

FDA Food Safety Modernization Act (FSMA)

Signed into law January 4, 2011

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Main Elements of New Law

1. New Responsibilities on Food Companies
2. New Controls over Imported Food
3. Enhanced Enforcement Powers
4. New Fees on Food Companies and Importers

New Responsibilities for Food Companies

Impacting daily operations in all registered facilities, domestic and foreign:

- Food Safety Plans/Preventive Controls (Hazard Analysis)
- Supply Chain Management
- Records Maintenance and Access
- Food Defense Plans

Hazard Analysis and Preventive Controls (Food Safety Plans)

- 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 include environmental and product testing

Hazard Analysis and Preventive Controls (continued)

- Reanalysis required every 3 years or a change that creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard
- Records required to be maintained for 2 years
- Food safety plan and all related records available to FDA during inspection (paper and electronic)

Hazard Analysis Defined

- Biological
- Chemical
- Physical
- Radiological
- Natural Toxins
- Pesticides
- Drug Residues
- Decomposition
- Parasites
- Allergens
- Unapproved food and color additives

Types of Controls Defined

- Sanitation for food contact surfaces & utensils, including food contact surfaces of equipment
- Supervisor, manager, and employee training
- Environmental monitoring program
- Food allergen control program
- Recall plan
- Current Good Manufacturing Practices
- Supplier verification activities that relate to the safety of food

Actions we are taking related to Food Safety Plans:

- Review record retention from 3 to 2 years for Food Safety (FS) records
- CCPs with scientific validation documented
- Develop Finished Product pathogen testing verification program
- Supplier verification that relates to Food Safety (FS Audit)
- Formal change management process to initiate a new hazard analysis

Actions we are taking related to Food Safety Plans:

- HACCP Controls
 - Add Radiological Risk to Risk Assessment
 - Assure we address natural toxins, pesticides, drug residues, decomposition, and parasites
 - Include intentionally introduced hazards (Food Defense integration)
- Expansion of HACCP training
- Risk Assessment and HACCP Plan in place before manufacture begins

Supply Chain Management

- Know who your suppliers are (not just distributors)
- Have a plan for assuring adherence to food safety requirements
- Appropriate to make plan risk-based according to product type and facility history
- Goal is to assure product not adulterated or misbranded (due to undeclared allergens)

Actions we are taking related to Supply Chain Safety:

- Develop Supplier Food Safety Plan based on risk of supplied product and facility history
- Get to better know the suppliers that our distributors are using
- Foreign Supplier Verification Program review
 - “Brokers, importers will pass responsibility on to you”
 - FDA Guidance – Good Importer Practices

Records Maintenance and Access

- FDA will have legal access to see and copy records related to FS Plan and related documents:
 - Includes environmental and finished product testing
 - Includes corrective actions and related rationale
 - Includes customer/consumer complaints related to food safety
 - Includes monitoring of supply chain
- Good documentation practices will be critical

Actions we are taking related to Food Safety Records:

- Record retention – 3 to 2 years?
- Review record creation practices
- Review existing records
 - Food Safety or Quality?
 - Consistency
- Establish protocol that any documents FDA takes copies of are marked “Confidential Business Information”

Actions we are taking related to Food Safety Records:

- Corrective Action Process Review
 - Clear rationale as to decision is documented
 - Corrective Action database updates

Intentionally Introduced Hazards (Food Defense Plans)

- To be included in hazards analysis, including hazards that may be introduced by acts of terrorism
- “Reasonably foreseeable standard” does NOT apply
 - Use Vulnerability Assessment Tool to determine risk
- Implement appropriate mitigation step

Actions we are taking related to Food Defense:

- To assess intentionally introduces hazards:
 - Use of vulnerability assessment tools
 - Implement appropriate mitigation steps

Not To Be Forgotten

- Bi-annual registration begins 2012
- Traceability
- Records access under Bioterrorism Act
- Sanitary Food Transportation Practices

Import-Related Provisions

- Foreign Supplier Verification Program
- Third-Party Certification
- Accreditation Process for Third-Party Auditors
- Laboratory Accreditation
- Voluntary Qualified Importer Program

We are not importers, BUT are responsible to verify our brokers, importers are following the law

Implementation Timetable

- Various effective dates for different provisions
- FDA has over 50 obligations to meet
 - guidance documents
 - Study reports to Congress
 - implementing regulations - key provisions become effective even without FDA regulations
- Longer implementation time for small and very small businesses
- Funding?? (\$1.4 billion over 5 years)

Implementation Timetable

- Basic timeline
 - 18 months – food safety plans
 - sanitary food transportation
 - 24 months – foreign supplier verification
 - Longer for traceability
 - Bi-annual registration begins 2012
- Provisions effective immediately
 - Mandatory Recall
 - Records Access under Bioterrorism Law

Implications to Dairy: “High Risk” Criteria

- “High Risk” comes up in two relevant provisions
 - Inspection frequency
 - Traceability
- FDA to determine what falls under “high risk” category
 - Likely to be influenced by recent recalls
 - Listeria risk assessment of 2001 may apply

FDA Inspections will Change

- FDA Inspections will change dramatically
 - Currently based on observations in the plant
 - New inspections will be based on document review
- Key word is “document, document, document”
- Consistency of documentation and clear rationale for decisions will be paramount

Conclusion

- Food companies should focus on 3 areas
 - Food safety plans (including food defense)
 - Supply chain management (domestic and foreign)
 - Records (creation, maintenance, access policies)
- FDA regulations and guidance
 - Review
 - Comment