

# Weaknesses in the U.S. Food Safety System

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# Weaknesses in U.S. Food Safety System

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- Surveillance
  - Inspections
  - Imported Food Inspection/Testing
  - 3rd Party Audits
  - Differences among companies in commitment to food safety
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# Surveillance

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- PulseNet is the principal food safety surveillance system for detecting foodborne outbreaks
  - State health departments identify cases of foodborne illness and isolate and molecular subtype (PFGE) pathogens (e.g., *Salmonella*, *E. coli* O157, *Listeria monocytogenes*) and send results to CDC
  - CDC accumulates and analyzes data
    - ▲ Monitors about 30 outbreaks daily
    - ▲ Reports more than 1200 outbreaks annually
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# Surveillance

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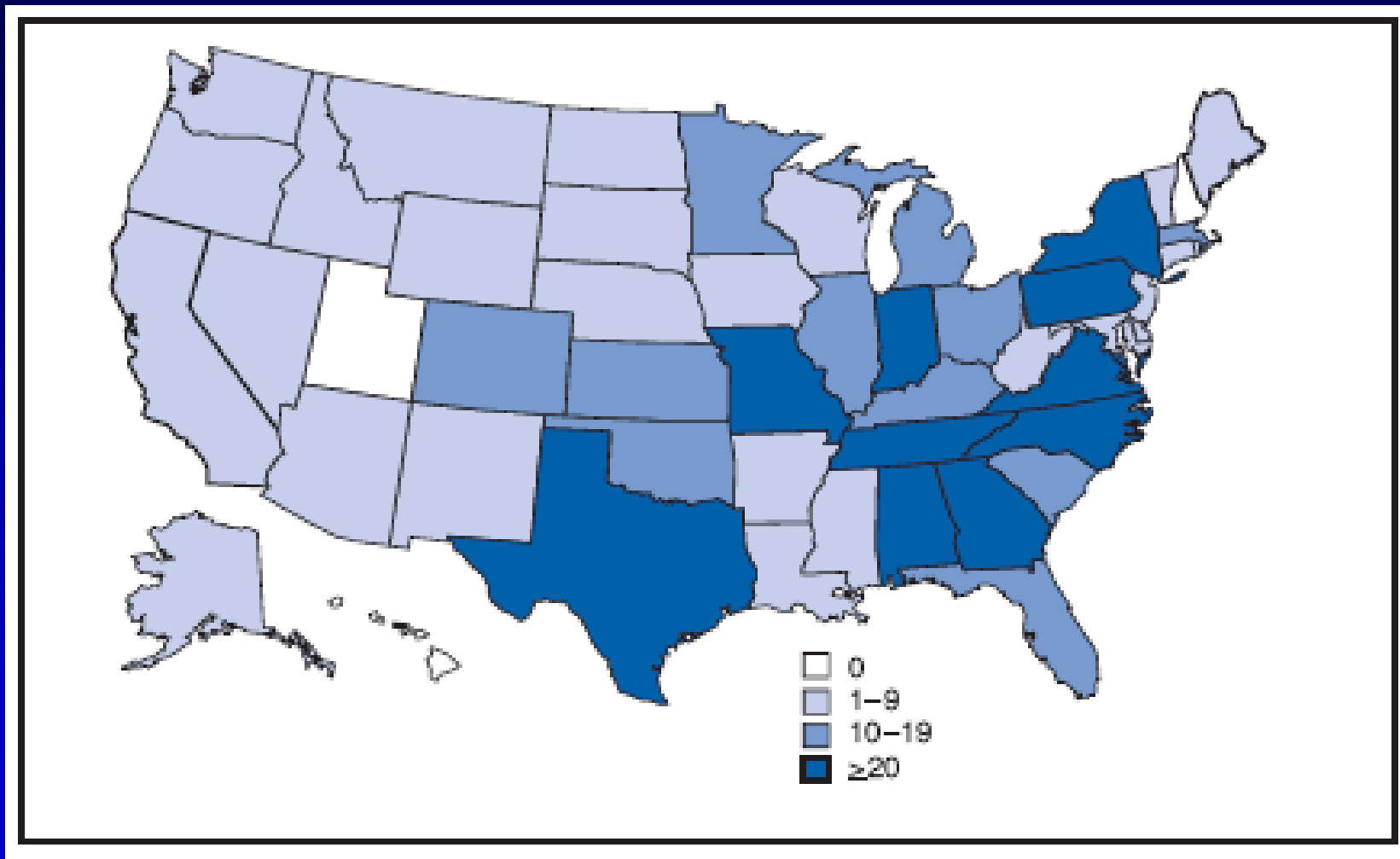
- Food source is not identified for most (> 50%) outbreaks
  - Many states are not equally committed (limited resources) to participating in PulseNet
    - ▲ Examples, Florida, Mississippi, Louisiana, South Carolina
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# ***Salmonella* Tennessee Outbreak Associated with Peanut Butter**

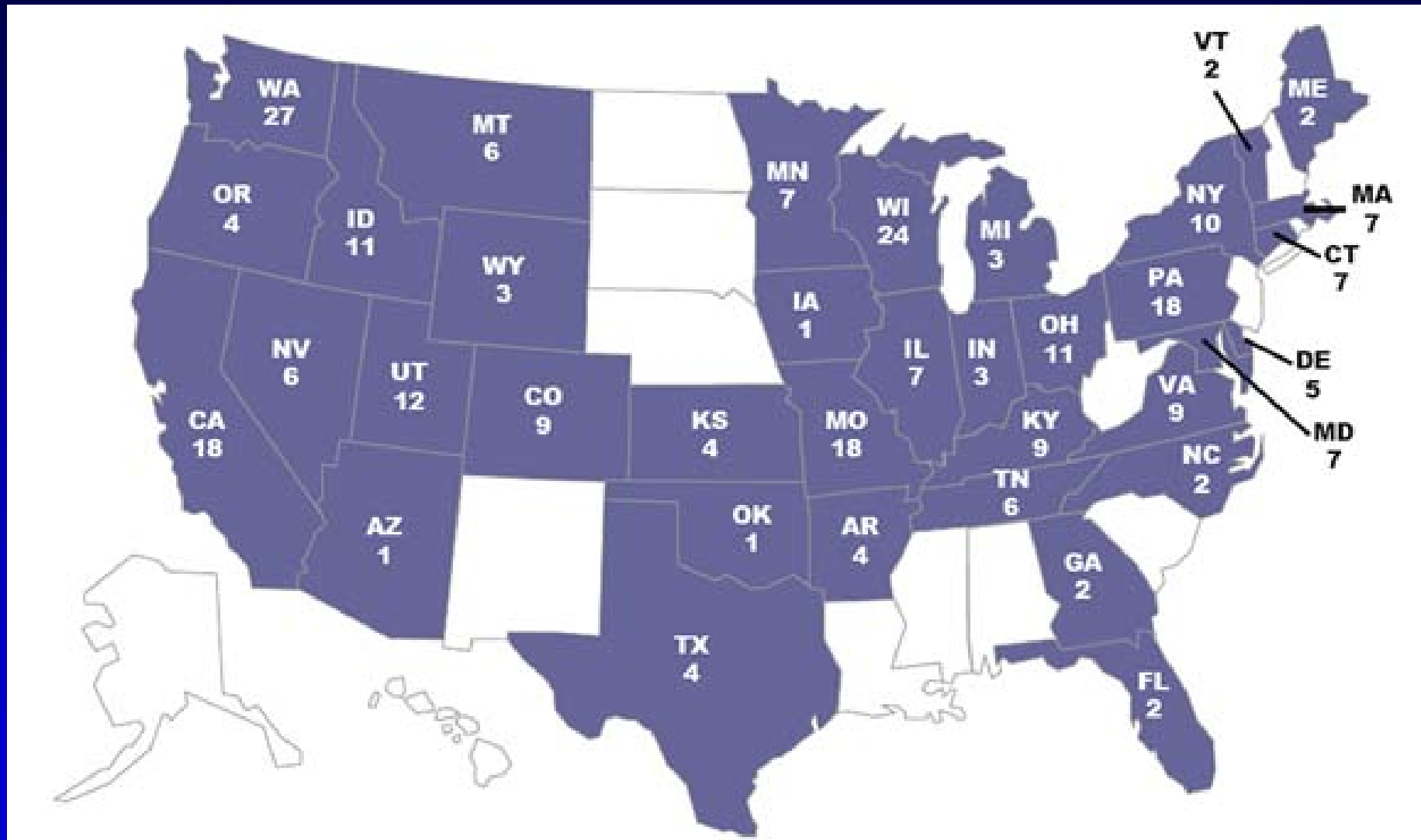
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- Early stages of investigation there were no *S. Tennessee* cases identified in Florida
    - ▲ Implicated company reported four times more sales of implicated peanut butter in Florida than any other state
  - Of 628 cases of *S. Tennessee* infection attributed to peanut butter as of May 2007, 7 cases were reported in Florida
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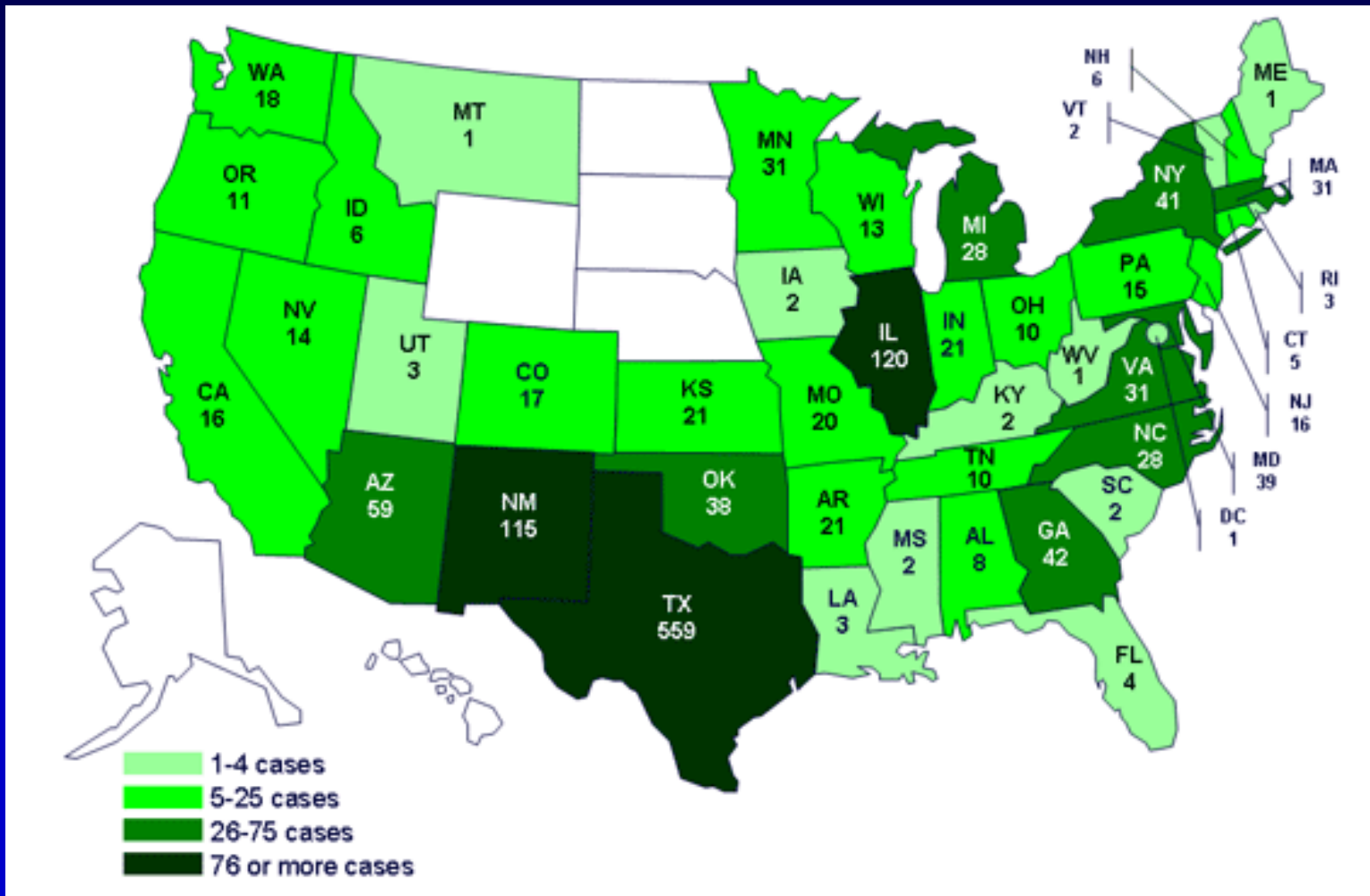
**Number of confirmed cases (N = 628)\* of Salmonella Tennessee infection associated with consumption of peanut butter by state – United States, August 1, 2006 - May 22, 2007**



**Cases of *Salmonella* I 4,[5],12:i:- Infection with the Pot Pie-Associated Outbreak Strain, by State, January 1 to October 29, 2007**



**Cases infected with the outbreak strain of *Salmonella* Saintpaul, United States, by state, as of August 25, 2008 9 pm EDT (Jalapeno Pepper/Tomato-Associated Outbreak)**





# Food Plant Inspections

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- FDA delegates large percentage of inspections to states
  - Inspection programs within states vary in competence of inspectors, depth of inspections, adequacy of inspection programs, frequency of inspections, follow up when deficiencies observed
    - ▲ Some inspectors do not have educational background or training to understand inherent food safety risks associated with food processing
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# Food Plant Inspections

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- ▲ Many inspection programs have a “one-size fits all” approach to inspection
    - ◆ Inspection of dairy plant should have different points of emphasis than that of a dry food (e.g., peanut butter) plant
  - ▲ Many states do not follow up to ensure corrective action taken when deficiencies are noted on prior inspections
  - ▲ Do not share findings with FDA
    - ◆ Need electronic reporting system that is maintained by FDA
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# Food Plant Inspections

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- FDA inspections
    - ▲ Infrequent; may range from 1 to 4 years between inspections depending on “risk”
    - ▲ Inspection force covers pharmaceuticals, foods and medical devices
      - ◆ Need specialists
    - ▲ Need standardized inspections between federal and states
      - ◆ Need to verify competency of inspectors
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# Food Plant Inspections

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- USDA-FSIS has oversight of meat, poultry, and egg products; about 20% of food supply
  - Meat and poultry inspection is based in part on statutes that are more than 100 years old (Federal Meat Inspection Act)
    - ▲ Post-mortem inspection of every carcass
      - ◆ Handling carcasses can transmit *Salmonella* and *Campylobacter* from contaminated carcasses to uncontaminated carcasses
      - ◆ Studies have revealed that inspectors miss large percentage (>10%) of defects
        - ▶ Replace with automated “defect” sensors, but need change in statutes
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# Third Party Audits

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- Many food companies use third party auditors to determine compliance of suppliers with SSOPs, GMPs and HACCP
    - ▲ Auditors may not be knowledgeable or adequately trained for type of plant inspected
    - ▲ Auditors may have bias because paid by company requesting audit
    - ▲ Audits are often announced so plants on best behavior and condition during inspection
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# Third Party Audits

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- ▲ Laboratory testing varies in credibility
    - ◆ Competence of laboratorians, efficacy of methods
  - ▲ Sampling protocols can vary in credibility
    - ◆ Example, test core samples of lettuce for foodborne pathogens to “represent” field contamination
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# Food Import Trends in USA

2004 was the first year on record the United States imported more food than it exported

## Trends in U.S. Food (exclude feed and other non-food agricultural-related products) Imports vs. Exports

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- Dramatic increase in U.S. importation of food

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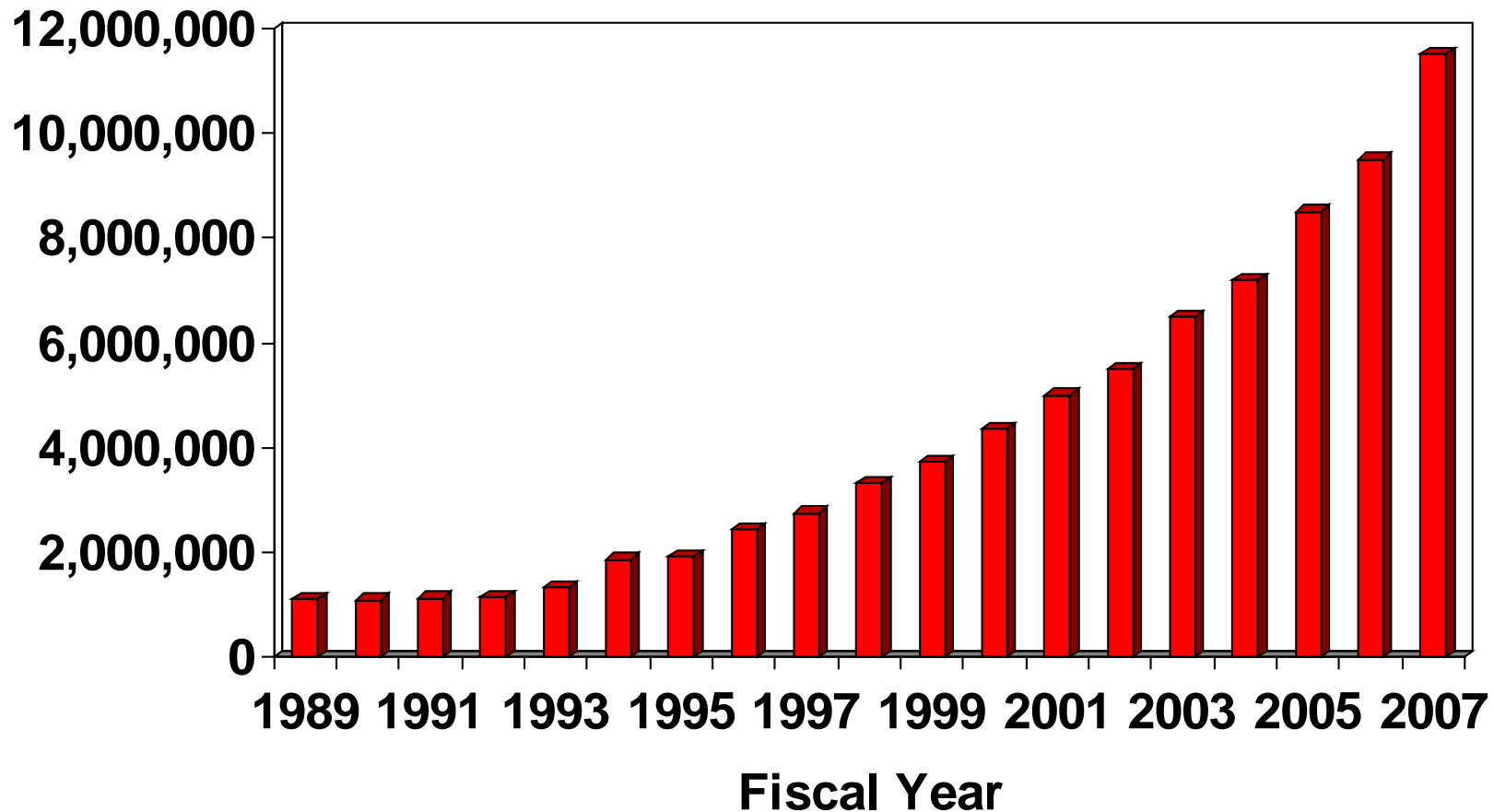
	2001	2002	2003 (\$ million)	2004	2005
Import	34,115	35,826	40,888	47,234	51,892
Export	37,813	38,569	40,987	44,023	45,851

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USDA, ERS ([www.ers.usda.gov/publications/Agoutlook/AOTables/AOTables.htm](http://www.ers.usda.gov/publications/Agoutlook/AOTables/AOTables.htm))

# Globalization of Food Industry

FDA Import Entries Foods Only



# United States Food Imports

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- Approximately 15% of food consumed in USA in 2006 was imported
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## Examples of Trends of Import Share of U.S. Food Consumption for Specific Foods

Selected items	1980	1990	2000	2001
(Percentage)				
Beef	8.7	9.7	11.0	11.6
Lamb	9.5	10.2	36.6	39.8
<b>Fish and Shellfish (Fresh &amp; Frozen)</b>	<b>56.8</b>	<b>65.8</b>	<b>81.7</b>	<b>83.3</b>
Fruits (Fresh and Frozen)	5.8	15.6	22.3	23.1
Fruit Juices	11.6	48.7	31.9	31.5
<b>Tree Nuts</b>	<b>25.6</b>	<b>35.7</b>	<b>39.3</b>	<b>48.9</b>
Vegetables (Fresh & Frozen)	5.9	9.6	14.0	16.0

Andy Jerardo, USDA, ERS ([www.crs.usda.gov](http://www.crs.usda.gov)) FAU79-01, July 2003

# U. S. Importation of Fruits

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- Ca. **44%** of total U.S. fruit supply was imported in 2005
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# U. S. Importation of Vegetables

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- Ca. **16%** of total U.S. vegetable supply was imported in 2005
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## United States Imports of Fresh Vegetables from Leading Countries

Country	2001	2002	2003	2004	2005
	(\$ Million)				
1. Mexico	1,614	1,618	1,935	2,185	2,319
2. Canada	453	515	609	661	730
3. Peru	63	79	97	119	140
4. Netherlands	107	107	104	90	71
5. China	9	24	28	45	59
6. Costa Rica	43	41	38	51	55
7. Guatemala	9	9	11	14	21

Department of Commerce, U.S. Census Bureau, Foreign Trade Statistics

## 2007 Import Share of Consumption by Leading Exporter of Produce Product

Produce Product	Largest Exporter	% of Domestic Consumption
Apple Juice	China	60.9
Asparagus	Peru	44.8
Avocados	Mexico	44.6
Broccoli (Frozen)	Mexico	58.9
Cauliflower (Frozen)	Mexico	51.5
Cucumbers	Mexico	44.1
Garlic	China	51.4
Grapes	Chile	41.3
<i>(Continued)</i>		

## 2007 Import Share of Consumption by Leading Exporter of Produce Product (Continued)

Produce Product	Largest Exporter	% of Domestic Consumption
Kiwis	Chile	32.4
Limes	Mexico	98.3
Mushrooms (Processed)	China	42.3
Orange Juice	Brazil	23.4
Peppers, Bell	Mexico	25.7
Potatoes, Frozen	Canada	21.5
Squash	Mexico	39.2
Tomatoes	Mexico	34.3

## All Tree Nuts (Shelled) Imported and Total Consumption in United States

Season	Imports	Total Consumption
	1,000 pounds	
1980/81	101,117	409,652
1990/91	198,400	609,564
2000/01	297,080	722,956
2004/05	462,372	1,058,364

USDA-ERS, Fruit and Tree Nuts Situation and Outlook Yearbook/FTS-2005/October 2005

## United States Imports of Nuts from Leading Countries

Country	2000	2001	2002	2003	2004	2005
	(\$ Million)					
1. India	249	223	221	195	260	269
2. Vietnam	51	48	71	100	175	168
3. Brazil	151	95	85	117	154	158
4. Mexico	83	43	67	99	148	147
5. China	22	28	39	45	66	74
6. Philippines	41	29	35	37	34	39
7. Australia	23	14	10	14	33	27

Department of Commerce, U.S. Census Bureau, Foreign Trade Statistics

# Primary Sources of U.S. Imported Fish and Seafood in 2005

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- Shrimp: ca. 1.1 billion pounds
  - ▲ Thailand, Ecuador, Indonesia, China, Vietnam, India
- Salmon: ca. 480 million pounds
  - ▲ Canada and Chile account for ca. 90% of all Atlantic salmon imports
- Tilapia: ca. 300 million pounds
  - ▲ China, Taiwan, Ecuador

# **Gaps in Food Safety Net for Imported Foods**

# Microbiological Safety Issues Associated with Imported Foods

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- Sanitation practices for food production and preparation are not universally equivalent throughout the world
  - Importing foods can move pathogens from areas where pathogen is indigenous to locations where it seldom or does not exist
    - ▲ Example, *Cyclospora* in raspberries from Guatemala to U.S. and Canada
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# Pathogen Contamination of Produce

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- Sources of pathogens:
    - ▲ Sewage/manure used as soil fertilizer or through environmental contamination
    - ▲ Irrigation water
    - ▲ Processing water
    - ▲ Poor personal hygiene of infected foodhandlers
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# Examples of Food Safety Concerns Associated with Imported Produce

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- Centuries old tradition of using human excreta on farmland is widespread in east Asia, especially in China and Vietnam
  - Irrigation water often contaminated with untreated human and animal fecal waste
    - ▲ About 10% of human sewage from Mexico City is treated; rest goes untreated into rivers
  - Insanitary harvesting practices of exporting countries
    - ▲ Mexican children infected with Norovirus or Hepatitis  
A accompany parents in produce field during harvest
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# Fecal Waste Used in Aquaculture Production

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- Raw domestic sewage and/or livestock manure are frequently used in fish farming in many Asian countries
    - ▲ Estimates at least two-thirds of the world production of farmed fish is grown in ponds fertilized with animal manure or human sewage
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# Chicken/Shrimp Farming in Thailand

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- Chicken/shrimp farming is only means of income for many small stakeholders
  - ▲ Chicken coops (e.g., 20,000 birds/farm) sit in rows suspended over ponds that hold shrimp and fish
    - ◆ Livestock below feeds on waste from above

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BBC News, January 27, 2004





# Antibiotic Resistant Microbes in China

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- “The situation with respect to overuse of antibiotics and antibiotic resistance in China is severe.”
    - ▲ Reynolds et al. Health Policy 2008
  - “China has the world’s most rapid growth rate of resistance (22% average growth in a study spanning 1994 to 2000)”
    - ▲ Zhang et al. Global Health 2:6 (2006)
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## Examples (March 2008) of Pathogen or Toxin Contamination of Foods Imported into U.S. (FDA Refusals)

Country of Origin	Product	Contaminant
China	Melon Seeds	Aflatoxin
China	Frozen Dried Croaker	<i>Salmonella</i>
Honduras	Soft Cheese	<i>Salmonella</i>
India	Cumin Seed	<i>Salmonella</i>
India	Sesame Seed	<i>Salmonella</i>
India	Black Pepper	<i>Salmonella</i>
India	Curry Powder	<i>Salmonella</i>
India	Frozen Raw Peeled Shrimp	<i>Salmonella</i>
Mexico	Marshmallow Sandwich Cookies	<i>Salmonella</i>
Mexico	Chocolate Nuggets	Aflatoxin
Mexico	Chili Powder	<i>Salmonella</i>
Vietnam	Roasted Melon Seeds	Aflatoxin

FDA Import Program ([www.fda.gov/ora/import/ora\\_import\\_program.html](http://www.fda.gov/ora/import/ora_import_program.html))

# Future Trends in U.S. Importation of Foods

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- California produce production shifting to Mexico
- Brazil dominant global agricultural producer and exporter

## Export rankings (2005):

<b>Orange juice:</b>	<b>80%</b>	<b>(1)</b>	<b>Coffee:</b>	<b>26%</b>	<b>(1)</b>
<b>Sugar:</b>	<b>42%</b>	<b>(1)</b>	<b>Beef:</b>	<b>24%</b>	<b>(1)</b>
<b>Poultry:</b>	<b>35%</b>	<b>(1)</b>	<b>Pork:</b>	<b>13%</b>	<b>(4)</b>
<b>Soybeans:</b>	<b>35%</b>	<b>(2)</b>	<b>Corn:</b>	<b>35%</b>	<b>(4)</b>
<b>Soy meal:</b>	<b>25%</b>	<b>(2)</b>			

- China becoming dominant food exporter to USA
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# “Adulteration of Food Big Problem in India” (1984)

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- India suffering from widespread adulteration of food and beverages
  - ▲ India tea is sometimes cut with coal tar and lead
  - ▲ Sugar is laced with ground glass
  - ▲ Flour contains dust of animal bones
  - ▲ Spices are intentionally mixed with cow dung, sawdust and industrial dyes
  - ▲ Toffees contain wax and lollipops have ash
- Profits make adulteration lucrative and widespread
  - ▲ Nationwide sampling found 37.7% of milk, 10.4% of cooking oils and fats, 9.6% of sugar, 9% of spices, 4.5% of fruit products, and 4.4% of tea, coffee and chicory were adulterated

# Illegal Additives Still Blight Food in China

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- China's Vice Minister of Health, Chen Xiaohong, reported some Chinese dairy products, flour, meat and other foods remain dangerously tainted with illegal additives
  - ▲ Some food and liquor makers continue to use banned additives, and high tech law breakers were "challenging the oversight and administration capacity of law enforcement agencies"
  - ▲ Chen said, "Some food businesses still lack a grasp of the harmfulness and severity of illegal additives. Their commitment to correcting this is not high."

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Reuters, July 7, 2009

# FDA Food Import Inspection Program

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- 80% of U.S. food supply is under FDA jurisdiction
  - Inspection at border is primary FDA oversight for imported foods
  - About 1% of FDA-regulated imported food is visually inspected
  - Less than 0.5% of FDA-regulated imported food shipment are tested
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# FDA Food Import Inspection Program

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- Representative samples of large shipments of imported foods are inadequate
  - Many methods used for testing food contaminants are decades old and need updating
  - “Risk-based” testing
    - ▲ Ill defined; not scientifically vetted
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# Not All Food Processors are Equally Committed to Food Safety

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- Secondary suppliers
    - ▲ Variability in oversight by food processors
  - Safety of ingredients, especially from developing countries
    - ▲ Spices, vitamins, citric acid, ascorbic acid, nuts
    - ▲ Rely on Certificates of Analysis
  - Economics are primary driver for many companies
    - ▲ Cheaper labor, raw materials and transportation
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# Not All Food Processors are Equally Committed to Food Safety

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- Co-packers
    - ▲ Example, fruits processed in California and packaged in China
    - ▲ Variability in oversight by food processors
  - Finished product testing
    - ▲ Many companies do not test finished products for harmful microbes
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# Reasons for Testing Finished Products

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- Detect *Salmonella* contamination that could result in foodborne illnesses
  - Verify that process is effective in eliminating *Salmonella*
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# Impediments to Testing Finished Product for Salmonella

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- Must hold (control) product until results are reported (may be > 2 days)
    - ▲ Requires warehousing product
  - Cost of testing
  - Positive finding in plants with extended operations (no clear separation of lots by clean up and sanitation, e.g., peanut butter processing) can implicate multiple lots (e.g., 2 years) of product
  - Limited methods to sufficiently clean and sanitize if positive result is found in products from dry plant processing
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# **What Should be Primary Driver of Finished Product Testing?**

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**PROTECTION OF PUBLIC HEALTH**

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# Conclusions

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- Major weaknesses in the U.S. food safety net:
    - ▲ Minimal commitment to foodborne disease surveillance system by several states
    - ▲ Food inspection (federal and state) has major deficiencies including competence of inspectors, depth of inspections, adequacy of inspection programs, frequency of inspections, and follow up on corrective actions
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# Conclusions

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- ▲ Third-party audits are highly variable in quality and credibility as are contract laboratories
  - ▲ Not all food companies are equally committed to food safety and for FDA-regulated plants may receive minimal regulatory oversight until an adverse event occurs
    - ◆ Philosophy/statutes for FDA is food is considered safe unless proven otherwise, largely by an adverse event (such as an outbreak of foodborne illness)
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