FDA Food Safety Modernization Act

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How Much Do You Know About FDA?

Which item is *not* under the jurisdiction of the Food and Drug Administration?
a. Spam
b. puppy food
c. chocolate covered cherries
d. frozen spinach
e. imported caviar
a. pesticide residues in lettuce
b. canned tomatoes
c. oven cleaner
d. spaghetti
e. pet turtles
a. baby pacifiers
b. baby bottle nipples
c. ceramic ware for food use
d. coffee mugs
e. eye chart
a. kidney dialysis machine
b. tongue depressor
c. toothpaste
d. fluoridated toothpaste
e. hair dryer
WHAT IS THE NEW LAW?

- Food Safety Modernization Act (FSMA)
- Effective Jan 4, 2011
- Biggest change since 1938
What’s so historic about the law?

• Involves creation of a new food safety system
• Broad prevention mandate and accountability
• New system of import oversight
• Emphasizes partnerships
• Emphasizes farm-to-table responsibility
• Developed through broad coalition
New law updates authority and tools

1906 – Pure Food and Drug (Focus on Sanitation)

1938 – Food, Drug, and Cosmetic Act (Reactionary)

2011 – FSMA (Prevention, Risk Analysis)
Why is the law needed?

• Globalization
  – 15 percent of U.S. food supply is imported
    (75% of Seafood, 50% of Fruit, 20% of Vegetables)
Why is the law needed?

• Food supply more high-tech and complex
  – More foods in the marketplace
  – New hazards in foods not previously seen

• Shifting demographics
  – Growing population (about 30%) of individuals are especially “at risk” for foodborne illness
The Public Health Imperative

• Foodborne illness is a significant burden
  – About 48 million (1 in 6 Americans) get sick each year
  – 128,000 are hospitalized
  – 3,000 die

• Immune-compromised individuals more susceptible
  – Infants and children, pregnant women, older individuals, those on chemotherapy
The Public Health Imperative

• Foodborne illness is not just a stomach ache—it can cause life-long chronic disease
  – Arthritis, kidney failure
Headlines

2006

• FDA Continues Investigation of *E. Coli* O157:H7 Cases Associated with Taco Bell Restaurants

• FDA warns US consumers not to eat spinach after *E coli* outbreak
PEPPER?

PENICILLIN. SAY WHEN, SIR...
Headlines

2007

• Supplier of tainted Veggie Booty flavoring ID’d
• ConAgra estimates peanut butter recall will cost $60m
• FDA Issues Chili Sauce Botulism Warning
• Melamine contaminated Pet Foods
Went out for pizza - S.
Headlines

2008

• *Salmonella* Saintpaul Outbreak

• FDA Warns of Salmonella Risk with Cantaloupes from Agropecuaria Montelibano
Headlines

2009

• Salmonella recall could cost peanut producers $1 billion

• Nestlé USA’s Baking Division Initiates Voluntary Recall
HE MUST HAVE EATEN HIS OWN SALMONELLA-TAINTED PEANUT BUTTER, BECAUSE IT CAME OUT CRUNCHY AND THEN IT CAME OUT CREAMY!
Headlines

2010

• FDA recalls some foods with flavor enhancer HVP

• 550 Million Eggs Recalled Due to Salmonella Poisoning
Headlines

2011

• Outbreak of Shiga toxin-producing E. coli 0104:H4 Infections Associated with Travel to Germany

• Citing Papaya Outbreak, DeLauro Says Fund FSMA

• Next?
1998

“Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables”
The Food Protection Plan (2007)

**FOOD PROTECTION**

- **PREVENTION:** Build safety in from the start
- **INTERVENTION:** Risk based inspections and testing
- **RESPONSE:** Rapid reaction, effective communication

**FOOD SAFETY**

**FOOD DEFENSE**
Main Themes of the Legislation

Prevention

Enhanced Partnerships

Inspections, Compliance, and Response

Import Safety
Prevention:
The cornerstone

- Comprehensive preventive controls for food and feed facilities
  - Prevention is not new, but Congress has given FDA explicit authority to use the tool more broadly
  - Strengthens accountability for prevention
- Produce safety standards
- Intentional adulteration standards
Before FSMA…

• FDA mostly a “gatekeeper”
• Addressed problems only after they arose

After FSMA…

• Proactive, Risk-Based approach
• Inspections, verifications
• More comprehensive regulation to prevent food safety incidents
• The trigger for FDA's enhanced inspectional authority is broad: "a reasonable belief that an article of food, and any other article of food that [FDA] reasonably believes is likely to be affected in a similar manner."
Inspection, Compliance, and Response

• Mandated inspection frequency
  – More inspections, but with preventive controls in place, we can consider new ways to inspect

• New tools
  – Mandatory recall
  – Expanded records access
  – Expanded administrative detention
  – Suspension of registration
  – Enhanced product tracing
  – Third party laboratory testing
Import Safety: Most groundbreaking shift

- Importers now responsible for ensuring that their foreign suppliers have adequate preventive controls in place
- FDA can rely on third parties to certify that foreign food facilities meet U.S. requirements
- Can require mandatory certification for high-risk foods
Import Safety: Most groundbreaking shift

- Voluntary qualified importer program--expedited review
- Can deny entry if FDA access for inspection is denied
- Requires food from abroad to be as safe as domestic
Import Safety Mandates

Sec. 201. Targeting of inspection resources

• Increased inspection of foreign as well as domestic facilities
Import Safety Mandates

Sec. 301. Foreign supplier verification program
• Requires importers to verify their suppliers use risk-based preventive controls that provide same level of protection as U.S. requirements.

Sec. 302. Voluntary qualified importer program
• Allows for expedited review and entry; facility certification required
Import Safety Mandates

Sec. 303. Certification for high-risk food imports

• FDA has discretionary authority to require assurances of compliance for high-risk foods

Sec. 304. Prior notice of imported food shipments

• Requires information on prior refusals to be added to prior notice submission
Import Safety Mandates

Sec. 305. Capacity building
- FDA mandate to work with foreign governments to build food safety capacity

Sec. 306. Inspection of foreign food facilities
- Can deny entry if FDA access for inspection is denied
Import Safety Mandates

Sec. 307. Accreditation of third-party auditors
• FDA can rely on accredited third parties to certify that foreign food facilities meet U.S. requirements

Sec. 308. Foreign Offices of the Food and Drug Administration
• Establish offices in foreign countries to provide assistance on food safety measures for food exported to the U.S.
Import Safety Mandates

Sec. 309. Smuggled Food

• In coordination with DHS, better identify and prevent entry of smuggled food
Trade Agreements

• Section 404, Compliance with International Agreements, explicitly notes that FSMA must be consistent with our agreement with the World Trade Organization (WTO) and any other treaty or international agreement.

• At each stage of the implementation process, we will make every effort to ensure that our proposed activities, policies, and measures are consistent with the WTO.
Role of Third-Party Certification Programs

• Tool for importers to obtain needed assurances to meet their obligations for the foreign supplier verification program (sec. 301)

• A way for importers to participate in the voluntary qualified importer program to expedite movement of food through the import process (sec. 302)
Role of Third-Party Certification Programs

- Can be required by FDA to accompany high-risk foods (sec. 303)
Accreditation Body
Accredits 3rd parties (Sec. 307)

3rd Party Certification
Certify high-risk food imports
Sec. 303

Foreign supplier verification program
Foreign firms obtain 3rd party certification as needed
Sec. 301

Voluntary Qualified Importer Program
Importer inspection and product certification enable expedited product entry
Sec. 302
Enhanced Partnerships: Vital to Success

- Reliance on inspections by other agencies that meet standards
- State/local and international capacity building
- Improve foodborne illness surveillance
Enhanced Partnerships: Vital to Success

International capacity building

- FDA has mandate to work with foreign governments to build their food safety capacity
- Allows FDA to rely more heavily on foreign government oversight
- Capacity building helps to prevent problems before products reach the U.S. port of entry
Enhanced Partnerships: Vital to Success

- National agriculture and food defense strategy
- Consortium of laboratory networks
- Easier to find recall information
Implementation Approach

• Implementation already underway
• Coalition needed
• Transparency a priority
• Focus on public health protection
• Engage with stakeholders to help determine reasonable and practical ways to implement provisions
Many Challenges

• Enormous workload
  – 50 new rules, guidance documents, reports in 3 years

• Tight deadlines

• Changes won’t appear overnight
  – Building new system will be a long-range process

• Resources
Implementation Progress
(as of Aug. 1, 2011)

- Fees (107)
- New dietary ingredients
- (sec.113)
- Anti-smuggled food strategy (sec. 201)
- Registration of Food Facilities (sec. 103)

http://www.fda.gov/fsma
Implementation Progress
(as of Aug. 1, 2011)

- Prior Notice of imported food shipments (sec. 304)
- Administrative detention of food (sec. 207)
- Consumer-friendly web search for recalls (sec. 205)
- Guidance to Seafood Industry on food safety hazards (sec. 103)

http://www.fda.gov/fsma
Produce Safety Regulation

- Announced in 2010
- Mandated by FSMA
- Mandatory, science-based, minimum standards
- Listening sessions in 13 states
- Expect to publish proposed rule by the end of 2011
- Final rule anticipated sometime in 2012
Will all of the requirements for preventive controls apply to all facilities?

FSMA provides for exemptions or modified requirements in certain circumstances, such as when a facility is already required to comply and is in compliance with seafood or juice HACCP, or if a facility is very small.
MANDATING FOOD RECALLS

• FDA has mandatory food-recall authority (Sec. 423; 21 U.S.C. 3501)

• Where an article is adulterated or misbranded and exposure to such article will cause serious adverse consequences to consumer
http://www.fda.gov/fsma
For more information

http://www.fda.gov/fsma

• Subscription feature available

• Send questions to FSMA@fda.hhs.gov