Food Safety

Who does What, and What needs Changed

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Leading Change
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• FIRST, you must create a “sense of urgency”
• $500,000,000 for O157 might do that, or
• 76,000,000 food borne illnesses might do that, or
• Food Borne Illnesses cost America $154 Billion per year might do that, or
• 2.2 million pounds of Ground Beef, 550 million eggs or 150 million pounds of beef recalled, just might do that
Just The “Facts”, Ma’am

- 76,000,000 Illnesses last year
- 325,000 Hospitalizations last year
- 5,000 Deaths last year
- Say What ???????

Source: Food Related Illness and Death in the U.S., CDC
More “Facts”

• Known pathogens account for:
  A. 14,000,000 illnesses
  B. 60,000 hospitalizations, and
  C. 1,800 deaths each year

• Listeria monocytogenes, Salmonella and Toxoplasma account for 1,500 of the deaths each year

• Unknown agents account for the remaining 62 million illnesses and 3,200 deaths (?)

• Source: “Emerging Infectious Diseases” Vol 5 No 5 Sept-Oct 1999 Mead et al
Estimated Numbers of FBI by Bug by Year

- *Campylobacter* 2,000,000
- *E. coli 0157:H7* 62,000
- *E. coli non-0157 STEC* 31,000
- *Listeria Monocytogenes* 2,500
- *Salmonella* 1,340,000

- **Total** 3,435,500
Estimated Numbers of FBI by Bug per Year

• 14 million minus 3.5 million?

• What causes the other 10.5 million FBIs by “known” pathogens?

• Norwalk-like Viruses
The Real Facts

• 1999 report based on 1983-1997 data
• Bacterial infections have decreased significantly since then (next page)
• Added Norwalk virus, and assumed that 40% (52 million) were food borne (30% would decrease the 76 Million to 63 Million)
• May include petting zoos, turtles, person-to-person, drinking water and mountain streams
• FoodNet is comprised of 10 regions, 15% of the population
• According to the CDC, in its “Preliminary FoodNet Data on the Incidence of Infections with Pathogens Transmitted Commonly Though Food---10 States, 2009” as reported in its Morbidity and Mortality Weekly Review (MMWR) April 16, 2010:

“In 2009, a total of 17,468 laboratory confirmed cases of infection were identified.”
Food Borne Illness Rate Declines 2009 compared to 1996-1998

- *Shigella*, down 55%
- *Listeria*, down 26%
- *Campylobacter*, down 30%
- *E coli* O157:H7, down 41%
- *Yersinia*, down 53%
- *Salmonella*, down 10%

Source: MMWR, April 16, 2010/ 59(14); 418-422
• For illness rates, CDC used a multiplier of 38 or 20 for non-bloody and bloody diarrhea agents.

• For deaths and hospitalizations, doubled the number of admissions and deaths and then multiplied this figure by the proportion of infections attributable to foodborne transmission.

• “Like illnesses and hospitalizations, deaths are also underreported.”

Source: CDC’s “Emerging Infectious Diseases” Vol 5, No 5, Sept-Oct 1999
E. coli 0157:H7 example

• Why E coli for the example? 500,000,000 reasons why
• CDC estimates 73,000 illnesses, 2,000 hospitalizations and 60 deaths per year based on data from 1982-1997
• In 1996 there were 2.5 persons ill with 0157 per 100,000
• In 2009 there were 0.99 persons ill with 0157 per 100,000
E. coli 0157 example

- The reduction in known illnesses from 0157 is 60%
- The new estimates (not accounting for population increase from 1996) would be:
  ---29,000 illnesses
  ---800 hospitalizations, and
  ---24 deaths
Gastrointestinal Illnesses in 1997

- Bacterial-13%
- Parasitic-7%
  - Giardia
- Viral-80%
  - Norwalk
  - Hepatitis A
- 33% Foodborne
All Gastrointestinal Illnesses in 1997

- Bacterial 13%
- Parasitic 7%
- Viral 80%
- Foodborne GI Illnesses in 1997 (33% of all Gastrointestinal illnesses)
  30% Bacterial
  3% parasitic
  67% viral
E coli Outbreaks 1982-2002
All Causes

- Foodborne  61%
- Drinking Water  15%
- Unknown  9%
- Person to person  8%
- Animal contact  4%
- Recreational Water  3%
E. Coli 0157:H7
Foodborne Outbreaks 1982-2002

• Produce 34%
• Ground Beef 33%
• Other Beef 11%
• Dairy 6%
• Other 4%
• Unknown 12%
• (Until 1990, all E coli outbreaks were associated with GB, this decade it is 25%)

• Source: Tauxe PP for E coli conference 04/09/08
E. Coli Beef recalls and Illness Data

- 2002: 21 recalls, 2 with reported illness
- 2003: 12 recalls, 5 with reported illness
- 2004: 6 recalls, 3 with reported illness
- 2005: 5 recalls, 4 with reported illness
- 2006: 8 recalls, 0 with reported illness
- 2007: 21 recalls, 10 with reported illness
- 2008: 13 recalls, 5 with reported illness
E. Coli Beef Recalls and Illness data

• 2009: 15 recalls, 4 with reported illness
• 2010: 11 recalls, 4 with reported illness (Jan 1-Oct 10)
• DeLauro: “We have seen the E. coli incidence go down in the past only to rise the next year”
• AMI: We have seen the numbers go up before, we know they will go back down.
• No Tracebacks, a plaintiff’s lawyer’s dream
E. coli Recall Trend Changes since 2007

- Trim recalls (3)
- Imported trim recalls (5)
- Bison meat recalls (Hastings NE)
- Most importantly, recalls are being seen for steaks, boxed beef, boneless beef and primals (10)
- The above changes are 18 recalls out of 39. Only 21 recalls for ground beef, before was nearly 100 % (7/year)
E coli recall trend changes

- 2006
  Spinach with 205 ill and 5 deaths
  Taco Bell with 71 cases linked to lettuce, not Ground Beef

- 2009
  Cookie Dough
  Tenderized Steaks
  Salmonella beef recall of 1.3 million pounds was bigger than all beef E coli recalls combined
E coli recall trend changes

• Since 1995, there have been 20 E coli O157 outbreaks tied to salad greens.
E coli 0157:H7 little known facts

• Cases per 100,000 population
  Urban 0.5
  Suburban 0.8
  Semi-rural 1.5
  Rural 2.0

• So much for “Know your Farmer, Know your Food”

• Source: Tauxe PP for E coli conference 04/09/08
More Little Known E coli Facts

- Northern tier states from Minnesota-Iowa west to Oregon-Wash have the highest rates of illness at 3.0-6.2 per 100,000

- Southern tier states from California to Florida have the lowest rates of illness at 0.2-0.8 per 100,000
Who Handles What?

Source: United States Department of Agriculture Food Safety and Inspection Service
“The Food Safety and Inspection Service (FSIS) is the public health agency in the US Department of Agriculture responsible for ensuring that the nation’s commercial supply of meat, poultry and egg products is safe, wholesome and correctly labeled and packaged, as required by the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act.” (Emphasis added)

US Department of Agriculture’s FSIS Mission Statement on web home page
Statutory Authority

• FSIS performs its food safety, public health and food defense activities under four main acts:
  – The Federal Meat Inspection Act of 1906
  – The Poultry Products Inspection Act of 1957
  – The Egg Products Inspection Act of 1970
  – The Humane Methods of Slaughter Act of 1958

• Additional Statutes
  – 1906 Pure Food and Drug Act
  – 1938 Federal Food, Drug and Cosmetics Act replaces the 1906 statute
  – Agricultural Marketing Act 1946
FSIS History

• President Lincoln founded the USDA
• 1870s, refrigerated RR cars and later electricity allowed meat packing to be centralized and operate year round
• 1884 Pres. Arthur established the Bureau of Animal Industry (BAI), the forerunner to the FSIS, and moved animal quarantine stations from the Treasury to BAI. Purpose was to keep meat from diseased animals from becoming food
FSIS History

- 1890. Initial Meat Inspection Act was for exported meats (salted pork and bacon) only
- 1891 MIA expanded for all exported meat
- 1906 FMIA and Food, Drug and Cosmetic Act
- Bureau of Chemistry (USDA)=FDCA
- BAI=FMIA
- Post WWII. Refrigerated trucks and competition, plants move to rural areas
FSIS History

• 1953. BAI and Bureau of Dairy abolished and moved to Agriculture Research Service (ARS)
• 1957. PPIA
• Animal disease as a food safety issue decreasing in the 50s and 60s, but large scale processing increasing.
• 1958. Food Additive Amendment to the 1906 Food Drug and Cosmetic Act to deal with added ingredients and animal drug residues
FSIS History

• 1968 saw the merging of the Poultry and Meat Inspection Systems into one program located with the Consumer and Marketing Service still in ARS
• 1972 Name changed again and merged with the Animal and Plant Health Inspection Service (APHIS)
• 1977 Food Safety and Quality Service
• 1981 Food Safety and Inspection Service (FSIS)
FSIS History

• 1993  Jack in the Box
• Science based evolving from organoleptic inspection
• 1996 Pathogen Reduction/ Hazard Analysis and Critical Control Point (HACCP) Systems rule released
• PulseNet and FoodNet
FDA History

• 1906 Food and Drug Act enforced by the Bureau of Chemistry within the USDA
• 1927 Bureau of Chemistry became the Food, Drug and Insecticide Administration
• FDIA became the Food and Drug Administration (FDA) in 1931 (still in USDA)
• FDA was transferred to the Federal Security Agency in 1940, which became the Dept of Health, Education and Welfare in 1953 (Now Health and Human Services)
USDA or FDA???

• Sandwiches:
  – Open faced vs. Closed?

• Pizza:
  – Pepperoni vs. Anchovy vs. Veggie?

• Fish:
  – Catfish vs. Salmon?
USDA or FDA?

- EGGS
- L. monocytogenes at the Deli counter
- Casings
- Retorts inspection and canning regulation
- Spices and flavoring with meat or poultry base
- Baby food
- Chicken Noodle vs Split Pea soup
- Corn dogs vs bagel dogs
USDA or FDA?

• Pet food—Melamine---Animal Feed
• Animal Feed (Chicken Litter?) (Probiotics)
• Animal Vaccines (FSIS or FDA?)
• Phages, rinses, etc. Food additive (FDA) or processing aid (USDA)?
• Lactic Acid rinse vs Bromide rinse or chlorine soak
• Whole carcass, low dose irradiation. Is it a processing aid (FSIS) or an additive (FDA)?
In 1997...

- *Salmonella* meant Poultry
- *E. coli O157:H7* meant Ground Beef
- *Listeria* meant Hot Dogs and Deli Meat
Now, thanks to PulseNet

- **2007 Salmonella Outbreaks**
  - Veggie Pockets
  - Frozen Pot Pies
  - Peanut Butter
  - Turtles
- **E. coli O157:H7**
  - Spinach
- **2008-2009**
  - Lettuce, Cantaloupes, Jalapenos peppers, Tomatoes, more peanut butter, cookie dough, sprouts
And 2010

- Eggs, eggs and more eggs
- Milk, milk, and more milk
- More Sprouts and Cantaloupes
- Black pepper and chicken soup
- And many, many more
Now, thanks to PulseNet

- 2006  200 food recalls
- 2007  350 food recalls
- 2008  400 food recalls
- 2009  500 food recalls, and as of Sept 1,
- 2010  689 food recalls

- Are we getting better at what we do, or is this getting closer to a “sense of urgency”?
Results of Broiler Carcasses Analyzed for *Salmonella* from 2001 to 2005

Percentage of Positive Regulatory Samples

Source: United States Department of Agriculture Food Safety and Inspection Service
Results of Broiler Carcasses Analyzed for *Salmonella* from 2005 to 2007

Percentage of Positive Regulatory Samples

- 2005: 16%
- 2006: 11%
- 2007: 6%
Results of Broiler Carcasses Analyzed for Salmonella 2008-2009

- **2008** 7.9% total positive, but:
  - Large: 5.9% positive
  - Small: 10.0% positive
  - Very Small: 27.6% positive
- **2009** 7.1% positive, but:
  - Large: 5.0% positive
  - Small: 11.0% positive
  - Very Small: 21.0% positive

- Know your Farmer, Know your Food?
- Bigger isn’t always Badder
Next steps for Salmonella in Poultry?

- Parts is Parts, and they aren’t tested
- Salmonella remains the number one foodborne illness, occurring at a rate of app. 16 illnesses per 100,000 population which is 2 ½ times the Healthy People 2010 goal
- Vaccines, Phages, and Rinses
- Air Chillers
- HSUS/PETA
- 1.6 seconds
Outbreaks in 2009

• *E. coli*:
  – 25.7% of infections were associated with outbreaks (was 15%)

• *Salmonella*:
  – 7.4% of infections were associated with outbreaks

• More Testing
• Better Testing
• More Consumer Awareness

Source: MMWR April 10, 2009 / 58(13):333-337
Foodborne Disease Surveillance in the United States

- **PulseNet**
  - Laboratory network that performs microbial sub-typing
  - Spinach Outbreak

- **FoodNet**
  - Active surveillance
  - Non O157 STEC’s
  - Variances region to region
USDA/FSIS Headlines created a sense of urgency

- Hallmark --- video monitoring, retail
- Topps Recall --- New computer system, increased inspection with change in ownership, trim testing at the borders
- Increase in positive product testing --- Vaccines released for phase III testing
- Bird Flu and one temp
FSIS, Who are They and What are Their Responsibilities?

- 9,500 FTEs, of which:
  - 6,500 are inspectors
  - 1,000 are public health Vets
- One Billion dollar plus budget (added 185 full time inspectors and 27 million dollars in 2009)
- 15 Districts
- Beltsville MD and back up central offices
- Omaha Tech Center and back up central office
FSIS Areas of Responsibility

• Field Operations: 6,500 federally inspected plants, 2,500 state inspected plants (27 state programs)
• Public Health Science: 3 labs, Data collection, Public Health Information System, Risk Assessment
• Food Defense and Emergency Response: Offices of Data Integration and Food Protection, Coordination for Emergencies
Inspection for Slaughter

• Must be daily and continuous in every slaughter facility. Every animal must have ante-mortem and post-mortem inspection.
• Viscera and carcasses are still inspected by FSIS inspectors on the line for animal diseases (HIMP exception) before applying the mark of inspection.
• No inspector, the slaughter facility cannot operate
Inspection for Processing

• Must be daily and continuous inspection for plant to operate, but:
  1. not continuous on site
  2. exceptions to the rule based on size and geography
  3. cooking only not necessarily under inspection
• No inspector the plant can’t operate
Inspection

• Inspectors can walk away from a plant and in essence shut it down for:
  1. Gross and unsanitary conditions (Montana)
  2. Verbal or physical threats or harm (California)
  3. Inhumane handling of live animals (Hallmark)
FSIS Areas of Responsibility

- Food Safety Education and Communication: Ask Karen, Ask FSIS, Food Safety Discovery Zone, Food Safety Education Education Conference, Meat and Poultry Hotline
- Codex Alimentarius: Chairs the US Policy Committee (State, HHS, EPA, Ag, USTR, Commerce), hosts 4 Codex Committees
- Policy and Rules development
- Recalls (more later)
FSIS Areas of Responsibility

• Office of Outreach, Education and Employee Training: Critical for small plant outreach, and more uniform education, understanding and enforcement by the work force.

• International Affairs: (Frequently we read about how imports are not inspected and are a threat to our health, but no one seems to want to differentiate between the FDA products and FSIS products.....SO next slide)
FSIS and Import Safety

• FSIS has a strong system in place to ensure the imported products we regulate are just as safe as products produced in the U.S.

• FSIS regulated imports have remained stable and the Agency now has more full time employees and Import Surveillance Liaison Officers to handle the imports as a result of 9/11

• Increased from 36,000 pounds of product set aside in 2006 to over 2.1 million pounds in 2008.

Source: United States Department of Agriculture Food Safety and Inspection Service
FSIS and Imported Meat and Poultry Products

• FSIS ensures the safety of imported products by:

  – Determining the equivalence of 34 foreign countries food regulatory systems to ensure that they provide the same level of protection as that of the United States, and only the 34 can export to the US

  – Having ongoing equivalence verified through periodic (annual) audits in the foreign country (Brazil, Israel, Mexico)

  – Conducting the re-inspection of “all” meat, poultry and egg products at app. 60 U.S. ports of entry.

Source: United States Department of Agriculture Food Safety and Inspection Service
Public Health Inspection Data System

• Started in 2009 with the budget increase allotted for 185 additional inspectors, and will improve greatly the agencies capacity for:
  • Domestic Inspection
  • Import Activities
  • Export Activities
  • Predictive Analytics
Ways that FSIS Protects PH

- Analyzes over 100,000 microbiological samples a year for *E. coli O1567:H7* in ground beef and trim, *Salmonella* in raw products, *Listeria monocytogenes* and *Salmonella* in Ready-To-Eat products, and for residues
- Investigates links between human illness and exposure to meat, poultry or egg products
- Requests recalls for adulterated or misbranded products (Tysons)
Other ways that FSIS Protects PH

- Conducts annual reviews of the 27 state inspection programs (and delists them)
- Food Defense and Security verifications
- Model food security programs for industry
- Public Health education and outreach campaigns targeted to consumers and the underserved and at-risk populations
- Food Safety Assessments
Needed Changes

• Common Sense Goals:
  – Implementing Public Health/Risk Based Inspection
    • Putting inspectors where they are most needed
  – Releasing the names of the stores that have sold recalled products to consumers in an effective manner
  – Creating a practical solution to how we handle *E. coli* positive boxed beef and carcasses

Source: United States Department of Agriculture Food Safety and Inspection Service
Needed Changes

• Epidemiologic based outbreak investigations and recalls mixed in with common sense based, effective recall notifications

• TOPPS and Florida sentinel case (frozen patty)
  10/05/07 (32 illnesses)

• Hastings NE, and bison burgers “Distributed only to Institutions and restaurants in CO”
  7/25/07

• Jim’s Market in Harlan, Iowa. 10/6/06 Dist 9/1
Needed Changes

- Raw milk prohibited for use by children
- Government mandate and subsidization for an effective *E coli* vaccination program (Why not? We do it for every other vaccine that prevents childhood illnesses, and we provide clean up funds for toxic environmental areas. It is now an environmental issue.)
- Gov’t mandate subsidy for an effective Salmonella vaccination program
Needed Changes

- Trace back to the source for product testing positive, not just outbreaks (law suit just waiting to happen)
- Whole carcass, low dose, non-penetrating irradiation as a processing aid
- Action on blade or needle tenderized meats
- Non-0157 STECs declared adulterants (better yet, why not all E coli since FSIS and USDA have a “zero tolerance” for fecal material)
THE Needed Change

- USDA—All things animal and all animal products (Eggs, cheeses, milk, fish, seafood, bison)

- FDA---All things canned or bottled. All things that have meat and poultry that has already been inspected at least twice added to it (pizzas, flavorings, sauces, sandwiches, soups)
THE Needed Change

• Just think about it for one minute.
• FDA has responsibility for Bison, a creature that looks like, acts like, tastes like and even can cause a foodborne illness like a cow
• USDA has farm grown Catfish, which looks a little like Tilapia, acts like Tilapia, and can cause a foodborne illness like farm grown Tilapia can
THE SECOND Needed Change

• Slide 20. “FSIS is the public health agency in the USDA…..”
• Then they should start acting like a public health agency, and work with other PH agencies
  • Ruskin, NE
  • Christmas Day, NJ
  • Dallas-Fort Worth
Changes Not Needed

• Mandatory Recall Authority

• Single Food Safety Agency

• A new Administrator or Undersecretary

• AMI’s list of 8 things to do before making our meat safer
Questions?