

Food Safety Modernization Act (FSMA)





FDA FSMA – Timeline

- July 29, 2009 – House version passed
 - Votes 283-142
- Nov. 30, 2010 – Senate version passed
 - Votes 73-25
- Dec. 19, 2010 – Senate revised version passed
 - Unanimous consent
- Dec. 21, 2010 – House approved
 - Votes 215-114
- Jan. 4, 2011 – Signed by President Obama;
 - H.R. 2751 – 89 pages, GPO



Federal Food, Drug, and Cosmetic Act

- U.S. Law: **Feed/Grain** are Food

- Section 201(f) Federal Food, Drug, and Cosmetic Act:

“The term “food” means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.”



FSMA: Historic Legislation

- 1906 – Pure Food and Drug Act
- 1938 – Food, Drug, and Cosmetic Act
- 2011 – Food Safety Modernization Act



What's so Historic about the Legislation?

- It's NOT just recalls and inspections
- It's a call for a new, prevention-oriented food safety system that includes:
 - A broad prevention mandate
 - Strong accountability for prevention
 - New system of import oversight
 - Full partnership with states



FSMA Content

- *Title 1:* Improving Capacity to Prevent Food Safety Problems; 16 sections
- *Title 2:* Improving Capacity to Detect and Respond to Food Safety Problems; 10 sections
- *Title 3:* Improving the Safety of Imported Foods; 9 sections
- *Title 4:* Miscellaneous Provisions (funding, budget considerations, etc.); 5 sections



FSMA Major Impacts

- Increased facility registration requirements
- Develop/implement written food/feed safety plans
- Develop/implement written food/feed defense plans (high-risk products only)
- Increased FDA access to existing records
- Develop/implement foreign supplier verification program if importing food in the U.S.
- Pay fees to FDA for re-inspections, if subject to mandatory recall, if utilizing FDA export certificates, or participating in voluntary qualified import program



Proposed Rules

- Animal Feed CGMP's/Preventive Controls
 - March 31
- Foreign Supplier Verification
 - January 27
- Third Party Certification
 - January 27
- Intentional Adulteration
 - March 31
- Sanitary Food Transportation (not yet released)
 - May 31



Inspection of Records (Section 101)

- Authorizes FDA to access and copy all facility records if it believes there is “reasonable probability” that food, or similar foods, will cause serious adverse health consequences or death to humans or animals
 - Applies to all records relating to the manufacture, processing, packaging, distribution, receipt, holding, or importation of such foods
 - Records for imported foods are to be maintained for at least 2 years
- Provision effective immediately



Registration of Food Facilities (Section 102)

- 2002 Bioterrorism Act: One time event
- FSMA: Renew and update registration every two years between Oct. 1 and Dec. 31 of even-numbered years, beginning in 2012
 - FDA has authority to suspend registrations if agency determines there is a reasonable probability that food from a facility could cause serious adverse health consequences or death to humans or animals
 - If registration suspended, facility is prohibited from importing or distributing food



Hazard Analysis and Preventive Controls (Section 103)

- Most registered facilities will be required to conduct and document a written analysis of hazards that are “known or reasonably foreseeable that may be associated with the facility”
 - Types of Hazards
 - Biological
 - Physical
 - Chemical
 - Includes hazards that may be “intentionally introduced, including by acts of terrorism”



FSMA Impacted Facilities

- Grain elevators;
- Feed and feed ingredient manufacturers;
- Pet food manufacturers
- Grain processors, including corn and flour milling operations, soybean processors and others;
- Biofuels producers manufacturing co-products;
- Exporters of grains, feed and feed ingredients, and processed commodities



Hazard Analysis and Preventive Controls (Section 103)

- Covered facilities will be required to:
 - Implement a written preventive control plan to prevent or minimize hazards so that food products are not adulterated or misbranded
 - Plans are to utilize “risk-based and reasonably appropriate” controls to “significantly minimize or prevent” hazards
 - Plans are to include monitoring and verification that indicates controls are working, corrective actions, as necessary, and recordkeeping
 - Maintain records for at least two years that document monitoring activities (i.e. testing, etc.), instances of any nonconformance and corrective actions taken



Hazard Analysis and Preventive Controls (Section 103)

- Facilities will be required to reanalyze hazards and preventive controls, as well as their written food/feed safety plans, at least every three years or sooner if significant changes in operations occur
- FDA may, as authorized by law, exempt or modify the hazard analysis and preventive controls requirements for “facilities that are solely engaged in the production of food for animals other than man”



Hazard Analysis and Preventive Controls (Section 103)

- Certain facilities exempted (exemption does not apply to facilities required to meet law's produce standards)
 - During the 3 year period preceding the applicable calendar year, the average annual food sales (including sales by affiliates/subsidiaries) sold directly to “qualified end-users” exceeds the average annual value of food sold to all other purchasers; and
 - Average annual monetary value of all food sold by such facility during such period (including sales by affiliates/subsidiaries) was less than \$500,000, adjusted for inflation



Hazard Analysis and Preventive Controls (Section 103)

- Definition of “Qualified End-User”
 - The consumers of the food (businesses are not CONSUMERS);
or
 - A restaurant or retail food establishment (as defined by the Bioterrorism Act) that is located
 - In the same State as the qualified facility that sold the food to such restaurant or establishment; or
 - Not more than 275 miles from such facility and is purchasing the food for sale directly to consumers at the restaurant or retail food establishment



Hazard Analysis and Preventive Controls (Section 103)

- Requires FDA to develop and implement regulations by July 2012
 - FDA Center for Veterinary Medicine propose regulations for feed/grain are out
- What hazards may need to be addressed at feed and grain facilities?
 - Contaminants for which FDA already has established tolerances or guidelines
 - Mycotoxins
 - Salmonella
 - Pesticides
 - Heavy Metals
 - Drug residues/carry-over
 - Dioxins, furans
 - BSE
 - Feed additives



HACCP Principles

1. *Conduct a Hazard Analysis (HA)*
2. Determine Critical Control Points (CCPs)
3. Establish Critical Limits (CLs)
4. Establish Monitoring Procedures
5. Establish Corrective Actions (CA)
6. Establish Verification Procedures
7. Establish Record-Keeping Procedures



Performance Standards (Section 104)

- Requires FDA, in coordination with USDA, to evaluate and determine at least every two years whether it is appropriate to set contaminant-specific and science-based regulations or guidance documents
- Where appropriate, FDA is required to differentiate between animal food and human food when issuing any such regulations or guidance



Protection Against Intentional Adulteration (Section 106)

- Law requires facilities to analyze “known or reasonably foreseeable hazards” that could be intentionally added to food
 - Food/Feed Defense Plans
- FDA required to issue regulations by July 2012 to mitigate such hazards for foods where there is a “high-risk” of intentional contamination proposed rule is out



Authority to Collect Fees (Section 107)

- FDA is required to access fees for:
 - Re-inspecting facilities that fail an original inspection
 - Cost of conducting FDA-mandated recalls
 - Implementing a “Voluntary Qualified Importer Program”
 - Issuing export certificates for food and animal feeds



Sanitary Transportation of Food (Section 111)

- By July 2012, FDA is required to implement regulations governing the use of conveyances used to transport food/feed products
 - Provision designed to reiterate Congress's mandate passed in 1990 that FDA develop such regulations
 - FDA already involved in rulemaking proposed rule out soon



Inspections (Section 201)

- Requires FDA to:
 - Determine which facilities are “high-risk” and inspect such facilities within next 5 years, and every 3 years thereafter
 - Inspect all other domestic facilities within next 7 years, and every 5 years thereafter
 - Inspect 600 foreign facilities during 2011, then double the number of foreign facility inspections each year during the next 5 years:
 - 2012 – 1,200
 - 2013 – 2,400
 - 2014 – 4,800
 - 2015 – 9,600
 - 2016 – 19,200



Inspections (Section 201)

- Law sets a goal of hiring 1,000 additional field personnel by fiscal year 2014
- Estimated 5-year cost of the bill is \$1.4 billion, majority of amount relates to hiring personnel
- FDA's ability to hire personnel and conduct increased inspections dependent upon Congressional funding



Enhanced Tracking and Tracing of Food (Section 204)

- Requires FDA to:
 - Within 9 months conduct one or more pilot programs to explore ways to improve tracking/tracing of food
 - Propose regulations by Jan. 2013 to establish additional recordkeeping requirements for “high-risk” foods
- Law specifically prohibits FDA from imposing traceability requirements that would limit commingling of grain and feed



Mandatory Recall Authority (Section 206)

- Effective immediately, law authorizes FDA for the first time to issue mandatory recalls if it determines there is a “reasonable probability” that food is adulterated or misbranded, and would cause serious adverse health consequences or death to humans or animals
 - FDA is required to allow firm to first conduct a voluntary recall
 - FDA Commissioner is to issue any mandatory recall orders



Administrative Detention Authority (Section 207)

- Law significantly expands FDA's authority to administratively detain food
 - Under Bioterrorism Act, FDA is to have “credible evidence or information” that food “presents a threat of serious adverse health consequences or death to humans or animals”
 - Under FSMA, FDA may detain food if it has “reason to believe” the food is adulterated or misbranded
 - Provision to take effect by July 2011



Import Requirements (Sections 301-309)

- Requirements in FSMA are intended to apply to foreign facilities that export food to U.S.
- Foreign Supplier Verification Programs: U.S. importers required to develop/implement risk-based program to verify that imported food is not adulterated
 - Importers required to maintain records associated with verification activities for two years
 - FDA required to issue regulations for verification activities by Jan. 2012, with regulations taking effect by Jan. 2013
 - Proposed rule is out



Import Requirements (Section 301-309)

- Voluntary Qualified Importer Program: Established by law to expedite food imports from trusted foreign suppliers
- Importer required to:
 - Submit application to FDA
 - Achieve certification by FDA-accredited third-party auditor
 - FDA recognition of third-party certification is limited to foreign facilities
- FDA required to issue guidance on program by July 2012



FSMA – Effective Dates for Major Provisions

- Immediate – Jan. 4, 2011
 - Section 101: Inspection of Records
 - Section 102: Registration of Food Facilities
 - Requirements to register every two years
 - Section 107: Fees
 - Section 201: Inspections
 - Enhanced inspection frequency
 - Identification of “high-risk” facilities
 - Section 206: Mandatory Recall



FSMA – Effective Dates for Major Provisions

- Effective at Later Date
 - Section 103: Hazard Analysis and Preventive Controls Plan – July 2012; phase in period expected
 - Section 106: Protection Against Intentional Adulteration – July 2012
 - Section 111: Sanitary Food Transportation – July 2012
 - Section 301: Foreign Supplier Certification Program – Jan. 2013



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FSMA 2014

- Final Comment
 - You can choose to ignore the FSMA.
 - HOWEVER;
 - You cannot choose to ignore the consequences of ignoring the FSMA.

Questions or Comments

THANK YOU

