The Global Food System and FDA’s Food Protection Plan

Go Global: Food Processing and Safety Conference
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Overview

- Changes in the Food Supply
- Challenges
- Overview of the Approach
- The Food Protection Plan
Trends in Consumption

- Americans are eating a greater variety of foods and desire a wide variety of foods year round
- US per capita consumption of fresh fruits and vegetables increased 36% from 1981 to 2000
- A typical grocery store carried a 173 produce items in 1987 and is now carrying 345 produce items
- Retailers now routinely provide produce items that were once considered seasonal on a year-round basis
- Convenience foods increasing in popularity – e.g., fresh-cut fruits and vegetables
** Global Food Supply **

- **16.3 million** import lines
- **9.1 million** food lines

**Estimated**

- IMPORT LINES (000)
- FOOD LINES (000)
- Poly. (IMPORT LINES (000))
- Poly. (FOOD LINES (000))
Changes in Imports Over Time

Volume of Imports

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

Percent Change, 1995-2005
(Weight of shipments)
Changes in Food Safety Risks

- Rapid globalization of food production and trade has increased the potential likelihood of national and international incidents involving food contaminated with microbial or chemical contaminants.
- No evidence that food imports as a whole pose greater safety risks than food domestically produced.
  - With more countries exporting, concern about poor control systems.
Changes in Demographics

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-compromise
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
Bioterrorism

- 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
The Melamine Incident

- 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
Communication Challenges

- Outdated FDA data handling capacity.
  - Growing imports
  - Need for integrated systems

- Information to protect consumers difficult to deliver.
  - Consumer level
  - Retail level
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
Time for a New Approach

Reactive

Proactive
The Food Protection Plan

FOOD PROTECTION

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

FOOD SAFETY

FOOD DEFENSE
Focus on risks over a Product’s life cycle –
Target resources to achieve maximum risk reduction
  • Gather the science
  • Rank products based on risk
  • Focus prevention and intervention
Integration of food safety and food defense
Use science and modern technology systems
Food Protection Plan

Three core elements:
- Prevention
- Intervention
- Response

Under each element
- Key steps
  - FDA actions
  - Legislative proposals
Relationship to the Import Safety Report and Action Plan

- Presidential Initiative led by HHS Secretary Leavitt
- Involvement of 12 Federal Departments and Agencies
- Same three organizing principles as the Food Protection Plan
  - prevention, intervention and response
- Import Safety Action Plan will strengthen FDA food protection efforts and support the agency’s ongoing collaboration with other Federal agencies with role in U.S. food supply
- Import Safety Action Plan is comprised of
  - 14 recommendations
  - 50 action steps
    - 27 of the action steps are food related with HHS/FDA listed as a lead agency on implementation
Food Protection Plan

- 38 FDA Administrative Actions
- 10 Legislative Proposals
Prevention

Core Element No. 1

- Promote Increased Corporate Responsibility
- Identify Food Vulnerabilities and Assess Risk
- Expand Understanding and Use of Effective Mitigation Measures
Prevention

Corporate Responsibility

- Solicit stakeholder input on Food Protection Plan
- Provide guidance on developing food protection plans and other preventive measures for industry
- “Push the borders out” to address imports
  - Meet with trading partners to discuss domestic efforts on prevention and approaches to improving prevention abroad
  - Improve FDA’s presence overseas
Prevention

Vulnerabilities and Risk Assessment

- Work with partners to generate data needed to understand risks and vulnerabilities
- Use available tools to evaluate and prioritize risk from food and feed agents
- Work with CDC to attribute pathogens and illnesses to specific foods
- Establish a process for ongoing evaluation of FDA products that contribute the most to foodborne illness
Prevention

Mitigation Measures

Research plan on mitigation approaches (source, spread, prevention) for high-risk foods

Research and develop new detection methods

Develop platforms for disseminating research results
Intervention

Core Element No. 2

- Increase Risk-Based Inspections and Sampling
- Enhance Risk-Based Surveillance
- Improve the Detection of Food System “Signals” that Indicate Contamination
Intervention

Risk-Based Inspections and Sampling

- Increase food and feed safety inspections and sampling
- Identify and implement methods and tools for quick and accurate contaminant detection
- Train investigators on new, complex food manufacturing processes
- Collaborate with foreign authorities to reduce risk of imported food
US/China Memorandum of Agreement

Signed December 11, 2007

Key points

• New registration and certification requirements
• Greater information sharing
• Increased access to production facilities
• Greater regulatory cooperation (standards, capacity building)
Implementation of agreement will be in with designated covered products:

- LACF/AF
- Pet food/treats of animal or plant origin
- Ingredients for food and feed (e.g. wheat gluten)
- Aquaculture farming products
Intervention

Risk-Based Surveillance - Imported Food

- Enhance targeting of imports for inspection based on risk
- Conduct additional foreign food and feed inspections
- Enhance screening capability and data handling capacity for food imports
- Expand information sharing agreements with foreign countries
**Intervention**

*Detection of Contamination Signals*

- Deploy tools to rapidly screen and identify pathogens
- Improve adverse event and consumer complaint reporting systems
- Establish a Reportable Food Registry (FDAAA)
- Develop a database for veterinarians that captures data on food safety incidents (FDAAA)
Response

Core Element No. 3

- Improve Immediate Response
- Improve Risk Communication to the Public, Industry, and Other Stakeholders
Response

Immediate Response

- Enhance capabilities of FDA’s Emergency Operations Network Incident Management System
- With stakeholders, develop an action plan for more effective traceback (process/technologies) of contaminated food and feed
- Enhance IT networking for real-time lab communication
Response

Risk Communication to Stakeholders

- Design and conduct consumer communications and behavior response studies
- Use study information to update Food Protection Risk Communication Plan with strategies to effectively communicate with consumers
- Website for food protection information
- In a food emergency, implement Food Protection Risk Communication Plan to get appropriate information to consumers, retailers, industry, healthcare community, public health officials, and other stakeholders
Prevention Legislative Proposals

- Preventive Controls Against Intentional Contamination by Terrorists or Criminals at Points of High Vulnerability
  - Focus in areas of greatest risk
  - Foods in bulk/batch form
  - Excludes produce and on farm (except milk)

- Preventive Controls for High-Risk Foods
  - Foods associated with repeated instances of serious illness or death
  - Explicit authority to issue preventive control regulations

- Registration Renewal Every Two Years and Modification of Registration Categories
  - Scheduled updates of information
  - Expand available food categories to reflect current food types
Intervention
Legislative Proposals

Accredit Third Parties for Food Inspections
• FDA accreditation program, including audit and training
• FDA not bound by third party certifications
• Certification could be considered for import review and domestic inspection priorities

Reinspection Fee for Facilities that Fail to Meet cGMPs
• Part of the 2008 budget process
• Facilities that fail to comply with FDA standards bear the cost of reinspection
Intervention Legislative Proposals, cont’d

- Electronic Import Certificates for Designated High Risk Products
  - FDA determines products of concern and criteria for certification
  - Inspection burden shared by exporting country
  - Shipments without proper certification are refused entry

- Food and Feed Export Certification Fee
  - Part of the 2008 budget process
  - No redirection of resources from food/feed safety programs

- Refusal of Admission if Inspection Access Is Denied
  - Currently, FDA cannot refuse admission if foreign inspections are denied or delayed
  - Provides a level playing field for domestic & foreign manufacturers
Response Legislative Proposals

- Mandatory Recall of Food Products
  - Reasonable belief the food is adulterated and presents a risk of serious illness or death
  - Used only when firm refuses or delays a voluntary recall

- Enhanced Access to Food Records during Emergencies
  - Current access requires reasonable belief that a food is adulterated AND presents a risk of serious illness or death
  - Would allow access when specific adulterant has not been identified
  - Expand access to records for related foods, such as food produced on the same production line
Information Technology

- Enhance IT systems related to domestic and imported foods
- Collaborate with CBP to enhance data systems to better identify importers and screen entry data
- Enhance infrastructure and disaster recovery for IT systems
Public Health Impact of the Food Protection Plan

- Better Prevention & Stronger Intervention
  Reduced chances of contaminated product reaching the consumer

- Faster Response
  Remove exposure faster

Less Illness & Reduced Chance of a Successful Attack on the Food Supply
Summary

- The U.S. food supply is one of the safest in the world, although recent outbreaks have caused loss of consumer confidence in food safety.
- Changes in the food supply necessitate a new approach to food protection.
- Plan is integrated with greater emphasis on Prevention, plus effective Intervention and rapid Response.
- Results: reduced chance of exposure and more rapid response when outbreaks occur.
More Information

http://www.fda.gov/oc/initiatives/advance/food/plan.html
Questions?