Equivalence – Ensuring the Flow of Safe Meat, Poultry and Egg Products Across Country Borders

Linda Swacina, J.D.
Deputy Administrator
Food Safety and Inspection Service
United States Department of Agriculture

FSIS’ administrator is the Agency’s chief inspection official or central competent authority in international negotiations.

Dr. Barbara J. Masters
Acting Administrator
Food Safety and Inspection Service
U.S. Department of Agriculture
FSIS’ Mission

The Food Safety and Inspection Service protects consumers by ensuring that meat, poultry, and egg products are safe, wholesome, and accurately labeled.

FSIS’ Responsibility

Jurisdiction over products that generate more than $120 billion (approximately 1.4 trillion pesos) in sales annually.
Inspections of Food Animals Per Year (And Egg Products)

- 39 million cattle and calves
- 97 million swine
- 3.5 million sheep and lambs
- 8 BILLION poultry and fowl
- 3.2 BILLION pounds (1.4 million metric tons) of liquid egg products
- 3.8 BILLION pounds (1.7 million metric tons) of imported product re-inspected

A Decline of Infections from Foodborne Pathogens

The U.S. Centers for Disease Control and Prevention documents a significant decline in bacterial foodborne illnesses from 1996 through 2003.
A Decline of Infections from Foodborne Pathogens

**A Decline of illnesses caused by Salmonella Typhimurium from 1996 through 2003.**

- 38%

**A Decline of illnesses caused by E. coli O157:H7 from 2002 through 2003.**

- 36%

FSIS documents a 60% decline in positive samples 2002 to 2003.
Salmonella Incidence Declining

Salmonella rates have fallen by 66% over the past six years.

FSIS Shows a Significant Decline in Ready-To-Eat Products Containing *Listeria monocytogenes*
The Trade of Safe Food

FSIS is required by law to evaluate a foreign country’s inspection system before meat, poultry and egg products can be exported to the United States.

- Federal Meat Inspection Act
- Poultry Products Inspection Act
- Egg Products Inspection Act

Sanitary and Phytosanitary Measures Agreement

- Lays out basic rules to ensure food safety for international trade.
- Countries are allowed to develop their own standards.
- Regulations must be scientifically based.
◆ Article 4.1 of the SPS Measures Agreement:

“Members shall accept the sanitary...measures of other members as equivalent, even if these measures differ from their own...if the exporting member objectively demonstrates...that its measures achieve the importing member’s appropriate level of sanitary...protection.”

◆ Exporting country has burden to demonstrate equivalence.

◆ Importing country has the right to decide if system is:
  ◆ Equivalent;
  ◆ Inadequate to achieve its appropriate level of protection; or
  ◆ Unable to demonstrate equivalence adequately.
FSIS regulations amended to reflect “equivalent to” as the standard for eligibility.

Criteria for evaluating foreign systems are set forth in FSIS’ regulations.

Each criterion constitutes a sanitary measure as defined in the SPS Agreement.

Examples include:
- End product criteria;
- A specific sampling procedure;
- A testing, inspection or certification procedure; or
- A packaging and labeling requirement directly related to food safety.
An Important Term Cited Within the SPS Agreement

“Appropriate Level of Protection”

- Each nation has the right to choose its own level of protection.
- Exporting countries may use measures that differ from those used by importing countries.
- Exporting countries can use either the same or equivalent sanitary measures to obtain the same level of protection set by the importing nation.

Example: FSIS requires generic *E. coli* testing to determine adequate process control during the slaughter of animals.

A country that decides to export to the United States can decide either to:

1) Adopt FSIS’ requirements, or
2) Use another microorganism to determine whether the slaughter process is under control.
Countries that are eligible to export can ask FSIS to explain its appropriate level of protection and how any requirements are relevant.

FSIS then provides an explanation, and the exporting country can either implement FSIS’ requirements or develop a case for implementing different requirements.

If a country decides to implement a different requirement, then FSIS will review documentation and will decide either to:

1) Determine whether the different sanitary measure is equivalent to FSIS’ current requirements;
2) Request more information; or
3) Reject the different sanitary measure.
FSIS-OIA makes two kinds of equivalence determinations:

- **Initial Equivalence Determination** is used when a country wants to begin exporting the U.S.

- **On-going Equivalence Determination** is used to decide whether a country continues to maintain an equivalent inspection program.
Any country may apply for eligibility to export meat and poultry products. The process begins with by sending copies of U.S. Laws, FSIS regulations, questionnaires and other documents that set forth meat and poultry inspection.

An initial document analysis is conducted after receiving a completed application package. The document analysis compares foreign inspection system sanitary measures with those in the United States. FSIS works collaboratively with countries to get necessary information.
A determination is made whether the foreign food regulatory system meets all U.S. import requirements in an equivalent manner and provides the same level of public health protection.

Once these objectives are met FSIS-OIA sends a team of experts to the country to conduct an on-site inspection.

After FSIS-OIA conducts the on-site audit, the Agency publishes a proposed regulation, adding the country to list of eligible exporters.

Public comments to proposed change are collected and used to make a final decision.
FDA’s inspection requirements are company specific.

FSIS does not conduct food inspections in other countries.

**The Initial Equivalence Determination**

**FSIS**
- FSIS’ inspection requirements are country specific.

**Versus**
- FDA’s inspection requirements are company specific.

**On-going Equivalence Determination**

FSIS-OIA uses a three-step process to make ongoing equivalence decisions.

- Document Analysis
- System Audits
- Port-of-entry Reinspection
**On-going Equivalence Determination**

**Document Analysis**

- Fundamental laws, regulations, policies
- Food Production requirements
- Regulatory oversight, verification and enforcement requirements

**System Audit**

- Assesses foreign inspection system, particularly in respect to implementation of any FSIS' new requirements.
- Each country that exports to the United States is audited at least once each year.
- Audits focus on process control and government oversight
On-going Equivalence Determination

Port-of-Entry Reinspection

- Reinspection of randomly selected samples at ports of entry around the United States.
- Samples are collected by an automated, centralized computer database.
- All shipments checked for damage, accurate labeling, proper certification and for general condition.

U.S. Exports of Meat and Poultry

- With the centralized inspection in the United States, we rely heavily on FSIS' inspection force to assure that plants are producing the safest possible products for export.

An internal system of checks and balances consists of:

- Front line inspectors
- Inspectors-in-charge
- Export Library
- Circuit supervisors
Improving public health must be a global effort.

Contact Information

FSIS’ Web site
www.fsis.usda.gov

Office of International Affairs’ Web site
www.fsis.usda.gov/OPPDE/IPS

Office of International Affairs Phone Number
Karen Stuck, Assistant Administrator (202) 720-3473