

The Expanding Risks of Importing and Producing Safe Products in a Global Economy



**Joe Reardon, Director
Food & Drug Protection**

Food Safety

Prevention

Leadership

Food

Intervention

Commitment

Protection

**Vital to Public Health
and the Economy**

Response

Resources

Food Defense

Today's Discussion

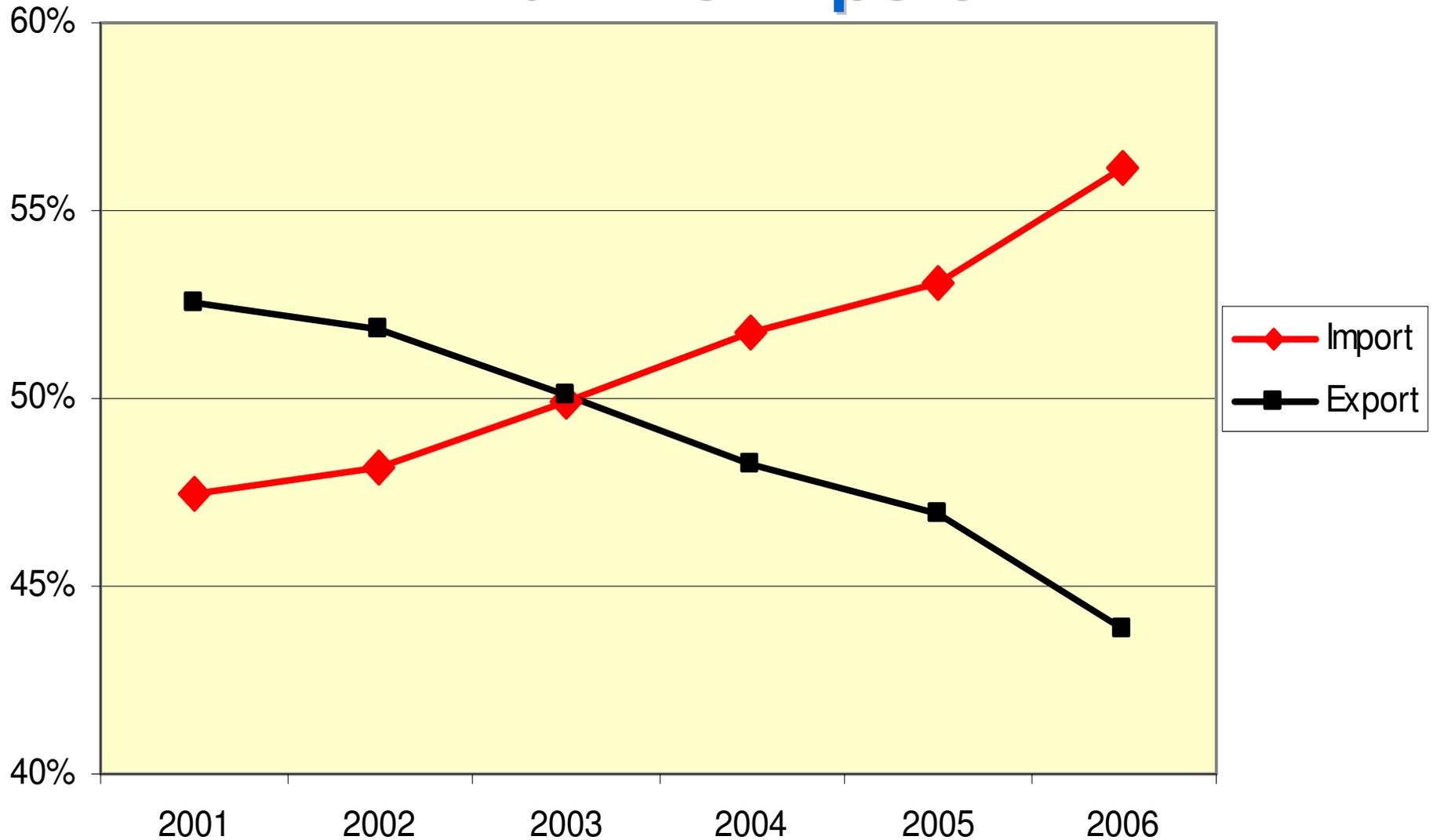
- Globalization of the Food Supply
- What is the Impact? Public Health & Economic
- Current Federal Initiatives
- Current State Initiatives

Where does our food come from?



**The US imported \$65.3 Billion of
food in 2006**

We Now Import More Food Than We Export



Source USDA, ERS (www.ers.usda.gov/publications/Agoutlook/AOTables/AOTables.htm)

Stats About the Farm to Fork Food Chain

■ Domestic

- +2 million farms
- 136,000 registered domestic food facilities
- 935,000 food service establishments

■ International

- 189,000 registered foreign facilities
- 384,000 food firms in China alone – only 12,000 registered

Source: FDA Food Protection Plan

**Food Safety Practices Are
Not Equivalent
Across the Globe**

The Top 10 Importers and Violators

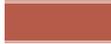
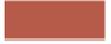
Country	\$Billion US Ag Imports
Canada	15.617
Mexico	9.844
China	4.184
Thailand	3.146
Italy	2.811
Indonesia	2.801
Chile	2.726
Australia	2.578
Brazil	2.367
Ireland	2.326

Country	FDA Import Refusals
Mexico	1,271
India	1,109
China	720
Dominican Republic	593
Vietnam	335
Indonesia	334
Japan	295
Italy	228
Thailand	218
U.K.	206

Sources: FDA Import Refusal Reports for OASIS and USDA, ERS

Food Refused at the Border

An analysis of food imports denied by the F.D.A. in the last year reveals the variety and extent of violations.

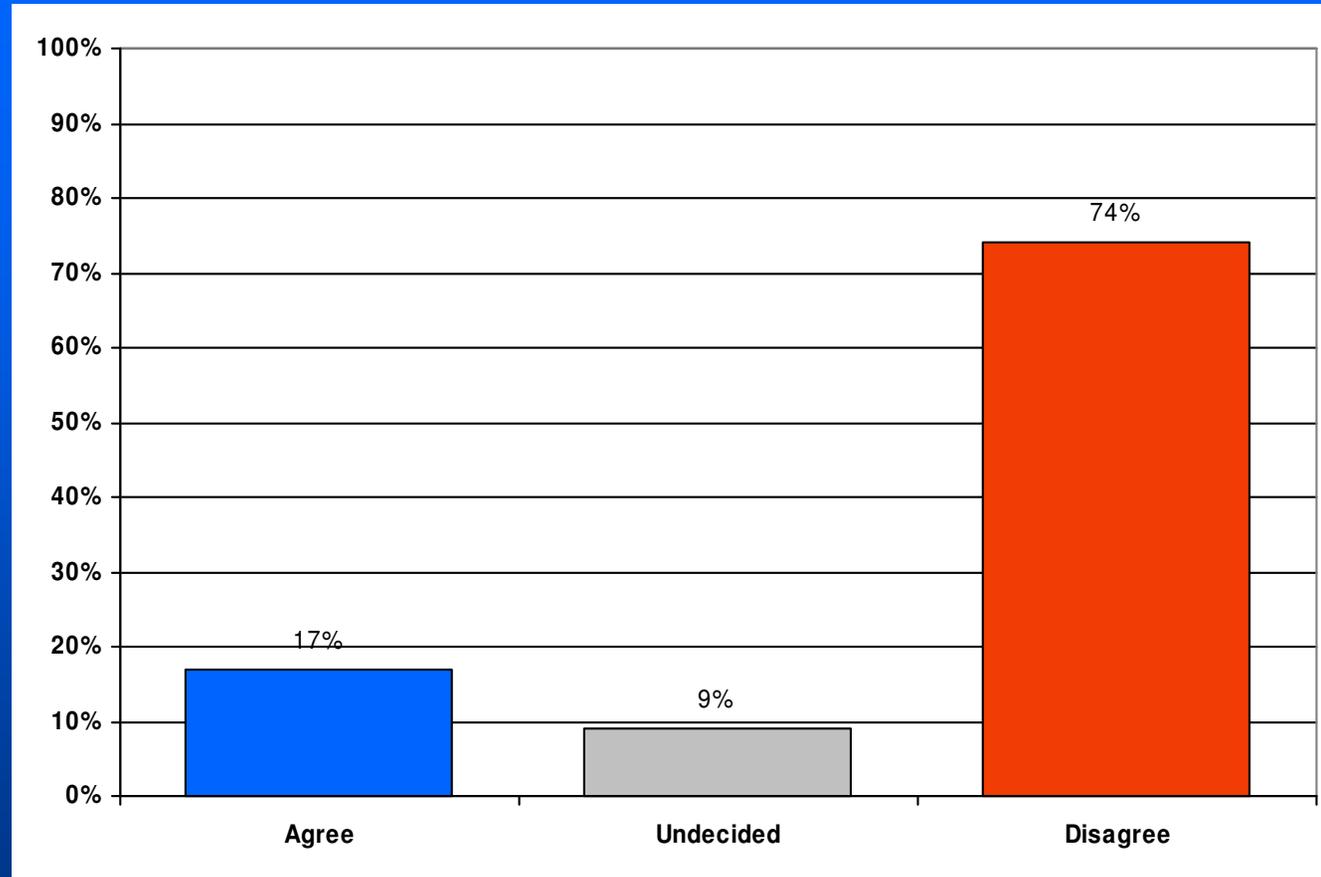
	Number of refused food shipments for selected countries <i>July '06 to June '07</i>		Most frequent food violation and counts <i>July '06 to June '07</i>		Total value of food imports <i>2006</i>
Mexico	1,235		Filth (mostly on candy, chilis, juice, seafood)	385	\$9.8 billion
India	1,187		Salmonella (spices, seeds, shrimp)	256	1.2
China*	899		Filth (produce, seafood, bean curd, noodles)	287	3.8
Dominican Republic	821		Pesticide (produce)	789	0.3
Vietnam	385		Salmonella (seafood, black pepper)	118	1.1
Indonesia	344		Filth (seafood, crackers, candy)	122	1.5
Japan	305		Missing documentation (drinks, soups, beans)	143	0.5
Italy	273		Missing documentation (beans, jarred foods)	138	2.9
Denmark	87		Problems with nutrition label (candy)	82	0.4

*Does not include Hong Kong

Sources: Food and Drug Administration; U.S. International Trade Commission

The Globalization of Food: How Americans Feel About It

Figure 1. If the U.S. could buy all its food from other countries cheaper than it can be produced and sold here, we should.



Source: Compiled by R.C. Wimberley from S-276 national 2001 survey data, item 3p, N = 819.

Source: <http://sasw.chass.ncsu.edu/global-food/foodglobal.html>

Import Trends of US Food Consumption

Selected items	1980	1990	2000	2005
	(Percentage)			
Lamb	9.5	10.2	36.6	39.8
Fish and Shellfish (Fresh & Frozen)	56.8	65.8	81.7	84.3
Fruits (Fresh and Frozen)	5.8	15.6	22.3	23.1
Tree Nuts	25.6	35.7	39.3	48.9
Vegetables (Fresh & Frozen)	5.9	9.6	14.0	16.0

Sources: Andy Jerardo, USDA, ERS (www.crs.usda.gov) and Michael Doyle, Center for Food Safety, UGA

Global Aquaculture

Fastest Growing Sector of Food Economy

- Aquaculture produces half of all seafood
- Asia accounts for 90% of aquaculture production
 - China largest producer in the world and third largest supplier to US
- Driving factors
 - Consumer demand
 - Growing population
 - Overfished fisheries



Aquaculture facility in Israel

Source: http://en.wikipedia.org/wiki/Fish_farming

Why is Global Aquaculture a Health Concern?

- **Four import alerts for seafood issued since 2001 for unsafe additives and/or unapproved animal drugs**
 - July 2007 most recent
 - Louisiana, Alabama, Mississippi banned catfish imports before import alert
- **Foreign aquaculture practices contribute to antibiotic usage**
 - Only 48% of Asia has access to sewage treatment
 - Overcrowded fisheries

Aquaculture Practices Make Antibiotic Use Necessary



Shrimp, Fish, and Poultry Production in Thailand
BBC News on January 27, 2004

NCDA & CS Announces Recall of Imported Fish from Vietnam for Unapproved Antibiotics July 2, 2007

- **Fluoroquinolone detected**
 - Risk-based retail survey program
 - Continuously updated – import alerts, recalls, consumer alerts, complaints



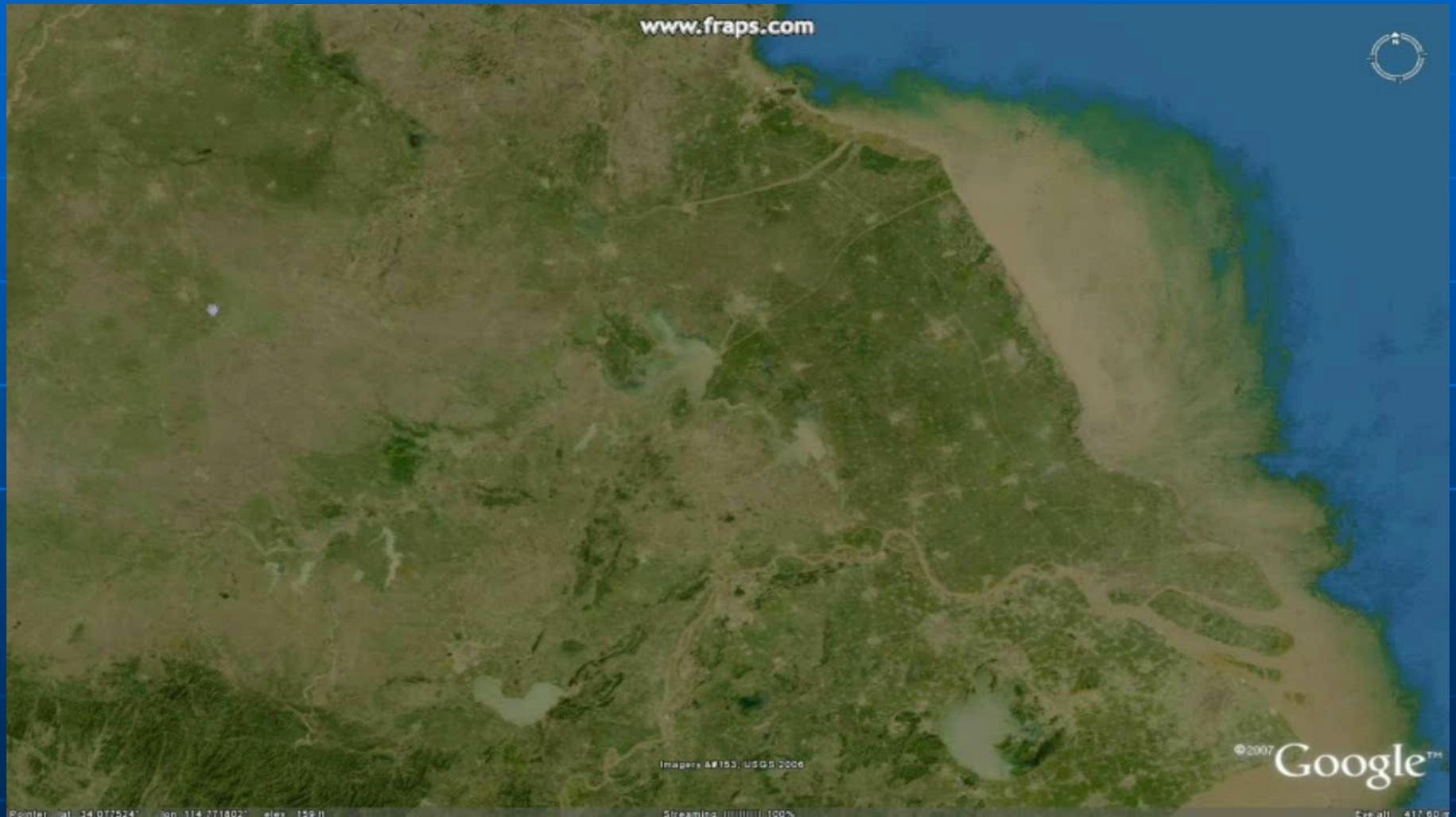
Public Health Impact

- Residues of the parent antibiotic or its metabolites detected in edible portion of fish
- Increase of antimicrobial resistance in human pathogens
- Prolonged exposure to nitrofurans, malachite green, and gentian violet has been shown to have a carcinogenic effect

Economic Impact

- **Domestic producers placed at economic disadvantage**
 - From 2000 to 2002, value of US shrimp harvest plunged more than 50%
 - US has becoming dumping grounds for seafood rejected by other countries
- **Result: In 2005, US Shrimp industry wins antidumping cases against 6 countries**

Today's Economy is Truly Global and Integrated



Inclusion of Melamine in Vegetable Proteins

- **Economic adulteration - Falsely increase the protein value vegetable glutens (or flours falsely labeled)**
 - **Common practice in China**
- **Binding agent in fish food in US**
- **Prior to 2007, believed to be non- or minimally toxic**

Traditional Uses of Melamine

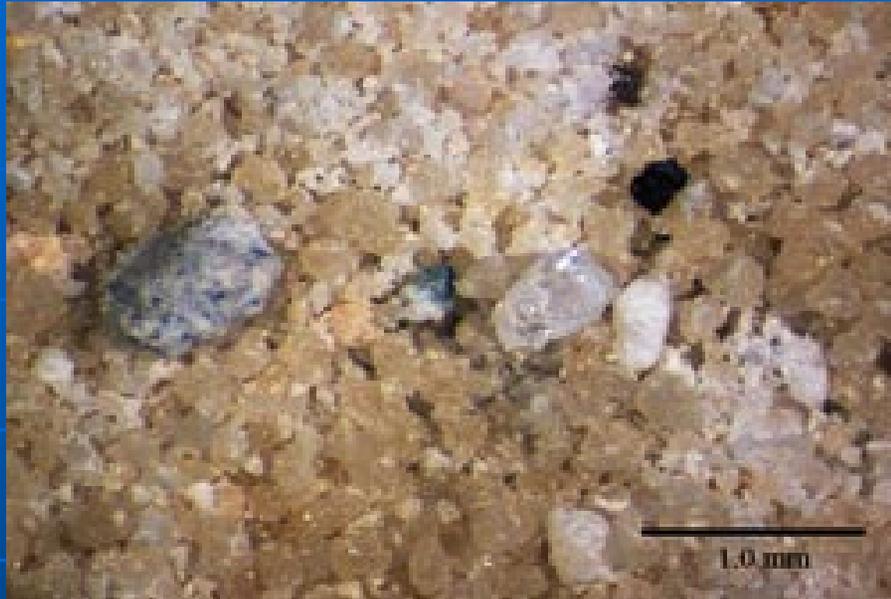
- Countertops, cookware, fabrics, glues, and flame retardants
- Major components in Pigment Yellow 150, a colorant in inks and plastics
- Used to make fertilizers due to high nitrogen content

Filler in Animal Feed Is Open Secret in China



Pieces of melamine displayed by a worker. The melamine is ground into a powder and added to animal feed as a filler to keep costs low.

Source: http://www.nytimes.com/2007/04/30/business/worldbusiness/30food.html?_r=1&oref=slogin



**Wheat gluten
contaminated with
melamine**



Normal wheat gluten

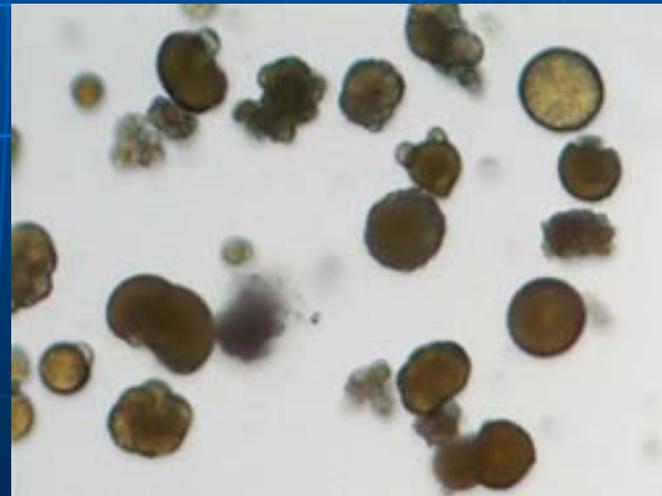
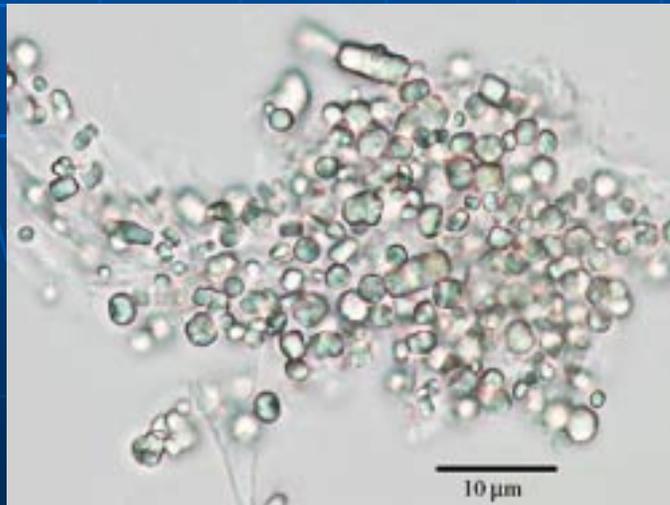
Cyanuric Acid

- *Another economic adulterant or an analogue of melamine?* Incomplete reactions during melamine production could lead to the formation of cyanuric acid and other analogues.
- However, according to chemical manufacturers...
“The substance is nontoxic — it’s legal to add it to animal feed,” Mr. Yu at Juancheng Ouya Chemical said of cyanuric acid. “The practice has been around for many years. I often sell it to animal feed makers.”

Source: <http://www.nytimes.com/2007/05/09/business/worldbusiness/09food.html>

Combination of Melamine & Cyanuric Acid

- Melamine/cyanuric acid crystals produced *in vitro*
- Melamine/cyanuric acid crystals in the urine of a cat



Melamine Timeline, 2007

Pet Health Perspective

Feb 20 — Menu Foods receives first report of food-related death

Feb 27 — Clinical reports revealed renal failure as cause of death
Menu Foods begins testing product and ingredients

Mar 8 — Wheat gluten suspected as issue. ChemNutra, supplier, quarantines inventory

Mar 16
to
May 17 — **Multiple Recalls Initiated for Pet Food**

Nearly 100 brands of 5,300 pet food products recalled

June 5 — Ornamental fish food (domestically produced) recalled — melamine used as a binder

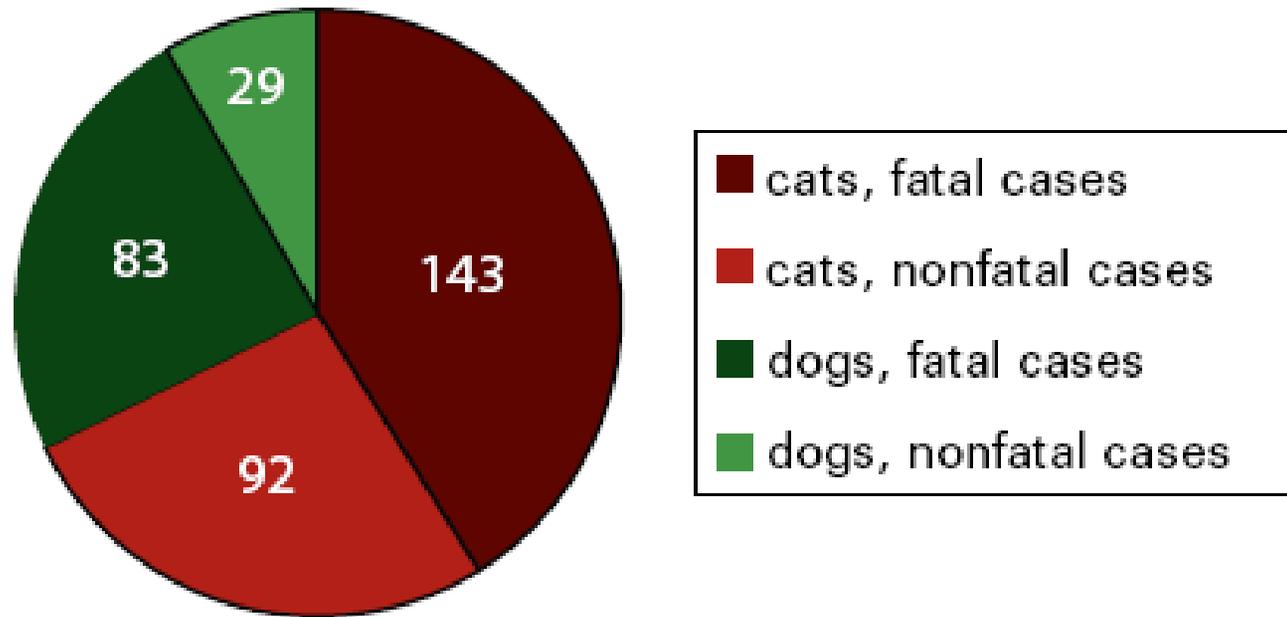
Impact to Consumer Confidence

- 60% of households have a pet, many of which are considered family members



- Amazon book sales sky rocketed for homemade pet food recipes
- Increased demand for organic pet food

AAVLD survey of pet food-induced nephrotoxicity
in North America, April to June 2007

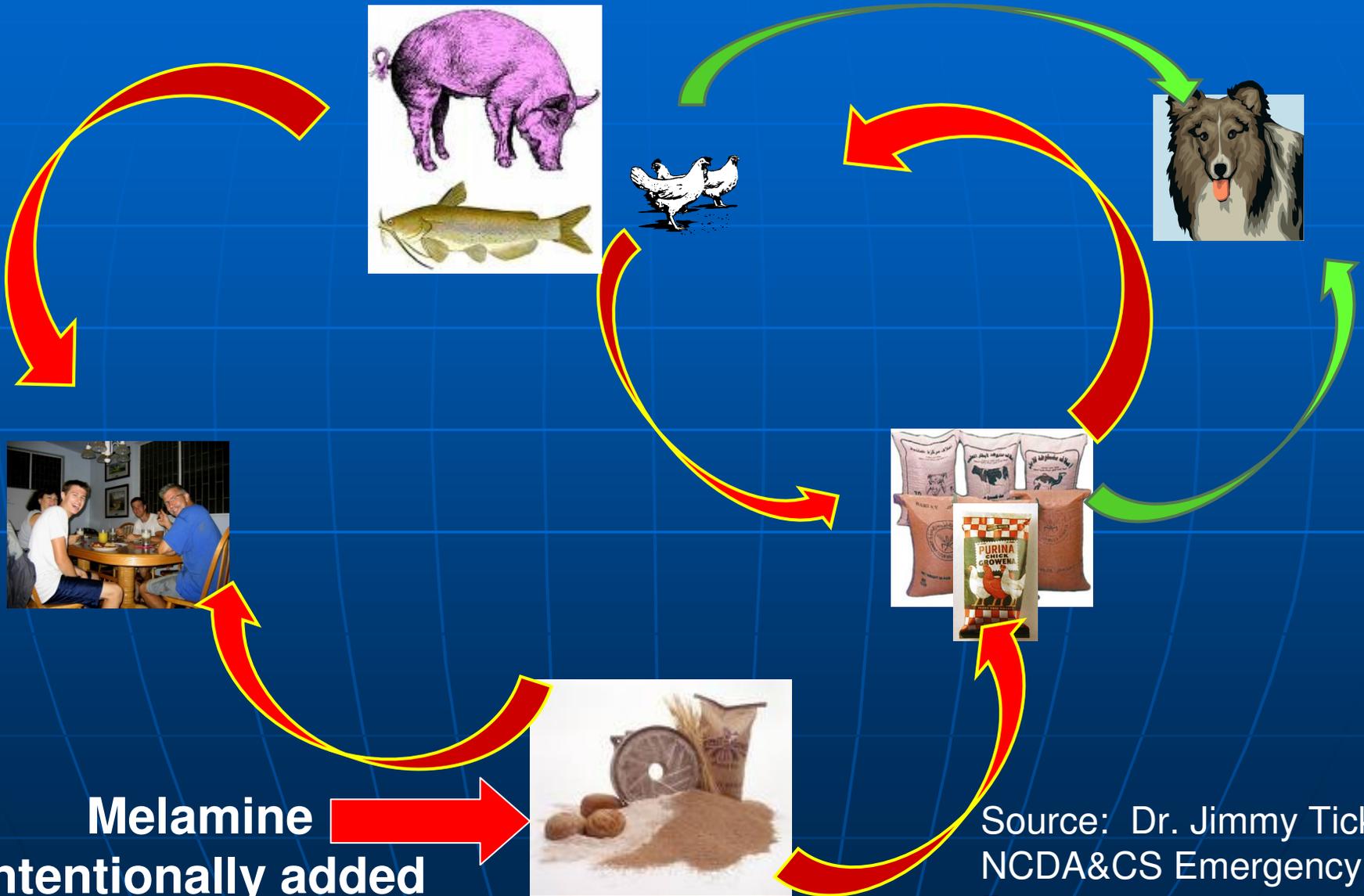


FDA received over 12,000 complaints in 3 weeks

No system to correlate pet deaths to food

Source: American Association of Veterinary Laboratory Diagnosticians (AAVLD)

It really is a small world.....and it's all connected



Melamine intentionally added

Source: Dr. Jimmy Tickel,
NCDA&CS Emergency
Programs

Melamine Timeline, 2007

Human Health Perspective

Apr 19	FDA investigates reports contaminated pet food fines had been used as an ingredient in hog feed in CA
Apr 26	6,000 hogs quarantined in CA, NY, NC , SC, UT, KS, OK, OH 345 hogs in the food chain already
May 1	Indiana reports poultry fed contaminated feed in food chain
May 8	Contaminated wheat flour used in fish feed used in US aquaculture and fish hatcheries
Apr 30	Chicken farms in Indiana also used the contaminated pet food
May 15	56,000 swine are cleared for processing after revised risk assessment by FDA and USDA
May 22	Melamine detected in catfish import from Asia – deemed not to pose public health risk

Human Health Perspective

A person weighing **132 pounds** would have to **eat 800+ pounds daily** of food containing melamine and its compounds to approach a level of health concern.

Economic Perspective

- Movement of feed grains halted at US – Canadian border = major supply problems for cattle farmers in Border States
- Loss of consumer confidence – is pork, poultry, or fish safe?
- NC hog producer
 - Forced to sell below market value
 - USDA indemnification very slow

Lessons Learned

- **ICS at the Federal level would have been extremely beneficial**
 - Complaint management
 - Ingredient and product testing
 - Necropsies
 - Communication
- **ICS provides the framework to effectively manage and force-multiply resources**



Domestic Food Safety Concerns



Public Health

- 435 illnesses in 44 states
- 20% of patients hospitalized

Economic

- Recall alone cost \$50-\$60 million
- Plant closed for 7 months
 - \$150 million annual revenue

Consumer Confidence

- To be determined

Public Health

- 3 deaths / 102 hospitalizations
- 31 cases of kidney failure by HUS
- 205 confirmed illnesses, 26 states

Economic

- Destroyed \$258.3 million industry

Consumer Confidence

- 50% of spinach consumers not eating spinach 6 months later

Austex Onion Hot Dog Chili Sauce, 10 oz can (UPC 3030097101)
Austex Hot Dog Chili Sauce, 10 oz can (UPC 3030099533)
Austex Beef Stew, 15 oz can (UPC 3030090815)
Austex Chili With Beans, 15 oz can (UPC 3030091015)
Austex Chili With Beans, 19 oz can (UPC 3030092519)
Austex Chili No Beans, 15 oz can (UPC 3030097715)
Austex Chili No Beans, 19 oz can (UPC 3030097719)
Best Yet Corned Beef Hash, 15 oz can (UPC 4217841082)
Best Yet Chili With Beans, 10 oz can (UPC 4217841082)
Big Y Chili No Beans, 15 oz can (UPC 1899480417)
Big Y Corned Beef Hash, 15 oz can (UPC 1899480425)
Big Y Chili With Beans, 15 oz can (UPC 1889480425)
Black Rock Chili With Beans, 15 oz can (UPC 3030001715)
Bloom Hot Dog Chili Sauce, 10 oz can (UPC 2543992448)
Bryan Hot Dog Chili Sauce With Beans, 10 oz can (UPC 5340030010)
Bryan Corned Beef Hash, 15 oz can (UPC 5340030010)
Bryan Chili No Beans, 15 oz can (UPC 5340030020)
Bryan Chili With Beans, 15 oz can (UPC 5340030205)
Bryan Chili No Beans, 10 oz can (UPC 5340035264)
Bunker Hill Hot Dog Chili Sauce, 10 oz can (UPC 7526604152)
Bunker Hill Chili No Beans, 10 oz can (UPC 7526604152)
Bunker Hill Spicier Chili No Beans, 10 oz can (UPC 7526604152)
Castleberry's Hot Dog Chili Sauce, 10 oz can (UPC 3030007101)
Castleberry's Brunswick Stew Chicken & Beef, 15 oz can (UPC 3030000315)
Castleberry's Barbecue Pork, 10 oz can (UPC 3030000915)
Castleberry's Barbecue Pork, 14.5 oz can (UPC 3030000915)
Castleberry's Barbecue Beef, 10 oz can (UPC 3030000915)
Castleberry's Beef Stew, 15 oz can (UPC 3030000815)
Castleberry's Corned Beef Hash, 15 oz can (UPC 3030000915)
Castleberry's Chili With Beans, 15 oz can (UPC 3030001015)
Castleberry's Sausage Gravy, 10 oz can (UPC 3030000915)
Castleberry's Sausage Gravy, 10 oz can (UPC 3030000915)
Castleberry's Hot Chili With Beans, 15 oz can (UPC 3030000915)
Castleberry's Chili No Beans, 10 oz can (UPC 3030007701)
Castleberry's Chili No Beans, 15 oz can (UPC 3030007715)
Castleberry's Georgia Peach Chicken & Beef Stew, 15 oz can (UPC 3030000915)
Cattle Drive Beef Stew, 15 oz can (UPC 3030000915)
Cattle Drive Chili No Beans, 15 oz can (UPC 3030001520)
Cattle Drive Chicken Chili With Beans, 15 oz can (UPC 3030001525)
Cattle Drive Chili With Beans, 15 oz can (UPC 3030001515)
Firefighters Chicken Chili With Beans, 15 oz can (UPC 7372500413)
Food Club Corned Beef Hash, 15 oz can (UPC 3680080204)

Food Club Chili No Beans, 15 oz can (UPC 3680080404)
Food Club Chili With Beans, 15 oz can (UPC 3680080504)
Food Lion Hot Dog Chili Sauce, 10 oz can (UPC 3582606911)
Goldstar Original Chili, 10oz can (UPC 2457500001)
Goldstar Chili, 15oz can (UPC 2457500005)
Goldstar Tex-Mex Chili With Beans, 15 oz can (UPC 2457500008)
Great Value Chili With Beans, 15 oz can (UPC 8113179994) – CANADA ONLY
Great Value Hot Chili With Beans, 15 oz can (UPC 8113179995) – CANADA ONLY
Kroger Hot Dog Chili Sauce, 10 oz can (UPC 1111083930)
Kroger Beef Stew, 15oz can (UPC 1111083920)
Kroger Chili With Beans, 15 oz can (UPC 1111083930)
Kroger Chili No Beans, 15 oz can (UPC 1111083908)
Lowe's Foods Chili No Beans, 15 oz can (UPC 4164301092)
Lowe's Foods Corned Beef Hash, 15 oz can (UPC 4164301092)
Lowe's Foods Chili With Beans, 15 oz can (UPC 4164301092)
Meijer Hot Dog Chili Sauce, 10 oz can (UPC 4125095221)
Meijer Chili No Beans, 15 oz can (UPC 4125095220)
Meijer Chili With Beans, 15 oz can (UPC 4125095221)
Meijer Corned Beef Hash, 15 oz can (UPC 4125095229)
Morton House Chili With Beans, 15 oz can (UPC 7526665829)
Morton House Corned Beef Hash, 15 oz can (UPC 7526665830)
Morton House Chili With Beans, 15 oz can (UPC 7526665993)
Paramount Hot Dog Chili Sauce, 10 oz can (UPC 7526600510)
Paramount Chili for Hot Dogs, 15 oz can (UPC 7526600526)
Paramount Chili No Beans, 15 oz can (UPC 7526600731)
Paramount Chili With Beans, 15 oz can (UPC 7526600732)
Piggly Wiggly Chili With Beans, 15 oz can (UPC 4129037252)
Piggly Wiggly Chili No Beans, 15 oz can (UPC 4129037354)
Piggly Wiggly Chili No Beans, 10 oz can (UPC 4129037355)
Piggly Wiggly Corned Beef Hash, 15 oz can (UPC 4129037357)
Prudence Corned Beef Hash, 15 oz can (UPC 4114100015)
Southern Home Chili No Beans, 10 oz can (UPC 1825947713)
Southern Home Chili With Beans, 15 oz can (UPC 1825947713)
Southern Home Corned Beef Hash, 15 oz can (UPC 1825947713)
Southern Home Chili With Beans, 15 oz can (UPC 1825947713)
Southern Home Corned Beef Hash, 15 oz can (UPC 0788015359)
Steak n Shake Chili With Beans, 10 oz can (UPC 5184400720)
Triple Bar Ranch Chili With Beans, 15 oz can (UPC 3030005801)
Triple Bar Ranch Chili With Beans, 15 oz can (UPC 3030005804)
Triple Bar Ranch Chili No Beans, 15 oz can (UPC 3030005805)
Value Time Beef and Chicken Chili With Beans, 15 oz can (UPC 1122542159)

The Castleberry Recall

Over 90 Different Food Products

27 Different Brands

Millions of Cans

One of the largest recalls related to botulism in canned products



By using ICS, North Carolina coordinated the efforts of 1,000+ personnel statewide in 3 State agencies and 86 local agencies

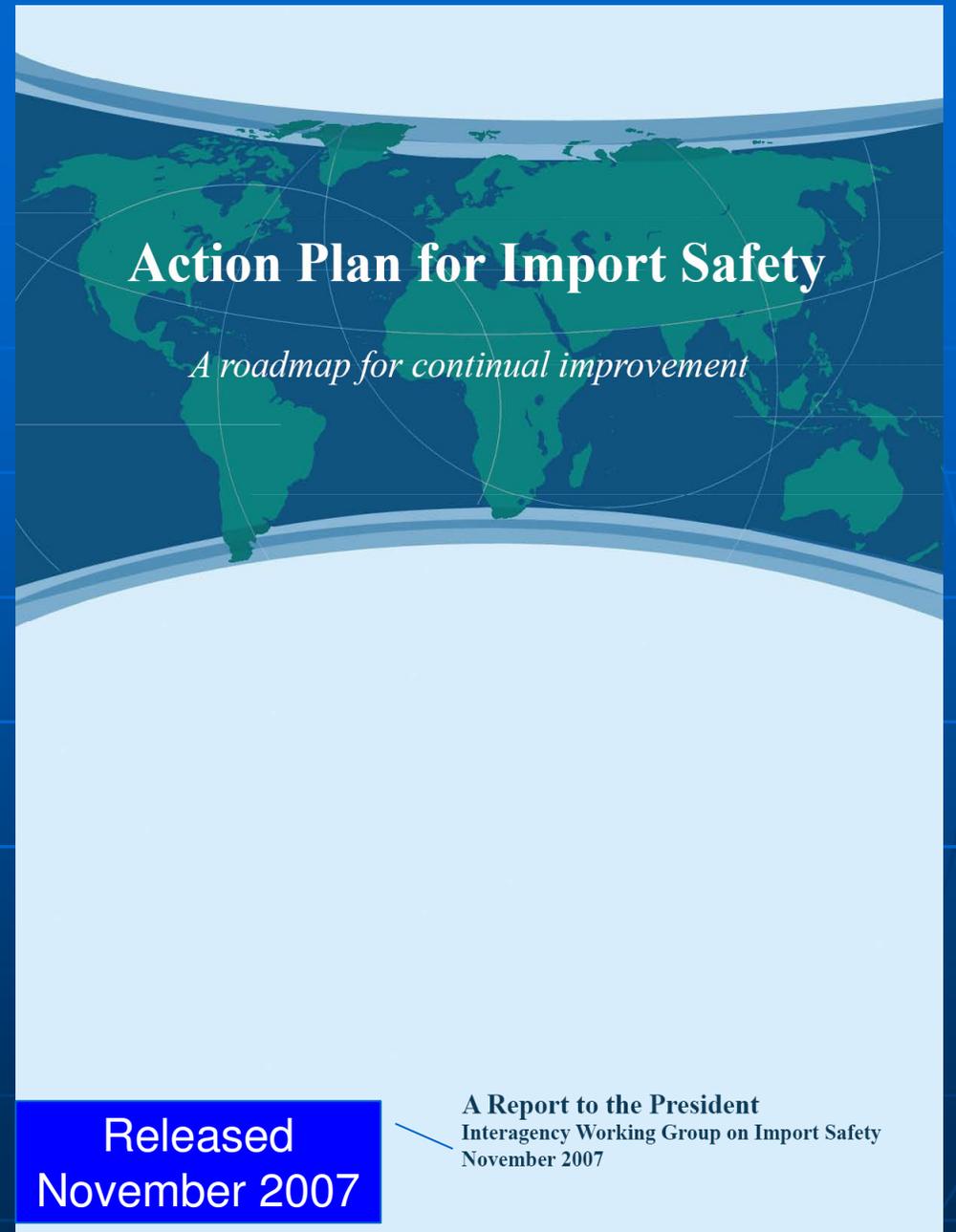
	NC	USDA-FSIS	FDA
Sites visited	~16,000	~800	12,989
Cans removed	~35,000		13,000

Current Federal Initiatives

Global Safety Concerns Are Not Limited to Food

“The sheer magnitude of the import-export enterprise makes clear that our Nation cannot inspect its way to safety. Last year, the United States imported nearly \$2 trillion of goods through more than 825,000 importers. Experts project that the value of imports will triple by 2015.”

•Highlights include a stronger certification process, increase information exchange globally, increase US presence overseas, enhance standards, and strengthen penalties



Action Plan for Import Safety

A roadmap for continual improvement

Released
November 2007

A Report to the President
Interagency Working Group on Import Safety
November 2007

• Prevention

- Risk-based analysis of imported foods
- Improve FDA's presence overseas

• Intervention

- Risk-based testing for food and feed
- Collaborate with foreign authorities

• Response

- Enhance communications
- Rapid traceback abilities



Department of Health and Human Services
U.S. Food and Drug Administration

Food Protection Plan

An integrated strategy for protecting the nation's food supply

NOVEMBER 2007

Released
November 2007

PREVENTION · INTERVENTION · RESPONSE

Proposed Legislation

- **National Agriculture and Food Defense Act of 2007**
 - U.S. Senators Richard Burr (R-North Carolina) and Susan Collins (R-Maine)
- **Foreign Seafood Safety Act of 2007 H. R. 3077**
 - Congressman Walter Jones (R-North Carolina)

Current State Initiatives

**Standardization, Uniformity, &
Communications**

State and local programs performed more than 80% of the food safety and defense work in the United States

- 90% of inspections conducted in FDA regulated facilities, 2.5 million inspections
- Respond to 28,000 food emergencies
- Analyze 328,000 food samples
- Investigate 3,000 foodborne outbreaks
- Respond to 46,000 consumer complaints

Standardization of State Regulatory Programs

- **Manufactured Food Regulatory Program Standards by FDA and AFDO**
 - Increase regulatory oversight and decrease the risk of a food emergency
 - Risk based inspections
 - NC is one of 5 pilot states
- **FoodSHIELD – Communications platform**

Standardization of State Laboratory Programs

- **ISO 17025 Accreditation**
 - Federal and International partners can accept data with confidence
 - Cornerstone of prevention, detection and response
 - Initiative of NCDA&CS Food & Drug Protection
- **Exponentially increase nation's laboratory *capability & capacity***

The Federal government may build the glove used to protect the food supply, but State and Local programs will be the fingers in the glove if we are to be successful.