

FDA

**U.S. FOOD & DRUG
ADMINISTRATION**

CENTER FOR FOOD SAFETY & APPLIED NUTRITION

Systems Recognition Implementation

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Objective

Discussion on the process FDA used to develop activities for its Systems Recognition Implementation Plan.



How Does Systems Recognition Benefit FDA?

Systems Recognition allows us to:

- Focus our resources in a more risk-based manner.
- Leverage the resources of recognized foreign partners.
- Improve and expand information sharing.

Objectives of the Implementation Plan

The Implementation Plan is designed to help FDA

- 1) **standardize** SR processes across the agency
- 2) **define** the roles and responsibilities of FDA components
- 3) **coordinate** communication with SR countries
- 4) **forecast** resource needs



Benefits Supported by SR Implementation Activities

- ***Resource Reallocation Benefits (Key Procedures)***
 - PREDICT
 - Sampling and Field Exams
 - Foreign Food Inspections
- ***Public Health Benefits (Key Procedures)***
 - Detention Without Physical Examination
 - Recalls and RFR
 - Communication During Emergency Situations

Points for Discussion

- Benefits
- For Concurrence: Changes to FDA Procedure for SR Countries
- For Information: New Approaches to Information Sharing
- For Awareness: Performance Monitoring, Management and Maintenance Projects

Areas needing Agency consensus

- 1) PREDICT
- 2) Foreign Inspection Strategy
- 3) Sampling and Field Examinations
- 4) Detention Without Physical Examination



For Information

1. Communication During Food Safety Emergencies
2. Recalls and RFR
3. Commodities Excluded
4. Transshipment (Country of Origin definitions)



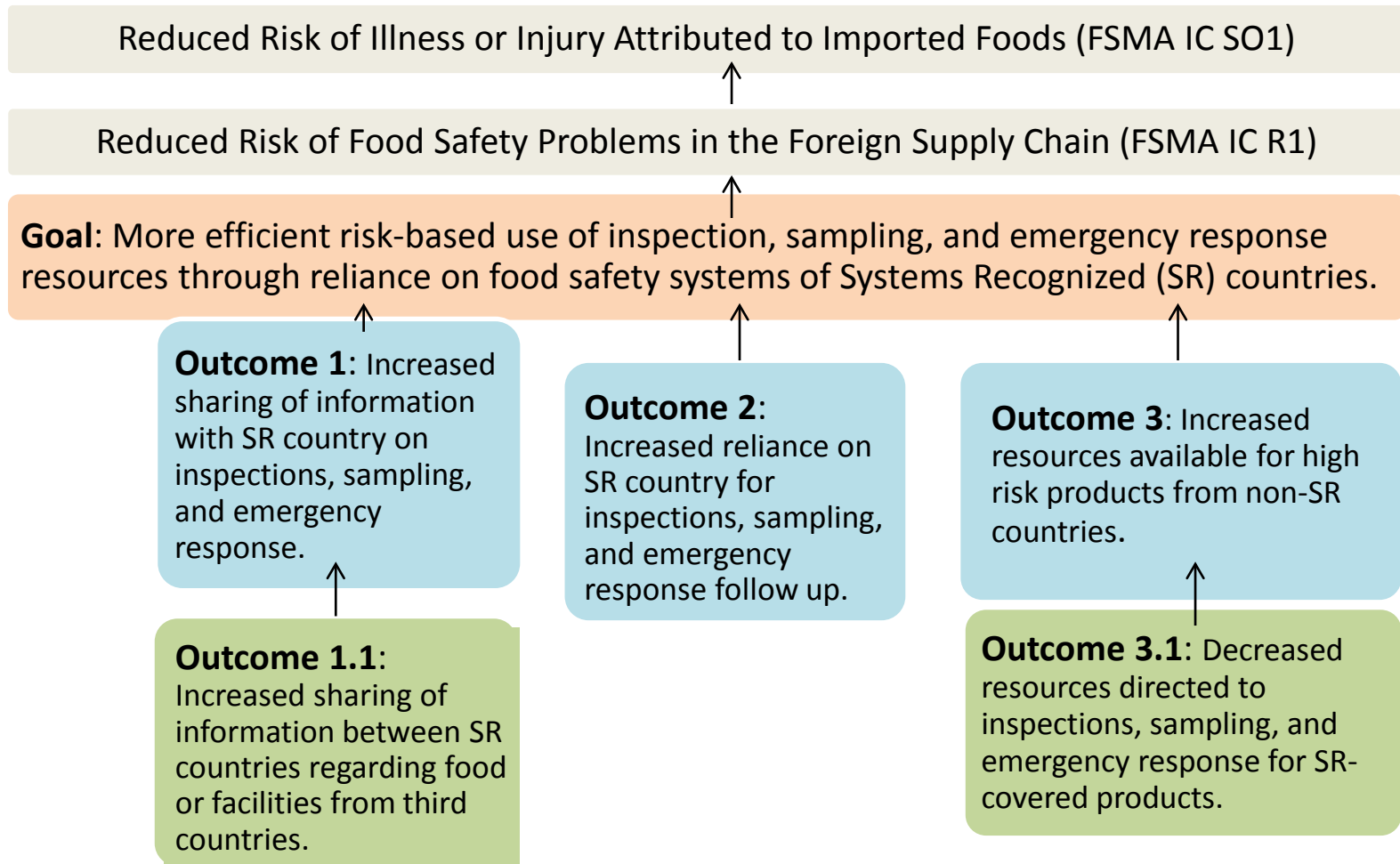
Mechanisms for Systems Recognition and Implementation

1) SR Assessment

2) Implementation Procedures

3) Management and Maintenance

For awareness: Systems Recognition Strategic Framework



For awareness: Assessments, Management and Maintenance Activities

- EC Assessments
- New Zealand 5 Year Reassessment
- FDA Manuals
- Consideration of Additional Covered Commodities (e.g. non-medicated animal feed, infant formula)
- Ongoing Maintenance Activities
 - FSMA Rules Implementation

“Thank you” to the Systems Recognition Implementation Working Group

- Ellen Buchanan (ORA)
- Jorge Christian (ORA)
- Caroline Smith DeWaal (CFSAN)
- Deb DeVlieger (ORA)
- Anna Ferus (OIP)
- Sema Hashemi (OIP)
- Michael Roosevelt (CFSAN)
- Lisa Romano (ORA)
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