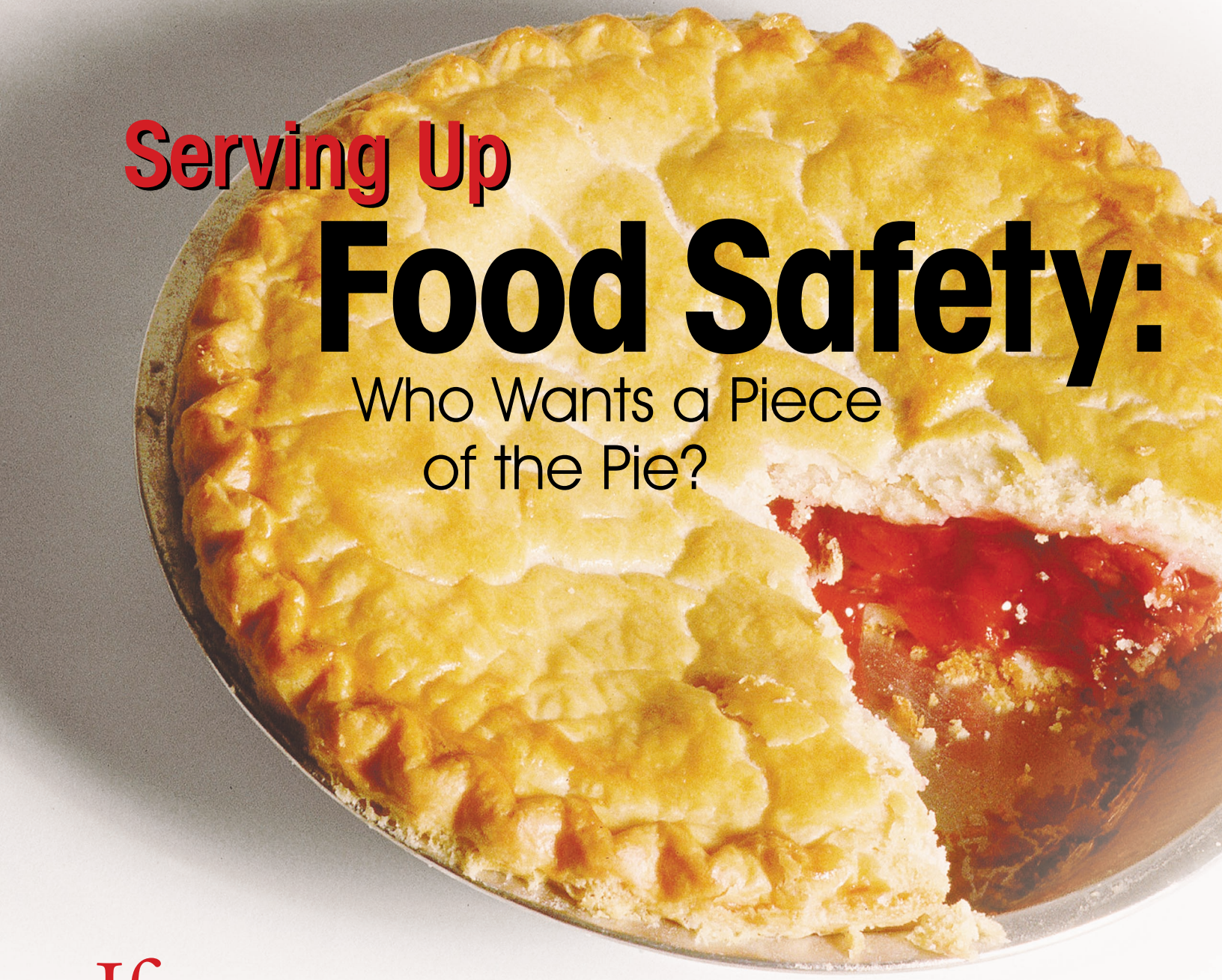

Serving Up Food Safety: Who Wants a Piece of the Pie?

If you're looking for a symbol of government waste and inefficiency, you don't have to look much farther than frozen pizza. In testimony before the Senate Committee on Agriculture, Nutrition, and Forestry titled *Food Safety: U.S. Needs a Single Agency to Administer a Unified, Risk-Based Inspection Program (GAO/T-RCED-99-256)*, issued in August 1999, the General Accounting Office (GAO) points to six federal agencies that carve out a piece of the regulatory pie over the safety of this culinary companion to the evening news. They include the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and four agencies of the U.S. Department of Agriculture (USDA): the Animal and Plant Health Inspection Service (APHIS), the Food Safety and Inspection Service (FSIS), the Agricultural Marketing Service, and the Grain Inspection, Packers and Stockyards Administration. Responsibility for pizza safety at retail is split between two agencies: cheese pizza goes to the FDA, while pepperoni and other meat pizzas fall to the FSIS.

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In all, 12 federal agencies—in addition to their state counterparts—contribute to the regulatory snarl that governs safety of the American food supply. With so much federal oversight one might expect U.S. foods to be virtually risk-free. But this is hardly the case: The most recent available figures, released in 1999 by the Centers for Disease Control and Prevention (CDC), show contaminated food is responsible for 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths in the United States each year.

Caroline Smith DeWaal, director of food safety at the Washington, D.C.–based nonprofit group Center for Science in the Public Interest and one of the current system's most outspoken critics, points to these statistics as evidence that foodborne illness poses a considerable public health burden. "The food safety infrastructure in this country isn't even equipped to handle common bacteria, let alone modern worries like mad cow disease or genetically modified foods," she says.

To provide one example of how a food commodity slips through cracks in the system, consider health inspection of the egg. The USDA has jurisdiction over plants that pasteurize eggs for processed foods. The FDA inspects shell eggs (as opposed to processed egg substitutes or egg-containing products), but because of limited resources the inspections are carried out rarely—usually in response to food poisoning outbreaks. APHIS inspects chickens, but its mandate is to ensure animal health, not egg safety. The bottom line: despite oversight from three federal agencies, most shell eggs sold at retail are never inspected. Meanwhile, the CDC reports that 300,000 people a year get sick from eating raw or undercooked eggs infected with the bacterium *Salmonella enteritidis*. Of these, up to 230 will die.

Michael Taylor, director of the Center for Risk Management at the Washington, D.C.–based nonprofit organization Resources for the Future and former administrator of the FSIS under the Clinton administration, says regulatory gaps in food safety highlight the need for centralized leadership. "Right now the responsibility is scattered throughout the government," he explains. "Consider *E. coli* O157:H7 [a lethal bacterium that kills 500 of the 20,000 people it infects annually]. No one is in charge of reducing the risk of foodborne illness from this bug. Instead we have multiple agencies, each with a piece of it. Fragmentation in the system is an obstacle to getting things done, and to me that's a serious problem."

The conclusion of the GAO—and also of the National Reseach Council in its August 1998 report *Ensuring Safe Food: From Production to Consumption*—is that creation of a single agency with centralized authority is the best solution to U.S. food safety problems. The concept has garnered congressional support, much of it spearheaded by Senator Dick Durbin (D–Illinois), who has repeatedly introduced legislation to create a single food safety agency, legislation that he intends to reintroduce in the 107th Congress this year. Other supporters include the American Society for Microbiology, the American Meat Institute, the Food Marketing Institute, and the American Public Health Association, among others.

The idea isn't without its skeptics, however. Kelly Johnston, executive vice president for government affairs and communications at the National Food Processors Association in Washington, D.C., describes allegations of excessive consumer risk from the current system as "outrageously false." Claiming the vast majority of foodborne illness originates from mishandling of foods in the home, he adds, "The current food safety system may not be perfect, but it works. Most Americans won't think twice about the safety of their meal. By consolidating food

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–Michael Taylor, Resources for the Future

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safety under a single, presumably politically appointed individual, we eliminate the current checks and balances of the current system and, more importantly, run the risk of politicizing the agency. Nothing will destroy public confidence in food safety faster than politicizing it."

In fact, recent data compiled from 1996 to 2000 by the CDC show significant drops in rates of foodborne illness from a number of pathogens, including *Campylobacter*, *Shigella*, and *Salmonella*. According to the CDC, these reductions—published in the 6 April 2001 issue of the *Morbidity and Mortality Weekly Report*—may be a consequence of the introduction of the FDA's Hazard Analysis and Critical Control Point (HACCP) system and increased attention to food safety. Nevertheless, the CDC cautions that the data have some important limitations, such as natural variation in local disease rates that will be better understood with more long-range surveillance.

Who Regulates What?

The majority of the responsibility for food safety in the United States is currently divided between three key agencies. The FSIS has jurisdiction over poultry, processed egg products, fish, and meat. Under statutory mandate, the FSIS regulates imported foods in these categories by ensuring that other countries have safety systems comparable to those in the United States and then reinspecting imports at the border. Under the authority of the Food, Drug, and Cosmetic Act, the FDA is given jurisdiction over all the imported and domestic foods that aren't covered by the FSIS, as well as responsibility for ensuring that the drugs, feeds, and veterinary devices used in livestock don't render meats unsuitable for human consumption. As an additional responsibility, the FDA also sets allowable limits for environmental pollutants, additives, preservatives, and artificial colorings in food. The EPA sets allowable limits (or tolerances) for agricultural chemicals and also regulates drinking water contaminants, which ultimately translates to safety standards for bottled water. Finally, nine additional agencies have varying responsibilities including, among other things, outbreak response and surveillance (the CDC), overall grading and quality assessment (the Agricultural Marketing Service), coordination of food safety research (the Agricultural Research Service), and coordination of voluntary seafood inspection programs (the National Marine Fisheries Service).

Among the most fundamental problems with the current system, experts say, is inequitable distribution of resources and responsibility between the FSIS and the FDA. In 1906, the Federal Meat Inspection Act directed the FSIS to visually inspect every single carcass on a production line. Today, at least 7,400 federal inspectors are needed to comply with this statutory mandate. The task of inspecting carcasses and meat plants is so great that in 1999 it consumed $712 million—70% of the federal monies allocated to the two agencies for food safety programs. In the same year, the FDA did its best to monitor the rest of the food supply with the remaining $288 million. In short, the FSIS monitors 20% of the food supply with 70% of the budget, while the FDA monitors 80% of the food supply with only 30% of the budget. Ironically, many experts say the carcass-by-carcass inspection policy at the FSIS is outdated and ineffective for threats such as *E. coli* O157:H7. "Federal inspectors take an average of two seconds to inspect a chicken carcass," says Taylor. "That may be enough to detect grossly visible contamination, for example fecal matter, but not dangerous bacteria."

Meanwhile, the underfunded FDA appears overwhelmed by the magnitude of its responsibility. With its limited resources, it can only inspect the 57,000 food establishments under its jurisdiction an average of once every five years. Imported foods cross U.S. borders with almost no visual inspection whatsoever. According to the GAO, only 1% of food imports are visually inspected by the FDA during random port investigations, while just 0.3% are tested for the presence of bacterial and chemical contaminants.

Lack of regulatory oversight at the FDA is raising increasing concerns, most recently for contaminated seafood. In January 2001, the GAO released a scathing report titled *Food Safety: Federal Oversight of Seafood Does Not Sufficiently Protect Consumers*. During its investigation, the GAO found that only 44% of seafood plants were compliant with the HACCP system for seafood, which uses scientifically based methods to prevent contamination during processing [see "HACCP Hassles," p. A307 this issue]. The GAO also found that up to half of all seafood plants were in violation of their HACCP programs but that the FDA had done little to respond—in many cases not even issuing warning letters to violators. Finally, the GAO concluded that the FDA lacks a baseline of "objective, quantifiable data" to assess how effectively its seafood HACCP system is protecting the public.

Sharon Lindan Mayl, a senior policy advisor in the Office of Policy, Planning, and Legislation at the FDA, says the agency is doing the best it can to monitor food safety in the face of its budgetary constraints. "We're making progress, but there are areas that need better funding," she says. "We need more inspectors and more money for inspection. We also need more surveillance funding and better tools for education and training." Mayl also points out that the FDA's hands are often tied by statutes that limit its regulatory authority. "We can't recall products or impose monetary penalties, and we also don't have the authority to require registration of food establishments," she says. "Joe Smith can open a cookie factory, and until we see his ad in the Yellow Pages we don't have any idea that he's there."

Obstacles to Institutional Change

The FSIS has attempted to deploy its personnel more efficiently, for example by relying on plant employees to sort clearly damaged products before they reach federal inspectors. Taylor suggests this is a way for the agency to save on resources without compromising its statutory inspection mandate. Assuming the total federal budget for food safety remains fixed, such a change could free up money for more productive food safety inspection tasks throughout the meat production systems to address risks wherever they arise, he says. However, he adds, no such change is really possible without regulatory change first.

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–Caroline Smith DeWaal, Center for Science in the Public Interest

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–Sharon Lindan Mayl, Food and Drug Administration

But so far, every attempt by the FSIS to modify its inspection program has been blocked by union intervention and the courts. In 1997 the FSIS suggested that plant employees—rather than federal inspectors—could assume responsibility for carcass-by-carcass inspection with FSIS oversight. In response, the American Federation of Government Employees (representing the meat inspectors' union) sued the agency, charging the FSIS with "trying to weaken the entire meat and poultry inspection process . . . and abdicate its responsibility to American consumers." At press time, the lawsuit was ongoing in the U.S. District Court for the District of Columbia.

The fact that the FSIS can't even overcome union opposition to reform of its inspection program merely hints at the challenges facing the creation of a single food agency. Not surprisingly, most stakeholders view this revolutionary change as unlikely, at least in the near term. The President's Council on Food Safety, created under the Clinton administration to respond to the 1998 National Research Council food safety report, released a food safety strategic plan in January 2001 that skirted the issue altogether. Instead, that plan favors legislative proposals to strengthen existing statutes, improved agency coordination, and legislation that would emphasize risk-based allocation of resources and science-based regulation, enforcement, and education.

Taylor, who supports the single food agency concept, says proposals like these are an important step in the right direction. "At the most fundamental level we need to create a risk-based system and change statutory mandates for inspection," he says. Mayl agrees, but adds that a single food safety agency won't necessarily solve the problems faced by federal regulators. "It's more important to deal with resource disparities and outmoded laws," she says. "And there are costs to creating a single agency that haven't been adequately assessed. It would be hugely disruptive to the FDA—what would happen to nutrition labeling? What about the EPA? Would a single food agency take responsibility for pesticides? I don't think the EPA would go along with that."

Just how the Bush administration will handle the issue remains to be seen. At press time, many key positions within the FDA, the USDA, the EPA, and other relevant agencies had still not been filled, and response to the food safety strategic plan (which was addressed to President Clinton) had not been adequately gauged. But most stakeholders acknowledge the need for strong leadership to carry the process forward. Says Taylor, "If any kind of restructuring or statutory reform is going to get off the ground, it's going to require a strong hand in the White House. It's not fair to expect the agencies to initiate changes that result in fundamental changes to their own turf."

Charles W. Schmidt