Food Protection Plan

In May 2007, the Secretary of HHS and the Commissioner of Food and Drugs charged FDA with developing a comprehensive, integrated Food Protection Plan:

- Food for people and animals
- Domestic and imported
- Food safety and food defense

Changes and Challenges

Trends in Consumption & Demographics

- Consumer demand for items 24/7, year round
- Convenience foods are increasing in popularity
- Spending on foodservice equals half of U.S. food spending
- Consumers are eating more fresh produce
- 20 – 25% of the population is high risk
  - In 1980 - 15% over age 60
  - In 2025 - 25% will be over age 60
- 4% of the population is immune-compromised

New Foodborne Pathogens Since 1977

- Campylobacter jejuni
- Cryptosporidium parvum
- Shiga toxin-producing E. coli
- Noroviruses
- Vibrio cholerae O139
- Vibrio parahaemolyticus
- Campylobacter fetus
- Cyclospora cayetanensis
- Listeria monocytogenes
- Salmonella Enteritidis
- Vibrio vulnificus
- Yersinia enterocolitica
- Enterobacter sakazakii
- Salmonella Typhimurium DT104

Importation of FDA Regulated Products

Changes in Imports Over Time

- Total Foods
- Pet Foods
- Confections
- Produce
- Seafood

Volume of Imports

Percent Change, 1995-2005
(Weight of shipments)
Intelligence indicates terrorists have discussed components of the food sector. Manuals for intentional contamination of food are widely available. Food and Agriculture are critical assets and concern exists for exploitation of soft targets, such as the food supply. Use of biological or chemical weapons against our food supply could cause mass casualties. Even an ineffective attack could cause significant economic and psychological damage.

Changes and Challenges

Bioterrorism

- Intelligence indicates terrorists have discussed components of the food sector
- Manuals for intentional contamination of food are widely available
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Challenges of Globalization

Globalization has fundamentally changed the environment for regulating food and medical products and has created unique regulatory challenges for FDA:

- More foreign facilities supplying the United States
- Increasing volume of imported products
- More outsourcing of manufacturing and clinical trials
- Greater complexity in supply chains
- Growing complexity of products and manufacturing methods
- Imports coming from countries with less well-developed regulatory systems
- Greater opportunities for economic fraud
Changes and Challenges

Bioterrorism

Melamine
- Deliberate act for economic gain, not bioterrorism
- Sickness and death of cats and dogs
- Spread into the human food supply
- Imported product
- Complex multinational supply chain
- Demonstrated potential vulnerability

21st Century Reality
- Now our borders are boundaries to our jurisdiction
- Borders are not barriers to
  - disease
  - information flow
  - product acquisition
  - challenges of globalization
- And borders cannot be barriers to FDA’s realm of activities

International Strategy
- Establish FDA global presence
- Regulatory capacity-building
- International standards development and harmonization
- Increase timely foreign inspections
- Receive and use inspection reports from foreign competent authorities
- Third-party certification
- Enhance information technology tools
Outdated FDA data handling capacity.
• Growing imports
• Need for integrated systems
• Information to protect consumers difficult to deliver.
  • Consumer level
  • Retail level

Breakdown of New FDA Hires
• 43 US National FTEs
  – 5 Regional/Country Directors
  – 21 Senior Technical Experts in foods, medicines, or devices
  – 9 inspectors with expertise in food/feed or medical products
  – 8 support personnel at Headquarters
• 20 Locally employed staff

Office of International Programs Responsibilities
• Provides leadership for all international matters in all program areas
  – interactions with foreign counterpart regulatory authorities and multilateral organizations
  – capacity building
  – managing FDA’s foreign offices
  – making formal international arrangements
  – exchanging non-public information
  – trade issues

Changes and Challenges
Communication
• Outdated FDA data handling capacity.
  • Growing imports
  • Need for integrated systems
  • Information to protect consumers difficult to deliver.
  • Consumer level
  • Retail level
FDAAA of 2007

- **TITLE X – Food Safety**
  - Section 1002 – Ensuring the Safety of Pet Food
  - Section 1003 – Ensuring Efficient and Effective Communications During a Recall
  - Section 1004 – State and Federal Cooperation
  - **Section 1005 – Reportable Food Registry**
  - Section 1006 – Enhanced Aquaculture and Seafood Inspection
  - Section 1007 – Consultation Regarding Genetically Engineered Seafood Products
  - Section 1009 – Annual Report To Congress
  - Section 1010 – Publication of Annual Reports

FDAAA 1005 Reportable Food Registry

**Reportable Food Registry**
- Establish a Reportable Food Registry, to which instances of reportable food may be submitted via an electronic portal and a unique number issued to the person submitting the report upon receipt.

FDAAA 1005 Reportable Food Registry

**What is a “reportable food”?**
- “Reportable food” – an article of food (other than dietary supplements and infant formula), which has a reasonable probability of causing serious adverse health consequences or death to humans or animals.

FDAAA 1005 Reportable Food Registry

**Who has to report?**
- Requirement – Instances of reportable food shall be submitted by:
  - A “responsible party,” i.e., the individual who submits the food facility registration under section 415(a), and
  - **Voluntarily by Federal, State, and Local Public Health Officials**
FDAAA 1005 Reportable Food Registry

What foods are covered?
Reportable Food Registry covers:
• All FDA-regulated foods, except dietary supplements and infant formula.
• Domestic and imported foods

FDAAA 1005 Reportable Food Registry

FDA:
• Will establish an electronic portal to receive submissions
• Shall promptly review and assess information submitted to the Reportable Food Registry
• Will issue a unique identifier to the incident

FDAAA 1005 Reportable Food Registry

FDA:
• Shall issue or cause to be issued an alert or notification with respect to a reportable food as deemed necessary after consultation with the responsible party

FDAAA 1005 Reportable Food Registry

FDA:
• Shall share information and coordinate efforts with the U.S. Department of Agriculture
• Shall share information and coordinate efforts with state and local public health and regulatory agencies

FDAAA 1005 Reportable Food Registry

FDA:
• If Secretary believes food is intentionally adulterated, must notify the Department of Homeland Security
• Shall issue guidance to industry about how to submit reports to the electronic Reportable Food Registry

Food Safety Enhancement Act of 2009

1. Creates an up-to-date registry of all food facilities serving American consumers: Requires all facilities operating within the U.S. or importing food to the U.S. to register with the FDA annually.

2. Generates resources to support FDA oversight of food safety: Requires registered facilities to pay an annual registration fee of $1,000 in order to generate revenue for food safety activities at the FDA; requires registered facilities to pay for FDA’s costs associated with reinspections and food recalls; allows FDA to charge a fee to domestic firms requesting export certificates for exported food.

3. Prevents food safety problems before they occur: Requires all facilities operating within the U.S. or importing food to the U.S. to implement safety plans that identify and protect against food hazards. FDA would have the authority to specify minimum food safety plan requirements and to audit food safety plans.

4. Requires safety plans for fresh produce: Directs FDA to issue regulations for ensuring the safe production and harvesting of fruits and vegetables.
Food Safety Enhancement Act of 2009

5. Increases inspections of food facilities: Sets a minimum inspection frequency for all registered facilities.
   - High-risk facilities at least once every six to 18 months
   - Low-risk facilities at least once every 18 months to three years
   - Warehouses that store food at least once every three to four years
   - Refusing, impeding, or delaying an inspection is prohibited.

6. Improves traceability of food: Enhances FDA's ability to trace the origin of tainted food in the event of an outbreak of foodborne illness. FDA would be required to issue regulations that require food firms to maintain the full pedigree of the origin and previous distribution history of the food and to establish an interoperable record to ensure fast and efficient traceback.

7. Enhances the safety of imported food: As an additional layer of protection, FDA can require food to be certified as meeting all U.S. food safety requirements by the government of the country from which the article originated or by certain qualified third parties. Third party certifying entities must meet strict requirements to protect against conflicts of interest with the firm seeking certification.

8. Expands laboratory testing capacity: Requires FDA to establish a program to recognize laboratory accreditation bodies and to accept test results only from duly accredited laboratories. Gives FDA the ability to require laboratories to send test results to FDA.

9. Provides strong, flexible enforcement tools: Provides FDA new authority to issue mandatory recalls of tainted foods. Strengthens criminal penalties and establishes civil monetary penalties that FDA may impose on food facilities that fail to comply with safety requirements.

10. Creates fast-track import process for food meeting security standards: Permits FDA to develop voluntary security guidelines for imported foods. Importers meeting the guidelines would receive expedited processing.

11. Enhances the safety of infant formula: Enhances FDA’s ability to assure the safety of new infant formulas before they go on the market.

12. Advances the science of food safety: Directs the Secretary to include food in an active surveillance system to assess more accurately the frequency and sources of human illness. The Secretary is also directed to identify industry and regulatory approaches to minimize hazards in the food supply.

13. Enhances FDA's ability to block unsafe food from entering the food supply: Strengthens FDA’s authority to administratively detain unsafe food products. Grants FDA “quarantine” authority under which the agency may restrict or prohibit the movement of unsafe food products from a particular geographic area.

14. Directs FDA to assess the use of carbon monoxide in certain foods: Requires FDA to conduct a safety review of the use of carbon monoxide in meat, poultry, and seafood products.

15. Enhances transparency of GRAS program: Requires posting on FDA’s website of documentation submitted to FDA in support of a “generally recognized as safe” (GRAS) notification.

16. Requires country-of-origin labeling and disclosure: Requires all processed food labels to indicate the country in which final processing occurred. Requires food manufacturers to disclose the country of origin for all ingredients on their websites. Requires country-of-origin labeling for all produce.
Mark your calendars:

2010 Rocky Mountain Food Safety Conference
- May 18 and 19, 2010
- Red Rocks Park and Amphitheater
- Visitor's Center

Thank you!