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Protecting and Promoting Public Health

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# ***Salmonella* in Low-Moisture Products – United States Perspective**

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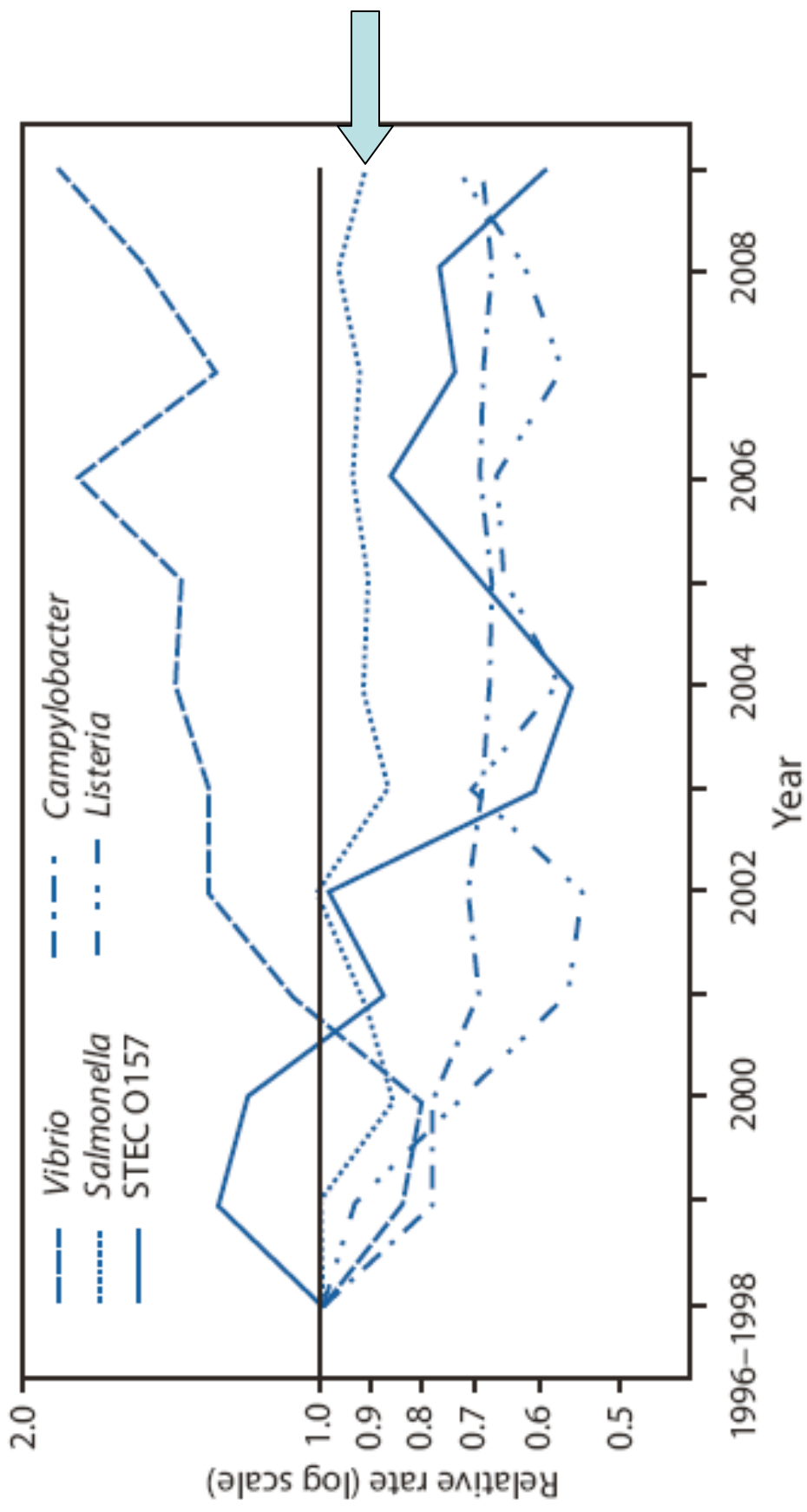
# *Salmonella* Continues to be a Challenge

- 7,039 infections
- 15.2 infections/100,000 population
- US population = 309,277,115
- ~47,000 cases a year (X 38=1.79 million)
- 45% of cases  $\geq$  50 were hospitalized
- 1.2% of cases  $\geq$  50 died

Preliminary 2009 FoodNet Data (active surveillance)

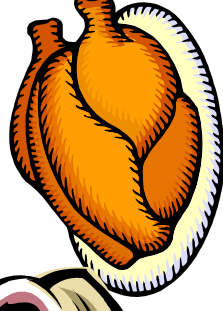
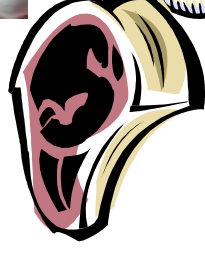


# Relative Rates of Laboratory-Confirmed Infections



# Sources of Salmonellosis

- Foods of animal origin
  - Meat, poultry, eggs, seafood
- Foods of plant origin
  - Fresh produce
- Animal- to-human transmission





## Concern with Low-Moisture Foods

- Not a new problem – spray-dried milk in 1960s

**BUT:**

- Increased number of outbreaks being detected
- Increased number of contamination events being detected

# Salmonella Outbreaks

- *Salmonella* outbreaks from low-moisture products are relatively rare.
- Often impact large number of people
  - Cereal (1998, US) – 209 cases
  - Chocolate (2001-02, Europe) – 439 cases
  - Peanut butter (2008-09, US) – 691 cases

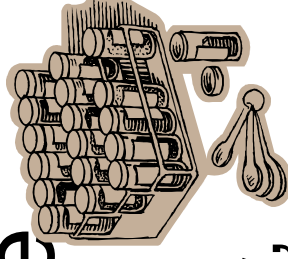




# Salmonella Outbreaks - US

Year	Product	Serotype
2003-04	Raw almonds	Enteritidis
2006-07	Peanut butter	Tennessee
2007	Children's snack	Wandsworth, Typhimurium
2008	Cereal	Agona
2008-09	Imported White pepper	Rissen
2008-09	Peanut butter & products	Typhimurium
2009-10	Salami/ imported black & red pepper	Montevideo

# Contaminated Low-Moisture Products



- Dry seasonings and spices (black pepper, cumin, oregano, paprika, sage, thyme, basil)
- Dehydrated vegetables (e.g., onions, mushrooms)
- Sesame seeds
- Soybean meal
- Nuts (e.g., peanuts, pistachios)
- Dry pet foods and treats





# Reasons for FDA Concern

- *Salmonella* in low-moisture products has caused illness.
- *Salmonella* cannot grow in low-moisture products, but it can survive.
  - Survival can occur for long periods of time.
  - Low-moisture foods can have long shelf lives.
  - Low numbers of salmonellae can cause illness.
- Increased heat resistance at low-moisture levels
- Belief that low-moisture foods are not risky because they do not support growth of pathogens.



# Reportable Food Registry

- 2007 law required FDA to establish a Reportable Food Registry, to which instances of reportable food may be submitted via an electronic portal
- “Reportable food” – an article of food (other than dietary supplements and infant formula) that has a reasonable probability of causing serious adverse health consequences or death to humans or animals
- Initiated September 8, 2009 for domestic and imported foods.



## RFR *Salmonella* Contamination Events

- Granola bars, nutrition bars
- Spices: leaf savory, pepper, cumin
- Soy grits, soy flour, soy protein concentrate
- Rice flour
- Nuts: pine nuts, hazelnuts, macadamias
- Seeds: sesame
- Non-fat dry milk
- Hydrolyzed vegetable protein



# Ingredient Issues

- Increasingly seeing contamination in low-moisture ingredients
- Ingredients are increasingly being tested by customers (especially where going into RTE products)
- Positive finished product tests have led to positive ingredient tests (e.g., pistachios in trail mix; soy grits in nutrition bars)



# Recalls from Ingredient Contamination

Ingredient contamination events often lead to a cascade of multiple recalls:

- 2009 Peanut butter - over 3900 products recalled
  - Cakes, cookies, ice cream, snacks, toppings
- 2009 Pistachios – 664 products recalled
  - Cakes, candy, ice cream, snacks
- 2010 HVP – 177 recalls
  - Bouillon, seasonings, dips, snacks



# Contamination Events Lead to FDA Investigations

- Specific firm
- Firm's consignees
- Similar facilities
  - All peanut butter facilities
  - Nut processing facilities



## FDA Activities

- As a result of contamination of nuts with *Salmonella* in 2009, FDA issued an assignment to the field to inspect nut processing facilities in FY 2010.
- The assignment includes environmental monitoring to assess the potential for nut contamination from the environment.



## FDA Has a New Tool

- Environmental Sampling
- Environmental testing may lead to a determination that products have been prepared or packed under insanitary conditions.
- As a result, there have been additional recalls and plant shut downs to correct problems.



## Other Issues Uncovered

- In many instances the low-moisture ingredients are made with steps that provide lethality.
  - Lethality is not validated
  - Recontamination is not prevented
- In many cases the ingredients are used in products that have processes that provide lethality.
  - Lethality is not validated
  - Recontamination is not prevented



# Why the continuing problem?

- Lack of understanding of the ecology of *Salmonella*
- Lack of understanding of the risks from *Salmonella* in low-moisture foods
- Lack of understanding of the factors that increase the risk from *Salmonella* in low-moisture foods



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# Industry is Taking Action



- Almond Board of CA – Almond Action Plan
- Grocery Manufacturers Association 2009 Control of *Salmonella* in Low-Moisture Foods
- American Peanut Council – Good Manufacturing Practice and Industry Best Practices for Peanut Product Manufacturers
- GMA<sup>a</sup> – Industry Handbook for Safe Processing of Nuts



<sup>a</sup>APC, CA Pistachio Research Board, Peanut and Tree Nut Processors Assoc. Western Pistachio Assoc., numerous nut companies and food manufacturers



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# Congress is Responding

- Food Safety Enhancements Act of 2009  
(HR 2749)
- Food Safety Modernization Act (S 510)



# Food Safety Enhancements Act (FSEA) Provisions

- Requires each food facility to:
  - conduct a hazard analysis;
  - implement preventive controls; and
  - implement a food safety plan.



# FSEA Provisions

- Preventive Controls:
  - Sanitation procedures and practices
  - Training (supervisor, manager and employee hygiene)
  - Process controls
  - Allergen control program
  - GMPs
  - Supplier verification activities



## FSEA Provisions

- Food Safety Plan must include scientific/technical validation that the system of controls will prevent, eliminate or reduce hazards to an acceptable level.
- FDA would have access to all records relating to determining whether a food may be adulterated or misbranded.



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# FDA is revising its GMPs

- “Food CGMP Modernization – A focus on Food Safety” (2005)
- White Paper available at:  
<http://www.fda.gov/ohrms/dockets/dockets/04n0230/04n-0230-rpt0001-vol4.pdf>



## The Bottom Line

- The food industry will face new requirements sooner rather than later.
- It would be prudent for processors of low-moisture foods to develop and implement appropriate, validated controls for hazards such as *Salmonella*.
- Low-moisture food facilities need to implement robust environmental monitoring programs for *Salmonella*.



# The Bottom Line



- FDA will continue to take action against products that contain *Salmonella*
- FDA will continue to take action against companies producing low-moisture foods under insanitary conditions as evidenced by the presence of *Salmonella* in the environment.
- FDA is urging companies to take action so FDA doesn't have to.



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Thank you!

