FSMA-Its impact on Artisan Cheesemakers

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Some of the material presented here was adapted from previous presentations on the subject including FSMA's Update: Proposed Preventive Controls, Foreign Supplier Verification & Third Party Certification (Allen Sayler for Dairy Foods Magazine) and The Food Safety Modernization Act: What It Means for Your Cheese Plant (Clay Detlefsen and Janet Raddatz for the American Cheese Society).

Food Safety Modernization Act (FSMA)

- 2011: The most significant change in U.S. food safety law since passage of the Food Drug & Cosmetic Act in 1938
  - Changes focus from reaction to prevention
  - Documentation: If you didn't document it, it didn't happen!
- FDA will likely elaborate in guidance documents (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/default.htm)
- Food Safety Preventative Controls Alliance (FSPCA) will develop materials and training to assist
  - specifically targeted for small-medium sized businesses

FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Sayler, A. 2012. Prepare your plant to comply with Food Safety Act. Dairy Foods..
Silliker. 2012. FDA Food Safety Modernization Act: Marking a New Era in U.S. Food Safety. Food Safety Magazine
Leavitt, J. 2012. Food Safety: Preparing For FSMA. Dairy Foods Magazine

Registration: §102

- The requirements are similar to the Bioterrorism Act requirements
- Facilities must register and renew their registrations every other year, between October 1 and December 31 of each even-numbered year
- Requires the registration to include an assurance that FDA will be permitted to inspect the facility
- Provides for FDA to suspend a food facility's registration
- Identifies food categories:
  - Cheese is now divided into 4 categories: Soft, Ripened Cheese; Semi-Soft Cheese; Hard Cheese; Other Cheeses and Cheese Products

http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm315290.htm
http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm331959.htm

Fees

- FDA has expressed a desire to collect User Fees from registered facilities, but it does not have the legal authority
- No fee to register facility or for initial inspection
- Fees to reimburse FDA costs for re-inspections and recalls
  - Rates (starting Oct. 1 2013): Domestic = $237/hr; Foreign = $302/hr
- FDA does not intend to issue invoices for re-inspection or recall order fees until it has published a guidance document to outline the process through which small businesses may request a reduction of fees

http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm

FSMA: New or enhanced enforcement powers

- Mandatory food recall authority (§ 206);
- Expanded access to records when a food safety risk is suspected (§ 101);
  - FDA will have legal access to see and copy records related to:
    - Food safety plan and related documents
      - Environmental and finished product testing
    - Expands to foods handled in a similar manner to that of the suspect food
- It is a prohibited act to:
  - Fail to establish or maintain records
  - Fail to make records available to FDA as required by the act and this regulation
  - Refuse access to or verification or copying of any such required record

http://www.gpo.gov/fdsys/pkg/FR-2012-02-23/html/2012-4165.htm

Notable changes

- Increased inspections of food facilities (§ 201);
  - High Risk Domestic – within 5 years then every 3 years
  - Low Risk Domestic – every 5 years
- FDA is becoming more inspection oriented and enforcement minded
  - While it's not the FDA's intent, anecdotal reports suggest that inspections have become more aggressive and adversarial
- Inspections are changing focus to document review
  - Consistency of documentation and clear rationale for decisions will be critical
- Although not part of FSMA, FDA is becoming more public
  - Posting of observations (form 483)
  - Pursuing injunctions: suspend production and detain products

Inspections

- FY 2013 FDA planned inspections of 264 cheese facilities, mostly artisanal
- Domestic Assignments 1+2: FDA is inspecting soft/semi soft cheese manufacturing facilities swabbing for *L. monocytogenes*
  - Large, small, industrial and artisan
- Domestic Assignment 3: March 2013 includes inspection of aged cheese producers
  - will include both environmental and finished product sampling
  - *L. monocytogenes* and *E. coli* (including STECs)
- May target those companies with previous positives

Hazard Analysis and Risk-Based Preventive Controls (HARPC): §103

- Similar to HACCP, will now be called Food Safety Plan (FSP) or HARPC
- Owner, operator, or agent in charge of a facility must prepare, or have prepared, and implement a written FSP
  - Required to sign and date upon completion and upon any modification
- FSP must be prepared by, or its prep overseen by, a qualified individual
- Qualified individual is also responsible for:
  - Validation of Preventive Controls
  - Review of Records for implementation & effectiveness of PCs
  - Appropriateness of corrective action
  - Reanalysis of FSP

Qualified Individual

1. Successfully completed training in the development and application of risk-based preventive controls
   - Recognized as adequate by FDA
   - Training must be documented
2. Or qualified through job experience to develop and apply a food safety system

- Remember FDA has funded FSPCA to develop training curriculum

FSPCA

- Develop standardized HARPC training and distance education modules for industry & reg. personnel;
- Develop “train-the-trainer” materials;
- Create a technical assistance network for small- and medium-sized companies;
- Develop commodity/industry sector-specific guidelines for PCs;
- Assess knowledge gaps and research needs for further enhancement of PCs;
- Identify and prioritize the need for and compile critical limits for widely used PCs

Contents of FSP

- Written Hazard Analysis
- Written Risk-based Preventive Controls
- Written Procedures for monitoring the implementation of PCs
  - including frequency that they are to be performed
- Written Corrective Action Procedures
- Written Verification Procedures
- Written Recall Plan

Hazard analysis

- Develop product descriptions and process flow diagrams
- Identify “known or reasonably foreseeable hazards” at each step
  - Potential biological, chemical, physical, or radiological hazards that may be associated with the facility or the food,
  - naturally occurring or unintentionally introduced
  - Ready-to-eat (RTE) producers must identify environmental pathogens
- New Considerations:
  - Condition, function, and design of equipment and facility
  - Transportation practices
  - Intended or reasonably foreseeable use
- Hazards that are “reasonably likely to occur” must be addressed by PC

Preventive Controls (PCs)

- 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 under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis
  - significantly broader than HACCP CCPs, may or may not include critical limits

Preventive Controls (PCs)

- PCs include traditional Prerequisite Programs (PRPs)
  - Supplier Management
  - Allergen Control Program
  - Good Manufacturing Practices Program (21 CFR 110 (117))
  - Product Traceability/Recall
  - Food Defense
  - Employee Training (GMPs, sanitation, allergens, chemical use, etc.)
  - Processing Equipment Cleaning & Sanitizing

Preventive Controls (PCs)

- Food allergen controls
  - Ensuring protection from cross-contact, ensuring proper labeling
- Sanitation controls
  - To minimize or prevent hazards that are reasonably likely to occur
  - Prevention of cross-contact and cross-contamination
  - Cleanliness of food-contact surfaces
  - Required where RTE food is exposed to environment
- Process controls:
  - procedures, practices, and processes performed on food during manufacture (cooking, cooling, acidifying, etc.)

Preventive Controls (PCs)

- Must be validated to show they are capable of controlling the hazard
- Parameters associated with the PC must be monitored
- Efficacy of PCs must be verified
  - Verification activities may include environmental and finished product testing
  - FDA is currently seeking comment on this
- Develop corrective action plans for potential problems

Reanalysis of FSP

- 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

- Remember: Food safety plan and all related records must be available to FDA during inspection

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 and is seeking comment
   - <$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

Good Manufacturing Practices (cGMPs)

- Qualified facilities are not exempt from cGMPs
- cGMPs are updated and revised
  - Old GMPs 21 CFR 110
  - 21 CFR 117 to replace 21 CFR 110 in approximately 3 years
- 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

Estimated timeline

- Jan 16, 2013: Proposed Rule published in Federal Register and opened for public comment
- Nov. 16, 2013: Comment period closes
- Estimates:
  - July 1, 2014: FDA Publishes Final Rule
  - July 1, 2015: FDA enforces PC regulation on large dairy plants
  - July 1, 2016: FDA enforces PC regulation on small dairy plants
  - July 1, 2017: FDA enforces PC regulation on very small dairy plants

Planning ahead

- Companies should be proactive and focus
  1. Food safety plans:
     - Start with your HACCP plan, review mandatory HACCP regulations
     - May need consultant
     - Includes Environmental Monitoring and testing as needed
  2. Supply chain management, audits, traceability
  3. Records maintenance and access policies
     - Determine whether facility records are inspection-ready
- FDA to issue regulations and guidance
  - Review draft guidance documents as they become available

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