Domestic Facility Risk Categorization

Collaborative Food Safety Forum

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

Yes

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

OR

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

Yes

High-Risk

No

Compliance History
Inspection classifications within previous five years.
- Violative inspections,
- History of non-compliance.

No

Non-High-Risk

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.
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<td>Mike Taylor, Deputy Commissioner for Foods (Chair)</td>
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<td>Mike Landa, Bernadette Dunham</td>
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<td>Steve Solomon, Elizabeth Dickinson, David Dorsey</td>
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<td>Don Kraemer (Team Leader)</td>
<td>Barbara Cassens (Team Leader)</td>
<td>Roberts Wagner (Team Leader)</td>
<td>Joe Reardon (Team Leader)</td>
<td>Roxanne Schweitzer &amp; Bob Miller (Team Leaders)</td>
<td>David Dorsey (Team Leader)</td>
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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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