of 13 separate requests and not 10 as originally identified by FSIS. The documentation FSIS provided did not accurately identify that there were 13 actual requests. Additionally, we determined that two of the requests identified by FSIS were for the same ISM equivalence request. We also discovered inconsistencies in the labelling and classification of at least six ISM equivalence requests identified by FSIS. For instance, one of the ISM equivalence requests was not actually an ISM request, but was a request presented by a country to re-instate equivalence for a specific product. This request was inaccurately classified as an ISM when it should have been classified as a re-instatement request. FSIS officials also stated that the ISM requests were inaccurately classified, as they should not have been identified and provided to us as an ISM equivalence request. Based on our review of the documentation provided by FSIS officials, we determined that ISM requests were inaccurately classified. FSIS does not have a documented process for classifying or identifying ISM equivalence requests and, as a result, we determined that there is reduced assurance that ISMs are accurately identified and determined equivalent prior to implementation.

In addition, we determined that FSIS officials did not adequately identify or document the equivalence determination of ISM equivalence requests. Specifically, we determined that only 5 of the 10 ISMs identified by FSIS officials had documentation supporting the date of equivalence determination that was consistent with the lists provided by those officials. For example, we identified that FSIS was unable to produce any supporting documentation for one ISM equivalence determination and the FSIS official assigned to that country was also unable to answer questions about the ISM. Furthermore, ISMs that were identified on both lists had different equivalence determination dates given on each of the respective lists. Lastly, for one ISM, the date identified on the list of ISMs provided by FSIS corresponded with the date of equivalence determination documented on the ISM request; however, the country was notified of the equivalence determination decision more than four months prior to the documented date of equivalence determination. Since FSIS did not have adequate documentation to support the equivalence determination of ISM requests, we concluded that it was unable to accurately provide support that ISMs were determined equivalent prior to implementation.

Also, FSIS officials stated that they only required foreign countries to request an equivalence determination prior to the implementation of an ISM if a country planned to implement a "major" ISM change. FSIS officials did not require countries to request prior equivalence determination if the ISM change was "minor." These actions were inconsistent with FSIS' policy, which states that "Exporting countries should seek FSIS

determinations of equivalence well before any individual sanitary measure is implemented." Although FSIS officials recognized there was a difference between "major" and "minor" ISMs, we determined that the terms "major" and "minor" were not documented in agency policy. We inquired about the definition of what a "major" ISM change included and what guidance would identify a "major" versus "minor" ISM change. FSIS referred us to a draft procedure, dated January 2010. The policy provided additional procedures about the ISM equivalence determination process; however, it did not define the terms "major" versus "minor" or how the identification of "major" versus "minor" impacted FSIS' required review or equivalence determination of ISMs.

To clarify, an FSIS official explained that, due to volume, it would be impossible to review every ISM prior to implementation or require foreign countries to request a determination prior to implementing every ISM. The official stated that a "minor" ISM would include an insignificant or small change to policy or a country implementing a policy that had received a prior equivalence determination in other countries. A "major" ISM would include the implementation of a completely new policy, such as microbiological testing for *E. coli*, that had never been implemented or evaluated by FSIS and was different than the existing U.S. policy.[31] As noted above, FSIS' explanation was not consistent with FSIS policy that stated exporting countries should seek FSIS determination of equivalence before any ISM was implemented. Further, the terms "minor" versus "major" and the associated impact they could have on FSIS' required review and equivalence determination of ISMs were not documented in agency policy.

Overall, we concluded that FSIS lacked adequate policy to monitor, classify, evaluate, or determine equivalence of ISMs prior to implementation by equivalent countries. As a result, there is reduced assurance that ISMs were adequately monitored, classified, or determined equivalent by FSIS prior to implementation by equivalent countries. We also determined that FSIS' policy does not define a "major" versus "minor" ISM, or the impact that it has on FSIS' required review and equivalence determination process. As a result, countries could potentially produce and export products that do not comply with FSIS equivalence standards, thereby increasing food safety risks for U.S. consumers.

FSIS Needs to Strengthen and Document Policy for Equivalent Country Establishment Delistment

FSIS does not obtain details identifying the actual date or reason why certified foreign establishments were delisted or otherwise deemed no longer eligible to export product to the United States by equivalent countries. FSIS' policy only vaguely describes establishment delistment, and the required notification process.[32] Consequently, FSIS does not receive pertinent data detailing actual dates or causes of delistments and, therefore, cannot use that data to identify potential trends or other food safety issues

[31] ***Escherichia coli*** (abbreviated as ***E. coli***) is a large and diverse group of bacteria. Although most strains of ***E. coli*** are harmless, others can cause serious illness.

[32] "Delistment" is removing an establishment from an exporting country's list of establishments certified for export to the United States. Therefore, identifying that establishment as not eligible to export product to the United States.

within equivalent countries that could serve to mitigate risks and reduce the potential that unsafe products are exported to the United States.

Federal regulations state that establishment eligibility is subject to review by the agency, and foreign establishment certifications must be renewed annually. The FSIS Administrator may terminate the eligibility of any foreign establishment for the importation of its products into the United States if it does not comply with requirements, or if current establishment information cannot be obtained.[33] GAO Standards for Internal Control state that management communicates with, and obtains quality information from, external parties using established reporting lines.[34] External parties include suppliers, contractors, service organizations, regulators, external auditors, government entities, and the general public. Management communicates quality information with external parties to achieve its objectives and address related risks. Information communicated to management includes significant matters relating to risks, changes, or issues that impact the entity's internal control system. This communication is necessary for the effective operation of internal control.

We identified, during the scope of our audit, that 67 establishments were delisted by four equivalent countries that we non-statistically selected for review. Through our review of the delisted establishments, we determined that one country delisted a total of 55 establishments. We also identified that 52 of the 55 establishments were delisted on the same day. According to FSIS officials, it is not unusual for a country to have a large number of establishments delisted on the same day. The official explained that countries will provide an updated list of delisted establishments at one time; therefore, a large number of establishments are able to be delisted on one date. However, FSIS does not require countries to notify it within a specific timeframe of the actual date establishments had been delisted, or obtain details regarding why establishments had been delisted. As a result, we were unable to determine the actual date or the reason the 55 establishments were delisted. An FSIS official informed us that the country inadvertently excluded 54 of those 55 establishments from its list and, when it identified the error, the country submitted an updated list to rectify the error. However, through our analysis of FSIS' website and other supporting documentation to rectify the error, we identified that the establishments were still delisted. While we understand that errors can occur, FSIS does not document details or any further information regarding establishment delistment on its website, which provides the list of both eligible and delisted establishments. As a result, we determined that FSIS may be unaware of potential trends or other concerns identified by an equivalent country.

In addition, we concluded that equivalent countries can recertify (i.e., relist) an establishment as eligible to export product to the United States at any time without any type of FSIS review or certification from equivalent countries identifying that concerns or issues had been addressed by the foreign establishment.[35] FSIS relies on equivalent

[33] 9 C.F.R. § 327.2(a) (3), Imported Products, Sept. 30, 2015.
[34] GAO-14-704G, *Standards for Internal Control in the Federal Government*, Sept. 2014.
[35] "Relisting establishments" is adding an establishment to the country's list of establishments eligible to export to the United States, thereby making it eligible to export product to the United States.

countries to manage certified establishments, but should be aware of delistments as soon as a country delists establishments, and reasons for delistment and corrective actions taken to ensure those establishments meet U.S. food safety standards prior to shipping product.

While we understand that FSIS cannot conduct on-site visits to all establishments that have been delisted, FSIS should be notified timely when a country delists an establishment, and obtain detailed information identifying the reason for delistment and the subsequent corrective actions that have been initiated for relisting, as applicable. This practice is important because it will allow FSIS to ensure that establishments have implemented corrective actions prior to shipping product to the United States. It will also enable FSIS officials to verify that corrective actions were implemented when they conduct their next on-site audit.

FSIS' process to identify foreign establishments that have been delisted would be improved if it obtained timely notification from countries of delistment and the reason for delistment. Without obtaining the actual date of delistments and a record of reasons why establishments are delisted, FSIS cannot timely identify trends related to delistments or possible correlations to POE violations to determine if continuous delistments of particular establishments would warrant an on-site verification audit, an FSIS initiated delistment, or a country suspension. In addition, FSIS cannot ensure that the foreign country has adequately responded to the delistment in order to avoid repeat occurrences. As a result, FSIS could continuously receive products from countries and establishments that are not operating in compliance with U.S. food safety standards.

Overall, FSIS officials generally agreed that oversight controls of the equivalence program could be documented and strengthened. Specifically, FSIS officials acknowledged that judgmental factors used in the selection of countries for ongoing equivalence verification audits could be clearly identified and documented. The officials also acknowledged that the ongoing equivalence verification audit process could be strengthened by documenting the decisions made by auditors during an ongoing equivalence verification audit when specific areas of the audit plan are not completed. Finally, FSIS officials agreed that agency procedures should be updated for the ISM equivalence determination process, as well as for obtaining documentation for the delistment of foreign establishments.

Recommendation 1

Develop and document, as part of its annual ongoing equivalence verification audit planning process, how foreign countries are selected for ongoing equivalence verification audits. To the extent feasible, foreign country ongoing equivalence verification audit planning should be based on public health risk concerns, including each country's performance record. The criteria for selecting countries for ongoing equivalence verification audits should be clearly outlined in policy, and require documenting the public health risk considerations, country performance record, and judgmental qualitative factors used in the annual ongoing equivalence verification audit planning process. The policy should clearly identify that judgmental qualitative factors can be considered and require that they be documented.

Agency Response

In its August 23, 2017, response, FSIS officials stated that FSIS intends to update its instructions to FSIS personnel to clarify procedures concerning the annual planning and selection processes for annual ongoing equivalence verification audits. Specifically, FSIS will document annually, as part of the on-site verification audit planning process, how foreign countries were selected for on-site reviews during the upcoming fiscal year. To the extent feasible, selection of foreign countries will be based on public health risk considerations, including each country's performance record. The criteria for selecting countries for on-site reviews will be clearly outlined in the instructions to Agency personnel, and include the public health risk considerations and the judgmental qualitative factors used in the on-site audit planning process. The estimated completion date is September 30, 2018.

OIG Position

We accept management decision for this recommendation.

Recommendation 2

Update agency Directive 9780.1, *Verifying the Ongoing Equivalence of Foreign Food Safety Systems*, and/or other applicable guidance, to include more detailed instructions regarding the requirements of conducting ongoing equivalence verification audits. Specifically, include guidance pertaining to the following: completion and documentation of Component Analysis Verification Form (CAVF) procedures and audit findings; completion of the establishment checklist; how auditors are to select records for review; which on-site audit activities are mandatory, ensure auditors are consistently trained in completing ongoing equivalence verification audits; and any additional guidance that FSIS determines is appropriate or necessary to improve ongoing equivalence verification audits.

Agency Response

In its August 23, 2017, response, FSIS officials stated that FSIS acknowledges and agrees to update FSIS Directive 9780.1 to include more detailed procedures for conducting on-site verification audits. Specifically, including instructions pertaining to the following: completion and documentation of the CAVF procedures and audit findings; completion of the establishment checklist; general criteria on how to evaluate sites, how auditors are to select records for review; which on-site audit activities are mandatory; and ensure that auditors are consistently trained in completing on-site equivalence audits. The estimated completion date is September 30, 2018.

OIG Position

We accept management decision for this recommendation.

Recommendation 3

Develop and implement guidance to foreign countries to obtain FSIS equivalence determinations prior to implementing Individual Sanitary Measures (ISMs). Additionally, develop and implement policy or guidance identifying the requirements for reviewing and developing equivalence criteria for ISMs. Specifically, include guidance for classifying, monitoring, and determining equivalence of ISMs. This policy or guidance should also define or distinguish significant, non-routine or "major" ISMs from routine, non-significant or "minor" ISMs and the impact that designation has on the required equivalence determination process.

Agency Response

In its August 23, 2017, response, FSIS officials stated that FSIS has already developed guidance to foreign countries concerning ISMs. FSIS must determine if ISMs are equivalent before the country implements the ISM for product to be exported to the U.S. See page 12 of the Guideline for Countries on the Food Safety and Inspection Service's Equivalence Process (https://www.fsis.usda.gov/wps/wcm/connect/06aacde8-7023-49ee-83db-4c3a09592bea/Equivalence-Process-Guidance.pdf?MOD=AJPERES). Additionally, FSIS does not distinguish "major" and "minor" ISMs. The policy for ISMs is the same whether the ISM is significant (e.g., visual post-mortem) or routine (e.g., a change in lab protocol). FSIS's policy documents do not distinguish these ISMs because the process is the same. The procedures FSIS uses to evaluate ISMs are described on page 4 of FSIS Directive 9770.1, *Determining Initial and Reinstating the Equivalence of Foreign Food Safety Inspection Systems*. FSIS completed this corrective action on February 8, 2017.

OIG Position

We accept management decision for this recommendation.

Recommendation 4

Develop and implement guidance to foreign countries to notify FSIS of delistments and the reasons for them. This guidance should clearly identify that countries are to timely provide notification of delistment. Additionally, agency directives or other applicable guidance should be updated to document this requirement.

Agency Response

In its August 23, 2017, response, FSIS officials stated FSIS will review and update the current FSIS guidance to foreign countries on the reporting table for foreign country's certified establishment list to recommend that Central Competent Authorities notify FSIS of delistments, and align/update the appropriate Agency directive or guidance, within a reasonable period of time. FSIS does not currently have a regulation that requires CCAs to notify the Agency of delistments. The Agency would need to conduct rulemaking before the Agency could fully implement OIG's recommendation.

OIG Position

We do not accept management decision for this recommendation. While FSIS agreed to review and update current FSIS guidance to foreign countries to recommend that Central Competent Authorities notify FSIS of delistments within a reasonable period of time, it did not specify what a reasonable period of time would entail. In order to reach management decision, FSIS needs to clearly define what a reasonable period of time would entail and document this as part of their update of FSIS guidance to foreign countries.

Finding 2: FSIS Procedures for Conducting Ongoing Equivalence Verification Audits Did Not Include Corrective Actions from Prior Audit Recommendations

FSIS procedures for completing ongoing equivalence verification audits did not incorporate corrective actions previously agreed to for four out of seven prior recommendations related to equivalency from our 2008 audit (see Exhibit A).[36] The recommended actions, which in our view remain necessary to ensure foreign inspection systems are and remain equivalent, were to develop and implement procedures to enhance FSIS' process for conducting and documenting ongoing equivalence verification audits of foreign countries' food inspection systems. For one recommendation, FSIS did not incorporate new procedures into agency guidance to implement the recommendation. For the other three recommendations, FSIS did initially implement corrective actions by updating its management control manual. However, the agency did not incorporate these procedures into subsequent guidance when the management control manual was replaced in October 2015. Without these procedures documented in current agency guidance—which FSIS had agreed to in response to our prior audit recommendations—we determined that FSIS may not be consistently conducting ongoing equivalence verification audits of foreign inspection systems to identify whether these systems are, or remain, equivalent to U.S. standards.

In our 2008 audit report, we issued 19 recommendations to improve FSIS' inspection processes (i.e., equivalence determinations, on-site audits, and product re-inspection at U.S. POE). In our current audit, we reviewed seven of the prior recommendations to determine if the corrective actions agreed to by FSIS were sufficiently implemented (see Exhibit A).[37] For these seven recommendations, FSIS provided the Office of the Chief Financial Officer (OCFO) with evidence that agreed-upon corrective actions had been documented in agency procedures. However, we determined that four of the seven recommendations were not incorporated in FSIS' procedures in effect at the time of our audit.

We reported in 2008 that FSIS' methodology for selecting establishments to review while conducting ongoing equivalence verification audits of a foreign country's food inspection system needed strengthening. Specifically, FSIS did not follow established methodology for selecting the minimum number of establishments to review, nor did it have requirements for documenting deviations from its prescribed guidance to justify why FSIS auditors did not visit the minimum number of establishments required. We recommended that FSIS develop procedures for documenting deviations from visiting the minimum number of establishments as part of the ongoing equivalence verification audit, and that this documentation should provide sufficient, competent evidence that the establishments visited provided a reasonable basis for concluding that the foreign country's food safety system remained equivalent to the U.S. system.

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[36] Audit Report 24601-08-Hy, *Follow-up Review of Food Safety and Inspection Service's Controls over Imported Meat and Poultry Products*, August 2008.

[37] We only reviewed 7 of the 19 prior audit recommendations from the 2008 report because these recommendations related to equivalency. The other 12 recommendations dealt with product re-inspection at POE, which was not part of the objectives for this audit.

In FSIS' response to our prior report, the agency agreed to develop and implement a process to document the reasons for the number of establishments selected for ongoing equivalence verification audit, and that a description of this process would be included in the Office of International Affairs' (OIA) management control manual.[38] FSIS officials agreed to complete these actions by October 31, 2008. FSIS officials provided OCFO with an excerpt of its management control manual to support that these procedures were implemented to address our previous recommendation. We reviewed the entire management control manual in this audit to determine if the recommendation was adequately implemented by FSIS. We found that FSIS did not formally issue the management control manual that included the new procedures to fully implement the recommendation.

FSIS officials informed us that the management control manual was replaced in October 2015, due to the agency reorganization, and that the procedures included in the manual were incorporated into other FSIS directives and instruction manuals. We obtained and reviewed this documentation to determine if they contained the procedures FSIS agreed to implement from our previous recommendation. Based on our review, we determined that none of these documents contained the procedures that FSIS agreed to insert into agency guidance. FSIS officials agreed with our review and stated that they would revise FSIS Directive 9780.1 to include procedures for documenting deviations from visiting the minimum number of establishments as part of the ongoing equivalence verification audit, and that this documentation should provide sufficient, competent evidence that the establishments visited provided a reasonable basis for concluding that the foreign country's food safety system remained equivalent to the U.S. system.[39]

In 2008, we also reported that FSIS did not fully implement two prior recommendations from a 2005 audit related to the equivalence assessment of the Canadian inspection system.[40] These recommendations required FSIS to implement procedures for (1) determining which equivalence deficiencies would question a country's overall equivalence determination, and (2) postponing and cancelling a scheduled enforcement audit.[41] We issued a new recommendation in our 2008 report for FSIS to include these procedures in the agency's guidance. FSIS agreed to update OIA's management control manual to include these procedures by October 31, 2008. We reviewed the documentation FSIS provided to OCFO to close the 2008 recommendation and concluded that FSIS did adequately update its manual as agreed. However, we determined that FSIS did not incorporate these procedures into its current guidance when it reorganized and replaced its management control manual in October 2015. FSIS officials stated that Directive 9780.1 included some details concerning the postponement of ongoing equivalence verification audits; however, they also confirmed and agreed that the procedures in the directive

[38] FSIS administered its imported meat and poultry inspection program primarily through OIA until 2014. In 2015, FSIS reorganized and OIA was disbanded. Currently, FSIS' Office of International Coordination (OIC) is responsible for managing the equivalence process, with assistance from the Office of Policy and Program Development (OPPD), and the Office of Investigation, Enforcement, and Audit (OIEA).
[39] FSIS Directive 9780.1, *Verifying the Ongoing Equivalence of Foreign Food Safety Systems*, Oct. 7, 2015.
[40] Audit Report No. 24601-05-Hy, *Assessment of the Equivalence of the Canadian Inspection System*, Dec. 2005.
[41] Enforcement audits are conducted when a history of FSIS annual audits reveals continued deficiencies in the implementation and enforcement of FSIS requirements. FSIS procedures, including Directive 9780.1, no longer include any references to enforcement audits. FSIS now refers to such audits as "for cause" on-site audits. FSIS inspectors may conduct a for cause on-site audit at any time if it identifies a loss of process control resulting in repeated POE failed inspections or inadequate implementation of corrective actions.

did not document the process for cancelling or suspending an ongoing equivalence verification audit and that the directive should be updated.

Finally, we also reported in 2008 that FSIS did not have documented procedures related to performing an ongoing equivalence verification audit to ensure a country's food safety system remained 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. In our 2008 audit, we issued two recommendations for corrective actions that required FSIS to formalize procedures in its management control manual to conduct ongoing equivalence verification audits within a specified timeframe: (1) prior to the first shipments of products from new countries, and (2) prior to the first shipments of products from countries that had been suspended. FSIS agreed to include these revised procedures in its management control manual by October 31, 2008.

In the documentation provided to OCFO to close these recommendations, we concluded that FSIS did sufficiently update its management control manual to address the corrective actions. However, FSIS again did not incorporate these procedures in guidance after its manual was replaced in 2015. During the time of our review, FSIS officials confirmed that agency guidance did not include these procedures, and agreed that Directive 9780.1 should be revised to incorporate them.

Thus, since it is our view that the issue continues to be relevant, FSIS needs to ensure that its procedures for conducting ongoing equivalence verification audits are revised to include the corrective actions for the four recommendations from our 2008 report. These corrective actions are needed to ensure that foreign inspection systems are and remain equivalent. This should include updating FSIS Directive 9780.1 and/or other FSIS policy and guidance to include procedures for: (1) documenting deviations from agency guidelines when visiting the minimum number of foreign establishments as part of the ongoing equivalence verification audit, (2) postponing and cancelling enforcement audits (now referred to by FSIS as for cause audits), and (3) conducting ongoing equivalence verification audits, within a specified time period, for countries that are determined equivalent for the first-time as well as those reinstated after a suspension. Without these procedures being properly documented in agency guidance, FSIS may not be conducting ongoing equivalence verification audits of foreign inspection systems sufficiently to identify whether these systems are, or remain, equivalent to U.S. standards.

Recommendation 5

Revise FSIS directives, policy, or other guidance to include procedures for documenting deviations from visiting the minimum number of establishments as part of the ongoing equivalence verification audit and ensure that this documentation provides sufficient, competent evidence that the establishments visited provided a reasonable basis for concluding that the foreign country's food safety system remained equivalent to the U.S. system.

Agency Response

In its August 23, 2017, response, FSIS officials stated that FSIS will issue instructions to FSIS personnel to document the requirements and criteria for determining how many and which actual establishments are visited during audits. The instructions will clarify the procedures for developing and documenting the audit plan, which will include individual foreign audit plans, how many establishments are to be audited, and why particular establishments were selected for audits in the particular foreign food safety inspection system. The estimated completion date is September 30, 2018.

OIG Position

We accept management decision for this recommendation.

Recommendation 6

Revise FSIS directives, policy, or other guidance to include procedures for postponing and cancelling a scheduled ongoing equivalence verification audit or a for cause audit.

Agency Response

In its August 23, 2017, response, FSIS officials stated FSIS will revise FSIS Directive 9780.1 to provide procedures for postponing and cancelling a scheduled ongoing equivalence verification audit or a for cause audit. The estimated completion date is September 30, 2018.

OIG Position

We accept management decision for this recommendation.

Recommendation 7

Revise FSIS directives, policy, or other guidance to include procedures for conducting ongoing equivalence verification audits, within a specified timeframe, prior to the first shipment from countries newly determined as equivalent.

Agency Response

In its August 23, 2017, response, FSIS officials stated FSIS's current policy generally addresses this recommendation. FSIS audits a country as part of the equivalence determination process. A country that seeks an initial equivalence determination is the subject of a Notice and comment rulemaking process that provides the public an opportunity to contribute on the merits of granting equivalence. A foreign country is not eligible to ship product until the effective date of the final rule. FSIS cannot typically conduct an on-site audit in the middle of the rulemaking

process. In that situation, commenters may not have an opportunity to comment on the new audit findings before FSIS finalizes its rulemaking. FSIS has demonstrated that it can fully protect the public by doing increased sampling and product examination for newly equivalent countries in order to gain confidence in the foreign country's inspection system and then doing subsequent audits.

OIG Position

We do not accept management decision for this recommendation. While we agree that FSIS audits a country as a part of its initial equivalence determination process, its policies and directives do not include procedures for conducting ongoing equivalence verifications audits when there is an extended period of time between the initial equivalence determination and the date of the country's first shipment. In order to reach management decision, FSIS needs to revise directives or policy to clearly identify procedures for conducting ongoing equivalence verification audits when there is an extended period of time between initial equivalence determinations and a country's first shipment.

Recommendation 8

Revise FSIS directives, policy, or other guidance to include procedures for conducting ongoing equivalence verification audits, within a specified timeframe, prior to the first shipments from countries that have been re-instated as equivalent.

Agency Response

In its August 23, 2017, response, FSIS officials stated FSIS currently requires foreign countries to request reinstatement of equivalence from FSIS when it has been three or more years since the country has exported an equivalent species or process category or a country requests to export a new species or process category within an equivalent inspection system. FSIS generally performs an on-site verification audit as part of the reinstatement. FSIS will issue a FSIS Notice to clarify current procedures and criteria for when a reinstatement of equivalence needs to be requested and when to recommend an on-site verification audit as part of a re-instatement of equivalence determination.

OIG Position

We do not accept management decision for this recommendation. While we agree that FSIS currently requires foreign countries to request reinstatement from FSIS when it has been three or more years since the country has exported an equivalent commodity to the U.S., its policies and directives do not contain procedures for conducting equivalence verification audits, within a specified timeframe, prior to the first shipment from countries that have been reinstated as equivalent. In order to reach management decision, FSIS needs to revise directives or policy to clearly identify procedures for conducting equivalence verification audits, within a specific timeframe, prior to the first shipment from countries that have been reinstated as equivalent.

Scope and Methodology

We conducted our audit at FSIS' National Office in Washington, D.C. We also observed FSIS auditors conducting two ongoing equivalence verification audits in Northern Ireland and Denmark, both of which are equivalent countries that we non-statistically selected for review. The two countries were selected based on FSIS' ongoing equivalence verification audit schedule, which coincided with our audit work. We conducted fieldwork for this audit from August 2015 through February 2017.

We reviewed laws, regulations, and guidance documents that explained FSIS' oversight and determination process for ensuring exporting countries' food safety systems remained equivalent to the U.S. standards. Specifically, we evaluated criteria related to: monitoring and determining ongoing equivalence, scheduling and conducting ongoing equivalence verification audits, implementing individual sanitary measures, and the delisting of establishments.

In addition, we reviewed prior OIG Audit Reports 24601-0008-Hy, *Follow-up Review of Food Safety and Inspection Service's Controls Over Imported Meat and Poultry Products*, dated August 2008, and Report No. 24601-0005-Hy, *Assessment of the Equivalence of the Canadian Inspection System*, dated December 2005, to identify corrective actions FSIS agreed to implement as a result of recommendations issued, and to determine if it had implemented the appropriate and agreed upon corrective actions.

We also performed the following steps to accomplish our objectives:

- Determined whether FSIS had adequate and sufficient controls in place to ensure that exporting countries' food safety standards were equivalent to United States' standards;

- Selected a non-statistical sample of six prior audits conducted by FSIS in equivalent countries between October 1, 2013, and July 31, 2015, to determine if audits were consistently conducted in compliance with policy. These six countries were: Australia, Canada, Chile, China, Honduras, and Northern Ireland. The non-statistical selection was based on media concerns or public attention, hotline complaints, volume of product exported during the audit scope period, number of eligible establishments, and FSIS' on-site audit schedule for FY 2016. We selected countries that were the largest exporters of product with the largest number of establishments as well as mid-level exporters and smaller exporters to allow for a full range of review;

- Reviewed and analyzed records FSIS collected to validate equivalency and compared those records to ongoing importer inspections to determine whether discrepancies existed;

- Interviewed FSIS officials responsible for reviewing, assessing, and determining the equivalence of documentation presented by the foreign countries to determine the processes followed;

- Evaluated documentation maintained to support actions taken against establishments that did not meet the equivalence standards as a result of point-of-entry violations and previous foreign ongoing equivalence verification audit visits;

- Reviewed FSIS' monitoring of ongoing equivalence of selected countries;

- Assessed overall equivalence program controls including ongoing equivalence verification audit selection, staff training, and program communication; and

- Reviewed and analyzed ISM request information provided by FSIS corresponding to the audit scope period October 1, 2013, through July 31, 2015.

During the course of our audit, we identified and reviewed all applicable information technology systems employed by FSIS to determine if any had policies, procedures, or controls related to our objective, noting none. We also interviewed FSIS officials to obtain additional clarification regarding the implementation and use of these systems. We used PHIS data to perform basic analysis, which included identifying if equivalent countries were identified and accurately categorized, and whether establishment delistment data identified on FSIS' webpage coincided with data retained in PHIS. However, we did not review, analyze, or verify the system's general or application controls. We make no representation regarding the adequacy of any agency computer systems.

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

Abbreviations

ACE	Automated Commercial Environment
CAVF	Component Analysis Verification Form
CBP	Custom and Border Protection
C.F.R.	Code of Federal Regulations
FSIS	Food Safety and Inspection Service
FY	fiscal year
GAO	Government Accountability Office
ISM	Individual Sanitary Measure
OCFO	Office of the Chief Financial Officer
OIA	Office of International Affairs
OIC	Office of International Coordination
OIEA	Office of Investigation, Enforcement, and Audit
OIG	Office of Inspector General
OMB	Office of Management and Budget
OPPD	Office of Policy and Program Development
PBIS	Performance-Based Inspection System
PHIS	Public Health Information System
POE	Point-of-Entry

Exhibit A: Analysis of Implementation of Recommendations in Audit Report 24601-0008-HY

This exhibit lists the recommendations from Audit Report 24601-0008-HY, *Follow-up Review of Food Safety and Inspection Service's Controls over Imported Meat and Poultry Products*, issued August 2008, which we reviewed as a part of this audit.

A total of 19 recommendations were issued in the 2008 report. Of those recommendations, we determined that 12 of the 19 recommendations were not related to the objectives of this audit and therefore were not included in the analysis (recommendations 8 – 19). Our analysis of the remaining 7 recommendations (recommendations 1 – 7) is detailed in the following exhibit.

Recommendation		Was Sufficient Documentation Submitted to OCFO to Close?	Were Corrective Actions Adequately Implemented by FSIS?	Did FSIS' Guidance, at the time of our Audit, Incorporate Corrective Actions?
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.	Yes	Yes	Yes
2	Develop and implement protocols for documenting deviations from the guidelines on visiting the minimum number of establishments as part of the on-site 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.	Yes	No	No
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 on-site audit report).	Yes	Yes	Yes

4	Develop and implement criteria for judgmentally selecting foreign establishments for on-site review. The selection criteria should consider such information as (a) re-inspection results from FSIS' information system, or any subsequent system, (b) deficiencies noted in prior on-site audits, (c) establishments with a pattern of being decertified and subsequently recertified, and (d) and any other appropriate evaluation factors.	Yes	Yes	Yes
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.	Yes	Yes	No
6	Formalize procedures to conduct on-site audits, within a specified timeframe, prior to the first shipments from new countries in OIA's Management Control Manual.	Yes	Yes	No
7	Formalize procedures to conduct on-site 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 on-site audit to be performed before the country resumes exporting product to the United States.	Yes	Yes	No

USDA'S FOOD SAFETY AND INSPECTION SERVICE'S RESPONSE TO AUDIT REPORT

United States Department of Agriculture

Food Safety and Inspection Service

1400 Independence Avenue, SW, Washington, D.C. 20250

TO: Gil H. Harden
Assistant Inspector General
Office of Inspector General

FROM: Paul Kiecker **/ s /** **August 23, 2017**
Acting Administrator, Food Safety and Inspection Service

SUBJECT: Office of Inspector General (OIG) Official Draft Report – Evaluation of FSIS' Equivalency Assessments of Exporting Countries

We appreciate the opportunity to review and comment on this Official Draft report. The Food Safety and Inspection Service (FSIS) reviewed the Official Draft report and has general and technical comments followed by a response to each recommendation.

FSIS's General and Technical Comments

FSIS would like to emphasize that OIG determined during the audit that "FSIS has a robust system for determining initial equivalence, and found no public health concerns related to FSIS's ongoing equivalence." FSIS has implemented several enhancements to its equivalence program since the Agency's realignment in 2013, and continues to make improvements to the program. While we appreciate OIG's work in performing a review of our equivalence program, we would like to take this opportunity to clarify some statements made within the report.

Throughout the report, OIG appears to characterize directives as providing guidance to inspection program personnel (IPP). FSIS would like to clarify that directives are official communications and instructions to Agency personnel. Additionally, OIG states throughout the report that FSIS provides oversight of a foreign country's food system. FSIS would like to clarify that the Agency does not provide oversight, rather FSIS monitors and assesses whether a foreign country's system maintains equivalent standards to the U.S. food system on an ongoing basis through a three-part process that includes the following: 1) document reviews, 2) on-site audits, and 3) point-of-entry re-inspection.

On page 4, paragraph 2, OIG describes the process FSIS takes for products that are imported from a country that has been deemed equivalent. FSIS would like to clarify that FSIS performs point-of-entry (POE) re-inspections[1] on all shipments of imported meat, poultry, or egg products offered for import into the United States. During re-inspection, FSIS inspectors verify that all certifications and applications of imported meat, poultry, and egg products are complete and accurate and that the products are not adulterated or misbranded. FSIS does not sample every shipment of meat, poultry, and egg products and instead relies on the Public Health Information System (PHIS) randomly assigning sampling tasks as products enter the United States. In addition to

[1] Product re-inspection at U.S. points-of-entry refers to the inspection by FSIS inspectors of all meat, poultry, and egg products offered for import into the United States. FSIS inspectors verify that the certification and application of imported meat, poultry, and egg products, whether paper or electronic, are complete and accurate, and that the products are not adulterated or misbranded.

sampling, other types of inspection that the PHIS can assign include net weight checks of retail packages; examination of the containers' condition; examination for product defects; and incubation of canned goods. For newly equivalent countries, FSIS performs increased sampling and product examination in order to gain confidence in the foreign country's inspection system. Additionally, OIG states, "the purpose of the re-inspection is to ensure that exporting country certificates are authentic and accurate, and that products meet U.S. food safety and quality standards." FSIS does not determine the "quality" of any food product.

On page 5, paragraph 2, OIG does not accurately describe the role of FSIS's Office of International Coordination (OIC). OIC serves as the Agency's point of contact for foreign government officials on all regulatory matters and is responsible for coordinating international activities among program areas related to the public health and food safety mission of FSIS. Part of that mission includes ensuring that criteria used for measuring equivalence of a foreign food safety system align with existing and emerging domestic food safety regulations and policies. Additionally, FSIS would like to clarify that the reorganization of FSIS to improve efficiencies and integrate the Office of International Affairs into existing functional offices occurred in May of 2013, not 2008.

On page 9, paragraph 1, OIG makes a statement indicating it had to complete additional analysis to ensure information provided by FSIS was accurate and complete. It is FSIS' understanding that OIG's audit responsibilities include assessing, verifying, and further analyzing information from audited agencies as part of its documentation review process. It is unclear why OIG would include such a statement in its report, one that seems to criticize FSIS for providing additional documentation for OIG to assess, verify, and analyze.

On page 9, paragraph 3, OIG makes a statement that FSIS acknowledges that we have not audited all countries eligible to export at least once every 3 years. This is a misleading statement, since the list of eligible countries may include countries that are not currently shipping product to the United States. FSIS currently has a system in place to manage when it has been more than 3 years since a country has shipped a specific commodity. FSIS requires the country to request a reinstatement of equivalence determination. As part of FSIS' equivalence determination, FSIS assesses the country's documentation, and may perform an on-site verification audit before FSIS reinstates equivalence and allows the country to export the product to the United States.

On page 11, paragraph 4, OIG describes FSIS's on-site verification audit process. It fails to indicate that FSIS tailors each audit to the country to ensure each audit is based on on-site conditions and observations conducted. As described in FSIS Directive 9780.1, *Verifying the Ongoing Equivalence of Foreign Food Safety Systems*, FSIS uses its procedure, the Component Analysis Verification Form (CAVF), to form the basis, objectives, scope, and verification activities tailored to the unique situation for each country. The audit methods are neither inconsistent nor insufficient, and while some on-site audits are more detailed than other on-site audits, they are all adequate for Agency purposes. It is not appropriate for OIG to determine that the standard that Agency experts have established for conducting on-site verification audits is not adequate simply based on the level of detail in reporting.

As provided previously in our comments, FSIS does not "approve" individual sanitary measures (ISMs), nor does it, or should it, distinguish "major" and "minor" ISMs. FSIS determines whether the described ISM is equivalent to the U.S. standard. The policy remains the same

whether the ISM is significant or routine. FSIS disagrees with OIG's example of ISMs on page 16, paragraph 1, because the example describes differences between "major" and "minor." FSIS purposely did not include definitions such as "major" and "minor" in FSIS policies because we maintain that countries are to request an ISM equivalence determination from FSIS for all changes to their inspection system. This is outlined in guidance, specifically the *Guideline for Countries on the Food Safety and Inspection Service's Equivalence Process*, provided to foreign countries. Additionally, FSIS provided instructions to FSIS personnel on how to review and assess ISMs and determine whether they are equivalent on pages 4-5 of FSIS Directive 9770.1. In our written comments to the Discussion Draft report, we requested that recommendation 3 be removed. FSIS maintains that this recommendation is unnecessary and could complicate existing processes.

In regards to the section on prior audit recommendations, FSIS would like to clarify that the Agency's current procedures generally address OIG's recommendations 7 and 8. In regards to OIG's recommendation 7, a foreign country is not allowed to ship to the U.S. until an equivalency determination is made. A country that seeks an initial equivalence determination is the subject of a Notice and comment rulemaking process that provides the public an opportunity to weigh in on the merits of granting equivalence. FSIS always conducts an audit before initiating the rulemaking process. A foreign country is not eligible to ship product until the effective date of the final rule. OIG should note that FSIS cannot typically conduct an on-site audit in the middle of the rulemaking process because commenters may not have an opportunity to comment on the new audit findings before FSIS finalizes its rulemaking. Also, FSIS re-inspects every shipment from a foreign country, and if we detect a problem, we can do a for-cause audit. In fact, FSIS continues to protect public health by doing increased sampling and product examination for newly equivalent countries in order to gain confidence in the foreign country's inspection system and then doing subsequent audits. In regards to OIG's recommendation 8, FSIS currently requires foreign countries to request reinstatement of equivalence from FSIS when it has been 3 or more years since the country has exported product or a country requests to export a new species or process category within an equivalent inspection system. FSIS generally performs an on-site verification audit as part of the reinstatement determination process.

While further improvements may be needed to the program, FSIS is confident that our current, robust re-inspection process, and rigorous on-site verification audit process ensure that public health is not compromised.

FSIS' Response to OIG's Recommendations

Recommendation 1:

Develop and document, as part of its annual ongoing equivalence verification audit planning process, how foreign countries are selected for ongoing equivalence verification audits. To the extent feasible, foreign country ongoing equivalence verification audit planning should be based on public health risk concerns, including each country's performance record. The criteria for selecting countries for ongoing equivalence verification audits should be clearly outlined in policy, and require documenting the public health risk considerations, country performance record, and judgmental qualitative factors used in the annual ongoing equivalence verification audit planning process. The policy should clearly identify that judgmental qualitative factors can be considered and require that they be documented.

FSIS Response:
FSIS intends to update its instructions to FSIS personnel to clarify procedures concerning the annual planning and selection processes for annual ongoing equivalence verification audits. Specifically, FSIS will document annually, as part of the on-site verification audit planning process, how foreign countries were selected for on-site reviews during the upcoming fiscal year. To the extent feasible, selection of foreign countries will be based on public health risk considerations, including each country's performance record. The criteria for selecting countries for on-site reviews will be clearly outlined in the instructions to Agency personnel, and include the public health risk considerations and the judgmental qualitative factors used in the on-site audit planning process.

Estimated Completion Date:
FSIS will issue instructions to FSIS personnel by September 30, 2018.

Recommendation 2:
Update agency Directive 9780.1, *Verifying the Ongoing Equivalence of Foreign Food Safety Systems*, and/or other applicable guidance, to include more detailed instructions regarding the requirements of conducting ongoing equivalence verification audits. Specifically, include guidance pertaining to the following: completion and documentation of Component Analysis Verification Form (CAVF) procedures and audit findings; completion of the establishment checklist; how auditors are to select records for review; which on-site audit activities are mandatory, ensure auditors are consistently trained in completing ongoing equivalence verification audits; and any additional guidance that FSIS determines is appropriate or necessary to improve ongoing equivalence verification audits.

FSIS Response:
FSIS acknowledges and agrees to update FSIS Directive 9780.1 to include more detailed procedures for conducting on-site verification audits. Specifically, including instructions pertaining to the following: completion and documentation of the CAVF procedures and audit findings; completion of the establishment checklist; general criteria on how to evaluate sites, how auditors are to select records for review; which on-site audit activities are mandatory; and ensure that auditors are consistently trained in completing on-site equivalence audits.

Estimated Completion Date:
FSIS will modify and re-issue FSIS Directive 9780.1 instructions by September 30, 2018.

Recommendation 3:
Develop and implement guidance to foreign countries to obtain FSIS equivalence determinations prior to implementing Individual Sanitary Measures (ISMs). Additionally, develop and implement policy or guidance identifying the requirements for reviewing and developing equivalence criteria for ISMs. Specifically, include guidance for classifying, monitoring, and determining equivalence of ISMs. This policy or guidance should also define or distinguish significant, non-routine or "major" ISMs from routine, non-significant or "minor" ISMs and the impact that designation has on the required equivalence determination process.

FSIS Response:
FSIS has already developed guidance to foreign countries concerning ISMs. FSIS must determine ISMs equivalent before the country implements the ISM for product to be exported to the U.S. See page 12 of the Guideline for Countries on the Food Safety and Inspection Service's Equivalence Process (https://www.fsis.usda.gov/wps/wcm/connect/06aacde8-7023-49ee-83db-4c3a09592bea/Equivalence-Process-Guidance.pdf?MOD=AJPERES). Additionally, FSIS does not distinguish "major" and "minor" ISMs. The policy for ISMs is the same whether the ISM is significant (e.g., visual post-mortem) or routine (e.g., a change in lab protocol). FSIS's policy documents do not distinguish these ISMs because the process is the same. The procedures FSIS uses to evaluate ISMs are described on page 4 of FSIS Directive 9770.1, *Determining Initial and Reinstating the Equivalence of Foreign Food Safety Inspection Systems.*

Estimated Completion Date:
FSIS has completed the actions described in our response to recommendation 3.

Recommendation 4:
Develop and implement guidance to foreign countries to notify FSIS of delistments and the reasons for them. This guidance should clearly identify that countries are to timely provide notification of delistment. Additionally, agency directives or other applicable guidance should be updated to document this requirement.

FSIS Response:
FSIS will review and update the current FSIS guidance to foreign countries on the reporting table for foreign country's certified establishment list to recommend that Central Competent Authorities (CCAs) notify FSIS of delistments, and align/update the appropriate Agency directive or guidance, within a reasonable period of time. FSIS does not currently have a regulation that requires CCAs to notify the Agency of delistments. The Agency would need to conduct rulemaking before the Agency could fully implement OIG's recommendation.

Estimated Completion Date:
FSIS will review and update the guidance to foreign countries by March 31, 2018.

Recommendation 5:
Revise FSIS directives, policy, or other guidance to include procedures for documenting deviations from visiting the minimum number of establishments as part of the ongoing equivalence verification audit and ensure that this documentation provides sufficient, competent evidence that the establishments visited provided a reasonable basis for concluding that the foreign country's food safety system remained equivalent to the U.S. system.

FSIS Response:
FSIS will issue instructions to FSIS personnel to document the requirements and criteria for determining how many and which actual establishments are visited during audits. The instructions will clarify the procedures for developing and documenting the audit plan, which will include individual foreign audit plans, how many establishments are to be audited, and why

particular establishments were selected for audits in the particular foreign food safety inspection system.

Estimated Completion Date:
FSIS will issue instructions to FSIS personnel by September 30, 2018.

Recommendation 6:
Revise FSIS directives, policy, or other guidance to include procedures for postponing and cancelling a scheduled ongoing equivalence verification audit or a for cause audit.

FSIS Response:
FSIS will revise FSIS Directive 9780.1 to provide procedures for postponing and cancelling a scheduled ongoing equivalence verification audit or a for cause audit.

Estimated Completion Date:
FSIS will modify and re-issue FSIS Directive 9780.1 instructions by September 30, 2018.

Recommendation 7:
Revise FSIS directives, policy, or other guidance to include procedures for conducting ongoing equivalence verification audits, within a specified timeframe, prior to the first shipment from countries newly determined as equivalent.

FSIS Response:
FSIS's current policy generally addresses this recommendation. FSIS audits a country as part of the equivalence determination process. A country that seeks an initial equivalence determination is the subject of a Notice and comment rulemaking process that provides the public an opportunity to contribute on the merits of granting equivalence. A foreign country is not eligible to ship product until the effective date of the final rule. FSIS cannot typically conduct an on-site audit in the middle of the rulemaking process. In that situation, commenters may not have an opportunity to comment on the new audit findings before FSIS finalizes its rulemaking. FSIS has demonstrated that it can fully protect the public by doing increased sampling and product examination for newly equivalent countries in order to gain confidence in the foreign country's inspection system and then doing subsequent audits.

Estimated Completion Date:
FSIS actions are completed, or continuously occurring, for OIG's recommendation 7.

Recommendation 8:
Revise FSIS directives, policy, or other guidance to include procedures for conducting ongoing equivalence verification audits, within a specified timeframe, prior to the first shipments from countries that have been re-instated as equivalent.

FSIS Response:
FSIS currently requires foreign countries to request reinstatement of equivalence from FSIS when it has been 3 or more years since the country has exported an equivalent species or process category or a country requests to export a new species or process category within an equivalent inspection system. FSIS generally performs an on-site verification audit as part of the reinstatement. FSIS will issue a FSIS Notice to clarify current procedures and criteria for when a reinstatement of equivalence needs to be requested and when to recommend an on-site verification audit as part of a re-instatement of equivalence determination.

Estimated Completion Date:
FSIS will issue a Notice clarifying current procedures and criteria for when a verification on-site audit needs to be requested or recommended for a country that has been re-instated as equivalent by February 28, 2018.

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202-720-7257 (24 hours)