Domestic Facility Risk Categorization

Collaborative Food Safety Forum

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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

Identify known safety risks of Food
- Food commodity category associated with Outbreaks, Class I Recalls

Yes → Required to register under Sec. 415 Requirements (BT)¹

No → Section 421(a) requirements do not apply.

Yes → Facility manufactures food commodity category associated with outbreaks AND class I recalls within previous 5 fiscal years.

OR

Yes → Facility manufactures food commodity category associated with outbreaks OR class I recalls and NOT inspected within 5-years.

Yes → High-Risk²

No → Compliance History
- Inspection classifications within previous five years.
  - Violative inspections,
  - History of non-compliance.

No → Non-High-Risk³

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.
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!

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