



Systems Recognition



Camille E. Brewer
Director for International Affairs,
Office of Foods & Veterinary Medicine,
and Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration

**AFDO Annual Meeting, International & Government Relations Committee
June 18, 2017**

Points to Cover

- FDA's Imports Toolbox
- Systems Recognition
 - Definition
 - Benefits
 - Assessment Process
 - Relationship to Manufactured Food Regulatory Program Standards
 - Relationship to FSMA/Foreign Supplier Verification Programs
 - Next Steps
 - Resources

What “tools” are in FDA’s Imports Toolbox?

- 
- Border inspections, testing of samples, and compliance
 - Foreign inspections
 - Facility registration
 - FSVP, VQIP
 - Utilization of accredited laboratories for testing
 - Reliance on export programs
 - Third party certification
 - Import certificates
 - Bilateral agreements and arrangements
 - Capacity Building
 - **SYSTEMS RECOGNITION**

Systems Recognition A Non-FSMA Tool



What is Systems Recognition?

- A tool for **two-way** regulatory partnership
- Systems recognition describes whether a country's food safety system provides a similar, **though not necessarily identical**, system of protections; and the food safety authority provides similar oversight and monitoring
- It is **not** a market access tool

How Does Systems Recognition Benefit FDA?

- Systems recognition allows us to:
 - Focus our resources, particularly inspectional resources, in a more risk-based manner (i.e., shrink the haystack)
 - Identify those partners we can rely on for follow-up
 - Offers prospect of information sharing


What is the Systems Recognition Assessment Process?

- Consultation and compliance review
- Completion of International Comparability Assessment Tool (ICAT), which contains 10 core elements:
 - Regulatory Foundation
 - Training/Human Resource
 - Inspection Program
 - Program Assessment/Inspection Audit Program
 - Food related Illness and Outbreaks
 - Compliance and Enforcement
 - Industry and Community Relations
 - Program Resources
 - International Communications and Harmonization
 - Laboratory Support
- Documentation review – Are programs in place?
- Audit – Does the reality align with what is on paper?

The Manufactured Food Regulatory Program Standards (MFRPS)

- The goal of the MFRPS is to implement a nationally integrated, risk-based, food safety system focused on protecting public health.
- The MFRPS establish a uniform basis for measuring and improving the performance of prevention, intervention, and response activities of manufactured food regulatory programs in the United States.
- The development and implementation of the standards will help federal and state programs better direct their regulatory activities toward reducing foodborne illness.

The MFRPS Areas of Focus

- 
- A faint, light gray world map is visible in the background of the slide, centered behind the list of standards.
- Standard 1 - Regulatory Foundation
 - Standard 2 - Training Program
 - Standard 3 - Inspection Program
 - Standard 4 - Inspection Audit Program
 - Standard 5 - Food-related Illness and Outbreaks and Response
 - Standard 6 - Compliance and Enforcement Program
 - Standard 7 - Industry and Community Relations
 - Standard 8 - Program Resources
 - Standard 9 - Program Assessment
 - Standard 10 - Laboratory Services

System Recognition

- **Partner Countries**

- New Zealand (2011), Canada (2016), Australia (2017)
- Assessment of EU underway

- **Exclusions**

- Labeling, MRLs, Additives
- Meat, poultry, processed egg products, catfish
- Grade A Dairy and Dairy Products
- Bivalve molluscan shellfish
- Dietary supplements and Natural Health Products

Relationship to FSMA/FSVP

- Systems Recognition is not a “green lane”
- There are modified documentation requirements of Systems Recognized Countries
- The requirements only pertain to some **finished** foods (i.e., not all foods are within the scope of the arrangement)

Recognition Tools

More work to be done!

- Continue Assessments that are underway
- **IMPLEMENT** Systems Recognition to full program status
- Update assessments to consider FSMA
- Develop Options Regarding the Recognition of Foreign Competent Authorities to ensure the safety of specific commodities

See More Information on Systems Recognition:

- *Information for Foreign Governments: Frequently Asked Questions on Systems Recognition*

<http://www.fda.gov/Food/InternationalInteragencyCoordination/ucm367400.htm>

- *FDA Systems Recognition: Ensuring Imported Foods Are Safe*

<http://shar.es/iepZy>



Thank you for your attention!