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SAFEGUARDING THE FOOD ON YOUR DINNER TABLE: EMERGING PUBLIC-PRIVATE APPROACHES

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TRENDS

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The FDA Food Safety Modernization Act (FSMA) signed into law by President Obama on January 4, 2011 paves the way for the first major overhaul of U.S. food safety laws since 1938. This new law sets the stage for a new era in food safety regulation and oversight, the implementation of which will require participation on the part of industry and government alike. Spurred, in part, by recent high-profile events such as the 2008 Salmonella peanut butter contamination, the FSMA provides both new powers for the FDA and new responsibilities for private sector food companies. While the impact of FSMA will depend on subsequent funding to hire inspectors and perform other mandated tasks, it is clear that it will have a dramatic change in how food safety is viewed and implemented in the U.S. by public and private sector organizations alike.

—Noel P. Greis & Monica L. Nogueira

INTRODUCTION

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Most Americans purchase food for their family's dinner table with a high level of assurance that the food is safe. However, recent contaminations have brought into sharp focus gaps in our current food safety system 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 3,000 products were recalled. Early estimates of the costs to the peanut butter industry due to lost peanut butter and peanut sales were more than $1B.

Also in 2008, a mysterious case of contamination was reported in the southwestern United States. The source remained unknown for many weeks until it was traced to jalapenos 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 jalapenos. A sample of a jalapeno tainted with *Salmonella* Saintpaul found at the restaurants where affected people had eaten was linked to a sample from a packing plant in McCallen, Texas, that sourced its jalapenos from farms in Mexico.

The recent melamine contamination of milk products in China reminds us that the problem of safe food extends beyond U.S. borders. While the *Salmonella* Tryphimurium contamination in the U.S. was the result of improper processing and 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 products were found throughout Asia, including Taiwan and Hong Kong, as well as in Europe and the United States.

Here in the U.S., the *Wall Street Journal* reported that confections made from contaminated powdered milk produced in China had been pulled from the shelves of a retailer in the Midwest. Melamine-laced milk is still capturing headlines around the world. Even after the Chinese government shuttered several milk companies and executed nine executives, melamine continues to seep into milk products in China. In January 2010, the Chinese government closed down the Shanghai Panda Dairy Company and arrested three executives after melamine was again discovered during routine quality inspections of condensed, high-calcium milk powder that was being marketed to middle-age and elderly consumers in China. In January 2011, the Chinese police have arrested 96 people suspected of illegally using melamine-tainted powder leftover from the 2008 to produce dairy products or sell such products since July 2010.

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FOOD SAFETY

CURRENT LANDSCAPE OF FOOD SAFETY

"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 USDA and FDA are charged with 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 irrational. For example, different agencies regulate meat lasagna and vegetable lasagna because products with meat are the responsibility of USDA while vegetable lasagna is the responsibility of FDA. Similarly, inspection policies vary and are inconsistent. 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.

It is evident from recent history—from the 2008 *Salmonella* peanut butter contamination (see *Figure 1*) to the 2008 jalapenos contamination—that our food safety net has acquired large tears that continue to permit contaminated products to find their way to retail shelves causing considerable economic damage and irreversible human harm including death (see *Table 1*). 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 GDP. The Government Accounting Office has estimated that losses to the U.S. economy from halted agricultural exports at the border 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—is playing a key role in assuring safe food. Historically, food safety has been the purview of the patchwork of federal regulatory agencies that operate in an oversight role over the private sector. These 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.

> "The federal regulatory system for food safety, like many other federal program 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."
>
> *"Federal Oversight of Food Safety: High-Risk Designation Can Bring Attention to Limitations in the Government's Food Recall Programs (U.S. Government Accountability Office, April 2007).*

Increasing Opportunities for Food Contamination

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. Recent studies by the CDC studies estimate that contaminated food affects more than 47.8 million people in the U.S. each year causing more than 127,839 hospitalizations and 3,037deaths per year [Scallan, 2010a; Scallan, 2010b]. 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 [Chalker and Blaser, 1988; Voetschlker, 2004]. A summary of some of the major food contamination events in the U.S. over the last ten years is shown in *Table 2*. 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.

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 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

FIGURE 1: Chronology of PCA Peanut Butter Contamination

Late August – Early September 2008
FIRST CONTAMINATION ?

June 4, 2009
Last Known Recall of PCA Peanut Products From Providence Commerce, CA.

Mid September 2008
First laboratory-confirmed cases reported October 2008 by state health agencies.

April 2009
FDA still recalling peanut products from many companies.

November 2008
CDC confirms cluster of Salmonella Typhimurium.

March 8, 2009
PCA files for bankruptcy. Product recalls still being announced by FDA.

December 3, 2008
CDC holds nationwide conference call to confirm pattern of outbreaks.

January 10, 2009
First alerts and recalls issued. Other PCA facilities and products implicated. CDC and FDA investigate outbreaks in other states (e.g. Georgia and Connecticut).

January 7, 2009
CDC, FDA and Minnesota Dept. of Health discuss peanut butter as possible source.

January 9, 2009
FDA tests of King Nut peanut butter confirm source as Peanut Corporation of America (PCA).

Source: Chronology of Events Related to Peanut Butter Recall Involving PCA, AIB International, www.aibonline.org/press/AIBStatement04033009/Chronology.html

occur in two to three 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 rather by second-tier producers who compete on the basis of cost rather than quality and safety.

New trends in food consumption are also 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 non-processed 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 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. 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

TABLE 1: Major Food Contamination Events in U.S. (2000-2010)

YEAR	FOOD PRODUCT	PATHOGEN	COMPANY
2010	Shell Eggs	*Salmonella* Enteritidis	Wright County Egg & Hillandale Farms
	Hydrolyzed Vegetable Protein	*Salmonella* (various)	Basic Food Flavors
2009	Salami	*Salmonella* Montevideo	Daniele International
	Beef Products	*Salmonella* Newport	Cargill
	Pistachios	*Salmonella*	Setton Pistachio of Terra Bella
	Peanut Butter Paste	*Salmonella* Typhimurium	Peanut Corporation of America
	Refrigerated Cookie Dough	*E. coli O157:H7*	Nestle
2008	Jalapenos 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*	Topp's 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

TABLE 2: Attribution of Foodborne Illness 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.

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.

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. 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.

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 inadequate cold chain infrastructure. In these countries, products are not transported from 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 [A.T. Kearney, 2007].

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 Queenslander, 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 to be contaminated chicken wraps served on Virgin Blue flights between Australia, New Zealand and Bali. The wraps were produced by New South Wales-based company 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.

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 an event. *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 General Accounting Office (GAO), between 1996 and 1997 more than 2,000 culture-confirmed cases of *Salmonella* were reported to CDC's FoodNet surveillance system which covers approximately 15 percent of the U.S. population [U.S. GAO, 2008; Frenzen et al., 1999]. 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. 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. 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 $1B have been suggested including $500M due to lost peanut sales—as well as 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 $75M. 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% of the nation's peanuts and peanut sales during and immediately after the event declined more than 25% nationwide. While demand for peanuts subsequently rebounded, it was too late for PCA and its employees since 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 United States. 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 or GDP. 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.

PUBLIC-PRIVATE

EMERGING PUBLIC-PRIVATE APPROACHES

Closer engagement between public and private sectors can reduce the scale and scope of food contamination events by enhanced prevention and improved monitoring and surveillance to more efficient response. By working together to implement risk-based and customized process controls based on mutually agreed 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 food products 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 where 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. Under the new Food Safety and Modernization Act, food manufacturers will be required to register and to examine their processing systems to identify possible ways that food products can become contaminated and to develop detailed plans to keep that from happening. Companies must share those plans with the FDA, and provide the agency with records, including product test results, showing how effectively they can carry them out.

Private companies themselves are increasingly taking a pro-active role in food safety. In particular, the private sector has invested in the new tools to improve information sharing across the industry in the event of a food contamination. *The Rapid Recall Exchange* 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. Companies participate by subscription. In the event of a quality problem leading to a recall or withdrawal, a company posts a message for its customers that contains critical information about the recalled product, product handling instructions, reimbursement instructions, and comprehensive contact information.

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 Food and Drug Administration (FDA), especially, is underfunded with respect to its mandate. In today's economic climate, it is not possible to inspect all food production and retail organizations regularly. 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.

Thus, in a risk-based system, the allocation of effort and resources is aligned with the level of risk to the food system. 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 risk 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.

Risk-based strategies have the potential to not only reduce the incidence of foodborne disease, but also to achieve more efficient allocation of resources. The 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 USDA. While USDA regulates one-fifth of the food supply that is responsible for 27 percent of outbreaks, its food safety appropriations are double those given to FDA. In contrast, the FDA regulates 80 percent or more of the food supply and inspects food facilities, on average, just once every 10 years. 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 one percent was analyzed in a laboratory as part of its inspection process. By moving to a risk-based system under the new Food Safety Modernization Act, resources will be better allocated to protect the public from potential threats to the food system.

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.

The new Food Safety Modernization Act gives the FDA new authority to require traceability in the food chain. The use of new track-and-trace technologies, with supporting information and communication technologies, enables companies to not only trace the history of a contaminated food product back up the supply chain—referred to as trace back, but also to trace forward from a contaminated supplier to all affected products that may have been shipped to customers—referred to as trace forward. Traceback 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.

Traceability requirements will depend on the type of product. Full traceability may not be required across the entire food chain.

- The *breadth of tracebility* refers to the extent of information that is recorded. 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.
- The *depth of traceback* refers to how far upstream the system tracks relevant information about a product. In the case of field produce like spinach, traceback to the farm would be important to track pesticides. 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.
- The *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. 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.

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 the private sector that encourage them to implement and strengthen their traceability systems in 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.

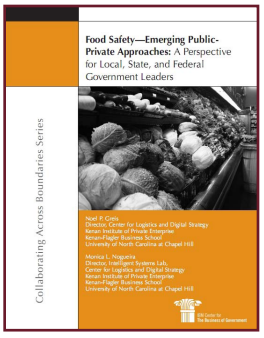
Policy-makers view co-regulation as a solution for bridging the gap between the high social costs of *laissez-faire* market approaches and the burdensome economic costs of over-regulation. A *laissez-faire* approach—letting the market alone weed out unsafe products and vendors—is not a reasonable option 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 may also 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.

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 Standards**: 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; and
- **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.

While co-regulation has the potential to improve food safety, barriers exist and solutions remain to be worked out. Given the different perspectives of the 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.

TO LEARN MORE



Food Safety—Emerging Public-Private Approaches: A Perspective for Local, State, and Federal Government Leaders
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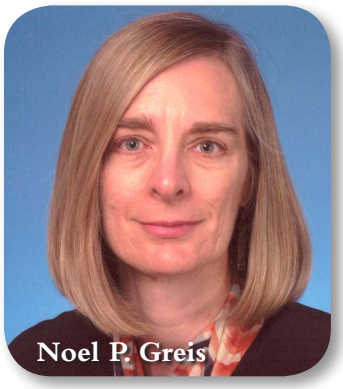
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Greis received her Ph.D., M.S.E. and M.A. degrees in engineering from Princeton University and her B.A. in mathematics from Brown University. She is the recipient of a number of awards for her work including a Distinguished Paper Award from the Decision 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 have been translated into several languages.

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CONCLUSION

CONCLUDING REMARKS

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. As a global leader, the U.S. can help set the standard for new models of food safety cooperation worldwide. New 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.

YOUR FOOD

SAFEGUARDING YOUR FOOD

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 towards safer food.

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