Systems Recognition

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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

• 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
  – 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/InternationalAllInteragencyCoordination/ucm367400.htm

• FDA Systems Recognition: Ensuring Imported Foods Are Safe
  http://shar.es/iepZy
Thank you for your attention!