



Melamine in Pet Food: FDA's Response

International Crises & Risk Communication Conference

University of Central Florida

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Objectives

- Discuss FDA response activities during the melamine pet food recall of 2007
- Give an overview of human risk assessments utilized
- Provide an understanding of FDA's role in the investigation
- Discuss the role of communication and collaboration in the melamine response



Introduction

March 15, 2007

FDA Notified of Animal Deaths

Introduction

- FDA investigators on-site within 24 hrs
- FDA worked with manufacturer to remove possible contaminated products from market

Introduction

- Consumers informed of danger in feeding animals suspect products
- Cat and dog food supplied to numerous pet food companies
- Voluntary recall was initiated



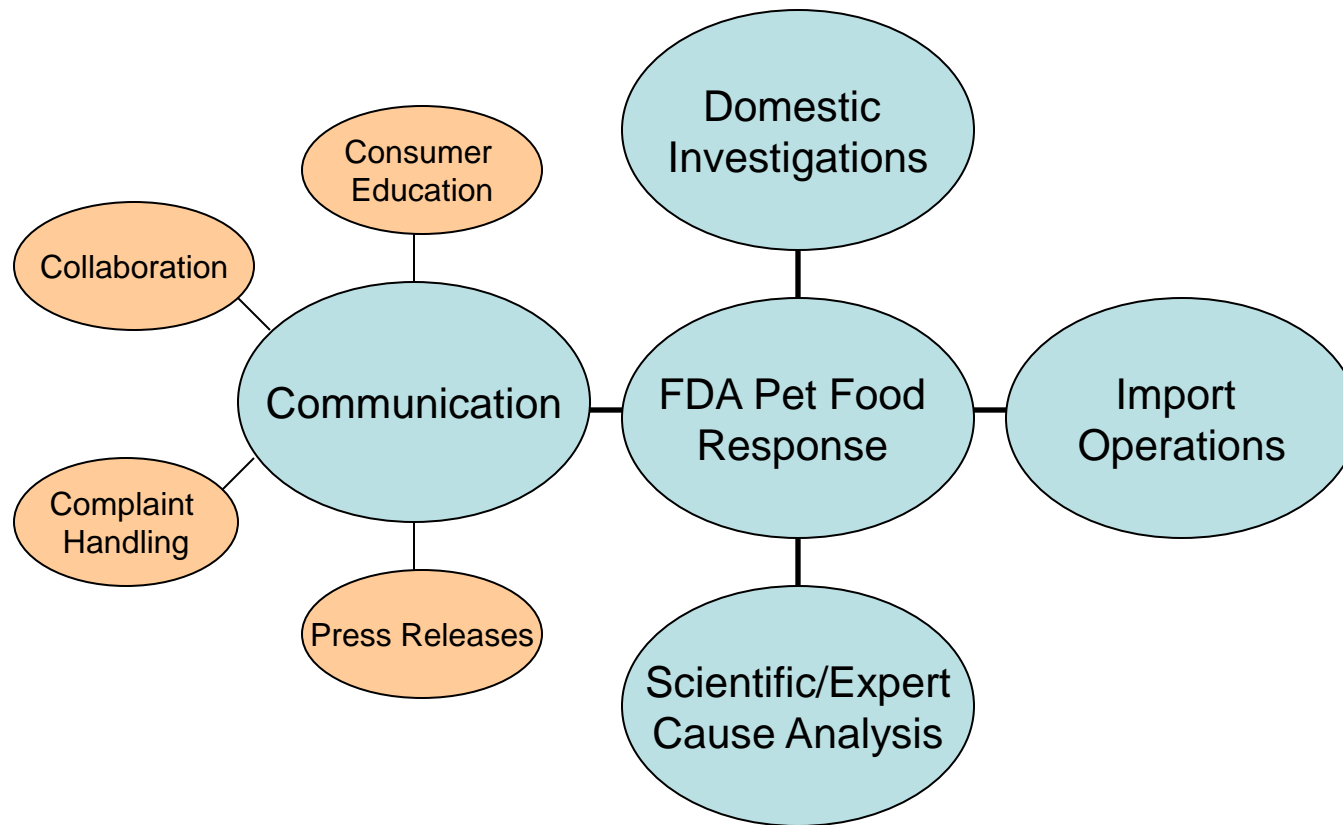
FDA's Charge

To Promote and Protect Public Health

Initial Actions

- Identify the ingredient causing deaths
- Determine the type of toxins/contaminants
- Suspect problem linked to new ingredient

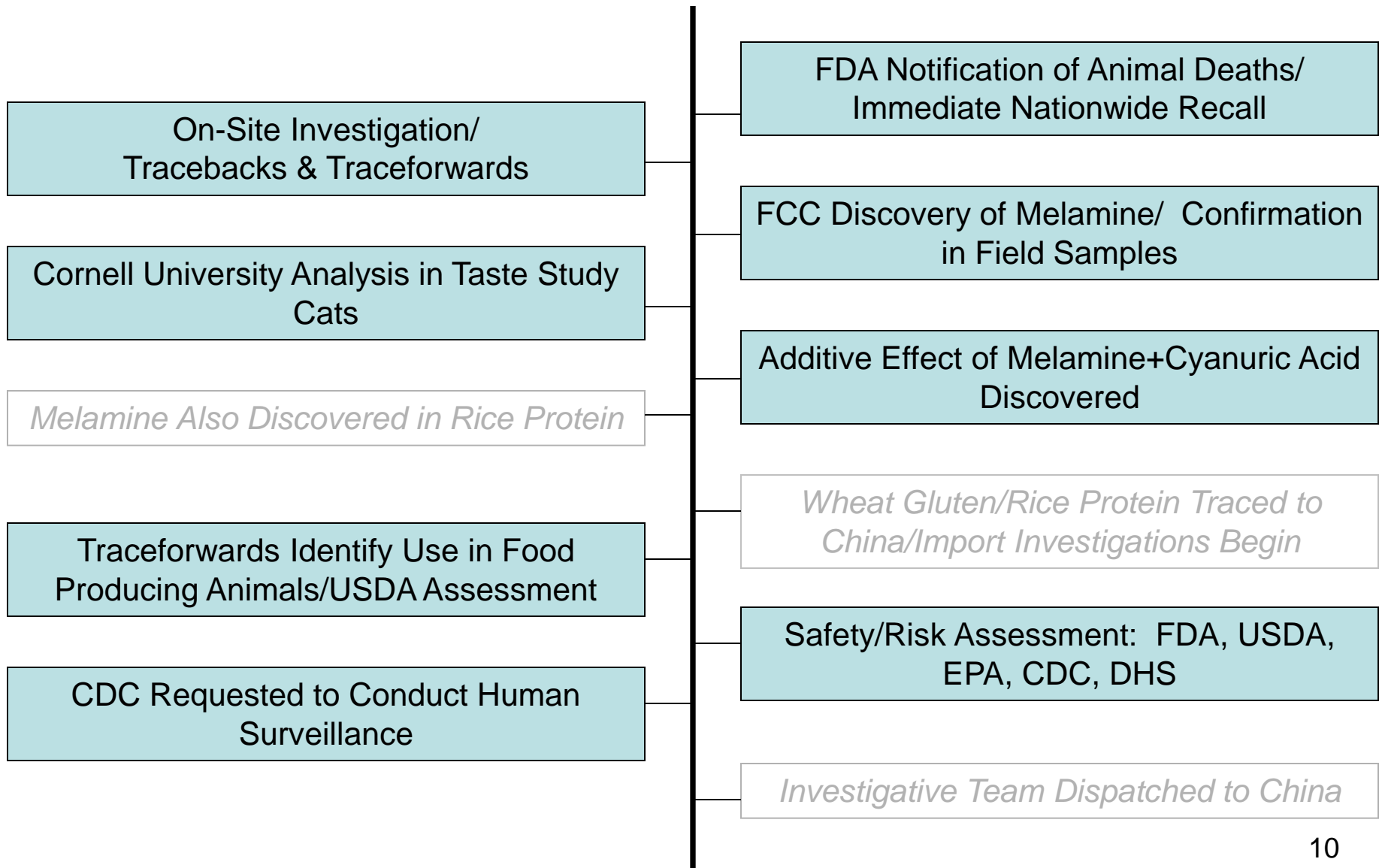
Interconnectivity of Multiple Response Efforts





Cause Analysis and Domestic Investigations

Timeline of Events



On-Site Investigation

- Within 24 hours
- Search for other causes of contamination
- Tracebacks and Traceforwards
 - 100 different brand name products involved

FCC Discovery of Melamine

- FDA Forensic Chemistry Center
(Cincinnati, OH)
- Melamine discovered in pet food and wheat gluten ingredient
- Melamine confirmed by FDA field labs in over 130 of 210 initial samples collected by field staff

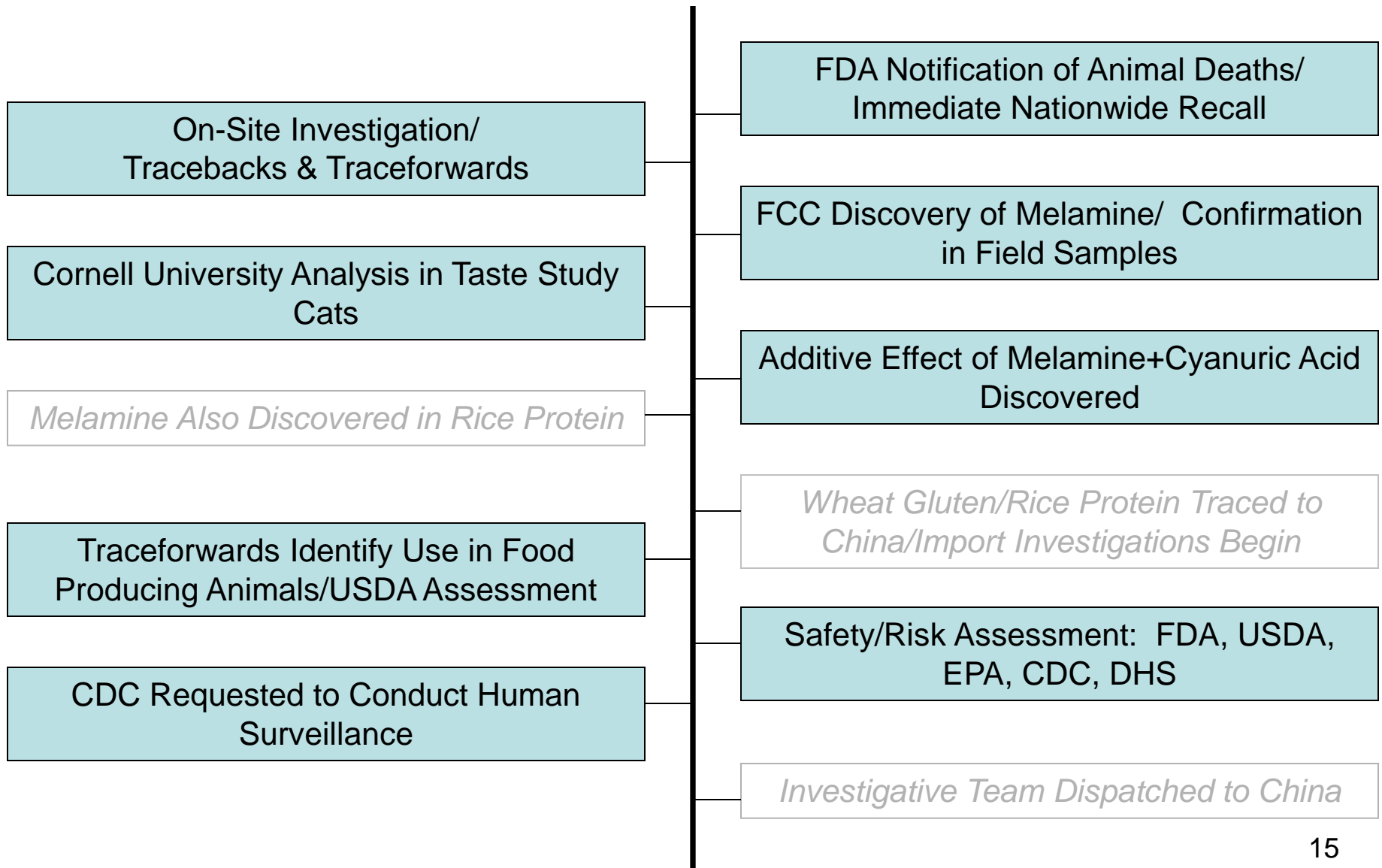
Cornell University Analysis

- Testing by Cornell, found melamine in the urine and kidneys of cats that were part of the manufacturer's pet food taste test study
- Possible link to pet deaths

Additive Effect Discovered

- Melamine is relatively non-toxic
- Interactions of melamine and related compounds examined
- Collaboration with veterinarians, toxicologists, pathologists
- Combination of melamine and cyanuric acid react to form crystals in the urine and kidney tissue, leading to kidney failure

Timeline of Events



Use in Food Producing Animals

- Contaminated pet food was used in animal feed for food-producing animals (hogs, poultry, fish)
- FDA coordinated with USDA to determine risks and implement control strategies

Human Food Consumption Risks

- A safety/risk assessment was prepared by FDA in collaboration with USDA/FSIS, CDC, EPA, and DHS
- Worst case scenario for potential exposure determined

Human Food Consumption Risks

- Melamine compounds do not accumulate in the body of animals (rapidly excreted in urine)
- No evidence of illness in the animals that ate contaminated feed
- No reports of illness in people from consuming foods that may have contained melamine or its related compounds

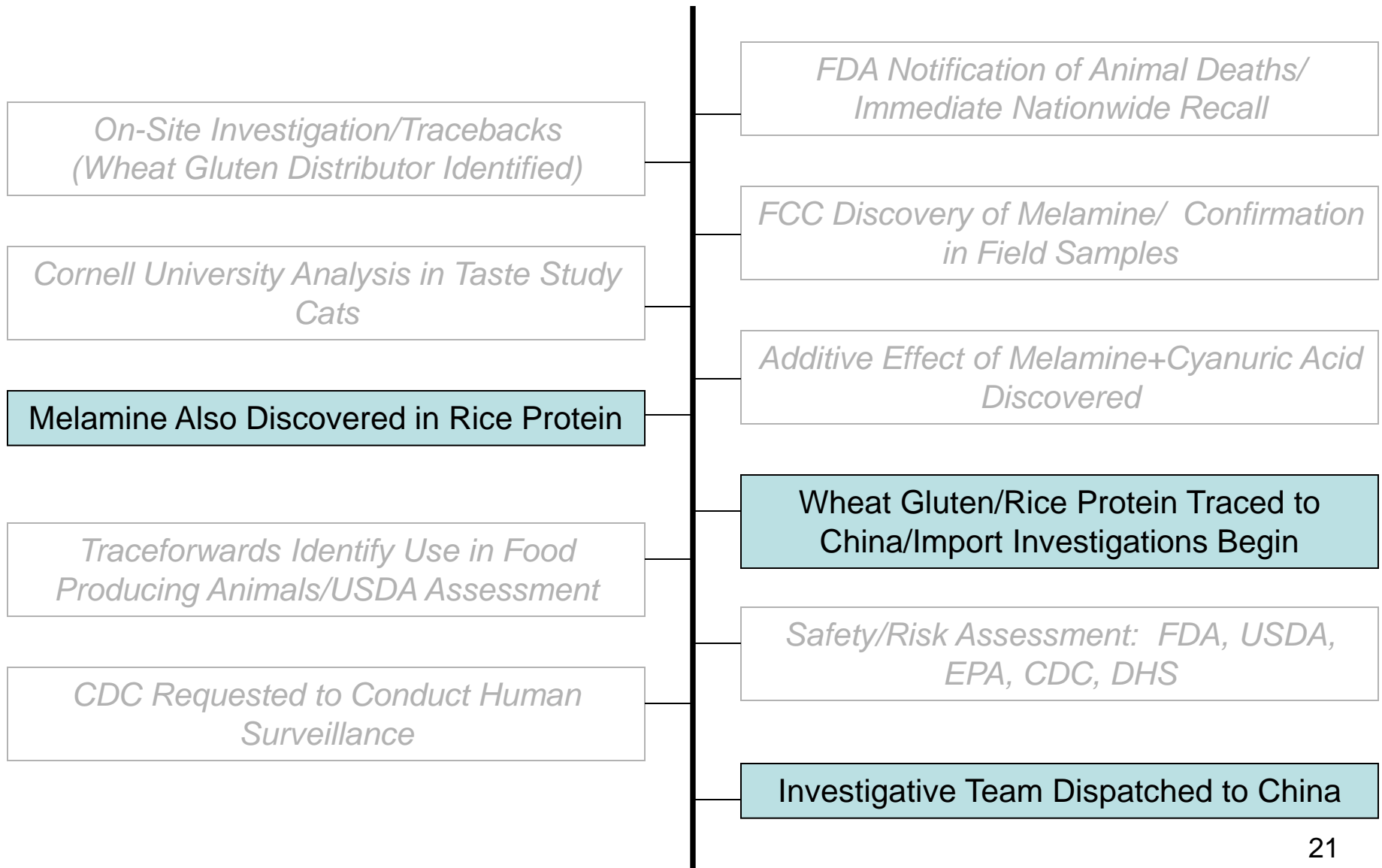
Human Food Consumption Risks

- FDA requested CDC to use its surveillance network to monitor for signs of human illness although risk of illness was low
- CDC surveillance did not show an increase in kidney failure (the most likely expected health outcome)



Import Operations

Timeline of Events



Import Operations

- Suspect shipment of rice protein concentrate was imported
 - white bags
 - pink bags - "melamine"
- FDA testing revealed melamine in both the white and pink bags

Import Operations

- Center for Veterinary Medicine notified of the suspect shipment
- A nationwide investigation
- Import initiated recall of all suspect rice protein concentrate

Import Operations

- Obtained distribution records
 - 5 pet food manufacturers in 7 locations
- Inspections began at pet food manufacturers in the United States and Canada
- Confirmation of “melamine” in pet food products containing rice protein concentrate

Import Operations

- Inspectors collected samples of the recalled pet food
- Import records examined
- Identified the distributor of the wheat gluten

Import Operations

- FDA's Forensic Chemistry Center
 - Melamine in pet food
 - Melamine in the wheat gluten

Import Operations

- Initial Import Alert issued focused on the supplier
 - 100 percent sampling of all wheat gluten
 - China
 - Netherlands
- An Import Alert is the Agency's Guidance to field personnel regarding a manufacturer, importer, or product with a problem



Import Operations



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U.S. Food and Drug Administration

Import Alert 72-05

[Import Program](#) > [Import Alerts](#) > [Import Alerts by Numbers](#) > [Import Alert](#)

(Note: This import alert represents the Agency's current guidance to FDA field personnel regarding the manufacturer(s) and/or products(s) at issue. It does not create or confer any rights for or on any person, and does not operate to bind FDA or the public).

Import Alert # 72-05

Published Date: 10/12/2011

Type: DWPE with Surveillance

Import Alert Name:

"Detention Without Physical Examination of Pet And Laboratory Animal Food Due To The Presence Of Melamine And/Or Melamine Analogs (Trazines)"



Import Operations



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U.S. Food and Drug Administration

Import Alert 99-29

[Import Program](#) > [Import Alerts](#) > [Import Alerts by Numbers](#) > [Import Alert](#)

(Note: This import alert represents the Agency's current guidance to FDA field personnel regarding the manufacturer(s) and/or products(s) at issue. It does not create or confer any rights for or on any person, and does not operate to bind FDA or the public).

Import Alert # 99-29

Published Date: 10/12/2011

Type: DWPE

Import Alert Name:

"Detention Without Physical Examination of All Vegetable Protein Products From China for Animal or Human Food Use Due to the Presence of Melamine and/or Melamine Analogs"



Import Operations



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U.S. Food and Drug Administration

Import Alert 99-30

[Import Program](#) > [Import Alerts](#) > [Import Alerts by Numbers](#) > [Import Alert](#)

(Note: This import alert represents the Agency's current guidance to FDA field personnel regarding the manufacturer(s) and/or products(s) at issue. It does not create or confer any rights for or on any person, and does not operate to bind FDA or the public).

Import Alert # 99-30

Published Date: 02/14/2012

Type: DWPE

Import Alert Name:

"Detention Without Physical Examination of All Milk Products, Milk Derived Ingredients and Finished Food Products Containing Milk from China Due to the Presence of Melamine and/or Melamine Analogs"



Import Operations



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U.S. Food and Drug Administration

Import Alert 99-31

[Import Program](#) > [Import Alerts](#) > [Import Alerts by Numbers](#) > [Import Alert](#)

(Note: This import alert represents the Agency's current guidance to FDA field personnel regarding the manufacturer(s) and/or products(s) at issue. It does not create or confer any rights for or on any person, and does not operate to bind FDA or the public).

Import Alert # 99-31

Published Date: 02/15/2012

Type: DWPE

Import Alert Name:

"Detention Without Physical Examination of Food Products Due to the Presence of Melamine and/or Melamine Analogs"

Import Operations

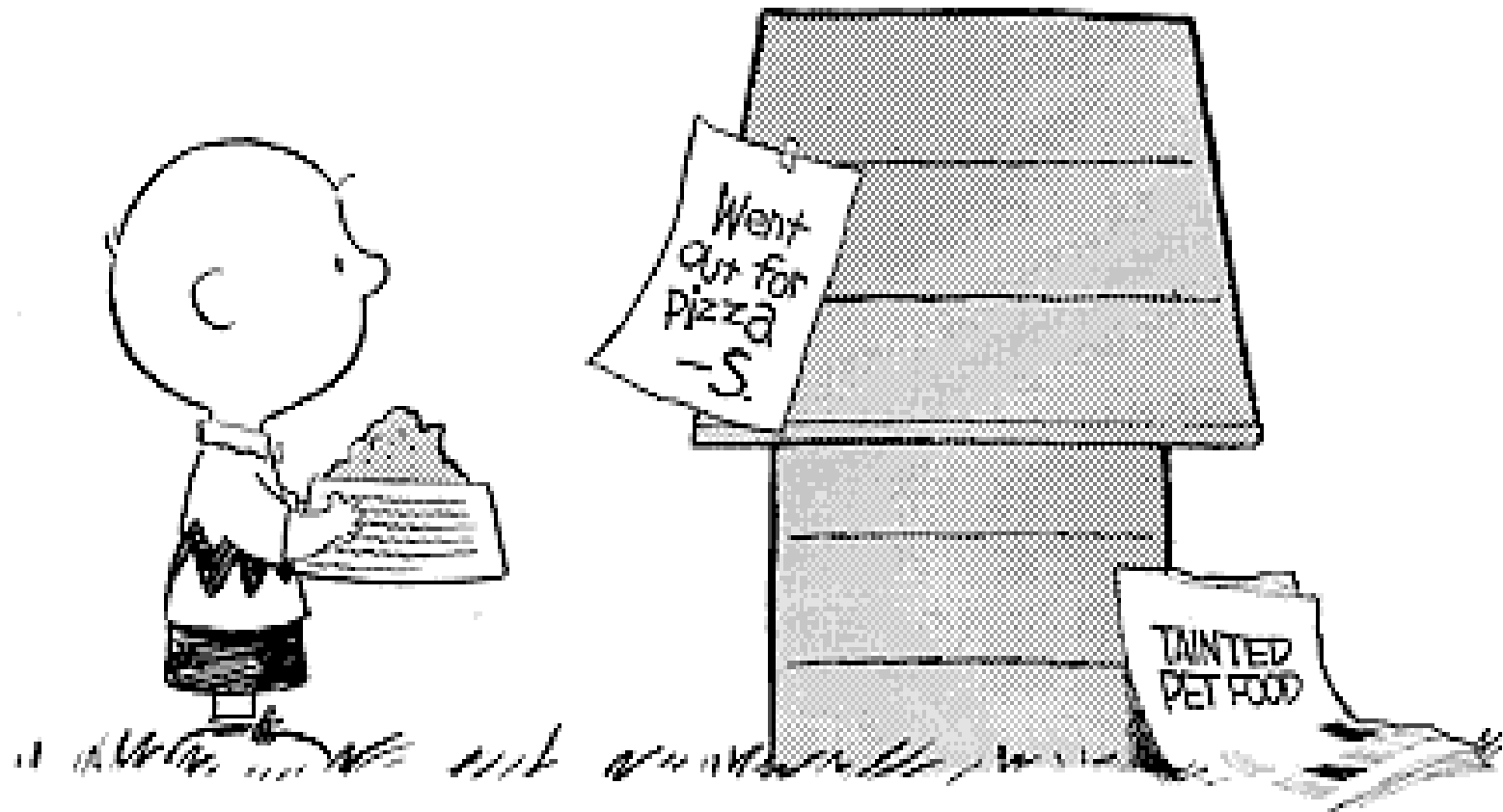
- Bioterrorism Act of 2002
 - Prior Notice
 - Registration
- Customs and Border Protection (CBP)
 - Assist with targeting shipments

Import Operations

- Foreign Inspection
 - Team sent to China
 - International Policy Specialist
 - Two Investigators



Communication and Collaboration



What is Risk Communication?

“An interactive process of exchange of information and opinion among individuals, groups and institutions.”

National Research Council (NRC)

FDA's Working Definition

- Multifaceted
 - Consumers
 - Industry
- Conveys the potential for bad and good outcomes
- Two-way street

Risk Communication

- Complex
- Multidisciplinary
- Multidimensional
- Evolving

Complexity

- Foreign production of FDA-regulated goods and materials has exploded over the last decade
- FDA-regulated products originate from more than 150 countries:
 - 130,000 importers
 - 300,000 foreign facilities

Globalization

- 24 million shipments arrive at >300 U.S. ports of entry annually
- Distinction between domestic and imported products is obsolete
- Global supply chain is complex



FDA's Charge

To Promote and Protect Public Health



Consumer Focused Risk Communication Goal

Promote changes in individual behavior



1. Has your pet food been recalled?
 - If pet shows symptoms, stop feeding the pet food and contact your veterinarian

2. If your pet food has been recalled:
- Do NOT feed to your animals
 - Return the pet food to the store where you purchased it for a refund



3. Report a reaction to a pet food

Communication and Collaboration

- Recalls/Complaints
- Press releases
- Media interviews
- Web site
- Off the hook! (14,000 calls in 4 weeks)



Communication and Collaboration

- Emergency Operations Center

Communication and Collaboration

Regulatory Partners

- 50 states and territories
 - Departments of Agriculture
 - Departments of Health

Communication and Collaboration

- Raised awareness with manufacturers
 - Know suppliers and safety of materials
- Encouraged manufacturers
 - Test materials



Communication and Collaboration

The Secretary of the HHS and the
Commissioner of FDA met with Chinese
officials

Communication and Collaboration

- USDA/FSIS
- CDC
- CBP
- EPA
- DHS
- Industry
- Academia

FDA's Efforts

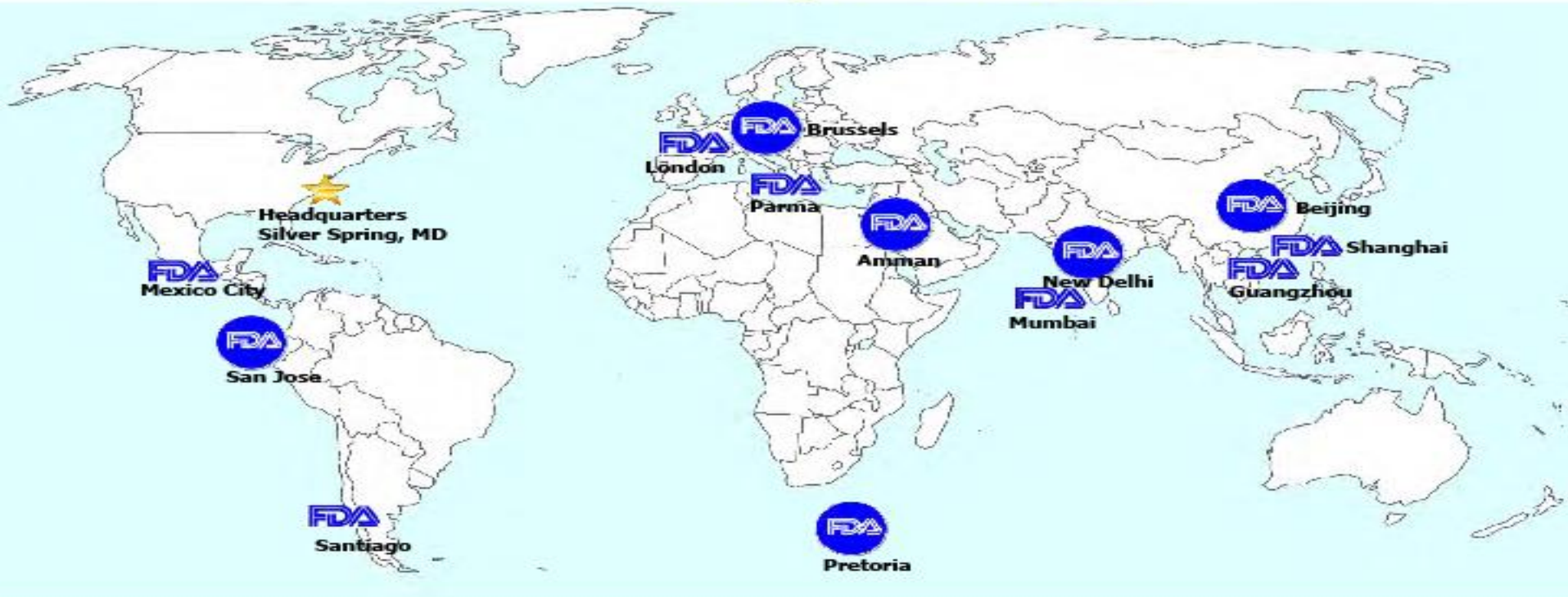
- FDA's Strategic Plan for Risk Communication
 - Fall, 2009
- Reportable Food Registry (FDAAA 2007)
 - Fall, 2009
- Establishment of foreign offices



Reportable Food Registry

- The Reportable Food Registry is an electronic portal for Industry to report **when there is reasonable probability that food or feed product will cause serious adverse health consequences.**
- Must report as soon as possible but no later than 24 hours

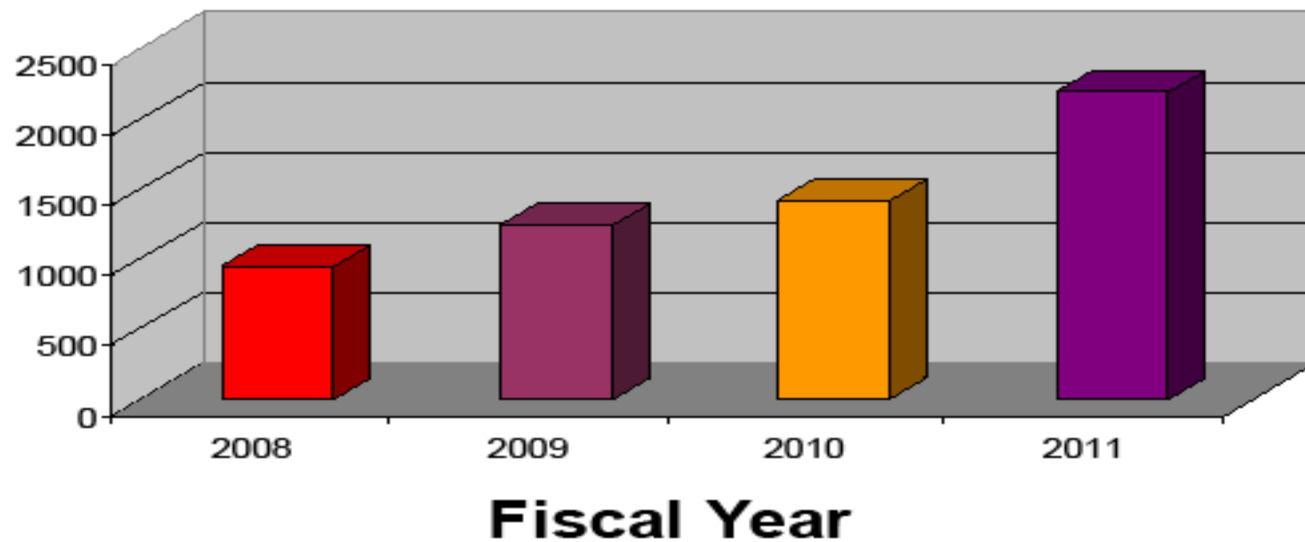
FDA Foreign Offices



FDA's Efforts

- Dedicated cadre of foreign inspectors
- Increased foreign Inspections

Foreign Inspections



FDA's Efforts

PREDICT, 2011

A risk based screening system



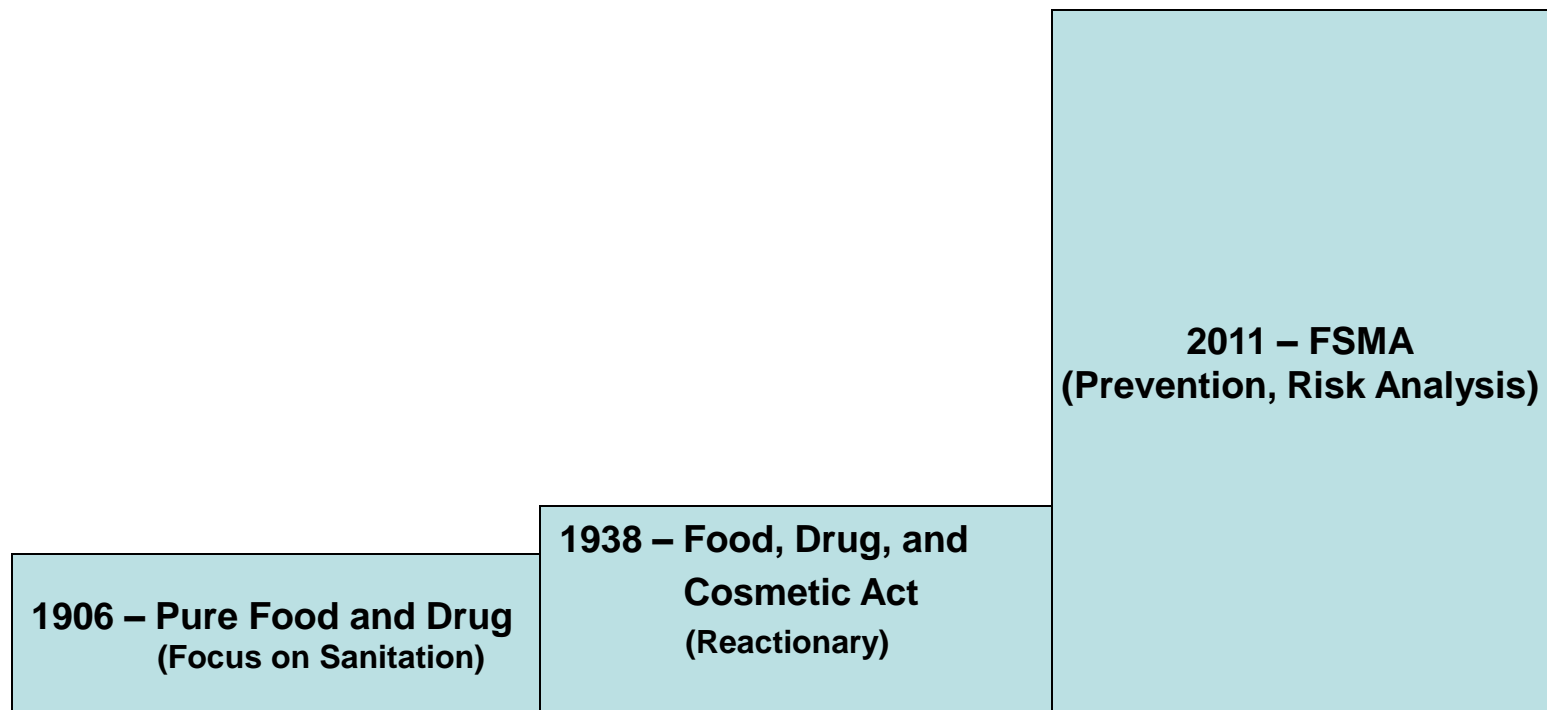
FDA's Efforts



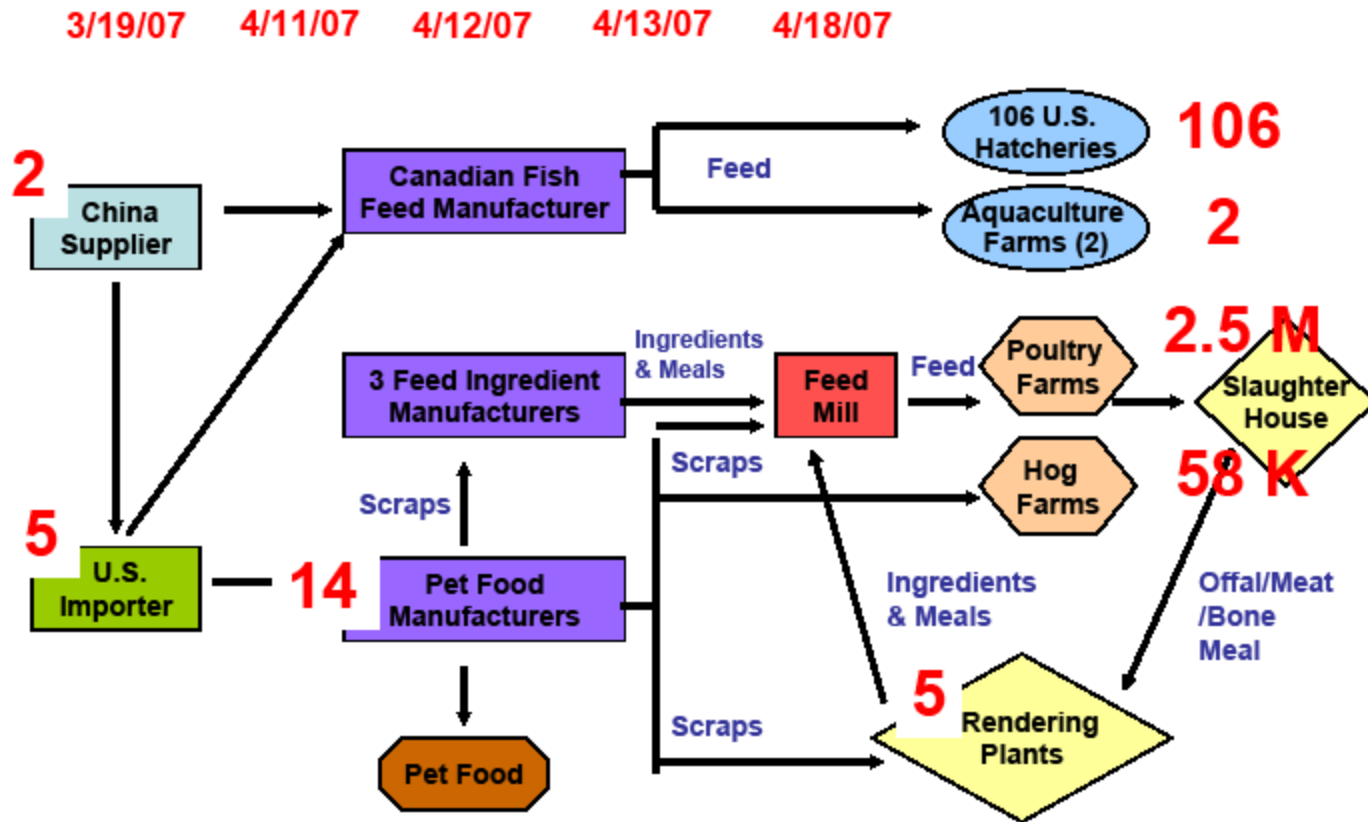
- Food Safety Modernization Act (FSMA)
- Effective Jan 4, 2011
- Biggest change since 1938



Food Safety Modernization Act



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



LARGEST RECALL – 18,700 calls in 11 weeks



QUESTIONS?

Thank you!