

## **Reforming Food Safety: A Model for the Future**

Michael R. Taylor

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Resources for the Future  
1616 P Street, NW  
Washington, D.C. 20036  
Telephone: 202-328-5000  
Fax: 202-939-3460  
Internet: <http://www.rff.org>

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# Reforming Food Safety: A Model for the Future

Michael R. Taylor \*

## Introduction

Debate about fundamental reform of the nation's food safety system is often oversimplified and reduced to a debate about whether we should unify the government's food safety agencies and form a single food regulatory agency. I am one who believes that the long-term success of the system requires unification but not for abstract "good government" or organizational neatness reasons.

Organizations exist to achieve objectives, and organizational structure, whether in government or elsewhere, should follow function. What do we want the federal government's food safety program to achieve? What are the attributes of a food safety system that can succeed in achieving it? What needs to be done legislatively and organizationally to have such a system? These are the questions that I will answer in this paper. By addressing these questions, we can build a model for the future of the food safety system and understand the role and value of organizational change.

## The Objectives: Why the Food Safety System Matters

The functional attributes and organizational structure of the food safety system are important because the system's objectives are important. Three objectives stand out for me – three things the system must do to be successful.

The most fundamental is *reducing foodborne disease* in the United States. Foodborne disease is a significant and largely preventable public health problem. The Centers for Disease Control and Prevention (CDC) estimate that known microbial pathogens alone cause 5,000

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\* Mr. Taylor is a Senior Fellow at Resources for the Future, an independent, nonprofit research organization in Washington, D.C. He has worked on food safety in the federal government as administrator of the Food Safety and Inspection Service at the U.S. Department of Agriculture (1994-1996) and as deputy commissioner for Policy at the U.S. Food and Drug Administration (1991-1994). Comments on this paper are welcomed via e-mail to [taylor@rff.org](mailto:taylor@rff.org).

deaths, 325,000 hospitalizations, and 79 million illnesses annually.<sup>2</sup> Virtually all of these illnesses are preventable if the right measures are taken at each appropriate step across the farm-to-table spectrum to prevent, minimize, and remove harmful contamination. No one intervention at any one point on the spectrum will by itself be adequate, but the cumulative and collaborative efforts of food producers, processors, distributors, retailers, and consumers can virtually eliminate foodborne disease. It's important to recognize that the ultimate capacity to make food safe rests in these private hands, but the government has a responsibility—and it should be the government's first objective—to reduce foodborne disease as much as is reasonably possible through research, regulation, and education.

The second important objective is *maintaining public confidence* in food safety and the food supply, which flows directly from success in reducing the risk of illness. Public confidence in food safety is a public good. It supports consumers in choosing diverse and healthy diets, unconstrained by food safety concerns. It creates a receptive environment for new food technologies. And it is what people want. People want the peace of mind that comes from knowing their food is safe, and peace of mind comes from knowing that government and those involved commercially in the food system have done everything it is reasonably possible to do to make the food safe.

Finally, it is important that the United States be capable of exerting *international leadership on food safety*. This is important for public health reasons: much of the U.S. food supply is imported from countries whose standards of food hygiene are not as high as ours. It is also important for economic reasons: important segments of the U.S. agricultural and food industry increasingly rely on exports for their economic sustainability and growth. We operate within a global food system in which World Trade Organization (WTO) agreements have an important impact on the standards that govern both food imports and exports. To achieve its legitimate public health and economic objectives within this system, the United States must be an international food safety leader.

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<sup>2</sup> Mead et al., "Food-related Illness and Death in the United States," 5 *Emerging Infectious Disease* 606-625 (1999).

## Attributes Required to Achieve the Food Safety Objectives

Four key attributes are required for the food safety system to be as successful as possible in reducing foodborne disease, maintaining public confidence, and exerting international leadership: prevention, accountability, integration, and risk-based resource allocation.

### *Prevention*

Prevention is a core value in public health and, logically, the only way to reduce the burden of foodborne disease. Put another way, achieving food safety is achieving the prevention of foodborne disease. The principle of prevention should thus be built into the food safety system.

Hazard Analysis and Critical Control Points (HACCP) provides an accepted framework for prevention in the food safety context. It was originally developed for NASA's space program and implemented by the food industry as a process control system to achieve desired food safety outcomes. In the 1990s, it was adopted as a regulatory tool by the Food and Drug Administration (FDA) (for seafood processing)<sup>3</sup> and the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) (for meat and poultry slaughter and processing).<sup>4</sup>

HACCP calls for the food producer or processor to take responsibility for identifying potential hazards in its system, designing and implementing controls to prevent or minimize the hazards, and validating and continuously monitoring the effectiveness of the controls. Implemented properly, HACCP can be an effective means of building prevention into the food safety system. The preventive principles of HACCP have applications across the farm-to-table food safety spectrum and are being applied to varying degrees on a voluntary basis. Their application as a regulatory tool is limited, however, to seafood, meat, poultry, and juice, where it has been adopted through case-by-case rulemaking processes in reliance on broad statutory definitions of "adulteration."

Current U.S. food safety laws provide no mandate to build a preventive, farm-to-table food safety system. The Federal Food, Drug, and Cosmetic Act of 1938, which FDA administers, is by design a largely reactive enforcement statute. It empowers FDA to remove

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<sup>3</sup> 60 Fed. Reg. 65096 (December 18, 1995).

<sup>4</sup> 61 Fed. Reg. 38806 (July 25, 1996).

harmful or potentially harmful food from the market through court enforcement action but does not direct or explicitly empower FDA to mount a comprehensive strategy to prevent foodborne disease. The meat and poultry inspection laws, whose conceptual roots are more than a century old, mandate carcass-by-carcass and daily inspection by FSIS in slaughter and processing plants. In-plant inspection is important, but these laws force FSIS to focus virtually all of its resources on in-plant inspection and largely ignore the many points on the farm-to-table spectrum where risks may arise and be prevented.

### ***Accountability***

Accountability is a core function of all regulatory programs. In consumer protection regulation, the standard rationale for regulation is that the marketplace fails to provide the degree of the public good (in this case, food safety) that people want and are willing to pay for and that the good can be provided through the establishment of regulatory standards to which companies can be held accountable. Regulatory accountability substitutes for accountability the market does not adequately provide.

In the case of food safety, people seek assurance that the producers, processors, and purveyors of food are doing everything reasonably possible to make the food safe and thereby protect consumers from illness. The government responds by setting standards on behalf of the public and holding companies accountable for meeting the standards.

This principle of accountability is well-established and works well in the case of chemical hazards. Congress has established pre-market approval systems for most chemicals added intentionally to food, such as food additives, animal drug residues, and pesticides. The burden rests on the sponsor of the chemical to conduct safety testing and convince FDA or, in the case of pesticides, the Environmental Protection Agency (EPA) that the chemical is safe to consume within specified quantitative limits or tolerances. FDA and FSIS then use their enforcement tools to hold food producers and marketers accountable for ensuring that the tolerances are not exceeded. The pre-market approval requirement and the tolerances constitute food safety performance standards for the chemicals they cover.

The principle of accountability is less well-established for microbial hazards, which account for virtually all known cases of foodborne disease. In contrast to chemicals, there are no

provisions in current law that provide explicitly for microbial performance standards. When FSIS mandated HACCP for all meat and poultry plants in 1996, it used its general adulteration and inspection authority to establish performance standards for *Salmonella*.<sup>5</sup> The standards were intended to induce reductions in the incidence of *Salmonella* contamination in slaughter and raw ground meat processing plants. The public health judgment underlying the FSIS *Salmonella* standards was that a reduction in the incidence of pathogenic microbial contamination at this first point of entry into food would, in conjunction with HACCP and other elements of a broader pathogen reduction strategy, reduce the likelihood that consumers would be exposed to harmful bacteria through undercooking or cross-contamination in the kitchen, thus helping prevent foodborne disease. The regulatory concept was that, without the performance standards, there would be no accountability through the regulatory process for reducing pathogens.

The performance standards have been effective in inducing pathogen reduction, with FSIS reporting that the incidence of *Salmonella* contamination has been cut substantially since the standards were adopted.<sup>6</sup> Although it is too soon to draw definitive conclusions, CDC has reported declines in foodborne disease, which it attributes in part to the FSIS HACCP/pathogen reduction rules.<sup>7</sup> Nevertheless, the standards have been opposed by some in the meat industry. A ground beef processor that FSIS found in violation of the *Salmonella* standard sued FSIS, with the support of the National Meat Association, and won a ruling that the agency lacked legal authority under the current statutes to establish and enforce the standard as it applied to ground beef.<sup>8</sup> It is unclear whether the court's reasoning would extend to the *Salmonella* standards as they apply to slaughter plants. It is clear, however, that without the standards there is no direct accountability through the regulatory system to reduce *Salmonella* contamination.

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<sup>5</sup> The objectives and concepts underlying the standards are explained in the preamble to HACCP/Pathogen Reduction Rule. 61 Fed. Reg. 38806 et seq.

<sup>6</sup> For example, in the large plants that slaughter nearly all of the chickens Americans consume, the prevalence of *Salmonella*-contaminate carcasses has declined nearly 50%, from 20% prior to enactment of HACCP and the *Salmonella* standards to 10.3% in the most recent report. FSIS Backgrounder, Progress Report on *Salmonella* Testing of Raw Meat and Poultry Products (March 2000) (<http://www.fsis.usda.gov/OA/background/salmtest5.htm>).

<sup>7</sup> Stephen M. Ostroff, M.D., associate director for Epidemiologic Science, National Center for Infectious Diseases, CDC, statement before the Agriculture, Nutrition and Forestry Committee, United States Senate, Sept. 20, 2000 (available on the internet at <http://www.cdc.gov/washington/legislative/09202000.htm>).

<sup>8</sup> *Supreme Beef Processors, Inc. v. USDA* (5<sup>th</sup> Cir. 2001).

## Integration

In 1998, a committee of the National Academy of Sciences (NAS) issued a report documenting the multiplicity of differing food safety statutes and the fact that at least 12 federal agencies play important roles in food safety regulation and research.<sup>9</sup> The committee called for modernization and unification of the food safety laws and the lodging of responsibility for leading and managing the federal food safety program in a single accountable official.

The NAS committee's analysis and recommendations reflect the fact that reducing the burden of foodborne disease requires an integrated, holistic approach across the farm-to-table spectrum.<sup>10</sup> The highly virulent pathogen *E. coli* 0157:H7 originates in the gut of cattle but, with manure as its vehicle, spreads throughout the food supply, contaminating meat, fresh produce, juice, and other foods. Effective, preventive control of this problem will require research and strategically chosen regulatory and educational interventions at multiple points in the chain of food production, distribution, and consumption. Yet neither FDA nor FSIS has the statutory authority or practical mandate to forge an integrated strategy to reduce the burden of foodborne disease from this pathogen—a strategy that puts the research, regulatory, and educational tools of the government to work in a coherent farm-to-table effort to minimize the risk of illness from *E. coli* 0157:H7.

The same can be said of the other major microbial pathogens, whose presence and behavior in the food supply rarely respect the statutory and organizational boundaries between FDA and FSIS. Under President Clinton's Food Safety Initiative and with the current concern about food bioterrorism, the agencies are working more closely together than before, but no one person is in charge of and accountable for carrying out comprehensive, preventive strategies for reducing foodborne disease. The result is that less gets done to reduce disease than optimally could get done.

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<sup>9</sup> National Institute of Medicine/National Research Council, *Ensuring Safe Food From Production to Consumption* (National Academy Press, Washington, D.C., 1998).

<sup>10</sup> A similar conclusion was reached and well documented in a recent report issued by an expert panel convened by the Institute of Food Technologists (IFT). IFT Expert Panel, *Emerging Microbiological Food Safety Issues – Implications for Control in the 21<sup>st</sup> Century* (2002) ([www.ift.org](http://www.ift.org)).

## Risk-Based Resource Allocation

If the primary objective of the food safety system is to reduce the burden of disease, success requires risk-based resource allocation. The food safety system must make the best possible use of its resources to reduce the disease burden. This means focusing government effort on the greatest risks and the greatest opportunities to reduce risk, wherever they may arise. It means adopting the interventions—presumably some combination of research, regulation, and education—that will yield the greatest reduction in illness.<sup>11</sup>

The current system does not work this way, due in part to the lack of accepted decision tools for prioritizing food safety risks and opportunities for risk reduction.<sup>12</sup> Risk-based resource allocation also is precluded by the way the carcass-by-carcass and daily inspection mandates of the meat and poultry laws drive resource allocation. These mandates result in FSIS employing about 7,600 inspectors and consuming about \$800 million to regulate meat, poultry, and processed eggs products, while FDA has a total field staff of 1,700 for all of its food programs, including inspectors, laboratory technicians, and administrative staff.<sup>13</sup> This allocation would be defensible if the risk were heavily concentrated in the products FSIS regulates, but CDC says that, of the cases of illness reported to it for which a food source was known, about 85% were associated with FDA-regulated food products.<sup>14</sup>

Poultry slaughter inspection is a glaring example of how food safety resources are misallocated and cost effectiveness is lost. More than 15 years ago, the NAS concluded that the statutorily-mandated poultry slaughter inspection, which involves about two seconds of visual inspection for every one of the 7 billion chickens produced annually in this country, makes little contribution to food safety because it does not address *Salmonella* and other bacteria that cause disease.<sup>15</sup> It is largely a government-financed, quality-control sorting service for the industry in

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<sup>11</sup> See the IFT Report cited in n. 9, above, which documents scientifically why this is true.

<sup>12</sup> Taylor and Hoffmann, “Redesigning Food Safety,” *24 Issues in Science and Technology* 26 (Summer 2001).

<sup>13</sup> General Accounting Office (GAO), *Food Safety—Overview of Federal and State Expenditures*, (GAO-01-177, February 2001).

<sup>14</sup> *Ibid.* at 5. The multi-year database of foodborne disease outbreaks compiled by the Center for Science in the Public Interest suggests that 80% of outbreaks (instances of multiple cases of disease associated with a common cause) may be linked to FDA-regulated foods. CSPI, *Outbreak Alert! Closing the Gaps in Our Federal Food Safety Net* (this document is available on the CSPI website at [http://www.cspinet.org/reports/outbreak\\_alert/index.htm](http://www.cspinet.org/reports/outbreak_alert/index.htm)).

<sup>15</sup> National Research Council, Meat and Poultry Inspection, *The Scientific Basis of the Nation's Program* (National Academy Press, Washington, D.C., 1985).

which FSIS inspectors remove visibly unwholesome, but not necessarily unsafe, carcasses from the production line. Yet FSIS must spend more than \$200 million dollars and use 3,000 government inspectors to do this work.<sup>16</sup> Without question, these resources could be used better elsewhere in the regulatory system to reduce foodborne disease.

FDA has taken a step toward risk-based resource allocation with its annual adoption of “CFSAN Program Priorities,” an initiative of CFSAN Director Joseph Levitt that outlines how CFSAN plans to target its efforts in the coming year.<sup>17</sup> This approach should be applied across the entire food safety system for strategic as well as annual planning, with increasingly rigorous assessment and ranking of system-wide risks and the flexibility to deploy resources accordingly.

## Legislative Implications

### *The Need for Legislation*

The current food safety laws undermine all four attributes of a successful food safety system.

- There is no express statutory mandate to systematically build prevention into the system, from farm-to-table, such as by universal adoption of HACCP or other appropriate preventive process control approaches for food production and processing.
- Accountability for reducing microbial pathogens through adoption of performance standards or other measures is not expressly provided for under current law and is in legal jeopardy with the *Supreme Beef* case.
- Integration is blocked by the patchwork of food safety laws that govern the food safety system and the resulting, fragmented organizational structure, which divides responsibility and accountability for the success of the government’s program.

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<sup>16</sup> Personal communication with Andrew Moss, Office of the Under Secretary for Food Safety, U.S. Department of Agriculture.

<sup>17</sup> See CFSAN/FDA, “FY 2002 CFSAN Program Priorities” (January 29, 2002) (<http://www.cfsan.fda.gov/~dms/cfsa102b.html>).

- Risk-based resource allocation is impossible when outdated laws mandate misallocation of food safety resources, and no one is in charge of resource allocation across the entire system.

These features of the current system are a threat to its success. It is difficult to argue that the system is doing everything it reasonably can to prevent foodborne disease—its primary objective—when it wastes significant resources on antiquated inspection activities and perpetuates misalignment of resources in relation to risk.

Public confidence is a real and valuable asset of the U.S. food safety system, especially compared to the lack of public confidence in European food safety institutions. Public confidence is fragile, however, in an age of instant communication and close scrutiny of government programs, especially ones that are intended to protect public safety. European food safety agencies lost credibility and public confidence almost overnight following the disclosures of scientific and institutional failures to protect the public adequately or meet its expectations in the cases of BSE, *E. coli*, and biotech foods. With luck, the United States will not encounter crises of confidence in food safety on that order, but the system is vulnerable today to the reality that it is not doing everything it reasonably could to prevent illness.

America's international leadership on food safety also should not be taken for granted. It is jeopardized by FDA's lack of resources and clear statutory authority to educate and inspect overseas producers and to require them to produce in accordance with U.S. standards. It is also jeopardized by the inability of the United States to bring to international harmonization discussions a single voice and consistent approaches to food safety within our own borders.

For the food system to achieve its objectives in the long term, comprehensive legislative reform is required.

### ***Key Elements of Legislation***

Congress should replace the existing food safety laws with a unified law covering the entire food supply. Rather than just providing legal and regulatory tools, as under current law, the new law should spell out the objectives of the government's food safety system and provide a clear mandate and policy direction for the system. The key elements of the law should include:

- *A mandate and authority to pursue systematic prevention of foodborne disease from the farm to the table through HACCP-based process control or other preventive strategies.* The law should make HACCP mandatory for all processing operations, unless

exempted, and would direct that preventive steps be taken throughout the system where appropriate and effective to help reduce foodborne disease. This basic construct addresses the fact that foodborne disease is commonly caused by multiple factors arising at dispersed points along the farm-to-table spectrum and involving many parties.

- *A mandate and authority to establish performance standards or other objective criteria as tools of accountability for achieving acceptable food safety results.* Performance standards or other tools of accountability are essential to make HACCP or other preventive strategies effective in improving food safety and preventing disease.
- *A requirement for a national food safety plan that looks at the food supply as a whole, sets priorities, and adopts holistic strategies to prevent disease.* The plan would be revised and reissued every year with data on accomplishments, progress, and problems. The plan would be a vehicle for ensuring the food safety system operates in a focused, integrated way and making the system accountable for achieving its objectives.
- *A mandate to build and finance food safety partnerships with state and local authorities based on nationally uniform food safety standards and clearly defined roles for the states as part of a national food safety system.* The states play a critical food safety role, especially at the retail level, but the federal-state relationship is not well defined or financed. The goal should be to enlist the states in partnerships that help ensure the country's aggregate food safety resources are used optimally to prevent disease.
- *A mandate and authority for risk-based resource allocation to maximize disease reduction.* The law should direct that the government's resources for food safety research, regulation, and education be deployed in the manner most likely to maximize reduction in foodborne disease. This would require repealing the current FSIS inspection mandate and substituting a modernized mandate for the entire farm-to-table food safety system that would ensure an adequate resource base for inspection is preserved, but require that the inspection resource be distributed and used in the manner most likely to contribute to disease reduction.
- *Modern enforcement tools, including enhanced authority to oversee imported food.* The enforcement tools and import authorities available to FDA and FSIS are not consistent and, because the statutes are old, they lack some of the basic tools required to deal with today's problems, such as detention and recall authority, records access, establishment registration, and civil penalty authority. FDA also needs new authority

to inspect overseas food producers and hold imports to the same standards as domestically produced food.

- *A mandate to devise and implement food safety education programs as an element of the disease prevention strategy.* Research is required to determine what works to change individual behavior, but education for commercial food handlers and consumers should be an integral part of the food safety system.
- *A mandate to represent the U.S. food safety system and exert leadership in the international arena.* Despite the public health and economic importance of trade and other international issues, the food safety agencies have no statutory mandate or adequate budget for participation in international activities, such as Codex and the WTO. This leads to uncertainty about who represents U.S. food safety interests internationally and, by default, a prominent role for trade agencies, such as the Foreign Agricultural Service and the Office of the U.S. Trade Representative, which lack a food safety mission, expertise, and credibility.
- *A research mandate.* To carry out these new mandates, the food safety system will require research and data collection on many subjects, including the incidence and causes of foodborne disease, tools for risk ranking and resource allocation, new food safety technologies and prevention strategies, and consumer behavior.

## Organizational Implications

If organizational form should follow function, legislative modernization as outlined above would require organizational change. Today's fragmented structure would not be capable of implementing such a law. We would need instead a single food safety agency to devise and implement an integrated, national food safety plan, set priorities, allocate resources, and be held accountable for the results. These leadership and management functions cannot be done by committee or through coordination. They require an organizational and leadership structure that is capable of accomplishing the newly defined food safety mission.

The single food safety agency should include FSIS; the food regulatory functions of FDA (including the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine, and the food portion of FDA's field resource); and the food safety aspects of EPA's pesticide program. It would not be necessary to consolidate all the food safety research activities of the federal government, since most of them have specialized functions unrelated to the broad public health mission of the food safety agency, but the agency should have its own research

mandate and budget. The CDC's foodborne disease surveillance program could also remain separate as an independent source of information on emerging problems and on whether the food safety agency is achieving its disease prevention objectives. The unified agency should take on, however, all of the food regulatory functions now at FSIS and FDA, including the food labeling and nutrition functions.

The placement of the single agency within the federal government is an important and controversial issue. External food system stakeholders (industry and consumer alike) have strong and diverse views. Within the government, neither USDA nor HHS would welcome "losing" its food safety function to the other, which is one reason they have traditionally resisted organizational change. This stalemate could be resolved by establishing the new agency outside any existing department, like EPA. This would be justified by the importance of the food safety function of the government and the benefit of it being insulated from the competing priorities and political interests of the existing departments, but there may be reluctance to create an entirely new agency. The alternative would be to consolidate the food safety function within one of the existing departments.

HHS and USDA each have their strengths and weaknesses as homes for the food safety agency. Food safety regulation should be seen as a public health function of the government and thus its natural home is in the government's health department, HHS. Historically, however, food regulation has been a low profile, low priority function within HHS and FDA. Within HHS, health care, health financing, and health research are high profile and high priority with respect to both policy and budget issues. FDA regulatory programs have taken a back seat. And within FDA, the therapeutic side of the agency (drugs, vaccines, blood, and medical devices) receives the lion's share of senior management attention. Most FDA commissioners are physicians or other health professionals who generally have little background or experience in food safety regulation.

USDA's strength is that food and the success of the food system are at the heart of its mission. Thus, food safety is high profile and high priority at USDA, which is reflected in the resources available to FSIS and the attention food safety receives from the department's senior management, including the secretary. USDA's weakness as a home for food safety is that the department's primary role is to promote and protect the interests of U.S. agriculture. Powerful political constituencies regularly hold the department accountable for this, which creates a fundamental conflict of interest. In 1996, Congress attempted to separate USDA's food safety function from its agricultural marketing and promotion functions by establishing the position of Under Secretary for Food Safety. Because all these functions still report to the Secretary of

Agriculture, who must balance her food safety responsibilities with her economic and promotional functions, the conflict remains.

If it is not possible to create an agency outside the existing departments, the better option is to place a consolidated food safety agency at HHS. To ensure food safety receives due attention, the head of the agency should be appointed by and report directly to the secretary. If there were concerns about efficiency or other good reasons to keep FDA intact, FDA could be divided into two distinctly organized and managed programs, one for food and one for therapeutic products, with a commissioner for each.

### **Conclusion: A Political Reality Check**

The politics of change are always daunting. The politics of major organizational change are nearly impossible because of all the interests—in the executive branch, in Congress, and among external interest groups—that are vested in the status quo. Major statutory and organizational changes normally come only in response to extraordinary leadership from above (such as from the president or a very influential member of Congress) or in response to a real or perceived crisis. Food safety will likely be no different, despite the repeated calls for statutory and organizational change by NAS committees, the General Accounting Office, editorial writers, consumer organizations, and some industry groups.

The ideas in this paper are thus offered with a healthy sense of reality about the near-term prospects for change. Change is unlikely, absent some catalyzing event. This is okay; fundamental change in the mandate and structure of our food safety system will and should take time. We must be mindful of and carefully manage the disruptions and other costs associated with any major transition. But a catalyst for change will come. We can hope it will not be a public health crisis or a crisis of public confidence in food safety, such as that which sparked organizational change in the United Kingdom and the European Union. Whatever it is that sparks change, it will be important to have thought about the subject in advance and be ready to make changes that will prepare the system for success in this new century.