

One Team, One Purpose



Food Safety and Inspection Service
Protecting Public Health and Preventing Foodborne Illness



The FSIS Equivalence Process: Overview of Meeting



- What is Equivalence?
- Equivalence Background
- Types of Equivalence Determinations and the Process Steps
 - ✓ Initial
 - ✓ Ongoing
 - ✓ Reinstatement
 - ✓ Individual Sanitary Measure

2

Thank you for your interest in learning about the Food Safety and Inspection Service's (FSIS) equivalence determination processes. In this presentation I will first explain what equivalence is. Then I'll discuss the origin of equivalence and FSIS's requirements. Following that, I'll discuss the four (4) types of FSIS's equivalence determinations, which includes initial, ongoing, reinstatement, and individual sanitary measure, and the process steps involved for each type of equivalence determination.

Equivalence:
What is Equivalence?

What is Equivalence?

3

In order to understand FSIS's equivalence determination processes, let's first start out by clarify what equivalence means.

Equivalence: What is Equivalence?

Equivalence is the process of determining whether a country's food safety inspection system achieves FSIS's appropriate level of protection of public health as applied domestically in the US



4

Equivalence is the process of determining whether a country's food safety inspection system achieves FSIS's appropriate level of protection for public health as applied domestically in the United States (US).

Equivalence: What is Equivalence?

The country's food safety inspection system is also to provide standards equivalent to FSIS to ensure other non-food safety requirements are met, such as

- Humane handling
- Accurate labeling
- Assurance that products are not economically adulterated



5

The country's food safety inspection system is to provide standards equivalent to FSIS to ensure other non-food safety requirements are met, such as humane handling, accurate labeling, and assurance that meat, poultry, or egg products are not economically adulterated.

Equivalence: What is Equivalence?

Equivalence is the process by which the country must objectively demonstrate how its procedures meets the US level of protection

Equivalence does not mean that the country is required to develop and implement the same procedures as the US



6

Equivalence does not mean that the country is required to develop and implement the same procedures that the US does, but rather the country must objectively demonstrate how its procedures meets the US level of protection.

Countries wishing to become eligible to export meat, poultry, or egg products to the US must demonstrate that they have a regulatory food safety inspection system that is equivalent to that of the US.

Equivalence:
Why is This Important?

Equivalence Background

7

FSIS is the US Central Competent Authority (CCA) responsible for regulating and inspecting meat, poultry, and egg products.

The CCA is a country's national government authority that is responsible for ensuring the safety and truthful labeling of the food supply.

FSIS implements an equivalence determination process to ensure that US treaty obligations under the World Trade Organization's (WTO) *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement) are met.

Equivalence:

What is the WTO/SPS Agreement?

WTO/ SPS Agreement:

- Establishes that all countries maintain measures to ensure that food is safe for consumers, and to prevent the spread of pests or diseases among animals and plants
- Sets out the basic rules for food safety and animal and plant health standards

Principles:

- Science
- Risk Assessments
- Transparency
- Harmonization
- Equivalence

8

The World Trade Organization's (WTO)/Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) sets out the basic international rules for food safety, animal, and plant health standards.

FSIS ensures during the equivalence process that SPS Agreement principals are implemented.

Equivalence: FSIS Determinations

FSIS Equivalence Requirements

- FSIS statutes require countries meat, poultry, and egg products regulatory food safety inspection systems to be “equivalent to” FSIS requirements
- Regulatory requirements for equivalence are set forth in Title 9 of the Code of Federal Regulations (CFR):
 - § 327.2 for meat products
 - § 557.2 for fish of the order Siluriformes products
 - § 381.196 for poultry products
 - § 590.910 for egg products.

9

To ensure that meat, poultry, or egg products (including imported products) do not pose any public health risks to US consumers, FSIS implements the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), Egg Products Inspection Act (EPIA), Humane Methods of Slaughter Act (HMSA), and regulations under Title 9 Code of Federal Regulations (CFR) Parts 300-590.

FSIS ensures that a country’s food safety inspection system addresses FSIS’s food safety regulatory-based objectives. Food safety regulatory-based objectives are food safety goals for preventing the occurrence of an identified food safety hazard.

The criteria by which FSIS assesses the equivalence of a country’s food safety inspection system can be found under Title 9 CFR §327.2 (for meat products), §557.2 (for fish of the order Siluriformes products), §381.196 (for poultry products), and §590.910 (for egg products).

Equivalence: Why is This Important?

Importance Of Equivalence

- Protects public health
 - Facilitates trade
- World Trade Organization's (WTO)/Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)
 - Equivalence determinations of an exporting country's regulatory food safety inspection system for meat, poultry, or egg products is a **prerequisite for trade** with the US

10

Determining equivalence of a country's food safety inspection system is important because it protects public health and facilitates trade.

An equivalence determination of an exporting country's regulatory food safety inspection system for meat, poultry, or egg products is a prerequisite for trade for the United States Department of Agriculture's (USDA) FSIS.

Equivalence:
US Equivalence Reviews

**Types of Equivalence
Determinations and the Process
Steps**

11

Now that we have a better understanding of what equivalence is and FSIS's statutory and regulatory requirements associated with equivalence determinations, let's discuss FSIS's different equivalence determinations and the process steps.

Equivalence: US Equivalence Determinations

Types of US equivalence determinations:

- *Initial equivalence*
- *Ongoing equivalence verification*
- *Reinstatement of equivalence*
- *Individual sanitary measure*

FSIS evaluates exporting country's inspection system for equivalence through document review, on-site audits, and point-of-entry reinspection of product at the time of importation

12

There are four (4) types of equivalence determinations:

- (1) Initial Equivalence,
- (2) Ongoing Equivalence Verification,
- (3) Reinstatement of Equivalence, and
- (4) Individual Sanitary Measure.

Equivalence: Initial Equivalence

Initial equivalence is undertaken when a country wants to export meat, poultry, or egg products to the US for the first time

Initial Equivalence Process:

1. Country Submits Written Request to FSIS
2. Document Submission through Self-Reporting Tool
3. Document Review
4. On-Site Verification Audit
5. Public Notification-Proposed Rule in *Federal Register*
6. Final Determination of Equivalence- Final Rule in *Federal Register*; FSIS sends the country a letter
 - Requesting a sample health certificate and list of eligible certified establishments approved by the CCA to export to the US; and
 - Instructions about exporting meat, poultry, or egg products to the US

13

Initial Equivalence Process is undertaken when countries want to export meat, poultry, or egg products to the US for the first time. FSIS evaluates a country's food safety inspection system to make an initial equivalence determination before the country can export products to the US. This process is for countries that are not listed in the CFR as eligible to export meat, poultry, or egg products.

1. To start the initial equivalence process, countries are to have their CCA contact FSIS's Office of International Coordination (OIC) by sending a formal written request to start the initial equivalence process.
2. In response to a country's request, FSIS will send the country a packet of information that includes guidance and a Self-Reporting Tool (SRT). We will discuss what the SRT is on the next slide.
3. After FSIS receives an SRT with all referenced supporting documentation, FSIS reviews and decides whether the country's food regulatory system meets all US import requirements in an equivalent manner and cumulatively provides the level of public health protection as that attained domestically.
4. An on-site verification audit is an audit of the country's food safety inspection system with the goal of verifying, through objective evidence, that the country's inspection system has an equivalent level of public health protection as applied domestically in the US.

5. Based on the outcome of FSIS's SRT and supporting documentation review and the on-site audit, FSIS initiates rulemaking to propose that the country be listed in the CFR as eligible to export meat, poultry, or egg products to the US.
6. FSIS analyzes any received comments and publishes a final rule to list the country in the CFR as eligible to export meat, poultry, or egg products to the US. FSIS sends the country a notification letter about the published rule. The letter includes instructions about exporting meat, poultry, or egg products to the US.

Equivalence: Initial Equivalence What Is An SRT?

The **Self-Reporting Tool (SRT)** is a questionnaire that provides an organized means for the country's government to demonstrate that its inspection system achieves an equivalent level of protection

Six Equivalence Components:

- Government Oversight (e.g., Organization and Administration)
- Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling)
- Government Sanitation
- Government Hazard Analysis and Critical Control Point (HACCP) System
- Government Chemical Residues Testing Programs
- Government Microbiological Testing Programs

14

The SRT is a questionnaire that provides an organized means for the country's government to demonstrate that its inspection system achieves an equivalent level of protection as applied domestically in the US.

The SRT is arranged into six (6) components:

1. Government Oversight (e.g., Organization and Administration)
2. Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling)
3. Government Sanitation
4. Government Hazard Analysis and Critical Control Point (HACCP) System
5. Government Chemical Residues Testing Programs
6. Government Microbiological Testing Programs

Please refer to the SRT and the presentation on *How to Complete and Submit the SRT Using the Public Health Information System (PHIS)* for additional information on how a country should categorize its food safety inspection system, respond to the SRT, and submit a completed SRT to FSIS for review.

Equivalence:

Initial Equivalence

What Is An On-Site Verification Audit?

On-site verification is a system audit with the goal to verify through objective evidence that the foreign country's inspection system meets US levels of protection

When the document review process shows the country's system to be satisfactory, a technical team will visit the country for an on-site audit

Audit Objectives

- To verify that the country possesses an equivalent inspection system that attains US levels of protection

The Scope Of The Audit

- Includes all aspects of the inspection system regulating meat, poultry, or egg products

Audit Team

- Consists of one or more FSIS International Auditors

15

An on-site verification audit is an audit of the country's food safety inspection system with the goal of verifying, through objective evidence, that the country's inspection system has an equivalent level of public health protection as applied domestically in the US. If FSIS determines that a country's food safety inspection system is tentatively equivalent based on the SRT document review process, OIC will work with the country's CCA to arrange an on-site verification audit of the country's food safety inspection system.

Initial equivalence audits are conducted by FSIS International Auditors. The audit scope includes visual observations of all aspects of the country's food safety inspection system.

Equivalence:

Initial Equivalence

What Is An On-Site Verification Audit?

Technical team identifies appropriate locations to conduct the system audit within these sectors:

- Government offices (*central, regional, local*)
- Establishments (*slaughter, processing, and cold storage*)
- Laboratories

After the audit...

- FSIS sends the draft audit report to the country
- FSIS reviews and incorporates the country's comments
- FSIS issues the final audit report

16

During the on-site audit, International Auditors verify that the CCA implements, monitors, and verifies all of the procedures in the country's food safety inspection system. Typically, International Auditors will need to visit multiple sites that may include the following:

- Central, regional, and local government offices;
- Exporting establishments (slaughter and processing establishments) and warehouses (including cold storage); and
- Laboratories.

After the on-site audit, FSIS sends a draft audit report to the country applying for equivalence for the country's review and comment. FSIS then takes the country's comments into account and generates the final audit report.

Equivalence:

Initial Equivalence

How is an Equivalence Determination Made?

- The CCA shows through **documentation** that the **design** of its inspection system achieves the appropriate level of public health protection
(**Complete SRT responses with supporting documentation**)
- The CCA shows that it can **implement** the inspection system (e.g., laws, regulations, inspection procedures, and enforcement protocols) documented in the SRT
(**Acceptable audit results**)

17

In order for FSIS to make an initial equivalence determination, the CCA should show through documentation, which includes SRT responses and supporting documentation, that the design of its food safety inspection system achieves an equivalent level of public health protection.

Once the CCA can show through documentation that its food safety inspection system is equivalent, the CCA is to show FSIS that it can implement the inspection system as documented in the submitted SRT responses and supporting documentation.

Equivalent documentation and acceptable audit results will support FSIS to initiate rulemaking by publishing a proposed rule in a Federal Register.

Equivalence: Initial Equivalence Rulemaking

Public Notification through Rulemaking: FSIS initiates a proposed rule after the document review and the on-site audit steps have been satisfactorily completed.

- FSIS publishes a proposed rule in the *Federal Register* to add the country to the list of countries eligible to export meat, poultry, or egg products to the US
- In general, a 60-day period is provided for public comment on the proposed rule
- FSIS reviews and analyzes all comments received
- Based on its review, FSIS makes a final determination about the equivalence application. If positive, FSIS publishes a final rule in the *Federal Register* along with its responses to the public comments

18

Based on the outcome of FSIS's SRT and supporting documentation review and the on-site audit, FSIS initiates rulemaking to propose that the country be listed in the CFR as eligible to export meat, poultry, or egg products to the US. To initiate rulemaking, the country will need to provide 5 years of projected economic analysis information.

Upon publication, the public can submit comments (generally up to 60 days after publication) to FSIS about the proposed rule.

FSIS analyzes any received comments and publishes a final rule to list the country in the CFR as eligible to export meat, poultry, or egg products to the US. FSIS sends the country a letter notifying it of the published rule.

After the rule becomes effective, the country then certifies establishments as being eligible to export meat, poultry, or egg products to the US. After a country has compiled a list of eligible certified establishments, the country sends the completed list to OIC. A **certified establishment** is an establishment that the CCA determines as meeting US requirements and, therefore, eligible to export meat, poultry, or egg products to the US. Additionally, countries are to submit to OIC a sample of the health certificate they propose to use for exported meat, poultry, or egg product shipments to the US. Each eligible country's CCA is responsible for the certification of shipments of meat, poultry, or egg products to the US. Please refer to Title 9 CFR §327.4 (for meat), §557.4 (for fish of the order Siluriformes), §381.197 (for

poultry), and §590.915 (for egg products).

Equivalence: Initial Equivalence Determination

Animal Health Considerations

- Animal and Plant Health Inspection Service (APHIS) determines a country's eligibility to export certain animal products into the US based on the country's animal disease status
- For questions contact APHIS's National Center for Import and Export at:

USDA, Animal and Plant Health Inspection Service
Veterinary Services
National Center for Import and Export
4700 River Road,
Riverdale, MD 20737

Phone: (301) 851-3300, option 1
E-mail: AskNIES.Products@aphis.usda.gov

19

It is important to note that FSIS only determines whether a country's meat, poultry, or egg products food safety inspection system is equivalent. Countries should be aware that animal diseases are regulated by the USDA's Animal and Plant Health Inspection Service (APHIS) (Title 9 CFR Parts 92 through 95), and a country's animal disease status can impact what products the country can export to the US. For a list of USDA-recognized animal health status of countries, please visit APHIS's Animal Disease Status webpage (https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/ct_animal_disease_status).

Equivalence: Starting the Initial Equivalence Determination Process

All equivalence requests, self-reporting tools (SRTs) and supporting documentation, and questions should be directed to FSIS's **Office of International Coordination (OIC)**

US Department of Agriculture
Food Safety and Inspection Service
Office of International Coordination
1400 Independence Avenue, SW
Room 3143, South Building
Washington, DC 20250

Phone: (202) 708-9543

Fax: (202) 690-3856

E-mail: InternationalCoordination@fsis.usda.gov

20

Countries are to contact OIC for:

1. All questions and requests for technical assistance,
2. To submit formal equivalence requests,
3. To submit a paper copy of an SRT and supporting documentation for review, or
4. To notify FSIS that an SRT was submitted in PHIS.

Please submit all written equivalence requests to OIC by e-mail (preferred), mail, or fax.

Equivalence: Ongoing Equivalence

Ongoing equivalence applies to countries currently eligible to export meat, poultry or egg products to the US

FSIS Verification of Ongoing Equivalence:

- **Routine audits of the country's inspection system**
- **Information to provide FSIS annually no later than May 18**
 - Updated SRT responses OR communicate to FSIS that the country has verified its SRT responses and the responses are accurate and complete
 - Up-to-date list of all certified establishments eligible to export to US
 - Updated government residue control program, including previous year's test results and reactions to residue findings
 - Updated microbiological sampling and testing program, including previous year's test results and reactions to findings
- **Reinspection of product at point-of-entry**
 - Country's response to US Point-Of-Entry (POE) violations

21

Ongoing equivalence is applicable to countries that are listed in the CFR as eligible to export to the US and are actively shipping meat, poultry, or egg products to the US. FSIS will continuously evaluate and verify the equivalence of an exporting country's food safety inspection system through a three (3) part process: **(1)** on-site audits, **(2)** document reviews, and **(3)** point-of-entry (POE) reinspection of meat, poultry, and egg products.

FSIS will periodically conduct an on-site audit of every eligible country's food safety inspection system. These audits will be performed by FSIS International Auditors and are similar to the on-site verification audits that FSIS does as part of the initial equivalence process.

Countries are to submit the following for review at least annually **by May 18th**:

1. Either **(1)** updated SRT responses, or **(2)** communicate to FSIS that the Central Competent Authority (CCA) has verified its SRT responses, as recorded in FSIS's Public Health Information System (PHIS) (i.e., by reviewing the SRT electronically in PHIS) or by mailed hard copy of the version of SRT responses FSIS has entered for the CCA, are accurate and complete.
2. An up-to-date list of all certified establishments eligible to export meat, poultry, or egg products to the US.
3. An updated government residue control program, including the previous year's residue test results and reactions to residue findings.

4. Updated government microbiological sampling and testing programs, including the previous year's test results and reactions to **(A)** indicator organism results for intestinal or fecal contamination; **(B)** *Salmonella* and *Campylobacter* results for raw meat and poultry products; **(C)** *Listeria monocytogenes*, *Salmonella*, or other pathogens of public health concern in ready-to-eat (RTE) meat and poultry products and all lots of pasteurized egg products; and **(D)** shiga toxin-producing *Escherichia coli* (STEC) in raw beef products.

All imported shipments of meat, poultry, and egg products that enter the US are presented to FSIS for reinspection. If a POE violation is identified, FSIS notifies the countries, and requests and reviews corrective action responses.

Equivalence: Reinstatement of Equivalence Determination

Reinstatement of equivalence is undertaken when a country wants to start exporting meat, poultry, or egg products **again to the US**

Reinstatement of Equivalence Process:

1. Country submits written request to FSIS
2. Document submission through Self-Reporting Tool
3. Document review
4. On-site Verification Audit may or may not be needed
5. FSIS notifies the country of the reinstatement equivalence determination through a formal written letter

NOTE: Rulemaking is not needed for reinstatement of equivalence determinations

22

Countries wishing to reinstate previous equivalence determinations to start exporting meat, poultry, or egg products to the US again are to send a formal written request to OIC. Reinstatement of equivalence is only applicable to countries who are listed in the CFR as eligible to export to the US, but have not shipped meat, poultry, or egg products to the US for an extended period of time. A possible reason for a country to request a reinstatement of equivalence determination includes the lifting of a trade ban after an extended period of time due to a change in animal disease status allowing the export of certain animal products to the US.

A reinstatement of equivalence process follows the same process as the initial equivalence process, except that the country may be subjected to a verification audit, and will not be subjected to the rulemaking steps. The rulemaking steps are not applicable for a reinstatement of equivalence determination because the country's food safety inspection system has already been determined to be equivalent.

After FSIS completes its document review and, as needed, an on-site verification audit, OIC will notify the country of FSIS's decision through a formal written letter. The letter will discuss FSIS's basis for its decision to reinstate equivalence. If FSIS does not perform an audit as part of the reinstatement of equivalence process, then FSIS will verify the reinstated process during the next scheduled audit.

Equivalence: Individual Sanitary Measure Equivalence Determination

An **individual sanitary measure** is undertaken when a country wants to change a specific food safety procedure in its equivalent food safety inspection system

Individual Sanitary Measure Equivalence Process:

1. Country submits written request to FSIS
2. Document submission through self-reporting tool
3. Document Review
4. FSIS notifies country of its individual sanitary measure equivalence determination through a formal written letter

NOTE: Rulemaking is not needed for individual sanitary measure equivalence determinations

23

Countries wishing to change a procedure (sanitary measure) that the US has previously determined to be equivalent in their food safety inspection system are to send a formal written request to OIC. An individual sanitary measure is only applicable to countries who are listed in the CFR as eligible to export to the US, but want to change a previously determined equivalent procedure in their food safety inspection system. An example of an individual sanitary measure equivalence determination request is when a country wants to change its postmortem inspection procedures for livestock from traditional (hands-on) inspection to visual assessment.

An eligible country is to request an individual sanitary measure equivalence determination before the country implements the new procedure on products destined for export to the US. Countries are to submit a formal written request for an individual sanitary measure to FSIS's OIC. If a country does not notify FSIS of changes in its food safety procedures, a possible disruption of trade could result. FSIS will evaluate a request for an individual sanitary measure equivalence determination to ensure that the new procedure:

- Is equivalent to FSIS's relevant food safety regulatory objective-based criteria, and
- Achieves an appropriate level of protection from identified food safety hazards.

Countries that request an individual sanitary measure will need to update their SRT and submit supporting documentation to FSIS for review. The submitted

documentation should demonstrate that the measure provides an equivalent level of public health protection.

After FSIS completes its review, OIC will notify the country of FSIS's decision through a formal written letter. The letter will discuss FSIS's basis for its decision to either accept or reject the proposed individual sanitary measure. If FSIS accepts the individual sanitary measure, FSIS will verify the application of the individual sanitary measure during the next scheduled on-site verification audit.

Equivalence:

An Example of an Equivalent Food Safety Procedure Different from FSIS

Using a Sanitary Dressing Program to Ensure Raw Beef Products Are Free of Shiga Toxin-Producing *Escherichia coli* (STEC)

- FSIS has a food safety objective-based criterion that the CCA ensures that raw beef products are free of STEC at the end of the production process.
- In the US, beef slaughter and processing establishments use a combination of antimicrobial treatments and sanitary dressing procedures to control STEC.
 - Controls implemented focus on carcasses and other conditions (i.e. High Event Periods) and classes of raw beef products with increased likelihood of detecting STEC.

24

FSIS has a food safety objective-based criterion that requires the CCA to ensure that raw beef products are free of STEC at the end of the production process. In the US, beef slaughter and processing establishments use a combination of antimicrobial treatments and sanitary dressing procedures to control STEC.

Equivalence:

An Example of an Individual Sanitary Measure Equivalence Determination

Using a Sanitary Dressing Program to Ensure Raw Beef Products Are Free of Shiga Toxin-Producing *Escherichia coli* (STEC)

- Other countries prohibit the use of antimicrobial treatments and have submitted requirements that raw beef establishments are to implement robust sanitary dressing procedures to prevent STEC .
 - The CCA has verification procedures (including rigorous microbial sampling) that demonstrate sanitary dressing procedures ensure that raw beef products are free of STEC at the end of the process.
 - The CCA's controls include a focus on carcasses as well as other conditions (high event periods) and classes of raw products that collectively increase the likelihood of detecting STEC if present.
 - Based upon the evaluation of the CCA's verification procedures, controls, and receipt and evaluation of ongoing microbial results from the CCA, FSIS has determined this approach to be equivalent because the CCA demonstrates that it meets the food safety criterion.

25

However, other countries prohibit the use of antimicrobial treatments and have submitted requirements that raw beef establishments are to implement robust sanitary dressing procedures with additional controls and government verification procedures to prevent STEC.

In this situation, the CCA has verification procedures (including rigorous microbial sampling) that demonstrate sanitary dressing procedures ensure that raw beef products are free of STEC at the end of the production process. Additionally, the CCA's controls include a focus on carcasses as well as other conditions (high event periods) and classes of raw products that collectively increase the likelihood of detecting STEC if present. Based upon the evaluation of the CCA's verification procedures, controls, and receipt and evaluation of ongoing microbial results from the CCA, FSIS has determined this approach to be equivalent because the CCA demonstrates that it meets the food safety criterion.

Equivalence:
Contact Information

Contact Information:

US Department of Agriculture
Food Safety and Inspection Service
Office of International Coordination
Room 3143, South Building
1400 Independence Ave SW
Washington D.C. 20250-3700

Phone: 202-708-9543

Fax: (202) 690-3856

E-mail: InternationalCoordination@fsis.usda.gov

26

For all questions, including technical and equivalence questions, please contact OIC through methods listed above.

Equivalence:
Questions

