

# Food Safety in a Global Market

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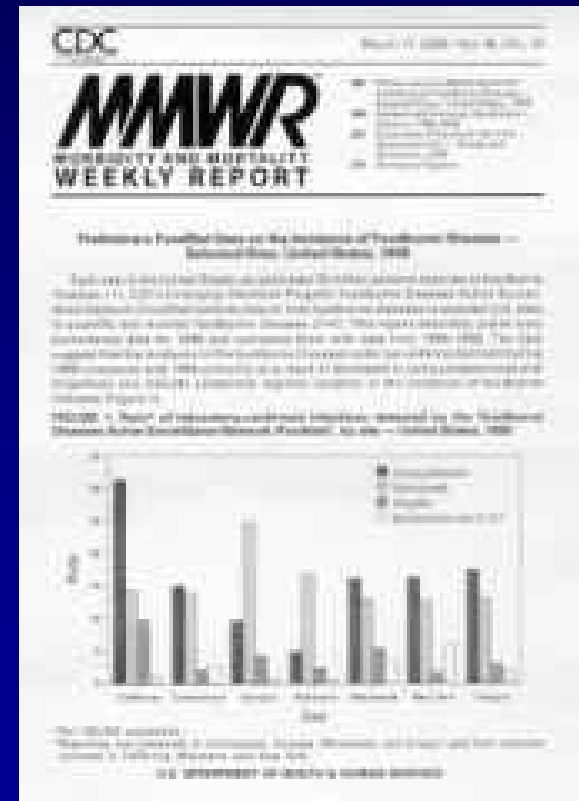
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# Public Health Problem

## Each Year in the US:

- 76 Million Foodborne Illnesses
- 325,000 Hospitalizations
- 5,000 Deaths



# Causes of Foodborne Disease

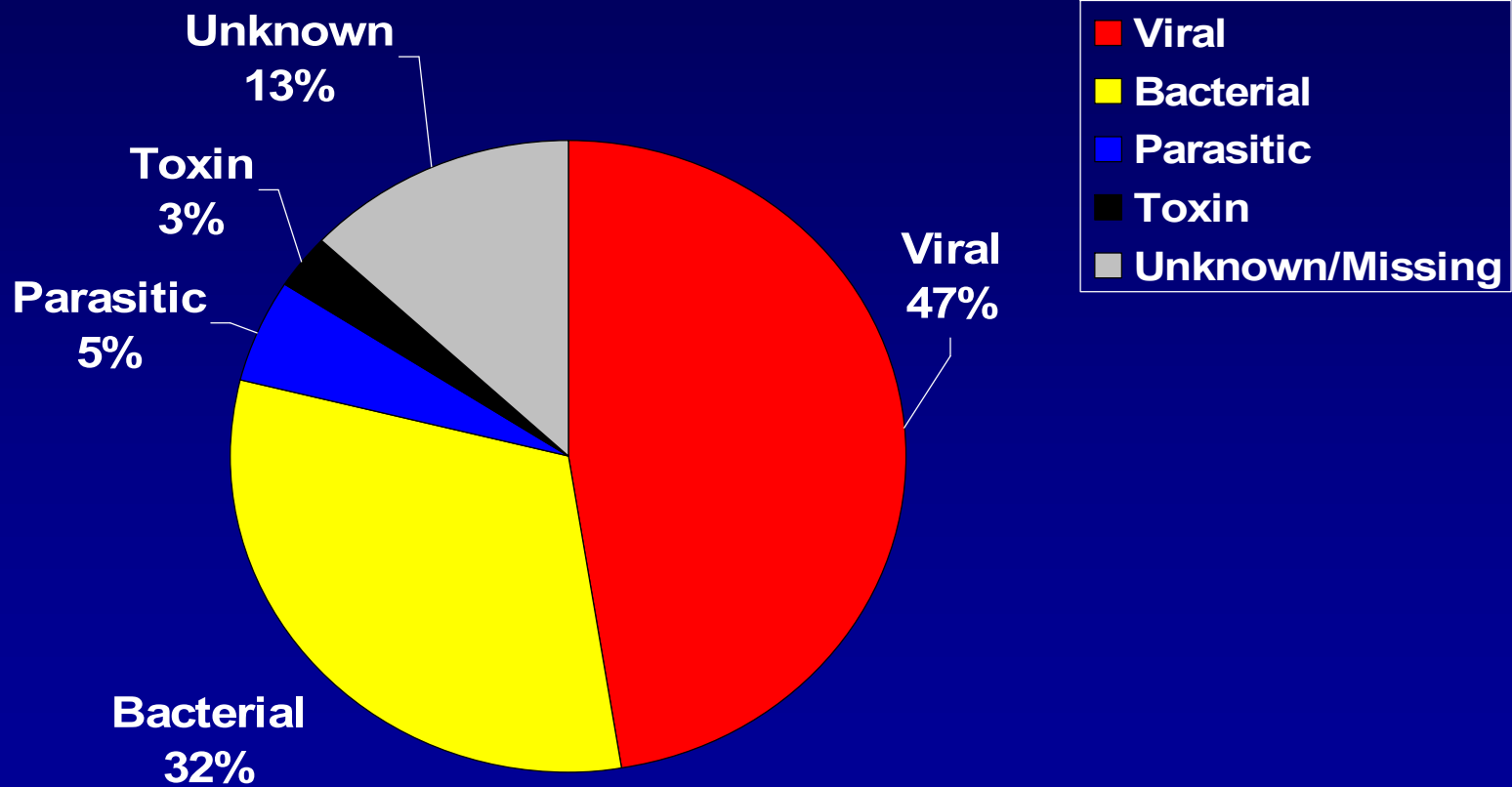
Agent	Number	% Disease
<b>Bacterial</b>	5,204,934	
• Campylobacter	~ 2.4 million	80%
• Salmonella	~1.4 million	80%
• Shigella	~0.5 million	20%
<b>Parasitic</b>	2,541,316	
• Giardia	~2 million	10%
<b>Viral</b>	30,883,391	
• Norovirus	~23 million	40%
• Rotavirus	~ 4 million	1%
• Astrovirus	~ 4 million	1%



Mead et al., Food Related Illness and Death in the United States, Emerging Infectious Disease, 1999



# Outbreak Causes (2002-2003)



# New Challenges

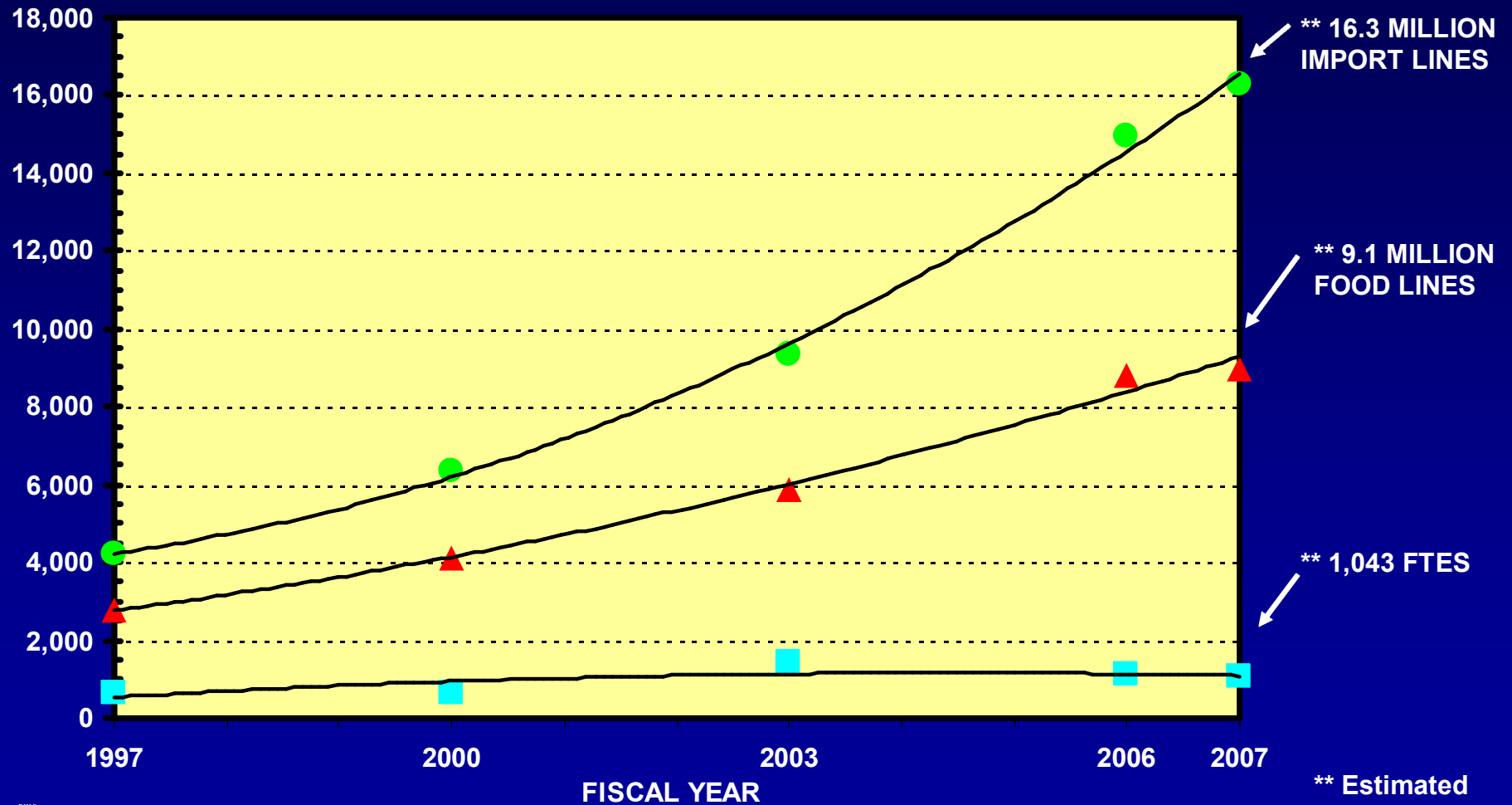
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FDA faces increasing challenges and risks to the nation's food system

- Increased globalization
- Changes in consumer expectations
- Changes in farming, manufacturing and processing
- Outdated infrastructure
- Terrorism
- Challenges in tracking food rapidly through wide distribution (e.g., melamine in pet food)



# Rising Food Imports



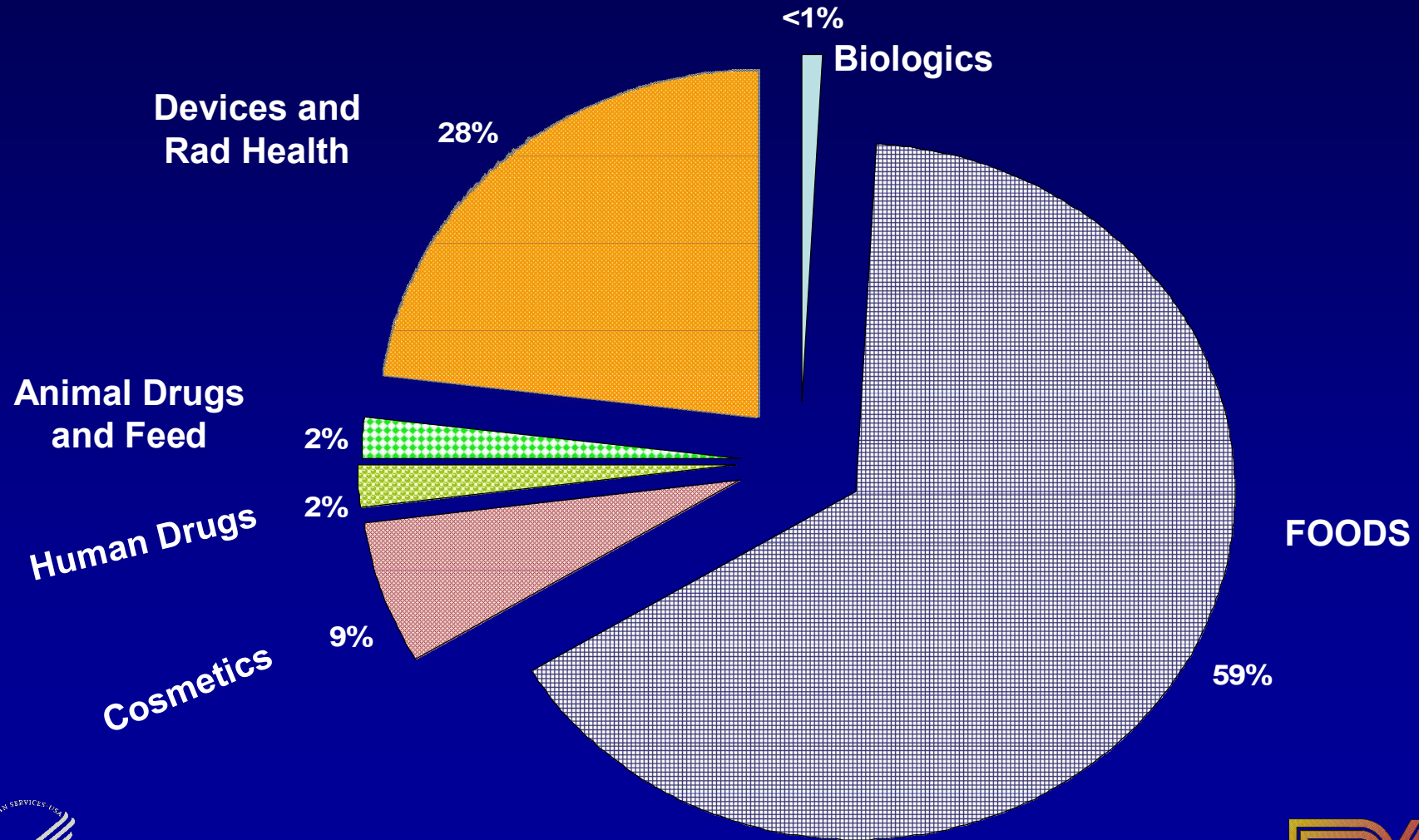
\*\* Estimated



■ FTEs (includes all import areas)  
● IMPORT LINES (000)  
▲ FOOD LINES (000)



# Types of Imported Goods



# Leafy Greens Outbreaks

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1995	3 - <i>E. coli</i> O157:H7	105 cases
1996	2 - <i>E. coli</i> O157:H7	68 cases
1997	1 - <i>Cyclospora</i>	12 cases
1998	2 - <i>E. coli</i> O157:H7	6 cases
1999	6 - <i>E. coli</i> O157:H7	86 cases
2002	2 - <i>E. coli</i> O157:H7	53 cases
2003	3 - <i>E. coli</i> O157:H7	60 cases
2004	2 - <i>Cyclospora</i>	95 cases
	1 - <i>Salmonella</i>	79 cases
	1 - <i>E. coli</i> O157:H7	6 cases
2005	1 - <i>E. coli</i> O157:H7	34 cases
2006	3 - <i>E. coli</i> O157:H7	356 cases



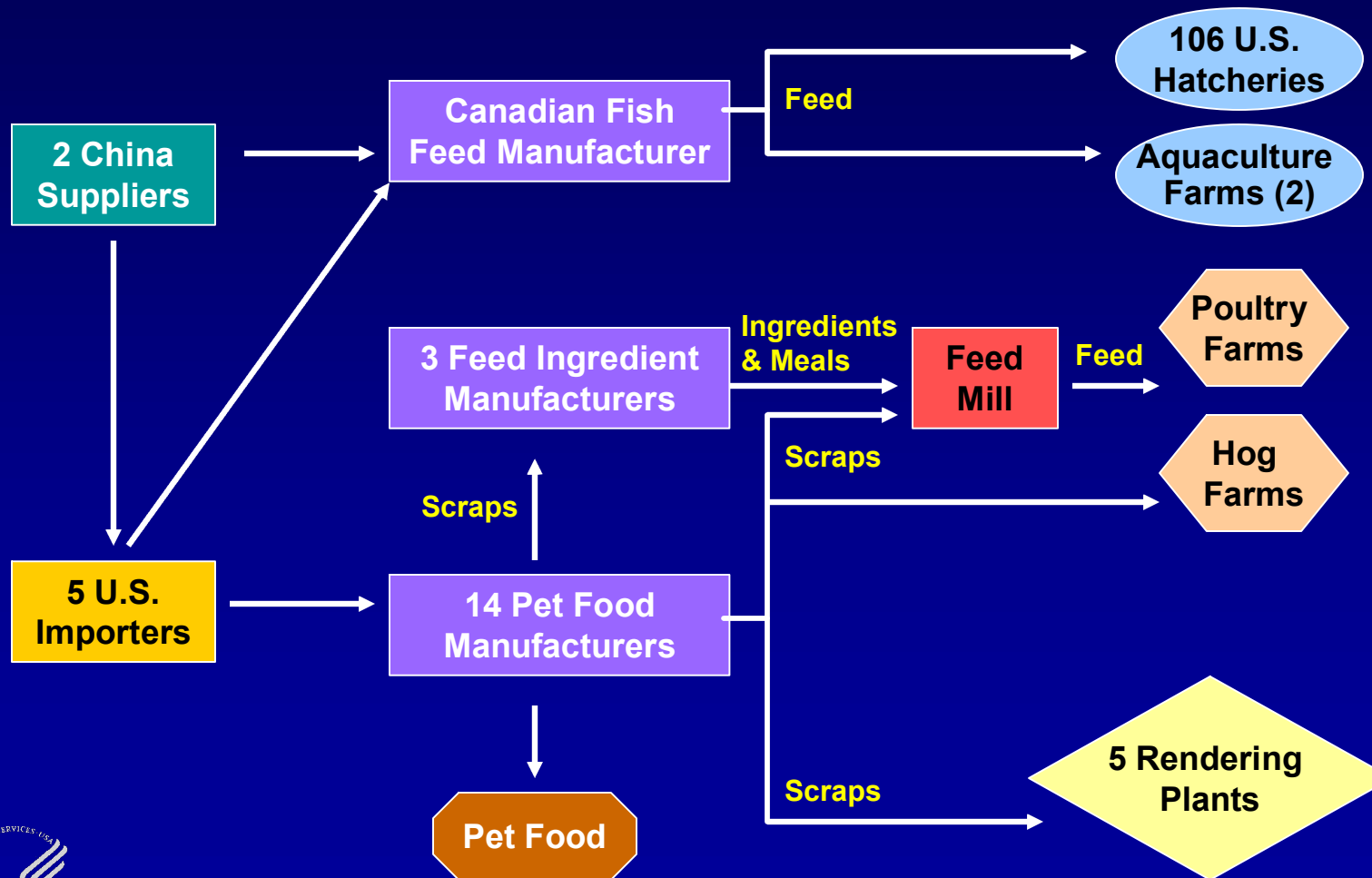
# S. Tennessee in Peanut Butter

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- 290 people in 30 states
- 46 hospitalized, no deaths
- Salmonella Tennessee
- Cutoff May 6, 2006
- Peter Pan or Golden Value Brands
- Con Agra recalled beginning 2/13/07
- FDA found the organism in open and unopened containers
- Con Agra voluntarily stopped production



# Melamine Sequence of Events



# Outcome

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- Chinese manufacturing facilities closed
- Chinese authorities will inspect all plant protein products before export
- Bilateral meetings ongoing
- FDA will provide training to Chinese food regulators on science and legal basis for U.S. regulatory requirements

# Botulinum Toxin in Canned Chili

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- 2 Children and their mother intoxicated in Texas
- Indiana couple intoxicated
- Both consumed Castleberry's Hot Dog Chili Sauce
- Products produced in Castleberry's facility in Augusta GA
- Firm voluntarily recalled on July 18 and expanded the recall on July 21, 2007



# FDA Amendments Act of 2007

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## ■ Selected Food Provisions

- Prohibition against drugs/biologics in foods
- Surveillance and early warning system to detect pet food adulteration/outbreaks
- Recall Communications
  - Enhanced quality and speed of communication with the public
- Enhanced State-Federal cooperation on food safety
  - Coordinated and cost-effective



# FDA Amendments Act of 2007

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## ■ Selected Food Provisions (cont'd)

- Reportable food registry
  - Required reporting of SAHCOD
- Enhanced aquaculture/seafood inspections
  - Congressional report including on feasibility of developing traceability system
- Annual Report to Congress on imported foods data
  - Including volume by country, inspectors/inspections of imported foods, findings and regulatory follow up.



# Food Protection Plan

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- Core Elements – Domestic Food Supply
  - Prevention
    - Build safety in from the start
  - Intervention
    - Verify prevention and intervene when risks are identified
  - Response
    - Respond rapidly and appropriately



# Prevention

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## ■ FDA Actions

- Analyze import data and integrate it into risk based inspection approaches
- Focus foreign inspections on high risk firms and products

## ■ Additional Legislative Authorities

- Require preventive controls against intentional adulteration
- Require registration renewal every 2 years



# Intervention

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- Focus inspections and sampling based on risk
- Enhance risk based surveillance
- Improve detection of food system signals that indicate contamination
- Improve immediate response

# Response

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## ■ Improve Immediate Response

- Enhance Emergency Operations
- Improve trace back process and technologies
- Increase collaboration with foreign, federal, state and local FDA partners
- Work with CDC and other fed, state, local labs

## ■ Additional Legislative Authorities

- Recall authority
- Enhanced records access in emergencies



# Imports Safety Action Plan

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## ■ Core Elements

- Prevention
  - Build safety in from the start
- Intervention
  - Verify prevention and intervene when risks are identified
- Response
  - Respond rapidly and appropriately



# Prevention

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- Create/strengthen safety standards
- Verify compliance of foreign producers through certification
- Promote good importer practices
- Strengthen penalties and strong enforcement action
- Make product safety a principle of diplomatic relationships and increase foreign assistance activities



# Intervention

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- Harmonize procedures and requirements for processing import shipments
- Complete a single window interface for the exchange of import data
- Expand lab capacity and develop rapid test methods

# Response

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- Maximize the effectiveness of product recalls
- Maximize federal/state cooperation
- Expedite consumer notification of product recalls
- Expand the use of electronic track and trace technologies

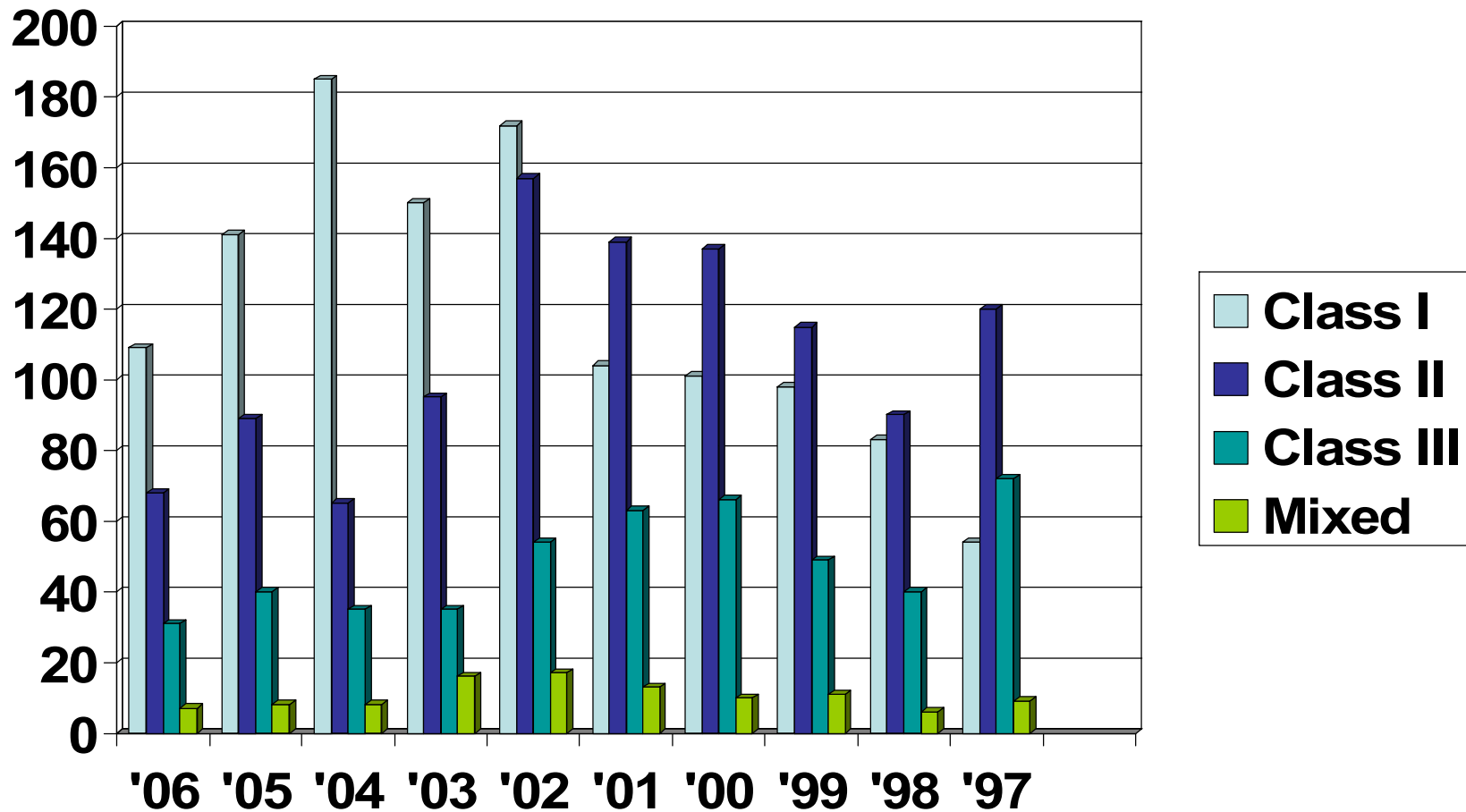
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# Recalls



# Food Recalls by Class

## FY 2006 – FY 1997



# Reasons for Class 1 Recalls FY 06

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- 52 Allergens
- 24 Undeclared Sulfites
- 22 *Listeria monocytogenes*
- 12 *Salmonella*
- 2 *Burkholderia cepacia*
- 2 Ephedra
- 1 *E. coli* O157:H7
- 1 Incorrect scoop size, special diet
- 1 *Serratia Marcescens*
- 1 Uneviscerated fish (bot hazard) and Leachable lead

# Reasons for Recall FY05

## Class I

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- 56 - Allergens
- 30 - Sulfites (>10mg/eating occasion)
- 26 - Salmonella
- 26 - Listeria monocytogenes
- 2 - Leachable lead
- 2 - Uneviscerated fish (botulism hazard )
- 1 - Dietary supplement containing aristolochic acid
- 1 - Overfortified dietary supplement
- 1 – E. coli O157H:7
- 1 – Infant formula with inappropriate formulation

# Reasons for Recall FY05

## Class II

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- 41 – Undeclared ingredients that can pose a hazard to health (allergens, sulfites, colors)
- 12 – Products contain pathogens or were manufactured under conditions whereby they may contain pathogens
- 9 – Unapproved color additives
- 7 – Foreign objects
- 6 – Pesticide residue
- 4 – Histamines in fish
- 4 – Dietary supplements containing androstenedione
- 3 – Products make drug claims
- 2 – Leachable lead
- 2 – Products contain animal drug residues
- 2 – Patulin in apple juice/cider products
- 1 – Food contaminated with formaldehyde
- 1 – Dietary supplement lacked iron warning statement
- 1 – Underfortified food
- 1 – Dietary supplements manufactured under poor conditions
- 1 – incorrect viscosity in food designed for patients with swallowing disorders

# Reasons for Recall FY05

## Class III

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- 23 – Miscellaneous misbranding
- 21 – Miscellaneous “unfit for food”  
(spoilage, filth, foreign objects, etc.)

# Balance

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- Industry should be able to strike a balance between recalling product that is not in violation (i.e. market withdrawal) and allowing violative and potentially hazardous product to remain in the marketplace prompting action by FDA
  - FDA Warning to Consumers
  - FDA Seizures or detentions
  - FDA Requested Recall

# Be Prepared

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- Records must be adequate to trace products forward and backwards
- Records should be adequate to know the exact ingredients of a finished food to limit a manufacturer's exposure
- Be familiar with the Recall Regulations and procedures
- Have an understanding of FDA's Press Practices – Examples on the Web



# Low Acid and Acidified Low Acid Canned Foods - Recent Issues

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- Acidified and Fermented Olives
  - Control of pH of acidified and fermented foods
- Canned Chili Sauce
  - Control of processing
- Canned Green Beans
  - Control of factors affecting the process
  - No botulinum was found but cans swelled

# Produce

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- Leafy Greens E. Coli O157:H7 2006
  - Spinach
  - Lettuce
- Tomatoes
  - Outbreaks of various Salmonella species
- Cantaloupes
  - Positive Salmonella findings, no illnesses

# Imported Foods and Food Components

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## ■ Protein Concentrates

- Addition of substances high in nitrogen allegedly to raise protein analytical results

## ■ Seafood

- Countrywide DWPE for certain species of fish from China due to drug residues
- Substitution of food species with puffer fish

# Investigations

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- Common thread through previous problems was the willingness to make assumptions on the extent and the source of the problem without a thorough investigation commenced quickly
- There is a tendency to “limit losses”
  - Leakers vs. under processing
  - Limited number of lots affected
  - No time for a go slow approach

# Imports Prevention

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- Know your supplier
- Price should not be the determining factor in selecting suppliers
- Certificates of analysis are not always dependable
- Test incoming products
- Test for what?
  - Identity, quality, likely contaminants, physical characteristics

# Challenges

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- Demands to provide the latest information immediately
- Ensuring all the appropriate parties are kept current
- Determining what can be shared with whom and when
  - Public information
  - Confidential commercial information

# Challenges

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- Communicators are often also working the problem
- Requests for multiple data sets in different formats
- Requests for multiple “briefings” with short time frames
  - Federal, congressional, states, industry
- Lack of scientific understanding for prevention



# Food Protection *Principles*

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**Proactive**



**Reactive**

# Summary

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- The U.S food supply is one of the safest in the world
- Overall foodborne illness and outbreaks rates unchanged
- Recent outbreaks have caused loss of consumer confidence in food safety
- Changes in recent years have resulted in a need to refocus food protection strategy
- Greater emphasis on prevention

# QUESTIONS ?

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