Collaborating Across Boundaries Series

Food Safety—Emerging Public-Private Approaches: A Perspective for Local, State, and Federal Government Leaders

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IBM Center for
The Business of Government

2010

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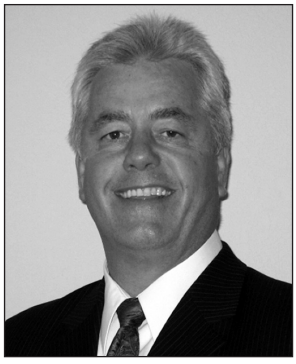
FOREWORD

On behalf of the IBM Center for The Business of Government, we are pleased to present this report, *Food Safety—Emerging Public-Private Approaches: A Perspective for Local, State, and Federal Government Leaders,* by Dr. Noel P. Greis and Dr. Monica L. Nogueira, at the University of North Carolina at Chapel Hill.

Jonathan D. Breul

Using food safety as a case study, the authors discuss new approaches to public-private partnerships. This use of new approaches to public-private partnerships is applicable to all government organizations, not just food safety agencies. New approaches to public-private partnerships include the following:

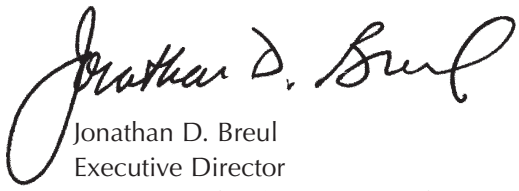
- **A new stakeholder model in which the private sector acts as a partner.** In food safety, the private sector is acting as partner in both maintaining a safe food supply and responding to food contamination events.
- **An increased emphasis on risk-based allocation strategies.** In food safety, a risk-based resource allocation will reduce disease incidence and reduce economic burden on private sector companies that have good safety records.
- **Increased use of technology and information systems.** In food safety, new food traceability techniques which utilize private sector information promises to speed up the recall process, thereby reducing the scale and scope of food contamination.
- **Increased use of co-regulation strategies.** In food safety, co-regulation assumes a variety of forms including setting standards, enforcement, and monitoring.



Michael D. Wasson

This report describes the current responsibilities of key federal agencies now responsible for food safety in America, including the Food and Drug Administration, the Food Safety and Inspection Service, and the Centers for Disease Control. The report also describes legislation now pending before Congress, which would modify the current responsibilities for agencies now involved in food safety.

We trust that this report will be both informative and useful to all government organizations now seeking to develop new forms of public-private partnerships, including federal agencies now responsible for food safety. We also hope that this report will inform ongoing public policy discourse on legislative reforms to the current food safety system in America.



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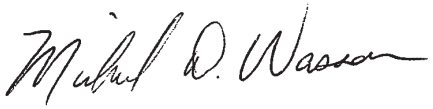

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EXECUTIVE SUMMARY

A slate of recent legislative initiatives at the national level represents the most expansive reform of food safety in the U.S. since the 1930s. Spurred, in part, by recent high-profile food contaminations, new legislation is now under consideration in Congress that not only gives the U.S. Food and Drug Administration (FDA) greater regulatory powers over the nation's food providers—but also dramatically alters the food safety landscape. Four separate bills have been introduced in this session of Congress. Provisions in these bills range from new authority for mandatory recalls for the FDA, to new risk-based approaches for inspection, and to new information management responsibilities for the private sector for "traceback" of its products in the food chain in the event of a contamination. A common theme of all the proposed bills is greater engagement between the public and private sectors in the interest of safer food.

It is evident in recent history—from the 2008 *Salmonella* peanut butter contamination to the 2008 jalapeños contamination—that our food safety net has acquired large tears that continue to permit contaminated products to find their way to retail shelves, causing irreversible human harm and considerable economic damage. The total cost of food contamination in the U.S. was recently estimated to be $152 billion, including health and human welfare costs as well as economic damage to companies and entire industries. At the same time, the food and agriculture industry represents more than $1 trillion in economic activity—or approximately 13 percent of the gross domestic product. The Government Accountability Office has estimated that losses to the U.S. economy from halted agricultural exports at the border that were attributed to food contamination exceeded $86 million in 2006.

In an effort to reduce the incidence and cost of food contamination, new thinking is emerging about the respective roles and responsibilities of the public and private sectors. A new stakeholder model is emerging in which the private sector—and even the consumer—are playing key roles in assuring safe food. Historically, food safety has been the purview of a patchwork of regulatory agencies that operate in an oversight role over the private sector. More than 15 agencies and 30 laws at the federal level are collectively responsible for food safety. These federal agencies are supported by thousands of state and local public health agencies and agricultural departments that engage in continuous surveillance and recall activities to identify, confirm, and respond to food contamination events.

Closer engagement between public and private sectors can reduce the scale and scope of food contamination events by providing enhanced prevention and improved monitoring and surveillance to ensure a more efficient response. By working together to implement risk-based and customized process controls based on mutually agreed-upon performance standards, many food contamination events can be prevented, thereby avoiding excessive costs to both industry and government. Better sharing of information related to suspected problems during production or processing would help to achieve earlier awareness of a foodborne disease outbreak—as well as faster determination of its cause and execution of recall activities. Co-regulation strategies have the potential to achieve safer food at a lower regulatory cost—while helping to maintain the competitiveness of a company or food industry.

These new developments are implicit in the emerging food safety landscape and are reflected in pending

legislation and emerging policy. Four key organizing principles define a new framework for food safety:

1. **A new stakeholder model is emerging that recognizes the role of the private sector as a key partner in both maintaining a safe food supply and responding to food contamination events.**

The new framework builds on collaboration among all stakeholders—both public and private—to work together with the common goal of safer food. The private sector has strong financial incentives to protect its markets and customers, as well as the reputation of its products. However, government regulation is needed to ensure safe food because market transactions do not take into account social costs such as medical costs and lost work time. Most importantly, consumers generally cannot discern the safety of a food product before eating it. Current pressures on governments to be more active in monitoring food safety in an environment of strained budgets, and on the private sector to produce competitive products for global markets, make public-private cooperation not only desirable, but critical. Relationships are moving from an arms-length, sometimes adversarial, relationship between regulator and regulated to a cooperative partnership, wherein each sector brings its respective knowledge and skills to the food safety table.

The private sector is assuming a more visible role. For example, facilities that manufacture, process, or hold food for consumption in the U.S. now must report any problem within 24 hours through the Reportable Food Registry, the FDA's online portal, if there is a reasonable probability that the food will cause serious adverse health consequences. Increasingly, private companies are being proactive within their organizations in implementing process controls and reporting possible problems in their manufacturing processes. The online Rapid Recall Exchange service has been developed by the industry to allow companies to inform their suppliers and customers of recalls and/or withdrawals of products in a timely fashion. At the same time, consumer complaint hotlines, along with new emerging social networking systems, are providing rapid communication about potential foodborne disease.

2. **Risk-based resource allocation strategies will reduce foodborne disease incidence, resulting in lower public sector costs of surveillance and response and reduced economic burden on private sector companies that have good safety records.**

The constraints of the current economic climate are stretching food safety resources to the breaking point. The FDA, especially, is underfunded with respect to its mandate. In today's economic climate, it is not possible to inspect regularly all food production and retail organizations. Risk-based resource allocation policies, as the words imply, allocate resources where the risks are greatest. The intent of risk-based resource allocation is to:

- Identify actions that mitigate against food contamination in accordance with the risk that they present,
- Set priorities among those actions, and
- Allocate resources to implement these actions so as to minimize those risks effectively and efficiently.

For example, under risk-based resource allocation, regulating agencies would identify food products or food types that are associated with the highest risks and inspect companies that make those products more frequently. Similarly, companies that have experienced food contamination problems in the past and/or have a high inspection violations rate would be considered to be higher risks and subject to more frequent inspections. With respect to testing, the scientific focus would be on developing improved tests for pathogens most likely to cause disease, based on the recent past.

3. **Food chain traceability will utilize private sector information about the food chain to speed up the recall process, thereby reducing the scale and scope of food contamination events and their associated social and private sector costs.**

All of the legislation pending before Congress gives the FDA new authority to require that products be traceable in the food chain—referred to as "traceback." The use of new track-and-trace technologies, with supporting information and communication technologies, enables companies not only to trace the history of a contaminated food product back up the supply chain, but also to trace forward from a

contaminated supplier to all affected products that may have been shipped to customers. Thus, trace-back is needed to pinpoint the source of a contamination to correct a faulty process or environmental condition; trace forward is needed to determine the location of other affected products in the event of a recall.

Clearly, the public and private sectors need to work together to achieve full food chain traceability. Companies typically have access to much of this information but have been reluctant to share it with the government for fear of revealing competitive information about manufacturing processes and suppliers. Yet traceability can yield positive benefits for companies, such as reduced costs, better service, and better supply chain control. The challenge for policy makers is to provide incentives to private sector companies that encourage those firms to implement and strengthen their traceability systems—thereby creating a win-win situation.

4. Co-regulation strategies are a win-win opportunity to shape food safety policies so as to reflect the mutual organizational and financial interests of public and private sectors alike.

Policy makers view co-regulation as a solution for bridging the gap between the social costs of *laissez-faire* market approaches and the economic costs of strict overregulation. Co-regulation can assume a variety of forms:

- **Setting Standards:** Industry, and even consumers, can provide input into the standards-setting process. In some industries, companies have established voluntary standards that are higher than the regulated standards.
- **Process Standards:** Regulatory agencies and private sector companies can work together to establish best practice standards for the processes by which foods are produced and/or transported. With co-regulation, industries are able to adapt these standards to their business environment for better alignment with their business strategy.
- **Enforcement:** Co-regulatory approaches for enforcement try to achieve a delicate balance between industry self-regulation and complete second-party oversight. Market-based regulatory mechanisms are an effective form of co-regulation. For example, the "scores on doors" approach—where inspection reports are publicly available at restaurants—serves as a market-based driver for improved performance.

Abbreviations and Acronyms

CDC	Centers for Disease Control and Prevention
CFSAN	Center for Food Safety and Applied Nutrition
DHS	U.S. Department of Homeland Security
eFORS	Electronic Foodborne Outbreak Reporting System
EIP	Emerging Infections Program
eLEXNET	Electronic Laboratory Exchange Network
EPA	U.S. Environmental Protection Agency
ERS	Economic Research Service
FDA	U.S. Food and Drug Administration
FERN	Food Emergency Response Network
FoodNet	Foodborne Diseases Active Surveillance Network
FSIS	Food Safety Inspection Service
GAO	U.S. Government Accountability Office
GDP	Gross domestic product
HACCP	Hazard Analysis and Critical Control Points
HHS	U.S. Department of Health and Human Services
ISO	International Organization for Standardization
OutbreakNet	Outbreak Network for Foodborne Disease Surveillance and Response (CDC)
PCA	Peanut Corporation of America
PFGE	Pulsed-field gel electrophoresis
PulseNet	National Molecular Subtyping Network for Foodborne Disease Surveillance (CDC)
RFF	Resources for the Future
RFID	Radio frequency identification
RFR	Reportable Food Registry
RRE	Rapid Recall Exchange
USDA	U.S. Department of Agriculture

- **Monitoring:** Many companies have implemented internal monitoring processes as part of their quality control programs. Companies also hire third-party inspectors—with mixed results. Voluntary certification programs can provide a broader co-regulatory base, with standards set by government and certified by industry.

In sum, globalization and the growing complexity of the food chain demand new approaches that reflect the concerted and coordinated efforts of both public and private sector leaders—both critical stakeholders in our emerging food safety network. To be sure, contaminated food products will continue to be a concern worldwide and a threat to the health of U.S. citizens. However, a new stakeholder model that recognizes the roles and responsibilities of both government and business leaders alike is a first step in the right direction toward safer food.

Introduction

"The federal regulatory system for food safety, like many other federal programs and policies, evolved piecemeal, typically in response to particular health threats or economic crises. During the past 30 years, we have detailed problems with the current federal food safety system and reported that the system has caused inconsistent oversight, ineffective coordination, and inefficient use of resources. We have cited the need to integrate this fragmented system as a significant challenge for the 21st century, to be addressed in light of the nation's current deficit and growing structural fiscal imbalance."[1]

Most Americans purchase food for their family's dinner table with a high level of assurance that the food is safe. However, recent incidents of contamination have brought into sharp focus existing gaps in our current food safety net and drawn attention to needed changes. Beginning in 2008, the nation's attention was focused on a home-grown *Salmonella* Tryphimurium contamination in peanut butter paste that was traced to a Georgia (U.S.) peanut processing plant owned by the Peanut Corporation of America (PCA). This event sickened more than 700 people in 44 states and was associated with nine deaths—and also resulted in the largest dollar-valued food recall in U.S. history. More than 3,900 products were recalled. Early estimates of the costs to the peanut butter industry due to lost sales were more than $1 billion.[2]

Also in 2008, a mysterious case of contamination was reported in the southwestern U.S. The source remained unknown for many weeks until it was traced to jalapeño and serrano peppers grown on farms in Mexico and sold to restaurants in the U.S. The Centers for Disease Control and Prevention (CDC) estimated that a total of 1,442 people were sickened by this rare strain of *Salmonella* Saintpaul. More than 286 were hospitalized—with at least two deaths. Early investigations pointed to raw tomatoes, possibly plum or Roma tomatoes, as the likely source of contamination. It was subsequently determined that the culprit was not tomatoes but jalapeños after a sample of jalapeños tainted with *Salmonella* Saintpaul was found at the restaurants where the affected people had eaten. This sample was linked to a sample from a packing plant in McCallen, Texas, that sourced its jalapeños from farms in Mexico.

The recent melamine contamination of milk products in China reminds us that the problem of safe food extends far beyond U.S. borders. While the *Salmonella* Tryphimurium peanut contamination in the U.S. was caused by improper processing and a lack of sanitary conditions, melamine was intentionally added to milk in China to artificially inflate the protein content, thereby securing a higher price in the market. As a result of melamine-adulterated milk, more than 60,000 children in China were diagnosed with kidney stones—with unknown long-term health effects. Products containing melamine-adulterated milk were found throughout Asia, including Taiwan and Hong Kong, as well as across Europe. Here in the U.S., confections made from contaminated powdered milk produced in China were found on the shelves of a retailer in the Midwest.

Recently, cancer-causing dioxins were found in Irish pork and beef being sold in the United Kingdom.[3]

Melamine in Milk—The China Connection

The connectedness of our global food chains and their potential threats to food safety were clearly illustrated by the recent melamine contamination of milk and milk powder in China. This crisis occupied the headlines around the globe for many months during 2008, and its impacts were felt worldwide. More than 60,000 Chinese infants fell sick from drinking melamine-laced milk, and four died. Melamine was intentionally added to the milk by middlemen in the Chinese milk supply chain in order to make the milk appear to have a higher protein level. Melamine is a chemical additive used in plastics manufacture. Higher levels of protein command higher market prices—hence, profits. The problem was brought to light in June 2008 by a surge of kidney stone diagnoses in infants in Jiansu Province near Shanghai.

The root of the Chinese milk scandal lies in the economics of the milk supply chain. Chinese do not have a tradition of drinking milk. But as incomes rise, Chinese are buying more milk and yogurt because it is viewed as a healthy food, especially for the young. Consequently, the Chinese milk market has grown at an average annual rate of 23 percent since 2000. In 2006, milk production reached 30 million tons, 10 times the volume of a decade before.[4] Historically, milk farmers have sold their product directly to local dairies. To meet growing demand, however, middlemen created a business by collecting farmers' milk and selling it to processors in distant markets in large urban areas. The middlemen recognized the opportunity to increase profits—in a regulated industry with slim profit margins and virtually no product testing or inspections—by adding melamine to milk.

Like King Nut peanut butter, melamine-laced milk and milk powder found its way into thousands of other derivative products. A survey by the Chinese government revealed that 31 out of 265 products made with milk powder were reported to be contaminated. Twenty countries banned the import of Chinese milk products, with disastrous results for the industry and China's reputation. Small famers lost their entire sources of income, forcing the government to subsidize farmers as part of a rescue plan.

The health crisis turned into a global scandal when reports surfaced that the Chinese government knew of the problem as early as spring 2008, but failed to act so as not to disrupt the 2008 Olympic Games. The first deaths occurred on May 1, 2008, several months before the start of the Olympics. When the crisis broke in mid-September, a month after the Olympics, several Chinese reporters stated that they had reported to authorities about babies being hospitalized after drinking tainted milk, but that their reports were ignored.

The industry is still in a recovery period, and some melamine-tainted milk continues to be found. It should be noted that melamine may be entering the food chain in a number of other ways. Melamine was found last year in Chinese pet food exported to the U.S., when many cats and dogs developed acute kidney failure and died. Derivatives of melamine are used as a pesticide and also may enter the food chain through contaminated animal feed.

The alert was issued after dioxin levels between 80 and 200 times the legal limit were found in samples of pork from animals that had been fed contaminated feed. Irish investigators traced the source of the contamination to a single animal-food maker, Millstream Power Recycling Ltd. Contaminated feed had been sent to 10 pig farms that produce around 10 percent of the total supply of pork in the country. Animals from these farms are processed by meat plants that supply some 80 percent of Ireland's pork and pork-based products. The problem also spread to beef farms. In all, products supplied to as many as 23 countries were affected—13 within the European Union and the remainder outside Europe, including the U.S. and spanning at least three continents.

It should be apparent from the above examples that the U.S. is not alone in experiencing large-scale foodborne disease and contaminated food products. Today, public sector administrators at all levels of government must stay abreast of a dynamic global environment, in which the risk of contaminated food products crossing our borders is growing and in which an increasingly complex fabric of global regulations and laws govern the monitoring and management of food safety events. At the same time, agriculture represents an important segment of our national economy, producing products that not only appear on domestic grocery shelves, but that also support a critical export economy.

The public must decide what value it places on food safety. It will never be possible to create a food system that does not experience failure. How much risk is the public willing to accept? How much of the cost of food safety should fall on the private sector? Is one public dollar better spent on prevention, or surveillance, or outbreak response in modernizing the food safety net? What roles and responsibilities should each of the stakeholders—public and private—have in this national effort, and what relative costs should they bear? This is the crux of the current food safety debate in the U.S.

This report provides a broad framework for public sector officials at all levels—local, state, and federal—to think about current trends in global food production and the respective roles and responsibilities of all stakeholders—regulatory agencies, food processors and distributors, as well as consumers—in building a modern national food safety system. We discuss the reasons for the increasing risk of foodborne contamination in their communities and the existing safety net. Two recent case studies illustrate how our food safety system works in practice, and we explore emerging strategies by which public and private sectors are beginning to work together in a win-win relationship to meet the often conflicting goals of safer food and a globally competitive food industry.

Food Safety: One Hundred Years of History

Like the Peanut Corporation of America contamination of 2008, the 1905 publication of Upton Sinclair's book, *The Jungle,* represented a defining moment in American food safety history. *The Jungle's* fictionalized account of Lithuanian immigrants living and working in Chicago's stockyards at the turn of the century described the harsh working conditions of the time. While Sinclair's fictionalized exposé of squalor in Chicago's meatpacking houses is widely thought to be the stimulus for the creation of the FDA, it was not Sinclair's original intent. He wanted to elevate consciousness of the need for socialism, not to press for reform of meat safety. His lifelong goal was rather to end poverty, and later, in the 1920s, Sinclair moved to Monrovia, California, where he founded the state's chapter of the American Civil Liberties Union. Intended or not, *The Jungle* contributed to the passage of the Pure Food and Drug Act on June 30, 1906, a federal law that provided federal inspection of meat products and forbade the manufacture, sale, or transportation of adulterated food products and poisonous patent medicines. At the urging of Sinclair, President Roosevelt also signed into law the Federal Meat Inspection Act on June 30, 1906, which required federal inspection of meatpacking houses for the first time. In 1910, the USDA's Bureau of Animal Industry was assigned responsibility for enforcing the Meat Inspection Act. Within one year, the number of meat inspectors at the bureau grew from 981 to 2,290, operating in more than 700 establishments. Today, USDA's FSIS employs more than 8,000 inspectors nationwide.

The Current Landscape of Food Safety

"The food safety net just showed us another huge tear as the result of contaminated peanut butter products. The problem will be felt for years in the peanut industry and will likely change the food safety landscape in many ways."[5]

It is difficult to estimate the true extent of foodborne disease. However, it can safely be said that foodborne disease occurs more frequently than reported and incurs more costs than estimated. On its website, the CDC estimates that more than 76 million people in the U.S. are affected by foodborne disease every year, and that there are more than 325,000 hospitalizations and 5,000 deaths.[6] These figures are more than 10 years old and are in need of an update, but they can be accepted as a baseline for today's rate of incidence. Further, for every foodborne illness case that is reported, it has been estimated that as many as 40 more illnesses are not reported or lab-confirmed.[7] A summary of some of the major food contamination events in the U.S. over the last 10 years is shown in Table 1. It is apparent from the table that, while the events are distributed across many types of food products, contaminations of meat and poultry products, as well as fresh produce, dominate the list.

Increasing Opportunities for Food Contamination

There are several reasons for the increasingly frequent headlines about failures of our food safety system and increases in foodborne disease. These headlines can be attributed in part to the changing demographics of our country. Foodborne illness disproportionately affects certain segments of our population—in particular the elderly, the very young, pregnant women, and people with compromised immune systems. These groups make up 20 percent to 25 percent of our current population, or as many as 75 million people. As our population continues to age, these numbers will grow. It is estimated that chronic, secondary complications resulting from foodborne illness occur in 2 to 3 percent of cases. These already-at-risk populations are at even greater risk of foodborne disease because institutional food products destined for nursing homes, food banks, prisons, and other public institutions may not be produced by brand-name manufacturers but by second-tier producers who compete on the basis of cost rather than quality and safety.

New trends in food consumption also are contributing to the increased likelihood of foodborne disease. As a result of a growing desire for healthful eating, more people are demanding fresh and organic produce and nonprocessed foods. While these may have lower levels of pesticides and other additives, they also have a higher risk of contamination or spoilage along the food chain than do processed foods. According to unpublished FDA data, there were at least 96 outbreaks, 10,253 illnesses, and 14 deaths associated with the consumption of fresh produce between 1996 and 2006.[8] A portfolio of new, conveniently packaged produce—from fresh-cut fruit to bagged greens—is increasingly vulnerable. And, as standards of living rise around the world, people are spending an increasing fraction of their disposable income eating outside the home in restaurants or fast-food outlets—and even from street vendors. Not only is the likelihood of contamination of non-home food higher, but the potential for more widespread illness is larger.

Table 1: Major Food Contamination Events in the U.S. (2000–2009)

Year	Food Product	Pathogen	Company
2009	Salami	***Salmonella* Montevideo**	Daniele International
	Beef Products	***Salmonella* Newport**	Cargill
	Peanut Butter Paste	***Salmonella* Typhimurium**	Peanut Corporation of America
	Refrigerated Cookie Dough	***E. coli O157:H7***	Nestle
2008	Jalapeño and Serrano Peppers	***Salmonella* Saintpaul**	Mexican Farm
2007	Milk Products	***Listeria***	Whittier Farms
	Chicken and Turkey Pot Pies	***Salmonella***	ConAgra
	Beef Products	***E. coli O157:H7***	Topps Meat Co.
	Spinach	***Salmonella***	Metz Fresh
	Chili Sauce	**Botulism**	Castleberry Food Company
	Peanut Butter	***Salmonella***	Peter Pan and Great Value
	Beef	***E. coli O157:H7***	United Food Group
2006	Green Produce (green onions)	***E. coli O157:H7***	Taco Bell
	Bagged Spinach	***E. coli O157:H7***	Natural Selection Foods
2003	Green Onions	***Hepatitis A***	Pennsylvania
2002	Ground Beef	***E. coli O157:H7***	ConAgra
	Chicken	***Listeria***	Pilgrim's Pride
	Beef	***E. coli O157:H7***	Emmpak Foods
2000	Bean Sprouts	***Salmonella***	Pacific Coast Sprout Farms
	Raw Beef	***E. coli O157:H7***	Sizzler Restaurant and Excel Meat Packing
	Suspected Beef	***E. coli O157:H7***	Wendy's

Also, our current food safety systems are not in alignment with our global way of eating. Many products found on American dining tables have one or more ingredients that originate abroad—often in emerging markets. The Center for Science in the Public Interest estimates that the average American eats more than 260 pounds of imported food each year—or 13 percent of their annual diet.[9] Globalization and the cross-border operations of many food-processing companies appear to be shifting the sources of consumer-ready food products from traditional suppliers such as Canada to developing countries in Asia and Latin America, where manufacturing costs are lower and quality control may be limited. According to a 2009 study by the USDA, U.S. food imports increased overall from $41 billion in 1998 to nearly $78 billion in 2007. The share of U.S. food imports attributed to developing countries grew from 49 percent in 2002 to 53 percent in 2007.[10]

Globalization means that food products are traveling *farther* and, in many cases, originate in or travel through regions that do not have adequate logistics for maintaining the safety of perishables. Food products are traveling *faster,* as well, so that a contaminant can find its way from one continent to another in a matter of hours. The ability to ship perishables via air freight is a contributing cause. The declining costs of air cargo for overnight delivery virtually anywhere around the world have resulted in entire new categories of imported food on our dining tables. We enjoy Chilean sea bass, seafood from China, shrimp from Thailand, and exotic fruits from sources worldwide. Many of these products come from countries with an inadequate cold chain infrastructure. In these countries, products are not transported from the point of harvest to the airport in refrigerated "reefer" trucks or stored in refrigerated warehouses prior to shipment. For example, China enjoys only 1.6 cubic feet per middle-class capita of

cold storage facilities, compared with 16 cubic feet in the United States.[11]

The speed with which contaminated food can travel to multiple destinations simultaneously also complicates both surveillance and timely response to foodborne disease. In August 2009, five Queensland, New Zealand, residents contracted listeriosis food poisoning. Listeriosis is caused by parasitic bacteria and affects primarily pregnant women, young children, and people with weakened immune systems. The cause was pinpointed as contaminated chicken wraps served on Virgin Blue flights between Australia, New Zealand, and Bali. The wraps were produced by New South Wales-based GMI Food Wholesalers. As many as 5,000 flights in May and June of that year could have carried the snacks laced with potentially deadly *Listeria* bacteria. Subsequent investigations revealed that listeria-laden contaminated wraps were linked to two premature births.[12]

Increasing Costs of Food Contamination Events

The growing complexity of global food chains has increased not only the incidence of contamination events but also the ultimate cost of one. *Salmonella* infection, one of the leading causes of foodborne disease, represents a significant portion of the costs of food contamination in the U.S. The CDC has estimated that 95 percent of *Salmonella* infections are foodborne in origin. Salmonellosis is likely vastly underreported. Since *Salmonella* poisoning usually presents as diarrhea and other low-grade symptoms, its costs are frequently underestimated because people do not seek medical care but rather stay home from work and recover on their own. Many other foodborne illnesses are likely to be underreported, since not everyone with a gastrointestinal illness seeks medical attention.

According to a 2008 report by the Government Accountability Office (GAO), between 1996 and 1997 more than 2,000 culture-confirmed cases of *Salmonella* were reported to the CDC's Foodborne Diseases Active Surveillance Network (FoodNet), which covers approximately 15 percent of the U.S. population.[13] Assuming that people across the U.S. are equally likely to fall ill from *Salmonella* at the same rate, we can project that 35,621 cases would have been reported to FoodNet during the same period over the entire U.S. population. To estimate the total number of cases, the CDC uses accepted multipliers to estimate total population incidence based on the number of reported cases (or in this case, the reported cases extrapolated over the entire U.S. population). Based on the 2,092 cases reported to FoodNet, the CDC estimated that 1.4 million salmonellosis cases occur annually in the U.S.

The costs of disease attributed to specific foodborne pathogens are tracked and estimated by the Economic Research Service (ERS) of the USDA.[14] ERS published its first comprehensive cost estimates for 16 foodborne bacterial pathogens in 1989. In 2003, ERS introduced the Foodborne Illness Cost Calculator, an interactive online version of the updated ERS cost estimator, for five selected foodborne pathogens. The Cost Calculator provides detailed information about the assumptions underlying each estimate, and allows users to make alternative assumptions and re-estimate the costs.[15] The first estimates using the Cost Calculator were computed for *Salmonella*. ERS estimates that the annual economic cost of all cases of salmonellosis—the illness caused by the *Salmonella* bacterium—is approximately $2.6 billion (in 2008 dollars). The Center for Science in the Public Interest recently estimated the total national cost of foodborne disease in the U.S. to be as high as $152 billion. This amount includes not only medical costs, the costs of premature death, and lost productivity as noted above, but also public health costs related to the tasks of detecting and responding to an event—many of which fall to local communities and the states.

In addition to public health costs, the economic costs to companies, industries, and regional economies can be significant and lasting. Although the final tally of total industry and economic costs for the PCA contamination is not yet available, estimates of nearly $1 billion have been suggested, including $500 million due to lost peanut sales as well as to a loss of consumer confidence in the government's ability to protect its citizens. The Kellogg Company has estimated its losses alone to be more than $75 million. Within the local Blakely, Georgia, community, the impacts were devastating. Blakely is the self-proclaimed peanut capital of the world, and a large portion of the local economy depends on peanut products. Already struggling with high unemployment and recession, the PCA plant closing only

exacerbated existing difficulties. The peanut industry is also central to the Georgia state economy. Georgia produces 45 percent of the nation's peanuts, and peanut sales during and immediately after the event declined more than 25 percent nationwide. While demand for peanuts subsequently rebounded, it was too late for PCA and its employees, because the firm had ceased operations.

New food safety regulation must consider costs and benefits across all stakeholders in the food safety nexus. The calculus is tricky. In particular, government is increasingly being asked to make trade-offs between the costs of implementing new food safety regulations, which are borne largely by the private sector, and the public health and economic costs of contamination events. The stakes are high. The food and agriculture industry is the largest industry and employer in the U.S. According to the GAO, the industry currently accounts for more than $1 trillion in economic activity, or about 13 percent of the gross domestic product. The GAO estimates that, in 2006, the losses to the U.S. economy from halted agricultural exports due to economic disruptions attributed to contaminated food exceeded $86 million.[16]

Responsibilities of Key Federal Agencies

"Fragmented" is the word most often used to describe the U.S. food safety system. Today, more than 15 different U.S. agencies collectively administer more than 30 laws related to food safety. The U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA) are charged with the inspection of food products produced within the U.S. and crossing our borders, but systems are fractured and unconnected. And the lines delineating authority are often unclear and overlapping—and seemingly inconsistent. A third entity, the CDC, plays a critical role working with the FDA and the USDA to perform surveillance activities that detect foodborne illness and contamination events.

For example, different agencies regulate meat lasagna and vegetable lasagna, because meat products are the responsibility of the USDA while vegetable products are the responsibility of FDA. Similarly, inspection policies vary and are inconsistent, as proponents of reform like to point out. An open-faced ham-and-cheese sandwich is inspected by the USDA, while a closed-face ham-and-cheese sandwich is inspected by the FDA. In another example, eggs still in the shell fall under the purview of the FDA, while the USDA takes over once the eggs are broken. The respective roles of the primary departments and/or agencies that share responsibility for the safety of our nation's food supply are further discussed in the appendix.

The Food and Drug Administration (FDA) located within the Department of Health and Human Services (HHS), enjoys principal responsibility for the safety of most of the U.S. food supply as well as for food labeling. The FDA oversees 80 percent of the U.S. food supply, including oversight of most of the imported food products from international trading partners. The FDA is also responsible for overseeing food additives such as color additives, preservatives, and other nutrient additives. As we will see later, the FDA has responsibility for the routine inspection of food production facilities, as well as for the testing of food products in the event of a contamination. In the event of an outbreak, the FDA will perform "traceback" activities in collaboration with states to locate the source of an outbreak and will request voluntary recalls by manufacturers. The FDA also has oversight responsibility for farms and retail food establishments. Within the FDA, the Center for Food Safety and Applied Nutrition (CFSAN) is responsible for initiatives to reduce the risk of foodborne illness, including standards setting and compliance strategies.

The Food Safety and Inspection Service (FSIS) located within the USDA, is responsible for the safety of meat, poultry, and processed egg products—approximately 20 percent of our food supply. More than 7,800 FSIS inspectors have oversight of more than 6,000 slaughterhouses, meat processing facilities, and import establishments across the country. By federal mandate, they are required to visit each processing facility once during each operating day. Under statute, the USDA is also responsible for visual inspection of every meat and poultry carcass—totaling more than 8 billion chickens and 125 million heads of livestock annually. To meet this mandate, USDA contracts with state inspection agencies on a state-by-state basis. The FDA, in contrast, does not currently have a federal mandate to inspect food production facilities on a prescribed schedule.

Food safety is only one of the USDA's mandates. The USDA is also charged with supporting agricultural trade and enhancing the competiveness of U.S. agriculture abroad; improving farm economics, especially for rural farms; improving the nutrition of U.S. citizens through agriculture; and generally protecting the nation's agricultural resources. Many view the USDA's mission to expand market opportunities for agricultural products to be at odds with its role as an overseer of food safety.

The Centers for Disease Control and Prevention (CDC) located within HHS, is responsible for surveillance and epidemiological activities by which foodborne disease is detected, and works with the FDA and USDA to respond to a confirmed outbreak. The CDC's primary role is to collect and analyze public health data in the event of suspected foodborne disease outbreaks, especially those which cross state boundaries. States and localities regularly report epidemiological data to the CDC, which then uses analytics and other statistical tools to confirm that an outbreak has occurred. The CDC has developed a number of information networks and informatics tools that have been very effective in both detecting and confirming signals of an outbreak, and in working with the FDA and FSIS to manage the outbreak once it has been confirmed.

While federal agencies like the FDA, the FSIS, and the CDC coordinate food safety at the federal level, the larger role in detecting and responding to foodborne disease and food contamination events falls to local communities and states. Local communities and state agencies are the workhorses of our national food safety system and play a signature role in all aspects of the food safety process, from data collection and surveillance to forensic investigations to pinpoint the source of a contamination—and to the inspection of millions of restaurants and retail food operations across the country. States perform about 50 percent of FDA inspections under contract, thereby taking on a large fraction of the burden from the FDA. It is estimated that state and local health organizations perform more than 80 percent of the food safety work.[17]

In fact, most outbreaks of foodborne disease or food contaminations are usually first detected at the local level—from a pattern of local emergency room visits, from physician reports, from observations by state epidemiologists of multiple common illnesses, or from reports to state surveillance systems. More than 3,000 local public health departments work with state departments of public health and agricultural agencies, state epidemiology laboratories, and other related state agencies to keep unsafe foods off our grocery shelves. In other cases, a state laboratory may notice a cluster of related infections, which it then reports to the CDC so that the CDC can check whether other states are experiencing similar cases. Sometimes state agricultural departments discover contaminated food products during routine facility inspections—before they cause public health problems.

The complexity of the regulatory landscape for food safety has prompted calls for consolidation, or rationalization, of all food safety responsibilities at the federal level in a single agency.[18] One of the first efforts to consolidate food safety oversight in the U.S. was the reintroduction of the Safe Food Act in 2005 by Senator Dick Durbin and Representative Rosa DeLauro. And on February 9, 2009, Secretary of Agriculture Tom Vilsack advocated the consolidation of all food safety responsibilities into a single agency. Proponents argue that the single-agency solution would reduce the duplication of responsibilities, service gaps, inconsistencies, and confusion about which agency oversees what type of food. Others argue that, while current agencies do seem overwhelmed, better solutions involve more industry self-control, along with more funding and authority to the USDA and the FDA so that they can better perform the functions with which they have been charged. Some argue that the redundancy and overlap across agencies actually helps to protect our food supply through a network of checks and balances.

How the Food Safety System Works in Practice

"On a summer's day in 1906 Theodore Roosevelt pushed through new food safety regulation. The Food and Drug Act passed that day over 100 years ago was the last time the U.S. food safety system was modernized."[19]

The first defense against a food contamination event is prevention. One of the most widely used tools for avoiding food contamination during production and processing is the systematic risk assessment system known as Hazard Analysis Critical Control Points (HACCP). Like Total Quality Management tools, HACCP is a management process that is implemented by an organization to determine potential risk points during food production and to define a strict management and monitoring system to minimize the risks at those points. Systematic approaches like HACCP address possible physical and biological hazards in the food production process in an effort to prevent food safety events rather than rely solely on the inspection of finished products.

HACCP can be applied to all stages of the food production and preparation processes, including packaging and distribution, and to different food products. The FDA regulates the use of HACCP for the juice and seafood industries and promotes the voluntary use of HACCP for operators of other food service and retail establishments. The USDA regulates HACCP for meat and poultry processing plants. The use of HACCP is currently voluntary in other food processing industries, and is being increasingly used in commercial endeavors such as in the pharmaceutical and cosmetics industries. HACCP's seven principles are shown in Table 2.

Risk assessment systems like HACCP that minimize the risk of foodborne disease through better management of the food production and transport processes will never completely eliminate food contamination events. When prevention fails and contamination occurs, effective surveillance and response activities are essential to minimize the scale and scope of any potential outbreak.

The CDC, working with the FDA and the USDA, has developed several information systems to help improve the coordination of foodborne disease surveillance and response at the national level. Three of the most important are FoodNet, PulseNet, and OutbreakNet.

FoodNet is a major component of CDC's surveillance program.[20] Established in 1996, FoodNet is a collaborative project of the CDC and 10 Emerging Infections Program (EIP) sites including California, Colorado, Connecticut, Georgia, New York, Maryland, Minnesota, Oregon, Tennessee, and New Mexico, as well as the USDA and the FDA. FoodNet conducts surveillance at the 10 EIP sites for laboratory-confirmed cases of infection caused by nine pathogens commonly associated with foodborne disease (*Campylobacter*, *Cryptosporidium, Cyclospora, Listeria*, *Salmonella*, Shiga toxin-producing *Escherichia coli* O157, *Shigella*, *Vibrio*, and *Yersinia*). In 2006, the catchment area of FoodNet represented 44.1 million persons, or only 15 percent of the U.S. population. FoodNet is an active surveillance system, which means that local public health officials are able to contact laboratories directly to discover

Table 2: Seven HACCP (Hazard Analysis Critical Control Point) Principles

Principle	Description of HACCP Principle
Conduct a hazard analysis	Determine the food safety hazards and identify the preventive measures the plant can apply to control these hazards. A food safety hazard is any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.
Identify critical control points (CCPs)	A CCP is a point, step, or procedure in a food manufacturing process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to an acceptable level.
Establish critical limits for each CCP	A critical limit is the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level.
Establish CCP monitoring requirements	Monitoring activities are necessary to ensure that the process is under control at each CCP. In the U.S., the FSIS is requiring that each monitoring procedure and its frequency be listed in the HACCP plan.
Establish corrective actions	HACCP plans must identify corrective actions to be taken if a critical limit is not met. Corrective actions are intended to ensure that no product injurious to health or otherwise adulterated as a result of the deviation enters commerce.
Establish record keeping procedures	A plant maintains certain documents, including its hazard analysis and written HACCP plan, and records documenting the monitoring of CCPs, critical limits, verification activities, and the handling of processing deviations.
Establish HACCP validation procedures	Validation ensures that the plants do what they were designed to do; that is, they are successful in ensuring the production of safe product. Plants will be required to validate their own HACCP plans.

Source: *www.fsis.usda.gov and en.wikipedia.org, last accessed July 16, 2010.*

new cases of foodborne diseases and report them electronically instead of waiting for the reports to flow back from the CDC.

When cases of foodborne disease are suspected, laboratory samples are sent to the CDC for testing to confirm the possible presence of a common foodborne pathogen that would indicate an emerging outbreak. Like humans, pathogens have distinctive genetic characteristics or DNA that can be used to determine whether the same pathogen is responsible for multiple instances of foodborne disease.

PulseNet, perhaps one of the most significant innovations in food forensics, is the system for genetic "fingerprinting" of these pathogens using a process called pulsed-field gel electrophoresis (PFGE).[21] For example, when the CDC receives information through FoodNet that two or more clusters of foodborne disease have been detected at the state level, PulseNet is able to determine whether these clusters are due to the same pathogen through an analysis of genetic subtypes.

After the PFGE patterns are generated, they are entered into an electronic database of DNA fingerprints at state, local, and federal laboratories. The patterns are also uploaded to the CDC's national database. These databases are available on demand—allowing rapid comparison of the DNA patterns. Database managers at the CDC also perform regular searches of the database, looking for clusters of patterns that are indistinguishable from one another. The results are reported back to the state labs, CDC epidemiologists and, if relevant, to the WebBoard, the PulseNet listserv.

The PulseNet database today includes more than 120,000 patterns. All 50 state public health departments participate in PulseNet, along with some local public health laboratories and the USDA and FDA. A similar PulseNet system in Canada is able to exchange DNA fingerprints in real time with PulseNet in the U.S. PulseNet now has a much broader international presence through PulseNet International Networks, which congregates not only the U.S. and Canadian networks but also PulseNet Latin America and the Caribbean, PulseNet Europe, PulseNet Asia Pacific, and PulseNet Middle East.[22]

OutbreakNet is a network of public health epidemiologists at the local, state, and federal levels who

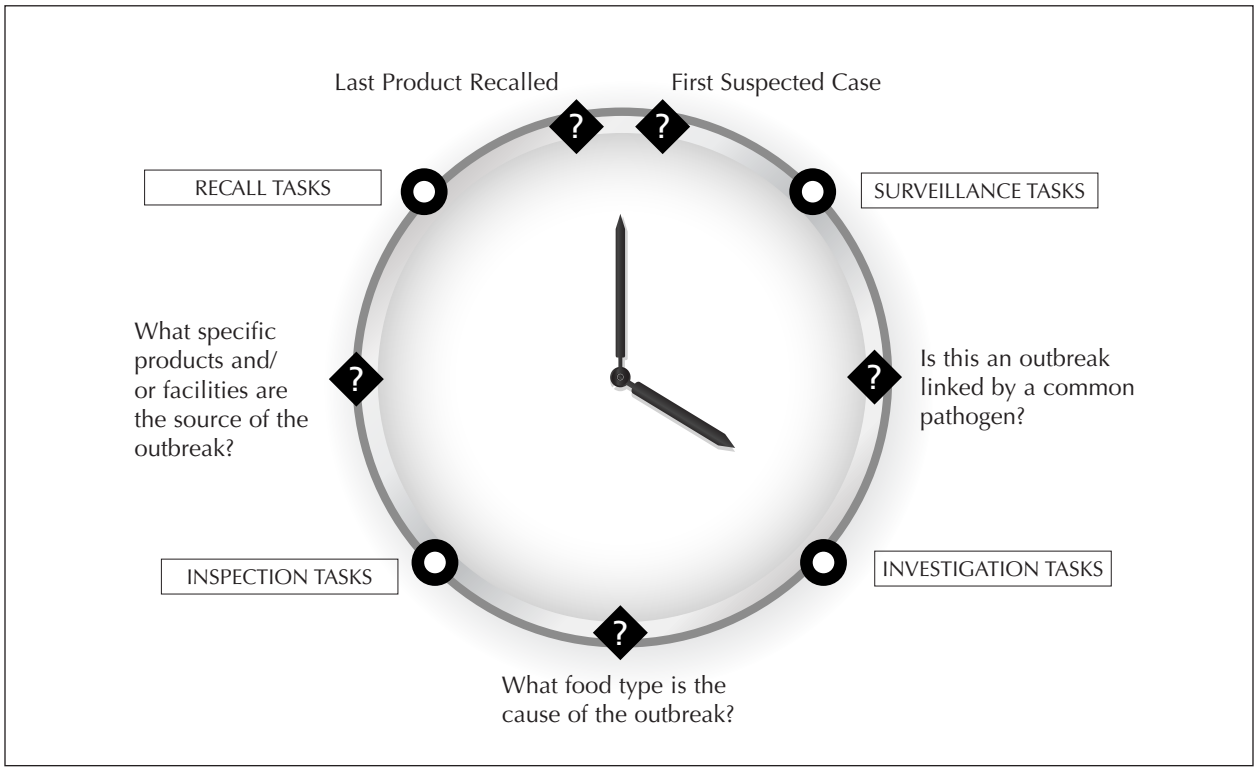
investigate foodborne disease outbreaks to pinpoint their source.[23] After the pathogen responsible for an outbreak has been confirmed, the CDC's OutbreakNet team collaborates with the national network of epidemiologists and other public health officials to conduct investigations into possible sources of the contamination. The purpose of OutbreakNet is to help ensure rapid, coordinated detection and response to multistate outbreaks of foodborne (and other) diseases. Teams of epidemiologists and biostatisticians conduct time-consuming interviews and investigations to identify potentially contaminated food products. OutbreakNet participants use standardized interview methods and forms to assess whether there are statistically significant common exposures among the patients that would help identify a common outbreak source.

The Food Emergency Response Network (FERN) is a national network of local, state, and federal testing laboratories that is responsible for testing potentially contaminated food products for the responsible pathogen.[24] In addition to these systems, other agencies have developed their own systems. The FDA worked closely with the CDC and USDA to establish FERN. The FDA is currently working with the USDA and other federal and state agencies on the Electronic Laboratory Exchange Network (eLEXNET), the first integrated, web-based data exchange system for sharing food testing information. When finished, eLEXNET will allow multiple agencies engaged in food safety activities to compare and coordinate findings of laboratory analyses. Many states have also developed their own state-wide surveillance systems that report directly to CDC systems.

The above process of surveillance and response is represented by the four phases of the food safety wheel in Figure 1. The scale and scope of a foodborne event is directly related to the speed with which the following tasks can be performed in each phase:

- ***Phase One: Determine that an outbreak has occurred.*** During Phase One, public health officials engage in surveillance activities, for example using FoodNet, to determine whether cases are part of a larger outbreak. Local public health departments are usually the first to pick up the signals of foodborne disease. These signals may correspond to isolated reports of illness or they may be causally linked and part of a larger outbreak. When state and local officials suspect a set of similar cases, samples are sent to the CDC for DNA "fingerprinting" using PulseNet to confirm that the illness is due to the same pathogen. Through this method, the CDC is able to identify similar clusters across states, which is critical since the likelihood of cross-state contamination from a single source is quite high for ingredient-driven contaminations.
- ***Phase Two: Determine the cause of the foodborne outbreak.*** Confirmation of the pathogenic source becomes the starting point for investigations by the response teams to determine the specific food types that are responsible for the illness. Once a common pathogen has been identified and an outbreak has been confirmed, epidemiologists such as those on the OutbreakNet team conduct interviews to discover the offending food types (e.g., tomatoes) in Phase Two. After laboratory results confirm a specific pathogen strain linking cases to an outbreak cluster, epidemiologists conduct detailed interviews with affected individuals to determine their food history and any other relevant details that may be related to their illness. Early investigation efforts may point to certain food types or food products as the cause of the contamination.
- ***Phase Three: Determine the source of the foodborne outbreak.*** During Phase Three, suspected food products and facilities are tested and inspected to identify specific product brands and/or production facilities. Results may be reported to FERN and exchanged using eLEXNET. Once a possible food type has been determined to be the cause (cf. tomatoes), inspectors and other state and local officials test product samples at companies that are suspected to have produced the contaminated product. Determining the cause and source of an outbreak can be a time-consuming, iterative process during which public health and agricultural experts work together to link a suspected food type with specific products and/or facilities through laboratory tests for suspected pathogens.
- ***Phase Four: Locate and recall all contaminated products.*** The time-consuming, difficult task of recalling all contaminated products is accomplished in Phase Four. Once a particular food

Figure 1: Key Tasks in Surveillance and Response Processes



product or production facility has been identified, activities are launched to identify growers, manufacturers, and others that may be linked in the food distribution chain. If contamination occurs at a facility that produces an ingredient, it is important to know all downstream customers who may have used this ingredient in their products. Advisory alerts may be issued by health and consumer service officials warning the public to avoid these specific food products. At the same time, voluntary recalls may be issued for that specific product and any derivative products. Recalls may require time-consuming investigation—both *traceback* to the source of the contamination and *trace forward* over the product's supply chain to propagate the recall to all its derivative products already in the food chain.

The whole process—from detection of an outbreak and identification of the offending pathogen to identification of the contaminated products and issuance of recalls—is plagued by multiple delays caused by many factors. The primary sources of delay include the lack of integration across multiple sources of data at different jurisdictional levels during surveillance and the lack of integration between government agencies and the private sector data during traceback. Although considerable effort is being made currently to develop interoperable systems, the diversity of systems at the state level and the proliferation of systems across agencies at the federal level complicate this task.

Gaps in Theory and Practice: Two Case Studies

"Fewer than one in four consumers now believe the U.S. food supply is safer than it was a year ago, according to new data from the University of Minnesota's Food Industry Center. After January's national Salmonella outbreak, just 22.5 percent of consumers in the study said they were confident the food supply is safer than a year ago, the lowest reading since the study began in May 2008. Eight people died and more than 500 have become ill in the most recent outbreak, which may have originated in a Georgia peanut plant and spread through peanut-butter products sold nationwide. The drop in confidence mirrors a similar drop last June, when a Salmonella outbreak later traced to jalapeño peppers sickened nearly 1,500 people."[25]

In this section, we explore the two recent U.S. foodborne disease outbreaks cited above to illustrate the practical difficulties of responding to food contamination events and to expose current gaps in the public food safety net described in the previous section.

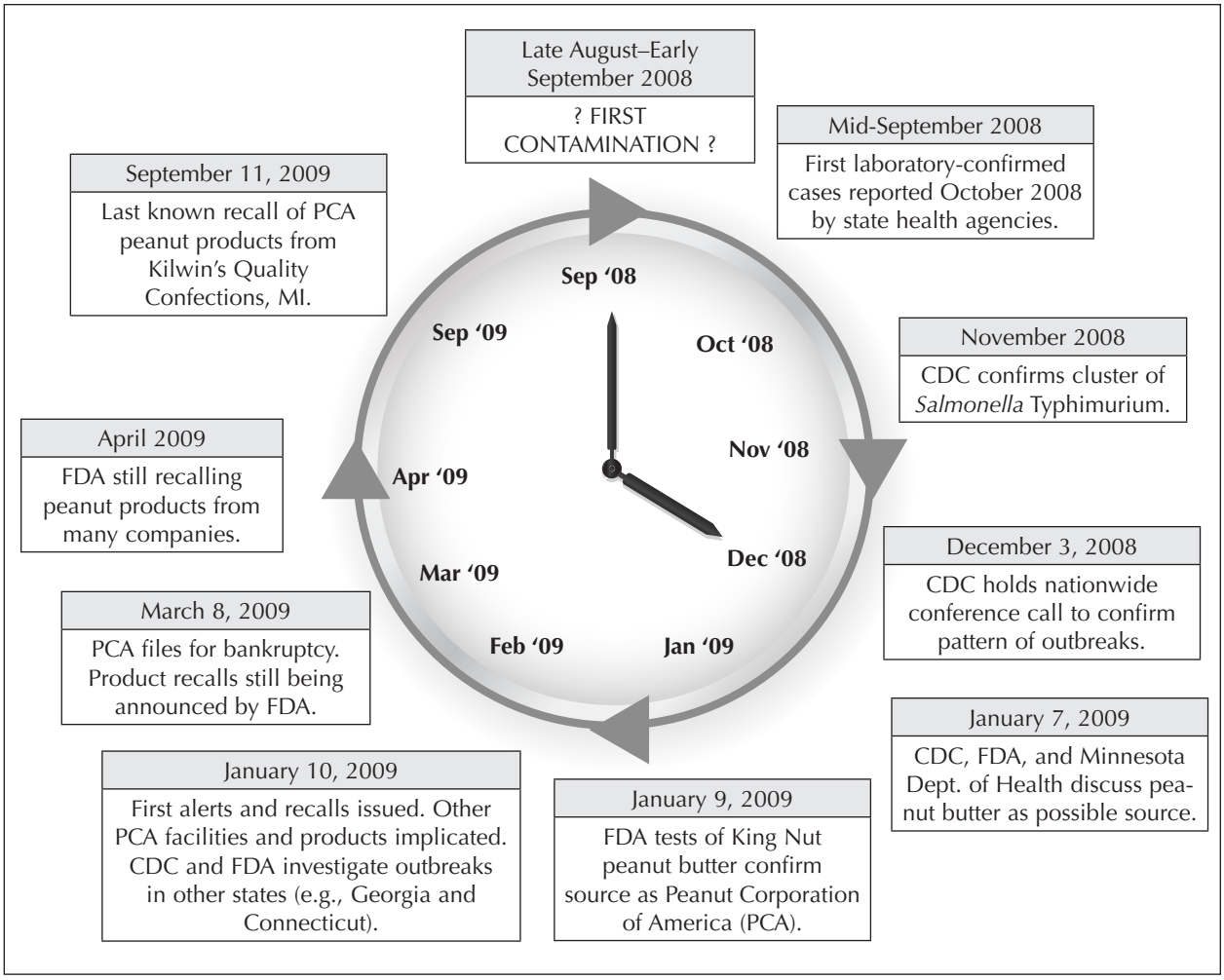
King Nut Peanut Butter

Food safety was headline news in the U.S. for nearly 12 months during 2008 and 2009. The culprit was peanut butter and peanut paste sold under the King Nut brand made by Virginia-based Peanut Corporation of America (PCA). The PCA King Nut peanut butter contamination has become a signature case that will be used in the foreseeable future as a guide for understanding the failures of our food safety net.[26] CDC publications provide an excellent trail of events, from confirmation of the outbreak through the ensuing investigation.[27] As can be seen in Figure 2, the latency between first reported illness and the recall of the last contaminated product from retail shelves was nearly 12 months.

On November 10, 2008, a cluster of 13 *Salmonella* Typhimurium isolates appeared in PulseNet with a similar PFGE pattern. These isolates had been reported to the CDC by 12 different states. The reporting states were as dispersed as Minnesota and Connecticut. By November 25, 2008, the cluster had grown to include 35 isolates. On November 24, 2008, the CDC noticed the appearance of a second cluster of 27 isolates with very similar patterns to those of the first cluster. After more testing, this cluster was determined to be the same pathogen and was grouped together with the initial cluster as a single outbreak case for further epidemiological analysis. The first reported illness for this cluster was logged on September 1, 2008.

The determination of this single cluster launched a process of detailed, open-ended interviews with patients by the CDC, along with state and local health departments, to determine its source. In order to determine which food products might be causing the illness, epidemiologists perform what is called a control panel study. Patients are interviewed to determine their food history—what foods have been eaten and where. The foods eaten by individuals who are "ill" are compared with food consumed by "well" individuals in a normal population to see if there is a common thread. During the initial control panel, the most frequently reported food exposure in the first group of "ill" individuals during the seven days before onset of illness was chicken (86 percent) and peanut butter (77 percent). During control studies, a normal population, when asked the same question, replied that they had eaten chicken (85 percent) and peanut butter (59 percent)—so suspicion was directed toward peanut butter.

Figure 2: Chronology of PCA Peanut Butter Contamination



Source: *Chronology of Events Related to Peanut Butter Recall Involving PCA, AIB International, www.aibonline.org/press/AIBStatement04033009/Chronology.htm, accessed October 19, 2009.*

An important clue pointing to King Nut and PCA as the source was the early association of the cluster with institutional settings and institutional brands. Minnesota, which experienced three deaths early in the outbreak, discovered on December 28, 2008, that some infected patients lived or ate meals in three institution settings—an elementary school and two long-term care facilities. Further, the only food common to those institutions was King Nut peanut butter sourced from a single food distributor in North Dakota. To further harden the case against King Nut, six additional cases in six institutions were also confirmed to have eaten King Nut peanut butter. On January 12, 2009, a sample from an open peanut butter jar from one of the affected institutions was positively confirmed as containing the *Salmonella* Typhimurium strain associated with the laboratory reports of all ill individuals.

Almost five months had elapsed from first reported diagnosed illness on September 1, 2008, to the confirmation of *Salmonella* Typhimurium in King Nut peanut butter on January 12, 2009. On January 16, 2009, Connecticut also confirmed the presence of the outbreak strain of *Salmonella* Typhimurium in a previously unopened container of King Nut peanut butter.[28] All of the offending peanut butter was traced to the PCA peanut processing facility in Blakely, Georgia. Products were shipped in bulk from this plant to institutions, food service industries, and private-label food companies, but were not sold directly to consumers or distributed to retail shelves across the country. While this may appear to have been a positive finding, it also was a clue that the contamination would be more broadly distributed than through just a small number of products. Meanwhile, clusters of the outbreak strain were continuing to

appear in other states. By January 28, 2009, 16 clusters of cases had been reported in five additional states. These clusters also involved institutional settings, and all involved King Nut peanut butter.

However, continuing investigations and interviews indicated that many people had not eaten peanut butter in institutions yet were becoming sick—pointing to another source or vector for the outbreak. A second control panel was performed on the new cases. The results showed that these individuals were more likely than the normal population to have eaten prepackaged peanut butter crackers during seven days before onset of illness—and that the two brands most frequently associated were Austin and Keebler. Both of these brands were produced at one facility that received peanut paste from PCA. Thus, while King Nut peanut butter was not sold directly to consumers, individual consumers were still at risk from products produced from peanut paste made by PCA and sold to well-known manufacturers. In fact, this particular outbreak affected other well-known brands such as Kellogg's and retailers such as Trader Joe's, GNC—and even PetSmart dog food.

On January 10, 2009, a team from the FDA confirmed that a sample of peanut butter paste taken directly from the Blakely plant had tested positive for *Salmonella* Typhimurium and PCA issued its first voluntary recalls. Also, the FDA revealed that, on 12 occasions since 2007, the plant had shipped products that had tested positive for four different strains of *Salmonella*. This was determined by inspection of internal company records. Companies typically perform internal testing of their products—often by third-party inspection companies—in addition to inspections by the FDA and USDA. According to protocol, after a contamination is discovered production lines should be cleaned to remove residual contaminated product. The line is then retested and, if no *Salmonella* is found, production is resumed. However, it is common for *Salmonella* to be localized in a product, so any particular batch can yield both positive and negative results. At PCA, production lines were never cleaned. When a retest showed clean products, production resumed and products were sold to customers. However, the *Salmonella* Typhimurium was still in the production system.

Production at the Blakely plant ceased on January 9, 2009, and voluntary recalls began the following day. Further testing confirmed PCA as the source of the contamination and, on January 28, 2009, PCA expanded its voluntary recall to all peanut butter and peanut paste products produced at the plant since January 2007. Upon further inspection of the plant, FDA inspectors reported unsanitary conditions including a leaking roof, mold, and insects—significant because *Salmonella* thrives in moist conditions. Roof gaps as large as two feet near air conditioner intakes and skylights open to rain and other elements were discovered. In January 2009, attention was focused on another PCA facility in Plainview, Texas, where a sample of peanut meal tested positive for the same strain of *Salmonella*. The Texas Department of State Health Services shut down the plant on February 9, 2009, after inspectors found dead rodents and rodent excrement in a crawl space above the production area.

Once the contaminated products had been identified, along with the manufacturer PCA, the task of removing the affected peanut products from distribution centers, warehouses, and retail shelves—as well as homeowner pantries—began. The FDA traced the shipments of these products to more than 200 retail accounts nationwide. Recalled products were sold under numerous brands and included cookies, crackers, cakes, pies, donuts, candy, ice cream, vegetables, or apples packed with peanut butter dip, prepackaged meals, snack bars, snack mixes, and pet treats. The list of recalls expanded to include all peanut products from the plant including roasted peanuts, peanut butter and paste, granulated peanuts, and peanut meal. In all, PCA peanut butter contamination was responsible for 714 illnesses and 9 deaths nationwide. More than 3,900 food products were recalled. The earliest onset of illness, as best can be determined, occurred on September 1, 2008, and the last illness was reported on April 4, 2009. The last recall was initiated on September 11, 2009.

In sum, the key gaps in detecting and responding to the PCA contamination with respect to the four phases of the food safety wheel were:

- Latency in determining that an outbreak had occurred because cases across different states were not picked up as part of an emerging outbreak but rather appeared as isolated cases;

- Difficulty in determining the cause of the outbreak because the cases occurred in institutional settings across state borders;
- Since this contamination was ingredient-driven, latencies resulted from multiple and confounding product sources containing peanut butter; and
- Latency in recalling all products from retail shelves because of the ingredient basis of the contamination.

The Jalapeños Scare—or Was It Tomatoes?

Another recent nationwide food safety scare pointed out the difficulty of pinpointing the cause of the contamination with the current system. On May 22, 2008, the New Mexico Department of Health notified the CDC that four individuals had indistinguishable strains of *Salmonella* Saintpaul—and that another 15 ill persons appeared to have the same strain—but that it had yet to be confirmed in PulseNet. Over the course of this outbreak, more than 1,400 persons were affected across 43 states and the District of Columbia. Unlike the PCA King Nut event, where a key problem was locating and removing all affected products, this outbreak offers a lesson in the difficulties of isolating the sources of the offending *Salmonella* bacteria once a contamination has occured.[29]

The first 19 *Salmonella* cases in Texas were detected and subtyped using PulseNet in mid-May 2008 and subsequently confirmed as the *Salmonella* Saintpaul strain. A first control panel indicated significant association with the consumption of raw tomatoes and a possible association with eating tortillas. Significantly, in the first control panel the illness was not associated with salsa, guacamole, or other foods types associated with Mexican cuisine. At this point in the investigation, it seemed clear that tomatoes were the likely culprit since no other food types appeared in the initial case control panel. In June, however, more cases were being reported that matched the PFGE PulseNet pattern and a second control panel was performed of 47 persons who had eaten in a Mexican-style restaurant in Texas. Unlike the first results, this panel indicated that illness was significantly associated with salsa—of which raw tomatoes is a major ingredient.

In early June 2008, the FDA issued first warnings regarding raw tomatoes, in particular tomatoes known commercially as plum tomatoes and red Roma tomatoes. They recommended that retailers, restaurants, and other food service providers not serve these varieties unless they were from sources not associated with the outbreak. Many large chains complied, including McDonald's, Wal-Mart, Burger King, Kroger, and Outback Steakhouse, as well as many school districts. Twenty-one states were not associated with the outbreaks including California and Minnesota, as well as foreign exporters of tomatoes such as the Dominican Republic, Guatemala, and Israel.

To the CDC's surprise, people continued to become ill and the CDC performed a third panel study on individuals who ate at another Mexican-style restaurant in Texas. Again, the results pointed to salsa. However, the CDC was surprised to learn that the salsa served at this restaurant was prepared from canned tomatoes and raw jalapeño peppers, but NOT raw tomatoes. Were tomatoes or jalapeños, or both products, responsible? Such an intersection might occur if farms grew tomatoes early in the spring and then switched to pepper harvesting. It also could occur if distribution centers handled both products in a contaminated facility.

The CDC and 29 states continued to probe the source through additional control panels at the state and local levels. A fourth panel of 141 "ill" individuals who ate at a Mexican-style restaurant and 281 "well" control individuals showed that disease was significantly associated with eating pico de gallo, corn tortillas, and fresh salsa containing raw tomatoes during the week prior to the onset of illness. Because tomatoes and jalapeños are both ingredients of these products, no conclusion could be drawn. The final discriminatory piece of information came from a follow-up control panel, conducted by the Minnesota Department of Health, of 19 persons who became sick after eating in a natural foods restaurant. Based on statistical analysis, the results showed that illness was significantly associated with eating raw jalapeño peppers.

Lest one become too convinced that the problem was limited to jalapeños, a subsequent study by the North Carolina Division of Public Health during July 2008 studied 13 persons who also became ill after

eating in a Mexican-style restaurant. The illness was significantly associated with eating guacamole. The ingredients of this guacamole included raw Roma tomatoes and raw Serrano peppers but not raw jalapeño peppers. Clearly, the culprit was not JUST raw jalapeños. In July 2008, the Arizona Department of Public Health also performed a control panel of nonrestaurant cases that showed a significant association with raw Serrano peppers and a borderline association with raw jalapeño peppers.

To help resolve the mystery—raw tomatoes, jalapeño peppers, or Serrano peppers—the FDA began a traceback analysis of tomatoes to see whether they could pinpoint the source of the contamination along the food chain. The traceback did not point to any single farm or packer in the U.S. However, the FDA was able to trace jalapeño peppers from two of the restaurant clusters to distributors in Texas that received peppers from Mexico. Jalapeños from one of these distributors tested positive for *Salmonella* Saintpaul. These jalapeños were likely grown on two farms in Tamaulipas, Mexico. One farm *also* grew Roma tomatoes and Serrano peppers. Serrano peppers and a sample from an irrigation pond from the second farm tested positive for this particular strain of *Salmonella*. The second farm also grew jalapeños but not tomatoes. The CDC concluded that both jalapeño and Serrano peppers were the causes of the outbreak, and issued a nationwide advisory on July 9, 2008, against eating jalapeño and Serrano peppers grown in Mexico. The CDC and FDA pulled their advisories about raw tomatoes on July 17, 2008.

This case illustrates the challenge of tracing the cause of outbreaks when contaminations are confounded by nonspecific results, thereby adding considerable time to the investigation and compromising the ability to identify contaminated products quickly. Initial panel results led to a faulty indictment of raw tomatoes and advisories that resulted in more than $100 million in damages to the U.S. tomato industry. The pepper industry also could have been severely affected had the pepper source not been determined to be Mexico. Most of the U.S. chili pepper industry is located in New Mexico, where it contributes $500 million to state coffers. The ability to trace the peppers back to Mexico, albeit belatedly, saved the U.S. pepper industry from unnecessary recalls and severe economic damage.

Again, the key gaps in detecting and responding to the PCA contamination with respect to the four phases of the food safety wheel were:

- Due to the localized nature of the initial outbreak, the latencies in determining that an outbreak had occurred after initial contamination were reduced.
- The confounding results of the control panel tests led to considerable delays in determining the true cause of the contamination.
- Latencies in determining the source of the contamination in Mexico were hampered by its location outside the U.S.
- The problems of "false" recalls of tomatoes hampered the recall of the offending jalapeños from grocery shelves.

Filling The Gaps: An Emerging Framework For Public-Private Cooperation

"Policy-makers frequently argue that the primary responsibility for food safety lies with the private sector, whereas the definition of basic standards, monitoring and policing is the responsibility of the public sector. However, in an era of heightened concern for food safety, both public and private regulations and activities are jointly instrumental to the delivery of a safer food supply."[30]

Current pressures on governments to be more active in monitoring food safety in an environment of strained budgets, and pressures on the private sector to produce competitive products for global markets make public-private cooperation not only desirable, but essential. Both public and private sectors have a common interest in maintaining a safe national food supply. The private sector has strong financial incentives to protect its markets, the reputation of its products, and the health and safety of its customers. Government has a parallel responsibility not only to promote trade and economic growth but also to protect the health and well-being of its citizens.

A new framework for thinking about food safety is emerging that bridges existing gaps to create a modern food safety system and reflects the current realities of global food production and eating.[31] This framework, implicitly recognized in pending U.S. food safety legislation, acknowledges the growing engagement of the public and private sectors in the common interest of safe food. In this section, we explore four emerging organizing principles that underlie this framework.

New Stakeholder Model for Integrated Food Safety

A new stakeholder model is emerging that recognizes the role of the private sector as a key partner in both maintaining a safe food supply and responding to food contamination events.

The goal of an integrated food safety system is to create a system in which all stakeholders behave collectively in a purposeful and coordinated way, with the common goal of eliminating or reducing foodborne disease. We already have seen how the current system spans more than 15 government agencies working in an often unorchestrated and disconnected manner. The current system includes local, state, and federal agencies (as well as territorial partners) that often work independently of one another, are subject to differing standards, and lack adequate system interconnectivity.

Looking ahead, the above concept of an integrated food safety system is being expanded to include the private sector along with its regulatory and public health counterparts. It is a major premise of this report that the private sector is an increasingly important stakeholder in our emerging food safety system and must be recognized as a critical partner in the constellation of stakeholders that comprise a modern, integrated food safety system. These private sector stakeholders include companies that grow, process, transport, and sell food products, as well as their supply chain partners.

Over the course of the past 18 months, four different food safety bills have been introduced into Congress. A new dynamic of explicit (and implicit) responsibilities and roles for public and private stakeholders is reflected in this legislation. Current bills are summarized in Table 3 and described briefly below.

Table 3: Food Safety Legislation Pending in The 111th Congress

PROVISIONS IN BILL	H.R. 875 - FOOD SAFETY MODERNIZATION ACT	H.R. 759 (H.R.2749) - FDA GLOBALIZATION ACT (FOOD SAFETY ENHANCEMENT ACT)	H.R. 1332 - SAFE FOOD ENFORCEMENT, ASSESSMENT, STANDARDS AND TARGETING (FEAST) ACT	S. 510 - FDA FOOD SAFETY MODERNIZATION ACT
Process Controls: Require process controls for all food processors, and tie agency inspections to an audit of these systems.	X	X	X	X
Performance Standards: Set performance standards based on the best available science on hazards linked to specific food products and other public health considerations.	X	X	X	X
Inspections: Create a system of risk-based inspection, based on the type of food handled and the processes used.	X	X	X	X
Imports: Establish a system under which governments or foreign food establishments seeking to export food to the U.S. can certify their food safety systems.	X	X	X	X
Research and Education: Establish programs to support FDA regulatory programs, state food safety agencies, and the food industry's own efforts.	X	X		
Farm: Develop and enforce on-farm food safety programs.	X	X	X	X
Recall: Mandatory recall authority to ensure that recalled foods are removed from the market.	X	X		
Traceback: Authority to require products to be traceable in the supply chain.	X	X	X	X
Detention: Authority to detain and destroy unsafe food when inspectors find it.	X	X	X	X
Penalties: Establish penalties for violating food safety laws as a deterrent to future violations.	X	X		X
Whistleblower: Protection for those providing information or assisting in the investigation of a violation of a food safety law.	X	X		

Source: *http://www.cspinet.org/foodsafety/legislation.html, last accessed May 4, 2010.*

The Food Safety Modernization Act (H.R. 875) was introduced in February 2009 by Representative Rosa DeLauro of Connecticut and called for the creation of a new administrative agency within the HHS focused on food safety.[32] The introduction of H.R. 875 unleashed a firestorm of protest by various stakeholders, especially organic gardeners, who feared that the bill would put small farms out of business. As of July 2010, this bill currently remains in committee.

After extensive negotiations, a bill named the Food Safety Enhancement Act (H.R. 2749) was introduced on June 8, 2009, by Representative John Dingell.

This bill was passed by the House of Representatives on July 29, 2009, by a vote of 283 to 142.[33] H.R. 2749 is considered the first major piece of federal food safety legislation since 1938 to be passed in Congress. However, unlike H.R. 875's call to create a new agency, this bill would amend the Federal Food, Drug and Cosmetic Act to give more authority over food safety to HHS, which houses the FDA. H.R. 2749 has moved to the Senate where it has been read twice on the floor.

Two other bills have also been introduced into the Senate, so attention may focus on one of those companion bills, rather than on H.R. 2749. In particular, the FDA Food Safety Modernization Act (S. 510), introduced by Senator James Durbin on March 3, 2009, is virtually the same bill as H.R. 2749. A fourth bill, the Safe FEAST Act (H.R. 1332), introduced to the House by Representative Jim Costa on March 5, 2009, is also similar.

There is more commonality across these four bills than there are differences. First, under all bills, the FDA is being given new authority for the inspection of food production facilities and products. With respect to inspections of domestically-produced foods, the FDA currently lacks minimum inspection mandates for the domestic food companies that it regulates. Regular and periodic inspections of food processing and retail facilities are key elements of a national food safety strategy. However, as recent history has shown, periodic inspections of all facilities have not been sufficient to prevent regular outbreaks of foodborne disease in the U.S. Unlike the USDA, which is required to inspect meat and poultry production facilities daily, the FDA has insufficient funds to inspect domestic food facilities under its authority more than once every 10 years.[34] Pending legislation will require minimum inspections and product sampling at both domestic and foreign producers by the FDA. Currently, less than 2 percent of the food traveling into the U.S. from overseas sources is currently inspected by the FDA.[35]

Under the proposed bills, the FDA would also have a greater role in establishing process controls and performance standards to prevent contaminations. As discussed earlier, the private sector has embraced the HACCP quality assurance program as a tool of process control. However, HACCP is not mandated across all food industries—only in seafood, juices, and raw and processed meat and poultry—so holes exist in the safety net. Emerging legislation recognizes private sector responsibility for process control within companies' own organizations and generally requires that each food facility conduct a hazard analysis of its processes, put in place preventive controls, and implement a food safety plan. The bills would implement audits of these process controls that are linked to inspection results. With respect to oversight of the food industry broadly, the bills would also require the FDA to issue science-based performance standards for the private sector.

Probably the most significant element of the proposed legislation is the authority of the FDA to initiate mandatory recalls of contaminated products. At the same time, the private sector must maintain critical information about its suppliers and customers in order to traceback a product's ingredients up the supply chain to determine the source of the contamination. During recent cases of food contamination, the FDA has been constrained by its lack of authority to recall contaminated food products from retail shelves or to detain them at their place of origin. Currently, with some exceptions such as infant formula, industry response to a recall is voluntary.

In theory, the FDA should not need the authority to initiate mandatory recalls. One could argue that a company has a moral obligation to comply with a voluntary recall. But more importantly, its corporate instincts should be to protect the reputation of its product. The choice, however, is not always straightforward. The scale and scope of a food emergency is not always known at the outset. A company may make a hedged decision not to recall a product—opting to avoid connecting its company name with negative publicity in case the contamination is minimal. Should a firm not initiate a recall, the FDA does currently have the authority to initiate a court action to remove contaminated products or prevent their distribution. This constitutes a "seizure." However, the effect of a seizure is limited, in that court actions are needed for each place in which product is located. In the case of ingredient-based contaminations, this presents an insurmountable task to be performed in a small amount of time.

Not only is emerging legislation placing new roles and responsibilities on private companies, but private companies themselves are increasingly taking a

proactive role in food safety. For example, the FDA has established the Reportable Food Registry (RFR) which is an electronic portal for industry to report when there is reasonable probability that an article of food will cause serious adverse health consequences.[36] The original intent for the RFR was to provide another tool to track patterns of adulteration in food and reduce risk of large-scale contamination. An added goal was to support efforts by the FDA to better target limited inspection resources. Companies are required to report when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals.

The private sector has also invested in new tools to improve information sharing across supply chain partners in the event of a food contamination. The Rapid Recall Exchange (RRE) was developed by the Food Marketing Institute, in collaboration with the Grocery Manufacturers Association and GS1, as an online service for 24/7 notification about product recalls or withdrawals.[37] Companies participate by subscription. In the event of a quality problem leading to a recall or withdrawal, a company would post a message for its customers that contains critical information about the recalled product, product handling instructions, reimbursement instructions, and comprehensive contact information.

Risk-Based Resource Allocation

Risk-based resource allocation strategies will reduce foodborne disease incidence, resulting in lower public sector costs of surveillance and response and reduced economic burden on private sector companies that have good safety records.

Inspection is an important tactic for keeping contaminated food out of the food chain and for tracking contaminated food products. However, there is widespread agreement that we cannot inspect our way to absolute food safety. The immenseness of the inspection task indicates against this approach. Consider the fact that a food product can be contaminated at any point in the food chain—from the farm to production site to distribution center and to consumer—and that there are a wide range of potential pathogens that require specific tests. Testing at all potential points of contamination is impractical if not improbable in terms of time and cost. At every stage in the global supply chain, there are questions about what to test for, how to test for it, and how frequently to test.

Using the dairy chain as an example, assuming a cost of $5 per test, the annual cost of daily inspections at all dairy farms in the U.S. would be $150 million, while the cost of testing every tanker delivering milk to a production facility would be $210 million each year—and that is only for one contaminant.[38] Using the Mexican jalapeño peppers as another example, from March 2008 through June 2008 when the jalapeños contamination was being investigated, there were more than 500 pepper producers in Mexico, more than 300 importers, and more than 25,000 shipments of peppers to the U.S. Inspecting at all points in the pepper food chain as a preventive measure is simply inefficient in terms of cost and time. Similarly, once *Salmonella* was determined to be the culprit, the task of working backward in the chain to identify all affected products in the food chain is prohibitive.

Another issue is inadequate testing capability for trace amounts of many contaminants at the low levels of concentration that would occur in some foods. This is especially true of certain chemicals and toxins that may be the vehicle for intentional contamination and terrorist activity. Testing for the neurotoxin botulinum, for example, is done by mouse assay, which is very costly and takes considerable time to implement. False positives can distract from the task at hand. To follow the milk example cited earlier, even with a low false-positive rate of 1 per 100,000 tests, the dairy industry would experience a false positive every 8.5 days.

If total inspection is not a realistic goal, then what other approaches are better aligned to the globally networked food systems of today? Attention is being given to the development of risk-based systems that allocate resources based on the level of assessed risk.[39] In a risk-based system, the allocation of effort and resources is aligned with the level of risk to the food system. Risk-based strategies would identify those food products (or companies or industries) determined to be of high risk to health based upon known and potential food hazards associated with these foods (or companies or industries). The larger share of resources would be allocated to these products, companies, or industries. Monitoring of low-risk

or no-risk products would be maintained at a lower level, as necessary, to assure compliance. As an example, meat products would be subject to more frequent inspections because they are associated with higher historical rates of contamination. And, since *E. coli* is a frequent source of meat contamination, allocating a larger share of funds to developing a faster and/or more reliable test for *E. coli* in meat products would be an example of risk-based resource allocation.

A recent study by Resources for the Future (RFF) attempted to rank the risk of particular foodborne illnesses as a tool for shaping risk-based national policy.[40] Most foodborne illnesses can be attributed to 11 major pathogens (*Bacillis cereus*, botulism, *Campylobacter jejuni*, *Clostridium perfringens, Escherichia coli*, *Listeria monocytogenes*, *Salmonella* species, *Shigella*, *Staphylococcus*, *Vibrio parahaemolyticus*, and *Yersinia enyterocolitica*). Viruses such as norovirus, hepatitis A, and Rotavirus also can cause foodborne illness. However, it has been estimated that more than 97 percent of all foodborne illness occurrences can be attributed to just *three* pathogens—*Salmonella, Listeria,* and *Campylobacter*. The RFF study suggested that incidence is also highly concentrated in specific food types. Four food groups (produce, seafood, poultry, and ready-to-eat luncheon meats) account for 60 percent of all foodborne illnesses, 59 percent of all hospitalizations, and 46 percent of all deaths, as shown in Table 4. Under a risk-based strategy, inspections would target food products with the highest incidence of foodborne disease and test for the most likely pathogens or viruses.

Risk-based strategies have not only the potential to reduce the incidence of foodborne disease, but also the opportunity to achieve a more efficient allocation of resources. As noted previously, responsibility for safe food is principally shared by the FDA and USDA. Historically, the FDA has suffered from a disproportionate responsibility for food safety given its available resources when compared with those of the USDA. While the USDA regulates one-fifth of the food supply—the segment which is responsible for 27 percent of outbreaks—its food safety appropriations are double those given to the FDA. USDA funds are used to inspect meat and poultry plants daily, as required by law. Under federal law, USDA's FSIS must inspect and approve all meat and poultry products before they can be sold with the "USDA Approved" stamp.

Table 4: Attribution of Foodborne Illness Cases and Death by Food Type

Food Category	Percent Of Total Cases	Percent Of Total Deaths
Produce	29.4	11.9
Seafood	24.8	7.1
Poultry	15.8	16.9
Luncheon/Other Meats	7.1	17.2
Breads and Bakery Items	4.2	0.6
Dairy	4.1	10.3
Eggs	3.5	7.2
Beverages	3.4	1.1
Beef	3.4	11.3
Pork	3.1	11.3
Game	1.1	5.2
Total Percent	100	100
Total Cases	12, 908,605	1,765

Source: *"Attributing U.S. Foodborne Illness to Food Consumption," Sandra A. Hoffmann, Resources, Summer 2009.*

In contrast, the FDA regulates 80 percent or more of the food supply and inspects food facilities, on average, just once every 10 years. The agency does not currently enjoy a minimum inspection mandate for food companies under its oversight, unlike the USDA. This may change under H.R. 2749, if passed, since this bill would require FDA to inspect high-risk facilities at least every six to 18 months. The FDA is also responsible for overseeing more than 200,000 restaurants and food service companies. The USDA employs more than 7,800 inspectors who are stationed in 6,282 establishments to carry out its inspection mandate. The FDA, meanwhile, has fewer than 2,000 inspectors who are spread across 136,000 domestic food processors and warehouses.

Compounding the problem, the FDA's need for more inspectors in critical areas, such as imported foods, has been continuously increasing. Imports of FDA-regulated foods have more than doubled recently—from 4 million shipments in 2000 to approximately 9 million shipments in 2006. Of these 9 million

shipments, less than 1 percent were analyzed in a laboratory as part of its inspection process.

Food Chain Traceability

Food chain traceability will utilize private sector information about the food chain to speed up the recall process, thereby reducing the scale and scope of food contamination events and their associated social and private sector costs.

All of the pending legislation includes traceability—both traceback and trace forward—across the food chain to speed up the recall process and thereby minimize the scope and impact of a contamination event. Traceability is defined as the ability to follow the movement of a food product through specified stages of production, processing, and distribution to the consumer—or from farm to table. The International Organization for Standardization (ISO) formally defines traceability as "the ability to trace the history, application, or location of that which is under consideration," but does not specify a standard for the process by which traceability is achieved, the technologies to be used, or even what is meant by the term "that which is under consideration."[41]

It should be noted that traceability, per se, does not assure food safety. Rather, it helps to minimize the scope and scale of events by reducing the latencies in identifying the source and location of contaminated products. If the source of contamination is *Salmonella*-tainted spinach at a grocery store, traceability will ensure that the information trail looking one echelon upstream will identify the distributor—who will have information one echelon farther up the chain about the farm where the produce was picked. Or, if a source of contamination is determined to be at a dairy farm, then downstream milk products shipped from that dairy farm can be identified and located.

Traceability systems have differing requirements depending on product. Current technology is capable of the complete forward and backward tracking and tracing of products. However, under a risk-based system, full traceability may not be indicated. Many products have minimal traceability requirements because they are low risk. Traceability requirements might include certifications of product identity, identification of upstream suppliers and downstream customers, and periodic checks of suppliers to make sure that proper procedures and records are being kept. Traceability systems can be characterized by their breadth, depth, and precision:

- ***Breadth of traceability*** refers to the amount and scope of information collected. From a cost perspective, it is not possible to retain all information about a product. Principles of risk management can help design the system to define the parameters of the system to maximize its utility for traceback. For example, it may not be necessary to retain information about the specific location in which an item of produce was grown, but rather it might be necessary to record the types and frequency of pesticide treatment.
- ***Depth of traceback***—how far upstream the system tracks relevant information—is another system design decision. As a general principle, the depth of the traceback should extend as far upstream as it is possible for contamination to enter the food chain. In the case of field produce like spinach, traceback to the farm would be important. Similarly, for meat products the depth of the traceback should extend to the feed lots from which the cattle were fed. For processed foods that undergo extreme heat treatment during processing, it may not be necessary to go farther upstream than the processing and packaging plant.
- ***Precision of traceability*** refers to the degree of assurance with which we can pinpoint the movement of a particular unit of food along the food chain. While the degree of precision is a design decision, it is also limited by the nature of the food production process. For example, milk from multiple cows will be mixed in holding tanks, making it impossible to trace a potential pesticide contamination to a specific cow. Similarly, contaminated and noncontaminated grains will be mixed in silos, and shrimp from different harvest fields will be mixed and sorted by size, making it virtually impossible to pinpoint the exact source of *aflotoxin* contamination or contamination by heavy metals or other agrochemicals.

As private sector retailers like Wal-Mart in the U.S. and Tesco in Europe adopt new information systems and "track-and-trace" technologies like radio frequency identification (RFID)[42], they are becoming

the repository of large amounts of data relating to the source, transport, and disposition of products in the global food chain. Sharing this information is essential to achieving traceability. Until recently, and unlike many countries in Europe, U.S. companies were under no obligation to share this information with public officials. Under pending legislation, the FDA will have the authority to require traceback information from the private sector in the event of a major contamination or other food safety threat.

Clearly, public and private sectors need to work together to utilize this data in the event of a food emergency. The food industry is already benefiting from track-and-trace technologies like bar codes and RFID because they not only reduce their internal business costs, but also increase the quality and safety of their products. Benefits and cost savings are due to better inventory management and reduced shrinkage, as well as to better customer service. As companies continue to further develop and refine their ability to track their products—not only within their own factories or businesses, but along the entire supply chain—additional benefits can be expected. At the same time, profit margins in the food industry are already razor thin, and investment in traceability also must be a good business decision.

Companies have been reluctant to share traceback information in the past for a variety of important reasons, including liability concerns and the fear of exposing proprietary information about suppliers. This is especially true as food industries struggle to launch innovative new products into the marketplace. These products are frequently differentiated by unusual—often secret—ingredients and/or suppliers whose identity might be compromised by release of this information to public health officials. As the government continues to modernize our food safety system, it must also understand the concerns of the private sector and develop policies that encourage the private sector to share data in a nonthreatening and positive way. It is necessary to look at the motivations for traceability from both public and private perspectives to find the common ground, as shown in Table 5.

The challenge for food safety policy makers is how to provide incentives to the private sector to strengthen their traceability systems and create a win-win situation. While fines and threatened plant closures can provide incentives, they also may be so burdensome

Table 5: Public and Private Sector Motivations for Implementing Traceability

Private Sector	Public Sector
Create more efficiency in supply chains to reduce time and cost.	Reduce latency in identifying the root cause of a foodborne illness.
Facilitate traceback in cases of quality issues.	Identify a particular food product as the source of contamination.
Provide more customized products directly to customers.	Identify individuals who may have purchased or eaten an affected product.
Reduce costs and increase revenues through reduced shrinkage.	Reduce latency of response to a foodborne event and reduce costs to business.

that the company is unable to survive. It is easy to argue that such companies should be out of business. However, these companies are likely to be small-to-medium size enterprises which provide diversity in our food production landscape—and which sustain our national economy through job creation.

Co-Regulation Strategies

Co-regulation strategies are a win-win opportunity to shape food safety policies so as to reflect the mutual organizational and financial interests of public and private sectors alike.

The basis of a successful cooperation is shared goals achieved through common actions that benefit all parties. While both public and private sectors share the same social goals of safe food, building an efficient food safety system may not yield efficient outcomes from a private business perspective. Similarly, creating a fail-safe food safety network, while socially desirable, may be unacceptable to business if the costs of achieving it exceed the benefits to the corporate bottom line. And a stringent regulatory environment may result in suboptimal improvements in food safety—and in some cases can result in belligerent noncompliance with unintended consequences.

As a general principle, when there is a question about the role of government in market intervention or regulation, policy makers typically frame their decisions according to an economic analysis as to

whether the costs of a regulatory action outweigh its benefits—for example, whether the costs of preventing an uncertain food safety hazard outweigh the expected benefits. Regulatory actions can be warranted when markets fail to deliver adequate levels of social welfare. In the case of food safety, regulatory actions can take a number of shapes, from closure of facilities to mandatory recalls. In practice, these calculations are hard to assess in the event of food safety since there is a wide disparity in the estimates of the cost of a food event, the likelihood of its occurrence, and the costs of implementing preventive policy.

Policy makers view co-regulation as a solution for bridging the gap between the high social costs of *laissez-faire* market approaches and the burdensome economic costs of overregulation. A *laissez-faire* approach—letting the market alone weed out unsafe products and vendors—is not a reasonable option, since it is not proactive and would not eliminate events like PCA. At the other end, strict regulation can have undesirable and disproportionate effects on small and medium-sized food enterprises—or have a direct effect on consumers through increased product prices. And the regulatory process itself can have significant costs, which also may discourage government from imposing regulation. In theory, co-regulation could achieve safer food at lower regulatory cost while maintaining the competitiveness of the food industry.[43]

Different forms of co-regulation can target different stages of the regulatory process–spanning standards setting, process standards, enforcement, and monitoring.[44]

Standards Setting. The setting of food safety standards is a domain in which public and private interests intersect. While governments have the authority to set mandatory food safety standards without industry input, this is not the usual route in the U.S. or in other Western countries such as the UK and Canada. Typically, input is sought from industry as well as from the consumer. In many cases, industries themselves create voluntary standards of "good" practice independent of government action. Companies within the industry agree to adhere to the standard, which may be higher than the regulated standard. For example, individual companies may set high standards to differentiate their products in the marketplace.

Such voluntary standards are more prevalent in the UK, where 85 percent of the production of milk, eggs, chicken, and pork and 65 percent of production of beef, lamb, and horticultural products are covered by voluntary standards and industry consortia.[45] Voluntary standards are less prevalent in the U.S., perhaps because of some of the difficulties associated with enforcing standards in a large country with a diverse food industry. One problem is the complexity of the adoption of different standards, even within the same industry, depending on industry concentration and cost structure. Divergent standards also can cause problems when suppliers sell their products to retailers with different voluntary standards, and vice versa.

Industry and consumers influence food safety standards in the U.S. through the political process. The announcement of proposed regulation initiates a process of public review and input, during which industry and consumer groups provide input. Industry impact assessments can shape discussions within Congress, as can consumer reactions. Because of their deep pockets, many feel that industry has a louder voice than the public in standards discussions. One complaint about the political process is that, through the process of dialogue and accommodation, standards can be "watered down," with the net result that the best achievable (and perhaps desirable) standards are never promulgated. On the other hand, standards that are reached through dialogue can be more complete and better designed.

Process Standards. Public and private sectors also can work together to establish best practice standards for processes by which food products are produced. Within the framework of co-regulation, these standards are typically flexible and performance-based, so industries and companies are able to adapt them to their own corporate environment for maximum effectiveness and better alignment with their own business goals and strategies. HACCP is a good example of process-based co-regulation. Rather than focus on finished product inspection to assure that safety standards are met, HACCP focuses on prevention through process standards.

There is a question as to whether HACCP is capable of providing the desired level of safety under the new farm-to-table paradigm. The increasing adoption

of HACCP globally and the success of the HACCP system in the food processing industry has, perhaps, created false expectations. The food chain should be thought of not as a collection of food processing plants, but as a pipeline that begins at the farm, involving transportation, storage, and other processes in addition to food processing that are not always included under the HACCP framework. Some argue that the adoption of HACCP alone is a necessary but not sufficient program to assure safe food.[46]

Enforcement. A co-regulatory approach for enforcement may seem to be a contradiction in terms, since enforcement implies the oversight of a secondary party, usually government. In reality, enforcement in food safety requires a delicate balance between industry regulation and of second-party enforcement (cf. FDA or USDA). The role of the USDA or FDA is to assure customers that food safety is a government priority and to impart confidence that the government is doing its job to assure safe food. On the other hand, the agencies, especially the USDA, want to maintain a positive relationship with the food industry in order to promote its investment in practices and technologies that enhance food safety—and also to avoid adversarial relationships.

Co-regulation in the enforcement arena can be achieved by promoting the opportunity for market gains and improved business performance through compliance. Company boards and consumers do not want to see quality problems in the press because public visibility can result in declines in stock prices and mass defections of a company's consumer base. In a type of co-regulation, policy makers have resorted to a range of market-based reputational mechanisms that qualify as enforcement but that also provide public exposure to a company's performance. Examples include what are called "scores on doors" approaches for restaurants, where inspection results are available to the public in a prominent location and can serve as a driver for improved performance that lift scores. This can be more effective for large companies and chains, for whom the magnitude of fines for noncompliance is small in relation to the overall size of the company and its market share.

Monitoring. Enforcement requires frequent and systematic monitoring. Budget cuts at the FDA and USDA, as well as the lack of alignment between the budget and inspection responsibilities, have made monitoring for noncompliance difficult. And it is unlikely that increased inspections alone under pending legislation can improve food safety beyond current levels without expensive new systematic programs. Given budget and other constraints, co-regulation presents an opportunity for government agencies like the USDA and FDA to rely more on private mechanisms of food safety control. Possible programs include HACCP, ISO 22000, and other industry-specific codes of practice. Leaving the task of monitoring to the companies requires, as a counterbalance, sufficient incentives for effective and complete follow-through.

As mentioned earlier in the discussion of the King Nut case, food retailers routinely hire private inspection companies to help assure that their and their suppliers' processes and products are safe. While companies hire these companies to increase safety, they also minimize liability by pushing the risk onto a third party. However, the use of private auditors and inspectors may not always have the intended result. The findings of an external audit tend to reduce the likelihood that employees at a company will report problems, because they have more confidence in the private corporate audit than in their own assessments. And when problems are found, the company does not always report the problem to the government or take steps to reduce the hazard. Also, these inspectors are paid by the companies that they are inspecting, which may reduce any incentive to produce a highly critical report. New public-private systems like the FDA's RFR and the RRE represent opportunities to change this calculus.

In sum, while co-regulation, as discussed above, has the potential to improve, food safety barriers exist and solutions remain to be worked out. Given the different perspectives of public and private sectors, and especially given private sector concern about the cost of regulation, negotiations to arrive at a commonly accepted solution can be difficult and time-consuming. As with any negotiated solution, there will be concern on each side that its own goals were being compromised. Government and consumers may feel that safety standards are being lowered, while companies may resist what they perceive as the overzealous hand of government in their business. Given current constraints on government resources, as well as the role of the private sector in

managing traceability information, it is likely that discussions about co-regulation will continue. In the end, the key to successful co-regulation is a focus on shared goals and an understanding of the win-win opportunities that can be realized by all stakeholders.

Conclusion

"The challenge lies in designing a system in which consumers can have confidence, while avoiding the draconian measures that hamper the competitiveness of an industry with little marginal benefit for consumers. There exists a complicated mix of market, supply chain, and regulatory incentives for firms to provide safer food."[47]

Our nation's health and the well-being of its citizens depend on a coordinated and effective web of safeguards to protect the food supply—whether it originates in China or California. Government regulations governing the private sector are a first line of defense and, combined with oversight and inspection by responsible government agencies, have provided minimally acceptable levels of protection, to date. However, this web of safeguards is being stressed as a result of increasing food imports from emerging markets, budget cutbacks, and politics.

This report has offered government officials at the local, state, and federal levels a perspective about the gaps, solutions, and emerging public-private strategies that can help to assure the safety of food that ends up on the plates of U.S. citizens. As a global leader, the U.S. can help set the standard for new models of food safety cooperation worldwide. Pending legislation provides an important step forward. In particular, the private sector can be expected to play an increasing role as we move toward new public-private approaches that recognize the private sector as an important stakeholder in a modern, integrated food safety system.

Appendix: Food Safety Roles and Responsibilities of U.S. Agencies

U.S. Department	Monitoring Agency	Food Overseen	Food Safety Role
U.S. Department of Health and Human Services	Food and Drug Administration	All domestic and imported food sold in interstate commerce, including shell eggs, but not meat and poultry Bottled water Wine beverages with less than 7 percent alcohol	• Inspect food manufacturing plants and warehouses • Review safety of food and color additives before marketing • Review animal drugs for both animals and humans • Request and monitor recall of unsafe food products • Monitor safety of animal feeds used in food-producing animals • Develop codes, ordinances, guidelines, and interpretations and work with states to implement them in regulating milk, shellfish, and retail food establishments • Take appropriate enforcement actions • Work with foreign governments to ensure safety of certain imported food products • Conduct research on food safety
	Centers for Disease Control and Prevention	All foods	• Investigate sources of foodborne outbreaks • Maintain nationwide system of foodborne disease surveillance • Develop and advocate public health policies to prevent foodborne diseases • Conduct research to help prevent foodborne illness • Train local and state food safety personnel

U.S. Department	Monitoring Agency	Food Overseen	Food Safety Role
U.S. Department of Agriculture	Food Safety and Inspection Service	Domestic and imported meat and poultry and related products Processed egg products	• Inspect food animals for diseases • Inspect meat and poultry slaughter and processing plants • Collect and analyze food products for microbial and chemical contaminants, and infectious and toxic agents • Ensure all foreign meat and poultry processing plants exporting to the U.S. meet U.S. standards • Seek voluntary recalls by meat and poultry processors of unsafe products
	Cooperative State Research, Education, and Extension Service	All domestic foods, some imported	• Develop research and education programs with U.S. universities on food safety for farmers and consumers
	National Agricultural Library; USDA/FDA Foodborne Illness Education Information Center	All foods	• Maintain a database of computer software, audiovisuals, and other educational materials on preventing foodborne illness • Help educators, food service trainers, and consumers locate educational materials on preventing foodborne illness
U.S. Department of Homeland Security		Food events related to terrorism	• Have overall responsibility for food defense • Monitor for possible attacks related to food terrorism • Apprehend terrorists responsible for attacks of food supplies and food chains
U.S. Environmental Protection Agency		Drinking water	• Establish safe drinking water standards • Regulate toxic substances and wastes to prevent their entry into environment and food chain • Assist states in monitoring quality of drinking water and preventing its contamination • Determine safety of new pesticides, set tolerance levels for pesticide residues in foods, and instruct in safe use of pesticides
U.S. Department of Commerce	National Oceanic and Atmospheric Administration	Fish and seafood products	• Inspect and certify fishing vessels, seafood processing plants, and retail facilities for federal sanitation standards through fee-for-service Seafood Inspection Program
U.S. Department of the Treasury	Bureau of Alcohol, Tobacco and Firearms	Alcoholic beverages, except wine beverages containing less than 7 percent alcohol	• Enforce food safety laws governing production and distribution of alcoholic beverages • Investigate cases of adulterated alcoholic products, sometimes with help from FDA
U.S. Customs Service		Imported foods	• Work with federal regulatory agencies to ensure that all goods entering and exiting the U.S. do so according to U.S. laws and regulations

U.S. Department	Monitoring Agency	Food Overseen	Food Safety Role
U.S. Department of Justice		All foods	• Prosecute companies and individuals suspected of violating food safety laws • Through U.S. Marshals Service, seize unsafe food products not yet in the marketplace, as ordered by courts
Federal Trade Commission		All foods	• Enforce variety of laws that protect consumers from unfair, deceptive or fraudulent practices, including deceptive and unsubstantiated advertising
State and Local Governments		All foods within their jurisdictions	• Work with FDA and other federal agencies to implement food safety standards for fish, seafood, milk, and other foods produced within state borders • Inspect restaurants, grocery stores, and other retail food establishments, as well as dairy farms and milk processing plants, grain mills, and food manufacturing plants within local jurisdictions • Embargo (stop the sale of) unsafe food products made or distributed within state borders

Source: *Table information obtained from the FDA's CFSAN website http://www.cfsan.fda.gov/~lrd/foodteam.html#usdafoot, last accessed on March 16, 2009.*

Endnotes

1. See "Federal Oversight of Food Safety: High-Risk Designation Can Bring Attention to Limitations in the Government's Food Recall Programs" (April 2007) U.S. Government Accountability Office.

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10. See N. Brooks, A. Regmi, and A. Jerard, "U.S. Food import Patterns, 1998-2007," (2009) Economic Research Service, U.S. Department of Agriculture,www.ers.usda.gov/Publications/FAU/2009/08Aug/FAU125/FAU125.pdf, last accessed May 08, 2010.

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14. For further details, see http://www.ers.usda.gov/Briefing/FoodSafety/economic.htm, last accessed May 4, 2010.

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26. It should be noted that PCA was not the only recent contamination due to peanut butter. In 2006 and 2007, *Salmonella* Tennessee was found in both Peter Pan peanut butter and the Great Value brand sold by Wal-Mart. The CDC traced the *Salmonella* to a processing facility in Sylvester, Georgia, owned by ConAgra. The CDC confirmed that 290 people from 39 states were made ill by *Salmonella* Tennessee as a result of this outbreak. Forty six patients were hospitalized, with three unofficially reported deaths. As with PCA, contamination was linked to a leaky roof and two occasions on which a sprinkler system was activated by mistake. It is likely that moisture from these three events mixed with the dormant *Salmonella* in the raw peanuts and peanut dust. This contamination was estimated to cost ConAgra more than $60 million. And again, as with PCA, earlier violations and complaints by FDA inspectors in 2005 about an alleged incident of *Salmonella* within the plant were ignored.

27. See "Multistate Outbreak of *Salmonella* Infections Associated with Peanut Butter-Containing Products, United States, 2008-2009" (2009), http://www.cdc.gov/mmwr/preview/mmwrhtml/mm58e0129a1.htm, last accessed February 1, 2010. See also K. Wittenberger and E. Dohlman, "Peanut Outlook: Impacts of the 2008-2009 Foodborne Illness Outbreak Linked to *Salmonella* in Peanuts" (2010), www.ers.usda.gov/Publications/OCS/2010/02Feb/OCS10A01/ocs10a01.pdf, last accessed May 8, 2010.

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31. For a comprehensive discussion of the elements of a modern food safety system, see C. Smith DeWaal, and D. Plunkett (2007) "Building a Modern Food Safety System: For FDA Regulated Foods," Center for Science in the Public Interest.

32. See www.govtrack.us/congress/bill.xpd?bill=h111-875 for a summary of the full text of this bill and its current status in Congress. This bill was referred to committee for review, but there are no indications that it is actively under review as of this writing.

33. The Food Safety Enhancement Act is largely based on H.R. 759, the Food and Drug Administration Globalization Act of 2009. See www.govtrack.us/congress/bill.xpd?bill=h111-2749 for a summary and the full text of this bill and its current status in Congress.

34. From the FDA's Mission Statement, www.fda.gov/aboutfda/whatwedo/default.htm, last accessed April 20, 2010.

35. Center for Science in the Public Interest, www.cspinet.org/, last accessed April 20, 2010.

36. For further details, see the FDA website, www.fda.gov/food/foodsafety/FoodSafetyPrograms/RFR/default.htm.

37. See www.rapidrecallexchange.org/, last accessed May 7, 2010.

38. See S. Kennedy (2008) "Why Can't We Test Our Way to Absolute Food Safety?" *Science* 32: 1641-1643.

39. See "*Toward Safer Food: Perspectives on Risk and Priority Setting*" (2005) eds. Sandra Hoffman and Michael Taylor, Resources for the Future Press, Washington, D.C.

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41. From International Organization for Standardization (ISO) 2005:2007, adapted from Codex Alimentarious (CAC/GL 60-2006). In this report, we distinguish between *transparency*, defined as the extent to which all of the chain's stakeholders have a shared understanding of and access to product and process-related information that they request, and *traceability,* which we define as the ability to trace the history, application, or location of an entity using the identification recorded.

42. The big push for RFID adoption came from Wal-Mart, which issued a mandate to its suppliers in 2005 that they must be RFID-capable by January 2007. In order to retain the business of one of their largest customers, most companies rushed to tag their products and invested in information systems to accommodate the large new stream of data. According to IDTechEx, the largest comprehensive database of RFID adoptions, more than 3,500 RFID adoption pilots have been implemented in a range of industries, including the food and transport industries. See www.idtechex.com.

43. Private sector regulation of food safety is discussed in more detail in the following articles: T. Havinga, (2006) "Private Regulation of Food Safety by Supermarkets," Law and Policy, 28(4), October 2006, pp. 515-533; D. Fuchs, A. Kalfagianni, and T. Havinga (2009) "Actors in Private Food Governance: the legitimacy of retail standards and multistakeholder initiatives with civil society participation," Agric Hum Values, Springer Netherlands, available at: www.springerlink.com/content/m237228605223463/, last accessed July 20, 2010; S. Henson and N.H. Hooker (2001) "Private sector management of food safety: public regulation and the role of private controls," Intl. Food and Agribusiness Mgt. Review, 4, pp. 7-17.

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Noel P. Greis is Director of the Kenan Institute of Private Enterprise's Center for Logistics and Digital Strategy and Professor of Operations at the Kenan-Flagler Business School at the University of North Carolina (UNC) at Chapel Hill. Dr. Greis is an expert in the area of logistics and supply chain management, and advises companies on the development of global strategies for sourcing and distribution. The center's Intelligent Enterprise Initiative helps industry leverage advances in digital technology such as RFID to redesign their business processes to be more real-time, event-driven, and secure in complex global markets. Software prototypes developed in the center's Intelligent Systems Lab are addressing the food safety and security problem.

Dr. Greis is principal investigator for the NCFOODAFE project. Supported by the U.S. Department of Homeland Security through the Institute for Homeland Security Solutions, she and her colleagues are developing a new software tool that leverages data fusion, analytics, and visualization to create situational awareness and decision support tools in the event of a food contamination event. She also is developing new traceability and visibility tools for managing cold chains for food, drugs, and other perishables.

Dr. Greis is the Co-Director of the UNC-Tsinghua Center for Logistics and Enterprise Development in Beijing, China, a joint center of Tsinghua University's Department of Industrial Engineering and the Kenan-Flagler Business School. This new, joint center is developing a major research initiative in the areas of food safety and logistics, especially between the U.S. and China. Under its auspices, UNC and Tsinghua University have built a virtual simulation laboratory that links the two organizations for the exploration of critical research problems related to global food supply chains.

She organized the 2009 International Symposium on Food and Drug Safety in Beijing on June 2, 2009. The event brought business together with government and the academic community to address critical issues related to the safe and secure transport of food and other perishables such as pharmaceuticals. She is currently the guest editor for a special issue of the *Journal on Operations Management* on food and product safety that will appear in 2011.

Dr. Greis received her Ph.D., M.S.E., and M.A. degrees in engineering from Princeton University and her B.A. in mathematics from Brown University. Dr. Greis is the recipient of a number of awards for her work, including a Distinguished Paper Award from the Decision Sciences Institute and a Citation of Excellence from the ANBAR Management Intelligence. Her papers have received awards in the Decision Sciences Institute Best Interdisciplinary Paper Competition and the Production and Operations Management Society William Abernathy Management of Technology Competition, and also have been translated into several languages**.**

Monica L. Nogueira directs the Intelligent Systems Laboratory of the Center for Logistics and Digital Strategy (CLDS) at the Kenan Institute of Private Enterprise. She leads the laboratory's effort to identify, experiment with, and transfer new technologies to CLDS' corporate and institutional customers, with an emphasis on exploring novel intelligent processes and logistics practices, and new simulation modeling tools and computational capabilities. Her current work is focused primarily on the development of intelligent software applications/prototypes for the center's customers, using state-of-the-art computational tools. Recent applications have been implemented in the areas of: business, e.g., financial processes; health, e.g., food safety and smart applications for health care; homeland security, e.g., intelligence and situation awareness; defense; aviation, e.g., logistics and optimization; and business intelligence.

In the area of food safety, Dr. Nogueira has developed and implemented a number of projects and tools that demonstrate the use of radio frequency identification (RFID) technology for controlling the safety of perishable products (i.e., cold chain for food and medical drugs) by enabling the tracking and tracing of the perishables and total visibility throughout the supply chain to guarantee their safety. A current project, NCFOODSAFE, seeks new strategies for utilizing corporate food-related data and the development of new algorithms for fusing public health data and products' recall data to reduce latencies of surveillance and response in food contamination events in North Carolina.

Last year, she co-authored a research brief on the use of informatics tools to reduce latencies in the North Carolina food safety system. Other related projects include ongoing collaborative work with Cranfield University (UK) to compare differences in the rates and policies between U.S. and European countries with regard to border refusals; alerts and recalls of contaminated food products; and a project with the North Carolina Preparedness and Emergency Response Research Center to develop new information models based on principles of systems dynamics that support North Carolina's efforts to build new capability in public health preparedness, including foodborne disease outbreaks.

Dr. Nogueira works closely with the joint UNC-Tsinghua Center for Logistics and Enterprise Development in Beijing, China. She has collaborated with Kenan-Flagler Business School faculty and students to develop and implement several RFID simulations to demonstrate the capabilities of the SIMSpace virtual environment linking the CLDS Intelligent Systems Laboratory and Tsinghua Logistics Laboratory in Beijing. Other projects connected to her research on RFID include ongoing collaboration with UNC Business School faculty on a comparative study of RFID adoption worldwide. In 2009, she also co-authored a research brief on the uses of RFID in national identification documents such as e-passports, PASS cards, and drivers' licenses. She is currently working on research to implement agent-enabled diagnostics, prognostics for logistics, and decision support.

Dr. Nogueira holds a Ph.D. in computer engineering from The University of Texas at El Paso, an M.S. degree in computer science from the Universidade Estadual de Campinas, Brazil, and B.S. degrees in electrical engineering and electronics engineering from the Fundação Universidade do Amazonas, Brazil, and the Instituto de Technologia da Amazonia, Brazil, respectively. She has published a number of papers in the areas of answer set planning and programming.

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