

# 1. Introduction

## ***1.1 FAO/WHO Series of Guidelines on Microbiological Risk Assessment***

Risk assessment of microbiological hazards in foods (Microbiological Risk Assessment – MRA) has been identified as a priority area of work by the Codex Alimentarius Commission (CAC). Following the work of the Codex Committee on Food Hygiene (CCFH), CAC adopted Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC/GL-30 (1999) – CAC, 1999). Subsequently, at its 32nd session, the CCFH identified a number of areas in which it required expert risk assessment advice. At the international level it should also be noted that the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (WTO, no date) requires members to ensure that their measures are based on an assessment of the risks, as appropriate to the circumstances, taking into account the risk assessment techniques developed by the relevant international organizations.

In response therefore to the needs of their member countries and Codex, FAO and WHO launched a programme of work with the objective of providing expert advice on risk assessment of microbiological hazards in foods. The purpose of this work is to provide an overview of the available relevant information as well as the risk assessments that have already been undertaken, and from these to develop risk-based scientific advice to address the needs of Codex and to develop risk assessment tools for use by member countries.

FAO and WHO also undertook development of guideline documents for the hazard characterization, exposure assessment, and risk characterization steps of risk assessment, the last-named being the subject of this volume. Details of other documents in the series and how they may be obtained are provided on the inside covers of this document. The need for such guidelines was highlighted in the work being undertaken by FAO and WHO on risk assessment of specific pathogen–commodity combinations and it is recognized that reliable and consistent estimates of risk in the risk characterization step are critical to risk assessment.

The FAO/WHO series of guidelines is intended to provide practical guidance and a structured framework for carrying out each of the four building blocks of a microbiological risk assessment (hazard identification, hazard characterization, exposure assessment, risk characterization), whether as part of a full risk assessment, as an accompaniment of other evaluations, or as a stand-alone process.

The primary audience for these MRA guidelines is the global community of scientists and risk assessors, both experienced and inexperienced in risk assessment, and the risk managers they serve.

The MRA guidelines are not intended to be prescriptive, nor do they identify pre-selected compelling options. On some issues, an approach is advocated based on a consensus view of experts to provide guidance on the current science in risk assessment. On other issues, the available options are compared and the decision on the approach appropriate to the situation is left to the analyst. In both of these situations, transparency requires that the approach and the supporting rationale be documented.

## **1.2 FAO/WHO Guidelines for Risk Characterization**

### **1.2.1 Risk characterization defined**

Risk Characterization, as an element of MRA, was defined by CAC as:

“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.”

It is in the risk characterization step that the results of the risk assessment are presented. These results are provided in the form of risk estimates and risk descriptions that provide answers to the questions risk managers pose to risk assessors. These answers, in turn provide the best available science-based evidence to be used by risk managers to assist them in managing food safety.

### **1.2.2 Scope**

These guidelines address risk characterization and related issues in MRA. They provide descriptive guidance on how to conduct risk characterizations in various contexts, and utilizing a variety of tools and techniques. They have been developed in recognition of the fact that reliable estimation of risk is critical to the overall risk assessment.

### **1.2.3 Purpose**

Although these guidelines may be prospective at times, anticipating where best practice may next lead, they are not intended to be considered prescriptive guidelines. Instead, this document is intended to provide practical guidelines on a structured framework for carrying out risk characterization of microbiological hazards in foods. As with other documents in the MRA series, the primary audience for these risk characterization guidelines is the global community of scientists and risk assessors, both experienced and inexperienced in risk assessment, and the risk managers they serve.

The overarching objectives of these guidelines are to help this audience to:

- identify the key issues and features of a risk characterization;
- recognize the properties of a best practice risk characterization;
- avoid some common pitfalls of risk characterization;
- recognize and understand assumptions that may be implicit in the choice of specific risk characterization measures; and
- prepare risk characterizations that are responsive to the needs of risk managers.

### **1.2.4 The evolution of microbiological risk assessment**

Microbiological risk assessment of water has been undertaken since the early 1990s, and for foods since the mid-1990s, after the earlier development of nuclear and toxicological human health risk assessments. There has been just a decade of development of techniques for assessing microbiological risk, and for aligning the scientific disciplines that contribute data to risk assessment. These guidelines therefore represent the best practice at the time of their preparation. It is hoped that these guidelines and others produced in this series will help stimulate further developments and disseminate the current knowledge.

### **1.3 Risk characterization in context**

Risk characterization is the final step in the risk assessment component of risk analysis. Risk analysis comprises three elements: risk management, risk assessment and risk communication. Risk assessment is initiated by risk managers who develop risk assessment policy and give the risk assessment its direction by establishing the specific risk assessment goals and by posing specific questions to be answered by the risk assessment. The questions posed by managers are usually revised and refined in an iterative process of discovery, discernment and negotiation with risk assessors. Once answered, the risk managers have the science-based information they need to support their decision-making process with the science-based information they need to support their decision-making process.

Risk characterization is the risk assessment step in which most of the risk managers' questions are addressed. While 'risk characterization' is the process, the result of the process is the 'risk estimate'. The risk characterization can often include one or more estimates of risk, risk descriptions, and evaluations of risk management options that may include economic and other evaluations in addition to estimates of changes in risk attributable to the management options. The risk characterization should also address quality assurance of the overall risk assessment, as discussed in Chapter 6.

Many of the recent quantitative microbiological risk assessments use the Codex risk assessment framework (Figure 1.1). This entails a risk characterization that integrates relevant knowledge from the other three risk assessment steps—hazard identification, exposure assessment and hazard characterization—to obtain a risk estimate.

Although this is a common context for undertaking risk characterization, it is by no means the only context. In actual practice an assessment of the risk may include some or all of these steps. The scientific analyses comprising any one of these steps may be sufficient on their own for decision-making. For example, in Denmark, the number of human cases of salmonellosis attributed to different animal sources is estimated without a precise exposure assessment and without using a dose-response model (Hald et al., 2004). This could be done since serotypes and phagetypes are, to some extent, specific to the food source, i.e. epidemiological information indicating the type of *Salmonellae* causing human infection could be used to estimate the proportion of human cases due to each food type providing, in effect, a risk ranking of the various food sources.

Risk characterization, as used in these guidelines, cannot be represented by any one model or description. Commonly used approaches to risk characterization are described in the chapters that follow.

### **1.4 Reading these guidelines**

FAO and WHO have produced a series of documents to support the conduct of microbiological risk assessments. Ideally, the risk assessor would begin with the Report of a Joint FAO/WHO Consultation entitled *Principles and guidelines for incorporating microbiological risk assessment in the development of food safety standards, guidelines and related texts* (FAO/WHO, 2002). That report appropriately establishes the purpose of risk assessment as meeting the needs of risk managers. With that report as background the reader would ideally read these guidelines for risk characterization next.



**Figure 1.1** A schematic representation of the components of risk analysis according to Codex Alimentarius Commission definitions.

Risk characterization presents the results of the risk assessment and is intended to respond to the risk managers' needs. It is therefore most useful to understand what this risk characterization is expected to include, and to anticipate some of the issues that can be encountered as the risk assessment is undertaken. Equipped with an understanding of risk characterization, the reader would then benefit by reading the guidelines: (i) Hazard Characterization for Pathogens in Food and Water (FAO/WHO, 2003); and (ii) Exposure Assessment of Microbiological Hazards in Food (FAO/WHO, 2008).

These risk characterization guidelines are presented in eight chapters. Following this introduction, the uses and goals of risk assessments and different types of risk characterization measures are considered in Chapter 2. Qualitative risk characterizations are the subject of Chapter 3 and semi-quantitative risk characterization is discussed in Chapter 4. Quantitative risk characterizations, which emphasize estimation of variability and uncertainty, are considered in Chapter 5. Quality assurances, including sensitivity analysis and methods to verify, anchor and validate risk characterizations, are found in Chapter 6. Chapter 7 describes approaches for inclusion of health outcomes and cost-benefit analysis in microbiological food safety risk characterization. The guidelines conclude with a consideration of some aspects of risk communication in Chapter 8.