GENERAL CONSIDERATIONS The elements of risk analysis are: Risk assessment, risk management, and risk communication.In relation to the microorganism the following are important: microorganisms are capable of replicating; the virulence and infectivity of microorganisms can change depending on their interaction with the host and the environment; genetic material can be transferred between microorganisms leading to the transfer of characteristics such as antibiotic resistance and virulence factors; microorganisms can be spread through secondary and tertiary transmission; the onset of clinical symptoms can be substantially delayed following exposure; microorganisms can persist in certain individuals leading to continued excretion of the microorganism and continued risk of spread of infection; low doses of some microorganisms can in some cases cause a severe effect; and the attributes of a food that may alter the microbial pathogenicity, e.g., High fat content of a food vehicle.In relation to the host the following may be important: genetic factors such as human leucocyte antigen (HLA) type; increased susceptibility due to breakdowns of physiological barriers; individual host susceptibility characteristics such as age, pregnancy, nutrition, health and medication status, concurrent infections, immune status and previous exposure history; population characteristics such as population immunity, access to and use of medical care, and persistence of the organism in the population.4.6 RISK CHARACTERIZATION Risk characterization represents the integration of the hazard identification, hazard characterization, and exposure assessment determinations to obtain a risk estimate; providing a qualitative or quantitative estimate of the likelihood and severity of the adverse effects which could occur in a given population, including a description of the uncertainties associated with these estimates.For example, these factors are influenced by 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.Relevant information includes data in areas such as: clinical studies, epidemiological studies and surveillance, laboratory animal studies, investigations of the characteristics of microorganisms, the interaction between microorganisms and their environment through the food chain from primary production up to and including consumption, and studies on analogous microorganisms and situations.This relates to socio-economic and cultural backgrounds, ethnicity, seasonality, age differences (population demographics), regional differences, and consumer preferences and behavior.Exposure assessment estimates the level, within various levels of uncertainty, of microbiological pathogens or microbiological toxins, and the likelihood of their occurrence in foods at the time of consumption.Contributions by interested parties in the risk assessment process can improve the transparency of the risk assessment, increase the quality of risk assessments through additional expertise and information, and facilitate risk communication by increasing the credibility and acceptance of the results of the risk assessment.Information on hazards can be obtained from scientific literature, from databases such as those in the food industry, government agencies, and relevant international organizations and through solicitation of opinions of experts.Microbial pathogen levels can be dynamic and while they may be kept low, for example, by proper time/temperature controls during food processing, they can substantially increase with abuse conditions (for example, improper food storage

temperatures or cross contamination from other foods).The presence, growth, survival, or death of microorganisms, including pathogens in foods, are influenced by processing and packaging, the storage environment, including the temperature of storage, the relative humidity of the environment, and the gaseous composition of the atmosphere.4.5 HAZARD CHARACTERIZATION This step provides a qualitative or quantitative description of the severity and duration of adverse effects that may result from the ingestion of a microorganism or its toxin in food.Qualitatively foods can be categorized according to the likelihood that the foodstuff will or will not be contaminated at its source; whether or not the food can support the growth of the pathogen of concern; whether there is substantial potential for abusive handling of the food; or whether the food will be subjected to a heat process.Other relevant factors include pH, moisture content or water activity (aw), nutrient content, the presence of antimicrobial substances, and competing microflora.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.Biological variation includes the differences in virulence that exist in microbiological populations and variability in susceptibility within the human population and particular subpopulations.The scenarios might reflect effects of processing, such as hygienic design, cleaning and disinfection, as well as the time/temperature and other conditions of the food history, food handling and consumption patterns, regulatory controls, and surveillance systems.In the absence of a known dose–response relationship, risk assessment tools such as expert elicitations could be used to consider various factors, such as infectivity, necessary to describe hazard characterizations.Data uncertainties include those that might arise in the evaluation and extrapolation of information obtained from epidemiological, microbiological, and laboratory animal studies.Microbiological risk assessors may have the opportunity to compare the predicted risk estimate from microbiological risk assessment models with reported human illness data for the purpose of gauging the reliability of the predicted estimate.It is important to demonstrate the influence of the estimates and assumptions used in risk assessment; for quantitative risk assessment this can be done using sensitivity and uncertainty analyses.4.8 REASSESSMENT Surveillance programs can provide an ongoing opportunity to reassess the public health risks associated with pathogens in foods as new relevant information and data become available.The importance of using high quality information when conducting a risk assessment is to reduce uncertainty and to increase the reliability of the risk estimate.Output might, for example, take the form of an estimate of the prevalence of illness, or an estimate of annual rate (incidence of human illness per 100,000) or an estimate of the rate of human illness and severity per eating occurrence.For microbiological agents, exposure assessments might be based on the potential extent of food contamination by a particular agent or its toxins, and on dietary information.Factors that must be considered for exposure assessment include the frequency of contamination of foods by the pathogenic agent and its level in those foods over time.A desirable feature of hazard characterization is ideally establishing a dose–response relationship.Additionally, experts may be able to devise ranking systems so that they can be used to characterize severity and/or duration of disease.Risk characterization brings together all of the qualitative or quantitative information of the previous steps to provide a soundly based

estimate of risk for a given population.The use of quantitative information is encouraged to the extent possible, but the value and utility of qualitative information should not be discounted.These estimates can be assessed by comparison with independent epidemiological data that relate hazards to disease prevalence.The degree of confidence in the final estimation of risk will depend on the variability, uncertainty, and assumptions identified in all previous steps.To ensure a transparent risk assessment a formal record, including a summary, should be prepared and made available to interested independent parties so that other risk assessors can repeat and critique the work.The formal record and summary should indicate any constraints, uncertainties, and assumptions and their impact on the risk assessment.It should be recognized that sufficient resources will not always be available and constraints are likely to be imposed on the risk assessment that will influence the quality of the risk estimate.Where such resource constraints apply, it is important for transparency purposes that these constraints be described in the formal record.In this phase, evidence to support farm–to–table modelling of risk might be structured or mapped into the framework of risk assessment.4.3 HAZARD IDENTIFICATION For microbial agents, the purpose of hazard identification is to identify the microorganisms or the microbial toxins of concern with food.4.4 EXPOSURE ASSESSMENT Exposure assessment includes an assessment of the extent of actual or anticipated human exposure.Exposure assessment should specify the unit of food that is of interest, i.e., the portion size in most/all cases of acute illness.Other factors to be considered include: the role of the food handler as a source of contamination, the amount of hand contact with the product, and the potential impact of abusive environmental time/temperature relationships.The weight of evidence integrating quantitative and qualitative data may permit only a qualitative estimate of risk.Differentiation of uncertainty and variability is important in subsequent selections of risk management options.4.7 DOCUMENTATION The risk assessment should be fully and systematically documented and communicated to the risk manager.Understanding any limitations that influenced a risk assessment is essential for transparency of the process that is important in decision making.The functional separation of risk assessment from risk management helps assure that the risk assessment process is unbiased.However, certain interactions are needed for a comprehensive and systematic risk assessment process.Whenever practical, efforts should be made to provide a risk assessment process that allows contributions by interested parties.Scientific evidence may be limited, incomplete or conflicting.Where appropriate, the record should include an evaluation of the impact of the resource constraints on the risk assessment.The output form and possible output alternatives of the risk assessment should be defined.Hazard identification will predominately be a qualitative process.Hazards can be identified from relevant data sources.Another factor that must be considered in the assessment is patterns of consumption.Therefore, the exposure assessment should describe the pathway from production to consumption.Scenarios can be constructed to predict the range of possible exposures.Predictive microbiology can be a useful tool in an exposure assessment.A dose–response assessment should be performed if the data are obtainable.These may include ranking of hazards and risk assessment policy decisions.It is the transparent unbiased nature of the process that is important, not who is the assessor or who is the manager.The microbiological risk assessment may require a preliminary investigation phase.There are several important factors that need to be considered in hazard

characterization. When establishing a dose–response relationship, the different end points, such as infection or illness, should be taken into consideration. For example, expert judgements should be identified and their rationale explained. This comparison emphasizes the iterative nature of modelling. When new data become available, a microbiological risk assessment may need to be revisited. Where risk management issues are taken into account in risk assessment, the decision–making process should be transparent. In such cases, transparent informed decisions will have to be made on how to complete the risk assessment process. 4.2 STATEMENT OF PURPOSE OF RISK ASSESSMENT At the beginning of the work the specific purpose of the particular risk assessment being carried out should be clearly stated. Risk characterization depends on available data and expert judgements. Uncertainty is associated with the data themselves, and with the choice of model. These are related to both the microorganism, and the human host.