Preparing America's Food Safety System for the Twenty-First Century

by Michael R. Taylor

Recent regulatory changes will help the food safety system focus on prevention and should clearly define the respective roles of government and industry. But more work is needed to assure the system's future success.

In announcing a new round of food safety initiatives in connection with his FY98 budget proposal, President Clinton called for a national discussion about the future of the nation's food safety system. Recently, federal agencies have gone a long way toward improving that system by adopting a regulatory framework that focuses attention on prevention and more clearly defines the roles the food industry and the government must play. But as the President's new initiatives indicate, more work needs to be done—and new working relationships forged—in preparing our food safety system for the next century.

The organizational and statutory fragmentation of the current system makes it difficult for the federal food safety agencies to take full advantage of the newly adopted regulatory framework. Efforts to assign clear responsibility and accountability for food safety within the government are frustrated by the fact that several different federal agencies are involved in regulatory matters concerning food safety. They operate under thirty-five distinct statutes. Further, although the federal government spends more than $200 million annually on food safety research, no formal mechanism or strategy exists to coordinate the twenty-one distinct federal agencies conducting such research (see "A Fragmented Food Safety System"). To say the least, the current "system" is not the one anyone would design if starting from scratch.

The new federal framework for food safety regulation is cause for optimism nonetheless. To understand why requires some familiarity with the current U.S. food safety system, which actually consists of *two* systems: one for meat and poultry, administered by the U.S. Department of Agriculture (USDA), and one for seafood and all other foods, administered primarily by the Food and Drug Administration (FDA). It is these two agencies that have decided to adopt a new regulatory framework based on what is known as a Hazard Analysis and Critical Control Points (HACCP) approach.

America's Two Food Safety Systems

In the USDA system, inspectors carry out "continuous inspections" of meat and poultry plants by physically examining every carcass passing through slaughterhouses and making daily inspections of plants that process products ranging from fresh, cut-up chicken parts to pepperoni pizza and chicken noodle soup. USDA employs nearly 7,500 full-time inspectors who continuously inspect more than 6,000 plants. In

A Fragmented Food Safety System

Responsibility for America's food safety is widely dispersed among government agencies at federal, state, and local levels. The roles of these agencies vary widely depending on their statutory authority and resources. The resulting fragmentation undercuts the government's ability to marshal the most effective food safety program possible and it muddles accountability. A few examples illustrate this point:

- FDA is responsible for the safety of eggs in shells and USDA for the safety of processed egg products, but it is USDA—not FDA—inspectors that visit shell egg packing houses on a daily basis to grade eggs for quality.

- Plants producing pepperoni pizza are subject to daily inspections whereas those producing cheese pizza are rarely inspected. Meat accounts for the difference in oversight. USDA oversees the former type of plant and FDA the latter. USDA also inspects the animal from which the pepperoni was made at the time of slaughter as well as the processing of the meat into pepperoni.

- To implement the pesticide reform law that Congress passed last year, the Environmental Protection Agency will make hundreds of important food safety decisions about chemicals in foods—many more than FDA will make—even though FDA is considered the federal government's leading food safety agency.

- The Centers for Disease Control and Prevention (CDC) are responsible for monitoring foodborne illnesses at the federal level and they conduct investigations of outbreaks of illnesses at the invitation of state health officials. FDA and USDA also investigate outbreaks of illness, albeit for different purposes. While the CDC focus is on determining the causes of illnesses, the agencies look to see if regulatory action is needed, such as seizure or product recall.

- State and local agencies have their own food safety programs that play a critical role in the nation's food safety system. In addition to investigating outbreaks of illness within their boundaries, they conduct food safety inspections at the retail level—grocery stores and restaurants—and they have primary oversight for certain product categories such as milk products and shellfish.

Because fundamental structural reform in the federal government is politically difficult to achieve, the agencies are working among themselves to improve the existing structure, using HACCP as their conceptual framework.

1994, inspectors individually examined approximately 130 million head of livestock, and 7.5 billion chickens, turkeys, and other poultry. Carcasses and processed products cannot be shipped into commerce without the USDA mark of inspection.

The USDA system reflects its historical origins in the early 1900s, when the public's primary concerns were extremely unsanitary conditions in meatpacking houses and the use of diseased animals or visibly contaminated carcasses for human food. The system has worked well to address these problems, but it has done so by playing a prominent role in the operation of the plants it inspects and for the quality and safety of products leaving those plants. For example, USDA inspectors bear the primary responsibility for sorting diseased carcasses from wholesome ones; USDA approves facility blueprints, processing equipment, and product labels prior to their use; and inspectors, rather than plant managers, have traditionally made the daily decisions on whether or not a slaughter plant has been adequately cleaned and is ready to begin operations.

The strength of the traditional USDA system is that it puts government inspectors in a position to promptly detect and correct obvious food safety and sanitation problems. It also provides the assurance that many consumers evidently want—external oversight of production. The system's primary weakness is that slaughterhouses have no clearly defined responsibilities for preventing or minimizing contamination of carcasses with the most significant forms of contamination—microbial pathogens, such as *Salmonella, Campylobacter*, or *E. coli* 0157:H7—which are not visually observable by inspectors.

Moreover, before 1994, the USDA did not consider any microbial pathogens on raw meat and poultry products to be adulterants under law, partly because proper cooking was thought to kill the bacteria. This policy insulated slaughterhouses from responsibility for reducing bacterial contamination and meant that, when the presence of *E. coli* in hamburgers in the Pacific Northwest caused an outbreak of illness in 1993, USDA investigators determined that the inspection system had worked as it was designed to work. Unfortunately, the system's failure to assign responsibility for reducing microbial contamination undermines not only its effectiveness in minimizing the risk of illness but also the public's confidence in the safety of the food supply.

More broadly, the USDA system has also, in some respects, stood in the way of progress on food safety. For some companies, the extensive system of command-and-control regulation associated with continuous USDA inspection has discouraged or delayed adoption of new food safety technologies. For others, the USDA mark of inspection has been a crutch that plant operators have depended on in lieu of taking responsibility themselves for food safety and sanitation.

In contrast, the FDA relies much less heavily on inspection than the USDA does. The FDA instead ensures food safety by establishing quantitative limits on various chemical contaminants, specifying in some cases which microbial pathogens adulterate various foods, issuing regulations on the use of additives, and providing general guidance concerning the "good manufacturing practices" that FDA considers necessary to prevent insanitary conditions. FDA enforces these provisions when violations are encountered as a result of outbreaks of illness, consumer or industry complaints, or observations made during periodic FDA inspections.

FDA has jurisdiction over 53,000 establishments that produce, process, or store food, ranging from seafood plants to warehouses to high-tech food processing facilities. The agency's 250 food inspectors conduct about 5,000 annual inspections. A typical FDA enforcement action involves removal of an adulterated food from commerce, either through voluntary recall by the responsible company or through an FDA-initiated court action. Because FDA inspection is infrequent for any one firm—a year or more can pass between inspections, even in plants with relatively high-risk operations—the system relies heavily on the commitment and competence of food companies to produce safe products. Most companies take their food safety responsibility seriously.

The strength of the FDA system is that is has spelled out what it considers to be an appropriate standard of safety and, through its enforcement activity, has created added incentive for companies to meet those standards. The system's primary weaknesses are the infrequency of its inspections and its largely reactive stance: the system has lacked strategies and mechanisms to systematically anticipate and prevent the most significant food safety problems, such as ones associated with microbial pathogens.

A New Approach: HACCP

In the 1960s, food industry experts developed the Hazard Analysis and Critical Control Points system to monitor foodstuffs at several important junctures in the preparation process, rather than waiting until products were ready to go to market before inspecting them for safety. The approach is a proactive and preventive one. The operator of a food production process develops a HACCP plan for producing safe food, one that identifies the potential hazards in the process—such as the possibility of harmful contamination with bacteria or chemicals. Such a plan also specifies process controls—for example, proper cooling of perishable raw materials or adequate cooking temperatures—that are validated as effective in preventing or minimizing health risks. Recordkeeping and monitoring procedures enable an operator to verify on a continuing basis that the controls are working and to detect and promptly correct food processing errors.

USDA adopted the HACCP system in 1996 following the recommendation of the National Academy of Sciences. In the early 1990s, FDA began developing its own HACCP-based food safety strategy for seafood, culminating in its 1995 regulations that mandate HACCP for seafood processors.

While food safety laws in the past have *implicitly* made food companies responsible for preventing safety hazards and producing safe food, HACCP makes their responsibility *explicit* and establishes a general standard of process control that companies must achieve. Under HACCP as adopted by USDA, for example, a slaughter plant's responsibility to target and reduce contamination with harmful bacteria is now crystal clear.

HACCP also clarifies the government's role. For example, USDA inspectors will continue to inspect each carcass in every slaughter plant and make daily inspections in processing plants, but they will no longer attempt to control—and, in effect, take responsibility for—so many details in a given plant's day-to-day operations. Instead USDA will focus on verifying through its inspection activity that every company-designed HACCP plan is appropriate and working properly and that each company is meeting food safety performance standards. For USDA, taking an HACCP approach will permit more efficient deploy-

ment of its inspectors, allowing them to focus on the most important food safety concerns in the plants they monitor.

For FDA, the HACCP system can compensate to some extent for the infrequency of its inspections. All HACCP plans include recordkeeping procedures to provide an ongoing indication of plant conditions and whether food safety controls remain effective between inspections. Documentation includes how plant employees have detected and corrected processing problems.

Strategies for the Next Century

The HACCP approach is at the heart of the Clinton administration's farm-to-table food safety strategy. HACCP's core concepts—prevention, clearer assignment of responsibilities, and better use of resources—establish a solid foundation for the food safety system of the future, but it is only a first step. To satisfy the public's food safety expectations and realize the food industry's full potential in the global food economy will require a new kind of effort and collaboration. It won't simply be a matter of more regulation. What is needed besides are investments—and new mechanisms for management and coordination—to bolster the scientific capabilities of our food safety system and its readiness to address a changing set of food safety challenges, including those posed by foodborne illnesses and the globalization of the food economy.

Looking into the next century, reducing the risk of foodborne illness will remain a central priority and challenge. Food safety problems are persistent and new problems emerge, such as the recent appearance of *E. coli* 0157:H7 in apple juice. Most experts agree that more efforts are needed to improve epidemiological surveillance, better focus and prioritize food safety research, and expand education of food service employees and consumers in safe food handling practices.

Fostering new technology is another challenge but also an opportunity. New technologies have long been central to building the safety, economy, and convenience of the American food supply, and the new HACCP framework encourages industry adoption of new technologies and procedures to control harmful bacteria. Continued success requires investment in technology development, rigorous but prompt government approval processes, and public understanding and acceptance of technology and its benefits.

Trade-related issues will also loom large in the years ahead. Food imports and exports are expanding, and the growth prospects of American agriculture and the food industry rest heavily on meeting the rising demand overseas for high-quality, value-added food products. Traditional economic barriers are coming down, but food safety concerns are increasingly the basis for disruptions in trade. The United Kingdom, for example, is struggling to resume exports of beef in the wake of the "mad cow" disease scare, and the United States is contesting Europe's refusal to allow imports of U.S. beef from cattle treated with FDA-approved growth hormones. As the world moves toward greater harmonization of food regulatory standards, the U.S. challenge is to ensure that imported food continues to meet America's high safety standards and that U.S. exports are not blocked by unfounded concerns.

An Opportunity for Collaboration

With all of these concerns in mind, the food industry, the government, and consumers should take President Clinton's food safety initiative as a cue and join in a collaborative process to resolve what we want our food safety system to do for us in the next century, who will be responsible for what, and how we are going to pay for it.

Michael R. Taylor is a visiting scholar at RFF's Center for Risk Management and is a partner in the law firm King & Spalding. Previously he was deputy commissioner for policy at FDA and the administrator of USDA's Food Safety and Inspection Service, where he played leadership roles in developing the HACCP reforms described in the article.