



U.S. Department of Agriculture
Office of Inspector General
Food Safety Initiative
Meat and Poultry Products

**FOOD SAFETY AND INSPECTION SERVICE
IMPORTED MEAT AND POULTRY
INSPECTION PROCESS
PHASE 1**



**Report No.
24099-3-Hy
June 2000**



UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250



DATE: June 21, 2000

REPLY TO

ATTN OF: 24099-03-Hy

SUBJECT: Imported Meat and Poultry Inspection Process

TO: Thomas J. Billy
Administrator
Food Safety and Inspection Service

ATTN: Margaret O' K. Glavin
Associate Administrator

This report presents the results of our audit of the Food Safety and Inspection Service's oversight and controls to ensure that imported meat and poultry products entering U.S. Markets are safe and wholesome. This review is part of the Office of Inspector General's food safety initiative, which also included the implementation of the Hazard Analysis and Critical Control Point System, District Enforcement Operations' compliance activities, and the agency's procedures established for testing meat and poultry products. Your response to the official draft report, dated June 7, 2000, is included as exhibit A with excerpts and the Office of Inspector General's position incorporated into the Findings and Recommendations section of the report. Based on your response, management decisions have been reached on all recommendations except Nos. 6, 14, 15, 16, 19, 26, 32, and 33.

Please follow your agency's internal procedures in forwarding documentation for final action to the Office of the Chief Financial Officer. Management decisions can be reached once you have provided the additional information outlined in the report sections, OIG Position.

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

/s/

ROGER C. VIADERO
Inspector General

EXECUTIVE SUMMARY

FOOD SAFETY AND INSPECTION SERVICE IMPORTED MEAT AND POULTRY INSPECTION PROCESS PHASE 1 AUDIT NO. 24099-03-Hy

RESULTS IN BRIEF

This report presents the results of the first phase of our evaluation of controls to ensure that imported meat and poultry entering U.S. consumer channels is safe and wholesome. This review was part of the Office of Inspector General's food safety initiative, which also included the implementation of Hazard Analysis and Critical Control Point System, District Enforcement Operations' compliance activities, and the procedures established for U.S. Department of Agriculture laboratory testing.

The Food Safety and Inspection Service (FSIS) fulfills its responsibility for ensuring that imported meat and poultry in the U.S. marketplace is safe and wholesome by (a) determining if foreign countries and their establishments have implemented food safety systems and inspection requirements equivalent to those in the United States, and (b) reinspecting imported meat and poultry products from these countries, on a spot-check basis, to verify the purity of the imports.

FSIS administers its food imports safety program primarily through the Office of Field Operations, which reviews foreign countries' inspection systems and reinspects imported meat and poultry products at ports of entry, and the Office of Policy, Program Development and Evaluation, which makes equivalence determinations of foreign country inspection systems. These review and reinspection activities form the basis of FSIS' determinations of whether a country's systems are equivalent to U.S. standards.

Equivalency determinations are FSIS' way of applying the new requirements of the Pathogen Reduction Program and the Hazard Analysis and Critical Control Points (HACCP) Program to overseas operations. Our objective for this phase was to evaluate FSIS policies, procedures, and controls for implementing these programs in

a continuing effort to ensure that food safety systems in foreign countries are equivalent to those in the United States. As part of this objective, we assessed how effectively FSIS carried over its import inspection controls when it reorganized its operations in 1997.

During Phase II and Phase III of our review, we will examine import reinspection activities at selected U.S. ports, and initial equivalence determinations for new countries.

During a 1996 audit we performed of the import inspection program, we recommended that for purposes of reorganization, FSIS develop procedures to ensure that controls present under the pre-HACCP structure would carry over under the new structure. FSIS did not fulfill this recommendation. FSIS implemented its reorganization without developing a comprehensive, detailed plan to ensure that controls were maintained over import inspection operations. Detailed control processes and procedures for determining the equivalency or the continuing eligibility of foreign inspection programs to export meat and poultry products to the United States were not adequately developed, were not incorporated in formal agency procedures for distribution to responsible personnel, or were not functioning as required by regulation. Responsibilities were also not well defined, resulting in unclear lines of authority, minimal supervisory oversight, and training goals that had not been achieved. The absence of a strong internal control structure does not provide reasonable assurance that objectives of the import inspection program are being achieved. Nothing came to our attention during this audit, however, to indicate FSIS allowed unsafe products to enter U.S. commerce.

We found that the absence of formal procedures affected all areas of the import inspection program: requirements for annual certifications and residue test plans have gone unenforced; the eligibility status of importers has not been kept current; and FSIS' equivalency determinations of foreign countries' food safety systems have been based on insufficient documented analysis and support.

Annual certifications. Foreign governments are required to certify annually that each of the establishments in their country that export meat and poultry products to the United States continue to comply with U.S. standards. FSIS did not enforce this requirement and 19 countries were allowed to continue to export to the United States, even though they had not certified their establishments as meeting U.S. standards during 1999.

Residue test plans. Foreign inspection systems are also required to maintain residue control standards equivalent to U.S. standards in order to identify the use of such residues determined by the exporting country's meat inspection authorities or by FSIS as potential contaminants. As of April 29, 1999, 15 of 36 countries that were certified to ship meat and poultry products to the United States had not submitted their 1999 residue test plans.

Eligibility status of importers. When FSIS or foreign inspectors declared an establishment ineligible to export product to the United States, FSIS did not always timely update its reinspection system with this information. As a result, seven establishments from four foreign countries shipped over 4 million pounds of meat and poultry products and presented them for reinspection although they were delisted by their foreign inspection systems. Documentation provided by FSIS did not conclusively prove that all products were produced prior to the delistment date. Also, we could not determine whether FSIS timely updated its reinspection system with critical laboratory results of microbiological tests. These tests are used to determine if a product should be allowed to enter the United States at ports of entry. They are also used, in part, as a basis to determine how products should be sampled at ports of entry and what microbiological tests should be performed. Nothing came to our attention during this audit, however, to indicate FSIS allowed unsafe products to enter U.S. commerce.

Analysis of foreign food safety systems. FSIS cannot demonstrate that it judged the foreign food safety systems of current trading partners according to U.S. standards. At the time of our audit, FSIS had not yet determined equivalence for HACCP and *Salmonella* standards. Control procedures for equivalency determinations were not developed or adequately documented, technical subject-matter experts were not always involved in the process, and specific areas of foreign inspection systems have not yet been reviewed to verify that they are equivalent to U.S. standards. FSIS' country files did not contain sufficient evidence of FSIS' analysis of the information the country governments submitted to document their inspection systems. Moreover, FSIS granted equivalency status for six countries before it performed onsite equivalency verification reviews, and the onsite reviews that were performed were not adequately documented to support what was reviewed and what deficiencies were found. FSIS also lacked timeframes within which to make SSOP and *E. coli* equivalency determinations, and failed to meet the timeframes established for HACCP and *Salmonella* standards.

We concluded that inadequate planning for the transition to the new organization structure, as well as inadequate management oversight of the operational changes to the import inspection processes, contributed to the breakdown in controls that were designed to ensure the safety and wholesomeness of imported products entering the United States.

The weaknesses disclosed during this audit are material control weaknesses in FSIS' import inspection program. As such, they should be included in the agency's annual management control report required by the Federal Manager's Financial Integrity Act.

KEY RECOMMENDATIONS

We recommend that FSIS conduct an assessment of the current organizational structure, clarify roles and responsibilities, and establish a system of management and operating control objectives and processes to ensure the safety and wholesomeness of imported meat and poultry products. FSIS also needs to conduct independent internal control reviews, emphasizing those processes that changed in the reorganization, provide management control training, and report the conditions disclosed in this audit as material management control weaknesses in the import inspection process.

We also recommend that FSIS develop and implement formal procedures, approved by FSIS management, for all aspects of its import inspection program, most specifically those related to (1) making equivalency determinations based on an evaluation of each foreign country's food safety regulatory system, as appropriate, (2) its enforcement of sanitary measures, and (3) entering country eligibility information into FSIS' reinspection system. We also recommend that FSIS enforce the regulatory requirements for countries to submit their residue test plans and test results and establishment certifications by foreign inspection systems.

Concerning equivalency determinations, FSIS needs to establish a time-phased plan to complete each determination and ensure that technical subject-matter experts are involved, as appropriate, in determinations; the determinations are documented; and onsite verification reviews are conducted prior to granting equivalency status. For current trading partners, FSIS needs to develop and implement a policy for onsite verifications of changes in the requirements for foreign systems and ensure that onsite audits are conducted annually.

AGENCY RESPONSE

FSIS accepted 33 of the 35 recommendations in the report. However, FSIS does not believe the issues outlined in the audit report constitute a material management control weakness. FSIS also believes management oversight of import inspection operations is adequate. We have incorporated excerpts from FSIS' response in the Findings and Recommendations section of this report, along with the position of the Office of the Inspector General (OIG). FSIS' response, in its entirety, is attached as Exhibit A.

OIG POSITION

OIG disagrees with FSIS' position that the findings in this report are not material management control weaknesses and that evidence of management oversight was adequate. Basic internal control activities such as documented policies, procedures, supervisory reviews and approvals, delegated responsibilities, and clear lines of authority were lacking in FSIS' operations. OIG will continue to report our conclusion that the findings in this report are material management control weaknesses and should be reported in FSIS' internal control and management accountability reports.

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INTRODUCTION

BACKGROUND

The Federal Meat Inspection Act and the Poultry Products Inspection Act require foreign countries that export meat and poultry to the United States to establish and maintain inspection systems that are equivalent to the U.S. inspection system. Meat and poultry imported into the United States must originate in countries and plants approved to export to the United States. FSIS is responsible for (1) reviewing and assessing foreign inspection systems and facilities that export meat and poultry to the United States to ensure that standards are equivalent to those in the United States, and (2) reinspecting imported meat and poultry products at ports of entry to ensure that only safe, wholesome, unadulterated, and properly labeled products enter U.S. commerce.

Food safety equivalence evaluations are based upon provisions in the Agreement on the Application of Sanitary and Phytosanitary Measures (Agreement), which appears in the Final Act of the Uruguay Round of Multilateral Trade Negotiations, signed on April 15, 1994. The Agreement became effective in January 1995 concurrently with establishment of the World Trade Organization, which superseded the General Agreement on Tariffs and Trade (GATT), as the umbrella organization for international trade. Article 4.1 of the Agreement requires each member to accept as equivalent the food regulatory system of another country if the exporting member objectively demonstrates to the importing member that its measures achieve the importing member's appropriate level of sanitary protection. Regulations governing FSIS operations are codified in 9 Code of Federal Regulations (CFR) Chapter III, Parts 300, 416, and 417.

Under FSIS' pathogen reduction/Hazard Analysis and Critical Control Point (HACCP) regulatory proposal published in February 1995, HACCP programs would be required in meat and poultry plants, along with interim targets for pathogen reduction in slaughter establishments and microbial testing to meet those targets. In fiscal year (FY) 1996, the Final Rule was published on the pathogen reduction system and the HACCP system. Under these systems, a country's status as having controls and performance standards "equivalent" to those in the United States is determined in four areas.

HACCP. All plants must develop, adopt, and implement a HACCP plan for each of their processes. Under HACCP, plants identify critical control points during their processes where hazards such as microbial contamination can occur, establish controls to prevent or reduce those hazards, and maintain records documenting that controls are working as intended.

Mandatory Generic *Escherichia coli* (*E. coli*) testing in slaughter plants. All meat and poultry slaughter plants are required to conduct microbial testing of carcasses for generic *E. coli* as an indicator of the adequacy of the plant's control over fecal contamination.

Pathogen reduction performance standards for *Salmonella*. Slaughter plants and plants producing raw ground products are required to ensure that their *Salmonella* contamination rate is below the current national baseline incidence.

Sanitation Standards Operation Procedures (SSOP). As of the beginning of 1997, all plants were required to implement plant-specific operating procedures for sanitation to ensure they were meeting their responsibility to keep their facilities and equipment clean.

Prior to FSIS' reorganization, FSIS focused on individual plants and evaluated whether foreign food regulatory systems were "at least equal to" the U.S. system. The principle underlying FSIS' current import inspection activities is the "systems approach," which focuses on a country's overall inspection system rather than on individual plants. The systems approach includes an evaluation of the inspection system of each country seeking to export or already approved to export to the United States to ensure it has inspection controls equivalent to those of the United States. FSIS does not suspend trade with exporting countries while this process is underway.

Because the eligibility of countries to export meat or poultry to the United States was initially evaluated on a case-by-case basis through analysis of applications followed by onsite audits, all "at least equal to" countries that were eligible for export of meat and poultry to the United States were allowed to continue to export to the United States until their inspection systems could be determined "equivalent" under the pathogen reduction/HACCP standards. A total of 37 countries were approved under the "equal to" system. The burden for demonstrating equivalence rests with the exporting country and the importing country

is free to set any level of protection it deems appropriate to control or eliminate a food safety hazard.

Before a foreign country can initially export meat or poultry to the United States, it must apply for a determination of equivalency. Applications must contain enough technical and scientific evidence for FSIS to determine that the country's sanitary measures, oversight, and enforcement are equivalent to the U.S. system. This evaluation is to consist of a document review and an onsite equivalency verification review. The initial equivalence determination for a new trading partner is subject to notice and comment rule making when the country is listed in the Code of Federal Regulations as eligible to export to the United States.

A document review is an evaluation of laws, regulations, directives, and other written material used by the foreign country to operate its inspection program. FSIS will evaluate the country's inspection system in five risk areas which include controls over animal diseases, sanitation, residue, processing and slaughter, and enforcement. If the document review finds the country's system satisfactory, FSIS will conduct an onsite equivalency verification review to evaluate the foreign country's oversight program and practices, and to determine whether system controls are operating as represented to FSIS.

After a country is determined to have an equivalent system and is eligible to export to the United States, FSIS will rely on the country to carry out daily inspections. However, FSIS will monitor the country's activities. Besides randomly sampling meat and poultry products for reinspection as they enter the United States, FSIS will conduct onsite reviews of the country's inspection systems to ensure that its procedures and standards remain equivalent. Reviewers will visit certified plants and focus on the five areas of risk. These reviews should generally be conducted annually, but their frequency depends on the country's performance history and on the results of product reinspections at the ports of entry. A total of 30 onsite reviews were conducted in exporting countries in 1997, and a total of 24 in 1998. Based on information provided to us during the field work phase, 13 onsite reviews had been conducted in 1999.

The reinspection of imported meat and poultry products at U.S. ports of entry provides FSIS with a means of assessing the effectiveness of a foreign government's inspection system while ensuring that only safe, wholesome, unadulterated, and properly labeled products enter U.S. commerce. Reinspection is directed by FSIS' Automated Import

Information System, which stores reinspection results from all ports of entry for each country and plant. A description of each lot arriving at any of the approximately 150 official U.S. import inspection establishments is entered into the Automated Import Information System. Lots are reinspected for transportation damage, labeling, proper certification, general condition, and accurate count. The Automated Import Information System may, for example, generate residue and microbiological laboratory test assignments based on the compliance histories of the plants, countries, and products being presented for reinspection. Products that pass reinspection are allowed to enter U.S. commerce; products that do not pass are stamped "U.S. Refused Entry" and must be exported, destroyed, or converted to animal food.

FSIS administers its imported meat and poultry inspection program primarily through the Office of Policy, Program Development and Evaluation, which reviews food safety requirements imposed by foreign governments, and the Office of Field Operations, which inspects overseas plants and imported meat and poultry products. These review and inspection activities form the basis of FSIS' determinations of whether a country's inspection systems are equivalent to U.S. standards.

Within the Office of Policy, Program Development and Evaluation, the International Policy Division is responsible for providing leadership in international policy development for all programs, regulations, and activities for the agency. Within this division, the Equivalence and Planning Branch is responsible for formulating policies for determining a foreign country's eligibility to export meat and poultry products to the United States.

During 1998, the United States imported about 3 billion pounds of meat products and about 53 million pounds of poultry products. The volume of imports from Australia, Canada, New Zealand, Argentina, and Denmark totaled approximately 2.8 billion pounds during 1998. About 21 percent of the products presented to FSIS for reinspection were subjected to further examinations including laboratory analysis, product examination, and condition of containers. Approximately 1.6 percent of these reinspected products were rejected for contamination, processing defects, unsound condition, violative net weight, pathological or labeling defects, missing shipping marks, composition/standard, Animal and Plant Health Inspection Service/Veterinary Services requirements, residues, container condition, transportation, or miscellaneous reasons.

For 1999, about 3.3 billion pounds of meat and poultry products were shipped by foreign countries to the United States and presented for FSIS reinspection. The countries which shipped the greatest amount of meat and poultry products in 1999 were: Canada (1.6 billion pounds), Australia (735 million pounds), New Zealand (461 million pounds), followed by Denmark (119 million pounds), Brazil (106 million pounds), Argentina (103 million pounds), and Uruguay, (51 million pounds). These seven countries accounted for nearly 97 percent of the total meat and poultry products shipped by foreign countries to the United States during 1999. Fresh red meat represented over 85 percent of the total amount – nearly 13 percent was processed product, and the remainder was fresh poultry.

With the advent of HACCP and the pathogen reduction program, FSIS began implementing a comprehensive reorganization of the agency to streamline its operations and increase the efficient use of its resources. By 1997, FSIS substantially completed this reorganization. The new field structure unified four separate functions to carry out all inspection and compliance activities, 46 regional and area offices were reduced to 18 district offices, and a Technical Service Center was opened in Omaha, Nebraska, to provide inspection expertise for the onsite reviews and the port-of-entry reinspection process.

OBJECTIVES

The purpose of our review was to evaluate FSIS' policies and procedures to ensure that foreign countries and their establishments have adequately implemented food safety systems and inspection requirements equivalent to U.S. requirements. Our secondary objective was to determine whether controls that existed over the inspection process before FSIS reorganized had been maintained after reorganization.

SCOPE

To evaluate FSIS' policies and procedures over the food imports safety program, we focused on operations and statistical information for 1997, 1998, and 1999 through July 1999. However, we reviewed prior years' operations as deemed necessary. During the next phases of our audit, we will continue our evaluation of the reinspection process, and the initial equivalence determination process.

We performed work at FSIS' Headquarters in Washington, D.C., and the Technical Service Center in Omaha, Nebraska. Staff at FSIS' Headquarters are responsible for (a) developing international policy

for all programs, regulations, and activities, (b) formulating equivalency determination policies, (c) determining a foreign country's eligibility for importation of meat and poultry products into U.S. markets, (d) managing a program of regulatory oversight and inspection to ensure that meat and poultry products are safe, wholesome, and properly labeled, and (e) maintaining FSIS' computer data base which assigns reinspection levels for meat and poultry products imported from those countries and establishments eligible to export products to the United States. We reviewed the files for 37 countries who applied for equivalency determinations to determine whether equivalency determinations were adequately documented and whether procedures were in place to ensure regulatory requirements were met. As of April 15, 1999, 28 countries had been approved as equivalent for SSOP and *E. coli* testing procedures. During the course of our fieldwork, equivalency determinations (documentation reviews) were in process for HACCP and *Salmonella* standards; therefore, we did not comment on these areas in this report. We will review these areas in a future audit.

Staff at the Technical Service Center are responsible for (a) providing technical assistance, guidance, and advice for inspection personnel and the industry, (b) conducting foreign reviews, including the development of systems, methods, and procedures for conducting these reviews, and (c) entering laboratory test failure results into the FSIS computer data base. The review system is intended to assure consumers that foreign countries seeking eligibility to export meat and poultry products to the United States, or those already determined eligible to do so, have an inspection system equivalent to U.S. requirements.

Our work was initiated in October 1998 and was conducted in accordance with generally accepted Government auditing standards.

METHODOLOGY

To accomplish our objectives, we discussed current operations with FSIS officials and staff and reviewed supporting documentation. At FSIS Headquarters, we concentrated on the responsibilities of the Office of Policy Program, Development and Evaluation; the Office of Field Operations; and the Office of Management Internal Control Staff. Our review included analysis of records and other documents and discussions to determine if agency responsibilities are being carried out as intended by regulation.

At the Office of Field Operations' Field Automation and Information Management Division, we familiarized ourselves with FSIS' computer data base, the Automated Import Information System. We obtained a basic understanding of how information is entered into the Automated Import Information System relating to foreign country and establishment certifications and laboratory test results, and we obtained the Automated Import Information System computer printouts of products presented for FSIS reinspection by foreign countries.

At the Technical Service Center, we acquired a basic understanding of the evolving responsibilities regarding the reinspection process, particularly those related to laboratory test results. We also obtained information about the role of the Technical Service Center foreign review staff in conducting audits to ensure that the inspection systems of foreign countries comply with equivalency requirements.

At FSIS' Headquarters offices, we reviewed documentation and performed analysis of files for all 37 countries that applied for participation in the import program under the HACCP and pathogen reduction standards. We also evaluated procedures used to determine whether country inspection systems were equivalent to those in the United States. We reviewed and analyzed procedures used by FSIS to implement the requirements of the Federal Managers Financial Integrity Act. These documents included yearend management control reports and FSIS directives for management controls.

FINDINGS AND RECOMMENDATIONS

CHAPTER 1	FSIS MANAGEMENT CONTROLS OVER THE IMPORT INSPECTION PROGRAM NEED TO BE ENHANCED
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Office of Management and Budget (OMB) Circular No. A-123, Management Accountability and Control, dated June 1995, states that agency managers shall incorporate management controls in the strategies, plans, guidance and procedures that govern their programs and operations. However, we found that when FSIS reorganized, management controls and written operational procedures were inadequate to assure that controls over the import inspection program were maintained under the new organizational structure. Our review disclosed: a lack of management controls over key import inspection functions; inadequate documentation to support the equivalence determination process; non-compliance with existing controls; a lack of documentation to ensure that ongoing monitoring and supervision occurred; and processes that did not reflect operating procedures as outlined in functional statements and documents provided to the Office of Inspector General (OIG) and the general public. In addition, all personnel have not received adequate training for the tasks assigned. FSIS implemented the reorganization prior to developing a comprehensive, detailed plan to ensure the effectiveness of controls over all aspects of the import inspection process. In the absence of sufficient management controls, there is reduced assurance that the goals and objectives of the import inspection program are being fulfilled.

FINDING NO. 1

**COMPREHENSIVE
REORGANIZATION
IMPLEMENTATION PLAN
WAS NOT DEVELOPED**

The U.S. General Accounting Office's Standards for Internal Control in the Federal Government,¹ dated November 1999, states that internal controls should provide reasonable assurance that the objectives of the agency are being achieved. We found that program controls have not been established or are inadequate to assure that the import

inspection program is operating as intended. Although FSIS had originally planned to reorganize over a 3-year period, a decision was made to make the transition to the new structure within 1 year. As a result, the transition was made without FSIS ensuring adequate controls were in place and functioning. The separation of functions that resulted from the reorganization requires considerable coordination between staffs which, in key areas, has either not occurred, or not effectively occurred. In addition, a planned retraining program for FSIS personnel has not been fully implemented.

As a result of our requests for documentation to support FSIS' transition to its current organizational structure, we were provided with a history of planning proposals that were never carried out, and a "Top-to-Bottom Review" that was self-described as a brainstorming project. This internal FSIS review recognized the need to establish and maintain a strong internal control structure within FSIS.

In February 1995, FSIS published a proposed rule, Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, which outlined its strategy to change inspection to a more scientific, industry performance-based system that would better protect the public health. In conjunction with the proposed rule, the FSIS Administrator announced that the Agency would look at itself from "top to bottom" and define an organizational structure compatible with the goals and strategies of the pathogen reduction/HACCP regulation.

FSIS prepared a report, entitled "Top-to-Bottom Review," dated August 1995, which outlined FSIS' regulatory roles and proposed an organizational structure. The review recommended that FSIS appoint an implementation team to develop a reorganization plan, assess the

¹These standards were updated in 1999 because of revisions to OMB Circular A-123 and other laws that have prompted a renewed focus on internal control (The Government Performance and Results Act of 1993, the Federal Financial Management Improvement Act of 1996). The federal standards also recognize internal control guidance developed by the Committee of Sponsoring Organization of the Treadway Commission (COSO).

organization on an ongoing basis, and identify complementary measures that would enhance organizational effectiveness. During our audit, we determined that many of the recommendations included in the "Top-to-Bottom Review" were not implemented by FSIS. We could not obtain information explaining why they were not.

In 1996, the U.S. Department of Agriculture (USDA) Secretary announced a comprehensive reorganization of FSIS designed to prepare for implementation of HACCP. An April 16, 1997, memorandum from the Director, Import Inspection Division, to the Deputy Administrator, Office of Field Operations, outlined a plan to provide assurance that the import inspection functions were properly controlled during the transition to the new organizational structure. The memorandum also recognized the OIG concerns about the change in management of the import inspection function and called for an assessment to be conducted after reorganization to determine what actions would be needed to properly control the reinspection of imported products for the long term. However, many of the activities outlined in this plan were never accomplished, and, again, we could not obtain information explaining why they were not.

According to an FSIS official involved in the transition, it was important that all facets of the transition connect before the reorganization was officially implemented. One important facet involved inspector retraining. Former Import Field Office Supervisors were converted to Import Coordinators and were to assist District Managers and Circuit Supervisors as they gained import inspection expertise. It was important that domestic inspectors receive import inspection training because domestic and import inspections have notable differences. For example, if the hindquarter of a carcass contains *E. coli*-causing fecal traces or some other defect, the domestic inspector can allow the affected portion to be removed. However, the import inspector would be required to reject the entire shipment.

According to the proposed transition plan, the reorganization was to be completed over a 3-year period ending September 1998. However, before it was assured that all of the components of the transition were in place, including inspector retraining, an October 23, 1997, memorandum from the Deputy Administrator, Field Operations, stated that all supervisory responsibilities for import inspection activities and personnel were to be transferred to Circuit Supervisors on October 12, 1997. USDA's 1999 Budget Explanatory Notes for Committee on Appropriations states, "although the original plan was to implement the reorganization by FY 1999, a determination

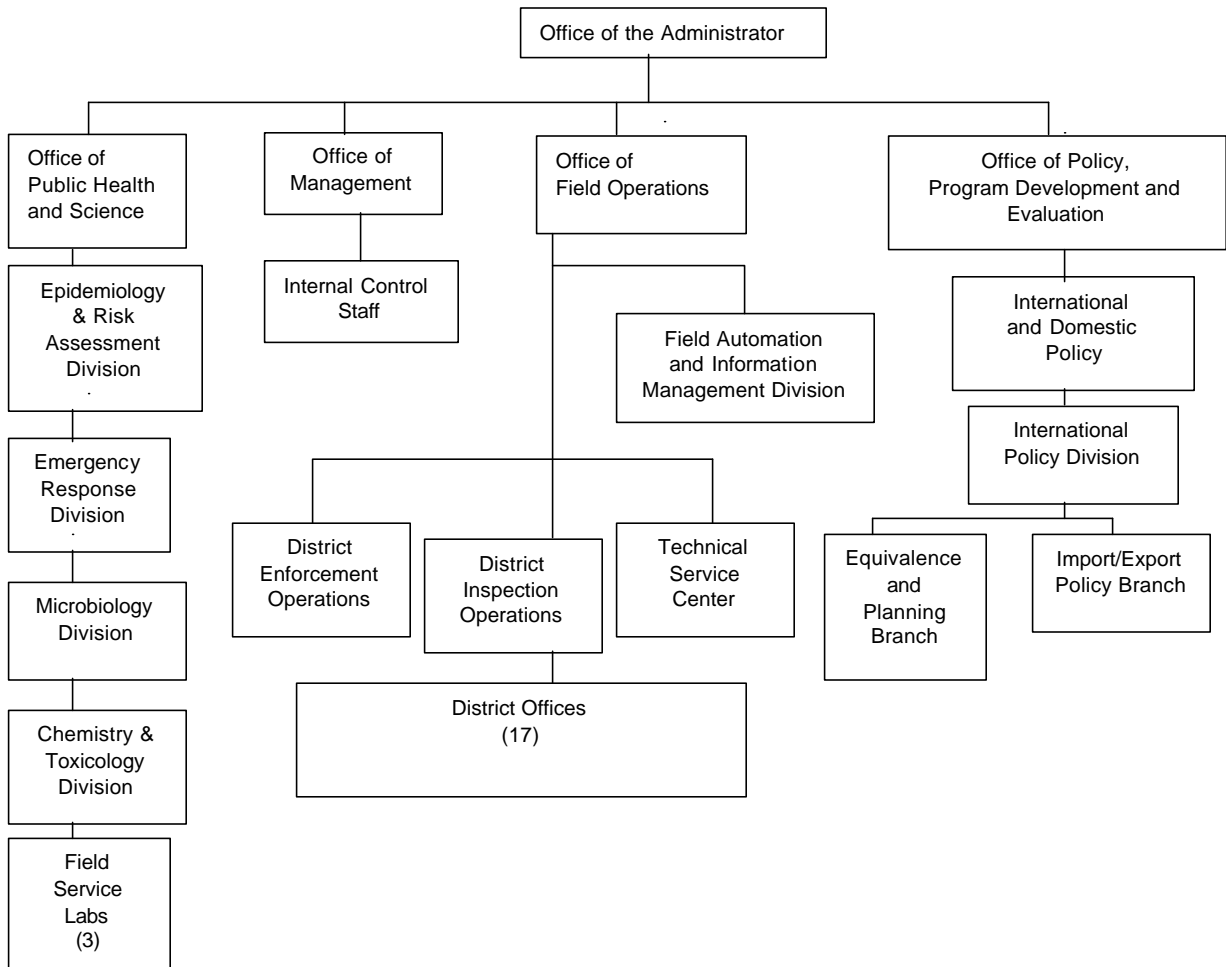
was made to move forward and complete the reorganization as quickly as practical." As a result, the reorganization went into effect before the transition plan was fully implemented.

Prior to 1985, FSIS operated under an organizational structure similar to the one currently in place. According to an FSIS official, FSIS internal reviews of this structure, as well as reviews by the OIG and the U.S. General Accounting Office, concluded that controls could be more effective. Between 1985 and 1996, the responsibility for carrying out the requirements of Federal meat and poultry inspection laws for imported products was unified within one office, FSIS' International Programs, under a single deputy administrator. FSIS consolidated its import inspection program and achieved a structure that contributed to the efficiency of the program. The import inspection function was separate from all other functions, and the unit responsible for it had both line and policy-making authority. An OIG audit performed to evaluate this organizational structure (Audit No. 38002-4-Hy, dated March 1989) concluded that controls over the import inspection process had improved since a prior (1987) audit.

An OIG audit, Audit No. 24099-01-Hy, conducted in 1996, recommended that as FSIS' reorganization was implemented, existing controls over the import meat and poultry inspection process be maintained. In response, FSIS indicated that the Director, Import Inspection Division, would ensure that accountability was in place for imported product and that inspection expertise was maintained. The response also stated that a comprehensive and detailed plan of action would be developed to maintain an effective import function. Based on our discussions with responsible FSIS officials, we found the plan was never developed.

In reorganizing, FSIS separated import inspection responsibilities between the Offices of Management; Field Operations; Public Health and Science; and Policy, Program Development and Evaluation. Under the reorganization plan, FSIS unified some functions, separated others, and reduced its office network from 46 field offices to 17 district offices. FSIS also established a Technical Service Center, located in Nebraska. Although this new field structure unified formerly separate functions to carry out inspection and compliance activities, it had the effect of fragmenting import inspection activities and increased the need for a strong internal control structure to ensure effective operations. The chart on the opposite page depicts the primary part of FSIS' reorganized structure that affects the import inspection program.

Figure 1: FSIS Organizational Structure Related to the Import Inspection Process



We found that as a result of the reorganization, the import inspection process is scattered among different entities and the operations are diffused among a number of districts. The separation of functions has required greater coordination between staffs, and has resulted in the need for retraining inspectors and the Technical Service Center foreign inspection system reviewers. However, FSIS has not developed adequate policies and procedures to facilitate this coordination, and training requirements have not been fully achieved.

OMB Circular A-123 requires managers to ensure that appropriate authority, responsibility, and accountability are defined and delegated to accomplish the mission of the organization, and that an appropriate organizational structure is established to effectively carry out program responsibilities. While we recognize there are transition difficulties in any reorganization effort, FSIS recognized the need, but did not take action, to ensure that its foreign inspection process control systems

are adequately developed, documented, and communicated to its staff. We conclude the findings in this report have occurred because FSIS did not adequately plan for the transition to the new organizational structure. In addition, there has been inadequate management oversight of the operational changes to the import inspection processes. As a result, a breakdown in controls that were designed to ensure the safety and wholesomeness of imported products entering the United States has occurred. Nothing came to our attention during this audit, however, that indicated FSIS allowed unsafe meat and poultry products to enter the United States.

According to FSIS officials, the audit failed to acknowledge the oversight in place that is responsible for managing change to import policies and procedures. However, the audit report does recognize the roles and responsibilities of these management officials. The audit disclosed weaknesses in FSIS' management control structure at various levels of the import inspection function after FSIS' reorganization. These controls include clearly defined roles and responsibilities, documented management reviews and approvals, directives/operating manuals, properly managed and maintained documentation, and a positive and supportive management attitude toward internal control. Controls over the reinspection process at U.S. ports of entry will be evaluated during Phase II of this audit.

RECOMMENDATION NO. 1

Conduct an in-depth assessment of the current organizational structure to establish a system of control objectives and processes to ensure that the goals of

import inspection process are achieved.

Agency Response

FSIS agrees with this recommendation. FSIS will assess the current organizational structure and identify import inspection controls, objectives and processes. The assessment will be completed by May 2001.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 2

Require increased management oversight and approval of changes to import inspection operations and procedures.

Agency Response

FSIS believes that management oversight and approval of changes to import inspection operations and procedures is adequate. Inspection of imported meat and poultry product is controlled through a multi-tiered supervisory and management oversight structure.

FSIS will prepare a summary of the management oversight functions and procedures. These procedures will outline FSIS' efforts to strengthen management controls for all import operations. The consolidated written procedures will be developed by March 2001.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 3

Provide management control training to agency managers.

Agency Response

FSIS agrees with this recommendation. FSIS believes in continuous education and refresher training for its managers in a number of areas. FSIS will make arrangements for its Imported Meat and Poultry Inspection managers at Headquarters, District Offices, and the Technical Service Center to receive additional training on management controls. The agency will arrange for training similar to the Management Accountability and Control (OMB Circular A-123) course offered by the Government Audit Training Institute at the Graduate School, USDA by December 1, 2000. FSIS will explore including a training module on management controls in its Management Leadership and Development Program, which will be available to all agency managers.

OIG Position

We accept FSIS' management decision.

FINDING NO. 2

**INDEPENDENT INTERNAL
CONTROL REVIEWS
HAVE NOT BEEN CONDUCTED**

FSIS has not conducted independent internal control reviews of the import inspection program. According to the Director, Internal Control Staff, few resources were assigned to the staff; consequently, FSIS relied on each branch and program area to review its own activities and determine if vulnerabilities

in operations exist. In the absence of independent internal control reviews, FSIS management has reduced assurance that adequate controls are in place, and functioning, over the import inspection program. These reviews are critical since FSIS has dispersed the responsibilities for the import inspection program among various operational units.

The Federal Manager's Financial Integrity Act requires each agency to evaluate the adequacy of its management controls. The correction of material weaknesses is to be considered in the agency's strategic planning, annual performance planning, and reporting processes.

As part of FSIS' reorganization, the Internal Control Staff was established and placed within the Office of Management. The Internal Control Staff is responsible for assisting management in carrying out its management control responsibilities specified in OMB Circular A-123 and FSIS Directive 1090.1, "Management Controls." To fulfill these responsibilities, the staff is empowered to independently and objectively assess the effectiveness of the agency's internal control systems, provide deputy administrators and program managers with assessments of its effectiveness, and monitor correction of any identified material weakness.

We found that the Internal Control Staff has not conducted independent assessments of import inspection activities to ensure that programs are managed effectively and comply with applicable laws and regulations. Each program office within FSIS has conducted its own assessment or evaluation of its programs to ensure compliance with management accountability and controls. The program offices responsible for the import inspection program have consistently found no areas of vulnerability during their own reviews, and the Internal Control Staff has not validated these findings.

Standards for Internal Control in the Federal Government states, in part, that qualified and continuous supervision should be provided to ensure that internal control objectives are achieved. In addition, the

"Top-to-Bottom Review" stated that FSIS' new organizational structure should have resulted in an improved supervisory span of control. However, we were unable to identify documented evidence of supervisory review or oversight over district office functions, the Technical Service Center, and the Equivalence and Planning Branch. According to an Office of Field Operations management official, if staff members are doing what they are supposed to do, then they do not need oversight. The Office of Field Operations has not conducted any reviews of the Technical Service Center and district office activity and assumed that personnel were doing a good job based on positive comments from industry and foreign governments.

The Director of the Internal Control Staff agreed that independent reviews are necessary, but noted that insufficient staff precluded his office from performing the reviews. He also noted that during the reorganization, the Internal Control Staff was assigned eight staff members and that this has proven insufficient to complete the activities mandated by FSIS Directive 1090.1.

We found, however, that some of the activities mandated by FSIS Directive 1090.1 are no longer required by OMB Circular A-123. FSIS' requirements are based on a 1986 version of the OMB circular, which has been superseded by a 1995 revision. The circular no longer requires agencies to segment themselves into assessable units, perform risk assessments of these units, rate the units, develop a 5-year management control plan, and conduct evaluations of units rated high or medium risk. It now provides a framework for integrating management control assessments with other work performed by agency managers, auditors and evaluators. In addition, the circular allows agencies to determine the appropriate level of documentation needed to support their annual assurance statements to Congress. FSIS did not incorporate any of these changes in its directive on management controls.

We were advised that the Internal Control Staff is in the process of re-engineering its internal control process. According to an FSIS official, a program management plan is being developed which will address procedures that will be used for assessing the controls and monitoring activities for programs within FSIS.

RECOMMENDATION NO. 4

Revise FSIS Directive 1090.1 to incorporate the provisions of OMB Circular A-123, Revised, "Management Accountability and Control," dated

June 21, 1995, and to document specific program control objectives and the review procedures that will provide management reasonable assurance on the effectiveness of controls.

Agency Response

FSIS agrees with this recommendation. FSIS has updated its Directive 1090.1 to incorporate the provisions of OMB Circular A-123, Revised, Management Accountability and Control," dated June 21, 1995. The draft directive outlines a process for establishing program control objectives and procedures that will provide management reasonable assurance on the effectiveness of controls. The draft document has been reviewed internally and is currently being reviewed by the National Joint Council, an employee union. We expect the directive to be finalized by October 1, 2000.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 5

Require the FSIS Internal Control Staff to conduct periodic independent assessments of FSIS' programs and operations, emphasizing those processes

that changed in the reorganization.

Agency Response

FSIS agrees with the intent of this recommendation. FSIS will establish selection criteria for conducting periodic independent assessment of FSIS' programs and organizations as appropriate. The Executive Steering Committee for Management Controls will identify and prioritize for independent assessment selected processes that changed during the 1997 reorganization that should be reviewed. It should be noted that FSIS already requires the Internal Control Staff (ICS), to conduct independent assessments of FSIS' programs and operations. However, FSIS will direct the ICS, through guidance provided by the FSIS Executive Steering Committee on Management Controls, to conduct independent assessments of selected processes that changed during the 1997 reorganization. A memorandum of instruction to the ICS will be issued by September 1, 2000, from the Executive Steering Committee on Management Controls to address this recommendation.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 6

Report the conditions disclosed in this audit as material management control weaknesses in the import inspection process.

Agency Response

FSIS strongly disagrees with the OIG recommendation that the issues outlined in this audit report constitute a material management control weakness. They acknowledge the need to strengthen management controls and procedures, but they do not believe that the findings of this audit represent a reportable material management control weakness. Although FSIS agrees with most of the suggested management controls improvements in this audit, they do not believe they constitute a reportable material weakness of the import inspection process. FSIS will address opportunities for strengthening the management controls identified in this audit report and report them in accordance with the Agency's assessment of OMB Circular A-123 requirements.

OIG Position

OIG disagrees with FSIS' position that the findings in this report are not material control weaknesses. Basic control activities, such as documented policies, procedures, supervisory reviews and approvals, delegated responsibilities, and clear lines of authority were lacking in FSIS' operations. In the absence of the in-depth assessment of controls agreed to in response to Recommendation No. 1, FSIS should report the findings in this audit as material control weaknesses in the import inspection operations.

FINDING NO. 3

COORDINATION AMONG RESPONSIBLE PERSONNEL HAS NOT BEEN EFFECTIVE

Key features of the "Top-to-Bottom Review" proposed organizational model included highly integrated organizational components. We found, however, that there was a lack of effective coordination between the Office of Policy, Program Development and Evaluation and the Office of Field Operations and clear

separation of specific foreign system review (audit) tasks related to the equivalency determination process. This occurred, in part, due to unclear lines of authority and training goals that had not been achieved. As a result, there is reduced assurance that controls over the import inspection program have been maintained.

a. Roles and Responsibilities Overlap and are not Clearly Defined

The "Top-to-Bottom Review" report stated, in part, that although the current organizational structure² may appear to be adequate, the roles and responsibilities set out in agency functional statements have eroded over time. It also made reference to a duplication of effort and confusion about relative roles and responsibilities between specific staffs. We found this situation has occurred between the Technical Service Center and the Equivalence and Planning Branch staffs. In the absence of proactive management over the Technical Service Center and the Equivalence and Planning Branch, the two units created a working relationship, with the Equivalence and Planning Branch assuming a greater role in the equivalency verification process than specified in its functional statement.

According to a paper prepared by FSIS entitled Importing Meat and Poultry to the United States, a country must apply for a determination of equivalency before initially exporting meat or poultry to the United States. A two step evaluation consisting of a document review and an onsite equivalency verification review is conducted to determine that the country's sanitary measures, oversight, and enforcement are equivalent to the U.S. system. The Equivalence and Planning Branch maintains control over the document review process and the Technical Service Center reviewers conduct the onsite equivalency verification reviews. These reviews and inspection activities form the basis of FSIS' determinations of whether a country's inspection systems are equivalent to the United States.

The Standards for Internal Controls in the Federal Government states that key duties and responsibilities need to be divided or segregated among different people to reduce the risk of error. Agency functional statements assign the Technical Service Center responsibility for: interacting on a regular basis with other staffs to stay abreast of current issues, trends, and problems encountered, and integrating this information into onsite reviews of country

² The organizational structure in place prior to the 1997 reorganization.

inspection systems; designing operating systems, methods, guidelines, and processes for reviewing foreign, state, and domestic programs and conducting targeted program reviews of these operations; and, reviewing foreign programs to ensure compliance with equivalency requirements. Agency functional statements assign the Equivalence and Planning Branch responsibility for developing methods of review for foreign inspection systems and specifies that the Equivalence and Planning Branch is to maintain liaison with the Technical Service Center. However, we found that the Equivalence and Planning Branch does not routinely provide Technical Service Center reviewers with documentation provided by foreign countries to support their inspection programs prior to the Technical Service Center's onsite equivalency reviews. According to FSIS officials, copies of all incoming documents from foreign countries that export to the United States are routinely sent to the Director of the Technical Service Center Review Staff. However, we did not identify this type of documentation during our review of files maintained at the Technical Service Center. FSIS provided an April 13, 2000, document which stated, "Although EPB does not have written procedures for transmitting information to the TSC, the review staff now routinely reviews all documents received by IPD concerning the audit countries."

The Equivalence and Planning Branch has assumed a greater role in the foreign equivalence review process than outlined in functional statements and written documents prepared by FSIS. This expanded role includes reviewing and editing the foreign equivalency review (audit³) reports. However, the functional statements appear to provide for a separation of duties between the documentation review and the onsite verification review and subsequent audit report.

According to an FSIS paper entitled, "FSIS Process For Evaluating The Equivalence of Foreign Meat And Poultry Food Regulatory Systems," dated March 1999, equivalence decisions based on foreign food regulatory system documentation of specific sanitary measures are subsequently verified by onsite audits. However, our reviews of country files maintained at the Technical Service Center disclosed limited information on the Equivalence and Planning Branch document reviews of foreign food regulatory systems that need to be verified as part of the onsite reviews. The Equivalence

³ While FSIS refers to these equivalency reviews as audits, they are not conducted in accordance with Government Auditing Standards.

and Planning Branch instituted a pre-audit telephone conference with the Technical Service Center reviewers to review information compiled by Equivalence and Planning Branch program analysts concerning prior audit issues, establishments known to have problems, port-of-entry violations, consumer complaints, and other matters. Equivalence and Planning Branch program analysts obtain this information from the Import/Export Policy Branch, the Automated Import Information System, country files, and other resources and divisions throughout the agency. The Technical Service Center reviewers are to use this information as a basis for planning their foreign equivalency reviews. However, documentation provided by the foreign country was not forwarded to the Technical Center Reviewers in order to ensure that all information submitted by the foreign country is verified during the onsite review. According to FSIS officials, the Technical Service Center reviewers can request that all documentation in the International Policy Division country file be sent to them.

Agency functional statements state that the Technical Service Center provides feedback on the results of its foreign inspection reviews to agency managers and the Equivalence and Planning Branch. The Technical Service Center review staff prepares a draft audit report and sends it to the Equivalence and Planning Branch for review. According to Equivalence and Planning Branch officials, the Technical Service Center reviewers are not to make recommendations because they do not determine equivalency. Recommendations for corrective actions are made by the Equivalence and Planning Branch, with input from the Technical Service Center. The Equivalence and Planning Branch staff reviews the draft reports and makes changes, primarily grammatical but sometimes substantive. In some reports we reviewed, the Equivalence and Planning Branch inserted recommendations and conclusions concerning system failures and corrective actions taken by foreign country officials. According to the Director of the Technical Service Center review staff, the Equivalence and Planning Branch is involved in the report review process due to a lack of staff, namely an Assistant Director of the review staff. He added that the reviewers are not obligated to make substantive changes, but will discuss them with the Equivalence and Planning Branch and reach an agreement. If the changes are substantive, the Equivalence and Planning Branch may request to see the report after revisions have been made.

In response to our concerns over the Equivalence and Planning Branch's role in the report process, FSIS officials provided an April 3, 2000, document which stated that the purpose of the Equivalence and Planning Branch review of the report is to ensure that all relevant information that the reviewer collected is presented in the report. While reviewing the report for substantive information, editorial comments are made for the purpose of clarifying the findings. Reviewers are not asked to change the facts. Rather, they may be asked to clarify facts so that the International Policy Division, in making equivalence determinations, can use the report.

The Equivalence and Planning Branch also maintains control over the audit resolution process. The Equivalence and Planning Branch staff sends letters to the foreign countries and receives their corrective action plans. Although the Equivalence and Planning Branch should share this information with the Technical Service Center as part of the resolution process, we found that the Technical Service Center staff was not always kept informed of agreements reached. For example, the Equivalence and Planning Branch granted a country flexibility in species testing, but the Technical Service Center reviewers were not told this prior to the onsite equivalency review.

The Equivalence and Planning Branch program analysts are to use information from the Technical Service Center audit reports to make equivalency determinations. Based on functional statements which require the Technical Service Center to provide feedback on the results of foreign inspection reviews to agency managers, the Technical Service Center audits should represent independent research upon which the Equivalence and Planning Branch can base its conclusions of equivalency or non-equivalency. However, FSIS officials believe that the issue of independence is off base, and that by organizational design the two units work closely on audits.

The position of FSIS officials is that the OIG audit should focus on outcome, not how FSIS has decided to manage this function. FSIS views the roles and working relationship between the Technical Service Center and the Equivalence and Planning Branch as very positive and harmonious, and added that the Director of the Technical Service Center Review Staff and the Chief of the Equivalence Branch are in daily contact regarding equivalence determinations.

The Equivalence and Planning Branch must also coordinate with the Office of Field Operations' Field Automation and Information Management Division to ensure that information about delisted establishments is updated in FSIS' database, the Automated Import Information System. We found that the Equivalence and Planning Branch has not always properly coordinated with the Field Automation and Information Management Division and that some information in the Automated Import Information System on delisted establishments is inaccurate and not timely updated (see Finding Nos. 6 and 7).

This audit has raised a number of concerns regarding the coordination among several units within FSIS and identified examples of breakdowns in several processes. At the time we visited the Technical Service Center, the country files contained limited information received by the Equivalence and Planning Branch from foreign inspection systems. Also, undated administrative processing procedures developed by the Equivalence and Planning Branch did not include the Technical Service Center for distribution of incoming documents from foreign inspection systems. Our discussions with staff from the Equivalence and Planning Branch, and the Field Automation and Information Management Division disclosed confusion as to roles and responsibilities. FSIS needs to revisit its functional statements and develop procedures to clearly define the roles and responsibilities of the staffs involved.

b. Training Plan Not Fully Implemented

Standards for Internal Controls in Federal Government requires management to ensure that skill needs are continually assessed and that the organization is able to obtain a workforce that has the required skills that match those necessary to achieve organizational goals. According to recommendations outlined in the "Top-to-Bottom Review," FSIS personnel must be at least as knowledgeable as the regulated industry. Therefore, training was critical. Even though FSIS assigned new duties to personnel under its reorganized structure, it did not fully implement a training program to ensure that employees were proficient in those duties.

Under the current organizational structure, inspectors who formerly performed only domestic inspections may be required to perform import inspections. Also, import inspectors may be supervised by circuit supervisors who are only knowledgeable of domestic

inspections. Former import supervisors now serve as "import coordinators" to provide guidance to import reinspection activities in the district to which they are assigned. As previously discussed, an Import District Transition Plan was developed to ensure that district office personnel, circuit supervisors, and domestic inspectors were trained in import inspection activities during the transition to the new structure. However, FSIS officials were unable to provide adequate documentation that all personnel were trained in areas related to their current job responsibilities.

RECOMMENDATION NO. 7

Review the roles and responsibilities of personnel involved in the equivalence determination process, the onsite review process, and the input of data to update the Automated Import Information System, and define more specifically the authority and responsibilities of those units.

Agency Response

FSIS agrees to review the roles and responsibilities of personnel involved in the equivalence determination process, the onsite review process, and the input of data to update the Automated Import Information System (AIIS).

By October 1, 2000, FSIS will review and revise as necessary the functional statements of the International Policy Division (IPD) where joint and separate functional responsibilities exist in onsite equivalence audits, audit reports, and follow-up on equivalence issues raised during onsite audits.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 8

Prior to the onsite review, ensure that the Technical Service Center reviewers are provided with all information necessary to verify data provided by foreign countries for equivalence determinations.

Agency Response

FSIS agrees to develop formal procedures that will continue to ensure that the TSC is provided all information necessary for the reviewers to verify data provided by foreign countries during equivalence determinations. The procedures will be completed in December 2000.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 9

Provide training to all inspectors responsible for conducting inspections of imported products.

Agency Response

FSIS is currently developing updated import training for field inspectors who conduct import inspection activities. Training is scheduled to begin in FY 2001. This training plan is projected to include on-the-job training, pre-classroom CD-ROM's that cover basic import inspection procedures, and a formal training session at various U.S. ports of entry. The training plan will be completed in December 2000.

OIG Position

We accept FSIS' management decision.

FINDING NO. 4

WRITTEN PROCEDURES WERE NOT ADEQUATE TO ENSURE COMPLIANCE WITH REGULATORY REQUIREMENTS OR TO DOCUMENT THE PROCESS FOR DETERMINING COUNTRY EQUIVALENCY

Processes and procedures for determining equivalency were not detailed enough to ensure that all aspects of a country's regulatory system would be reviewed in accordance with applicable regulations. We also found that agency procedures were not always functioning as represented in documents provided during our review (see Chapters 2 and 3).

We obtained documents (some of which were undated or in draft form), which outlined procedures for performing

specific tasks related to the Equivalence and Planning Branch operations. Based on our review of these documents and discussions with FSIS officials, we determined that several of these procedures

were developed or revised on an "as-needed" basis without being subject to any formal review or approval process. In addition, no reviews were performed to determine the adequacy of the procedures. For example, procedures for reviewing documents submitted for equivalency determinations were revised during the course of our audit as a result of questions we raised about the process.

The "Top-to-Bottom Review" prepared for the pending reorganization recognized that "FSIS lacks a clearly defined and consistent approach to regulation development and is in need of a revamped process for carrying out this critical function. FSIS has developed regulations in a piecemeal fashion and issued policy memos or directives to avoid rulemaking. Not only does this approach result in implementation problems, but there is the risk of legal challenges when the agency publishes policy without rulemaking and tries to enforce a requirement that is not in the regulations." The "Top-to-Bottom Review" report recommended that a clearly established regulatory agenda process be created which would rely on subject-matter experts for input about substantive issues throughout the regulation development process. We were provided with an April 13, 2000, paper prepared by FSIS entitled: The Management Review of Equivalence Process, which outlined management's involvement in the equivalence review process; however, there was no documented evidence to support that these activities occurred.

a. Guidelines for Determining Equivalency Were Not Adequate

According to OMB Circular No. A-123, management controls include the methods and procedures adopted by management to ensure that its goals are met. Although FSIS developed basic guidelines for determining the equivalency status of a country's food inspection system, those guidelines were not detailed enough to ensure that required aspects of a country's regulatory system would be reviewed. To determine equivalency, Equivalence and Planning Branch program analysts must review the foreign government's performance standards and determine if those standards include implementation of a HACCP and pathogen reduction program, which includes SSOP, *Salmonella* testing, and *E. coli* testing. To assist the program analysts in making these determinations, procedures consisting only of a one-page document for each type of review were prepared. The guidelines described each process in very general language, and did not adequately address the processes needed to ensure compliance with federal requirements. For example, the guideline for *E. coli*

did not include an evaluation to determine whether the foreign inspection system programs maintained a process for ensuring that establishments prepare criteria for evaluating test results. The guidelines for HACCP did not include procedures for evaluating foreign inspection systems' process for ensuring that establishments validate the adequacy of HACCP plans at least annually and whenever changes occur that could affect the plan.

b. FSIS Lacks Procedures for Terminating a Foreign Country From Participating in the Import Inspection Program

FSIS actions were inconsistent when the agency handled countries that failed to timely submit required documents for equivalency determinations, or that had not implemented food regulatory systems as outlined in documents submitted for equivalency determinations. Regulations⁴ outline conditions under which a foreign establishment's eligibility to import product to the United States may be terminated. However, FSIS has not developed written procedures for enforcing this regulation. There are no procedures for suspending the eligibility of exporting countries that do not provide sufficient documentation to support their continued compliance with U.S. equivalency standards, or are found to be in noncompliance based on the results of an onsite equivalency review.

An April 3, 2000, response prepared by FSIS to our draft report stated, in part, that it is not feasible to develop written procedures for terminating the eligibility of foreign establishments or an entire country's ability to export. Each situation presents itself with different factual patterns. Therefore, written procedures would have to be so general and vague, as to serve no useful purpose given that these situations require case by case assessment. However, it is our position that in the absence of written guidelines, FSIS can not be assured that each country is given due process and equal treatment.

According to FSIS' undated document on importing meat and poultry, if a country does not continue to operate an inspection system equivalent to the U.S. system, it is removed from the list of countries eligible to export to the United States. Loss of eligibility can also occur when FSIS is unable to get necessary information about a country's inspection system. Another undated document entitled, "Pathogen Reduction/HACCP Equivalence

⁴ Title 9 CFR, Part 327.2, dated January 1, 1998.

Determinations," states, "three circumstances could, however, result in trade suspension. One is where an emergency sanitary measure is not implemented to address a hazard that is so severe that no product can enter the marketplace from a foreign establishment until the control is in place. The second is where an exporting country does not provide satisfactory documentary evidence of an equivalent sanitary measure. The third is where a system audit reveals that an exporting country is not implementing a sanitary measure in the manner that FSIS initially determined to be equivalent."

Based on our concerns over the equivalency determination process, the Equivalence and Planning Branch prepared a document which stated, in part, that, "in some cases, where a country failed to respond to requests for information, a draft cable was prepared which showed the country that FSIS would be forced to begin regulatory proceedings, in the form of an official action, to remove the country from the list of countries eligible to export to the United States." It also stated, "the process of initiating an official action against the importation of product from a particular country involves an extensive preparation and presentation of information to brief top executives within FSIS and USDA. Local Foreign Agricultural Service officials, agricultural attaches, U.S. Trade Representative officials, and the State Department are notified of the content of the cable or letter because of potentially serious U.S. trade considerations and political implications."

During our review of files maintained for each country eligible to export meat and poultry products to the United States, we noted that one country was immediately suspended from participation in the import inspection program when violations were found, while others with apparently similar violations continued under equivalency status without any formal deadline for corrective action. We noted this particularly in the cases of Country A and Country B.

Country A was suspended from participation in the import inspection program because it had not responded to FSIS' request for additional information for both SSOP implementation and *E. coli* testing. The Technical Service Center annual onsite equivalency reviews also revealed numerous deficiencies in the slaughter operations of three slaughter establishments in that country. These deficiencies included feces, hair, paint, dirt, and

other contaminants on the carcasses waiting to be deboned or placed in coolers. A fourth establishment showed evidence of past serious unsanitary conditions in its canning operation. None of the four establishments implemented an *E. coli* testing program.

While the conditions in Country A plants may indeed merit suspension, we noted that FSIS found several deficiencies in Country B, but did not suspend that country. An FSIS Microbiology Division document review disclosed that Country B was not complying with HACCP and pathogen reduction requirements. The review noted that Country B was not taking an appropriate sample size, did not use appropriate sampling techniques, and did not implement a formal *Salmonella* performance standard testing program. Like Country A, Country B had submitted insufficient data on its implementation of SSOP and *E. coli* testing, but in the case of Country B, FSIS continuously asked for additional information without imposing a deadline for its receipt. Those attempts continued for over a year while the country continued to export products into the United States. On one occasion, 7 months elapsed between the time FSIS requested information (February 1997) and the time Country B responded (September 1997). The data submitted was still incomplete.

FSIS and Country B reached an agreement that Country B would modify its program in relation to test site and test area, and as a result of this agreement, in November 1998, FSIS notified Country B that its *E. coli* testing was compatible with legislative requirements of equivalency. However, in contrast to the agreement, the onsite verification review conducted in March 1999 revealed numerous variances or deficiencies in Country B's testing programs that did not support documentation previously submitted to the Equivalence and Planning Branch. The onsite equivalency review found inadequate monitoring of SSOP and HACCP implementation, deviations or deficiencies in the *Salmonella* testing programs and in carcass sampling techniques, and imported meat products were not tested or included in the national residue monitoring program.

c. Procedures Used for Approving Alternative Inspection Methods Were Not Established

FSIS did not establish procedures for evaluating and documenting the assessment of alternative food safety inspection methods. Prior to 1995 when the United States implemented provisions of

the GATT Treaty, including the Sanitary Phytosanitary Agreement, all countries, which exported meat and poultry to the United States, were required to have inspection systems equal to the U.S. system. Subsequent to GATT, Congress changed the inspection laws to accept alternative, but equivalent inspection standards and procedures.

FSIS' process for evaluating different sanitary measures requires the exporting and importing countries to cooperate in a series of steps that meet mutual international obligations. The steps that countries choose depend on circumstances and trading experience between the two nations. Where sanitary measures differ, the food safety objective may need to be further explained by the importing country.

We identified four countries (Country C, Country E, Country D, and Country B) that requested to use alternative *E. coli* testing methods. Initially, FSIS determined that the four countries' alternative *E. coli* testing methods were not equivalent. Consequently, Country C decided to implement the same method used in the United States; however, the other three countries continued to seek approval for their alternative methods. During our evaluation of FSIS' process for reviewing these alternative systems, we could not determine what procedures FSIS used to approve an alternative method. Without a procedure in place, there is reduced assurance that FSIS' evaluations of alternative methods will be consistent and in accordance with U.S. standards.

An FSIS official in the Microbiology Division stated in a letter dated May 13, 1998, that during the review of Country D's submission of its microbiological testing program, there was no policy [alternative methods] in place for *E. coli* testing. Therefore, the microbiologist prepared a list of differences between the microbiological testing program in Country D and the generic *E. coli* testing program outlined in the pathogen reduction/HACCP final rule. On April 12, 2000, we were provided with documentation which outlined FSIS' Proposal For Equivalency Study, dated January 11, 1999, and a March 7, 2000, letter from FSIS to Country D's Chief Veterinary Officer concerning the equivalency of its *Enterobacteriaceae* testing program. However, these documents were not included as part of the country file during the time of our field work, and do not represent a policy for evaluating alternative methods for *E. coli* testing.

According to documentation provided to FSIS from Country E in 1997, Country E implemented the provisions of the final rule for *E. coli* testing at cattle slaughter facilities but limited its program for *Salmonella* testing on swine. It also used different sampling techniques and analytical methods. In a May 22, 1997, cable, FSIS asked Country E to provide scientific documentation that demonstrated the equivalency of these alternative techniques. Based on the onsite equivalency review, conducted between November 14, 1997, and December 18, 1997, the audit report for Country E, dated March 3, 1998, disclosed that sampling procedures, randomization, and analytical methods did not conform to U.S. requirements. In addition, pre-operational and operational SSOP's and inspection controls were not effective in most establishments reviewed.

A telefax from Country E to FSIS, dated March 27, 1998, included the raw data on the results of a study comparing the U.S. sponge technique for *E. coli* testing with Country E's gauze-tampon technique. We did not find documentation to show the analysis of this information. On April 12, 2000, we were provided with a written summary of an August 25, 1998, teleconference between FSIS and Country E's meat inspection officials to discuss deficiencies found during the 1997 onsite audit, and to address specific equivalence issues regarding Country E's *E. coli* testing program. The summary stated, in part, that International Policy and Development (IDP) presented a draft cable that determined Country E's *E. coli* testing program to be equivalent, provided they use statistical process control techniques to evaluate test results when using a method of sample collection other than the excision method. IDP asked the inspection officials to respond to the draft conditional cable by early next week (i.e., by September 1, 1998). In addition, the Country E officials agreed to address variances in their *E. coli* contamination controls.

We were also provided with a copy of a September 3, 1998, letter from FSIS to Country E's Veterinary and Food Administration that summarized prior discussions concerning deficiencies noted during the 1997 audit, and corrective actions taken by Country E. The letter included a statement that Country E officials agreed to address variances in their *E. coli* testing program regarding random sampling procedures, process control charting, and *E. coli* contamination controls, and a suggestion to reconvene to confirm upcoming corrective actions regarding issues not fully resolved. However, we were not provided with documentation to support a

subsequent meeting between FSIS and Country E officials to confirm corrective actions regarding issues not fully resolved. Also, a December 9, 1998, cable from FSIS to Country E stated that its *E. coli* testing program is "equivalent" based on its agreement to use statistical process control techniques to evaluate test results when using the gauze-tampon method of sample collection. However, we were unable to obtain documentation of information provided by Country E officials, and confirmation of agreements reached, or a subsequent analysis conducted by the Microbiology division to determine the equivalence of Country E's gauze-tampon technique to the U.S. sponge technique for *E. coli* testing.

Country B's file contained correspondence between FSIS and Country B from December 1996 to February 1999 pertaining to Country B's alternative proposal for conducting *E. coli* testing. This alternative *E. coli* testing system was found "equivalent" by FSIS as documented in a November 12, 1998, cable to Country B. Even though we were provided with documents dated from October 1997 to June 1998 to support subject-matter experts' reviews of Country B's submissions, the process for determining equivalency did not provide adequate documentation to conclude that Country B's alternative *E. coli* testing system was equivalent.

Detailed operational procedures are needed to ensure that equivalency determinations are made in accordance with regulations and that the critical areas in the five risk areas are addressed satisfactorily with respect to standards, activities, resources, and enforcement. During the course of our review, the Assistant Deputy Administrator, Office of Policy, Program Development and Evaluation, held meetings with the Equivalence and Planning Branch staff in order to conduct a comprehensive analysis of the documentation review process, along with a review of equivalency determinations previously rendered for specific countries. If this process continues, we view this as a positive step in improving the adequacy and accountability of the Equivalence and Planning Branch's equivalency determination process.

RECOMMENDATION NO. 10

With the help of technical subject-matter experts, develop and implement comprehensive guidelines as a means of ensuring propriety and consistency in decisions involving equivalency determinations.

Agency Response

FSIS agrees to develop comprehensive written guidelines for equivalence determinations by January 2001. FSIS had developed general guidelines to ensure that the foreign governments had addressed all the components of the PR/HACCP requirements. These guidelines were not the only documents used to review foreign country submissions.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 11

Develop written criteria and procedures for suspending the eligibility of exporting countries that do not provide sufficient documentation to support their continuing compliance with U.S. equivalency standards or are found to be in noncompliance based on the results of an onsite equivalency review.

Agency Response

FSIS agrees with this recommendation. FSIS regulations, 9 CFR 327.2, delineate criteria for both initially determining the eligibility of a foreign country to import products into the United States and for withdrawing a foreign country's eligibility to import. FSIS will consolidate this requirement into formal procedures and guidelines by March 2001.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 12

Develop written procedures which ensure comprehensive evaluations of foreign countries' alternative import inspection methods, and require the analysis of these systems be documented, as well as the decisions reached.

Agency Response

FSIS agrees with this recommendation. Consolidated written procedures will be developed by March 2001 to document

equivalence decisions regarding alternative import inspection methods. Effective July 1, 2000, new equivalence decision files will document: 1) All FSIS correspondence with foreign countries; 2) All foreign country submissions (translated and in the originating language); 3) Summary IPD reviews of submissions; 4) Summary of all meetings and teleconferences with foreign officials; 5) Summary of all reviews by subject-matter experts; 6) Documentation of equivalence criteria; 7) Summary of all FSIS management formal reviews and approvals; and 8) Decision memorandum of the equivalence determinations.

OIG Position

We accept FSIS' management decision.

CHAPTER 2	THE REINSPECTION PROCESS DID NOT ENSURE THAT INELIGIBLE IMPORTERS WERE PROPERLY IDENTIFIED AND THAT RECOGNIZED PATHOGEN VIOLATIONS WERE RESPONDED TO PROMPTLY
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FSIS did not adequately control its resources to ensure that foreign countries importing meat and poultry products to the United States were eligible to do so. Residue test plans and eligibility certifications for foreign establishments were not always obtained and analyzed; those that were obtained were not posted to the Automated Import Information System in a timely manner. The Automated Import Information System also did not timely reflect the results of laboratory analyses performed during reinspections. Under these conditions, FSIS could not ensure that information concerning foreign imports was accurate and was available to the appropriate officials for action in a timely manner. For example, 7 establishments from 4 foreign countries shipped 4,625,363 pounds of meat and poultry products and presented them for reinspection even though the establishments were delisted (i.e., removed from the list of approved importers). This included 625,582 pounds of frozen cooked beef from an establishment that was barred from sending products because of *Listeria* violations. Discrepancies in documentation and summary information provided by FSIS raises questions about the conclusion of FSIS officials that the shipments were certified by foreign governments before the establishments were delisted. Deficiencies in FSIS' certification and delistment activities occurred largely as a result of unclear or nonexistent procedures (see Finding No. 1). FSIS officials stated that foreign countries are not required to provide information about the dates that products are produced. Therefore, we were unable to determine if foreign establishments produced products that were presented for reinspection during their delistment period. Nothing came to our attention during this audit, however, to indicate that FSIS allowed unsafe product to enter the United States.

Under FSIS' reinspection process, imported meat and poultry products from countries with equivalent status are allowed into the United States with sample testing at ports of entry. The test results are posted in the Automated Import Information System. In addition, the Automated Import Information System should include delistment information as a result of onsite equivalency reviews, as well as establishments certified/decertified by foreign countries as meeting U.S. inspection program standards. These elements form a

compliance history and the basis for assigning future inspection levels for products shipped to the United States from these establishments.

Foreign countries and establishments that have a history of noncompliance are delisted. The Office of Policy, Program Development and Evaluation is primarily responsible for ensuring that the foreign countries provide information about delistment and for promptly forwarding that information to the Field Automation and Information Management Division for timely updating of the Automated Import Information System. The Automated Import Information System is FSIS' primary means of ensuring that products from delisted establishments are refused entry.

FINDING NO. 5

INCONSISTENT REPORTING OF LABORATORY RESULTS WAS INEFFICIENT AND POTENTIALLY ERROR-PRONE

FSIS has no clear process for entering the results of laboratory tests into the Automated Import Information System. The Import Inspectors Manual (manual) does not provide adequate guidance on who is responsible for entering the information. In practice, the manner in which the results are processed and the persons responsible for processing those

results vary with the type of test conducted. We also found that despite the importance of the laboratory results, neither the Technical Service Center nor the Field Automation and Information Management Division officials have established a supervisory review system for ensuring that the results are promptly and accurately entered into the Automated Import Information System. This lack of consistency could jeopardize the integrity of the Automated Import Information System data base and its ability to make appropriate reinspection assignments.

Regulations⁵ state that the computerized Automated Import Information System shall be consulted for reinspection instructions. The Automated Import Information System will assign reinspection levels and procedures based on established sampling plans and established product and plant history.

When a shipment is ready to be reinspected by FSIS, the Automated Import Information System will generate an inspection assignment based solely on the compliance history of the establishment and the foreign country for the specific product. The Automated Import Information System records the results of the inspection, and can

⁵ Title 9 CFR, Part 327.6 (a) (3), dated January 1, 1998.

generate reports based upon the results. The inspection assignments could include the following laboratory testing programs: residue, microbiological (*Staphylococcal aureus enterotoxin*, *Salmonella*, *Escherichia coli*, and *Listeria*), abnormal containers, food chemical, etc.

Instructions for entering laboratory test results into the Automated Import Information System are outlined in the laboratory sampling section of the manual, dated September 30, 1998. We found that procedures outlined in the manual do not reflect what is actually occurring. For example, the manual indicates that import coordinators are responsible for entering the positive (failure) results of various microbiological tests. In reality, these results are entered by Technical Service Center staff officers, who explained that they assumed this responsibility after the manual was issued. They further explained that the manual had not been revised to reflect these procedural changes because of plans to convert the manual to an FSIS Directive. Although Technical Service Center officials claimed that the Automated Import Information System is promptly updated to record laboratory test results, copies of the failure notices are not maintained at the Technical Service Center to document the reasons for, and the timeliness of their actions. Furthermore, Technical Service Center management has not instituted a system for ensuring that Technical Service Center staff are timely and accurately entering the test results into the Automated Import Information System.

The manual also states that the Field Automation and Information Management Division is responsible for entering both positive and negative residue test results into the Automated Import Information System. We learned that, in this case, the results take a circuitous route before they reach the Field Automation and Information Management Division. Positive results are conveyed to the Technical Service Center for referral to the Field Automation and Information Management Division and entry into the Automated Import Information System, while negative results are entered by the laboratories into the Microbiological and Residue Computer Information System. Because the Microbiological and Residue Computer Information System does not interface with the Automated Import Information System, the Field Automation and Information Management Division needs to download the results from the Microbiological and Residue Computer Information System into the Automated Import Information System. The timeliness of processing both negative and positive results is critical. The Automated Import Information System should reflect the most current information because inspection assignments are being

made for subsequent reinspections. Nevertheless, Field Automation and Information Management Division officials have not established a supervisory review system to ensure that all procedures are completed and that entries are made in a timely and accurate manner.

We concluded that the current system with its numerous processes for entering the various types of laboratory results (such as microbiological and residue test results) into the Automated Import Information System is prone to error and should be streamlined.

During our review, we learned that inspectors are responsible for selecting the appropriate samples and performing the tests assigned by the Automated Import Information System for products shipped from foreign establishments. The inspectors are also responsible for entering results for some test programs along with other types of data relating to the inspection process into the Automated Import Information System. Circuit supervisors have the immediate supervisory responsibility for assuring that these tasks are performed in a correct and timely manner.

We will visit inspection houses during the next audit phase to determine if the circuit supervisors and the inspectors are fulfilling these responsibilities.

RECOMMENDATION NO. 13

Streamline the process and establish procedures that would allow expeditious entry of laboratory test results into the Automated Import Information System.

Agency Response

FSIS agrees that additional documentation would assist in clarifying the current system to both Agency personnel as well as outside auditors. FSIS is reevaluating the current system as part of the redesign of the AIIS and will improve the documentation by December 2000 to outline the procedures for entering laboratory results into the AIIS system.

As an interim measure, in March 2000, the Field Automation Information Management (FAIM) Division instituted non-automated procedures to streamline the entry of residue and microbial results. As of March, FAIM receives faxes from the TSC of laboratory Form 9770-2 for all positive residue results. The FAIM Division then documents directly on the laboratory form both the date it was

received (via fax) and the date/time the lab results were entered into AIIS. Entries into the AIIS are made the same day they are received. Also, an internal verification process will be established to monitor the data being entered into the AIIS.

Also, FSIS is working to replace the AIIS. The new system, eventually sharing Sybase SQL tables with the Microbiological and Residue Computer Information System (MARCIS) and other agency systems will ensure real time accuracy of both negative and positive results of residue tests and microbiological tests. The FAIM Division began work on the new AIIS application in March 2000, with a test pilot planned for the first quarter of 2001. We expect the system to be fully operational by December 2001.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 14

Require the Office of Field Operations to work with the Technical Service Center and the Field Automation and Information Management Division to develop

management controls and a supervisory review process to ensure that all laboratory test results are promptly and accurately entered into the Automated Import Information System. Management controls must include requirements for maintaining records of when failure notifications are received and when the entries are made into the Automated Import Information System.

Agency Response

FSIS agrees with this recommendation. The FAIM Division is focusing on incorporating the required management controls in the replacement AIIS, which should be completed by December 2001. The new import computer system will document when laboratory failure results are received and incorporated into the system data tables. In the interim, FSIS has established a manual tracking process that documents when notification of failures is received and when the entries are made into the AIIS. Entries are made within 24 hours of receipt of the positive laboratory results. Negative results are obtained via a weekly download from MARCIS and entered that same day into the AIIS.

FSIS believes that the management controls and supervisory review process can be enhanced to ensure that all laboratory results are promptly and accurately entered into the AIIS. Management controls currently include requirements for maintaining records that indicate when failure notifications are received, and when the entries are made into the AIIS.

OIG Position

To reach management decision, FSIS needs to provide a target completion date as to when the management controls and supervisory review process will be documented in agency procedures.

FINDING NO. 6

FSIS DID NOT ENSURE THAT ESTABLISHMENTS MET ANNUAL CERTIFICATION REQUIREMENTS

Foreign governments are required to certify annually that each of the establishments in their countries that export meat and poultry to the United States continue to comply with the food safety systems under which they were granted equivalent status. The FSIS Administrator may terminate the eligibility of any foreign establishment if a current certification of that establishment is not obtained⁶. We found that FSIS management did not ensure that the annual certification requirement was fulfilled. Also, FSIS is not ensuring that certification information is posted in the Automated Import Information System so that inspection officials are aware of each establishment's status. We further found that, as of April 29, 1999, FSIS had not received the 1999 annual certifications from establishments in 19 foreign countries which shipped about 2.3 billion pounds of product to the United States during 1999; or the 1998 annual certifications from establishments in 4 foreign countries which accounted for 1.4 billion of the 3 billion pounds of product shipped to the United States during 1998. Allowing countries to delay their certifications reduces the control to prevent products from uncertified establishments from entering the United States. In addition, the Secretary's annual report to Congress, "Foreign Countries and Plants Certified to Export Meat and Poultry to the United States," may not be accurate. This report is to be submitted to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture and Forestry of the Senate no later than March 1 of each year.

⁶ Title 9 CFR, Part 327.2 (a) (3), dated January 1, 1998.

Regulations⁷ state that only those establishments that are certified by a responsible official of the foreign meat inspection system as fully meeting U.S. requirements are eligible to have their products imported into the United States. Certifications are to be renewed annually.

The Automated Import Information System must be annually updated to reflect activity during the previous year that would affect current inspection assignments. We were advised that FSIS assigned January 1 of each year as the due date for foreign certifications. However, documentation to affirm this date could not be provided. At the beginning of 1998 and 1999, the foreign governments should have provided FSIS with comprehensive lists of establishments certified to ship meat and poultry products to the United States for those years. According to functional statements, the Assistant Deputy Administrator for International and Domestic Policy, through the Equivalence and Planning Branch, is responsible for reviewing certification information and forwarding it to the Field Automation and Information Management Division for entry into the Automated Import Information System. The Equivalence and Planning Branch is also responsible for making delistment decisions and forwarding this information for entry into the Automated Import Information System. We found that the January 1 deadline became merely a target date that few countries observed. The annual certifications were sent to FSIS at any time during the year, and were not necessarily addressed to the same FSIS official each time.

Reporting methods were inconsistent because FSIS had not established procedures to ensure that critical information, including the certification and delistment of foreign establishments, was distributed to the appropriate staff members and promptly posted in the Automated Import Information System. Staff members within the Equivalence and Planning Branch and the Field Automation and Information Management Division were unclear regarding the proper processing of the certifications. We were told that lapses began occurring after the reorganization, when related functions were parceled out to separate entities within FSIS and older procedures were abandoned.

We reviewed the Field Automation and Information Management Division's lists of annual certification information. The "Annual Certification of Plants for 1998" report shows that as of April 29, 1999, 4 of the 36 foreign countries (eligible to ship meat and poultry products to the United States) had not submitted their comprehensive annual

⁷ Title 9 CFR, Part 327.2 (a) (3), dated January 1, 1998.

certification listings that had been due in January 1998. According to the Field Automation and Information Management Division officials, the status of a foreign country or establishment in the Automated Import Information System cannot be changed without first receiving authorization from the Equivalence and Planning Branch. The Field Automation and Information Management Division raised concerns that it could not update the Automated Import Information System or the Secretary's report to Congress because the comprehensive annual certification information was not provided. An Equivalence and Planning Branch official contacted the Field Automation and Information Management Division and confirmed that four countries had not provided 1998 certifications, but advised the Field Automation and Information Management Division to "go with the same establishments" certified for 1997. These four countries exported 1.4 billion pounds of meat and poultry products to the United States during 1998.

The Field Automation and Information Management Division's "Annual Certification of Plants for 1999" shows that as of April 29, 1999, only 17 of the 36 foreign countries submitted their comprehensive annual certification lists for 1999. The Automated Import Information System also continued to show that hundreds of foreign establishments from the 19 remaining countries remained eligible to ship products to the United States even though they had not been certified for 1999.

FSIS officials stated that a country's certification of its establishments never expires unless the nation removes itself from trade or unless the United States chooses to do so as a safety measure. FSIS requires that a foreign meat inspection certificate accompany each consignment. Each certificate, for each shipment, indicates that the exporting plant is certified by the foreign meat inspection system, and that the product complies with FSIS requirements. FSIS officials stated that the annual certification requirement is an "unnecessary redundancy."

Regulations currently require an annual certification of its establishments by the foreign meat inspection authority, as well as inspection certificates to accompany each shipment. OIG views these requirements as compensating controls since prior audits and investigations have identified weaknesses in controls over inspection certificates (both foreign and domestic) and concerns regarding their validity.

RECOMMENDATION NO. 15

Officially notify all countries importing meat and poultry into the United States that annual certifications are due no later than the established date and that

establishments that are not certified by this date may be delisted. Incorporate this requirement in regulations.

Agency Response

FSIS agrees that meat and poultry products exported to the United States must be produced in properly certified foreign establishments. To ensure that this occurs, the FAIM Division has established a web site with search capabilities that allows import inspectors to obtain the status (certification, delistment, relistment) of foreign establishments.

FSIS agrees to continue to notify all countries that certifications of establishments must be renewed annually, and if establishments are not certified annually they may be delisted. However, FSIS does not agree with the OIG's assertion that allowing countries to delay their certifications "reduces the control to prevent products from uncertified establishments from entering the United States".

Annual certification lists are often obsolete soon after they arrive because importing countries add and delete certified establishments throughout the year. Furthermore, an additional method exists to verify that the imported product was produced in an establishment certified for export to the United States. This method is set forth in 9 CFR 327.4, "Imported products, foreign certificates required." A foreign meat inspection certificate must accompany each consignment of fresh meat, fresh meat byproducts, or meat food products. All such consignments (or lots) offered for entry into the United States from any foreign country must be reinspected by an FSIS import inspector before they are allowed into this country. An authorized foreign government official signs the certification accompanying each lot.

FSIS believes that these certificates provide ample evidence that the product they accompany was produced in a foreign-certified establishment. By September 2001, FSIS will publish a proposed revision of Part 327, Imported Products, to eliminate the annual certification requirement.

OIG Position

We agree with FSIS' response to notify all countries that certifications of establishments must be renewed annually, and if establishments are not certified annually, they may be delisted. However, we disagree that FSIS should eliminate their compensating control of requiring annual certifications from a responsible official of the foreign inspection systems. To reach management decision, FSIS needs to provide a target date as to when countries will be notified of the annual certification requirement. Also, if the annual certification requirement is discontinued, FSIS needs to develop compensating controls to ensure the validity of the foreign inspection certificate accompanying each shipment of product to the United States.

RECOMMENDATION NO. 16

Establish a followup process to obtain the annual certification lists from the countries which have not submitted them.

Agency Response

FSIS has established a follow-up process to obtain annual certification lists from countries that have not submitted them. This process is subject to change after the proposed revisions (see response to Recommendation 15) in Part 327 are implemented.

Annual certification lists are sent from foreign countries to the IPD. In July 1999, effective for calendar year 2000, the FAIM Division established a procedure to notify IPD of every country for which FAIM has not received an annual certification of establishments. Starting in February 2000, and continuing on a monthly basis, the FAIM Division has notified the IPD of outstanding certification lists.

OIG Position

To reach management decision, FSIS needs to provide a target date for developing a follow-up process to include actions to be taken by the IPD when notified of outstanding certification lists.

RECOMMENDATION NO. 17

Immediately conduct a reconciliation between establishment certification information maintained by the Equivalence and Planning Branch and the Automated Import Information System to ensure that the Automated Import Information System includes only those

establishments certified by their foreign governments to ship products to the United States.

Agency Response

FSIS agrees with the recommendation. Following the onsite portion of the OIG audit, the FAIM Division established a program of quarterly crosschecks of foreign government certification documents against the establishment listings contained in the AIIIS. In addition, effective April 1999, the FAIM Division began sending to the IPD a weekly report listing all certified and decertified establishments maintained in the AIIIS. IDP will begin reconciliation of the FAIM reported data and their internal records by December 2000.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 18

Establish time requirements and a management control process for reviewing and processing certification information in the Automated Import

Information System.

Agency Response

FSIS agrees with this recommendation. The FAIM Division maintains an internal AIIIS Import Manual of procedures document that will be updated by December 2000, to address time requirements and management control processes. Supervisory oversight will be established whereby all changes to the AIIIS status of establishments will be forwarded to the Branch Chief of the FAIM Applications Systems Development Branch for review.

OIG Position

We accept FSIS' management decision.

FINDING NO. 7

FSIS DID NOT ESTABLISH A SYSTEM FOR TRACKING DELISTMENTS

Neither the Office of Policy, Program Development and Evaluation nor the Office of Field Operations had formulated supervisory review procedures to ensure that all delistment, relistment, and related information was processed for accurate and timely entry into the Automated Import Information System. Technical

Service Center officials were not timely informing the Office of Policy, Program Development and Evaluation about foreign establishments that were delisted prior to, or because of, their onsite reviews. Furthermore, after the reorganization, FSIS abandoned a system for tracking delistments and did not replace it. We found that in the absence of a tracking system, establishment delistments were not timely entered in the Automated Import Information System. As a result, these delisted establishments incorrectly remained eligible to present meat and poultry products for entry to the United States. We found seven establishments from four countries shipped about 4.6 million pounds of meat and poultry products and presented them for reinspection even though the establishments were delisted. Based on documentation provided by FSIS, we were unable to determine whether product was produced prior to the delistment period. Nothing came to our attention during this audit, however, to indicate that FSIS allowed unsafe product to enter the United States.

During our review of the Technical Service Center equivalency review (audit) reports, we noted that delistment information resulting from these reviews was not being timely provided to the Field Automation and Information Management Division for entry into the Automated Import Information System. In one case, the Technical Service Center reviewers learned that a foreign establishment had been slaughtering more than one species of animal in the same slaughterhouse and delisted the slaughterhouse in October 1998. However, the Field Automation and Information Management Division was not informed of this fact. As of May 4, 1999, the establishment remained certified in the Automated Import Information System even though the foreign country's February 25, 1999, annual certification list to the Equivalence and Planning Branch excluded the establishment. As of May 6, 1999, no product from this establishment had been presented for reinspection at U.S. ports.

In another case, the Technical Service Center reviewers learned that a foreign government delisted an establishment prior to their March 1999 onsite review. As of May 4, 1999, the Field Automation

and Information Management Division had not been informed about the delistment so the Automated Import Information System was not updated to reflect the establishment's delisted status.

This lack of internal controls raises questions about the integrity of the data in the Automated Import Information System. For example, on December 29, 1998, the Office of Policy, Program Development and Evaluation received notifications from a foreign country's Bureau of Animal Industry to withdraw approval (delist) two establishments in their country. However, the Office of Policy, Program Development and Evaluation did not provide this information to the Field Automation and Information Management Division for input to the Automated Import Information System until February 8, 1999. According to handwritten notes on the notification maintained by the Field Automation and Information Management Division, the delistment was entered into the Automated Import Information System on the day that it was received, February 8, 1999. However, an Automated Import Information System report dated April 28, 1999, shows that the establishments were not delisted. From January 25, 1999 to February 23, 1999, 355,104 pounds of meat products were presented for reinspection from these two foreign establishments. Field Automation and Information Management Division personnel could not explain why the two establishments had not been delisted in the Automated Import Information System. However, because of our inquiries about the situation, the Automated Import Information System files for these two establishments were opened and these establishments were delisted. Field Automation and Information Management Division personnel made this adjustment without approval by a management official.

We reviewed delistment information for 19 establishments from 8 foreign countries. We compared this information to an Automated Import Information System printout of delisted establishments dated May 6, 1999, and to an Automated Import Information System printout of products presented for FSIS reinspection during the time these establishments should have been delisted. We found that in no instance was the information promptly provided to the Field Automation and Information Management Division to update the Automated Import Information System with the delistment status of the establishments. For example, the printout dated May 6, 1999, indicated that three establishments remained eligible to ship products to the United States even though one of the establishments was officially delisted in February 1999 and the other two in April 1999.

Most importantly, seven establishments from four countries shipped over 4.6 million pounds of meat and poultry products and presented them for reinspection even though the establishments were delisted. This included:

- 625,582 pounds of frozen cooked beef from one establishment that was delisted because *Listeria* was found in previous shipments of its frozen cooked beef;
- over 1 million pounds of meat products from an establishment that shipped 20 shipments over a 5-month period after its delistment date (December 24, 1998). [Note: we were able to determine that two of the shipments, representing about 95,000 pounds of meat products, were produced prior to the delistment date and were eligible for FSIS reinspection; however, because FSIS maintains limited information, we could not verify other shipments]; and
- 664,272 pounds of beef by a delisted establishment that had been cited for sanitation problems, *Listeria* violations, and the presence of metal fragments in previous shipments of its beef products. [Note: the limited information being maintained by FSIS shows that 55,409 pounds were produced prior to the establishment's delistment and were eligible for FSIS reinspection.]

FSIS officials provided documentation to support their conclusion that although the establishments were delisted, 4.9 million pounds of their products were eligible for FSIS reinspection because the shipments were certified by their foreign governments prior to the establishments' delistment periods. However, during our review of the documentation provided by FSIS, we found discrepancies significant enough to raise questions about the conclusion reached by FSIS officials. For example:

- the 4.9 million pounds reported by FSIS erroneously included shipments that were presented for FSIS reinspection prior to the delistment period and improperly included categories of products that were eligible for shipment to the United States. (Note: The 4.6 million pounds reported by OIG included only those products presented for FSIS reinspection while the foreign establishments should have been delisted).
- shipments reported by FSIS as being sent to the United States prior to the delistment period actually were sent during the delistment period.

- at least 20 of the documents provided by FSIS could not be matched with specific shipment information, thus limiting our ability to verify the FSIS documentation and summary information.
- FSIS used incorrect beginning delistment dates for three establishments.
- FSIS did not have documentation for at least 16 shipments and did not indicate what action will be taken to determine if the shipments were certified by the foreign governments prior to the time that the products were presented for FSIS reinspection.

According to FSIS, if the documentation has a date which coincides with the delistment period, the FSIS inspectors should have contacted FSIS headquarters or their respective district offices to verify eligibility of the shipments. The verification process should have also included contacting the foreign governments for clarification as to when the shipments were produced. However, FSIS noted in a summary of the documentation provided to OIG during April 2000, that the foreign governments will now be contacted to verify when these shipments were produced. Most of the products were shipped to the United States from December 1998 to June 1999. Thus, the verification is not occurring until 10 to 16 months have lapsed since these products were presented for FSIS reinspection. During our review of the documentation, we noted that at least 25 of these shipments had already been stamped "U.S. Inspected & Passed."

In March 1999, an official in FSIS' International Policy Division began noticing that delistments were not being adequately tracked. The official learned that a foreign establishment had not been delisted despite deficiencies in its slaughter operations and post mortem inspections, and despite failures in *E. coli* and *Salmonella* tests of its products. These deficiencies were noted by Technical Service Center staff during an onsite review of the establishment, but they were not communicated to the Equivalence and Planning Branch until about a month later. The Equivalence and Planning Branch waited another week before informing the Field Automation and Information Management Division of the deficiencies and requesting that the establishment be delisted in the Automated Import Information System.

Even after FSIS management became aware of the delays in the flow of delistment information, corrective action was not initiated until

2 months later, when we began reviewing the process. During our audit, the Equivalence and Planning Branch Chief instructed a management assistant to develop written procedures outlining how certification documentation should flow to the Field Automation and Information Management Division for entry into the Automated Import Information System, with weekly verifications between the Field Automation and Information Management Division and the Equivalence and Planning Branch. Such a procedure, however, does not seem to be efficient because the Automated Import Information System is incapable of printing a summary report of entries for a particular period. The Field Automation and Information Management Division program analyst informed us that they must download data about each separate establishment to present proof that the entries were made.

Field Automation and Information Management Division officials informed us that a document control numbering system existed prior to FSIS' reorganization. A control number log system was used to record and track all critical documents, particularly those relevant to the eligibility of a country or foreign establishment. Under this system, the Equivalence and Planning Branch would prepare a letter transmitting certification and delistment documents bearing the control number. After the Field Automation and Information Management Division received the information and made the entries into the Automated Import Information System, the transmittal letter would be signed by a Field Automation and Information Management Division official and a copy would be returned to the Equivalence and Planning Branch as evidence that the Automated Import Information System was updated. The Field Automation and Information Management Division staff suggested that the Equivalence and Planning Branch reinstate the document numbering system abandoned during reorganization.

We concluded that FSIS management needs to become more actively involved in maintaining the integrity of certification and delistment information in the Automated Import Information System. Specifically, the Office of Policy, Program Development and Evaluation needs to establish procedures for sending certification and delistment information to the Field Automation and Information Management Division and monitor those procedures to ensure compliance.

RECOMMENDATION NO. 19

Take immediate action to ensure that the Technical Service Center, the Field Automation and Information Management

Division, and the Equivalence and Planning Branch coordinate efforts to verify that all delisted establishments have been timely entered into the Automated Import Information System.

Agency Response

FSIS agrees with this recommendation. FSIS will improve its system to verify that all delisted establishments are timely and properly entered into the AIIIS. FSIS will establish, by October 1, 2000, a team comprised of OFO and OPPDE personnel, responsible for examining every aspect of the issue of ensuring that only product from approved and eligible establishments gains entry into the United States.

In FY 2000, the FAIM Division expanded its Intranet Web Site with a posting of all delisted foreign establishments. This information is available to the TSC, IPD, and all field inspectors. The web site is updated when FAIM receives information from the IPD.

OIG Position

To reach management decision, FSIS needs to provide a target date for completing its review.

RECOMMENDATION NO. 20

Establish a management control process to ensure that the Technical Service Center Director promptly forwards to the Office of Policy, Program Development and Evaluation information about foreign establishments that were delisted prior to, or because of, Technical Service Center foreign reviews.

Agency Response

FSIS has established a management control process to address this recommendation. Information regarding foreign country establishments that are delisted prior to TSC reviews is received either by fax or electronic mail from the foreign country government or through the Foreign Agricultural Service. This information is shared by all of the stakeholders, and discussed at the pre-audit conference held between the TSC and the IPD.

Foreign country establishments are also delisted based upon results of onsite reviews by the TSC reviewers. Reviewers are instructed to report this information, by phone, to the Review Staff Director or Chief

of the International Review Branch as soon as possible, but no later than the day following the onsite review. This information is detailed in an electronic mail message that is sent immediately to the Chief of the Equivalency and Planning Branch, IPD and also to the Director of the Import/Export, Program Analysis, IRM Staff at the TSC. A paper copy of the electronic mail message is placed in the foreign country file at the TSC.

Both types of delistments are discussed at the post-audit exit conference held between the TSC and the IPD. The reviewer discusses the reasons given by the foreign country officials for delistment of any establishments prior to the review, and also discusses, in-depth, the reasons for any establishment delistment based upon the onsite review.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 21

Establish a management control process to ensure that delistment information is (a) reviewed and signed by a designated official to the Field Automation and

Information Management Division, via a dated control number, and (b) processed and verified in the Automated Import Information System.

Agency Response

Pursuant to this report, the FAIM Division implemented in May 2000, a management control process whereby the Branch Chief, Application Development and Support Branch, FAIM Division will be notified via e-mail of all incoming delistments received from IPD. Notification will include the date delistments are received, the date the information was entered into the AIIIS, and a printout of all establishments as they appear in the AIIIS. This procedure will be complete by October 2000.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 22

Modify the Automated Import Information System to produce daily process control reports to enable verification of input.

Agency Response

FSIS agrees with this recommendation. The FAIM Division has begun replacing the AIIIS that was first deployed in the 1970s. Available resources will be better used in continuing development of the replacement AIIIS, rather than making the recommended changes to the current AIIIS. The new system will incorporate this recommendation in its design. The intent of this recommendation will be met when the new computer system is completed by December 2001.

OIG Position

We accept FSIS' management decision.

FINDING NO. 8

RESIDUE TEST PLANS WERE NOT REVIEWED FOR COMPLIANCE WITH U.S. STANDARDS

We found that for 1998, 33 of 36 countries that were certified to ship meat and poultry products to the United States submitted residue test plans. However, 13 of 36 countries did not submit the corresponding test plan results to FSIS. Also, as of April 29, 1999, 15 of the 36 certified countries did not submit their 1999 test plans. We could find no

evidence that FSIS followed up with countries to obtain either their residue plans or test plan results. The residue test plans received were not reviewed by the Equivalence and Planning Branch, and the test results were not provided to the Technical Service Center for verification and followup during onsite reviews. Also, notes of entrance conference discussions between the Equivalence and Planning Branch and Technical Service Center staffs for 7 of the 12 foreign inspection system reviews conducted during the first 3 months of 1999 showed that residue test plans were discussed for only 2 of the 7 countries.

Foreign countries that ship products to the United States are required to have residue control standards equivalent to those of the United States. These standards include (a) random sampling of animals at slaughter, (b) approved testing methods, (c) testing of appropriate target tissues, and (d) testing for compounds identified as potential contaminants of meat exported to the United States.

Each foreign country is required to submit annually a residue test plan, which identifies the drugs and chemical residues that will be its

monitoring focus during the year. Foreign countries are also required to provide the results of tests performed during the previous year. FSIS should be using this information to monitor how well the countries and their establishments are adhering to their residue test plans. Furthermore, the Technical Service Center's foreign review staff should be using residue test plans and results as they prepare for their foreign onsite equivalency reviews.

Regulations⁸ state that the foreign inspection system must maintain a program to ensure that equivalency requirements are being met. The program as implemented must provide for "random sampling of internal organs and fat of carcasses at the point of slaughter and the testing of such organs and fat, for such residues having been identified by the exporting country's meat inspection authorities or by [FSIS] as potential contaminants, in accordance with sampling and analytical techniques approved by the Administrator."

Although a number of countries submitted residue test plans and results, nothing much was done with the information, according to one FSIS official, because it was not made part of a data base. The official added that comparisons were not made to determine if the countries actually performed the tests outlined in their plans for the previous year. In this regard, we also noted that two of the 1998 residue test plans and one of the residue test plan results submitted by three foreign countries had not yet been translated into the English language for review by FSIS officials.

On May 7, 1999, the Office of Policy, Program Development and Evaluation sent a questionnaire to the foreign countries to update residue information originally provided during their pre-HACCP initial eligibility determinations. An official advised that because this questionnaire is comprehensive, the countries are still preparing their responses.

RECOMMENDATION NO. 23

Establish procedures to ensure that all residue documents submitted by foreign countries are received, reviewed, and analyzed based on requirements outlined

in regulations.

Agency Response

See Recommendation No. 25.

⁸ Title 9 CFR, Part 327.2 (a) (2) (iv), dated January 1, 1998.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 24

Obtain the residue test plans not submitted since 1998 to determine if the foreign countries have residue control standards equivalent to the United States.

Agency Response

See Recommendation No. 25.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 25

Obtain and analyze the residue test plan results not submitted since 1998 to determine the adequacy of foreign countries' adherence to their residue test

plans.

Agency Response to Recommendation Nos. 23, 24 and 25

FSIS agrees with the recommendations. FSIS agrees that it needs to strengthen its review of foreign country test plans. An interagency team was created on June 1, 2000, and expects to complete its initial review by December 2000. The team is responsible for the receipt, review, and analysis of all foreign country residue submissions. The team is comprised of representatives of OPPDE, OFO, and OPHS. The team will review the submissions based on U.S. regulations to determine if the information is adequate, if the documents indicate the countries meet U.S. requirements, and if additional information is needed.

The test plans and results are only a part of the basis for assessing a foreign country's residue program. FSIS onsite audits include reviews of the country's laboratory testing capability and FSIS annually collects more than 8,000 statistically selected samples at the port of

entry for laboratory analysis. Consequently, FSIS questions the need for collecting past residue plans and results because much more comprehensive information has been requested from every country through a lengthy questionnaire, which negates the value of the earlier submissions.

Responses to the questionnaire will provide this information along with other information such as production practices, veterinary drug usage, agricultural chemicals and incidence of environmental contaminants and pesticides, basis for the residue plan, and actual implementation and operation of the program. By December 2000, FSIS will have a more complete and current assessment of the country's controls. If, upon reviewing the responses, FSIS determines that required information is missing, it will be requested from the country. FSIS believes that focusing on in-depth reviews is a more productive use of its resources.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 26

Develop procedures to ensure that (a) a review of residues identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants are included as part of the Technical Service Center onsite equivalency reviews, and (b) appropriate action is taken in those instances where the plans are inadequate, the results vary from the plans, or violations are detected.

Agency Response

The IPD will provide the Director of the Review Staff at the TSC with a summary of the information in residue questionnaires submitted by countries eligible to export to the United States. The Review Staff will be part of the team that will review the submissions. The Review Staff and the IPD will use this information, along with port-of-entry results and information from past audits, to plan upcoming reviews.

This year, FSIS is initiating in-depth reviews of residue programs in a number of countries exporting to the United States. These reviews will make a comprehensive evaluation of the effectiveness of the country's controls over drugs and chemicals that could contaminate meat and poultry. This will include a review of documents, an assessment of whether the country is testing for the appropriate

compounds, whether the plan is implemented as designed, laboratory capability, and enforcement. The reviews are expected to be completed by June 2001.

OIG Position

Management decision can be reached when FSIS provides a targeted completion date for developing, documenting, and implementing residue review procedures.

FSIS cannot demonstrate compliance with regulatory requirements for determining foreign countries as having equivalent inspection systems and, thus, eligible to export meat and poultry products to the United States. The involvement of technical subject-matter experts in the process for determining equivalency was not always documented and process control procedures were not developed and/or adequately documented. In some cases, FSIS' timeframes within which to make equivalency determinations were inconsistent; in other cases, FSIS did not meet the timeframes it established.

We also found that FSIS' documentation reviews and foreign equivalency review (audit) reports did not always provide a sound basis for equivalency determinations.

- The Equivalence and Planning Branch's analysis of foreign countries' import inspection systems was poorly documented, offering inadequate support that the Equivalence and Planning Branch reviewed all of the information submitted by foreign countries for equivalency determinations.
- Data needed to track equivalency determinations was incomplete.
- FSIS reports for equivalency verification audits did not contain evidence that all equivalency requirements had been fully addressed. FSIS analysts made equivalency decisions in cases where audit reports provided insufficient details of the tests made, and where onsite equivalency verification audits had not been conducted.

Regulations⁹ require that the determination of the acceptability of foreign countries to import meat and poultry products to the United States include an evaluation that the foreign country inspection program is equivalent to U.S. standards. To be equivalent, the inspection system must require (1) a process similar to HACCP, (2) mandatory *E. coli* testing, (3) pathogen reduction standards for *Salmonella* and other pathogens, and (4) operating procedures for sanitation, referred to as SSOP. The foreign inspection system must

⁹ Title 9 CFR, Part 327 (a) (2), dated January 1, 1998.

have a program that is adequately staffed by qualified inspectors, that is controlled by the national government, and that is provided with adequate administrative and technical support. It also needs to demonstrate that it maintains a program of inspection, sanitation and quality species verification.¹⁰

FINDING NO. 9

**TECHNICAL
SUBJECT-MATTER
EXPERTS DID NOT ALWAYS
PARTICIPATE IN EQUIVALENCY
DETERMINATIONS**

Contrary to documents provided by FSIS to support their equivalency determination process, technical experts are not always made a part of determining whether a country's food safety regulatory system is equivalent to the U.S. system. Also, when they were involved, their participation was not always adequately documented (see Finding No. 10). According to FSIS officials, all equivalence determinations,

where a country proposes to adopt alternative sanitary measures, are made after review and consultation with agency subject-matter experts. If the foreign country adopted the identical *E. coli* testing approach, there was no need for the Microbiology Division to review those documents. However, we believe FSIS' equivalence determinations could be subject to adverse publicity if evidence does not exist that appropriate technical experts participated in the review and approval process for all determinations that foreign country inspection systems are equivalent to U.S. standards.

The determination of whether a foreign country's import inspection system is equivalent to U.S. standards involves the review of highly technical documentation. According to an FSIS paper entitled, "FSIS Process for Evaluating the Equivalence of Foreign Meat and Poultry Food Regulatory Systems," dated March 1999, FSIS developed a process to conduct equivalence evaluations of foreign food regulatory systems or of individual sanitary measures that vary from U.S. requirements. These evaluations employ evolving international concepts of the linkage between a sanitary measure designed to protect life or health, and the appropriate level of protection it is intended to achieve. Stressing the degree to which sanitary measures require a technical knowledge of food hazard controls, FSIS procedures state that "FSIS experts [should] review the country's program to assure that approved analytical methods are used, that foreign officials are knowledgeable about the use of chemical compounds in their country, and that the country tests for those compounds with potential for getting into the U.S. food supply."

¹⁰ Title 9 CFR, Part 327.2 (a) (2) (i), dated January 1, 1998.

FSIS provided us various documents which purportedly documented their procedures for determining equivalency. An undated paper entitled "Importing Meat and Poultry to the United States," states, that for initial equivalence determinations, "FSIS technical experts evaluate information to assure that critical areas in the five risk areas (contamination, disease, processing, residues, and compliance and economic fraud) are addressed satisfactorily with respect to standards, activities, resources, and enforcement. This review is conducted by a multi-disciplinary team composed, typically of a veterinarian, chemist, microbiologist, statistician, compliance officer, and food technologist." However, we found that this multi-disciplinary team was not always used during equivalency determinations.

The Standards for Internal Control in the Federal Government states that management should ensure that skill needs are continually assessed and that the organization is able to obtain a workforce that has the required skills that match those necessary to achieve organizational goals. We question whether the Equivalence and Planning Branch, collectively, has the technical expertise to make equivalency determinations, in the absence of technical subject-matter experts. According to FSIS, the Equivalence and Planning Branch's function is not to do technical reviews of equivalence issues, but to facilitate the equivalence determinations with Agency technical experts. However, if a country chose to adopt, in its entirety, the FSIS requirements, then equivalence determinations were made by the Branch.

The Equivalence and Planning Branch's operating procedures for determining equivalence were developed by the Equivalence and Planning Branch Chief and are outlined in an undated document entitled "Procedures for Review of Documents Submitted for Equivalence Determination." These procedures state that the Chief, Equivalence and Planning Branch, determines whether the document review should be undertaken by the Equivalence and Planning Branch, or if a special review team is needed. Based on discussions with the Equivalence and Planning Branch Chief, we found that this special review team consists of the Equivalence and Planning Branch program analysts. The procedures also state that, if necessary, portions of the documents are provided to subject-matter experts for additional review. Comments from these experts are reviewed and considered during the equivalence meetings. According to the Equivalence and Planning Branch Chief, assistance from FSIS

microbiologists, chemists, or other experts is requested if a country wants to use an alternative system.

Once documents are reviewed and additional information is requested and received, team reviews are conducted only for what the Equivalence and Planning Branch Chief regards as complex cases. In response to questions that we raised concerning the Equivalence and Planning Branch's internal procedures, the Equivalence and Planning Branch Chief wrote in a July 16, 1999, memo that, "if the equivalence determination is complex or particularly difficult, a team review will be initiated. If the issue is reasonably simple to address, a team review may not be initiated.... I have the discretion to make a decision as to whether I have a team review a document, I review the document, or I assign someone else to review a document."

According to our discussions with Equivalence and Planning Branch staff, Equivalence and Planning Branch's determination of equivalency is based on a roundtable discussion by the program analysts after they review the documents submitted by the foreign countries under consideration. In many instances, along with the branch chief, the program analysts reviewed documents related to a foreign country's inspection system without the involvement of a technical subject-matter expert. Based on our review, we found correspondence from technical subject-matter experts in only 19 of 37 foreign country files reviewed.

According to FSIS officials, FSIS employs a multi-disciplinary team for initial equivalence determinations, but not for ongoing equivalence decisions about specific measures adopted by countries that have already been found to have equivalent systems. FSIS officials also stated that "...each *E. coli* equivalence determination of any sanitary measure that differed from FSIS requirements was fully vetted and reviewed by... five levels of management." FSIS officials acknowledged that this review process, however, was not documented.

FSIS officials disagree with OIG concerns regarding the qualification of the Equivalence and Planning Branch staff to make equivalence decisions, and stated that the positions in this Branch have not been classified as having a specific educational degree requirement; the staff collectively possess the knowledge, skills, and ability necessary for their position.

FSIS recognized the importance of, and the technical expertise needed in, making sound equivalence determinations. An undated document prepared by the Equivalence and Planning Branch entitled "Pathogen Reduction/HACCP Equivalence Determinations," states that, "FSIS' process for evaluating the equivalency of foreign meat and poultry food regulatory systems is both pathfinding and precedence setting. No other food regulatory system in the world, to our knowledge, is actively engaged in applying the concepts of equivalence to the degree and extent as is FSIS. The matter of exactly how an importing country judges, and determines equivalence is controversial. The world is watching how FSIS carries out its equivalence process." On April 14, 2000, FSIS provided copies of e-mails, memos, and other correspondence to show subject-matter experts' participation in reviews of *E. coli* testing programs. These documents, however, were not maintained in the country files. FSIS needs to implement procedures to ensure that technical subject-matter experts are involved in equivalency determinations, as appropriate, and that their equivalency determinations are adequately documented.

RECOMMENDATION NO. 27

Develop procedures that require the participation of technical subject-matter experts, as appropriate, in equivalency determinations, and document the experts' participation, analyses, and conclusions.

Agency Response

FSIS agrees to develop formal procedures by October 2000, for participation of technical subject-matter experts, as appropriate, in equivalence determinations. FSIS will apply this approach, in making equivalence determinations, where a foreign country proposes to adopt requirements that are *different* from FSIS requirements. When a country proposes to adopt an *identical* requirement, then it is not necessary to involve subject-matter experts in those determinations. This is often the case during FSIS' evaluation of foreign country documents submitted in response to the HACCP/pathogen reduction regulation.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 28

Document and implement a system of internal controls to ensure the adequacy and support for foreign equivalency determinations. This should include a

formal review and approval process for the equivalence determinations made.

Agency Response

FSIS agrees with this recommendation. FSIS will formalize its procedures and documentation of equivalence decisions. By December 2000, FSIS will complete the implementation of an internal controls system for foreign equivalency determinations. Effective July 1, 2000, new equivalence decision files will document: 1) All FSIS correspondence with foreign countries; 2) All foreign country submissions (translated and in the originating language); 3) Summary IPD reviews of submissions; 4) Summary of all meetings and teleconferences with foreign officials; 5) Summary of all reviews by subject-matter experts; 6) Documentation of equivalence criteria; 7) Summary of all FSIS management formal reviews and approvals; and 8) Decision memorandum of the equivalence determinations.

OIG Position

We accept FSIS' management decision.

FINDING NO. 10**EQUIVALENCE
DETERMINATIONS WERE NOT
ALWAYS SUPPORTED BY
FILE DOCUMENTATION**

The Standards for Internal Control in the Federal Government states that internal controls and all transactions and other significant events need to be clearly documented, and documentation should be readily available for examination. As part of the "Top-to-Bottom Review" for the pending reorganization, FSIS identified the increased need for clear and concise

documentation, along with the ability to explain the results of various tests and findings. We found that the Equivalence and Planning Branch's files containing the results of documentation reviews of foreign inspection systems did not always include adequate documentation to support equivalence determinations for SSOP's and *E. coli* testing. (FSIS was in the process of determining the equivalence of foreign systems for HACCP and *Salmonella* testing during our field work. Therefore, we were not able to evaluate the

support for equivalence determinations for these areas.) In all instances, the Equivalence and Planning Branch did not document how it determined that a country's SSOP and *E. coli* testing requirements were equivalent to U.S. standards, while in some instances, the files did not contain the information the Equivalence and Planning Branch would have needed to make a determination. Procedures had not been developed to ensure that this type of documentation was prepared and maintained to support equivalency determinations. In one case, the Equivalence and Planning Branch conferred "provisional equivalency" on a country even though available documentation, including an onsite equivalence verification review, suggested the country's alternative system was not equivalent.

In August 1996, the Equivalence and Planning Branch sent foreign countries a copy of the requirements for pathogen reduction and HACCP, along with an implementation schedule. In October of that year, the Equivalence and Planning Branch provided additional information on the new requirements and requested information on country plans to implement the SSOP and *E. coli* testing requirements. Foreign countries wishing to be approved for equivalency status were requested to submit responses to questionnaires and documentation to support that the requirements of HACCP and pathogen reduction have been met. Countries were also requested to provide copies of all statutes, regulations, directives, circulars, manuals, and other written instructions that implement the HACCP and SSOP requirements, and *Salmonella* and *E. coli* testing program requirements. In addition, the country governments' plans for meeting these requirements by adopting the same or an equivalent set of sanitary measures were also required. Countries were to submit their SSOP and *E. coli* testing plans no later than December 31, 1996.

We evaluated the Equivalence and Planning Branch's process and procedures for making equivalence determinations and reviewed the country files for the 37 countries that applied for eligibility to import to the United States under the new standards. Documents in the files included the countries' submission of their SSOP and *E. coli* testing programs, telegrams sent by the Equivalence and Planning Branch to the countries, Equivalence and Planning Branch minutes of their review of countries' submissions, microbiology laboratory results, and other internal correspondence.

a. Equivalence Analysis Was Not Adequately Documented

Documentation was not always sufficient to show how the Equivalence and Planning Branch determined the equivalency of the 37 countries reviewed for SSOP and *E. coli* testing. According to the Equivalence and Planning Branch Chief, information provided by the foreign countries was copied and distributed to members of the Equivalence and Planning Branch review team for an evaluation of each country's inspection system. After each evaluation, the team arrived at a consensus on each issue of equivalence, which was summarized in minutes of its discussions of foreign country submissions. However, based on our review of these summaries, they are very broad and do not describe what information was reviewed, the events that occurred, or the results of the Equivalence and Planning Branch's analysis which led to the equivalency conclusion.

The following represent examples of instances in which we were unable to determine the process used by FSIS to evaluate the adequacy of foreign countries' food inspection systems.

Country F. The file on Country F contained insufficient documentation to explain how the Equivalence and Planning Branch determined the adequacy of Country F's *E. coli* testing program. There was no evidence in the file to show that Country F had responded to all of FSIS' requests for documentation. Summaries of Equivalence and Planning Branch's discussions on what Country F had submitted were prepared for January, February, and July 1997. The July summary stated that the SSOP information was sufficient, but the summary showed no analysis that resulted in this conclusion. The summary also stated that the Equivalence and Planning Branch would wait for the Microbiology Division to review Country F's *E. coli* sampling submissions, but there were no follow-up summaries on this issue.

An onsite equivalency review of Country F's inspection system was conducted from November 20 through December 10, 1997. The review report concluded that Country F's inspection system did not have effective controls in place to consistently prevent, detect, control, and correct product adulteration. The one slaughterhouse did not have *E. coli* testing procedures in place.

In April 1998, the Microbiology Division completed its analysis of Country F's *E. coli* testing procedures. The results stated that

Country F needed to revise information it provided about its sampling techniques. The file shows no additional information between April and August 1998, when an Equivalence and Planning Branch memorandum was sent to the FSIS Administrator stating that Country F had implemented an equivalent *E. coli* testing program. As of the completion of our field work, a subsequent onsite equivalency review had not been conducted to verify the equivalency of the *E. coli* testing program.

Country D. An August 1998 Office of Policy, Program Development and Evaluation memorandum stated that Country D's *E. coli* system was not equivalent, but as of April 15, 1999, Country D is shown as "provisionally equivalent." However, we were unable to identify information in Country D's file that would support this determination. A comparison study between the *E. coli*-based system of the United States and the *Enterobacteriaceae*-based system of Country D was not completed, and issues related to the collection of indicator organisms had not been resolved as of the completion of our field work.

An onsite review performed at the end of 1997 identified significant operational and systems deficiencies pertaining to in-plant inspection system controls and *E. coli* testing requirements. It is unclear, however, whether Country D's use of an alternative system of *E. coli* testing was reviewed. The report stated, "*E. coli* testing was not performed in any establishments that slaughtered swine and bovine." However, Technical Service Center reviewers asked managers in Country D the same series of questions asked in the United States to determine if U.S. requirements are being met.

Even though FSIS maintained concerns over Country D's *E. coli* testing, an onsite equivalency review was not conducted in 1998. The Microbiology Division's January 28, 1998, review of information submitted by Country D concluded that none of the documents pertained to generic *E. coli* testing, and that the bacteriological testing procedures submitted were not equivalent to the generic *E. coli* testing program required under HACCP and pathogen reduction. As stated in FSIS' April 21, 1998, telegram to Country D requesting additional information, "Country D's testing program establishes Aerobic Colony Counts and *Enterobacteriaceae* Colony Counts as the indicator organisms for validating and verifying the process control of fecal contamination.

The pathogen reduction/HACCP final rule establishes generic *E. coli* as the indicator organism." Also, a May 13, 1998, memorandum from a Microbiology Division staff member to the Equivalence and Planning Branch states, "The pathogen reduction/HACCP final rule specifies that generic *E. coli* is the most effective measure of process control for fecal contamination. Since we do not yet have a policy statement on generic *E. coli* testing, I have simply prepared a list of differences, between the generic *E. coli* testing outlined in pathogen reduction/HACCP and Country D's system."

Even though the Microbiology Division had determined that the alternative sampling method that Country D wanted to adopt was not equivalent to generic *E. coli* as the indicator organism, a September 10, 1998, letter from Country D's government to FSIS' stated, "I am pleased that you agree to Country D's proposal to use Aerobic Plate Counts and *Enterobacteriaceae* bacterial counts as test indicators." Subsequent to this, Country D sent the Equivalence and Planning Branch an equivalence assessment plan (for alternative *E. coli* testing) dated September 30, 1998. The Microbiology Division's October 7, 1998, assessment of this plan stated that parts of the draft submission were unclear and confusing, and suggested improvements to the plan. Of note was the choice of a different indicator organism, indicating that Country D would need to provide a comparative study between the United States' *E. coli* testing program and Country D's *Enterobacteriaceae* testing program. In response to FSIS' request for clarification and additional information to be added to Country D's plan, Country D resubmitted the same information that was previously found lacking by the Microbiology Division, and dated it October 27, 1998.

Country D drafted a November 5, 1998, "Experimental Plan" in order to conduct a comparative study analysis between Aerobic Plate Counts *Enterobacteriaceae* and generic *E. coli* testing and the differences in the size of the surface areas sampled. However, a November 9, 1998, memorandum from the microbiologist reviewing the "Experimental Plan" stated that it should be resubmitted with a more detailed protocol because it was unclear as to exactly what the researchers would be doing in each part of the study. The memorandum also stated that FSIS hoped to resolve the issues in an upcoming meeting in January 1999.

As a result of the January 12 and 13, 1999, conference with Country D officials in Washington, DC, a "Proposal for Equivalency Study" was adopted. The study was to be completed by May 1; however, the Technical Service Center onsite equivalency review performed from January 25 to February 26, 1999, concluded that Country D had not fully implemented pathogen reduction and HACCP requirements. Therefore, at the time of the onsite review, Country D was not in compliance with the pathogen reduction/HACCP requirements for generic *E. coli* testing.

To respond to our questions concerning missing documentation, the Equivalence and Planning Branch Chief prepared a chronology, dated July 14, 1999, which outlined events related to Country D's equivalency determination. According to the chronology, on December 3, 1998, FSIS advised Country D that testing for *Enterobacteriaceae* was equivalent to *E. coli* testing provided that they initiate a study comparing the two testing programs in those areas where they differed. On December 15, 1998, a document listing two of the remaining issues outstanding from the documentation and outlining the comments raised by the Microbiology Division and the Equivalence and Planning Branch were faxed to Country D for comment. Subsequently, a December 21, 1998, letter was sent to the Equivalence and Planning Branch thanking FSIS for accepting *Enterobacteriaceae* testing.

The chronology noted that most of the document review deficiencies were resolved between FSIS and Country D officials at the January 12-13, 1999, meeting. On March 10, 1999, a meeting with Country D officials was initiated to address the remaining document review issues and each finding as a result of the Technical Service Center onsite review. On April 21, 1999, a letter was faxed by Country D, which satisfactorily addressed the document review issues. On June 1, 1999, the Microbiology Division provided a favorable evaluation of the results of Country D's research comparing *E. coli* testing to *Enterobacteriaceae* testing.

None of the additional information included in the July 1999 chronology prepared by the Equivalence and Planning Branch was documented in the country file for Country D.

Country G. A Technical Service Center onsite equivalency review completed in June 1998 found that Country G (1) was not

performing species verification testing, (2) had not developed actions to take if establishments failed to implement pathogen reduction and HACCP requirements, (3) did not follow U.S. standards in sampling for *E. coli*, and (4) did not monitor for *Listeria* and *Salmonella* in ready-to-eat products. We noted that the approval date for the 1998 onsite review report was March 9, 1999, 9 months after it was completed and 4 months after the FSIS cable confirming Country G's equivalency status. The review report recommended that Country G outline the procedures it planned to implement to correct the deficiencies noted in the report.

Country G's *E. coli* testing program was determined equivalent based on a November 1998 cable from FSIS to the Agriculture Counselor for Warsaw that stated that Country G has agreed to use an equivalent, internationally recognized method to analyze *E. coli*. We were unable to locate documentation in the country file to support this agreement. However, on April 14, 2000, FSIS provided documentation of an October 6, 1998, cable from Country G to FSIS which stated that Country G Veterinary Officials confirmed that they would be able to comply with the conditions required by FSIS for *E. coli* testing by October 8, 1999.

The November 1998 cable also stated that FSIS was unsure if Country G took the required 12 months to complete its baseline study to establish performance criteria for *E. coli* testing, and noted that unless Country G met the baseline study qualification, FSIS would **assume** (emphasis added) it was using the statistical process control techniques it had agreed to implement. Based on the inadequacy of information to clarify FSIS' uncertainties about Country G's performance criteria and corrective actions taken to address the deficiencies found in the 1998 onsite review, we question FSIS' equivalency determination.

According to the July 14, 1999, chronology for Country G prepared by the Equivalence and Planning Branch in response to our questions, the May/June 1999 onsite equivalency review of Country G found that statistical process control techniques for *E. coli* testing were implemented in all but one establishment. However, we continue to have concerns over the Equivalence and Planning Branch's equivalency determination process since Country G was determined to be equivalent in November 1998, which was prior to the results of the May/June 1999 onsite review.

b. The Equivalence and Planning Branch Did Not Adequately Track the Data Involved in Equivalence Determinations

The Standards for Internal Control in the Federal Government states, in part, that control activities include the creation and maintenance of related records which provide evidence of execution of activities, as well as appropriate documentation. As part of our review, we requested the Equivalence and Planning Branch to provide all documentation related to equivalence determinations for each country approved to export meat and poultry products to the United States. We were informed that all information would be included in documentation review files maintained for each foreign country. However, we found that the Equivalence and Planning Branch documentation review files did not include all information pertaining to equivalence for each country. During our evaluation of the countries' files, we identified information for 17 countries that was missing from the files. The type of information that could not be located included Microbiology Division analysis results and telegrams sent to countries regarding their SSOP's and *E. coli* testing.

Of those 17 countries where there was insufficient data in the country file, 15 were approved as having an SSOP and *E. coli* testing program equivalent to U.S. requirements.

For example, based on a March 13, 1998, cable from FSIS to the chief meat and/or poultry inspection official for Country H, information dated February 2, 1997, April 1997, June 19, 1997, and July 15, 18, 19, and 21, 1997, regarding the implementation of *E. coli* testing was submitted by Country H. However, our review of the country file for Country H did not identify any of these documents in the files. In addition, the file for Country I contained a September 10, 1997, response to an August 4, 1997, request from FSIS concerning their implementation of SSOP and *E. coli*. However, the file did not include FSIS' August 4, 1997, request for information in order to determine the adequacy of Country I's response.

We conclude that FSIS needs to strengthen internal controls relating to its documentation of the processes used and analyses made in reaching equivalence determinations.

RECOMMENDATION NO. 29

Develop a management control process and procedures to ensure equivalence decisions are adequately documented. The procedures should require that files

contain supporting evidence, including detailed analysis of information received and reviewed, resolution of issues raised during the review process, and conclusions reached.

Agency Response

FSIS agrees with this recommendation. FSIS agrees that equivalence decisions should be adequately documented and that the files must be complete. Therefore, FSIS will institute the same measures described in response to Recommendation 28.

The examples that OIG cites to demonstrate their concern with the equivalence determination process is misplaced and erroneously concludes that the equivalence process was incomplete. The process was complete, but not all of the documents were in the country files at the time of the audit.

OIG Position

We accept FSIS' management decision.

FINDING NO. 11**EQUIVALENCE
DETERMINATIONS WERE
NOT MADE IN A TIMELY
MANNER**

At the time of our audit (July 1999), FSIS had not completed reviews to determine the equivalency status for foreign countries that continue to export meat and poultry products into the United States under HACCP and pathogen reduction standards. FSIS did not establish timeframes for completing reviews of *E. coli* and SSOP submissions

from foreign countries, and it did not meet the timeframes it established for completing reviews of *Salmonella* and HACCP submissions. These reviews are critical in determining the adequacy of foreign country food safety systems.

During the implementation of HACCP and pathogen reduction requirements for imported meat and poultry, establishments in the 37 countries that had been approved for importing these products into the United States under the pre-HACCP system were allowed to continue their importations pending the Equivalence and Planning

Branch's approval of their governments' food safety systems and its determination that those systems are equivalent to U.S. standards. According to regulations,¹¹ establishments with 500 or more employees were required to have an equivalent system in place by January 1998, and establishments with between 10 and 500 employees were required to have a system in place by January 1999. (Establishments with fewer than 10 employees had until January 2000 to implement a system.) An FSIS official stated that a decision was made to review country SSOP and *E. coli* testing programs before reviewing HACCP and *Salmonella* because the SSOP and *E. coli* requirements were to be in effect as of January 27, 1997.

The Equivalence and Planning Branch is responsible for ensuring that eligible countries implement both systems by the established dates. However, a formal plan for completing the equivalency determinations for SSOP and *E. coli* testing was never established. The Equivalence and Planning Branch prepared a plan to complete the HACCP and *Salmonella* equivalency determinations and notify all 14 countries by June 30, 1999. However, as of July 1999, the documents were still under review by Equivalence and Planning Branch officials.

RECOMMENDATION NO. 30

Establish a time-phased plan to expedite the process for determining equivalency.

Agency Response

FSIS agrees with this recommendation. FSIS will implement time-phased plans for future equivalence determinations, effective October 1, 2000.

OIG Position

We accept FSIS' management decision.

¹¹ Title 9 CFR, Part 304 et al., dated July 25, 1996.

FINDING NO. 12

EQUIVALENCY DETERMINATIONS WERE MADE WITHOUT ONSITE REVIEWS FOR CURRENT TRADING PARTNERS

The Equivalence and Planning Branch made HACCP and pathogen reduction equivalency determinations for current trading partners in cases where Technical Service Center reviewers had not performed onsite equivalency verification reviews. Regulations¹² state, in part, that maintenance of eligibility of a country for importation of products into the United

States depends on the results of periodic reviews of the foreign meat inspection system in operation by a representative of the Department. According to documentation provided by FSIS, these periodic reviews are generally repeated annually. In addition, each equivalency decision should be based, in part, on an onsite verification review. However, we found that for current trading partners, onsite reviews of foreign food regulatory systems were not being conducted on an annual basis. FSIS did not place a high enough priority on the reviews to prevent budgetary constraints from restricting overseas travel. In addition, we found that six countries were approved equivalent for SSOP and *E. coli* without onsite reviews to verify the country inspection program was operating as represented by documentation submitted to FSIS.

In response to our concerns over the equivalence determination process, FSIS prepared a document which stated, in part, that OIG has incorrectly interpreted that audit (onsite review) findings have an impact on document review equivalence decisions, and that the timing of an audit must impact on the equivalence decision. In addition, an April 3, 2000, document prepared by FSIS, in response to our draft report, states that the regulations do not require that an onsite review must be made before equivalence determinations regarding new FSIS requirements that must be implemented by current trading partners to maintain equivalence. However, without the onsite equivalency verification review, there is no validation that the foreign country's food regulatory system is operating as represented to FSIS.

The Equivalence and Planning Branch made equivalency decisions for current trading partners after completing their documentation reviews, but without the results of onsite verification reviews. In these cases, the Technical Service Center had not conducted onsite reviews to validate the equivalency of the foreign country's food regulatory system. In 1997 and 1998, 37 countries were subject to review, but only 30 onsite reviews were conducted in 1997 and 24 in 1998. A

¹² Title 9 CFR, Part 327 (a) (2), dated January 1, 1998.

Technical Service Center management official stated that reviews were postponed because of a 40-percent cut in the International Review Staff's budget. However, FSIS had not developed a contingency plan for cases where a country had not received an onsite review as part of the equivalency determination process, or as part of the maintenance of eligibility requirement.

Documents prepared by the Equivalence and Planning Branch for determining equivalency state that the onsite review is conducted after the Equivalence and Planning Branch completes its documentation review. However, for six countries, the Equivalence and Planning Branch granted equivalency status for SSOP and *E. coli* testing programs prior to an onsite review. The Equivalence and Planning Branch's documents for determining equivalence also state that before a final equivalency determination is made, another onsite audit is completed, and the findings and subsequent documents are thoroughly reviewed. We found that for five countries, the Equivalence and Planning Branch granted equivalency status after completion of the documentation review, but before the onsite verification. Country B was granted equivalency in November 1998 and was not subject to an onsite verification review in either 1997 or 1998. A March 1999 onsite review of this country's inspection system identified variances in their testing programs.

Table 1: Foreign Countries Determined "Equivalent" Prior to an Onsite Review

Country	Type of Approval Per Foreign Country Cable	Date of Approval	Date Documentation Review Completed	Date of Onsite Audit	Comments
B	Equivalent	Nov. 12, 1998	Nov. 12, 1998	None	No audit conducted in 1997 or 1998.
E	Equivalent	Dec. 9, 1998	Dec. 9, 1998	Dec. 1997	No audit conducted in 1998. Cable stated equivalent for <i>E. coli</i> .
G	Equivalent	<i>E.coli</i> Nov. 13, 1998 SSOP Feb. 20, 1998	Nov. 13, 1998	June 1998	No audit conducted after documentation review. Cable stated equivalent for <i>E. coli</i> .
J	Fully Equivalent	Dec. 2, 1998	June 23, 1998	Apr. 1998	No audit conducted after documentation review.
K	Fully Equivalent	Dec. 9, 1998	Sept. 4, 1998	June 1998	No audit conducted after documentation review.
L	Fully Equivalent	Dec. 2, 1998	June 11, 1998	Mar. 1998	No audit conducted after documentation review.

Country E received an onsite review as early as 12 months before the documentation review was completed. Countries G, J, K, and L received onsite reviews as early as 2 to 5 months before the documentation reviews were completed. FSIS has not established any procedures that would allow use of the results of onsite reviews that had been performed prior to the completion of the documentation review. Specific areas reviewed during the onsite review may not be sufficient to verify information submitted by foreign countries for use in determining equivalency with U.S. requirements.

RECOMMENDATION NO. 31

Ensure that onsite audits for current trading partners are conducted at least annually.

Agency Response

FSIS agrees with this recommendation. This issue will be incorporated into the FSIS procedures for import inspections by December 2000.

OIG Position

We accept FSIS' management decision.

RECOMMENDATION NO. 32

For current trading partners, develop and implement a policy for onsite verifications of changes in the requirements for foreign inspection systems.

Agency Response

FSIS agrees with this recommendation. The equivalence process begins with a document review, to determine if the foreign country's written submission documents how its sanitary measures meet the United States' appropriate level of protection. This evaluation is then verified by an onsite audit to confirm that the foreign country has in fact implemented its sanitary measures, as described in its written submission.

However, the finding for this recommendation reflects a misinterpretation of 9 CFR 327.2. The misinterpretation is evidenced by a statement: "We found that the food regulatory systems of six countries were determined "equivalent" by the Equivalence and Planning Branch without verification by an onsite review."

This statement is incorrect. The six countries (cited later in a table) have food regulatory systems that were found fully equivalent to the U.S. system many years ago. Each of these countries has undergone initial equivalence evaluations to include an extensive onsite audit and are listed as equivalent at 9 CFR 327.2(b) Additionally, each of these countries has been audited onsite many times since their food regulatory systems were initially found equivalent.

When an eligible country proposes an alternative sanitary measure to FSIS for an equivalence decision, FSIS conducts a full document analysis of only that component of the foreign food regulatory system that is affected by the change. A final determination of equivalence for a proposed sanitary measure is verified by onsite audit. Trade continues in the interim. Three circumstances could result in an interruption of trade. One, where an emergency sanitary measure is implemented by FSIS to address a hazard that is so severe that no product can enter the marketplace from a foreign establishment until the control is in place. Two, where an exporting country does not provide satisfactory documentary evidence of an equivalent sanitary measure. Three, where a system audit reveals that an exporting country is not implementing a public health sanitary measure in the manner that FSIS initially determined to be equivalent. None of these three conditions applied during FSIS evaluations of PR/HACCP alternative sanitary measures proposed by foreign countries.

OIG Position

To reach management decision, FSIS needs to provide a target date for the development and implementation of a policy for onsite verifications of changes in the requirements for foreign inspection systems.

RECOMMENDATION NO. 33

Clarify the regulations regarding FSIS' procedures for determining equivalence for current trading partners, taking into consideration major changes such as

HACCP and pathogen reduction requirements.

Agency Response

FSIS has been properly applying its regulations regarding equivalence determinations. In the future, FSIS will take into consideration major changes, such as PR/HACCP, as it documents its procedures for determining whether equivalence is maintained for current trading partners, as referenced in our response to Recommendation No. 12.

OIG Position

To reach management decision FSIS needs to provide a target date for the development and implementation of a policy for onsite verifications of changes in the requirements for foreign inspection systems.

FINDING NO. 13**ONSITE EQUIVALENCY
VERIFICATION REVIEWS
NEED TO BE BETTER
DOCUMENTED**

Technical Service Center onsite equivalency verification review (audit) reports and their supporting notes do not provide documented evidence that U.S. equivalent inspection requirements were verified as functioning. In addition, we found inconsistency in the information included in the audit reports and supporting review notes. Reporting and

evidence standards had not been established to support the adequacy of the onsite reviews and subsequent equivalency determinations. Although FSIS refers to their onsite verification reviews as audits, these reviews are not conducted and/or reported in accordance with Generally Accepted Government Auditing Standards. FSIS does not maintain sufficient, competent evidence to support the scope of the verification work or the conclusion that foreign systems were equivalent to U.S. inspection standards.

Documentation provided by FSIS on April 3, 2000, states, in part, that “The annual ongoing equivalence onsite reviews are not required to cover all aspects of a country’s inspection system on each visit. Prior to becoming eligible to export to the United States, all countries had previously been subjected to an onsite team audit by Agency experts. These annual audits focus primarily on new FSIS inspection requirements and sampling of inspection requirements on other risk areas on a case by case basis.”

We reviewed audit reports for 31 countries and determined that none of the reports or supporting review notes included sufficient information to be used as a basis for making equivalency determinations. Many of the reports and supporting review notes lacked sufficient information about deficiencies identified during the review. Therefore, there is a risk that equivalency determinations are not supported and that adequate followup on corrective actions will not occur during subsequent reviews.

The Technical Service Center staff is responsible for conducting onsite equivalency reviews to verify whether a country's food safety regulatory inspection system meets U.S. standards. The review seeks evidence that the exporting country has instituted sanitary measures that will provide the same level of protection for American consumers that is ensured by the domestic system.

The audit reports are provided to the Equivalence and Planning Branch and, according to FSIS procedures, are used as a basis for making equivalency decisions. However, according to subsequent documentation provided by FSIS, the audit reports are not the only basis for making equivalence determinations. Prior to the equivalency decision, the Equivalence and Planning Branch staff members review the reports to determine if the country's system of oversight and compliance, as represented in their laws, regulations, and other documentation, is in place and functioning. Regulations¹³ require that FSIS review country documentation to ensure that foreign inspection programs meet U.S. requirements. Those requirements identify an "equivalent" system as a national food safety program that meets U.S. standards with regard to organization and staffing, supervision of employees, qualification of inspectors, enforcement authority, and national sanitation and residue standards. Regulations further identify an "equivalent" inspection program as one that provides periodic inspections, random sampling, and written reports.

We reviewed audit reports performed of establishments in foreign countries during 1997 and 1998 and found that none of the reports specifically addressed U.S. equivalent elements relating to HACCP and pathogen reduction requirements, as outlined in Federal regulations. We could not determine if required elements were reviewed by the Technical Service Center staff. For example, the reports for Country H, Country N, and Country O make no reference to inspector qualifications and supervision. The reports for Country H, Country N, and Country O also make no reference to any review of the enforcement authority the national governments claimed to have over meat and poultry establishments. The reports for Country A, Country P, Country Q, Country R, Country G, Country S, Country T, Country U, Country V, and Country J include a general statement that a visit was made with foreign national inspection officials to discuss their oversight program and practices. However, neither the reports or supporting review notes provide sufficient information to document that U.S. requirements relating to organizational structure, staffing, and qualifications of inspectors were validated.

According to FSIS officials, the organizational structure, staffing, and qualifications of inspectors had not changed since the prior audit, and reviewers had verified this through discussions with the country inspection officials during the entrance conference.

¹³ Title 9 CFR, Part 327.2, dated January 1, 1998.

For Country P, we noted the report stated that residue control and processed product control were adequate at the sites visited. However, neither the report nor supporting review notes gave details concerning what was reviewed. The report for Country R stated that controls over laboratory reviews, disease, residue, and compliance fraud were in place but provided no information about the methodology used to arrive at this conclusion. The reports for Country A and Country E both noted that deficiencies were present at several establishments visited, but did not include the specific establishments where the deficiencies were disclosed.

In some cases, the sufficiency of the review work performed could not be determined due, in part, to lack of adequate documentation of the work performed and any deficiencies disclosed. For example, as part of the 1997 audit report for Country P, the Technical Service Center reviewer offered no details of what was reviewed under residue control, compliance/economic fraud control, and processed product control. In addition, Country P's national residue laboratory was not reviewed because according to the reviewer's notes, it had been reviewed the previous year. However, based on our analysis of the 1996 report for Country P, we could not conclude that the national residue laboratory had been reviewed. For residue, the report stated only that "sampling and analysis is done per a residue national program, complying with USDA requirements." No other documentation was provided to substantiate a review of the national residue laboratory. According to FSIS officials, the Agency followed up its 1998 onsite review with a review of one national residue control laboratory that was found satisfactory.

We also noted in the audit report for Country P that no formal exit meeting was held with Country P's meat inspection officials. The exit meeting section of the report stated, "the Head of the Meat Hygiene Unit accompanied the reviewer and was aware of findings and review results." However, the report did not identify any findings, so we were unable to determine the nature of the findings and review results of which the Head of the Meat Hygiene Unit was made aware.

Based on our discussions with Technical Service Center staff, we concluded that the reviewers possess the competence and expertise needed to conduct onsite equivalency reviews of foreign food regulatory systems. Guidelines need to be developed to provide both reporting and evidence standards to support the adequacy of the onsite reviews and the resulting equivalency determinations. Based

on discussions with TSC officials on April 6, 2000, a new reporting format has been developed to improve the reporting process.

RECOMMENDATION NO. 34

Ensure that reporting and evidence standards developed for equivalency verification reviews provide for appropriate documentation of all areas required to be reviewed by regulation.

Agency Response

According to 9 CFR 327.2 (a) (2) (iii) "Maintenance of eligibility of a country for importation of products into the United States depends on the results of periodic reviews of the foreign meat inspection system..." The regulatory requirement of periodic reviews does not mandate that each review encompass all aspects of a country's inspection system.

Nevertheless, FSIS is committed to ensuring that these reviews are consistent and thoroughly documented. At the time of the OIG audit, FSIS was in the process of developing an enhanced uniform audit format that addressed the following five risk areas: 1) animal disease controls; 2) sanitation controls; 3) enforcement controls; 4) slaughter and processing controls; and 5) residue controls. These five risk areas cover all of the FSIS regulatory requirements for countries that export to the United States. Subsequent to the OIG audit, the audit format was finalized.

The new audit format has been implemented for all FSIS audits conducted in fiscal year 2000. Also, audit planning has been enhanced to ensure that onsite audits cover all relevant areas.

OIG Position

We accept FSIS' management decision.

FINDING NO. 14
EQUIVALENCY REVIEW
REPORTS WERE NOT
ISSUED IN A TIMELY
MANNER

We found that equivalency review reports were not issued in a timely manner. For almost half the reports that bore a date and were released for onsite reviews performed in 1997 and 1998, the elapsed time between the completion of the fieldwork and the issuance of the report was 4 months or longer.

We conducted a comparison between the completion date for a foreign country's onsite review and the date of the final audit report for that country and noted that a substantial length of time had elapsed between these dates. As noted in Finding No. 3, the draft report is forwarded from the Technical Service Center to the Equivalence and Planning Branch for review and comment prior to issuance. In 1997 and 1998, 37 foreign countries were subject to review as part of the HACCP and pathogen reduction requirements. In 1997, 30 onsite reviews were conducted by the Technical Service Center reviewers, but only 24 audit reports were issued. Reports were not issued for Country H, Country N, Country M, Country W, Country X, and Country Y. In 1998, 24 onsite reviews were conducted, but only 17 reports were approved as final. As of July 1999, four reports were still in draft. These draft reports are for Country H (onsite review conducted in November 1998), for Country M (onsite review conducted in October 1998), and for Country Z and Country AB (both onsite reviews conducted in April 1998). Reports had not been issued for Country I, Country P, and Country Y as of the end of our field work.

Of the 41 final reports that were issued in 1997 and 1998, seven reports were undated. Of the remaining 34 reports that included a date, we found delays ranging up to 15 months between the date the onsite review was completed and the date the final report was issued. Of these reports, 15, or 44 percent, were completed 4 to 15 months after the onsite review.

According to an April 3, 2000, document prepared by FSIS, the major reason that these reviews were not released within a shorter timeframe was that the Director of the Review Staff had to perform the functions of three positions: the Director of the Review Staff, the Branch Chief for Domestic Review, and the Branch Chief for International Review which precluded him from focusing only on the reports. In addition the document stated that the length of time for audit reports to be finalized does not preclude the agency from taking action on findings, and that depending on the seriousness of

the finding, the Equivalence and Planning Branch initiates immediate action prior to the completion of the audit report.

RECOMMENDATION NO. 35

Develop procedures for timely completing reports documenting reviews of foreign inspection systems.

Agency Response

FSIS agrees with this recommendation. Formal procedures will be completed by December 2000. In 2000, new foreign country reporting requirements were instituted. Draft foreign country reports are due from the reviewers within 10 working days of their return to the office. Exceptions to the 10-day rule must be requested in writing, with justification, through the Branch Chief of the International Review Branch or Director of the Review Staff. Similar timeframes are in effect throughout the process, creating a timeline that has the report completed and in "Draft Final" form to be sent to the foreign country government officials for comment within 60 days from the date of the exit conference with the foreign officials. This 60-day commitment is also detailed in the cable that each reviewer sends to the foreign country prior to each audit. Because of language differences, and necessary time for response, the foreign countries are allowed 60 days to submit their response to the report. The foreign country response is then added to the report as an attachment, and the report is finalized.

OIG Position

We accept FSIS' management decision.

GENERAL COMMENTS

We noted that as part of the pre-audit process, FSIS transmits a copy of its audit plan to the foreign country at least 30 days before implementation. The plan identifies each establishment that the Technical Service Center reviewers will visit during the onsite review. A document entitled FSIS Process for Evaluating the Equivalence of Foreign Meat and Poultry Food Regulatory Systems, dated March 1999, states, "the audit protocol is sufficiently detailed to inform the exporting country of the audit objectives, scope, and criteria, who they will be visiting, what they wish to see, where they wish to go, and when they wish to do so." We found that in one instance, a foreign country delisted an establishment that was known by the government to be in noncompliance with U.S. inspection requirements after receipt of the audit plan but prior to initiation of the onsite review. Therefore, another establishment was selected since delisted establishments are not reviewed. Having advance knowledge of the establishments selected for review may have been the reason that the foreign government delisted the establishment. We were provided with a copy of a letter sent to all countries concerning FSIS' delistment policy. However, in order to validate the true condition of a foreign country's food regulatory inspection system during its onsite equivalency verification reviews. FSIS should reconsider the benefits of providing advance notice to the foreign countries of the establishments to be reviewed.

EXHIBIT A – FSIS RESPONSE TO THE DRAFT REPORT



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

TO: James R. Ebbitt
Assistant Inspector General
for Audit
Office of the Inspector General

JUN 7 2000

FROM: *fo* Thomas J. Billy
Administrator

SUBJECT: Office of Inspector General's (OIG) Draft Report on the Imported Meat and Poultry Inspection Process Phase 1, Audit Number 24099-03-Hy

We appreciate the opportunity to review the subject report. The Food Safety and Inspection Service (FSIS) offers the following responses to the recommendations. FSIS recognizes the need to make improvements in the current program. While we have accepted many of the report's recommendations, nevertheless, there are a number of areas in which we disagree. The actions that FSIS will take to enhance the imported meat and poultry inspection process are outlined in our responses.

Key Recommendations:

We recommend that FSIS conduct an assessment of the current organizational structure, clarify roles and responsibilities, and establish a system of management and operating control objectives and processes to ensure the safety and wholesomeness of imported meat and poultry products. FSIS also needs to conduct independent internal control reviews, emphasizing those processes that changed in the reorganization, provide management control training, and report the conditions disclosed in this audit as material management control weaknesses in the import inspection process.

We also recommend that FSIS develop and implement formal procedures, approved by FSIS management, for all aspects of its import inspection program, most specifically those related to (1) making equivalency determinations based on an evaluation of each foreign country's food safety regulatory system, as appropriate, (2) its enforcement of sanitary measures, and (3) entering country eligibility information into FSIS' inspection system. We also recommend that FSIS enforce the regulatory requirements for countries to submit their residue test plans and test results and establishment certifications by foreign inspection systems.

Concerning equivalency determinations, FSIS needs to establish a time phased plan to complete each determination and ensure that technical subject-matter experts are involved in determinations, the determinations are documented, and onsite verification reviews are conducted prior to granting equivalency status. For current trading partners, FSIS needs to develop and implement a policy for onsite verifications of changes in the requirements for foreign systems and ensure that onsite audits are conducted annually.

Agency Response:

We agree with the key recommendations with the exception that FSIS does not believe the issues outlined in this audit report constitute a material management control weakness. FSIS expects to complete the recommendations outlined in this report by March 2002.

FSIS firmly believes that enhanced internal controls will help in managing change from shifting environments and evolving demands and priorities in the import arena. FSIS will employ a comprehensive and continuous effort to ensure that the imported meat and poultry inspection processes use a system and a risk management approach in applying management controls in its operations.

Recommendation No. 1:

Conduct an in-depth assessment of the current organizational structure to establish a system of control objectives and processes to ensure that the goals of import inspection process are achieved.

Agency Response:

FSIS agrees with this recommendation. FSIS will assess the current organizational structure and identify import inspection controls, objectives and processes. The assessment will be completed by May 2001.

Recommendation No. 2:

Require increased management oversight and approval of changes to import inspection operations and procedures.

Agency Response:

FSIS believes that management oversight and approval of changes to import inspection operations and procedures is adequate. Inspection of imported meat and poultry product is controlled through a multi-tiered supervisory and management oversight structure. The port of entry import inspections are conducted in 15 of the 17 FSIS Districts. The Circuit Supervisor, Assistant District Manager, District Manager, Assistant Deputy Administrator and Deputy Administrator, Field Operations all serve to provide progressive levels of supervisory/management oversight and controls to inspectors conducting imported product inspections.

Additionally, the Technical Service Center (TSC) provides technical guidance and support to Agency inspection personnel, including supervisors and managers, with regard to all aspects of the import process. The TSC also works directly with Office of Policy, Program Development and Evaluation (OPPDE) in order to achieve clarity and changes to Agency policy issues as needed. When changes in policy occur that impact import inspection operations and procedures, this information is conveyed to all FSIS personnel involved with import inspection through electronic generated import messages and through changes to the import manual of procedures. FSIS will prepare a summary of the management oversight functions and procedures. See item 7 of the response to recommendation 12. These procedures will outline FSIS' efforts to strengthen management controls for all import operations. The consolidated written procedures will be developed by March 2001.

Recommendation No. 3:

Provide management control training to agency managers.

Agency Response:

FSIS agrees with this recommendation. FSIS believes in continuous education and refresher training for its managers in a number of areas. FSIS will make arrangements for its Imported Meat and Poultry Inspection managers at Headquarters, District Offices, and the Technical Service Center to receive additional training on management controls. The agency will arrange for training similar to the Management Accountability and Control (OMB Circular A-123) course offered by the Government Audit Training Institute at the Graduate School, USDA by December 1, 2000. FSIS will explore including a training module on management controls in its Management Leadership and Development Program, which will be available to all agency managers.

Recommendation No. 4:

Revise FSIS Directive 1090.1 to incorporate the provisions of OMB Circular A-123, Revised, Management Accountability and Control," dated June 21, 1995, and document specific program control objectives and review procedures that will provide management reasonable assurance on the effectiveness of controls.

Agency Response:

FSIS agrees with this recommendation. FSIS has updated its Directive 1090.1 to incorporate the provisions of OMB Circular A-123, Revised, Management Accountability and Control," dated June 21, 1995. The draft directive outlines a process for establishing program control objectives and procedures that will provide management reasonable assurance on the effectiveness of controls. The draft document has been reviewed internally and is currently being reviewed by the National Joint Council, an employee union. A copy of the draft Directive 1090.1 is attached. We expect the directive to be finalized by October 1, 2000.

Recommendation No. 5:

Require the FSIS Internal Control Staff to conduct periodic independent assessments of FSIS' programs and operations, emphasizing those processes that changed during the reorganization.

Agency Response:

FSIS agrees with the intent of this recommendation. FSIS will establish selection criteria for conducting periodic independent assessment of FSIS' programs and organizations as appropriate. The Executive Steering Committee for Management Controls will identify and prioritize for independent assessment selected processes that changed during the 1997 reorganization that should be reviewed. The Executive Steering Committee for Management Controls was established in July 1999 with the purpose to:

- Provide Agency policy direction for management accountability, controls, and prioritizing of oversight activities.
- Emphasize management accountability and effective use of management controls.
- Implement and facilitate a corporate framework for improving management controls by identifying and eliminating critical vulnerabilities in Agency systems in ways that stress problem prevention as well as problem resolution.
- Ensure reliable, timely and complete analysis of documentation in support of the Agency's management control system.

It should be noted that FSIS already requires the Internal Control Staff (ICS) to conduct periodic independent assessments of FSIS' programs and operations. However, FSIS will direct the ICS, through guidance provided by the FSIS Executive Steering Committee on Management Controls, to conduct independent assessments of selected processes that changed during the 1997 reorganization. A memorandum of instruction to the ICS will be issued by September 1, 2000, from the Executive Steering Committee on Management Controls to address this recommendation.

ICS was established as a result of the 1997 reorganization. ICS has conducted several independent reviews since the beginning of this audit in October 1998. In October 1998, ICS had four full time employees (FTEs) (i.e., the Director, two GS-9 management analysts, and a secretary). ICS currently has 10 FTEs (including three vacancies). ICS positions currently consists of the Director, a secretary, an operations research analyst, two investigators, a physical scientist, a veterinarian and vacancies for a financial management analyst and two program analysts.

Recommendation No. 6:

Report the conditions disclosed in this audit as material management control weaknesses in the import inspection process.

Agency Response:

FSIS strongly disagrees with the OIG recommendation that the issues outlined in this audit report constitute a material management control weakness. We acknowledge the need to strengthen our management controls and procedures, but we do not believe that the findings of this audit represent a reportable material management control weakness. Although FSIS agrees with most of the suggested management controls improvements in this audit, we do not believe they constitute a reportable material weakness of the import inspection process. FSIS will address opportunities for strengthening the management controls identified in this audit report and report them in accordance with the Agency's assessment of OMB Circular A-123 requirements.

Recommendation No. 7:

Review the roles and responsibilities of personnel involved in the equivalence determination process, the onsite review process, and the input of data to update the AIIS, and define more specifically the authority and responsibilities of those units.

Agency Response:

FSIS agrees to review the roles and responsibilities of personnel involved in the equivalence determination process, the on-site review process, and the input of data to update the Automatic Import Information System (AIIS).

By October 1, 2000, FSIS will review and revise as necessary the functional statements of the International Policy Division (IPD) where joint and separate functional responsibilities exist in on-site equivalence audits, audit reports, and follow-up on equivalence issues raised during on-site audits.

The sharing of information between the IPD and the TSC has evolved since the Agency's reorganization, and has matured into a very efficient and effective system. All foreign country documents and correspondence received by the IPD are copied and forwarded to TSC for inclusion in their country files. This information is available to the reviewers as they prepare for foreign reviews. The reviewer's independent assessment of these documents is discussed with the Review Staff Director, Chief of the International Review Staff, and with various IPD personnel during the pre-audit conference conducted prior to each foreign country audit. Any recent updates or questions regarding supporting documentation are discussed at these pre-audit conferences. All relevant information needed for the reviewer to verify that a foreign country is adhering to written procedures or policies is made available to the reviewer prior to his departure to the foreign country.

During the 1997 reorganization, FSIS determined as a matter of policy to have the on-site audit function separated. Prior to the reorganization, significantly less emphasis was placed on either audit preparation or audit follow-up. In addition, the Agency did not have a uniform audit report that could be easily understood by foreign governments and U.S. consumers. As a result of the reorganization, controls over on-site audits have been significantly strengthened. OPPDE and the TSC have developed a thorough, in-depth reporting format for foreign country audits.

Included in this process was the development of a series of "checklists" that detailed the Pathogen Reduction/Hazard Analysis Critical Control Points (PR/HACCP) requirements. Although reviewers had been verifying these requirements during the foreign country audits, they had very limited written documentation to verify the process. The new report format, including checklists, is now in place and being used by the reviewers during their foreign country audits and as they prepare their report documenting their observations and findings.

The TSC provides the results of on-site foreign inspection system review to the OPPDE so that it can make on-going equivalence determinations. It is imperative that the on-site audits include collecting information on specific equivalence subjects in order that OPPDE can make sound equivalence determinations.

The evaluation and analysis of the FSIS audit findings and the resultant course of action is a policy matter that is managed by the OPPDE. Management in this situation includes, but is not limited to: (1) determining the severity and meaning of the audit findings in the scope of the overall foreign country's inspection system; (2) determining what is expected of the foreign country's inspection system in regards to correcting the deficiencies, both short term and long term, both establishment specific and system specific; and (3) communicating with the foreign inspection officials.

Recommendation No. 8:

Prior to the onsite review, ensure that the Technical Service Center reviewers are provided with all information necessary to verify data provided by foreign countries for equivalence determinations.

Agency Response:

FSIS agrees to develop formal procedures that will continue to ensure that the TSC is provided all information necessary for the reviewers to verify data provided by foreign countries during equivalence determinations. The procedure will be completed in December 2000.

Recommendation No. 9:

Provide training to all inspectors responsible for conducting inspections of imported products.

Agency Response:

FSIS is currently developing updated import training for field inspectors who conduct import inspection activities. Training is scheduled to begin in FY 2001. This training plan is projected to include on-the-job training, pre-classroom CD-ROM's that cover basic import inspection procedures, and a formal training session at various U.S. ports of entry. The training plan will be completed in December 2000.

Recommendation No. 10:

With the help of technical subject-matter experts, develop and implement comprehensive guidelines as a means of ensuring propriety and consistency in decisions involving equivalency determinations.

Agency Response:

FSIS agrees to develop comprehensive written guidelines for equivalence determinations by January 2001.

FSIS had developed general guidelines to ensure that the foreign governments had addressed all the components of the PR/HACCP requirements. These guidelines were not the only documents used to review foreign country submissions.

When reviewing the foreign country submissions, FSIS used the specific detailed regulatory requirements listed in the Code of Federal Regulations (CFR), documents published in the Federal Register, FSIS directives and guidelines prepared by the Microbiology Division. The following Federal Register documents were used in the review of foreign submissions:

- Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems Rule, Volume 61, Federal Register, pages 38806-38989, published on July 25, 1996.
- Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Technical Corrections and Amendments Rule, Volume 62, Federal Register, pages 26211-26220, published on May 13, 1997.
- Pathogen Reduction; Hazard Analysis and Critical Control Point Systems-Sample Collection-Technical Amendments and Corrections Rule, Volume 62, Federal Register, pages 61007-61009, published on November 14, 1997.

When reviewing submissions from foreign governments concerning Sanitation Standard Operating Procedures (SSOP), FSIS used the specific detailed regulatory requirements set forth in 9 CFR 416.12 through 416.17. When reviewing the individual submissions concerning generic *Escherichia coli* (*E. coli*) testing, FSIS used the specific detailed regulatory requirements set forth in 9 CFR 310.25(a) and 9 CFR 381.94. In addition, FSIS used the following guidelines for reviewing SSOP and generic *E. coli* testing programs that were developed by program experts within the Agency and were published as appendixes to the PR/HACCP rule on July 24, 1996:

- Appendix A—Guidelines for Developing a Standard Operating Procedure for Sanitation (Sanitation SOP's) in Federally Inspected Meat and Poultry Establishments;
- Appendix B—Model of a Standard Operating Procedure for Sanitation;
- Appendix F—Guidelines for *Escherichia coli* Testing for Process Control Verification in Cattle and Swine Slaughter Establishments; and

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- Appendix G—Guidelines for *Escherichia coli* Testing for Process Control Verification in Poultry Slaughter Establishments.

Other guidelines used in the review of generic *E. coli* submissions included Agency directives and a three page summary guideline prepared by the Microbiology Division for use in reviewing foreign submissions.

When reviewing PR/HACCP submissions, FSIS used the specific detailed regulatory requirements set forth in 9 CFR Part 417. When reviewing the individual submissions concerning generic *Salmonella* testing, FSIS used the specific detailed regulatory requirements set forth in 9 CFR 310.25 (b) and 9 CFR 381.94. In addition, FSIS used the following guidelines to review HACCP and *Salmonella* testing submissions that were developed by program experts within the Agency and were published as appendixes to the PR/HACCP rule on July 24, 1996:

- Appendix C—Guidebook for the Preparation of HACCP Plans;
- Appendix D—Hazards and Preventive Measures Guide; and
- Appendix E—FSIS Sample Collection Guidelines and Procedure for Isolation and Identification of *Salmonella* from Raw Meat and Poultry Products.

Other guidelines used in the review of generic *Salmonella* testing submissions included a six page summary guideline prepared by the Microbiology Division for use in reviewing foreign submissions. This document incorporated all of the regulatory requirements and the procedures used by FSIS in *Salmonella* testing.

Although many countries elected to adopt the identical requirements as stated in the regulations, some countries chose to adopt different requirements as permitted under the Agreement On The Application Of Sanitary And Phytosanitary Measures (SPS Agreement) and 9 CFR 327.2 and 381.196. In those cases, the countries had to provide sufficient scientific evidence to demonstrate equivalence. The appropriate subject-matter experts within FSIS reviewed the foreign country submissions. In some cases, FSIS subject-matter experts worked with the scientific experts from other countries to develop scientific protocols for comparative studies. In addition, all equivalence determinations were reviewed within the Agency and criteria for each decision was developed with the assistance of the subject-matter experts. The decisions and the criteria used were announced and discussed at a public meeting on December 14, 1999. A document summarizing the guidelines, the criteria, and the equivalence determinations for each country for the PR/HACCP rule was provided at the public meeting.

Recommendation No. 11:

Develop written criteria and procedures for suspending the eligibility of exporting countries that do not provide sufficient documentation to support their continuing compliance with U.S. equivalency standards or are found to be in noncompliance based on the results of an onsite equivalency review.

Agency Response:

FSIS agrees with this recommendation. FSIS regulations, 9 CFR 327.2,¹ delineate criteria for both initially determining the eligibility of a foreign country to import products into the United States and for withdrawing a foreign country's eligibility to import. FSIS will consolidate this requirement into internal procedures and guidelines by March 2001.

Initial determinations of eligibility and withdrawals of eligibility require notice and comment rulemaking under the Administrative Procedure Act (APA).² The APA contains provisions that ensure all interested parties receive equal treatment and due process under the laws and regulations of the United States. Full public participation occurs at each stage in this process. Specific regulatory criteria exist both for initial determinations of eligibility and for subsequent withdrawals. For example, FSIS may publish a proposed regulation to withdraw the eligibility of a foreign country under any of three clearly stated regulatory criteria:³

1. The system of meat inspection maintained by such foreign country does not ensure compliance with requirements equivalent to all the inspection, building construction standards, and other requirements of the Act and the regulations...as applied to official establishments in the United States.
2. Reliance cannot be placed upon certificates required under 9 CFR Part 327 from authorities of such foreign country.
3. For lack of current information concerning the system of meat inspection being maintained by such foreign country.

FSIS may withdraw but may not suspend the eligibility of any country to import meat or meat products into the United States. The Agency may, however, take action to ensure that *products* from a particular country are not admitted into the United States if they are adulterated or misbranded.⁴ USDA regulations, the Federal Meat Inspection Act, and the Poultry Products Inspection Act define the term "adulteration" to mean any product if it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.⁵

FSIS has established three criteria under which it would suspend the importation of product:

1. An emergency sanitary measure is not implemented to address a hazard that is so severe that no product can enter the marketplace from a foreign establishment until the control is in place.

¹ Imported poultry products are regulated by 9 CFR Part 381, Subpart T. This discussion pertains to both meat and poultry as the imported product regulations are virtually identical.

² 5 U.S.C. 551 et seq.

³ 9 CFR 327.2(a)(4)

⁴ 9 CFR 327.3 (a)

⁵ 9 CFR 301.2 See definition (4) of "adulterated," 21 U.S.C. 453 (g)(4), and 601 (m)(4)

2. Where an exporting country does not provide satisfactory documentary evidence of an equivalent sanitary measure.
3. Where a system audit reveals that an exporting country is not implementing a sanitary measure in the manner that FSIS initially determined to be equivalent.

During the audit, OIG saw evidence of FSIS taking action to suspend the importation of product from Country A because serious sanitation problems had been discovered in establishments located in that country. That action, in itself, did not affect the eligibility of Country A to export meat products to the United States. Only notice and comment rulemaking can do that. Rather it served to protect American consumers from products that were adulterated under U.S. law because they were produced in establishments that had serious sanitation problems. The situation in Country A could, however, lead to the loss of its eligibility under criteria 1 or 2 above if the problems in its establishments were judged to be systemic.

The situation in Country B was entirely different. FSIS had engaged Country B in a lengthy discussion of alternative sanitary measures proposed by that country to meet the U.S. level of protection under our PR/HACCP requirements. With Country B, the issues were wholly procedural and methodological—different ways to reach the same safe food goal. At no time was there a question about the safety of Country B products. Consequently, FSIS took no action to stop the importation of Country B products even when it was found during on-site audit that some of the agreed upon procedures and methodologies had not yet been fully implemented.

FSIS encountered several similar type situations during the document analysis portion of its PR/HACCP equivalence evaluations. Trade did not stop while discussions continued in good faith because no product safety issues were involved. In the end, FSIS made equivalence decisions in every case that became import requirements for the foreign country. In the event that a foreign country ultimately fails to adopt equivalent sanitary measures, FSIS would be obliged to propose rulemaking under criterion 1 above to withdraw its eligibility status.

Recommendation No. 12:

Develop written procedures, which ensure comprehensive evaluations of foreign countries' alternative import inspection methods and require the analysis of these systems be documented, as well as the decisions reached.

Agency Response

FSIS agrees with this recommendation. Consolidated written procedures will be developed by March 2001 to document equivalence decisions regarding alternative inspection methods. These procedures will reflect and strengthen the Agency's management controls. Effective July 1, 2000, new equivalence decision files will document:

1. All FSIS correspondence with foreign countries;

2. All foreign country submissions (translated and in the originating language);
3. Summary IPD reviews of submissions;
4. Summary of all meetings and teleconferences with foreign officials;
5. Summary of all reviews by subject-matter experts;
6. Documentation of equivalence criteria;
7. Summary of all FSIS management formal reviews and approvals; and
8. Decision memorandum of the equivalence determinations.

FSIS has existing procedures for reviewing countries' alternative inspection methods, including an internal IPD review; a referral to the appropriate subject-matter experts within the Agency; development of equivalence criteria with subject-matter experts; and, discussion and review by senior Agency management officials. In addition, on-site audits are used to verify that countries have implemented the programs properly, and if not, resolve differences and clarify requirements.

In the case of the submission of different inspection methods for the implementation of requirements under the PR/HACCP requirements, appropriate subject-matter experts within FSIS reviewed the submissions from the countries. In some cases, FSIS subject-matters experts worked with experts from other countries to develop scientific protocols for comparative studies. In addition, all equivalence determinations were reviewed within the Agency and criteria for each decision was developed with the assistance of Agency subject-matter experts. Because FSIS had procedures and applied them in the review of these submissions, FSIS was assured that the evaluations were consistent and in accordance with the U.S. standards.

For example, all PR/HACCP requirement decisions and the criteria used to make them were announced and discussed at a public meeting on December 14, 1999. A document summarizing the guidelines, the criteria, and the equivalence determinations for each country for the PR/HACCP requirements was provided at the public meeting.

An example of how the procedure was applied is Country D's submission on generic *E. coli* testing. The original submission was reviewed by the IPD and sent to the Microbiology Division for review. The Microbiology Division correctly determined that Country D's submission had a number of differences and that at the time there had been no policy decision with respect to those differences. As a result, the Microbiology Division worked with the IPD to develop a protocol for a comparative study that would compare Country D's program with the U.S. generic *E. coli* program. Analyzing and developing criteria is one of the steps in developing the protocol. During the development of the protocol, scientists from Country D met in Washington, D.C. with representatives of the Agency to finalize the study. The reason that these documents were not in the Country File at the time of the OIG audit was that a staff officer was using the documents and they had not been consolidated into the Country File.

Another example is the implementation of generic *E. coli* testing and *Salmonella* testing in Country E. Approximately one year after generic *E. coli* testing was implemented, in cattle establishments, Animal and Plant Health Inspection Service (APHIS) imposed a ban on importation of cattle from Country E and other European countries because of BSE outbreaks. As a result, Country E did not need to implement *Salmonella* testing in cattle establishments. The APHIS restrictions on the importation of cattle are still in place. Although Country E has provided documentation that *Salmonella* testing is being conducted in cattle establishments, until the restrictions are lifted, Country E does not need to implement *Salmonella* testing in cattle establishments.

In addition, the Agency has recognized the gauze tampon (pad) that Country E and other countries use as an equivalent sampling tool. The Agency is familiar with this sampling tool and it is generally recognized as an appropriate sampling tool within the scientific community. The merits of this sampling tool was further discussed with the Microbiology Division, criteria developed, and the sampling tool was found to be equivalent. A memorandum summarizing the decision was reviewed within the Agency. FSIS agrees to make certain that this memorandum and the criteria for different sampling tools published at the public meeting December 14, 2000 will be filed in the Country File.

Further, the on-site audit of Country E revealed that Country E had some implementation problems with Sanitation Standard Operating Procedures (SSOP) and generic *E. coli* testing. As often the case when implementing programs that are based on English documents that have been translated into another language, dialogue is needed to clarify requirements and improve implementation. Country E and the Agency entered into such a dialogue and corrective actions were taken to improve the implementation of the SSOP and generic *E. coli* testing programs. Country E was subsequently audited in May 1999. The auditor found that SSOP, generic *E. coli* testing, HACCP, and *Salmonella* testing programs met the basic requirements. FSIS will document those areas that have not been documented in the Country Files.

FSIS determined that Country B's implementation of generic *E. coli* testing is equivalent, based on a thorough scientific review of the documentation provided by Country B. There were differences in Country B's program, some of which FSIS found to be equivalent and others that were not found to be equivalent because of insufficient scientific evidence. Although an audit in March 1999 raised some implementation issues, Country B has resolved the issues. An FSIS on-site audit in April 2000 confirmed that SSOP, generic *E. coli* testing, HACCP, and *Salmonella* testing have been implemented.

Recommendation No. 13:

Streamline the process and establish procedures that would allow expeditious entry of laboratory test results into the Automated Import Information System.

Agency Response:

FSIS agrees that additional documentation would assist in clarifying the current system to both Agency personnel as well as outside auditors. FSIS is reevaluating the current system as part of

the redesign of the AIIS and will improve the documentation by December 2000 to outline the procedures for entering laboratory results into the AIIS system.

As an interim measure, in March 2000, the Field Automation Information Management (FAIM) Division instituted non-automated procedures to streamline the entry of residue and microbial results. As of March, FAIM receives faxes from the TSC of laboratory Form 9770-2 for all positive residue results. The FAIM Division then documents directly on the laboratory form both the date it was received (via fax) and the date/time the lab results were entered into AIIS. Entries into the AIIS are made the same day they are received. Also, an internal verification process will be established to monitor the data being entered into the AIIS.

Also, FSIS is working to replace the AIIS. The new system, eventually sharing Sybase SQL tables with the Microbiological and Residue Computer Information System (MARCIS) and other agency systems will ensure real time accuracy of both negative and positive results of residue tests and microbiological tests. The FAIM Division began work on the new AIIS application in March 2000 with a test pilot planned for the first quarter of 2001. We expect the system to be fully operational by December 2001.

Recommendation No. 14:

Require the Office of Field Operations to work with the Technical Service Center and the Field Automation and Information Management Division to develop management controls and a supervisory review process to ensure that all laboratory test results are promptly and accurately entered into the Automated Import Information System. Management controls must include requirements for maintaining records of when failure notifications are received and when the entries are made into the Automated Import Information System.

Agency Response:

FSIS agrees with this recommendation. The FAIM Division is focusing on incorporating the required management controls in the replacement AIIS, which should be completed by December 2001. The new import computer system will document when laboratory failure results are received and incorporated into the system data tables. In the interim, FSIS has established a manual tracking process that documents when notification of failures is received and when the entries are made into the AIIS. Entries are made within 24 hours of receipt of the positive laboratory results. Negative results are obtained via a weekly download from MARCIS and entered that same day into the AIIS.

FSIS believes that the management controls and supervisory review process can be enhanced to ensure that all laboratory results are promptly and accurately entered into the AIIS. Management controls currently include requirements for maintaining records that indicate when failure notifications are received, and when the entries are made into the AIIS.

Recommendation No. 15:

Officially notify all countries importing meat and poultry into the United States that annual certifications are due no later than the established date and that establishments that are not certified by this date may be delisted. Incorporate this requirement in regulations.

Agency Response:

FSIS agrees that meat and poultry products exported to the United States must be produced in properly certified foreign establishments. To ensure that this occurs, the FAIM Division has established a web site with search capabilities that allows import inspectors to obtain the status (certification, delistment, relistment) of foreign establishments.

FSIS agrees to notify all countries that certifications of establishments must be renewed annually, and if establishments are not certified annually they may be delisted. However, FSIS does not agree with the OIG's assertion that allowing countries to delay their certifications "reduces the control to prevent products from uncertified establishments from entering the United States".

Annual certification lists are often obsolete soon after they arrive because importing countries add and delete certified establishments throughout the year. Furthermore, an additional method exists to verify that imported product was produced in an establishment certified for export to the United States.

This method is set forth in 9 CFR 327.4, "Imported products; foreign certificates required."⁶ A foreign-meat-inspection certificate must accompany each consignment of fresh meat, fresh meat byproducts, or meat food products. All such consignments (or "lots") offered for entry into the United States from any foreign country must be reinspected by an FSIS import inspector before they are allowed into this country.⁷ For example, every lot of product is routinely given a visual inspection by an FSIS import inspector for appearance and condition, and checked for certification and label compliance.

An authorized foreign government official signs the certification accompanying each lot. Each foreign certificate contains information such as kind of product, species of livestock it was derived from, number of pieces or containers in the lot, shipment weight, shipping marks, and the producing establishment number. FSIS believes that these certificates provide ample evidence that the product they accompany was produced in a foreign-certified establishment.

The value of an annual list as proof of establishment certification diminishes quickly, however, and must be supplemented by prompt notifications from foreign governments of changes—additions and deletions of establishments—as soon as they occur. Thus, the focus of FSIS management controls should be on receipt and posting of updates rather than the annual compilation of changes. By September 2001, FSIS will publish a proposed revision of Part

⁶ Imported poultry products are regulated by 9 CFR Part 381, Subpart T. This discussion pertains to both meat and poultry as the imported product regulations are virtually identical.

⁷ 9 CFR 327.6 (a)(1)

327—Imported Products to eliminate the annual certification requirement.

Recommendation No. 16:

Establish a follow-up process to obtain the annual certification lists from the countries which have not submitted them.

Agency Response:

FSIS has established a follow-up process to obtain annual certification lists from countries that have not submitted them. This process is subject to change after the proposed revisions (see response to Recommendation 15) in Part 327 are implemented. Attachment 1 is a copy of our current follow-up process.

Annual certification lists are sent from foreign countries to the IPD. In July 1999, effective for calendar year 2000, the FAIM Division established a procedure to notify IPD of every country for which FAIM has not received an annual certification of establishments. Starting in February 2000, and continuing on a monthly basis, the FAIM Division has notified the IPD of outstanding certification lists.

Recommendation No. 17:

Immediately conduct reconciliation between establishment certification information maintained by the Equivalence and Planning Branch and the Automated Import Information System to ensure that the Automated Import Information System includes only those establishments certified by their foreign governments to ship products to the United States.

Agency Response:

FSIS agrees with the recommendation. Following the on-site portion of the OIG audit, the FAIM Division established a program of quarterly crosschecks of foreign government certification documents against the establishment listings contained in the AIIS. In addition, effective April 1999, the FAIM Division began sending to the IPD a weekly report listing all certified and decertified establishments maintained in the AIIS. IPD will begin reconciliation of the FAIM reported data and their internal records by December 2000.

Recommendation No. 18:

Establish time requirements and a management control process for reviewing and process certification information in the Automated Import Information Certification System.

Agency Response:

FSIS agrees with this recommendation. The FAIM Division maintains an internal AIIS Import Manual of procedures document that will be updated by December 2000, to address time requirements and management control processes. Supervisory oversight will be established

whereby all changes to the AIIS status of establishments will be forwarded to the Branch Chief of the FAIM Applications Systems Development Branch for review.

Recommendation No. 19:

Take immediate action to ensure that the Technical Service Center, the Field Automation and Information Management Division, and the Equivalence and Planning Branch coordinate efforts to verify that all delisted establishments have been timely entered into the Automated Import Information System.

Agency Response:

FSIS agrees with this recommendation. FSIS will improve its system to verify that all delisted establishments are timely and properly entered into the AIIS. FSIS will establish, by October 1, 2000 a team comprised of OFO and OPPDE personnel, responsible for examining every aspect of the issue of ensuring that only product from approved and eligible establishments gains entry into the United States.

In FY 2000, the FAIM Division expanded its Intranet Web Site with a posting of all delisted foreign establishments. This information is available to the TSC, IPD, and all field inspectors. The web site is updated when FAIM receives information from the IPD.

Recommendation No. 20:

Establish a management control process to ensure that the Technical Service Center Director promptly forwards to the Office of Policy, Program Development and Evaluation information about foreign establishments that were delisted prior to, or because of, Technical Service Center foreign reviews.

Agency Response:

FSIS has established a management control process to address this recommendation. Information regarding foreign country establishments that are delisted prior to TSC reviews is received either by fax or electronic mail from the foreign country government or through the Foreign Agriculture Service. This information is shared by all of the stakeholders, and discussed at the pre-audit conference held between the TSC and the IPD.

Foreign country establishments are also delisted based upon results of on-site reviews by the TSC reviewers. Reviewers are instructed to report this information, by phone, to the Review Staff Director or Chief of the International Review Branch as soon as possible, but no later than the day following the on-site review. This information is detailed in an electronic mail message that is sent immediately to the Chief of the Equivalency and Planning Branch, IPD and also to the Director of the Import/Export, Program Analysis, IRM Staff at the TSC. A paper copy of the electronic mail message is placed in the foreign country file at the TSC.

Both types of delistments are discussed at the post-audit exit conference held between the TSC and the IPD. The reviewer discusses the reasons given by the foreign country officials for delistment of any establishments prior to the review, and also discusses, in-depth, the reasons for any establishment delistment based upon the on-site review.

Recommendation No. 21:

Establish a management control process to ensure that delistment information is (a) reviewed and signed by a designated official to the Field Automation and Information Management Division, via a dated control number and (b) processed and verified in the Automated Import Information System.

Agency Response:

Pursuant to this report, the FAIM Division implemented in May 2000 a management control process whereby the Branch Chief, Application Development and Support Branch, FAIM Division will be notified via e-mail of all incoming delistments received from IPD. Notification will include the date delistments are received, the date the information was entered into the AIIS, and a printout of all establishments as they appears in the AIIS. This procedure will be complete by October 2000.

Recommendation No. 22:

Modify the Automated Import Information System to produce daily process control reports to enable verification of input.

Agency Response:

FSIS agrees with this recommendation. The FAIM Division has begun replacing the AIIS that was first deployed in the 1970s. Available resources will be better used in continuing development of the replacement AIIS, rather than making the recommended changes to the current AIIS. The new system will incorporate this recommendation in its design. The intent of this recommendation will be met when the new computer system is completed by December 2001.

Recommendation No. 23:

Establish procedures to ensure that all residue documents submitted by foreign countries are received, reviewed, and analyzed based on requirements in regulations.

Agency Response:

See Rec. No. 25

Recommendation No. 24:

Obtain the residue test plans not submitted since 1998 to determine if the foreign countries have residue control standards equivalent to the United States.

Agency Response:

See Rec. No. 25

Recommendation No. 25:

Obtain and analyze the residue test plan results not submitted since 1998 to determine the adequacy of foreign countries' adherence to their residue test plans.

Agency Response to Rec. Nos. 23, 24 and 25:

FSIS agrees with these recommendations. FSIS agrees that it needs to strengthen its review of foreign country test plans. An interagency team was created on June 1, 2000, and expects to complete its initial review by December 2000. The team is responsible for the receipt, review, and analysis of all foreign country residue submissions. The team is comprised of representatives of OPPDE, OFO, and OPHS. The team will review the submissions based on U.S. regulations to determine if the information is adequate, if the documents indicate the countries meets U.S. requirements, and if additional information is needed.

The test plans and results are only a part of the basis for assessing a foreign country's residue program. FSIS on-site audits include reviews of the country's laboratory testing capability and FSIS annually collects more than 8,000 statistically selected samples at the port of entry for laboratory analysis. Consequently, FSIS questions the need for collecting past residue plans and results because much more comprehensive information has been requested from every country through a lengthy questionnaire, which negates the value of the earlier submissions.

Responses to the questionnaire will provide this information along with other information such as production practices, veterinary drug usage, agricultural chemicals and incidence of environmental contaminants and pesticides, basis for the residue plan, and actual implementation and operation of the program. By December 2000, FSIS will have a more complete and current assessment of the country's controls. If, upon reviewing the responses, FSIS determines that required information is missing, it will be requested from the country. FSIS believes that focusing on in-depth reviews is a more productive use of its resources.

Recommendation No. 26:

Develop procedures to ensure that (a) a review of residues identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants are included as part of the Technical Service Center on-site equivalency reviews, and (b) appropriate action is taken in those instances where the plans are inadequate, the results vary from the plans, or violations are detected.

Agency Response:

The IPD will provide the Director of the Review Staff at the TSC with a summary of the information in residue questionnaires submitted by countries eligible to export to the United States. The Review Staff will be part of the team that will review the submissions. The Review Staff and the IPD will use this information, along with port-of-entry results and information from past audits, to plan upcoming reviews.

This year, FSIS is initiating in-depth reviews of residue programs in a number of countries exporting to the United States. These reviews will make a comprehensive evaluation of the effectiveness of the country's controls over drugs and chemicals that could contaminate meat and poultry. This will include a review of documents, an assessment of whether the country is testing for the appropriate compounds, whether the plan is implemented as designed, laboratory capability, and enforcement. The reviews are expected to be completed by June 2001.

Recommendation No. 27:

Develop procedures that require the participation of technical subject-matter experts, as appropriate, in equivalency determinations, and document the experts' participation, analyzes, and conclusions.

Agency Response:

FSIS agrees to develop formal procedures by October 2000 for participation of technical subject-matter experts, as appropriate, in equivalence determinations. FSIS will apply this approach in making equivalence determinations, where a foreign country proposes to adopt requirements that are *different* from FSIS requirements. When a country proposes to adopt an *identical* requirement, then it is not necessary to involve subject-matter experts in those determinations. This is often the case during FSIS' evaluation of foreign country documents submitted in response to the HACCP/pathogen reduction regulation.

As a matter of policy, FSIS has determined that the best way to facilitate equivalence determinations was to establish a Branch within IPD responsible for equivalence judgements. The personnel in that Branch possess the necessary expertise to make equivalence judgement when a country is proposing to adopt *identical* requirements. Whenever an equivalence decision involves alternative measures then, subject-matter experts participate in the equivalence decision making.

The OIG noted that a "multi-disciplinary team was not always used during equivalency determinations". That statement is correct because FSIS makes equivalence determinations in two areas: initial equivalence determinations and equivalence maintenance determinations. When making an initial equivalence determination as to whether a country is eligible to export meat, poultry, or egg products to the United States, the country is subject to a multi-disciplinary team audit. Once a country has been approved to export product to the United States the Agency normally conducts annual audits by a veterinary medical officer. In the case of SSOP and generic *E. coli* testing programs, the individual auditors possess the necessary training and skills

to verify that these programs had been implemented. It is unnecessary for FSIS, on a routine basis, to assign multi-disciplinary teams to conduct on-going equivalence audits. However, there have been a number of instances in which FSIS has expanded its audits of current trading partners to include subject-matter experts.

Recommendation No. 28:

Document and implement a system of internal controls to ensure the adequacy and support for foreign equivalency determinations. This should include a formal review and approval process for the equivalence determinations made.

Agency Response:

FSIS agrees with this recommendation. FSIS will formalize its procedures and documentation of equivalence decisions. By December 2000, FSIS will complete the implementation of an internal controls system for foreign equivalency determination. Effective July 1, 2000, new equivalence decision files will document:

1. All FSIS correspondence with foreign countries;
2. All foreign country submissions (translated and in the originating language);
3. Summary IPD reviews of submissions;
4. Summary of all meetings and teleconferences with foreign officials;
5. Summary of all reviews by subject-matter experts;
6. Documentation of equivalence criteria;
7. Summary of all FSIS management formal reviews and approvals; and
8. Decision memorandum of the equivalence determinations.

Recommendation No. 29:

Develop a management control process and procedures to ensure equivalence decisions are adequately documented. The procedures should require that files contain supporting evidence, including detailed analysis of information received and reviewed, resolution of issues raised during the review process, and conclusions reached.

Agency Response:

FSIS agrees with this recommendation. FSIS agrees that equivalence decisions should be adequately documented and that the files must be complete. Therefore, FSIS will institute the same measures described in response to Recommendation 28.

The examples that OIG cites to demonstrate its concern with the equivalence determination process is misplaced and erroneously concludes that the equivalence process was incomplete. The process was complete, but not all of the documents were in the Country files at the time of the audit.

OIG states that there is inadequate information regarding FSIS's equivalence determination for Countries F, D, and G. With respect to the documentation of the generic *E. coli* implementation in Country F, the OIG report neglects to state that there are currently no approved Country F slaughter establishments certified to export product to the United States. During the on-site audit of Country F, the only certified slaughter establishment was voluntarily delisted by Country F because generic *E. coli* was not properly implemented in that establishment. Until Country F wishes to certify a slaughter establishment to export to the United States, Country F does not need to implement generic *E. coli* testing.

In addition, the OIG notes a lack of documentation regarding the equivalence determination for generic *E. coli* for Country D. FSIS provided OIG evidence of additional documentation prior to the final draft of the audit report. That documentation was not in the Country Files, but still in the program officer's working files.

Furthermore, OIG's concerns about Country G are based on a misunderstanding of the equivalence process. The equivalence process involves both a document review and an on-site review. Normally, but not always, the on-site audit follows the document review process. Based on the document review, discussions with representatives from Country G, and a previous on-site audit, FSIS sent Country G a cable telling Country G that their generic *E. coli* program was equivalent and reminding them that it was based on their agreement to use statistical process control.

Recommendation No. 30:

Establish a time-phased plan to expedite the process for determining equivalency.

Agency Response:

FSIS agrees with this recommendation. FSIS will implement time-phased plans for future equivalence determinations, effective October 1, 2000.

Recommendation No. 31:

Ensure that onsite audits for current trading partners are conducted at least annually.

Agency Response:

FSIS agrees with this recommendation. This issue will be incorporated into the FSIS procedures for imported inspections by December 2000.

Recommendation No. 32:

For current trading partners, develop and implement a policy for onsite verifications of changes in the requirements for foreign inspection systems.

Agency Response:

FSIS agrees with this recommendation. The equivalence process begins with a document review, to determine if the foreign country's written submission documents how its sanitary measures meet the United States' appropriate level of protection. This evaluation is then verified by an onsite audit to confirm that the foreign country has in fact implemented its sanitary measures, as described in its written submission.

However, the finding for this recommendation reflects a misinterpretation of 9 CFR 327.2. The misinterpretation is evidenced by a statement on page 60: "We found that the food regulatory systems of six countries were determined "equivalent" by the Equivalence and Planning Branch without verification by an onsite review".

This statement is incorrect. The six countries (cited later in a table on page 62) have food regulatory systems that were found fully equivalent to the U.S. system many years ago. Each of these countries has undergone initial equivalence evaluations to include an extensive on-site audit and are listed as equivalent at 9 CFR 327.2 (b). Additionally, each of these countries has been audited on-site many times since its food regulatory system was initially found equivalent.

When an eligible country proposes an alternative sanitary measure to FSIS for an equivalence decision, FSIS conducts a full document analysis of only that component of the foreign food regulatory system that is affected by the change. A final determination of equivalence for a proposed sanitary measure is verified by on-site audit. Trade continues in the interim. Three circumstances could result in an interruption of trade. One, where an emergency sanitary measure is implemented by FSIS to address a hazard that is so severe that no product can enter the marketplace from a foreign establishment until the control is in place. Two, where an exporting country does not provide satisfactory documentary evidence of an equivalent sanitary measures. Three, where a system audit reveals that an exporting country is not implementing a public health sanitary measure in the manner that FSIS initially determined to be equivalent. None of these three conditions applied during FSIS evaluations of PR/HACCP alternative sanitary measures proposed by foreign countries.

Recommendation No. 33:

Clarify the regulations regarding FSIS' procedures for determining equivalence for current trading partners, taking into consideration major changes such as HACCP and pathogen reduction requirements.

Agency Response:

FSIS has been properly applying its regulations regarding equivalence determinations. FSIS

makes two types of equivalence determinations: (1) determinations of initial equivalence (termed “eligibility” in current regulations) for countries that are not yet trading partners; and (2) determinations of whether equivalence is being maintained by countries that are now trading partners.

Regulatory authority for all equivalence determinations is at 9 CFR 327.2, “Eligibility of foreign countries for importation of products into the United States.” Imported poultry products are regulated by 9 CFR Part 381, Subpart T. This discussion pertains to both meat and poultry, as the imported product regulations are virtually identical.

The criteria for initial country equivalence are set forth at 9 CFR 327.2 (a) (2) (i) and (ii). The process through which a foreign country may request an initial determination of equivalence and the manner in which FSIS makes these determinations are described at 9 CFR 327.2 (a) (2) (iii).

Mention is also made in 9 CFR 327.2(a)(2)(iii) of two criteria for maintaining country equivalence. They are as follows: (1) the result of periodic reviews of the foreign meat inspection system; and (2) the timely submission of documents and other information related to the conduct of the foreign inspection system. Additional criteria for maintaining equivalence are provided at 9 CFR 327.2(a)(2)(iv).⁸ All FSIS activities in connection with verification that foreign countries have implemented equivalent PR/HACCP sanitary measures were conducted in full accordance with the regulatory provisions cited in this paragraph.

In the future, FSIS will take into consideration major changes, such as PR/HACCP, as it documents its procedures for determining whether equivalence is maintained for current trading partners, as referenced in our response recommendation No. 12.

Recommendation No. 34:

Ensure that reporting and evidence standards developed for equivalency verification reviews provide for appropriate documentation of all areas required to be reviewed by regulation.

Agency Response:

According to 9 CFR 327.2 (a) (2) (iii) “Maintenance of eligibility of a country for importation of products into the United States depends on the results of periodic reviews of the foreign meat inspection system...” The regulatory requirement of periodic reviews does not mandate that each review encompasses all aspects of a country’s inspection system.

Nevertheless, FSIS is committed to ensuring that these reviews are consistent and thoroughly documented. At the time of the OIG audit, FSIS was in the process of developing an enhanced uniform audit format that addressed the following five risk areas: (1) animal disease controls; (2) sanitation controls; (3) enforcement controls; (4) slaughter and processing controls; and (5) residue controls. These five risk areas cover all of the FSIS regulatory requirements for countries that export to the United States. Subsequent to the OIG audit, the audit format was

⁸ FSIS would add that the results of port-of-entry product reinspections are also critical to the maintenance of equivalence.

finalized. The new audit format has been implemented for all FSIS audits conducted in Fiscal Year 2000. Also, audit planning has been enhanced to ensure that on-site audits cover all relevant areas.

Recommendation No. 35:

Develop procedures for timely completing reports documenting reviews of foreign inspection systems.

Agency Response:

FSIS agrees with this recommendation. Formal procedures will be completed by December 2000. In Fiscal Year 2000, new foreign country reporting requirements were instituted. Draft foreign country reports are due from the reviewers within 10 working days of their return to the office. Exceptions to the 10-day rule must be requested in writing, with justification, through the Branch Chief of the International Review Branch or Director of the Review Staff. Similar timeframes are in effect throughout the process, creating a timeline that has the report completed and in "Draft Final" form to be sent to the foreign country government officials for comment within 60 days from the date of the exit conference with the foreign officials. This 60-day commitment is also detailed in the cable that each reviewer sends to the foreign country prior to each audit. Because of language differences, and necessary time for response, the foreign countries are allowed 60 days to submit their response to the report. The foreign country response is then added to the report as an attachment, and the report is finalized.

EXHIBIT B – COUNTRIES ALLOWED TO CONTINUE EXPORTING TO THE UNITED STATES PRIOR TO IMPLEMENTATION OF HACCP.

Argentina	Iceland
Australia	Israel
Austria	Italy
Belgium	Japan
Brazil	Mexico
Canada	Netherlands
Costa Rica	New Zealand
Croatia	Nicaragua
Czech Republic	Northern Ireland
Denmark	Poland
Dominican Republic	Republic of Ireland
Finland	Romania
France	Slovenia
Germany	Spain
Guatemala	Sweden
Honduras	Switzerland
Hong Kong	United Kingdom
Hungary	Uruguay

NOTE: Paraguay was delisted as an eligible exporter of meat products to the United States as of September 5, 1997.

ABBREVIATIONS

<i>E. coli</i>	- Escherichia coli
FSIS	- Food Safety and Inspection Service
FY	- Fiscal Year
GATT	- General Agreement on Tariffs and Trade
HACCP	- Hazard Analysis and Critical Control Point
OIG	- Office of Inspector General
OMB	- Office of Management and Budget
SSOP	- Sanitation Standards Operation Procedures
USDA	- U.S. Department of Agriculture