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Special Libraries Association
Annual Conference

# Bad Food: The Life Cycle of a Food Recall

## Crisis Management and Insurance Coverage Issues



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# Hostile Recall Environment

- Catastrophic Costs of Product Recalls
- 24/7 News-Internet-Social Media
- Globalization – Extended Supply Chains
- Increase In Multi-State Outbreaks
- Supply Chain (“Strict”) Liability
- Consumer (“No-Injury”) Class Actions
- Pathogen Resistance
- Food Supply Vulnerable to Climate Change
- Increased Government Regulation

# Catastrophic Costs Of Product Recalls

- Foodborne illnesses cost the United States $152 billion in annual health-related expenses.
- Foodborne diseases cause approximately 48 million illnesses (1 in 6 Americans), 128,000 hospitalizations, and 3,000 deaths in the United States each year.
- In 2012, the FDA handled nearly one Class I recall every day.



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# 24/7 News-Internet-Social Media





# Globalization – Extended Supply Chains

"Global Business Explosion Sparks Insurance Needs"

> "As companies become increasingly global and venture into emerging markets, they are likely to encounter new risks such as economic or political instability and gaps in insurance coverage. Demand for insurance products designed to address those issues is growing…as more small and midsize businesses begin expanding globally and demanding global insurance products..."

*Law 360 07/30/09*



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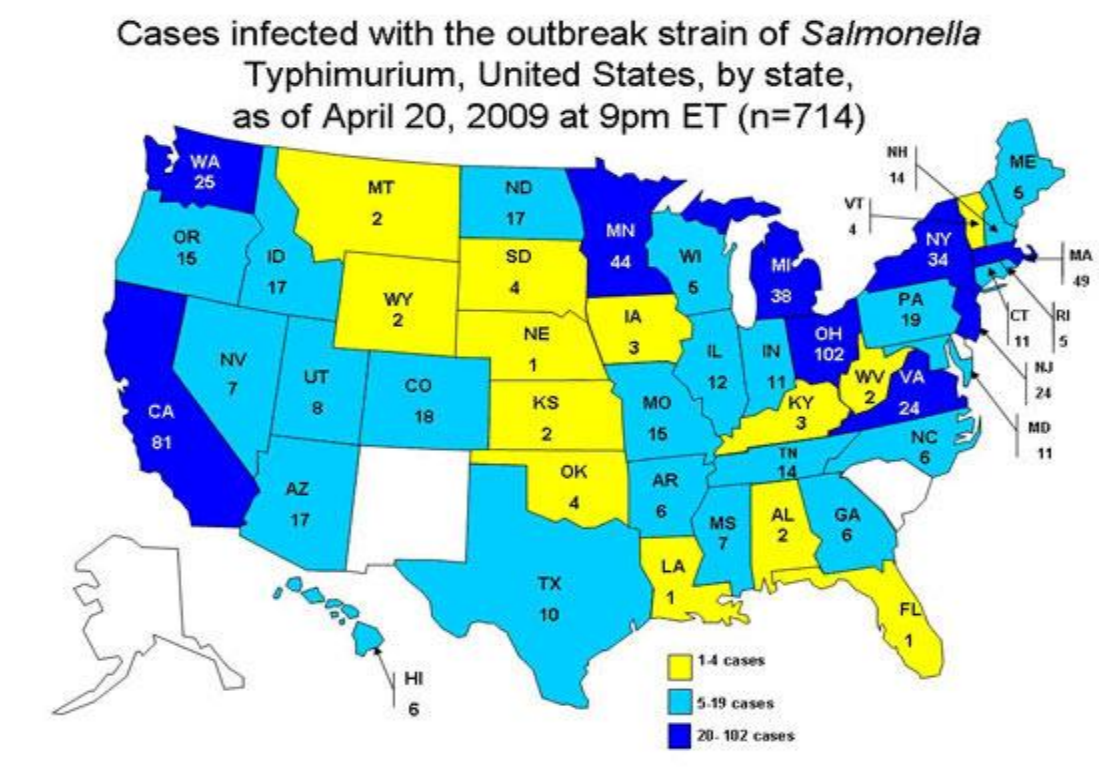
# Increase In Multi-State Outbreaks



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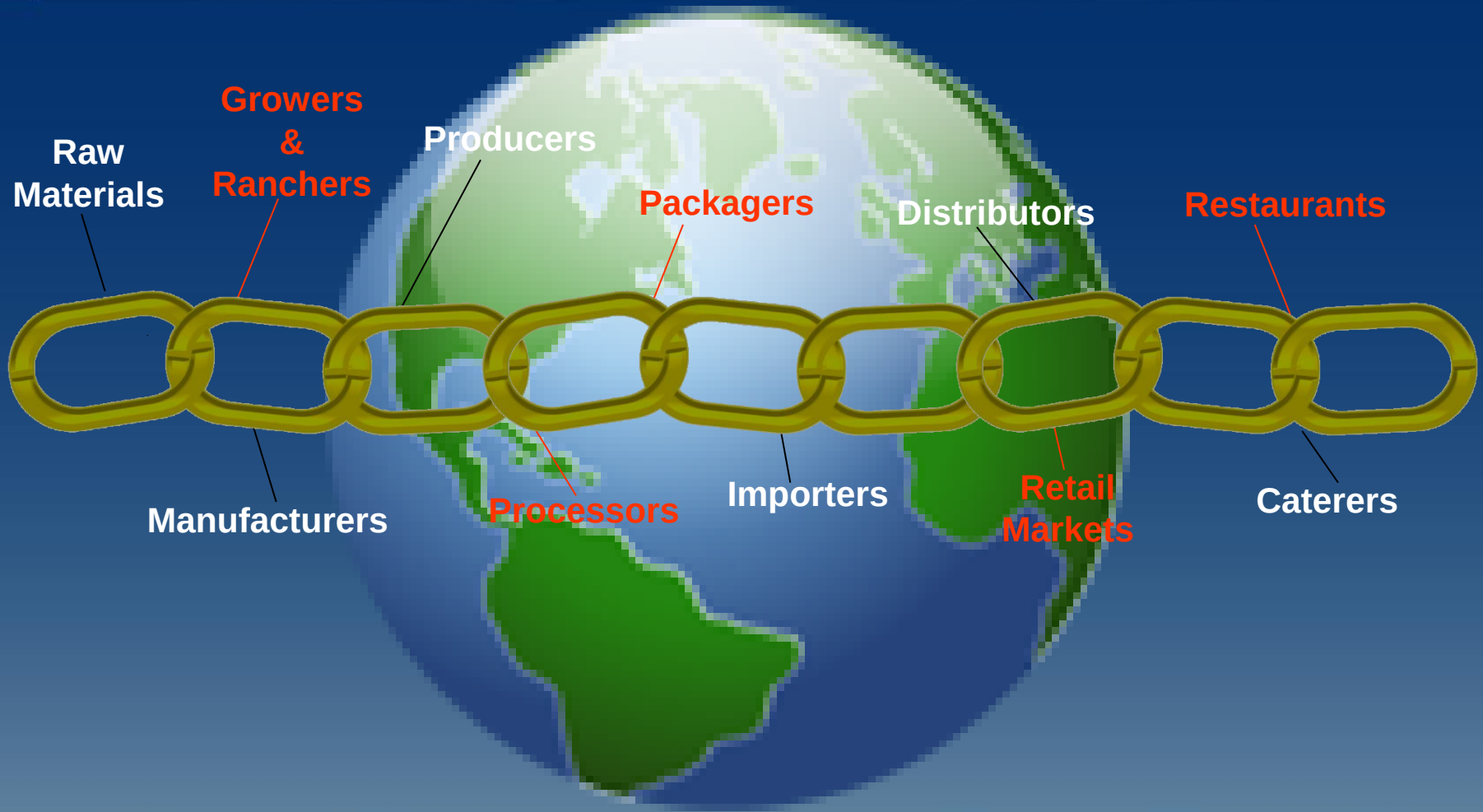
# Supply Chain ("Strict") Liability



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# Consumer (“No-Injury”) Class Actions

- An alternative to the traditional personal injury or property damage suit, the consumer (“no-injury”) class action provides plaintiffs’ attorneys with a number of advantages.

# Pathogen Resistance

- Multidrug-resistant Superbugs contaminate nearly half of the supply of retail meat and poultry products.
- E. coli's deadly strain, O157:H7, was isolated in 1982, and tracked by the CDC only as far back as 1976. USDA testing for O157:H7 did not begin until 1994.
- Salmonella Typhimurium and Salmonella Newport have evolved to resist most antibiotics that doctors feel comfortable giving to children.

# Pathogen Resistance

- E. Coli outbreak O121 Multistate Outbreak
  - 35 ill in 19 states, 852 with complications
  - First Outbreak to involve non-O157 strain
  - Involves frozen food snack products

# Pathogen Resistance

CDC 2013 survey finds food poisoning on the rise

- Salmonella, the most common cause of food poisoning has increased by 3%
- Campylobacter has increased by 14%
- Vibrio infections have increased by 43%

# Food Supply is Vulerable to Climate Change

- Salmon
- Wine
- Oranges
- Beef
- Maple Syrup
- Chocolate
- Corn
- Rice

# FDA Food Safety Modernization Act ("FSMA")

- General Considerations
  - The FSMA is hailed as a long over due overhaul of U.S. food safety regulation.
  - The aim is to fundamentally shift the manner in which the FDA regulates food from a reactive perspective to a proactive approach.
  - The focus is on detecting and halting the distribution of contaminated food from domestic and international sources.

# Title I

## Improving Capacity to Prevent Food Safety Problems

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# Section 101. Inspection of Records

- Records Inspection: Adulterated Food
  - If the FDA believes that there is a **reasonable probability** that the use of or exposure to an article of food and, any other article of food that the FDA **reasonably believes** is affected in the same manner, **will cause serious adverse health consequences or death** to humans **or animals**.
  - Each person (excluding farms and restaurants) who **manufactures, processes, packs, distributes, receives, holds or imports** such food article shall, at the request of a FDA officer or employee and, upon receipt of written notice, must **provide access to and a copy of all records relating to such food article (s).**

# Section 102. Registration of Food Facilities

## Suspension of Registration:

- If the FDA determines that food manufactured, processed, packed, received or held by a facility registered under the Act has a reasonable probability of causing serious health consequences or death to humans or animals.
- The FDA may by order suspend the registration of a facility that created, caused or was otherwise responsible for such reasonable probability; or that knew of or had reason to know of such reasonable probability; and packed, received or held such food.

# Suspension Order Impact:

- The effect of a suspension order is that no person shall import, export or introduce food into U.S. interstate or intrastate commerce from such facility.

# Hearing on Suspension

- The FDA shall provide the registrant subject to an order with an opportunity for an informal hearing, to be held as soon as possible but not later than 2 business days after the issuance of the order on:
    1. the actions required for reinstatement of registration
    2. why registration should be reinstated

# Corrective Action Plan

- If the FDA determines that the suspension remains necessary, the registrant must submit a corrective action plan and the FDA shall review the plan not later than 14 days after submission or such other time period as determined by the FDA.

# Section 103. Hazard Analysis and Risk-Based Preventive Controls

- Generally, companies must evaluate hazards that could affect food manufactured, processed, packed or held by such facility and identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards.

# Title II

## Improving Capacity to Detect and Respond to Food Safety Problems

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# Section 201. Targeting of Inspection Resources for Domestic Facilities, Foreign Facilities, and Ports of Entry; Annual Report

## Identification

- FDA shall identify high-risk facilities based on following factors
  - A. Known safety risks of the food;
  - B. Compliance history of a facility
  - C. Rigor and effectiveness of the facility's hazard analysis and risk-based preventive controls
  - D. Whether food meets criteria for priority
  - E. Whether the food or facility has received a certification
  - F. Any other necessary and appropriate criteria.

# Inspections

A. Domestic High-Risk: within 5 years of Act's enactment and every 3 years thereafter

B. Domestic Non High-Risk: within 7 years of Act's enactment and every 5 years thereafter

C. Foreign Facilities: 600 facilities inspected within first year of Act's enactment. In each year for the next 5 years, FDA shall inspect not fewer than twice the number of foreign facilities inspected the previous year

# Additional Recordkeeping Requirements for High-Risk Foods

- In order to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak and within 2 years of Act's enactment, the FDA will propose regulations to establish recordkeeping requirements. The requirements will include making records available to the FDA within 24 hours of a request.
- The FDA may require a facility to retain records for up to 2 years, taking into consideration the risk of spoilage, loss of value or loss of palatability of applicable food.



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# Section 205. Surveillance

Definition of Foodborne Illness Outbreak:

> "Foodborne illness outbreak" means the occurrence of 2 or more cases of a similar illness resulting from the ingestion of a certain food.

Foodborne Illness Surveillance Systems:

> Acting through the CDC, the FDA shall enhance foodborne illness surveillance systems to improve the collection, analysis, reporting and usefulness of data on foodborne illness.

# Section 206. Mandatory Recall Authority

A. Voluntary Procedures:

1. If the FDA determines through use of the reportable food registry ("RFR") or other means that there is a reasonable probability that an article of food (other than infant formula) is adulterated or misbranded; and
2. The use of or exposure to such article will result in serious adverse health consequences or death to humans or animals.
3. The FDA will provide the responsible party with an opportunity to cease distribution and recall such article.

# Section 207. Administrative Detention Authority

- The “FDA can order administrative detention if there is a reason to believe that an article of food is adulterated or misbranded.”
- FDA can detain a food article for up to 30 (calendar) days.
- Detention decisions are to be “made on a case by case basis.” No consistent standard.
- FDA expects to use the detention authority in Class I and Class II situations.
- Since Authority went into effect, the FDA has enforced it multiple times.

# Title III

## Improving the Safety of Imported Food

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# Section 302. Voluntary Qualified Importer Program

No later than 18 months after the Act's enactment, the FDA will establish a program:

1. to provide for expedited review and importation of food by importers that have voluntarily agreed to participate in such program
2. to create a process for the issuance of a facility certification to accompany food for importation by importers who voluntarily agree to participate in such program

Voluntary Participation:

An importer may request the FDA to provide for an expedited review and importation of designated foods in accordance with the program.

# Section 306. Inspection of Foreign Food Facilities

The FDA may enter into arrangements or agreements with foreign governments to facilitate the inspection of foreign facilities.

Effect of Inability to Inspect:

Food shall be refused admission into the U.S. from a foreign factory, warehouse or other establishment of which the owner, operator or government refuses to permit entry of U.S. inspectors, upon request, to inspect such facility.

Admission must be provided within 24-hour period after request is submitted.

# Traditional Insurance Portfolio Fails To Protect




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# Significant First-Party Coverage Issues

- Direct Physical Loss
  - Technical Violations of FDA Regulations
  - 2003 Mad Cow Disease Claim
  - No Contamination Established
- Exclusions
  - Contamination
  - Government Action
  - Faulty Workmanship
  - Pollution
  - Delay, Loss of Use, Loss of Market
  - Stock Processing
  - Product Recall
- Business Interruption Insurance
  - Business Income
  - Extra Expense
  - Period of Restoration
  - Loss Determination
  - Market Loss

# Significant Third-Party Coverage Issues

- Property Damage
  - Economic Loss
  - Product Incorporation
  - Loss of Use
- Number of Occurrences
  - Cause v. Effect
- Bodily Injury
  - Fear of Injury Claims
  - Medical Monitoring Claims
- Personal and Advertising Injury Liability
- Vendors Endorsements
- Additional Insureds
- Exclusions
  - Pollution
    - Inorganic v. Organic
  - Business Risk
    - Damage to "Your Product"
    - Impaired Property
  - Sistership
    - Who Ordered Recall
    - Scope of Recall
    - Product Actually Failed
  - Recall of Products, Work or Impaired Property

# Product Contamination Specialty Policies

- Includes Pre and Post-Crisis Management Consultants entitlements.
- Insured Event means any Accidental Contamination, Governmental Recall, Malicious Product Tampering or Insured Products Extortion.
- Loss under this Policy includes only the following reasonable and necessary expenses or costs listed below that are incurred by the Insured directly or solely in connection with a covered Insured Event and subject to the Limits of Liability stated on the Declaration Page:
  - Crisis Consultant Costs
  - Pre-incident Consultant Costs
  - Business Interruption Expense
  - Destruction Costs
  - Insured Product Extortion Costs
  - Pre-Recall Expenses
  - Recall Costs
  - Redistribution Costs
  - Rehabilitation Expenses
  - Replacement Costs

# The Cost Of An Incomplete Portfolio

What are the average costs of a recall?

$_____

Can you afford this amount without proper protection?

# Thank you

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