UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

9790.1 | 2/8/17

WRITING AN AUDIT REPORT OF FOREIGN FOOD SAFETY INSPECTION SYSTEMS

I. PURPOSE

This directive provides instructions to International Auditors (IA) in the International Audit Staff (IAS), Management Control and Audit Division (MCAD), Office of Investigation, Enforcement, and Audit (OIEA) on the drafting of uniform report of the results of foreign countries' meat, poultry, or egg products food safety inspection system on-site verification audits.

II. DEFINITIONS

A. Finding: A non-compliant practice or condition related to regulatory oversight identified during the on-site verification audit. If left unresolved, it could directly bear on equivalence.

1. Isolated: A non-compliant practice or condition, typically identified at individual foreign establishments, that does not necessarily indicate ineffective implementation of the foreign government food safety system.

2. Systemic: A non-compliant practice or condition that is associated with food safety system deficiency in design, implementation, or ineffective government oversight.

3. Significant: A non-compliant practice or condition that reflects a deficiency in the inspection system so substantial that it presents a potential threat to public health and requires an immediate regulatory response by the central competent authority (CCA).

III. BACKGROUND

A. The Food Safety and Inspection Service (FSIS) conducts on-site verification audits of foreign countries' meat, poultry, or egg products food safety inspection systems as part of the equivalence process. In addition, FSIS performs on-site verification audits as part of the initial equivalence process for countries that wish to begin exporting meat, poultry, or egg products to the United States (U.S.) and to reinstate equivalence when a country wishes to resume export of a specific product after a long period of trade inactivity. This process is outlined in FSIS Directive 9770.1, *Determining Initial and Reinstating the Equivalence of Foreign Food Safety Inspection Systems*.

B. FSIS conducts on-site verification audits of foreign countries that currently export meat, poultry, or egg products to the U.S. to verify that the implementation of the equivalence components of the country's food safety inspection system is consistent with its design as documented by the CCA in the self-reporting tool (SRT). This process is outlined in FSIS Directive 9780.1, *Verifying the Ongoing Equivalence of Foreign Food Safety Systems*.

C. The purpose of on-site verification audits is to verify whether a foreign country's food safety inspection system that was evaluated and determined equivalent as documented in the Component Analysis Verification Form (CAVF), is implemented and effective in providing an equivalent outcome to the U.S. inspection system. The IA is to examine a representative and informative sample of procedures, documents, records, and sites to verify whether the CCA has implemented controls as described in the

SRT. The CCA is the country's national government authority that is responsible for ensuring the safety and accurate labeling of the food supply. The IA is to use a systems approach by assessing the food safety inspection system as a whole which focuses on verifying the controls and recognizes that any observations or findings identified must be viewed in the context of the overall food safety inspection system. The process to prepare for and conduct an on-site verification audit is outlined in FSIS Directive 9770.1.

D. After completing an on-site verification audit, the IA drafts an audit report, which is a systematic and transparent assessment of the CCA's food safety inspection system. The IA documents his or her on-site verification audit observations that describe whether the CCA has implemented its food safety inspection system for the following six equivalence components: (1) Government Oversight (e.g., Organization and Administration), (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling), (3) Government Sanitation, (4) Government Hazard Analysis and Critical Control Points (HACCP) System, (5) Government Chemical Residues Testing Programs, and (6) Government Microbiological Testing Programs.

E. The Audit Report is to:

1. Specify whether the CCA is implementing its food safety inspection system as documented in the CAVF;

2. Characterize non-compliant practices or conditions;

3. Describe immediate and planned corrective actions; and

4. Describe immediate and planned FSIS verification activities.

IV. DRAFTING THE AUDIT REPORT

A. The IA, after considering the audit scope and availability of historical information, is to include an appropriate level of detail in the report.

1. Background information that describes the audit scope and objectives is to be sufficiently relevant to support subsequent analysis discussed in the report (e.g., audit verification methods used, findings, and conclusions).

2. For ongoing verification audits, the report is to address any substantive changes made to the CCA's food safety inspection system or changes introduced in response to new FSIS regulatory changes and policies since the previous audit. For example, for a country that is eligible to export raw pork products and has requested an initial equivalence determination to export raw beef products to the U.S. for the first time, the audit report is to focus on the country's raw beef food safety inspection system.

B. The IA is to describe how a CCA's food safety inspection system is being implemented for each of the six equivalence components, as described in Sections V. A. 7 through 12.

C. The IA is to present audit findings in a consistent manner.

1. For each finding, the IA is to:

    a. Describe the country's ability or inability to implement its food safety inspection system as documented in the CAVF; and

b. Consider the impact that the finding has on the ability of the foreign food safety inspection system to provide an equivalent level of public health protection as applied domestically in the U.S.

2. The IA is to determine the impact of each audit finding after considering:

a. Existing controls related to the food safety inspection system design and execution. This may include the absence of documents that demonstrate national commitment or implementation;

b. The presence of additional evidence that provides confidence in the country's ability to export product that is safe, wholesome, and properly labeled and packaged to the U.S.; and

c. The presence of other mitigating factors.

D. The IA is to present audit conclusions in a consistent manner.

1. In the "Executive Summary" section, the IA is to include a summary of the findings on a component-by-component basis (not a finding-by-finding list), and is to highlight any significant findings. The SRT questions are the equivalence criteria that FSIS uses to determine equivalence. The IA is to refer to the component questions under each of the six equivalence components to describe how he or she verified that the foreign food safety inspection system is being implemented as described in Sections V. A. 7 through 12.

2. In each component section, the IA is to explain the country's ability or inability to implement controls as documented in the CAVF.

3. In the "Conclusions and Next Steps" section, the IA is to describe his or her conclusions including a summary of findings by CAVF component, and the CCA's proposed corrective actions as described in Section V. A. 13.

V. ORGANIZATION OF THE DRAFT AUDIT REPORT

A. The audit report is to contain the following sections:

1. A title page that includes the name of the country audited, audit dates, and food safety inspection systems audited;

2. The "Executive Summary" section is to provide an overview of why the audit was conducted, a clear understanding as to whether the CCA has implemented its food safety inspection system as documented, and issues that require future deliberations. The section is not to exceed one page or contain any information that is not in the audit report. The section is to contain the following:

a. Summary that contains the purpose for the audit, the audit dates, the food safety inspection systems audited, and the six equivalence components audited;

b. Summary of audit findings on a component-by-component basis. For example, the IA would summarize under Component 1- Government Oversight the following audit findings: (1) the CCA is not communicating to government inspection personnel import requirements as the U.S. issues them, and (2) the CCA is not providing specialized ongoing training to government inspectors assigned to certified establishments eligible to export meat, poultry, or egg products to U.S.;

c. Summary of corrective actions proposed by the CCA; and

NOTE: Do not include the status of corrective actions from the previous audit or point-of-entry (POE) violations unless the CCA was unable to demonstrate that it has corrected previous deficiencies.

d. FSIS's recommended verification activities to verify the CCA's corrective actions;

3. The "Table of Contents" is to list each of the sections as described in Sections V. A. 4 through 13, and V. B;

4. In the "Introduction" section, the IA is to identify the country that was audited, the dates that the audit was performed, and information about the entrance meeting;

5. In the "Audit Objective, Scope, and Methodology" section, the IA is to provide a narrative on audit objective, scope, and methodologies used, e.g., number of selected sites audited;

6. The "Background" section is to provide information about food safety inspection systems audited, the establishments audited, and the types of products the establishments produce. For ongoing verification audits, information for this section is to be based on data collected for at least the past year, e.g., point of entry (POE) reinspection data and updates to their food safety inspection system documented in the SRT. For initial and reinstatement audits, information is to be gathered from the CCA as described in FSIS Directive 9770.1. The section is to include the following:

   a. Summary of all exported production volumes, establishments audited, and types of product the audited establishments produce;

   b. Description of any elevated enforcement actions initiated by FSIS (e.g., refusing to relist certified establishments, increased POE sampling and results of POE sampling); and

   c. Analysis of trends related to performance within the six equivalence components (including significant POE violations and prior audit findings) and how these relate to current audit findings;

7. The "Component 1: Government Oversight (Organization and Administration)" section is to describe how the foreign food safety inspection system met equivalence criteria in component 1 of the SRT. The section is to include the following:

   a. Description of component-specific equivalence criteria as documented in the CAVF in the Public Health Information System (PHIS) by the International Equivalence Staff (IES);

   b. Description of verification methodology as documented in the CAVF in PHIS, POE testing results and on-site verification activities performed;

   c. Description of any enforcement actions taken by the CCA at facilities, and their significance within the context of the current audit; and

   d. Presentation of audit findings as described in Section IV. C.;

8. The "Component 2: Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling)" section is to include the following:

   a. Description of component-specific equivalence criteria as documented in the CAVF in PHIS by IES;

   b. Description of verification methodology as documented in the CAVF in PHIS, POE testing results and on-site verification activities performed; and

c. Presentation of audit findings as described in Section IV. C.;

NOTE: FSIS regulations under Title 9 Code of Federal Regulations (CFR) Part 590 prescribe the food safety requirements for egg products. The IA is to evaluate all food safety controls for egg products under component 2 (including discussion of egg product HACCP programs, if applicable).

9. The "Component 3: Government Sanitation" section is to include the following:

    a. Description of component-specific equivalence criteria as documented in the CAVF in PHIS by IES;

    b. Description of verification methodology as documented in the CAVF in PHIS, POE testing results and on-site verification activities performed; and

    c. Presentation of audit findings as described in Section IV. C.;

NOTE: Isolated findings at audited establishments are to be documented by the IA in the "Individual Foreign Establishment Audit Checklist" but not in the body of the audit report.

10. The "Component 4: Government HACCP System" section is to include the following:

    a. Description of component-specific equivalence criteria as documented in the CAVF in PHIS by IES;

    b. Description of verification methodology as documented in the CAVF in PHIS, POE testing results and on-site verification activities performed;

    c. Discussion of the effectiveness of establishment controls and government verification, e.g., critical control points (CCPs), "zero-tolerance," carcass chilling, lethality requirements for ready-to-eat (RTE) products); and

    d. Presentation of audit findings as described in Section IV. C.;

11. The "Component 5: Government Chemical Residue Testing Programs" section is to include the following:

    a. Description of component-specific equivalence criteria as documented in the CAVF in PHIS by IES;

    b. Description of verification methodology as documented in the CAVF in PHIS, POE testing results and on-site verification activities performed;

    c. Discussion of the implementation status for the CCA's annual government chemical residues testing program;

    d. An indication of whether a hold and test procedure is implemented for government testing; and

    e. Presentation of audit findings as described in Section IV. C.;

12. The "Component 6: Government Microbiological Testing Programs" section is to include the following:

    a. Description of component-specific equivalence criteria as documented in the CAVF in PHIS

by IES;

b. Description of verification methodology as documented in the CAVF in PHIS, POE testing results and on-site verification activities performed;

c. Discussion of the implementation status for the CCA's annual government microbiological testing programs;

d. An indication of whether a hold and test procedure is implemented for government testing; and

e. Presentation of audit findings as described in Section IV. C.; and

13. In the "Conclusion and Next Steps" section, the IA is to describe his or her conclusions. The section is to include:

a. A summary of the exit conference;

b. A summary of the findings on a component-by-component basis, including whether or not there were significant findings; and

c. If findings were identified during the audit, the IA is to include:

i. A summary of corrective actions and verification activities taken or proposed by the CCA, including the timeframe for implementation and how the corrective actions will be communicated with and agreed to by FSIS; and

NOTE: Corrective actions submitted by a CCA after the in-country audit has concluded are not to be included in the final audit report because the actions were not observed as part of the audit. They may, however, be published as an addendum to the final audit report and can be included as part of the administrative records associated with the equivalence rulemaking process.

ii. A summary of recommended FSIS verification activities taking into account the nature and details of the finding. Verification activities may include, but are not limited to follow up audit and increased level of reinspection (see FSIS Directive 9900.6, *Laboratory Sampling Program for Imported Meat, Poultry, and Egg Products*).

B. Appendices

1. The IA is to attach the following documents to the audit report:

a. Appendix 1. Individual Foreign Establishment Audit Checklists; and

b. Appendix 2. The foreign country's response to the draft audit report (when available).

VI. FINALIZING THE AUDIT REPORT

A. IES, in consultation with Issuance Staff (IS) and Import and Export Policy Development Staff (IEPDS), OPPD, will provide the IA with a statement on the country's equivalence status in the determination process to include in the transmittal letter that accompanies the audit report for an initial or reinstatement audit report.

B. IES, in consultation with IEPDS, will provide the IA with a statement of whether or not the country continues to maintain equivalence with U.S. requirements to include in the transmittal letter that accompanies the audit report for an ongoing audit report.

C. The transmittal letter that accompanies the audit report is to explain how the findings have a bearing on equivalence, which is based on input from IES.

D. For initial and reinstatement equivalence determinations, the IA is to refer to FSIS Directive 9770.1.

E. For ongoing equivalence determinations, the IA is to refer to FSIS Directive 9780.1.

VII. QUESTIONS

Refer questions through supervisory channels.

Assistant Administrator
Office of Policy and Program Development