U.S. Food Safety Policy Enters a New Era

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- In late 2010, Congress passed the Food Safety Modernization Act (FSMA), the most comprehensive reforms to Federal food safety laws since 1938.
- The farm-to-fork, preventive approach embodied in the Act reflects an established scientific/managerial consensus on how to improve food safety systems.
- Economic research on similar food safety initiatives by industry and government can help guide implementation of the FSMA.

FDA

The 2011 Food Safety Modernization Act has implications across the entire food system, from the farmer to the food retailer.

A series of highly visible foodborne illness outbreaks in recent years helped create the political momentum to pass the most extensive reform of the Food and Drug Administration's (FDA) food safety authority since 1938. The Food Safety Modernization Act (FSMA), signed into law in January 2011, reflects a systematic approach to food safety management shaped by science, industry, and government over the past two decades. As FDA's Deputy Commissioner recently explained, the FSMA shifts the focus of FDA activities from "catching food safety problems after the fact to systematically building in prudent preventive measures across the food system, from the farm to the table."

While the FSMA directly affects only FDA authority, its implementing regulations and policies are likely to influence food safety practices throughout the Federal Government and the food and farm sectors. More efficient regulation could reduce the burden of new programs on producers and consumers while helping to ensure that food safety goals are met. ERS research conducted over the past two decades provides a number of lessons that can help identify efficient and effective means of implementing the Act.

Markets and Lawsuits Alone Provide Insufficient Safeguards

Each year, roughly 1 in 6 Americans—47.8 million people—get a foodborne illness. Most of these illnesses are mild and resolve in a matter of days. But many result in chronic, even lifelong, outcomes, including kidney disease, arthritis, and digestive disorders. About 128,000 people per year are hospitalized from these illnesses; 3,000 die. While the chances of getting ill from any particular meal are very small, foodborne sources cause as many illnesses and deaths as the flu in a typical year.

Providing food safety is not free. In an unregulated market, firms cannot afford to invest in safety if buyers are not able to distinguish between the safety of competing products and are not willing to pay a premium for the safer offering. Unfortunately, the safety of food products is usually unobservable to consumers, and often even to companies in the food industry.

Because consumers cannot directly observe food safety, retail markets will generally undersupply it. But there are other places in the supply chain where market incentives help ensure food safety. Major recalls or other food safety failures are more likely to harm companies with significant brand equity, particularly those involved in retail sales. To protect themselves, some companies—particularly national restaurant chains and suppliers of branded meats—have set up supply contracts that specify safety standards or reward use of innovative technologies to improve safety. But such firms supply only a portion of the Nation's food.

Some see liability suits as a major driver for firms to invest in food safety. ERS research shows that jury awards in personal injury suits offer limited incentives. The nature of foodborne illnesses makes the likelihood low of identifying what food and which producer caused injury. Plaintiffs were found to be most likely to win if they could link their illnesses to a specific pathogen or a large outbreak. Yet, Centers for Disease Control and Prevention (CDC) epidemiological studies can identify the pathogen source for only 20 percent of U.S. foodborne illnesses in a typical year. Less than 1 percent of foodborne illnesses are part of an outbreak.

New Act Better Aligns FDA Programs With Recognized Food Safety Principles

The FSMA builds on efforts to modernize the U.S. food safety system that began in the early 1980s. This modernization movement emphasizes the efficient use of both public and private resources as reflected in a shift from inspection and outbreak response to prevention and the use of flexible, risk-based management practices.

Key elements in the FSMA include:

- Requirements for food processors to analyze food safety hazards and implement risk-based preventive controls;
- Mandatory FDA recall authority with greater public outreach;
- Enhanced traceability systems for food products;
- Improved disease surveillance and use of science-based risk assessments to target FDA activities;
- Onfarm safety standards for produce; and
- Redesign of FDA's import safety control system by coupling third-party certification and private-sector verification with FDA inspection of foreign food facilities.

ERS research has examined a broad range of food industry and consumer behavior issues related to food safety. This article focuses on the first four key elements. This research can help inform FDA's implementation of the FSMA.

Managerial Flexibility Critical to Risk-Based Controls

The FSMA focuses on prevention of food contamination as the first line of defense against food safety hazards. The Act requires that virtually all food processors, manufacturers, and packers analyze hazards and adopt risk-based preventive controls to manage product safety. Prior to the Act, such preventive controls were only required for juice, seafood, meat, and poultry under Hazard Analysis and Critical Control Points (HACCP) regulations, though many other firms follow its principles in their operations.

HACCP is a quality management system that looks at the operation as a whole. In an HACCP plan, firms must identify potential food safety hazards and where they might arise in their operation. Firms then must develop plans for monitoring these "critical control points" and responding if hazards are detected. HACCP plans also require a recordkeeping system to assist firms and inspectors in verifying that the system is under control. FDA is in the process of defining what will be required under the FSMA.

USDA's Food Safety and Inspection Service (FSIS) issued one of the first U.S. HACCP rules in 1996. ERS research on the meat and poultry industries' experience with these HACCP regulations may provide useful insights for FDA and industry. USDA's regulations kept some conventional proscriptive sanitation and process requirements, such as proper hand-washing procedures and temperature controls, in effect along with the new, more flexible HACCP requirements.

Based on results from a 2002 nationwide survey and FSIS *Salmonella* product testing data, ERS researchers found that conventional proscriptive requirements were responsible for only a third of the decrease in positive pathogen test samples. Managerial decisions to invest in human and physical capital, food safety technology, and changes in firm organizational structure were responsible for the remainder.

These management decisions were influenced both by HACCP requirements and market forces. Nearly half the *Salmonella* reduction was tied to direct contractual relationships in which suppliers were paid a price premium, given a guaranteed quantity agreement, or provided other incentives for paying more attention to food safety. The study's results suggest that HACCP is a more effective means of improving food safety than conventional proscriptive requirements.

Concern about potential impacts on small firms played a large role in congressional debates over the FSMA. In the ERS study of USDA's HACCP rules, small plants producing specialty meat products had higher average HACCP-related costs than large plants producing commodity products. However, the study suggests that the costs to small firms would have been even higher if FSIS had specified fixed expenditures rather than allowed plants flexibility in creating their own HACCP plans.

To protect their customers and their sales, many companies use supply contracts that specify food safety standards.

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Recalls and Public Notification Prevent Illnesses With Limited Industry Impact

Even with the best prevention efforts, food sometimes becomes contaminated. Recalls and consumer notification are important tools to prevent illness once contamination has occurred. They also help ensure that the responsible firms bear more of the cost of failing to prevent contamination than they otherwise would.

The FSMA enhances FDA's power to respond to problems when contamination occurs in three ways. First, the Act gives FDA mandatory recall authority. Currently, FDA cannot require a recall, though firms generally do so voluntarily when requested by FDA. The second, and more significant, change is that new provisions make it easier for FDA to detain products may violate food safety law or to suspend a facility's registration, thus preventing it from legally distributing food. Third, under the FSMA, FDA will develop standards for displaying information about recalls both on the Internet and in grocery stores.

Under an HACCP food safety plan, firms must identify where safety problems could occur, monitor these problem points, and take action if hazards are detected.


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The financial impact of recalls and consumer notification on businesses that do not produce contaminated products depends on the information consumers receive and how they respond. ERS research on the sales impacts of major food safety incidents over the past 10 years suggests that consumers have responded to recalls and outbreaks in a measured way that has limited spillover effects. In the cases studied, sales dropped significantly for a few weeks following the incidents, though in some cases a small decline in demand continued for as much as 8 months.

Traceability Systems Need To Vary by Product

For recalls to be effective, firms need to be able to trace product distribution. Traceability systems are also crucial to speedy identification of the source of contamination in CDC outbreak investigations. The FSMA directs FDA to establish pilot programs to evaluate alternative methods of tracing at least three different types of foods. Based on knowledge gained from these pilot programs, FDA will develop rules to improve product tracing systems for most of the U.S. food supply, building on and enhancing existing systems.

In 2004, ERS researchers studied traceability systems for U.S. produce, cattle/beef, and grain and oilseeds. They found the diverse characteristics of the three commodities—the perishability of produce; the need to prevent theft and credibly assert livestock breeding lineage; and the ability to blend, grade, and store grain—led to the development of very different traceability systems in the three sectors.

Three broad conclusions can be drawn from this research. First, uniform systems applied across all sectors of the food industry are likely to be more costly and less effective than ones that recognize the unique characteristics of different sectors. Second, government-mandated traceability systems need to allow firms flexibility to adjust to changing technology and changing consumer demand. Third, the private sector has been successful in developing traceability systems that meet private-market needs, even evolving new organizational structures, like contracts, cooperatives, and vertical integration to facilitate traceability. But, markets have not been as effective in encouraging traceability that meets public needs related to food safety.

A Narrow Range of Pathogens and Foods Cause Most of the Harm From Foodborne Illness

The FSMA greatly increases FDA responsibilities for food safety and mandates more frequent inspections. The Act directs FDA to use risk-based prioritization to target efforts toward the most serious foodborne health hazards. FDA is expecting to look at factors such as firms' and importing countries' past food safety records, indicators of a firm's financial stability, the inherent riskiness of foods, and most critically, the relative contribution of different foods to the total burden of foodborne illness in the United States.

Comparing the illness burden of different pathogens and food sources is not easy. CDC can only identify the responsible pathogen in 20 percent of foodborne illness cases overall, though CDC can identify the pathogen for 44 percent of cases that send people to the hospital or result in death.


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FDA will study existing traceability systems to develop rules to improve the ability of companies to trace the distribution of their products.

And, cases with different outcomes are not directly comparable. Some pathogens cause many mild illnesses. Others cause fewer illnesses but fatal outcomes or serious chronic conditions.

Health economists have developed two aggregate measures to facilitate comparison of health burden across diverse diseases: monetary measures and a measure called a quality-adjusted life year (QALY). The cost of illness—typically measured as treatment costs plus the value of lost time from work and individuals' willingness to pay to reduce risk of death—is usually used as a monetary metric in food safety policy analysis, even though it underestimates the burden of illness.

The QALY approach allows patients, medical experts, or a sample of the general population to rank the relative impact of illnesses on the quality of life. This measure was developed to help health care analysts and doctors evaluate the cost effectiveness of alternative medical treatments. The Office of Management and Budget recently allowed the QALY approach to be used in regulatory analysis.

Researchers at ERS conducted some of the earliest studies of the economic costs of foodborne illness. ERS's online Foodborne Illness Cost Calculator provides a transparent framework for estimating the cost associated with foodborne illness due to *Salmonella* and STEC:O157 (formerly *E.coli*: O157:H7). This work is ongoing. As patterns of disease, detection, and treatment change, the public health and economic burden also changes.

Building on earlier ERS cost-of-illness models, a team of researchers from the University of Florida and ERS recently estimated that 14 pathogens impose a little over $14 billion annually in cost of illness and cause a loss of about 61,000 QALYs each year. These pathogens account for over 95 percent of the foodborne illnesses, hospitalizations, and deaths CDC can tie to specific pathogens. This study also estimates the share of foodborne illnesses attributable to consumption of 10 broad food categories such as beef, poultry, or produce.

The results suggest that it should be possible to target public and private food safety control efforts to reduce illnesses more effectively. Just 5 pathogens account for 90 percent of the cost of foodborne illness from these 14 pathogens. Ten food/pathogen combinations are responsible for almost 60 percent of the public health burden of the 14 pathogens, whether measured by cost of illness or QALYs.

The FSMA is a major change in FDA legal authority aimed at bringing FDA's food safety programs more in line with recognized food safety management principles. But it is *not* a major change in the scientific consensus about the direction food safety management needs to move. Many of the policies FDA will be implementing—like prioritizing risk and encouraging producer initiative—are already in use elsewhere. Research by ERS and other institutions on the design and impacts of past regulatory efforts can inform policymakers as they move forward.

This article is drawn from . . .

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