



Systems Recognition



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International
Affairs
Staff

Camille E. Brewer, M.S., R.D.
Director, International Affairs Staff
Office of the Center Director
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration

Points to Cover

- 
- Background/Systems Recognition
 - Definition
 - Benefits
 - How Countries are Recognized
 - Next Steps

What is Systems Recognition?

- A tool for regulatory partnership with foreign governments
- 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.

Is systems recognition needed for market access for FDA-regulated foods?

No! • Ne! • Nyet! • Wala! • Nien! • La! • Jo! • Non!

**Can we rely on the partner country/agency
when there is a problem**

and can the partner rely on FDA?

Yes! • Huo! • Ja! • Si! • Ebo! • Hai!

How Does Systems Recognition Benefit FDA?

- Systems recognition allows us to:
 - Focus our resources, particularly inspectional resources, in a more risk-based manner
 - Identify those partners we can rely on for follow-up
 - Offers the prospect of information sharing on additional issues

What is the Assessment Process?

- **Step 1: Pre-Screen**
 - Examines trading and compliance history, including refusal of admissions, import alerts and outbreaks linked to the country's products
 - Looks at data from other federal agencies (USDA's Global Agriculture Information Network)
 - Evaluates whether a country is likely to be a successful candidate for systems recognition

What is the Assessment Process? (cont.)

- **Step 2: Completion of International Comparability Assessment Tool (ICAT)**
 - Documentation review: Are programs comparable with those used in the United States?

THE ICAT

International Comparability Assessment Tool (ICAT) contains 10 core elements:

- Regulatory Foundation (**Includes Preventive Controls**)
- Training/Human Resource
- Inspection Program
- Program Assessment/Inspection Audit Program
- Food related Illness and Outbreaks
- Compliance and Enforcement (**Includes Verification Activities**)
- Industry and Community Relations
- Program Resources
- International Communications and Harmonization
- Laboratory Support

Who Conducts the Assessment?

- A team of technical experts from FDA reviews the ICAT submission.
- The process provides a “deep dive” into the foreign system, including its legal foundation and approaches to regulating the food industry.

In-Country Assessment

- **Step 3:** An FDA team goes to the country to check that what is done in practice aligns with the ICAT submission.
- The audit team conducts interviews, reviews records, visits government agencies, and accompanies government officials on facility audits and inspections.

What Foods are Covered?

Scope of Assessments

- All foods for human consumption under FDA regulation **except for** Grade A dairy and molluscan shellfish and dietary supplements. Animal feed is generally excluded as well.
- Certain product specific regulatory requirements and standards are not included in the scope.
 - Food contact substances
 - Maximum residue levels for pesticides and veterinary drugs
 - Food additive approvals
 - Labeling requirements

Next Steps

- We are moving from the pilot phase to adoption of systems recognition.
- Two countries have been recognized:
New Zealand (2012); Canada (2016).
- Australia has gone through the three step process with FDA and is in the final stages of the process.
- The European Commission has just begun the ICAT process.
- Following recognition, reassessments will occur every 5 years, or more frequently if changes make it necessary.

Questions?

