



U.S. Import Safety Action Plan: An FDA Perspective

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Overview

- Challenges
- Import Safety Action Plan
- Conclusion



Challenges Facing FDA

- Globalization
 - Increased demand for foreign products
 - More foreign facilities/sites supplying U.S.
- Product Complexity
 - Advanced products and processes
- Counterterrorism Responsibilities
- Emerging Pathogens
- Aging Population
- Information Technology
 - Integration challenges
- Resources

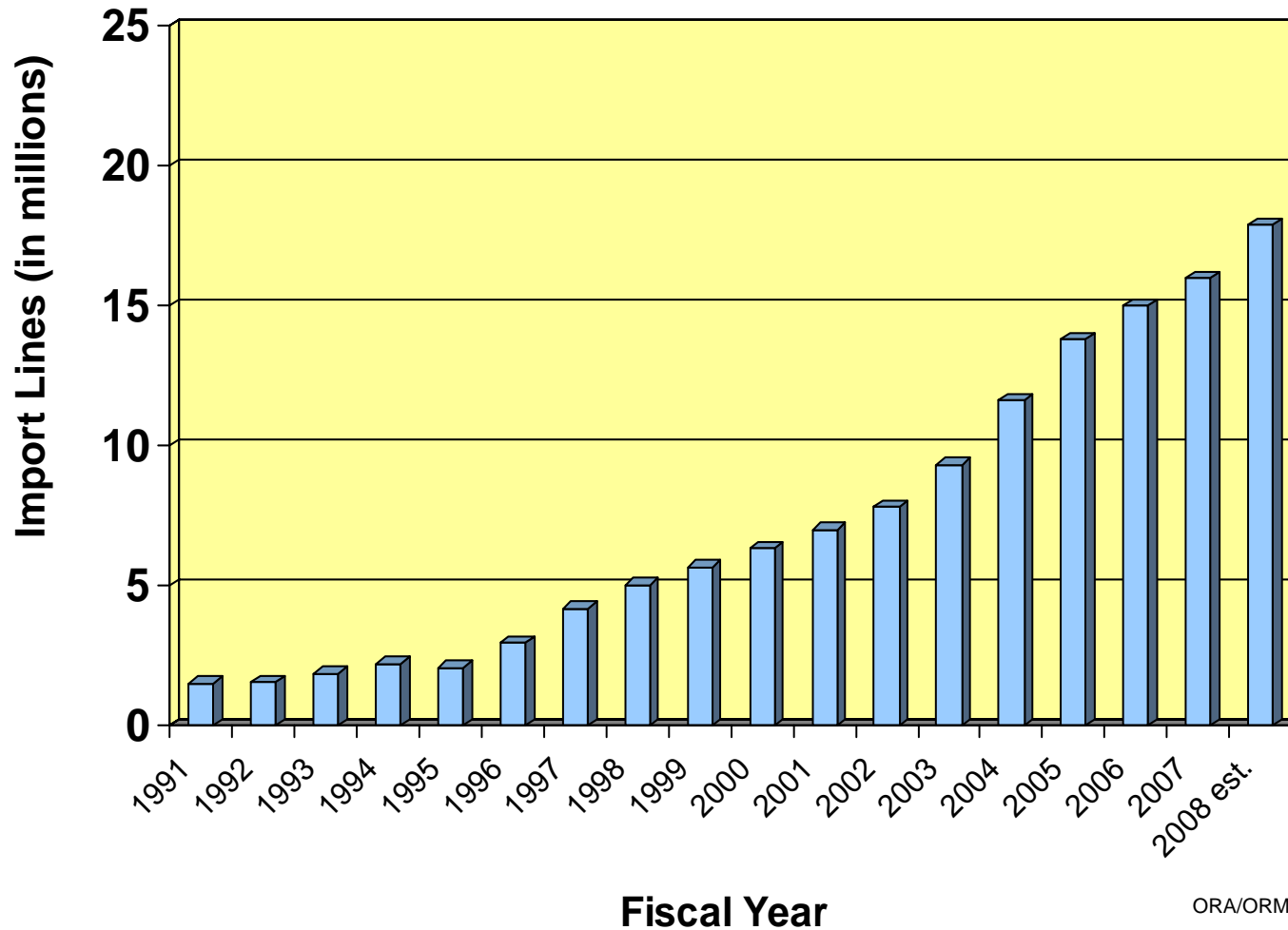


Import Volume History

14.98M Lines Actual for FY2006

16M Lines Actual for FY2007

17.9M Lines Estimated for FY2008



Size of International Market

- >150 countries exporting FDA regulated goods
- >130,000 importers of record
- >300,000 foreign manufacturers



Import Safety Action Plan

- 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/Keystones
 - Prevention (with Verification)
 - Intervention
 - Response
- Action Plan – November 2007
 - 14 Broad Recommendations
 - 50 Specific Action Steps
 - Short and Long Term

Organizing Principles/Keystones

- **Prevention—Prevent harm in the first place**
 - Safety must be built into manufacturing and distribution processes every step of the way
 - Federal government will need to work with the import community to better identify vulnerabilities and determine effective controls
- **Intervention—Intervene when risks are identified**
 - Federal, State, Local and Other governments, along with the importing community, must adopt more effective techniques for identifying potential import hazards
- **Response—Respond rapidly after harm has occurred**
 - Act swiftly to limit potential exposure and harm if an unsafe imported product enters domestic commerce
 - Need robust, collaborative system of response

Prevention with Verification

– Recommendations

- Safety Standards
 - #1--Create New and Strengthen Existing Safety Standards
- Certification
 - #2—Verify Compliance of Foreign Producers with U.S. Safety and Security Standards Through Certification
- Good Importer Practices
 - #3—Promote Good Importer Practices
- Penalties
 - #4—Strengthen Penalties and Take Strong Enforcement Actions to Ensure Accountability
- Foreign Collaboration and Capacity Building
 - #5—Make Product Safety an Important Principle of our Diplomatic Relationships with Foreign Countries and Increase the Profile of Relevant Foreign Assistance Activities

Intervention

– Recommendations

- Common Mission
 - #6—Harmonize Federal Government Procedures and Requirements for Processing Import Shipments
- Interoperability
 - #7—Complete a Single Window Interface for the Intra-agency, Interagency, and Private Sector Exchange of Import Data
- Information Gathering
 - #8—Create an Interactive Import Safety Information Network
- New Science
 - #9—Expand Laboratory Capacity and Develop Rapid Test Methods for Swift Identification of Hazards
- Intellectual Property Protection
 - #10—Strengthen Protection of Intellectual Property Rights (IPR) to Enhance Consumer Safety



Response

– Recommendations

- Recall

- #11—Maximize the Effectiveness of Product Recalls

- Federal-State Rapid Response

- #12—Maximize Federal- State Collaboration

- Technology

- #13—Expedite Consumer Notification of Product Recalls

- #14—Expand the Use of Electronic Trace-and-Trace Technologies

Conclusion

- Full administration support for this plan
- Greater coordination and collaboration among governments, agencies, and private sector is critical
 - Moving toward harmonization of standards, processes, and procedures
 - Leveraging current programs
 - Information technology
- Significant opportunity to improve the safety of imported products