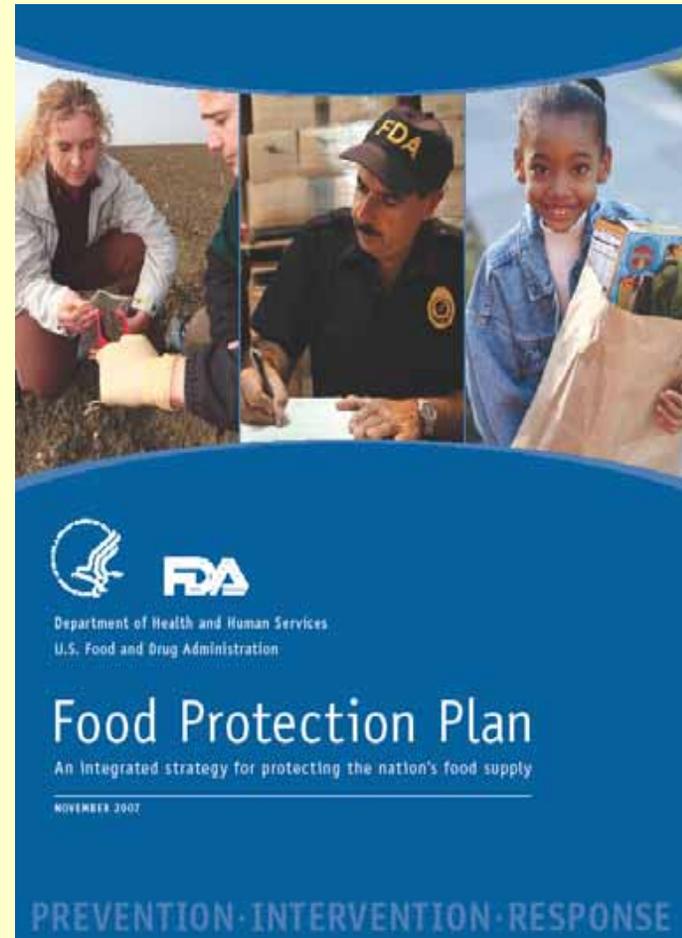


U.S. Food and Drug Administration

Food Protection Plan

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Foods



Outline

- Why the need for a Food Protection Plan?
 - Changes that need to be addressed regarding imported foods
 - Shift from “port of entry” to “production life cycle” approach
- Food Protection Plan
 - Major elements
 - Legislative proposals



FDA's Role

- Responsible for protecting about 80% of the food supply
 - All foods except meat, poultry and egg products
 - Includes food for humans and animals
- Dietary supplements
- Bottled water



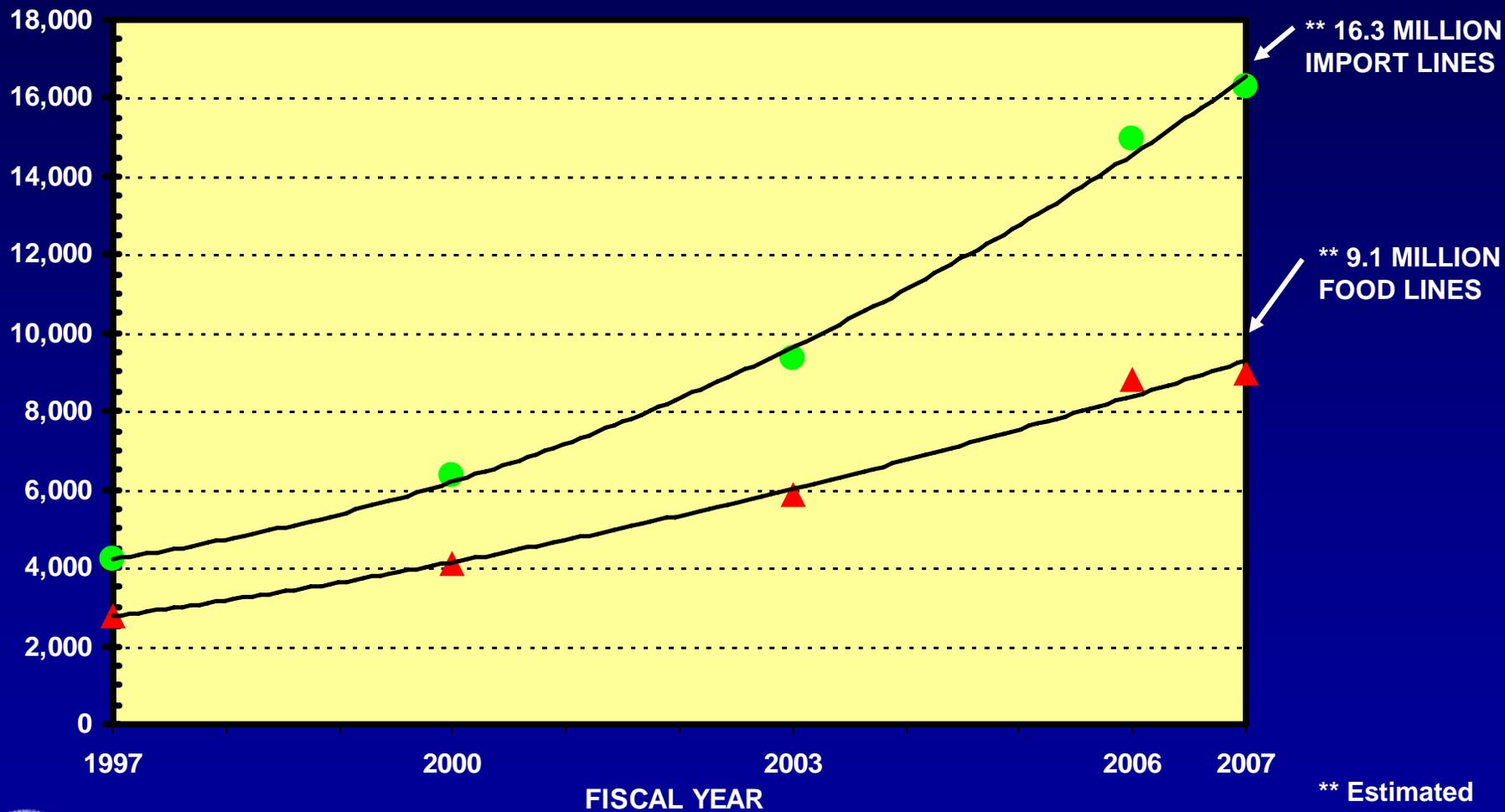
Changes and Challenges

Trends in Consumption

- Consumer demand for items 24/7, year round
- Increasing global food supply
 - Approximately 15% of FDA regulated food is now imported

Changes and Challenges

Global Food Supply



** Estimated

● IMPORT LINES (000)

▲ FOOD LINES (000)

— Poly. (IMPORT LINES (000))

— Poly. (FOOD LINES (000))



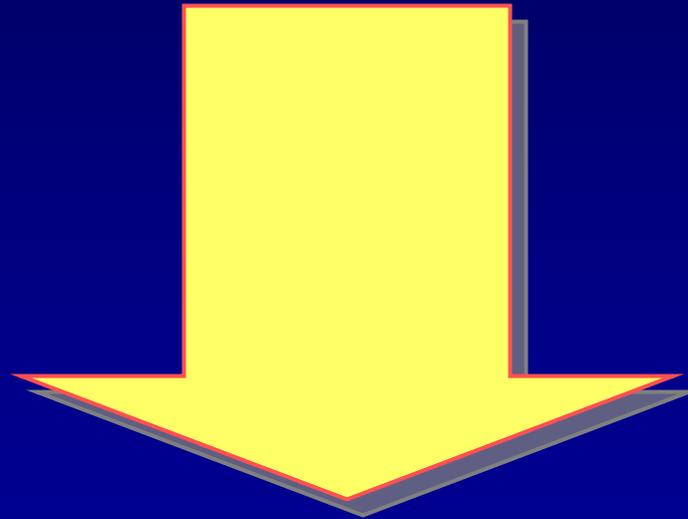
Import Universe

- Import from over 150 countries
- Import through over 300 ports
- Approx 200,000 foreign firms registered with FDA for imports
- Importers have to
 - Be registered
 - Submit prior notice



Time for a New Approach

Reactive



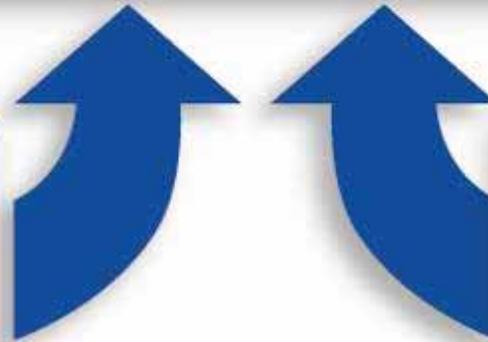
Proactive

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**

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 (e.g. traceability)
- 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



Action Plan for Import Safety

- Executive Order 13439 – July 2007
- Involvement of 12 Federal Departments and Agencies - Led by HHS Secretary Leavitt
- Strategic Framework – September 2007
 - Risk-Based, Life Cycle Approach
 - Organizing Principles
 - Prevention (with Verification)
 - Intervention
 - Response
- Action Plan – November 2007
 - 14 Broad Recommendations
 - 50 Specific Action Steps
 - Short and Long Term



Current Major Focus For Imports

- Outreach
 - States and locals - St. Louis meeting
 - Foreign governments
 - Industry
- Establishing an updated Risk Based Approach
 - PREDICT
- Voluntary certification programs for imports
 - Shrimp pilot to determine feasibility
- FDA beyond our borders
 - Shift from “port of entry” to “production life cycle” approach
 - FDA presence in various parts of the world
- Legislative proposals



FDA – Beyond our Borders

■ China

- MOA signed December 2007
- Establish an office in 2008 (9 FTEs)

■ India

- Establish an office (11 FTEs)

■ South/Central America

- Development of an MOU
- Establish a presence (7 FTEs)

■ Europe

- Presence planned (3 FTEs)

■ Middle East

- Presence planned (3 FTEs)



Summary

- Changes in the food supply necessitate a new approach to food protection
- Food Protection Plan is an integrated approach with greater emphasis on Prevention, plus effective Intervention and rapid Response
- Need for changed approach for imports

Questions?
