Refresher on Food Recalls and Recall Protection

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Preliminary Word

- This presentation provides information about the law. Legal information is not the same as legal advice, which involves the application of law to an individual's specific circumstances. The interpretation and application of the law to an individual’s specific circumstance depends on many factors. This presentation is not intended to provide legal advice.

- The information provided in this presentation is drawn entirely from public information. The views expressed in this presentation are the authors’ alone and not those of the authors’ clients.
Agenda

- Introduction
- Brief overview of recalls
- Traceback/traceforward
- Lessons learned from recent recalls
- Increasing criminal inquiries
- Best practices
- Purchasing insurance
- Maximizing available insurance recovery
Introduction – Food-Borne Pathogens

- More recalls than ever before
  - King Soopers *deli chicken salad* (Listeria mono.)
  - Waterfront Bistro *tartar sauce* (undeclared egg)
  - Cherry Valley *cupcakes* (undeclared milk)
  - Death Wish Coffee Co. *nitro cold brew coffee* (botulin toxin)

- The stakes are higher than ever
  - Class action litigation
  - Criminal liability
    - Austin and Peter DeCoster
    - *eggs* (salmonella)
    - 8th Circuit upholds sentences
Supply Chain Liability Example

Exhibit 7 – Illustrative supply chain for canned tuna

Products often traverse complex global supply chains to reach U.S. consumers

Supply chain for canned tuna

Strict Liability in the Food Chain

- Strict Liability
- Indemnity Agreements
  - Good for adjoining link
  - But still can be “jerked” in the chain
Supply Chain Liability (cont’d)

- Supply Chain Liability and Obligations
  - FDA/FSMA – Foreign Supplier Verification Program
  - State Attorneys General
  - Consumer Class Actions in “Food Court”
  - Food Fraud/Contamination
  - Competitor Lawsuits
  - Recalls/Criminal Enforcement
Recall Definition

- A company’s removal or correction of marketed products that are in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and against which FDA would otherwise initiate legal action
  - Violation – adulterated or misbranded products
  - Food can be adulterated if it has been:
    - Manufactured under such conditions that it is unfit for food; or
    - Prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health
Not a Recall

- Stock Recovery – retrieval of violative product “within company’s control”
- Market Withdrawal – withdrawal of products with insignificant violations, or of nonviolative products for commercial reasons, such as quality
Recall Classifications

- **Class I** – reasonable probability that use of or exposure to product will cause serious adverse health consequences or death to humans or animals (acronym is “SAHCODHA”)

- **Class II** – reasonable probability that use of or exposure to product may cause temporary or medically reversible adverse health consequences or where probability of serious adverse health consequences is remote

- **Class III** – use of or exposure to product is not likely to cause adverse health consequences
Recall Plan – FSMA

- Under the Hazard Analysis and Risk-Based Preventive Controls regulation (HARPC), a recall plan is required for every food that has a hazard requiring a preventive control.

- Recall plan must be written and must include the procedures and persons responsible for performing the following tasks:
  - Notifying direct consignees
  - Notifying public
  - Conducting effectiveness checks
  - Disposing of recalled food (or reconditioning recalled food, if appropriate)
Reportable Food Registry (RFR)

- RFR report: if reasonable probability that a food will cause serious adverse health consequences or death to humans or animals – Class I recall risk

- Exemption from reporting:
  - The adulteration originated with the responsible party; **and**
  - The responsible party detected the adulteration prior to any transfer of the food to another person; **and**
  - The responsible party corrected the adulteration or destroyed the food.
FDA Enforcement Actions

- Mandatory recall
- Suspension of registration
- Seizures
- Injunctions
- Criminal actions
- Administrative detention
- Warning letters
- Adverse publicity
Recall – Health Hazard Evaluation

- **FDA Guidelines**
  - Have illnesses/injuries occurred
  - Do conditions present health hazard
  - Risk for segments of population
  - Degree of hazard for populations at risk
  - Likeliness of occurrence of hazard
  - Consequences of occurrence of hazard
Office of Inspector General (OIG)

- OIG preliminary report to FDA (6/2016)
  - “Early Alert: The Food and Drug Administration Does Not Have an Efficient and Effective Food Recall Initiation Process”
    - “We suggest that FDA revise its policies and procedures to instruct recall staff to establish set timeframes for (1) FDA to request that firms voluntarily recall their products and (2) firms to initiate voluntary food recalls.”
  - FDA has established a team to review recall investigations and to get involved if cases are complex or otherwise delayed
### Traceback/Traceforward

- **Whole genome sequencing (WGS)**
  - Examines complete genome
  - WGS is solving outbreaks with as few as 2 illnesses (down from 10-12 illnesses in the past, using pulsed field gel electrophoresis)
  - GenomeTrakr – international lab network and database with >142,000 isolates (food, environmental, human clinical isolates) and accompanying metadata (location, date, etc.)

- FDA inspection “swab-a-thons” (100-300 swabs)
  - Concern about pathogens that are established in a facility rather than transient. FDA expects aggressive “seek and destroy” efforts
  - Environmental sampling by FDA can trigger a recall

- Greater likelihood now of agencies being able to link a product/facility to an illness outbreak, even years later

- Regulatory, criminal liability, and civil litigation implications
Strict Criminal Liability

- Dept. of Justice (DOJ) grand jury subpoenas
- Typically issued after a serious foodborne illness outbreak, with traceback to a company’s product
- Subpoena is for records – broad request
- Purpose – to investigate whether any criminal activity contributed to the adulteration
- FDA and DOJ publicly emphasize their focus on criminal prosecutions of individuals for food safety violations
Strict Criminal Liability

- “Responsible corporate officer doctrine”/“Park” doctrine – 1975 Supreme Court strict criminal liability theory

- Misdemeanor conviction under public welfare laws (such as FD&C Act) based on:
  - Position in company and relationship to violation
  - Authority to prevent/correct violation
  - No knowledge/participation necessary
Strict Criminal Liability

- FDA’s Regulatory Procedures Manual - Other factors to consider include:
  - Whether the violation involves actual or potential harm to the public;
  - Whether the violation is obvious;
  - Whether the violation reflects a pattern of illegal behavior and/or failure to heed prior warnings;
  - Whether the violation is widespread;
  - Whether the violation is serious;
  - The quality of the legal/factual support for the proposed prosecution; and
  - Whether the proposed prosecution is a prudent use of agency resources.
Recall Best Practices

- Recall team
- Recall manual
- Comprehensive production procedures
- Training
- Mock recalls
- Effective traceability system
- Outside experts/resources
  - Legal
  - Scientists/labs
  - Crisis management
  - Recall support, such as phone lines
- Insurance Coverage
Areas Covered in this Section

- Why general liability and 1st-party property policy does not provide adequate coverage
- An overview of product contamination (Food Recall) Insurance and what it is designed to cover
Recent Food Contamination Situations

- Spinach
- Peanuts
- Chicken
- Pistachios
- Parsley
- Cumin
- Peanut Butter
- Ground Beef
- Pomegranates
Food Poisoning’s Legacy

- *Salmonella, E.coli* and other foodborne illnesses could trigger serious health problems years after patients survived the initial complications

- “The future medical cost alone can then be in the millions”
  - Bill Marler, Seattle lawyer who sues food retailers and food companies on behalf of food poisoning victims
Why General Liability and 1st-Party Property Insurance Policy Does Not Provide Adequate Coverage
Commercial General Liability (CGL) Coverage

What It Covers:

- CGL coverage is essentially 3rd-party “Litigation Insurance”
- Covers bodily injury/property damage
CGL Coverage

- "Bodily injury"
  - Covered in most jurisdictions
  - Does not include *emotional distress* unless there are physical manifestations

- "Property damage"
  - Incorporation of a tainted ingredient into an otherwise unadulterated food could be enough to cause "property damage"
CGL Coverage (cont’d)

- Likely CGL exclusions on a food contamination claim include:
  - “Recall” exclusion
  - “Pollution” exclusion
  - “Mold, mildew, bacteria” exclusion
Property/Business Interruption Coverage

- **Property Coverage**
  - Many property policies cover “all risks of physical loss or damage” to “personal property”
  - If the company can show contamination of product inventory, then it could be entitled to recover
Other Potential Coverage

- D & O Liability Insurance
- Marine Cargo Insurance
- Specialized Food Recall Insurance
  (Product Contamination Insurance)
AN OVERVIEW OF PRODUCT CONTAMINATION (FOOD RECALL) INSURANCE AND WHAT IT IS DESIGNED TO COVER
Product Contamination Insurance

Basic Coverage for Accidental Contamination

- Recall Expenses
- Business Interruption
- Lost Gross Profit
- Rehabilitation Expenses
- Crisis Management/Consultants
Recall Expenses Include:

- Transportation/disposal of the product
- Replacement product
- Additional personnel/overtime
- Expenses for rental of warehouse space for storage
- Notification to third parties
- Combing supermarket shelves to remove contaminated product
- Cleaning the equipment
- Laboratory analysis
Product Contamination Insurance

- Does not cover prophylactic recalls
  - Most food recalls are prophylactic

- Trigger is the key
  - Policies only apply to recalls necessary when the policyholder’s contaminated food “has resulted in or would result in bodily injury” or property damage...

  - Or as at least one policy puts it, “may likely result in bodily injury” or property damage ...
Essential Provisions in Policy:

- 3rd-party recall liability provision
- Product refusal provision
- Malicious product tampering
- Some exclusions should be modified
Product Contamination Insurance (cont’d)

Endorsements

- Government Recall Endorsement
- Adverse Publicity Endorsement
THANK YOU!

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Contact info@khlaw.com for a complimentary copy of The Risk Report article "Insurance for Food Recall" written by Keller and Heckman attorney, Art Garrett, which explores the world of food recall insurance coverage.
Join Keller and Heckman attorneys and scientists for the Practical Food Law Seminar. The conference will provide members of the food industry with a detailed understanding of the applicable statutory and regulatory framework in the United States for foods (including dietary supplements). The course will focus on food safety, labeling and advertising, and FDA enforcement capabilities. The seminar presenters will also contrast the U.S. regulatory requirements with the comparable provisions in the E.U.

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