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Hazard identification and exposure assessment for microbial food safety risk assessment

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Abstract

The four cornerstones of microbial food safety risk assessment are hazard identification, exposure assessment, hazard characterization, and risk characterization. These steps represent a systematic process for identifying adverse consequences and their associated probabilities arising from consumption of foods that may be contaminated with microbial pathogens and/or microbial toxins. This paper presents a discussion of the first two steps: hazard identification and exposure assessment, and considerations for different approaches that can be used to analyze the relevant information.

Keywords: Microbial risk assessment; Hazard identification; Exposure assessment; Monte Carlo analysis

1. Introduction

To manage food safety risks, it is important to identify which foods, pathogens, or situations lead to foodborne illness, and to determine the magnitude of the impact these have on human health. Such information is needed to make rational decisions about whether or not resources should be allocated for increased management or regulation of any one hazard over another, and the kind of interventions which would be most effective in reducing foodborne disease.

Microbial foodborne disease may occur when a susceptible individual consumes a food contaminated by a viable microbial pathogen(s), and/or microbial toxin(s). However, not every exposure to a pathogen in food will result in infection or illness, and not all individuals in a given population are equally susceptible to all pathogens. Therefore, the risk of foodborne disease is a combination of the likelihood of exposure to a pathogen in a food, the likelihood that exposure will result in infection or intoxication and subsequently illness and the severity of the illness. On a population basis, a calculation of risk can predict the expected number of specific illnesses or deaths per 100 000 population per year attributable to the pathogen/food in question, or risk can be defined as the probability of a specific adverse outcome per exposure to the food. In a system as complex as the production and consumption of food, many factors affect both the likelihood and severity

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of the occurrence of foodborne disease. Many factors are variable and often there are aspects for which little information is currently available. To effectively manage food safety, a systematic means of examining these factors is necessary. Risk assessment is a process that provides an estimate of the probability and impact of adverse health effects attributable to potentially contaminated foods.

Risk assessment is a science-based investigation consisting of four steps: hazard identification, exposure assessment, hazard characterization and risk characterization (Fig. 1). This is the framework adopted by the Codex Alimentarius Commission (CAC), the international standard-setting body for foods in international trade (CAC, 1999). The term 'hazard' refers to a biological agent, that is, the microorganism and/or its toxin(s), that has the potential to cause an adverse health effect. The four steps of risk assessment describe a systematic process for identifying and evaluating the significance of microbial hazards in the food(s) of concern. The outcome of the process is a risk estimate, a measure

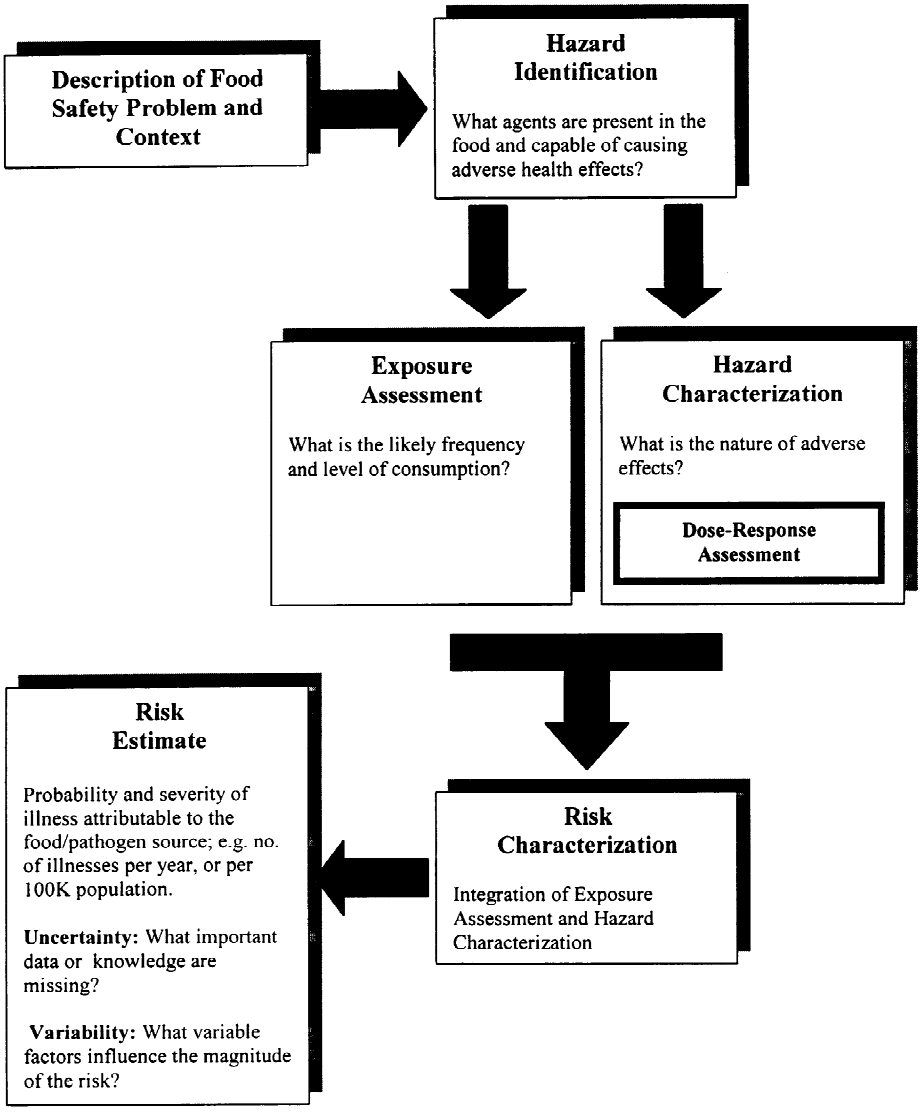

Fig. 1. Steps of microbial food safety risk assessment.

of the magnitude of risk, based on current scientific knowledge and understanding. Risk assessment is only one element of risk analysis, an overall strategy that also includes risk management considerations and risk communication activities (Lammerding, 1997). Risk analysis has been incorporated by the CAC, and other international organizations, for the management of public health risks for hazards in food (FAO/WHO, 1995, 1997, 1998).

This paper will consider the first two steps of microbial food safety risk assessment, hazard identification and exposure assessment. This information is translated into a risk estimate after evaluation of the dose–response relationship between pathogen and human host in the hazard characterization step, with all the information combined in risk characterization. These last two important steps are described in a companion paper in this issue (Buchanan et al. 2000).

2. Preliminary considerations

The scope of a risk assessment is dependent on the risk management question and the reason for doing the assessment. Therefore, a critical initial phase of the process is to develop an unambiguous statement of the problem and its context.

The identification of the problem may arise from any one of a number of sources: regulators, public health sectors, the food industry, scientists, or consumers. Generally, the background information about the issue is assembled by a risk manager or decision-maker, providing a 'risk profile' that describes the food safety problem and its context. It is important that there is a high degree of consultation and communication between the risk manager(s) and the risk assessor(s) to ensure a common understanding of the problem and the scope of information that should be taken into consideration. The general analytical approach to be taken, the available resources and time frame, the desirable form of the risk estimate (per exposure or per year risk, individual or population risk, or risk to a specific segment of the population), and other information that would be useful for decision-making should also be discussed at the beginning of the assessment. These considerations will help guide the direction and selection of information and ensure the right questions are asked and answered through the conduct of the risk assessment.

There are two general approaches to risk assessment, described as qualitative and quantitative (FAO/WHO, 1995; CAC, 1999). Qualitative risk assessments are descriptive or categorical treatments of information, whereas quantitative assessments are mathematical analyses of numerical data. A quantitative risk assessment is the preferred choice if the necessary quantitative information and resources are available. When data, time and/or other resources are limited, the only option available may be to conduct a qualitative risk assessment. Or, a qualitative assessment may be undertaken as a first evaluation of a food safety issue to determine if the risk is significant enough to warrant a more detailed analysis. Qualitative risk assessments should be more than simply a literature review or summary of the available information about an issue. A qualitative assessment should follow the same systematic approach as quantitative risk assessment, including sections dealing with hazard identification, exposure assessment, hazard characterization and risk characterization. Ideally, a qualitative approach would include a framework for translating qualitative information from different aspects of a risk issue into an objective evaluation of the overall risk. The structured framework should assist in reducing the bias associated with the risk assessor's interpretation of qualitative information and help ensure that descriptive statements are not misinterpreted by risk managers or others that will use the assessment.

Quantitative risk assessments can be divided into two categories: deterministic and stochastic. More descriptively, these will be referred to, respectively, as 'point-estimate' and 'probabilistic' risk assessments in this paper. The primary difference between these two approaches is in their description of the inputs to a risk assessment. The point-estimate approach uses single values such as the average or worst case as inputs to a risk assessment. For example, to estimate the average number of a pathogen that an individual may be exposed to, the average level of contamination of a food is combined with the average amount of food consumed by an average consumer. The point-estimate approach produces a single (average, or if selected, worst-case, etc.) value for the risk estimate. The probabilistic approach considers all of the data available and uses

probability distributions, as opposed to single values, to describe the parameters that contribute to the risk. This produces a distribution of risk that characterizes the *range* of risk that might be experienced by an individual or population.

The probabilistic approach, despite its increased complexity over point-estimate calculations, is becoming the method of choice for quantitative assessments. This is a result of recognizing that risk characterizations should include the variability and uncertainty in the information used to derive the risk estimate (Thompson and Graham, 1996). Variability is essentially a property of nature, a result of natural random processes, and represents the diversity in a well-characterized population or parameter. Each step in the production, processing and marketing of a food has variability; both the microbial pathogen and human host responses are highly variable. On the other hand, uncertainty results from the lack of knowledge about a phenomenon or parameter and the inability to characterize it. Recognizing and characterizing variability and uncertainty are important since they have different ramifications in the results of a risk assessment and for the risk management decisions pursued. If variability in a parameter is the driving force that leads to a large risk estimate, then better control of the process or factor may be warranted to reduce the risk. If a large risk estimate is the result of uncertainty in one or more parameters, then the management decision may be to focus research activities on collecting more data to better characterize the important uncertain parameters. However, if some action must be taken under circumstances where uncertainty is significant and additional data are not readily obtainable, then a conservative (cautious) decision might be warranted, with the understanding that more information would allow a better risk management strategy.

3. Hazard identification

Hazard identification is the first step in a formal risk assessment. This activity is largely a qualitative evaluation of the risk issue and a preliminary examination of information that is analyzed in more detail in the subsequent steps of the process. In traditional fields of risk assessment, e.g., toxicology and environmental health, the major focus of the hazard identification step is to determine if there is sufficient evidence to consider a substance (e.g., a chemical) as the cause of an adverse health effect (e.g., cancer). In contrast, the hazard in microbial risk assessment is usually already identified as being capable of causing human illness prior to the initiation of the risk assessment. The cause-and-effect relationship for microbial hazards can often be measured over short periods of time (hours, days or weeks) compared to chemical hazards in which most timeframes are usually in the order of years or lifetimes. The short time period for the cause-and-effect relationship results in a greater likelihood for an adverse effect exhibited in a population to be positively associated with a pathogen/food combination. Microbial pathogens are also often isolated from the individual that exhibit(s) the adverse health effect(s), again providing a positive evidence for a cause-and-effect relationship.

Hazard identification may be a more intuitive title for application to chemical risk assessment, and for microbial hazards other terminology (and frameworks) have been proposed. However, fundamentally, these are all conceptually similar and consider the same risk-producing parameters. One example is the assessment process developed under the auspices of the International Life Sciences Institute's Risk Science Institute (ILSI-RSI, 1996). In this framework, originally developed for waterborne microbial hazards, the hazard identification element is not explicitly defined. Instead, the assessment process begins with a problem formulation step. This initial step encompasses the consideration of purpose, goals and focus, relevance and context of the issue, an initial characterization of exposure and health effects and the development of a conceptual model outlining the assessment scenario and data needs. In essence, this problem formulation step is more comprehensive and detailed, and it provides specific guidance for both risk assessors and risk managers involved in the assessment. The framework was recently modified to improve applicability and utility for assessing human health risks associated with exposure to both water-borne *and* food-borne pathogens, and will be made available on the ILSI-RSI website in the near future (personal communication, S. Ferenc, ISLI-RSI, Washington, DC).

Ultimately, regardless of the specific title for this step, the initial activity in microbial risk assessment

is primarily concerned with determining the major sources of exposure to the pathogen, or determining which pathogen(s) may be of concern in a specific food or food commodity group. Since the link between pathogen and adverse health effect is usually well established, it does not require detailed evaluation; however, this information should be collected so as to provide greater insight and a frame of reference around the assessment. Epidemiological investigations are typically the first indication of foodborne hazards, and can provide context for the events leading to foodborne outbreaks. Surveillance studies may identify high-risk products or processes. However, clinical and microbiological evidence should also be considered in support of epidemiological information. Inferences from experimental or clinical observations are relevant in gaining insight about the nature and behaviour of the hazard. Issues such as acute versus chronic disease, and the existence of specific sensitive populations should also be noted.

4. Exposure assessment

Exposure assessment is the estimation of how likely it is that an individual or a population will be exposed to a microbial hazard and what numbers of the microorganism are likely to be ingested. The exposure assessment phase of microbial risk assessment is faced with a much more dynamic hazard compared to traditional chemical risk assessments because of the potential for microorganisms to multiply and/or die in foods (Jaykus, 1996; ICMSF, 1998). Assessments of intoxication must evaluate both the characteristics of the microorganism, and the chemical-like health effects of the toxin. It is seldom possible to measure the numbers of the pathogen that are present in a food at the time of consumption. Therefore, models and assumptions are necessary to translate available data into quantitative estimates of the amount of pathogen ingested by an individual at random in the population at risk. The unit of exposure is typically a per meal portion size.

For viral and parasitic agents that do not grow in foods, contamination frequency, concentration and distribution, and the effectiveness of decontamination and/or inactivation steps are of primary concern. For bacteria, however, the growth and/or inactivation of the organism within the food must be accounted for, with consideration for the effects of any processing steps and/or temperature abuse under predicted handling and preparation practices. The assessor should consider the influence of factors such as the characteristics of the pathogenic agent, the microbiological ecology of the food, the initial contamination of the raw material including considerations of regional differences and seasonality of production, the level of sanitation and process controls, the methods of processing, packaging, distribution and storage of the foods, as well as any preparation steps such as cooking and holding. The mixing or blending of raw materials or ingredients can result in contamination of a larger volume of material, which can magnify the risk if the pathogen multiplies following mixing. Alternatively, if there is no multiplication, dilution of the hazard occurs when contaminated raw material is mixed with uncontaminated food. For example, a single lot of minced meat typically contains trimmings from several different animal carcasses; bulk tank milk is collected from several different cows; broken eggs are combined prior to pasteurization. These processes will dilute the hazard when not all sources are contaminated. A pathogen may also be introduced into food after processing by contact with unclean equipment or by food handlers with poor personal hygienic practices.

Patterns of food consumption are part of the exposure assessment. Information is needed about typical serving sizes, weekly or annual consumption rates, and circumstances under which the food is prepared and consumed. Socio-economic and cultural backgrounds, ethnicity, seasonality, regional differences, and consumer preferences and behaviour may influence consumption patterns. Where possible, exposure assessments should include information about specific groups, such as infants, children, pregnant women, elderly or immuno-compromised populations, who may have different eating habits and levels of exposure, and who are often more susceptible to infection or illness than other segments of the population (Gerba et al., 1996). When risk assessments are conducted for international trade purposes, differences in exposure data between countries and regions and for different populations must be considered.

Sources of information for exposure assessments will be diverse. In addition to published literature,

the risk assessor should consult with people who are familiar with the various aspects of the exposure pathway(s), and may have access to additional sources of information. These can include microbiologists, food scientists, epidemiologists, animal health experts, food processors, nutritionists, public health authorities and others. Animal health data may be relevant for zoonotic pathogens. Food monitoring data are often unpublished but held within record repositories of regulatory agencies or food companies. Consumer organizations can be the source of information about consumer practices, and many food trade associations have data about food/commodity consumption rates. Some information may be extracted from well-conducted outbreak investigations; however, it is usually (and unfortunately) the case that quantitative exposure information is not collected, or is very limited. Nevertheless, information from reconstruction of the chain of events that led to an outbreak can be useful in developing plausible scenarios of exposure (Potter, 1994).

Most often the available data will not be exactly representative for the required assessment, or several data sets from different studies conducted at and over different periods of time, using different sampling and testing techniques, will be combined to provide suitable information for the assessment. The use of non-representative data should be clearly acknowledged and any influence on the results of the exposure assessment should be made explicit. Assessors should consider the sensitivity, specificity and overall validity of the sampling and testing procedures that were used to produce experimental data, and note how any limitations arising from these aspects affect the results of the assessment. In some cases, poor methodology may lead to rejection of data; this too should be noted and if warranted, the rationale for exclusion should be provided in the assessment document.

To reduce uncertainty in the exposure assessment, another source of information is the elicitation of expert opinion. Expert judgement is not evidence in itself, but inference based on available evidence. However, just as there are ‘rules’ for acquiring and using data from laboratory or field experiments, the elicitation and use of expert judgement is also subject to a structured set of rules (Vose, 1996).

Constructing models is an important part of risk assessment. For qualitative assessments, simple models that describe pathways of exposure should be developed, although more complex representations may be incorporated for some of the parameters. In quantitative assessments, relationships between the components of the assessment are modelled mathematically. Predictive microbial models are very useful sub-models within the larger exposure model. These use mathematical expressions to describe how bacterial numbers change with time and how the rate of change is influenced by environmental conditions. Significant advances have been made in this field in recent years, which have resulted in increasingly sophisticated models and applications (Ross and McMeekin, 1994; Buchanan and Whiting, 1996). Predictive models are categorized as primary and secondary level models, representing different degrees of precision and sensitivity to environmental factors (Whiting and Buchanan, 1994). A third category encompasses tertiary level models, where primary and secondary models are integrated within advanced software packages and expert systems (Buchanan and Whiting, 1998). The degree of sophistication that is required for an exposure assessment is dependent on the degree of precision needed to adequately describe the behaviour of the microbe. A logical approach is to begin with simple growth or inactivation models, and to advance to more complex models if these attributes are important factors that influence the outcome of the assessment (van Gerwen and Zwietering, 1998).

The scope of the risk assessment, as defined by the nature of the risk manager’s problem, will determine the comprehensiveness, structure, and detail required for the exposure assessment. If the primary goal of the assessment is to estimate, as accurately as possible, the risk to a population from a food-pathogen combination, the exposure assessment should be structured so as to utilize data and information as close to the final exposure point as possible. This approach would generate an assessment that is highly focused on one issue: an estimate of the expected number of illnesses in a population. This type of assessment is also useful for risk ranking; however, due to the narrow focus, the information has limited application in gaining insight into the factors responsible for magnifying the risk, or ways to reduce the risk. A risk assessment model that incorporates the influence of various factors before the food reaches the consumer provides the most information relative

to food safety risk management. This latter approach, which has also been described by various authors as 'farm-to-fork' assessments, process risk models, or product/pathogen pathway analyses, allows consideration of a broad range of risk management options along the food chain.

Fig. 2 shows the elements of a farm-to-fork risk assessment that estimates the changes in prevalence and concentration of a pathogen from the farm level through processing and retail to final consumption by the consumer. For example, a farm-to-fork exposure assessment for salmonellae in fresh poultry would involve collecting the data, generating estimates, creating models, and/or making assumptions to describe the following parameters:

4.1. Farm

- The prevalence of chickens infected with salmonellae at the farm.
- The concentration of salmonellae on contaminated chickens.

4.2. Process

- The effects of transportation from the farm to the processing plant on the prevalence and concentration of salmonellae in the chickens.
- The transfer of contamination to the surface of defeathered chicken carcasses.
- The impact of processing steps on prevalence and concentration of salmonellae on carcasses; processing steps may reduce or increase prevalence and concentration.

4.3. Post-process (retail and home)

- Contaminated chickens exiting the processing plant may be exposed to time and temperature combinations that permit the growth of salmonellae, at retail or in the home.
- Prior to consumption the chicken is likely to be cooked to some degree of doneness, resulting in a decrease in the number of cells that might be consumed.
- The amount of chicken consumed in a single meal.

The factors listed above represent a few of the basic issues that should be addressed. It is likely that additional details within each of these broad categories should also be characterized before any level of confidence can be placed in the results of the assessment. Undertaking a farm-to-fork assessment is complex and resource-intensive, and requires substantial inputs of data and expert knowledge from diverse sources. However, exposure assessments may focus only on one segment of the food chain, if that is a focal point for risk reduction measures, or is the only point under the risk manager's control. For

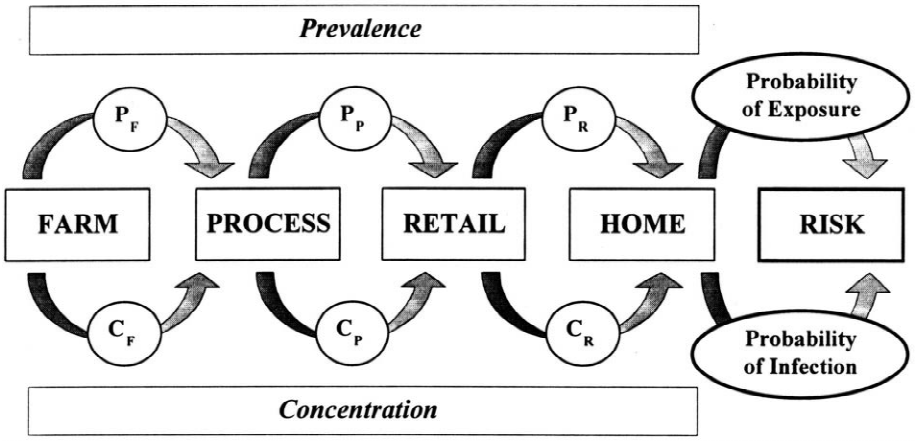

Fig. 2. Elements of a 'farm-to-fork' risk assessment. Factors that influence or alter the prevalence and/or concentration at the farm (P_F and C_F), during food processing (P_P, C_P), retail storage and handling (P_R, C_R) and in the home (P_H, C_H) are described in the exposure assessment.

example, in-factory post-processing contamination may be the primary source for introduction of a foodborne hazard. This has often been the case when ready-to-eat foods contain *Listeria monocytogenes,* a pervasive environmental contaminant. In this situation, the assessment could focus on characterizing only the events that occur after processing.

To date, only a few comprehensive quantitative exposure models for microbial risk assessments have been published. These include studies about *Escherichia coli* O157:H7 in home-cooked ground beef hamburgers (Cassin et al., 1998; Marks et al., 1998), *Salmonella enteritidis* in shell eggs (Baker et al., 1998) and in liquid pasteurized eggs (Whiting and Buchanan, 1997), salmonellae in frozen poultry products (Brown et al., 1998), and *Listeria monocytogenes* in soft cheeses made from raw milk (Bemrah et al., 1998). In other papers, the focus of the work is to characterize and quantify the factors that contribute to exposure without quantifying the associated human health risk. These include the contamination of milk by *Listeria monocytogenes* (Peeler and Bunning, 1994), *Bacillus cereus* (Zwietering et al., 1996; Notermans et al., 1997) and *Mycobacterium paratuberculosis* (Nauta and van der Giessen, 1998), and the contamination of animal carcasses during processing (Berends et al., 1997).

4.4. Probabilistic versus point-estimate assessments

Quantitative risk assessments use mathematical models to estimate risk as a function of several inputs. Observed and estimated quantities at various points along the farm-to-fork chain are incorporated into the model and an estimate of the risk to the consumer at the end of the chain is derived. The variations in the data used for risk assessments, described previously, are often separated into two categories: variability and uncertainty. Point-estimate assessments ignore variability and uncertainty by using a single value to represent a given data set, for example the mean, or the 95th percentile to represent 'worst-case' events. A probabilistic assessment substitutes probability distributions for the single point-estimate values to describe the inputs. A range of values is used and the frequency with which different values occur is also characterized.

The difference between a point-estimate and a probability distribution to describe an input is illustrated in Fig. 3. The hypothetical 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 data set. The 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 empirical data, knowledge of the underlying biological phenomena, or may even be derived from expert opinion if no other information is available (Vose, 1998). 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, nor that 'average' occurrences or events are likely to cause significant problems (Potter, 1994). Consideration of the extremes of distributions, and how likely or unlikely it is that such events will occur, and who might be affected, should be part of sound risk management deliberations.

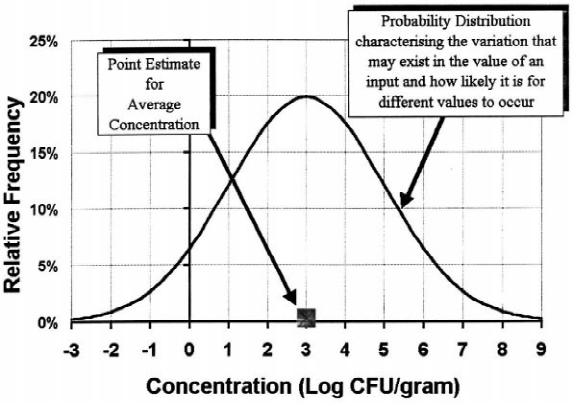

Fig. 3. Comparison between a point-estimate and a probability distribution to characterize a data set.

Probabilistic risk assessments can be evaluated using analytical techniques. However, this approach can be tedious for even a simple model. An alternative to the analytical solution is to use Monte Carlo analysis, a numerical technique that is especially suited to computer applications. Monte Carlo analysis is based on randomly selecting a single 'point-estimate' value from each of the probability distributions assigned for each input parameter. The randomly selected single values are used to calculate

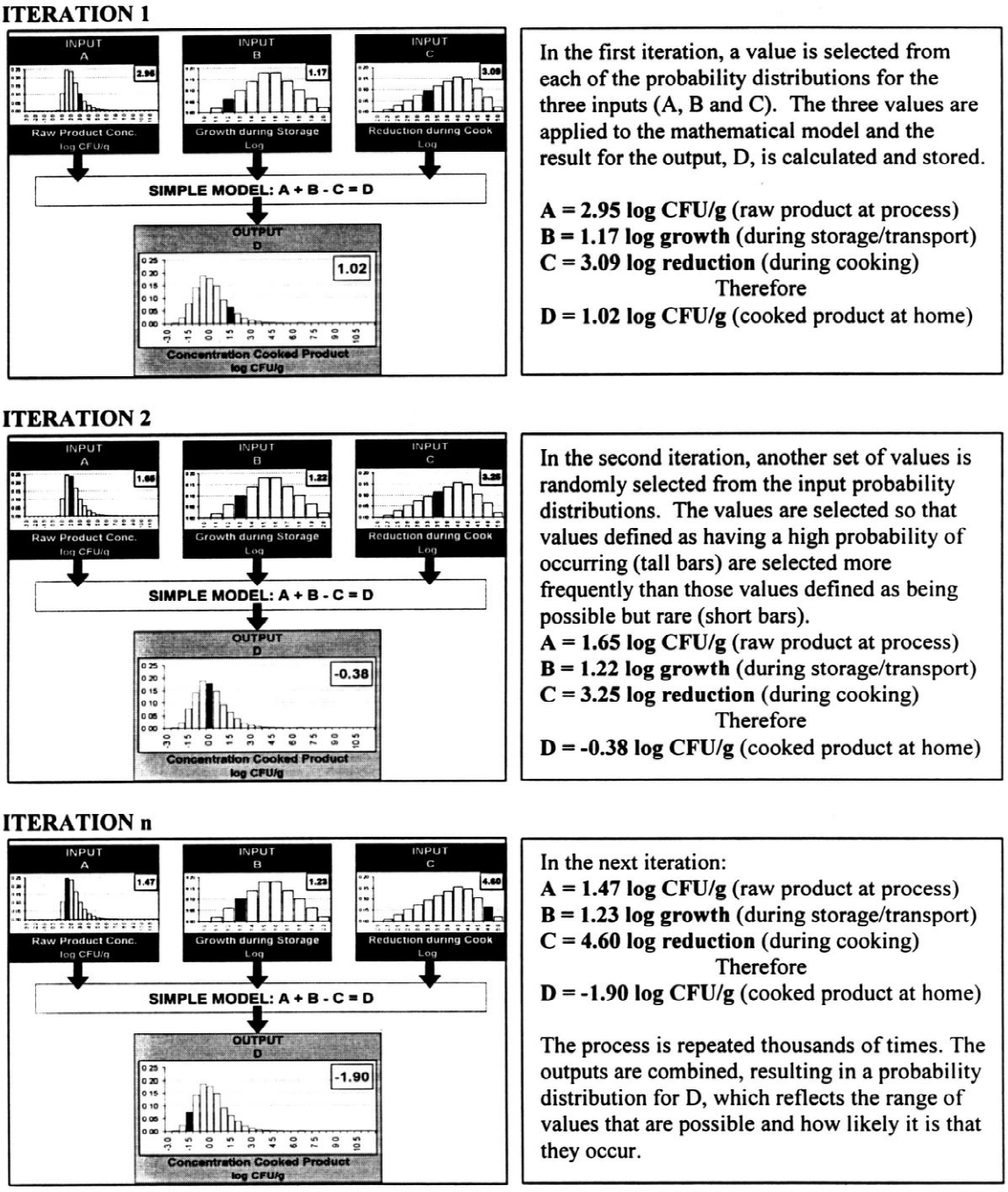

Fig. 4. Illustration of Monte Carlo simulation. This simple illustration shows a simulation to determine the concentration of a pathogen in a food product. There are three inputs: (A) the concentration of a pathogen in the raw food product, log CFU/g; (B) the log growth that can occur during transport and storage; and (C) the log reductions that occur when the product is cooked to various degrees of doneness.

a mathematical solution defined by the risk assessment model, and the result is stored. This sequence is repeated several thousand times (iterations), with a different set of values for the inputs selected at each iteration. Values that are more likely to occur, according to the defined probability distribution, are selected more frequently. The result of the analysis is a frequency distribution for the output of interest, which represents the combined ranges and frequencies of the input parameters. A simplified illustration of a Monte Carlo simulation for a hypothetical exposure assessment is shown in Fig. 4.

Of necessity, the modelling of complex systems requires some simplification and the use of assumptions. Every effort should be made to validate the results produced by an exposure assessment, preferably against independent observed data if such data are available. At the very least, the assessment should undergo peer review to ensure that the results are reasonable and/or plausible. For example, intermediate outcomes were considered in a process risk model that was developed to identify those steps in the animal-to-ground-beef-hamburger pathway that most significantly affected the risk outcome (Cassin et al., 1998). The estimated distribution of the pathogen *Escherichia coli* O157:H7 in ground beef packages at retail as predicted by the exposure model was reasonable when compared to published survey data. Similarly, predicted loads of *Campylobacter jejuni* on broiler chicken carcasses after chilling, derived by modelling the changes in pathogen levels during processing operations, were comparable to actual survey data (Fazil et al., 1999). These comparisons were made with considerations for the limitations of microbiological testing. Unrealistic outcomes would indicate that the assessor should re-examine the appropriateness of the data, models and assumptions that were used in the assessment.

Deficiencies in knowledge, data or understanding can be accommodated with risk assessment as long as these are clearly documented, with the aim of improving upon these, if warranted, through further research or the development of better analytical tools to interpret the data and/or knowledge. Constructing exposure assessments as a series of modules representing the different stages of production, processing, distribution, handling and consumption, facilitates the incorporation of new data when made available. The systematic examination of factors that affect consumer exposure to pathogens in food(s), using a structured approach, helps to identify important data gaps and provide a focus for future research and data gathering efforts.

Thus, the outputs from the exposure assessment can be highly informative for risk management decision-makers by providing estimates of, for instance: the concentration of the hazard in the food product; the likelihood of producing a contaminated product; and factors within the process that influence the contamination. The exposure assessment is also likely to produce intermediate estimates for which validations of the risk model could be made against independent observed data.

In summary, hazard identification identifies the issues of concern and provides the focus of the risk assessment. The exposure assessment generates estimates of the likelihood and magnitude of exposure to the hazard, setting the stage for the next two steps of the assessment, hazard characterization and risk characterization, in which the exposure outputs are translated into a measure of risk.

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