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

FSIS DIRECTIVE	9780.1	10/7/15

VERIFYING THE ONGOING EQUIVALENCE OF FOREIGN FOOD SAFETY SYSTEMS

CHAPTER I – GENERAL

I. PURPOSE

This directive provides instructions to the International Audit Staff (IAS), Office of Investigation, Enforcement and Audit (OIEA); International Equivalence Staff (IES), Office of Policy and Program Development (OPPD); the Recall Management and Technical Assistance Staff (RMTAS), Office of Field Operations (OFO); the Data Analysis and Integration Group (DAIG), Office of Data Integration and Food Protection (ODIFP); the Science Staff, Office of Public Health Science (OPHS); and the Office of International Coordination (OIC) for verifying the ongoing equivalence of foreign food regulatory systems and the actions to be taken when equivalence is not maintained. OPPD/IES, OIEA/IAS, ODIFP/DAIG, OFO/RMTAS, OPHS/Science Staff, OIC, and the PHIS Import Librarian are to refer to Attachment 1 for a schedule of time elements associated with tasks outlined in this directive.

KEY POINTS:

- *Outlines FSIS personnel's roles and responsibilities related to verifying the ongoing equivalence of foreign food regulatory systems*

- *Outlines the actions to be taken when available information suggests that a foreign inspection system may have changed and appears to no longer be equivalent to that of 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)*

- *Outlines FSIS's process for collecting information associated with the annual certification of eligible export establishments by foreign CCAs*

II. TERMS RELATED TO THE ONGOING EQUIVALENCE OF FOREIGN FOOD SAFETY SYSTEMS

A. *Annual List of Certified Establishments*: Lists of certified, export-eligible establishments submitted to FSIS by foreign governments in accordance with 9 CFR 327.2 and 9 CFR 381.196.

B. Appropriate level of protection (ALOP): The level of protection provided by a sanitary measure, as deemed appropriate by the U.S., to protect human, animal or plant life or health within its territory. FSIS and The Food and Drug Administration (FDA) take the lead on food safety and public health protection in the U.S. Both collaborate with the Animal and Plant Health Inspection Service (APHIS) on the animal disease aspects of public health protection.

C. *Audit Plan*: Internal document that provides an overview of the basis, objectives, scope, and verification activities of an on-site equivalence verification audit as derived from an auditor's Component Analysis Verification Form (CAVF).

D. *Audit Notification Letter:* Official correspondence to CCA advising it of scheduled audit dates, objective, scope, and authorities.

E. *Audit Itinerary*: Document outlining the day-to-day schedule and locations for audit activities.

F. *Audit cycle*: The period of time between foreign on-site audits during which equivalence verification activities are performed.

G. *Auditor*: The individual or team conducting the in-country equivalence audit, which is managed and coordinated by IAS/OIEA.

H. C*AVF*: The CAVF is a tool used by FSIS equivalence officers and auditors to evaluate foreign inspection systems within six equivalence components: (Government Oversight, Statutory Authority and Food Safety Regulations, Sanitation, HACCP, Chemical Residues, and Microbiological Testing Programs). The CAVF is a template-based work space within which Equivalence Officers document the results of their analysis of CCA self-reporting tool (SRT) responses and identify areas requiring follow-up verification. The CAVF forms the basis for audit planning, scope, and reporting and identifies the records and processes that an auditor is to assess during an on-site equivalence audit. IAS Auditors also use the CAVF to record the results on on-site audit verification activity, and to develop a draft foreign audit report.

I. *Country Performance Assessment:* An algorithm-based tool that compares the food safety performance of export eligible countries. The assessment includes a statistical analysis of compliance data from point-of-entry (POE) re-inspections and results from FSIS's previous on-site audits of the country's government offices, establishments, and laboratories.

J. *Equivalence Verification Plan (EVP)*: A set of activities identified by the Equivalence Review Team (ERT) and approved by the OIEA Assistant Administrator (AA) to be performed by FSIS to resolve outstanding equivalence questions raised by FSIS in relation to foreign audit findings or POE violations or through document review associated with a country's annual SRT submission.

K. *Equivalence Review Team (ERT)*: A team of subject matter experts from OIEA/IAS, OPPD/IES (and other OPPD staffs as appropriate), OPHS/Science Staff, and OFO/RMTAS that is organized and managed by OIC to determine the equivalence implications of on-site foreign audit findings, POE violations, and foreign CCA corrective actions taken in response to audit findings and POE violations.

L. *Observation*: A non-compliant practice or condition related to a CCA's inspection oversight for which the CCA has existing controls, but that is observed by the auditor during an audit, identified in discussion with CCA personnel, or discovered through records review. An on-site audit observation is to be noted by the auditor as an appendix or attachment to the draft audit report and requires an official response from the CCA in its comments on the draft audit report.

M. *Finding:* An audit observation verified as being in violation of an equivalent CCA or FSIS requirement, or for which no equivalent measure is on file. A finding may arise from a non-compliance, a change in the CCA's inspection program, or a change in FSIS requirements and must be addressed by the CCA to FSIS' satisfaction within 60 days of official notification because it has a bearing on equivalence. There are three categories of findings:

1. *Isolated Finding: A*n audit finding that does not reflect a pattern of occurrence at more than one facility;

2. *Systemic Finding: A*n audit finding that reflects a pattern of occurrence at more than one facility; and

3. *Significant Finding: A*n audit finding that reflects a deficiency in the inspection system so significant that it presents a potentially imminent threat to public health and that requires an

immediate regulatory response by FSIS (e.g., prohibition on export of a product or all product from a production process).

N. *Point of Entry Violation Assessment (POEV) Case File*: A set of files maintained by OFO/RMTAS regarding POEVs and associated corrective actions by a country.

O. *Verification Points*: Components of a foreign food safety system identified in an EVP for FSIS follow-up verification.

P. *Draft Audit Report* – An audit report that must complete the internal Agency clearance process.

Q. *Draft Final Audit Report* – An Agency cleared draft audit report that will be sent to the CCA for comment.

R. *Final Audit Report* – An audit report that includes CCA comments and is published on the FSIS website.

III. EQUIVALENCE VERIFICATION OVERVIEW

A. Requirements for equivalence are established by the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and Egg Products Inspection Act (EPIA) and are set forth in 9 CFR 327.2 for meat products, 9 CFR 381.196 for poultry products, and 9 CFR 590.190 for egg products. The requirements to establish equivalence are grounded in the World Trade Organization's Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). A country may be listed as eligible to export meat, poultry, or egg products to the U.S. if FSIS determines that the country's inspection system provides a level of protection that is appropriate, ensures that there is compliance with standards that are equivalent to the requirements applied to FSIS-inspected domestic establishments, and issues export certificates that reliably attest to the safety of the products.

B. FSIS has categorized these requirements into six "equivalence components" for the purposes of assessing a country's food regulatory system and granting eligibility to export meat, poultry, or egg products to the U.S. Specifically, FSIS evaluates a country's national government to ensure that it is imposing equivalent requirements with respect to:

1. Government oversight;
2. Statutory authority and food safety regulations;
3. Sanitation;
4. HACCP;
5. Chemical residues; and
6. Microbiological testing programs.

NOTE: HACCP and Sanitation Standard Operating Procedures (Sanitation SOPs) are not required for domestic egg products establishments, so FSIS does not apply these requirements to exporting countries.

This process for determining initial equivalence is outlined in FSIS Directive 9770.1, *Determining the Initial Equivalence of Foreign Food Safety Systems*, and described fully at: Performance-Based Approach to Foreign Country Equivalence Verification Audits and Point-of-Entry (POE) Reinspections.

C. Once equivalence has been established, a country is eligible to export meat, poultry, or egg products to the U.S. FSIS ensures that countries maintain equivalence through a three-part process, involving:

1. Recurring equivalence reviews (e.g., through the country SRT or other documentation from the CCA) of the exporting country's applicable laws and regulations;

2. Periodic on-site equivalence verification audits in the exporting country; and

3. Ongoing POE reinspection for shipments received from the exporting country. These POE activities, also known as types of inspections (TOIs), include product examination, condition-of-container examinations, and laboratory analytical testing (see FSIS PHIS Directive 9900.2, *Import Reinspection of Meat, Poultry, and Egg Products*).

D. Trend analysis is one aspect of assessing ongoing equivalence. FSIS may identify cumulative developments that, over time, create cause for concern. Repetitive POE violations for a specific product, process category, or establishment suggest that the foreign inspection system is unable to ensure consistently that exported products are not adulterated and properly marked, labeled, and packaged. The same holds true for repeated failures by a CCA to provide requested program information. In response to these and other circumstances that give rise to concerns about a country's food safety system, as is explained in more detail in Chapter III of this directive, OIC organizes a multidisciplinary ERT to make a determination about the country's continued equivalence. ERTs are comprised of subject matter experts, which can include representatives from:

1. OFO/RMTAS (lead for POE violations);

2. OIEA/Management Control and Audit Division (MCAD)/IAS (lead for audit findings);

3. OPPD/IES (lead for equivalence verification of program changes) and from other OPPD staffs with relevant technical expertise;

4. OPHS Science Staff (technical review of microbiology and residue components); and

5. OIC, within the Office of the Administrator (oversees all FSIS international activities and manages communications with foreign government).

CHAPTER II – ONGOING EQUIVALENCE VERIFICATION PROCEDURE

I. DOCUMENT REVIEW

A. FSIS uses the SRT to collect information from foreign governments. The SRT is a standardized questionnaire that IES provides to foreign governments to gather information that characterizes foreign inspection systems according to the six equivalence components and as required by 9 CFR 327.2, 9 CFR 381.196 and 9 CFR 590.190. Countries must provide responses to mandatory, "core" SRT questions in order to be considered for eligibility to export meat, poultry, or egg products to the U.S. Other SRT questions are optional. Responses to those questions are used to judge the relative sophistication, or "Level of Advancement" of a country's inspection system. Along with the SRT, FSIS requires foreign governments to submit documentation, such as their inspection system laws, regulations, policy issuances, and implementing instructions to government inspection personnel and supervisors, that support their responses to SRT questions.

B. SRTs are to be updated each year by the foreign CCA to reflect any changes made to that country's inspection program. FSIS requires foreign CCAs to update their SRTs in the Public Health Information System (PHIS) by May 18 of each year. If the CCA elects to use the Microsoft Word format SRT, IES is to upload the responses into PHIS. When SRT gaps are identified, the IES equivalence officer is to assist the

CCA with the submission of its SRT response by the established deadline before initiating enforcement action as outlined in Chapter III of this directive.

C. By June 30 of each year, the IES equivalence officer is to complete the review of the foreign country's SRT submission to determine whether the country has responded to every SRT question. As part of its review, IES is to document within the PHIS CAVF its analysis of SRT responses for countries scheduled for an audit, identify those questions for which responses were not received, and request additional information from the CCA as necessary to answer all SRT questions. By July 30 of each year, IES is to provide IAS with an estimated timetable for completing an updated SRT analysis in the CAVF for each country scheduled by IAS for an on-site equivalence verification audit during the upcoming fiscal year. This timetable is to account for the completion of translations for any country SRT submissions not provided in English. IES is to add its updated SRT analysis to the CAVF no later than 60 days before the start of a planned audit. To meet this deadline, IAS is to provide the IES equivalence officer with a 10 day notice request to include an updated SRT analysis in the CAVF.

D. Using the CAVF, IAS is to determine the scope of a foreign audit and to develop the audit verification plan. IAS is to use the CAVF to plan activities to verify the effectiveness of any modifications made to an equivalent inspection system since the country's last SRT submission, as well as to follow up on the elements of an EVP, if one has been established. A CAVF is a living document that is started for each new audit cycle after the posting of the last cycle's audit report and is closed after the final audit report for the current audit cycle is posted to the FSIS website. The CAVF relies on the updated SRT analysis provided by IES to identify the records and processes IAS will audit to verify ongoing equivalence and identifies documentary evidence collected during the audit. Additionally, IAS includes in the CAVF its review and analysis of previous audit reports, POE violations, findings from the audit that is conducted based on the CAVF, and CCA corrective actions.

II. POINT-OF-ENTRY REINSPECTION

A. FSIS import inspection personnel are to conduct a reinspection using the assigned TOIs for all meat, poultry, and egg products offered for import into the U.S.

B. If import inspection personnel detect non-compliant shipments during FSIS POE reinspection, IES, in collaboration with RMTAS, is to work with the exporting country's CCA to ensure that appropriate corrective action is taken. Following corrective action, IES is to ensure that the foreign CCA updates its SRT to reflect any changes made to its program based on its corrective actions. If repeated POE failures originating from the same establishment indicate a loss of process control, and FSIS finds that a foreign CCA's actions to correct the situation are not effective, FSIS will take action in accordance with Chapter III of this directive to suspend the export eligibility of that establishment and may conclude that a "for cause" on-site audit of the CCA is necessary. When shipments from multiple establishments repeatedly fail POE reinspection, FSIS will question the country's on-going equivalence. FSIS may pursue regulatory action at the system level, up to and including a suspension of the country's export eligibility.

C. RMTAS is to document POE violations in PHIS in accordance with 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*; and

3. FSIS PHIS Directive 9900.8, *Meat, Poultry, Egg Products, and Shell Eggs Refused Entry into the United States.*

D. For failed POE TOIs, the RMTAS analyst is to open a POE Violation Assessment case file where violations, corrective actions, and corrective action verification are to be logged. When FSIS import

reinspection, including verification sampling, results in the identification of a POE violation, the RMTAS Director is to notify the foreign country's CCA of the violation within two business days through an official POE violation letter, cleared through IAS, IES, and OIC. The violation letter is to include a request that the CCA provide a comprehensive investigative report on the violation within 30 days, including an analysis by the CCA's subject matter experts and a description of the corrective actions and associated verification activities that will be conducted by the CCA.

E. When RMTAS receives a CCA's proffered corrective actions and verification measures in response to notified POE violations, the RMTAS analyst is to:

1. Immediately provide notification of the received response to the assigned IAS and IES staff officers;

2. Request that the OIC convene a meeting of the ERT within one week of receiving the CCA's response;

3. Lead the ERT's evaluation of the CCA response within the broader context of information FSIS possesses in the SRT about the design and operation of that country's inspection system;

4. Document the outcome of the ERT's analysis, including any equivalence concerns or recommended action;

5. Circulate meeting minutes to ERT members for review and upload finalized minutes to the EVP case file folder on the IAS SharePoint; and

6. Prepare the ERT's analysis and recommended actions in the form of a Decision Memorandum to the Administrator for clearance through the RMTAS, IAS, and IES directors, OIC, and the OIEA, OFO, and OPPD AAs.

F. The ERTs analysis of POE violations is to account for 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;

3. Inadequate SRT responses or supporting documentation; and

4. Relationship to previous POE violations or audit findings.

G. The ERT's analysis of a country's POE violations is to be factored into the development of the next audit plan for that country as specified in Section III.B of this chapter.

H. If a country's CCA fails to respond with an adequate investigative report within 30 days of the date of the official notification letter, RMTAS is to draft and distribute a "10-day letter" for OIC signature notifying the foreign CCA of the actions that may result from its failure to respond.

I. The RMTAS analyst is to draft any letters required to obtain additional information or clarification from the foreign CCA regarding its proffered corrective actions and verification measures. The letters are to be submitted to the RMTAS, IAS, and IES directors, their AAs, and OIC for clearance.

J. If the ERT determines that a CCA's response is adequate, the RMTAS analyst is to close the POEV Assessment case file and transfer the file to the IAS auditor who is to document the assessment conclusions in the PHIS/CAVF.

K. Upon resolution of documented POE violations, the ERT is to consider the country's POE reinspection history, facts of the case, and the CCA's response to determine whether there are specific ongoing verification tasks to perform. Ongoing equivalence verification tasks may be the responsibility of IAS or IES and may be performed through document review or direct observation during the next on-site audit.

L. If a CCA responded to a POE violation by identifying inspection system changes, the IES equivalence officer is to document those changes in the CAVF and to ask OIC to notify the country to ensure that the CCA updates those changes in the SRT, including the upload of relevant supporting documentation.

III. ANNUAL AUDIT - SCHEDULE AUDITS

A. IAS is responsible for planning and conducting ongoing equivalence verification audits of foreign inspection systems. By June 30 of each calendar year, the IAS Director is to propose to the OIEA AA and Deputy Assistant Administrator (DAA) which countries to audit for the next fiscal year. IAS is to follow the procedure outlined in paragraphs D through E below to select countries for on-site audits. Once the OIEA AA concurs with the list of countries selected for audit, he or she is to present the proposed list to Office of the Administrator (OA) for concurrence.

B. By December 1 of each year OIC is to notify the CCA of each country eligible to export meat, poultry, or egg products to the U.S. of the need for it to update its SRT responses and to provide supplemental Level of Advancement (LOA) information. This notification is to also include a request that CCAs submit their annual certified eligible establishments list as per Chapter IV of this directive.

C. For countries that fail to provide an updated SRT response by May 18, the IES Director is to follow steps outlined in Chapter III of this directive.

D. To begin planning and drafting an on-site audit schedule for an assigned country, the IAS auditor is to obtain an analysis of country performance from ODIFP. ODIFP is to generate this analysis using the Country Performance Algorithm, a data analysis tool that prioritizes foreign inspection system audits. This algorithm factors data derived from three information streams:

1. POE reinspection data – PHIS data analyzed from two perspectives: 1) process control – countries are ranked based on the number and type of failures for all TOIs, and 2) risk footprint – countries are ranked based on product volume weighted by relative risks posed by the process category, product category, and species, taking into account the processing season associated with products exported to the U.S. Country POE rankings reflect combined process control and risk footprint rankings. Lower ranked countries receive a higher audit priority;

2. Previous On-site audit findings – CAVF-based compliance scores from the most recent audit findings are categorized by the ERT based on food safety significance and on whether the finding is system-wide or isolated. Systemic findings are weighted more heavily than isolated findings, and scores are summed for each of the six equivalence components. Audit findings are classified as follows:

    a. Category 3: findings that evidence a definite loss of the food safety system's process control, thereby inhibiting the system's ability to prevent adulterated product from entering commerce;

    b. Category 2: findings that evidence that there is a reasonable probability that the food safety system will experience a loss of process control;

    c. Category 1: findings that evidence that there is a remote probability that the food safety system will experience a loss of process control; and

d. Category 0: no findings, or findings that conditions do not comply with parts of 9 CFR regulations but do not rise to the level of categories 1, 2, or 3;

NOTE: These scores do not appear in the audit reports, nor are they shared with foreign governments. They are used by IAS as part of the country performance algorithm to prioritize countries for future audits and to develop the annual audit schedule.

3. LOA analysis of foreign food regulatory systems – The LOA questions are identified as optional in the SRT and ask foreign countries to provide additional information, above and beyond responses to the mandatory core SRT questions, to characterize the use of risk analysis principles; the impact of organizational, structural, or administrative change in an exporting country's CCA; the availability of contingency plans in the country for containing and mitigating the effects of food safety emergencies; the CCA's willingness and ability to take appropriate actions to manage food safety incidents; and the effectiveness of foodborne disease surveillance systems. Country LOA rankings are based on the aggregate score of each response to an LOA question.

E. For each data source, low rankings correspond to a higher priority for audit. ODIFP is to weight the quantitative rankings for each data source and to combine them into an overall performance ranking for each country. IAS is to use the country performance rankings as the basis for each fiscal year's audit schedule. Thus, IAS is to use the results of previous on-site audits and of POE examinations to appraise the performance of exporting countries and to determine the frequency of audits.

F. IAS will promptly notify IES of the countries and dates selected for on-site equivalence verification audits for the upcoming fiscal year. Generally, IAS is not to schedule on-site equivalence verification audits within one year of the posting of the preceding final audit report for that country unless special circumstances arise that establish a special need for such action. IES is to prioritize its country equivalence reviews, including equivalence determinations for individual sanitary measures, in accordance with the IAS audit schedule and is to promptly advise IAS of any equivalence issues before finalizing the on-site audit schedule proposed to OA.

IV. ANNUAL AUDIT - AUDIT PLAN

A. To begin planning a scheduled audit, the auditor who has been designated to do the audit is to confirm with the assigned IES equivalence officer that the country's SRT information in PHIS is up-to-date and to work with ERT subject matter experts to review any active EVP case file for that country. The auditor is also to work with the ERT to develop a proposed audit plan. The audit plan is developed by the auditor as an internal document to identify and explain the objective, scope, and type of activities to be undertaken during the on-site audit to verify the equivalence of the country's inspection system. The audit plan is derived from the CAVF, which functions as a workspace for the auditor to inventory those aspects of a country's inspection system that need to be verified during an on-site audit, and to document the evidence collected during the audit to verify the equivalence of the country's inspection system.

B. Based on the outcome of the FSIS Country Performance Algorithm outlined above, the auditor is to document within the CAVF qualitative annual assessments of country performance for that audit cycle.

C. Auditors are also to include in the CAVF:

1. The foreign CCA's official controls as contained in the SRT;

2. Any corrective actions taken by the CCA in response to previous audit findings or POE violations;

3. Any new equivalence determinations made for that country by IES;

4. Any changes in FSIS requirements that have been notified to the foreign government that require modification to the foreign country's system; and

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

D. Before IAS notifies a country of FSIS's planned on-site ongoing equivalence verification audit (approximately 70 calendar days prior to the start of the audit), the auditor is to request the following information for the country that will be audited:

1. From IES: The IES equivalence officer is to report whether the SRT is complete and up to date. The IES equivalence officer is also to identify those issues arising from his or her review of the SRT that need to be verified by the auditor during the audit. Specifically, the IES equivalence officer is to identify individual sanitary measures for which equivalence determinations have been made, characterize OPHS's review of the country's annual residue plan and sampling results, and identify any issues pertaining to the country's microbiological or chemical residue testing programs. The IES equivalence officer is to notify the IAS auditor of any issues with the country that would prevent the audit from taking place as scheduled; and

2. From RMTAS: The RMTAS staff officer is to provide three years of POE data to assess at the country and individual establishment level the following information: volumes of products imported to the U.S.; types (inherent hazards) of products imported to the U.S; and the frequency and nature of POE inspection violations. The RMTAS staff officer is also to identify any active EVP verification activities to be included in the audit plan, taking care to notify the IAS auditor of any outstanding issues that would prevent the audit from taking place as scheduled.

E. Once this information is received, the auditor is to compile a CAVF that identifies the records and processes that he or she needs to verify during the on-site equivalence verification audit. The auditor is to notify the ERT members when the CAVF will be ready for review. The IAS auditor is to circulate the working CAVF to members of the audit technical team for review, additional input, and comment.

F. The ERT members are to document their analysis and comments into the CAVF within 10 business days of receiving the CAVF.

1. As part of the review, the IES equivalence officer is to ensure that the proposed on-site audit activities sufficiently address any equivalence criteria, corrective actions, or findings arising since the last audit cycle. The IES equivalence officer is to document within the CAVF his or her analysis of SRT information for each equivalence component, including a determination that the information reviewed for the country's food safety system demonstrates equivalence.

2. The RMTAS staff officer is to review the CAVF to ensure that the proposed audit includes verification activities related to corrective actions proffered by the CCA to address POE violations; and

3. The OPHS technical subject matter experts are to review the CAVF to ensure that verification of the microbiological and chemical residue testing programs are included as part of the planned audit activities.

G. In its review of the CAVF, the ERT is to identify any equivalence concerns that provide reason to postpone a scheduled audit. The ERT is to document and notify these concerns to the IAS Director for a determination about whether or not to proceed with the audit.

H. Once ERT members have completed their submissions to and review of the CAVF and signed off on it, the auditor is to close the CAVF and begin development of the audit plan.

I. On-site audits of CCA offices, laboratories, and exporting establishments are conducted as part of a broader equivalence assessment of a country's food safety system. As such, IAS, in consultation with the ERT, is to plan audits to assess how a country's system is working, not to uncover individual establishment, laboratory, or administrative findings that offer little insight into the overall functioning of the system. The auditor and the ERT are to proceed from the premise that evidence of a deficient food safety system will be apparent in multiple sites and types of sites. IAS is to combine a targeted audit approach with a statistical site selection methodology to be assured of identifying system deficiencies where they exist. For these reasons, the IAS auditor and the ERT are to consider that it is neither efficient nor necessary to audit all, or in some countries even most, offices, laboratories, and establishments.

J. Within five working days of an IAS auditor's request, OIEA program analysts in OIEA's MCAD are to provide the auditor with guidance on the range of sites to consider auditing with a goal of achieving 95 percent confidence of identifying at least one site with potential systemic findings if findings are actually present in 20 percent or more sites. The auditor is to plan the audit taking this input into account, and to document the rationale for the proposed site selection in the audit plan.

K. In some countries, the number of establishments exporting to the U.S., the number of CCA offices, and the number of laboratories is sufficiently small that the IAS auditor and the ERT elect to audit most or all of the pertinent sites. In countries with a large number of in-scope sites, it is neither efficient nor necessary to conduct an on-site audit at all or even most sites. In such countries, auditors are to follow the guidance outlined in the next paragraph.

L. When auditing fewer than all the eligible sites in a given country, auditors are to consider both statistical and non-statistical factors to maximize effective use of Agency resources. The auditor is to plan each audit to meaningfully inform the overall determination of ongoing equivalence. FSIS auditors are to examine establishment-level data on product volumes, product types, POE reinspection findings, results from prior audits, and other information to inform the audit plan. Auditors are also to consider logistics while planning audits. If selecting a particular single site in a country would preclude the inclusion of multiple sites during the same audit, auditors are to plan accordingly. Auditors are also to consult with OIEA program analysts and ODIFP statisticians to seek input on the statistical considerations of site selection.

M. If the auditor identifies potentially systemic findings during the audit, he or she is to conduct additional audit activities at that site and at other sites to determine whether the findings are in fact systemic. The IAS auditor is to coordinate as necessary with the ERT to evaluate the findings.

N. The auditor is to make changes to the audit plan as needed based on the ERT's input, with the goal of gaining the consensus of the team. Once ERT team consensus is reached, the IAS auditor is to submit an audit plan to the IAS Director for concurrence, along with a draft notification letter to the CCA. The notification letter is to advise the CCA that the objectives, scope, and itinerary of the audit are predicated on the country's most recent SRT submission and is to clearly define the parameters and time period of program review covered by the audit. The notification letter is to advise the CCA that no program modifications or updates will be considered outside the scope of the audit. The IAS Director is to share the audit plan with the IES Director to include as background in the IES country file. In the audit plan, the auditor is to provide justification for the audit and include:

1. Audit plan overview, including IES's determination for each equivalence component;

2. Proposed itinerary and notification letter; and

3. Details of the selection methodology and justification of proposed audit sites, including:

    a. Government Offices (central, regional, and local);

    b. Laboratories (Microbiological and Residue); and

c. Eligible Export Establishments.

O. The auditor is to select the locations to be visited during the audit based on parameters that include the volume of production and relative hazard associated with products the CCA is seeking to export to the U.S., establishments with POE violations, new determinations of equivalence for alternate sanitary measures, and newly listed or relisted establishments. Thus, in making selections, the IAS auditor is to focus on:

1. Government offices that oversee the inspection personnel at establishments that produce higher volumes of higher risk products, such as product sampled with zero tolerance for pathogens (e.g. raw ground beef or not fully cooked ready-to-eat (RTE) product);

2. Laboratories that conduct pathogen or chemical testing of products from establishments that produce higher volumes of higher risk products; and

3. Establishments that produce higher volumes of higher risk products.

P. OIC is to send the audit notification letter through USDA's Foreign Agricultural Service (FAS) to the CCA no later than 45 days before the start of the scheduled audit. At least 35 days before the scheduled audit, the IAS auditor is to submit the audit plan for clearance through the IAS Director who will then provide it to the OIEA/AA.

Q. Based on the approved audit plan, the IAS Director is to send a draft audit itinerary through OIC and FAS to the CCA for review and comment at least 30 days before the scheduled audit. The auditor is to coordinate the audit itinerary and logistics with the CCA and the FAS personnel in the U.S. embassy in the country being audited. The auditor is to finalize the audit itinerary and logistics with the CCA and FAS in country before departing the U.S.

R. Based on the approved audit plan, the auditor is to use the Agency approved slide template to prepare the audit entrance meeting presentation. The presentation slides outline the audit's standards, scope, verification activities, and previous audit findings, including corrective actions taken by or required of the CCA.

S. Before leaving on the audit, the IAS auditor is to schedule a pre-audit entrance meeting with the IAS Director and the ERT to review the slide presentation prepared by the IAS auditor for the audit entrance meeting with the CCA. The pre-audit entrance meeting agenda is to include a review of the audit plan, the final audit itinerary, and the entrance conference slides. Additionally, the auditor is to schedule the time of the audit pre-exit meeting during this meeting.

V. ANNUAL AUDIT - CONDUCTING THE ON-SITE AUDIT

A. The auditor, or in some cases the audit team, is to audit an exporting country's inspection headquarters, regional offices, laboratories, and certified establishments as specified in the audit plan.

B. Before meeting with officials from the CCA, the auditor is to offer to meet with FAS embassy personnel, if applicable, to explain the basis for the audit and to provide information regarding the audit objectives, scope, and itinerary and, if required, to schedule a briefing with the U.S. Embassy's Regional Security Officer.

C. At the entrance conference with the CCA, the auditor is to make clear that the audit objective is to determine whether the national system of inspection is being implemented as designed, to identify significant trends or changes in operations, to determine whether the system continues to meet FSIS's

ALOP and to verify that the CCA has addressed any problems that FSIS has identified with the system. The auditor is to discuss the audit itinerary, present the entrance slides, and finalize audit logistics.

D. Following the audit plan, the auditor is to examine a sample of program records that evidence the importing country's regulatory activities and to accompany CCA officials on field visits to a representative sample of establishments that are certified for export to the U.S.

E. As needed, the auditor is to provide a briefing during the audit to the IAS Director approximately every three days.

F. The auditor is to immediately notify the IAS Director about any finding that constitutes a food safety or equivalence concern. In case of the latter, the IAS Director is to immediately advise the IES Director of the issue. Under these circumstances, and while the audit team is still in-country, the IAS Director (or IES Director in the case of an equivalence issue) is to collect the relevant audit evidence into a briefing for the appropriate senior Agency officials regarding the seriousness of the concern and recommendations for corrective or enforcement action.

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

1. How the in-plant inspection personnel are verifying that the establishment is producing safe products for export to the U.S.;

2. The inspection program's ability to identify and resolve non-compliances; and

3. The need for possible enforcement action by the CCA.

H. Before leaving on the audit, the auditor is to schedule the audit pre-exit meeting with the IAS Director and the ERT. While in country, the auditor is to develop exit conference slides capturing preliminary audit findings and circulate these slides to the ERT for review and feedback before the audit pre-exit meeting. Before the exit meeting, the auditor is to make changes to the slides based on input received during the pre-exit meeting.

I. The auditor is to use the Agency approved slide template to prepare exit slides that outline the audit standards, scope, verification activities, and preliminary findings, including corrective actions taken by or required of the CCA. The exit slides also are to convey information on post-audit activity, specifically the steps involved with drafting, reviewing, and publishing the audit report.

J. After the exit slides are cleared by the IAS Director and the ERT, the auditor is to present preliminary audit findings to the CCA at the exit conference.

VI. ANNUAL AUDIT - POST-AUDIT ACTIVITY

A. A draft final audit report is to be sent to the CCA of the audited country no later than 90 days from the third day following the exit conference, allowing for the auditor's return travel to the U.S. and return to the office.

B. Upon return to the U.S., the auditor is to conduct a post-audit analysis of all data collected on-site to determine whether the exporting country's food safety system has in fact been implemented as documented and determined by FSIS as equivalent through its review of the SRT and supporting documents. This analysis is to establish whether the country continues to maintain an equivalent food safety system for the products being exported to the U.S. The post-audit analysis is to commence no later than three days after the conclusion of the exit conference.

C. The auditor is to record his or her post-audit analysis in the CAVF for ongoing or future verification purposes and to prepare a draft final audit report (DFAR). The auditor is to consult IES on whether the DFAR adequately captures the country's equivalence status.

D. Within 21 calendar days of initiating the post-audit evaluation, the auditor is to submit a DFAR to the IAS Director, including audit checklists as attachments. In the report, the auditor is to document whether and how the exporting country has satisfied each of the six FSIS equivalence components, and whether the audit findings provide the basis for a determination that the foreign inspection system is equivalent to the FSIS system. If audit findings support that one or more equivalence components have not been met, the audit report is to set out what actions would be necessary to maintain equivalence.

E. The IAS Director is to review the draft audit report for technical accuracy and editorial correctness. The IAS Director will be responsible for the movement of the DFAR until it is submitted for review by the MCAD Director.

F. The IAS Director is to bring any sensitive or controversial matter to the immediate attention of OIEA senior management.

G. The IAS Director is to share the DFAR with the designated staff officers from OPPD/OFO/OPHS/ Office of Public Affairs and Consumer Education (OPACE)/OIC for review.

H. The program area reviewers are to:

1. Acknowledge receipt of IAS Director clearance request;

2. Respond to inquiries from the IAS Director about the status of their DFAR review, and

3. Submit their review comments or concurrence of the DFAR and all report-related correspondence directly to the IAS Director.

I. The IAS Director is to respond to comments received from program area reviewers on the DFAR.

J. Once the program area reviewers concur with the audit report, the IAS Director is to submit the draft audit report to the MCAD Director.

K. The MCAD Director is to review the DFAR for technical accuracy and editorial correctness and submit the DFAR to the OIEA AA for review and submission for Agency clearance through the Enterprise Content Management (ECM) system. The MCAD Director is to be responsible for the movement of the draft audit report until it is cleared by OA.

L. IAS is to track all steps of the clearance process, including informing the OIEA AA and MCAD Director of DFAR clearance progress at the end of each week so that updated status reports can be provided at the international coordination weekly meeting.

M. The IAS Director is to:

1. Intervene when steps in the clearance process are close to exceeding response deadlines requested by the IAS Director,

2. Send a reminder to reviewing parties three (3) working days before the due date for their review;

3. Send the assigned auditor all clearance-related comments; and

4. If no comments are received from reviewers by the COB on the due date, the IAS Director is to elevate the DFAR to the next level of clearance and notify the AA's and OIC that no comments were received and that the DFAR has been elevated to the next level of clearance.

N. Once the DFAR has received all required clearances, the IAS Director, through OIC, is to send the DFAR to the CCA for comment. While the review of the DFAR is to be completed within 90 calendar days, the DFAR is not to be sent to the exporting country if there are any remaining questions that were raised during the review process, unless the Administrator directs that the DFAR be sent in spite of those questions.

O. The IAS Director is to draft a transmittal letter that informs the exporting country that it has 60 calendar days from receipt of the draft final audit report to provide comments and to submit corrective actions, if required. In cases where audit findings are of a systemic nature, the transmittal letter is to inform the CCA that failure to submit corrective actions within an FSIS established timeframe may result in an action by FSIS, up to and including a suspension of all imports from that country, until such time as FSIS has been able to review and verify the effectiveness of CCA correction action. The transmittal is also to request that the CCA update the SRT with any changes made to its inspection program accepted by FSIS as corrective actions in response to FSIS findings.

P. If the CCA has not provided comments, and the 60 day comment period deadline is approaching, IAS is to contact the CCA to inquire about whether and when it plans to submit comments. The auditor is to notify the CCA that if it does not provide comments or request a comment deadline extension, then FSIS will post the draft audit report as final to the FSIS website within 75 days of its original transmittal to the CCA for review and comment.

Q. If the CCA does not provide comments on the DFAR or request a comment deadline extension, the auditor is to note the CCA's non-response in the conclusion of the audit report and in the transmittal letter that accompanies the final audit report. The IAS Director, through OIC, is to transmit the final audit report to the exporting country's CCA and post it on the FSIS Website.

R. If the CCA provides comments on the DFAR, the auditor is to arrange translation of the CCA's comments as needed, share the translated comments with the ERT, attach them as an appendix to the draft final audit report along with FSIS's response to the CCA's comments, and submit the report to the IAS Director for final review. The IAS Director, through OIC, is to submit the final audit report to the exporting country's CCA, then post the report on the FSIS website once the official translation has been received.

S. For audit findings with a bearing on equivalence, the ERT is to determine whether any immediate action is warranted in accordance with Chapter III of this directive.

T. If the country's comments include proposed corrective actions, the auditor is to conduct a meeting with the ERT upon receipt of the country's comments or corrective actions. This review is to consider the EVP procedures. The ERT is to consider whether each systemic audit finding should be added to an EVP for future verification see Chapter II of this directive.

U. Concurrent with the preparation and transmittal of the final audit report, the auditor is to initiate an EVP for any significant food safety findings identified during the audit process. Audit findings that result in establishment delistments identify points in a foreign inspection system that apparently have failed. The significance of point failures would increase if FSIS were to find other gaps in the effectiveness of the CCA's system. FSIS audit conclusions about system equivalence will depend in part on FSIS's analysis of whether the point failures can be viewed as isolated correctable events or as direct evidence of system failure. The auditor is to classify audit findings in the audit report as either isolated or systemic.

VII. EQUIVALENCE VERIFICATION PLAN

A. When audit findings, POE violations, or incomplete SRT information cause the ERT to question a foreign country's equivalence, the ERT Team Lead is to open an EVP to document the conditions associated with a possible failure of a country to maintain an equivalent inspection system. The EVP is used to document deficiencies requiring a response from the foreign CCA, the response received from the CCA in regard to those deficiencies, and points for follow-up verification. The ERT Team Lead is to seek the ERT's concurrence on the draft EVP.

B. Based on the ERT-approved EVP, OIC is to provide written notification to the foreign CCA of those specific findings that indicate a possible failure of the country to maintain an equivalent system and that require the CCA's response. After receiving a CCA's response, OIC is to determine whether translation services are needed, arrange for them as required, forward the response to all ERT team members within 1 business day, including one business day after translation if translation is required, and set up a meeting of the ERT within 7 business days to evaluate and analyze the CCA's response to determine whether the documented actions are sufficient to affirm equivalence and to identify discreet items requiring follow up verification by FSIS to affirm equivalence.

C. The EVP is a set of tasks associated with the verification of CCA corrective actions that are to be accomplished through direct observation during an on-site audit or through document review. EVP tasks identify as verification points those components of a foreign inspection system that require scrutiny. For each verification point, the EVP is to identify discreet verification activities to be undertaken to verify equivalence. Verification points contained in an EVP may originate from:

1. Issues identified as equivalent during document review that warrant follow-up verification;

2. Equivalence Failure

    a. Failure to meet FSIS equivalence criteria, such as foreign program modifications that alter the country's system in a way that FSIS cannot find to be equivalent, or a CCA's failure to implement program changes or to adopt alternate sanitary measures in response to a change in a FSIS regulation or policy;

    b. The inability of the foreign government to ensure that there is uniform implementation and enforcement throughout its system of the laws and regulations that prevent the adulteration or misbranding of product for export to the U.S. For example:

        i. Foreign establishment deficiencies identified in the on-site audit that are likely to result in product adulteration or in misbranding by a significant number of audited establishments. Such deficiencies could include findings involving HACCP, Sanitation SOP, labeling, microbiological or chemical sampling and testing programs, or ante- or post-mortem inspection issues;

        ii. U.S. POE violations caused by adulterated or misbranded product originating in establishments that export to the U.S.; or

        iii. The lack of control and supervision by the CCA over official activities of employees, including inspection program personnel (IPP) assigned to establishments;

3. Corrective Actions – those actions taken by a foreign CCA in response to FSIS-identified issues (audit finding, POE violation); and

4. Unforeseen Events – Natural or man-made disasters having a potential impact on food safety.

D. For each verification point in the EVP, the ERT team lead is to provide the following to the IAS auditor and IES country officer:

1. A description of the specific finding, e.g. POE violation, non-compliance, or non-equivalent finding;

2. A description of the foreign country's corrective actions and verification measures that were submitted to FSIS;

3. A description of the specific regulation, policy, or instruction that the CCA cited in its submitted corrective actions; and

4. A description of the specific verification items associated with each verification point identified for follow up through document review or on-site observation and by which staff follow-up verification should proceed.

E. The ERT team lead is responsible for drafting letters to the CCA explaining the ongoing equivalence verification process and requesting specific documents to demonstrate that the actions proposed by the CCA have been implemented and are effective. In some cases, additional verification will occur when the IAS auditor directly observes the changes during the next on-site audit.

F. When corrective actions are received as part of CCA comments on the draft final audit report, the IAS auditor is to review the corrective actions with the ERT to make a judgment regarding their adequacy. The ERT is to determine whether the verification of corrective actions can occur through document review or direct observation. The IAS auditor is to document ERT decisions in this regard to the CAVF. The IAS auditor is to refer any corrective actions that result in changes to the CCA's program to IES for updates to the SRT.

G. In order to close out a verification item within an EVP, the ERT team lead is to document the ERT decisions regarding that item and summarize all reviewed documentation received from the CCA to verify the implementation of effective corrective action, as well as any observations made during the on-site audit, and is to include an analysis and supportable conclusions regarding the country's ongoing equivalence.

H. In the event that a foreign CCA fails to provide verifiable corrective actions in response to audit findings and POE violations, or otherwise fails to respond to FSIS requests for information on the operation of its inspection program, or the ERT determines that corrective actions taken by the CCA are inadequate, and that action is warranted, the ERT is to draft a Decision Memorandum to the Administrator recommending action in accordance with Chapter III of this directive.

CHAPTER III –ACTIONS ASSOCIATED WITH FAILURES TO MAINTAIN EQUIVALENCE

I. GENERAL

A. Only those establishments that are determined and certified to FSIS by an exporting country CCA as fully meeting the requirements of 9 CFR 327.2, 381.196, or 590.910 are eligible to export their products to the U.S.

B. The export eligibility of any country may be withdrawn by FSIS in accordance with provisions outlined in 9 CFR 327.2 and 381.196.

C. In addition to the provisions outlined in the meat, poultry, and egg products inspection regulations, FSIS may suspend a country's export eligibility for:

1. Failure to respond to FSIS requests for information on its inspection system;

2. Refusal to allow FSIS to conduct an on-site audit or restricting FSIS access to audit locations;

3. Establishment delistments for cause; and

4. Failure to maintain an equivalent food safety system.

D. The ERT is to recommend the suspension of a country's export eligibility after concluding, based on an analysis of a CCA's response to audit findings, POE violations, or EVP-generated requests from FSIS, that action on a country's eligibility to export to the U.S. is warranted. ERT recommendations for suspension are cleared through the OIEA and OPPD AAs and provided to OIC in the form of a Decision Memorandum to the Administrator, accompanied by the supporting evidence for the ERT's recommendation.

II. FOREIGN GOVERNMENT FAILURE TO PROVIDE ADEQUATE DOCUMENTATION

A. In the event that a foreign government fails to provide updated SRT information by an established deadline, IES is to draft a letter for OIC signature that includes the original request for information and advises of possible action if the required information is not received within 10 days of the date of the letter. OIC is to work through the USDA's FAS and the CCA's Chief Veterinary Officer (CVO) to encourage submission of the country's SRT response in lieu of Agency action. In accordance with Chapter II of this directive, the letter is to repeat offers of technical assistance to complete SRT submissions, while also outlining FSIS' authority to suspend or terminate eligibility to export product to the U.S.

B. FSIS can take the following measures whenever a CCA fails to respond to FSIS requests for information about its programs or corrective actions the CCA plans to take in response to FSIS audit findings or POE violations:

1. Conduct targeted sampling or increased level of reinspection at POE with mandatory hold of lots sampled or reinspected, pending acceptable results. The ERT is to collaborate with OPPD to determine appropriate sampling criteria within PHIS;

2. Delist one or more establishments as eligible to export to the U.S.;

3. Suspend specific HACCP process categories as eligible to be exported by any of a country's establishments;

4. Suspend a country's export eligibility; or

5. Any combination of the above.

C. In response to these failures to provide documentation, the ERT is to compile a Decision Memorandum for the Administrator, with prior concurrence from the OIC, OFO, OPHS, OIEA, and OPPD AAs, that presents the facts of the case and provides support for one or more of the recommended courses of action.

E. OIC is to notify the CCA that, under the provisions of 9 CFR 327.2, 381.196, and 590.910, imports from that country are temporarily suspended pending the country's reinstatement of equivalence. The ERT team lead is to work with OIC to develop a Notification of Suspension letter to include:

1. The reasons for the suspension, citing relevant FSIS regulations;

2. The effective date of the suspension;

3. The status of “pipeline” product that has already been certified for export but not yet presented for FSIS reinspection;

4. CCA actions necessary to reinstate equivalence;

5. FSIS verification steps necessary to lift suspension; and

6. Notice that the country’s export eligibility will be terminated if conditions leading to the country’s suspension are not corrected within one year of the suspension date.

III. ESTABLISHMENT DELISTMENTS

A. Exporting country CCAs are required by FSIS regulations to submit annual lists of establishments that are certified for export to the U.S (9 CFR 327.2, 381.196, and 590.190). Removal of an establishment from the certified list (delistment) may be for one of several reasons:

1. At the request of the CCA for any reason;

2. CCA delistment for cause; and

3. FSIS delistment for cause.

B. CCAs notify IES when they delist establishments. In this situation, the IES Director is to request that the PHIS Import Librarian remove the establishment from PHIS and update the website. The PHIS Import Librarian is to make these updates to PHIS within 24 hours of notification by IES.

C. Re-certification of an establishment that has been delisted by the CCA for cause may occur at any time and will normally be accepted by FSIS upon concurrence by the assigned IES officer. The PHIS Import Librarian is to inform the IES equivalence officer when the CCA submits establishments for recertification that have been delisted for cause.

D. A different situation applies when a foreign establishment is identified by FSIS for a visit during an on-site audit. The CCA is notified of that selection by the IAS auditor, and then the CCA requests delistment, so that the FSIS audit visit never occurs. If the CCA requests the relisting of a specific establishment after such a chain of events, FSIS will not accept recertification until the establishment is audited by FSIS during the next on-site audit, which may not occur for a year or more.

E. When a CCA delists one or more establishments based on FSIS audit findings, the following describes the actions that are to be taken by FSIS:

1. When a CCA delists an establishment, or terminates eligibility of specific products or processes based on audit findings, the auditor on-site is to notify the IAS Director by e-mail as soon as practicable on the day of delistment. The auditor is also to send the e-mail to the PHIS Import Librarian. The auditor’s e-mail notification is to include the foreign establishment number, establishment name, the production date of delistment, and the reasons for the action. If the CCA makes a determination to remove eligibility of specific products or processes, but not the entire establishment, then the auditor’s e-mail is to provide the foreign establishment number, establishment name, and the species and process category affected by the CCA’s action; and

2. Upon notification by the auditor, the IAS Director is to inform IES, OIC, and the OIEA and OPPD AAs of the action taken. The IAS Director is also to immediately organize a conference call to include the IAS auditor and the ERT to evaluate the findings and to determine whether FSIS will accept any product from the establishment regardless of production date, and whether a recall may be warranted. The IAS Director is to advise OIEA and OPPD AAs of the ERT’s recommendations regarding product from the affected establishment. The AAs are to review the factual situation and

communicate their concurrence or nonconcurrence with the recommendations. The IAS Director is to advise the IAS auditor of the Agency's decision. The auditor is to orally communicate FSIS's decision to the CCA.

F. FSIS can also delist an establishment for cause while an auditor is in-country conducting an audit. If the IAS auditor finds egregious conditions, e.g., that an establishment had not been operating under a HACCP plan, or that the auditor observed gross insanitary conditions resulting in adulterated product, then the auditor is to immediately notify the CCA that the he or she will recommend to FSIS Headquarters that the establishment be delisted based on those findings, thus providing the CCA with an opportunity to take appropriate action. The IAS auditor is then to notify the IAS Director of this situation.

G. During the exit conference, the IAS auditor is to:

1. Make formal notification to the CCA of the delistment and communicate that the delistment evidences that the country's system failed to adequately ensure that equivalent requirements were sufficiently implemented and verified at the establishments in question;

2. Inform the CCA of the steps required to relist the establishment and of FSIS's decision regarding the disposition of product in transit to the U.S.;

3. Request that the CCA conduct a review of inspection activities in all or a sample of comparable certified establishments to determine whether the failures detected represent systemic problems; and

4. Request that the CCA provide FSIS, within 30 days, with a summary of the review, conclusions, and actions taken as a result.

H. Procedures listed above will be followed when either the CCA or FSIS initiates an establishment delistment based on an ERT recommendation, and only after the OIEA-AA obtains concurrence from the FSIS Administrator.

I. Within one business day of the Administrator's concurrence, the IAS Director is to prepare a delistment confirmation letter for OIC to issue to the CCA by e-mail followed by a hard copy to the CCA through FAS. The letter is to include:

1. A summary of the deficiencies that led to the delistment;

2. The production date of lots affected by the delistment;

3. Notice of FSIS determination made in relation to item E. 1 of this section; and

4. Notice that the delistment or other action will remain in effect until corrective actions are provided by the CCA to FSIS, and FSIS is able to verify, either through a review of the CCA's corrective action documentation or by observation during the next on-site audit, that the corrective actions have been effective.

J. For the purpose of removing delisted establishments from the list of eligible foreign establishments maintained in PHIS, the OIC is to notify and copy the PHIS Import Librarian on all delistment confirmation letters.

K. Such findings may evidence inadequate regulatory enforcement by the CCA in that establishment. The IAS auditor is to discuss the findings during the audit exit conference and document them in the CAVF and audit report.

IV. SUSPENSION OF COUNTRY ELIGIBILITY

A. Decisions to suspend a country's export eligibility are based on a determination by the ERT that the country has failed to maintain an equivalent food safety system.

B. The ERT obtains evidence of inspection system failure through audit, POE reinspection, or document review.

C. The ERT assesses the evidence associated with document review or audit findings, as well as POE violations.

D. The ERT need only find failure in one equivalence component (see Chapter II of this directive) to determine that a foreign inspection system has failed to maintain equivalence.

E. The ERT takes the following steps to determine whether a country has maintained equivalence with the U.S. inspection system:

1. Gather information from the EVP;

2. Identify areas that indicate a deficiency in one or more equivalence criteria;

3. Classify deficiencies by equivalence criterion; and

4. Make a recommendation whether system equivalence has or has not been met.

F. If the ERT determines that a country has failed to maintain equivalence, the IES Director is to draft a letter of suspension to the CCA and a decision memorandum to the Administrator that identifies an equivalence component failure by the foreign country.

G. The IAS and IES Directors, if they concur, are to sign the decision memo and forward it and the letter of suspension to the OPPD and OIEA AAs and to OIC for concurrence.

H. If the AAs and OIC concur, they are to forward the decision memorandum recommending suspension to the Administrator for concurrence and necessary notifications within the Department.

I. If the Administrator affirms the suspension decision, the OIC is to issue the letter of suspension to the exporting country.

J. The suspension letter is to include:

1. The reasons for the suspension of export eligibility, citing the relevant FSIS regulatory requirements;

2. The effective date;

3. The status of product in transit to the U.S.;

4. CCA actions necessary to correct system deficiencies; and

5. FSIS verification steps before exports can resume.

K. The IES Equivalence Officer is to notify the PHIS Import Librarian and RMTAS by e-mail to the ImportInspection@fsis.usda.gov mailbox of a country's suspension once the country suspension letter has been issued.

CHAPTER IV - CERTIFICATION OF FOREIGN MEAT, POULTRY, AND EGG PRODUCT EXPORT ESTABLISHMENTS

I. ADDING AND REMOVING FOREIGN CERTIFIED ESTABLISHMENTS TO THE PHIS LIST OF ELIGIBLE ESTABLISHMENTS

A. By December 1 of each year, OIC is to send a notification to the CCAs of export eligible countries requesting those countries' updated list of certified eligible establishments for the coming calendar year. This notification is to request that the CCAs submit the annual certification lists by January 31.

B. OIC is to ensure that annual certifications are presented by foreign CCAs, as prescribed by 9 CFR 327.2 for meat and 381.196 for poultry. Annual certifications for new establishments, or any establishments for which the information from the previous year has changed, must include the date, the foreign country, the establishment's name, address, and establishment number, the type of operation (e.g., slaughter, processing, storage, exporting warehouse), and the establishment's eligibility status (e.g., new or relisted (if previously delisted). Slaughter and processing establishments must address the species and type of products produced (e.g., the process category). Paper certificates must contain the foreign official's title and signature. If the establishment information provided on the preceding year's annual certifications has not changed, the annual certification must contain the date, the foreign country, the establishment's name, and for paper certificates only, the foreign official's title and signature. OIC is to inform CCAs that certifications are to be submitted by January 31 of each year to the International Equivalence mailbox at internationalequivalence@fsis.usda.gov. IES is to check the mailbox weekly for new foreign certifications and is to forward CCA annual certification lists to the PHIS Import Librarian within 7 business days of their receipt.

C. Upon receipt of approved CCA annual certification lists from IES, the PHIS Import Librarian is to update PHIS and the FSIS web site within 10 business days so that shipments from the newly certified establishment can begin receiving import reinspection assignments. Updates by the PHIS Import Librarian are also to include removal of establishments that were delisted or no longer certified, as well as changes in the names of establishments and products, process categories, and product categories covered by the CCA annual certification. The PHIS Import Librarian is to remove from PHIS any establishments not listed on the CCA annual certification using the annual certification date as the effective date of delistment. For newly delisted establishments, only shipments with production dates prior to the CCA annual certification date are to be given reinspection assignments in PHIS. All others are to be refused entry.

D. Similarly, IES is to forward requests to list new or previously listed individual establishments (i.e. those received separately from the annual list of certified establishments) to the PHIS Import Librarian within 7 business days of their receipt for updating in PHIS by the PHIS Import Librarian as per item C above.

E. If the foreign CCA fails to include all of the information required by 9 CFR 327.2(a)(3)(i) and 381.196(a)(2)(iv), the IES equivalence officer is to return inadequate certifications to the foreign CCA within 7 business days with a written explanation of the inadequacies. The IES equivalence officer is to disapprove establishment certifications in cases where the CCA has certified establishments to export products or process categories that fall outside the scope of any equivalence determination made for that country.

F. If no updated list of certified establishments is received from a CCA by January 31, then the IES equivalence officer is to send the CCA an e-mail reminder to submit the list within 14 business days. If, after those 14 days, no new list is received, then the prior year's list will remain operative in PHIS minus any establishment delistings arising from enforcement actions taken by the CCA or FSIS. Shipments received from a foreign establishment not included in the PHIS inventory of certified establishments for that country are to be refused entry.

G. Whenever a foreign CCA adds or removes an establishment from its certified eligible list, the PHIS Import Librarian is to add or remove a foreign establishment from the FSIS website and the PHIS list of certified eligible foreign export establishments within 10 business days of being notified by IES.

CHAPTER V - QUESTIONS

Refer questions regarding this directive through your supervisor or submit questions through askFSIS. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field:	Enter **Directive 9780.1**
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 and at the next screen press **Finish Submitting Question**.

NOTE: Refer to FSIS Directive 5620.1, Using askFSIS, for additional information on submitting questions.

Assistant Administrator
Office of Policy and Program Development

Attachment 1: Ongoing Equivalence Verification Process Schedule

January 31 (annually)	Deadline for CCA submission of annual certified establishments list. IES to send CCA a 14 day reminder notice to submit an updated certified establishment list or consent to maintaining the list from the preceding year.
May 18 (annually)	Deadline for CCAs to complete SRT updates in PHIS.
June 30 (annually)	Deadline for IES review of SRT updates. IAS proposed foreign audit schedule for upcoming FY due to OIEA management.
July 30 (annually)	IES to provide IAS with estimated timetable for completing SRT analysis in CAVF.
December 1 (annually)	OIC to notify eligible country CCAs to submit annual SRT update. IES Director to send official request for CCA annual notification of certified establishments.
70 days prior to planned audit	IAS to request CAVF updates from IES on equivalence issues and three years of POE data from RMTAS.
60 days prior to planned audit	Deadline for IES to complete SRT analysis in CAVF.
45 days prior to planned audit	OIC to send audit notification letter to CCA.
35 days prior to planned audit	IAS to submit audit briefing memo and draft audit itinerary for OIEA-AA clearance.
30 days prior to planned audit	IAS to send draft audit itinerary to CCA for comment.
Within 21 calendar days of auditor's return to the U.S.	Deadline for submitting DFAR to IAS Director for review.
Within 5 days of receiving an IAS request	OIEA program statisticians to provide guidance on the range of sites to consider auditing with a goal of achieving 95 percent confidence of identifying at least one site with potential systemic findings if findings are actually identifiable in 20 percent or more sites.
Three days prior to DFAR clearance review deadline.	IAS Director to send comment deadline reminder to DFAR reviewers.
Within 90 days of auditor's return to the U.S.	Send DFAR to CCA for comment.
60 days from receipt of DFAR	Deadline for CCA comments on DFAR
75 days from DFAR transmittal to CCA	Post audit report to FSIS website if no CCA comments received.
Within 2 days of recording POE violation	RMTAS to issue POE violation letter to CCA

Attachment 1: Ongoing Equivalence Verification Process Schedule

If no CCA response to POE violation letter received within 30 days.	OIC to issue a "10-day" letter to CCA outlining actions agency may take in relation to non-response.
Within 7 days of receiving CCA corrective action(s) response to audit findings.	IAS to request OIC to convene meeting of ERT to review CCA response.
Within 7 business days of receiving CCA list of annual certified establishments or a CCA's notification of an individual certified establishment.	IES to forward CCA annual certification list or individual establishment certification to PHIS Import Librarian
Within 10 business days of receiving CCA annual list of certified establishments from IES	Import Librarian to update establishment eligibility in PHIS and the FSIS web site