

Paul Krugman recently announced in a *New York Times* op-ed that he was doing something risky—he was eating a salad. He meant to shock. And he did. Americans are accustomed to assuming that their food is safe, but Paul Krugman was more right than he may have known. Eating food is a bit like walking a high wire. Risky, yes, but with skill and the right support system—like a good safety net—it can be done safely. But events of the past year have left many consumers wondering if there aren't some serious gaps in the system of private and public efforts that assure the safety of the U.S. food supply.

Consumers want to take food safety for granted and there are sound economic reasons for this. Managing most aspects of food safety is simply not to consumers' comparative advantage. There are significant economies of scale and gains from specialization in managing food safety in complex modern supply chains. And while they will always need to watch for spoilage and handle food properly, many modern food safety failures are difficult for consumers to observe. Spinach contaminated with *E. coli* O157:H7 looks pretty much like uncontaminated spinach. The food industry also prefers that food safety be taken for granted because jittery consumers can mean loss of business, or worse, collapse of a market segment. The U.S. beef industry suffered daily losses of \$27 million following the announcement in December 2004 that a single cow had tested positive for mad cow disease. And in general, government officials find life a bit more pleasant when they're not scrambling to fix food safety crises. Yes, everyone prefers that food safety stays below consumers' radar. But this past year it didn't.

Mending Our Food Safety Net

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Don't Eat Your Spinach

It all started with Popeye's favorite food. In September 2006, many U.S. consumers woke to news of the Centers for Disease Control and Prevention (CDC) announcing a multistate outbreak of foodborne illness associated with *E. coli* O157:H7 in ready-to-eat spinach. The U.S. Food and Drug Administration (FDA) called for bagged fresh spinach to be removed from grocery stores across the country and warned people not to eat uncooked fresh spinach. Many consumers were surprised to learn that even washing would not remove bacterial contamination that had found its way into the plant tissue.

E. coli O157:H7 is a particularly virulent strain of *E. coli* that produces a toxin that can cause kidney damage. By the time this outbreak ended, 199 people in 26 states were reported ill: of those, 102 were hospitalized, 31 developed kidney failure, and 3 died.

A very prompt and exhaustive investigation into the September spinach outbreak narrowed the contaminated product to prepackaged spinach produced on August 15, 2006, during a single shift, at one plant in California's Salinas Valley. But no one has yet been able to sort out exactly how the contamination occurred. In October, FDA announced the end of the outbreak, saying fresh spinach was "as safe as it was before the outbreak."

Then in early December, CDC announced a second outbreak of foodborne illness caused by *E. coli* O157:H7 in produce, followed by another smaller outbreak later in December. These outbreaks were ultimately traced to prepackaged lettuce from California's Central Valley. A total of 80 cases of illness were reported, with 61 people hospitalized and 9 diagnosed with kidney failure.

Peanut Butter and What?

In February 2007, newspapers across the country reported a new outbreak, *Salmonella* in another American staple, peanut butter. By early March, CDC reported that 425 people from 44 states had been sickened, 71 of whom were hospitalized. Government investigators traced the source of the illnesses to a peanut butter plant in Georgia. ConAgra estimated that its recall of Peter Pan and Great Value peanut butter cost \$50–\$60 million. Because peanut butter is cooked, outbreaks are rarely associated with the product. FDA investigators worked with plant managers to identify the source of the bacteria. Moisture from a leaking roof had activated dormant *Salmonella* in the Georgia plant and contaminated the product in the short time between its final heat treatment and jarring.

Now, the Focus Is on China

U.S. consumers had not even had a chance to stop talking about contaminated peanut butter, when, on March 16, several major U.S. pet food manufacturers announced a voluntary recall of 6 million packages of pet food. More than 14,000 dogs and cats had been sickened after eating their products. FDA forensic scientists determined that wheat gluten from China used to thicken "gravy" in the products was contaminated with melamine, a plasticizer with high nitrogen content. FDA later found that Chinese rice gluten ex-

ported to the United States for use in pet food also contained melamine. In late April, FDA and U.S. Department of Agriculture (USDA) announced that more than 6,000 hogs and as many as 3 million chickens may have been fed melamine-tainted feed; some had entered the human food supply. The agencies determined that the potential human exposure from this use of melamine was far too low to pose a threat to human health and allowed the meat on the market, even though melamine is not approved for human or animal consumption. In a story that could be right out of Sinclair Lewis' *The Jungle*, investigators learned that Chinese firms often add melamine to gluten as a cheap means of making the gluten appear higher in protein content than it really is.

Then on June 1, just as the pet food news was beginning to die down, FDA advised consumers to throw out toothpaste labeled as made in China due to concern that it might contain diethylene glycol, a sweet-tasting substance found in some antifreeze. Diethylene glycol can cause kidney and liver failure and is banned from use for human consumption in the United States. But Chinese counterfeiters have found it profitable to substitute it for more expensive glycerin, a closely related substance that is approved as a safe food additive. Last year, 365 reported and 100 confirmed deaths occurred in Panama when counterfeit glycerin from China that

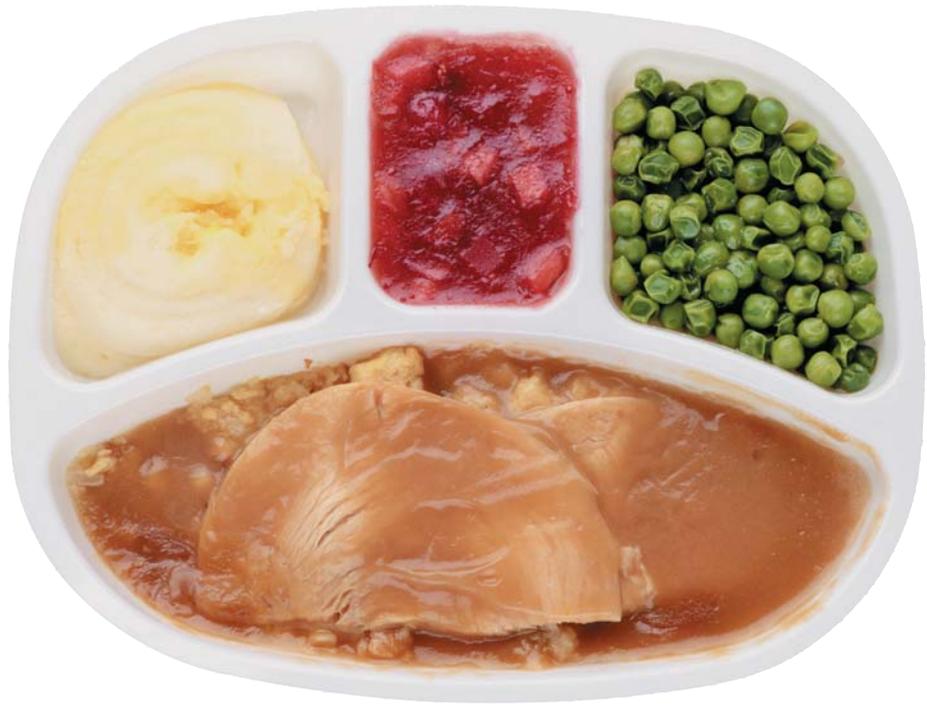
was mixed in cold medicine turned out to be diethylene glycol. Most of the dead were children.

On June 28, FDA announced that it would be detaining certain farm-raised Chinese fish and seafood at the border until the shipment was proven to be free of antibiotics not approved for aquaculture use in the United States. Over the prior six months, FDA had repeatedly found that farm-raised seafood from China contained carcinogenic antimicrobials. They also found residues of fluoroquinolones, a new class of antibiotics relied on as one of medicine's "last defenses" for serious human infections when other antibiotics fail. U.S. authorities ban use of fluoroquinolones in animal production because this practice has been shown to decrease its effectiveness in treating human disease.

Who Is Minding the Store?

The U.S. public is used to seeing a major food safety story every few years—Alar in the late 1980s, *E. coli* O157:H7 in ground beef in the 1990s, a "mad cow" or two that never entered the food supply in the past few years. Small foodborne illness outbreaks or recalls occur regularly and large ones every few years. But to have five major product-safety stories in 12 months—that's unusual. It may be simply that the press was sensitized by the spinach outbreak, so other food safety stories that usually would have been on page 18 ended up on page 1 of the morning paper. It may be that anxiety about changes in trade patterns, and China's dominance in manu-





facture of consumer goods has fed into the snowballing story on Chinese food safety.

But it may be that the American consumer is right to be asking, what's up with the food supply? And why is Paul Krugman, someone who writes on such weighty issues as labor and international finance, filling *New York Times* column space with commentary on food safety?

Congressional committees have held an almost continuous series of hearings since last fall, responding to each food safety crisis in turn. In early May, FDA appointed a food safety "czar" to direct development of an agencywide strategy for addressing food safety crises. On July 19, President Bush announced the creation of a Cabinet-level commission to address food safety issues with imports from China. So it does appear that there's more to recent events than simply newspaper sensationalism or consumer jitters.

Where Do We Go from Here?

First, we need a diagnosis. Paul Krugman blames his risky salad on Milton Friedman, the conservative University of Chicago economist who, in 1999, called for the elimination of both the food and the drug sides of FDA. Krugman also blames the dominance of an ideology, legitimated by Friedman's work, that sees little role for government. He would likely see the more concrete diagnoses and associated remedies being offered as symptomatic of this underlying malady.

But just as food may be inherently riskier than Krugman realizes, the political situation may also be worse. In federal food safety policy circles, Friedman's neo-conservative view

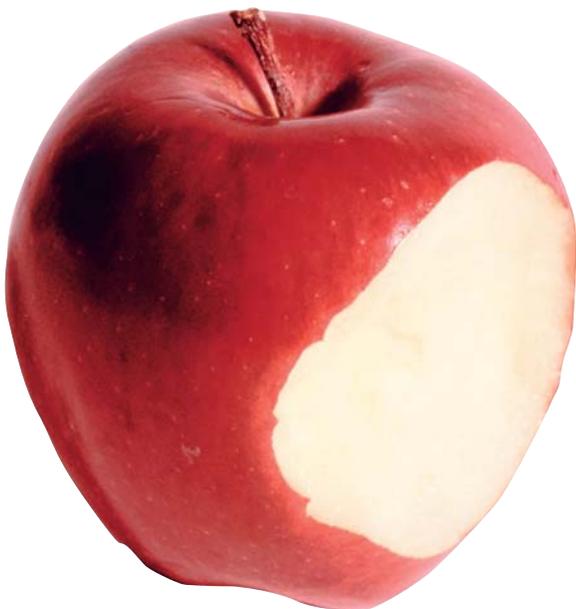
that government is neither needed nor useful is met with defensiveness from food safety professionals and advocates, including many major U.S. companies. A purposeful or unintentional policy of inattention and underfunding of food safety programs is met with a call for "more inspection, better labeling, and stronger standards."

It's as though two bulls had locked horns, each trying to push the other back over some unseen line. Little creativity is likely to emerge from such a shoving match. So the solutions that are being promoted—restoring FDA funding, hiring more import inspectors, consolidating food safety agencies to improve coordination, replacing visual inspection of chicken carcasses with testing for bacteria—are incremental when real creativity is exactly what is needed.

The underlying problem is that U.S. food law is antiquated, and we have not had the vision or political will to make reforms of the depth that are required to address the problems we face. Meat and poultry are regulated under acts that are essentially unchanged from their original adoption in 1906. FDA regulates most of the remainder of the food supply under a 1938 statute. In 1906, line inspection was at the forefront of industrial quality control. Federal meat and poultry inspection legislation still mandates visual inspection of each carcass as it comes down the line. Effectively, our food safety statutes still largely embody an early 20th-century perspective on quality management.

The news is not all bad. We have learned a tremendous amount about product quality and safety management since 1906. Statistical process controls were not even developed until the 1920s. They weren't widely applied in industry until Total Quality Management (TQM) guru W. Edwards Deming helped turn around postwar Japanese manufacturers' reputation for poor product quality. The 1970s and 1980s saw widespread adoption of TQM concepts in U.S. and European industry. These lessons and others from risk management in environmental quality management are available for gleaning.

Within the constraints of their antiquated statutory authority, federal agencies have worked to incorporate some of these lessons into food safety regulation. In the 1990s, both FDA and USDA adopted Hazard Analysis and Critical Control Point (HACCP) regulations. These regulations require food-processing plants to adopt more modern quality control systems and put government in the role of monitoring whether these systems are in place and functioning properly. Plant managers developing HACCP systems analyze where hazards are likely to enter their production plant, identify critical points in the system for controlling the hazard, and develop a system of monitoring those points and a plan for actions to take to bring the system back under control if needed.



HACCP provides an analogy for the ways drafters of a new food safety statute need to think about the role of government in food safety management. Of course, government's role is to manage safety in the entire food supply, not at one plant or even one firm. But the basic roles are broadly the same. Industry will likely always be one step ahead of government in recognizing the rapid changes in technology and supply chains we're experiencing. This calls for rethinking the relative roles of government and industry. The news here is good too because economists and business managers have developed much more sophisticated tools for understanding and tracking changes in industrial structure as well as new approaches to using incentives and quality management systems at an industry level. Many of these lessons are being applied by industry and government successfully in areas as diverse as supply-chain management and environmental regulation.

Information will be the foundation to using modern quality management to improve the food safety system. We need to commit to funding improved, regular, public data collection and analysis if we want a safer food supply. In designing HACCP regulations, USDA conducted nationwide baseline studies of the prevalence of microbial hazards throughout the meat supply. Only now, 20 years later, is USDA able to repeat that monitoring effort. FDA has no such studies. This kind of information needs to be collected more widely and more regularly. Similarly, better and more timely information is needed on human disease incidence—the most recent estimate of U.S. foodborne disease dates back to 1999. And regular, focused collection of economic data on changes in sourcing, costs, and trade flows will also be needed.

Conventional wisdom in food safety circles is that real policy change only comes in the face of real crisis. Because U.S. consumers take food safety for granted and because the system has worked reasonably well for a long period, it is difficult to get legislators to step up and expend political capital on significant reform. But significant reform is what is needed. Incremental solutions like restoring funding, appointing a food safety czar, consolidating agencies, and even eliminating the "silos" around regulation of different food products, will not do the job. Bringing food safety governance into the 21st century will require applying 20th-century quality management lessons to food safety administration. Government agencies have to take on the role of system safety manager rather than line inspector. ■

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