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

By Noel P. Greis and Monica L. Nogueira

This article is adapted from Noel P. Greis and Monica L. Nogueira, "Food Safety—Emerging Public-Private Approaches: A Perspective for Local, State, and Federal Government Leaders" (Washington, DC: IBM Center for The Business of Government, 2010).

"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."

"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.

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 riskbased 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.

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Table 1: 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.

It is evident in recent history—from the 2008 Salmonella peanut butter contamination (see Figure 1) 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 (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 gross domestic product. The Government Accountability Office has estimated that losses to the U.S. economy from halted

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Late August-Early September 2008 FIRST CONTAMINATION? Mid-September 2008 September 11, 2009 First laboratory-confirmed Last known recall of PCA cases reported October 2008 peanut products from by state health agencies. Kilwin's Quality Confections, MI. November 2008 CDC confirms cluster of April 2009 Salmonella typhimurium. FDA still recalling peanut products from many companies. December 3, 2008 CDC holds nationwide March 8, 2009 conference call to confirm pattern of outbreaks. PCA files for bankruptcy. Product recalls still being announced by FDA. January 7, 2009 CDC, FDA, and Minnesota January 10, 2009 Dept. of Health discuss pea-First alerts and recalls issued. Other nut butter as possible source. PCA facilities and products implicated. CDC and FDA investigate outbreaks in other states (e.g., Georgia and January 9, 2009 Connecticut). FDA tests of King Nut peanut butter confirm source as Peanut Corporation of America (PCA).

Figure 1: 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.

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



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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

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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

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Table 2: 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	Х	Х
Inspections: Create a system of risk-based inspection, based on the type of food handled and the processes used.		Х	X	Х
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	Х	Х
Research and Education: Establish programs to support FDA regulatory programs, state food safety agencies, and the food industry's own efforts.		Х		
Farm: Develop and enforce on-farm food safety programs.		X	X	X
Recall: Mandatory recall authority to ensure that recalled foods are removed from the market.		X		
Traceback: Authority to require products to be traceable in the supply chain.		X	X	X
Detention: Authority to detain and destroy unsafe food when inspectors find it.		X	X	X
Penalties: Establish penalties for violating food safety laws as a deterrent to future violations.		X		Х
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.



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" (see Table 2). The

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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, 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.

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.

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 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.

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.

"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."

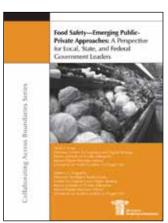
Our nation's health and the well-being of its citizens depend on a coordinated and effective web of safeguards to protect the food supply—whether it originates in China or California. Government regulations governing the private sector are a first line of defense and, combined with oversight and inspection 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.

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Our research offers 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.

TO LEARN MORE

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The report can be obtained:

- In .pdf (Acrobat) format at the Center website, www.businessofgovernment.org
- By e-mailing the Center at businessofgovernment@us.ibm.com
- By calling the Center at (202) 551-9342