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

FSIS DIRECTIVE

9770.1
Revision 1

2/8/17

DETERMINING INITIAL AND REINSTATING THE EQUIVALENCE OF FOREIGN FOOD SAFETY INSPECTION SYSTEMS

I. PURPOSE

This directive provides instructions to the International Audit Staff (IAS), Management Control and Audit Division (MCAD), Office of Investigation, Enforcement and Audit (OIEA); International Equivalence Staff (IES), Office of Policy and Program Development (OPPD); and the Office of International Coordination (OIC) for making initial determinations of equivalence and reinstatements of equivalence regarding foreign food safety inspection systems.

KEY POINTS:

- *Outlines the process FSIS personnel follow when responding to foreign governments' requests for determinations of initial equivalence and reinstatement of equivalence, including the collection and analysis of foreign food safety inspection system documentation*
- *Outlines FSIS personnel's roles and responsibilities when conducting initial equivalence and reinstatement of equivalence reviews, on-site verification audits, and the reporting of equivalence review and audit findings*
- *Provides general information on rulemaking related to an initial determination of equivalence*
- *Identifies the requirements and tasks associated with reinstatement of foreign country equivalence*

NOTE: For the purpose of this directive, the timeframes provided in which FSIS personnel will complete a specific action, when that timeframe is exceeded, FSIS will provide a rationale in the file that explains why the timeframe was not met.

II. SIGNIFICANT CHANGES

A. This revision provides new instructions for IES to enter the Self-Reporting Tool (SRT) and Component Analysis Verification Form (CAVF) information into the Public Health Information System (PHIS).

B. This revision clarifies the instructions on:

1. Reinstatement of equivalence determination process;
2. Equivalence assessments; and
3. Roles and responsibilities of Equivalence Officers (EO), International Auditors (IA), and OIC.

III. CANCELLATION

FSIS Directive 9770.1, Determining the Initial Equivalence of Foreign Food Safety Systems, 11/19/14

IV. BACKGROUND

A. FSIS' equivalence determination is the process of deciding whether a foreign food safety inspection system 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 and was adopted by the United States (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. does, but the foreign government must 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 Code of Federal Regulations (CFR) 327.2 for meat products, 9 CFR 381.196 for poultry products, 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 respect to (1) government oversight (e.g., Organization and Administration), (2) government statutory authority and food safety and other consumer protection regulations (e.g., inspection system operation, product standards and labeling, and humane handling), (3) government sanitation, (4) government Hazard Analysis and Critical Control Point (HACCP) system, (5) government chemical residues testing programs, and (6) government microbiological testing programs.

C. To make an initial equivalence determination, FSIS first reviews a foreign country's Self-Reporting Tool (SRT) responses and the corresponding supporting documentation provided by the CCA. If FSIS concludes that the SRT and supporting documentation indicate that the country maintains a food safety inspection system that provides an equivalent level of protection, then FSIS conducts an on-site verification audit of the country's food safety inspection system. If the on-site verification audit indicates that the country maintains a food safety inspection system that provides an equivalent level of protection, FSIS will then notify the public of its intention to amend its regulations by adding the country to the list of countries eligible to export meat, poultry, or egg products to the U.S. FSIS addresses all comments received from the public notification of the proposed rule change and publishes the final rule, if appropriate.

D. A reinstatement of equivalence is the process by which FSIS establishes that a foreign food safety inspection system remains equivalent to the U.S. system after a long period of trade inactivity. Reinstatements of equivalence involve a document review of the SRT responses and supporting documentation, and may require an on-site verification audit but do not require rulemaking because the country is already listed in the regulations as eligible to export meat, poultry, or egg products to the U.S. Sections VI, VII, VIII, and IX of this directive may not apply to requests for reinstatement of equivalence. Section X of this directive does not apply to requests for reinstatement of equivalence.

NOTE: A long period of trade inactivity occurs when an eligible country does not export an equivalent commodity to the U.S. for three or more years.

E. FSIS receives information from foreign governments on how their food safety inspection system is equivalent to that of the U.S. in the SRT (see Self-Reporting Tool). The SRT is a questionnaire that provides an organized means for the CCA of a country to demonstrate that its food safety inspection system achieves an equivalent level of protection as provided by FSIS in the U.S. Information in the SRT is used to populate the CAVF. The EO is to develop the CAVF to document an equivalence assessment of inspection system information submitted by the CCA in the SRT. The IA is also to use the CAVF to document the results of his or her audit verification activities. The CAVF provides a systematic tool that an EO and IA use in analyzing whether the six principal equivalence components of a foreign food safety

inspection system identified in Section IV. B. provide an equivalent level of protection to the U.S. system and to document the results of that analysis. The CAVF forms the basis for audit planning, scope, and reporting and identifies the records and processes that an IA is to assess during an on-site verification audit.

V. INITIAL EQUIVALENCE OR REINSTATEMENT OF EQUIVALENCE DETERMINATION PROCEDURES

A. Upon receipt of a written request for a determination of initial equivalence or reinstatement of equivalence from a foreign government's CCA, the OPPD IES Director is to assign an EO as the project lead.

B. The EO is to:

1. Draft an FSIS acknowledgement letter to the CCA within 10 working days that lists those products that the foreign government stated it is interested in exporting to the U.S., and includes the SRT and other relevant guidance information. The EO is to have the IES Director review and clear, then the OPPD Assistant Administrator (AA) review and concur, and then send to OIC for review and transmittal.

2. Set up an initial equivalence or reinstatement of equivalence project plan for that country that identifies the step-by-step activities of the initial equivalence or reinstatement process. The EO is to use the project plan to document all activities related to the initial equivalence or reinstatement process. The EO is responsible for updating the project plan once a month.

C. If the foreign government does not provide an SRT response within one year of the date of the FSIS acknowledgement letter, or fails to respond to follow-up requests for information from FSIS or provide supporting documentation to the EO within that period of time, the EO is to designate the country's file inactive. The EO is to draft a letter to the CCA stating that the request is being designated as inactive. The EO is to have the IES Director review and clear, then the OPPD AA review and concur, and then send to OIC for review and transmittal. The EO is to keep any inactive file open for an additional year.

D. After 24 months of the country not responding, the EO is to draft a letter to notify the CCA (using the review process described in Section V. C.) that FSIS has closed its file and the CCA can request that the file be reopened at any time. If a CCA requests in writing that a file be reopened, the EO is to draft an acknowledgement letter to the CCA with the most recent version of the SRT.

E. Once a CCA submits what it considers to be a completed SRT with supporting documentation in PHIS or by paper copy, the EO is to:

1. Upload original foreign SRT responses and associated documents into PHIS;

2. Arrange for translation of SRT responses and associated documents into English. Enter English translated SRT responses into PHIS, upload associated translated documents, and begin an initial review and assessment of the English-translated SRT responses while providing the CCA the opportunity to verify the accuracy of the translations through OIC;

3. Provide an initial review and assessment of the SRT responses and communicate through OIC to the CCA to address any gaps or issues with the submitted information;

4. Review and analyze the completed SRT and associated documents with the assistance of subject matter experts to determine whether equivalence criteria have been met, and the EO is to document analysis in the SRT Analysis section of the CAVF in PHIS (using the process described in Section V. G.);

5. Document findings in the SRT Analysis-Findings section of the CAVF in PHIS; and

6. Document verification activities to be conducted during the on-site verification audit in the Audit Verification Plan section of the CAVF in PHIS.

F. The IES Director is to request the assistance of subject matter experts to assist the EO in a technical review of the CCA's SRT responses and associated documentation as well as the EO's initial recommendation as to whether the equivalence criteria for each of the six components is met. The IES Director is to select subject matter experts based upon the CCA's requested inspection system.

G. Within 120 working days of receiving a CCA's SRT responses and associated documentation in English, or the completed document translations, the EO with the assistance of subject matter experts is to review SRT responses and associated documentation.

1. The EO is to convene and document the meetings with subject matter experts and coordinate correlation sessions to reconcile assessments of foreign food safety inspection system design across multiple SRT components.

2. The subject matter experts are to review the SRT and evaluate whether the CCA adequately addresses each of the six equivalence components.

3. Equivalence criteria for FSIS sanitary measures are embedded within the SRT questions. If equivalence criteria do not exist for a given foreign sanitary measure, then the EO, with the assistance of the subject matter experts, is to develop criteria to evaluate the measure by updating or adding a question to the SRT specific to the requesting country.

4. To develop new equivalence criteria for an individual sanitary measure, to be added in an SRT question, the EO, with the assistance of subject matter experts, is to:

    a. Identify the relevant FSIS food safety requirements related to the foreign sanitary measure;

    b. Identify the objectives of the FSIS food safety requirements and the expected outcomes;

    c. Establish measurable points (outcomes) associated with the FSIS food safety requirements that need to be satisfied by the foreign sanitary measure; and

    d. Identify and request any additional information from the CCA needed to establish a conclusive comparison between the foreign sanitary measure and the measurable points identified for the FSIS food safety requirements.

NOTE: An individual sanitary measure is requested by eligible countries currently exporting meat, poultry, or egg products to the U.S. when they want to change requirements, procedures or other aspects of their food safety inspection system.

5. In rare cases, before deciding whether to recommend an on-site verification audit or reinstatement of equivalence of a foreign food safety inspection program, the EO may determine that a specific sanitary measure may be sufficiently novel or complex to warrant an assessment. In this situation, the EO may need to review the novel specific sanitary measure in-country in order to fully understand and identify the associated alternative inspection procedures and standards that would need to be addressed in order to develop the equivalence criteria and subsequent verification activities to be verified during an on-site verification audit. In such cases, the EO is to draft a Decision Memorandum to Recommend an In-Country Assessment. The Decision Memorandum to Recommend an In-Country Assessment identifies the objective and scope of the assessment, and the FSIS staff resources needed to support the assessment.

6. The IES Director is to review and sign the draft Decision Memorandum to Recommend an In-Country Assessment, and send it to the OPPD AA for review and concurrence within 20 working days. The final decision to perform an in-country assessment, including the scope and make-up of the participating staff, will be determined through the governance process and the FSIS Enterprise Steering Board.

7. Upon the EO's return from the in-country assessment, he or she will have 30 working days to complete his or her document review of the SRT and document his or her analysis in the CAVF. The EO is to incorporate information obtained during the in-country assessment in the CAVF. Upon completion of the document review and CAVF analysis that contains information gathered during the in-country assessment, the EO is to follow procedures under Section V. G. to prepare a Decision Memorandum to Audit for initial equivalence, or a Decision Memorandum to Reinstate Equivalence.

8. Within 120 working days of receiving a foreign government's SRT response in English, or the completed translated documents, the EO is to document the conclusions based on his or her initial document review in a CAVF. If the CCA provides additional information or supporting documents per FSIS' request, FSIS will review the information within 120 working days after the receipt, or upon receipt of completed document translations. Within 10 working days of completing the document review, assuming that all necessary information has been received from the foreign government, the EO is to complete the SRT Analysis section in the CAVF and use the information to prepare a Decision Memorandum to Audit for initial or reinstatement of equivalence, or a Decision Memorandum to Reinstate Equivalence for a tentative reinstatement of equivalence determination. A tentative reinstatement of equivalence determination is applicable until an on-site verification audit has been completed. In either case, the EO is to draft a letter to the CCA explaining the outcome of FSIS' decision concerning the country's request for reinstating the equivalence of its foreign food safety inspection system. The EO is to have the IES Director review and clear, then the OPPD AA review and concur, and then for OA review. Once cleared by OA, then send to OIC for review and transmittal.

9. The EO is to summarize the following in the Decision Memorandum to Audit or Decision Memorandum to Reinstate Equivalence:

    a. CCA's SRT response;

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

    c. The EO and subject matter experts' evaluation of the CCA's food safety inspection system, including recorded minutes of document review meetings; and

    d. The products, species, and process categories intended for export to the U.S.

10. The IES Director is to review the Decision Memorandum and, when satisfied with its content, send the Decision Memorandum to the OPPD AA for review and concurrence within 20 working days. 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.

VI. PREPARING FOR THE ON-SITE VERIFICATION AUDIT

A. Procedures related to the IA's preparation and scheduling of an on-site verification audit are as follows:

1. The purpose of the on-site verification audit of the CCA's offices, laboratories, and potential exporting establishments is to verify that the implementation of the equivalence components of the applicant country's food safety inspection system is consistent with its design as documented by the CCA in the SRT. As such, the IA is to plan the on-site verification audit to assess how a country's food safety inspection system is working. The IA is to use a systems approach by assessing the food safety inspection system as a whole, focusing on verifying the controls and recognizing that any findings identified must be viewed in the context of the overall food safety inspection system.

2. Once the Agency has decided to conduct an on-site verification audit, the IA is to submit a draft audit notification letter to the IAS Director for clearance. The IAS Director then sends the notification letter to OIC for signature and transmission. The letter is to notify the applicant country's CCA of the decision to audit, to suggest a date for the start of the audit (including a date for the entrance conference), and to advise the CCA of the objectives and scope of the on-site verification audit. The Audit Verification Plan is to be included as an attachment to this letter.

3. The IA is to follow a pre-audit checklist to arrange the on-site verification audit. Within 60 working days before the audit entrance meeting, the IA is to:

    a. Complete the Audit Verification Plan section of the CAVF in PHIS and share with the EO for review and comment;

    b. Review third-party audit reports of the applicant country that have been published by the CCAs of countries equivalent to the U.S. within the last three years;

    c. Review the applicant country's government chemical residues and microbiological testing programs; and

    d. Based on information provided by the CCA in its SRT submission, select establishments, laboratories, and government offices to be audited.

4. The IA is to ensure that the audit notification letter and Audit Verification Plan are delivered to the applicant foreign government 45 working days before the on-site verification audit start date that FSIS is suggesting.

B. The IA is to combine a targeted audit approach with a site selection methodology based on statistics to be assured of identifying system deficiencies where they exist. For these reasons, the IA is to consider that it is neither efficient nor necessary to audit all, or, in some countries, even most offices, laboratories, and establishments. 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 IA is to examine a representative and informative sample of procedures, documents, records, and sites to verify whether the CCA has implemented controls as described in the SRT.

1. The IA is to select places to audit based on the volume of production and relative hazard associated with products that the CCA is seeking to export to the U.S. Thus, in making selections, the IA is to focus on:

    a. Government offices that oversee the inspection personnel at establishments that produce higher volumes of higher risk products;

    b. Laboratories, including private laboratories, that conduct pathogen or chemical testing of products from establishments that produce higher volumes of higher risk products; and

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

NOTE: Because point-of-entry (POE) re-inspection data may not be available to estimate actual exporting establishment risk, the IA (through OIC) will confer with CCA officials to determine which establishments are most likely to be exporting the greatest volumes of particular products.

2. Within five working days of an IA's request, program analysts in OIEA's MCAD are to use a statistical methodology to provide the auditor with guidance on the number of sites to be audited.

3. In some countries, the number of potential establishments exporting to the U.S, the number of CCA offices, and the number of laboratories is sufficiently small enough that the IA is to 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 verification audit at all or even most sites. In such countries, the IA is also to consider logistics while planning on-site verification audits. If selecting a particular single site in a country would preclude the inclusion of multiple sites during the same on-site verification audit, the IA is to plan accordingly. The IA is also to consult with OIEA program analysts and Office of Data Integration and Food Protection (ODIFP) statisticians to seek input on the statistical considerations of site selection.

4. After selecting locations to audit, the IA is to develop and submit a proposed audit plan, notification letter, and itinerary to the IAS Director for review 35 working days prior to the entrance meeting and:

    a. Set the time and date for a pre-exit meeting with OPPD;

    b. Review Animal and Plant Health Inspection Service (APHIS) animal disease status for the applicant country;

    c. Complete FSIS – OA Foreign Travel Auth Request form to request travel authorization through the Office of the Administrator (OA) for the Administrator's signature; and

    d. Submit a proposed audit itinerary to the CCA through OIC.

5. Within 30 working days prior to the entrance meeting, the IA is to:

    a. Submit an AD-121 passport/visa request;

    b. Prepare a country clearance letter for transmission through OIC;

    c. Schedule an in-country meeting through OIC with the Foreign Agricultural Service (FAS); and

    d. Finalize translation arrangements, the audit itinerary, and logistics (e.g., lodging, daily schedule, flight/transportation schedules) with the CCA through OIC.

6. Within 15 working days prior to the entrance meeting, the IA is to:

    a. Collate audit forms;

    b. Assemble relevant FSIS and CCA documents (e.g., statutes, regulations, directives, notices, compliance guides);

    c. Secure their passports, visas, country clearances (eCC), and travel authorizations;

    d. Prepare and clear entrance slides with IAS Director. Entrance slides are to outline the audit objectives, scope, and itinerary;

    e. Conduct a pre-entrance meeting with IES and OIC; and

f. Secure loaner USB secure storage drive, laptop, and cell phones.

VII. PROCEDURES RELATED TO THE CONDUCT OF THE ON-SITE VERIFICATION AUDIT

A. Based on the EO's analysis of documentation collected from the CCA through the SRT, the EO should have enough information to make a tentative determination as to whether a country's food safety inspection system is equivalent to that of FSIS. Only after an on-site verification audit is actually conducted, and verifies adequate implementation of an equivalent system can the Agency determine whether to initiate rulemaking to add the country to the list of countries eligible to export meat, poultry, or egg products to the U.S. in the CFR. In some cases, the equivalence process may require more than one audit to verify implementation of corrective actions by the foreign government in response to prior findings. Similarly, FSIS may need to conduct an on-site verification audit to reinstate a country that has been inactive for three or more years. The on-site verification audit is necessary to provide the basis for a determination of initial equivalence, and may be necessary for a reinstatement of equivalence determination. The on-site verification audit allows FSIS to assess operational equivalence by observing the CCA's implementation of the requirements it would enforce should FSIS grant equivalence.

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

C. Upon arrival in-country, the IA is to meet with FAS, if requested by FAS, to provide a courtesy briefing that outlines the audit objective, scope, and itinerary and obtain a security and protocol briefing from FAS.

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

E. In accordance with the Audit Verification Plan, the IA is to examine a representative and informative sample of procedures, documents, and records that evidence the importing country's regulatory activities and accompany CCA officials on field visits to a representative sample of locations identified in the audit plan.

F. If the IA identifies potential findings during the on-site verification 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.

G. The IA is to provide a briefing report during the on-site verification audit to the IAS and IES Directors approximately every three working days. In cases where an observation constitutes a public health concern, the IA is to immediately inform the IAS and IES Directors.

H. 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 establishment or facility is meeting the applicable requirements; and

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

I. The IA is to prepare exit conference slides and hold a pre-exit conference call with the IAS Director, IES Director, OIC, and EO are to review and approve the preliminary audit findings and content of the slides. The exit slides are to outline the audit standards, scope, and 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, and subsequently in the draft audit report as a finding for which the country will need to provide an explanation or corrective action in order to gain equivalence or

reinstatement, as described in *FSIS Directive 9790.1*, *Writing an Audit Report of Foreign Food Safety Inspection Systems*. The exit slides are also to convey information on post-audit activities, specifically the steps involved with drafting, reviewing, and publishing the audit report, and the steps involved in a rulemaking associated with FSIS recognition of the equivalence of the country's food safety inspection system.

J. At the exit conference and at the direction of the IAS Director, 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.

VIII. EQUIVALENCE COMPONENT REVIEW

A. Upon return to the U.S., the IA is to work with the EO to review audit findings and verify whether the food safety inspection system met each equivalence component by taking into account the impact of audit findings. The IA is to enter observations and analysis into the Onsite Analysis-Comments and Onsite Analysis-Findings sections into the CAVF in PHIS.

NOTE: As needed, the IA and EO are to consult with subject matter experts during the equivalence component review.

B. The IA is to consider the implementation of the foreign country's food safety inspection system as follows:

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, and 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.

C. The IA is to verify whether each equivalence component passes or fails, based on an assessment of the country's ability or inability to implement its food safety inspection system and the effectiveness of the inspection system.

D. To assess the adequacy of corrective actions submitted by the CCA in response to audit findings, the IA, in consultation with the EO and subject matter experts, is to determine whether the proposed corrective action satisfies FSIS requirements:

1. For findings associated with written requirements, a document review may be sufficient to verify that an equivalent food safety inspection system was implemented. For example, revision of a laboratory protocol in response to audit findings when FSIS did not identify overarching implementation concerns may be sufficiently verified through the document review process.

2. In general, findings associated with implementation of programs for any equivalence component will require an additional on-site verification audit to evaluate equivalence. If findings are associated with the type and extent of CCA monitoring and verification of establishment food safety inspection systems, the CCA's proposed corrective actions in terms of their *potential* to adequately verify process control are to be evaluated. A determination will require verification through direct, on-site observation.

IX. DRAFTING THE AUDIT REPORT

A. Within 60 working days of completing the initial on-site verification audit, the IA is to prepare a cover letter and draft audit report for review by the IAS Director.

B. The IAS Director is to review and clear the draft audit report and cover letter and send the package to the OIEA AA for review and clearance before transmitting for AA and eventual OA review and clearance.

C. After the draft audit report has cleared AA and OA review, the IA is to send the draft audit report to the CCA through OIC for review and comment and inform the CCA that it has 60 working days to provide comments on the draft report.

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

D. Once comments and corrective actions have been received from the CCA and analyzed by the EO and, if applicable, subject matter experts, the IA is to complete and circulate a draft final audit report to the IAS Director, then OIEA AA for clearance within 20 working days.

E. The IA has 10 working days to incorporate comments from the clearance review into a final audit report and cover letter for concurrence by the IAS Director and the OIEA AA.

F. Following OIEA AA clearance, the IA is to clear the final report through AA clearance followed by OA clearance.

G. Upon final clearance, the IAS Director is to prepare the cover letter and final audit report for delivery to the CCA through OIC. This includes the electronic transmission of a scanned PDF copy of the audit report to the CCA and FAS post. The IAS Director is to ensure that the final audit report is posted to FSIS' website.

X. DRAFTING A PROPOSED AND FINAL RULE TO ADD A COUNTRY TO THE LIST OF EXPORT-ELIGIBLE COUNTRIES IN THE CODE OF FEDERAL REGULATIONS

A. After publication of the audit report, the EO is to prepare a Decision Memorandum for the OPPD AA that summarizes the analysis of the SRT document review and results of the on-site verification audit in Sections V and IX above. The Decision Memorandum is to include the rationale for country equivalence, the compilation of results, the summary of the equivalence review, and the description of how all the issues from the SRT document review and systems related on-site verification audit findings were resolved. A recommendation for equivalence means the country's SRT responses and any corrective actions submitted in response to audit findings were assessed and determined to meet the equivalence criteria. This rationale for tentatively concluding that the country's food safety inspection system is equivalent to FSIS' system will be the basis for the proposed rule. Once the OPPD AA concurs, he or she is to brief the Administrator with the recommendation for equivalence.

B. Once the Administrator approves the equivalence determination, the EO is to work with the OPPD Issuances Staff (IS) to draft a proposed rule to add the country to the list of countries eligible to export meat, poultry, or egg products to the U.S. and follow the process for developing, clearing, and publishing proposed rules in the *Federal Register*. The EO is also to draft and send a letter to the CCA notifying the country that FSIS has determined that its food safety inspection system is equivalent and is proceeding with rulemaking. The cover letter is also to request the country provide the information described in the

attachment, *Regulatory Impact Analysis Information*, should FSIS determine the CCA's food safety inspection system to be equivalent. The information described in the attachment is needed to complete the regulatory impact analysis associated with a proposed rule to add the country to the list of countries in the CFR as eligible to export meat, poultry, or egg products to the U.S. The EO is to have the IES Director review and clear, then the OPPD AA review and concur, and then send to OIC for review and transmittal.

C. The EO is to work with IS to review any comments that are received on the proposed rule. The EO is to consult subject matter experts to develop agency responses and follow the process for developing, clearing, and publishing final rules in the *Federal Register*.

D. Once the final rule is published, the EO is to draft a letter to advise the CCA of the publication of the final rule in the *Federal Register*, identify the effective date of the final rule, and provide information on the next steps, labeling, and requirements for certifying establishments for export. The letter must emphasize that no product will be allowed entry into the U.S. until after the effective date in the published final rule. The EO is to have the IES Director review and clear, then the OPPD AA review and concur, and then send to OIC for review and transmittal.

XI. QUESTIONS

Refer questions through supervisory channels.

Assistant Administrator
Office of Policy and Program Development

Regulatory Impact Analysis Information

This attachment describes the information, in the form of questions to the CCA, that is needed by the PAS, OPPD, to complete a regulatory impact analysis associated with the publication of a proposed rule to add the country to the CFR as eligible to export meat, poultry, or egg products to the U.S.

Requested information includes:

1. At the national level:

    a. For the past 5 years, what was the **national production volume** of relevant product? *Please provide this information specifying it by product type and with annual weight labeled in either kilograms or pounds.*
    b. For the past 5 years, what were the **average domestic whole sale prices** for relevant products? *Please provide this information specifying it by product type and labeled in local currency per kilogram or pound.*
    c. For the past 5 years, what amount of **export tariffs or subsidies**, if any, was exported product subject to? *Please provide this information specifying tariffs or subsidies by product type and labeled in local currency per kilogram or pound.*

2. For the initial set of establishments to be certified as eligible to export to the U.S.:

    a. What is the estimated **number of initial establishments** that will be certified to export to the U.S.?
    b. For the past 5 years, what was the **production volume of** each of these establishments? *Please provide this information specifying it by product type and with annual weight labeled in either kilograms or pounds.*
    c. For the past 5 years, what was the **export volume** of each of these establishments? *Please provide this information specifying it by product type, destination country and with annual weights labeled in either kilograms or pounds.*
    d. For the next 5 years, what is the **projected volume** each establishment expects to export to the U.S.? *Please provide this information specifying it by product type and with annual weights labeled in either kilograms or pounds.*

3. In addition to the initial establishments:

    a. What is the **estimated number of additional establishments** expected to pursue eligibility to export to the U.S.?
    b. For the past 5 years, what was the **production volume of** each of these establishments? *Please provide this information specifying it by product type and with annual weight labeled in either kilograms or pounds.*
    c. For the past 5 years, what was the **export volume** of each of these establishments? *Please provide this information specifying it by product type, destination country and with annual weights labeled in either kilograms or pounds.*
    d. What is the **projected export volume** each of these additional establishments expects to export to the U.S.? *Please provide this information specifying it by product type and with annual weights labeled in either kilograms or pounds.*