Hogan Lovells

FDA Implementation of FSMA

Updates and Outlook
October 5, 2011

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Presentation to the American Spice Trade Association

Agenda

- Introduction
  - Overview of where things are
  - Main elements of the new law
- FDA Activities
  - Pre-rulemaking activities/ FDA outreach
  - Agency Actions
- Provisions Already in Effect
- Issues to Watch
- What's Next
- Preparation

Overview

- Law signed on January 4, 2011
- FDA has conducted extensive outreach
- FDA has already completed some actions
- Some provisions already in effect
- Messaging from FDA mostly positive, but some issues are surfacing
- Activity over the coming year will accelerate
- Food companies have started to prepare

Main Elements of FSMA

1. New Responsibilities on Food Companies
2. New Controls over Imported Food
3. New Powers for the FDA
4. New Fees on Food Companies and Importers

New Responsibilities for Food Companies

- Impacting daily operations
  - Food Safety Plans/Preventive Controls
  - Supply Chain Management
  - Records Maintenance and Access
  - Food Defense Plans
- Applies to all Registered Facilities
  - Including warehouses
  - Including foreign facilities

Not To Be Forgotten

- Bi-annual registration
- Safety standards for fruits and vegetables
- Traceability
- Records access under Bioterrorism Act

New Controls Over Imported Food

- Supply chain verification procedures
- Foreign facilities subject to all the same requirements as U.S-based facilities
- FDA authority to require third party certification for food safety-related reason
- Accredited laboratory must be used for certain testing
- Expedited entry at border if safety and security guidelines met

New or Enhanced Enforcement Powers for FDA

- Increased inspection frequency
  - High Risk Domestic – every 3 years
  - Low Risk Domestic – every 5 years
  - Ramp up Foreign inspections
    (600 to 9,600 over 5 years)
- Suspension of registration
- Mandatory recall
- Expanded administrative detention authority

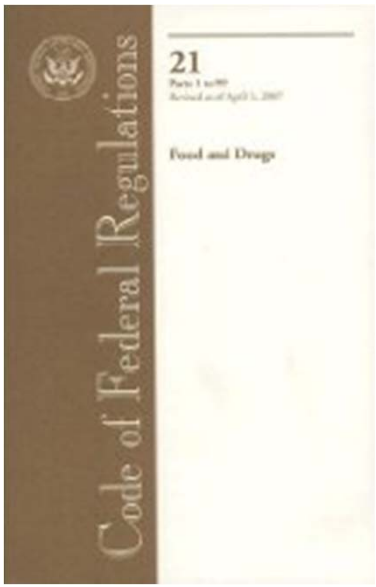
New Fees on Food Companies and Importers

- Reimbursement to FDA
  - Reinspections
  - Recall (very limited)
- Export certificates
- Fast lane for imports

- Note that reinspection fees and export certificate fees start October 2011

Implementation Timetable

- Various effective dates for different provisions
- Longer implementation time for small and very small businesses
- Basic timeline
  - 18 months – food safety plans
  - 24 months – foreign supplier verification
  - Longer for traceability
  - Bi-annual registration begins 2012
- Detailed schedule for FDA regulations and guidance



Due Dates for Regulations

The statute includes the following due dates for required rulemakings:

- **120 days:**
  - § 304 – Prior Notice (interim final rule)
  - § 207 – Administrative Detention of Food (interim final rule)
- **1 year:**
  - § 301 – Foreign Supplier Verification Program (final rule)
  - § 105 – Produce Safety (proposed rule; final rule within 1 year of close of comment period)
- **18 months:**
  - § 103 – Preventive Controls (final rule)
  - § 106 – Food Defense (final rule)
  - § 111 – Sanitary Transportation of Food (final rule)
- **2 years:**
  - § 204 – Traceability (proposed rule for “high risk” foods)
- **No deadline:**
  - § 102 – Suspension of Registration (interim final rule)

Due Dates for Guidance Documents

The statute includes the following due dates for Guidance Documents:

- **1 year:**
  - § 105 – Produce Safety (Updated Good Agricultural Practices)
  - § 106 – Food Defense
  - § 301 – Foreign Supplier Verification Program
- **18 months:**
  - § 302 – Voluntary Qualified Importer Program
- **No Deadline:**
  - § 103 – Preventive Controls

FDA Outreach

- FDA outreach has been extensive
- Agency conducted 3 public meetings in the spring
  - Import provisions
  - Preventive controls
  - Inspections and enforcement

  → Each meeting followed by open public docket
- Additional docket opened for guidance documents to support preventive controls rulemaking
- Meetings held with subject matter experts and trade associations

FDA Actions

- Published interim final rules for revisions to administrative detention and prior notice of imports
- Published notice of reinspection fee costs
- Selected IFT to conduct traceability pilots
- Updated website with improved search capability for recalls
- Issued anti-smuggling strategy
- Issued series of Q & A documents
- Met other statutory deadlines (reports to Congress, updating Seafood HACCP Guidance, issuing guidance on new dietary ingredient notifications)

Administrative Detention

- Expands existing provision (from the Bioterrorism Act)
- Trigger is: “reason to believe” an article of food is “adulterated or misbranded”
  - Likely to be used in Class II type situations
- Still tied to seizure and injunction actions
- District Director or above

Prior Notice

- Interim final rule amends existing regulations
- Requires that a prior notice for an imported food identify any country to which the article of food has been shipped, but refused entry

User Fees

In general, FDA can assess fees against:

(1) domestic facilities to cover reinspection-related costs

(2) domestic facilities to cover recall-related activities performed by FDA if the facility refuses to comply with a mandatory recall order

(3) importers to cover administrative costs of participating in the voluntary qualified importer program

(4) importers to cover reinspection-related costs

User Fees continued…

- Starting October 1, 2011: $224/hour; $325/hour if foreign travel required (per person)
- Reinspection: previous inspection was OAI and the noncompliance was materially related to food safety
- Recall: not initiating a recall as ordered by FDA; not conducting the recall in the manner specified by FDA in the recall order; or failing to provide FDA with requested information, as ordered
- Imports: reconditioning of imported food; importers seeking admission of an article that has been detained; entities requesting removal from an import alert for detention without physical examination; and destruction of food that has been refused admission

Traceability Pilots

- FDA has contracted with IFT to do the pilots
  - Produce; packaged food
  - 3 types of food; subject of outbreaks in the last 5 years
  - Representative of supply chain
- Stakeholder meetings on pilot scope
  - Seattle; Washington, DC; Chicago
- Completion and report next spring

Provisions Already in Effect

- Mandatory recall
- Suspension of registration
- Administrative detention (expanded version)
- Prior notice of imports (expanded version)
- Emergency access to records (expanded version)
- Re-inspection fees (October 1st)

Mandatory Recall

- FDA has mandatory recall authority if:
  - A company refuses to voluntarily recall a product
  - For which "there is a reasonable probability" that the food is adulterated or contains an undeclared food allergen and consumption of the food will cause "serious adverse health consequences or death."

  → This is the same standard as applies to a Class I recall
- Failure to comply triggers a civil money penalty of no more than $50,000 per individual and $250,000 per entity, not to exceed $500,000 for all related violations ; PLUS fees

Suspension of Registration

- Standard: food manufactured, processed, packed, or held by that facility "has a reasonable probability of causing serious adverse health consequences or death"
  - For a facility that merely packs, receives, or holds food, the standard is narrowed to those circumstances where the facility "knew or should have known"
    - This standard prevents a warehouse operator from being held accountable for contamination caused by the manufacturer
- Currently effective, but regulations to come
- Much still unknown

Issues to Watch

- Remote access to food safety plans
- Finished product testing may be expected
- Consultative audits subject to direct reporting to FDA of serious health risks
- Voluntary traceability may be sought beyond boundaries of statute
- Role of third party accreditation
- Use of accredited laboratories
- Exemption for warehouses
- Additional user fees

What's Next

- Proposed rules should start issuing by November/December
- FDA priorities appear to be:
  - Preventive controls
  - Fresh produce
  - Foreign supplier verification
  - Third-party accreditation standards
- Comment periods likely to be short (60 days), with no extensions
- Final rules sought by summer of 2012 (pre-election), or by January 2013 (end of Obama's first term)
- Enforcement dates to be specified in final rules

Preparing Now

- Initial briefings of senior management
- Initial trainings:
  - Quality staff and plant managers
  - Co-manufacturers and suppliers
- Review/update:
  - HACCP plans
  - Supplier qualification procedures
  - Records maintenance procedures
- Work with ASTA to file comments

Conclusion

- FDA has been very open
- FDA appears driven to complete required actions and implement the law in a timely manner
  - Election year
  - Budget
- Implementation/enforcement is just around the corner

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