Food Safety Research Consortium
A MULTI-DISCIPLINARY COLLABORATION TO IMPROVE PUBLIC HEALTH

DISCUSSION PAPER SERIES

DECEMBER 2005

Prioritizing Opportunities to Reduce the Risk of Foodborne Illness

A Conceptual Framework

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Abstract:

Determining the best use of food safety resources is a difficult task faced by public policymakers, regulatory agencies, state and local food safety and health agencies, as well as private firms. The Food Safety Research Consortium (FSRC) has developed a conceptual framework for priority setting and resource allocation for food safety that takes full account of the food system's complexity and available data but is simple enough to be workable and of practical value to decisionmakers. The conceptual framework addresses the question of how societal resources, both public and private, can be used most effectively to reduce the public health burden of foodborne illness by quantitatively ranking risks and considering the availability, effectiveness, and cost of interventions to address these risks. We identify two types of priority-setting decisions: Purpose 1 priority setting that guides risk-based allocation of food safety resources, primarily by government food safety agencies, across a wide range of opportunities to reduce the public health impact of foodborne illness; and Purpose 2 priority setting that guides the choice of risk management actions and strategies with respect to particular hazards and commodities. It is essential that such a framework be grounded in a systems approach, multi-disciplinary in approach and integration of data, practical, flexible, and dynamic by including ongoing evaluation and continuous updating of risk rankings and other elements. The conceptual framework is a synthesis of ideas and information generated in connection with and during the three FSRC workshops convened under a project funded by the Cooperative State Research, Education, and Extension Service of USDA.

Workshop materials are available on the project website: http://www.card.iastate.edu/food_safety/.

Prioritizing Opportunities to Reduce the Risk of Foodborne Illness

A Conceptual Framework

The Food Safety Research Consortium (FSRC) has developed a conceptual framework for prioritizing opportunities to reduce the risk of foodborne illness under a project funded by the Cooperative State Research, Education, and Extension Service (CSREES) of the United States Department of Agriculture (USDA), National Integrated Food Safety Initiative.[1] The project takes advantage of the FSRC's ongoing development of a computer-based model for quantifying and ranking the public health impact of specific foodborne hazards. The project Prioritizing Opportunities to Reduce the Risk of Foodborne Illness addresses the follow-on question of how societal resources, both public and private, can be used most effectively to reduce the public health burden of foodborne illness.

The fundamental idea behind this conceptual framework is that public and private actors can improve how they set food safety priorities and allocate resources by quantitatively ranking risks and considering the availability, effectiveness, and cost of interventions to address these risks.

Introduction

Determining the best use of food safety resources is a difficult task because the food system itself and the natural and human factors that contribute to the cause and prevention of foodborne illness are very complex. The goal of this project, therefore, is to devise a conceptual framework for priority setting and resource allocation for food safety that takes full account of the system's complexity and available data but is simple enough to be workable and of practical value to decisionmakers. The framework is only the starting point. The next step is the development of specific analytical tools and data systems to implement the

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A grant from USDA's Cooperative State Research, Education, and Extension Service (CSREES), National Integrated Food Safety Initiative, Award No. 2003-51110-02063 provided financial support for this work.

[1] More information on the FSRC is available on the website: http://www.rff.org/fsrc/fsrc.htm. This document was produced through the collaborative effort of researchers at all seven FSRC institutions. The project is coordinated by Helen H. Jensen at Iowa State University. Other co-principal investigators are Julie Caswell, University of Massachusetts; Mike Doyle, University of Georgia; Jerry Gillespie, University of California at Davis; J. Glenn Morris, Jr., University of Maryland; and Michael Taylor, formerly Resources for the Future (RFF) and now University of Maryland. Other key contributors include Ewen Todd, Michigan State University; James Dickson, Iowa State University; Catherine Woteki, formerly at Iowa State University and now Mars, Inc.; John Galland, University of California at Davis; and Michael Batz, Sandra Hoffmann, and Alan Krupnick, RFF.

framework and thus help achieve the ultimate goals of better resource allocation and risk management and a reduced public health burden of foodborne illness. The proposed conceptual framework and analytical tools harness available information on the magnitude and distribution of risks and the effectiveness and cost of interventions to inform objectively, but not dictate, decisions about priority setting and resource allocation.

An "opportunity" to reduce the risk of foodborne illness exists when there are identifiable actions or control strategies that could be applied to a specific hazard. We define these risk management actions and strategies as "interventions," a broad term intended to capture typical government and private actions, including but not limited to implementing changes to a process or behavior, introducing physical measures to prevent or decrease contamination, setting food safety performance standards, defining best practices (Good Agricultural Practices, Good Manufacturing Practices, Hazard Analysis and Critical Control Points), changing labeling requirements, or educating food handlers.

In this document, we first identify two types of priority-setting decisions and provide some key principles of the framework. Next, we introduce the four analytical elements that comprise the framework. We detail how these four analytical elements inform Purpose 1 priority setting and, subsequently, how they inform Purpose 2 decisions.

The framework is a synthesis of ideas and information generated in connection with and during the three workshops convened under this FSRC project. Workshop materials are available on the project website: http://www.card.iastate.edu/food_safety/. Appendix A contains the objectives of and a listing of presentations for the three workshops.

Two Purposes

The nature of the data and analysis required to set food safety priorities depends on the purpose for which the priority setting is being done, and there can be a host of such purposes in both the public and private sectors. Relevant food safety priority-setting decisionmakers include Congress and those developing annual federal budgets; regulatory agencies such as the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA); the Centers for Disease Control and Prevention (CDC); state and local food safety and health agencies; and private enterprises involved in food production, processing, marketing, and preparation. For a more detailed review of the institutional contexts for priority-setting decisions, see Appendix B.

For the sake of simplicity and clarity, the conceptual framework defines two priority-setting contexts relevant for these decisionmakers and organizations:

- *Purpose 1* is to guide risk-based allocation of food safety resources, primarily by government food safety agencies, across a wide range of opportunities to reduce the public health impact of foodborne illness arising from diverse hazards and commodities. Purpose 1 priority setting helps policymakers identify the risks in the food supply and the points on the farm-to-table continuum that should be targeted for reducing these risks but does not reveal the most effective risk management actions or strategies. Purpose 1 can be described, therefore, as broad resource allocation.

- *Purpose 2* is to guide the choice of risk management actions and strategies, by either public or private risk managers, with respect to particular hazards and commodities. Purpose 2 priority setting involves more data-intensive analysis aimed at quantifying and comparing, where possible, the relative effectiveness of alternative risk management actions and strategies. Purpose 2 can be described, therefore, as targeted risk management.

Within the conceptual framework, Purpose 1 priority setting typically involves looking at the broad range of risks that arise across the food system or jurisdiction of an agency. An example of a Purpose 1 context is determining which of many possible pathogens or chemical residues pose the greatest concern to public health and therefore deserve priority attention for action or further analysis.[2] Typically, regulatory agencies look at Purpose 1 within their own jurisdictions or, in the case of CDC and other crosscutting agencies, across the entire food system. The conceptual framework for Purpose 1 priority setting would be particularly helpful to programs or agencies during strategic planning, in developing annual work plans and annual budget requests. Eventually, Congress could use such analysis to inform the authorization of legislation and annual appropriations.

Because of the breadth and complexity of the food safety issues confronted in Purpose 1 priority setting, the analysis is necessarily and appropriately

[2] Potential hazards arising from intentional contamination of the food supply, such as through a bioterrorism incident, are also important to consider in priority setting. Efforts to quantify the public health importance of such hazards and assess the cost and effectiveness of interventions to minimize them, however, pose data and methodological challenges that differ in important respects from hazards posed by the more traditional and better-studied hazards that result from unintentional contamination. Intentional contamination is thus not addressed in this framework but is an important topic for future work.

conducted to consider major policy decisions or broad resource allocation compared with the more intensive and narrowly focused analysis that supports Purpose 2 priority setting.

Purpose 2 risk management strategies typically focus on particular hazardous agents or categories of hazards, such as

- Specific agent–food combinations, for example, *E. coli* O157:H7 in ground beef, or *Salmonella enteritidis* in eggs;
- A grouping of foods associated with a particular pathogen or other agent, for example, *Listeria monocytogenes* in meat, dairy, and other commodities; or
- All agents associated with a particular food or food category, for example, the safety of broiler chickens as affected by *Salmonella*, *Campylobacter*, and other pathogens, or the safety of produce as affected by all microbial and chemical hazards.

Purpose 2 risk management involves priority setting in the sense that choices must be made about how to target interventions in ways that minimize the risks under review. These choices should be informed as much as possible by assessments of the feasibility, effectiveness, and cost of interventions, as well as of their public health benefits. Of course, risk management decisions and interventions must produce results that satisfy legally applicable food safety standards. The question is how to achieve these results and other food safety goals most effectively.

Purpose 2 analysis is likely to be significantly more data-intensive than Purpose 1, both because it can be and because it often needs to be. Detailed quantitative models can be developed and risk assessments can be conducted to identify and compare interventions for specific hazards in specific foods, but these resource-intensive analyses are not feasible for the large array of hazards relevant for Purpose 1 resource allocation decisions. Furthermore, Purpose 2 analysis may need to be more data-driven if it is intended to result in government regulatory action or spending decisions by private entities. In these cases, decisionmakers may seek more detailed and case-specific information about the effectiveness and cost of proposed actions to justify their decisions.

Priority setting for food safety cannot be reduced to a formula for either purpose, however. Determining the resource allocations or risk management strategies that are best for public health will always require judgment concerning a range of values and factors — political, policy, legal, or scientific — that are not amenable to quantitative analysis. Nevertheless, basic comparisons can be made on the available scientific information.

Key Principles

In developing a proposed conceptual framework for priority setting, the FSRC has identified some key principles that it considers important in making such a framework workable and useful.

- The goal is to improve the scientific and factual basis for
  - risk-based allocation of food safety resources; and
  - reducing the public health burden of foodborne illness.

- Practicality must guide both the conceptual framework and the development of specific analytical approaches and tools, in recognition of the actual needs of decisionmakers, the inherent limitations of available data, and the financial and time costs of analysis.

- Within the bounds of practicality, the conceptual framework and analytical tools for priority setting must be
  - based on the best available science;
  - grounded in a "systems" understanding of how foodborne illness is caused and prevented;
  - transparent regarding assumptions and limitations; and
  - flexible as a tool for analysts and decisionmakers, not a source of the "right answer" on food safety priority setting.

- The priority-setting framework should be used prospectively to guide program planning and resource allocations; it should not be used to impede normal public health and regulatory decisionmaking that must occur routinely in the face of incomplete information and uncertainty.

- The priority-setting framework should foster iterative, dynamic, and continuing evaluation, decisionmaking, and re-evaluation as new data and lessons from experience become available.

Four Analytical Elements

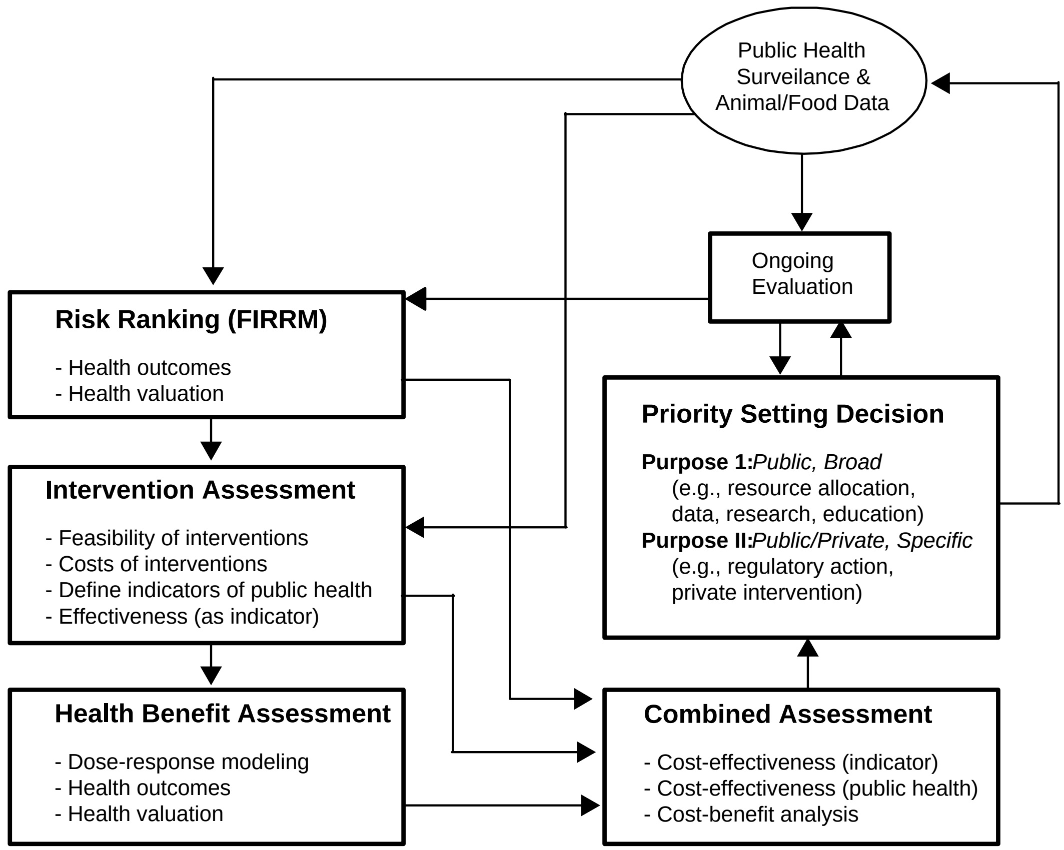
We organize the conceptual framework around four analytical elements — risk ranking, intervention assessment, health impact estimation, and combined evaluation — that apply to both Purpose 1 and Purpose 2 priority setting, albeit to widely varying degrees. These elements are summarized in this section, with a more detailed discussion of the conceptual framework for Purpose 1 and Purpose 2 priority setting given in the following section.

- *Risk ranking* — to rank the relative public health impact of the food safety risks under consideration based on known human health outcomes, which may be supplemented in Purpose 2 priority setting by information from more detailed risk characterizations and assessments.
- *Intervention assessment* — to identify potential risk reduction interventions and, when available data permit, understand their feasibility, effectiveness, and cost. In intervention assessment, effectiveness is computed in terms of a surrogate measure for public health impact, such as level of contamination.
- *Health impact estimation* — to compute, as permitted by available data, the public health effectiveness and benefits of specific interventions and intervention strategies considered in the intervention assessments. In health impact estimation, effectiveness is computed in terms of public health outcome measures, such as annual illnesses, hospitalizations, or fatalities, and benefits are computed using aggregate measures, such as economic valuation or quality-of-life metrics.
- *Combined evaluation* — to integrate data from the risk ranking, intervention assessment, and health impact estimation to inform resource allocation and risk management decisions. Combined evaluation includes cost-effectiveness analysis and cost–benefit analysis, when appropriate.

These four analytical elements of the framework for decisionmaking about setting food safety priorities are shown in Figure 1. The figure also shows the important role of data collection and *ongoing evaluation* of intervention effectiveness and health outcomes. As public health surveillance data, contamination data from animals and food, and other data bearing on the effectiveness of intervention efforts become available following changes in oversight, regulation, agency policy, or resource allocation, these data should feed back into subsequent decisionmaking. Figure 1 shows the iterative nature of the conceptual framework. Effective food safety decisions will result in reductions in specific risks in subsequent years; risk rankings and subsequent priority setting should reflect these changes. If interventions prove through ongoing evaluation to be ineffective or less effective than newly available interventions, this too should be considered in future decisionmaking.

While the four elements apply conceptually to both Purpose 1 and Purpose 2 priority setting, the priority-setting purpose and institutional context will heavily influence the relevance and data intensity of the assessments, as outlined in the next section.

Figure 1: A Conceptual Framework for Food Safety Priority-Setting Decisions



Purpose 1 Risk Ranking

The primary analytical element applicable to broad Purpose 1 priority setting is the identification, quantification, and comparison of the public health impact of the most significant risks to human health, wherein risk is defined as the likelihood of adverse health outcomes associated with particular hazards (such as a particular microbial pathogen contaminating a particular food).[3] Risk ranking, therefore, identifies *which* hazards are the most significant, not *how* to address them.

[3] Estimates of national annual incidence of such health outcomes are implicit risk measures, as one could simply divide by population to obtain annual per-person risk rates.

The Foodborne Illness Risk Ranking Model (FIRRM), which the FSRC has developed to perform the necessary risk ranking for microbial pathogens, is quantitative and driven by empirical data, but semi-quantitative or qualitative methods might also be used for the identification of the most important hazards.

The key questions that the risk ranking should answer to support Purpose 1 priority setting are the following:

1. What is the quantified public health impact of each agent–food combination under consideration?
2. What is the quantified public health impact of each food, aggregated across all significant agents?
3. What is the quantified public health impact of each specific pathogen, chemical, or other agent, aggregated across foods?
4. What are the ordinal rankings of the public health impacts associated with these agent–food combinations, foods summed across agents, and agents summed across foods?

Discussion and Proposed Approach

- **Risk ranking and context.** Risk ranking is the critical first step in priority setting for food safety because the largest risks also present the largest *potential* opportunities to reduce the public health burden of foodborne illness. Risk ranking may also serve a "screening" purpose for determining which risks to focus on in Purpose 2 decisionmaking. For broad resource allocation purposes, the initial ranking of risks in Purpose 1 need not be comprehensive, but it should encompass the agents, agent–food combinations, and foods or food categories that account for a substantial majority (such as 75%-90%) of public health outcomes attributable to known hazards within the jurisdiction of the body doing the priority setting. An adequately robust ranking of risks in accordance with the questions previously outlined would provide important insights on most significant hazards from a public health perspective and could, without further analysis, justify immediate shifting of resources and risk management attention to particular significant hazards. Risk ranking also would enable decisionmakers to focus further and more refined Purpose 1 intervention assessments (in which the feasibility, effectiveness, and cost of interventions are considered) on the top tier of hazards.

- **Public health impact.** In Purpose 1 priority setting, it is important to focus on the public health impact of illnesses attributable to specific hazards, rather than on other intermediate metrics of potential health impact, such as measures of contamination. This ensures that broad priority-setting and resource allocation decisions are driven as much as possible by actual health outcomes, which is the ultimate concern of the food safety system. The FSRC's risk-ranking model (FIRRM) takes this approach. Some of the lessons learned from development of FIRRM are summarized in Appendix C.

- **Food categorization.** Foods may be categorized in different ways for priority-setting purposes. For example, foods can be categorized by commodity at the single-ingredient level (for example, wheat flour) or by type of food as eaten (for example, bread). Food categories should reflect the characteristics of the risks being compared. For example, trace chemical pesticide risks that enter at the farm stage and may remain relatively constant through production may be better served by analysis at the level of raw commodities, whereas microbiological risks that can be introduced or increased throughout the system, including during preparation, may be better served by analysis of foods as eaten.

- **Measures and ranking.** There are numerous measures one might use to estimate the public health impact of hazards, including estimates of total cases of illness, annual hospitalizations, or fatalities. However, comparing illnesses with different symptoms, severities, fatality rates, and chronic sequelae requires the use of aggregate measures such as economic valuation or Quality Adjusted Life Years (QALYs). These should be the basis for primary rankings but simpler, more narrowly defined measures may be useful to consider as well. For example, a decisionmaker may be particularly interested in impacts on sensitive populations (such as kidney failure in small children or pregnancies resulting in miscarriage).

- **Routine risk ranking.** Risk ranking should be performed routinely. As new data become available, preferably annually, the impacts of different food–hazard combinations should be re-ranked. Changes from previous years may reflect the success or failure of priority-setting decisions and resulting interventions or may show growing or declining risks.

Purpose 1 Intervention Assessment

While priority setting for broad resource allocation purposes can be usefully informed by risk ranking alone, the deployment of resources and targeting of efforts should also be informed to the extent possible by information on the feasibility, effectiveness, and cost of interventions to reduce risk. Once risk ranking identifies *which* hazards are most significant, intervention assessment identifies *how* to address them.

The following four questions should guide the intervention assessment:

1. At what points across the farm-to-table continuum could interventions be applied to reduce the risk (and public health impact) of foodborne illness?
2. What is known about the technical feasibility of available interventions?
3. What is known about the relative effectiveness of available interventions?
4. What is known about the relative costs to government of implementing available interventions?

Discussion and Proposed Approach

- **Role of intervention assessment.** Intervention assessments can add to the quality of Purpose 1 priority setting because some higher-ranked hazards may not have known or available interventions, whereas important but lower-ranked hazards may be readily amenable to available interventions that are known to be cost-effective. In such a case, the risk manager may choose to focus regulatory resources or other active interventions on the latter hazards, while choosing to focus research efforts on developing possible interventions for the former.

- **Food system perspective.** The intervention assessment for Purpose 1 should look broadly at the food system as a whole in identifying opportunities to reduce risk, rather than focusing on a specific point in the system or small set of alternatives. Purpose 1 intervention assessments can be much less quantitative than for Purpose 2 priority setting, as they should focus more on the availability and feasibility of interventions rather than on quantitative measures of effectiveness.

- **Interventions.** Information exists in the literature and in the expertise of food producers, processors, and food safety practitioners on identifying possible interventions to reduce major risks and assessing their feasibility. Some interventions may affect multiple hazards and introduce complementarities across hazards in the effectiveness of control. Although the exact relationship likely will not be known, Purpose 1 intervention assessment and priority setting can account for these effects through sensitivity analysis using available data in order to understand better the potential for interventions to reduce a hazard or hazards and improve public health.

- **Measurement of effect.** For Purpose 1 priority setting, quantitative assessment of the effectiveness of interventions is not likely to be practical. Ideally, effectiveness of interventions should be measured in terms of public health outcomes, but even surrogate measures for public health impact, such as reductions in pathogen load, are beyond Purpose 1 analysis. The methods and issues involved in quantifying effectiveness are discussed in connection with Purpose 2 intervention assessment.

- **Costs.** In Purpose 1 priority setting, information about costs to the government of implementing interventions — such as the costs of researching, setting, and enforcing standards at different points across the food system — could help influence the choice about where to target efforts since it would be desirable to give higher priority to risks and opportunities to reduce risk for which cost-effective interventions are available. Detailed data on government costs may not be readily available on the wide array of possible interventions that might be considered in Purpose 1 priority setting, and such data are not essential to such priority setting since it is focused on guiding resource allocation at a broad system level and targeting future analytical and risk management efforts rather than selecting specific interventions and intervention strategies.

Purpose 1 Health Impact Estimation

Despite the difficulty of predictively linking possible interventions to health outcomes, health impact estimation is important to priority setting for food safety because improving health outcomes is the ultimate goal. For Purpose 1, however, the FSRC conceptual framework does not envision the quantitative estimation of health benefits from interventions, as Purpose 1 intervention assessment is largely qualitative, and because this level of detail is not necessary as a guide to broad resource allocation decisions. Issues and approaches to quantitative health impact estimation are discussed in connection with Purpose 2.

Purpose 1 Combined Evaluation

Purpose 1 priority setting should be based on a ranking of the most important hazards from a public health perspective, informed when appropriate and possible by an attempt to identify and assess opportunities to reduce these hazards. That is, the risk ranking results should be combined with the results of the intervention assessment. The prioritization of opportunities to reduce the public health impact of foodborne illness at the Purpose 1 level therefore involves three summary questions:

1. Based on the risk ranking (such as that derived from FIRRM), what are the most significant hazards in terms of public health impact, and what are their relative rankings?

2. To what extent are certain hazards and associated public health impacts more amenable than others to reduction with available interventions?
3. Considering what is known about the feasibility and, if available, cost-effectiveness of available interventions, which intervention opportunities are likely to make the greatest contribution to reducing the public health impact of foodborne illness, including addressing multiple hazards at once?

Discussion and Proposed Approach

- **Practical rankings and evaluation.** As a practical matter, a reasonably comprehensive ranking of risks based on public health impact (such as anticipated from FIRRM) can by itself make a meaningful contribution to improving resource allocation by helping ensure that both immediate public interventions and further analysis are focused on the most health-significant hazards. Purpose 1 priority setting can be further refined by incorporating even qualitative information on the availability and effectiveness of interventions to identify the most productive opportunities to reduce risk and public health impact.

- **Decisions made in the presence of uncertainty.** It is not typically practical or wise for policymakers to await perfect quantitative assessments of intervention effectiveness and health benefits to make broad Purpose 1 priority setting and resource allocation decisions. Decisions must be made in the face of uncertainty. Priority-setting analyses can inform decisionmakers and improve food safety, but risk managers often must act in the face of incomplete information and scientific uncertainty; such necessary action to improve food safety should not be delayed solely for the sake of improving priority-setting analyses.

Purpose 2 Risk Ranking

Purpose 2 priority setting largely concerns the targeted management of risk from specific hazards that have been previously determined, possibly through Purpose 1 analysis, to be significant enough to warrant specific action. As a result, Purpose 2 risk ranking is not as broad as Purpose 1 risk ranking, and may incorporate detailed information from "bottom up" risk assessments or other quantitative analyses. For example, the series of risk assessments by USDA and FDA on *Listeria monocytogenes* in ready-to-eat foods were used to rank risks of the pathogen from numerous food vehicles. Because the Purpose 2 risk ranking is intended to support risk management decisionmaking, other more in-depth information from risk assessments may also be relevant, such as whether there are specific sub-populations that are of special concern. Otherwise, Purpose 2 risk ranking is guided by the same questions and approach relevant for Purpose 1 risk ranking.

Purpose 2 Intervention Assessment

In Purpose 2 priority setting to inform risk management, intervention assessment becomes perhaps the most critical and difficult analytical element. With respect to each significant hazard under review, the following questions should guide the intervention assessment:

1. At what points across the farm-to-table continuum could interventions be applied to reduce the risk (and public health impact) of foodborne illness?
2. What technically feasible interventions are available at each point?
3. How effective are available interventions in reducing the risk of illness in terms of surrogate measures for adverse health outcomes?
4. What are the costs to government, industry, and consumers of implementing the intervention(s)?
5. Are there supply chain effects (that is, changes in behavior either up or down the supply chain from where the intervention takes place) that will significantly influence the ultimate effectiveness of the interventions being analyzed?

Discussion and Proposed Approach

- **Key role in ranking interventions.** In Purpose 2 priority setting for risk management purposes, intervention assessment is likely the most critical step because only by understanding the relative effectiveness for risk reduction of the range of available interventions is it possible to select the interventions and intervention strategies that will contribute most successfully to reducing the public health impact of foodborne illness. The intervention assessment step is difficult because it requires predictions about the outcomes that specific interventions will achieve. In public risk management decisionmaking, the goal of intervention assessment is to support ranking of the relative effectiveness of available interventions in reducing the public health impact of the hazards under review. In private decisionmaking, a range of legal, regulatory, and business needs may also motivate intervention assessments.

- **Selection of interventions.** It is important to look broadly at the system as a whole in identifying and assessing possible interventions to reduce risk. While detailed assessments may properly focus on one or a small number of possible interventions, the larger context influences the effectiveness of particular interventions and thus needs to be considered. Once the whole system has been reviewed, a list of candidate interventions for specific points in the system must first be identified and then assembled. Assembling a list itself requires judgment, since resources are normally available to assess only a limited number of interventions, although substantial information exists in the literature, and different food safety practitioners and stakeholders have expertise and experience.

- **Measurement and data.** Ideally, Purpose 2 priority setting would be based on direct assessments of intervention effectiveness in terms of reductions in public health outcomes, but quantifying the relationship between an intervention, the degree of remaining contamination, and specific human health outcomes is difficult. Insufficient investment has been made in the data, methodologies, and surveillance systems needed to assess the public health effectiveness of interventions.

- **Surrogate measures.** Surrogate measures (for example, pathogen incidence or chemical levels post-processing or at the point of consumption) are feasible and useful alternatives to quantifying the relationship between contamination and health effect. Purpose 2 intervention assessment involves estimating effectiveness in terms of such surrogates, while subsequent health impact estimation (discussed next) quantifies the public health effectiveness of interventions. It is important that surrogates be reasonable proxies for public health outcomes, as the entire purpose of intervening is to reduce the public health impact of foodborne illness. Likewise, the ability to predict reasonably such health outcomes based upon surrogate measurements or estimates is important. Surrogates are practical because in many cases considerable data on the effectiveness of specific interventions with respect to surrogates may be available in the literature and in the hands of government research organizations and food companies.

For decisionmaking at the private level, surrogates may be preferable to public health outcomes in measuring effectiveness. For example, regulators might set a performance standard for some surrogate variable such that this degree of contamination would decrease predicted illnesses to an acceptable level (based on dose-response modeling). When assessing alternative interventions to meet this standard, industry would focus on effectiveness in terms of an intervention's ability to decrease the performance standard surrogate below some threshold, not in terms of the predicted public health impact. Similarly, surrogates may be useful from a compliance perspective because they are directly measurable. One can measure changes in frequency and level of contamination, but measuring illnesses caused by contamination from that specific food and pathogen will likely remain difficult.

- **Estimation of impact.** Estimating the impact of an intervention on some surrogate measure may be based on different types of analysis; for example:
    - Experimental data collection: technological innovations, changes to process, and other interventions may be evaluated in a controlled environment or limited case studies. The results of these experiments can then be used to predict the impacts of implementing the intervention in the field, or on a wider scale.
    - Microbial risk assessment methods: knowledge about bacterial growth and decline under certain changes to the environment (for example, chilling, heating, changes in acidity, chlorination) can be used to predict the impact of an intervention.

- **Costs.** Intervention assessment includes consideration of the system-wide costs of adopting and implementing available interventions.
    - Costs to government include, for example, specific costs involved in researching, setting, and enforcing standards that address the risk(s) in question.
    - Industry costs of implementing interventions are relevant to both government and private decisionmaking about risk management, though in different ways and to varying degrees depending on the decisionmaking context.

- **Secondary adjustments**. Applying an intervention at one stage in the supply chain may induce adjustments at other points in the supply chain that need to be considered in evaluating the overall effectiveness and costs of an intervention. Response to any intervention is a dynamic process with short-run and long-run effects, and there is often considerable uncertainty about response time, adjustment lags, and longer-run technological and structural response that should be considered in estimating intervention effectiveness and costs. Economic model simulations to evaluate producer and consumer response to relative price changes in inputs or final products, or in available technologies can be used to evaluate the sensitivity of final market outcomes to specific interventions.

- **Modeling intervention and effect.** Intervention analysis requires modeling of both the physical process of risk generation and transmission and the economic costs and incentives that influence the types and levels of interventions adopted. These two steps in the analysis have frequently been sequential rather than integrated. For example, a small number of interventions are evaluated in terms of their ability to reduce contamination (or improve public health outcomes) and then an accounting exercise is carried out to estimate the costs of the interventions. While useful at a simplified level, this type of cost accounting does not measure the full outcome of an intervention in terms of changed incentives, technological responses, and ultimate costs. Moving toward integrated predictive and economic modeling will yield more accurate intervention assessments.

Purpose 2 Health Impact Estimation

The health impact estimation builds on the effectiveness assessment by asking, with respect to the significant hazard(s) under review, the following questions:

1. What specific health outcomes (that is, the symptoms and severities of illnesses, including hospitalizations, deaths, and chronic sequelae) are generally associated with the hazard(s)?
2. Based on the assessment of intervention effectiveness, to what extent will the incidence of these outcomes be reduced?
3. What is the public health benefit, in economic and/or quality-of-life terms, of reducing these outcomes (as measurable by FIRRM)?

Discussion and Proposed Approach

- **Measurement of health benefits.** Purpose 2 health impact estimation is intended to produce quantitative measures of health benefits by linking interventions with actual health outcomes and estimating the impact of interventions on incidence and severity of illness. Valuing the health outcomes, either in economic or quality-of-life terms, is an important component of impact assessment and is necessary for comparing illnesses with different symptoms, severities, fatality rates, and chronic sequelae.

When interventions can be linked predictively with specific health outcomes (rather than non-health surrogates), the data and analytical tools for valuing the public health benefit of risk reduction reside largely within FIRRM.

- **Linking intervention to health outcome.** Linking an intervention to public health outcomes is more difficult than linking to a surrogate measure but may be addressed using similar methods through predictive modeling or epidemiological approaches.

    - **Predictive modeling**. Information on contamination, consumption, and dose–response relationships may be used to make predictive estimates of illnesses resulting from contamination measured at the surrogate metric. This is essentially a risk assessment approach to modeling interventions. Dose–response functions representing the individual human health response to a pathogen or other agent may be uncertain or biased, however, because of the limitations of the data and analyses on which they might be based. The sources of data include the following:
        - *Data from controlled experiments*: laboratory experiments can test the dose–response of human beings of various ages and immuno-compromised status to different levels of pathogen contamination.
        - *Data from natural experiments*: outbreaks or other observed cases of illness may be associated with laboratory-confirmed pathogen levels on contaminated food.
        - *Extrapolation from other pathogens*: information about dose–response relationships may be extrapolated from better-known pathogens that have similar properties.
        - *Extrapolation from animal data*: information may be available about the relative dose–response relationship of the pathogen on different animal systems.
        - *Expert judgment*: elicitation of expert opinions may serve to combine incomplete information from the aforementioned approaches or to estimate a dose–response relationship when not enough data are available.

    - **Epidemiological and contamination data**. It may be possible to discern a relationship between an indicator variable of contamination and consequential human illnesses if historical data are available. This approach does not model the physical process of what happens when an individual consumes contaminated food but rather compares data before and after exposure. Such data are necessarily confounded because of cross-contamination between foods, human contamination of foods post-processing, and differences in food storage and preparation. These data are often only available *after* an intervention has been put in place. There are various data that might be used, including the following:

- *Traceback*: if data were available, investigations into the foods associated with outbreaks or cases of illness might be traced back through the food system to a point at which contamination testing data are available.
- *Temporal analysis*: routine food testing data and similarly routine public health surveillance data may be analyzed for correlations; a spike in contamination may or may not correlate with a spike in numbers of persons reporting ill with gastroenteritis.
- *Sub-typing methods*: pathogen subtyping methods may be used to connect human illnesses to specific animal reservoirs.

- **Inherent complexity**. No matter the approach used to estimate the public health impact of interventions, there are complexities inherent in capturing the physical and behavioral responses in the modeling, including those posed by the following:
  - **Food handling.** It may be difficult to ascertain the public health impact of an intervention if there are growth or transfer points closer to consumption. Cross-contamination from one food to another, contamination from human contact, improper storage, or insufficient cooking can all offset the benefits of an intervention and make direct assessments difficult. That is, as the indicator is estimated or measured further and further from the point of exposure, the link between surrogate and public health is less and less reliable.
  - **Sensitive subpopulations.** Many foodborne illnesses are primarily associated with susceptible subpopulations, such as the young, old, pregnant, and immuno-compromised. Reductions in exposure to healthy consumers may not reduce overall illnesses, and, likewise, sensitive populations may remain susceptible even to lowered exposures.
  - **Antimicrobial resistance.** If an intervention decreases contamination of some pathogen but could increase antimicrobial resistance of that pathogen, the offsetting effects should be considered.

Purpose 2 Combined Evaluation

The risk-ranking, intervention assessment, and health impact estimation previously outlined provide information about particular opportunities, across a range of hazards being assessed, to reduce the public health impact of foodborne illness. To inform decisionmaking on risk management, it is necessary to compare the opportunities to reduce risk by asking these questions:

1. What is the ranking of opportunities to reduce risk based on their relative potential contribution to reducing the public health impact of foodborne illness?
2. What is the ranking of opportunities to reduce risk based on their relative cost-effectiveness ratios and cost–benefit analyses?
3. Considering both rankings, how can interventions be most effectively targeted to minimize the public health burden of foodborne illness?
4. What is the likely timing of alternative interventions and responses?

Discussion and Proposed Approach

- **More detailed information for rankings.** The framing of questions for Purpose 2 priority setting reflects the assumption that the intervention and health impact estimations will have yielded more quantitative and in-depth information than the corresponding assessments under Purpose 1. The combined evaluation of opportunities to reduce risk, whether associated with a specific agent–food combination, many hazards (across a number of foods) posed by a particular pathogen or agent, or many hazards (arising from a number of agents) associated with a particular food or food category, can generate the following:
    - A ranking based only on the amount of risk reduction (as measured by indicators or health outcomes directly) that can be achieved, considering the magnitude of the risk and the effectiveness of the interventions available to reduce it.
    - A ranking based on cost-effectiveness ratios or cost–benefit analyses that reveal the relative efficiency with which particular hazards can be reduced by specific interventions (as measured by indicators or health outcomes directly or benefits versus costs in dollar terms). This permits comparisons across diverse hazards and opportunities to reduce foodborne illness risk.
    - "What if" analysis or comparison of alternative scenarios based on firms' expected use of alternative technologies. Evaluation of interventions that allow firms (producers, processors) to choose alternative technologies must rely on assumptions about which alternative technologies will be adopted.

- **Dynamics.** Assessment of the timing of interventions and resulting reduction in the level or incidence of a hazard may reveal both short- and long-run responses, and these responses may differ. The short-run response reflects existing technology and operating systems, whereas in the longer run new technologies and operating systems may be developed and adopted that change the cost and effectiveness of interventions. Thus, evaluation or sensitivity analysis of likely adjustments over time is needed to inform the combined evaluation of an intervention.

- **Input for risk management decisions.** The combined evaluation of opportunities to reduce risk, taking into account the magnitude of the risk and the feasibility, effectiveness, and cost of interventions, is an input to risk management decisionmaking by government and private parties. It does not select the "right" intervention but informs the decisionmaker on the likely impacts of choosing particular interventions. Post hoc evaluation of the predictions and outcomes assessments derived from these analyses are vital to improving over time their quality and helpfulness as an input to decisionmaking.

Purpose 1 and Purpose 2 Ongoing Evaluation

Priority setting for food safety is a dynamic, iterative process, not a one-time exercise. It is thus vital to include ongoing evaluation of intervention effectiveness and health outcomes in the priority-setting process so that knowledge gained from experience — regarding successes, failures, and unintended consequences — can be incorporated more systematically in future decisionmaking. For Purpose 1 resource allocation decisions, this likely involves big-picture trend analysis, comparing broad data, such as from public health surveillance, before and after significant changes in priorities. For Purpose 2 decisions, the ongoing evaluation analysis should be more quantitative and comprehensive and should, to the extent possible, answer the following questions:

1. Was the intervention effective, as measurable using surrogate metrics, and how does the effectiveness compare to predicted values?
2. What is the public health impact of the intervention, and how does it compare to predicted values?
3. How do the realized costs to government, industry, and consumers compare to predicted values?
4. How do the realized cost-effectiveness and cost–benefit analyses of the intervention compare to predicted values?

Discussion and Proposed Approach

- **Data.** Public health surveillance and animal and food contamination data are probably the most important data sources for evaluating intervention effectiveness and health outcomes. Ideally, the data needed for ongoing evaluation should be defined at least generally as part of the priority-setting process and defined in some detail in connection with the development of intervention strategies for risk managers flowing from Purpose 2 priority setting. In the latter case, the decisionmaker should ask, What data are necessary to evaluate this intervention? When specific data not currently being collected are necessary for such an evaluation, data collection should be built into the risk management strategy. Ideally, baseline data generated prior to implementing a new intervention would be available as the starting point for evaluation, but the absence of such data should not be allowed to delay the implementation of interventions judged necessary, based on available information, to address a food safety problem.

- **Timing.** Immediate evaluations for some interventions may be possible while others may involve significant lags or long-term trends that would not be captured by short-term analysis. Certain interventions may not be adequately evaluated for many years after their initiation.

- **Review and response.** If the intervention or risk management action is not as successful as anticipated, the decision should be re-evaluated. Knowledge from ongoing evaluation may inform ways in which the intervention can be altered or replaced. Likewise, knowledge gleaned from ongoing evaluation can be used to inform future predictive modeling and decisionmaking for similar food safety hazards.

Comments and Next Steps

A draft of this document was provided to participants in a national conference convened by the FSRC at Resources for the Future on September 14, 2005. During and following the conference, the FSRC received numerous helpful comments and suggestions, many of which have been incorporated in this final version and for which we are grateful.

One important set of comments and questions concerns risk communication and stakeholder participation, including a suggestion that the FSRC develop key principles on these topics as they relate to priority setting for food safety. This topic has not yet been incorporated in the framework and is an important subject for future work. While the conceptual framework might be considered "only" an analytical tool for decisionmakers, it deals with an issue —priority setting and resource allocation for food safety — in which the public has a strong stake and that could be misconstrued if not well explained and understood. Better priority setting is a powerful tool for reducing the risk of foodborne illness and making food safer. To be implemented effectively and to achieve that goal, however, public participation and good risk communication are essential. The FSRC welcomes further suggestions and collaboration as it considers how to address these issues.

The conceptual framework also requires testing and refining, especially as it applies to Purpose 2 priority setting and risk management. Such an application could be applied in particular contexts, such as specific commodities and/or pathogens. The FSRC is committed to this and other work to help make the conceptual framework operational as a practical tool for more data-driven approaches to priority setting and resource allocation for food safety. Besides applying and continuing to refine the framework, these efforts include making the FIRRM model operational as a tool to inform priority setting; developing the additional analytical tools required to support intervention, health benefit, and combined evaluations for priority setting for food safety; and working with the food safety community to improve how the data needed to improve priority setting for food safety and risk management are collected, stored, and shared.

Conclusion

The conceptual framework for prioritizing opportunities to reduce the risk of foodborne illness outlined in this document is

- **grounded in a systems approach** to understanding how foodborne illness is caused and prevented;
- **multi-disciplinary** in its integration of information and perspectives from risk assessment, food science and technology, public health, economics, and public policy;
- **practical** in its effort to balance the desire for a scientifically rigorous and data-driven approach to priority setting with a realistic accommodation of methodological, data, and resource limits on the analysis that is possible in the real world;
- **flexible** in embracing multiple purposes and institutional contexts for priority setting that influence the nature and depth of the necessary analysis;
- **dynamic and iterative** in its emphasis on ongoing evaluation and continuous updating of risk rankings and other elements of the framework; and
- **a work in progress**, by virtue of the clear need to solve challenging methodological and data problems and test the framework with real-life case examples.

Appendix A: Summary of Workshops

Workshop 1: Approaches to Predictive Modeling

Iowa State University, Ames, Iowa
June 15 and 16, 2004

The first workshop was organized by Iowa State University and the University of California-Davis to further develop an integrated approach to analyzing hazards and prioritizing opportunities for reducing food safety risk in the U.S. food safety system. The workshop focused on identifying and critiquing alternative approaches to predictive modeling and the integration of risk assessment and risk-control processes across an integrative system.

Session 1: The Needs of Regulators and the Policy Process

How do agencies address priority setting for food safety? What drives the priority setting? What might future directions be? What vision do the agencies have for improvements? What are the priorities for data?

- Robert Buchanan, CFSAN, FDA: *Agency Perspective*
- Arthur Liang, Food Safety Office, CDC: *Agency Perspective*
- Philip Derfler, FSIS, USDA: *Agency Perspective*

Session 2: Taking a System-Wide Approach

What is known about where risk enters the food supply? What is known about how risk is amplified or reduced? Conceptually, what data should be considered? What data do we have? What are the key data gaps?

- Arie Havelaar, RIVM Netherlands: *A Systems Perspective on Managing Risk*
- Linda Harris, University of California-Davis: *The Systems Approach in Context: Fruits and Vegetables*
- Liz Wagstrom, National Pork Board: *The Systems Approach in Context: Animal and Meat Products*

Session 3: Overview of Approaches to Modeling in a Global Context

How can food safety models inform decisionmaking? What characteristics should food safety models include? What are the greatest challenges? How can models be used to identify points of possible intervention? How can we compare food safety interventions?

- Glenn Morris, University of Maryland: *A Three-Tiered Approach*
- Jeffrey Wolt, Iowa State University*: Data and Modeling Requirements for Policy*

- Birgitte Borck, Danish Zoonosis Center: *The Danish Approach for Associating Food Groups with Cases of Human Foodborne Illness*
- Michael Doyle, University of Georgia: *Issues with Respect to Interventions*
- Julie Caswell, University of Massachusetts: *Economic Context*

Session 4: Considering Different Approaches to Risk Modeling

What different methodologies are used or could be used in food safety models? How do they differ? What are the key advantages and disadvantages of these methods? Which models work best in which situations?

- David Hartley, University of Maryland: *Descriptive Models*
- David Kendall, Research Triangle Institute: *The RTI Food Handling Practices Model*
- Robert Buchanan, CFSAN, FDA: *Risk Assessments*
- John Galland, University of California-Davis: *UC-Davis Model*

Session 5: Breakout Sessions

Breakout sessions focused on feasibility, relevant (best) models and methodologies to identify and assess risks, and data requirements and availability from existing data collection systems.

Workshop 2: Economic Measures of Interventions

University of Massachusetts, Amherst, Massachusetts
December 2 and 3, 2004

The second workshop in the series "Building a Framework for Prioritizing Opportunities to Reduce Risk" was held at the University of Massachusetts-Amherst and focused on developing an integrative modeling system approach for evaluating the effectiveness of risk-reducing interventions. The approach developed was meant to incorporate the technical effectiveness of interventions in reducing risk, the resulting benefits from improvements in public health, and the costs of intervention.

Session 1. Approaches to Integrative Modeling for Food Safety Interventions

- Paul McNamara and Gay Miller, University of Illinois: *A Farm-to-Fork Stochastic Simulation Model of Pork-Borne Salmonellosis in Humans*
- Marie-Josée Mangen, G.A. Wit, and A.H. Havelaar, CARMA, Netherlands: *Controlling Campylobacter in the Chicken Meat Chain – Towards a Decision Support Model*
- Michael Ollinger and Danna Moore, ERS, USDA and Washington State University: *Approaches to Examining HACCP Costs and Food Safety Performance and Technologies*

Session 2. Approaches to Integrative Modeling for Food Safety Interventions

- Scott Malcolm, University of Delaware: *Operations Research and Firm-Level Food Safety*
- H. Scott Hurd, Iowa State University: *Risk-Based Optimization of the Danish Pork-Salmonella Program*

Session 3. How Good Is the Match Between These Approaches and How Should Risk Management Decisions Be Made? Viewpoints

- Derrick Jones, Food Standards Agency, United Kingdom: *The UK Food Standards Agency*
- Caroline Smith DeWaal, Center for Science in the Public Interest: *Risk Assessment/Risk Management: Working Together?*

Session 4. Relevant Studies of Modeling Effects, Benefits, and Costs

- Fred Angulo, CDC: *Current Work on Food Attribution*
- Neal Hooker, Ohio State University: *Evaluating Risk Management Efforts*
- Willian Nganje, North Dakota State University: *HACCP Implementation and Optimality in Turkey Processing*
- Seda Erdem and Julie Caswell, University of Massachusetts: *A Prototype Decision Tool: Effectiveness and Costs of Interventions Ranking Model (ECIRM)*

Workshop 3: Food Safety Interventions and Food Attribution

Decatur, Georgia
April 26 and 27, 2005

The third workshop for the project "Building a Framework for Prioritizing Opportunities to Reduce Risk" was organized by the University of Georgia and focused on identifying, comparing, and evaluating opportunities to reduce risk for both public decisionmakers and private firms. Presentations and discussions were centered on two primary objectives:

1. Identify locations (intervention points) in the food continuum where food safety interventions would have the greatest impact in providing health protection.
2. Develop analytical methods to evaluate the effectiveness of food safety interventions in reducing foodborne illnesses.

Session 1. Introductory Comments

- Michael Taylor, RFF: *Constructing the Analytical Tools for a Systems and Risk-Based Approach to Food Safety*

Session 2. Food Attribution

This session served as an update on some of the issues discussed at the October 2003 FSRC Food Attribution Workshop: How can we best attribute cases of foodborne illness to food items or food commodities? How can we identify locations in the food continuum contributing the most to foodborne illnesses? What are the primary data gaps and obstacles in food attribution?

- Glenn Morris, University of Maryland: *Update on Foodborne Illness Risk Ranking Model (FIRRM) and Food Categorization Issues*
- Sandy Hoffmann, RFF: *Expert Elicitation for Foodborne Illness Attribution*
- Robert Tauxe, CDC: *CDC Efforts in Addressing Food Attribution*
- John Painter, CDC: *Status of Foodborne Diseases Outbreak Data for Food Attributio*n
- Frederick Angulo, CDC: *Blending Data from Sporadic Case-Control Studies and Outbreaks for Food Attribution*
- Elaine Scallan, CDC: *Attempting to Apply the Danish Food Attribution Model in the U.S. Using USDA, HACCP, and CDC Surveillance Data*
- Bob Adak, Laboratory Centre for Foodborne Disease Surveillance, London: *Overview of UK Efforts Addressing Food Attribution*

Session 3a. Food Safety Interventions: *Salmonella/E. coli* O157:H7 in Food Animal Production

The first food-pathogen session focused on *Salmonella* and *E. coli* O157:H7 in poultry, beef, and other food animal production. Presenters represented multiple stakeholders, including industry, academia, regulators, and public health agencies.

- Chuck Hofacre, University of Georgia: Salmonella *Reduction in Poultry Production*
- Dell Allen, Cargill (retired): E. coli *O157:H7 Reduction through Interventions*
- Sean Altekruse, FSIS, USDA: *Strategies to Identify and Evaluate the Efficacy of Food Interventions: Impact on Public Health*
- Bob Adak, Laboratory Centre for Foodborne Disease Surveillance, London: *Strategies to Identify and Evaluate the Efficacy of Food Safety Interventions*

Session 3b. Food Safety Interventions: *Listeria monocytogenes* in Ready-to-Eat Foods

The second food-pathogen session focused on ready-to-eat foods and *Listeria monocytogenes.* Presenters represented multiple stakeholders, including industry, academia, regulators, and public health agencies.

- Leon Gorris, Unilever: *Minimum Requirements for Effective Food Safety Interventions: Cost, Effectiveness of Interventions?*
- Randall Huffman, American Meat Institute Foundation: *Minimum Requirements for Effective Food Safety Interventions to Reduce* Listeria monocytogenes *Contamination of Ready-to-Eat Meat Products*
- Michael Doyle, University of Georgia: *Continuous Improvement in Reductions in Foodborne Listeriosis: Identification of Approaches Having the Greatest Impact*
- Robert Buchanan, CFSAN, FDA: *Strategies to Identify and Evaluate Efficacy of Food Safety Interventions Having the Greatest Impact on Providing Public Health Protection*
- Robert Tauxe, CDC: *Listeriosis Prevention: Identifying Successes and Further Opportunities*

Session 4. Discussion

The second day of the workshop focused on discussion. This was guided by questions presented to the workshop group by the conference organizers. Regarding the selection of interventions, the following questions were posed:

1. What principles should govern choices about *where* to intervene on the production to consumption continuum?
2. What principles should govern choices about *how* to intervene?

3. How do we predict the cost-effectiveness of proposed interventions?
4. What data are needed to make these decisions and how should the data be obtained?
5. How do we balance the desire for scientific rigor with the practicality of decision processes and available data?

Regarding the evaluation of interventions, the following questions were posed:

1. Is it feasible to measure directly the health impact of specific interventions?
2. If not, are there appropriate and practical surrogates that could provide a reasonable measure of public health benefit?
3. What data are needed to support post hoc evaluation of intervention effectiveness? Who should be collecting these data? Should they be shared, and, if so, how?
4. How should data collected to evaluate effectiveness of interventions in place be brought back into the process for selecting interventions?

Appendix B: Institutional Context

The food safety priority-setting concepts being developed in this project have relevance for a range of public and private institutions involved in food safety.[4] The purposes for which these institutions establish and consider food safety priorities in their operations are quite diverse, however, and consequently their analytical needs vary.

Congress and the Office of Management and Budget (OMB)

The highest-level opportunity for priority setting for food safety in the federal system is among political decisionmakers through legislation and in the annual budget process. The current legislative mandates and broad allocation of resources among the principal food safety agencies are a de facto statement about food safety priorities, and, through the budget process, OMB and Congress have the opportunity annually to refine that statement by reallocating resources or by directing how current resources are to be spent.

In the recent past, for example, Congress has provided the Food and Drug Administration with additional resources to inspect imports, based on a concern about foreign threats to food safety. This high-level allocation of resources to address a particular category of problems involves what we define for this project as Purpose 1 priority setting.

Food and Drug Administration (FDA)

The FDA has food safety regulatory responsibility for all foods except meat, poultry, and certain processed egg products. Working through its Center for Food Safety and Applied Nutrition (CFSAN), Center for Veterinary Medicine (CVM), and a field network of inspectors and laboratories, FDA implements the food safety provisions of the Federal Food, Drug and Cosmetic Act (FDCA). The FDCA includes provisions that place FDA in charge of pre-market review and approval of food and color additives and animal drug residues, but FDA uses most of its food safety resources to enforce statutory food safety standards that are defined in broad terms by the various "adulteration" provisions of the FDCA. These provisions generally require FDA to prove that a particular lot of food or a particular food manufacturer is violating the relevant standard. FDA is also authorized to educate the industry

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[4] A more complete version of this discussion can be found in a July 2003 report prepared by several FSRC researchers: Taylor, Michael R., Margaret O'K Glavin, J. Glenn Morris, Jr., and Catherine E. Woteki. 2003. Food Safety Updated: Developing Tools for a More Science and Risk-Based Approach. New York, NY: Milbank Memorial Fund and Washington, DC: Resources for the Future. (Available online: http://www.milbank.org/reports/2003foodsafety/030731foodsafety.html.)

and the public about food safety and to work with state and local governments, which focus their food safety efforts at the retail level.

The FDCA provides FDA with a range of tools for performing its food safety roles, such as the power to issue regulations further defining safety standards and imposing safety-related requirements on food producers, processors, and handlers; inspecting domestic production facilities, checking imported foods, and collecting and analyzing product samples; and taking administrative and judicial enforcement action to remove potentially unsafe food from commerce or punish violators of safety requirements. The FDCA and Congress provide FDA with little or no direction, however, on how the agency is to deploy those tools or otherwise allocate its resources across the wide range of potential hazards and risks arising in the food supply. FDA makes these decisions almost continuously in what we label as Purpose 1 priority setting.

Once FDA focuses on a topic, such as produce safety or *Listeria* in dairy products, it must still decide what tools to use (for example, new regulations, inspection and enforcement, or some combination) and where to focus efforts (for example, at the production, processing, or retailing stage). This involves making choices about how best to tackle a particular problem to achieve the greatest public health benefit with the available tools and resources. This is a risk management activity that includes Purpose 2 priority setting.

Food Safety and Inspection Service (FSIS), USDA

FSIS implements several laws governing the safety of meat, poultry, and certain processed egg products. The agency's meat and poultry jurisdiction covers slaughter and processing plants producing both raw and cooked products, including plants that produce products containing as little as 2% meat or poultry. The FSIS jurisdiction is thus quite broad and includes as much as 25% of the U.S. food supply.

In contrast to the FDCA, the laws administered by FSIS provide a very specific mandate that determines to a large extent the deployment of FSIS resources. The agency is required by law to visually inspect and pass every beef, pork, and poultry carcass leaving the nation's slaughter plants — numbering in the billions annually — as a prerequisite for the carcass entering commerce and being used for food. It also must by law inspect at least daily every meat and poultry processing plant, with no distinction made in the law concerning the nature of the hazards or degree of risk presented in those plants. Implementing this comprehensive inspection mandate is the focus of the FSIS program and consumes the vast majority of its resources. Unlike FDA, FSIS is not authorized to inspect or otherwise regulate on the farm.

The inspection mandate narrows the scope of the priority-setting opportunity and need at FSIS. Nevertheless, though focused on a narrower range of products and the in-plant inspection role, FSIS still must decide what pathogens or other potential food safety problems (such as BSE) deserve concentrated attention, which is a form of Purpose 1 priority setting. In addition, and more commonly, FSIS must decide how to deploy its inspection resources and other tools (such as regulations implementing the food safety standards in the meat and poultry laws by imposing processing, product testing, or other requirements) to address a particular problem. This is Purpose 2 priority setting.

Environmental Protection Agency (EPA)

EPA implements the pesticide provisions of the FDCA, under which EPA determines, prior to approval of an agricultural pesticide, how much of a pesticide can remain safely in food and sets binding tolerances to limit residues to such levels. In addition to reviewing new pesticides, EPA is charged with investigating and addressing safety problems with currently marketed pesticides and systematically reviewing old tolerances to be sure they have been subject to up-to-date testing and meet current safety standards. EPA makes far more safety decisions about chemical residues in food than do FDA and FSIS combined, making EPA an important food safety agency.

Priority setting for food safety is important for EPA in the same way it is for FDA and FSIS in the sense that the agency has finite resources and must decide how best to deploy them to protect public health. This need is especially great with respect to already-marketed pesticides, which requires Purpose 1 priority setting in choosing which pesticides or particular pesticide-related safety problems deserve priority in the deployment of field investigatory and scientific review resources.

Centers for Disease Control and Prevention (CDC) and Other Research Agencies

CDC is responsible at the federal level for foodborne disease surveillance and outbreak investigations. CDC coordinates the Foodborne Diseases Active Surveillance Network (FoodNet), which tracks laboratory-confirmed cases of foodborne illnesses associated with selected pathogens in select catchment areas. CDC also coordinates PulseNet, a national network of federal, state, and local public health and food regulatory agency laboratories that perform standardized molecular fingerprinting of foodborne disease-causing bacteria. In these roles, CDC works closely with federal and state regulatory agencies and generates large amounts of data that can contribute to food safety priority setting by those agencies. Like any government research agency, CDC has finite resources, and it must decide continuously how to deploy those resources: which pathogens or other hazards to target and how best to mount data collection and dissemination activities to advance its public health mission.

By some counts, as many as 20 federal agencies in addition to CDC are involved in food safety research, including FDA and EPA, the Agricultural Research Service and CSREES in USDA, and such diverse agencies as the National Marine Fisheries Service and the Department of Defense. Government-sponsored research can make an important contribution to improving food safety; thus, choices about how to deploy scarce research resources are amenable to Purpose 1 food safety priority setting, with a view to enhancing that contribution.

State and Local Food Safety Agencies and Health Departments

State and local agencies focus primarily on food safety at the retail level and on investigating and containing outbreaks of foodborne illness. Many also work closely with federal authorities and conduct inspections on behalf of federal agencies. They are an important part of the national food safety system. Priority-setting needs at the state and local level are similar to FDA's in that the volume of facilities and problems within their jurisdictions far exceed their resources, and, lacking detailed legislative mandates, they must constantly make resource allocation decisions and find cost-effective solutions to problems. State and local food safety agencies and health departments thus engage in both Purpose 1 and Purpose 2 priority setting.

Private Firms and Enterprises Across the Farm-to-Table Continuum

The safety of food when it reaches consumers is ultimately determined by the individuals and companies that produce, process, and market that food. These private actors must operate in accordance with the food safety regulatory standards established by federal and state agencies, but they retain substantial discretion and responsibility to make their own decisions about how to meet those standards, and, for business reasons, many companies operate food safety systems that exceed what is required by regulation.

As with government agencies, the food safety resources available to private firms are finite, and decisions often must be made about how to deploy those resources to achieve the greatest food safety gain. Many of today's food companies are large and vertically integrated and thus face a wide array of potential food safety issues and many possibilities for how and where in the system to intervene. In choosing problems (such as particular pathogens) or food categories in which to make significant new investments, companies engage in a form of Purpose 1 priority setting. More typically, however, companies are involved in system design and risk management for particular problems and seek cost-effective ways to target interventions and other risks to achieve the desired level of food safety performance. This involves Purpose 2 priority setting.

Appendix C: Lessons Learned from Developing FIRRM

The development of the FSRC Foodborne Illness Risk Ranking Model (FIRRM) was motivated by the need to provide answers to the risk-ranking questions for both Purpose 1 and Purpose 2 priority setting. FIRRM focuses on microbiological foodborne hazards because of their documented public health significance and the availability of workable methods for ranking such hazards. FSRC recognizes that chemical hazards are also important to public health and need ultimately to be included in any comprehensive risk-ranking and priority-setting scheme.

While developing FIRRM, and in subsequent discussions in the "modeling" workshop (Workshop 1) included as part of this project, we came to some important conclusions about appropriate methodology for answering these questions. Seven stand out as the most important:

- **Focus on public health impact**. We need to focus on the public health impact of illnesses, not other intermediate metrics such as measures of contamination, when making broad assessments of which hazards are most important. As further discussed in what follows, this raises significant data issues: while rates of contamination are directly measurable, there remain significant gaps in our ability to link health outcomes back to contamination levels. Nonetheless, there should be an awareness of the need to use health impact as the final outcome and, correspondingly, the need to develop data sources that facilitate the linkages among health outcomes, contamination levels, and risk.

- **Focus on food-hazard combinations.** For microbiological hazards, we need to focus on food–pathogen combinations; knowing which pathogens are responsible for illnesses is not enough to guide us toward interventions, as interventions are food or process specific. There may also be a significant proportion of illnesses related to a specific pathogen that is not attributable to food: limiting analysis to pathogen data may provide a very skewed picture of actual food-related risks.

- **Incorporate valuation of health states.** Valuation of health outcomes, either in economic or quality-of-life terms, is necessary to compare illnesses with different symptoms, severities, fatality rates, and chronic sequelae. Dollars and QALYs (Quality Adjusted Life Years) (or DALYs [Disability Adjusted Life Years]) provide aggregate measures of impact to human health across all health states, and such approaches capture individual preferences between these health states. One can compute from these data a value per case of illness (averaging over all possible health states). Computing these aggregate measures is resource and data intensive and requires detailed knowledge and assumptions regarding symptoms and treatment, but doing so is absolutely critical to the eventual estimation of benefits of interventions.

- **Identify data gaps.** The broader the scope of an analysis such as a risk ranking, the more likely it is that critical gaps may exist in the data. Identifying these data needs is vital, as it may be a valid and important priority-setting decision to gather better or additional data, rather than proceed with reallocation of resources. In the development of FIRRM, the lack of data for attributing illnesses from pathogens to foods presents significant obstacles for risk ranking. The best comprehensive source of data is outbreak reports, which do not capture sporadic cases and have regional, temporal, and other biases. To address the lack of data, we gathered additional data and performed an expert elicitation to help inform food attribution. Nonetheless, the acknowledged data gap led us to convene the Food Attribution Workshop in October 2003 (Batz et al. 2005), which has resulted in progress in data availability and research into alternative attribution approaches.

- **Consider uncertainty.** It is important to consider explicitly the uncertainty of estimates; whether using epidemiological methods or predictive modeling approaches, data are fraught with gaps, variation, and uncertainty. Providing point-estimates alone may lead to a false sense of certainty in results that could lead to poor priority-setting decisions.

- **Strive for simplicity and transparency.** Transparency and simplicity are goals to strive for, even if they cannot always be achieved. Workshop presentations and discussions cautioned researchers to be wary of overly complex models. Modeling is a very useful approach for unraveling difficult problems, but the complexity of a model is not necessarily related to its accuracy or utility. The more detailed a model's accounting of the complexity of the transport, growth and inactivation of a pathogen in a food, the more likely it is to include errors and uncertainties that are not quantified or that may remain hidden to an analyst. There is a clear tendency to deal with complexity and uncertainty in the system by increasing complexity in the associated model, a process that has a high likelihood of giving spurious results.

- **Consider alternate approaches.** Although FIRRM is "top down" and is based on analysis of public health surveillance data, other foodborne hazards likely require alternative approaches. The public health impacts of exposure to chemicals cannot be easily measured through surveillance and so concentration-response functions based on epidemiological and experimental data must be used to estimate impacts. Likewise, priority setting regarding risks with uncertain future components cannot rely on current data. Emerging pathogens (unidentified bacteria, the spread of avian influenza), pathogens with changing antimicrobial resistance (strains of *Campylobacter* and *Salmonella*), hazards with uncertain exposures or long "incubation" windows (BSE), and hypothetical risks (bioterrorism) require predictive modeling methods.