

**AMS Fruit and Vegetable
Industry Advisory
Committee
February 7, 2008**

**FDA's Food
Protection Plan**

**Nega Beru, Ph.D.
Director, Office of Food Safety
Center for Food Safety and
Applied Nutrition
Food and Drug Administration**



Department of Health and Human Services
U.S. Food and Drug Administration

Food Protection Plan
An integrated strategy for protecting the nation's food supply

NOVEMBER 2007

PREVENTION · INTERVENTION · RESPONSE

Overview

- The Charge to FDA
- Changes and Challenges Facing FDA
- Overview of the Approach
- The Food Protection Plan
- Relationship to the Import Safety Report



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

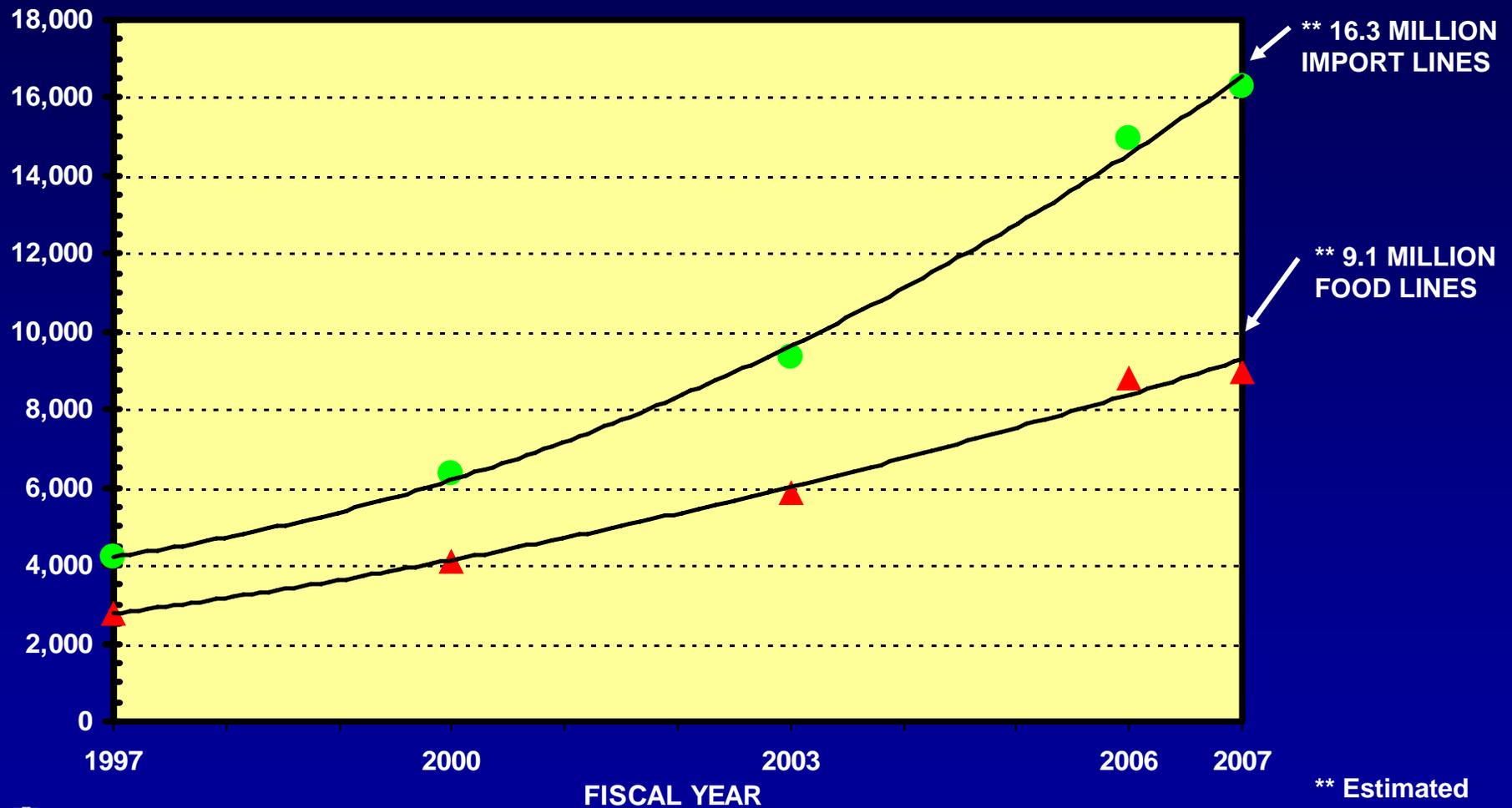
Trends in Consumption & Demographics

- 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-compromise



Changes and Challenges

Global Food Supply



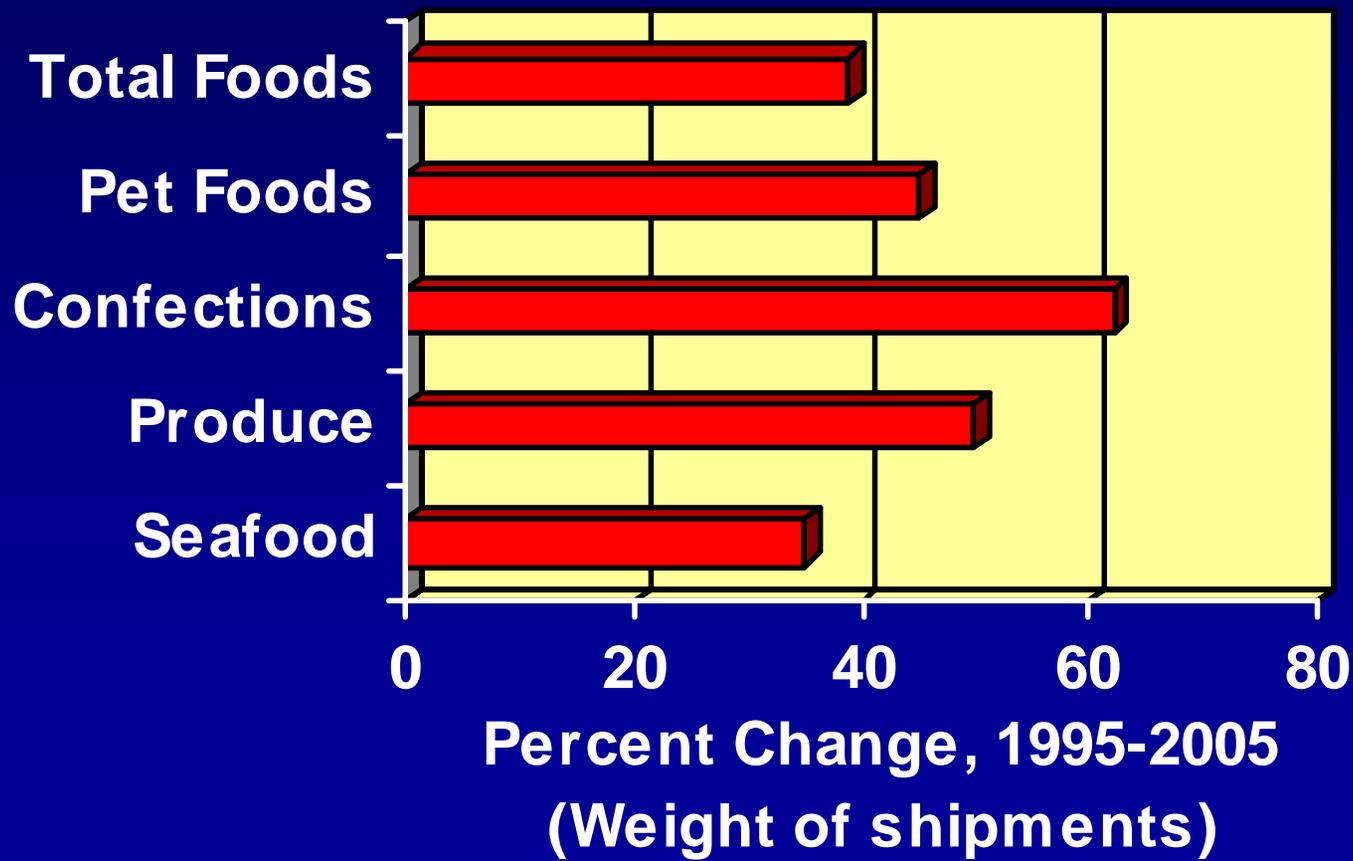
● IMPORT LINES (000) ▲ FOOD LINES (000)
— Poly. (IMPORT LINES (000)) — Poly. (FOOD LINES (000))



Changes and Challenges

Changes in Imports Over Time

Volume of Imports



Changes and Challenges

New Foodborne Pathogens Since 1977

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



Changes and Challenges

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



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



Changes and Challenges

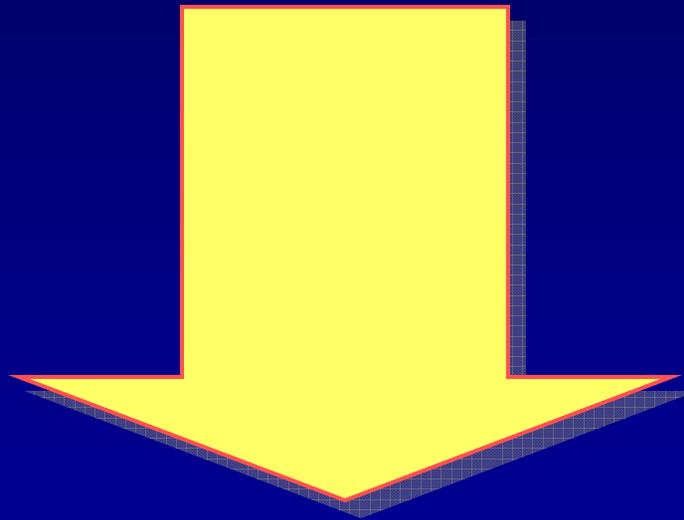
Communication

- Outdated FDA data handling capacity.
 - Growing imports
 - Need for integrated systems
- Information to protect consumers difficult to deliver.
 - Consumer level
 - Retail level



Time for a New Approach

Reactive



Proactive

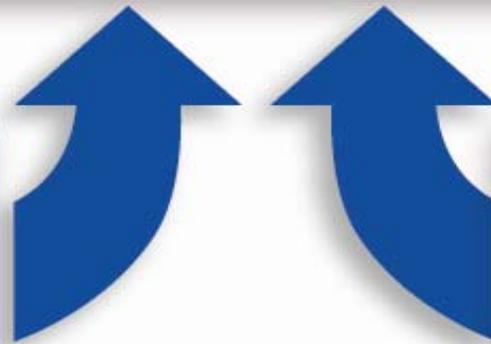


The Food Protection Plan

FOOD PROTECTION

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

**FOOD
SAFETY**



**FOOD
DEFENSE**



Food Protection

Cross-Cutting Themes

- 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

Agency Actions:

- 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

Corporate Responsibility

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



Prevention

Vulnerabilities and Risk Assessment

Agency Actions:

- 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

Agency Actions:

- 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

Agency Actions:

- 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



Intervention

Risk-Based Inspections and Sampling

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

Risk-Based Surveillance - Imported Food

Agency Actions:

- 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

Risk-Based Surveillance - Imported Food

Legislative Proposals:

- 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



Intervention

Detection of Contamination Signals

Agency Actions:

- 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

Agency Actions:

- 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

Immediate 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



Response

Risk Communication to Stakeholders

Agency Actions:

- 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



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?

