Food Safety Updated: Developing Tools for a More Science- and Risk-Based Approach

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Foreword

The authors of this report describe decision tools that could inform policy for reducing the burden of foodborne illness. These tools would rank risks, prioritize opportunities to reduce them, and clarify the constraints and contingencies that affect decisions about allocating resources for regulatory interventions to improve public health.

The report is grounded in the authors' firsthand knowledge of relevant science and of policymaking for food safety. This knowledge enables them to contextualize the need for new tools and the work required to devise them. The context they present includes balanced descriptions of the problems and achievements of the U.S. food safety system and of the challenges to developing and using the decision tools they propose.

The Milbank Memorial Fund and Resources for the Future cooperated in planning, writing, reviewing, and publishing this report. The Fund, an endowed philanthropic foundation, collaborates with decision makers in the public and private sectors to develop and implement policy that maintains and improves health. In addition to Milbank Reports, the Fund also publishes the *Milbank Quarterly* and a book series in collaboration with the University of California Press.

Resources for the Future (RFF) has served for the past 50 years as the premier independent institute dedicated exclusively to analyzing natural resource, environmental, and energy topics. Developing the intellectual underpinnings of entirely new analytic approaches is at the center of RFF's work in areas such as food safety and agriculture, international trade and the environment, and valuing environmental and health benefits.

The report is also the first publication of the newly created Food Safety Research Consortium (FSRC). This Consortium is a collaboration among six food safety research institutions: the Center for Food Safety at the University of Georgia; the Department of Epidemiology and Preventive Medicine at the University of Maryland's School of Medicine; the Food Marketing Policy Center at the University of Massachusetts; the Institute for Food Safety and Security at Iowa State University; Resources for the Future; and the Western Institute for Food Safety and Security at the University of California, Davis.

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Executive Summary

Food safety is a difficult and dynamic problem. In response to continuing and new challenges to the U.S. food safety system, food safety experts in government, academia, industry, and the consumer advocacy community have called for changes to make the system more effective in preventing foodborne illness and mitigating its burden, including the adoption of a more science-based approach to setting priorities and allocating resources. Although there is general consensus that this is the approach that ought to be taken toward food safety, the question remains: How can the concept of a science- and risk-based approach to food safety be made operational in a practical way? There is a need both to further develop the functional tools for achieving this goal and to come to terms with the difficulties of the undertaking. These issues are addressed in this report, and they are the central focus of the newly formed multidisciplinary and multi-institutional Food Safety Research Consortium.

According to the National Research Council (NRC), the General Accounting Office (GAO), and the President's Council on Food Safety, the current food safety policy and regulatory systems fall short of the vision of a science- and risk-based approach to food safety. Some new measures take steps in the right direction, such as the Hazard Analysis and Critical Control Points (HACCP) system used in seafood, juice, and meat and poultry plants to prevent food safety risks. Much remains to be done, however, to address the lack of integration across the food safety system, which prevents the best possible use of research, regulatory, and educational resources.

Practical tools are lacking for ranking risks and prioritizing opportunities for risk reduction at appropriate points across the entire farm-to-table spectrum, and this hampers food safety officials' ability to set priorities and allocate resources effectively. The realization of a science- and risk-based approach to reducing the burden of foodborne illness requires decision tools that will allow for a more systematic collection and analysis of data on foodborne hazards, on their causes, and on the cost and effectiveness of interventions to prevent or minimize hazards. These tools, which the Food Safety Research Consortium will work to develop, will enable policymakers to:

- Plan and prioritize food safety research from a public health perspective
- Choose and set priorities for regulatory interventions based on what is most likely to maximize risk reduction
- Identify the most productive opportunities for private-sector initiatives and public-private collaboration to reduce risk
- Plan and target commercial food handler and consumer food safety education

Three types of decision tools need to be developed: a *risk-ranking model* to rank the public health impact of significant foodborne hazards (such as microbial pathogens and chemical contaminants) and intentional threats (such as bioterrorism); *models that prioritize opportunities to reduce risk*, taking into account the various interventions' feasibility, cost, and effectiveness; and *resource allocation models* that begin with risk

ranking and prioritizing opportunities to reduce risk and then incorporate legislative mandates; other public health and public policy priorities, such as bioterrorism; and necessary contingencies for unplanned and unpredictable events. These models will not produce "right answers," but will instead provide decision makers in government and the private sector with tools for prioritizing opportunities to reduce risk and for allocating food safety resources more effectively.

The elements required to create these decision tools include data on the incidence of foodborne disease and the hazards posed by chemical contaminants; risk assessment methodologies with respect to microbial and chemical hazards; health risk valuation methodologies; and methods for cost-effectiveness and cost-benefit analysis of regulatory interventions. For risk ranking, there is a large pool of available knowledge and analytical methods. The key challenges to creating practical tools for risk ranking will be to advance understanding of how specific pathogen-food combinations contribute to foodborne illness; to develop techniques for comparing chemical food safety risks with microbial food safety risks; and, overall, to determine how to compare and rank diverse health outcomes associated with the broad universe of food safety hazards.

There is less available information and instititutional experience to help prioritize opportunities to reduce risk. The fundamental challenge in this area will be determining how to compare the feasibility, effectiveness, and cost of interventions at various points along the farm-to-table spectrum, in the context of the multiple factors that contribute to the occurrence of foodborne illness. Once the risk-ranking models and models to prioritize opportunities to reduce risk are developed, the challenge in developing risk allocation models will be to identify and account for other factors (such as legislative mandates and unplanned events) that will affect resource allocation decisions.

Developing these decision tools, and getting to the point of being able to apply them, will be complex and time-consuming—but the results will make explicit, and bring greater analytical rigor to, the many health and other factors that properly influence the design and management of a large and multifaceted program to reduce the burden of foodborne illness.

Introduction

For more than 20 years, scientists and public health regulators have worked to apply the science of risk assessment to food safety decision making. As a result of their efforts, the U.S. food safety regulatory system has a well-deserved reputation for making careful, science-based decisions about the safety of chemicals used in food production, including pesticides and food additives, in addition to contaminants like lead and aflatoxin. Federal regulators have also begun applying the tools of risk assessment to foodborne microbial pathogens, such as *Listeria monocytogenes* and *E. coli* O157:H7.

Based on its record of making sound, science-based decisions about specific foodborne hazards, the U.S. food safety system has generally high credibility with consumers and high standing internationally as being among the best in the world. Food safety remains, however, a difficult and dynamic problem. New food safety challenges flow from changed eating patterns and the aging of the population; increased reliance on food imports potentially carrying exotic pathogens; new food production and processing technologies; and the emergence of new pathogens. Issues as diverse as large-scale meat recalls and the threat of bioterrorism keep food safety on the front burner both for the public and for policymakers, and the Centers for Disease Control and Prevention (CDC) continues to report that foodborne illness is an important public health problem. The CDC's best estimate, based on recently improved data and a number of extrapolations, is that there are 76 million foodborne illnesses each year, resulting in an estimated 325,000 hospitalizations and 5,000 deaths.[1]

In response to these challenges, food safety experts in government, academia, industry, and the consumer advocacy community have called for changes to make the regulatory system more effective in preventing food safety problems, including a more science-based approach to setting priorities and allocating resources. In 1998, a committee of the National Research Council (NRC) issued a report analyzing the current system and recommending broad legislative and organizational changes to improve food safety across the spectrum "from production to consumption."[2] A central thrust of the NRC report was that the food

safety system should be more science- and risk-based—embracing, for example, allocation of resources more in accordance with the distribution of risk and with opportunities for risk reduction across the food supply.

Such an approach would build on the use of risk assessment that is established in the current system for making decisions about specific hazards, but it requires more than that. It requires using a broader set of risk analysis tools to evaluate the system as a whole, set risk reduction priorities, and allocate resources accordingly. More broadly, it requires coming to grips with what we mean, in today's dynamic food safety environment, by a "science- and risk-based" food safety policy and regulatory system. Most agree, at least in concept, on the need for such an approach to food safety, but the question remains: How can the concept of a science- and risk-based approach to food safety be made operational in a practical way?

To address this question, the authors are collaborating on behalf of their respective institutions in the development of a multidisciplinary, multi-institutional research consortium. The founding institutions of the Food Safety Research Consortium are Iowa State University's Institute for Food Safety and Security; Resources for the Future (RFF), a Washington-based think tank; the University of Georgia's Center for Food Safety; the Department of Epidemiology and Preventive Medicine at the University of Maryland School of Medicine; the Food Marketing Policy Center at the University of Massachusetts; and the Western Institute for Food Safety and Security at the University of California at Davis. The Milbank Memorial Fund collaborated in the development of the consortium.

The initial objective of the consortium is to work with scientists, policymakers, and food system stakeholders on development of the decision tools required to make operational a science- and risk-based approach to food safety policy and regulation, including a more risk-based allocation of food safety resources. The task is difficult: There are significant methodological issues and gaps in currently available data relevant to the problem. In addition, there are competing societal values and public health, regulatory, and agricultural policy issues that must be addressed through collaborative research, analysis, and consensus building among experts and stakeholders in the field. The Food Safety Research Consortium will seek to foster such collaborative work.[3]

There is also a need to build understanding of the challenges—and the opportunities—involved in working toward a more science- and risk-based approach. This paper is a first step in that process. It provides a brief overview of the current food safety system and the need for new decision tools in the context of that system. It then summarizes the relevant state of the art in food safety risk ranking and priority setting, what needs to be done to develop the new tools, and some of the challenges we expect to encounter. This paper is not intended to provide an in-depth, technical treatment of these topics but rather an overview and useful background for a nontechnical audience of policymakers and stakeholders interested in improving the public health outcomes and overall performance of the food safety system.

One important caveat: This paper focuses on the government's role in food safety, even though the authors recognize that government is only one part of the food safety equation. All those involved in the production, processing, distribution, and sale of food have a primary role in and responsibility for food safety, as do consumers. Indeed, the private participants in the food system play the most direct role and have the most direct interest in ensuring that food is safe. An important part of the government's role in food safety is to interact with the private sector in a way that fully harnesses the food safety expertise and incentives of private parties. Beyond this, however, government has a critical and unique role to play because of society's reliance on it to set and enforce food safety standards; to conduct productive illness surveillance, research, and education; and to solve contamination and illness outbreak problems when they arise. The continued success of the government's program is necessary both to reduce the risk of foodborne illness and to maintain public confidence in the food supply.

We present this paper in the hope of stimulating discussion and collaborative efforts. Comments of any kind are invited and welcome.

Overview of the U.S. Food Safety System

The federal food safety system has its roots in statutes and agencies that are nearly 100 years old. The system has evolved in response to scientific and social change, and the pace of change has accelerated in recent years; but the system currently operates within a structure and under general approaches to regulation that, in most cases, have been in place since the 1950s or before. The system divides responsibility for food safety regulation primarily among three agencies: the Food and Drug Administration (FDA), located within the Department of Health and Human Services (DHHS); the Food Safety and Inspection Service (FSIS), which is part of the U.S. Department of Agriculture (USDA); and the Environmental Protection Agency (EPA). The programs of each of the three agencies have distinctive features.

This section provides a brief overview of the three agencies and their programs, the critique of the overall system contained in the 1998 NRC report and reports of the General Accounting Office (GAO), and an evaluation of the progress the agencies are making toward a more science- and risk-based food safety program. We conclude that the current regulatory system has important strengths and is improving, but that it falls short of the vision of a science- and risk-based approach to food safety, outlined by the NRC and the GAO.

The Federal Agencies and Their Programs

The Department of Health and Human Services

The Food and Drug Administration is the organizational successor to the Bureau of Chemistry in the Department of Agriculture, which was the first food safety agency at the national level in the United States and the only one in existence when the first national food safety laws were passed in 1906. The FDA was moved in 1940 from the USDA to what is now DHHS based on perceptions of a conflict between the FDA's food safety mission and the USDA's primary goal of promoting and supporting American agriculture.[4] The FDA is now part of the Public Health Service in the Department of Health and Human Services.

The FDA's statutory authority for food safety comes primarily from the federal Food, Drug, and Cosmetic Act of 1938 (FDCA) and the Food Additives Amendment of 1958 (FAA).[5] The FDA also regulates food safety under a number of other product-specific laws, including the Color Additive Amendments of 1960, the Animal Drug Amendments of 1968, the Infant Formula Act of 1980, and the Dietary Supplement Health and Education Act of 1994. Under these laws, the agency has regulatory responsibility for the safety of all foods (except meat, poultry, and processed eggs); for substances intentionally added to food or used in food processing; and for natural and man-made food contaminants. The FDA's legal jurisdiction over food and food processing extends from the point of production to retail sale, assuming one or more components of the food in question have moved in interstate commerce. At the retail level the FDA's authority overlaps with the food safety authority of the states, to which the agency defers with respect to most regulatory activity at the retail level.

The FDCA defines the conditions under which foods are deemed adulterated and thus precluded from commerce. In general, the law prohibits the sale of food that may be injurious to health owing to potentially harmful contamination, including from naturally occurring contaminants, or that has been prepared or held under unsanitary conditions. The law authorizes the FDA to inspect food establishments, to sample and test products for safety violations, and to pursue remedies in court to remove adulterated food from commerce and, in extreme cases, criminally prosecute violators. The FDCA is, in essence, an enforcement law, providing the FDA with legal tools to uncover and remedy food safety problems but no explicit mandate regarding the frequency or nature of inspections or the public health goal to be achieved. Under these provisions, the burden rests on the FDA to prove that an actual or potential safety hazard exists.

The FAA operates differently with respect to intentional additives, by establishing a pre-market approval requirement for such substances.[6] The FAA defines "food additive" to include any substance the intended use of which results or is reasonably expected to result in its becoming a component of food, unless the substance is generally recognized as safe (GRAS), based on a long history of use in food or a scientifically well-founded consensus among experts; is a pesticide; or falls within one of several other statutory exceptions. The sponsor of a new food additive must come to the FDA and demonstrate to the agency's satisfaction, prior to marketing, that the substance meets the "reasonable certainty of no harm" safety standard for food additives.

In addition to using its basic inspection and enforcement tools and its pre-market oversight of food additives to ensure food safety, the FDA implements its general policy and rulemaking authority to establish guidelines

and standards for the food industry to follow. Historically, the FDA has used this authority primarily to establish action levels for contaminants and guidelines for good manufacturing practices that it then uses as the basis for deeming products adulterated and taking enforcement action. More recently, however, the agency has issued regulations mandating that two segments of the food industry—seafood and juice processors—adopt the Hazard Analysis and Critical Control Points (HACCP) system of preventive process control for food safety, which is considered science- and risk-based because it is based on a food production operator's identifying potential food safety risks in the process, developing and implementing scientifically validated controls to minimize or eliminate the risks, and monitoring the process to verify that controls are working as intended and corrective actions are taken when needed. The FDA mandated HACCP for seafood processors in 1995 and for juice processors in 2001[7] —part of the emerging shift to a more science-based and preventive approach to food safety, which we will discuss further below.

The FDA carries out its food safety responsibilities through a headquarters organization, the Center for Food Safety and Applied Nutrition (CFSAN); a field force stationed in a network of offices around the country; and agreements with state regulatory agencies. The CFSAN establishes policies and standards, manages the pre-market approval program, and sets priorities for the field inspection and compliance force. The field force is managed by the Office of Regulatory Affairs and includes technically trained inspectors, compliance officers, and laboratory analysts whose primary roles are to enforce standards and take corrective actions when needed to protect consumers from potentially unsafe food.

In Fiscal Year (FY) 2001, the FDA's total budget for its food regulatory program was about $288 million, of which $126 million was allocated to the CFSAN and $162 million to the field. This budget supported a full-time equivalent staff of 879 in the CFSAN and 1,566 in the field.[8] In FY 2002, the FDA food program received a supplemental appropriation of nearly $100 million, which has been added to the FDA's budget base to respond to the threat of bioterrorism. With other increases, this brought the FDA's total food regulatory budget in FY 2002 to about $405 million, of which $145 million and 909 staff years go to the CFSAN and $259 million and 1,942 staff years go to the field. The FDA is responsible for food labeling and food quality standards, but it uses most of its resources for food safety-related activities.

The FDA has full discretion in how it allocates the field portion of its food regulatory resources. The average inspection frequency for the 50,000 establishments under the FDA's jurisdiction is about once in five years—though the recent increase in resources may increase this frequency—and the agency seeks to inspect "high-risk" plants at least annually.

Within the FDA, the Center for Veterinary Medicine (CVM) regulates the manufacture and distribution of animal feed additives and drugs that will be given to animals, including food animals, and thus enter the human food supply. The CVM's food safety activities include pre-market approval, surveillance, research, and education to ensure that animal feed and animal drugs do not jeopardize human food safety.

Also within the Department of Health and Human Services, the Centers for Disease Control and Prevention (CDC) leads federal efforts and works cooperatively with states to gather data on foodborne illnesses, investigate foodborne illnesses and outbreaks, and monitor the effectiveness of prevention and control efforts. The CDC also identifies prevention strategies and works to improve the epidemiology, laboratory, and environmental health skills of state and local health departments so as to enhance their foodborne illness surveillance and outbreak response. The CDC has become a partner with the regulatory agencies in tracing outbreaks and in evaluating regulatory interventions.

The U.S. Department of Agriculture

The USDA's food safety program is carried out primarily by the Food Safety and Inspection Service (FSIS). The FSIS is the organizational successor to the Bureau of Animal Husbandry, which was kept at the USDA when the FDA was transferred to the Public Health Service in 1940. The FSIS's statutory authority resides in the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA). Under these statutes, the FSIS has regulatory responsibility for the safety of meat (defined as the carcasses and parts of cattle, sheep, swine, goats, horses, mules, and other equines), poultry (defined as the carcass or part of "any domesticated bird"), and processed egg products.

Like the FDCA, the laws the FSIS administers define the conditions under which meat and poultry products are deemed adulterated and thus precluded from commerce, and they do so in similar terms. In contrast to the FDCA, however, the meat and poultry laws contain affirmative mandates for FSIS inspection that largely define the contours of the FSIS program and its resource allocation. These laws require the FSIS to conduct carcass-by-carcass inspections in slaughter plants, which involves examining annually more than 8 billion

chickens and turkeys and 130 million head of cattle, hogs, and other livestock.[9] (FSIS regulatory authority does not extend to the farm but begins with ante mortem inspection at the slaughterhouse.) They also require continuous inspections in all meat and poultry processing plants, which the FSIS has interpreted as daily inspection. Only products found affirmatively by the FSIS not to be adulterated can receive the familiar USDA mark of inspection and lawfully enter commerce. The EPIA contains similar inspection and marking requirements for processed egg products. The FSIS's primary food safety enforcement tool is the withholding or withdrawal of inspection, which effectively suspends a plant's operation.

Like the FDA, the FSIS has rulemaking authority, which it has used to establish standards for sanitation and safe processing with respect to meat and poultry.[10] In 1996, the FSIS required the adoption of the HACCP system in all meat and poultry processing plants, microbial testing to verify process control in slaughter plants, and performance standards to reduce the incidence of *Salmonella* contamination in raw meat and poultry.[11] The *Salmonella* standards were subsequently invalidated by a federal appeals court as they apply to raw ground beef, raising a question about the FSIS's legal authority under its inspection laws to establish performance standards for reducing pathogenic contamination in raw products.

The FSIS's inspection mandate requires a large workforce of in-plant inspectors and veterinarians, numbering some 7,600, who are stationed in more than 6,000 plants (including 140 import stations) across the country. An additional 2,000 employees staff FSIS headquarters, three field laboratories, a technical service center, and an enforcement program.

In FY 2001, the FSIS's total budget was $851 million; the 2002 budget is $892 million, including $15 million in supplemental funds for homeland security needs. These figures include appropriations as well as reimbursements and trust funds. (The FSIS collects approximately $100 million each year in overtime fees and fees for voluntary inspections.) More than 90 percent of the agency's budget is expended for inspection in slaughter and processing plants and at import inspection stations.[12] The FSIS also reviews and approves foreign inspection systems and plants that export meat, poultry, or egg products to the U.S., and it assists and oversees some 26 state meat inspection programs to ensure that they are equal to the federal program.

Other agencies with food safety responsibilities within the USDA include the Agricultural Research Service (ARS), the Cooperative State Research, Education and Extension Service (CSREES), and the Economic Research Service (ERS), all of which conduct food safety research and analysis. The Animal and Plant Health Inspection Service (APHIS) contributes to the food safety mission by providing surveillance of animal diseases (including zoonotic diseases), tracing affected animals to herds of origin, and conducting risk assessments.[13]

The Environmental Protection Agency

The Environmental Protection Agency's involvement in food safety stems primarily from its jurisdiction over agricultural pesticides, which EPA regulates through its Office of Pesticide Programs (OPP). Like the FDA's food safety program, pesticide regulation was originally housed at the USDA, from which it was transferred in 1970 when the EPA was created.[14]

The EPA regulates the environmental safety of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)[15] and the safety of pesticide residues in food under the FDCA.[16] In its food safety role, the EPA evaluates the safety of residues that are expected to remain in food as a result of the proposed use of an agricultural pesticide and, on the basis of that evaluation, establishes tolerances (which are binding legal limits) to ensure that safe levels of human consumption of the pesticide residue are not exceeded. In 1996, Congress amended the pesticide tolerance provisions of the FDCA to establish with respect to all pesticide residues in food the same "reasonable certainty of no harm" safety standard applicable to food additives.[17] It also directed the EPA, when setting tolerances, to consider exposure to the pesticide from all sources along with the special sensitivities of children and to ensure that pesticides already on the market met these new health standards.

The EPA's role is limited to establishing pesticide tolerances; the tolerances are enforced by the FDA and the FSIS. Nevertheless, the EPA's food safety role is important because of the large volume of risk assessments and safety decisions it makes concerning chemical residues in food. As part of its program to grant new pesticide tolerances and review old ones, the EPA makes hundreds of chemical-specific risk assessments and safety evaluations annually, compared with the few dozen that the FDA makes each year.

In FY 2001, the EPA's budget for food safety was $125 million, which supported 817 FTE (full-time

equivalent) staff. The FY 2002 budget was $109 million supporting 777 FTE, and essentially the same amount is requested in the president's FY 2003 budget ($110 million and 770 FTE).[18]

Other Government Agencies

The food safety programs of DHHS, the USDA, and the EPA are supported and supplemented by a number of other government organizations, including the National Marine Fisheries Service (NMFS) within the Department of Commerce, which conducts a voluntary seafood inspection and grading program to ensure the quality and safety of commercial seafood.[19] The U.S. food safety system depends also on state and local food regulatory agencies, which are typically part of the health or agriculture department of state or local government. Their activities include illness outbreak investigations and response, retail licensing and inspection, and laboratory analysis. The U.S. General Accounting Office surveyed state agencies and health departments and reported that their total expenditures for food safety were $292 million in FY 1998 and $301 million in FY 1999.[20] Nearly half of the expenditures reported were for licensing and inspections of meat, poultry, seafood, dairy, and egg product plants and retail food service establishments, such as groceries, restaurants, and hospitals.

The NRC and GAO Critiques of the Current Regulatory System

National Research Council

The 1998 NRC report cited earlier defined the mission of the U.S. food safety system this way:

> The mission of an effective food safety system is to protect and improve the public health by ensuring that foods meet science-based safety standards through the integrated activities of the public and private sectors.[21]

With this public health mission in mind, the report documented the strengths and weaknesses of the federal government's food safety regulatory system, outlined the elements of an effective system, made findings about where the system falls short, and recommended changes to improve the system. Many of the findings and recommendations addressed what the report characterized as "inconsistent, uneven and at times archaic food statutes" and "lack of integration" among the 12 federal agencies it found to be involved in food safety.[22]

The first element of an effective food safety system cited by the report involved risk-based resource allocation. The report said that an effective system

> should be science-based, with a strong emphasis on risk analysis, thus allowing the greatest priority in terms of resources and activity to be placed on the risks deemed to have the greatest potential impact.[23]

The report's recommendations were geared largely toward achieving this objective. In addition to statutory and organizational change to make the system more science- and risk-based, the report called for the development of a "comprehensive national food safety plan" under which

> funds appropriated for food safety programs (including research and education programs) should be allocated in accordance with science-based assessments of risk and potential benefit.[24]

The NRC committee did not provide a more formal analysis of the current system to determine the extent to which the system reduces the risk of foodborne illness and does or does not achieve the goal of risk-based resource allocation. It noted, however, that the FSIS inspection budget is four times as great as the FDA food inspection budget, despite the broader FDA jurisdiction. It attributed this to the statutory mandate for carcass-by-carcass inspection in slaughter plants, which consumes most of the FSIS's resources, and noted that the methods used in those inspections "are not appropriate or adequate to detect the major microbial and chemical hazards of current concern."[25] The NRC report was issued just as the FSIS was beginning implementation of HACCP and related measures to reduce pathogens in meat and poultry, however, and thus did not take account of the effect those changes have had in reducing pathogens and the risk of illness. The NRC report also was issued prior to recent increases in the FDA's budget for field inspectors to deal with the threat of bioterrorism.

General Accounting Office

The GAO has issued more than 20 reports on food safety in the last decade, many of which relate to the resource allocation issues addressed in the NRC report and document the current allocation of resources in the food safety system.[26]

The GAO has found that "federal food safety expenditures are based on legal requirements, not on risk."[27] In comparing the food safety jurisdictions and expenditures of the FDA and the FSIS, the GAO found that, in FY 1999, the FSIS used 72 percent of expenditures to oversee facilities that account for about 21 percent of federally regulated foods and 15 pecent of reported illnesses. The FDA used 28 percent of its total expenditures to oversee the remainder of the food system, which accounts for 79 percent of federally regulated foods and 85 percent of reported illnesses.

Like the NRC committee, the GAO has not conducted a more formal risk analysis of the current system, and the data on the distribution of reported illnesses provide only a rough approximation of the distribution of risk in the food supply. Based on its analysis of current resource allocation, however, the GAO has endorsed the NRC committee's conclusions and recommendations and called for the creation of "a single food safety agency to administer a uniform, risk-based inspection system."[28] Like the NRC committee, the GAO has emphasized science-based and preventive regulatory strategies—such as adoption of HACCP, where appropriate—as the standard for food safety process control in food processing plants.[29]

Recent Progress toward a Science- and Risk-Based Food Safety System

Federal regulators and policymakers have embraced the concept of a science- and risk-based approach to food safety, and they have made real progress in several areas, including data collection on foodborne illness, regulatory strategies, priority setting, and coordination.

Foodborne Illness Data Collection

Reliable data on the incidence and causes of foodborne illness are essential for determining and ranking food safety risks. In 1996, the CDC significantly improved data collection for foodborne illness by establishing the Foodborne Diseases Active Surveillance Network (FoodNet) as a collaborative effort of the CDC, the FSIS, the FDA, and selected state health departments. A major impetus for the creation of FoodNet was the interest of the FSIS and the FDA in monitoring the changes in foodborne illness rates resulting from implementation of new HACCP regulations. By maintaining active surveillance with respect to foodborne illnesses associated with seven bacterial and two parasitic pathogens, rather than relying on passive reporting of cases, FoodNet, combined with data from other surveillance systems and health care surveys, provides far more complete and reliable data on foodborne illness than we have had before.[30] The CDC has also revised the foodborne outbreak reporting process, making it electronic and swift. As a result, the number of reported outbreaks has doubled since 1998.

Science-Based, Preventive Regulatory Strategies

The HACCP systems adopted by the FDA and the FSIS are a step toward a more science- and risk-based approach to food safety. They require processors to identify the hazards reasonably likely to occur in their plants and to implement process controls that focus on preventing those hazards. In addition to focusing the efforts of food processors on the most significant risks in their production systems, HACCP has the potential to better focus the use of government food safety resources. Inspectors can concentrate on ensuring that the process control systems are working effectively to prevent significant hazards rather than having to detect and correct hazardous situations themselves. Moreover, building preventive process control into the food production system is a key element of any effective strategy to reduce the risk of foodborne illness.

In addition, the FSIS HACCP rules for meat and poultry include microbial performance standards that slaughter and grinding operations are required to meet. Since adoption of the FSIS HACCP rule and the *Salmonella* performance standards, the prevalence of *Salmonella* contamination in slaughter and grinding plants has declined markedly. For example, in the large plants that slaughter nearly all of the chickens Americans consume, the prevalence of *Salmonella*-contaminated carcasses has declined over 50 percent, from 20 percent prior to enactment of HACCP and the *Salmonella* standards to 9.7 percent in the most recent report.[31] And the CDC reports declines in foodborne illness that occurred coincident with implementation of the FSIS requirements.[32]

Planning and Priority Setting

Under the Government Performance and Results Act of 1993 (GPRA), all government agencies are required to develop strategic plans, including specific goals and performance measures, to ensure that they use their resources wisely to fulfill their missions. The FDA has taken an important step toward risk-based resource allocation for food safety with its annual adoption of "CFSAN Program Priorities," which outlines how the CFSAN plans to target its efforts in the coming year, including specific goals to be worked on or completed.[33] The priority list, which is based on public health and regulatory judgment rather than any comprehensive risk analysis, is a useful tool for informing both FDA staff and the public how the CFSAN intends to use its resources to address the very broad range of issues within its jurisdiction.

The FSIS has developed a strategic plan using the classic risk analysis model of risk assessment, risk management, and risk communication. The plan identifies a single goal—protect the public health by significantly reducing the prevalence of foodborne hazards from meat, poultry, and egg products—and four objectives, complete with outcomes and outcome measurements. One planned outcome is that the most significant meat, poultry, and egg product risks from farm to table are minimized or eliminated, with performance measures adopted for specific hazards, such as *Salmonella* in raw meat and poultry products and *Listeria monocytogenes* in ready-to-eat products. These objectives become the agency's food safety priorities—which are then reflected in budget planning, within the constraints of budget limitations and legislative mandates.

The President's Council on Food Safety

This cabinet-level council was formed in 1998 to respond to recommendations in the 1998 NRC report for better coordination among the food safety agencies and a more science- and risk-based regulatory system. In January 2001, the Council issued a strategic plan for the nation's food safety system that essentially embraced the NRC report's vision of a unified, risk-based program, declaring as its first goal that the "federal food safety system [be] based on sound science and risk assessment."[34] The Council's strategic plan made improvement in public health the test of success and called specifically for risk-based allocation of resources:

> [T]he Council recognized that assessment of food safety risks must play a critical role in setting priorities and determining the effective use of our resources. Priorities must be based on where the scientific data show the greatest food safety risks. Risk-based priority setting will continue to be the most defensible way to shape budget choices, research agendas, and risk management targets—indeed to guide every aspect of the effort to strengthen food safety programs.[35]

The Council's strategic plan reflects broad recognition among the food safety agencies of the role risk analysis should play in designing and managing the government's food safety program.

Presidential Food Safety Commission

The interest in moving toward a more science- and risk-based approach to food safety has recently resulted in the inclusion of a provision in the 2002 Farm Bill establishing a presidentially appointed Food Safety Commission to recommend improvements in the federal food safety system that "build on, to the maximum extent practicable," the NRC report.[36] The commission is expected to make recommendations to improve public health, help create a "harmonized framework for managing Federal food safety programs," and "enhance the effectiveness of Federal food safety resources (including the application of all resources based on risk, including resources for inspection, research, enforcement, and education)."[37] The commission is an effort to begin converting the analysis and recommendations of the NRC and the GAO into concrete proposals for making the government's food safety program more science- and risk-based. Once the commission is funded and appointed and has its first meeting, it will have one year to develop and make its recommendations.

Where We Are Today

The U.S. food safety regulatory system is among the strongest and most highly respected in the world. Its strength lies in its scientific and public health tradition and the commitment of its people to the food safety mission. The system's weakness lies in its relatively limited ability to shift resources and respond optimally to today's new food safety challenges, whether it be foodborne illness due to microbial pathogens, imported foods, or the threat of bioterrorism. In the case of the FDA, this has been caused in large part by the lack of sufficient resources to meet more than the minimal need for inspections and risk reduction initiatives, though

recent increases in funding will give the agency discretionary resources. In the case of the FSIS, statutory mandates largely control resource allocation and compel an approach to inspection that may not be optimal for reducing risk. In the case of the EPA, food safety resource allocation is almost entirely controlled by the statutorily directed tolerance-setting program.

The agencies are keenly aware of these challenges and have made substantial efforts to address them, but the core insights of the NRC report and the GAO's many analyses remain sound: The system does not make the best possible use of its research, regulatory, and educational resources to reduce the risk of foodborne illness. While the presidentially appointed Food Safety Commission provides an opportunity to devise changes that the agencies need in order to fully realize the vision of a science- and risk-based approach to food safety, there is another need that the commission will not be able to address. The pursuit of a more science- and risk-based food safety system, including risk-based resource allocation, requires tools for ranking risks and prioritizing opportunities for risk reduction that do not exist today. These tools are needed regardless of whether Congress changes our food safety laws and organizational structure or leaves the current system and structure in place.

The Need for New Decision Tools

Setting priorities and allocating resources accordingly are not new for government agencies. The annual budget process is de facto a priority-setting exercise in the sense that the allocation of resources through the budget process is inherently an expression of the agency's priorities, whether the agency thinks about it in those terms or not. The strategic planning and priority-setting mandates of the Governnment Performance and Results Act are requiring all agencies to be more conscious about priority setting and about linking resource allocation to the achievement of important outcomes.

In the food safety area, priority setting has long been a necessary feature of the FDA's food safety program, because the FDCA generally does not direct the allocation of the FDA's food safety resources. This means that the FDA must continually decide what food safety tasks to work on and how to use its limited human and financial resources. It has done this over the years using its best judgment, with public health priorities being an important factor but with other factors playing an important role as well, including past spending patterns, the demands of the agency's many public constituencies, and the problem of the moment from a public or political perspective. The recent CFSAN Program Priorities initiative brings a more regular process and transparency to the FDA's priority setting.

Though the FSIS has less discretion than the FDA to allocate resources based on risk, it too has attempted to target its efforts in ways such as testing meat and poultry for pathogens and chemical hazards where such testing will do the most good, and setting pathogen reduction performance standards for slaughter and grinding.

But the vision of a science- and risk-based approach to food safety requires more. That vision is based on the understanding that minimizing the risk of foodborne illness requires preventive interventions at appropriate points across the entire farm-to-table spectrum. It also recognizes that the opportunities for effective government intervention include research and education as well as a wide range of possible regulatory measures. Considering the wide diversity of potential risks in the food supply, a food safety vision based on farm-to-table prevention and risk-based allocation of resources demands careful analysis. It requires a more systematic collection and analysis of data on foodborne hazards, on their causes, and on the cost and effectiveness of various government interventions than the agencies have attempted in the past. More specifically, optimally allocating resources to reduce risk requires ranking the public health impact of significant risks and then prioritizing the opportunities to reduce those risks through government intervention.

Such risk ranking and priority setting is needed to:

- Plan and prioritize food safety research from a public health perspective
- Choose and set priorities for regulatory interventions based on what is most likely to maximize risk reduction

- Identify the most productive opportunities for private-sector initiatives and public-private collaboration to reduce risk
- Plan and target commercial food handler and consumer food safety education

These are all key tasks under a more science- and risk-based approach to food safety. The risk-ranking and priority-setting tools required to perform them systematically and rigorously, however, do not presently exist within the regulatory framework. It is these tools that the Food Safety Research Consortium will develop. The next two sections discuss the state of the art in this area and the work that needs to be done to develop the decision tools necessary for a science- and risk-based food safety system.

Current State of the Art in Risk Ranking and Food Safety Priority Setting

The risk ranking and prioritization of opportunities to reduce risk that are required for risk-based allocation of food safety resources are challenging, but feasible. Although the practical tools that policymakers need for this purpose do not exist, many of the elements required to construct such tools do exist, albeit in varying states of maturity—and of acceptance in the expert and stakeholder communities. These elements include data on the incidence of foodborne illness and the hazards posed by chemical contaminants; risk assessment methodologies for microbial and chemical hazards; health risk valuation methodologies; and methods for cost-effectiveness and cost-benefit analysis of regulatory interventions.

The state of the art with respect to these elements, as they apply to food safety, is summarized briefly in this section, together with some of the gaps in available tools and data. We conclude that the data and analytical tools required for risk ranking, while not yet optimal, are better developed than those required to prioritize opportunities to reduce risk.

Risk Ranking

Data on Foodborne Illness and the Hazards Posed by Chemical Contaminants

As discussed earlier, the CDC and the regulatory agencies have collaborated to improve data collection on foodborne illness through FoodNet and other enhancements of illness surveillance. This makes possible much more reliable estimates of illness associated with particular foodborne pathogens than have been previously available. Our ability to estimate illness occurrence is being further enhanced by ongoing community-based studies of diarrheal and foodborne illness. The result is a robust and growing body of data that provides a good basis for developing risk-ranking methodologies and a good starting point for risk ranking.

There remains, however, considerable room for improvement with respect to the data on foodborne illness. The FoodNet system addresses only a limited number of important foodborne pathogens and focuses on identifying the pathogen associated with the illness rather than the food. This means that CDC illness estimates still rely on important assumptions and extrapolations and that available estimates of illness associated with specific pathogen-food combinations are much more tenuous than the estimates linking illness to particular pathogens. There is a need to compile and integrate the existing foodborne illness data and expand data collection in order to improve our understanding of how specific pathogen-food combinations contribute to foodborne illness. For example, better data from reported foodborne outbreaks, along with a comparison of pathogens from people, foods, and food animals, can improve the assessment of the associations among these factors.

With respect to chemical contaminants—such as aflatoxin, lead, mercury, and dioxins at the levels prevalent in the U.S. food supply—epidemiological data showing the incidence of human illness are limited. However, large bodies of data derived from animal toxicity studies, which are commonly relied on for chemical risk assessment, generally do exist. Exposure data for chemical contaminants, which are essential for risk assessment, are also available for the major contaminants, though incomplete in some cases. The challenge in the case of chemicals will not be finding data for risk assessment but developing methods for

comparing chemical risks with microbial risks.

Risk-Assessment Methodologies

Methods for chemical risk assessment are relatively well developed;[38] they provide the basis for assessing the risks to humans posed by a given level of exposure to a chemical toxicant. Available methods of chemical risk assessment have important limitations and uncertainties, however, in that they involve extrapolation from animal data to assess human risk and typically provide estimates of statistical upper bounds on risk rather than point estimates of actual human risk. Moreover, there are debates about which methods are most appropriate and reliable for making judgments about actual human risk. Nevertheless, the wealth of experience with chemical risk assessment provides a basis for selecting methods that can serve adequately to compare chemical risks for purposes of risk ranking.

Methods for quantitatively assessing the risks posed by microbial hazards under various conditions of exposure have been developed in recent years, but they are less advanced than methods of chemical risk assessment.[39] The methodological challenges are substantial, because pathogens, unlike chemicals, grow, and their toxicity can change amid the wide range of conditions under which they may enter and be present in food as it moves from production through processing and to the point of consumption. Microbial risk assessment has been used only to a limited extent by food safety agencies, most notably in the recent comparative risk assessment of *Listeria monocytogenes* in various foods, conducted jointly by the FDA and the FSIS, and in assessments of *Salmonella* Enteriditis in eggs and *E. coli* O157:H7 in hamburger. The National Academy of Sciences has recently completed, at the request of the FSIS, a peer review of the agency's *E. coli* O157H:7 risk assessment. The review, which is critical of FSIS methodology, should serve to improve the state of microbial risk assessment. The immaturity of microbial risk assessment is not a significant limiting factor for food safety risk ranking, however, because of the availability of epidemiological data on the incidence of illness associated with specific pathogens.

Health Risk Aggregation Methodologies

Risk ranking begins with risk assessment and data on the incidence of foodborne illness, such as the numbers of illnesses, hospitalizations, and deaths associated (or estimated to be associated) with particular hazards, as outlined in the preceding paragraphs. It also requires, however, an evaluation of the relative public health impact of the adverse outcomes associated with each hazard. From a public health standpoint, a transitory gastrointestinal infection is not the same as an infection that requires hospitalization or causes permanent disability or death. Similarly, an illness, disability, or death experienced by a child may have a different public health impact than one experienced by adults of various ages. To address this issue, methodologies have been developed to evaluate and compare these outcomes.

The challenge is to find common units or metrics to characterize and compare the health impact of diverse risks and health outcomes. The simplest approach is to determine the number of adverse outcomes (illnesses, hospitalizations, and deaths) associated with each hazard of concern and then estimate their economic cost in terms of medical expenses and lost income and productivity. This approach does not take into account the full impact of illnesses and other adverse outcomes, however: It does not consider the pain and suffering of the individual, the burden on family members, or other factors, such as the age of the victim, that might be considered relevant to assessing the full health impact of an illness from an individual or societal perspective. This approach, therefore, is not sufficient for our risk-ranking purposes.

Alternative methods have been developed that provide a common metric for more fully valuing and comparing health risks. These include the quality-adjusted life year (QALY) method and its variant, the disability-adjusted life year (DALY) method, in addition to methods for expressing health impact in monetary terms, primarily on the basis of individuals' willingness to pay (WTP) to avoid the risk involved.

Briefly, the QALY method provides a common metric for assessing both the mortality and morbidity impact of a health risk by estimating the number of life years affected by the risk and assigning numeric weights to "quality-adjust" the life years, with one representing a year of completely healthy life and zero representing death. The weights have been determined on the basis of expert judgment and surveys of individuals. The QALY method is commonly used in public health settings to compare the efficacy of alternative medical interventions to improve health status.

The DALY method is similar, but it includes age-weights—so that a life year for an infant or elderly individual is given less importance than a life year for the young and middle-aged—and it establishes these weighting factors based on tradeoffs individuals would make among various health states at the societal level (e.g.,

preventing ten premature mortalities). It is thus considered by some to be preferable to the QALY method for making societal resource allocation decisions.

The WTP method is based on the economic notion that value is a measure of how individuals would trade off one thing they value for another, in this case choosing between health and other goods. Because money is a common unit of exchange, economists consider it well suited for the analysis of such tradeoffs. The data that economists use to assess value using the WTP method come from the choices that individuals make between reducing health and safety risks and meeting other needs, or from individuals' expressed willingness to pay to avoid a given risk or illness. The WTP method is most commonly used in cost-benefit analyses of specific interventions to reduce risk rather than in risk ranking or resource allocation among diverse risks, though conceptually, it could be used to help value risk reductions in a global risk comparison or priority-setting exercise.

Each of these valuation methods has its distinctive strengths and weaknesses, which affect its suitability for use in food safety risk ranking. No one method is likely to be ideal, and any acceptable risk-ranking model is likely to involve the integration of findings obtained using one or more of these methods with other factors that are relevant to ranking the public health impact of diverse food safety hazards, such as the reversibility of harm and judgments about the public health importance of preventable deaths. The availability of these tools provides options, however, for including objective and quantitative measures of health impact in the risk-ranking model.

Models for Risk Ranking

Most efforts to rank the health impacts of food-related risks have occurred in the context of broad comparative-risk projects. In these ranking exercises, foodborne illness is treated as a single category to be ranked vis-à-vis others (e.g., air pollution), rather than being separated out into different pathogens or food-related threats. (See Appendix for a brief summary of past efforts to rank and compare food safety risks.)

There is no accepted model for comparison and ranking among the diverse health outcomes associated with the broad universe of food safety hazards. Most of the ingredients for developing such a model do exist, however. The challenge is to devise a practicable approach that integrates all of the factors that are relevant to ranking and comparing both microbial and chemical hazards. A key difficulty will be resolving how to compare microbial risks, which generally are determined on the basis of direct measures of human health outcomes, with chemical risks, which are determined in most cases on the basis of data from animal studies. The process of developing an acceptable risk-ranking model will likely involve creating multiple prototypes, each incorporating different assumptions and units of comparison, and then testing and refining possible models so as to arrive at an approach that is transparent, practical, and widely acceptable as a basis for food safety priority setting and resource allocation.

Prioritizing Opportunities to Reduce Risk

Risk ranking is the proper starting point for risk-based resource allocation, because it would permit policymakers to focus attention on the most significant public health problems and develop strategies for addressing them. In a science- and risk-based system, however, resources for research, regulation, and education should be deployed in a manner that maximizes the public health benefit achieved through risk reduction. This means considering, in addition to the relative magnitude of various risks and the value society places on their reduction, the feasibility, cost, and effectiveness of reducing the risks through one or more government interventions at one or more points on the farm-to-table food safety spectrum. In other words, risk-based resource allocation requires prioritizing opportunities to reduce risk, taking into account what we know about what works.

Regulators today certainly draw on their experience about what interventions are effective in reducing hazards and ensuring compliance with risk-related regulatory requirements. For example, the adoption of HACCP for seafood, meat, and poultry was based on knowledge about its effectiveness gained through experience with HACCP elsewhere in the food industry. Likewise, the FDA's pesticide monitoring program is designed and funded at a level that experience and data accumulated over the years show is effective in ensuring adequate compliance with pesticide tolerances. Choices about regulatory priorities and resource allocation are generally made, however, on the basis of informed but subjective judgment and within the context of an existing allocation of resources that is not based on rigorous risk analysis. The vision of a more science- and risk-based system requires establishment of priorities for risk-reduction based on a more rigorous and data-driven analysis. And the state of the art with respect to this kind of systemwide

comparison of risk-reduction opportunities is poor.

We have established tools for and ample experience in assessing individual regulatory interventions, at least prospectively. In response to executive orders going back to President Carter, regulatory agencies have been conducting cost-benefit analyses of major regulations.[40] In the case of food safety regulation, this involves comparing the cost to government and industry of implementing the proposed rule with the benefits of the rule in terms of reduced illness and death. The Office of Management and Budget (OMB) guidelines for such analyses also require at least some analysis of how the costs and benefits of the proposed intervention compare with those of alternative ways of reducing the same risk. These prospective analyses generally show that food safety regulations produce net benefits.[41]

Cost-benefit analysis of specific interventions will remain relevant in a science- and risk-based food safety system to help ensure that the benefits of specific regulations continue to exceed the costs. But much more is required analytically to support risk-based allocation of the government's food safety resources. The question to be answered is not whether a specific intervention to address a specific risk or set of risks passes a cost-benefit test; the question is whether the risks the government has selected to work on and the interventions the government has chosen to reduce them are optimal for risk.

One tool that is available to help answer this question is cost-effectiveness analysis, in which the cost of a regulatory intervention is divided by the benefit (in terms of illnesses or deaths prevented, for example) to reveal the cost per unit of health benefit. Unlike cost-benefit analysis, cost-effectiveness analysis does not monetize the benefits of risk reduction. Rather, it provides a basis for comparing the costs of reducing risk through various interventions and, thus, can help a policymaker determine how resources could best be allocated to achieve maximum risk reduction with the available resources.

Historically, however, little has been done to evaluate the actual effectiveness of regulatory interventions and to compare their effectiveness. In recent years, the FDA and the FSIS have conducted and sponsored some evaluations of specific programs or interventions, such as the FDA's evaluation in 2000 of its seafood HACCP program[42] and an ongoing evaluation the FSIS has commissioned on its HACCP and pathogen-reduction programs.[43] These will be useful, but studies completed to date generally focus on the extent of compliance with regulatory requirements and have neither gone to the level of evaluating the impact of regulatory strategies and interventions on risk reduction nor involved cost-effectiveness comparisons *among* strategies and interventions.

For example, the FDA and the FSIS have attempted to shift from command-and-control regulation to reliance on performance standards, which express the required food safety outcome but provide companies flexibility with regard to how to achieve it. HACCP and the FSIS's *Salmonella* standards are examples of this shift. But is this approach more or less effective in reducing risk than mandating specific interventions? Is it more or less costly to government? To industry? Answering such questions is critical to knowing what regulatory strategies to pursue in the future, but it requires retrospective data collection along with analysis of what has worked in the past and what the actual costs have been. Such retrospective analyses and comparisons are rarely performed.

Little is done as well to compare the feasibility, effectiveness, and cost of regulatory interventions at various points on the farm-to-table spectrum. Traditionally, both the FDA and the FSIS have focused inspection resources and standard setting on processing establishments rather than on the farm or the fishing boat or on downstream distribution, storage, or retail sale of food. This may make sense in general terms, but are there important risks that could be more effectively reduced by intervention at the point of production, such as those occasioned by *E. coli* O157:H7? Are there research, regulatory, or educational interventions at storage or retail levels that could effectively reduce risk? How do interventions on the farm, at the storage level, and at the retail level compare in terms of cost and potential for risk reduction, with actions that could be or are being taken elsewhere? There is important work being done in this area, especially by the Agricultural Research Service and the Economic Research Service, but more is needed.

The lack of sufficient systematic study of what interventions work and why means that we lack the data required to prioritize opportunities for risk reduction. It also means that we lack recognized methods and processes for carrying out such analyses. For example, how can the contributions to reducing foodborne illness made by food safety research and education be measured and compared among themselves and in relation to regulatory interventions? What data and expertise are required? What entity should gather the data and conduct the analysis?

Developing the Decision Tools: Work That Needs to Be Done

The vision of a more science- and risk-based approach to food safety assumes that government has the information it needs to make scientifically sound decisions about the management of specific risks. More broadly, this approach involves making better use of what we know and can come to know in order to deploy the government's efforts in a way that more effectively reduces the burden of foodborne illness. It thus rests fundamentally on having the right decision tools: organized ways of collecting and using relevant information so as to make good regulatory strategy and resource allocation decisions. We see these decision tools as falling into three categories and as requiring considerable work to develop.

The first is a *risk-ranking model* that ranks the public health impact of significant foodborne hazards—including microbial pathogens, chemical contaminants, and intentional threats, such as bioterrorism. A basic risk-ranking model should take into account:

- The incidence and severity of adverse health outcomes resulting from specific hazards
- The economic impact of such health outcomes in terms of the cost of illness and lost productivity
- Social values and other factors relevant to judging the significance of a potential hazard for population health, such as pain and suffering, the impact on children, and the reversibility of adverse impacts

To be useful, such a model needs to be transparent in its criteria and efficient in its use of available data. The challenge is to integrate all the relevant factors in a way that yields a common metric, such as an index value, that will be practical and widely acceptable as the starting point for priority setting. Because this involves multiple scientific disciplines and public health perspectives and there is no empirically "right" way to achieve this goal, the model should be developed collaboratively by a diverse group of experts in risk assessment, public health, food safety, and decision science, and vetted widely among all food system stakeholders. The Food Safety Research Consortium has initiated such a process to develop a risk-ranking model in a project funded by the Robert Wood Johnson Foundation.

The second required category of decision tools comprises *models to prioritize opportunities to reduce risk*. As indicated earlier, such a model would start with what is known about the relative risk or public health impact of specific hazards and then integrate information on the feasibility, cost, and effectiveness of possible interventions, so as to rank opportunities for risk reduction according to the net public health and other social benefits of those opportunities. Developing and implementing such a model means taking an integrated, system approach to understanding how foodborne illness is caused and can be prevented or minimized through the interaction of multiple factors across the entire food system, from production to consumption. It requires, among other things:

- Understanding the relative contributions of specific foods and pathogen-food combinations to the risk of illness
- Understanding the nature and magnitude of the potential risks avoided by the current system—for example, by current pre-market approval and inspection systems
- Knowing what the remaining significant risks are, how they arise, and how they can be controlled, including their amenability to reduction through government intervention or changes in market-based incentives
- Understanding what interventions (for example, research, regulation, and education) are feasible and most likely to be effective in reducing risk
- Understanding who will bear the cost of interventions
- Understanding and comparing the cost to the government and society of various interventions in relation to the degree of risk reduction likely to be achieved

To develop this information and understanding, new protocols and data collection are needed to assess, for example, how the factors affecting the cause and prevention of illness interact across the system; how food safety research is linked to risk reduction; how food safety education affects the behavior of food handlers and, in turn, reduces risk, and how the cost effectiveness of diverse regulatory interventions can be

measured and compared. This work requires substantial involvement by scientists and policymakers working in the food safety regulatory agencies, because it must draw upon intimate knowledge of the agencies' programs, including their objectives, their outcomes, and the resources expended on them.

Ultimately, the vision of a science- and risk-based approach to food safety requires *resource allocation models* that begin with risk ranking and prioritization of opportunities to reduce risk but also take account of legislative mandates (including pre-market approval systems and mandated inspection activity); other public health and public policy priorities, such as bioterrorism; and necessary contingencies for unplanned and unpredictable events. (Bioterrorism poses a novel threat to the safety of the food supply, and the intentional nature of a terrorist attack on the food supply has important implications for hazard and risk assessment. Though a terrorist attack on the food supply has features in common with other conventional foodborne hazards that have emerged in recent years, and decision models used to assess the risk of unintended food contamination can be applied to the possibility of a terrorist attack, additional factors will need to be considered.)

Resource allocation models will not provide a single "right answer" for how to allocate resources. Rather, they will provide a way to consider a variety of parameters—health outcomes, societal values, legislative mandates and restrictions, costs and benefits—in a methodical manner. Policymakers will have to decide which parameters to take into account and how to weight them. Effective resource allocation models will permit them to do this in a systematic and transparent way.

The management of the government's food safety program cannot be reduced to a formula, and resource allocation models must be seen as tools for policymakers, not constraints on sound decision making. A commitment to a science- and risk-based approach, however, implies a commitment to risk-based resource allocation to the greatest extent possible. And that requires an organized framework for considering the factors that are relevant to resource allocation in such a system. The development and use of a risk-based resource allocation model would not only help guide policymakers in deciding how best to use resources; it would also help explain and justify their decisions to Congress and the public. To the extent that there is a need to make significant shifts in resource allocation so as to improve risk reduction, the existence of a credible and transparent model for making and explaining such shifts will help attract the necessary public and political support.

Implementation Challenges

Developing the decision tools and getting to the point of being able to apply them will be complex and time-consuming. The concept of moving toward a more science- and risk-based food safety system whose mission is to reduce the burden of foodborne illness is widely accepted, but the government's food safety program affects a wide range of interests and values in both the public and private sectors and thus has many stakeholders who should be involved in designing any significant change in the system. Their participation in the process of developing important new decision tools will be a necessary but time-consuming part of the process.

The task is difficult for technical reasons. As discussed above, there is an insufficiency of data in some areas, such as that required to evaluate the feasibility and effectiveness of various interventions, and there are novel methodological issues, especially in prioritizing opportunities for risk reduction and creating an inclusive resource allocation model. Substantial data collection, model development, and scientific consensus building will be required.

Finally, it is important not to forget the inherent complexity of the analysis required to design and implement a science- and risk-based food safety system. The decision tools discussed here would make explicit, and bring some analytical rigor to, the many health and other factors that properly influence the design and management of a large and multifaceted regulatory program. Many of these factors are already taken into account by regulatory policymakers, if only subjectively and intuitively, while others are not considered at all today. Putting all of the many factors on the table and analyzing them in some rigorous way is complex and difficult.

For this reason, it will be important to stay focused on the need for the new decision tools to be practical and useful for policymakers and regulators. Their development cannot be an academic exercise, but rather must be a pragmatic effort to develop instruments that can be used realistically, in real life, to improve food safety. This means, as much as possible, distilling something relatively simple out of all the complexity.

Conclusion

The U.S. food safety system rests on a strong foundation, but there is considerable room for improvement if we are to achieve the vision of a science- and risk-based food safety system that makes the best use of available resources in order to reduce the risk of foodborne illness. New decision tools, such as those described in this report, are needed to rank risks and opportunities to reduce risk, which in turn will drive the development of an improved science of program evaluation and priority setting with respect to food safety. The necessary research and methods development requires the collaboration of multiple disciplines in the natural and social sciences, multiple research institutions, and parties in both the public and private sectors. The authors plan to pursue this work through the multidisciplinary, multi-institutional Food Safety Research Consortium. The consortium will seek close interaction with government policymakers and scientists and stakeholders in the consumer and industry communities. The goal is to produce tools of practical utility to policymakers and regulators and to help move toward a more science- and risk-based approach to food safety that all stakeholders can embrace.

Appendix: Experience Ranking Health, Environmental, and Food Safety Risks

by Peter Nelson[*]

This appendix provides a brief summary of experience with risk ranking using different approaches. The first section surveys risk ranking using the quality-adjusted life year (QALY) method and monetization techniques. Experience with ranking food risks has been fairly limited; the second section presents a brief survey of selected literature.

Rankings Using QALY and Monetization Techniques

The Global Burden of Disease is a study by the Harvard School of Public Health that attempted a comprehensive assessment of mortality and disability from diseases, injuries, and risk factors in 1990 and projected to 2020 using the disability-adjusted life year (DALY) approach (Murray and Lopez 1996). The ranking based on DALYs differs significantly from a mortality-based ranking or a ranking based on life years lost.

The National Institutes of Health has examined whether its allocation of research dollars is correlated with DALYs from different diseases and conditions (Gross, Anderson, and Powe 1999). QALYs have been used as the basis for an EPA-sponsored study of the risk-risk tradeoffs involved in improving drinking water quality. Adding disinfectants to drinking water reduces the risk of outbreaks of microbe-related illnesses but also carries with it an increased cancer risk. By modeling different scenarios based on their cost effectiveness per QALY, the study attempts to highlight the tradeoffs (i.e., giardiasis versus cancer) implicit in different scenarios (EPA 1998).

The most prominent use to date of QALY analysis to try to realign priorities was Oregon's Medicaid reform of the early 1990s, which began with a QALY-type approach; a short summary of the Oregon effort can be found in Kaplan (1995). This effort ran into serious difficulties on two fronts. First, the initial rankings produced from the analysis were peculiar, placing treatments for things like thumb-sucking above treatment

for AIDS. Tengs and colleagues (1996) attribute this to technical flaws in the procedure for developing the rankings, but Hadorn (1996) attributes it to weaknesses in cost-effectiveness analysis "at its present state of development." A revised list that omitted costs and was adjusted to reflect the preferences of an 11-member commission was rejected by the first Bush administration on the grounds that it violated the Americans with Disabilities Act.

The ranking of alternative threats (damages) using monetization, or alternative interventions in a cost-benefit framework, has not been that common. This is partly due, no doubt, to difficulties in reconciling different methodologies across studies. In most comparative risk projects, health effects have not been valued beyond the direct costs they impose on the economy. A notable exception is the Arizona Comparative Environmental Risk Project (ACERP). Arizona's economics work group took a broad approach to measuring economic costs (including the assignment of a cost per statistical death); most other states avoid assigning a cost per life. The work group assigned a monetary value to fatalities of $2 million each (Arizona Department of Environmental Management 1995).

Monetary valuation has also been used to rank problems at the national level. The most notable example is the World Bank's *Clear Skies, Blue Water* report, which presents monetary estimates of air and water pollution damage in China. Margulis (1996) presents similar damage estimates for Mexico. Air and water pollution have been estimated to cost 0.4–0.9 percent of gross domestic product (GDP) in the Netherlands and 4 percent of West Germany's GDP in the mid-1980s (Pearce, Markandya, and Barbier 1989).

Experience Ranking Food Safety Risks

Broad Comparative-Risk Projects

The impacts of food-related risks have most commonly been ranked in the context of broad comparative-risk projects. In these ranking exercises, foodborne illness is treated as a single category to be ranked with others (e.g., air pollution) rather than being separated out into different pathogens or food-related threats.

Konisky (2001) surveys a large number of comparative-risk projects conducted in the United States at state, local, and regional levels, using a methodology to standardize rankings from the different projects. Out of the 39 comparative-risk projects considered by Konisky, a threat falling under the category "food quality" was included for ranking 18 times and ranked as a threat of "high" importance seven times (amounting to 18 percent of the total projects surveyed). In a consolidated ranking based on the results of all the projects surveyed, "food quality" ranked as either the third highest or fourth highest threat, depending on the approach used to compute the results; it ranked ahead of such problems as drinking-water pollution, pesticides, toxics, and hazardous waste.

Because each project defined the set of problems to be considered somewhat differently, the term "food quality" served as a rubric for a variety of threats ranked in the different projects, including food contamination (seafood); food contamination/food quality/food safety; pesticide residues on food; and naturally occurring toxins in food. For example, the broad category of foodborne illness was not one of the threats ranked in the EPA's Unfinished Business project, but one component, pesticide residue, *was* included for ranking.

De Hollander and colleagues (1999) ranked environmental threats in the Netherlands using the disability-adjusted life year (DALY) approach. They presented estimates of DALYs from a wide range of environmental threats, including particulate air pollution, ozone air pollution, the presence of lead in drinking water, environmental noise, and foodborne illness. By far the most significant threat was long-term exposure to particulate air pollution, which accounted for almost 60 percent of environmental-related health loss in the Netherlands. Foodborne illness was ranked fourth, behind particulate air pollution, environmental noise, and indoor air pollution. Foodborne illness was estimated to be responsible for more than 4,000 disability-adjusted life years annually, or about 3 percent of the annual environmental-related health loss in the Netherlands.

Incidence and Cost of Illness

While studies of this sort are useful for ranking threats from a broad societal perspective, they do not provide much guidance for reallocating resources within a particular category like foodborne illness. That task requires a finer analysis, focusing on specific diseases, pathogens, and/or pathogen-food combinations. The most notable rankings of specific food-related threats in the United States are the Centers for Disease Control and Prevention estimates of the incidence of foodborne illness (Mead et al. 1999) and the Economic

Research Service's estimates of the economic costs imposed by food-borne bacteria (Buzby et al. 1996).

According to the CDC (1999), three pathogens—Norwalk-like viruses, *Campylobacter*, and *Salmonella*—were responsible for approximately 90 percent of the illnesses and 75 percent of the hospitalizations attributable to known foodborne pathogens; *Salmonella, Listeria*, and toxoplasma acccount for 75 percent of the deaths so attributable. In all, known foodborne agents account for almost 14 million illnesses, 61,000 hospitalizations, and 1,800 deaths annually. Table 1 presents the health impacts of selected foodborne pathogens.

Table 1. Estimated Annual Health Impacts of Known Foodborne Pathogens, United States

AGENT	ILLNESSES		HOSPITALIZATIONS		DEATHS	
	Total	*1997 Rank*	*Total*	*1997 Rank*	*Total*	*1997 Rank*
Campylobacter	1,963,141	(2)	10,539	(3)	99	(5)
Salmonella	1,341,873	(3)	15,608	(2)	553	(1)
Listeria	2,493	(21)	2,298	(4)	499	(2)
Toxoplasma gondii	112,500	(6)	2,500	(5)	375	(3)
Norwalk-like viruses	9,200,000	(1)	20,000	(1)	124	(4)
Total (selected agents)	12,620,007		50,945		1,650	
Total (all known agents)	13,814,924		60,854		1,809	

Source: Mead et al. 1999.

A large proportion of gastrointestinal illnesses, however, are caused by unidentified foodborne agents—and taking into account illnesses caused by unidentified agents raises the numbers considerably. There are 62 million cases of gastroenteritis from unknown foodborne causes each year; of these illnesses, 263,000 result in hospitalization and 3,360 result in death. Therefore, according to CDC estimates, foodborne diseases cause a total of approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths in the United States each year. A less detailed analysis of the comparative impacts of different foodborne diseases in Europe is presented in World Health Organization (1999).

The most comprehensive analysis of the economic costs imposed by foodborne pathogens focuses on a subset of pathogens—namely, bacterial pathogens (Buzby et al. 1996). (This study predates the Mead et al. study, so it relies on somewhat older data.) The Buzby study estimates economic costs using a cost of illness (COI) framework, which they say is likely to yield an underestimate because it fails to take into account the value of avoiding pain and suffering (Harrington and Portney 1987). Six diseases were analyzed: salmonellosis, listeriosis, *E. coli* disease, campylobacteriosis, *Staphylococcus aureus* illness, and *Clostridium perfringens* illness. According to the study, these six illnesses were responsible for between $2.9 and $6.7 billion in economic costs annually (in 1993 dollars). The cost estimates for each disease are presented in Table 2.

Table 2. Economic Costs Imposed by Selected Bacterial Pathogens in the United States, 1993

PATHOGEN	FOODBORNE CASES	DEATHS	COSTS (IN BILLIONS)
Campylobacter jejuni or coli	1.375M–1.75M	110–151	0.6–1.0
Clostridium perfingens	10,000	100	0.1
E. coli	8,000–16,000	160–400	0.2–0.6
Listeria monocytogenes	1,526–1,767	378–485	0.2–0.3
Salmonella (non-typhoid)	0.7M–3.8M	696–3,840	0.6–3.5
Staphylococcus aureus	1.5M	1,210	1.2
Total	3.6M–7.1M	2,654–6,546	2.9–6.7

Source: Buzby et al. 1

The Economic Research Service (ERS) did an assessment of the costs and benefits of strengthening the food inspection process by requiring all federally inspected meat and poultry plants to adopt Hazard Analysis and Critical Control Points (HACCP) procedures (Crutchfield et al. 1999). This analysis required several key assumptions concerning:

- The effectiveness of the regulation in reducing contamination
- The impact of reducing contamination on the incidence of foodborne illness
- The valuation of different health impacts

(The ERS has recently developed a Web-based analytical tool that will allow users to test the costs and benefits of proposed interventions under different assumptions.)

Costs of the HACCP regulation were estimated to be between $1.1 and $1.3 billion over 20 years; benefits were estimated to range from $1.9 to $170 billion. Therefore, even using very conservative assumptions with regard to benefits, the regulation passed a cost-benefit test. The Food and Drug Administration (FDA) has made similar estimates in connection with its regulations mandating HACCP for seafood processors (FDA 1995). In addition to the efforts described above, there have been numerous studies that have looked at the economic costs and benefits of particular food safety policies, but these are not comparative in nature.

One study that looks at the impacts of a specific foodborne pathogen using a DALY framework is the one by Havelaar, de Wit, and van Koningsveld (2000), which estimates the health burden in the Netherlands from *Campylobacter*. Similarly, Mauskopf and Morales (2001) employ a quality-adjusted life year (QALY) framework to present sample estimates for comparing the benefits of inspecting a product for botulism residue versus inspecting a product for pesticide residue. Mauskopf and French (1991) present a procedure for converting QALY measures of foodborne illnesses such as botulism and salmonellosis into monetary values.

Conclusion

Limited efforts have been made to compare food-related risks with those posed by other environmental hazards. Substantial efforts have been made by the CDC and by food safety regulatory agencies to estimate the incidence and costs of foodborne illness associated with specific pathogens. The literature reveals no systematic effort to rank the risks posed by specific pathogen-food combinations or to compare specific pathogen-related risks with risks posed by chemical contaminants.

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Notes

[1]Mead et al. 1999.

[2]Institute of Medicine 1998.

[3]The authors are aware of legislative proposals and the ongoing debate about the need for organizational change to better address food safety problems. The focus of the consortium and of this paper, however, is not on legislative or organizational change but on the development of analytical and decision tools and improved approaches to food safety that can be applied to reduce the burden of foodborne disease under the current laws and organizational structure or any foreseeable new ones.

[4]Merrill and Francer 2000, 83.

[5]Codified at 21 U.S.C. § 321 et seq. (2000).

[6]Section 201(3) of the FDCA and 21 U.S.C. § 321(s) (2000).

[7]60 Fed. Reg. 65096 (December 18, 1995), and 66 Fed. Reg. 6137 (January 19, 2001).

[8]Food and Drug Administration 2002, 42.

[9]Food Safety and Inspection Service 2001.

[10]Food Safety and Inspection Service 1996.

[11]*Supreme Beef Processors, Inc. v. United States Department of Agriculture*, no. 00-11008 (5th Cir., December 6, 2001).

[12]Testimony of Dr. Elsa Murano, Under Secretary for Food Safety, before the House Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, March 14, 2002.

[13]President's Council on Food Safety 2001.

[14]Merrill and Francer 2000, note 3, 86–87.

[15]Act of October 30, 1947, chap. 125, 61 Stat. 163, codified at 7 U.S.C. § 136 et seq. (2000).

[16]See 21 U.S.C. § 346a (2000).

[17]The Food Quality and Protection Act, Pub. L. No. 104–170, 110 Stat. 1489, now codified in 21 U.S.C. § 346a (2000).

[18]Environmental Protection Agency 2002.

[19]President's Council on Food Safety 2001, 13.

[20]U.S. General Accounting Office 2001b.

[21]Institute of Medicine 1998, 4.

[22]Ibid., 9.

[23]Ibid., 5.

[24]Ibid., 11.

[25]Ibid., 27.

[26]Robinson 2001, 21–2; U.S. General Accounting Office 2001a, 2001b.

[27]Robinson 2001, 4.

[28]Ibid., 16.

[29]U.S. General Accounting Office 1994.

[30]Mead et al. 1999.

[31]Food Safety and Inspection Service 2002.

[32]Centers for Disease Control and Prevention 2002; Ostroff 2000.

[33]Food and Drug Administration, Center for Food Safety and Applied Nutrition 2002.

[34]President's Council on Food Safety 2001, 10.

[35]Ibid., 7.

[36]Section 10807, Farm Security and Rural Investment Act of 2002 (P.L. No. 107–171; May 13, 2002) and Statement of Managers on the 2002 Farm Bill, 238–39.

[37]Statement of Managers on the 2002 Farm Bill, 239.

[38]For a general primer on such methods, see Rodricks 1992.

[39]For a general primer, see International Life Sciences Institute 2000.

[40]Office of Management and Budget 1996.

[41]In the case of the USDA's meat and poultry HACCP rule, for example, the Regulatory Impact Assessment required by OMB estimated the 20-year costs of the rule (in present value) to be $1.02–1.2 billion and the 20-year public health benefit to be $7.13–26.59 billion.

[42]Food and Drug Administration, Center for Food Safety and Applied Nutrition 2000.

[43] Food Safety and Inspection Service 1999.

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