
Managing the Risk of Foodborne Illness

Contaminated food poses a serious public health risk. The food industry, in partnership with local, state and federal authorities, does a very creditable job of providing safe and wholesome food to the United States public. However, there are still significant numbers of foodborne illness incidents reported, and potentially, a much larger number of incidents that go unreported.

The court system in the United States has awarded plaintiffs multi-million dollar damages in cases alleging liability for foodborne illness incidents. The most commonly cited defense is that there were no other cases reported. Clearly, this defense can only be successful if the food delivery system is fundamentally safe, and demonstrably *avoids* such incidents. While there is a probability that defendants will win, litigation on average takes over three years to conclude, occupying company resources and potentially damaging company reputations. Further, the probability of a plaintiff both winning and receiving a relatively larger award increases with severity of the injury.

The focus of this paper is to define the issues involved and to outline some of the measures recommended by regulatory agencies to minimize risks to public health. Cold chain management is addressed as a critical element of a food safety plan.

Public Health Risks

Foodborne illnesses come from eating food that has been contaminated, either by bacteria, viruses or other impurities. The Centers for Disease Control (CDC) have identified more than 400 food-related diseases. Foodborne illnesses can be quite serious, and even deadly, particularly for seniors, infants, children and anyone suffering from weakened immune systems, such as patients with AIDS or some liver diseases.

The system for reporting cases of foodborne illnesses to the CDC by local and national authorities is still under development. Currently, CDC estimates that only 1% to 5% of incidents are reported. The problem is significant enough for CDC to establish FoodNet, a specialized reporting vehicle. In 1998, on a covered population of only 20.5 million people, FoodNet reported 9,214 cases of bacteria-related foodborne illnesses and 574 cases of parasite-related illnesses.

CDC studied the issue further, and in 1999 released the report, "Food-Related Illness and Death in the United States". In this study, CDC estimated that in the US, foodborne pathogens are responsible for 76 million illnesses, 5,000 deaths and 325,000 hospitalizations. This costs the US over \$5 billion each year in direct medical expenses and losses of both wages and productivity, according to the Council for Agriculture Science and Technology.

Legal Risks

On a per capita basis, the number of court cases involving foodborne illness indicates that the US food supply and all of the associated distribution systems are among the safest in the world. However, this can be viewed as a negative factor in considering legal risks. Because the food safety record of the industry is good, a specific incident can stand out because there are so few.

The USDA analyzed court cases alleging liability for propagating foodborne illnesses. In its 2001 study, "Product Liability and Microbial Foodborne Illness", the USDA Economic Research Service surveyed the 175 court cases from 1988-1997 that a) alleged harm from foodborne pathogens, and b) that proceeded to jury verdict. This number of cases, according to the authors, does not cover the number of complaints that may have been settled out of court.

Of the cases that went to a jury verdict:

- Plaintiffs won 30% of the time.
- Damage award amounts are variable. However, the average award is \$133,000 (with a range of \$2,256 to \$2.4 million), not necessarily including litigation costs.
- Average time to resolution of an action going to a jury decision is 3.1 years, consistent with other product liability cases.
- Size of the award correlates to severity of the injury and probability of the plaintiff prevailing.

The study does not address the harm done to public perception of the foodservice firms being sued. However, it is a reasonable assumption that given the length of time required to resolve these complaints, there is ample opportunity for negative press coverage.

The study also examined the defenses employed in the suits, although the authors indicate that the data are incomplete. The most commonly employed defense was the absence of other, similar complaints. This defense was used 30% more often than any other of the reported defenses. Other, less frequently cited defenses were allegations of pre-existing conditions and inconsistencies of timing between the incubation period of the suspected pathogen and the plaintiff's reported symptoms.

The items around which suits were filed represent a significant cross section of menu items offered by the different types of foodservice vendors:

Food Item	Percentage of Lawsuits - %*
Single Vehicle:	
Sandwiches (ex. Hamburgers and Egg)	8.4
Seafood (ex. Oysters)	6.2
Chicken	5.6
Hamburgers and Ground Beef	5.1
Oysters	5.1
Salad	3.9
Sausages and Unknown Meat	2.8
Beverages (ex. Milk)	2.8
Mexican Food	2.8
Baked Goods	2.2
Chinese Food	2.2
Packaged Meals	1.7
Pork	1.7
Ice Cream	1.1
Other Beef	1.1
All Other Single Vehicle (e.g., "Lasagna")	10.8
Subtotal, Single Vehicle	63.2
Multiple Vehicle (e.g., "Dinner")	25.8
	8.4
Not Specified	
Total	100.0%

**Percentages may not add to 100% due to rounding.*

Further, every type of food service operator was affected.

Defendant Company Type	Percentage of Lawsuits (Includes Multiple Defendant Suits)--%
Restaurants	31.6
Food Stores	11.5
Distributors	4.7
Manufacturers (Including Farms and Dairies)	12.4
Parent Companies	25.6
Other (Hotels, Insurers, Vending Operators, etc.)	14.1
Total	100.0%

Food store operators should also take their changing product mix into account when analyzing risk. For many retailers, the fastest growing product categories are associated with meal-replacement options. The more closely a food store’s offering matches a restaurant, their risk profiles will also match more closely.

Addressing the Risks—Foodservice Operators and Retail

The regulations that govern food safety come from a variety of sources in the US. Many different agencies of the federal government are involved in regulation and rule making. Adding to the complexity, foodservice establishments, retail food stores and other foodservice operations such as those in nursing homes are overseen by state and local regulatory agencies. The US Department of Health and Human Services, Public Health Service and Food and Drug Administration publish the “Food Code” every two years as a reference document for those state and local agencies. According to the Joint Introduction:

“...the Food Code provides practical, science-based guidance and manageable, enforceable provisions for risk factors known to cause foodborne illness.”

“...Food Code adoption and implementation in all jurisdictions is an important strategy for achieving uniform national food safety standards and for enhancing the efficiency and effectiveness of our nation’s food safety system.”

One food safety program model recommended by the Food Code is the Hazard Analysis Critical Control Point (HACCP) methodology. Federally inspected establishments must demonstrate compliance to performance standards via “an appropriately designed, validated HACCP plan”.

While not a federally mandated requirement at retail, the FDA characterizes HACCP as:

“...a common sense, technique to control food safety hazards. It is a preventative system of hazard control rather than a reactive one. Food establishments can use it to ensure safer food products for consumers. It is not a zero risk system, but is designed to minimize the risk of food safety hazards...”

HACCP plans are built on seven principals:

- Perform a Hazard Analysis
- Decide on Critical Control Points (CCP's)
- Determine Critical Limits
- Establish Procedures to Monitor CCP's
- Establish Corrective Actions
- Establish Verification Procedures
- Establish a Record Keeping System

According to the FDA, the hazards include biological concerns (contamination, growth, toxin production, etc.), physical objects (stones, glass, packaging materials, etc.) and chemical contamination (lubricants, cleaning compounds, pesticides, etc). Of these potential hazards, the CDC identified bacterial agents as the leading cause of laboratory-confirmed outbreaks in their report Surveillance for Foodborne-Disease Outbreaks-United States, 1988-1992. That same report documents that improper temperature management (Holding Temperature and Improper Cooking) accounted for more than half of the root causes of those outbreaks.

Using Cold Chain Management to Control the Risks

From the statistics provided by FDA and CDC, effective cold chain management is a key component of any initiative designed to manage the risk of foodborne illness, whether in the foodservice, food processing or food retailing industry. A very important first step is mapping and measuring the processes that involve managing temperatures. These may include refrigerated transportation, storage, display and processing.

Data generated by a monitoring system are useful in two ways. First, immediate decisions on the quality and/or safety of a food product can be made. If a HACCP-style plan is being used, measurements are required to ensure that control limits are not being violated. There are also longer-term benefits to a properly designed monitoring system. Analysis of properly archived data can show how widely those processes vary over time, and therefore, where improvement is needed. By putting those improvements in place, potential risks to food products are minimized in the future, cold chain costs can be better managed and more consistent product quality is delivered to the customer.

Summary

The United States has one of the safest food delivery systems in the world. However, even with that solid record, food borne illnesses still levy heavy costs on the American public, in lost time, lost wages, health care spending and even in loss of life. Historical data shows that all participants in the food supply system are potentially vulnerable to litigation, from food manufacturers to those firms providing the final delivery to the consumer. The most commonly cited defense was a lack of similar events, a strategy that can only work if the risk in the food delivery system is sufficiently well managed.

Improper management of that risk can be devastating to a foodservice establishment. If a consumer's complaint regarding a food borne illness goes to a jury verdict, awards can range to over \$2 million and take over three years to settle. Further, as different types of retail food outlets provide increasingly similar offerings, their risk profiles will likely also become more similar.

The US Health and Human Services Administration, the Public Health Service and FDA recommend approaching risk management via a HACCP plan, beginning with analyzing the risks to food products. In analyzing those risks, The Centers for Disease Control identified bacterial agents as the leading cause of foodborne illness outbreaks, and of those, temperature management was the root cause in over half of the cases.

Proper temperature management must be based on an active monitoring plan, and where data are appropriately archived, combined with analyses of trends that show where continuous improvement should be targeted.

About Sensitech

Sensitech is the leading independent provider of cold-chain information and analysis that enable global leaders in food and pharmaceuticals to protect the integrity, freshness and efficacy of their temperature-sensitive products. In the past decade, Sensitech has protected more than \$200 billion of its customers' assets around the globe. The company is based in Beverly, Massachusetts, and has offices in Redmond, Washington, and Fresno, California, with service and distribution offices around the world. For additional information about Sensitech, call 978-927-7033 or visit www.sensitech.com.

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