Food Safety Research Consortium

Constructing the Analytical Tools for a Systems and Risk-Based Approach to Food Safety

Initial Framework Paper for the FSRC Project on Prioritizing Opportunities to Reduce Foodborne Disease*

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Background

Important shifts have occurred over the past twenty years in how food safety experts in government and the private sector think about achieving food safety. These include the increasing use of risk analysis, especially risk assessment, in food safety decision making; a much-expanded focus on microbial hazards in the food supply; and a new emphasis on prevention of foodborne hazards and illnesses. These shifts are grounded in an improved understanding of the health consequences of foodborne hazards and their associated costs. They are also motivated by growing public demand for continuous improvement in the food safety performance of government, food producers, processors, retailers, and food service operators. New technologies are emerging that facilitate the enhancement of food safety.

These developments and their implications for the federal government's food safety program are charted in two seminal reports of the National Academy of Sciences (NAS). The 1998 report *Ensuring Safe Food From Production to Consumption* (IOM 1998) called for a more integrated effort among the federal food safety agencies and the pursuit of a more science and risk-based approach to reducing foodborne illness, including the allocation of resources across the system in ways most likely to reduce the risk of illness. The 2003 NAS report *Scientific Criteria to Ensure Safe Food* (FNB 2003) discussed the

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* This paper is a collective product of the Food Safety Research Consortium and includes input from representatives of all seven FSRC institutions, including the University of California at Davis (Dr. Jerry Gillespie), the University of Georgia (Dr. Michael Doyle), Iowa State University (Dr. Catherine Woteki and Dr. Helen Jensen), the University of Massachusetts (Dr. Julie Caswell), the University of Maryland (Dr. Glenn Morris), Michigan State University (Dr. Ewen Todd), and Resources for the Future (RFF) (Michael Taylor, Dr. Alan Krupnick, and Dr. Sandra Hoffmann). Additional information on the Food Safety Research Consortium and its agenda are available on its website at http://www.rff.org/fsrc/fsrc.htm (accessed November 23, 2003). Comments on this paper can be submitted to Michael Taylor (taylor@rff.org) or Julie Caswell (caswell@resecon.umass.edu).

need to link food safety hazards and interventions throughout the food production and processing system with health outcomes. It recommended that the federal government establish performance standards at appropriate points in the system as measures of accountability and success in controlling foodborne hazards.

Together these developments point toward a food safety system of the future that is much improved in four key areas: (1) prevention of foodborne illness, (2) clarified responsibility and accountability for the effectiveness of interventions, (3) an integrated approach to food safety, and (4) risk-based allocation of government resources. The 1998 NAS report recommended fundamental statutory and organizational modernization of the federal food safety system to achieve these improvements but, with or without such change, government and private sector policymakers can benefit from new analytical and decision tools to design and manage a more science- and risk-based food safety system.

The Food Safety Research Consortium (FSRC) is developing these tools through a systematic work plan, the groundwork for which was laid in a report issued in 2003 by The Milbank Memorial Fund and Resources for the Future (Taylor et al. 2003). The first major tool, a risk ranking model and decision tool, is already under development by the FSRC, with funding from The Robert Wood Johnson Foundation. The next major phase of the FSRC work plan is to develop the models and decision tools required to prioritize opportunities to reduce risk across the food system, taking into account the relative magnitude of various risks and the feasibility, effectiveness and cost of possible risk reduction interventions. The FSRC has received funding to begin this phase of its work plan from the U.S. Department of Agriculture's Cooperative State Research, Education, and Extension Service (CSREES), through its National Integrated Food Safety Initiative.

The goal of the CSREES-funded project is to develop a conceptual framework for prioritizing opportunities to reduce the risk of foodborne illness. This conceptual framework will be based on an integrated, systems understanding of foodborne illness and will include a connected set of proposed models and decision tools, as described preliminarily in this paper. This paper is the starting point for the project. Comments are invited. The ideas in this paper will be further developed and refined throughout the project based on the work of FSRC researchers and input from the expert and stakeholder communities.

An Integrated, Systems Approach to Food Safety

We propose to begin with an integrated, systems model of foodborne illness, which permits a more complete investigation and understanding of the many factors that contribute to the causation and prevention of foodborne illness caused by a specific foodborne hazard, such as a pathogenic organism or chemical toxin. This approach recognizes that opportunities to reduce the risk of foodborne illness arise throughout the food system. Our premise is that the goal of reducing foodborne illness can best be achieved by harnessing the best available scientific data and understanding and then deploying effort and resources in ways that produce the greatest reduction in illness with the resources available.

The effort and resources relevant to this approach to food safety reside all across the food, agriculture, and health sectors, in both public and private institutions, and include:

- Government regulatory programs at the federal, state, and local level, including standard-setting, inspection, and enforcement, at any appropriate point on the food system spectrum from farm to table;

- Government investments in the form of research, technology transfer, and education that can make available new knowledge and interventions and contribute to the behavioral changes required to reduce the risk of illness;

- The actions of private sector, commercial participants in the food system, as influenced by the incentives of the marketplace and by government interventions, and that contribute to both causing and reducing the burden of illness;

- National, state, and local public health and health care infrastructures, as they affect surveillance, diagnosis, and treatment of foodborne illness and thus the overall effort to reduce the burden of illness; and

- The actions of individuals as purchasers, preparers, and consumers of food and thus as agents in the causation and prevention of illness.

This spectrum of actors and actions comprise the nation's *food safety system*. The basic assurance of food safety that Americans enjoy today rests on the day-to-day activities of these actors. The food safety agencies are implementing food safety laws and regulatory programs, as mandated by Congress, that require commercial participants in the system to observe good sanitation practices and guard against the presence of harmful chemicals and bacteria in food. Food producers, processors, retailers, and food service operators have their own food safety programs that often, in response to market pressures, go beyond what the government requires. Consumers themselves play a significant role in the causation and prevention of illness through their food handling and preparation practices, and their purchasing power and personal preferences influence both commercial food producers and government agencies.

The persistence of foodborne illness as a significant public health issue demonstrates that there is room for improvement in how the food safety system works to prevent such illness.[1] The question is how to best undertake this improvement.

- How do we know what are the most important foodborne hazards from a public health perspective?

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[1]For example, the Centers for Disease Control and Prevention (CDC) estimates that the known bacterial and viral pathogens in food result annually in 5,000 deaths, 325,000 hospitalizations, and 76 million cases of illness (Mead et al 1999).

- If we are to shift effort and resources to more productive risk-reduction activities, how do we decide what they are?
- How do we prioritize opportunities to reduce risk?
- How do we integrate answers to these questions with all the other factors that are properly relevant to allocating both public and private food safety resources?

Policymakers answer these questions every day, sometimes explicitly, based on their judgment and available information about specific problems. At least as often, they answer these questions implicitly, through their decisions and actions, without overt consideration of how particular actions compare with other possible actions in terms of potential contribution to risk reduction. Across the board, policymakers currently lack the tools that would permit them to systematically analyze all data and options in order to make rigorous, risk-based, outcome-driven decisions about how best to deploy their efforts and resources. The development of such tools is essential if the aspirations for a science- and risk-based food safety system are to be fulfilled.

Constructing a Systems Approach: Models and Decision Tools

The development of the tools for a more science- and risk-based food safety system should be grounded in an integrated, systems approach to understanding both the causation and prevention of foodborne illness. Causation and prevention are products of interaction among multiple factors across the entire supply chain from farm inputs to on-farm production, through food processing, retail distribution, food service preparation, and in-home consumption. This integrated understanding of foodborne illness is not new from a scientific perspective but is just now starting to become an important factor in the evolution and design of the government's current food safety activities (Taylor et al. 2003).

Causation and prevention can be thought of as parallel tracks in the food system. At every step along the supply chain and exposure pathway where microbial or chemical risks are introduced or multiply, there is an opportunity for a change in behavior or an intervention to reduce the level of risk. If the cumulative, net effect of any such measures is to reduce the level of exposure below that required to cause infection or trigger a toxic response, illness is prevented.

With this understanding in mind, the Food Safety Research Consortium's goal is to develop tools that will facilitate the use of sound risk analysis in the evaluation and choice of measures to prevent foodborne illness and, ultimately, enable decision makers to prioritize opportunities to reduce food safety risks. The tools must address several analytical steps, including (1) risk-based assessment of foodborne hazards, (2) ranking the public health impacts of specific hazards, (3) measurement and valuation of the benefits of reducing risk, (4) evaluation of the effectiveness and cost of risk reduction intervention options, and (5) integration of these analyses to prioritize risk reduction opportunities and allocate food safety efforts and resources accordingly. It is also important to develop post hoc evaluation tools to measure the actual success of prevention efforts in reducing foodborne illness.

The FSRC will construct its overall framework for decisionmaking and decision tools through the development of connected modules. Figure 1 shows the overall framework and the flow of information needed for risk-based priority setting and decision making, with each box representing a distinctive set of information. Some boxes in Figure 1 will be supplied by existing information (e.g., risk assessments conducted by federal agencies), while others will be comprised of modules developed by FSRC to generate and organize information. Some boxes represent outputs that will contain combinations of existing and FSRC-generated information.

The FSRC modules will contain models and/or decision tools. The distinction between the two is:

- Models are representations of important functional relationships in parts of the food safety system coupled with data that permit these relationships to be understood and analyzed. Examples include toxicology and risk ranking models, intervention effectiveness models, and models of cost transmission in supply chains.

- Decision Tools are computer- and web-based, interactive programs that organize and aggregate information needed for decision making on foodborne illness prevention. Empirical information from the models will frequently be inputs to these tools. The tools allow users to alter assumptions in order to evaluate a range of "what if" scenarios (e.g., put more emphasis on some health outcomes rather than others, use different assumptions about the effectiveness of given interventions).

In practice, the models and decision tools form a continuum from the underlying conceptualization and measurement of relationships through to presenting information from the models in a tool format that can be used by policymakers. Following is a discussion of the content of the Figure 1 boxes.

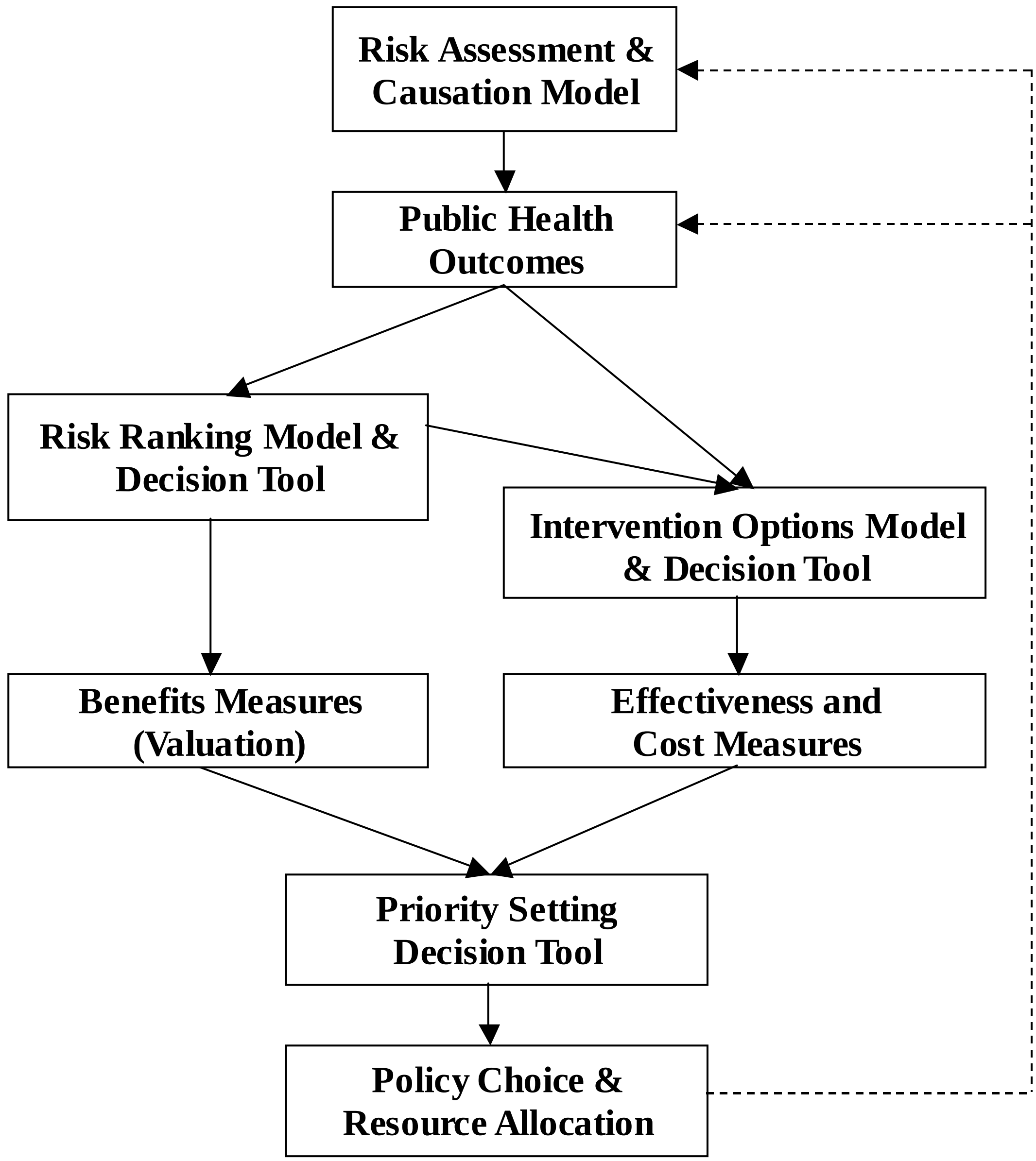

Figure 1. A Framework for A Systems Approach to Foodborne Illness Prevention

Risk Assessment and Causation Model

The risk assessment and causation model element of the systems approach involves consideration of the conditions, events, and behaviors that contribute to a person becoming ill from a foodborne hazard. In the end, whether a foodborne hazard—such as a microbial pathogen or chemical contaminant—makes a person ill depends on the inherent pathogenicity or toxicity of the hazardous agent, the level and duration of exposure, and the sensitivity of the consumer to the agent. The interaction of these factors is the *exposure event*.

For chemical hazards, such as lead, mercury, and dioxins, the interaction of these factors at the point of consumption is generally considered and described in a predictive, toxicological model based largely on data from animal studies (Rodricks 1992). For microbiological hazards, the causation of illness at the point of consumption is generally described retrospectively through clinical or epidemiological observation, though predictive risk assessments have been conducted in several important cases, such as *Salmonella enteriditis* in eggs (FDA 1998), *Listeria monocytogenes* in selected ready to eat foods (FDA 2001), *Vibrio parahaemolyticus* in raw Molluscan shellfish (FDA 2001), and *E. coli* O157:H7 in ground beef (USDA 2002).

In addition to the exposure event at the point of consumption, a causation model requires consideration of the factors that lead to the presence of the pathogen or chemical contaminant in food at a level capable of causing illness (referred to as the *transmission pathway*). For chemical contaminants, these factors include: (1) the human activities and natural processes that produce the chemical and result in its presence in food; (2) any bioaccumulation that might occur through the food chain, such as with lipophilic compounds like dioxins; and (3) the level of contamination and patterns of consumption of foods containing the chemical, which, when aggregated for any individual, determine both acute and chronic exposure to the chemical.

For microbiological hazards, the transmission pathway includes all these factors but is made more complicated by the biological fact of growth, when conditions permit, and the possibility that pathogens can be killed and rendered harmless during processing or cooking. Thus, whether a microbial pathogen is present in food at the point of consumption at a level that is sufficient to cause illness will be a function not only of the level of initial contamination, but also of all the factors that affect the potentially rapid growth and possible death of the pathogen.

In the case of *E. coli* O157:H7, for example, the complex transmission pathway begins in the bovine gut, where specific ecological factors affect the likelihood of colonization and the presence of the pathogen in the feces, which become the vehicle for contamination of food. The complexity continues in that conditions and practices at the animal production level affect the growth and spread of the pathogen among animals; and conditions and practices at slaughter and initial processing affect the spread among beef carcasses. The slaughter step is where the initial contamination of meat typically occurs and the likelihood of contamination and the number of organisms is affected by factors such as the particular carcass dressing practices used, carcass sanitizing interventions, and temperature conditions. The transmission pathway then extends all the way through final processing (such as to produce ground beef), storage, distribution, retail sale, and final preparation and cooking for consumption. At each step, the level of contamination—and ultimately the level at which the consumer is exposed—can increase or decrease depending largely on human-controlled conditions of time and temperature and the application of specific pathogen reduction interventions.

The understanding of the *causation* of illness for a particular chemical or pathogen is the first element in the integrated, systems approach to understanding foodborne illness. For particular analyses, the Consortium may rely on existing risk assessments and/or model the relevant risk situation to generate information for the subsequent analysis.

Public Health Outcomes

The risk assessment and causation model leads to an understanding of the incidence and etiology of foodborne illness, which is the public health outcome of central concern in an integrated, systems approach to food safety. The public health outcomes box in the systems approach diagram emphasizes this central role. While measures of public health outcomes are central to all the boxes, we include this separate box as a point of overall evaluation of the performance of the system, particularly over time as new sets of interventions are put into place.

Risk Ranking Model and Decision Tool

A crucial step in designing and implementing a science- and risk-based food safety system is identifying the most important food safety problems from a public health perspective. This knowledge does not, by itself, answer the question of how best to deploy food safety efforts and resources, but it helps policymakers focus their further analytical work and possible data collection on the specific foodborne hazards that are making the greatest contribution to foodborne illness and its adverse health consequences.

As depicted in Figure 1, the risk ranking model provides initial guidance on where to focus further analytical efforts, a framework for targeted collection of data to refine and adjust rankings over time, and an ongoing tool for monitoring changes in the relative importance (and thus possible priority) of foodborne hazards. The linked decision tool is a means of presenting information on risk ranking from the model to decision makers in a format that they can easily use and work with to produce “what if” scenarios. This model provides a means not only to rank the public health impact of specific hazards but also to assess the benefits of risk reduction.

The FSRC’s work on the risk ranking model, decision tool, and related benefits measures is well underway, with funding from the Robert Wood Johnson Foundation. This tool is in the form of an interactive and adaptable computer-based model for ranking the public health impact of specific pathogen-food combinations, such as *Salmonella* in poultry, *Listeria monocytogenes* in dairy products, and *E. coli* O157:H7 in ground beef (FSRC 2003). It produces rankings by integrating data on: (1) the incidence of adverse health outcomes associated with specific pathogens, (2) the attribution of these outcomes to specific food categories, and (3) the relative importance of these outcomes using alternative measures of impact. The Consortium risk ranking model and decision tool is organizing the best available information in these three areas, but more work is needed on this model and decision tool, primarily to expand and refine the data on food attribution and economic valuation, before it will be useful for policymaking purposes.[2]

Data on the incidence and severity of foodborne illnesses has improved substantially in recent years but remains incomplete in certain respects. On the microbial risk side, the Centers for Disease Control and Prevention reports through its FoodNet sentinel site surveillance system on illnesses associated with specific pathogens. Based on these and other data, CDC estimates the nationwide incidence of illness—reported as the number of cases, hospitalizations, and deaths—associated with a range of bacterial and viral pathogens (Mead et al. 1999). The data on incidence of illness are improving through the FoodNet active surveillance system administered by CDC in collaboration with state health departments.[3] There are significant gaps, however, in the data that permit the linking of illnesses to specific pathogen-food combinations. Currently, the best available data for making such attributions are derived from investigations and reports of illness outbreaks,[4] but further work is required to learn more about the foods and pathogens causing the sporadic cases that comprise the majority of foodborne illness outcomes. On October 31, 2003, the Food Safety Research Consortium convened a workshop, including representatives of USDA, the Centers for Disease Control, the Food and Drug Administration, and the Environmental Protection Agency, to discuss ways of improving food attribution data.

Economic and other valuation measures are important because rankings of public health impact need to consider and compare the relative significance of illnesses associated with specific pathogen-food combinations. Some pathogens result mostly in transitory gastrointestinal infection and diarrhea. Others pose a greater risk of hospitalization, long-term health damage, and death. To rank the public health impacts of pathogen-food combinations, and the related benefits of avoiding these impacts, diverse health outcomes must be valued in some fashion so that, for example, the public health importance of 1000 transitory cases of diarrhea can be compared with the public health importance of 10 hospitalizations, or one death.

[2] To date the Consortium's risk ranking effort has focused on microbial sources of foodborne illness. For policymaking purposes, it is important to include risks posed by chemicals in the ranking, especially those posed by environmental contaminants such as lead, mercury, dioxin and aflatoxin. These chemicals are not subject to a pre-market safety review, such as applied to food additives and pesticide residues, and may pose risks that justify further control efforts.

[3] Further information is available on the FoodNet website at http://www.cdc.gov/foodnet/ (accessed November 23, 2003).

[4] The most complete, publicly accessible compilation is maintained by the Centers for Science in the Public Interest. http://www.cspinet.org/reports/outbreak_report.pdf (accessed November 23, 2003).

The risk ranking model and decision tool incorporate alternative methodologies for enumeration and valuation of health outcomes. These include: (1) direct measures of health outcomes such as illness, hospitalization, and death, (2) measures of loss of health function used in the medical field, such as the quality adjusted life year (QALY) tool, (3) economic calculations of the cost of illness in terms of medical costs, lost productivity, and other costs, and (4) economic calculations of individuals' willingness to pay (WTP) to avoid the loss of welfare associated with an illness, including pain and suffering.

The point of these valuations and comparisons is to give full weight in food safety decisionmaking to the actual public health impacts foodborne hazards and not to suggest that any illness is unimportant or unworthy of preventive efforts. Under current food safety laws, the food industry has a general obligation to prevent harmful contamination of any kind, and even transitory illnesses are of concern to consumers. The point of these comparisons is to inform decisions about how best to deploy available and inevitably scarce resources within the food safety system to do a better job of reducing the public health impact of foodborne illness.

Benefits Measures

An important output of the risk ranking model and decision tool is measures of the potential benefits that could be achieved by addressing specific foodborne risks. While this output is a part of the risk ranking box, we put it in a separate box in Figure 1 to highlight its contribution to priority setting in the next step of the framework. There is a very active debate about how best to measure the value of health outcomes and, in turn, the benefits of preventing illnesses.[5] Moving toward a more common understanding of how best to value health outcomes for food safety purposes, using one or more of the available valuation methods, or perhaps an integrated valuation index, is important to the future use of risk ranking in policymaking. The risk ranking decision tool generates rankings based on several valuation methodologies at the discretion of the user.

Intervention Options Model and Decision Tool

A key objective of the integrated, systems approach to food safety is to allocate resources in a way that is likely to be most effective in reducing the overall public health burden of foodborne illness. This requires knowing what the most significant risks are, but it also requires knowing which intervention options at what points in the system are likely to make the greatest contribution to reducing risk, based on a thorough analysis of their feasibility, cost and effectiveness, and of incentives, both public and private, to adopt those options. The Consortium is in the process of outlining a methodology to model intervention options, their effectiveness, and their costs. The Consortium will also develop a decision tool, comparable to and compatible with the risk ranking decision tool, which can be used by decision makers to explore the likely outcomes of different scenarios of interventions. The model and decision tool will incorporate the current set of

[5] See materials from a Resources for the Future (RFF) Conference on Valuing Health Outcomes, conducted in February 2003. http://www.rff.org/rff/Events/calendardetail.cfm?eventID=254&eventyear=2003 (accessed November 23, 2003).

interventions (i.e., the status quo) as a base case to which changes may be compared. As this effort is under development, we here discuss several considerations that enter into this development.

Existing levels of foodborne health risk reflect the success of current interventions in reducing risk. Understanding what current interventions are achieving with respect to those risks, and at what cost, is essential to the eventual analysis of changes in interventions. The analysis of current interventions requires identifying the practices and interventions that are currently in place throughout the food chain to reduce risk. These interventions include: (1) actions by commercial participants in the food system through preventive controls and other contamination and exposure reduction strategies, (2) government interventions, including food safety research, regulation and education; and (3) actions of individuals as purchasers, preparers, and consumers of food.

The types of questions that must be addressed in analyzing current practices and interventions in relation to specific hazards include:

- How are generally observed food hygiene practices in the commercial food production sector and among consumers addressing the initial contamination and resulting risk?

- Have targeted interventions to minimize the risks been implemented? If so:

    - At what point in the farm-to-table spectrum?
    - By whom?
    - In response to what type of signal: regulatory, tort liability, or market pressure?

- How effective are current interventions, both general and targeted, in reducing risk and foodborne illness outcomes?

- What are the costs of current interventions?

    - To the private sector?
    - To government?
    - To consumers?

The answers to these questions permit an appraisal of how well and at what cost current food safety practices and interventions are working to reduce the risk of illness.

The next step is to identify and evaluate potential alternative interventions. An integrated, systems understanding of foodborne illness requires consideration of all plausible opportunities to reduce the risk of illness across the spectrum from production to consumption. For example, for *E. coli* O157:H7, alternatives might include vaccination of cattle or other interventions to prevent initial colonization, even though initial colonization of cattle with these bacteria often occurs naturally, or targeted interventions and testing to control the pathogen in ground beef. It could also include better reporting and sharing of data on illness outbreaks so that more effective steps can be taken to contain outbreaks and learn from them to improve future prevention measures.

Questions involved in identifying and evaluating alternative interventions include:

- Are there known or potential practices or technologies that could prevent or mitigate hazards at particular points in the supply chain?

- What are the obstacles to their implementation?

- How might implementation of these interventions be induced?

    - Through government regulation?
    - Through market-based incentives?
    - Through commercial food handler or consumer education?
    - Other approaches?

- For any intervention or set of interventions, what degree of effectiveness can be expected in reducing contamination and resulting foodborne illness?

- What are the costs of the interventions and how are they shared throughout the food system?

    - By the private sector?
    - By the government?
    - By consumers?

- Are there key gaps in knowledge that limit the ability to prevent or mitigate hazards and that could be filled through data collection or other research?

    - At what cost?
    - Over what time frame?

- Are there possible changes in current practices for reporting, diagnosing and treating illness that would reduce the public health impact of foodborne illness? At what cost?

The overall goal of the effort to develop an intervention options model and decision tool is to provide a flexible approach to analyzing alternatives that: (1) takes into consideration the regulatory and private incentives to produce food safety, (2) measures the impact of changes in interventions across the food supply chain through to consumers, and (3) evaluates the effectiveness and costs of intervention alternatives. The decision tool will be designed to allow users to work with different assumptions regarding these factors.

Effectiveness and Costs Measures

An important output of the intervention options model and decision tool is measures of the potential effectiveness and costs of alternative interventions for reducing foodborne health risk. While this output is a part of the interventions options box, we put it in a separate box here to highlight its contribution to priority setting in the next step of the framework. As with benefits measures, there is an active debate regarding the appropriate methodology to be used in generating measures of intervention effectiveness and cost.

Data and estimates from the model will be generated in a format that may be used in different ways. For example, the data can be used, in combination with health outcome measures from the benefits box, to calculate measures of cost effectiveness (e.g., the cost per statistical life saved, QALY gained per each $1 million of expenditure). Cost estimates may be used in combination with economic estimates of benefits to conduct benefit/cost evaluations of potential interventions. The decision tool will allow use of different approaches at the discretion of the user.

Priority Setting Decision Tool

The priority setting decision tool is intended to inform choices and resource allocation in both the public and private sectors. The tool will bring together information on risks of illness and their causation, as well as interventions that can prevent or reduce the risk of illness. The data and understanding it will generate about the effectiveness of current and proposed interventions is intended to lead to the development of more effective risk management strategies for food safety.

The priority setting decision tool will permit analysts for the first time to link possible changes in food production and handling practices with health outcomes and to project the likely effect of possible risk reduction interventions. Just as the risk ranking model provides the basis for focusing on the most significant hazards in the food supply, the intervention options model will provide the basis for focusing on the points in the farm-to-table continuum where interventions are likely to have the most effective impact in reducing illness. Deciding how to prioritize opportunities to reduce risk and allocate food safety efforts and resources is risk management. In food safety decisionmaking to date, little has been done to rigorously evaluate and compare current and proposed interventions, especially regarding their relative benefits and cost-effectiveness and how they interact with each other and with the other factors that affect the risk of illness, and to set priorities and allocate resources accordingly. This tool is intended to provide a framework for the improvement of risk system-wide management.

The priority setting decision tool will integrate and analyze the results of the risk ranking and intervention options modules. It will allow the user to: (1) project and place a value on the risk reduction benefit that is achievable through one or some combination of alternative interventions, and (2) rank the risk reduction opportunities and intervention strategies on the basis of their public health impact, cost effectiveness, or benefit/cost ratio.

For policymakers responsible for designing the government's food safety program and allocating its efforts and resources, a primary consideration is the cost to the government of designing and implementing an intervention. Private sector costs are also relevant to the analysis, however, for two public policy reasons. First, under current Executive Orders, the costs and benefits of significant regulatory interventions must be evaluated, with the goal of maximizing benefits in relation to the costs and, ideally, ensuring that the overall social benefits exceed the social costs.[6] Second, in a food safety system that is recognized to encompass both public and private sector efforts and in which all possible intervention strategies are considered, the feasibility and cost of risk reduction interventions to commercial participants are relevant to devising, through public policy, both regulatory interventions and market-based incentives for reducing the risk of illness.

Over the past two decades, an enormous amount of foodborne illness and food safety research and data collection that is relevant to priority setting have been conducted by government, academic, and food industry researchers. Much of the required data for food safety priority setting thus exists. The critical challenge is to access and assemble existing data, while filling data gaps, in a way that makes them useful to analysts seeking to improve the effectiveness of the food safety system in reducing risk. An important benefit of developing modules of the Consortium's systems approach is to help identify the most critical data that need to be assembled and the gaps in data that need to be filled through future research, data collection, and data assembly.

Policy Choice and Resource Allocation

The policy choice and resource allocation box is included in the systems approach to acknowledge that policy makers take into consideration a broader range of factors in making decisions than are included in our risk analysis and priority setting framework. Our approach is a tool for public policymakers to help incorporate the insights gained through risk analysis into a big picture understanding of how best to manage the food safety system. In a more science- and risk-based food safety system, policymakers will ground their priority setting efforts in risk ranking and evaluation of intervention options. In allocating their resources prospectively, however, policymakers must also take account of legislative mandates (including the cost and risk reduction effectiveness of 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. Risk management must also take into account public preferences and perceptions about risk, the social and human factors affecting change within the food system, and other factors that do not fit neatly into a data-driven risk analysis framework.

[6] See Memorandum for the President's Management Council, from John D. Graham, Administrator, Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget, Executive Office of the President, Re: Presidential Review of Agency Rulemaking by OIRA, September 22, 2001. http://www.whitehouse.gov/omb/inforeg/oira_review-process.html (accessed November 23, 2003).

These are important but beyond the scope of this paper. In the end, the risk-based, systems approach to food safety developed by the Consortium will be supplemented with consideration of additional factors, and risk management decisions will be a product of risk analysis and the other legitimate public policy considerations that enter the decision process.

Feedback Loops

The systems approach detailed in Figure 1 is a continuous loop, with much simultaneous activity. In the light of prior risk management decisions and other developments, risk assessment and causation models need to be reassessed for accuracy. Public health outcomes will be measured on an on-going basis. New risk rankings and new sets of alternative interventions will be analyzed. Adjustments will be made to priority settings and policy choices as new information becomes available and the results of prior efforts are evaluated. The central focus throughout is on making the best use of available resources to achieve desirable public health outcomes.

Conclusion

The test of the framework outlined here will be whether the resulting models and tools have practical utility for policymakers and others interested in how best to reduce the public health burden of foodborne illness. This framework is intended to be used in an on-going, dynamic process that makes data collection, risk analysis, and program evaluation "built-in" features of how society addresses foodborne illness, with continuous feedback as risk patterns change and progress occurs over time.

This approach builds on much that has been done within the food safety system over the past decade to improve the system's focus on the most significant hazards and on the goal of reducing foodborne illness. It is an approach that is, by design, more quantitative and analytically rigorous than current approaches to food safety policymaking and resource allocation. It is intended to be a practical approach that is useful in the real world of government decisionmaking. Much work remains to be done to develop the tools described here. For the tools to achieve there purpose and make a meaningful contribution to improving food safety in the United States, the work must engage the creativity and effort of scientists, policymakers, and food safety practitioners throughout the food system.

For further information on the FSRC's current CSREES project on Prioritizing Risk Reduction Opportunities, please contact Dr. Helen Jensen at Iowa State University (hhjensen@iastate.edu) or Jody Tick at RFF (tick@rff.org).

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