30th ANNIVERSARY IN A DAIRY STATE OF MIND
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The Food Safety Modernization Act: What It Means for Your Cheese Plant

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Clay Detlefsen, IDFA
Janet Raddatz, Sargento Foods Inc.
Dennis D'Amico, PhD. University of Connecticut
Registration - FSMA §102

- Bi-annual registration started last Fall, between October 22nd and January 31, 2013.

- The requirements are similar to the Bioterrorism Act requirements with two notable changes.

- Cheese is now divided into 4 categories: Soft, Ripened Cheese; Semi-Soft Cheese; Hard Cheese; Other Cheeses and Cheese Products.
Food Safety Plans, Hazard Analysis and Preventive Controls - FSMA §103

• Conduct hazard analysis of hazards *reasonably likely* to occur

• Put into place controls designed to significantly reduce or prevent those hazards

• Implement preventive controls through monitoring, corrective actions, and verification activities

• Verification activities *may* include environmental and finished product testing

• Reanalysis of food safety plan required every 3 years

• Food safety plan and all related records must be available to FDA during inspection
Supply Chain Management

- Know who your suppliers are (not just distributors)

- Have a plan for assuring adherence to food safety requirements

- It is appropriate to make the plan risk-based according to product type and facility history

- Goal is to assure product not adulterated or misbranded (due to undeclared allergens, etc.)
Traceability - FSMA §204

- Limited to “high risk” foods -- not facilities
- FDA has conducted pilot projects, assessed the cost and benefits and feasibility of new requirements
- FDA may not prescribe the use of specific technologies or require creation of duplicate records
- FDA cannot require “full pedigree”
- Congress recognized a need for an exemption for “commingled raw agricultural commodities”
- FDA has access to farm distribution information in case of an outbreak
Intentionally Introduced Hazards (Food Defense) - FSMA § 103 & §106

- Despite the express FSMA language, this has been extracted from the food safety plans
- Despite the express FSMA language to the contrary, “reasonably foreseeable standard” WILL apply
- Goal is to implement reasonable mitigation measures
- FDA to issue regulations at an unspecified time, but probably in 2016, well beyond the date envisioned by Congress
Food Safety Plan
Records and Access

• FDA will have legal access to see and copy records related to:
  – Food safety plan and related documents
  – Environmental and finished product testing
  – Corrective actions and related rationale
  – Monitoring of supply chain

• Good documentation practices are critical
New or Enhanced Enforcement Powers for FDA

• Increased facility inspection frequency
  – High Risk Domestic – every 3 years
  – Low Risk Domestic – every 5 years
  – Ramp up Foreign inspections
    (600 to 9,600 over 5 years)

• Suspension of registration

• Mandatory recall

• Expanded administrative detention authority
Fees on Food Companies and Importers

• Fees to reimburse FDA costs for
  – Reinspections
  – Recalls (very limited)

• Rates: Domestic = $224/hr; Foreign = $325/hr

• Export certificates - rates unknown

• Fast lane for imports - rates unknown

• Note that reinspection fees and export certificate fees started in 2011

• FDA has also expressed a desire to collect User Fees from registered facilities, but it does not have the legal authority
Are You In a FSMA State of Mind?

Med-Large facility perspectives
Food Safety Plan ≠ HACCP

Based Largely on HACCP Principles

* To highlight differences
FSMA Rosetta Stone

- HACCP → Food Safety Plan (FSP) or Hazard Analysis and Risk-based Preventive Controls (HARPC)
- Some PRPs → Preventive Controls (PC)
- CCP → Critical Limit of Preventive Control
- Cross-contamination allergen → Cross-contact
- Cross-contamination microbiological → Cross-contamination
Requirements for a FS Plan §117.126

• Responsibility

• Contents

• Qualified Individual
Responsibility

- Owner, operator, or agent in charge of a facility must prepare, or have prepared, and implement a written Food Safety Plan*

- Required to sign and date upon completion and upon any modification
Qualified Individual*

• Food Safety Plan must be prepared by a qualified individual
  – Or its preparation overseen by a qualified individual

• Also responsible for:
  – Validation of Preventive Controls
  – Review of Records for
    • implementation & effectiveness of PCs
    • appropriateness of Corrective Action
  – Reanalysis of FSP
Qualified Individual*

- Successfully completed training in the development and application of risk-based preventive controls
  - Recognized as adequate by FDA
  - Training must be documented

- Or qualified through job experience to develop and apply a food safety system

Note: FDA has funded FSPCA to develop training curriculum
Contents of FS Plan

1. Written Hazard Analysis
2. Written Preventive Controls*
3. Written Procedures for monitoring the implementation of Preventive Controls
   • including frequency that they are to be performed
4. Written Corrective Action Procedures
5. Written Verification Procedures
6. Written Recall Plan*
FS Plan Contents: Hazard Analysis - Identification

- Hazard identification must consider hazards that may occur naturally or be unintentionally introduced
  - Biological
  - Chemical
  - Physical
  - Radiological*
FS Plan Contents:
Hazard Analysis - Evaluation

New Considerations:

- Condition, function, and design of equipment and facility*

- Transportation practices*

- Intended or reasonably foreseeable use*
FS Plan Contents: Preventive Controls*

- Preventive controls significantly broader than HACCP CCPs

- Preventive controls may or may not include critical limits

- Preventive controls include programs that we have called Prerequisite Programs (PRP) under HACCP
FS Plan Contents: Preventive Controls*

• Parameters associated with the control of a hazard and the values to which any parameter must be controlled (CCPs)

• Process controls – include procedures, practices, and processes performed on food during manufacture (cooking, cooling, acidifying, etc.)
FS Plan Contents: Preventive Controls*

- **Food allergen controls**
  - Ensuring protection from cross-contact
  - Ensuring proper labeling

- **Sanitation controls**
  - To minimize or prevent hazards that are reasonably likely to occur
  - Required where RTE food is exposed to environment

Note: Allergen & Sanitation controls have typically been PRPs
FS Plan Contents: Preventive Controls*

• Sanitation controls must include procedures for:

  – Cleanliness of food-contact surfaces

  – Prevention of cross-contact and cross-contamination

  – The owner, operator, or agent in charge of a facility must take action to correct, in a timely manner, conditions and practices not consistent with procedures and document
FS Plan Contents: Preventive Controls*

• Recall Plan that includes procedures with responsibility assigned for the following:

  – Notification of direct consignees

  – Notification of the public when appropriate to protect public health

  – Conducting effectiveness checks

  – Disposal of recalled product
FS Plan Contents: Preventive Controls*

- Other Controls necessary to assure that product is not misbranded or adulterated
  - Temperature control during transportation of refrigerated foods
  - PRPs may fall under this

- FDA is seeking comments on supplier approval and verification programs
Preventive Controls are Subject to:

- Monitoring
- Corrective Action
- Verification
Food Safety Plan Reanalysis

- At least once every 3 years

- When a significant change creates the potential for a new hazard or a significant increase in one previously identified

- When there is new information about potential hazards associated with a food

- When a preventive control is not properly implemented, ineffective, or there was no established CA procedure
Qualified facilities

• Exempt from Hazard Analysis and Risk-Based Preventive Controls (HARPC) requirements
  
  – Won’t have to submit food safety plans

1. “very small” businesses
   – FDA proposed 3 different categories based on average annual revenues of previous 3 years
     – $250,000: 65% of ACS survey respondents
     – $500,000
     – $1 million: 17% between $250,000-1M
Qualified facilities

2. Tester Amendment

– Based on average of previous 3 years

– <$500,000 in average annual sales AND,

– >50% of sales go to “qualified end-users”
  • consumers anywhere
  • restaurants or retail food establishments in the same state as the farm or not more than 275 miles away
Qualified facilities

• Owner, operator, or agent in charge must submit statement certifying facility meets the definition of qualified facility
  – Not required to submit financial information
  – Make available to FDA upon request
Modified requirements

• Required to:

1. Certify you have identified potential hazards and are implementing and monitoring the performance of preventive controls to address the hazards to ensure they are effective to satisfy this requirement OR,

2. Submit documentation that you comply with a state, local, county, or other non-federal food safety law

• May include: licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight
Modified requirements

- If you choose the former (and I hope you do…) your food safety plan should closely resemble HARPC

- This could include a HACCP plan with relevant additions
Modified requirements

• If you choose the latter you must provide the name and complete business address of the facility where the food was manufactured

• must appear prominently and conspicuously:
  
  – on the label of the food
  
  – at the point of purchase, on a label, poster, sign, placard, or documents delivered with the food or in an electronic notice, if sold over Internet
Qualified facilities

• Documentation must be submitted to FDA initially within 90 days of the compliance date of the rule
  – resubmitted at least every 2 years, or whenever there is a material change to the information

• Maintain records used to support the documentation
  – financial basis, % sales to qualified end users (if applicable)
  – food safety plan, operating license issued by a state or local authority, etc.

• Make available to FDA upon request
Qualified facilities

• FDA may withdraw the exemption:

– in the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility OR,

– if it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions at facility
Current Good Manufacturing Practices

- Qualified facilities are not exempt from cGMPs
- cGMPs are updated and revised
  - Old GMPs 21 CFR 110
- Language in the regulation will be updated
  - “shall” will be replaced with “must”
  - “facility” replaced with “establishments” or “plants”
- Certain recommendations would be deleted
  - Become FDA guidance
cGMPs

• Examples of significant new requirements:

  – Controls for cross-contact from allergens throughout the manufacturing process

  – Protection of food packaging materials from cross contamination

  – Verification that cleaning and sanitizing chemicals are safe for use

  – All plant equipment must be installed to facilitate its cleaning and cleaning of adjacent areas
cGMPs

• Some recommendations that may now be required:

  – Personnel responsible for food safety must have background of education, experience, or combination of both to provide competency to process safe food

  – Mandatory training for employees and supervisors
    • requirement for records that document training

  – cleaning non-food-contact surfaces of equipment as frequently as necessary to protect against contamination of food and food-contact surfaces
cGMPs

• Some recommendations that may now be required:
  
  – Portable equipment and utensils **must** be stored in a way to prevent cross contact and cross contamination
  
  – Incoming shipments of raw materials and containers **must** be inspected on receipt for contamination
  
  – Food **must** be protected from contaminants that drip, drain, or are drawn into food
Final note

• While family-owned farms, small growers, and small business alliances laud the exemptions...many regulators, inspectors, public health officials and food safety experts do not

• Please show due diligence for all of us
Making Cheese in a Changed World
Even Without FSMA, FDA is Changing

• FDA's Culture Has Changed
  – it is more inspection oriented
  – it is more enforcement minded

• FDA is more public
  – Posting of 483's
  – Pursuing injunctions

• Inspections are more aggressive, intense and adversarial
FSMA Applied – How an FDA Inspection Will Change

• FDA inspections are changing dramatically
  – Historically inspections were based on observations in the plant
  – New inspections will be based on document review (more like an IRS audit) - show me this, show me that

• Key word is “document, document, document”

• Consistency of documentation and clear rationale for decisions will be paramount
FSMA Conclusion

• Food companies should focus on 3 areas
  – Food safety plans (mandatory HACCP)
    • Includes Environmental Monitoring
  – Supply chain management (foreign and domestic)
  – Records maintenance and access policies

• FDA to issue regulations and guidance
  – Review mandatory HACCP regulations
  – Review draft guidance documents as they become available
Questions?

Clay Detlefsen, IDFA
Vice President, Regulatory Affairs and Counsel
cdetlefsen@idfa.org

Janet Raddatz, Sargento Foods, Inc.
Vice President, Quality and Food Safety Systems
Janet.Raddatz@sargento.com

DJ D'Amico
University of Connecticut
djdamico1@gmail.com