

our  
recipe  
for  
growth

ConAgra  
Foods<sup>®</sup>  
Food you love

# Food Safety Modernization Act Thinking Two Steps Ahead

---

Bonita Funk  
August 17, 2011

# Everything You Always Wanted to Know (or not) About FSMA



## Food Safety Modernization Act (FSMA):

- How big is it?
- Business Impact
- Evolution of FDA Authority
- Specific Provisions
- Provisions CAG Is Monitoring Closely
- Questions

# How Big is FSMA?



Estimated to cost \$1.4 billion and 5 years to implement  
>50 new regulations, guidances & reports to Congress

# Business Impact

our  
recipe  
for  
growth



# Evolution of FDA Authority



our  
recipe  
for  
growth

- **Significant Broadening of FDA Authority**
  - Focus on Prevention vs. Reaction (shifts much more responsibility to food manufacturers)
  - Expanded records access
  - New powers: mandatory recall authority, administrative detention and suspension of registration
  - Authority to impose fees
- **Import Safety**
  - “Responsible Party” required to verify safety of food imports
- **Enhanced Partnerships**
  - Local, State, Territorial, Tribal and Foreign Governments, 3<sup>rd</sup> parties

# Specific Provisions



## § 101: Inspection of Records

- Reasonable belief standard: a reasonable probability that the food will cause SAHCODHA (serious adverse health consequences or death to human or animals)
- Replaces “credible evidence” criteria
- Access to all records for that food and any other which is believed to be similarly affected

## § 102: Registration of Facilities

- Biennial registration renewal (Oct – Dec, even #’ed years)
- Suspension of registration: reasonable belief SAHCODHA
  - Equivalent to USDA withdrawal of inspection
  - Only the secretary of HHS has authority

# Specific Provisions

- § 103: Hazard Analysis & Risk-Based Preventive Controls
  - Biological, chemical, physical and radiological hazards; natural toxins, pesticides, drug residues, decomposition, parasites, allergens, unapproved food/color additives
  - Intentionally-introduced hazards
  - Written plan of preventive controls
  - Monitoring of effectiveness
  - Corrective actions
  - Verification
  - Recordkeeping
  - Exemptions: juice, seafood. LACF (micro provisions), very small businesses



# Specific Provisions



- § 105: Standards for Produce Safety
  - Science-based regulatory standards for those fruits and vegetables (raw agricultural commodities), based on known safety risks, including history of foodborne illness outbreaks
  - With respect to growing, harvesting, sorting, packing, storage, includes soil amendments, hygiene, packaging, temperature controls, animals in the growing area, water
  - Natural, unintentionally- and intentionally-introduced hazards



# Specific Provisions

- § 106: Protection Against Intentional Adulteration
  - Foods for which there is high risk of intentional contamination
  - Could cause SAHCODHA
  - Clear vulnerabilities such as short shelf life or susceptibility to intentional contamination at CCPs
- § 107: Authority to Collect Fees
  - 100% of cost for reinspection-related activities
  - Failure to comply with mandatory recall
  - Voluntary Qualified Importer Program (VQIP)
  - Export certificates



# Specific Provisions



- § 108: Food Defense
- § 201: Targeting of Inspection Resources
  - Increased inspection frequency based on level of risk
    - Known risks of the food
    - Known risks of the country of origin
    - Compliance history of the importer
    - Rigor and effectiveness of FSVP of importer
  - Domestic and foreign facilities
  - Ports of Entry



# Specific Provisions

- § 204: Enhancing Traceability
  - Produce traceability pilots
  - FDA SOW on traceability of processed products
- § 205 and § 209: Surveillance by and Training of State, Local, Territorial, Tribal Food Safety Officials
  - Authority to conduct FDA inspections granted to these groups
- § 206: Mandatory Recall Authority



# Specific Provisions

- § 207: Administrative Detention of Food
  - Authority granted under bioterrorism regulation
  - “Reason to believe” (analogous to Class II Recall) replaces “credible evidence” criteria (probable cause, analogous to Class I Recall)
  - Precedes FDA action to seize the food
  - Interim final rule published May 5



# Specific Provisions

- § 301: Foreign Supplier Verification Program
  - Work of internal team already underway
  - Risk-based verification
  - Food is safe for consumption, complies with all US regulations and is not adulterated
  - Record keeping requirements
- § 302: Voluntary Qualified Importer Program (VQIP)
  - Certification of foreign facility required
  - Fees charged

# Specific Provisions

- § 303: Requirement for Import Certification
  - Known safety risks of the food
  - Known food safety risks associated with the country
  - Adequacy of food safety regulations in country of origin
  - Certifying bodies:
    - Agency of the foreign government
    - FDA-accredited 3<sup>rd</sup> parties
- § 304 Prior Notice of Imported Food Shipments
  - Interim final rule published May 5
  - Requires identification of any country that has refused entry

# Specific Provisions

- § 307: Accreditation of 3<sup>rd</sup> Party Auditors
  - Accrediting bodies TBD by FDA
  - 3<sup>rd</sup> party auditor can be:
    - Foreign government
    - Agency of foreign government
    - Foreign cooperatives that aggregate the products of growers or processors
    - Any party the Secretary deems appropriate
  - Consultative vs. regulatory audits
  - When acting on behalf of FDA, 3<sup>rd</sup> party must report to FDA any condition that could cause or contribute to a serious risk to public health



# Provisions Being Monitored Closely



- **Imports: Foreign Supplier Verification**
  - Good Import Practices draft guidance
  - “Responsible Party” definition
- **Definition of “High Risk”** (basis for inspection frequency, can require mandatory certification)
- **FDA Authority to Require Sampling**
  - Volume of testing (environment, ingredient, product)
  - Test and Hold?
- **3<sup>rd</sup> Party Accreditation**
  - By July 14, 2013, requirement to use 3<sup>rd</sup> party auditors when food safety incident identified
  - Requirement for sending results directly to FDA

# Provisions Being Monitored Closely



- **Re-inspection**
  - Criteria?
  - Fees include labor, travel, administrative
- **Traceability**
  - Ultimate farm to fork goal
  - One step forward, one step back?
  - Complex product traceability (includes FSIS- and FDA-regulated ingredients)

# Constraints & Considerations

- Statutory deadlines – extremely tight
- Multiphase implementation
- FDA funding
- Capabilities of FDA “partners”
  - Inconsistent inspection from state to state
  - Inconsistent understanding and abilities of inspectors
  - Lab and 3<sup>rd</sup> party accreditation criteria
- International Considerations
  - WTO Agreements – technical barriers to trade?
  - Codex sanitary and phytosanitary standards



