

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

FSIS NOTICE

25-18

4/30/18

CRITERIA FOR RECOMMENDING AN ONSITE VERIFICATION AUDIT AS PART OF A REINSTATEMENT OF EQUIVALENCE DETERMINATION OR WHEN MAKING AN EXPANSION OF INITIAL EQUIVALENCE DETERMINATION REGARDING EQUIVALENT COUNTRY REQUESTS TO ADD A NEW SPECIES/PROCESS CATEGORY

I. PURPOSE

The purpose of this directive is to provide instructions to the International Equivalence Staff (IES), Office of Policy and Program Development (OPPD), for recommending an onsite verification audit as part of a reinstatement of equivalence determination process; making an expansion of initial equivalence determination on equivalent country requests to add a new species in a raw inspection system (i.e., Raw-Intact and Raw-Non Intact processing categories); and for addressing a country request to add a new processing category in a processed products inspection system (i.e., Thermally Processed-Commercially Sterile, Not Heat Treated-Shelf Stable, Heat Treated-Shelf Stable, Fully Cooked-Not Shelf Stable, Heat Treated-Not Fully Cooked-Not Shelf Stable, Products with Secondary Inhibitors-Not Shelf Stable, or Egg Products processing categories). This directive also provides instructions to IES for notifying the International Audit Branch (IAB), Management Control and Audit Division (MCAD), Office of Investigation, Enforcement and Audit (OIEA); the Recall Management and Technical Analysis Division (RMTAD), Office of Field Operations (OFO); and the Office of International Coordination (OIC) that IES recommends an onsite verification audit. Onsite verification audits that are performed as part of the reinstatement of equivalence determination process are described in [FSIS Directive 9770.1](#), *Determining Initial and Reinstating the Equivalence of Foreign Food Safety Inspection Systems*.

II. BACKGROUND

A. FSIS's 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 Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA). FSIS evaluates the equivalence of foreign countries meat, poultry, or egg product inspection systems to ensure that requirements set forth in 9 CFR 327.2 for meat products, 9 CFR 381.196 for poultry products, and 590.910 for egg products are met.

B. A country must request a reinstatement of equivalence when it has been three or more years since the country has exported meat, poultry, or egg products to the United States (U.S.) and the country wants to resume exporting such products to the U.S. On an annual basis IES will request and review official Agency import data for the previous three years to determine what species in a raw inspection system or processing category in a processed products inspection system require a reinstatement of equivalence before the country can resume shipping.

C. A country also needs to request an expansion of initial equivalence determination when a country wants to export a new species in a raw inspection system or a new processing category in a processed products inspection system. In both cases, FSIS will need to complete a document review of the Central

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Competent Authority's (CCA) Self-Reporting Tool (SRT) responses and supporting documentation, and may require an FSIS onsite verification audit, as described in [FSIS Directive 9770.1](#).

D. A reinstatement of equivalence or an expansion of initial equivalence establishes that a foreign food safety inspection system remains equivalent to the U.S. system or is equivalent for additional products or species and is only applicable to countries listed in Title 9 Code of Federal Regulations (CFR) as having an equivalent inspection system for meat, poultry, or egg products.

NOTE: For the purpose of equivalence determinations, species in a raw inspection system are categorized as adult cattle (i.e., beef), veal, pork, sheep (which includes lamb and mutton), goats, poultry, ratites, and egg products. The [FSIS Product Categorization](#) guide describes the process categories.

III. CRITERIA FOR WHEN AN ONSITE VERIFICATION AUDIT IS NEEDED FOR REINSTATEMENT OF EQUIVALENCE OR AN EXPANSION OF INITIAL EQUIVALENCE TO ADD A NEW SPECIES OR PROCESS CATEGORY TO AN EQUIVALENT COUNTRY

A. After the Equivalence Officer (EO) completes the document review, he or she updates the Component Analysis Verification Form (CAVF) in the Public Health Information System and makes a tentative determination of reinstatement of equivalence or expansion of initial equivalence based on the CCA's SRT responses and supporting documentation. The EO is to determine whether to recommend an onsite verification audit as part of a reinstatement of equivalence or expansion of initial equivalence determination. The EO is to recommend an onsite verification audit when:

1. It has been three or more years since the country has exported an equivalent species in a raw inspection system or processing category in a processed products inspection system (e.g., a country is listed in the CFR as equivalent for meat but has not exported raw beef in more than three years due to an Animal and Plant Health Inspection Service (APHIS) disease restriction such as Bovine Spongiform Encephalopathy (BSE). Upon APHIS lifting the disease restriction, the country will need to obtain a reinstatement of equivalence determination prior to resuming exportation of raw beef to the U.S.);
2. A country requests to export a new species in a raw inspection system or processing category in a processed products inspection system; or
3. FSIS has identified adulterants, such as Shiga toxin-producing *Escherichia coli* (STEC) in raw beef and veal products, and *Salmonella* and *Listeria monocytogenes* in ready-to-eat meat and poultry, and processed egg products.

B. It is not anticipated that an onsite verification audit will be necessary when FSIS has audited and verified the suitability of the raw source materials for pork, sheep, goats, poultry, and ratites within the last three years, and the CCA is now requesting an equivalence determination to use the raw source in a processed products inspection system. Additionally there are no microbiological pathogens in the raw source materials that would adulterate the product (e.g., a country has been found equivalent to export a cooked pork product to the U.S. using raw source materials produced in country and now the country wants to also export raw pork products to the U.S.). Note, however, FSIS will conduct an onsite verification audit within six months for countries that have had their equivalence reinstated or expanded, and that did not require an onsite verification audit as part of that reinstatement or expansion of initial equivalence determination.

NOTE: If the previously conducted audit of the processed products inspection system identified findings associated with implementation of programs for raw source materials, the EO is to recommend an onsite verification audit to verify implementation of associated corrective actions through direct observation.

C. The EO is to document his or her recommendation and rationale in either the Decision Memorandum to Audit or the Decision Memorandum to Reinstate Equivalence or Expansion of Initial Equivalence. The

EO is to follow the instructions provided in [FSIS Directive 9770.1](#) to prepare the referenced Decision Memorandum for IES Director's review and once cleared by the IES Director, is to send the Decision Memorandum to the OPPD Assistant Administrator (AA) for review and concurrence.

D. The IES Director is to notify the IAB Branch Chief, Branch Chief of OFO RMTAD-Imports Headquarters staff, and OIC in writing with the signed Decision Memorandum of IES's recommendation to perform an onsite verification audit as part of the equivalence reinstatement or expansion of initial equivalence process.

IV. QUESTIONS

Refer questions through supervisory channels.

A handwritten signature in black ink that reads "Alexander J. Wagner". The signature is written in a cursive style with a large, stylized initial "A".

Assistant Administrator
Office of Policy and Program Development