Food Safety Modernization Act (FSMA)

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Food Safety Modernization Act

“I thank the President and members of Congress for recognizing that the burden that foodborne illness places on the American people is too great, and for taking this action.”

Margaret A. Hamburg, M.D.,
Commissioner of Food and Drugs
Main Themes of the Legislation

Prevention

Enhanced Partnerships

Inspections, Compliance, and Response

Import Safety
I. Prevention Standards Provisions in FSMA

- Produce Safety Regulation
- Produce Safety Guidance
- Preventive Controls Regulation
- Guidance on Hazard Analysis and Preventive Controls
- Sanitary Food Transportation
- Preventing Intentional Contamination
Major Rules to Issue Soon

• Produce Safety Standards
• Preventive Controls for Human Foods
• Preventive Controls for Animal Foods
• Foreign Supplier Verification Program
FSMA Requirement for Preventive Controls

• Under FSMA Section 103 (Section 418 of the Federal Food, Drug, and Cosmetic Act) facilities are required to conduct a hazard analysis and implement preventive controls for identified hazards.

• Applies to businesses that are required to register under the Bioterrorism Act of 2002.

• Applies to domestic and to foreign facilities exporting to the United States.
FSMA Definition of Preventive Controls

• *Preventive controls*: risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified in the hazard analysis…and that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.
FSMA Preventive Controls

- Sanitation procedures for food-contact surfaces and utensils and food-contact surfaces of equipment;
- Supervisor, manager and employee hygiene training;
- An environmental monitoring program to verify the effectiveness of pathogen controls in processes where a food is exposed to a potential contaminant in the environment;
FSMA Preventive Controls (cont.)

- A food allergen control program;
- A recall plan;
- Current Good Manufacturing Practices under 21CFR 110;
- Supplier verification activities that relate to the safety of food.
Guidance

• FSMA requires the Secretary to issue a guidance document related to the regulations on hazard analysis and preventive controls.
Exemptions

• Facilities required to comply with
  – Seafood HACCP regulation
  – Juice HACCP regulation
  – Low-acid canned foods regulation (for microbiological hazards only)
  – Dietary supplement GMPs

• Alcoholic beverages

• A “qualified facility” (very small business or one with limited annual sales (< $500K) with more than half of sales going directly to consumers or to restaurants/ retail food establishments in the same state or within 275 miles)
Requirements for Qualified Facilities

• Submit documentation that the facility has identified potential hazards and implemented preventive controls and is monitoring the PCs; or

• Submit documentation of compliance with non-federal food safety law; and

• Submit documentation that the facility is a qualified facility.
Hazard Analysis

• Identify and evaluate known or reasonably foreseeable hazards
  - Biological, chemical, physical and radiological (natural toxins, pesticides, drug residues, decomposition, parasites, allergens, unapproved food and color additives)
  - Hazards that occur naturally or may be unintentionally introduced
Preventive Controls

- Identify and implement preventive controls, including at critical control points, if any, to significantly minimize or prevent the hazards identified in the hazard analysis
Monitoring and Corrective Actions

• Monitor the performance of the preventive controls
• Establish corrective action procedures for improper implementation of preventive controls
Verification

- The preventive controls are adequate to control the hazards
- Monitoring is being conducted and appropriate decisions are made about corrective actions
- The preventive controls are effectively and significantly minimizing or preventing the occurrence of the identified hazards
  - Including through use of environmental and product testing programs
- Reanalysis of the plan (no less frequently than every 3 years)
Recordkeeping

Written plan and documentation of

- Monitoring of preventive controls
- Instances of nonconformance material to food safety
- Results of testing and other verification activities
- Instances when corrective actions were implemented
- Efficacy of preventive controls and corrective actions

Available to authorized representative of FDA on request
HACCP but not HACCP

• The law looks a lot like HACCP but is different in many aspects
  – FSMA included identification and evaluation of intentionally introduced hazards
  – Preventive controls are not restricted to implementation at CCPs
HACCP but not HACCP

• The law looks a lot like HACCP but is different in many aspects (cont.)
  – Preventive controls (procedures, practices, and processes) include
    • CGMPs/sanitation
    • Environmental monitoring
    • Training
    • Recall plan
II. Inspection, Compliance, and Response

• Mandated inspection frequency
  – Considering new ways to inspect

• New tools
  – Mandatory recall
  – Expanded records access
  – Expanded administrative detention
  – Suspension of registration
  – Enhanced product tracing
  – Third party laboratory testing
III. Import Safety: Most groundbreaking shift

- Importers now responsible for ensuring that their foreign suppliers have adequate preventive controls in place
- FDA can rely on third parties to certify that foreign food facilities meet U.S. requirements
- Can require mandatory certification for high-risk foods
- Voluntary qualified importer program--expedited review
- Can deny entry if FDA access for inspection is denied
- Requires food from abroad to be as safe as domestic
IV. Enhanced Partnerships: Vital to Success

- Reliance on inspections by other agencies that meet standards
- State/local and international capacity building
- Improve foodborne illness surveillance
- National agriculture and food defense strategy
- Consortium of laboratory networks
- Easier to find recall information
What’s Next?

- The proposed rules are under review at OMB.
- There will be a notice and comment period.
- FDA will make revisions based on the comments and develop a final rule.
- Both industry and regulators will need education and training.
- Industry will need additional guidance from FDA.
What’s Next?

• There is much to do while waiting for the FSMA-mandated rules.
• Industry can assess what the requirements of FSMA mean for them in large part by careful reading of the legislation.
• FDA encourages firms to take preventive measures for hazards now.
FSMA Provides Opportunities

- Develop risk-based, prevention-oriented procedures for manufacturing/processing/packing/holding food
- Disseminate industry best practices for food safety
- “Raise the bar” for food safety
How Does FSMA Relate to Feeding the World Population Today and Tomorrow?
FSMA and Feeding the World

- Only if we produce safe food can we be effective in feeding the world’s population.
- FSMA shifts safety of the food supply from responding to contamination to preventing it.
- FSMA stresses increased collaboration between regulatory agencies, both foreign and domestic, and the food industry in designing and implementing new food safety systems.
Thank you!