




**U.S. Food and Drug
Administration**

What is FDA Doing to Protect the Food Supply?

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Food Protection Plan

An integrated strategy for protecting the nation's food supply

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PREVENTION · INTERVENTION · RESPONSE

Outline

- Changes and Challenges
- FDA's Food Protection Plan
 - Major elements
 - Legislative proposals
- Implementation of the FPP
 - Current Focus
- Industry role



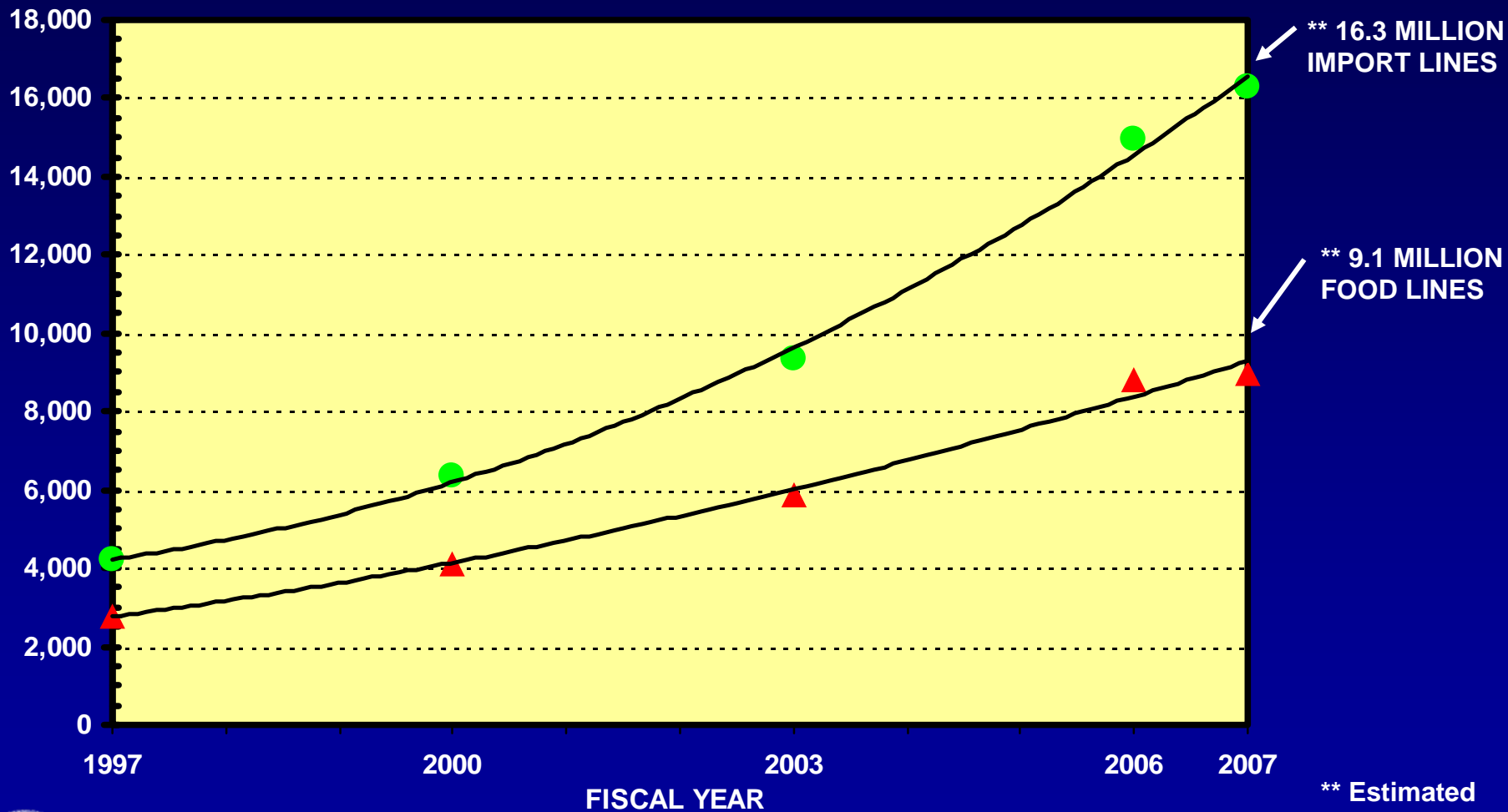
Changes and Challenges

Trends in Consumption

- Consumer demand for items 24/7, year round
- Convenience foods are increasing in popularity
- Increasing global food supply
 - Approximately 15% of food is now imported

Changes and Challenges

Global Food Supply

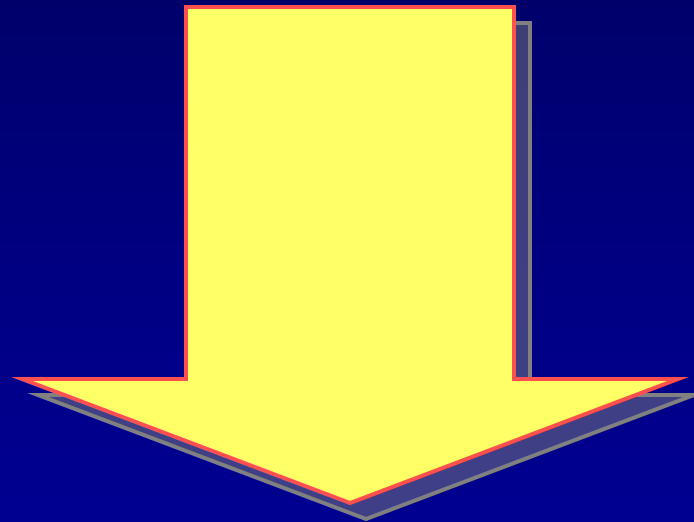


Changes and Challenges

- Increasing numbers of high risk individuals
 - Elderly
 - Immune compromised
- New questions emerging
 - Melamine, BPA etc.
 - Risk/benefit analysis
- Bioterrorism
- Deliberate adulteration for economic gain
- High profile outbreaks in recent years
 - Diminished consumer confidence

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
- Revised strategy regarding imported foods
 - Production life cycle vs. Port of entry

Agency Actions

■ Prevention

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

■ Intervention

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

■ Response

- Improve Immediate Response
- Improve Risk Communication to the Public, Industry, 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
- Preventive Controls for High-Risk Foods
 - Foods associated with repeated instances of serious illness or death

Intervention

Legislative Proposals

- **Accredit Third Parties for Food Inspections**
 - FDA accreditation program, including audit and training
 - Certification could be considered for import review and domestic inspection priorities
- **Electronic Import Certificates for Designated High Risk Products**
 - FDA determines products of concern and criteria for certification
 - Shipments without proper certification are refused entry



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

Expectations

- What is FDA doing to protect the food supply?
- How is FDA using newly appropriated money and base money to protect the food supply?
- What is the detailed implementation plan to ensure that the various components of the agency charged with protecting the food supply (CFSAN, ORA, CVM, NCTR, OC) are integrated, and coordinated
- What plan does FDA have for protecting the food supply beyond 2009.
- How will FDA measure the impact of the food protection activities on public health?



Current Major Focus

- Establishing a Risk Based Approach
 - Focus on inspections, research needs, imports
- Outreach
 - States and locals - St. Louis meeting
 - Foreign governments
 - Industry
- Track and trace systems
 - Public meeting in the fall
- Voluntary certification programs
 - FR notice published
 - Shrimp pilot to determine feasibility
- Import strategies
 - Greater sophistication for risk based inspections (PREDICT)
- FDA beyond our borders
 - FDA presence in various parts of the world
- Legislative proposals



FDA – Beyond our Borders

■ China

- MOA signed December 2007
- Establish an office in 2008

■ India

- Technical team visit in March 2008
- Establish a presence in 2008

■ South/Central America

- Development of an MOU/office

■ Europe

- Presence planned

■ Middle East

- Presence planned



Success depend on partnerships

- Between regulators
 - Federal/State/Local/Tribal
 - Foreign governments
- With industry
 - Domestic
 - Foreign
- With academia
- With consumers



Industry

■ Preventative controls

- Basic standards
- Risk-based focus

■ Supply chain

- Ability to track product
- Know your suppliers

■ Reaction to consumer complaints, illness

■ Find ways to interact with FDA

Summary

- The U.S. has one of the safest food supplies in the world
- Changes in the food supply necessitate a new approach to food protection – much greater focus on prevention
- Food Protection Plan is an integrated approach with greater emphasis on Prevention, plus effective Intervention and rapid Response
- Build partnerships to address the global food supply
- Recognition that this is a long term activity



Questions?

