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**
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—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…

- **Imported**: 4.2 Billion lbs. of meat/poultry
- **From**: 39 Eligible countries
- **Consisting of**: 85% Fresh red meat, 11% Processed meat/poultry, 4% Raw poultry

Other 18% split into:
- Canada, 41%
- Australia, 18%
- New Zealand, 12%
- Mexico, 11%
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.
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.
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).
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
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
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)

- Upon verification of proper documentation, inspector enters data into PHIS
- Centralized database that generates Type of Inspection (TOI) and stores reinspection results
- Links ports of entry
- Tracks results from each country
- Tracks results from each foreign establishment
Food Safety and Inspection Service: POE Reinspection Types of Inspection (TOI)

FSIS Inspection Personnel perform several types 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)
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
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
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
<table>
<thead>
<tr>
<th>Country</th>
<th>Product Category</th>
<th>Rulemaking</th>
<th>WTO Notifications</th>
<th>Comments</th>
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<tbody>
<tr>
<td>Czech Republic</td>
<td>Meat</td>
<td>Direct final - April 12, 1995 (60 FR 18540)</td>
<td>None</td>
<td>Changed Czechoslovakia to Czech republic (former listed since 1948).¹</td>
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<tr>
<td>Mexico</td>
<td>Poultry (processed only from U.S. or other approved country)</td>
<td>Proposed - Nov. 28, 1997 (62 FR 63284)</td>
<td>Final - Sept. 14, 1999 (64 FR 49640)</td>
<td>G/SPS/N/USA/104 (12/8/97) (proposed)</td>
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<td>Slovakia</td>
<td></td>
<td>Proposed - Aug. 13, 2001 (66 FR 42472)</td>
<td>Final - Feb. 8, 2005 (70 FR 6554)</td>
<td>G/SPS/N/USA/490 (8/17/01) G/SPS/N/USA/1035 (2/23/05)</td>
</tr>
<tr>
<td>New Zealand and Australia</td>
<td>Poultry (ratites only)</td>
<td>Direct Final - June 23, 2003 (68 FR 37069)</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>San Marino</td>
<td>Meat products</td>
<td>Proposed - Aug. 13, 2004 (69 FR 50086)</td>
<td>Final - Oct. 4, 2005 (70 FR 57725)</td>
<td>G/SPS/N/USA/950 (8/20/04) G/SPS/N/USA/950/Add.1 (10/17/05)</td>
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<tr>
<td>China</td>
<td>Poultry (processed only from US or other approved country)</td>
<td>Proposed - Nov. 23, 2005 (70 FR 70476)</td>
<td>Final - April 24, 2006 (71 FR 20867)</td>
<td>G/SPS/N/USA/1168 (11/30/05) G/SPS/N/USA/1168/Add.1 (5/11/06)</td>
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<td>Australia</td>
<td>Equivalence of Australia’s, Meat Safety Enhancement Program (MSEP), an alternative to the conventional meat inspection system</td>
<td>Notice – March 3, 2011 (76 FR 11752)</td>
<td>G/SPS/N/USA/2173 (3/8/11)</td>
<td>Individual sanitary measure</td>
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<tr>
<td>Korea</td>
<td>Poultry</td>
<td>Proposed - Nov. 27, 2012 (77 FR 70724)</td>
<td>Final - March 26, 2014 (79 FR 16656)</td>
<td>No</td>
</tr>
<tr>
<td>Lithuania</td>
<td>Meat</td>
<td>Proposed - Dec. 17, 2014 (79 FR 75073)</td>
<td>G/SPS/N/USA/2724 (1/13/15)</td>
<td></td>
</tr>
</tbody>
</table>

¹ 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.
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

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E-mail: InternationalCoordination@fsis.usda.gov
The second U.S. perspective:

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


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
Grade "A" milk products (including fluid milks and creams, yogurts, cottage cheese) are regulated by FDA in cooperation 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).
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:

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Equivalence
Overview of the U.S. Food Safety System

QUESTIONS?