

# **The U.S. Food Safety System and Equivalence: Perspectives from Two U.S. Agencies**

**WTO SPS Committee  
Thematic Session on Equivalence – Part 2  
18 March 2019**

# Equivalence

## Overview of the U.S. Food Safety System

- **Department of Health and Human Service**
  - Food and Drug Administration (FDA)
  - Centers for Disease Control and Prevention
- **United States Department of Agriculture**
  - Food Safety and Inspection Service
  - Animal and Plant Health Inspection Service
- **Environmental Protection Agency (EPA)**
- **Department of Commerce - NOAA/NMFS**
- **Bureau of Customs and Border Protection (CBP)**
- **Alcohol and Tobacco Tax and Trade Bureau (TTB)**
- **State and Local Health and Agriculture Agencies**

# Equivalence

## Overview of the U.S. Food Safety System

**Two perspectives in today's presentation:**

- **Department of Agriculture**
  - Food Safety and Inspection Service (FSIS)
- **Department of Health and Human Services**
  - Food and Drug Administration (FDA)

# Equivalence:

## Why is This Important?

### Importance Of Equivalence

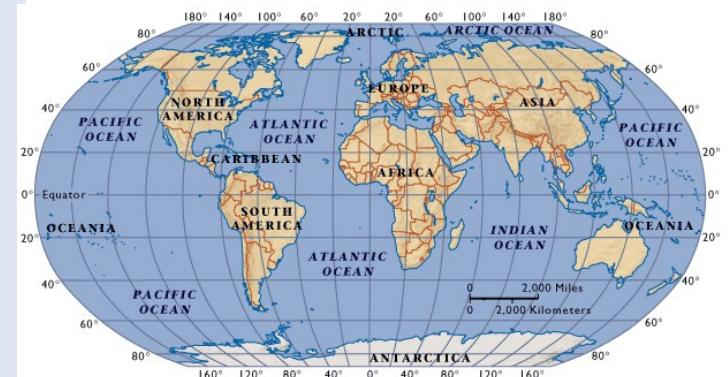
- Protects public health
- Ensures compliance with safety policies of imported food
- Facilitates trade

- World Trade Organization (WTO)/Sanitary and Phytosanitary (SPS) Measures 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 United States

# Equivalence

## What is Equivalence?

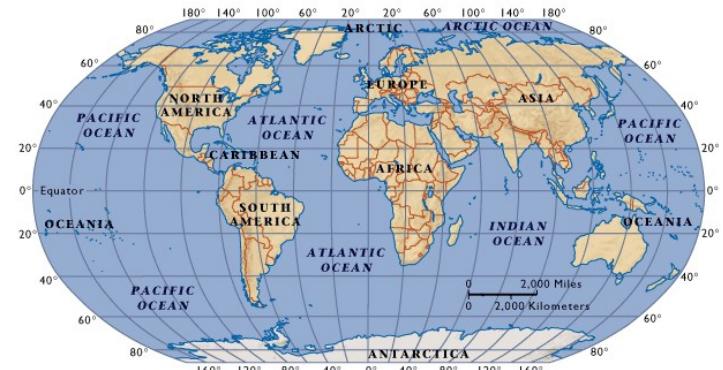
Equivalence—the process of determining whether a country's food safety system achieves the appropriate level of protection for public health as applied domestically in the United States



# Equivalence

## What is Equivalence?

The equivalence process requires the exporting country to objectively demonstrate how its food safety system, including laws, regulations, policies, and food safety procedures achieve comparable results as the US food safety system



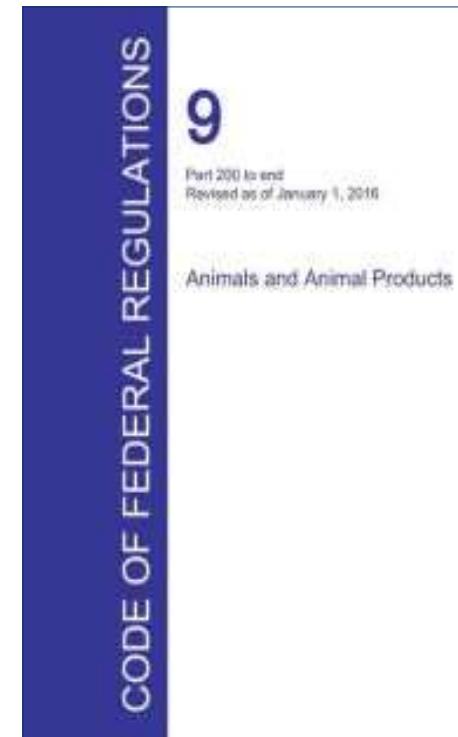
# Food Safety and Inspection Service

## U.S. Laws and Regulations

- Federal Meat Inspection Act (FMIA)
- Poultry Products Inspection Act (PPIA)
- Egg Products Inspection Act (EPIA)
- Humane Methods of Slaughtering Act

### Title 9 of the Code of Federal Regulations

- Parts 300 – 500 Meat (Siluriformes)
- Parts 362, 381 Poultry
- Parts 590, 592 Egg Products



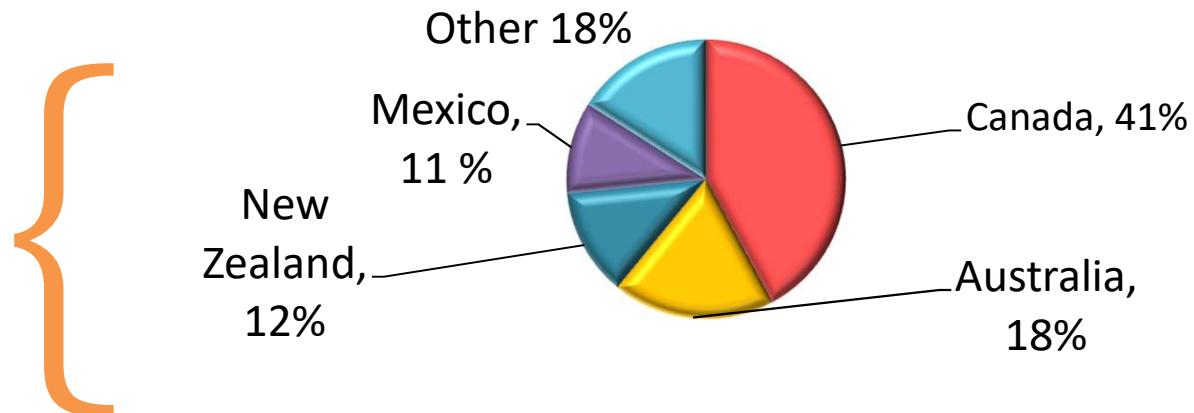
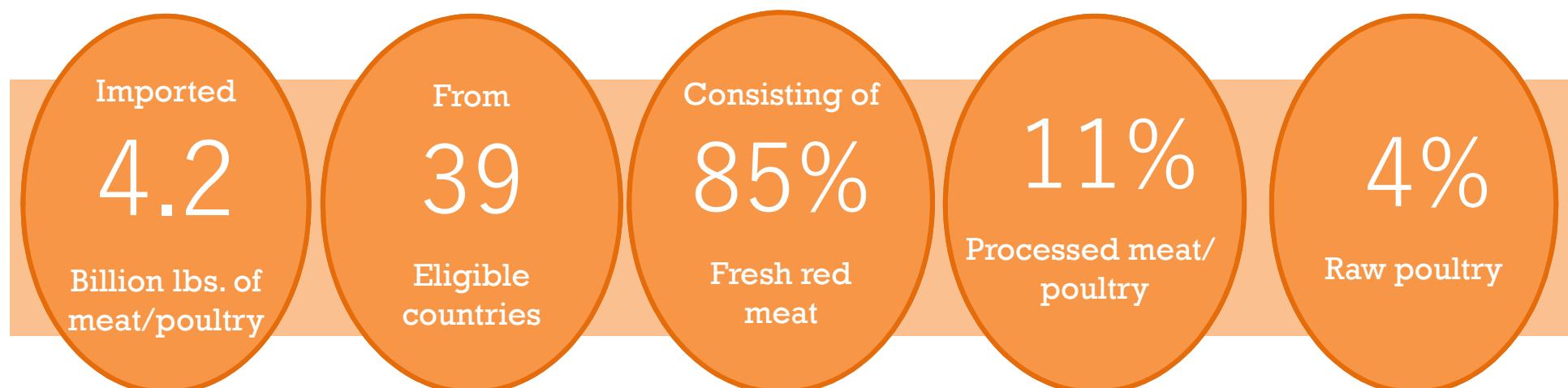
# Equivalence

## FSIS Requirements

- FSIS statutes require foreign meat, poultry, and egg products food regulatory systems to be “equivalent to” US requirements
- Regulatory requirements for equivalence and eligible foreign countries listed in:
  - § 327.2 for meat products
  - § 381.196 for poultry products
  - § 590.910 for egg products.

# Food Safety and Inspection Service: Imported Meat and Poultry Products

In CY 2017, the U.S...



# Food Safety and Inspection Service: Imported Egg Products

In CY 2017, the U.S...



Imported  
**10.4**  
Million lbs. of  
egg products



From  
Canada and  
the  
Netherlands

Note: Canada and the Netherlands are the only countries approved to export egg products to the U.S. at this time.

## Equivalence:

### FSIS Risk-Based Equivalence Determinations

#### Types of FSIS equivalence reviews:

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

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

# Equivalence

## Initial Equivalence

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

### Steps for 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*;
7. Country provides a sample health certificate, list of eligible certified establishments approved by the central competent authority (CCA) to export to the US

# Equivalence: Initial Equivalence Document Submission

The **Self-Reporting Tool (SRT)** is a questionnaire that provides an organized means for the country's government to document how 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

## Equivalence:

### Initial Equivalence 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 verification 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 under consideration for equivalence (e.g. meat, poultry, and/or egg products)

## Equivalence:

### Initial Equivalence 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

## **Equivalence: Initial Equivalence Determination**

- The Central Competent Authority (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 demonstrates during the course of an on-site verification audit that it can **implement** the inspection system (e.g., laws, regulations, inspection procedures, and enforcement protocols) documented in the SRT  
**(Acceptable audit results)**

# Equivalence: Initial Equivalence Rulemaking

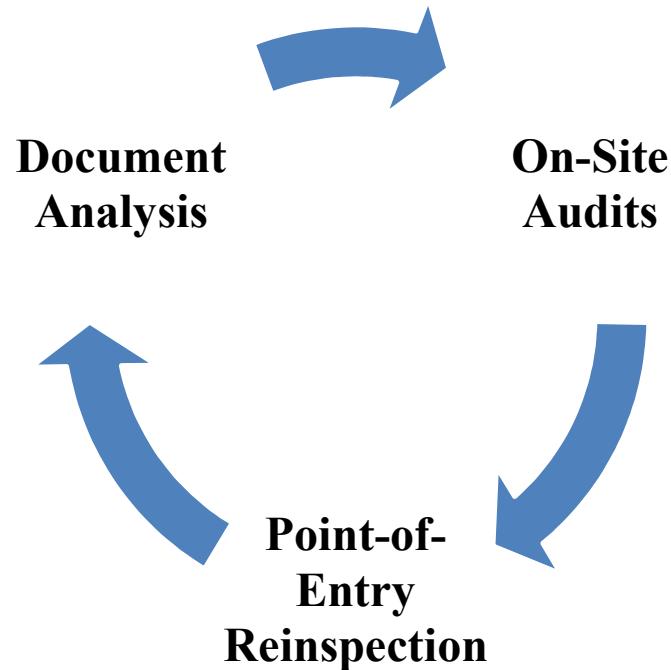
**Public Notification through Rulemaking:** FSIS initiates a proposed rule after the document review and the on-site audit steps have been satisfactorily completed.

- 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
- Proposed rule is notified to the WTO SPS Committee
- 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

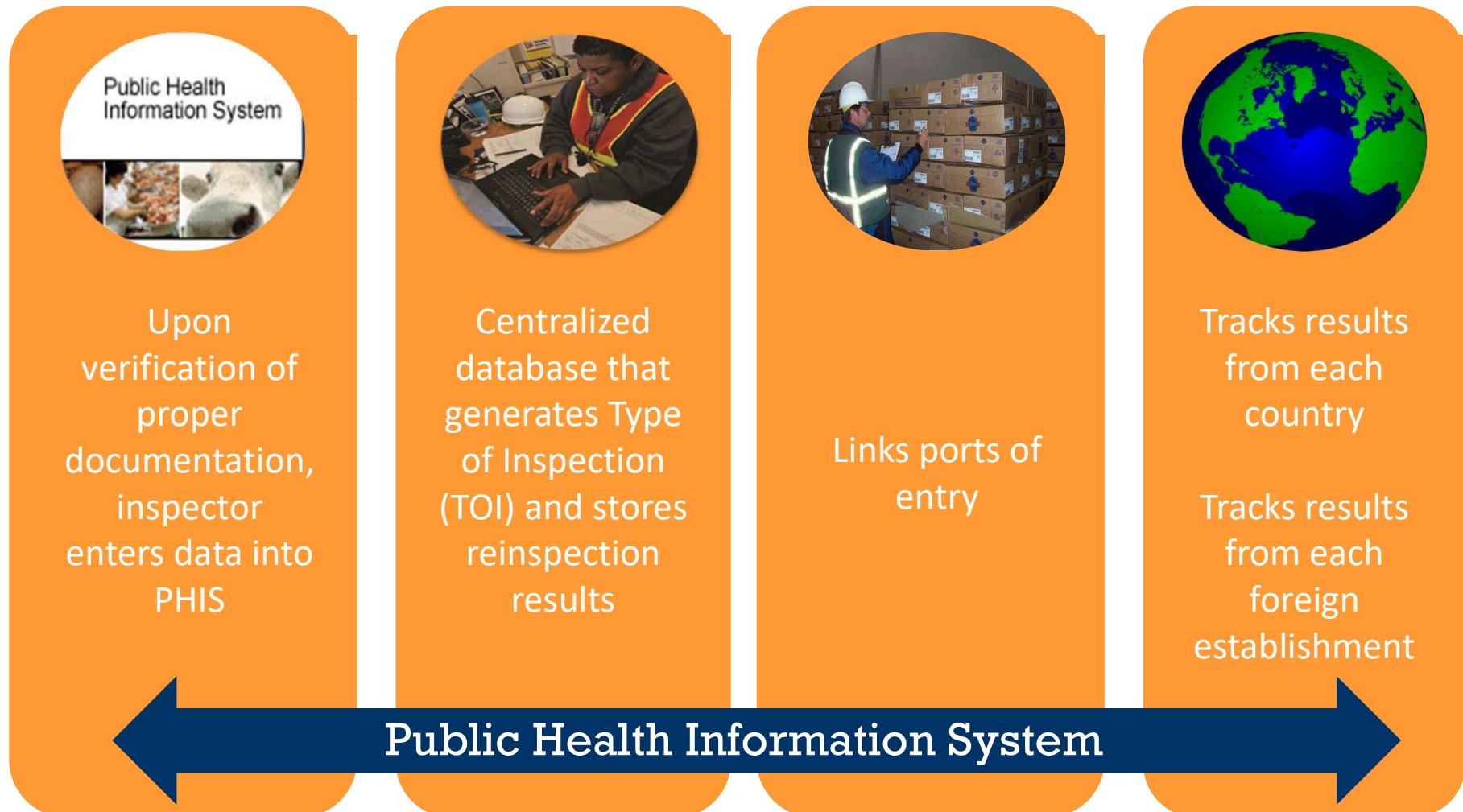
# Equivalence

## Ongoing Equivalence

**Ongoing equivalence** applies to countries currently eligible to export meat, poultry or egg products to the United States



# Food Safety and Inspection Service: Public Health Information System (PHIS)



# Food Safety and Inspection Service: POE Reinspection Types of Inspection (TOI)

FSIS Inspection  
Personnel perform  
several type of  
Physical  
Examinations

Ensure that the products that FSIS regulates are safe, wholesome, and properly labeled

- Product Exams
  - Public health and food safety standards
- Condition of Container
- Net Weight Verification
- Pink Juice Test (cooked beef)



# Equivalence

## Ongoing Equivalence

**Ongoing equivalence** applies to countries currently eligible to export meat, poultry or egg products to the United States

- **Routine audits of the country's inspection system by FSIS**
- **Annual update of information by exporting country**
  - Updated SRT responses OR verification current SRT responses are up-to-date
  - Up-to-date list of certified establishments eligible to export to US
  - Updated government residue control program and microbiological sampling and testing program, including previous year's test results and reactions to residue findings
- **Reinspection of product at point-of-entry (POE)**
  - Responses to US POE violations

## Equivalence:

### Reinstatement of Equivalence Determination

**Reinstatement of equivalence** is undertaken when a country wants to resume exporting meat, poultry, or egg products to the United States

#### 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

# 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. An equivalence assessment may or may not be needed
5. 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

# Equivalence

## Notifications to WTO SPS Committee

Country	Product Category	Rulemaking	WTO Notifications	Comments
Slovenia and Croatia	Meat	Proposed - April 29, 1992 (57 FR 18079) Final - Aug. 17, 1992 (57 FR 36889)	None	
Czech Republic	Meat	Direct final - April 12, 1995 ( <a href="#">60 FR 18540</a> )	None	Changed Czechoslovakia to Czech republic (former listed since 1948). <sup>1</sup>
Mexico	Poultry (processed only from U.S. or other approved country)	Proposed - Nov. 28, 1997 ( <a href="#">62 FR 63284</a> ) Final - Sept. 14, 1999 ( <a href="#">64 FR 49640</a> )	G/SPS/N/USA/104 (12/8/97) (proposed)	
Slovakia		Proposed - Aug. 13, 2001 ( <a href="#">66 FR 42472</a> ) Final - Feb. 8, 2005 ( <a href="#">70 FR 6554</a> )	G/SPS/N/USA/490 (8/17/01) G/SPS/N/USA/1035 (2/23/05)	
New Zealand and Australia	Poultry (ratites only)	Direct Final - June 23, 2003 ( <a href="#">68 FR 37069</a> )	None	
San Marino	Meat products	Proposed - Aug. 13, 2004 ( <a href="#">69 FR 50086</a> ) Final - Oct. 4, 2005 ( <a href="#">70 FR 57725</a> )	G/SPS/N/USA/950 (8/20/04) G/SPS/N/USA/950/Add.1 (10/17/05)	
Chile	Meat	Proposed - May 10, 2005 ( <a href="#">70 FR 24485</a> ) Final – Nov. 21, 2005 ( <a href="#">70 FR 70033</a> )	SPS/N/USA/1072 (5/13/2005)* SPS/N/USA/1072/A1 (11/28/2005)*	*Approximate dates from STAR
China	Poultry (processed only from US or other approved country)	Proposed - Nov. 23, 2005 ( <a href="#">70 FR 70746</a> ) Final - April 24, 2006 ( <a href="#">71 FR 20867</a> )	G/SPS/N/USA/1168 (11/30/05) G/SPS/N/USA/1168/Add.1 (5/11/06)	
Chile	Poultry	Proposed - Feb. 26, 2007 ( <a href="#">72 FR 8293</a> ) Proposed - May 10, 2007 ( <a href="#">72 FR 26567</a> ) (supplemental information). Final - Nov. 1, 2007 ( <a href="#">72 FR 61793</a> )	SPS/N/USA/1520 (4/16/2007) SPS/N/USA/1520/A1 (5/23/2007) SPS/N/USA/1520/A2 (11/21/2007)	
Australia	Equivalence of Australia's, Meat Safety Enhancement Program (MSEP), an alternative to the conventional meat inspection system	Notice – March 3, 2011 ( <a href="#">76 FR 11752</a> )	G/SPS/N/USA/2173 (3/8/11)	Individual sanitary measure
Korea	Poultry	Proposed - Nov. 27, 2012 ( <a href="#">77 FR 70724</a> ) Final - March 26, 2014 ( <a href="#">79 FR 16656</a> )	No	
Lithuania	Meat	Proposed - Dec. 17, 2014 ( <a href="#">79 FR 75073</a> )	G/SPS/N/USA/2724 (1/13/15)	

<sup>1</sup> Before 1948, the Bureau of Animal Industry (an FSIS forerunner) did not publish equivalence determinations. In 1938, the relevant regulation, 9 CFR 27.2, stated that the Secretary may refuse products from countries found *not* to be equivalent.

## Equivalence

### USDA, FSIS 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](mailto:InternationalCoordination@fsis.usda.gov)

# Equivalence

## Overview of the U.S. Food Safety System

### The second U.S. perspective:

- **Department of Health and Human Services**
  - Food and Drug Administration (FDA)
    - Center for Food Safety and Applied Nutrition (CFSAN)

## Equivalence

### Trade and Economic Overview

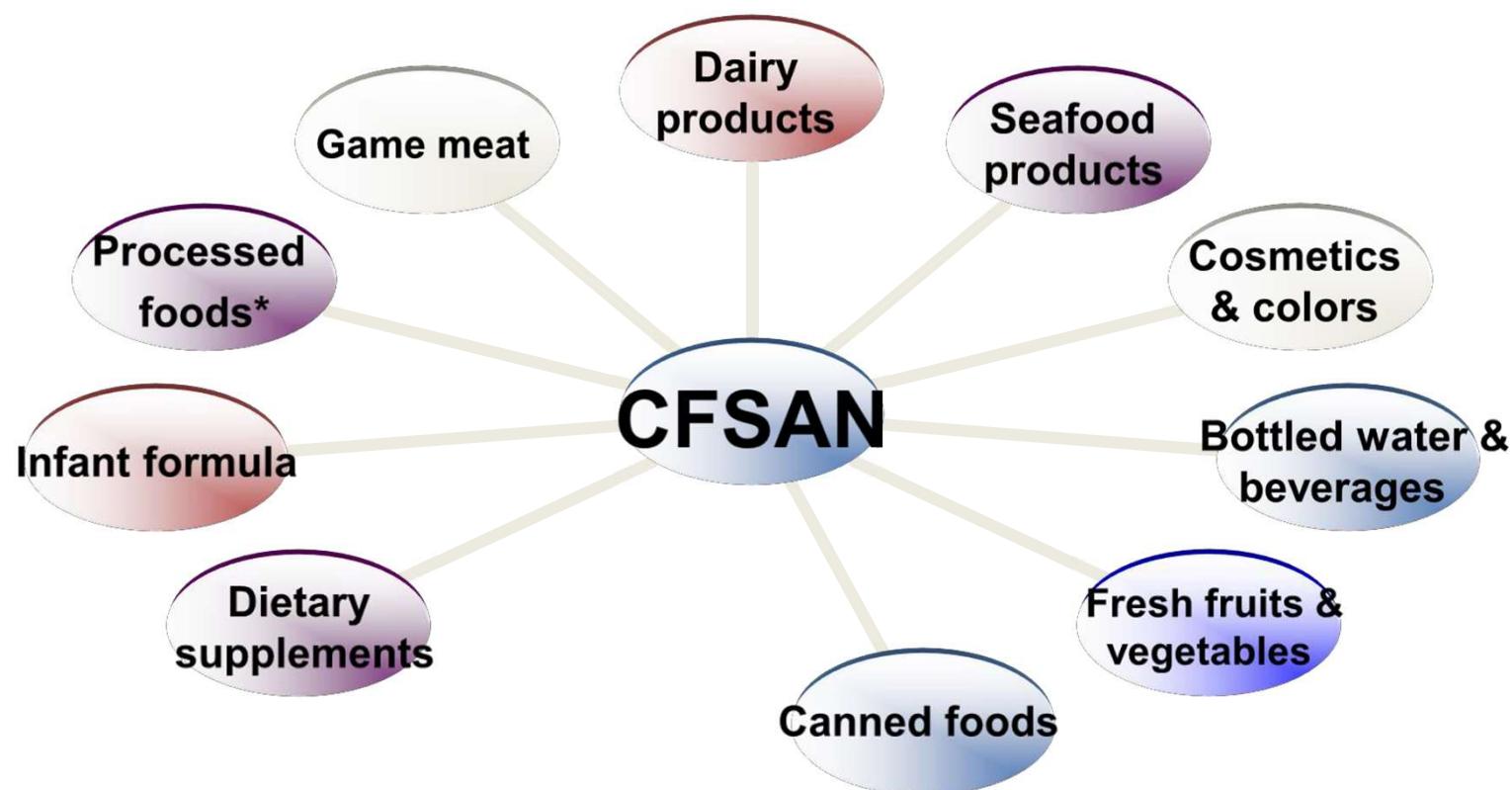
- 25 cents of every consumer dollar is spent on FDA-regulated products. Of that amount, approximately 75% is spent on food.
- FDA's Center for Food Safety and Applied Nutrition (CFSAN)
- The American food industry accounts for 20% of U.S. Gross National Product and employees 14 million.

# Equivalence

## FDA, CFSAN Food Safety Mission

CFSAN, in conjunction with the Agency's field staff, is responsible for promoting and protecting the public's health by ensuring that the nation's food supply is safe, sanitary, wholesome and honestly labeled, and that cosmetic products are safe and properly labeled.

# Products Regulated by CFSAN



\* containing <  
2% poultry  
or beef

# Equivalence

## FDA, CFSAN Requirements

- Equivalence is **NOT REQUIRED** as a condition of market access for U.S. imported foods regulated by FDA
  - FDA requires exporting countries to meet premarket conditions for two types of products
- FDA uses the PREDICT system, scoring each entry line on the basis of risk factors and surveillance requirements
- FDA does **NOT REQUIRE** certification or listing requirements attesting to food safety
- FDA does **NOT REQUIRE** food safety questionnaires

# Equivalence

## Equivalence Determinations

- Can apply to individual measures, groups of measures, or control systems for particular commodities.
- **FDA and FSIS use the same risk-based approach to an equivalence assessment, both review a Member's legal controls followed by an on-site audit to observe how the Member implements controls.**
- FDA requires exporters or exporting countries to meet premarket conditions only for raw shellfish and Grade A dairy products. Equivalence can be used to facilitate trade in these two areas.
- FDA reviews information from the exporting Member, to determine whether the exporting Member objectively demonstrates that its measures achieve the appropriate level of sanitary or phytosanitary protection.

# Equivalence Framework for Equivalence Determinations

FDA developed its equivalency determination process based on Codex Guidance:  
See CAC/GL-53-2003, *Guidelines on the judgement of equivalence of sanitary measures associated with food inspection and certification systems.*

1. Formal request for equivalence.
2. Agreement reached to undertake equivalency determination.
3. FDA works with its counterpart competent authority in Exporting Member country to exchange information on its systems.
4. Commitment of time and resources on the part of both FDA and its counterpart competent authority in the Exporting Member country.

# Equivalence

## Process for Determining Equivalence

### Paper Review – Audit – Report

#### Scope – Article 4 of the SPS Agreement

- Specific measures (HACCP, testing methods, inspection frequencies)
- Specific areas (labs, inspections, pathogens)
- Facilities (processors, importers, warehouses)
- Partial systems (e.g., shellfish and Grade “A”, seafood, supplements)

#### Approaches

- Quantitative (log reductions, performance standards, public health metrics, temperatures)
- Qualitative (training, oversight, authority, resources, etc.)
- Broad food safety goals and public health purposes

#### Experts – Subject Matter Expert Conclusions

## Equivalence

### Grade "A" Dairy –Regulatory Approach

- Grade "A" milk products (including fluid milks and creams, yogurts, cottage cheese) are regulated by FDA in co-operation with the states (and Puerto Rico).
- We regulate via standards and procedures that have been agreed upon under the aegis of the National Conference on Interstate Milk Shipments (NCIMS).

## Equivalence

### Options to Facilitate Trade in Grade “A” Dairy

There are four options for exporting Grade “A” dairy products to the United States:

1. Equivalence determination upon request of an Exporting Member for Grade "A" milk and Milk products.
2. Membership in the NCIMS - country or a subdivision (e.g. a province or state).
3. 3rd Party Certification - A firm in an Exporting Member may opt to have its milkshed approved as Grade "A" so that the firm can be IMS-listed.
4. A participant in the NCIMS (e.g. a state) can determine that a firm and its milkshed can be approved as Grade A and thus the firm can be IMS-listed.

# Equivalence Options to Facilitate Trade in Raw Shellfish

- Raw Molluscan shellfish include bivalves such as oysters, clams, mussels and scallops.
- The Interstate Shellfish Shippers Conference (ISSC) fosters and promotes shellfish sanitation under direct oversight of FDA.
- Foreign entities must demonstrate that the controls they use to ensure the safety of raw molluscan shellfish provide the same level of protection as the controls in the NSSP.
- Assessment includes review of exporting Member's written submission, on-site audit, audit report, proposed determination, final determination.

# Equivalence

## FDA, CFSAN Contact Information

### Contact Information:

Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
5001 Campus Drive  
College Park, MD 20740

[IAS-Action@fda.hhs.gov](mailto:IAS-Action@fda.hhs.gov)

# **Equivalence**

## **Overview of the U.S. Food Safety System**

**QUESTIONS?**