FSIS DIRECTIVE	9000.8	8/15/13

AUDITS OF THE U.S. MEAT, POULTRY, AND EGG PRODUCTS INSPECTION SYSTEM BY OFFICIALS OF FOREIGN COUNTRIES

I. PURPOSE

This directive provides instructions to FSIS personnel for planning, organizing, and working with officials of foreign countries when they audit the United States (U.S.) inspection system for meat, poultry, or egg products establishments.

KEY POINTS:

- *Outlines the process to be used by FSIS personnel to prepare for and work with foreign officials when they audit the U.S. inspection system*

- *Outlines the roles and responsibilities of FSIS personnel when preparing for and working with foreign officials when they audit the U.S. inspection system*

- *Provides information on post-audit activities and responsibilities*

II. BACKGROUND

A. Foreign governments conduct periodic audits of the U.S. meat, poultry, and egg products food regulatory system to determine whether the U.S. inspection system is equivalent to the foreign country's inspection system, to verify that the U.S. system is maintaining equivalence, or to verify that other requirements of the foreign country are being met by U.S. meat, poultry and egg products establishments exporting products to foreign countries.

B. The Import/Export Coordination and Policy Development Staff (IECPDS) of the Office of Policy and Program Development (OPPD) serves as liaison to the auditing country in preparation for the audit and provides a coordinator to ensure that the audit is appropriately planned, organized, and carried out. IECPDS provides audit team members based upon availability of resources. If needed, IECPDS may also ask the following offices to provide audit team members: the International Audit Staff (IAS) of the Office of Office of Investigation, Enforcement and Audit (OIEA); the Office of Field Operations (OFO); additional staffs within OPPD; and the Foreign Agricultural Service (FAS) of USDA.

III. AUDIT NOTIFICATION BY COUNTRY

A. IECPD/OPPD receives initial notification from a foreign country, from FAS, or otherwise of the country's intent to conduct an audit of the U.S. system.

B. Once notified of an upcoming audit, the Director, IECPD, is to appoint an FSIS Audit Coordinator. The FSIS Audit Coordinator is the central contact point for the audit and is responsible for coordinating the audit activities with all involved FSIS programs. When products regulated by other U.S. agencies, e.g., the Agricultural Marketing Service (AMS) or the U.S. Food and Drug Administration (FDA), will be included in the audit, FAS is usually responsible for overall coordination of the audit. The FSIS Audit Coordinator will be responsible for coordinating the portion of the audit that addresses FSIS-regulated products, even if FAS coordinates the audit.

C. The FSIS Audit Coordinator is to provide the initial notification of the intent to audit to both the Assistant Administrator (AA), OFO and the Director, OPPD/International Relations and Strategic Planning Staff (IRSPS). Once contacted, these two officials are to identify a point of contact for the audit. Throughout the audit process, the FSIS Audit Coordinator is to maintain communication with the OFO point of contact, OPPD/IRSPS point of contact, other program areas, and other agencies, if applicable.

IV. AUDIT PLANNING

A. The FSIS Audit Coordinator is to work with FAS or, in some cases, directly with the auditing country to obtain:

1. The purpose, objectives, and scope of the audit (which can also be identified as a review or inspection by the foreign country);

2. The audit standards (e.g., what standards the US system is being audited against);

3. The number of teams and number of team members;

4. The facilities to be audited: for example, kinds and number of establishments and facilities approved for export certification service (other facilities); one or more of the FSIS laboratories; one or more OFO District Offices; FSIS headquarters, Washington, DC; and AMS Grading and Verification Division headquarters, Denver, CO, if export verification establishments or programs are being audited;

5. Information on whether the country plans to have an entrance conference and an exit conference; and

6. Information on how final audit reports, if applicable, will be communicated to FSIS.

B. If the country provides a Pre-Audit Questionnaire or similar document seeking information before the start of the audit, the FSIS Audit Coordinator is to coordinate within OPPD as well as with FAS to ensure completion of and delivery of the document to the foreign country. FSIS personnel are not to sign or otherwise endorse the Pre-Audit Questionnaire.

C. The FSIS Audit Coordinator, with assistance from any OFO representatives identified by the OFO point of contact, are to develop an audit itinerary based on a proposed list of establishments and other facilities to be audited or other information provided by the country and FAS. In doing so, they are to contact the proposed establishments to confirm their availability for the site visit. The FSIS Audit Coordinator is to work with FAS or, in some cases, directly with the auditing country to develop a final itinerary.

D. If an establishment or other facility proposed for audit declines to participate in the audit, IECPDS is to inform the auditing country that the establishment or other facility has declined to participate in the audit and is to take action to immediately remove the eligibility of the establishment or other facility to export to the auditing country.

E. The FSIS Audit Coordinator is to work with other program areas to identify the Audit Field Team whose members are to accompany the foreign auditors. The Audit Field Team may include representatives from OFO, the Office of Public Health Science (OPHS), and OPPD, as well as other agencies, such as AMS and FAS. As needed, the FSIS Audit Coordinator is to hold teleconferences or convene meetings with the Audit Field Team to develop plans for the audit.

V. DATA AND INFORMATION COLLECTION ACTIVITIES

A. Once a final itinerary is prepared, the FSIS Audit Coordinator is to contact the Data Analysis and Integration Group (DAIG) of the Office of Data Integration and Food Protection and request certain data through the FSIS Footprints system about the establishments and other facilities that are on the audit itinerary (Attachment 1—Example of DAIG data request). Even after the establishments have been notified that there will be an audit, the foreign country may make changes in the list of establishments and other facilities that it will audit.   If a country makes changes to the list of establishments or other facilities selected, the FSIS Audit Coordinator is to contact the DAIG and request information about the new establishments or other facilities identified by the country through the FSIS Footprints system. The FSIS Audit Coordinator is to forward the data and other information received from DAIG to the FSIS personnel accompanying the foreign auditors and the IRSPS point of contact.

B. The FSIS Audit Coordinator is to request the data listed in V.C. for the 6 months preceding the date of the request unless there is a need to request data for a different time period.

C. At a minimum, the FSIS Audit Coordinator is to request the following data (if applicable) for each establishment or facility selected for audit:

1. FSA summary page. If further actions were recommended against an establishment or other facility, request the full report;

2. Closed noncompliance reports;

3. Open noncompliance reports;

4. Microbiological and residue sampling results;

5. Humane handling violations if meat slaughter plants are to be audited; noncompliance reports for problems with "good commercial practices" under 04C04 with 9 CFR 381.65(b) (re: poultry slaughter establishments).

D. The FSIS Audit Coordinator is also to obtain the following information from the following sources (not the DAIG):

1. Background from establishment profile in PHIS:

   a.   Grant of inspection;

   b.   FSIS staffing levels;

   c.   HACCP process categories; and

   d.   Operating schedule.

2. From IECPDS and OFO:

    a.   Past deficiencies and corresponding corrective actions from previous audits by country and port of entry violations reported by the auditing country and corresponding corrective actions; and FSIS verification documentation on effectiveness of corrective actions;

    b.   Status of export activity—active or inactive; and

    c.   AMS audit reports (if plants to be audited operate under an AMS Export Verification (EV) program or other AMS process verification program).

E. Once the data are received from the DAIG and other sources, the FSIS Audit Coordinator is to convene a meeting with the audit team to review the data to identify possible problem areas and other concerns. Serious problems or concerns are those that could negatively impact the outcome of the audit if not addressed prior to the start of the audit. If the audit team does not identify any problems, the FSIS Audit Coordinator is to proceed with preparing for the audit.

F. Using the identified purpose, scope, and objective of the upcoming audit as provided by the foreign country (if this information is provided by the auditing country), combined with any concerns or problems resulting from the analysis of data, the FSIS Audit Coordinator will identify the topics and the type of information, if any, that will be prepared and given to the auditing country during the audit entrance meeting. There may also be specific country requests or interests related to the significant policies and operational procedures the audit is covering or related to recent or pending FSIS initiatives.

VI. MEETING WITH OFO DISTRICT OFFICES TO DISCUSS DATA RESULTS AND THE FINAL ITINERARY

A. If the data review or information gathered identifies problems that could negatively affect the outcome of the audit, the FSIS Audit Coordinator is to share the information with the appropriate OFO/Executive Associate for Regulatory Operations (EARO) and is to discuss with the EARO problem areas and any other concerns. The FSIS Audit Coordinator and EARO are to provide their determinations and recommendations to the AA, OFO, and AA, OPPD for concurrence.

B. The FSIS Audit Coordinator is to send the final itinerary for the audit to the AA and affected EAROs, OFO; the Director, IRSPS, OPPD; each of the FSIS personnel traveling with the team; the AA and the Executive Associate for Laboratory Services, OPHS (if the audit includes one or more FSIS laboratories); the designated point of contact within the FAS; and to appropriate industry trade associations (e.g., USMEF, USAPEEC, etc.). The FSIS Audit Coordinator is also to send the final itinerary to the Director, Grading and Verification Division, AMS and to the designated contact point within the FDA, if these agencies are involved with the audit. The affected OFO/EAROs are to notify District Managers, field supervisors, and in-plant personnel regarding the audit itinerary.

C.   After providing the final itinerary to OFO, the FSIS Audit Coordinator is to arrange a teleconference with the EAROs, appropriate District Managers, the Director, IRSPS, and all audit team members. District Managers are to notify appropriate field supervisors and in-plant personnel of the teleconference. The purpose of the teleconference is to ensure that all involved FSIS personnel are informed of the upcoming audit, know what to expect, and know how to handle questions or concerns from the foreign auditors. The teleconference will also provide OFO personnel with an opportunity to ask questions and to confirm itinerary arrangements.

VII. OFO AUDIT PREPARATION ACTIVITIES

A. After the meeting with the FSIS Audit Coordinator and other audit team members, the designated representatives from the affected District Offices are to take the necessary action to ensure that all affected IPP and the management of selected establishments and facilities approved for export certification service are aware of the upcoming audit and the approximate dates of visits by the foreign auditors. The DO representatives are also to take steps to ensure that IPP at the selected establishments and other facilities are prepared for the audit;

1. The SPHV or FLS responsible for the selected establishments and other facilities are to direct IPP to become familiar with the Export Library entry, if any, for the auditing country.

2. At the next weekly meeting after being notified by the DO or FLS of the audit, the SPHV or the IPP at the selected establishments are to discuss the upcoming audit with establishment management, and for those facilities that are approved for export certification service, the SPHV or the IPP assigned to the facility are to discuss the upcoming audit with facility management. IPP are to document the establishment meeting or the facility meeting in a Memorandum of Interview in accordance with FSIS PHIS Directive 5000.1, *Verifying an Establishment's Food Safety System*, and FSIS Directive 5010.1, *Food Safety Related Topics for Discussion During Weekly Meetings*.

3. At least 10 days before the audit visit, IPP are to perform an SPS and HACCP verification task, if applicable, at the selected establishment or facility. When performing these tasks, IPP are to focus on any areas of concern and ensure that the establishment has implemented any programs required by the auditing country as described in the Export Library. IPP are to document any findings of regulatory noncompliance in accordance with FSIS PHIS Directive 5000.1 and FSIS PHIS Directive 13,000.1, *Scheduling In-Plant Inspection Tasks in the Public Health Information System*.

4. IPP are to report to the DO, through supervisory channels, any concerns related to their review of the Export Library entry, the weekly meeting with the establishment, or the SPS and HACCP verification task.

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B. The DO representative is to advise the FSIS Audit Coordinator of all concerns arising from the audit preparation activities as soon as possible after the concerns have been identified, as well as the steps that the DO is taking to have the concerns appropriately addressed by the establishment.

C. The FSIS Audit Coordinator is to advise the Director, IECPDS and the OFO/EARO of all concerns arising from the audit preparation activities so that they can verify that the concerns have been adequately addressed. Any unresolved concerns are to be elevated to the AA, OFO and AA, OPPD to agree on a course of action to ensure on-going compliance with FSIS and foreign country requirements.

VIII. OFO ACTIVITIES DURING THE AUDIT

The DO is to ensure that at least one management official from the DO is present and accompanies the foreign auditors during each audit of individual establishments and other facilities.

IX. ENTRANCE MEETING

A. The FSIS Audit Coordinator is to arrange for the audit entrance meeting.

B. Invitees are to include:

1. AA, OFO;

2. EAROs, OFO (as applicable);

3. AA, OPPD;

4. Director, IECPDS, OPPD;

5. Director, IAS, OIEA;

6. Director, IRSPS, OPPD ;

7. Field Team members; and

8. Other Program areas and Agencies as necessary and appropriate (e.g., OPHS, AMS, FAS, APHIS).

C. If the entrance meeting is held in Washington, DC, the FSIS Audit Coordinator is to arrange for a conference room. The entrance and exit meetings may or may not be held in Washington, DC.

D. If a country wishes to have an entrance conference before the foreign audit team arrives in the U.S., the FSIS Audit Coordinator is to work with FAS to arrange a teleconference or Digital Video Conference with the country.

X. ACTIVITIES AND PROCEDURES DURING THE AUDIT

A. During the audit, Audit Field Team members are to complete the Establishment Audit Worksheet (Attachment 2) for each establishment visited to record daily audit observations and findings. The daily audit observations and findings are to describe the foreign audit team's observations and findings. If the foreign audit team's observations or findings are violations of FSIS regulatory requirements, the Audit Field Team members are to document how any observed deficiencies violate FSIS regulatory requirements by citing the applicable regulation and summarizing the regulatory requirement. In addition, the Audit Field Team members are to advise the foreign auditors that a noncompliance report will be issued by IPP. If an observation or finding contradicts or is in conflict with FSIS regulations or policies, the Audit Field Team is to include corresponding comments in the Daily Summary Audit Report on the observation or finding from the FSIS perspective.

NOTE: If, at any time during the audit, controversial or problematic issues are identified by either the country or FSIS personnel, the audit team members are to immediately notify the Director of IECPDS, who will discuss the situation with OFO and OPPD management.

B. Audit Field Team members are to submit summary reports and worksheets by email to the FSIS Audit Coordinator as soon as possible at the conclusion of the day's activities.

C. If the foreign auditors decide to delist an establishment or to take another adverse regulatory action, the Audit Field Team member is to immediately inform the IECPDS of this information. IECPDS is to immediately advise appropriate OFO and OPPD managers and AMS (if the establishment is operating under an AMS-approved Export Verification (EV) program or other process verification program) of the delistment or other adverse regulatory action. IECPDS is to post a notice of the delistment of the specific establishment in the Export Library with the effective date.

D. During the audit, the FSIS Audit Coordinator is to prepare a summary of the previous day's results and observations and is to e-mail the summary to the designated points of contact in OFO, OPPD, and other Program areas, as appropriate.

E. An example of a completed Daily Summary Audit Report is attached (Attachment 3). The FSIS Audit Coordinator is to use this format to report daily results. At the end of the audit, the FSIS Audit Coordinator is to assemble a complete Daily Audit Summary Report, including all daily reports.

XI. PRE-EXIT MEETING

A. The FSIS Audit Coordinator is to schedule an internal pre-exit meeting at least one day before the conclusion of the audit to discuss the audit findings, the appropriate FSIS response to the audit findings, and any other potential issues that may have arisen during the audit.

B. Invitees are to include:

1. OFO, EAROs (as applicable);

2. Director, IECPDS, OPPD;

3. Director, IAS, OIEA;

4. Director, IRSPS, OPPD;

5. Field Team members; and

6. Other Program areas or agencies as necessary and appropriate (e.g., OPHS, AMS).

XII. EXIT MEETING

A. IECPDS is to schedule an exit meeting with the foreign country at the beginning of the audit. The exit meeting is normally to be held on the day after the conclusion of field visits. The meeting can be held in Washington, DC or at another USDA/FSIS office if this arrangement is more convenient for the foreign auditors.

B. Invitees are to include:

1. AA, OFO;

2. Director, IECPDS, OPPD;

3. Director, IAS, OIEA;

4. Director, IRSPS, OPPD ;

5. Field Team members; and

6. Other program areas or agencies as necessary and appropriate (e.g., OPHS, AMS, FAS, APHIS).

C. The FSIS Audit Coordinator is to prepare an agenda for the exit meeting and is to distribute the agenda to the FSIS participants and the foreign country participants prior to the exit meeting. Exit agenda topics are to include:

1. Audit findings; and

2. Discussion.

D. After the exit meeting, the FSIS Audit Coordinator is to prepare a summary of the discussion at the exit meeting, including the corrective action items needed and any additional information to be provided to the country and is to distribute the summary to the FSIS participants as the final entry in the Daily Summary Audit Report.

E. The FSIS Audit Coordinator is to assemble all documents relating to the audit, have them scanned for electronic filing, and post them on the OPPD SharePoint site. All audit team members are to have access to this site. Documents to be posted include:

1. Audit entrance and exit meeting agendas;

2. The final Daily Summary Audit Report with cumulative findings;

3. All Establishment Audit Worksheets;

4. Corrective or other actions needed by audited establishments and other facilities;

5. The draft audit report if provided by the foreign country; and

6. The final audit report if provided by the foreign country.

XIII. RESPONSE TO DRAFT AUDIT REPORT

A. If the foreign auditors indicate that they will submit a draft audit report, and if the draft report is not received from the auditing country within the timeframes agreed to during audit notification or audit exit meeting, IECPDS is to contact the country or request that FAS contact the country to ask about the status of the report.

B. Upon receipt of the draft audit report, the FSIS Audit Coordinator is to circulate it to the following representatives for comment.

1. AA, OPPD;

2. AA, OFO;

3. AA, OIEA;

4. Director, IECPDS, OPPD;

5. Director, IAS, OIEA; and

6. Director, IRSPS, OPPD.

C. The FSIS Audit Coordinator is to compile the comments, determine whether the comments warrant changes to the draft audit report, and ensure that the comments are cleared by the Director, IECPDS, the Director, IRSPS, and the AAs of OFO and OPPD before they are sent to the country.

XIV. FINAL AUDIT REPORT

A. Upon receipt of the final audit report, the FSIS Audit Coordinator is to post the final audit report to the SharePoint site.

B. The FSIS Audit Coordinator will distribute copies of the final report to:

    1. AA, OPPD;

    2. AA, OFO;

    3. AA, OIEA;

    4. Director, IECPDS, OPPD;

    5. Director, IAS, OIEA; and

    6. Director, IRSPS, OPPD.

XV. DATA ANALYSIS

IECPDS and IRSPS will develop an end-of-year report that summarizes the findings and corrective actions taken as a result of audits performed by foreign countries to identify any trends or relationships of non-compliance for individual establishments, any District–specific concerns, or any FSIS systemic problems. The results will be used to guide FSIS in the development of industry guidance documents, industry outreach activities, inspection procedures, or changes to FSIS directives or regulations.

XVI. QUESTIONS

Refer questions regarding this directive through askFSIS or by telephone at 1-855-444-9904. When submitting a question, use the Submit a Question tab and enter the following information in the fields provided:

Subject Field: Enter Directive 9000.8
Question Field: Enter question with as much detail as possible.
Product Field: Select **Import** from the drop-down menu.
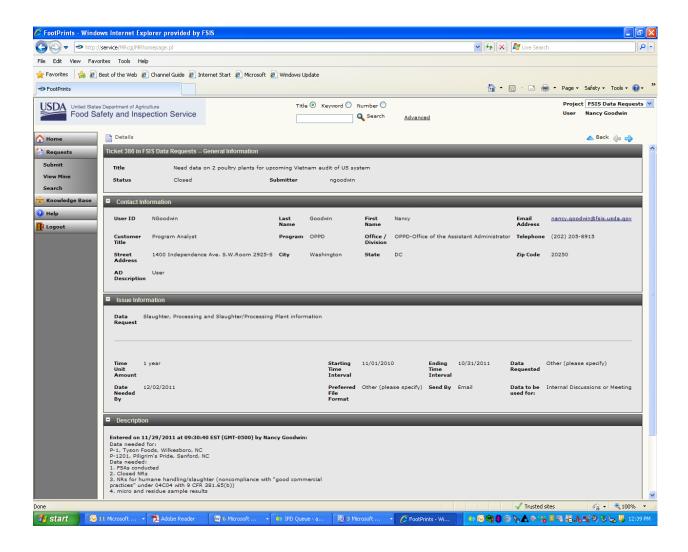Category Field: Select **Basic Import Answers** from the drop-down menu.
 Policy Arena: Select **International (Import/Export)** from the drop-down menu.

When all fields are complete, press **Continue**.

Assistant Administrator
Office of Policy and Program Development

Example of DAIG Data Request

United States
Department of
Agriculture

Food Safety
and Inspection
Service

Office of International
Affairs

1400 Independence Avenue, SW
Room 2137-South Building
Washington, DC   20250

ATTACHMENT 2

Establishment Audit Worksheet

DATE	

ESTABLISHMENT NUMBER	

ESTABLISHMENT OPERATIONS	

PERSONS PRESENT FOR AUDIT[1]	
AUDITOR(S)	
FSIS ESCORT	
OFO PERSONNEL	
PLANT PERSONNEL	

IS PLANT A CURRENT OR RECENT (WITHIN LAST YEAR) EXPORTER?	NO	YES	IF YES, WHAT PRODUCTS?

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[1] You can collect and attach business cards.

ATTACHMENT 3

Summary of Results
Country Review of the U.S. Inspection System
Date

Year	Team 1: Member Names	Team 2: Member Names
Date Sunday	Travel	Travel
Date Monday	Review Est. #, NAME Deficiencies found by the auditor: **FSIS perspective on deficiency:**	Review Est. #, NAME Deficiencies found by the auditor: **FSIS perspective on deficiency:**
Date Tuesday	Review Est. #, NAME Deficiencies found by the auditor: **FSIS perspective on deficiency:**	Review Est. #, NAME Deficiencies found by the auditor: **FSIS perspective on deficiency:**
Date Wednesday	Review Est. #, NAME Deficiencies found by the auditor: **FSIS perspective on deficiency:**	Review Est. #, NAME Deficiencies found by the auditor: **FSIS perspective on deficiency:**
Date Thursday	Review Est. #, NAME Deficiencies found by the auditor: **FSIS perspective on deficiency:**	Review Est. #, NAME Deficiencies found by the auditor: **FSIS perspective on deficiency:**
Date Friday	Review Est. #, NAME Deficiencies found by the auditor: **FSIS perspective on deficiency:**	Review Est. #, NAME Deficiencies found by the auditor: **FSIS perspective on deficiency:**
Date Saturday		
Date Sunday		

United States   Food Safety   Office of International   1400 Independence Avenue, SW
Department of and Inspection Affairs   Room 2137-South Building
Agriculture   Service   Washington, DC 20250

Date Monday	Review Est. #, NAME Deficiencies found by the auditor: **FSIS perspective on deficiency**	Review Est. #, NAME Deficiencies found by the auditor: **FSIS perspective on deficiency:**
Date Tuesday	Review Est. #, NAME Deficiencies found by the auditor: **FSIS perspective on deficiency:**	Review Est. #, NAME Deficiencies found by the auditor: **FSIS perspective on deficiency:**
Date Wednesday	Review Est. #, NAME Deficiencies found by the auditor: **FSIS perspective on deficiency:**	Review Est. #, NAME Deficiencies found by the auditor: **FSIS perspective on deficiency:**
Date Thursday	Review Est. #, NAME Deficiencies found by the auditor: **FSIS perspective on deficiency:**	Review Est. #, NAME Deficiencies found by the auditor: **FSIS perspective on deficiency:**
Date Friday	Exit Conference	Exit Conference