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

FSIS DIRECTIVE

9780.1 Revision 1	7/26/18

VERIFYING THE ONGOING EQUIVALENCE OF FOREIGN FOOD SAFETY INSPECTION SYSTEMS

CHAPTER I – GENERAL

I. PURPOSE

This directive provides instructions to the International Audit Branch (IAB), Management Control and Audit Division (MCAD), Office of Investigation, Enforcement and Audit (OIEA); International Equivalence Staff (IES), Office of Policy and Program Development (OPPD); the Recall Management and Technical Analysis Division (RMTAD) Imports Branch, Office of Field Operations (OFO); and the Office of International Coordination (OIC) for verifying the ongoing equivalence of foreign food safety inspection systems and the actions to be taken when equivalence is not maintained.

KEY POINTS:

- *Outlines FSIS personnel's roles and responsibilities related to verifying the ongoing equivalence of foreign food safety inspection systems through document reviews, on-site verification audits, and analysis and response to reinspection point-of-entry (POE) violations*

- *Outlines FSIS personnel's roles and responsibilities related to evaluating and responding to individual sanitary measure equivalence requests from foreign governments*

- *Outlines the process to take place when an equivalent foreign food safety inspection system needs to be reexamined because it appears to no longer achieve an equivalent level of public health protection as achieved domestically in the United States (U.S.), or when FSIS is unable to make an equivalence determination because of a lack of information from the foreign Central Competent Authority (CCA)*

NOTE: For the purpose of this directive, meat includes fish of the order Siluriformes.

II. SIGNIFICANT CHANGES

A. The directive is restructured in this revision to reflect the ongoing equivalence determination process.

B. This revision clarifies the instructions on the:

1. Ongoing equivalence determination process;

2. Individual sanitary measures equivalence determination process;

3. Roles and responsibilities of Equivalence Officers (EO), International Auditors (IA), RMTAD Analysts, and OIC who comprise the technical review team; and

4. Determination process and associated actions with failures to demonstrate maintenance of equivalence.

III. CANCELLATION

FSIS Directive 9780.1, *Verifying the Ongoing Equivalence of Foreign Food Safety Systems*, 10/7/15

IV. BACKGROUND

A. FSIS's equivalence determination is the process of deciding whether the food safety inspection system in a foreign country is equivalent to FSIS's inspection system. The principle of equivalence is grounded in the World Trade Organization's Agreement on the Application of Sanitary and Phytosanitary Measures. This was adopted by the U.S. in amendments to the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA). Foreign meat, poultry, and egg products food safety inspection systems are not required to develop and implement the same procedures that the U.S. follows but that the foreign governments are to objectively demonstrate how its procedures achieve an equivalent level of public health protection as achieved by the U.S. inspection system under FSIS.

B. Regulatory requirements for equivalence are set forth in Title 9 of the Code of Federal Regulations (CFR) 327.2 for meat products, 9 CFR 381.196 for poultry products, 9 CFR 557.2 for fish of the order Siluriformes, and 9 CFR 590.910 for egg products. FSIS has categorized these requirements into six equivalence components. Specifically, FSIS evaluates the Central Competent Authority (CCA), the country's governmental authority that is responsible for ensuring the safety and accurate labeling of the food supply, to verify whether it maintains equivalent requirements with regard to (1) government oversight (e.g., organization and administration, enforcement authority, government inspection personnel-training/staffing), (2) government verification of food safety and other consumer protection regulations (e.g., humane handling, ante-mortem inspection, post-mortem inspection, product standards and labeling), (3) government sanitation verification, (4) government Hazard Analysis and Critical Control Point (HACCP) system verification, (5) government chemical residue program, and (6) government microbiological pathogen and process control programs.

C. Ongoing equivalence verification pertains to countries that are listed in the CFR as eligible and are currently exporting meat, poultry, or egg products to the U.S. FSIS will continuously evaluate and verify the equivalence of an exporting country's food safety inspection system through a three part process.

1. Recurring document reviews of the Self-Reporting Tool (SRT) (see Self-Reporting Tool) responses and supporting documentation. Recurring document reviews also include submitted certified establishment lists, government residue control programs, government microbiological sampling and testing programs, including the previous year's test results and responses to violative findings;

2. On-site verification audits of every eligible country's food safety inspection system at least once every three years to verify whether the country continues to maintain an equivalent inspection system; and

3. POE reinspection of each shipment of meat, poultry, and egg products received from the exporting country.

D. For the purposes of this directive, the technical review team will consist of the designated IAB IA, IES EO, OFO RMTAD-Imports Analyst (RMTAD Analyst), OIC, and may include subject matter experts from other program areas. The technical review team is to discuss technical issues and request clarification from the CCA. The office who convenes the technical review team is responsible for drafting official correspondence or decision-making documentation. The lead technical review team member is to ensure the rest of the team members are provided an opportunity to review and comment. The lead technical

review team member will provide their supervisor the official correspondence or decision-making documentation for review and approval. The respective office's Assistant Administrator (AA) and the OIC Executive will provide comments or clearance. All final documents will be sent to the OIC Executive for transmittal to the CCA.

CHAPTER II – RECURRING DOCUMENT REVIEWS

I. GENERAL

A. The EO is to confirm that countries submit the following to FSIS for review at least annually, by May 18, to ensure that complete and up-to-date information (identified in points 1-4, below) of foreign countries' food safety inspection systems are being considered as part of FSIS's annual ongoing equivalence assessment.

1. An update to the SRT responses or verification that the current SRT responses continue to be accurate and complete;

2. An update to the certified establishment list or verification that the current list is accurate and includes all establishments used in the production of products within the country for export of eligible meat, poultry, or egg products to the U.S.;

3. The current year's government residue control program and previous year's government chemical residue control program results including a brief description of follow up activities taken by the CCA associated with any violation linked to products intended for export to the U.S.; and

4. The current year's government microbiological sampling and testing program and previous year's government microbiological sampling and testing program results including a brief description of follow up activities taken by the CCA associated with any violation linked to products intended for export to the U.S.

II. SELF-REPORTING TOOL

A. When the CCA submits annual required information identified in Chapter II, Section I. A. 1, 3, and 4 in the Public Health Information System (PHIS) or by paper copy, the EO is to:

1. Enter into PHIS the original foreign SRT responses and upload associated documents, including referenced supporting documentation in the SRT and the annual submissions on the government residue and microbiological sampling and testing programs. In cases not requiring translation, begin a review and assessment of the SRT responses and associated documents.

2. Arrange for translation of SRT responses and associated documents into English. Prior to sending documents for translation, the EO is to use available resources to identify specific information that needs translation. Enter English-translated SRT responses into PHIS, and upload associated translated documents; begin a review and assessment of the English-translated SRT responses and associated documents.

3. Review and assess the SRT responses and associated documents, as well as the government residue and microbiological sampling and testing programs with the assistance of subject matter experts, as needed, to determine whether the equivalence criteria continues to be met. If a country submits partial information or additional information is needed to evaluate ongoing equivalence, the EO is to follow-up with the CCA, through OIC, to address any gaps or findings in the submitted information.

NOTE: A document review **gap** is identified missing information (e.g., required documents outlined in Chapter II, Section I. A., that were not submitted, or supporting documents referenced in SRT responses that were not provided), whereas a **finding** may bring into question whether the country's food safety inspection system is equivalent.

4. Document the analysis of this annual review as outlined in subsequent Chapter II, Section V.

B. When the CCA affirms that no SRT response updates were made or are needed, then the EO is to review the SRT responses at least annually to determine whether issuance of new FSIS policies (e.g., Federal Register notices that announce significant policies) may impact the country's equivalence. If the EO determines that a country may be impacted, then the EO is to notify the CCA, through OIC, of the impacts of the new FSIS policies and implement procedures outlined below (in Chapter II, Section II. C.) and Chapter V, Section I. G.

C. If the EO identifies any gaps or failures to respond to findings during the document review, then the EO is to discuss the gaps or findings with the technical review team. If the EO determines that the CCA did not provide in whole or part the required annual information identified in Chapter II, Section I. A., then the EO will notify the CCA, through OIC, of the concerns. If the CCA still does not provide adequate information needed by FSIS to determine the foreign country's maintenance of equivalence, then IES is to initiate the procedures outlined in Chapter VI.

D. If a teleconference call is to be held with the CCA, then the EO is to develop an agenda and ensure that the members of the technical review team are made a part of the meeting. The agenda is to highlight the concerns identified during the document review for OIC to share with the CCA. The EO is to provide the agenda to OIC for review and transmittal to the CCA. During the teleconference, the EO is to make notes for the meeting minutes, and share the draft minutes with the FSIS participants for review and comment. Once meeting minutes are finalized, the EO is to upload the minutes into PHIS under the associated country and mark the uploaded minutes as an "internal" document.

E. If the EO determines during the document review that the current laboratory protocol is not equivalent with FSIS's Microbiology Laboratory Guidebook (MLG) or Chemistry Laboratory Guidebook (CLG), then the EO is to contact the CCA, through OIC:

1. To request documentation that demonstrates how the method used is equivalent to FSIS's MLG and CLG protocols, and

2. To recommend that the CCA submit an official request for an Individual Sanitary Measure (ISM) equivalence determination. The EO is to follow procedures outlined in Chapter II, Section IV. (below) when an ISM has been officially requested by the CCA.

III. CERTIFICATION OF FOREIGN MEAT, POULTRY, AND EGG PRODUCT ESTABLISHMENTS

A. When the CCA submits a certified establishment list by correspondence, OIC is then to share this list with IES and Import and Export Policy Development Staff (IEPDS). When the CCA submits the certified establishment list through PHIS, then EO is to share the list with OIC and IEPDS. The assigned EO is to:

1. Review the CCA's certified establishment list to ensure compliance with requirements outlined in 9 CFR 327.2(a)(3) for meat and 381.196(a)(3) for poultry.

2. Ensure for new establishments, or any establishments for which the information from the previous year has changed, that the following information has been provided:

a. The date, foreign country, establishment's name, address, and establishment number, type of operation (e.g., slaughterhouse, non-slaughter processing, cold storage, exporting warehouse, or source establishment – see Note, immediately below), and the establishment's eligibility status (e.g., new, relisted, or delisted).

b. Slaughter, processing, and source establishments are to address the species and type of products produced (See FSIS Product Categorization guide).

c. Paper certified establishment lists are to contain the foreign official's title and signature.

3. When the establishment information provided on the preceding year's annual certified establishment list has not changed, then the EO is to ensure that the certified establishment list contains the date, the foreign country, the establishment's name and, for paper certified establishment lists only, the foreign official's title and signature.

NOTE: A **source establishment** is applicable when FSIS may approve an eligible country to use slaughtered product from a certified slaughter establishment within its own country in further processed meat or poultry products that are exported to the United States. Source establishments are not eligible to export to the United States.

4. Verify that list of certified establishments includes all establishments involved in the production or storage (facilities that repackage, label or relabel, or export) of meat, poultry, or egg products to be exported to the United States.

5. Provide the CCA, through OIC, an explanation of the inadequacies for compliance with the certified establishment list regulatory requirements. In addition, if a previously eligible establishment is missing from the recently submitted annual certified establishment list, then EO is to follow-up with the CCA, through OIC, to request clarification if the missing establishment is in error. If the missing establishment is in error, then the EO is to request an updated certified establishment list. The EO is to verify the updated certified establishment list contains required information in Chapter II, Section III. A. 1.

6. Send the approved certified establishment list to the PHIS Import Librarian, IAB, RMTAD, and OIC.

B. If the CCA submits a certified establishment list that includes an establishment for export of a processing category, product category, or product group that in fact is not eligible for export to the United States, then the EO is to ask the CCA, through OIC, if the country is interested in exporting the identified ineligible product. If the CCA confirms that the country is interested in exporting an ineligible product to the United States, then the EO is to notify the CCA, through OIC, of the reason that FSIS disapproves an establishment certification.

C. Upon receipt of the approved CCA certified establishment list from the EO, the PHIS Import Librarian is to update PHIS, with priority given to delisted and newly certified establishments. In situations where a foreign country suspends an establishment's eligibility or FSIS terminates an eligible establishment's ability to export meat, poultry, or egg products to the United States, then the Import Librarians are to implement procedures outlined in Chapter VI, Section G. The PHIS Import Librarian's updates are also to include, but is not limited to, removal of establishments that were delisted, as well as changes in establishment names and products, process categories, and species covered by the CCA certification. The PHIS Import Librarian is to delist in PHIS any establishments identified as "delisted" using the effective date (or annual certification date if none provided as the effective date) of delistment. Once PHIS is updated, the Import Librarian is to then send a request to the Office of Public Affairs and Consumer Education (OPACE) Web and Digital Communications Staff (WDCS) (OPACE/WDCS@fsis.usda.gov) to

update the eligible foreign establishment table on FSIS' website. If at any point FSIS has determined that a foreign country has certified product for export to the United States from a delisted establishment, FSIS is to initiate procedures under Chapter VI.

IV. INDIVIDUAL SANITARY MEASURE (ISM)

A. Upon receipt of an official request for an ISM equivalence determination in writing from a foreign government's CCA, the IES Director is to assign an EO as the project lead.

B. The EO is to:

1. Draft official correspondence acknowledging the CCAs request. The official correspondence is to cite relevant ISM criteria, reference the question numbers in the SRT that the CCA needs to update, and explain that submitted documentation should demonstrate that the measure provides an equivalent level of public health protection. If criteria for a given ISM does not exist, the EO is to perform procedures outlined in Chapter II, Section IV. C and D (below).

2. Request that the technical review team read and comment on draft official correspondence, that the IES Director review and clear, and that the OPPD AA review and concur. The EO then sends to OIC for transmittal.

3. Upon receipt of the CCA's updated SRT responses and supporting documentation, follow procedures outlined in Chapter II, Section II. A. to review and assess whether the equivalence criteria are met. The EO is to follow procedures outlined in Chapter II, Section V. for updating the Component Analysis Verification Form (CAVF) in PHIS.

C. Equivalence criteria for FSIS sanitary measures are embedded within the SRT questions. If equivalence criteria do not exist for a given ISM, then the EO, with the assistance of subject matter experts, is to develop criteria to evaluate the measures.

D. The EO, with the assistance of subject matter experts and the technical review team, is to develop new equivalence criteria for an ISM, to be added in an SRT question, through the process of:

1. Identifying the relevant FSIS food safety requirements related to the ISM;

2. Identifying the objectives of the FSIS food safety requirements and the expected outcomes; and

3. Identifying and requesting any additional information from the CCA that includes objective data to establish a conclusive comparison between the ISM and the FSIS food safety requirements.

E. Once the EO completes the review of the additional information from the CCA, the EO is to prepare a Decision Memorandum determining the ISM Equivalent or Not Equivalent for OA and notify the CCA, through OIC, of FSIS's decision about the ISM. The notification is to explain the basis for the FSIS decision to either accept or reject the ISM.

F. The EO is to summarize the following in the Decision Memorandum determining the ISM Equivalent or Not Equivalent:

1. CCA's SRT response;

2. Equivalence criteria against which CCA's food safety inspection system has been evaluated; and

3. The EO and subject matter experts' evaluation of the CCA's food safety inspection system.

G. The EO is to ask the technical review team to read and comment on the draft notification and Decision Memorandum, ask the IES Director to review and clear, ask the OPPD AA to review and concur, and ask to OA to review and approve. Once approved by OA, the EO then is to send the notification to OIC for transmittal to the CCA. Also upon approval, the EO is to upload the signed Decision Memorandum into PHIS under the associated country and mark the uploaded Decision Memorandum as an "internal" document.

H. If FSIS accepts the ISM, FSIS will verify the application of the ISM during the next scheduled on-site verification audit. If the EO or IA determine at any point during the ongoing equivalence verification process that an eligible country currently exporting meat, poultry, or egg products to the United States is implementing a new procedure on products destined for export to the U.S., then either IES or IAB is to initiate measures outlined in Chapter VI to determine whether there is an imminent threat to public health concerning products exported to the U.S.

V. COMPLETING THE CAVF FOR RECURRING DOCUMENT REVIEWS

A. Each year by December 31, the EO is to complete the SRT Analysis-Comments section in the CAVF in PHIS, and also the Audit Planning section in those years when an audit is scheduled. The EO is to prioritize completing these sections in the CAVF based upon the audit schedule. Seventy days prior to the audit start date, the EO is to have completed the SRT Analysis-Comments and Audit Planning sections. The Lead EO is to coordinate and ensure that all relevant food safety inspection system information is entered into the CAVF by the EO assigned to a country with ongoing equivalence.

B. For the annual analysis of the document review, the EO is to:

1. Complete the **SRT Analysis-Comments** section. Under each component, the EO is to state whether the component as a whole meets, partially meets, or does not meet requirements. The EO is to follow this statement with an explanation for each relevant SRT question as to whether each criterion is met, partially met, or not met. The EO's explanation is to include under each relevant SRT question outstanding gaps and findings (e.g., concerns with or lack of government oversight, or no control programs for Shiga toxin-producing *Escherichia coli* (STEC) in raw beef products or *Listeria monocytogenes* and *Salmonella* in ready-to-eat products), and identify all relevant SRT evaluation criteria.

NOTE: If the EO determines that one or more criteria under a component is not met, it does not necessarily result in the whole component being identified as "not met." The EO is to consider the food safety and public health impacts of the not met or partially met criteria.

2. Complete the **Audit Planning** section (only for years when an audit is scheduled). Under the relevant food safety-objective based criterion, the EO is to document unique verification tasks that align with specific concerns associated with the document review that the IA is to review and observe during the on-site verification audit. Refer to Chapter IV, Section III. F. and G. for instructions on how the IA is to complete the Audit Planning section in the CAVF in PHIS.

CHAPTER III – POINT-OF-ENTRY VIOLATIONS (POEV)

I. GATHERING POEV INFORMATION AND GENERATING A POEV CASE FILE IN PHIS

A. FSIS inspection program personnel (IPP) conduct POE reinspection by using the assigned types of inspection (TOI) generated in PHIS for all meat, poultry, and egg products offered for import into the U.S. For each non-compliant shipment, IPP implement instructions contained in:

1. FSIS PHIS Directive 9900.2, *Import Reinspection of Meat, Poultry, and Egg Products*;

2. FSIS PHIS Directive 9900.6, *Laboratory Sampling Program for Imported Meat, Poultry, and Egg Products*;

3. FSIS PHIS Directive 9900.8, *Meat, Poultry, and Egg Products Refused Entry into the United States (U.S.);*

4. FSIS Directive 14100.1, *Speciation, Residue, and Salmonella Testing of Fish of the Order Siluriformes at Official Import Inspection Establishments;* and

5. FSIS Directive 14950.1, *Inspection Program Personnel Responsibilities at Official Import Inspection Establishments that Receive Shipments of Siluriformes Fish and Fish Products.*

B. OFO RMTAD-Imports is made aware of public health lot failures.

C. For each public health lot failure, the RMTAD Analyst is to:

1. Verify that a public health violation has occurred;

2. Review the country's and associated establishment's history of previous POEVs;

3. Follow-up with the designated Frontline Supervisor, if needed, to request any additional documentation to support the case file; and

4. Generate a POE Violation Assessment case file in PHIS upon determining that a POEV has occurred, and upload all supporting documentation into the case file in PHIS. Supporting documentation may include, but is not limited to, received case file information from the field, Laboratory Information Management System (LIMS) and Biological Information Transfer Email System (BITES) reports, official correspondence, and submitted corrective actions.

NOTE: A POEV case file is typically generated for each non-compliant lot that is identified as a public health failure in PHIS. Multiple types of public health failures could be included in a POEV. Also, multiple POEVs could be identified in a single shipment (which contains multiple lots). Examples of when a POEV may not be determined include, but are not limited to, when lots are refused for specific Animal and Plant Health Inspection Service (APHIS) animal disease restrictions which do not impact food safety, or when investigated off-condition failures are a result of transport issues (e.g., refrigeration breakdown of a container).

D. The RMTAD Analyst is to notify the OFO RMTAD-Imports Branch Chief if at any point in the POEV process the technical review team identifies (1) a pattern of recurring POEVs, (2) egregious POEVs which may demonstrate an imminent threat to public health concerning products exported to the United States, or (3) POEVs that demonstrate a loss of process control. The OFO RMTAD-Imports Branch Chief is then to initiate procedures outlined in Chapter VI.

II. NOTIFYING THE CCA OF A POEV

A. The RMTAD Analyst is to draft a notification to the CCA for each determined POEV and ask the technical review team to review and comment on the draft notification. The notification is to include a request that the CCA provide a report of the investigation of the violation, including an analysis by the CCA's subject matter experts, and a description of the corrective actions, preventative measures, and associated verification activities that the CCA will implement. When applicable, the notification is to include a request for information from the CCA on whether additional shipments exported to the United States are associated with the public health failure.

B. When LIMS or BITES reports a positive microbiological laboratory sample result, the RMTAD Analyst is to notify the CCA, through OIC, as outlined in Chapter III, Section II. A., when applicable. The RMTAD Analyst is to also include a request in the notification to the CCA for additional information concerning support for microbiological independence of products produced prior to and after the violative production lot (including consideration of high event periods, when applicable) and traceback activities (e.g., slaughter date of the product, and any additional certificates covering product exported to the U.S. from the same production lot/date or originating from the same slaughter lot/date).

C. The RMTAD Analyst is to have the OFO RMTAD-Imports Branch Chief review and clear the draft notification, and send to OIC for transmittal. The RMTAD Analyst is to upload the transmitted notification into the PHIS POE Violation Assessment case file.

III. EVALUATING THE CCA'S RESPONSE TO A POEV

A. When RMTAD receives a CCA's response about corrective actions and verification measures to a notified POEV, the RMTAD Analyst is to:

1. Analyze the response and identify discrepancies and missing information, and include in the analysis a need for proposed information or clarification;

2. Share the analysis and the CCA's response with the technical review team for review and comment; and

3. Upload the CCA's response into the PHIS POE Violation Assessment case file.

B. The technical review team's analysis of POEVs is to take into consideration both individual violations and all repetitive events that may be indicative of systemic equivalence concerns. Factors for analysis include but are not limited to:

1. Multiple violations by a single producing establishment;

2. Multiple violations from multiple producing establishments; and

3. Relationship to previous POEVs or on-site audit verification findings.

C. If the technical review team, including the RMTAD Analyst, identifies a need for additional information or clarification of the CCA's proposed corrective actions and verification measures in response to a notified POEV, the RMTAD Analyst is to notify the CCA, through OIC, of the concerns.

D. If a teleconference call is to be held with the CCA, then the RMTAD Analyst is to develop an agenda and ensure that the members of the technical review team actively participate in the teleconference call. The agenda is to highlight the information the CCA will need to fully address. The RMTAD Analyst is to provide the agenda to OIC for transmission to the CCA. The RMTAD Analyst is to record the meeting

minutes during the teleconference call, and share the draft minutes with the FSIS participants for review and comment. Once the meeting minutes are finalized, the RMTAD Analyst is to add the meeting minutes into the PHIS POE Violation Assessment case file.

E. When the CCA's response to a POEV includes suspending shipment of product from a specific establishment, or a specific species or process category, then the RMTAD Analyst is to follow instructions outlined in Chapter VI, Section I. G. and H.

F. If the CCA does not respond to the POEV notification or only provides part of the information requested in the POEV notification, then the RMTAD Analyst is to send a reminder to the CCA, through OIC. If the CCA still does not provide a response or requested outstanding information, OFO RMTAD-Imports is to initiate procedures outlined in Chapter VI.

IV. CLOSING OUT A POEV

A. When the RMTAD Analyst and technical review team determine that a CCA's response is adequate, the RMTAD Analyst is to:

1. Document the assessment conclusions in a Decision Memorandum to Recommend Closure of the POE Violation Assessment case file in PHIS;

2. Upload the Decision Memorandum to the PHIS POE Violation Assessment case file after the OFO RMTAD-Imports Branch Chief reviews and signs the Decision Memorandum;

3. Draft official correspondence to the CCA upon receiving agreement from the technical review team that the CCA has adequately addressed the POEV. The RMTAD Analyst is to ask the technical review team to review and comment on the draft correspondence, ask the OFO RMTAD-Imports Branch Chief review and clear the official correspondence, and send the final draft of the official correspondence to OIC for review and transmittal to the CCA; and

4. Close the POE Violation Assessment case file in PHIS.

CHAPTER IV – ON-SITE VERIFICATION AUDITS

I. AUDIT SCHEDULE

A. IAB is responsible for planning and conducting ongoing equivalence on-site verification audits of foreign food safety inspection systems. By July 31 of each calendar year, the IAB Branch Chief is to have an approved Audit Schedule of Foreign Countries Decision Memorandum for the next fiscal year. The IAB Branch Chief is to use the risk-based approach that is described fully in the *Methodology on How to Classify Foreign Countries for Prioritizing On-Site Equivalence Verification Audits*. When drafting the list of countries to audit and proposed dates for the next year, the IAB Branch Chief is to collaborate with the IES Director.

B. To begin planning and drafting the annual on-site verification audit schedule, the IAB Branch Chief is to obtain the following data from MCAD:

1. Risk Volume – as described in Appendix B of the *Methodology on How to Classify Foreign Countries for Prioritizing On-Site Equivalence Verification Audits*.

2. POE Reinspection Data – This analysis is to include the number and severity of failures for all TOIs per country for three one-year cycles of PHIS data.

3. Total number of days since the publication of the last final audit report.

C. When drafting the annual Audit Schedule, the IAB Branch Chief is to consider the public health risk determinants outlined in Appendix A of the *Methodology on How to Classify Foreign Countries for Prioritizing On-Site Equivalence Verification Audits,* as well as the following to determine the prioritization of equivalent countries to be audited:

1. Reinstatement of equivalence and initial equivalence determination audits;

2. For-cause audits; and

3. Newly determined equivalent countries which are to be audited within one year from the effective date listed in the final rule granting equivalence.

D. Based upon the information gathered in Chapter IV, Section I. B. and C., the IAB Branch Chief is to prioritize all ongoing equivalent countries into the following categories by utilizing the public health risk determinates in Appendix A of the *Methodology on How to Classify Foreign Countries for Prioritizing On-Site Equivalence Verification Audits*:

1. High priority countries are audited within 24 months;

2. Medium priority countries are audited within 30 months; or

3. Low priority countries are audited within 36 months.

NOTE: Ongoing equivalent countries are required to be audited at least once every three years from the publication date of the last final audit report. Typically, audits are not to be scheduled until at least one year after the last audit report is published.

E. The IAB Branch Chief is to send the draft Audit Schedule of Foreign Countries Decision Memorandum to the MCAD Director to review and clear, and to the OIEA AA for review and concurrence. Once the OIEA AA concurs with the list of countries selected for audit, the AA is to brief OA. The IAB Branch Chief is to share the signed Decision Memorandum with IES, OFO RMTAD-Imports, and OIC.

F. The IAB Branch Chief is to draft an addendum to the Audit Schedule of Foreign Countries Decision Memorandum when an audit needs to be postponed or canceled. The IAB Branch Chief is to share all addendums to the Decision Memorandum with IES, OFO RMTAD-Imports, and OIC.

II. AUDIT PLANNING

A. Once the Agency has determined to conduct an on-site verification audit, the IAB Branch Chief is to assign an IA to conduct each audit. The IA is to notify the CCA, through OIC, of FSIS intentions to conduct an on-site verification audit. The IA is to have the IAB Branch Chief review and send the cleared notifications to OIC and IES for review, and OIC transmits these notifications no later than September 1 each year. The IAB Branch Chief and IA are to arrange a follow-up teleconference call, through OIC, to organize the details of each on-site verification audit.

B. The IA is to use the *Foreign Site Ranking and Selection Process for Foreign Audits* methodology to develop a prioritized list of foreign sites (CCA offices, laboratories, and establishments). To initiate the audit planning process the IA is to obtain the following data from MCAD:

1. Risk Footprint – as described in Appendix B of the *Foreign Site Ranking and Selection Process for Foreign Audits* methodology.

2. The last three years of reinspection data per processing establishment categorized in PHIS, including a list of POE lot failures, and any positive test results.

3. Certified establishment profile information and product eligibilities.

C. When ranking foreign sites, the IA is also to consult with the technical review team. Based upon all gathered information, the IA is to rank all foreign sites by high, medium, or low priority based upon the risk determinants provided in Appendix A of the *Foreign Site Ranking and Selection Process for Foreign Audits* methodology. The IA is to prioritize foreign sites in descending order until the number of sites determined appropriate for the audit is reached.

D. The IA is to draft an Audit Scope Determination Decision Memorandum that includes a list of foreign sites that the IA will request to visit during the audit. In the draft Audit Scope Determination Decision Memorandum, the IA is to recommend an audit of the highest ranked foreign sites in descending order until the determined number of foreign sites is reached. If changes are made due to a CCA's request, or sites not ranked as the highest priority are selected (e.g., due to geographical considerations or the need to visit establishments representing different product categories), the IA is to explain this in the Audit Scope Determination Decision Memorandum. The IAB Branch Chief will review and concur. The IA is to upload the signed decision memorandum into PHIS under the associated country and mark the uploaded memo as an "internal" document.

E. The IA is to draft an audit itinerary notification that includes the finalized on-site verification audit dates, the audit objective, and proposed itinerary which incorporates the list of foreign sites to audit from the signed Audit Scope Determination Decision Memorandum. The IA is to have the IAB Branch Chief review and clear, send to OIC and IES for review, and for OIC to transmit 35 days before the start date of the on-site verification audit. The IA is to upload the audit itinerary into PHIS under the associated country.

NOTE: OIC is not to send the audit itinerary notification until the CCA and FSIS have finalized the on-site verification audit dates in writing.

F. The IA is to develop an audit plan in the Audit Planning section of the CAVF in PHIS. The audit plan is to describe the audit objective, scope, and type of verification activities to be reviewed and observed during the on-site verification audit. The mandatory verification activities are based on the SRT food safety-objective based criteria. The component questions in the SRT are the criteria that the IA is to use while developing the verification activities and performing the on-site verification audit to ensure that the foreign country's food safety inspection system has been implemented and is equivalent to the U.S. inspection system. In the Audit Planning section of the CAVF in PHIS, the IA is to document the applicable mandatory verification activities from the checklists. Also, the IA is to document any additional verification activities for each applicable SRT criterion relevant to the foreign country's food safety inspection system. While completing the Audit Planning section in the CAVF in PHIS, the IA is to collaborate with the technical review team and review the following information:

1. SRT Supporting Documentation and SRT Analysis-Comments sections in the country's most current CAVF in PHIS;

2. Last two published FSIS audit reports and last two completed Onsite Analysis-Comments and Final Analysis (which includes the CCA's corrective actions in response to previous audit findings and follow-up verification audit activities) sections in archived CAVFs in PHIS;

3. The last three years of POE reinspection data (including test results), POEVs, and the CCA's corrective actions in response to any identified POEVs;

4. New equivalence determinations made for that country by IES;

5. Any changes in FSIS requirements that countries have been notified of that require modification to the foreign country's food safety inspection system; and

6. Any issues raised in third party audit reports (e.g., European Commission's Foreign Veterinary Office – FVO) that are deemed relevant to the audit by the auditor and the technical review team.

G. After completing a draft of the Audit Planning section in the CAVF in PHIS, the IA is to share the draft audit plan with the technical review team to review and comment. The technical review team is to ensure that the proposed on-site audit activities sufficiently address the food safety-objective based criteria, corrective actions, or findings arising since the last audit. The IA is to incorporate into the Audit Planning section in the CAVF in PHIS any of the verification activities recommended by the technical review team that are based on the recurring document review or the country's POE reinspection results. The IA is to obtain approval from the technical review team on the audit plan prior to departing the United States.

NOTE: When the IA determines that the audit plan has more audit verification tasks than can be completed during the on-site verification audit, the IA is to collaborate with the technical review team to prioritize audit verification tasks. The technical review team is to identify which essential audit verification tasks are to be completed during the on-site verification audit. The technical review team is to identify essential audit verification tasks by highlighting these tasks in the audit plan.

H. The IA is to conduct a pre-entrance meeting with IES, OFO RMTAD-Imports, and OIC that reviews the entrance conference slides before departure. The IA is also to schedule a time for the pre-exit meeting during the pre-entrance meeting.

III. CONDUCTING THE ON-SITE VERIFICATION AUDIT

A. The IA is to structure the on-site verification audit to assess whether the CCA continues to demonstrate that the country has implemented the food safety inspection system as described in its SRT and corresponding documentation.

B. The IA is to conduct the on-site verification audit entrance conference with the CCA, and present the entrance slides that outline audit objectives, scope, itinerary, and post-audit follow-up activities.

C. In accordance with the approved audit plan, the IA is to perform the verification activities through either review of records, interviews, or direct observation. If the IA identifies potentially systemic findings during the audit, the IA is to conduct additional audit activities at that foreign site and at other foreign sites to determine whether the findings are in fact systemic. The IA is to note observations and results during the audit on the checklists.

D. During the on-site verification audit, the IA is to provide a briefing report to the IAB Brach Chief approximately every three working days. The IAB Branch Chief is to share the briefing report with the IES Director and OIC. In cases where an observation constitutes a public health concern, the IA is to immediately inform the IAB Branch Chief. The IAB Branch Chief is to initiate procedures as outlined in Chapter VI.

E. At the end of each audit day, the IA is to meet with the CCA to compare his or her observations with those made by the CCA regarding:

1. The in-plant inspector's verification that the foreign establishment or facility is meeting the applicable requirements; and

2. The food safety inspection system's ability to identify and resolve non-compliances.

F. The IA is to prepare exit conference slides and hold a pre-exit conference call with the IAB Branch Chief, IES Director, EO, RMTAD Analyst, and OIC to review and approve the preliminary audit findings and content of the slides. The exit slides are to outline the applicable food safety-objective based criteria used for comparison with the country's food safety inspection system, the scope of the audit, and the preliminary findings. If the IA observed an inspection practice that differs from a documented equivalent procedure on file with FSIS, the IA is to document this in the exit slides as a finding. Then the IA is to document this observed practice in the draft audit report as a finding for which the country will need to provide an explanation or corrective action, as described in FSIS Directive 9790.1, *Writing an Audit Report of Foreign Food Safety Inspection Systems*. In the exit slides, the IA is also to convey information on post-audit activities, specifically the steps involved with drafting, reviewing, and publishing the audit report.

G. At the exit conference and at the direction of the IAB Branch Chief, the IA is to present preliminary audit findings, including the updated exit meeting slides, to the CCA. Within his or her presentation, the IA is *not* to provide the CCA with an estimated timeline for completion of the draft audit report.

IV. DRAFTING THE FINAL AUDIT REPORT (DFAR) AND COMPLETING THE CAVF FOR ONGOING EQUIVALENCE ON-SITE VERIFICATION AUDITS

A. Upon return to the U.S., the IA is to meet with the technical review team to discuss audit observations and findings, and consider the impact of audit findings to determine whether the foreign food safety inspection system remains equivalent. The technical review team members are to take the following into account:

1. Related findings in different equivalence components. For example, significant findings under Component 4 (HACCP) may be the result of the lack of a well-defined training program (Component 1);

2. Evidence providing confidence in the country's ability to export product that is safe, wholesome, properly labeled and packaged. This evidence may include product testing conducted by the foreign government; and

3. Other factors that may affect an equivalence determination such as whether a foreign food safety inspection system demonstrates equivalence with new FSIS published regulatory requirements.

B. If the technical review team members identify additional findings upon further analysis of the audit observations and findings, the IA is to notify the IAB Branch Chief. The IAB Branch Chief is to notify the CCA, through OIC, of the additional findings.

C. If a teleconference call is to be held with the CCA, the IA is to develop an agenda and ensure that the members of the technical review team can actively participate in the teleconference call. The agenda is to highlight the findings and the specific information the CCA will need to provide to fully address FSIS's concerns. The IA is to provide the agenda to OIC for transmission to the CCA. The IA is to record the meeting minutes during the teleconference call, and share the draft minutes with the FSIS participants for review and comment. Once meeting minutes are approved by the participants, the IA is to upload the minutes into PHIS under the associated country and mark the uploaded minutes as an "internal" document.

D. In the **Onsite Analysis-Comments** section of the CAVF in PHIS, the IA is to document the country's ability or inability to implement its documented food safety inspection system and verify for each component that an equivalent level of public health protection is achieved as applied domestically by FSIS in the United States. The IA is to describe the audit activities performed, the observations, and the findings made for each food safety-objective based criterion. The IA is to include, where applicable,

discussion of audit activities performed, and observations made in response to verifying previous audit findings have been addressed.

NOTE: Section II. in FSIS Directive 9790.1 defines a **finding** as 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.

E. Within 20 working days of returning to the United States, the IA is to prepare draft official transmittal correspondence and a DFAR for review by the IAB Branch Chief. The IA is to follow procedures described in FSIS Directive 9790.1 for writing the DFAR. In the official transmittal correspondence, the IA is to include information on how the CCA should respond to the DFAR, when comments to the DFAR are due, and, if applicable, what corrective actions are acceptable. The IAB Branch Chief is to review and clear the DFAR and official transmittal correspondence package (the package).

F. Within 40 working days of returning to the United States, the IAB Branch Chief is to send the cleared package to IES, RMTAD, and OIC for review and concurrence, and provide a one-week comment period. The IA is to hold discussions with the reviewers to resolve issues. Upon resolving issues, the IA is to send the IAB Branch Chief a tracked changes version of the package with agreed upon edits. The IAB Branch Chief is to review and clear, and ensure that all program area comments were addressed or responded to as appropriate. The IAB Branch Chief is then to send the package to the MCAD Director to review and clear.

G. Within 50 working days of returning to the United States, the MCAD Director is to send the cleared package to OIEA AA for review and comment, and provide a one-week comment period. The IA is to send the MCAD Director a tracked changed version of the package with agreed upon edits. The MCAD Director is to review and clear.

H. Within 60 working days of returning to the United States, the MCAD Director is to send a clearance sheet with the cleared package for AA for review and clearance, and provide a one-week comment period. The clearance sheet is to identify the program areas, person who reviewed and responded for each program area, and date concurrence was provided. The IA is to work with the relevant program area to ensure AA concerns are addressed, and that agreement from all program area AA's is received before the package moves to OA for review.

I. Upon receiving OIEA AA clearance, the IAB Branch Chief is to send the final draft package, including a complete clearance sheet, for OA clearance. The IA is to address any comments received from OA, and share comments and responses with the IAB Branch Chief. If applicable, the IAB Branch Chief is to share impactful OA comments with international staffs (IES, OFO RMTAD-Imports, and OIC). Once OA comments are addressed and OA clearance is received, the IAB Branch Chief is to review the final draft to make sure all information is correct and send to OIC for transmittal to the CCA. OIC is to transmit the DFAR to the CCA of the audited country no later than 90 working days from the exit conference.

V. REVIEWING AUDIT CORRECTIVE ACTIONS AND ISSUING THE FINAL AUDIT REPORT

A. If the CCA has not provided comments or corrective actions to audit findings within the 60-day comment period, the IAB Branch Chief is send a reminder to the CCA, through OIC. The IAB Branch Chief is to include in the reminder that if the CCA does not provide comments or corrective actions, or if the CCA does not request an extension, then FSIS will post the draft audit report as final to the FSIS website. When the CCA does not provide comments to DFAR, the IA is to note the CCA's non-response in the conclusion of the audit report and in the official transmittal correspondence that accompanies the final audit report. When the CCA still does not provide corrective actions to documented audit findings, or if the CCA provides inadequate corrective actions, IAB is to initiate procedures outlined in Chapter VI.

B. If the CCA provides comments on the DFAR, the IA is to arrange translation of the CCA's comments including corrective actions, and share the translated comments with the technical review team. The IA is to amend the final audit report if the technical review team agrees with the CCA's comments. If the technical review team does not agree with the CCA's comments, then the IA is not to revise the final audit report. In either instance, the IA is to attach the CCA's comments as an appendix to the final audit report, and submit the report to the IAB Branch Chief for review.

C. At the end of the 60-day comment period, the IA is to prepare official transmittal correspondence and final audit report, including any received comments and submitted corrective actions as attachments, for review by the IAB Branch Chief. If applicable, the IA is to include in the final audit report language that FSIS is evaluating the adequacy of the CCA's proposed corrective actions and preventative measures and will base future equivalence verification activities on the information provided. The IA is to follow procedures described in Sections IV. and VI. in FSIS Directive 9790.1 for writing the audit report and official transmittal correspondence. The IAB Branch Chief is to review and clear, and send to the technical review team for review and comment, and then to OIC Executive for transmittal to the CCA.

D. Within 10 working days of OIC transmitting the final audit report to the CCA, the IAB Branch Chief is to send the final audit report with any attachments to OPACE for posting on the FSIS website and to draft a Constituent Update to announce the publication of the final audit report.

E. The IA is to share the corrective actions with the technical review team for review and comment. If the technical review team determines that additional information or clarification is needed, then the IA is to notify the CCA, through OIC, of the concerns.

F. If a teleconference call is to be held with the CCA, the IA is to develop an agenda and ensure that the members of the technical review team can actively participate in the teleconference call. The agenda is to highlight the technical review team's concerns and the specific information the CCA will need to provide to fully address FSIS's concerns. The IA is to provide the agenda to OIC prior to the meeting for transmission to the CCA. The IA is to record meeting minutes during the teleconference call, and share the draft minutes with the FSIS participants for review and comment. Once meeting minutes are finalized, the IA is to upload the minutes into PHIS under the associated country and mark the uploaded minutes as an "internal" document.

G. Once the technical review team approves the corrective actions, the IA is to refer to Chapter V on how he or she is to work with the EO to enter approved corrective actions and follow-up audit verification activities in the CAVF in PHIS.

CHAPTER V – EVALUATION OF EQUIVALENCE MAINTENANCE

I. GENERAL

A. On an annual basis, FSIS assesses information gathered from the ongoing equivalence verification process and determines whether a country's foreign food safety inspection system remains equivalent.

B. Each year, by December 31, the EO is to document in the Final Analysis section of the CAVF in PHIS whether each component of the foreign food safety inspection system remains equivalent. The EO is to include the following information in the Final Analysis section to support:

1. Final outcome of the document review, including discussion on any outstanding SRT gaps or findings. The EO is to include in the discussion evaluation of the country's annually submitted chemical and microbiological testing programs.

2. If applicable, final outcome of the audit findings, including discussion on the CCA's corrective actions and follow-up audit verification activities.

NOTE: When an ongoing verification audit is not performed, the EO is to document "An audit was not performed this year" in the Audit Planning and Onsite Analysis-Comments sections of the CAVF in PHIS.

3. Trend analysis of POE reinspection data (for the last three years), including discussion on what products remain eligible to export to the United States. The EO is to capture this information in the Final Analysis section in Component 1.

4. Discussion on the CCA's corrective actions to POEV and follow-up audit verification activities.

C. The EO is to collaborate with the technical review team to complete the Final Analysis Section of the CAVF in PHIS.

D. The Lead EO is to review all sections in the CAVF prior to archiving the SRT and CAVF in PHIS. The Lead EO is then to immediately generate a new SRT and CAVF.

E. If the EO determines that the foreign food safety inspection system is no longer equivalent, IES is to initiate procedures outlined in Chapter VI.

F. When the EO identifies that a foreign country is no longer eligible to export an equivalent species in a raw inspection system or to export a processing category in a processed products inspection system, then the EO is to notify the foreign CCA in the official annual reminder notification (described in Chapter V, Section I. G.) on how to request a reinstatement of equivalence determination in order to resume exporting such products to the United States. Upon transmission of the official notification, the EO is to update the country's eligibility table on the FSIS website and notify the PHIS Import Librarian to remove ineligible species in a raw inspection system or processing category in a processed products inspection system in PHIS.

G. By December 31 of each year, IES is to remind the CCA, through OIC, to submit annual required information identified in Chapter II, Section I. A. by May 18 of the incoming year. The EO is to draft the official annual reminder notification and include the following:

1. A request to submit clarifying information identified in Chapter II, Section I. A.;

2. The country's current eligibility to export meat, poultry, or egg products to the United States (procedures outlined in Chapter V, Section I. B. 3.). If the EO determines any products to be ineligible, the EO is to include information on how to request a reinstatement of equivalence determination in order to resume exporting products to the United States;

3. Results of the recurring document review;

4. Description of new FSIS policies that may impact equivalence; and

5. Summary of the past year's POE reinspection results.

H. The EO is to have the technical review team review and comment, then the IES Director review and clear, then the OPPD AA review and concur, and then send to OIC for transmittal.

I. If the CCA does not respond to the official annual reminder notification by June 18 or only provides part of the requested information, then the EO, through OIC, is to send a reminder to the CCA to address

outstanding concerns. If the CCA does not provide the required annual documentation for review, IES will need to initiate procedures outlined in Chapter VI.

CHAPTER VI – ACTIONS ASSOCIATED WITH FAILURES TO DEMONSTRATE MAINTAINENCE OF EQUIVALENCE

I. GENERAL

A. When IAB, IES, or OFO RMTAD-Imports determines that a country is unable to provide FSIS continued assurances that the foreign food safety inspection system is equivalent, the procedures outlined in this Chapter need to be initiated.

B. The initiating staff office (i.e., the IAB Branch Chief, IES Director, or OFO RMTAD-Imports Branch Chief) is to notify the other offices, which include OPPD's IEPDS, Office of Public Health Science (OPHS) and OIC, and then schedule a preliminary meeting to discuss concerns and request each staff office gather additional supportive information.

C. The initiating staff office is to provide the foreign country another opportunity to fully address outstanding concerns. The initiating office is to arrange a teleconference call with the CCA, through OIC, and include the staff offices (action team), as appropriate, to discuss the unresolved issues, identify the information needed, and provide a deadline for the CCA to submit adequate supporting documentation that addresses the outstanding concerns. The initiating staff office is to record the meeting minutes during the teleconference, and share the draft minutes with other members of the action team for review and comment. Once meeting minutes are finalized, the EO is to upload the minutes into PHIS under the associated country and mark the uploaded minutes as an "internal" document.

D. When one or more points in the equivalence process brings into question the country's maintenance of an equivalent food safety inspection system, FSIS can take the following actions:

1. Conduct targeted sampling or increased level of reinspection at POE with mandatory hold of lots sampled or reinspected, pending acceptable results. The action team is to collaborate to determine appropriate sampling criteria within PHIS;
2. Delist one or more establishments as eligible to export to the U.S.;
3. Remove eligibility for a specific HACCP process category as eligible to be exported by any of a country's establishments;
4. Remove a country's export eligibility; or
5. Any combination of the above.

E. If the CCA does not respond or provides inadequate information, the action team is to reconvene and discuss the relevant information. The action team is to consider the options outlined in Chapter VI, Section I. D. and use information gathered from IAB, IEPDS, IES, OPHS, and OFO RMTAD-Imports as evidence to support the recommended option. The initiating office is to draft official correspondence and Decision Memorandum. The official correspondence is to identify the information that the CCA needs to provide in order to address the outstanding concerns and thereby reinstate the country's eligibility (if applicable). The Decision Memorandum is to describe the issue, recommendation, background, analysis, and conclusion.

F. The initiating office is to provide the draft official correspondence and Decision Memorandum (the package) to the action team for review. The initiating office (i.e., the IAB Branch Chief, IES Director, or OFO RMTAD-Imports Branch Chief) is to review the package and sign the Decision Memorandum upon concurrence, and send the package for AA review and concurrence. The final decision to take the actions

outlined in the Decision Memorandum will be determined through OA. Upon OA clearance, OIC is to transmit the official correspondence to the CCA. Upon concurrence, the EO is to upload the signed Decision Memorandum into PHIS under the associated country and mark the uploaded Decision Memorandum as an "internal" document.

G. In situations where a foreign country intends to suspend shipment or no longer certify a specific species or process category for export to the United States, or FSIS removes a foreign country's eligibility to export a specific species or processing category, the applicable IA, EO, or RMTAD Analyst is to notify the PHIS Import Librarian to remove eligibility in PHIS by unchecking applicable species or processing categories. In addition, the applicable IA, EO, or RMTAD Analyst is to notify IES, IEPDS, IAB, OFO RMTAD-Imports, and OIC. Once PHIS is updated, the EO is to send a request to OPACE/WDCS to update the country's eligibility table on FSIS's website.

H. In situations where a foreign country suspends or delists an establishment's eligibility, or FSIS terminates an eligible establishment's ability to export meat, poultry, or egg products to the United States, the applicable IA, EO, or RMTAD Analyst is to notify the PHIS Import Librarian to delist the establishment in PHIS. In addition, the applicable IA, EO, or RMTAD Analyst is to notify IES, IEPDS, IAB, OFO RMTAD-Imports, and OIC. The effective date will be when the action was taken by the CCA or the date FSIS notified the CCA. Once PHIS is updated, the Import Librarian is to send a request to OPACE/WDCS to update the eligible foreign establishment table on FSIS's website.

CHAPTER VII - QUESTIONS

Refer questions through supervisory channels.

Rebecca J Wagner

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