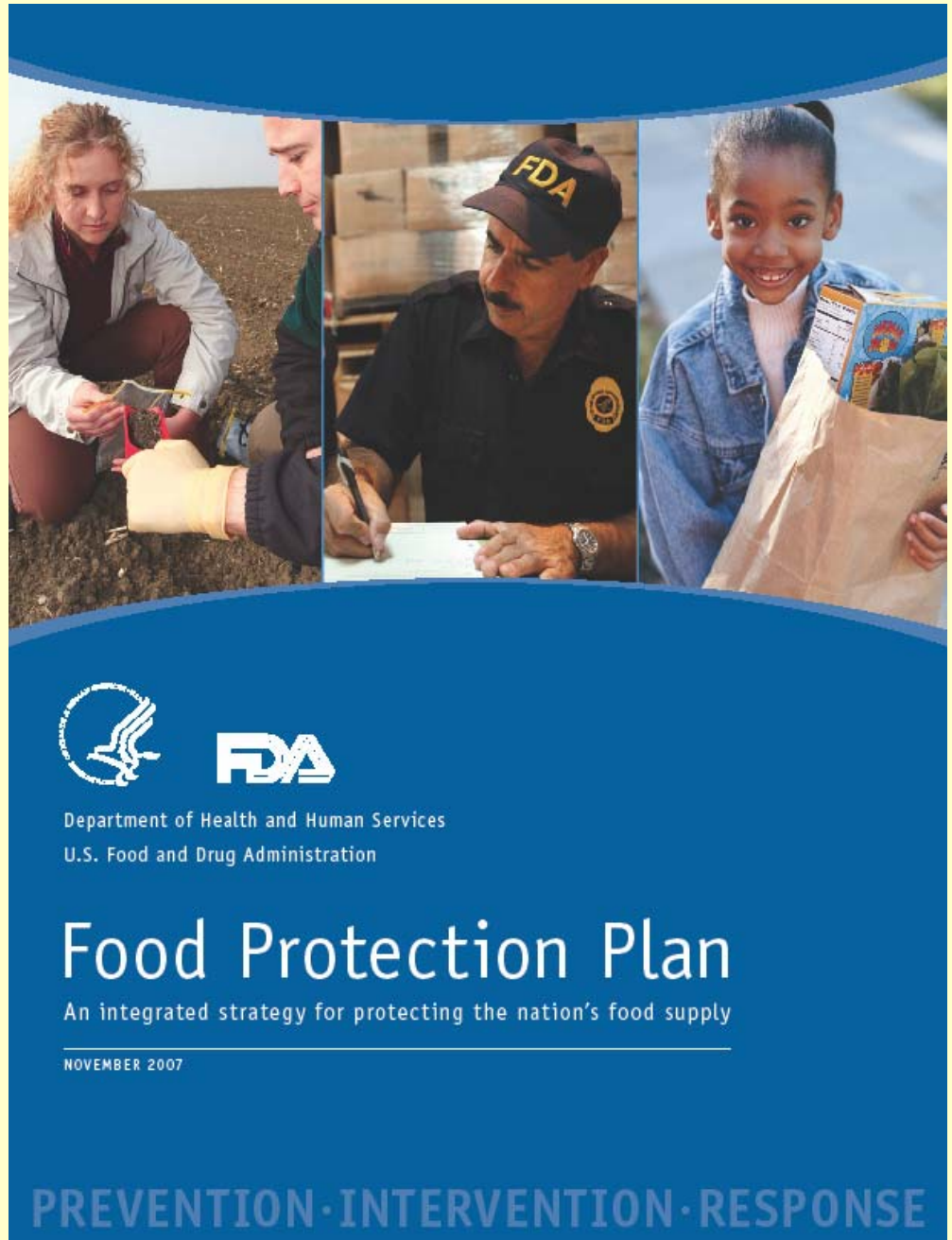


**U.S. Food and Drug
Administration**

Food Protection Plan

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Associate Commissioner for
Foods



Outline

- Changes that need to be addressed
- Food Protection Plan
 - Major elements
 - Legislative proposals
- Other activities
 - Import Safety Action Plan
 - China MOA
- Impact on the dietary supplement industry

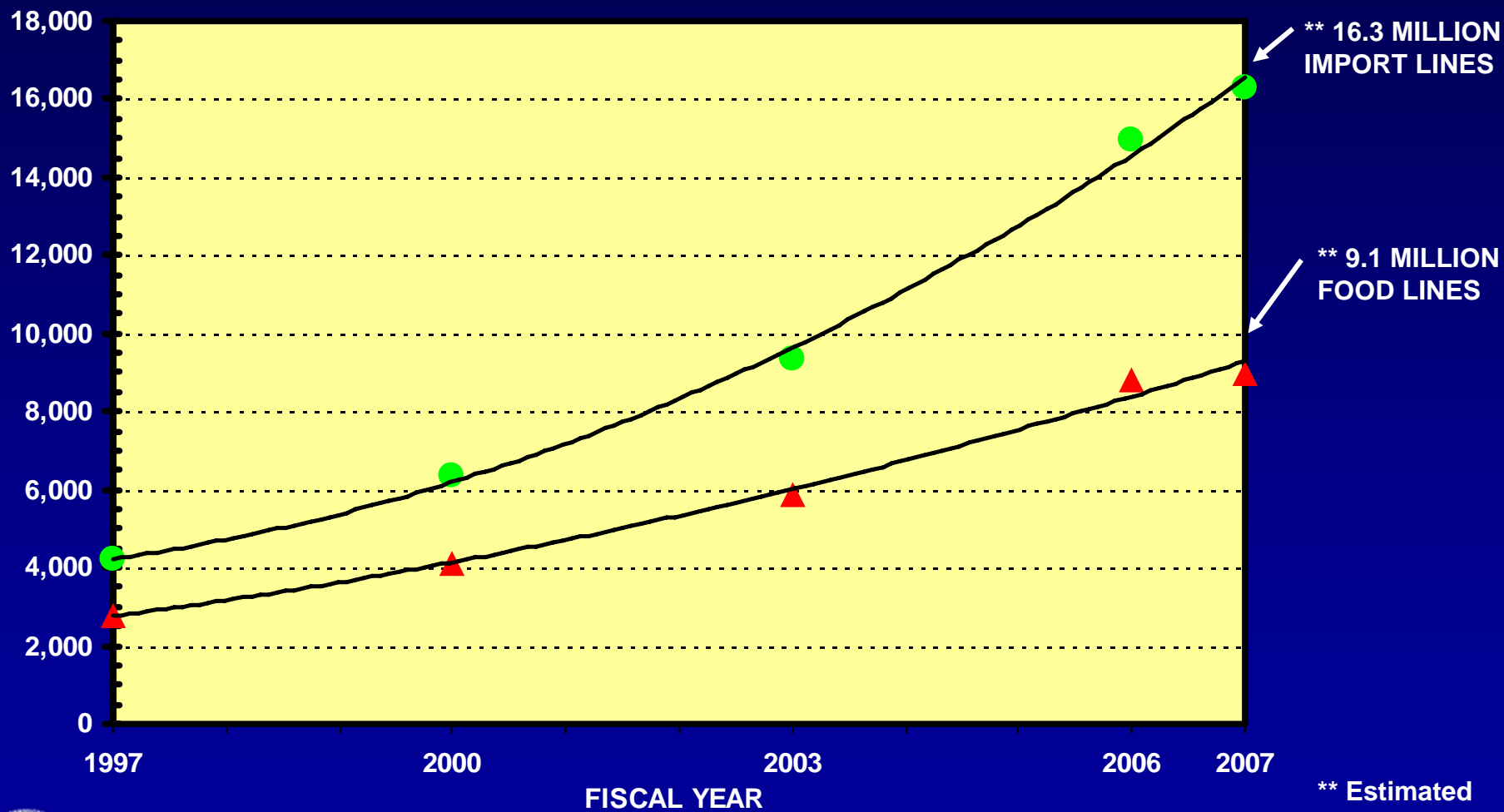
Changes and Challenges

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



** Estimated



Changes and Challenges

- Increasing numbers of high risk individuals
 - Elderly
 - Immune compromised
- New foodborne pathogens being discovered
- Bioterrorism

Changes and Challenges

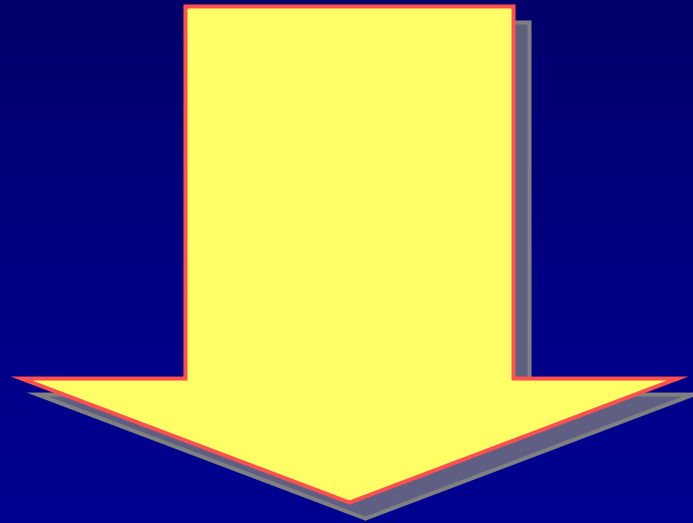
Communication

- Outdated FDA data handling capacity.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

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



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
- Approach
 - 38 FDA Administrative Actions
 - 10 Legislative Proposals



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
- Registration Renewal Every Two Years and Modification of Registration Categories
 - 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
 - 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
- **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



Next Steps

- Develop an implementation plan
- Initiate 2008 deliverables
 - Meet with stakeholders
 - Work with Congress on legislative proposals
- Degree of progress is resource dependent
- Integrate with China MOA and Import Safety Action Plan

Recognize that this is a long term activity



Summary

- Changes in the food supply necessitate a new approach to food protection
- Food Protection Plan is integrated with greater emphasis on Prevention, plus effective Intervention and rapid Response
- Coordination of various food-related activities within FDA
- Partnerships are critical to overall success



Questions?
