1 Introduction

Foodborne illness has major consequences worldwide, in terms of human health and financial burden to society and the food industry (Buzby et al., 1996; Todd, 1997; Buzby and Frenzen, 1999; Frenzen et al., 1999; Sackett and Todd, 2000). In the US, it has been estimated that about 76 million illnesses, 325,000 hospitalizations and 5020 deaths are caused by foodborne agents every year (Mead et al., 1999). Unknown agents account for more than 62 million (81%) of these cases. Of the 14 million cases in which the agent is identified, Norwalk-like viruses are estimated to cause 9.3 million illnesses, and *Salmonella*, *Listeria* and *Toxoplasma* are responsible for most of the 1510 deaths attributable to an etiological agent.

In recent years, many new food safety pathogens have been recognized and new food safety issues have arisen, including, for example, hamburger meat, apple cider, alfalfa sprouts and well-water contaminated with enterohemorrhagic *Escherichia coli*; coleslaw, soft cheeses, pâtés and hot dogs contaminated with *Listeria monocytogenes*; tomatoes, sprouts and melons contaminated with *Salmonella enterica*; mesclun lettuce, basil and raspberries contaminated with *Cyclospora cayetanensis*; *Cryptosporidium parvum* in water and produce; and antimicrobial resistance in several genera of pathogens (Smith and Fratamico, 1995; Beuchat, 1996; Altekruse et al., 1997; Como-Sabetti, 1997; Tauxe, 1997; Van Beneden et al., 1999; Millar et al., 2002; White et al., 2002). Better laboratory detection methods, targeted surveillance and better outbreak recognition have improved our ability to identify and track foodborne disease. However, there is a general consensus
that over the last two decades there has been a real increase in foodborne illness, although more recently there may be evidence of a decline in some foodborne diseases, at least in the US (Vugia et al., 2003). Despite exemplary improvements in the food industry at large, and unprecedented efforts of public and private organizations, disease-causing microorganisms are capable of adapting to new niches, new vehicles of transmission and new hosts, acquiring novel resistance and virulence mechanisms along the way. Microbiological hazards in food and water continue to impose a significant burden on public health and the economics of food production.

The recent statistics of foodborne disease indicate the extent of the problem and the need for safe preparation and handling of foods (Farber and Todd, 2000). However, although the risks are apparent, there is a need to better define the extent and severity of foodborne disease, especially for food products in commerce, together with a re-examination of current food safety priorities and practices. In 1994, the US Council for Agricultural Science and Technology published a report advocating the use of risk assessment techniques to establish priorities for managing and improving food safety (Foegeding and Roberts, 1994). The recommendations were revisited in 1998 with even stronger recommendations to base food safety policy on risk assessment and risk management practices (Foegeding and Roberts, 1998). It is recognized that there is no such thing as zero risk, and that it is not feasible to reduce all risks for all foods. However, food industry and regulatory risk managers should identify those risks that have the largest impact on public health, and implement programs to reduce the level of risk to the minimum that is practical, technologically feasible and socially acceptable. Recently, a risk-based approach to controlling foodborne disease has been proposed by the International Commission on Microbiological Specifications in foods (ICMSF, 2002). This includes setting specific public health goals relating to reduction of a disease by a certain time, and food safety objectives to meet these by industry.

What is ‘risk’? Risks, and their assessment, are common in our everyday lives. Generally, we think about risk as the likelihood, or probability, of some adverse event or situation occurring. We may be able to quantify it in broad terms, such as one-in-a-million chance if we think it is a rare possibility. However, that thought process should also address not only how likely it is that something will go wrong, but also how bad it will be if it does go wrong (Kaplan and Garrick, 1981). For perspective, a common example might be that although the likelihood of falling in the home is greater than that of having an automobile accident, the latter gives us more concern, partly because we read or hear about the more serious accidents more frequently.

Evaluations of risks associated with foodborne hazards in the past have most often been general considerations of the hazard, routes of exposure, handling practices and/or consequences of exposure. Quantifying any of these elements is challenging, since many factors influence the risk of foodborne disease. These complicate interpretations of data about the prevalence, numbers and behavior of microorganisms, and confound the interpretation of human health statistics. Consequently, policies, regulations, and other types of decisions concerning food safety hazards have been largely based on subjective information and observations. However, advances in science combined with increased consumer awareness, global trade and recognition of the economic and social impacts of microbial foodborne illness have moved us toward the threshold of using quantitative risk assessment to help determine food safety priorities.
This chapter focuses on aspects relevant to microbial food safety risk assessment. However, the principles and practices discussed also apply to assessment of the risk from all types of foodborne hazards, including all biological, chemical, and physical hazards.

2 Movement away from traditional methods to evaluate the safety of food

2.1 The need for change
Traditional visual or organoleptic tests to detect visible contamination and deterioration of raw foods, and end-product laboratory testing for pathogens or indicator organisms in prepared foods, does not necessarily deliver reasonable assurances of safety. This is because of the practical limitations of sampling enough of the food product, the time needed to obtain test results, and the lack of sensitivity and/or specificity of current methods (ICMSF, 2002). Pathogens are infrequently present in foods, and if they are they are usually present only in very low numbers. However, most bacterial agents can multiply under conditions of temperature abuse and/or survive improper cooking, and some can cause illness even if only a few cells are ingested. Thus, a more practical risk-based approach is required to make management decisions relative to the safety of a product up to the moment of consumption.

2.2 Regulation
An important motivation for the adoption of formal quantitative risk assessment is the demand for rational, scientifically valid regulations to replace the traditional, subjective approaches that were developed many years ago. For example, to move away from prescriptive regulations about the numbers of sinks, or cleanliness of walls in food-processing operations, to an ‘outcome-based’ approach focused on those aspects of food processing, preparation and handling critical to reducing or eliminating pathogens. Thus, a system is needed that quantifies the relationship between regulatory requirements and public health outcomes and will help to establish priorities for risk management.

2.3 HACCP
Given current systems of primary food production, it is difficult to prevent raw materials contaminated with potentially pathogenic microorganisms from entering the food supply. Food safety risk management strategies must include steps in the processing of foods that reduce or destroy microbes, prevent recontamination of product, and improve retail, food service and consumer practices to prevent the mishandling of foods. The Hazard Analysis Critical Control Point (HACCP) approach is one such strategy that can be applied to the entire food chain, from production to consumption. Key steps in the processing, distribution, marketing and preparation of a food that are critical to the safety of the product (i.e. critical control points or ‘CCPs’) are monitored and
controlled. However, HACCP is a risk-based management system that has been developed on the basis of qualitative assessments of hazards, their impacts and their control. The efficacy of HACCP is limited by its inability to quantify the potential combined result of multiple control-point deviations, and to relate the operation of a HACCP system to a measurable public health outcome (Buchanan and Whiting, 1998a).

2.4 Global food trade

Perhaps providing the greatest impetus for food safety risk assessment is international trade. The worldwide recognition of the importance of international commerce and the need to facilitate trade and ensure the quality and safety of food led to the establishment of the Joint FAO/WHO Food Standards Programme and the Codex Alimentarius Commission (CAC) in 1962 (Lupien and Kenny, 1998). Standards for foods in international trade are developed and agreed to by consensus among the Codex member countries. The Uruguay Round of the General Agreement on Tariffs and Trade (GATT), which was replaced by the World Trade Organization (WTO) in 1995, declared that formal risk assessment must be the basis for food standards and the resolution of non-tariff trade issues (Horton, 2001). Thus, it is important to develop uniform approaches to risk assessment.

3 Managing risk through risk assessment

Structured scientific risk assessment processes were introduced within US federal regulatory agencies during the late 1970s as a means of standardizing the basis for decision-making. These were driven by the need for regulatory action in situations where large numbers of people were, or could be, exposed to relatively low levels of chemical substances that had been identified as hazardous to health, but only under conditions of relatively intense exposures (Rodricks, 1994). The actual decision-making processes and the communication of information from the science-based risk assessment activities were defined as risk management and risk communication (NRC, 1983, 1994). The three elements, risk assessment, risk management and risk communication, are collectively referred to as risk analysis. This approach is widely used in fields such as environmental health, toxicology, cancer research, and chemical and nuclear industries. More recent is the use of risk analysis in microbial food safety.

It is noted that within each discipline, and even among workers within a field, some differences exist in terminology and approaches to categorizing activities and evaluating the risk parameters. However, the basic framework described by NRC underlies most developments in this field. At the international level, Codex is responsible for defining risk assessment principles and practices for all foodborne hazards, and for promoting consistency and clarity in the establishment of Codex standards through the use of risk analysis. Through a series of consultations, international discussion, debate and consensus, a framework, principles and guidelines have evolved for the application of risk analysis for food safety hazards (FAO/WHO, 1995, 1997, 1998). Table 2.1 lists the current definitions of terms for risk analysis, adopted in 1999 (CAC, 1999).
### Table 2.1 Definitions of risk analysis terminology for foodborne hazards (CAC, 1999)

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td><strong>Hazard</strong></td>
<td>A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect</td>
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<tr>
<td><strong>Risk</strong></td>
<td>A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food</td>
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<tr>
<td><strong>Risk analysis</strong></td>
<td>A process consisting of three components: risk assessment, risk management and risk communication</td>
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<tr>
<td><strong>Risk assessment</strong></td>
<td>A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization</td>
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<tr>
<td><strong>Quantitative risk assessment</strong></td>
<td>A risk assessment that provides numerical expressions of risk and indication of the attendant uncertainties</td>
</tr>
<tr>
<td><strong>Qualitative risk assessment</strong></td>
<td>A risk assessment based on data, which, while forming an inadequate basis for numerical risk estimations, nonetheless when conditioned by prior expert knowledge and identification of attendant uncertainties permits risk ranking or separation into descriptive categories of risk</td>
</tr>
<tr>
<td><strong>Hazard identification</strong></td>
<td>The identification of biological, chemical and physical agents capable of causing adverse health effects and which may be present in a particular food, or group of foods</td>
</tr>
<tr>
<td><strong>Hazard characterization</strong></td>
<td>The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with the hazard; for the purpose of microbiological risk assessment, the concerns relate to microorganisms and/or their toxins</td>
</tr>
<tr>
<td><strong>Dose–response assessment</strong></td>
<td>The determination of the relationship between the magnitude of exposure (dose) to a chemical, biological or physical agent and the severity and/or frequency of associated adverse health effects (response)</td>
</tr>
<tr>
<td><strong>Exposure assessment</strong></td>
<td>The qualitative and/or quantitative evaluation of the likely intake of biological, chemical and physical agents via food as well as exposures from other sources if relevant</td>
</tr>
<tr>
<td><strong>Risk characterization</strong></td>
<td>The process of determining the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse effects in a given population based on hazard identification, hazard characterization and exposure assessment</td>
</tr>
<tr>
<td><strong>Risk estimate</strong></td>
<td>Output of risk characterization</td>
</tr>
<tr>
<td><strong>Transparent</strong></td>
<td>Characteristics of a process where the rationale, the logic of development, constraints, assumptions, value judgments, decisions, limitations and uncertainties of the expressed determination are fully and systematically stated, documented and accessible</td>
</tr>
<tr>
<td><strong>Uncertainty analysis</strong></td>
<td>A method to estimate the uncertainty associated with model inputs, assumptions and structure/form</td>
</tr>
<tr>
<td><strong>Risk management</strong></td>
<td>The process of weighing policy alternatives in the light of results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures</td>
</tr>
<tr>
<td><strong>Risk communication</strong></td>
<td>The interactive exchange of information and opinions concerning risk and risk management among risk assessors, risk managers, consumers and other interested parties</td>
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</table>
Definitions and usage of the term ‘risk’ vary. Frequently, the word ‘risk’ is used to reflect the probability or likelihood of an event, i.e. the probability that an identified hazard will cause harm. However, more precisely, as indicated earlier, risk is a function of both the probability of an adverse outcome and the impact of that adverse event attributable to a hazard. ‘Severity’ is frequently used to describe the seriousness of the effect(s) of the hazard. For microbial hazards, estimates of severity include but are not limited to the number and impact of the symptoms, the proportion of cases hospitalized, the case/fatality ratio, the long-term effect of sequelae, and the duration of illness.

### 3.1 Risk assessment

Risk assessment is the scientific evaluation of the probability of occurrence and severity of known or potential adverse health effects resulting from exposure to a hazard. The result is an estimate of the likelihood and impact of an adverse effect on human health produced by a likely level of exposure to a hazardous agent.

Risk assessments are typically divided into four distinct steps: hazard identification, exposure assessment, dose–response assessment, and risk characterization (NRC, 1983). This basic framework has been modified by introducing the term ‘hazard characterization’ – a step that includes a dose–response assessment if the data are available, but allows more subjective assessments of the consequences of exposure if a dose–response assessment cannot be carried out (Figure 2.1).

### 3.2 Risk management

Risk management includes consideration of policy alternatives in light of the results of risk assessment and the selection and implementation of appropriate control options. Industry and regulators should strive for production and processing systems that ensure that all food is safe and wholesome. However, it is acknowledged that complete freedom from hazards is an unattainable goal.

The primary goal of the management of risks associated with food in international trade is to protect public health by controlling such risks as effectively as possible. The decision-making process takes into consideration the scientific evidence within the context of other factors and/or values. These may include cost–benefit assessment; social, cultural and ethical concerns; and political and legal issues. The extent to which decision-makers take into account additional factors is dependent on the risk issue and its context. For example, in the resolution of trade disputes between countries or in establishment of international food standards, decisions should be principally based upon the scientific assessment of the risk of human illness, and of the degree to which there are viable strategies to reduce the risk.

In the establishment of national priorities in relation to public health, managers will generally consider in their deliberations the values of regulation, surveillance or research; public perceptions of the risk and other social concerns; and the economics of different management options. The food industry will generally need to consider the business costs in making decisions. Risk management strategies for foods may range from promulgating regulatory standards and issuing microbiological guidelines, to
product labeling and consumer education. Options may include the implementation of interventions at any part of the food chain to prevent, reduce or eliminate contamination of food or limit opportunities for microbial growth. Finally, banning a food from the marketplace is also an action that can be taken if the risk from consuming a product is unacceptably high and no other feasible management options exists.

3.3 Risk communication

Risk communication emphasizes the need to exchange information and opinion interactively among risk assessors, risk managers and other interested parties. Interested parties, or stakeholders in the risk issue, may include, for example, growers, producers, processors, food workers, and consumer groups and associations.
Increasingly, it is realized that the entire process of assessing and managing risks should be open and interactive. Stakeholders may be able to provide specialized information and insights relevant to the risk assessment and development of management strategies. The participation of all parties during the process tends to increase the acceptability of the final outcome, as opposed to decision-making with no external input or no apparent explanation or justification.

The extent to which stakeholders are involved in the process, at what stage, and in what kind of forum (e.g. public meetings, written communications) will depend on the issue. Not every decision requires extensive processes. Limited deliberations and consultations may be more appropriate for routine decisions with little impact and little potential for controversy. It is also recognized that not all inputs into the process are necessarily going to be valid and free from bias. Thus judgment is called for, and managers must ensure that consultative processes do not unduly delay deciding on a course of action.

4 Risk assessment for microbial hazards

Chemical, physical and biological foodborne hazards are all considered within the realm of food safety risk management. The nature of the hazard will dictate what factors must be considered within the context of the framework, and what approaches are used in the analysis of the information. Many of the techniques used to assess chemical risks are not directly applicable to microbial pathogens (ICMSF, 1998). Microbial risks are primarily the result of single exposures. Unlike toxic or carcinogenic chemicals, there is little concern related to the chronic accumulation of a pathogen or microbial toxin through multiple exposures. Microbial pathogen populations are dynamic, and may increase or decrease throughout the stages of food processing, handling and preparation. Microorganisms are adaptable, and they may acquire or lose virulence-associated characteristics, or develop resistance to antimicrobial control measures. The risk assessment should consider microbiological growth, survival and death in foods, and the complexity of the interaction (including sequelae) between human and hazard following consumption. For many pathogens, the potential for further spread of the organisms from an infected host to others is also an important risk factor.

Biological agents of concern to public health include pathogenic strains of bacteria, molds, viruses, helminths, protozoa and algae, and certain toxic products they may produce. Bacteria that produce toxins, such as Clostridium botulinum and Staphylococcus aureus, require consideration of bacterial growth/inactivation characteristics as well as the resistance of the toxin to heat and other inactivation processes. Parasites and viruses are infective agents that do not grow in foods, and therefore reduction by decontamination or inactivation steps is an important consideration in an assessment. There are also two major groups of non-bacterial microbial toxins that can occur in foods: mycotoxins, produced by certain molds, and seafood toxins, synthesized by certain species of marine phytoplankton, mainly dinoflagellates. Since mycotoxins are normally ingested in small quantities over long periods of time, their
effect is more like chemical agents producing chronic illness, and they are normally treated as chemicals in the risk assessment process. In contrast, most of the seafood toxins cause acute effects, some with long-term sequelae, and perhaps should be included with the microorganisms and their products in risk assessments. However, there are other toxins, e.g. those produced by cyanobacteria (blue-green algae) in fresh or brackish water, that may cause both acute and chronic effects. In addition, the emergence of new foodborne diseases, such as hemorrhagic colitis and hemolytic uremic syndrome caused by Escherichia coli O157:H7, may have resulted from the incorporation of new genetic material from other known pathogens. As the field of microbial food safety risk assessment advances, there will be a need to develop novel techniques to assess or quantify the exchange of genetic material among pathogens, and the development of resistance to antimicrobial agents (Salisbury et al., 2002). However, for the most part, quantitative microbial risk assessments so far have assumed that all strains of the pathogen being assessed have similar characteristics, including their virulence.

5 Conducting a risk assessment

5.1 Purpose of the risk assessment and approaches to the process

Formal assessments require time, expertise and data. The decision to conduct a risk assessment should be made carefully. Not all food safety issues or management decisions require risk assessments, and in some cases not all elements of a risk assessment are needed. For example, there may be circumstances where only an exposure assessment is appropriate. Risk assessment is just one tool for decision-makers, and food safety managers should consider this within an overall sound decision-making framework.

Detailed, comprehensive assessments are generally recommended when significant decisions must be made about implementation of new regulations, or to resolve major safety or trade disputes. However, in addition to estimating risk, a systematic analysis of any issue can be useful for many different types of problems. An important benefit can be to identify significant data gaps about any one issue, and hence set priorities for research funding.

The work begins by identifying and understanding what information the risk manager needs in order to make a risk management decision and to help others understand that decision (ILSI, 1996; Lammerding and Fazil, 2000). Risk assessments can be developed to help rank hazards in relation to the impact they have on public health. This is most often used as a means of setting priorities when multiple health concerns are competing for limited resources. A second category is more detailed analyses of entire ‘farm-to-fork’ pathways, in order to identify likely sources of a pathogen and evaluate the impact that various activities associated with the production, transportation, marketing and consumption of a food product have on the final consumer risk. These types of assessments have been described as product/pathogen pathway analyses, and Process Risk Models (Cassin et al., 1998a, 1998b).
A detailed focus on only one phase of the food process is also useful to determine what interventions, if any, at that stage could help prevent foodborne illness. The food safety concern may be about a specific food produced by a specific process, or an entire commodity group – such as the risk of salmonellosis from all eggs produced in a country or region. The assessment may focus on a specific pathogen, or consider all microbial hazards associated with a foodstuff.

Stating the reason for doing the assessment at the beginning of the work will help to define the context and parameters of the assessment, and should reflect the importance of the activity. Setting guidelines for value judgment and policy choices, when assessors need to make decisions about selection or suitability of data, for example, is a risk manager’s responsibility, and should be carried out together with the risk assessor(s). The output form and possible output alternatives of the risk assessment should also be defined at the onset. Finally, choosing the most suitable approach to a specific risk assessment problem will depend on the problem being investigated, the time needed for the work and the availability of data.

Within the general guidelines, different approaches can be taken to assemble and analyze relevant information. In very general terms, a risk assessment may be qualitative or quantitative (or degrees in between); quantitative assessments may be point-estimate analyses or probabilistic (stochastic) analyses. The focus of the assessment may be only to derive a measure of the risk (e.g. for risk ranking), or it may be to help understand what factors in the production, distribution and consumption of a food contribute most significantly to a large risk, what data gaps exist, and what management strategies may be most effective.

Descriptive evaluations of a pathogen/food concern generally describe the background of the issue by providing a review of existing literature, and possibly providing suggestions for risk management. This has been the traditional approach to health hazard evaluations, and can be of value if the management question is simple and a clear-cut decision recommended. However, such descriptive reports generally lack an estimation of the magnitude of the risk, which, by definition, is the purpose of formal risk assessment.

Qualitative risk assessments include descriptive components but evaluate exposure and dose–response information in a categorical manner so that some estimate of likelihood and impact can be made. A qualitative estimate of risk may be derived using a ranking system to describe the probabilities of exposure and of becoming ill, such as negligible, low, medium or high. Impact or severity of illness can be similarly ranked. Such a process has been used to rank risks associated with various seafood products (Huss et al., 2000). However, qualitative statements and measurements must be precisely defined to avoid misinterpretations. Ross and Sumner (2002) provide an example of this within a spreadsheet software format. The user of the software selects from qualitative statements and/or provides quantitative data concerning factors that will affect the food safety risk to a specific population, arising from a specific food product and hazard. The spreadsheet converts the qualitative inputs into pre-defined numerical values and combines them with the quantitative inputs to generate indices of public health risk. Sumner and Ross (2002) applied the system to rank 10 seafood hazard/product combinations on a scale of 0 (no risk) to 100 (all meals are lethal).
When time, resources and/or data are limited, a simplified approach may be appropriate. Such a process may also provide a preliminary type of assessment to determine if a potential risk is important enough to warrant more detailed analysis (van Gerwen et al., 2000). However, at this time, no specific guidelines exist for qualitative or simple quantitative types of assessments, other than adherence to the general framework and principles of microbial risk assessment.

If the risk manager seeks information on the expected number of acute salmonellosis cases per 100 000 population associated with eggs or poultry, or the risk of salmonellosis per egg or chicken meal, quantitative risk assessment is required. This is a mathematical analysis of information, and gives a numerical estimation of risk. Until recently, the most common method for quantitative assessments was to use single values or point-estimates as inputs – for example, combining means, the fiftieth percentiles (medians) or the ninety-fifth percentiles (as an example of a worst-case scenario). The result of a point estimate assessment is an average, or worst-case, estimate of the risk. This approach has limitations in producing realistic outputs, particularly for diverse, dynamic and variable biological systems. This is particularly true if many worst-case scenarios are combined for an overall estimate of risk, because it leads to a value for the risk that is highly unlikely to occur. An example is the early assessment of Peeler and Bunning (1994), which was criticized for its use of worst-case scenarios by Cassin et al. (1996). The alternative to point-estimate analyses is probabilistic risk assessment, which uses the entire range of possible values for each input variable, described by unique distribution curves. The combined output calculated from the individual distributions of input factors is a distribution of the risk in a population, or for any random meal.

The difference between a point estimate and a probability distribution to describe an input is illustrated in Figure 2.2. The example shows the concentration of a pathogen in a unit of food. It can readily be seen that there is a substantial loss of information when a single point is used to describe an entire set of reported data. The

![Figure 2.2](image_url)
point-estimate specifies the value that a parameter could take, while the probability distribution specifies the range of values that could occur, as well as how frequently different values occur. Probability distributions are assigned based on actual laboratory or observational data, on knowledge of the underlying biological phenomena, or on expert opinion if no other information is available (Vose, 2000).

The importance of acknowledging the range of possible values is underlined by recognizing that it is unlikely that microbial risks to human health are uniformly distributed, or that 'average' occurrences or events are likely to cause significant problems (Potter, 1994). Consideration of the extremes, or tails, of how likely or unlikely it is that such events will occur and who might be affected should be part of sound risk management deliberations (Thompson and Graham, 1996). This is especially true when trying to consider the possibility of an outbreak occurrence where often it is the case that a failure or loss of control happens at more than one stage of the food chain – for example, temperature abuse during retail storage of raw meat, allowing growth of a pathogen, combined with cross-contamination in the home, or undercooking.

Probabilistic risk assessments can be evaluated using analytical techniques, but only for very simple models. More typically, these types of assessments require the application of Monte Carlo analysis – a numerical technique that is especially suited to computer applications. Monte Carlo analysis is based on randomly selecting a single number from each of the probability distributions assigned to the input parameters. These values are used to calculate the mathematical solution defined by the risk assessment model, and the end result is stored. This sequence is repeated several thousand times (iterations), with a different set of numbers for the inputs selected at each iteration. Values that are more likely to occur, according to the defined probability distribution, are selected more frequently. Within a complex model there are several distributions that will be combined – for example, distributions of specific pathogens in cattle, in the slaughterhouse, and at various steps in processing, storage, growth, cooking and serving. The ranges and frequencies of all the individual input parameters are combined to generate the output of interest. A simplified illustration of a Monte Carlo model is shown in Figure 2.3. Commercial software for Monte Carlo simulations include @Risk (Palisade Corp., Newfield, NY), Crystal Ball (Decisioneering, Inc., Denver, CO) and Analytica (Lumina Decision Systems, Inc., Los Gatos, CA).

5.2 Hazard identification

The first step in risk assessment is to describe the association between the microbial pathogen(s) in a food and human illness. Sources of information can include national surveillance databases, epidemiological investigations, process evaluations, clinical studies, animal studies, laboratory investigations of the characteristics of the pathogen and its interaction with the environment throughout the food chain from primary production to consumption of the final product, and/or studies on related organisms, foods and conditions. Expert elicitations and consultations may also provide input. Initial hazard information typically results from outbreak investigations, using epidemiological data and laboratory identification of the pathogen in human specimens and in the samples of food consumed. Laboratory-based surveillance also provides valuable information for
risk assessment, including characterizing the stages of food production, processing and handling, and also the populations that may be at greatest risk.

A hazard identification step is primarily a brief qualitative description of the risk issue, providing a background and rationale for the assessment. When the scope of the issue is broad – for example, all microbial hazards associated with the consumption of a meat product – the hazard identification stage can be used to identify the most significant organism(s), typically the most resistant or virulent pathogen that would be of most concern in the food. This allows narrowing the focus for more detailed analysis.

5.3 Exposure assessment

The exposure assessment is an estimate of the likelihood of ingesting a pathogen and the likely number (or dose) of the organism at the time of consumption. The nature of the pathogen and/or microbial toxin, the type of food, the scope of the assessment and the availability of relevant data will dictate the parameters that must be considered. The most important elements of an exposure assessment are data on the prevalence...
and concentration of a pathogen in the final product, and the relevant consumption 
data for that product (Jaykus, 1996; ICMSF, 1998; Lammerding and Fazil, 2000).

Factors affecting the presence and level of the agent, from the source of contamina-
tion (including interaction with the environment, soil and water) up to the point 
of consumption, should be considered. The exposure unit should be considered as 
the unit that could potentially result in illness, and for most biological agents in 
food this is normally considered to be a single-meal serving size. Rarely are data 
available at the exact point of consumption, and hence estimations must be derived 
from what is known about the contamination of the product at an earlier stage, and 
what factors will affect the level of contamination at the time of ingestion. This will 
require the construction of scenarios and models to describe and predict the range 
of possible exposures. In a quantitative assessment, this stage involves the derivation 
of mathematical equations to describe the relationship between model param-
eters. All potential sources of entry of the hazard into the food product should 
be evaluated, and consideration given to the verifiable effectiveness of existing 
control measures. In assessing individual data sets, the sensitivity, specificity and 
validity of sampling and testing methods used to collect the information should be 
taken into account.

Data on the prevalence and/or concentration of microorganisms in food are usu-
ally collected for raw materials before processing, during production, or in a finished 
product either before or after distribution to the retail level. Microbial populations 
may either increase through growth or decrease through inactivation or dilution 
with uncontaminated material during a formulation step. Most often, numbers of 
pathogens are too low to detect easily, or to detect without using non-quantitative 
enrichment. Microbial pathogen levels may be kept low, for example, by proper 
time/temperature controls during food processing, but they can substantially 
increase under abusive conditions such as improper food storage or inadequate 
cooking temperatures. Types of processing, the storage environment and its tempe-
ration, the relative humidity of the environment, and the gaseous composition of the 
atmosphere influence the survival and growth of microorganisms in foods. Other 
relevant factors include pH, moisture content or $a_w$, nutrient content, the presence 
of antimicrobial substances, and competing microflora. The time for transit from 
production to retail, and the length of storage by the retailer and consumer, are also 
critical factors influencing growth of the pathogens and need to be estimated. A final 
product inactivation step can be heat processing in a package, or cooking. Key ele-
ments that are typically unknown in a process, but which may greatly influence final 
concentrations of pathogens, are the consumer storage time and temperature for 
ready-to-eat foods.

Predictive food microbiology uses microbiological, mathematical and statistical 
information to develop models that describe the growth and decline of microbes 
under specified conditions, and can be used to predict population changes relative to 
changes in specific parameters (Ross and McMeekin, 1994; Whiting and Buchanan, 
1994; van Gerwen and Zwietering, 1998). Such parameters include temperature, pH, 
$a_w$, and the growth medium (i.e. in a food or nutritive broth). Pioneering work in 
predictive microbiology in the 1920s resulted in thermal death time calculations
using D and z values to predict the safe processing conditions for different sizes of various canned or pasteurized food products. These models have been extended to irradiated foods and are still in use today. Advances in this field provide valuable techniques for estimating exposure for microbial risk assessment. Whiting and Buchanan (1994) describe three levels of predictive models. The primary level models quantify colony-forming units/ml, production of toxin and other metabolic products, as well as absorbance and impedance, over time. The growth rate of a pathogen in broth can be calculated, for example, with the Gompertz function, one of the most widely used primary level models, to describe the lag, exponential growth and stationary phases. Secondary-level models show how other conditions affect the primary one – for example, how growth is increased or decreased by changes in pH or $a_w$. Buchanan and Whiting (1996) describe natural log-quadratic equations to measure growth in broth of different pathogens (Aeromonas hydrophila, Bacillus cereus, Escherichia coli O157:H7, Listeria monocytogenes, Shigella flexneri, Salmonella enterica, and Staphylococcus aureus) under different environmental conditions. Tertiary-level models depend on computer software to turn primary- or secondary-level models into packages for modelers. Using such software can test the potential effects of changing conditions on the growth of pathogens. One of the most widely used is the Pathogen Modeling Program of the USDA, originally developed by Buchanan and Whiting (1998b). This can be used for generating exposure assessment data to predict, for example, when a pathogen will grow to levels that could cause human infections.

Additional factors that are considered in exposure assessment are the distribution of the agent in the food, consumer handling practices, consumption patterns, and host demographics. Consumption patterns relate to socioeconomic and cultural backgrounds, ethnicity, seasonality, age differences, regional differences, and consumer preferences and behavior. A high-risk population is a segment of the population that has an increased likelihood of exposure to a hazard, an increased likelihood of illness due to exposure to a hazard, and/or an increased likelihood that the illness resulting from exposure to a hazard will be severe or life threatening (Gerba et al., 1996).

Typical meals involving the food in question can be determined from national surveys or small population studies. Data for specific target groups, like infants or the aged, are useful. There may also be cultural, social, economic or demographic factors that might influence estimation of consumption patterns and practices. When risk assessments are conducted for international trade considerations, differences in exposure data between countries and regions must be considered. Between nations, there will be some differences in pathogen prevalence and concentration attributable to underreporting due to the existing national control programs, as well as a real variation due to geographic and ecological differences. Food distribution systems can vary from one country to the next, including, for example, greater or lesser temperature control during storage, or differences in transit times. More typically, for most pathogen–food combinations in exposure assessments, prevalence and concentration data will be so limited that worldwide data have to be used. Consumption data, however, are national or regional statistics.
5.4 Hazard characterization and dose–response assessment

Hazard characterization is a qualitative or quantitative description of the consequences upon exposure to a pathogen or its toxin in a food. The specific response or adverse effect that is being measured may be infection (intestinal colonization without symptoms of illness), acute mild to acute severe illness, chronic complications such as reactive arthritis, and/or death. The dose–response assessment specifically refers to a mathematical relationship that translates the number of organisms ingested (e.g. colony- or plaque-forming-units) into a probability of an adverse outcome.

The likelihood of a pathogen causing illness is dependent on (a) the characteristics of the organism itself – e.g. virulence factors, resistance to gastric acidity and the host’s immune response; (b) the susceptibility of the host – e.g. immunocompetence or nutritional status; and (c) the characteristics of the food – e.g. a food with high fat content will protect the organism from gastric acidity.

Two distinct hypotheses have been proposed for the nature of the dose–response relationship for foodborne pathogens. The first is that there exists a threshold number of organisms, or minimum infectious dose, that must be ingested before any infection or illness occurs. The second hypothesis is that each pathogen cell has an equal capacity to cause an infection or illness. Thus there is no threshold number, and the probability of infection increases as the levels of the biological agent increase. For example, it has been estimated that a single cell of *Shigella* spp., a pathogen noted for its high infectivity, has a probability of 0.005 of causing an infection. Another way of expressing this concept is that if 1000 people each consumed one *Shigella* spp. cell, five individuals in the group would become infected (ICMSF, 1998).

The nature of dose–response relationships is currently a widely debated area. The few data that are available are based on feeding studies and information from outbreak investigations. The limited number of controlled human feeding studies that have been conducted have usually involved very small numbers of healthy adult males, which makes extrapolations to general or at-risk populations very limited (Teunis *et al.*, 1996, 1999; Buchanan *et al.*, 2000). Another issue is that most of these studies were conducted many decades ago. Ethical considerations make it unlikely that many such studies will be conducted in the future. Information from experimental feeding trials with animal models must be cautiously interpreted when extrapolating to the human population, although they have been used for years in chemical risk assessments. Data collected from foodborne outbreak investigations can be invaluable, but unfortunately information such as numbers of the pathogen in the food, estimates of amount of food consumed and the proportion of people infected or ill among all individuals exposed is often not obtained or reported. Another approach that has been taken is to use monitoring data about the prevalence and concentrations of a specific pathogen in a specific foodstuff, and compare those data with the incidence of related illness in the population exposed to that food (Buchanan *et al.*, 1997). However, for most pathogens, sufficient data about their levels in foods are currently not available, nor does the reporting of most foodborne illnesses provide accurate statistics or attribution to a food. Finally, experts’ opinions may help to arrive at some consensus about dose–response relationships (Martin *et al.*, 1995).
Risk assessments should be based on scientific evidence and knowledge. In many cases, data may be lacking or conflicting, or give a wide range of values for any one measurement. Two factors, then, have to be considered: the uncertainty and the variability of the data. These are distinct and should not be confused. The degree of confidence in the final estimation of risk depends on the uncertainty factors identified in the previous steps. High-quality quantitative data are preferable to qualitative information, but even these are rarely complete, especially in a farm-to-fork food process. Assumptions will be made during the course of the assessment, based on informed judgment. Recognition and acceptance of a degree of uncertainty are fundamental to an estimation of risk.

The basis of uncertainty is two-fold. First, there is uncertainty regarding the quantity and quality of the information used in the assessment. Secondly, there is uncertainty regarding the validity of the assumptions made during the process. Both aspects influence the degree of confidence in the risk estimation. Scientific and statistical uncertainties include those that might arise in the evaluation and extrapolation of information obtained from epidemiological, microbiological and laboratory animal studies. Uncertainties arise whenever attempts are made to use data concerning
the occurrence of certain phenomena obtained under one set of conditions to make estimations or predictions about phenomena likely to occur under other sets of conditions for which data are not available. One example is to use dose–response data for one pathogen (which already include a certain amount of uncertainty) as surrogate information applied to another related pathogen. More information can help to reduce uncertainty – for example, use of human outbreak data to limit the upper and lower bounds of the dose–response equation, or simply more research.

Variability, on the other hand, represents diversity or heterogeneity in a well-characterized population or phenomena. Biological variation includes the differences in virulence that exist in microbiological populations, and in the degree of susceptibility within the human population. Unlike factors that we are uncertain about, more research or further measurements will not reduce the variability in risk assessment data.

It is important to recognize the respective influences of uncertainty and variability on the results of a risk assessment and on the risk management decisions pursued. If the output of interest, i.e. the risk estimate, is influenced by uncertainty in a parameter, the management decision may be to do more research or collect more data to better characterize and understand that factor, and to add the new information into the assessment. However, if a risk mitigation decision is required under circumstances where uncertainty is significant and additional data are not readily obtainable, then a conservative (or ‘safe’) strategy may be warranted, with the understanding that more information would allow a better decision. If the variability in one or more parameters results in a large risk estimate, then better control of these processes or factors may be needed to reduce the risk. In a descriptive, qualitative assessment, the assessor will use descriptive estimates or language to highlight those factors that are uncertain and/or variable and have an important influence on the estimation of risk. Point-estimate quantitative assessments are limited because the use of single representative numbers excludes the variances in the data. Probabilistic assessments incorporate variability and uncertainty, and techniques are available to calculate quantitatively their respective influences on the risk estimate (Vose, 2000).

### 5.7 Modeling mitigation strategies

In its application to microbial food safety, an important benefit of risk assessment is the understanding derived from a systematic analysis of factors that may affect the presence of a pathogen in the food, and those related to the pathogen/host interaction. The approach is valuable in focusing researchers as well as managers on aspects for which insufficient data currently exist and, potentially, on steps in the food chain where interventions may be most effective.

The effectiveness of plausible interventions can be tested with risk assessment models, and specifically those constructed quantitatively using Monte Carlo computer modeling techniques (Cassin *et al.*, 1998b). Incorporating new data or hypothetical targets for pathogen reduction can create different scenarios, and the risk estimate can be recalculated with the new information or assumptions. The outcome of the recalculation allows comparison of proposed interventions against the current situation, in terms of how much risk reduction might be achieved. This application is very advanta-
geous if examining multi-step processes and models. As an example, a risk assessment for *E. coli O157:H7* in ground-beef hamburgers, which modeled the pathway from farm to human illness, was used to identify major factors that were important to the risk estimate for consumption of this product in North America (Cassin et al., 1998a). A number of these factors were proposed as potential points for intervention. Hypothetical values were incorporated into the model for different stages – for example, reduced levels of *E. coli O157:H7* entering a slaughterhouse by theoretically excluding cattle shedding high numbers. Other mitigations tested were the effect of stricter temperature controls in retail store meat cabinets, and some degree of consumer education to encourage better cooking of ground-beef patties in the home. Re-simulation of the model using these alternative values allowed a comparison of the risk reduction for each strategy. Clearly, the more accurate the initial assessment data, and the more realistic the assumptions about implementation and outcomes of interventions, the more realistic the calculated risk reduction estimates will be. Nevertheless, as quantitative risk assessments improve, the ranking of interventions based on their impact on the number of predicted illnesses will become important in assigning resources to improve food safety. This type of ‘what-if?’ experimentation with risk assessment models can provide more information for making risk management decisions, and insights for future research or data collection. These can be done relatively quickly once the basic model has been set up.

6 Applications of microbial risk assessment techniques for food safety

The field of microbial food safety risk assessment is relatively new, although advancing rapidly. Hence, only a limited number of examples are available in the literature at this time. Substantially more work is available on quantification of waterborne microbial risks, and the reader is directed to Haas et al. (1999) for further information and examples.

Quantifying microbial risks, or simply quantifying potential consumer exposure to pathogens in foods, was really not considered feasible until the mid-1990s. An example of a simple semi-quantitative risk estimation process was published by Todd (1996), regarding the risk of salmonellosis from eggs. The first efforts fully to quantify potential consumer exposures to pathogens in a food used point-estimate values for bacterial concentrations and prevalences, together with survival kinetics and consumption information, for *L. monocytogenes* (Peeler and Bunning, 1994) and *B. cereus* (Notermans et al., 1997) in pasteurized milk. Farber et al. (1996) combined quantitative values for a dose–response relationship with exposure estimates to provide a measure of the risk of listeriosis associated with the consumption of pâté and soft cheeses. The work by Cassin et al. (1998a) on *E. coli O157:H7* in ground beef was one of the first probabilistic risk assessments that modeled all the stages of the food production chain. Increasingly, probabilistic methods have been adopted to estimate risks associated with a number of different pathogen/food combinations. Table 2.2 lists some of the
### Table 2.2 Examples of published microbial food safety risk assessments

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Commodity</th>
<th>Scope/focus</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bacillus cereus</strong></td>
<td>Cooked, chilled vegetable</td>
<td>Retail and consumer phase model to estimate exposure; identify knowledge gaps</td>
<td>Nauta <em>et al.</em> (2003)</td>
</tr>
<tr>
<td></td>
<td>Cooked rice</td>
<td>Effects of storage and holding temperatures on risk of emetic disease</td>
<td>McElroy <em>et al.</em> (1999)</td>
</tr>
<tr>
<td><strong>Escherichia coli O157:H7</strong></td>
<td>Ground beef</td>
<td>Farm to consumer’s risk of illness; evaluation of possible interventions in food chain</td>
<td>Cassin <em>et al.</em> (1998a)</td>
</tr>
<tr>
<td></td>
<td>Ground beef</td>
<td>Estimation of public health impact in USA; input into regulatory decision-making</td>
<td>USDA-FSIS (2001)</td>
</tr>
<tr>
<td><strong>Campylobacter jejuni</strong></td>
<td>Ground and fresh beef</td>
<td>Retail to consumer; health impact due to antibiotic-sensitive vs antibiotic-resistant strains</td>
<td>Anderson <em>et al.</em> (2001)</td>
</tr>
<tr>
<td></td>
<td>Poultry meat</td>
<td>Farm to consumer risk of illness; effect of food handling practices and pre-consumer interventions</td>
<td>Rosenquist <em>et al.</em> (2003)</td>
</tr>
<tr>
<td><strong>Listeria monocytogenes</strong></td>
<td>Milk</td>
<td>PE values for raw milk contamination, survival of pasteurization, and consumer exposure</td>
<td>Peeler and Bunning (1994)</td>
</tr>
<tr>
<td></td>
<td>Pâté, soft cheese</td>
<td>PE exposure and dose-response</td>
<td>Farber <em>et al.</em> (1996)</td>
</tr>
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<td></td>
<td>Ready-to-eat meat, smoked fish</td>
<td>Dose-response model based on food survey and epidemiological data in a population</td>
<td>Buchanan <em>et al.</em> (1997)</td>
</tr>
<tr>
<td></td>
<td>Raw milk soft cheese</td>
<td>Raw milk contamination through cheese processing to consumer risk</td>
<td>Bemrah <em>et al.</em> (1998); Sanaa <em>et al.</em> (2004)</td>
</tr>
<tr>
<td></td>
<td>Smoked or gravad fish</td>
<td>Retail to consumer illness; factors influencing risk estimation</td>
<td>Lindqvist and Westöö (2000)</td>
</tr>
<tr>
<td></td>
<td>Meat and poultry</td>
<td>Processing to consumer; effectiveness of sanitation of food contact surfaces and other mitigation strategies</td>
<td>Gallagher <em>et al.</em> (2003)</td>
</tr>
<tr>
<td></td>
<td>Ready-to-eat foods</td>
<td>Retail to consumer risk, relative risk ranking of products to prioritize focus of regulatory actions</td>
<td>FDA/FSIS/CDC (2003)</td>
</tr>
<tr>
<td><strong>Mycobacterium paratuberculosis</strong></td>
<td>Milk</td>
<td>Raw milk and pasteurization phases to estimate consumer exposure; comparison of probabilistic vs PE estimations.</td>
<td>Nauta and van der Giessen (1998)</td>
</tr>
</tbody>
</table>
examples published in the literature or available on websites. The same methods can also be applied when the focus of the investigation is on only one component of a risk assessment – either exposure or the dose–response assessments.

Already, a number of diverse food safety concerns are being studied using the structured approach defined by the risk assessment process. Additionally, the process and techniques are typically used to quantify likely risk reductions for any one intervention implemented somewhere in the food chain, and/or to identify areas where information is lacking and more research is needed.

7 Summary

Risk assessment is a systematic process for the collection, organization and analysis of data that can be brought to bear to assist in rational, objective decision-making processes. As a structured inquiry into the hazard, exposure and dose–response parameters, the risk assessment document itself serves as a database of relevant information and a record of assumptions and decisions. The assessment can be readily updated as better information is acquired or a food system is changed.

It is acknowledged that assessors are faced with many data gaps and knowledge constraints when constructing quantitative risk models. Currently, there is a concerted international effort under the auspices of the World Health Organization and the Food and Agriculture Organization to begin to resolve exposure and dose–response issues by examining all available data for *Salmonella* spp., *Listeria*...
monocytogenes, *Vibrio* spp., *Campylobacter* and *E. coli* O157:H7 collected from around the world. The ones published so far are for *Salmonella* in eggs and broiler chickens, *L. monocytogenes* in ready-to-eat foods and *Enterobacter sakazakii* in powdered infant formula with the full technical reports and interpretive summaries (FAO/WHO, 2002a, b; 2004a, b; 2005). Such efforts will help to provide much-needed insights and parameters for microbial risk assessments. Furthermore, it might be anticipated that with increasing awareness of the information needs for risk assessment combined with the capabilities of advanced laboratory techniques, better information will be made available from food research, food surveillance and outbreak investigations in the future.

Despite its limitations, the quantitative approach is useful to gain insights and to make some inferences with relevance to risk management (Linqvist *et al*., 2002). Through rigorous problem definition, incorporation of all available data, and identification of variability and uncertainties, the risk assessment approach is a useful tool to improve the level of knowledge and the decision-making processes in food safety. The process can be used to examine risk factors from production through consumption, and to improve our understanding of key issues through model development and highlighting critical data gaps. There is a need for more information from human and animal surveillance systems; for improved outbreak investigation with quantification of pathogens found in suspected food vehicles; for greater knowledge regarding the prevalence and concentration of pathogens in foods and their ingredients throughout the food chain, the impact of competing flora and existing and proposed intervention procedures, the effect of consumer storage and preparation practices, and the consumption patterns of specific foods at the local and national level; and details of high-risk and normal populations relative to the food consumed and pathogens ingested.

It is also important to consider the value of different types of risk assessments. A complex, data- and resource-intensive assessment is not always a necessary or an appropriate process for a food safety risk management issue. A comprehensive risk assessment typically takes considerable time, and is thus not always an option for decision-makers. Also, more important than the assessment itself is translating and communicating the components and results of a risk assessment adequately to non-scientific audiences, for purposes of discussion and decision-making. In particular, probabilistic analyses, incorporating uncertainty and variability in the risk estimation, and resulting in a broad range of values (e.g. numbers of illnesses per population) are generally difficult to understand by non-risk assessors. As a basis for policy decisions, managers typically prefer median or mean figures that are more readily understood.

For a number of reasons, then, there is also a need to consider and develop alternate risk assessment methods, simplified risk models and analytical techniques that are aligned with the established principles of food safety risk assessment. Although structured and systematic, risk assessment should be a flexible tool to use as is appropriate for the task at hand.

As the field advances, development of risk assessments will not only lead to better management of risk to reduce human foodborne illness; it will also improve our understanding of processes and interactions in the food chain, such as the ecology, physiology and biovariability of microbial pathogens, and the nature and variability of the pathogen–host relationships that lead to foodborne illness.