In Focus: Examining the New FDA Food Safety Modernization Act

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About Faegre & Benson

• International law firm with practice focusing on Food, Agricultural and Biofuels industries

• Offices in Minneapolis, Denver, Boulder, Des Moines, London and Shanghai

• Litigate and counsel clients in the food and agricultural industries

How Did We Get Here: Major Foodborne Illness Outbreaks

- 1993: Undercooked hamburgers from Jack in the Box (E. coli)
- 2002: *Listeria* in processed poultry – largest recall in history
- 2007: Ground beef containing *E. Coli* – massive recall
- 2008: *Salmonella enterica* serotype Saintpaul linked to illnesses in 43 states. Initially reported as tomatoes, now thought to be peppers from Mexico.
- 2009: Salmonella in Peanut Corp of America peanut butter. CEO under criminal investigation.
- 2010: Salmonella associated with eggs

How Did We Get Here?

- July 2009: House passes HR 2749 by wide margin
- Nov. 2009: Senate HELP committee passes S 510
- Nov. 2010: S 510 comes to Senate floor, passes
- Dec. 2010: Oops! Funding must originate in House
- Late Dec. 2010: House quickly passes bill, Senate follows
- Jan 4, 2011: President signs bill into law
The Big Picture – What Is It?

FSMA: PL 111-353, 124 Stat. 3885

- Law divided into three general categories
  - Preventative Measures
  - Detection and Response Measures
  - Imported Foods

- Requires substantial rulemaking and guidance documents from FDA over next couple of years

To Whom Does This Apply?

- FDA-regulated facilities and foods, generally

- What’s not covered:
  - As a general matter, relates only to foods regulated by FDA
  - Excludes meat, poultry, and certain egg products regulated by USDA
  - Excludes most alcoholic products and related facilities

- Small-business exemption (“Tester Amendment”)
  - Exempt from Hazard Analysis and Produce provisions if:
    - 50%+ of food sold is to consumers, restaurants < 275 miles, and food for sale directly to consumers, and < $500k in yearly sales; OR
    - A “very small business”
Part 1: Preventative Measures

Preventative: Inspection and Registration (Sections 101-102)

- Records Inspections: now includes other food articles inspectors reasonably believe may be affected in similar manner
- Registration: must re-register every even-numbered year
- New powers to suspend registration of regulated facilities
Preventative: Hazard Analysis & Risk-Based Preventative Controls (Section 103)

- Requires written Hazard Analysis & Risk-based Preventive Controls plans for most facilities (Section 103)
  - Identify and analyze hazards
  - Identify and implement preventative controls, including at critical control points
  - Monitor effectiveness – does it work?
  - If it doesn't work, take corrective action
  - Verify system is being implemented properly

Re-analyze at least every 3 years or if significant changes occur

Certain exemptions for small businesses

Rule-making and guidance forthcoming

Failure to have written Hazard Analysis plan = prohibited act
Preventative: Performance Standards (Section 104)

FDA/USDA coordination to

- Review and evaluate public health data (toxicological and epidemiologic) every 2 years
- Determine “the most significant food-borne contaminants”
- Issue, by regulation or guidance, contaminant-specific performance standards

Preventative: Standards for Produce Safety (Section 105)

- FDA/USDA coordination
- Requires rulemaking re “minimum standards for safe production and harvesting of” certain high-risk, raw agricultural commodities
- Prioritizes high-risk fruits/vegetables with history of outbreaks
- Variances allowed upon request
- Requires flexibility for small businesses
- Limited exemption for some small businesses
Preventative: Intentional Adulteration (Section 106)

- Protection against intentional adulteration – focus on terrorism
- Study to determine foods at high risk
- Rulemaking (18 months)
  - Who should have to comply?
  - What measures should they have to take?
- Exempts farms (but not dairies)
- Guidance documents within a year (but possibly limited distribution)

Preventative: Ag & Food Defense Strategy (Section 108)

- National Agricultural and Food Defense Strategy
  - Enhanced preparedness of agricultural and food system
  - Improved detection capabilities
  - Ensured and efficient response to emergencies
  - Secured production after emergencies
- Developed by FDA, USDA, and DHS
- Limited distribution

- FDA, USDA, and DHS to coordinate with public and private entities re protecting ag and food systems
- FDA, USDA, and DHS to study variety of issues relating to food security, including regulations, traceback, surveillance, etc…
- Grants to local/state governments
- Sanitary transportation of food

Preventative: New Fees (Section 107)

- Authorizes fees where:
  - Facility is re-inspected due to noncompliance
  - Facility refuses to comply with a recall order
  - Importer participates in voluntary qualified importer program
  - Importer is re-inspected
- Guidelines forthcoming
- Common sense: If we need to come back, we're charging you for it
Part 2: Detection and Response Measures

Detection/Response: Targeted Inspections (Section 201)

- Target FDA's limited inspection resources to high-risk facilities/foods
- Identify high-risk facilities/foods, both domestic and imported
- Domestic high risk: At least once by 2016, at least every 3 years thereafter
- Other domestic: At least once by 2018, at least every 5 years thereafter
- Foreign facilities: No fewer than 600 this year, doubling each year in next 5 years
- Coordinate with USDA/DHS to identify high-risk candidates
Detection/Response: Food Laboratories (Section 202)

- Accreditation program for labs analyzing food
- Develop model standards for labs
- Labs to be used for testing food identified by FDA or for certain imported food

Detection/Response: Traceback (Section 204)

- FDA to run at least 1 traceback pilot program each for processed and raw produce
- New record-keeping requirements for facilities involved with high-risk foods.
  - FDA to identify high-risk foods within 1 year
  - Rule-making within 2 years
  - Some exemptions for direct sales from farms, grocery stores, etc...
- New powers to seek farm records in recall-type situations
Detection/Response: FBI Surveillance Systems* (Section 205)

- Directs FDA to improve foodborne illness (FBI) surveillance systems
- More coordination with/assistance to local & state governments
- Funded with $24 million a year through 2015

*FBI = Food-Borne Illness.

Detection/Response: Mandatory Recall Authority (Section 206)

- Step 1: Give opportunity to do voluntarily recall
- Step 2: If refuses, FDA can order to cease production/distribution, with notice downstream
- Step 3: Hearing within 2 days, if requested
- Step 4: Amend order as necessary, including ordering recall and giving notice to consumers, or vacate the order
- Failure to follow mandatory recall order is a prohibited act
Detection/Response: Administrative Detention (Section 207)

- Lowers standard for FDA inspectors to order administrative detention
- Used to be “credible evidence or information…” now just “reason to believe”
- Used to be same standard as Class I recall, now just “is adulterated or misbranded”
- Effective in 180 days; regulations forthcoming

Detection/Response: RFR Updates (Section 211)

- FDA can require responsible person to submit “critical information” – i.e. “consumer-oriented information” regarding a reportable food (UPC, contact info, etc…)
- FDA will create fact sheet using that information and distribute online
- Chain grocers to post one-page fact sheet in a conspicuous place to notify consumers
- 18 months out
Part 3: Imported Foods

Imported Food: Foreign Supplier Verification Program (Section 301)

- Importers must conduct risk-based foreign supplier verifications
  - Ensure compliance with food safety requirements
    (including Hazard Analysis and Risk-Based Preventative Controls)
  - Avoid adulteration/misbranding

- Importer = Owner of food item when enters U.S. or if none, U.S. agent/representative of foreign owner

- Records must be kept for 2 years, produced upon request

- Regulations & Guidance must be developed within one year, effective two years after enactment
Imported Food: Voluntary Qualified Importer (Section 302)

- Importers apply for participation in program for expedited review of food products
- Review looks at
  - Risk of food
  - Compliance history (suppliers & importer)
  - Exporting country’s ability to ensure compliance with U.S. food safety regulations
  - Recordkeeping
  - Adulteration risk
- Participation reviewed at least once every three years

Imported Food: Import Certifications (Section 303)

- May be required to provide Certificate of Compliance to allow import of certain food items
- Risks evaluated include:
  - Known risks associated with food item
  - Risks related to country/region of origin
  - Finding that originating country cannot adequately ensure U.S. regulations met
**Imported Food: Third-Party Auditors (Section 307)**

- FDA can authorize third parties to conduct food safety inspections
  - Foreign governments
  - Foreign cooperatives
  - Other third parties

- Must be accredited to conduct audits to ensure compliance with U.S. food safety regulations

- Model accreditation standards developed within 18 months

- Used to determine eligibility for voluntary qualified importer program and if food safety requirements satisfied

- Includes regulations related to potential conflicts of interest

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**Imported Food: Other Misc. Measures**

- Prior Notice of Imported Food Shipments (Section 304)

- Building capacity of foreign governments with respect to food safety (Section 305)
  - Within two years plan developed to "expand the technical, scientific, and regulatory food safety capacity of foreign governments, and their respective food industries"
  - Developed in consultation with other Departments, such as Agriculture, State & Homeland Security, and industry representatives

- Inspection of foreign food facilities (Section 306)
  - If inspection not allowed, food products denied entry to U.S.

- Foreign offices (Section 308)
  - FDA will establish foreign offices for support & risk-based inspections
Whistleblower Protections (Section 402)

- Expansive new protection for whistleblowers in the food industry
- Effective immediately
- Protected from retaliation for:
  - Providing information to employer or government for violations of Act
  - Testifying about violation
  - Assisting in investigation or proceeding
  - Preparing to testify or assist
  - Objecting to/refusing to participate in activity believed to violate Act
- Employee-friendly burden-shifting regime
- Nominal relief when employee makes frivolous complaint

Implementation/Effective Dates

Effective Already:

- Beefed-up authority to FDA to access and inspect records
- Mandatory recall authority
- Whistleblower provisions
- Increased inspections (domestic and foreign)
- Refusal of admission to imported foods where inspectors refused admission to foreign facility
### Upcoming Effective/Implementation Key Dates

#### July 2011:
- Food facility registration requirement
- Issue small entity compliance guide for hazard analysis plan requirement
- Guidelines for reinspection fees

#### October 2011:
- Establish pilot programs re rapid traceability
- Issue proposed rulemaking re hazard analysis for food packed/held on a farms

#### January 2012:
- Rulemaking re science-based minimum standards for produce safety
- Designation of high-risk foods for which additional recordkeeping is required
- Rulemaking re Foreign Supplier Verification Program

#### July 2012:
- Rulemaking re hazard analysis plan provisions
- Reportable Food Registry changes re consumer-oriented information are effective
- Voluntary Qualified Importer Program effective
- Rulemaking re third party accreditation program for foreign govt and other inspection agencies

#### January 2013:
- Establish program for testing of foods by accredited labs
- Proposed rulemaking re recordkeeping requirements for high risk foods
- Foreign Supplier Verification Program requirement becomes effective
Where Do We Go From Here?

- Extensive rulemaking and proliferation of guidance documents in next two years
  - Over 50 rulemaking processes, guidance documents, reports to Congress and other agency actions required under FSMA
- Greatly increases the amount of work FDA needs to do and amount of people it needs to hire
- Biggest issue: What will happen with funding?

RESOURCES

- FDA’s FSMA webpage: http://www.fda.gov/Food/FoodSafety/FSMA/default.htm
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FDA Food Safety Modernization Act