Food Safety Modernization Act (FSMA)

Key Points for Warehouses

June 2013

David Hakes- Regulatory Manager
Agenda

- Presentation Objective
- Why FSMA History & Leadership
- What is Congress & FDA trying to do
- Components & Timeline
- Your Initial Determination
- **FMSA Preventative Controls For Processing Facilities**
- **FMSA Specifics Warehouse Preventative Controls**
- Food Defense
- FMSA Resources
Objective

• Background on the law & regulations
• Knowledge of timing
• Key takeaway’s
• Invitation to learn more....and get prepared...
Why FSMA History

“...one of the deadliest foodborne illness outbreaks in U.S. history, in which contaminated Colorado cantaloupes sickened at least 147 people, including at least 30 who died and one woman who had a miscarriage.”
What is Congress/FDA trying to accomplish with FSMA?
FSMA FDA Leadership

• Lawyer, started at the FDA – know for a practical approach to food carcinogens
• Spent time in private practice in industry and academia.
• 1994- 1996 at (USDA), During that term he implemented a science-based approach Hazard analysis and critical control points (HACCP))
• July 7, 2009  Senior Advisor to the FDA Commissioner. And on January 13, 2010, he was appointed to another newly created post at the FDA, this time as Deputy Commissioner for Foods.
What does it mean to FDA

- Mandated Work
  - Facility Biannual Registrations
  - New Regulations, Guidance
  - More “Risk Based” Inspections
- More Access to Your Information
- More Judicial System Capability/Use
- More Budget and Fees
Components

- Prior Notice
- Detention of Foods
- Registration
- Records
- Access
- Current Good Manufacturing Practices
- Preventative Controls Food
- Preventative Controls Animal Feed
- Suppliers - Foreign & Domestic
- Food Defense
FSMA Public Law 111-353

- Prevention
  - Mandatory preventive controls for food facilities
  - Mandatory produce safety standards
  - Authority to prevent intentional contamination
  - Sanitary Transportation of Food
  - Inspection and Compliance
  - Mandated inspection frequency
  - Records access
- Response
  - Mandatory recall
  - Suspension of registration
  - Enhanced product tracing abilities
  - Additional Recordkeeping for High Risk Foods
- Imports
  - Importer accountability
  - Third Party Certification
  - Certification for high risk foods
  - Authority to deny entry
- Enhanced Partnerships
  - State and local capacity building
  - Foreign capacity building
  - Reliance on inspections by other agencies
  - Additional partnerships
Preventative Controls Exemptions*

- Business Size
- Dietary supplements
- Alcoholic beverages
- Seafood and Juice (HACCP) & low-acid canned food*
- Warehouse exemption
  - Non-refrigerated warehouses – exempt
  - Refrigerated warehouses – modified controls
  - Frozen warehouses – based on reason for freezing
  - Packaged foods that are not exposed to the environment
  - Packaged food for which refrigeration is not required for safety.“
- Storage facilities only raw agricultural commodities (low risk items such as grains. (No exemption for fruits and vegetables)

- Also exempt with respect to cGMPs but not all – part 117.206
Details still being explained

- Public Meeting Transcript Thursday, February 28, 2013
  Exposed food comments- day 1pg 247 also day 2 pg. 86.

- “example of an exemption that Congress asked us to look at...It has to do with warehouses that only store, emphasis on only, so the only product that they're storing is packaged foods that are **not fully exposed** to the environment.

- We looked at that, and recognized that in fact this is a very low risk situation, and we agreed that an exemption was in place, except that we also recognized that some of these commodities require refrigeration in order to stay safe.”

- “it's basically (the ability to have) a physical touch of the human body to the food item” -“correct.”

- ..proposed some modified requirements to make sure that the refrigeration, in fact, was carried out at the correct temperature.

- Qualified Individual comments Pg. 263
  ...They would have to review the records, **or oversee this review**...
Foreign Supplier Verification Program

• Regulation Not Published
• Responsibility is foreign producer & importer

Who is the —importer?

...the United States owner or consignee of the article of food at the time of entry of such article into the United States or the U.S. agent or representative of a foreign owner or consignee.
Timeline - Big Picture

- Recall, Re-Registration, Certain Records
- Otherwise the big wait for finalization
  - Timing your changes
    - Extension of comment period
      - From May to September 2013
    - Final Regulations to be published 2014?
  - Implementation: 60 days, plus 1 year, 2 or 3
- Awareness Training for large cross section of staff
- Organize how the changes are incorporated into your current quality management systems
June 18, 2012

James A. McCarthy
President and CEO
Snack Food Association
1600 Wilson Blvd., Suite 650
Arlington, VA 22209

Dear Mr. McCarthy,

This responds to your letter of May 29, 2012, concerning FDA’s plans regarding the preventive controls and foreign supplier verification provisions in sections 103 and 301 of the Food Safety Modernization Act (FSMA). Your letter was prompted by the approaching statutory effective date of July 3, 2012, for the preventive controls provision.

FDA is committed to full and timely implementation of FSMA and will be issuing proposed rules to implement sections 103 and 301. Those rules, when final, will contain provisions that clarify industry’s responsibilities and will foster compliance with FSMA’s new requirements in an orderly and effective manner. FDA will expect to enforce compliance with these new FSMA requirements in timeframes that will be described in the final rules.

Other food safety provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its implementing regulations for human and animal food continue in effect. If we find a food that poses a public health risk to humans or animals, or if an inspection reveals a facility operating under insanitary conditions or otherwise failing to operate safely, we will continue to take action as appropriate under the FD&C Act.

Sincerely,

Michael R. Taylor
Deputy Commissioner for Foods
Today’s Current Focus

Preventative Controls
Initial Determinations

• Are you exempt?

• What is impacted?
  • Food & Feed plants, Distribution/Storage Locations
  • FDA Processing Definition 21 CFR 1.225 "processing" means handling, storing, .. dockside unloading, holding, or heading, eviscerating, or freezing other than solely to prepare fish for holding on board a harvest vessel;
Initial Determinations

- Now is your chance to comment
  - “The last thing we want people to be doing is investing resources and changing what they’re doing if they’re already implementing modern preventative controls, if the change doesn’t make a practical difference to food safety.”
    - Mike Taylor 2013 Speaking to GMA.

- Personal Request
  Very Specific FDA Guidance Documents w/examples

- Disclaimer regarding actions to take
  - Requirements are subject to interpretation
    - Eyes of the inspector
cGMP’s

• 21 CFR 110 Replaced with 21 CFR Part 117
• Definitions & as a result who it applies to
  • Foreign and Domestic facilities
• Protection against allergen cross-contact
• Updated language (e.g., “must”)
• Updated Definitions (e.g., Packaging equal to food contact surface)
• Certain provisions containing recommendations would be deleted
• Comments requested on mandating training and whether rule should require, rather than recommend, certain provisions
cGMP’s

- Education & Training
- Hand Washing
- Clothing & Protective Garments
- Sanitation Controls... Environmental testing?.....
- Allergen Controls- Cross Contact
- Hygienic Controls.. Incoming Material Inspection!
- Building and Grounds
- Pest Control
- Waste Management
- And more... Calibration!
cGMP Examples

• Training- 117.10 Appropriate training for supervisors and workers to ensure that they have the necessary knowledge and expertise in food hygiene, food protection, employee health and personal hygiene to produce safe food products. Easily understood by the employee. Records must be maintained for each employee.

• Sanitation- Non-Food-Contact surfaces of equipment used in the operation of a food facility must be cleaned in a manner and as frequently as necessary to protect against cross contact and contamination of food and food-contact surfaces.
Stay with me..
Preventative Controls
Key Thought

• HACCP remains *plus*

• Pre-requisite programs have to be evaluated

• Specific ones are then basically managed as Critical Control Points termed Preventative Controls vs. CCP’s
Preventative Controls

- Specific cGMP’s
- Food Safety Plan
- Allergen Controls
- Sanitation Controls
- Record Keeping
Warehouse Perspective

- Exempt? - no
- Refrigerate for Safety? Yes
  - Exposed Product? Yes
    - ID Qualified individual
    - ID Owner, Operator Agent in Charge
    - Food Safety Plan
Written food safety plan

What will your written plan look like?

Include:

• A hazard analysis
• Preventive controls
• Monitoring procedures
• Corrective action procedures
• Verification procedures
• A recall plan (FSMA Requires More Detail!)

Look Familiar?
Hazard Assessment

- Hazard Assessment
  - Reasonably likely to occur, reasonably foreseeable hazard
  - Hazards - biological, chemical, physical, and radiological
  - “…which a prudent person who ..holds.. food would establish controls because experience, illness data, scientific reports or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur ... in the absence of those controls.”
- Health Risk Assessments - define the likelihood that the hazard will occur and its severity if it does occur
- Reanalysis of hazards - unexpected events
- Includes reconditioning of products
Preventative Controls

All preventive controls that are established to address a hazard identified as reasonably likely to occur must have a scientific and technical basis.

- Carefully consider specific activities that might introduce or prevent a risk
  - GMP’s - Is hand washing?
  - Sampling
  - Truck cleanliness and security inspections?
  - Goods integrity inspections?
  - Refrigeration - Warehouse temperature monitoring?

Do you have a study that shows how the temperature recording device location accurately reflects temperatures throughout the room, compartment, building?
Preventative Controls

• Consider in establishing all Preventative Controls if past failures equate to “reasonably likely to occur” and if effective corrective actions can be taken.

• Preventative Controls Require Validation & Verification
  • Training- Is your post training documentation i.e. “GMP test” scientific information… is it enough?
Example Food Safety Plan

- **Hazard Analysis** - Refrigerated Exposed Foods that are Ready to Eat Foods Group (intended or reasonably foreseeable use)
  - Must consider pathogens in the environment
  - Formulation of the food - refrigerated only for quality?
  - Condition of the facility, the equipment, materials, sanitation and transportation practices etc.
  - Would these bring hazards into the facility; could these increase the potential for hazards
  - Are there any manufacturing and processing procedures, that may either introduce hazards, or reduce hazards that are present
  - What is the health risk? i.e. Listeriosis infection causing death, miscarriage

- **What Controls** are then Preventative and are they Validated?
  - Sampler storage and sanitation
  - Environmental cleanliness preventing cross contact

- Written procedures addressing the above hazard assessment
  - the frequency with which they are to be performed (monitoring which requires calibration), corrective actions, and these records must be verified - which requires training
  - Recall plan
Information Availability
Record Separation?

- Receipt Qty’s
- Customer Supplier Names
- Calibration
- Scheduling SOP?
- Downtime SOP?
- Food Defense
- Maintenance
- Lean

HACCP Recall Plan
- SOP’s
- Preventative Controls and their validation, monitoring, verification and Corrective Actions
- Allergen Sanitation, Qualified Ind. Training

Proprietary Information
QCP’s & Other programs
Key Points on Documentation

• Decide which records if any to exclude!
• Document those records in the inspection procedure that are allowable records and:
  • When
    • Routine vs. Reasonable belief that a food will cause serious adverse
  • & How
    • Required to be made promptly available upon oral or written request.
  • & Copying? FSMA does not specifically allow it
Key Points on Documentation

• Include “Corporate” controlled processes

• Review current documents to ensure responsibilities are clearly assigned to competent supervisory personnel
Key Points on Documentation

• FDA definition of “Sanitation” is broad.
  • Focused on preventing cross-contamination (pathogens) and cross-contact (allergens) from people, “insanitary objects”, raw product, and packaging
• Ensure your SOP’s cover all areas of sanitation
  • Example- have a written Traffic Control SOP
  • Define “Food Contact Surface” within your procedures
Other Documentation Points

• Employee protections
  • HR Policies- Employees cannot be fired or discriminated against for reporting violations of the Food, Drug, and Cosmetic Act.

• Good Practices vs. FSMA Requirements
  • Electronic records (21 CFR part 11)
  • Laboratory accreditation
Storage and Distributions Locations vs. Plants

- Is the “food” exposed to the environment?
  - Hazard Analysis* etc. no real difference from a plant including Qualified Individual

- Does fully packaged food require temperature control for safety?
  - Modified Requirements
    - Controls, Trained Individual, Corrective Actions, Have records documenting verification activities
      - Records documenting the monitoring of the monitoring i.e. secondary sign of temperature records

- Neither- Fully packaged, not temperature controlled for food safety, follow GMP’s
Storage and Distributions Locations vs. Plants

GMP’s – Continue these traditional warehouse activities

- Pest Control
- Foreign Material protections- Glass, Hard Plastics
- Allergens- cross contact segregation & spill clean up
- Safe Storage of Chemicals
- Blood born pathogen protections
- Sick Employee Product Protections
- General Training
- Lot Tracking
- Food Defense*
Regulation Status

- cGMP & Preventative Controls Final FDA & OMB review
- Comment inclusion?
  - Supplier approval/verifications
  - Facility profiles
  - Product and Environmental testing
  - Complaint reviews

- More FSMA To Come including...
  - Foreign supplier requirements
  - Sanitary transportation of food
  - Preventative Controls specific to animal feed
  - Food Defense
    - intentional hazards/economic adulteration
    - Lot Tracing
Food Defense

- Food Defense - Protection from intentional and unintentional contamination. Different from “food security” which is about “availability”.

Photograph by Kyuchil Joo/Gary Images
Food Defense

- Also seeing interest by our large customers
- These Regulations have not yet been published but will likely include .... FSMA Act - 418
  - Conduct hazard analysis
  - Put into place preventive controls
  - Monitor the preventive controls
  - Implement corrective actions
  - Conduct verification activities
  - Give FDA access to records
  - Conduct a reanalysis
Food Defense – Top Line

- Have a designated written program
  Basics include:
  - Designated Food Defense Leader
  - Hazards to address Intentional and Unintentional
  - Risks Food Safety and Economic Adulteration
  - Employee Hiring, Training, Employee “Departures”
  - Information Security Requirements
  - Location Physical & Materials (seals, paperwork) Requirements
  - Question and report suspicious circumstances immediately
  - Audit it & Re-evaluate it
  - Note: Transportation contracts
    - Customer specific requirements for food defense including reporting and securing loads.
    - Special Programs Compliance CTPAT
Food Defense – Include Economically Motivated Adulterants

• For you, your suppliers, and your service providers
  • Is there a document policy that identifies objectives, responsibilities and details how economic adulteration is prevented?
  • Is the program audited?
  • Is there a Code of Ethical Conduct?
  • Are only approved and adequately qualified suppliers used?
  • Is there employee training on economic adulteration?
<table>
<thead>
<tr>
<th>CTEs</th>
<th>Transportation (exchange of goods) - Shipping</th>
<th>Transportation (exchange of goods) - Receiving</th>
<th>Transformation (creation/multiplication of products) - Input</th>
<th>Transformation (creation/manipulation of products) - Output</th>
<th>Depletion (exit from system) - Consumption</th>
<th>Depletion (exit from system) - Disposal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Currently Required KDES</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Owner (firm submitting information)</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>Date/Time</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>Event Location</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>Trading Partner¹</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Item (the good)</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lot/Batch/Serial#</td>
<td>BP*</td>
<td>BP*</td>
<td>R</td>
<td>R</td>
<td>BP</td>
<td>BP</td>
</tr>
<tr>
<td>Quantity</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>Unit of Measure</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>Linking KDES</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Activity Type (e.g., PO, BOL, Work Order)</td>
<td>C*</td>
<td>C*</td>
<td>R</td>
<td>R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Activity ID (number associated with PO, BOL, Work Order)</td>
<td>C*</td>
<td>C*</td>
<td>R</td>
<td>R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transfer Type²</td>
<td>C</td>
<td>C</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transfer Number²</td>
<td>C</td>
<td>C</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lot/Batch Relevant Date³</td>
<td>C</td>
<td>C</td>
<td>C</td>
<td>C</td>
<td>BP</td>
<td>BP</td>
</tr>
<tr>
<td>Carrier ID</td>
<td>C</td>
<td>C</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trailer Number</td>
<td>C</td>
<td>C</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

R = Required Field
C = Conditional Field; the need for this field would be determined by business circumstances, and in the instance of transport events that do not capture batch/lot numbers, this field may be required (*)
BP = Best practice is to capture the batch/lot number or relevant date whenever possible; however, in recognizing the current difficulty in capturing this information for transport and depletion events, Activity ID or another KDE that provides links is recommended.

Note GS1 Standard Development
Foreign Supplier Verification Program

- Regulation Not Published
- Responsibility is foreign producer & importer

Who is the —importer?

...the United States owner or consignee of the article of food at the time of entry of such article into the United States or the U.S. agent or representative of a foreign owner or consignee.
FSMA Resources

- FDA WEBSITE
  - Dr. Craig Henry at Deloitte
- Produce Safety Alliance
- Sprout Safety Alliance
- 1995 Seafood HACCP regulation
- 2001 Juice HACCP Alliance
- Preventive Controls Alliance
- Regulation Summary’s
  http://www.ifdaonline.org/Government-Relations/Regulatory-Watch/Food-Safety#fsma
Questions