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USING RISK ANALYSIS TO INFORM MICROBIAL FOOD SAFETY DECISIONS

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INTRODUCTION

Business and governments have used both formal and informal processes to make food safety decisions. In the past, scientific data, as well as other technical, economic, and consumer research have served as the basis for much of the decision-making process, including the determination of whether the benefit of an action outweighed its costs. Data gaps always exist, however, and when data are available, it often is difficult to compare multiple research studies with each other, especially when study design, results, and/or conclusions vary or differ. Although subjective approaches for estimating risk have been used in the past, a systematic method was lacking to analyze available information and knowledge and evaluate consequences of different food safety control measures on public health. In short, policymakers have not had a structured approach for making choices among a variety of management options. Furthermore, communication with stakeholders often has been overlooked or delegated to public affairs and media relations staffs only after the decisions have been made.

Protecting the public from food safety risks, while maintaining a viable agricultural and food industry in an open society, is a daunting task. Competing stakeholder interests, legal scrutiny, public awareness, media coverage, and the inherent uncertainty of all these complex issues impinge on the food safety decision-making process now more than ever. Risk analysis provides a systematic and transparent process for gathering information, estimating risks, weighing options, drawing conclusions, and communicating information to arrive at decisions that meet broad societal needs. This approach routinely is applied to managing chemical hazards in food and in the environment. More recently, risk analysis has been applied and expanded to the assessment of microbial public health threats, including minimizing infectious and toxigenic hazards. At a very basic level, risk analysis is a tool to foster complex problem solving and decision making. It is used increasingly to help solve food safety problems and better understand the complex interactions of pathogens, food, and human hosts.

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As defined and used in this paper, *risk analysis*[1] is composed of three activities: (1) risk assessment, (2) risk management, and (3) risk communication (CAC 1999). The process of risk assessment provides information on the extent and characteristics of the risk attributed to a hazard. Risk management includes the activities undertaken to control the hazard. And risk communication involves the exchange of information and opinions concerning risk and risk-related factors among risk assessors, risk managers, and other interested parties, stakeholders, and the public.

One risk analysis component in particular—risk assessment for food safety evaluations—is becoming increasingly sophisticated and may rely on simulation (mathematical and stochastic) modeling. As such, risk assessment can be thought of as the "bridge" between research and decision making in that quantitative models can link available data to public health outcomes. The types of data used in developing these models include (1) the distribution of the frequency and amount of contaminated food consumed and (2) the relationship between exposure to the hazard and the likelihood and severity of illness. With this tool, *risk managers*[2] can evaluate human health risks more objectively in the context of the costs, benefits, and societal acceptance of hazard control options. Although risk management is clearly the responsibility of government or regulatory bodies, risk assessment tools also can be adapted to assist in the evaluation of food safety concerns at the industry level (e.g., a particular food manufacturer) and to evaluate individual food safety control and management systems (Van Gerwen and Gorris 2004).

For risk managers to use risk assessment effectively in decision making, they need to understand their role in developing and interpreting the risk assessment information, with careful consideration of data limitations and uncertainties. In this paper, the authors describe the components of microbial risk analysis with an emphasis on risk assessment and the roles of regulatory agencies, industry, researchers, consumers, and others in the process. They also outline current risk assessment practices and future needs that will permit continued use and improvement of the application of risk analysis to food safety issues.

Historical Perspective

Food microbiologists and risk managers have conducted and used qualitative risk assessments and mathematical models for many years. For example, the Hazard Analysis and Critical Control Point (HACCP) system for food safety includes a "Hazard Analysis" as its first step. In this step, in an effort to identify which hazards are significant and must be addressed in the HACCP plan (NACMCF 1997), the HACCP team collects and evaluates information on hazards associated with the food under consideration. Another example is the development of mathematical models for home canning processes for low-acid foods as summarized by Andress and Kuhn (1998).

The process of evaluating risk was described formally in 1983 by the National Academy of Science's National Research Council (NAS–NRC) report titled "Risk Assessment in the Federal Government: Managing the Process" (NAS–NRC 1983). The NAS–NRC recommendations generally have been adopted by many agencies and organizations. For example, the United Nations Joint Food and Agriculture Organization (FAO)/World Health Organization (WHO) Expert Consultation on the Application of Risk Analysis to Food Standards Issues (UNFAO/WHO 1999) recommended adapting this process for food safety issues.

The use of risk assessment to assist the development of food safety policy was elevated onto the international trade agenda by the Uruguay Round of talks to develop policies for what was to become the World Trade Organization (WTO) in 1995 (WTO 1995). In particular, the Agreement on Sanitary and Phytosanitary Measures (also known as the SPS Agreement) establishes the rights and obligations of WTO members with respect to food safety and animal and plant health measures. The Agreement recognizes the right of countries to determine their appropriate level of protection, but also prescribes the discipline of risk assessment to ensure that SPS measures do not constitute disguised trade barriers. The SPS Agreement recognizes the standards, guidelines, and recommendations developed and adopted by the Codex Alimentarius Commission (CAC) as an international "safe harbor" for food safety measures. Importing countries must base their SPS measures on risk assessments, whereas exporting countries are obliged to demonstrate that their control practices achieve an equivalent level of protection. Thus, risk assessment as either a qualitative or quantitative means to evaluate the effectiveness of anticipated control practices is used to establish food hygiene standards. Furthermore, its use is an obligation under international trade agreements.

Interestingly, the WHO stated in 1995 that risk assessment, as applied to microbial agents, could not be done in the near term (UNFAO/WHO 1995). But the first quantitative microbial risk assessment in support of a regulatory initiative was completed in 1998 (USDA–FSIS 1998), and since then, dozens of others addressing different hazards and commodities have been completed by national governments, international intergovernmental organizations, and professional/trade organizations. Two recent microbial risk assessments are described in Appendices 1 and 2. See also

[1]In some disciplines, the term *risk analysis* is used to describe risk assessment.

[2]As used in this paper, the term *risk manager* refers to a national or international government organization with responsibility for microbial risk management (CAC 2004). It is recognized, however, that industry and individual consumers also engage in risk management activities.

the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), Food Safety Risk Analysis Clearinghouse website <http://www.foodrisk.org/risk_assessments.cfm> for a user-friendly search engine to locate relevant food safety risk analysis projects.

Microbial Risk Analysis: Key Concepts

The three components of risk analysis—namely, risk assessment, risk management, and risk communication—have distinct purposes, but the activities are integrated in a manner that maintains the integrity of each unique component while informing the others. As applied to microbial risk analysis, these components are defined within the context of microbial hazards in food and water (CAC 2001), as follows.

- **Risk assessment**: A scientifically based process of formally evaluating risks, consisting of (1) hazard identification, (2) hazard characterization, (3) exposure assessment, and (4) risk characterization.
- **Risk management**: The process, distinct from risk assessment, of weighing policy alternatives in consultation with all interested parties; considering risk assessments and other factors relevant to protecting consumers and promoting fair trade practices; and, if needed, selecting appropriate prevention and control options.
- **Risk communication**: The interactive exchange of information and opinions throughout the risk analysis process concerning hazards and risk; risk-related factors; and risk perceptions among risk assessors, risk managers, consumers, industry, the academic community, and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

Examples of risk management, risk assessment, and risk communication activities within a risk analysis framework are provided in Table 1. The process begins with a problem that may or may not require a risk assessment to solve. Not all food safety problems require this level of sophistication. For example, the problem may be simple and have only one practical or available solution or could be an emergency that requires immediate action. As discussed in the following sections, even if a risk assessment is needed, the available data may limit the usefulness of the risk assessment to fulfill the risk management objectives. Academic researchers, industry, trade representatives, and others who could assist in acquisition of data should be kept informed of these data gaps.

In the following sections, the authors describe key concepts that are critical to the successful application of microbial risk analysis, including how the activities and roles of risk assessors, risk managers, risk communicators, researchers, industry, stakeholders, and others interrelate within a risk analysis framework. The case studies provided in Appendices 1 and 2 illustrate the type of complex food safety problems that can be informed by risk assessments. The quantitative microbial risk assessments completed to date include a few that begin at the harvest phase of the food chain and many that include the postharvest processing end of the food chain; however, relatively few risk assessment models have included both preharvest (farm) and postretail (consumer handling) aspects of the entire food supply chain.

Importance of Defining the Problem

The scope and direction of a risk assessment ideally is derived directly from an articulated risk management problem that stems from an existing or potential public health problem. Therefore, the boundaries and direction of the risk assessment need to be crafted to best aid risk managers in reaching their decisions. At the same time, the scope and goals of the risk assessment become defined and focused by the interaction of risk assessors, risk managers, and other interested parties to help identify technical limitations and data sources.

It is critical that all participants understand the statement of the problem to be resolved and the questions that the risk assessment must answer in order to make appropriate decisions about the type of risk assessment to be conducted and—if quantitative—the structure of the model, the types of data needed, and the model outputs. Establishing clear goals for the risk assessment helps to keep the risk assessment effort focused on the problem and prevents deviation from the overall goal over time. The goals of the risk assessment should be written as a "charge" to the team (Textbox 1). Within the international community, specifically the CAC, there is a requirement for the development of a document, referred to as a Risk Profile,[3] before embarking on a risk assessment (CAC 1999). In some instances, the risk profile may be a sufficient tool to develop and evaluate risk management options.

A particularly difficult task is to frame risk assessment questions in a manner consistent with the types of analyses that a risk assessment can address while still providing answers in a form that is useful to the risk manager. The questions that risk managers must answer typically are different from those directed to risk assessors. For example, an underlying question that a risk manager may have to address is, How can the risk of listeriosis contracted from

[3]The content of a risk profile and the role it plays in risk analysis at the international level are still in development. Nonetheless, risk profiles also are being created and used at the national level. For example, see the risk profiles developed by the New Zealand Food Safety Authority <http://www.nzfsa.govt.nz/science/risk-profiles/#P35_8387>.

Table 1. Examples of risk management, risk assessment, and risk communication activities

Risk Management (RM) Activities	Risk Assessment (RA) Activities	Risk Communication (RC) Activities
Define problem		Assist interaction of RM and others to promote understanding of the problem
Form RM team	Form RA team	Form RC team
Develop RM strategy/plan	Develop plan for conducting risk assessment	Develop RC strategy/plan
Commission RA, if needed		Assist interaction of RM, risk assessors, and others to promote understanding of scope of the RA
Commission new research, if needed →	Collect data Identify data gaps Develop model	← Inform stakeholders of RA plans and request input on plans, approach, and data sources
Review RA, model, and results ↔	Revise and re-run model, as appropriate	← Assist interaction of RM and assessors to understand initial results and model changes needed
Review draft RA document ↔	Prepare draft RA document	↔ Review draft RA document for communication effectiveness
Consider available control options to solve problem If warranted, issue interim decision	Revise RA and issue for public comment	Develop communication messages related to RA and RM plan, if needed
Review revised RA ↔	Assess, respond to, and incorporate input and comments from stakeholders and interested parties into revised RA	↔ Obtain stakeholder input on draft RA
Make final decision to solve problem in consideration of RA and other information Implement decision ←	Issue revised RA	→ Develop and issue messages to relevant parties, including press releases, if applicable
Monitor and evaluate ↔ If needed, modify decision ←	Revise and re-run model, as appropriate	→ Evaluate whether relevant parties have made the identified changes or obtained the desired knowledge

eating foods served in restaurants be minimized? For risk assessors to help, however, this question must be translated into a series of questions that the risk assessors can consider, using risk assessment tools; for example, What is the exposure to *Listeria monocytogenes* from ready-to-eat foods served in the restaurants? What is the likelihood of at-risk populations contracting listeriosis from eating in restaurants? How much of the risk would be decreased if the restaurant shortened storage times or lowered refrigerator temperatures used for food storage?

Frequent interactions between risk managers and assessors may be required to formulate or clarify the risk assessment questions. Initially, the interactions may focus on clarification of vocabulary, the needs of the risk man-

Textbox 1. Charge to risk assessors (Source: USFDA 2002)

1. Statement of risk management problem
2. Questions the risk assessment should address
3. Scope of risk assessment
4. Key assumptions: Subpopulations of interest (e.g., pregnant women); endpoint of concern (e.g., severe illness)

agers for making decisions, limitations of the available data, and limitations of the risk assessment. Through discussions of this type, thoughtful and relevant risk assessment questions can be crafted that ultimately will lead to a risk assessment designed to assist the risk manager in addressing the food safety problem.

Clear Communication between Risk Managers and Risk Assessors

Risk communication is not only something that occurs between the regulatory agency and its stakeholders. Assessors must understand why the risk assessment is needed and how risk managers will use the results. It is equally important for risk managers to understand the impact or limitations of available data on the validity of the risk assessment and how assumptions may affect results. Both managers and risk assessors must respect each others' roles and practices in the risk analysis process. Much has been written about separation or functional boundaries between risk managers and risk assessors. The rationale for creating this distinction is to ensure that risk assessment is objective and is not influenced to support a predetermined policy (CAC 1999; NAS-NRC 1983; NRC 1996; UNFAO/WHO 1995). Nevertheless, the need for separation is mitigated by the interdependence and need for communication between risk assessors, who need to develop the assessment to address management questions, and the managers, who will use the risk assessment as a decision-making tool. Furthermore, the risk managers are often the subject matter experts on whom the risk assessors must rely to develop a useful risk assessment. Appropriate boundaries can be established, yet communication maintained, if responsibilities, roles, and limitations of the participants are defined clearly.

Microbial Risk Analysis Is Iterative

The risk analysis process is iterative. For instance, if new data become available—particularly if they are different from previous data—the risk model can be updated accordingly, which in turn allows risk management approaches and risk communication efforts to be revisited. This cyclic nature of risk analysis also can be multidimensional. At one stage, the risk assessment model may be developed, reviewed, and refined. Preliminary results may further be issued for public or stakeholder comment so that the assumptions, data used, and methodology can be questioned and the risk assessment subsequently improved. Similarly, if there are changes in the system being modeled, it may be necessary to recalibrate or rethink the input parameters to a risk model(s) in an effort to represent those changes properly. Changes in regulatory or societal acceptance of risk also might lead to reevaluation of a risk assessment. The iterative nature of the risk analysis process is illustrated further by the fact that the outcome of decisions based on risk analysis should, in practice, be monitored, evaluated, and modified if warranted, which in turn may lead to new risk assessment activities, new risk management decisions, and new risk communication efforts.

Transparency

It is often stated that risk analysis must be "transparent." Basically, transparency means that the steps, logic, key assumptions, limitations, and rationale that lead to a decision must be communicated (USEPA 2000a). Such transparency, however, can occur in a number of ways. The first way is transparency of process, or openness, which ensures that risk management is not done behind closed doors, that stakeholders are participants in the process, and that the reasons for decisions are communicated to affected stakeholders. If transparency prevails throughout the entire process, stakeholders likely will be more receptive to the risk management decision, promoting greater compliance with the food safety controls and resulting in improved public health.

The second way is transparency of science. At a minimum, a transparent quantitative risk assessment is one that is documented sufficiently to be reproduced independently by qualified experts (OMB 2002). In this instance, all the evidence, assumptions, and estimates used in the development of the model and the calculations should be disclosed and understandable to those reading the report or reviewing the model calculations. Risk assessors should be encouraged to use modeling approaches and documentation that promote transparency whenever possible, including making their models and related software available for examination by others.

Third, transparency is understood by some people as communication, or accessibility. Because microbial risk assessment often involves complex methods and complicated mathematical calculations, the details of the risk assessment itself may only be understood by or accessible to specialists. Food safety, like many other technical fields, often relies on professional judgment, adherence to generally accepted practices, and a negotiated process among

those with specialized training and experience. Full transparency requires that these deliberations and decisions be documented so that the rationale for the risk assessment can be understood by other experts not engaged in the development of a risk assessment.

Because of the complexity of the process, a perception exists that microbial risk assessment can present barriers to meaningful, broad participation and understanding by nonexperts. Indeed, transparency requirements may differ if the audience is the decision maker, a risk assessment expert, an industry stakeholder, a consumer advocate, or a lay person. In designing risk analysis documentation that promotes clarity, key questions must be posed: Who is the audience? What are their concerns, values, and perceptions? What input should they have into the risk assessment process? What information do they need to participate in a meaningful manner in the risk analysis process? For each audience, the reasons for and results of the risk analysis process should be presented clearly. This action may require that a risk assessment be presented in different formats, depending on the audience and its needs. For example, whereas a technical document would have information of interest to mathematical modelers or research scientists, an interpretative summary would be useful to a nonexpert audience.

In certain instances, there may be confidentiality issues if a risk assessment includes proprietary data or information not available to everyone. In such instances, transparency may require a third party to redact a database to exclude confidential business or personal information. An exception in transparency may be warranted if the information in the redacted data set leads to improved decision making. But participants who provide information and data should be encouraged to share that data as openly as possible.

Emphasis on Public Health Outcomes

A key attribute of microbial risk assessment is the linkage of contaminated food throughout the food production system and adverse public health events. Risk assessment endpoints may be based on individual risk (e.g., risk of illness per serving), population risk (e.g., annual incidence of illness), or both. The selection of risk assessment endpoints and the determination of the *appropriate level of protection*[4] should be informed by science but ultimately are policy judgments that depend on the organization's decisional criteria under existing policy. Although a human health outcome measure is the ideal assessment endpoint, it may not be feasible in some cases; these cases may require that food safety decisions be based on an endpoint short of human health outcomes. For example, it is difficult to determine the risk of disease to humans associated with the transmission of the bovine spongiform encephalopathy (BSE) agent due to the consumption of contaminated beef because adequate data are lacking on both exposure and the dose-response relationship in humans (Harvard and Tuskegee 2001). Nonetheless, decisions to minimize exposure to the infectious prion in the interest of protecting public health have been made and associated risk-informed programs implemented (USDA–FSIS 2005). Furthermore, if the purpose of the risk assessment is to understand the relative impact of available or potential control options, the accuracy of the dose-response portion of the model may be less important; the relative change in the predictions—not the precise predicted outcomes or cases of illnesses—is of primary interest.

Microbial Risk Assessment: Current Practice

A risk assessment report typically is organized into four components: (1) hazard identification, (2) hazard characterization, (3) exposure assessment, and (4) risk characterization. Descriptions of these components and their definitions are provided in Table 2.

Types of Microbial Risk Assessment

Risk assessments can be designed to answer questions such as, What can go wrong?, How likely is it to happen?, and What can we do about it? In answering these questions, food safety risk assessments fall into four types based on the problem to be addressed (Table 3). The structure and specific type of risk assessment conducted will depend on the public health problem to be addressed, the nature of the risk management question(s) to be answered, and the availability of data.

Data and Methodology

Depending on the pathogen-food combination, a wide variety of data sources may be available to inform the risk assessment (Table 4). These data generally are derived from three main sources: government agencies, published literature, and private industry. Data may be local, regional, national, or international in scope. Reviewing all data from the published literature is important to understanding the hazard; however, it may be difficult to pool data from the published literature because of methodological differences among studies. In these instances, it is important to establish clear criteria both for the inclusion/exclusion of data and, if necessary, for how data from different sources should be weighted. Industry data can be very valuable but are not

[4]The *appropriate level of protection* is defined as the level of protection deemed appropriate by the country establishing a sanitary or phytosanitary measure to protect human, animal, or plant life or health within its territory (WTO 1995).

Table 2. Risk assessment components related to microbial food safety (CAC 2001)

Component	Description
Hazard identification	The identification of a biological agent capable of causing adverse health effects, the food or group of foods that are associated with the transmission of the biological agent, and the adverse health effects that occur when food contaminated with the biological agent is ingested.
Exposure assessment	The qualitative and/or quantitative evaluation of the likely frequency and levels of ingestion of a biological agent via food. This also may require consideration of other nonfood sources of the biological agent to determine adequately the degree to which foods contribute to the overall adverse health impact.
Hazard characterization	The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with a biological agent, which may be present in food. Dose-response is the determination of the relationship between the magnitude of exposure (dose) to a biological agent and the severity and/or frequency of associated adverse health effects (response).
Risk characterization	The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization, and exposure assessment.

Table 3. Types of microbial risk assessments (USFDA 2002)

Type of Risk Assessment	Description	Example
Risk ranking	Compares relative risk among multiple hazards or foods; used to establish risk management priorities, allocate resources, and identify critical research needs	USDHHS/USDA 2003. *Listeria monocytogenes* in Ready-to-Eat Foods
	Risk ranking model	USFDA/IFT 2004
	Risk ranking model	FSRC 2005
Product pathway	Examines the factors that influence risk associated with food/hazard pairs along a specific product production, processing, distribution, and point of consumption pathway; used to identify key factors that modulate exposure including the frequency and level of contamination and impact of mitigation or intervention strategies on the predicted risk	USFDA 2005. *Vibrio parahaemolyticus* in raw oysters USDA–FSIS 1998. *Salmonella* in shell eggs
Risk-risk	Evaluates the substitution of one defined risk for another, used to compute the overall impact or trade-off in benefits of an intervention designed to decrease a public health risk in one area but that may, as a result, increase risk in another area	Waterborne disease versus health effects from disinfection (e.g., chlorine) by-products (Fawell et al. 1997)
Geographical	Examines factors that permit or restrict a hazard introduction and distribution and resulting public health impact with respect to space and time; useful for estimating the potential risks associated with failure of a food safety system	Development of new variant Creutzfeldt-Jakob disease (v-CJD) by transmission of BSE prion from cattle to humans (Harvard and Tuskegee 2001)

Table 4. Data types, sources, and application for modeling use in quantitative microbial risk assessment

Risk Assessment Component	Data Type	Data Sources	Data Applicability
Exposure	Pathogen occurrence: Frequency and levels detected on food throughout production, processing, storage, or meal preparation	Public and private reports containing laboratory analyses or estimates from predictive growth or inactivation models	Flawed methodology, geographical differences, seasonal fluctuations, or long-term changes may restrict validity or applicability of data. In many instances, the data used in risk assessments actually were collected for other purposes, (e.g., information on consumption was collected for nutritional purposes rather than for microbial risk assessment)
	Annual number servings consumed and serving size per meal	Government consumption statistics or private marketing sources	
Hazard characterization	Dose-response curves for various strains of microbial hazards and disease endpoints of concern for specific human subpopulations	Disease surveillance, clinical studies, animal studies, in vitro virulence studies, demographic data	Limited understanding of variation of microbial virulence and of human susceptibility to disease increases uncertainty. Dose-response curves may be applied broadly once developed

always relevant; also, these data may be considered proprietary and thus may not be readily accessible.

Published literature, governmental surveys, and industry data often are of limited use because of unintended statistical, geographical, or temporal biases. Seldom are data collected in a manner that they can be considered a statistically valid sampling of the frequency and extent of contamination within a region or a country. There is an ongoing revolution in terms of sharing of data through easily accessible computer databases that make it possible for all interested parties to share relevant data in a standard format. Although such databases are not yet as widespread or universally available as desired, the trend toward their use shows no sign of abating and likely will benefit future risk assessments.

Whereas the collection of data is critical, proper management of the data is equally important, and a number of data management issues should be addressed in any risk assessment. Experience has shown that industry involvement in providing data or information for risk assessment is essential if the best final product is to be developed. But the trade-off between transparency and accessibility must be taken into account; strict assurance of confidentiality and the proper use of data are essential if industry is to be involved to the fullest extent possible. Given the ease with which large quantities of data can be shared via the Internet, risk assessment reports should include as much data as possible, as long as the data are relevant, confidentiality is not breached, and the report is comprehensible and accessible. As already mentioned, however, increased data also increases the need for formal data management practices.

Perfect and comprehensive data rarely are available for all aspects of a quantitative microbial risk assessment, and a variety of options are available to accommodate less-than-perfect data or actual data gaps. First, there are formal procedures to elicit expert opinions (e.g., Cooke 1991; Morgan and Henrion 1990) when valid observational data are not available or when there are conflicting data sources. Although advanced methodology is available for pooling expert opinions (e.g., Ayyub 2001) and adjusting for bias (e.g., Morgan et al. 2001), expert elicitation is fundamentally a request for informed judgment.

A second option is to use analogous or surrogate data from a related subject. Expert knowledge also is needed in this situation, both to select the surrogate data and to determine its suitability. The problem associated with less-than-ideal data (i.e., incomplete, limited, or nonrepresentative data) is that it can limit the risk manager's confidence in the assessment results. An example is using food consumption data in a model from one country as a substitute for data that are lacking in a second country; these data certainly are less suitable if the dietary patterns of the countries are dissimilar. It may be possible or even necessary to use less suitable data in certain situations—for instance, as a worst- or best-case scenario—to produce a qualified result with an acceptable degree of confidence. But it is imperative that the data quality be revealed explicitly in the risk assessment narrative, along with the associated uncertainties. Doing so maintains transparency and enables stakeholders to identify readily the role and impact of all data in the risk assessment process.

Peer Review

Peer review is a fundamental activity in the advancement of science, including risk assessment, to ensure the quality of published information. It involves the evalua-

tion or critique of a draft product by experts not involved in producing the draft, either by individual letter review or by convening a panel of experts (OMB 2004). Documents are available that describe the mechanisms of conducting peer reviews, such as the selection of reviewers and development of the record of the peer reviewer comments (ILSI 2002; USEPA 2000b). Nonetheless, little practical guidance exists on how peer review can best be achieved, particularly for complex food safety risk assessments and models.

Peer review needs to yield three levels of assurance.

- The assessment needs to be evaluated by experts for technical quality and validity. Risk assessment policies regarding input data, model construct, and model outputs—all of which influence data quality and interpretation—as well as the management of uncertainty must be assessed rigorously. This type of peer review may be accomplished either by lengthy examination by selected experts with particular specialties or knowledge areas or by opening the risk assessment for public comment, giving stakeholders a chance to review and question the data and methods.
- Peer review should assess transparency and evaluate the writing quality and clarity of the report(s) for different groups of stakeholders.
- The risk assessment should be evaluated by peer reviewers to determine if the original risk management questions have been addressed adequately. The degree to which those questions are answered will determine the likelihood that the risk assessment will be a useful tool to make decisions that address the public health issue.

Quantitative Microbial Risk Assessment

Risk assessments can be qualitative or quantitative. The decision to conduct a qualitative vs. a quantitative risk assessment typically is based on the extent of knowledge or data available and also may take into consideration the complexity of the problem and the time available to conduct the assessment or to commission additional research. Qualitative risk assessment often is based on criteria that may be numeric, narrative, or both. The result of a qualitative risk assessment often is dichotomous, i.e., the product is/is not classified as acceptable, or the risk can be classified as high or low.

Quantitative microbial risk assessment yields an expression of the risk as a mathematical statement of the likelihood of illness or death after exposure to a specific pathogen. These risk assessments can be either deterministic or probabilistic. Deterministic risk assessment uses single numeric values or point estimates to calculate a single point estimate of risk. Probabilistic risk assessments express one or more of the input values as probability distributions, resulting in a risk estimate that is expressed as a range or distribution (Vose 2000). The latter approach is usually more desirable because most of the risk assessment inputs one wishes to incorporate are not fixed but vary in a defined manner or are uncertain and, more likely, are both variable and uncertain. For additional information on simulation models and the differences between deterministic and probabilistic risk assessment, see Vose (2000).

Model input variables are defined by distributions of values instead of point estimates for two primary reasons: the data are variable and the data are uncertain. Within this context, variability represents the heterogeneity in a well-characterized phenomenon, usually not reducible through further measurement or study (Voysey, Jewell, and Stringer 2002). On the other hand, uncertainty represents incomplete knowledge of an empirical quantity; the analyst may be able to reduce some of the uncertainty through additional research or data collection (Voysey, Jewell, and Stringer 2002).

Characterization of Variability and Uncertainty

A key advantage of using quantitative and probabilistic risk assessment as a decision-making tool for food safety and public health improvements is the opportunity to characterize variability and uncertainty. Stated another way, risk assessment should convey the level of confidence in the results. To better understand variability and uncertainty, consider the following examples. Foods stored in refrigerators in homes throughout the United States are exposed to a variety of temperatures. If the survey data on home refrigeration temperature (collected by Audits International, 1999) are graphed, they will display a normal distribution with an average temperature of 39.3ºF and a standard deviation of 3.4ºF (Figure 1A). These data are variable; people have different types of refrigerators set at different

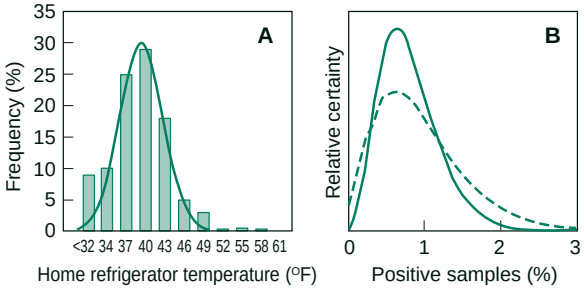

Figure 1. A. Variability represented by observed home refigerator temperatures (bars) superimposed with a normal distribution (line). B. Uncertainty represented by estimated *Salmonella* prevalence in lettuce given 1 positive out of 142 samples (dashed line) or 2 positives out of 284 samples (solid line).

temperatures with different abilities to hold a proper temperature. Conducting another survey will not change the fact that when considering all refrigerators in the United States, one expects to find different temperatures.

On the other hand, scientists are uncertain about the true prevalence of *Salmonella* in lettuce because of a lack of data. If a study were designed to collect and test 142 lettuce samples and only 1 sample was *Salmonella*-positive, the degree of certainty about the true prevalence of *Salmonella* in all lettuce might be expressed as shown by the dashed curve in Figure 1B. But if the number of tested samples doubles to 284 and the number of positives doubles to 2, the "true" prevalence of *Salmonella* in lettuce would be more certain, as shown in the solid curve in Figure 1B. Although the most likely value is 0.7% in either case (i.e., 1/142 or 2/284), the second case gives more confidence, or "certainty," about the true prevalence of *Salmonella* in lettuce.

The key feature of uncertainty distributions in risk assessment is that the collection of more data decreases the uncertainty. Indeed, there are many sources of uncertainty. Byrd and Cothern (2000) have described nine sources of uncertainty; these are detailed, along with relevant examples as applied to microbial food safety risk assessment, in Table 5.

Analytical Methodology

Variability and uncertainty are dealt with in probabilistic risk assessment by expressing input values as distributions and applying sample-based methods. In the sampling-based approach, a deterministic model is run repeatedly, drawing randomly from specified probability distributions for each uncertain model input in each model run. The set of simulations has the effect of propagating

Table 5. Selected sources of uncertainty and examples as applicable to microbial risk assessment

Source of Uncertainty	Example
Subjective judgment	In the absence of human challenge data for pathogens such as *E. coli* O157:H7, the dose-response relationship frequently is estimated using surrogate organisms such as *Shigella dysenteriae.* Choice of the appropriate surrogate, however, is dependent on the subjective judgment of experts.
Linguistic imprecision	Stating that the risk of contracting listeriosis from consumption of ice cream is minimal vs. a numerical result that the risk is 5×10^{-14} per serving or <0.1 case per 10 years within the U.S. population.
Statistical variation	Because *E. coli* O157:H7 carriage by cattle is sporadic and the product from several carcasses is pooled to make a "combo bin" of ground beef, there is wide statistical variation in the prevalence of *E. coli* O157:H7 contamination in this product.
Sampling	Pathogens usually are distributed through a batch of contaminated food; increasing the number of samples taken from the batch reduces uncertainty related to the true probability of contamination.
Inherent randomness	Pathogen contamination of fresh produce is likely a highly random event that occurs unpredictably.
Mathematical modeling	Uncertainty arises regarding the appropriate mathematical form or structure of the model itself. For example, variability in serving size could be modeled as a lognormal distribution, but this mathematical expression is an imperfect model of reality.
Causality	There is conflicting evidence that *Mycobacterium paratuberculosis* is causally associated with Crohn's disease in humans.
Lack of data or information	The biological dose-response relationship for the transmission of the BSE-vCJD agent to humans due to consumption of contaminated products. It is impossible to go back in time to measure the degree of exposure that resulted in disease; efforts might focus on trying to reconstruct the dose, but acquiring more data to decrease uncertainty is not possible.
Problem formulation	Problem formulation uncertainty often refers to normative disagreement about scope—deciding what to include and exclude from a risk assessment. This disagreement may be exacerbated by uncertainty, but it is distinct. Disagreements about problem formulation often are rooted in underlying value differences among stakeholders (Hatfield and Hipel 2002).

defined uncertainties from model inputs through to model outputs, where they can be analyzed statistically, as if they were an observed data set. The most common sampling-based method is the use of random sampling, otherwise known as Monte Carlo, although there are others. For more information about Monte Carlo modeling, see Helton and Davis (2000), Rubenstein (1981), and Fishman (1996). The output of Monte Carlo simulation is a density distribution reflecting the range of the risk estimate, which might correspond to uncertainty, variability, or both. A variety of sampling-based simulation tools are currently available on the market, including add-ins for spreadsheets; these tools are detailed in Textbox 2.

Modeling Dose-Response Relationships

The complex relationship between the magnitude of exposure to the pathogen (dose) and the manifestation and/or severity of the associated adverse event(s) caused by a pathogen (response) in the exposed population can be described mathematically using dose-response modeling (Jouve 2002). Figure 2 shows an example of a dose-response curve. In this instance, a dose-response model was fit to human clinical data from feeding trials using the pathogen *Shigella dysenteriae* (Levine et al. 1973). The "best" estimate of the dose-response relationship, shown by the solid curve in Figure 2, indicates that the probability of illness at an average dose of 1 colony-forming unit (CFU)/serving is 0.02 (i.e., 2%, or 1 in 50 consumers is expected to become ill at this dose). The uncertainty in the relationship (i.e., the confidence interval bounds) is indicated by the dashed curves. Indeed, there is substantial uncertainty in the dose-response relationship, inasmuch as at an average dose of 1 CFU/serving, the upper confidence limit for the probability of illness exceeds 10%. The confidence intervals account for uncertainty in the true value of the model parameters (i.e., uncertainty about the true mean response at a given dose in the population represented by

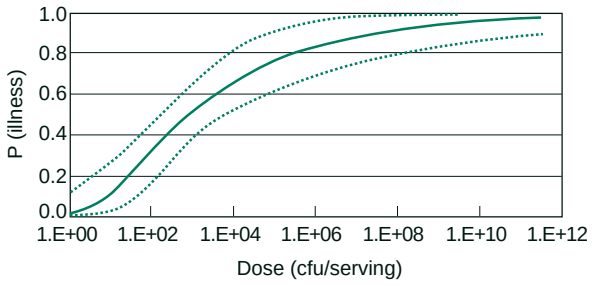

Figure 2. Estimated dose-response relationship, expressed as probability of illness [P(illness)] per given dose, for *S. dysenteriae*, a possible surrogate for *E. coli* O157:H7. Solid line displays estimated dose-response curve, dotted lines account for uncertainty in model parameters.

Textbox 2. Examples of simulation tools

"Add-ins" for Excel (Microsoft, Redmond, WA)

- @Risk (Palisades Corporation, Newfield, NY)
- Crystal Ball (Decisioneering Inc., Denver, CO)

Stand-alone tools

- Analytica (Lumina, Los Gatos, CA)
- GoldSim (GoldSim Technology Group LLC, Issaquah, WA)
- Stella (isee systems, inc., Lebanon, NH)
- WinBUGS: Bayesian inference Using Gibbs Sampling <www.mrc-bsu.cam.ac.uk/bugs/welcome.shtml>

Web-based

- CREMe (High performance computing, <www.cremesoftware.com>; used for chemical exposure modeling)

Statistical/Mathematical programming languages

- Mathematica (Wolfram Research, Inc., Champaign, IL)
- Matlab & Simulink (The MathWorks, Natick, MA)
- R <www.R-project.org>
- SAS (SAS Institute Inc., Cary, NC)
- S-Plus (Insightful Corp., Seattle, WA)

General programming languages

- Visual Basic (Microsoft)
- C++ and other similar programming languages

All these simulation tools have benefits and drawbacks; there are trade-offs in any tool that is selected. @Risk and Crystal Ball add probability distributions and Monte Carlo analysis to Excel. Analytica is a decision modeling system using influence diagrams. Goldsim and Stella are primarily dynamic simulation packages. WinBUGS can be used to develop Bayesian statistical models and evaluate them using Markov Chain Monte Carlo methods. CREMe is used for dose-response modeling, primarily for chemical exposure. Mathematica and Matlab are high-end mathematical programming languages with extensive statistical and dynamic simulation capabilities. R, SAS, and S-Plus include powerful statistical programming languages. R is open source and free. WinBUGS is free and an open source version (OpenBUGS) is available.

the trial subjects, assuming that the model is correct). But the intervals do not account for either the uncertainty about how representative the clinical trial subjects are of all consumers or the uncertainty about the correct shape of the dose-response curve. For example, model uncertainty may be particularly important in the low-dose region of the curve, because consumers are more likely to be exposed to such low doses. It is, therefore, important for risk assessors to document carefully the basis for model selection and the possible impact of that decision on the risk assessment results.

Sensitivity Analysis

Quantitative microbial risk assessment model outputs typically include some component of variability and/or uncertainty, and interpretation of these outputs can be complex. A common tool used to better understand the impact of uncertainty in model inputs (data) on a model output (risk estimate) is sensitivity analysis (see Saltelli, Chan, and Scott 2000 for additional information). In a sensitivity analysis, the influence of a variety of model parameters on a specific output is determined. One way of presenting sensitivity analysis results is using a tornado plot (Vose 2000). In such a plot, the "sensitivity" of the simulation output to specific input parameters used in the model is depicted using a vertical bar chart. The recent microbial risk assessment for the shellfish-associated pathogen *Vibrio parahaemolyticus* is used as an example (Figure 3). In this instance, the risk of disease (expressed as the number of illnesses in the population per year) is most influenced by input variables such as the concentration of the pathogen in the environment and the percentage of strains that are particularly pathogenic (Figure 3, top bars). Relatively speaking, the other input variables have proportionally less influence on disease risk when moving from the top to the bottom of Figure 3.

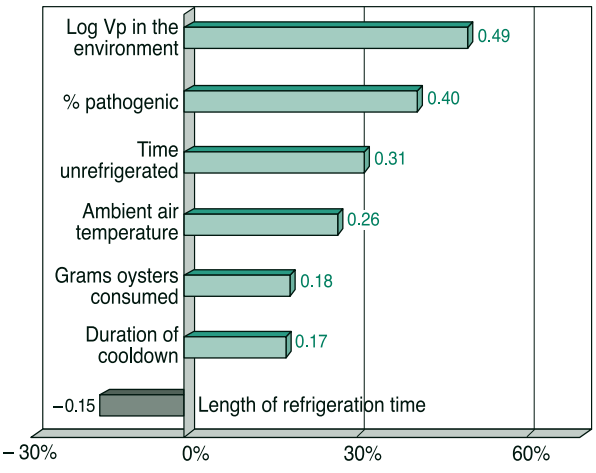

Figure 3. Example tornado plot from the FDA *Vibrio parahaemolyticus* (Vp) Risk Assessment (USFDA 2005).

What Microbial Risk Assessment Can and Cannot Deliver to the Process of Risk Analysis

The Presidential/Congressional Commission on Risk Assessment and Risk Management (1997) stated that:

> Results of a risk assessment are not scientific estimates of risk; they are conditional estimates of the risk that could exist under specified sets of assumptions and—with political, engineering, social, and economic information—are useful for guiding decisions about risk reduction.

Within this context, it is important to discuss the boundaries of what microbial risk assessment can and cannot provide.

What Risk Assessment Can Deliver

Risk assessment is an important tool to inform risk managers about food safety hazards, human health risks, and technical control options and to identify research needs. Microbial risk assessment links the presence of pathogens in food to public health outcomes, which facilitates regulatory and business decision making with regard to foodborne disease control. In a similar manner, the mathematical model associated with a microbial risk assessment can be used as a tool to determine the equivalence of different food safety systems. For example, a risk assessment model could be used to demonstrate that two different processes, technologies, or systems can yield the same level of microbial control and resulting public health protection when applied to the same food. This usage has the potential to offer protection to consumers in other countries and to provide open access to global markets for business. Whereas sporadic and epidemic foodborne disease can be described epidemiologically, microbial risk assessment combines epidemiological data and inferences with data and assumptions from other information sources in a rigorous, transparent manner to describe more fully the foodborne microbial hazard and the likely impact of control measures on the risk.

The presence of identifiable, diagnosable ill persons whose illnesses can be attributed epidemiologically to foodborne exposures creates information that can be used to characterize and quantify microbial foodborne disease risks. The nature of true human foodborne hazard exposures, however, is uncontrolled and generally difficult or impossible to quantify and fully characterize because of poor or incomplete information. For example, dose-response curves are highly uncertain, but so are underreporting factors for estimating disease incidence from

epidemiological surveillance data. Epidemiological and risk assessment approaches are, however, complementary and can be used to validate and inform each other. At the most basic level, microbial risk assessment models integrate exposure data (from contamination and consumption studies) with dose-response curves for specific microbial pathogens to characterize risk by predicting numbers of illnesses. This characterization can be done even in the absence of human health statistics.

Obviously, the models are more useful and credible if they are derived from data that encompass how foods are produced, processed, stored, prepared, and consumed and are evaluated in light of human health epidemiological data. But when data from one or more of these stages are unavailable, risk assessment can be used to estimate the impact of various production practices, food safety measures, and public health interventions in a transparent manner.

Using the risk assessment model, risk assessors—in consultation with risk managers—can exchange hypothetical data at critical nodes and rerun the risk assessment. In so doing, risk assessment techniques can be used to estimate which intervention strategies have the greatest impact on exposure or public health outcomes. Such "what-if?" scenario analyses run the gamut from estimating risk on an individual serving basis, to estimating annual risk for an entire population, or even quantifying the risk of illness for particularly susceptible subpopulations such as young children or the elderly. By including uncertainty in the assessment, risk estimates are "honest" and "true" in that they capture quantitatively the fact that predictions are not perfect. In addition, because risk assessment lays out existing data in a highly structured and transparent manner, data gaps are identified readily and it is possible to rank the importance of replacing proxy data, default assumptions, and expert estimates with real data from relevant food substrates.

Although the microbial risk assessments conducted to date have focused on single pathogens in single or multiple foods, risk assessment techniques also can be applied to the comparison and ranking of risks associated with multiple microbial hazards for the purpose of setting research or intervention priorities (Hoffmann and Taylor 2005). Finally, given the lengthy time frame of the risk analysis process (often several years), along with its transparency and the opportunity for periodic public comment, when regulatory action is finally taken, it is rarely a surprise to the constituents.

What Risk Assessment Cannot Deliver

Risk assessment is not risk management; microbial risk assessment cannot "make the decision." Rather, it provides a measure of the likelihood of a food safety event or adverse health event occurring. Risk assessment is one among a number of tools used to inform decision makers about risk associated with current practice or the estimated impact of control alternatives. Following are examples of the kind of estimates that result from risk assessments.

- Risk of listeriosis associated with deli meats compared with that of hard cheeses differs by almost 10,000,000-fold (USDHHS/USDA 2003).
- On the basis of typical ranges in household refrigeration temperature, controlling storage temperature is more effective than controlling storage time for reducing the risk of Listeriosis from foods that permit bacterial growth (USDHHS/USDA 2003).

The usefulness of risk assessments for decision making can be limited by the availability and quality of the data, as well as by the assumptions made in the analysis. It is rare that all the data desirable for a microbial risk assessment will have been collected, and, for some model inputs, no data will exist at all. Filling these data gaps by conducting experimental or epidemiologic studies or field surveys takes time as well as human and financial resources and may be technically or physically impossible. To deal with this situation, risk assessments incorporate uncertainty into the risk estimates. When uncertainty ranges are very broad, this may limit the apparent usefulness of the risk assessment in addressing risk management decisions. Nonetheless, decision making often proceeds despite large uncertainties. For example, business or government agencies may be required to proceed with a program despite substantial uncertainty, or risk managers may determine that the potential public health costs of delay outweigh the anticipated benefits of additional information. In these instances, quantitative microbial risk assessment may not be appropriate or timely and could be replaced with more qualitative approaches. If resources and time permit, however, the primary value of quantitative risk assessment in this context is to provide a reasoned basis for decision making, while clearly outlining the uncertainties.

Microbial risk assessment does not deliver a "final" answer but rather a snapshot of the current situation and available information; any change in the food supply systems would impact the estimated risk. In many instances, data are collected over a period of years and under different conditions; data on the prevalence and levels of pathogens in foods, for instance, may be derived over a period of decades and from many different countries. If the data collected over time and space are not representative of the current conditions and populations, the risk assessment results may not reflect the current risk or public health burden accurately. Changes in food or food production systems that occur over time also will affect risk. For example, growing antimicrobial resistance by pathogenic organisms may influence their response to various control measures or change the intensity of health impact (Claycamp and

Hooberman 2004; Threlfall et al. 2000). The prevalence of many pathogens in foods is expected to decline as industry improves food safety controls. But even with the inevitable changes that occur over time, microbial risk assessment provides a structure for reevaluation of risk management decisions based on updated estimates of risk as new technologies and/or additional data become available.

There are concerns that some microbial risk assessment models have difficulty predicting new situations. Even though models may undergo a calibration process (whereby unknown input values are modified so that the model output agrees with observed real-world data), a model that perfectly *describes* the current situation may fail to *predict* the effects of changes to the system. Therefore, model verification using an independent data set would provide further confidence in the model output and its predictive power. Unfortunately, these types of independent data sets are rarely available, although the situation is improving. For example, the dose-response model used in the 2003 *Listeria monocytogenes* Risk Assessment (USFDA–CFSAN 2003) was developed with the historically used mouse dose-response relationship, which then was scaled to match human listeriosis. This calibrated curve compared favorably with human listeriosis outbreak data, which served as a form of model validation.

Ideally, the objectives of the risk managers and the available data will determine the level of complexity used in the modeling process. In most instances, risk assessment uses data from studies designed for non-risk assessment purposes. Therefore, the limitations on inferences that can be drawn from the available data should be described in the risk assessment. In practice, however, availability of data also impacts the assumptions and resulting model complexity. Inherently, quantitative models tend to focus on aspects of a problem for which data are available. For example, cross-contamination during food preparation usually is assumed to be negligible or is excluded from the scope of existing microbial risk assessments. Although there is limited evidence (Gorman, Bloomfield, and Adley 2002) but a general belief that cross-contamination is important (Kusumaningrum et al. 2004), there are virtually no empirical data currently available for incorporating cross-contamination in a quantitative risk model. Also, most microbial risk assessments are concerned with a single bacterial species, yet microbial interactions often can limit the growth of some pathogens in foods (Alves et al. 2005; Grau and Vanderlinde 1992; Jameson 1962). Taken together, these examples illustrate the fact that microbial risk assessment models require some degree of simplification.

Roles, Benefits, and Perspectives

The roles and perspectives of various organizations that contribute to the risk analysis process by conducting or using risk assessments and the benefit of this approach to those groups are described in this section.

U.S. Regulatory Agencies

Food safety issues may be identified in several ways: (1) by public health officials who determine that sporadic illnesses and outbreaks of disease are being caused by contaminated food, (2) by food microbiologists who document the presence of foodborne pathogens in various foods, or (3) by other means. When national food safety issues arise, the primary purpose of risk assessment is to provide risk managers with information organized in a manner that assists in the selection of appropriate risk management strategies. It is the responsibility of regulatory agencies to initiate, support, and interpret the risk assessment from its inception to its completion, including its use as a risk management and communication tool. In the face of a public health emergency, a risk assessment by necessity will be cursory, and risk management decisions will be made quickly.

It may be appropriate, however, once the emergency has subsided, to conduct a more thorough and thoughtful risk assessment to guide development of prevention strategies for the future or to modify the initial decisions made. As part of this longer-term process, quantitative risk assessment provides the scientific basis for establishing good practice guidance, regulatory standards, and other objective measures of performance necessary to achieve public health goals. Risk assessments also can provide an agency with tools for ranking relative food risks and establishing priorities to allocate regulatory and research resources. Most importantly, when risk analysis is conducted in a scientifically credible, open, transparent, and well-documented manner, it provides a common understanding of the issues among government, industry, and consumers. This understanding facilitates the development of socially acceptable, technically and economically feasible solutions to food safety problems.

International Organizations

On an international basis, risk assessments are helpful in demonstrating the relationship between amounts of pathogen contamination and various public health outcomes. This information provides a scientific basis for trading partners to evaluate the equivalence of different food safety measures with respect to the desired level of protection. The WHO and the FAO are supporting the CAC, the international, intergovernmental food safety standards-setting body recognized by the WTO, through the conduct of expert consultations, the commissioning of "international" microbiological risk assessments, and the provision of risk assessment training in developing countries. These activi-

ties are fostering the elaboration of international standards by Codex committees that are appropriate and achievable, thereby facilitating the trade of safe food. Guidelines and international risk assessments are available at <http://www.who.int/foodsafety/publications/micro/en/index.html>.

Industry/Trade Associations

Today, many businesses use probabilistic modeling techniques to estimate likely financial outcomes. There is growing industry recognition, especially within the quality systems components of the food, beverage, and ingredient industries, of the value of process modeling and its integration with risk management. In addition, industry and trade associations representing industry groups have been participating with government in the risk assessment process by providing product data and working with federal risk assessors to evaluate the appropriateness of the scenarios used in the sector or segment targeted in the assessment. In a farm-to-table risk assessment, for example, industry will have the most current information on the manner and conditions in which food or ingredients are produced, processed, held, transported, retailed, and prepared for consumption. Because each of these steps may contribute to an increase or decrease in the targeted hazard, input from industry will assist in assuring that all likely scenarios are considered, and that the assumptions needed for completion of the risk assessment are informed by up-to-date information to the greatest extent possible.

Industry and trade associations also may be able to provide information needed to decrease uncertainty in the risk estimate. Such information may include historical data on hazard levels at various stages in the food chain, the effectiveness of current and potential interventions on the hazard of concern, and the likely time and temperatures of storage and distribution that may influence a change in the level of the hazard.

It also should be understood that the food industry is populated by diverse firms of all sizes and technical competencies. To a large extent, trade associations rely on voluntary efforts for technical inputs, especially when the inputs involve data. These limitations are likely to result in incomplete data and an inability to estimate levels and frequency of microbial hazards accurately in specific categories of foods produced by firms of various sizes. Risk assessors must be cautious in the use of data that may be representative only of larger, more technically sophisticated firms as opposed to being representative of foods produced under the variety of conditions that may exist. Despite these limitations, industry information and input are essential for a transparent and technically sound risk assessment.

Academia and Consulting Firms

Academic scientists and consultants also have a role in microbial risk analysis. Research by academic institutions and consulting firms supplies many of the data used in the risk assessment process. In addition, both groups provide a wealth of expertise on which risk assessment teams can draw. For instance, academicians and consultants frequently are tapped for participation on various risk assessment teams. Independent consultants also have been asked periodically to address issues germane to microbial risk assessments, such as adapting conventional sensitivity analysis methods historically used in chemical risk assessment to microbial food safety risk assessment. Likewise, modeling of some of the critical data needed in risk assessment, such as the effect of consumer food handling practices on risk, has been undertaken by the academic sector. The interface between food safety risks and the epidemiology of foodborne disease also has been explored under the guidance of consulting firms. Finally, academic laboratories can offer expertise in the design and implementation of studies to fill in data gaps that might be identified in the risk assessment process. Although food safety risk communication may be in its infancy, social scientists and experts in risk communication and health behavior are likely to have important roles in developing public messages that speak to the various constituents invested in food safety.

Consumers

Research studies consistently show that consumers are likely to have heard about certain foodborne pathogens, and a sizable number of them harbor some degree of concern about the safety of the food supply. Yet recent research shows that many consumers are unaware of, or unmotivated to take, the basic steps that can prevent foodborne disease, despite the availability of messages that promote safe food handling. The ability of individual consumers to participate meaningfully in food safety analysis and policy deliberations is necessarily limited by the time, resources, and specialized education and experience necessary to gain effective access to the process. Nonetheless, consumers are stakeholders as well, and they should be encouraged to take a proactive role in microbial risk analysis, from the beginning of the process through its completion. Creating opportunities for consumer involvement, including providing them with the tools necessary to facilitate such involvement, is critical.

In fact, consumers and especially consumer groups have played a vital role in microbial food safety by elevating food safety issues on the public agenda, scrutinizing the basis for risk management decisions, ensuring that public policy deliberations take place in the full light of day, and

holding government and industry accountable for food safety performance. Both consumer groups and the food industry share a common interest in ensuring transparency in microbial food safety risk analysis that is conducted in support of regulatory decision making. Because consumers are the ultimate arbiter of acceptability through their food purchase decisions, risk managers who are considering controversial risk management strategies or strategies that can only partly mitigate risk may wish to reach out to consumers through risk communication efforts to review possibilities as part of the deliberative process.

Conclusions and Future Needs

Risk analysis is a tool to improve complex problem solving and decision making in food safety. It is increasingly used to help solve food safety problems and to better understand the complex interactions of pathogens, food, and human hosts. The use of risk assessment as a tool to set food hygiene standards is not only the most objective or scientific way to determine the effectiveness of anticipated control practices but also is now an obligation under international trade agreements. It should be clear that risk analysis practices as applied to microbial food safety have developed rapidly over the last decade and will continue to be present for many years. Despite the rapid growth in the field, however, risk analysis as applied to food safety is still in its infancy. Recommendations regarding the future application of microbial risk analysis to the field of food safety include the following:

- Target research to decrease the most important uncertainties and data gaps identified by existing microbial risk assessments or that might impact future risk assessments. Regulatory agencies, industry, and academic units should be encouraged to collect data in a manner that would make it more useful to risk assessment modeling efforts. Although these types of studies are costly and time-consuming, their completion is essential for achieving substantial reductions in uncertainty, and hence better risk estimates, in the future.
- Develop improved methods to support risk assessment efforts. For example, improved epidemiological investigation and surveillance approaches, including attribution of pathogens to specific routes of contamination, food vehicles, and consumer behaviors, are needed so that more definitive links between contaminated foods and resulting foodborne illness cases can be established. Development of microbiological methods that allow for the quantification of pathogen load, rather than determining simple presence/absence, is needed. National food consumption surveys need to be redesigned for relevance to risk assessment efforts and to provide information relevant to changing food consumption patterns.
- Develop and apply the most appropriate modeling techniques. Continued improvements in computer technology and the application of techniques from the physical sciences, as applied to understanding biological structure and function, need to be incorporated into current modeling practice to continue to improve microbial risk assessment. Modeling techniques also can be applied to risk management and communication using decision analysis tools in an effort to develop more comprehensive understandings of risk.
- Promote ever-increasing transparency and continued dialogue among risk assessors, managers, and stakeholders. Assessors and managers must be made aware of the barriers to successful implementation of their assessments. More systematic and scientific efforts are needed to understand stakeholder values, perceptions, and concerns. Stakeholders throughout the food chain should seek to develop a greater understanding of risk assessment and how they can participate effectively in the process.
- Improve risk communication. Of the three components of risk analysis, this is probably the least well understood. Improved risk communication begins with recognizing the three separate and distinct steps to risk analysis. Efforts should focus on providing adequately funded risk communication resources for people and institutions working at the cutting edge of risk analysis.
- Encourage food microbiologists in academia, industry, and government to design and interpret their work in terms consistent with the support of risk assessment. In particular, universities should develop graduate-level programs to train future risk analysis practitioners in all risk analysis components, including risk assessment, risk management, and risk communication.

Appendix 1. Case Study: Antimicrobial Resistance Risk Assessment for Food Safety: Virginiamycin

The U.S. Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) conducts risk assessments for food safety risks associated with uses of new animal drug applications (NADAs) in food animals. Public concern for food animal uses of antimicrobial drugs has grown in proportion to the public's awareness of the resistance of human pathogens to antimicrobial drugs used in humans, and because some antimicrobials approved for

food animals are chemically similar or equivalent to drugs used to treat human infections. The particular adverse consequence of concern is that antimicrobial resistance among bacterial populations—not drug residues—in food animals might transfer "up" the food chain to bacteria, causing human illness.

Risk assessment for the transfer of antimicrobial resistance in the food supply adds another layer of complexity to food safety risk assessment compared with risk assessments for either bacteria or chemical residues. Antimicrobial resistance is carried either on the genome or on plasmids within bacteria and may transfer among bacteria adapted to either food animals or human hosts. Bacterial species carrying resistance might be either frank pathogens or commensal organisms that colonize or cause opportunistic infections. Additional complexity in risk assessment occurs from the mechanisms of drug resistance because there often are multiple and overlapping biochemical mechanisms for antimicrobial resistance for a given antimicrobial drug.

The CVM recently published in draft form its second antimicrobial resistance risk assessment: *Risk Assessment of Streptogramin Resistance in* Enterococcus faecium *Attributable to the Use of Streptogramins in Animals* (USFDA 2004). In this exercise, a probabilistic risk assessment was developed to link resistance to virginiamycin, a food animal streptogramin mixture, with possible resistance to Synercid, a drug for treating human vancomycin-resistant *Enterococcus faecium* (VREF) blood stream infections. The population at risk of VREF blood stream infections and, therefore, of receiving Synercid, is predominantly hospitalized individuals who have received venous or central line catheters.

The streptogramin-resistant *E. faecium* (SREF) risk assessment assembled data on the release of resistant SREF among food animal populations, the exposure of humans to retail meat and poultry possibly contaminated with SREF, the types and prevalence of streptogramin resistance genes among animal- and human-adapted *E. faecium* strains, and the rates of Synercid resistance among hospitalized populations. Similar to most new applications of risk assessment, there were many gaps in information and data that could directly inform the initial estimates in the model. Thus, CVM developed three modeling approaches, using reasonable surrogate data that were applied in parallel. These models were based on alternative starting assumptions and data from the National Nosocomial Infections Surveillance and National Hospital Discharge Survey data bases from the National Center for Health Statistics, the scientific literature, and sales volume information for Synercid.

The SREF risk assessment required an assumption of the potential attribution for food animal sources of resistance. The assumption, 10%, was derived from case-control studies on hospital *Enterococcus* infections in which this proportion was typical for cases that could not be explained by contact with hospital staff, equipment, or visitors. Under this assumption, the 95th percentile estimate of risk to the hospitalized population was estimated to range from 0.06×10^{-6} to 1×10^{-6} in 1 year , depending on which of the three models was used.

Although the draft SREF risk assessment includes significant remaining data and model uncertainty, nevertheless, risk managers are examining the results in conjunction with a parallel risk assessment from Australia, and information on the results of the European removal of virginiamycin for growth promotion purposes in food animals several years ago. The CVM risk managers currently are engaging stakeholders in discussions about the significance of the risk assessment results.

Appendix 2. Case Study: USDHHS/USDA *Listeria monocytogenes* Risk Assessment

The *Listeria monocytogenes* Risk Assessment (LMRA) was a joint effort led by the U.S. Food and Drug Administration's (FDA) Center for Food Safety and Nutrition (CFSAN) in collaboration with the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS), and in consultation with the U.S. Centers for Disease Control and Prevention (CDC). The LMRA was commissioned in response to a presidential request for federal agencies to develop control plans to decrease listeriosis by 50% by the year 2005. The purpose of the assessment was to identify which foods should receive the most regulatory attention. The risk assessment quantified for the first time the magnitude of the differences in the predicted risk of listeriosis for different ready-to-eat (RTE) foods. For example, there was an almost 10 million-fold differential between the risk associated with consumption of a serving of deli meats (one case of listeriosis in every 7.7×10^{-8} servings) and those associated with hard cheeses (one case in every 4×10^{-15} servings).

To help risk managers characterize the uncertainty in the risk predictions, a statistical technique referred to as "cluster analysis" was used. The simulation outputs (risk/serving and risk/annum) for each of 23 categories of RTE foods were grouped into clusters that subsequently were sorted into a two-dimensional matrix. Risk managers were able to use the matrix to develop different approaches to controlling listeriosis based on the relative risk and characteristics of specific foods.

Although the LMRA purposely did not consider contamination points along the pathways for the manufacture

of individual foods, the models developed can be used to estimate the likely impact of control strategies by changing one or more input parameters and measuring the change in the model outputs. This process, referred to as conducting "what if?" scenarios, can be used to explore how the components of a complex model interact. In the case of the LMRA, scenarios were run to allow comparison of the baseline calculations to new situations that might arise as a result of potential risk reduction strategies. One example of a "what if?" scenario was that of the impact of assuring that home refrigerators do not operate above 5ºC (41oF). In this example, the distribution of home refrigerator temperatures was truncated and the model rerun. Subsequently, the predicted number of cases of listeriosis was lowered from 2,105 to 28 cases per year. Based on this result, the FDA continues to emphasize in its consumer messages the need to maintain home refrigerators at the proper operating temperature. The models and "what-if?" scenarios identified five factors that affect consumer exposure: (1) amounts and frequency of consumption of an RTE food, (2) frequency and levels of *Listeria* in food, (3) potential of the food to support growth of *Listeria* during refrigerated storage, (4) refrigerated storage temperature, and (5) duration of refrigerated storage before consumption.

The scientific evaluations and mathematical models developed for the LMRA provided a systematic assessment of the scientific knowledge needed to evaluate the effectiveness of current policies, programs, and practices and to identify new strategies for minimizing the public health impact of foodborne *L. monocytogenes*. The LMRA was the basis of the revised FDA/CDC Action Plan to reduce listeriosis. Moreover, the assessment provided a foundation to assist future evaluations of the potential effectiveness of new strategies for controlling foodborne listeriosis. The LMRA is being used to evaluate and revise the provisions in the Food Code that address preventive controls for *L. monocytogenes* in retail and foodservice establishments.

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