Introduction

Risks from microbiological hazards are of immediate and serious concern to human health. Microbiological Risk Analysis is a science-based structured process consisting of three components: Risk Assessment, Risk Management, and Risk Communication, which has the overall objective to ensure public health protection. This document deals with Risk Assessment which is a key element in assuring that sound science is used to establish standards, guidelines and other recommendations for food safety to enhance consumer protection and facilitate international trade. The Microbiological Risk Assessment process should include quantitative information to the greatest extent possible in the estimation of risk. A Microbiological Risk Assessment should be conducted using a structured approach such as that described in this document. This document will be of primary interest to responsible competent authorities although other organizations, companies, and other interested parties who need to prepare a Microbiological Risk Assessment will find it valuable. Since Microbiological Risk Assessment is a developing science, implementation of these guidelines may require a period of time and may also require specialized training in our country. Although Microbiological Risk Assessment is the primary focus of this document, the method can also be applied to certain other classes of biological hazards.

1 Scope

The scope of this document applies to Risk Assessment of microbiological hazards in food.[1]

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

CAC/GL 30-1999, *Principles and Guidelines for the Conduct of Microbiological Risk Assessment*

3 Terms and definitions

The definitions cited here are to facilitate the understanding of certain words or phrases used in this document.

3.1
dose-response assessment
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)

3.2
exposure assessment
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

3.3
hazard
biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect

3.4
hazard characterization
qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents, which may be present in food

3.5

[1] These principles for risk assessment also apply to feed and feed ingredients for food-producing animals in cases where it could impact food safety.

hazard identification
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

3.6
quantitative risk assessment
Risk Assessment that provides numerical expressions of risk and indication of the attendant uncertainties (stated in the 1995 Expert Consultation definition on Risk Analysis)

3.7
qualitative risk assessment
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

3.8
responsible competent authority
refers to the regulatory agency responsible for the implementation of official food control system to ensure public health and safety across the food supply chain

3.9
risk
function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food

3.10
risk analysis
science-based structured process consisting of three components: risk assessment, risk management and risk communication

3.11
risk assessment
scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization

3.12
risk characterization
process of determining the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment

3.13
risk communication

interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions

3.14
risk estimate
qualitative and/or quantitative estimation of risk resulting from risk characterization

3.15
risk management
process, distinct from risk assessment of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options

3.16
sensitivity analysis
method used to examine the behavior` of a model by measuring the variation in its outputs resulting from changes to its inputs

3.17
transparent
characteristics of a process where the rationale, the logic of development, constraints, assumptions, value judgements, decisions, limitations and uncertainties of the expressed determination are fully and systematically stated, documented, and accessible for review

3.18
uncertainty analysis
method used to estimate the uncertainty associated with model inputs, assumptions and structure/form

4 General principles of microbiological risk assessment

4.1 Microbiological Risk Assessment should be soundly based upon science.

4.2 There should be a functional separation between Risk Assessment and Risk Management.

4.3 Microbiological Risk Assessment should be conducted according to a structured approach that includes Hazard Identification, Hazard Characterization, Exposure Assessment, and Risk Characterization.

4.4 A Microbiological Risk Assessment should clearly state the purpose of the exercise, including the form of Risk Estimate that will be the output.

4.5 The conduct of a Microbiological Risk Assessment should be transparent.

4.6 Any constraints that impact on the Risk Assessment such as cost, resources or time, should be identified and their possible consequences described.

4.7 The Risk Estimate should contain a description of uncertainty and where the uncertainty arose during the Risk Assessment process.

4.8 Data should be such that uncertainty in the Risk Estimate can be determined; data and data collection systems should, as far as possible, be of sufficient quality and precision that uncertainty in the Risk Estimate is minimized.

4.9 A Microbiological Risk Assessment should explicitly consider the dynamics of microbiological growth, survival, and death in foods and the complexity of the interaction (including sequelae) between human and agent following consumption as well as the potential for further spread.

4.10 Wherever possible, Risk Estimates should be reassessed over time by comparison with independent human illness data.

4.11 A Microbiological Risk Assessment may need reevaluation, as new relevant information becomes available.

5 Guidelines for application

These Guidelines provide an outline of the elements of a Microbiological Risk Assessment indicating the types of decisions that need to be considered at each step.

5.1 General considerations

5.1.1 The elements of Risk Analysis are: Risk Assessment, Risk Management, and Risk Communication. 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. These may include ranking of hazards and risk assessment policy decisions. Where Risk Management issues are taken into account in Risk Assessment, the decision-making process should be transparent. It is the transparent unbiased nature of the process that is important, not who is the assessor or who is the manager.

5.1.2 Whenever practical, efforts should be made to provide a Risk Assessment process that allows contributions by interested parties. 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.

5.1.3 Scientific evidence may be limited, incomplete or conflicting. In such cases, transparent informed decisions will have to be made on how to complete the Risk Assessment process. 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. The use of quantitative information is encouraged

to the extent possible, but the value and utility of qualitative information should not be discounted.

5.1.4 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. Where appropriate, the record should include an evaluation of the impact of the resource constraints on the Risk Assessment.

5.2 Statement of purpose of risk assessment

5.2.1 At the beginning of the work the specific purpose of the particular Risk Assessment being carried out should be clearly stated. The output form and possible output alternatives of the Risk Assessment should be defined. 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.

5.2.2 The microbiological risk assessment may require a preliminary investigation phase. In this phase, evidence to support farm-to-table modelling of risk might be structured or mapped into the framework of risk assessment.

5.3 Hazard identification

For microbial agents, the purpose of hazard identification is to identify the microorganisms or the microbial toxins of concern with food. Hazard identification will predominately be a qualitative process. Hazards can be identified from relevant data sources. 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. 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.

5.4 Exposure assessment

5.4.1 Exposure Assessment includes an assessment of the extent of actual or anticipated human exposure. 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. Exposure assessment should specify the unit of food that is of interest, i.e., the portion size in most/all cases of acute illness.

5.4.2 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. 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. Another factor that must be considered in the assessment is patterns of consumption. This relates to socio-economic and cultural backgrounds, ethnicity, seasonality, age differences (population demographics), regional differences, and consumer preferences and behavior. 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.

5.4.3 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). Therefore, the Exposure Assessment should describe the pathway from production to consumption. Scenarios can be constructed to predict the range of possible exposures. 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.

5.4.4 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. 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. 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. Other relevant factors include pH, moisture content or water activity (aw), nutrient content, the presence of antimicrobial substances, and competing microflora. Predictive microbiology can be a useful tool in an Exposure Assessment.

5.5 Hazard characterization

5.5.1 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. A dose-response assessment should be performed if the data are obtainable.

5.5.2 There are several important factors that need to be considered in Hazard Characterization. These are related to both the microorganism, and the human host. 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.

5.5.3 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.

5.5.4 A desirable feature of Hazard Characterization is ideally establishing a dose-response relationship. When establishing a dose-response relationship, the different end points, such as infection or illness, should be taken into consideration. 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. Additionally, experts may be able to devise ranking systems so that they can be used to characterize severity and/or duration of disease.

5.6 Risk characterization

5.6.1 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. These estimates can be assessed by comparison with independent epidemiological data that relate hazards to disease prevalence.

5.6.2 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. Risk Characterization depends on available data and expert judgements. The weight of evidence integrating quantitative and qualitative data may permit only a qualitative estimate of risk.

5.6.3 The degree of confidence in the final estimation of risk will depend on the variability, uncertainty, and assumptions identified in all previous steps. Differentiation of uncertainty and variability is important in subsequent selections of risk management options. Uncertainty is associated with the data themselves, and with the choice of model. Data 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. Biological variation includes the differences in virulence that exist in microbiological populations and variability in susceptibility within the human population and particular subpopulations.

5.6.4 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.

5.7 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. For example, expert judgements should be identified and their rationale explained. 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.

5.8 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. 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. This comparison emphasizes the iterative nature of modelling. When new data become available, a Microbiological Risk Assessment may need to be revisited.