



# **Process for Evaluating the Equivalence of Foreign Meat and Poultry Food Regulatory Systems**

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Food Safety and Inspection Service

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# Introduction

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- Introduction
- Background
- Concepts of Equivalence
- FSIS Equivalence Determinations
- Equivalence Verification
- Reference Material/Contact Information



# Introduction

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- Imported meat, poultry, and egg products must meet all safety standards applicable to similar products produced in the United States.



# Introduction

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- The concept that different sanitary measures can achieve the same level of protection is called equivalence.



# Introduction

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- The Food Safety and Inspection Service (FSIS) evaluates foreign meat and poultry food regulatory system equivalence through a process that consists of
  - Document Analysis,
  - On-Site Audit, and
  - Port-of-Entry Reinspection.



## Background

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- International food safety equivalence is a concept introduced by the *Agreement on the Application of Sanitary and Phytosanitary Measures*, or the “SPS Agreement.”



# Background

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- The burden for demonstrating equivalence rests with an exporting country.



## Key Terms

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- Equivalence: The state wherein sanitary measures applied in an exporting country, though different from the measures applied in an importing country, achieve, as demonstrated by the exporting country, the importing country's appropriate level of sanitary protection.





## Key Terms

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- *Food Safety Hazard*: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse human health effect.



## Key Terms

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- Sanitary Measure: Any measure applied:
  - (a) to protect animal life or health from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;



# Sanitary Measure

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- (b) to protect human or animal life or health from risks arising from additives, contaminants, and/or toxins.



## Key Terms

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- *Appropriate level of protection*: The level of protection from a food safety hazard that is deemed appropriate by a country in establishing a sanitary measure to protect human life or health within its territory.
- Also referred to as the “acceptable level of risk”



# Concepts of Equivalence

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- *Sanitary Measures*

- Sanitary measures **must**

- be based upon scientific principles and
    - be applied by an importing country in a manner that is not arbitrary and would not unjustifiably discriminate between its own industry and that of another country.



## Concepts of Equivalence

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- *Appropriate Level of Protection (ALOP)*
  - Importing countries may set any level of protection they deem appropriate and establish sanitary measures accordingly to eliminate or abate food safety hazards.



# FSIS Equivalence Determinations

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- FSIS makes two different types of equivalence determinations:
  - Initial Equivalence
  - Individual Sanitary Measures



## Initial System Equivalence

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- Normally, the application process begins with a letter to FSIS from a foreign government asking for approval to export its products for sale in the United States.





## Initial System Equivalence

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- FSIS responds to these letters with a standard package that contains two components:
  - Questionnaires designed to collect detailed information about the foreign food regulatory system;



# Initial System Equivalence

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- Copies of pertinent U.S. laws, FSIS regulations, and other documents that set forth meat and poultry food regulatory policy.



# Document Review

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- Self-Assessment Tool
  - Designed to assist countries in providing detailed information for 6 equivalence components: Government Oversight, Statutory Authority and Food Safety Regulations, Sanitation Controls, HACCP Systems, Chemical Residue Control Programs, and Microbiological Testing Programs



# Initial System Equivalence

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- Upon completion of the document analysis step, FSIS decides whether the foreign food regulatory system documentation:
  - (1) meets all U.S. import requirements in the same or an equivalent manner, and
  - (2) cumulatively provides the *same* level of public health protection attained domestically.



## Initial System Equivalence

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- When both the document analysis and on-site audit steps have been completed, FSIS publishes a proposed rule in the *Federal Register* that announces results of the first two steps and proposes to add the country to its list of eligible exporters in the Code of Federal Regulations.



## Initial System Equivalence

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- Upon receipt of public comments, FSIS makes a final decision about system equivalence based upon all available information and—if favorable—publishes a final rule in the *Federal Register* announcing country eligibility.



## Alternative Sanitary Measures

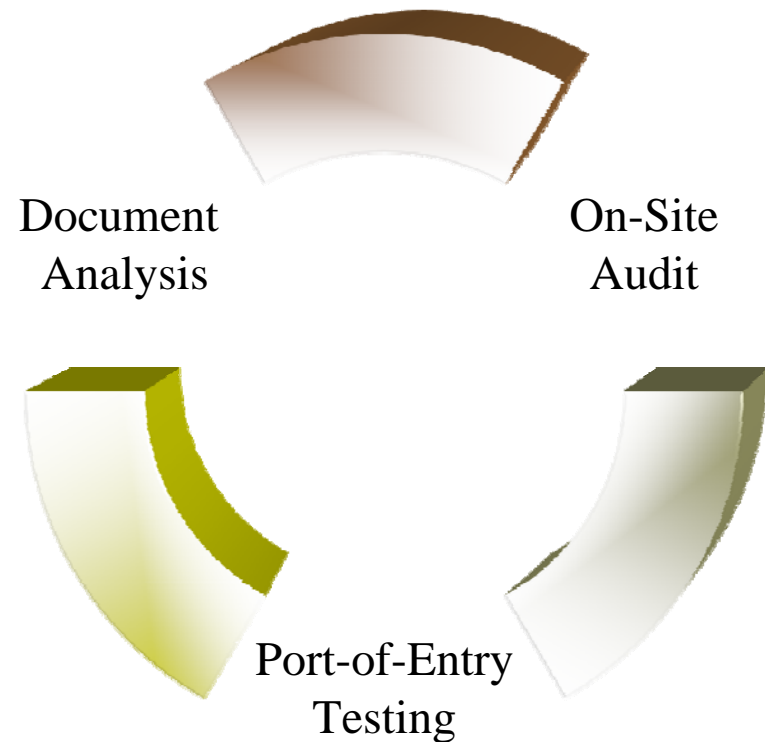
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- Document Review
- Measures are verified on-site during the next scheduled audit.

# Equivalence Verification

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- Document analysis
- On-Site Audit
- Port-of Entry Testing







# Equivalence Verification: Document Analysis

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- The purpose of a recurring document analysis is threefold:
  1. Verification
  2. Examination
  3. Evaluation



## Equivalence Verification: On-Site Audits

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- The system audit focuses on two essential components of safe food production:
  1. Process Control
  2. Regulatory or System Control



## **Equivalence Verification: Port-of-Entry Reinspection**

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- FSIS reinspects 100% of all imported meat, poultry and egg product shipments



# FSIS Reference Material

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- USDA, FSIS Equivalence Information
  - [http://www.fsis.usda.gov/Regulations\\_&Policies/equivalence\\_process/index.asp](http://www.fsis.usda.gov/Regulations_&Policies/equivalence_process/index.asp)
  
- U.S. Regulatory Requirements
  - <http://www.gpoaccess.gov/cfr/index.html>
  - 9 CFR 327.2 (a)(2) for meat, 9 CFR 381.196 (a)(2) for poultry



## FSIS Contact Information

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- Countries wishing to become eligible to export meat, poultry, or egg products to the United States must make a formal request by letter to:

U.S. Department of Agriculture  
Food Safety and Inspection Service  
Office of International Affairs  
International Equivalence Staff  
1400 Independence Avenue, SW  
Room 2137-S  
Washington, DC 20250-3700  
Phone: (202) 720-6400  
FAX: (202) 720-7990