



Domestic Facility Risk Categorization

Collaborative Food Safety Forum

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Melanie Mayor, MPH, REHS
CDR, USPHS
Special Assistant
FDA/CFSAN/Office of Compliance
Division of Field Programs and Guidance





Background

- Section 201, Targeting of inspection resources, for domestic facilities, foreign facilities, and ports of entry; annual report.
- FSMA establishes a mandated frequency, based on risk, for food facilities.
- Registered facilities are to be identified as high-risk or non-high-risk.



Background

High-Risk Facilities

- Each facility is inspected not less often than once in the 5-year period following date of enactment; and not less often than once every three years thereafter.

Non-High-Risk Facilities

- Each facility is inspected not less often than once in the 7-year period following date of enactment; and not less often than once every five years thereafter.



Categorization Factors

- Identifying high-risk facilities based on factors established by regulation:
 - Known safety risks of the food,
 - Compliance history of a facility,
 - Facility's hazard analysis and risk-based preventive controls,
 - Certifications for imported foods (VQIP),
 - Any other criteria deemed necessary.

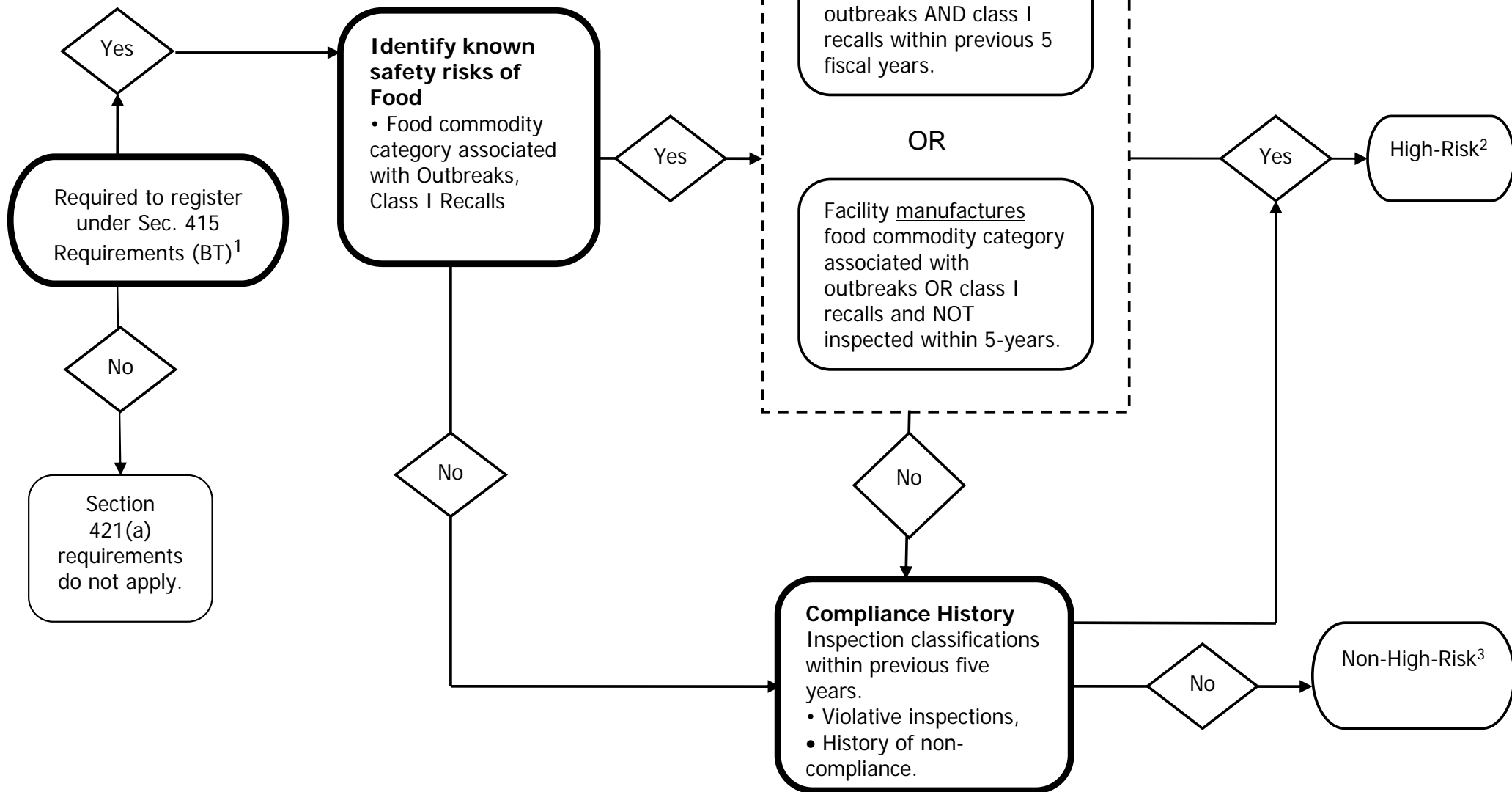


Categorization Factors

- Known safety risks of the food
 - Identified food commodity categories associated to food recalls and foodborne outbreaks.

- Compliance history of a facility
 - Facilities with a history of non-compliance with food safety regulations, those with violations of regulatory significance.

FSMA Domestic Facility Risk Categorization



1. Fiscal years based on data from agency's Official Establishment Inventory (OEI). Resources have been allocated for facilities not required to register under Sec. 415 but should be inspected.

2. Inspect within three-year period.

3. Inspect within seven-year period.



Current Status

- Approach is to inspect high-risk facilities at least once in the first **3-years** rather than the first 5-years.
- Food facility inventory based on agency's Official Establishment Inventory.



Current Status

- FDA may inspect facilities more often than the frequency mandate as a result of emerging public health information or follow-up to regulatory actions.
- Identifying high-risk and non-high-risk facilities will be an iterative process.



Challenges

- Limitations on data
 - Product level, processing, distribution, multiple food commodities.
 - Inventory is dynamic and subject to change.

- Communicating internally messages of enhanced surveillance program.



Challenges

- Competing resources with operational activities for other FDA-regulated products.
- Reporting and tracking requirements for Annual Report.



Next Steps



- Determine how to implement deliverables from other FSMA Workgroups.
- Consider other factors and criteria to determine facility risk categorization.
- Continue to enhance a data-driven decision-making process.
- Communicate and outreach to stakeholders.



Implementation Executive Committee
Mike Taylor, Deputy Commissioner for Foods
(Chair)
Mike Landa, Bernadette Dunham
Steve Solomon, Elizabeth Dickinson, David Dorsey

Strategic Communications & Outreach Team
Sharon Natanblut
(Team Leader)

<u>Prevention Standards</u> Don Kraemer (Team Leader)	<u>Inspections & Compliance</u> Barbara Cassens (Team Leader)	<u>Imports</u> Roberta Wagner (Team Leader)	<u>Federal/State Integration</u> Joe Reardon (Team Leader)	<u>Fees</u> Roxanne Schweitzer & Bob Miller (Team Leaders)	<u>Reports & Studies</u> David Dorsey (Team Leader)
Produce Safety Regulation	Mandatory Recall and Recall Communications	Importer Verification & VQIP	Operational Partnership	Inspection & Auditor Fees	Reports to Congress/ Studies
Produce Safety Guidance	Administrative Enforcement Tools	Import Certification	Capacity Building		
Preventive Controls Regulation	Registration	Accredited Third-Party Certification	Training		
Preventive Controls Guidance	Frequency of Inspections	Lab Accreditation & Integrated Consortium/FERN			
Safe Food Transport	Manner of Inspection/ Food Safety Plan Review	International Capacity Building			
Food Defense	Tracing	Comparability			
Contaminants	RFR Improvements	Task A: Prior Notice			

A text version of the Implementation Management Structure is also available.



Acknowledgements

FSMA Frequency of Inspections Workgroup

- **ORA**
 - Division of Planning, Evaluation, and Management
 - Office of Regional Operations
 - Risk Management
- **CFSAN**
 - Division of Field Programs and Guidance
 - Outbreak Team
 - Recalls Team

And many more....



Thank You!

Welcome comments!

melanie.mayor@fda.hhs.gov