



# Assuring Safety of Imported Foods: Public and Private Roles in a Risk-Based System

# Food Safety Legislation

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## CSPI and Development of Food Safety Reform

- The Center for Science in the Public Interest (CSPI) was founded in 1971 to represent consumers in the policy setting process
- Working on food safety reforms and to enhance public protection against contaminated food since 1990s



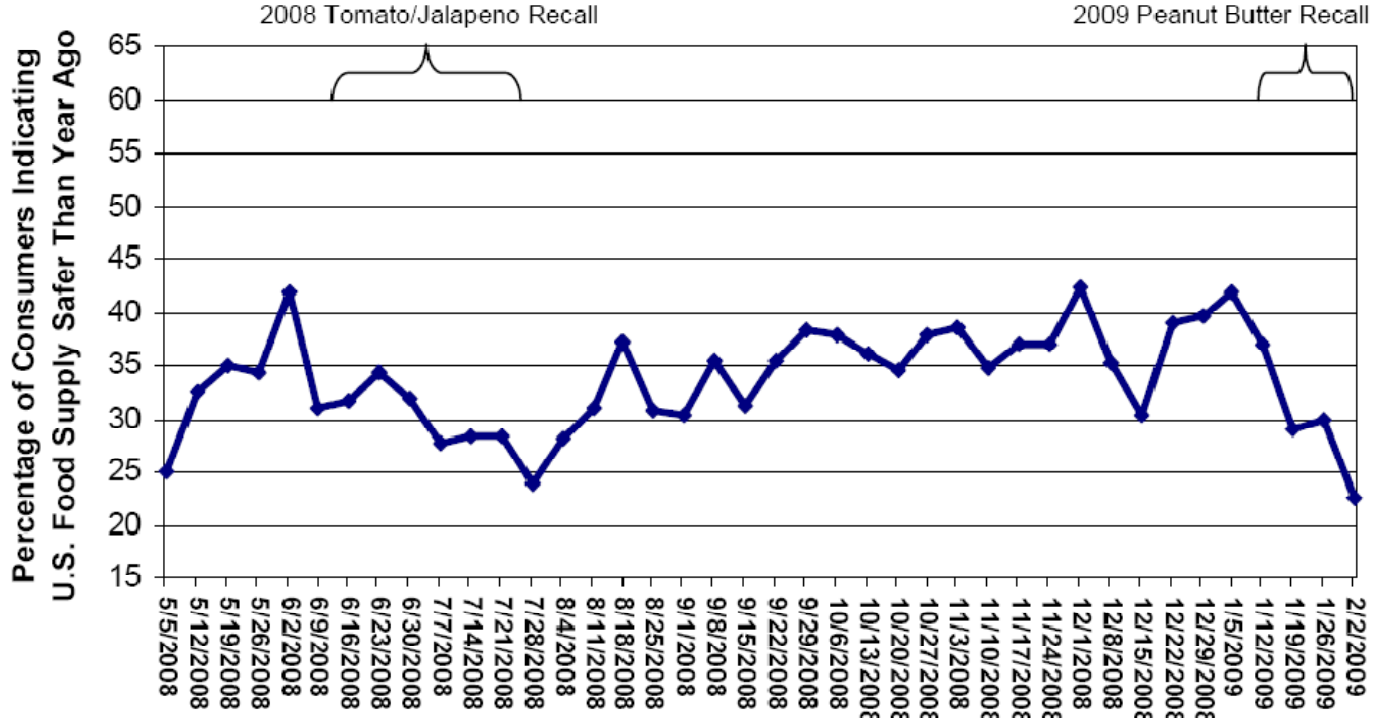


## Background Behind Development of Food Safety System Reform

- 76 million foodborne illnesses, 325,000 hospitalizations and 5,000 deaths annually
- FDA and USDA food safety systems operating under outdated laws
- Series of high profile outbreaks erode public confidence in food safety system



# Consumer Confidence Tracking



Source: University of Minnesota Food Industry Center; Louisiana State University AgCenter



## Imported Food

- More than 10 million line items enter each year
- Imported food = 13% of average American's diet
- FDA rarely inspects foreign plants (96 in 2007)
- Only 1.28% of imported food is inspected at border
- Consumers have less confidence imported food is safe
  - 8 out of 10 respondents to 2008 poll believed most food safety concerns are related to imported food

Ipsos/McClatchy poll 2008



## How Imports are Regulated Today

- Food Safety Inspection Service (USDA)
  - USDA must approve every country that wants to import meat to the U.S.
  - Regular country audits include USDA visits to plants approved for export to the U.S.
  - As much as 15% of meat may be inspected at the border
  - Up to 10% of that subject to microbiological testing
- Food and Drug Administration (HHS)
  - Does not have authority to inspect in importing countries or plants
  - Inspects 1% of imported food at the border



## Efforts on Federal Legislation



- In 1990's and 2000's, CSPI worked as an advisor to Congress during development of groundwork food safety reform bills "Consumer Food Safety Act" and "Safe Food Act."
- By 2007, there was strong consensus on need for reform for FDA especially by government (FDA's Food Protection Plan), industry (GMA's Four Pillars) and consumer associations (CSPI's White Paper)



## Three Key Sources that Influenced Reform Legislation

### FDA Food Protection Plan

- Bioterrorism Controls
- High-risk HACCP
- Biennial Registration\*
- 3<sup>rd</sup> Party Inspections
- Re-inspection/Export Fees\*\*\*
- Import Certificates\*
- Access for Inspection\*\*\*
- Mandatory Recall\*\*\*
- Record Access for Related Food Lines\*

### CSPI White Paper

- Process Controls\*\*\*
- Performance Standards\*\*\*
- Inspections\*\*\*
- Import Certification\*\*\*
- Research & Education\*\*
- On Farm Standards\*\*\*
- Enforcement
  - Mandatory Recall\*\*\*
  - Traceability\*\*
  - Administrative Detention\*\*\*
  - Civil Penalties\*\*
  - Whistleblower Protection\*\*\*

### GMA Four Pillars (for imports only)

- Foreign Supplier Quality Assurance\*
- Voluntary Qualified Importer Program\*
- Capacity Building\*
- Increase Resources
  - Targeted Inspections (Including Foreign)\*\*
  - Real-time Test Results
  - Enhanced Crisis Communication

#### KEY

- \* = Provision included in Senate Bill
- \*\* = Provision included in House Bill
- \*\*\* = Provision appears in Both Bills



## Broad Support Marks Two Major Bills Pending in 111<sup>th</sup> Congress

- H.R. 2749, Food Safety Enhancement Act
  - Negotiated through bipartisan discussions
  - Passed House July 30, 2009, with a bipartisan vote of 283-142
- S. 510, FDA Food Safety Modernization Act
  - Introduced by bipartisan co-sponsors
  - Approved by Senate HELP November 18, 2009
  - Awaiting final Senate approval



## Similarities between House and Senate Bills

- Structurally H.R. 2749 and S. 510 are similar
  - Registration
  - Written process control plans (HACCP)
  - Performance standards
  - Risk-based inspections
  - Traceability
  - High-risk imported food can be independently certified as complying with U.S. law
  - Mandatory recall of food likely to cause serious illness or death



## Process Control Requirements and Performance Standards are Foundation

- Apply to both domestic and foreign facilities
- Processors must analyze hazards and implement food safety plans
- Processors must meet FDA-defined performance standards
  - FDA to review data and establish performance standards for significant contaminants every 2 years
  - FDA can recommend sampling programs to demonstrate compliance and require reporting of data (House)



## Import provisions provide new structure for FDA imports

- Effort to institute necessary controls without unduly limiting foreign trade
- Recognition that FDA can't inspect and approve every food plant that ships product to the U.S.
- Dissimilar to import program utilized by the USDA for meat and poultry products where prior approval of foreign government program is required before any imports will be accepted

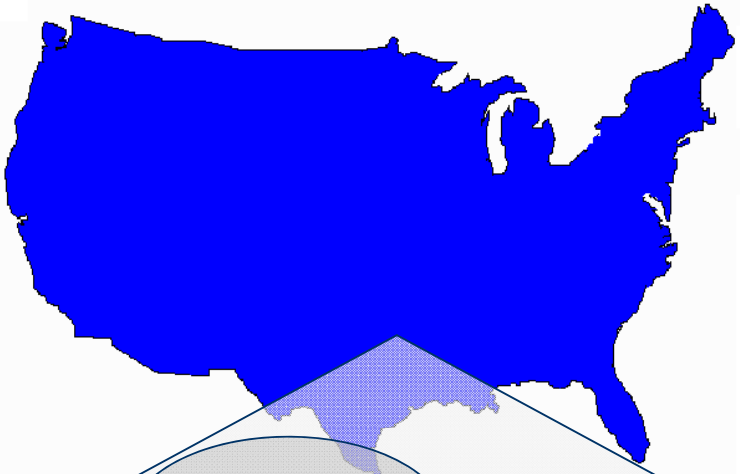


## Imports Controls, Including Certification

- Extending FDA's Reach Beyond U.S. Borders, through
  - Accreditation of foreign inspection authorities
  - Certification that foreign food meets U.S. standards
    - Uses “Trusted Partners” to certify imports, such as foreign national governments or third-party certifying agents.
  - Importer accountable for assuring safety
    - Utilizes importers to monitor foreign compliance (Good Importer Practices or Foreign Supplier Verification Program)
  - Inspection authority with power to refuse entry



# H.R. 2749 Import Program

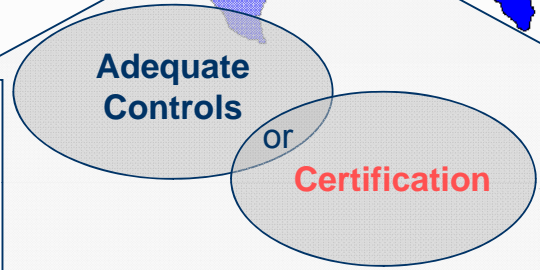


## FDA's Role

- Write regulations and guidance for Good Importer Practices
- Establish Safe and Secure Food Importation Program
- Conduct risk determination for high risk foods/countries
- Establish program for accrediting certifying entities
- Conduct risk-based inspections of foreign facilities

## Importer's Role

- Follow Good Importer Practices
- May request to participate in Safe and Secure Food Importation Program
- Pay \$500 registration fee



**Exporting Facility**

- Register with FDA annually
- Pay \$500 per facility fee
- Have a U.S. agent

Mandatory  
Designated High-risk products or countries

Voluntary  
A consideration in Safe and Secure Food Importation Program



## Inspection Mandate Covers Foreign and Domestic Facilities

- Mandatory inspection frequencies range from 6 months to every 5 years
- Dedicated foreign inspectorate created at FDA (House)
- Risk-based border inspection program (Senate)
- Five offices established in foreign countries by Oct. 1, 2010 (Senate)



## Third-Party Systems to Verify Compliance/Safety

- FDA can require certification that certain products comply with U.S. standards
  - high-risk imports
  - imports from high-risk countries
- Importers must follow assurance program (Good Importer Practices, House or Foreign Supplier Verification Program, Senate)



## Provisions for recognizing foreign governments

- FDA can establish process for demonstrating foreign government controls are adequate (no certification necessary if government controls are sufficient) (House)
- FDA can conduct audits to determine if foreign country's system meets or exceeds U.S. system's level of safety (Senate)

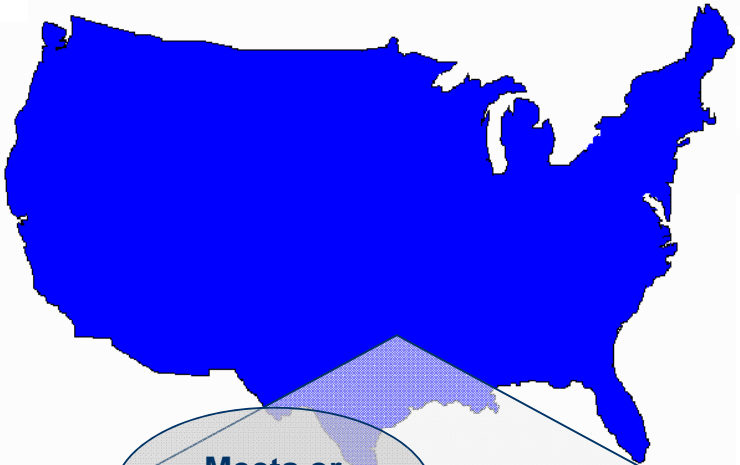


## Special Provisions: Produce and Traceability

- FDA sets scientific and risk-based safety standards for high-risk raw agricultural commodities
  - Covers fruits, vegetables, nuts or fungi (House)
  - Covers fruits and vegetables (Senate)
- Imported food must comply with traceability requirements when adopted for domestic products (Country-of- Origin labeling already required)



# S. 510 Import Program



## FDA's Role

Write regulations and guidance for Foreign Supplier Verification Program

List participating importers

Establish Voluntary Qualified Importer Program

Conduct risk determination for high risk foods/countries

Establish accreditation program for certifying agents

Conduct risk-based inspections of foreign facilities and at border

## Importer's Role

Have Foreign Supplier Verification Program

May request to participate in Voluntary Qualified Importer Program

Meets or Exceeds US Safety

Certification

## Exporting Facility

Register with FDA biennially  
Agree to permit inspection  
Have a U.S. agent

Mandatory  
Designated  
High-risk products or countries

Voluntary  
Voluntary Qualified  
Importer Program



## Questions?

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