



U.S. Food and Drug Administration
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Supply Chain Safety: FDA Perspective on the Future State

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Challenges Presented by Globalization

- More foreign facilities supplying the U.S.
- Increasing volume of imported products
- More outsourcing of manufacturing
- Greater complexity in supply chains
- Imports coming from countries with less well developed regulatory systems
- Greater opportunities for economic fraud

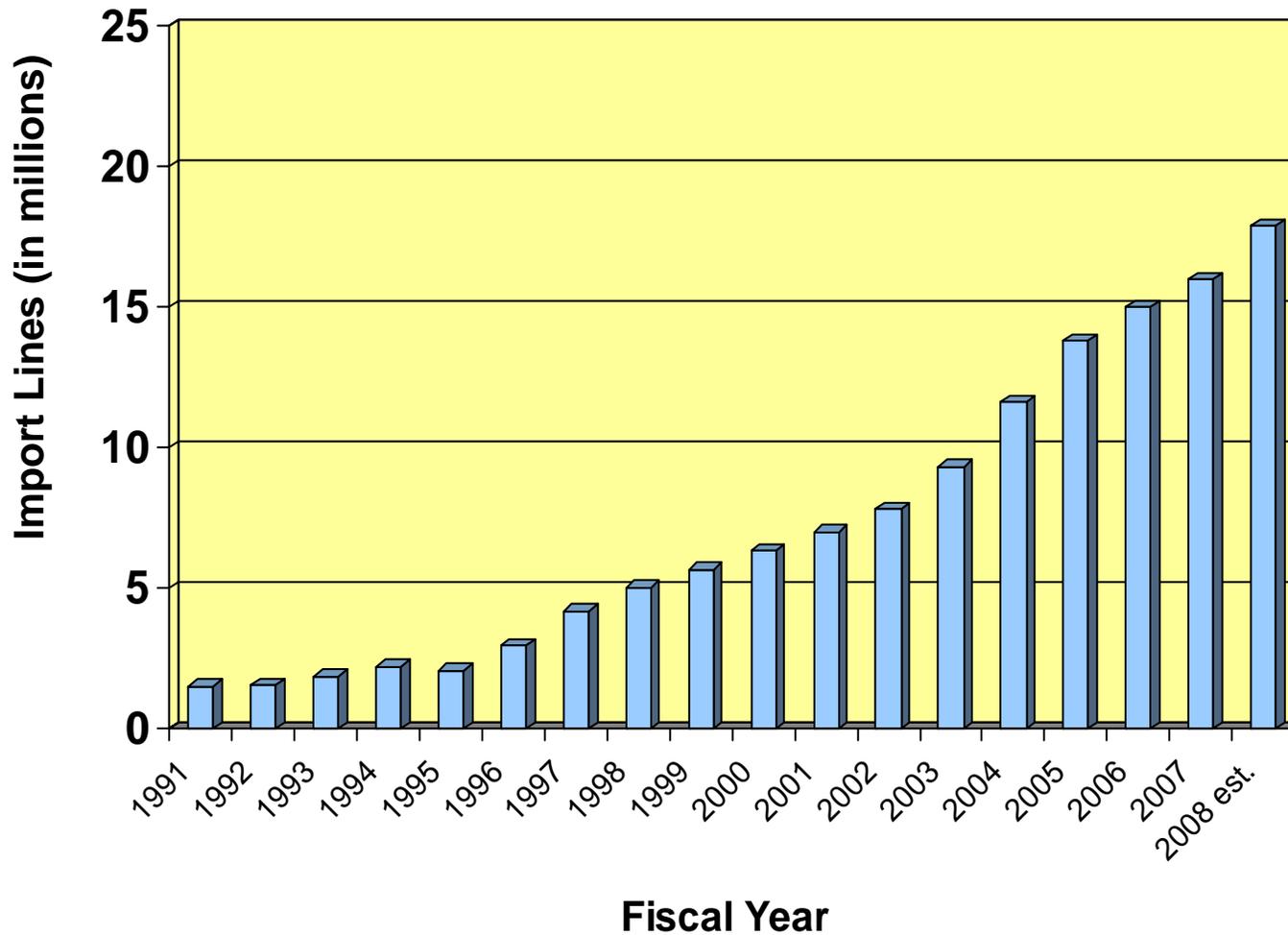


Import Volume History

14.98M Lines Actual for FY2006

16M Lines Actual for FY2007

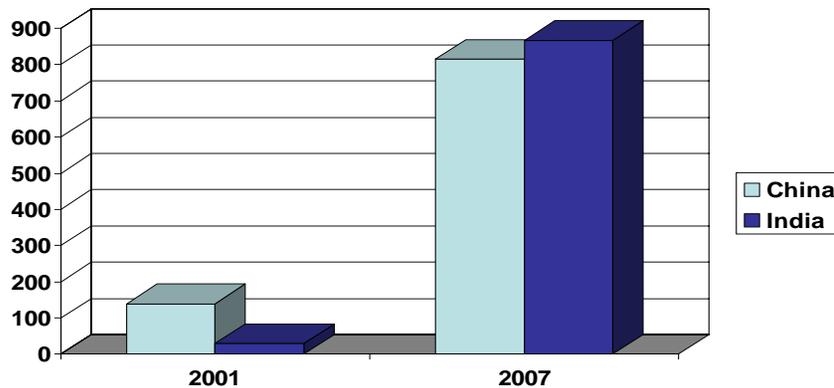
17.9M Lines Estimated for FY2008





Drugs from China and India

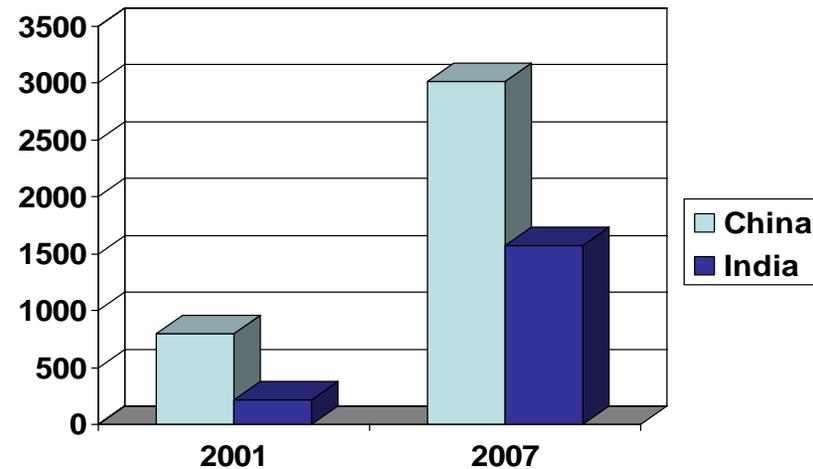
Listed Number of Drug Manufacturers



China: 7x increase

India: 25x increase

Different Types of Imported Drug Items



China: 4x increase

India: 7x increase



Size of International Market

- >150 countries exporting FDA-regulated goods
- >55,000 importers of record
- >300,000 non-U.S. facilities



Conclusion: The existing U.S. supply chain safety system for FDA-regulated products is not adequate to meet the growing challenges presented by globalization



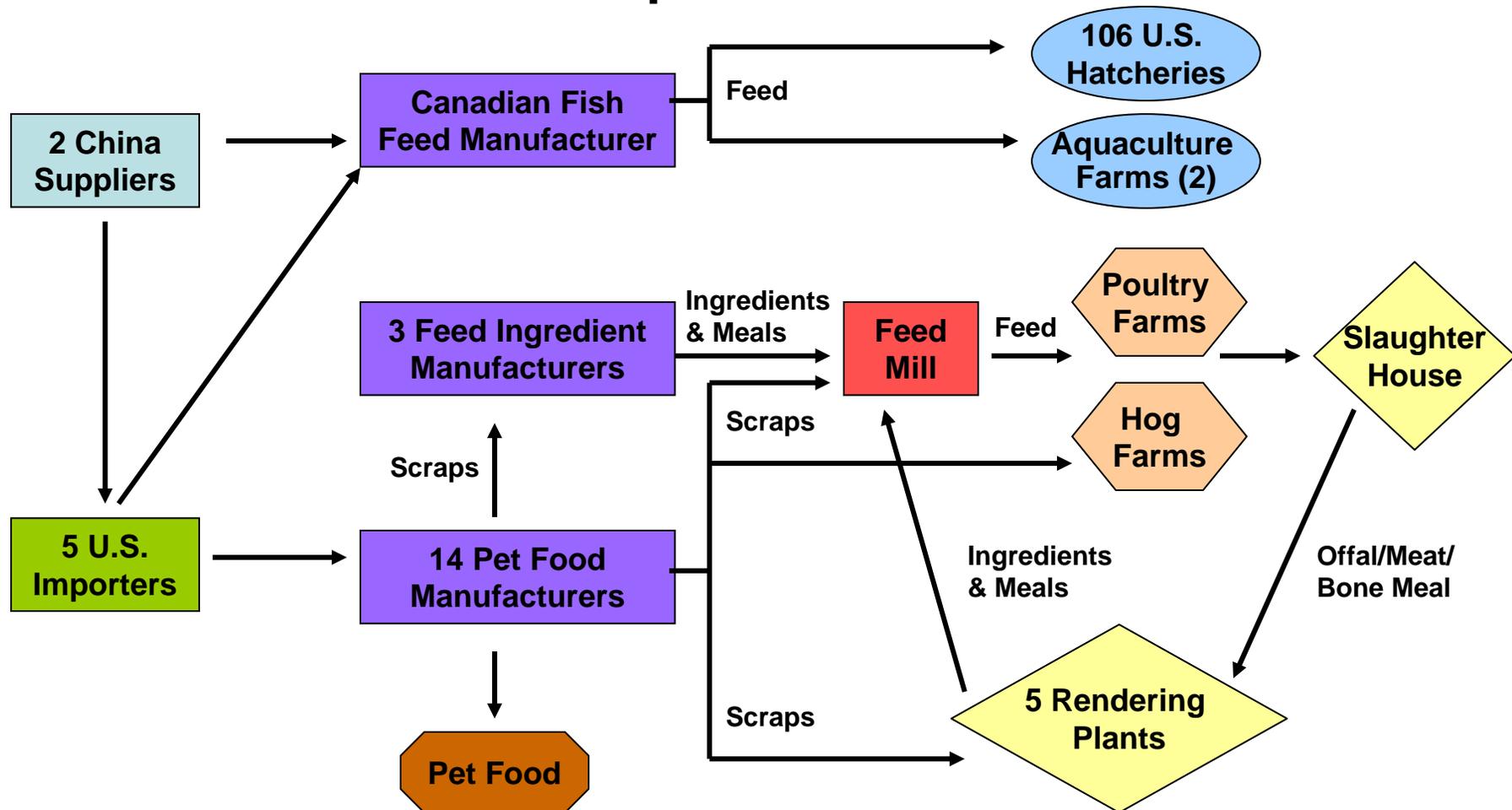
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Melamine: Britney Spears Redux

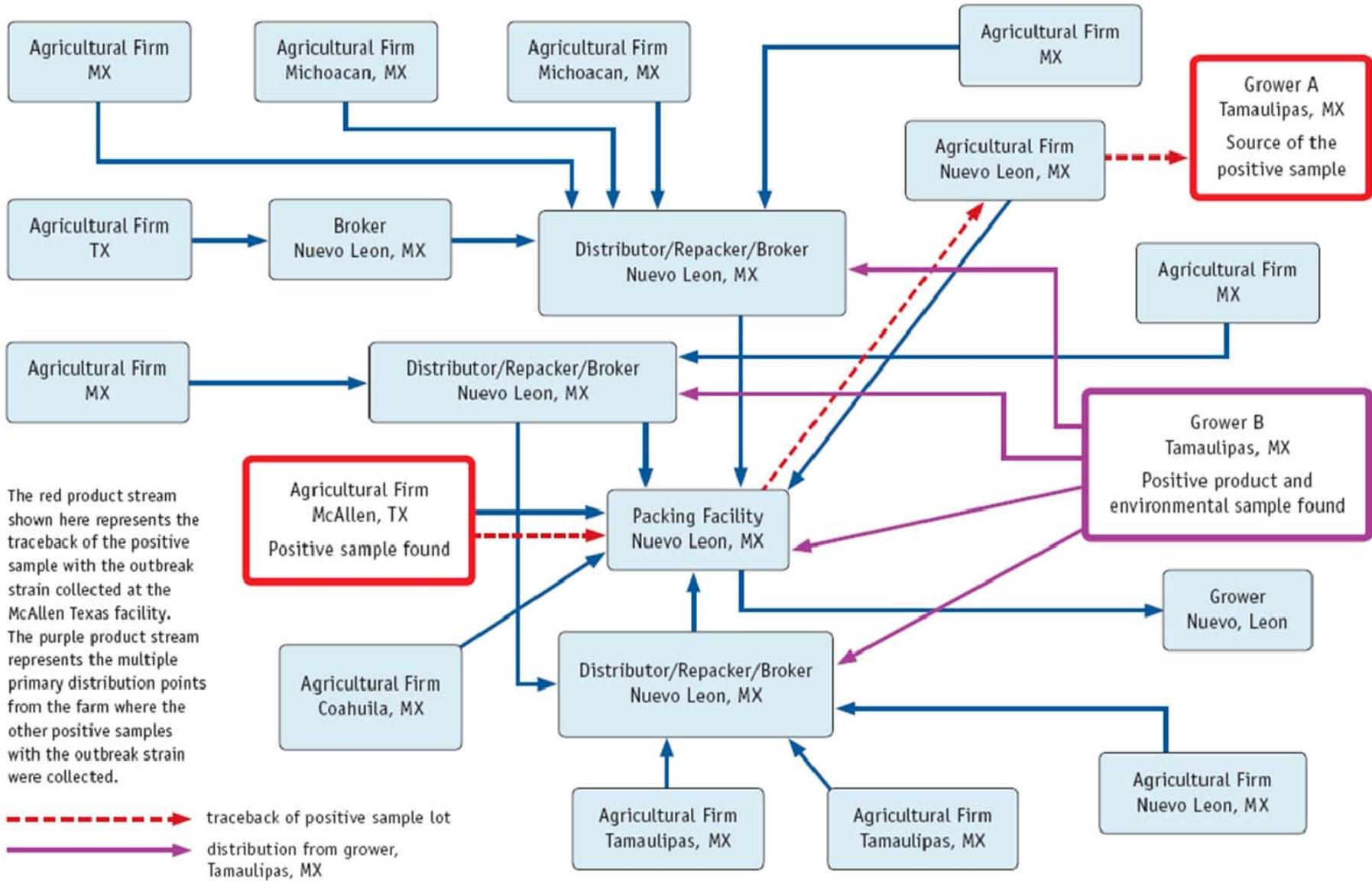


Contaminated Pet Food/Animal Feed Incident – 2007 Sequence of Events



Salmonella Saintpaul Outbreak Traceback & Distribution

Partial view of the traceback & distribution of peppers from Mexico: July 16 – July 30, 2008





Diethylene Glycol

- Incidents from medications contaminated with DEG
 - U.S. – mid-1930s – 107 deaths
 - Bangladesh – 1990 – over 300 children with kidney failure
 - Haiti – 1996 – 85 deaths in children
 - India – 1998 – 33 deaths in children
 - Panama – 2006 – 115 deaths



Heparin

- Contaminated with Over-Sulfated Chondroitin Sulfate (OSCS)
- Similar effect to heparin for blood thinning
- Previously studied as a potential alternative to heparin
- Over 60 reports of death associated with use of contaminated heparin in U.S.
- Additional reports of adverse events related to contaminated heparin overseas in Germany and Japan
- Subsequent identification of 11 countries with contaminated heparin

2/16

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Where a Drug Begins

More than half the world's heparin, the main ingredient in a widely used anti-clotting medicine, gets its start in China's poorly regulated supply chain. ([See related article.](#))

The men wring pulp from pig intestines and heat it in open cement vats. After further processing by more sophisticated plants, the chemical is made into intravenous drugs given to patients around the world having surgery or patients who need kidney dialysis or blood transfusions.

Gordon Fairclough

4/16

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Where a Drug Begins

More than half the world's heparin, the main ingredient in a widely used anti-clotting medicine, gets its start in China's poorly regulated supply chain. ([See related article.](#))

Workers use a machine to wring the pulp from the inside of the intestines.

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Where a Drug Begins

More than half the world's heparin, the main ingredient in a widely used anti-clotting medicine, gets its start in China's poorly regulated supply chain. [\(See related article.\)](#)

Since mid-2006, China's pig herds have suffered serious outbreaks of porcine reproductive and respiratory syndrome. In theory, sick animals are supposed to be rejected, but in practice, enforcement can sometimes be lax.

Gordon Fairclough

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Where a Drug Begins

More than half the world's heparin, the main ingredient in a widely used anti-clotting medicine, gets its start in China's poorly regulated supply chain. ([See related article.](#))

Yet there is so much demand that heparin traders are recruiting people to make the chemical. A company offering training programs for farmers advertised that annual profit could reach \$20,000 – a fortune in rural China.

Gordon Fairclough



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Recent Cases: Lessons Learned

Economic incentives and/or lax
regulatory oversight promote risky
or criminal behavior



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, Science-Led, 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



Import Safety Action Plan

- **Standards:** Promote international standards development and harmonization
- **Corporate Responsibility:** Greater supply chain accountability
 - Trust “good actors” but verify compliance
 - Impose stiff penalties on “bad actors”
- **Global Partnerships:** Push out the border



Import Safety Action Plan

- **Connectivity:** Transform ports-of-entry into integrated checkpoints using automated data collection and analysis across the product life cycle
- **Vertical Integration:** Greater coordination and collaboration between federal agencies and with the states, the private sector and the public
- **Modern Science:** Develop new tests, expand laboratory capacity, and harness new technologies



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FDA Implementation of ISAP



Supply Chain Safety Objectives

- Safety + Speed
 - Build in safety and quality from the start
 - Stop unsafe and/or poor quality products from reaching consumers
 - Facilitate the distribution of safe, high quality products
- In an appropriately regulated system, each failure is novel



One Size Does Not Fit All

- Role
 - Manufacturers – ingredient, finished product
 - Distributors
 - Importers
 - Retailers
- Behavior
 - Good intentions
 - Risky
 - Criminal



Caveats

- It will take new resources
- It will take modern science
- It will take an expanded toolkit



Paradigm Shift: Government

- Greater Reliance on Trusted Government Authorities
 - FDA Foreign Presence and Foreign Inspectorate
 - Joint Third-Party Inspections
 - Pilot Multi-Purpose Audit Program
 - Work and Information Sharing
 - EMEA-FDA-Australia API Pilot
 - Swissmedic Pilot
 - Vertical Integration with States



Paradigm Shift: Government

- Strengthened Risk-Based Decision-making
 - Information Collection
 - Supply chain transparency, including unique facility identifiers
 - Partnerships
 - Risk Analysis and Risk Modeling
 - Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT)
 - IT Systems
 - Harmonized Inventory
 - Mission Accomplishment and Regulatory Compliance Services (MARCS)
 - Automated Commercial Environment / International Trade Data System (ACE/ITDS)



Paradigm Shift: Industry

- **Manufacturers**
 - Preventive controls/quality systems
 - Know your business partners
 - Qualify/Audit your suppliers
 - Understand your product's risks and vulnerabilities in the supply chain
 - Look for red flags
 - Product tracing
 - Modern science
- **Importers**
 - Good Importer Practices



Paradigm Shift: Government and Industry

- Proactive Demonstration of Compliance = Facilitated Product Distribution
 - Third-Party Certification
 - Third-Party Certification Programs for Foods and Feeds Draft Guidance
 - Aquacultured Shrimp Pilot
 - Drug Excipients



Resources

- <http://www.importsafety.gov>
- <http://www.fda.gov/oc/initiatives/advance/imports>