Overview of the Food Safety Modernization Act

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Brief Background

- Food Safety Modernization Act (FSMA) was signed into law by President Obama on January 4th, 2011
- This new set of regulations is the biggest change in food law since 1938 and will impact many food manufacturers with facilities within the United States

Pillars of Legislation

50 New Rules under this mandate

- Prevention Standards
- Inspections, Compliance, and Response,
- Import Safety
- Enhanced Partnerships

- Prevention
  - Mandatory preventive controls for food facilities
  - Mandatory produce safety
  - Authority to prevent intentional contamination
- Inspection and Compliance
  - Mandated inspection frequency
  - Records access
  - Testing by accredited laboratories

- Response
  - Mandatory recall
  - Expanded administrative detention
  - Suspension of registration
  - Enhanced product tracing abilities
  - Additional Recordkeeping for High Risk Foods
- Imports
  - Importer accountability
  - Third Party Certification
  - Certification for high risk foods
  - Voluntary qualified importer program
  - Authority to deny entry

- Enhanced Partnerships
  - State and local capacity building
  - Foreign capacity building
  - Reliance on inspections by other agencies

Brief History of Food Law

- 1906-Pure Food and Drug Act
- 1938-The Federal Food, Drug, and Cosmetic Act
- 1969-Sanitation Programs began in milk, shellfish, food service
- 1990-Nutrition Labeling and Education Act requires all packaged foods to bear nutrition labeling and all health claims
- 1995-Seafood HACCP (Hazard Analysis Critical Control Point)
- 1998 -Juice HACCP rule

Brief History of Food Law, cont.

- 2006 -Food Allergen Labeling and Consumer Protection Act
- 2009 -Egg Safety (final) Rule issued – establishes requirements for control of *S. Enteritidis* in eggs from production through distribution
- 2010 -Implementation of the Egg Safety Rule began in July 2010 for large (50,000 layers+) producers; smaller producers must be in compliance by 2012

WHO DOES THIS LAW NOT EFFECT?

Tester's Act Exceptions

- "Qualified facilities"
  - 3 previous years sold majority of their food (greater than half) directly to "qualified end-users" and have an average yearly value of the food sold of less than $500,000
  - Qualified end-users are consumers, restaurants, or retail food establishments that sell directly to consumers and are located in the same state as the qualified facilities or located no further than 275 miles from them

Exemptions

- Activities subject to Hazard Analysis & Critical Control Points (HACCP) regulations (i.e., seafood and juice)
- Manufacturing, processing, packing, and holding of dietary supplements
- Alcoholic beverages at certain facilities
- Activities subject to low-acid canned food regulations (microbiological hazards only)

Other Exemptions

- Certain storage facilities such as grain elevators and warehouses that store only raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing
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- "Holding" includes activities performed for the safe or effective storage of RACs (e.g., drying, screening, fumigating)

WHO DOES IT EFFECT

FDA Regulated Food

- Dietary supplements
- Bottled water
- Food additives
- Infant formulas
- Non-USDA products

Statistics

- FDA is responsible for about 79% of the US food supply
- 15% of all foods consumed in the U.S. is imported
- It is estimated by the FDA that in 2009 more than 60% of all fruits and vegetables are consumed are imported
- FDA is only responsible for about 1% of all imported foods in the U.S. (1997)

- Cattle, sheep, swine, goats, horses, mules, or other equines including carcasses and parts
- Egg products: egg of domesticated chicken, turkey, duck, goose, guinea
- Egg product processing plants (egg breaking and pasteurizing operations)
- Egg Product: dried, frozen, or liquid eggs, with or without added ingredients

USDA more

- Pepperoni pizza or meat sauces with 3% red meat or more)
- Open faced beef sandwiches, hot dogs, corn dogs, chicken sandwich (open faced), chicken noodle soup

Non-USDA Products

- Products with 3% or less raw meat; less than 2% cooked meat or less than 30% fat, tallow or meat extracts
- Products with less than 2% cooked poultry meat; less than 10% cooked poultry skins, giblets, fat, and poultry meat
- Shelled eggs
- Egg processing plants (egg washing, sorting, packaging)

Animal Food

- Livestock
- Domestic Animals
- Applies to Human Food Facilities that donate or sell a by-product for use as animal food

Preventive Controls: Human/Animal

- In general, facilities that manufacture, process, pack or hold food
  - Facilities required to register with FDA under Bioterrorism Act
  - Not farms or retail food establishments
- Applies to domestic and imported food
- There are some exemptions and modified requirements for certain facilities

Farms may be subjected to Produce

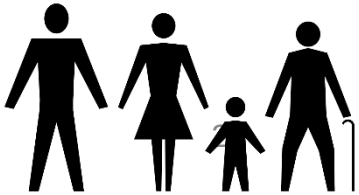
- A farm is exempt from FDA's food facility registration requirement.
- Facilities that do not have to register with FDA are not subject to the preventive controls requirements.
  - Depending on certain factors, farms may be subject to the forthcoming Produce Safety rule.

Evolution of the Farm Definition

- The final Preventive Controls for Human Food rule clarifies the definition and expands it further to cover two kinds of farming operations:
  - Primary production farm
  - Secondary activities farm

Primary Production Farm

- An operation under one management in one general, but not necessarily contiguous, location
- Devoted to the growing of crops, the harvesting of crops, the raising of animals, or any combination of these activities
  - The definition has been expanded to include operations that just grow crops and operations that just harvest crops.



Secondary Activities Farm

- An operation not located on a primary production farm that is devoted to harvesting, packing, and/or holding RACs.
- The primary production farm(s) that grow, harvest, and/or raise the majority of those RACs must own or jointly own a majority interest in the secondary activities farm.

TIMELINE OF IMPLEMENTATION

Final Rules

- Feb. 1, 2013: Criteria used to order administrative detention of food for human or animal consumption
- May 1, 2013: Information required in prior notice of imported food
- April 4, 2014: Establishment, maintenance, and availability of records: Amendment to record availability requirements
- Sept. 17, 2015: Current GMP and Hazard Analysis and Risk-Based Preventive Controls for Human Food
- Sept. 17, 2015: Current GMP and Hazard Analysis and Risk-Based Preventive Controls for Animal Food

Administrative detention

- FDA can order an administrative detention if there is reason to believe that an article of food is adulterated or misbranded
- “reason to believe” that food is adulterated or misbranded will be made on a case-by-case basis because such decisions are fact specific

Prior notice of imported food

- Requirement that FDA receive certain information about imported foods before arrival in the United States
- Requires a person submitting prior notice of imported food, including food for animals, to report the name of any country to which the article has been refused entry

Records

- Prior to the passage of FSMA, the Federal Food, Drug, and Cosmetic Act (the FD&C Act) provided the Secretary (by delegation FDA) with access to records relating to food that FDA reasonably believes to be adulterated and presents a threat of serious adverse health consequences or death to humans or animals.
- Expands FDA's former records access authority beyond records relating to the specific suspect article of food to include records relating to any other article of food that FDA reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals

Human Food

- Domestic and foreign firms that manufacture, process, pack or hold human food.
- Regulation for Current Good Manufacturing Practice (CGMP) in manufacturing, packing, or holding human food to modernize it and to add requirements for domestic and foreign facilities that are required to register under the Federal Food, Drug, and Cosmetic Act to establish and implement hazard analysis and risk-based preventive controls for human food

Animal Food

- Regulations for domestic and foreign facilities that are required to register under the FD&C Act to establish requirements for CGMP in manufacturing, processing, packing, and holding of animal food
- Require that certain facilities establish and implement hazard analysis and risk-based preventive controls for food for animals

Summary of Upcoming

- Oct. 31, 2015: Produce Safety
- Oct. 31, 2015: Food Supplier Verification Programs
- Oct. 31, 2015: Accreditation of Third-Party Auditors
- March 31, 2016: Food Defense
- March 31, 2016: Sanitary Transportation

Produce

- Section 105 of the Food Safety Modernization Act (FSMA) directs FDA to set science-based standards for the safe production and harvesting of fruits and vegetables that the Agency determines minimize the risk of serious adverse health consequences or death
- Set standards associated with identified routes of microbial contamination of produce, including: (1) agricultural water, (2) biological soil amendments of animal origin, (3) health and hygiene, (4) animals in the growing area, and (5) equipment, tools and buildings
- Additional provisions related to sprouts

Food Supplier Verification Programs

- Strengthen the oversight of foods imported for U.S. consumers
- Importers would be required to perform certain risk-based activities to verify that food imported into the United States has been produced in a manner that provides the same level of public health protection as that required of domestic food producers

Accreditation of Third-Party Auditors

- Accreditation for third-party auditors, also known as certification bodies, to conduct food safety audits and issue certification of foreign facilities and the foods they produce for humans and animals

- **Focused Mitigation Strategies to Protect Food Against Intentional Adulteration**
- Require domestic and foreign facilities to address vulnerable processes in their operations to prevent acts on the food supply intended to cause large-scale public harm

Sanitary Transportation

- Require those who transport food to use sanitary transportation practices to ensure the safety of food
- Maintain the safety of both human and animal food during transportation by establishing criteria (e.g., conditions and practices, training and record keeping) for the sanitary transportation of food

Compliance Dates

Rule	Final Status	General Compliance Period	Small Business Compliance	Very Small Business Compliance
Preventive Controls for Human Food	30-Aug-15	19-Sep-16	18-Sep-17	17-Sep-18
Preventive Controls for Food for Animals	30-Aug-15	19-Sep-16	18-Sep-17	17-Sep-18
Produce Safety	31-Oct-15	31-Oct-17	31-Oct-18	31-Oct-19
Food Supplier Verification Programs (FSVP)	31-Oct-15	1-May-17	1-May-17	1-May-17
Accreditation of Third-Party Auditors	31-Oct-15			
Food Defense	31-Mar-16	31-Mar-17	31-Mar-18	31-Mar-19
Sanitary Transportation	31-Mar-16	31-Mar-17	31-Mar-18	

Guidance

- Oct. 25, 2011: What you need to know about administrative detention of foods; small entity compliance guide
- Feb. 1, 2012: Questions and Answers regarding establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold or import food
- Dec. 1, 2012: Questions and Answers regarding food facility registration
- Apr. 4, 2014: FDA Record Access Authority under Sections 414 and 704 of Federal Food, Drug and Cosmetic Act

Questions

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