Food Safety & Modernization Act

WHAT DOES IT MEAN TO BUSINESSES

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Disclaimer

• This is brief general overview of the Food Safety Modernization Act
• Some regulatory text from the final rule is included in this presentation, but not all text is provided! Also, in many instances the text provided is abridged to make it more brief and emphasize major concepts.
• Bottom line – this is a complicated rule and this presentation does not cover all aspects or all requirements!
What We Will Talk About

• What is FSMA
• Who Does it Affect
• What Does it cover
• What is the next Step
What is FSMA

• The U.S. Food & Drug Administration - Food Safety Modernization Act

• Signed into Law January 4, 2011 – Issued December 2013

• Created Sweeping Reforms of Food Safety Laws

• Mandates new Prevention Based Regulatory system

• Requires FDA to develop and issue more than 50 regulations and/or guidance documents

• Shift Focus from being reactive to contamination prevention before there is a potential problem

• Requires FDA registration to be updated every two years
What’s so historic about the law?

• Involves creation of a new food safety system
• Broad prevention mandate and accountability
• New system of import oversight
• Emphasizes partnerships
• Emphasizes farm-to-table responsibility
• Developed through broad coalition
Why is the law needed?

• Globalization
  • 15 percent of U.S. food supply is imported

• Food supply more high-tech and complex
  • More foods in the marketplace
  • New hazards in foods not previously seen

• Shifting demographics
  • Growing population (about 30%) of individuals are especially “at risk” for foodborne illness
The Public Health Imperative

• Foodborne illness is a significant burden
  • About 48 million (1 in 6 Americans) get sick each year
  • 128,000 are hospitalized
  • 3,000 die

• Immune-compromised individuals more susceptible
  • Infants and children, pregnant women, older individuals, those on chemotherapy

• Foodborne illness is not just a stomach ache—it can cause life-long chronic disease
  • Arthritis, kidney failure
Main Themes of the Legislation

- Prevention
- Enhanced Partnerships
- Inspections, Compliance, and Response
- Import Safety
Who Does This Rule Affect?

• Any facility that is required to register with the FDA as a “Food Facility” Human and/or Animal
  • Food Facility includes any facility or entity that Manufacturers, Holds, Processes, Packages, Receives or Sales any ingredient or food product for Human or Animal use

• Some “Farm” Operations are exempted

• Definition revised “Retail Food establishment” to also include:
  • the sale of food products or food directly to consumers at roadside stand or farmers market or market other than where the food was manufactured or processed
  • The sale and distribution of such food through a community supported Agriculture program
  • The sale or distribution of such food at any other such direct sales platform as determined by the Secretary
Who Does this Rule Affect?

• There are many definitions and exemptions throughout the rule

• Exemption Example
  • A private residence is not a “facility” if it is a private home where an individual resides that is also used to manufacture, process, pack or hold food - would not need to register as a “facility”
  • But this producer or hobbyist would be expected to follow Current Good Manufacturing Practices (CGMP’s)

• Retail Food Establishments are exempt for the registration but the company/individual supplying the product to the retail establishment would be covered (if not exempted)

• Retail food establishment not exempt if it sales to another business
When do you need to comply?

• Depending on the sections of the rule effective dates vary for implementation
  • **Very Small Employer** (definition varies from $1 Million to $10 Million total revenue) usually up to 5 years after publication or 2020
  • **Small Employer** - Employing under 500 persons – usually up to 4 years after publication or 2019
  • **Other Businesses** – A Business that is not small or very small and does not qualify for exemptions – from 1 year up to 3 years after publication (Some rules already in effect)
  • All affected facilities (Exempt and non-exempt) should already be complying with CGMP’s
What Does the Rule Cover

THERE ARE SEVEN SECTIONS THAT ARE ADDRESSED IN THE FSMA

1) Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls for Human Food – Published September 17, 2015

2) Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls For Food for Animals – Published September 17, 2015
What Does the Rule Cover

THERE ARE SEVEN SECTIONS THAT ARE ADDRESSED IN THE FSMA

3) Standards for the Growing, Harvesting, Packing, and holding of Produce for Human Consumption – Published November 27, 2015

4) Foreign Supplier Verification Programs (FSVP) or Importers of Food for Humans and Animals – Published November 27, 2015
What Does the Rule Cover

THERE ARE SEVEN SECTIONS THAT ARE ADDRESSED IN THE FSMA

5) Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and Issue Certifications – Published November 27, 2015

6) Focused Mitigation Strategies To Protect Food Against Intentional Adulteration – Published May 27, 2016
What Does the Rule Cover

THERE ARE SEVEN SECTIONS THAT ARE ADDRESSED IN THE FSMA

7) Sanitary Transportation of Human and Animal Food – Published April 6, 2016
Prevention: The Cornerstone

• Comprehensive preventive controls for human and animal food facilities
• Prevention is not new, but Congress has given FDA explicit authority to use the tool more broadly
• Strengthens for prevention
• Produce safety standards
• Intentional adulteration standards
General Approach to Preventive Controls

1. Identify Hazard
2. Understand Cause
3. Implement Preventive Controls
4. Monitor Effectiveness
5. Review & Adjust
Prevention Standards Mandates

Sec. 103. Hazard analysis and risk-based preventive controls

Requires human and animal food facilities to:

• Evaluate hazards that could affect food safety;
• Identify and implement preventive controls to prevent hazards;
• Monitor controls and maintain monitoring records; and
• Conduct verification activities.
Examples of Compliance with Prevention Standards

• Sanitation
• Training for supervisors and employees
• Environmental controls and monitoring
• Food allergen controls
• Recall contingency plan
• Good Manufacturing Practices (GMPs)
• Supplier verification activities
Intentional Contamination

Sec. 106. Protection against Intentional Adulteration

- Issue final rule and guidance to protect against the intentional adulteration of food
- Conduct vulnerability assessments of the food supply and determine mitigation strategies
- Sec. 108 Prepare a National Agriculture and Food Defense Strategy with USDA, and DHS
Protection against Intentional Adulteration

• Last Rule to be Published – May 2016
• Who is covered: Both domestic and foreign companies that are required to register with the FDA as food facilities
• Does Not Cover Farms
• Requires companies to create a written food defense plan
• Plan must be reviewed at least every three years
Protection against Intentional Adulteration

• Food Defense Plan Must include
  • Vulnerability assessment
  • Mitigation Strategies
  • Mitigation Strategy Management Components
    • Monitoring
    • Corrective Actions
    • Verification
  • Training & Recordkeeping
Prevention Standards Mandates

Sec. 111. Sanitary Transportation of Food

• Addresses implementation of the Sanitary Food Transportation Act of 2005, which requires persons engaged in food transportation to use sanitary transportation practices to ensure that food is not transported under conditions that may render it adulterated.
Sanitary Transportation of Human and Animal Food

• Second to last rule to be released – April 2016

• Affects – Shippers, Receivers, loaders and carriers
  • Involved in transporting human and animal food in the United States by motor or rail vehicle

• Also affects shippers in other countries who:
  • Ship food to the United States directly by motor vehicle or rail (from Canada or Mexico) or by ship or air
  • And arrange for the transfer of the intact container onto a motor or rail vehicle for transport within the U.S.
Sanitary Transportation of Human and Animal Food

• A couple of exemptions:

• National Conference on Interstate Milk Shipments (NCIMS) Grade A Milk Safety Program

• Food establishments holding valid permits issued by a relevant regulatory authority, such as a state or Tribal agency, when engaged as receivers (controlled under the Retail Food Program, with state, territorial and local enforcement and FDA oversight)

• Looking at waiver for Molluscan Shell fish for entities that hold valid state permits under the National Shellfish Sanitation Program

• Compliance requirements:
  • Small Businesses – fewer than 500 persons or a carrier having less than $27.5 million annual receipts – Two years
  • Other Businesses – One year
Sanitary Transportation of Human and Animal Food

• Primary Responsibility on the shipper:
  • Shipper must develop written procedures to ensure that equipment and vehicles are in appropriate sanitary condition
  • Shipper of bulk food must develop and implement written procedures to ensure that a previous cargo does not make a food unsafe
  • Shippers of food that requires temperature control must develop and implement written procedures to ensure that food is transported under adequate temperature control
Prevention in Imports
Sec. 301 Foreign Supplier Verification Program (FSVP)

- Requires importers to conduct risk-based foreign supplier verification activities to verify that food imported into the United States is not adulterated and that it was produced in compliance with FDA’s preventive controls requirements and produce safety standards

Sec. 307. Third Party Auditor Accreditation

- Can be used by importers for supplier verification under FSVP
The Next Step to take

• Determine which rules apply to your business
• Evaluate to see if you are able to fit into any of the exemptions
• Determine what business size you fit into for each rule (this will help determine the time you have for compliance)
• Ensure that you renew your FDA registration this year between October and December (all registered facilities) – required every two years on the even year
The Next Step to take

• Remember that even though you may fit into one of the exemptions – You are expected to meet the Current Good Manufacturing Practices for that rule

• You should document how you meet the CGMP’s

• Be prepared for an inspection – There is a mandate for certain facilities to be inspected within a five year time frame
Things we did not have time for

• Certified/Approved supplier documentation – Supply Chain Integrity
• Recall Procedures – ingredients and finished product
• Inventory control/tracking – Raw ingredient and finished food product
• Facility Sanitation and Employee Sanitation/Hygiene
• Plant operations and equipment labeling and maintenance
• Animal Food Facility requirements
Conclusion

• The Food Safety Modernization Act is very detailed and complicated rule

• There is still time for most Businesses to meet the designated timelines

• You need to understand which areas apply to your business even if you are exempted from certain areas
For Assistance

• You Can Contact:

    Manufacturing & Technology Solutions
    605-367-5757

Or

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