RESOURCES
FOR THE FUTURE

FAX

Date:

To: John Morrall — **Fax:** 395-6974

Voice:

From: Mike Taylor — **Fax:** (202)

Voice: **(202)** 328-5066

Number of **pages,** including **this cover** sheet: 13

Note: Comments on Draft Report to Congress on Costs + Benefits of Federal Regulation

---

If you do **not** receive **all** pages noted above, **please** contact sender.

1616 P Street NW • Washington, DC 20036 • Telephone 202-328-5000 • Fax **202-939-3460**

RESOURCES
FOR THE FUTURE

50 Years of Path-Breaking Research

May 28, 2002

Mr. John Morrall
Office of Information and Regulatory Affairs
Office of Management and Budget
NEOB, Room 10235
725 17th Street, NW,
Washington, D.C. 20503

SENT VIA FAX: 202-395-6974

Re: Draft Report to Congress on the Costs and Benefits of Federal Regularions

Dear Mr. Morrall:

Please accept this lener and the attached articles as my comment on the draft report to Congress.

I am not addressing any of the specific regulations or guidance documents, but rather the need for better allocation of regulatory resources to reduce the risk of foodborne disease. The federal food safety system is famously fragmented and, under an antiquated statutory mandate for meat and poultry inspection, allocates the majority of its food safety staff and dollars to prescribed inspection activities that bear little relation to risk and that are relatively unproductive with respect to reducing foodborne disease. The National Academy of Sciences documented this phenomenon in irs 1998 report Ensuring Safe Food From Production to Consumption, as has the General Accounring Office in numerous reports over the last several years.

The first article suggests how risk analysis could be used to improve the allocation of resources (Taylor and Hoffmann, "Redesigning Food Safety," *Issues in Science and Technology,* Vol. XVII, Number 4,2001). The second lays out a legislative and organizational agenda for reform of the federal food safety system (Taylor, "Reforming Food Safety: A Model for the Future," *Food Technology,* Vol. 56, No. 5, May 2002).

I think it is important as OIRA considers how to improve regulation that it focus not only on specific regulations but on the design of the system as a whole, with emphasis on how the system allocates its resources to reduce risk. In the case of food safety, the United States continues to experience a large burden of preventable disease. The federal government should use risk analysis to support priority setting and better resource allocation to reduce the burden of disease. It should not reduce the resources available for food safety but rather make better use of them.

I am submitting this comment on my own behalf, not on behalf of Resources for the Future. RFF is an independent, non-profit research organization whose researchers seek to improve public policy rhrough research and analysis. RFF as an organizarion does not take positions on policy issues.

Sincerely yours,

Michael R. Taylor

Cc: Dr. John Graham

ISSUES IN SCIENCE AND TECHNOLOGY
National Academy of Sciences
National Academy of Engineering
The University of Texas at Dallas
Reprinted from ISSUES IN SCIENCE AND TECHNOLOGY, Volume XVII, Number 4 © 2001
The University of Texas at Dallas

MICHAEL R. TAYLOR
SANDRA A. HOFFMANN

Redesigning Food Safety

Controversy over genetically modified foods has helped put food safety in the headlines, but that issue, like others we read about—mad cow disease, Listeria and Salmonella outbreaks, chemical contamination—needs to be understood and addressed in the broader context of how we protect consumers from all foodborne hazards. This broader perspective is obscured, however, by the fragmented and in many ways outdated legal and organizational framework for food safety in the United States. Food safety law is a patchwork of many enactments that, all told, lack a coherent, science-based mandate for regulators and that split food jurisdiction among a dozen or more agencies, most prominently the Food and Drug Administration (FDA), the Department of Agriculture (USDA), and the Environmental Protection Agency (EPA).

Better deployment of the government's food safety resources is essential to minimizing the growing risks from foodborne illnesses.

The potential impact of this framework on the safety of biotech foods is important, but there is a broader and more fundamental public health question about the effectiveness of the current system in protecting consumers from foodborne illness. The Centers for Disease Control and Prevention (CDC) recently issued new, more reliable estimates of the persistently high incidence of foodborne illness in the United States: an estimated 5,000 deaths, 325,000 hospitalizations, and 76,000,000 illnesses annually, most of which are preventable.

In 1998, an Institute of Medicine/National Research Council (IOM/NRC) committee studied the current framework and called for a comprehensive statutory and organizational redesign of the federal food safety system. In its report, *Ensuring Safe Food from Production to Consumption*, the committee documented how the century-old accumulation of food safety laws and fragmented agency structure are impeding the efforts of regulators to reduce the risk of foodborne illness. The committee recommended a science-based, integrated food safety regulatory system under unified and accountable leadership; a system that would be better able to deploy resources in the manner most likely to reduce risk.

The IOM/NRC recommendations make common sense, but this does not mean that they will be readily adopted. The statutory and organizational status quo in Washington is politically difficult to change, which is why most major reforms in public health and environmental laws have occurred in response to some galvanizing event

Michael R Taylor (taylor@rff.org) is senior fellow and director of the Center for Risk Management, Resources for the Future, in Washington, D.C. From 1994 to 1996, he was administrator of USDA's Food Safety and Inspection Service; and from 1991 to 1994, he was the FDA's deputy commissioner for policy. Sandra A Hoffmann (hoffmann@rff.org) is a fellow at the Center for Risk Management.

or crisis. Fortunately for current health, if not policy for the future, the U.S. food safety system is not in crisis. It remains, in many respects, the strongest in the world, and it has made important strides in recent years toward more effective regulatory policies that properly emphasize preventive process control to reduce significant hazards.

The food safety system is, however, under serious stress, largely because of rapid change in the food system. Many of the cases of foodborne illness reported by the CDC arc linked to new and emerging microbial pathogens, changing U.S. eating habits, and an aging population. The system is also challenged by new agricultural and food technologies, such as genetically engineered food crops; by an 'increasingly globalized food supply, which makes European and Latin American food safety problems potential problems for the United States; and by intense public and media scrutiny of issues such as mad cow disease and biotech foods. Regrettably, chronically strained food safety budgets have seriously eroded the government's scientific staffing and inspection resources even as the food safety job has become more difficult.

In response to these stresses, and with an eye on lessons learned in Europe concerning the fragility of public confidence in food safety, U.S. lawmakers and nongovernmental organizations are showing growing interest in modernizing our food safety laws and structures along the lines contemplated by the IOM/NRC committee. Consumer groups that have been pushing for such reform have recently been joined by some food industry associations and scientific organizations. On Capitol Hill, Sens. Richard J. Durbin (D-Ill.) and George Voinovich (R-Ohio) recently wrote to President Bush calling for a bipartisan effort to combine the food safety functions of the FDA, the USDA, and the EPA into a single food safety agency. The Senate Agriculture Committee is also showing interest in the subject, with its chairman, Sen. Tom Harkin (D-Iowa), supporting the single agency concept.

The most compelling reason to modernize the food safety laws and unify the agencies is to allow, indeed mandate, science-based deployment of the government's food safety resources in the manner most likely to contribute to reducing foodborne illness. This means, among other things, prioritizing the opportunities for reducing risk by means of government intervention.

The government's role

The overarching purpose of food safety regulation and other government food safety interventions is to minimize the risk of foodborne illness. An effective food safety system provides an array of other important social and economic benefits, including maintenance of public confidence in the safety of the food supply and support for the export of U.S. food and agricultural products, but these benefits flow from success in minimizing food safety risk. The core public expectation, put simply, is that those involved in producing food and overseeing food safety are doing everything reasonably possible to make the food safe.

Food safety is first and foremost the responsibility of food producers, processors, and others throughout the food chain, including consumers. The government obviously does not produce food and cannot, by itself, make food safe or unsafe. The government does, however, play *two* important roles in the effort to minimize food safety risk.

The first and broadest role is to *set* and enforce food safety standards through laws, regulations, inspections, and compliance actions. Such standards range from general statutory prohibitions of adulterated food to specific limits on permissible levels of various chemical residues in food. Most of the government's food safety resources are devoted to setting and enforcing these standards, with the majority of those resources going to food inspection. This role fulfills the uniquely governmental function of ensuring that commercial firms involved in the food system have accountability to the public for meeting basic food safety standards. The USDA's recently adopted Hazard Analysis and Critical Control Points (HACCP) system for meat and poultry plants is an example of a food safety standard that has had measurable benefits in reducing harmful contamination and the risk of foodborne illness.

The government's second role in minimizing food safety risk is to mount initiatives to tackle food safety problems that are beyond the control of any individual participant in the food chain and that require more than a regulatory solution. For example, the pathogen *E. coli* 0157:H7, which poses a significant hazard when present in any raw or undercooked food,

originates primarily in the gut of cattle and is spread via manure through the environment to contaminate water and fresh produce. Through other pathways, it also contaminates beef during the slaughter process. Tackling this and many other food safety problems requires a strong research base; development of effective control measures; and collaboration among growers, animal producers, food processors, retailers, and consumers. The government has an essential leadership role to play in fostering research and collaboration on such issues.

Opportunities to reduce risk

In both of its primary roles, the government has substantial opportunities to improve performance through a more risk-based allocation of its food safety resources. The improvement would come from more systematic prioritization of risks and risk reduction opportunities and better allocation of resources in accordance with those opportunities.

Under current law, the FDA is authorized to inspect food establishments but is not required to do so. With about 50,000 processing and storage facilities under FDA's jurisdiction and with resources to conduct about 15,000 inspections per year, many plants under FDA's jurisdiction go years without inspection. Even plants rated by the FDA as "high risk" may be inspected only once a year or less. In contrast, the USDA has a statutory mandate to inspect every carcass passing through slaughter establishments and to inspect every meat and poultry processing plant every day, without regard to the relative riskiness of the operations in these plants.

There is growing support for the concept of a single food safety agency.

These approaches to inspection, which reflect fundamental differences in statutory mandates and modes of regulation between the FDA and USDA, skew the allocation of resources in ways that may not be optimal for public health and the government's ability to contribute to risk reduction. For example, USDA's budget for regulating meat and poultry is about $800 million per year. FDA's budget for all the rest of the food supply is less than $300 million. USDA employs about 7,600 meat and poultry inspectors, whereas the FDA has a total field staff of 1,700 for all of its food programs, including inspectors, laboratory technicians, and administrative staff. This is despite the fact that there are more reported cases and outbreaks of foodborne illness associated with FDA-regulated products than with USDA-regulated products. About 3,000 USDA inspectors are assigned to the statutorily mandated carcass-by-carcass inspection program in poultry plants alone, a largely visual process that primarily serves to address product quality rather than food safety concerns and thus makes a fairly minor contribution to food safety. Yet this poultry slaughter inspection program costs about $200 million per year.

The potential to improve this situation through risk-based priority setting and resource allocation is apparent. According to the IOM/NRC report, the agencies should be free to allocate their inspection and other resources across the entire food supply to "maximize effectiveness," which requires "identification of the greatest public health needs through surveillance and risk analysis."

Within the existing statutory framework, USDA has some limited flexibility to adjust its inspection models, so potentially it could redeploy resources to reduce risk more directly, such as through enforcement of HACCP and pathogen-reduction performance standards as well as oversight of distribution, storage, and retail facilities. The FDA legally has complete discretion to allocate its resources as it sees fit. Both agencies are making an effort to consider risk in making resource allocations. For example, USDA is developing new inspection models that would permit redeployment of some of its resources to oversee higher risk activities, and the FDA has traditionally attempted to target its limited inspection resources on plants that it judges to be high risk or likely to be committing safety violations.

Both agencies are severely constrained, however, by the current system. In USDA's case, the statutory inspection mandate commits most of the available resources to activities that are not planned primarily around risk. The FDA's food safety program is so

severely underfunded that it cannot even afford to analyze risk priorities systematically. Thus, as things stand today, neither agency is able to establish risk-based priorities for its inspection program or allocate resources accordingly. For these and other reasons, the IOM/NRC committee recommended that Congress change the law so that resources could be allocated and inspection and enforcement could be based on "scientifically supportable risks to public health."

The government can also be more effective in reducing risk by setting risk-based priorities for its initiatives that go beyond the core function of establishing and enforcing basic food safety standards. Such initiatives could include research, collaborative efforts with the food industry, targeted regulatory interventions, and consumer education. These efforts require significant money, staff time, and management attention, but they are necessary to bring about the change in practices and behavior that are required to reduce the risk of foodborne illness. In recent years, for example, the FDA and USDA have carried out initiatives to reduce the risk of illness posed by Salmonella enteriditis in eggs. These efforts have resulted in a decline in outbreaks and cases, but only after a significant investment of time and energy.

Risk-based priority setting is critical in deciding which initiatives to pursue and in managing those initiatives. For example, the CDC, through its FoodNet active surveillance program, now reports on cases of illness associated with nine specific bacterial and parasitic pathogens. These pathogens, which are the most significant known sources of foodborne illness, enter the food supply through a range of foods and at different stages of the food production process. If the government is to make the best use of its food safety resources, it should assess and compare the risks posed by various pathogen/food combinations and prioritize opportunities for reducing these risks through targeted food safety initiatives.

Likewise, the presence in food of environmental contaminants, such as mercury, lead, and dioxin, continues to be a matter of public health concern. The government has had success in the past with initiatives to reduce the levels of such contaminants, lead being a notable example. Through risk analysis, the government can identify opportunities for further risk reduction and mount initiatives accordingly.

Improving the role of risk analysis

The statutory, organizational, and resource constraints on risk-based priority-setting and resource allocation would have to be addressed through legislative action. However, there is also much that natural and social scientists can do to improve the risk analysis tools required to design and manage a more risk-based food safety system. These tools include the biological and statistical assessment of particular risks; risk comparison and ranking (in terms of public health significance); and prioritization of risk-reduction opportunities (raking into account feasibility, cost, and social considerations).

In the past, only one component of risk analysis — the risk assessment — has played an important role in food safety regulation, and that was limited to providing the basis for food safety decisions about specific substances. Today, there are much broader roles for risk analysis at the level of system design and management, but this will require improvement in the data and methods available to carry out such analyses.

Comparison and ranking of food safety risks according to public health significance are inherently complicated because of the diversity of risks and health outcomes of concern. Chemical risks range from the acute to the chronic, vary significantly with exposure, sometimes affect age groups differently. and often are predictable only with great uncertainty. Microbiological risks are also diverse, ranging from minor intestinal infections to permanently disabling disease and death, and vary among age groups. But unlike chemical risks, microbiological risk assessments are typically grounded in epidemiological data on actual illnesses in humans. How can these factors bc taken into account when comparing and ranking food safety risks? There is a need for public health experts and social scientists to collaborate in developing methods to value risks so that they can be compared and ranked.

The ultimate objective of risk analysis is not risk comparison and ranking for their own sake or to provide the basis for concluding that some food safety risks are unimportant. In the daily activities of people who produce, market, and consume food, any significant risk of harm is important and

should be prevented to the extent reasonably possible. For the government, however, the question is how best to allocate finite resources to reduce the risk of foodborne illness. This requires building on risk comparison and ranking to prioritize opportunities for risk reduction. It means not stopping with an understanding of the relative magnitude of food safety risks but examining how the government can make the best use of its resources to reduce risk.

With respect to standard setting and inspection, for example, which segments of the food supply or which specific food/pathogen combinations pose significant risks that are most amenable to reduction through government intervention? This analysis should start with the magnitude of the risk but also should consider the tools available to government and industry (standards, inspection, testing, new preventive controls) to reduce the risk, the feasibility and cost of reducing the risk in relation to other risk-reduction opportunities, and the value the public places on reducing the risk, as reflected, for example, in willingness to pay to reduce it. With respect to research, education, and other nonregulatory initiatives, where would government interventions have the greatest impact on risk reduction? There is currently no accepted model for considering these and other relevant factors in resource allocation and priority setting for the government's food safety program. Such a model should be developed.

According to the IOM/NRC committee report, "the cornerstone of a science-based system of food safety is the incorporation of the results of risk analysis into all decisions regarding resource allocation, programmatic priorities, and public education activities." We agree. Achieving this goal requires statutory and organizational reform, so that the results of risk analysis can be fully implemented in program design and management. It also requires significantly greater investment to improve the data and methods available for risk analysis. With these changes, the regulatory system can most effectively reduce the risk of foodborne illness and, in turn, maintain public confidence in the food supply and preserve our international leadership role on food safety.

FOOD TECHNOLOGY Feature

Reforming Food Safety: A Model for the Future

The long-term success of the U.S. food safety system requires unification of the existing agencies. Here's why and how this should occur.

Michael R Taylor

Debate about fundamental reform of the nation's food safety system is often oversimplified and reduced to a debate about whether we should form a single food regulatory agency. I believe that the long-term success of the system requires unification of the existing agencies, 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? 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.

Objectives of the Food Safety System

The functional attributes and organizational structure of the food safety system should reflect the system's important objectives. Three objectives stand out for me:

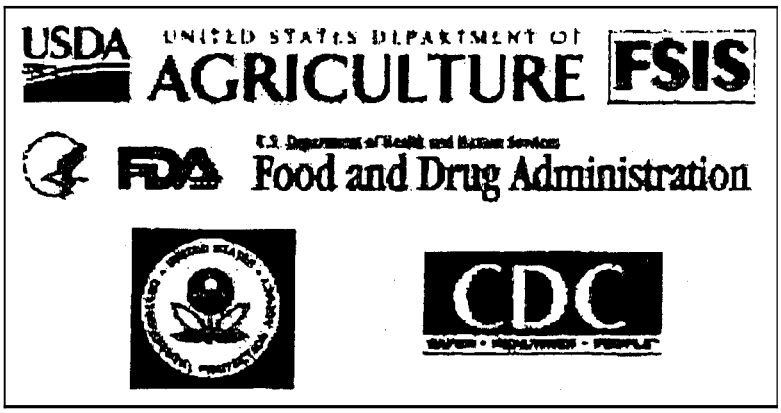
• **Reducing Foodborne Disease In the United States.** This is the most fundamental objective. Foodborne disease is a significant public health problem. The Centers for Disease Control and Prevention (CDC) estimates that known microbial pathogens alone cause 5,000 deaths, 325,000 hospitalizations, and 79 million illnesses annually (Mead et al., 1999). 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 collaborative and cumulative 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

The author, formerly Administrator of the U.S. Dept. of Agriculture's Food Safety and Inspection Service and Deputy Commissioner for Policy at the Food and Drug Administration, is Director and Senior Fellow, Risk Resource and Environmental Management Div., Resources for the future, 1616 P St., N.W., Washington, D.C. 20036.

food safe rests in these private hands but government has a responsibility—and it should be government's first objective—to reduce foodborne disease as much as is reasonably possible through research, regulation, and education.

• **Maintaining** Public Confidence in **Food** Safety and **the Food** Supply. 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 commerdally in the food system have done everything it is reasonably possible to do to make the food safe.

• **Exerting International Leadership on Food** Safety. It is important for **both** public health and economtc reasons that the U.S. be capable of exerting international leadership on food safety. Much of the **U.S.** food supply is imported from countries whose standards of food hygiene are not as high as ours. and important segments of the U.S. agricultural and food Industry increasingly rely on exports for their economic sustainability and growth. In today's global food system, in which World Trade Organization (WTO) agreements have an important impact on the standards that govern both food imports **and** exports, the **U.S.** must bc an international food safety leader.



Attributes Required to Achieve the Objectives

Broadly speaking, the food safety system must have four key attributes to achieve its objectives:

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

The Hazard Analysis and Critical Control Points (HACCP) approach provides **an** accepted framework for this purpose. It calls for the food producer or processor to rake 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. 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 h llm•ited. however. to tcafood, meat, poultry, and juice. where it has been adopted rhrough case-by-case rulemaking processes relying on broad statutory deflnitions 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 the Food and **Drug** Administration administers. is by design a largely reac•dve enforcement statute. It empowers FDA to remove 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 prevenr foodborne disease. The meat and poultry inspection laws, whose conceptual roots are more than a century old, mandate carcass-by-carcass and dally tnspection by the U.S. Depc. of Agriculture's **Food** Safety and Inspection Service (FSIS) in slaughter and processing plants. In-plant inspection is Important. but these laws force **FSIS** to focus virtually all of its resources on that one activity and largely ignore the many points on rhe farm-to-table spectrum where risks may arise and be prevented.

Accountability. This 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 bc provided through the establishment of regulatory standards to which companies can be held accountable. Regulatory accountability **substitutes** for accountability the market docs not adequately provldc.

In the case of food safety, people seek assurance that the producers. processors. and purveyors of food are doing every**thing** reasonably possible to make the food safe and rhcreby protect consumers from illness. 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 through pre-market approval systems and the enforcement of tolerances, which together 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 c u**M** of foodborne disease. In contrast to chemicals. there are **rio** 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 adulteratton and inspection authority to establish performance standards for Salmonella. The objectives and concepts underlying the standards are explained in the preamble to the HACCP/pathogen reduction rule (**FSIS,** 1996). The standards were intended to induce reductions in the incidence of *Salmonella* contamination **In** slaughter and raw ground meat processing plants based on the public hcalrh judgment 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, help 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 reductlon. with **FSIS** reporting that the inci-

Reforming Food Safety: A Model for the Future

dence of Salmonellacontamination has been cut substantially since the standards were adopted. For example, in the large plants that slaughter nearly all of the chickens Americans consume, the prevalence of *Salmonella*-contaminated 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, 2000). 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 (Ostroff, 2000).

Nevertheless. the standards have been opposed by some in the meat industry, which recently won a court ruling (*Supreme Beef Processors, Inc. v. USDA*, 5th Cir. 2001) that the agency lacked legal authority under the current statutes to establish and enforce the standard as it applied to ground beef. 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.

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 (NIM/NRC, 1996). 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. A similar conclusion was reached and well documented in a recent report. "Emerging Microbial Food Safety Issues—Implications for Control in the 21st Century," issued by the Institute of Food Technologists (IFT, 2002). The highly virulent pathogen *Escherichia coli* O157: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 foodbornc disease from this pathogen—a strategy that puts the research, regulatory, and educational tools of government to work in a coherent farm-to-rable effort to minimize the risk of illness from *E. coli* O157: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 bloterrorism, 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.

> Neither FDA nor FSIS has the statutory authority or practical mandate to forge an integrated strategy to reduce the **burden** of foodbornedisease. . . .

Risk-Based Resource Allocation. The food safety system must make the best possible use of its resources to reduce foodborne disease. 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 illncss. The IFT report cited above documents scientifically why this is true.

The current system does not work this way, in part because of the lack of accepted decision tools for prioritizing food safety risks and opportunities for risk reduction (Taylor and Hoffmann. 2001). Risk-based resource allocation also is precluded by the way the carcass-by-carcass and daily inspection mandates of the meat and poultry laws drlvc resource allocarlon. These mandates result in FSIS employing about 7,600 inspectors and consuming about 5800 million to regulate mcat, 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 adnunistratlvc staff (GAO. 2001). This allocation would be defensible if the risk were heavily cancentrated in the products FSIS regulates. but CDC says that about 85% of the cases of illness reported to it for which a food source was known were associated with FDA-regulated food products. The multi-year database of foodborne disease outbreaks (instances of multiple cases of disease associated with a common cause) compiled by the Center for Science in the Public Interest (CSPI. 2001) suggests that 80% of outbreaks may bc linked to FDA-regulated foods.

Poultry slaughter inspection is a glaring example of how food safety resources are misallocated arid cost effectiveness is lost. More than 15 years ago. 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 the U.S.. makes little contribution to food safety because it does not address *Salmonella* and other bacteria thar cause disease. Yet FSIS must spend more than $200 million and use 3.000 govcrnmrnt inspectors to do this work (Moss .2001). Without question. these resources could be used bener elsewhere in the regulatory system to reduct! foodborne disease.

FDA has taken a step toward risk-based resource allocation with its annual adopdon of "CFSAN Program Priorities" (FDA, 2002). An initiative of Joseph Levitt. Director of FDA's Center for Food Safety and Applied Nutrition, this document outlines how CFSAN plans to target its efforts in the corning year. 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.

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.
- 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.
- Risk-bas4 resource allocation is impossible when outdated laws mandate misallocation of food safety resources, and no one is in charge of resource allocadon across the entire system.

These features of rhe 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 when It wastes significant resources on antiquated inspection activities and perpetuates misalignment of resources in relation to risk.

Public confldencc is fragile in an age of Instant communication and dose scrutiny of government programs, as European food safety agencies learned following the disclosures of scientific and institutional failures to protect the public adequately or meet public expectations In the cases of bovine spongiform ancephalopathy (BSE), *E. coli*, and biotech foods. With luck, the U.S. 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 leadershlp 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 wirh U.S. standards. It is also jeopardized by the Inability of the U.S. to bring to international harmonization discussions a single voice and consistent approaches to food safety within our own borders.

Key Elements of Legislation

For the food system to achieve its objectives in the long term. comprehensive legislative reform is requlrcd. 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, 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 direct that preventive steps be taken throughout the system where appropriate and effective to help reduce foodborne disease.

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

- 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 maka 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 problcms. The plan would be a vehicle for ensuring rhat 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 aurhorities 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 that the country's aggregate food safety resources are used optlrnally to prevent disease.
- A mandate and authority for risk-based resource allocation. 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 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 authorlty 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 wirh today's problems. such as detention and recall authorlty, records access, establishment registration, and civil penalty authority. FDA also needs new authorlty to Inspect overseas food producers and hold imports to the same standards as domestically produced food.
- A mandate to implement food safety education programs as part 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 lcadarship In the international arena. The food safety agencies have no statutory mandate or adequate budget for participation In Intcrnational activities. such as Codex Alimentarius Commission and the WTO. This leads to uncertainty about who represents U.S. food safety interests internationally and, by default, a promlncnt role for trade agencies, which lack a food safety mission.

Reforming Food Safety: A Model for the Future

expertise, and credibility.

• A research mandate. A modernized 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

Organizational form should follow function. It is evident that change in the function and mandate of the food safety system on the order outlined here would require organizational change. 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. Anyone who has managed in government knows that these leadership and management functions cannot bc performed effectively by committee or through coordination. They require an organizational and leadership structure that is designed around and capable of accomplishing the newly defined food safety mission.

The single food safety agency should include FSIS; the food regulatory functions of FDA, including CFSAN, the Center for Veterinary Medicine, and the food portion of FDA's field resource; and the food safety aspects of the Environmental Protection Agency'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. 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. However, the unified agency should take on 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) havc strong and diverse views. Within government, neither USD.4 nor the Dept. of Health and Human Services (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 being insulated from the competing priorities and political interests of the existing departmcnts. The alternative would be to consolidate the food safety functions within one of the existing departmcnts.

> The unified agency should take on all of the food regulatory functions now at FSIS and FDA.. . .

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. USDA's strength is that food and the success of the food system are at the heart of its mission. Thus, food safety is a high-profile issue at USDA. USDA's weakness as a home for food safcty is that the department's primary role is to promorc and protect the interests of U.S. agriculture. which creates a fundamental conflict of interest because it forces the Secretary of Agriculture to balance her food safety responsibilities with her economic and promotions1 functions.

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 that food safety receives due attention, the head of the agency should be appointed by and report directly to the secretary of HHS.

A Political Reality Check

The politics of change are always daunting. Major statutory and organizational changes normally come only in response to extraordinary leadership from a president or influential member of Congress or in response to a real or perceived crisis. Food safety will likely be no different.

The ideas in this article are thus offered with a healthy sense of reality about the uncertain prospects for near-term change. This is okay. Fundamental change in the mandate and Structure of our food safety system should take time. We must be mindful of and carefully manage the disruptions and other costs associated with any major transition. But a political catalyst for change will come. When that happens, it will be important to have thought about the subject in advance and be ready to make changes that prepare the system for success in this new century.

REFERENCES

CSPI 2001. Outbreak alert! Closing the gaps n our federal food safety net Center for Science in me Public Interest Washington, DC (www cspinet org/reports/outbreak_alert/index htm).

FDA 2002 FY 2002 CFSAN program priorities. Food and Drug Admin Washington, D.C.

FSIS 1996 Pathogen reduction; Hazard Analysis and Critical Control Point (HACCP) systems; Final rule Food Safety and Inspection Service, US Dept of Agriculture, Fed Reg 61 38806

FSIS 2000 Backgrounder Progress report on *Salmonella* testing of Raw meat and poultry products Food Safety and Inspection Service, US Dept of Agriculture (www fsis usda gov/OA/background/salmtest5 him)

GAO 2001 Food safety—Overview of federal arid state expenditures GAO-01-177 General Accounting Office, Washington D.C

IFT 2002 Emerging microbiological food safety issues—Implications lor consd in the 21st centu', Inst of Food Technologists Chicago,Ill (www ift org,

Mead, *PS* Slutsker L ,Dietz, V. McCaig, L F., Bresee, J.S., Shapiro C., Griffin, P.M., and Touxe, R.V. 1999 Food-related illness and death in the United States Emerging Infectious Disease 5 606-625

Moss A 2001 Personal communication Office of the Under Secretary for Food Safety U.S. Dept of Agriculture Washington D C

NIM/NRC 1998 "Ensuring Safe Food from Production to Consumption " Natl Academy Press, Washingtc . D.C

Ostroff S M 2000 Statement of Associate Director lor Epidemiologic Science Natl Center lor Infectious Diseases, Centers lor Disease Control and Prevention before the Agriculture Nutrition and Forestry Committee, US Senate Sept 20 (www cdc gov/washington/legislative/09202000 htm)

Taylor and Hoffmann 2001 Redesigning lood safety Issues in Science and Technology 24 26

Based on a paper presented during the Institute of Food Technologists' Second International Food Safety and Quality Conference and Expo, Atlanta, Ga., February 20–22, 2002. ●