参考資料2

36

MICROBIOLOGICAL RISK
ASSESSMENT SERIES

Microbiological Risk Assessment Guidance for Food

GUIDANCE

Food and Agriculture Organization of the United Nations
World Health Organization

Rome, 2021

Required citation:
FAO and WHO. 2021. *Microbiological risk assessment - Guidance for food.* Microbiological Risk Assessment Series No. 36. Rome. https://doi.org/10.4060/cb5006en

ISSN 1726-5274 [Print]
ISSN 1728-0605 [Online]
FAO ISBN 978-92-5-134518-4 [PDF and print version]
WHO ISBN 978-92-4-002489-2 [electronic version]
WHO ISBN 978-92-4-002490-8 [print version]

Contents

TABLES

FIGURES

Preface

Risk assessment of microbiological hazards in foods, commonly referred to as Microbiological Risk Assessment (MRA), has previously been identified as one of the priority areas 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 (CXG-30) in 1999.

In response to the needs of their member countries and Codex, FAO and WHO launched a programme of work in the early 2000's with the objective of providing expert advice on risk assessment of microbiological hazards in foods, including technical guidance on microbiological risk assessment. Three technical guidance documents were published in the Microbiological Risk Assessment Series: Hazard characterization for Pathogens in food and water (2003), Exposure assessment of microbiological hazards in food (2008), and Risk characterization of microbiological hazards in food (2009a).

Science has evolved over the last decade and there is a need to update and incorporate new developments in the principles and methods for risk assessment of microbiological hazards. To consolidate and update the existing technical guidance documents on microbiological risk assessment, FAO and WHO established a group of experts and convened the Expert Meetings in Rome, Italy on 11-15 March 2019. The discussion and conclusion in this meeting were taken into consideration in finalizing this report. In addition, the document was also subject to peer review and public consultation before finalization.

Acknowledgements

The Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) would like to express their appreciation to all those who contributed to the preparation of this report through the provision of their time and expertise, data and other relevant information before, during and after the meeting. Special appreciation is extended to all the members of the Expert Panel for their dedication to this project and to Dr Emma Hartnett for her expert chairing of the Panel, and Dr Andreas Kiermeier for his excellent support as Rapporteur and assistance in preparing the final document. All contributors are listed in the following pages.

In addition, the contributors to the FAO/WHO guideline documents for the hazard characterization (FAO and WHO, 2003), exposure assessment (FAO and WHO, 2008), and risk characterization (FAO and WHO, 2009a) steps of risk assessment, which formed the basis for this consolidated and expanded document, are thanked.

The preparatory work and expert meeting convened to prepare this report was coordinated by the Secretariat of the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA).

Appreciation is also extended to all those who responded to the public consultation for the draft guidance that were issued by FAO and WHO and provided information and comments.

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Declaration of interests

All participants completed a Declaration of Interests form in advance of the meeting. They were not considered by FAO and WHO to present any conflict in light of the objectives of the meeting.

All the declarations, together with any updates, were made known and available to all the participants at the beginning of the meeting. All the experts participated in their individual capacities and not as representatives of their countries, governments or organizations.

Abbreviations and acronyms

ACMSF	Advisory Committee on the Microbiological Safety of Food [of the United Kingdom of Great Britain and Northern Ireland]
ALOP	Appropriate Level of Protection
ANOVA	Analysis of Variance
BSE	Bovine Spongiform Encephalopathy
BWO	Boil Water Order
CAC	Codex Alimentarius Commission
CCFFP	Codex Committee on Fish and Fishery Products
CDF	Cumulative Distribution Function
CFU	Colony Forming Unit(s)
COI	Cost of Illness
DALY	Disability-Adjusted Life-Year
EFSA	European Food Safety Authority
EKE	Expert Knowledge Elicitation
EC	European Commission
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FAST	Fourier Amplitude Sensitivity Test
FSANZ	Food Standards Australia New Zealand
FSIS	United States of America Department of Agriculture, Food Safety and Inspection Service
FSO	Food Safety Objective
GATT	General Agreement on Tariffs and Trade
GBR	Geographical BSE Risk
GEMS	Global Environment Monitoring System
HACCP	Hazard Analysis and Critical Control Points
HALY	Health-Adjusted Life Years
ICMSF	International Commission on Microbiological Specification for Foods
ILSI	International Life Sciences Institute
IPCC	Intergovernmental Panel on Climate Change
JECFA	Joint FAO/WHO Expert Committee on Food Additives

JEMRA	Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment
MII	Mutual Information Index
MPD	Maximum Population Density
MPN	Most Probable Number
MPRM	Modular Process Risk Model
MRA	Microbiological Risk Assessment
MRSA	Methicillin Resistant *Staphylococcus aureus*
NHMRC	[Australian] National Health and Medical Research Council
NOAEL	No Observed Adverse Effect Level
OECD	Organisation for Economic Co-operation and Development
OIE	World Organisation for Animal Health, formerly the International Office of Epizootics
PCR	Polymerase Chain Reaction
PRM	Process Risk Model
QALY	Quality-Adjusted Life-Year
QMRA	Quantitative Microbial/Microbiological Risk Assessment
RASFF	[European] Rapid Alert System for Food and Feed
RMF	Risk Management Framework
RTE	Ready-to-Eat
SPS	Sanitary and Phytosanitary
STEC	Shiga toxin-producing *Escherichia coli*
TBT	Technical Barriers to Trade
TSE	Transmissible Spongiform Encephalopathy
USDA	United States [of America] Department of Agriculture
USEPA	United States [of America] Environmental Protection Agency
USFDA	United States [of America] Food and Drug Administration
USNACMCF	United States [of America] National Advisory Committee on Microbiological Criteria
WHO	World Health Organization
WTO	World Trade Organization
YLD	Years lived with a disability
YLL	Years of life lost
YOPI	Young, Old, Pregnant, Immunocompromised

1

Introduction

1.1 FAO/WHO SERIES OF GUIDELINES ON MICROBIOLOGICAL RISK ASSESSMENT

The General Agreement on Tariffs and Trade (GATT), was established under the United Nations in 1947 as a series of international meetings at which nations would work together to reduce tariffs and other barriers to eliminate unfair and discriminatory practices in international commerce. In relation to food, the overarching principle was that export income from agricultural products was the first step in the economic development of many nations. Completion of the eighth, or 'Uruguay round', of GATT negotiations, in 1994, led to the creation of the World Trade Organization (WTO).

Importantly, the rules and disciplines of the WTO Agreements – the Sanitary and Phytosanitary (SPS) and the Technical Barriers to Trade (TBT) Agreements – are designed to minimize the negative effect on trade of food safety measures that cannot objectively be justified. What this means is that scientific data and arguments and conclusions based on them, i.e. 'science-based' arguments, are the only basis for restrictions to international trade in foods.

The WTO recommendations specified the need for science-based food safety measures but, when those rules were introduced, there were no established, internationally accepted procedures for science-based assessment of microbiological food safety risk. The development of science-based standards was considered the role of the Codex Alimentarius Commission (CAC). Accordingly, FAO and

WHO established the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA) (FAO, 2021a) – similar to the already well-established Joint FAO/WHO Expert Committee on Food Additives (JECFA) (FAO, 2021b) – to develop the methods and the tools needed to facilitate the WTO ambitions. As part of that process, CAC also developed a set of principles and guidelines for the conduct of microbiological food safety risk assessment (CAC, 1999).

FAO and WHO, through JEMRA, launched a programme of work in the early 2000s in response to the needs of their member countries and CAC with the objective of providing expert advice on risk assessment of microbiological hazards in foods. FAO and WHO undertook development of guideline documents for the hazard characterization (FAO and WHO, 2003), exposure assessment (FAO and WHO, 2008), and risk characterization (FAO and WHO, 2009a) steps of risk assessment. The need for such guidelines was highlighted in the work being undertaken by FAO and WHO on risk assessment of specific commodity-hazard combinations and it was recognized that reliable and consistent estimates of risk in the risk characterization step were critical to risk assessment.

Over the years, since the guidelines were first developed, much experience has been gained in risk assessment. By 2017, FAO and WHO recognized that a single, updated document on risk assessment was needed, including additional guidance on hazard identification. To this end, this present document is intended to provide practical guidance and a structured framework for carrying out each of the four components of a microbiological risk assessment, whether as part of a full risk assessment, as an accompaniment of other evaluations, or as a stand-alone process.

These guidelines are not intended to be prescriptive, nor do they identify preselected compelling options. They provide descriptive guidance on how to conduct a risk assessment, utilizing a variety of tools and techniques. They have been developed in recognition of the fact that reliable estimation of risk, combined with appropriate uncertainty analysis, is critical for transparent and consistent risk management decision making as well as for effective risk communication within the risk analysis framework.

1.2 SCOPE AND PURPOSE OF THESE GUIDELINES

This document provides guidance on undertaking risk assessment of all microbial hazards which may adversely affect human health in foods along the food supply chain. Included are microbial toxins that result in acute illness and where the dose of the microbial toxin is stoichiometrically related to the level of contamination

of the toxigenic organism in the food, e.g. *Staphylococcus aureus*. Excluded is the assessment of risks associated with deliberate contamination, i.e. food tampering. This document is also intended to provide practical guidance on a structured framework for carrying out risk assessment of microbiological hazards in foods, focusing on the four components including hazard identification, hazard characterization, exposure assessment and risk characterization. These guidelines therefore represent the best practice at the time of their preparation, and it is hoped that they will help stimulate further developments and disseminate the current knowledge.

The overarching objectives of these guidelines are to help the reader to:

- identify the key issues and features of a microbiological risk;
- recognize the properties of a best-practice risk assessment;
- avoid some common pitfalls of risk assessment; and
- perform risk assessments that are responsive to the needs of risk managers.

1.3 GUIDING THE READER THROUGH THIS DOCUMENT

The primary audience for this Microbiological Risk Assessment (MRA) guidance is the global community of scientists and risk assessors, both experienced and inexperienced in risk assessment, and the risk managers or others responsible for risk decision making and/or communication.

Ideally, the reader 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 and WHO, 2002b). 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 the current guidelines for risk assessment next.

This document largely reflects the established practice of MRA, based on the Codex principles for Risk Analysis. However, risk assessment is an evolving science, and while some recent developments are incorporated here, the document does not claim to present every new advance to date. However, this should not be considered as invalidating those developments, but rather it is a reflection of the richness of potential approaches available.

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.

1.4 HOW TO BEGIN WITH RISK ASSESSMENT

Microbial risk assessment can often seem overwhelming to those faced with the task of developing a risk assessment for the first time. There are several books that can be helpful for the beginner or the advanced beginner. Training courses are also available from recognized experts in the field. Finally, and perhaps of greatest value, is to work with an experienced practitioner over an extended period to develop a risk assessment. The list of texts and training providers below are not meant to be all-inclusive, nor do they imply endorsement, but they represent a good starting place.

Books

- Haas, C.N., J.B. Rose, and C.P. Gerba. Quantitative Microbial Risk Assessment. 2nd Ed. John Wiley & Sons, 2014.
- Schaffner, D.W. (editor). Microbial Risk Analysis of Foods. ASM Press, 2008.
- Vose, D. Risk analysis: A Quantitative Guide. John Wiley & Sons, 2008.
- Teunis, P. and J.F. Schijven. Generic guidance to quantitative microbial risk assessment for food and water. RIVM [Rijksinstituut voor Volksgezondheid en Milieu], 2019.
- WHO/FAO. Food safety risk analysis: A guide for national food safety authorities, 2007.

Training

- Center for Advancing Microbial Risk Assessment http://camra.msu.edu/
- Epiχ Analytics https://www.epixanalytics.com/
- FAO/WHO/ICD basic awareness course on Microbiological risk assessment available at: http://www.fao.org/waicent/faoinfo/food-safety-quality/mra/mra_en/index.html
- Joint Institute for Food Safety and Applied Nutrition https://jifsan.umd.edu/training/risk/registration/catalog
- Risk Sciences International, Inc. https://www.risksciences.com/course/quantitative-food-safety-risk-assessment/
- Vose Software https://www.vosesoftware.com/services/training/

Part 1
General considerations

2

Risk assessment in context

2.1 RISK ANALYSIS FRAMEWORK

Risk analysis is defined by CAC as "a process consisting of three components: risk assessment, risk management and risk communication" (CAC, 2019). It should be noted that the Codex definition differs from how risk analysis is defined in other contexts, e.g. animal health protection (OIE, 2018) or water safety management (WHO, 2016). In the current context, the three components of risk analysis are defined as follows:

- Risk Assessment: A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.
- Risk Management: The 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.
- Risk Communication: The 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.

Risk analysis is used to develop an estimate of the risks to human health, to identify and implement appropriate measures to control the risks, and to communicate

with stakeholders about the risks and measures applied. It can be used to support and improve the development of standards, to address food safety issues that arise from emerging hazards or from failures in food control systems. It provides risk managers with the information and evidence they need for effective decision-making. As a result, risk analysis contributes to better food safety outcomes and improvements in public health. Regardless of the institutional context, the discipline of risk analysis offers a tool that all food safety authorities can use to improve food safety.

2.2 RISK MANAGEMENT

A generic process for carrying out risk management is presented in Figure 1. Such an international framework can provide a useful template for countries developing their own risk management systems. In addition, the CAC has developed principles and guidelines for conducting microbiological risk management (CAC, 2008).

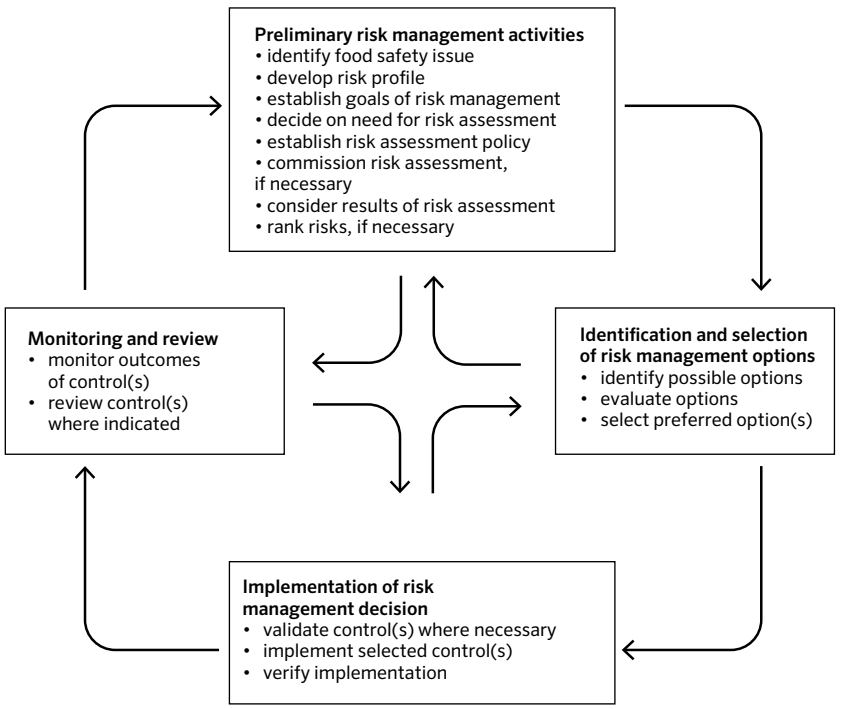

FIGURE 1. Generic risk management framework as presented by FAO/WHO (2006a, Figure 2.1)

The first phase of the Risk Management Framework (RMF) shown in Figure 1 consists of preliminary risk management activities. After a food safety issue has been identified, available scientific information is aggregated into a risk profile that will guide further action.

The second phase of the RMF consists of identifying and evaluating a variety of possible options for managing the risk. These may include controlling, preventing, reducing, eliminating or in some other manner mitigating the risk.

The third phase of the RMF refers to the implementation of the selected risk management options by the relevant stakeholders. In many countries, industry has the primary responsibility for implementing regulatory standards or other food safety measures under government or customer oversight. National food safety authorities, or so-called certified third-party auditors, verify implementation of regulatory standards. They also verify the implementation and effectiveness food safety programs, such as Hazard Analysis and Critical Control Points (HACCP) programs. In addition, other risk management options may be adopted to contribute to risk reductions. Examples include quality assurance schemes at the farm level or consumer education packages for food handling in the home. Guidelines on translating microbial food safety risk assessment into risk management actions are presented in "The use of microbiological risk assessment outputs to develop practical risk management strategies: Metrics to improve food safety" (FAO and WHO, 2006c).

Once control measures have been implemented, monitoring and review activities should be carried out as part of the fourth phase of the RMF. The goal is to determine whether the measures that were implemented are, in fact, achieving the risk management goals and whether they are resulting in any unintended effects. Both industry and government bodies are likely to be involved in those activities. Both sectors usually monitor levels of hazard control, while government generally carries out surveillance of the level of foodborne illness in the population. If monitoring information indicates a need to review the risk management options, then the risk management process can begin a new cycle, with all relevant stakeholders participating as appropriate.

When dealing with a specific food safety issue, the RMF can be entered at any phase and the cyclical process can be repeated as many times as necessary. Further details can be found in the food safety risk analysis guide published by FAO/WHO (2006a).

2.3 RISK ASSESSMENT

Risk assessment is a 'decision support' tool. Its purpose is not necessarily to extend scientific knowledge. Its aim is to provide risk managers with a rational and objective picture of what is known about a health risk and its causes at a particular point in time. It is the risk manager's responsibility to consider the risk alongside other decision criteria. Such factors include nutrition, food security, social and cultural aspects, technical feasibility, cost–benefit, environmental and economic aspects (FAO, 2017). Risk managers need a sound understanding of the scientific approaches and assumptions used by risk assessors.

In general, risk assessment is the umbrella term used to describe the complete process of assessing a risk and is often broken down into several stages. The CAC "Principles and guidelines for the conduct of microbiological risk assessment CAC/GL-30" (CAC, 1999) define risk assessment for microbiological hazards in foods as a science-based process comprising the four components described below (Figure 2). These components are systematically addressed in the various chapters of the present guidance document. For all components, the sources and magnitude of variability and uncertainty (see Chapter 14) should be described. The extent to which this can be done will depend on the data available and the risk assessment approach being taken.

- **Hazard Identification** (Chapter 4) is a qualitative process intended to identify microbial hazards of concern in food. Microbial hazards can include infectious agents or toxins produced by microorganisms. For well-documented microbiological hazards this step is straightforward, while more work will be required if the hazard is new or emerging. If a comprehensive risk profile has already been developed, then this step may be very simple. During hazard identification, the associations between microbiological hazards and specific food commodities and certain high-risk groups in the population should be identified.
- **Exposure Assessment** (Chapter 5) is the qualitative and/or quantitative evaluation of the likely intake of a microbial hazard via specific foods. It should provide a qualitative and/or quantitative estimate of the likelihood and level of the hazard in a specified portion of that food or volume of water. The exposure assessment may also identify the frequency and amount of food or water consumed in a given period for a given (sub)population and may combine the information to estimate the population exposure to a microbiological hazard. The exposure assessment should detail the various steps of the farm-to-fork pathway so that the effect of pertinent steps/processes, or changes to them,

can be assessed. This can be very powerful information for assessing risk management options.

- **Hazard Characterization** (Chapter 6) provides a description of the adverse effects that may result from ingestion of a hazard, whether that is a microorganism or its toxin. This should include a dose–response relationship where possible. Those health effects include, for example, diarrhoeal illnesses, hospitalizations and deaths. In the context of MRA are usually considered to be acute, rather than chronic, health effects. This component may include identification of different adverse effects, including sequalae and their likelihood, for different subpopulations, such as neonates or immunocompromised people.
- **Risk Characterization** (Chapter 7) is the integration of the three previous steps to derive a risk estimate, i.e. an estimate of the likelihood and severity of the adverse effects that occur in a given (sub)population, with associated uncertainties. 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/or risk descriptions that provide answers to the questions that the risk managers posed to the risk assessors. These answers, in turn, provide the best available science-based evidence to assist risk managers in controlling food safety risks.

The World Organisation for Animal Health, formerly the International Office of Epizootics (OIE), has also defined risk assessment (OIE, 2018). However, the components are slightly different as the OIE guidelines focus on risk assessment

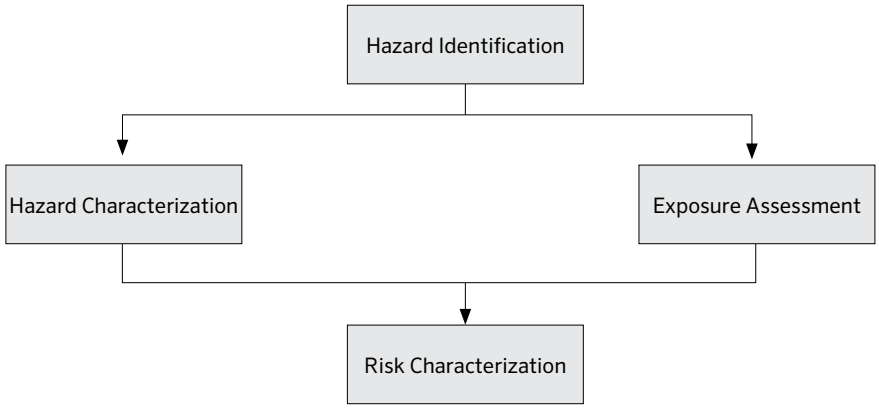

FIGURE 2. Components of a risk assessment

from the perspective of import and export of aquatic and terrestrial animals. Similarly, the WHO document "Quantitative Microbial Risk Assessment: Application for Water Safety Management" uses a slightly different framework to deal specifically with water-related hazards (WHO, 2016).

2.4 RISK COMMUNICATION

The ultimate objective of risk communication is to inform and enhance risk assessment and risk management strategies. This includes informing people who may be involved in implementing risk management options, and to enable people to be involved in how they protect their own and others' health from the food safety risk. For this reason, the results should be presented in ways that promote accessibility.

Risk communication is an integral and ongoing part of the risk analysis process and, ideally, all stakeholders should be involved from the start. This means that risk communication is a two-way process, which involves understanding and considering all stakeholder feedback, perceptions and willingness to accept risk, and the formulation of the most appropriate risk management strategies. Therefore, a risk communication strategy should be developed early in the risk analysis process, i.e. prior to commissioning a risk assessment (e.g. Ch 7 in FSANZ, 2013). To assist risk managers in communicating food safety risk information more effectively, FAO has developed a handbook on the subject (FAO and WHO, 2016).

Communication of relevant scientific information to risk managers by risk assessors can be challenging, especially when there is uncertainty about risk-affecting factors and the ultimate risk to consumers. For this reason, the interaction between risk assessors and risk managers should be ongoing throughout the process. Risk assessors and risk managers should discuss and agree on which stakeholders are consulted throughout the process. While risk managers of the competent authority have the ultimate responsibility for risk management, the risk perception of stakeholders, including industry and consumers, as well as their willingness to operationalize risk management options must be understood. In presenting the results of a risk assessment, the following points should be taken into consideration:

- Results should be presented in a transparent, objective manner. They should be in a form that enables people with little mathematical or statistical background to understand the essential aspects of the risk characterization. For example, a technical document, with all modelling details, could be paired with a less technical interpretive summary. Additionally, the use of illustrations, graphs

and tables for presentation of quantitative information from the model will be more informative than giving just parameter estimates or other statistics as numerical risk outputs.

- Numerical estimates should be supported, and communicated, by qualitative information about the nature of the risk and about the weight of evidence that defines and supports it.
- All assumptions, and their consequences for the risk estimates, sources of variation and uncertainty should be fully presented and acknowledged.
- All the information and data used in the MRA should be explicitly described in the report.
- To ensure transparency, all sources of information and data should be given and cited appropriately and unambiguously in the report and detailed in the reference list. A copy of any ephemeral information (e.g. from a website) should be saved and filed for reference.
- Any identified needs for additional data should be clearly communicated.

3

Food microbiological risk assessment (MRA)

3.1 PROPERTIES AND PRINCIPLES OF BEST-PRACTICE RISK ASSESSMENTS

Codex Guidelines CAC/GL-30 (CAC, 1999) for microbiological risk assessment contain a list of general principles of microbiological risk assessment, including that:

- Risk assessment be objective and soundly based on the best available science and presented in a transparent manner;
- Constraints that affect the risk assessment, such as cost, resources or time, be identified and their possible consequences described;
- MRA should clearly state the purpose, including the form of risk estimate that will be the output;
- The dynamics of microbial 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) be specifically considered;
- 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;
- The risk estimate should include a description of the uncertainty and where that uncertainty arose; and
- MRA should be conducted according to a structured approach that includes hazard identification, hazard characterization, exposure assessment and risk characterization.

The scope of the risk assessment in terms of content and timeframe should be appropriate to meet its objectives and fulfil the needs of the risk managers. As such, before embarking on a risk assessment, the purpose and scope should be clearly identified and articulated by those who commission it.

Risk assessments should be initiated in response to well-defined risk management questions; where possible these questions should target the evaluation of the specific risk management options under consideration. Discussions with risk managers are needed to define what information is required to support the decisions they have to make and the type of work that needs to be undertaken to provide that information. Depending on the question(s), this may, for example, include provision of surveillance data, or epidemiological data; a qualitative risk assessment; or a quantitative production-to-consumption exposure assessment. Even if a fully quantitative risk assessment is thought to be necessary, it may be useful to commence with a qualitative approach to better define the nature of the work, the feasibility and the time needed to meet the risk manager's requirements. This approach highlights the likely iterative nature of risk assessments.

The risk assessment for microbiological hazards should provide risk managers with a "best estimate" of the risk. The basis of this best estimate, whether the average risk (mean), or the most likely risk (mode), or some other metric, should be clearly communicated and include a description of why that metric is the best measure of risk. The chosen risk estimate should be as free of bias as is possible. Bias describes forms of error that lead to consistent over- or underestimation of the true risk. If bias cannot be eliminated (e.g. the decision to use a worst-case estimate), that bias and the reasons for it should be clearly stated.

Risk assessments should represent the real world as closely as possible and reflect the full range of possible outcomes. For example, this may include probabilities and levels of exposure and consequent risk (e.g. through a distribution of risk per serving). A risk manager may also express the need for information on a particular subset of outcomes, such as "most likely" or "worst-case" scenarios, and the MRA should accommodate those. However, deliberately conservative estimates can reduce the usefulness of the estimate for cost–benefit and cost–effectiveness studies and decrease the ability to describe the uncertainty of the risk estimates. However, they may be useful in certain situations, e.g. to better understand the effect of risk mitigations.

Specification of uncertainty and variability are critical in terms of correctly understanding and appropriately using the estimate of risk. It is important to

identify uncertainty and variability to the greatest extent possible. Their implications for the risk estimate(s) should be discussed and a description of uncertainty and variability should be provided as part of the final risk estimate. Uncertainty and variability are discussed in more detail in Chapter 14.

Independence and functional separation of the risk assessment from the risk management process are highly desirable. Nevertheless, interaction between managers and assessors is also essential to ensure that the risk assessment provides the best possible support for the decision(s) that the risk managers have to make. In addition, this interaction helps risk managers understand the principles and assumptions underlying the specific risk assessment.

The need for transparency of the risk assessment requires full documentation of the process. This includes transparency in the process, including calls for data and information, scientific peer review and public review, etc. The MRA report should include an explanation of the data used, a description of the models used to assess risk, and explanations of any assumptions made, including the likely effect those assumptions have on the risk estimates.

3.2 PURPOSE AND SCOPE OF MRA

Risk assessment is commonly undertaken to help risk managers understand which, if any, intervention strategies can best improve food safety outcomes, or if current risk management actions are adequate.

Before beginning a risk assessment, the purpose and scope should be clearly defined, either explicitly or implicitly through the risk management questions. This may involve a discussion between all relevant parties, including the risk managers, risk assessment team, risk communication specialist, and, when appropriate, relevant stakeholders. Definition of the purpose and scope usually specifically identifies the population that should be protected (e.g. general population, young children, pregnant women, immunologically compromised), the stages of the food supply chain that are to be included, as well as the metrics of risks best suited for decision-making. The scope may need to be revised during the preparation of the risk assessment if it becomes evident that the original scope cannot be achieved; any change in scope should be discussed and agreed with the risk manager.

If the risk assessment aims to find the option resulting in the greatest reduction in risk, then a statement of purpose should be prepared to identify all potential risk management options to be considered. The questions and the statement of purpose

will, to a great extent, guide the choice of the approach to be taken to characterize the risk. Clearly, this should be done prior to commencing the risk assessment so that the relevant data are gathered, synthesized and analysed in a way that most effectively informs the risk manager. However, if the purpose of the risk assessment is not clear initially, inappropriate data and information may be collected and analysed. While the results may provide insight into some aspects of the risk, they do not provide clear answers to inform the risk manager appropriately.

Risk managers initially define the intended use of a risk assessment in their preliminary risk management activities (Figure 1). They may need to iteratively interact with risk assessors to refine the specific questions to be answered, the scope, focus or outputs of the risk assessment, possibly throughout the conduct of the risk assessment. Risk managers are expected to ask risk assessors to answer specific questions about potential risk management options, which when answered, provide the managers with the information and analysis they need to support their food safety decisions (FAO, 2017).

One of the more important preliminary risk management activities is the elaboration of a risk profile (CAC, 2008). A risk profile comprises a systematic collection of the information needed to make a risk management decision and whether a full risk assessment is needed. Typically, the risk profile would be a short document, although sometimes it is expanded to a preliminary risk assessment, e.g. the approach used in New Zealand (e.g. Lake and Cressey, 2013) and in the Netherlands (Bogaardt *et al.*, 2004). This may help to determine the structure of the risk assessment, to fine-tune risk management questions, and assess the feasibility of a more comprehensive risk assessment. While the elaboration of a risk profile is the responsibility of the risk manager it may be commissioned out to other parties.

The purpose and scope of risk assessment can vary depending on the risk managers' questions. The following sections contain a discussion of three possible approaches to risk assessment. No *correct* approach can be recommended or specified; the choice of approach depends on the risk assessment question, the data and resources available, etc. Three approaches, considered as examples, are:

- Estimating a baseline risk;
- Comparing risk intervention strategies; and
- Research-related study or model.

3.2.1 Estimating baseline risk

A common and practical starting point for a risk assessment is to estimate the existing level of risk, often termed the *baseline risk*, i.e. the level of food safety risk posed without any changes to the current system. This risk estimate is most

frequently used as the baseline against which intervention strategies can be evaluated (Figure 3). Using the current level of risk as a baseline has the advantage that the magnitude of the risk after a change is relative to this baseline. This approach implies that the baseline risk is the starting point of any risk management actions. For some purposes, a baseline other than the existing level of risk might be used as a point of comparison. For example, the baseline risk could be set as that which would exist under some preferred (e.g. least costly) risk management approach, and the risk under an alternative approach compared with that.

Estimating a baseline risk may not be for the immediate purpose of managing the risk. It may be to estimate the magnitude of a food safety problem and hence decide whether the risk merits further management. Whilst in theory it may not be necessary to determine a baseline risk to evaluate intervention strategies, it is nonetheless almost always carried out in practice. Baseline risk does not always need a fully detailed farm-to-fork risk assessment and could instead rely mostly on epidemiological data and knowledge of underreporting rates (see also Section 3.2.2).

3.2.2 Comparing risk management strategies

Ideally, agencies with responsibility for safety of foods would consider all possible risk management options along the food chain without regard to who has the authority to enact them. This objective has led to the creation of integrated food safety authorities in many nations and regions. For example, Berends *et al.* (1998) considered the likely effects on exposure (i.e. *Salmonella* contamination of pork retail cuts) under different intervention strategies, covering various steps from the farm to the retailer.

A farm-to-table model may be most appropriate for this purpose, though for some risk questions, analysis of epidemiological data or a model of part of the food chain may be adequate. In practice, however, the scope of the assessment may be limited to those sections of the food chain within the risk manager's area of authority. Nevertheless, a more comprehensive risk assessment might identify areas where the risk manager needs to work with other stakeholders to achieve effective change in the food chain.

Evaluations of potential risk management actions are often based on comparisons of a baseline risk estimate with an estimate that could result from pursuing alternative strategies (FAO and WHO, 2009b; Perrin *et al.*, 2015; USFDA, 2005) as shown in Figure 3. Such alternatives may be evaluated through "what-if" scenarios. One includes a future with no new intervention, the other a future with a new intervention. Initially, a baseline model is constructed and run to give a baseline

estimate of risk and what is expected to happen in the future if no intervention is implemented. Then the model or selected model parameters are changed to determine the probable effect of the putative intervention(s).

The differences between the two risk estimates offer indications of the public health benefits of the proposed intervention(s) and, if possible, could also indicate the costs required to attain them. Combinations of interventions can be investigated in a similar fashion, to determine their joint effect, in an effort to find the optimal

There are many ways to approach an evaluation of risk management options, including gap analysis, before and after comparison, and with and without comparison (as illustrated in this example). The risk estimates, special studies, economic and environmental analyses, opinion surveys, analysis of the legal implications of proposed actions, and the like will vary from case to case. Not all of these elements are within the domain of risk assessment, but a few generic steps in the process can be identified. These include:

- Describe the exiting baseline risk condition, i.e. the current state of the risk, given the intervention strategies already in place.
- Describe the most likely future condition in the absence of a change in risk management intervention, i.e. the 'without' condition. Every option is evaluated against this same 'without' condition, labelled 'Future No Action' below. This future may exhibit an increasing, decreasing, flat or mixed trend.
- Describe the most likely future condition anticipated with a specific risk-management intervention in place, i.e. the 'with' condition. Each intervention has its own unique 'with' condition: in the example below, it is labelled 'Future With Intervention A'.
- Compare 'with' and 'without' conditions for each intervention option.
- Characterize the effects of this comparison: not all effects are equal in size, some are desirable, others are not.

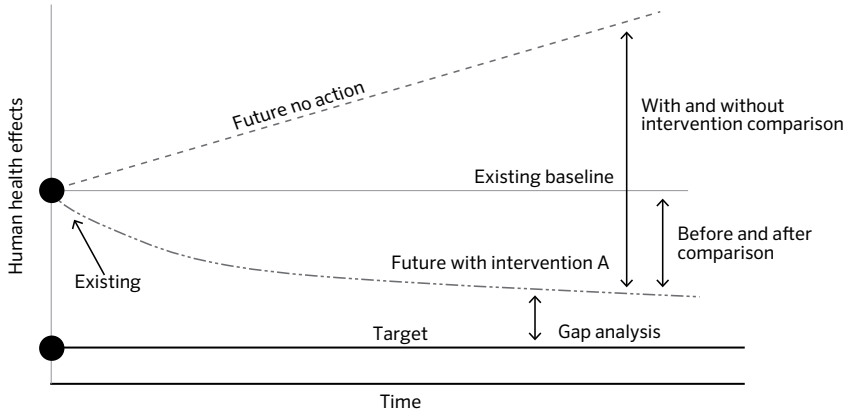

FIGURE 3. "With" and "without" intervention scenarios and changes in risk over time (FAO and WHO, 2009a, Box 2.2)

strategy. However, risk managers should also consider suboptimal strategies in the broader context, i.e. taking into account the multidimensional nature of risk management (FAO, 2017). In some cases, it is possible to estimate the change in risk without producing an estimate of the baseline risk, but caution must be used in these cases. For example, a risk assessment might determine that it is technically feasible to reduce a particular risk one-hundred-fold. However, if this risk was negligible at the start, then reducing it one-hundred-fold may not be a worthwhile course of action.

3.2.3 Research-related study or model

Reliable data are needed to do good risk assessment. There are a number of large microbiological risk assessment models that have been initiated as academic exercises (Guo *et al.*, 2015; Pang *et al.*, 2017; Van Abel *et al.*, 2017). These models have helped advance the field of microbiological risk assessment by identifying what techniques are necessary, developing new techniques, and stimulating research that has value within a risk assessment context. In some situations, those models have subsequently been used by risk managers to assist in making risk management decisions. Such models have also made apparent the changes needed in collection and reporting methods for microbiological, epidemiological, production, dietary and other data that would make the data more useful for risk assessment.

Risk assessment is also a very useful aid in identifying where gaps in knowledge exist and thus where additional information is needed. A risk assessment may be undertaken specifically or incidentally to identify research needs, to establish research priorities, and to help design commissioned studies. Experience with microbiological risk assessments has proven these assessments to be valuable in aiding understanding of complex systems. The very process of systematically investigating a food chain has contributed to the appreciation and understanding of the complexity of the systems that make up the food chain.

3.3 THE ROLE OF BEST- AND WORST-CASE SCENARIOS

It may be useful to evaluate the best- or worst-case scenarios to get a sense of the most optimistic and pessimistic risk estimates. These scenarios may be used as a filtering technique or as part of a risk profile. For example, the worst-case scenario can be used to filter out whether a risk, or an exposure pathway, is worth worrying about. No further analysis is necessary if the most pessimistic estimate shows the risk level to be below some threshold of interest, such as a negligible-risk level or an acceptable level of risk as defined by a competent authority.

Conversely, a best-case scenario can be used as a preliminary filter of possible risk management options. The risk manager can discount any options for which the most optimistic estimate of the benefits does not justify the cost of that option.

Best- and worst-case scenarios operate like extreme what-if scenarios. Where there is considerable but quantified uncertainty about a model parameter, a value is used that gives the required extreme. This will usually be an extreme value from the uncertainty distribution of the parameter, e.g. its 1st or 99th percentile. Where there is uncertainty about exposure pathways and risk attribution, the extreme risk estimate is achieved by picking the most pessimistic (or optimistic) pathway, for example, "imagine that all *Salmonella* came from chicken."

Potential problems with worst-case analyses include focusing the analysis on the consequences of the worst case, without the context of the probability of that scenario occurring – absolute extremes may be limited only by imagination, no matter how unlikely. In addition, there may be difficulty in specifying the conditions that could lead to the worst (or best) case. Conversely, when parameter values or exposure pathways are known with considerable certainty, they should be used to avoid exaggerating the extreme scenario beyond what is likely.

Of particular relevance in relation to the use of extreme scenarios is the concept of *compounding* or *compounded conservatism*. While a detailed explanation of the concept is beyond the scope of this document, the interested reader is directed towards scientific literature (Bogen, 1994; Burmaster and Harris, 1993; Cullen, 1994), including Cassin *et al.* (1996) who specifically discuss the dangers of compounding conservatism in quantitative microbial risk assessment.

3.4 ASSESSING THE RESULTS OF A RISK ASSESSMENT

When undertaking a risk assessment, the risk assessor needs to consider two basic probability concepts that can affect the outcome. The first is the apparently random nature of the world. The second is the level of uncertainty about how the real world is operating. Together, they limit the ability to predict the future and the consequences of decisions made. Inevitably, a risk assessment will not have included all possible information about a risk issue because of limited data access (for example, time constraints for the collection of data, or unwillingness of data owners to share information) or because the data simply do not exist. Complying with all the requirements of transparency – describing model and parameter uncertainties, and all explicit and implicit assumptions – does not necessarily

communicate to risk managers the degree of confidence that the risk assessor has in the results or limitations in its application. Thus, risk assessors should clearly explain how confident they are in the risk assessment results. The confidence in the results depends on the extent of variability and uncertainty in the model outcomes.

All assumptions should be acknowledged and made explicit in a manner that is meaningful to the risk manager. In particular, it should be explained what the assumption is, why it was made, why it is appropriate, and what the expected effect is if the assumption does not hold.

The process of microbiological food safety risk assessment is most affected by uncertainty, such as:

- uncertainty about what is happening in the exposure pathways resulting in human illness;
- uncertainty about processes that lead from ingestion through to infection and illness;
- uncertainty in the factors that dictate the severity of the illness in different people; and
- uncertainty about the parameter values that would describe those pathways and processes.

In general, risk assessments should be as simple as possible whilst meeting the risk manager's needs. The MRA should strive to balance greater detail and complexity (e.g. through addressing more questions or alternative scenarios) against having to include more assumptions that this would entail. That is because more assumptions increase the uncertainty in the results. A draft risk assessment, in which the data gaps and assumptions are clearly identified, may elicit new information, if distributed widely to important stakeholders.

Sometimes what is known at a particular time is insufficient for a risk manager to be comfortable in selecting a risk management option. If the risk manager's criteria for making a particular decision are well defined, a risk assessment carried out based on current knowledge can often provide guidance as to what, and how much, information would make a decision clearer. Another benefit of the risk assessment methodology is that it provides a basis for rational discussion and evaluation of data and potential solutions to a problem. Thus, it also helps to identify where additional data are required.

The purpose of a risk assessment is to help the risk manager make a more informed choice and to make the rationale behind that choice clear to all stakeholders. Thus,

in some situations, a very quick and simple risk assessment may be sufficient for a risk manager's needs. For example, imagine the risk manager is considering some change that has no cost associated with it, and a crude analysis demonstrates that the risk under consideration would be 10 to 90 percent less likely to occur following implementation of the change, with no secondary risks. For the risk manager, this may be sufficient information to authorize making the change, despite the high level of uncertainty and despite not having determined what the baseline risk was. Of course, most problems are far more complicated, and require balancing the benefits (usually human health effect avoided) and costs (usually the commitment of available resources to carry out the change, as well as human health effects from any secondary risks) of different intervention strategies. Thus, depending on the specific question posed, an exposure estimate may be enough to allow comparison between different interventions to be made, allowing the risk manager to make an informed decision.

In the process of performing a risk assessment one usually learns which gaps in knowledge are more, and which are less, critical. Some of those uncertainties are readily quantified with statistical techniques where data are available, which gives the risk manager the most objective description of uncertainty. If, however, a risk assessment assumes a particular set of pathways and causal relationships that are incorrect, then the assessment will be flawed. This is clearly different from variability and uncertainty (Chapter 14) and should be avoided as much as possible.

3.5 CHOOSING THE TYPE OF RISK ASSESSMENT TO PERFORM

Risk assessments methods span a continuum from qualitative through semi-quantitative to fully quantitative. These approaches may vary in their key attributes such as the quality of risk inference, timeliness, complexity, assessor training requirements, and data requirements. Regardless of the approach used, a scientifically sound risk assessment requires collection of suitable information/data/assumptions which are documented and fully referenced and synthesized in a logical and transparent manner. All are valid approaches to food safety risk assessment, but the appropriateness of a particular method depends on the ability of the risk assessment to address the specific risk question, i.e. that it is *fit-for-purpose* to support the risk management decision process. A benefit of undertaking a risk assessment, irrespective of the approach, is that solutions to minimize risk often present themselves out of the process of assessing risk.

- **Qualitative risk assessments** are descriptive or categorical treatments of information. A qualitative assessment may be undertaken as part of a first evaluation of a food safety issue, to determine if the risk is significant enough to warrant a more detailed analysis. This again highlights that risk assessments tend to be, and frequently are, iterative. Nevertheless, a qualitative exposure assessment alone may, in some circumstances, provide all the decision support needed by the risk manager. If a more detailed analysis is warranted, then a fully quantitative assessment is usually the preferred approach if data, time and resources are available to support it.
- **Semi-quantitative risk assessments** evaluate risks with a score. They provide an intermediary level between the textual evaluation of risk of qualitative risk assessments and the numerical evaluation of quantitative risk assessments. They offer a more consistent and rigorous approach to assessing and comparing risks and risk management strategies than qualitative risk assessment. They also avoid some of the ambiguities that a qualitative risk assessment may produce. Semi-quantitative risk assessments do not require the same mathematical skills of quantitative risk assessments, nor do they require the same amount of data, which means they can be applied where precise data are missing.
- **Quantitative risk assessments** provide numerical estimates of risk and most models use combinations of mathematics and logic statements. Quantitative risk assessments require the development of mathematical models. In these models the relationships between factors affecting exposure can be quantified and explained using logical tests and conditional statements. An exposure estimate may be combined with a mathematical function that quantifies the dose–response relationship to provide an estimate of risk.

It should be noted that there is a gradation of model types from qualitative to fully quantitative and while such classifications may be helpful, they are not strictly defined categories.

The importance of matching the type of risk assessment to its purpose has been emphasized previously. The United States of America's National Advisory Committee on Microbiological Criteria for Foods noted (USNACMCF, 2004):

> *Risk assessments can be quantitative or qualitative in nature, but should be adequate to facilitate the selection of risk management options. The decision to undertake a quantitative or qualitative risk assessment requires the consideration of multiple factors such as the availability and quality of data, the degree of consensus of scientific opinion and available resources.*

The Australian National Health and Medical Research Council (NHMRC, 2011, p38) cautions that:

> *Realistic expectations for hazard identification and risk assessment are important. Rarely will enough knowledge be available to complete a detailed quantitative risk assessment. ... Staff should have a realistic understanding of the limitations of these predictions, and this should also be conveyed to the public.*

The decision on the appropriate balance of the continuum of methods from qualitative to quantitative will be based on several factors, including those considered below.

3.5.1 Consistency

Risk assessments should limit subjectivity as far as possible and aim for consistency. Qualitative and semi-quantitative risk assessment can be made simple enough to be applied repeatedly across a range of risk issues. In contrast, quantitative risk assessment is more driven by the availability of data and may have to employ quite disparate methods to model different risks. Nevertheless, subjectivity can occur across the spectrum. Qualitative risk assessment is more prone to subjective judgements involved in converting data or experience into categories such as "high", "intermediate" and "low." Because it may be difficult to unambiguously define these terms repeatability of an analysis by others is less certain. On the other hand, quantitative risk assessments may involve subjective choices regarding model form and data analysis, e.g. in approaches to the selection and analysis of data. In all cases the basis of these judgements can, and should, be documented in a way that enables others to understand the reasoning and replicate the results.

3.5.2 Resources

Some basic capacities are needed to conduct MRA or its components. Risk assessments conducted at the international level (e.g. JEMRA) can assist countries by providing modules or building blocks that can be adapted or modified to suit other exposure or risk assessments. For example, FAO/WHO's Food Safety Risk Analysis Tools website (FAO and WHO, 2021) contains a risk assessment tool for *Cronobacter* spp. in powdered infant formula and a risk management tool for the control of *Campylobacter* and *Salmonella* spp. in chicken meat. The United States of America Food and Drug Administration's (USFDA) FDAiRISK® tool (FDA, 2021) allows users to create and share risk assessment models/modules. However,

it must be remembered that a risk assessment usually requires some country- or region-specific data to be useful.

The basic capacities for undertaking an MRA include the following.

- **Access to expertise**. While the assessment may be carried out by one individual or a small team, access to a range of expertise, from multiple disciplines, usually is needed. Depending on the task, this is likely to include trained risk assessors, modellers, mathematicians, statisticians, microbiologists, food technologists, animal and plant health specialists, agriculture technologists, human and veterinary epidemiologists, public health specialists, and other experts as needed. Quantitative risk assessments typically require that at least part of the assessment team have rigorous mathematical training. If this resource is in limited supply, then this may make qualitative risk assessment more practical, provided the risk question is amenable to this approach. Note that, while qualitative risk assessments may not be demanding in terms of pure mathematical ability, they place a considerable burden of judgement on the analyst to combine evidence in an appropriate and logical manner. The technical capability necessary to collate and interpret the current scientific knowledge is almost the same, regardless of the approach used.
- **Informed risk managers and policymakers** who are aware of the need for, use of and limitations of risk assessment. They need to be working in the context of an appropriate risk management framework, whether in government or industry. This framework must facilitate data collection, decision-making and implementation.
- **Financial and human resources** to complete the risk assessment in a timely manner and to an acceptable level that provides useful support for risk management decisions. For very large MRA projects, a dedicated project manager may be desirable.
- **Communication channels**. Good communication is needed between technical experts, risk managers and the risk assessors to facilitate efficient exchange of data and knowledge.
- **Information technology**. Computing facilities, both hardware and software, and access to appropriate information networks are needed to collect, collate and process data, and to provide outputs in a form suitable for communicating results. This should include access to international networks and databases, including access to scientific publications.
- Where data on microbiological hazards are not available, **the capacity to conduct surveillance for microbiological hazards**, including access to microbiologists, epidemiologists, trained field staff and competent laboratories, is needed.

While the above list is an ideal, benefits can also be obtained from conducting more modest risk assessments, but still according to the principles in these guidelines, even from teams with limited expertise. To assist groups with fewer resources, communication with more established groups should be actively encouraged (e.g. including training, mentoring and technology transfer).

With respect to scientific publications, access to subscription-based journals has repeatedly been identified as a substantial limitation in many countries. It is worthwhile to note that Research4Life (www.research4life.org) provides organisations in many low-income countries with free or low-cost access to academic and professional peer-reviewed content online.

To assist the risk assessors with their tasks, a range of software tools have been developed, including those listed by Bassett *et al.* (2012) and those at the Quantitative Microbial Risk Assessment (QMRA) Wiki (QMRA wiki, 2021). These tools are not necessarily specific to food safety risk assessments, although they include a range of food safety specific models and tools. These tools cover areas of risk ranking, predictive microbiology, specific risk assessment and sampling.

3.5.3 Theory or data limitations

Quantitative risk assessments tend to be better suited for situations where mathematical models are available to describe phenomena, e.g. dose–response models, and where data are available to estimate the model parameters. If either the theory or data are lacking, then a more qualitative risk assessment is appropriate.

3.5.4 Breadth of application

When considering risks across a spectrum of hazards and pathways, there may be problems in applying quantitative risk assessment consistently across a diverse base of theory and evidence, such as comparing microbiological and chemical hazards in food. The methodologies and measurement approaches may not yet be able to provide commensurate risk measurements to support decisionmaking where scope is broad.

3.5.5 Speed

Qualitative and semi-quantitative risk assessments generally require much less time to generate conclusions compared with quantitative risk assessment. This is particularly true when the protocols for qualitative and semi-quantitative risk

assessments have been firmly established with clear guidance in the interpretation of evidence. There may be some exceptions where the process of qualitative risk assessment relies on a process of consultation that requires considerable planning, briefing, and scheduling, e.g. when relying heavily on structured expert elicitation. Quantitative risk assessment may take longer to develop; if it is to be repeated once the model is established, then the speed to generate conclusions is similar to qualitative or semi-quantitative approaches.

3.5.6 Transparency

Transparency, in the sense that every piece of evidence and its exact effect on the assessment process is made explicit, is more easily achieved by quantitative risk assessment. However, qualitative or semi-quantitative approaches may be easier to understand by a larger range of stakeholders, who will then be better able to contribute to the risk analysis process. Quantitative microbiological risk assessment often involves specialized knowledge and a considerable time investment. As such, the analysis may only be accessible to specialists or those with the time and resources to engage them. Strict transparency is of limited benefit where interested parties are not able, or find it excessively burdensome, to understand, scrutinize and contribute to the analysis and interpretation. Consequently, errors in quantitative risk assessments may be more difficult to find.

3.5.7 Stage of analysis

Qualitative and quantitative risk assessment need not be mutually exclusive. Qualitative risk assessment can be very useful in an initial phase of risk management to provide timely information regarding the approximate level of risk. This allows risk managers to decide on the scope and level of resources to apply to quantitative risk assessment. As an example, qualitative risk assessment may be used to decide which exposure pathways (e.g. air, food, water; or raw versus ready-to-eat foods) will be the subject of a quantitative risk assessment.

Where available, comparing the outputs from both approaches, or from different stages of the analysis, may help the detection of errors that may have been made in either assessment.

3.5.8 Responsiveness

A major concern often expressed in regulatory situations is the lack of responsiveness of risk assessment conclusions when faced with new evidence. Consider a situation where a risk assessment has been carried out with older data indicating that the prevalence of a pathogen is 10 percent. After the risk assessment is published, it

is found that the prevalence has been reduced to 1 percent. In most quantitative risk assessments, there would be a clear effect of the reduced prevalence on the risk characterization. In some qualitative risk assessments, this effect may not be sufficiently clear. Qualitative risk assessments, particularly where the link between evidence and conclusion is ambiguous, may contribute to foster or support this lack of responsiveness. This in turn can generate mistrust and concern for the integrity of the risk assessment process.

4

Hazard identification

Hazard identification (HI) is conventionally the first step in MRA. For the purposes of the CAC, hazard identification related to food safety is defined as "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" (CAC, 1999). In particular, for microbiological agents "the purpose of hazard identification is to identify the microorganisms or the microbial toxins of concern with food" (CAC, 1999). In general, hazard identification is largely a qualitative examination of the foodborne hazard and associated potential adverse health outcomes due to specific foodborne exposure. It is supported by a critical review of knowledge about the hazards and/or food in question. In the context of MRA, the term *hazard* encompasses any microbiological agent able to cause harm, including bacteria, viruses, parasites, fungi, algae, including their toxins and metabolites, as well as prions.

4.1 OBJECTIVES OF HAZARD IDENTIFICATION

The main purpose of hazard identification is to identify the microbiological hazard(s) found in food that is/are the cause of adverse health outcomes. Since a wide range of microbiological hazards can cause foodborne illness, hazard identification should identify whether a potential hazard is realistic for the food product of interest. In some situations, i.e. depending on the risk managers' questions, the hazard identification may include a list of hazards and therefore, the final product of the hazard identification procedure is a practical list of microbiological hazards related to the specific food product (e.g. FAO and WHO, 2006b, 2007).

4.2 THE PROCESS OF HAZARD IDENTIFICATION

Hazard identification serves to establish the hazard as likely or real in the food product and to document the important information known about the relationships and interactions between the hazard, the food and host, as well as their relationship to human illness (Figure 4). With respect to the food these factors including intrinsic characteristics, environmental factors and production conditions.

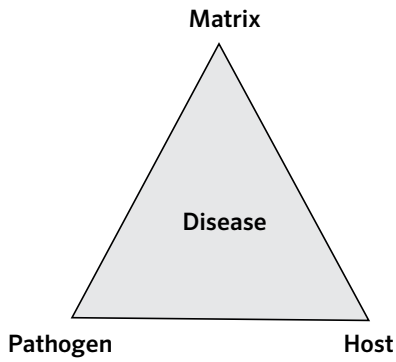

FIGURE 4. The epidemiology triangle (modified from Coleman and Marks, 1998)

There is some overlap between the information collated as part of the hazard identification step and the exposure assessment and hazard characterization steps – the hazard identification may provide only a general overview, while the latter steps document more detailed information, e.g. extent of exposure to the hazard and dose–response relationship. The information documented as part of microbiological hazard identification includes the following.

- What is/are the hazard(s) of concern associated with specific food in question?
- Is the hazard of concern to public health and what is the likelihood of the hazard causing an adverse health effect?
- What is the population at risk?
- What is the epidemiological evidence, including outbreaks and sporadic illness, that this hazard poses a potential risk in the food product?
- What adverse health effects could be associated with the exposure to the hazard and through what mechanisms?
- What host factors and life stages could affect the type and severity of adverse health outcomes among the population at risk?
- How do common exposure pathways link the adverse health effects with the hazard?

- How often does the hazard occur in the food product of interest?
- How do environmental conditions affect the hazard's transfer and fate along the exposure pathway?

A wide range of microbiological hazards are associated with foodborne illness. To identify the most significant hazards in the food of concern, characteristics of a range of hazards can be collectively evaluated. These include inherent properties of hazards such as invasiveness, virulence, pathogenicity, natural reservoir, transmissibility, and resistance to environmental factors and interventions in the food supply chain.

In addition, hazard identification highlights issues such as sensitive populations, acuteness of the illness (acute versus chronic disease) and other complications such as long-term sequelae. These may be considered consideration in more detail the hazard characterization (Chapter 6). Sensitivity to infection depends on the integrity of the hosts' immune system, the virulence/potency of the hazard and level of exposure to the hazard. The integrity of a host's immune system can be affected by life stage and health conditions. For example, due to their immature or compromised immune systems, young children and the elderly may be more sensitive to microbiological infection compared to young healthy adults. In turn this can lead to more serious and longer-lasting health outcomes. The exposure level of and ability of a hazard to elicit an adverse health effect at the time of consumption can be cumulatively affected by a series of environmental conditions throughout the food chain. The physical and chemical properties of the food matrix may affect the hazard's survival and persistence in the food. Together with growth, inactivation and survival characteristics of the hazard, the properties of the food can be elaborated in the exposure assessment (Chapter 5). For example, the presence of high levels of fat in food can protect *Salmonella* against thermal inactivation (Gurman *et al.*, 2016; Krapf and Gantenbein-Demarchi, 2010). The transmission and fate of a hazard may be affected by the complex interaction between the hazard and various intermediate pathways. For example, bacterial pathogens from food-producing animals may reach the human population directly through the consumption of contaminated animal products or indirectly through the consumption of crop products contaminated with animal faeces.

Sometimes evidence clearly identifies the significance of foodborne transmission for specific microbiological hazards and which foods are implicated before a microbiological risk assessment is conducted. In this situation, less effort can be expended in the investigation of the causal relationship between the occurrence of adverse health outcomes and the exposure to the foodborne hazard. Conversely,

emerging hazards are continually being identified through the mechanism of acquiring new traits. Through vertical or horizontal transfer of genetic traits among microorganisms, newer pathogenic or opportunistic strains can be produced. Consequently, this transfer could result in new microbiological hazards with higher virulence and/or persistence to various environmental conditions. In this situation, when a particular food is suspected, more thorough investigation is needed to indicate whether the hazard is likely associated with the food product of interest.

4.3 DATA SOURCES FOR HAZARD IDENTIFICATION

A large amount of relevant evidence-based information needs to be collected, appraised and interpreted in hazard identification. The main types of data sources providing useful information to the hazard identification process are as discussed in Chapter 10.

Epidemiologic data from disease monitoring programs, or investigations of foodborne outbreaks are often the first well documented indication of a food safety problem associated with a hazard. Food contamination surveillance data, together with product/process evaluations can aid the identification of hazard–food combinations. Evidence from these sources is usually quantitative, i.e. includes information about the concentration or number of units of the hazard in the food. These data may provide useful information for exposure assessment and/or establishing a dose–response relationship. Whole genome sequencing is being used increasingly for foodborne pathogen surveillance, outbreak investigation and contamination source tracking throughout food supply chains (Rantsiou *et al.*, 2018; WHO, 2018). Clinical research usually provides qualitative data, highlighting the mode of action with which the hazard affects the host, such as through the action of toxins, either in the food or, alternatively, through infectious mechanisms. Inferences from microbiological and clinical studies can be used to support the epidemiological and observational evidence. More details regarding the strength and limitation of different data sources can be found in Chapter 10.

5

Exposure assessment

5.1 THE PROCESS OF EXPOSURE ASSESSMENT

Codex defines exposure assessment as "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." (CAC, 1999). Consequently, exposure assessments are often specific to the production, processing and consumption patterns within a country or region.

Exposure assessment may be undertaken as part of a risk assessment, or it can be a stand-alone process, such as when there is not enough information available to undertake a dose–response assessment (i.e. a Hazard Characterization) or when the risk management question only involves quantifying or seeking ways to minimize exposure. The process of exposure assessment can be, and usually is, iterative. Discussions between risk managers and risk assessors may lead to a refinement of the initial question to be addressed. Similarly, consultation with other parties may result in new information, that can in turn lead to revision of assumptions or to further analysis. Also, nongovernmental bodies, such as food manufacturers or the food industry, may use exposure assessment, as a stand-alone process or as part of an MRA, to assess the safety of their food products. This may be particularly useful as part of food innovation research and before putting products on the market (van Gerwen and Gorris, 2004; Membré and Boué, 2018; Pujol *et al.*, 2013).

The goal of an exposure assessment may be to provide an estimate of the level of exposure to a hazard in a given population. The risk manager may also wish to limit the scope to specific regions, or populations, periods of time or parts of the supply

chain. This again reinforces the need for the risk managers to clearly articulate their needs to the assessors, including the level of detail required in the exposure assessment, and any constraints that would limit the range of management options. For example, when potential mitigations are to be compared, the risk managers should provide an indication of which measures they not consider acceptable under any circumstances.

Once there is a clear understanding of the requirements of the exposure assessment in relation to risk management, the next step is to consider the factors that have a direct effect on consumer exposure to the hazard. These including frequency of consumption of the product or commodity; frequency and levels of contamination with the hazard; and factors that affect the exposure. These factors may include potential for microbial growth, inactivation during cooking (or other processes), meal size, seasonal and regional effects, etc.

In addition, the exposure assessment should describe the relevant pathways of exposure. For example, if the purpose of the risk assessment is to identify and compare different mitigation strategies to be used from production to consumption, then the entire production-to-consumption pathway has to be addressed (Figure 5). In other cases, only the pathways from retail to consumers may be relevant. Thus, if the purpose of the assessment is to reach a decision on the maximum tolerable level of a pathogen in a ready-to-eat (RTE) product at the point of sale, then the assessment would be used to determine the potential for further changes in exposure due to consumer handling (such as time and temperature of storage, effect of cooking or other food preparation steps, potential for cross-contamination in the home, etc.).

The level of detail required in the different pathways reflects the question asked and the information needed by the risk managers and may be modified based on the information available. For example, if it has been shown that the prevalence and/or numbers of a hazard differs between carcases according to the type of abattoir, then such information might influence the level of detail required and the selection of pathways in the exposure assessment. Food supply pathways can be multiple and complex, for example, 'ready-to-eat' meals are a synthesis of food components (e.g. meat, vegetable and dressing) that arise from different pathways.

Risk managers may have specific questions concerning specific processes, such as organic farming, logistic slaughtering (the order in which animals are slaughtered (e.g. Nauta *et al.*, 2009)), or imported foods (e.g. Skjerve, 1999) that they want to be addressed. Accordingly, these specific interests would need to be taken into account in selecting the pathways to consider and the types of data to include.

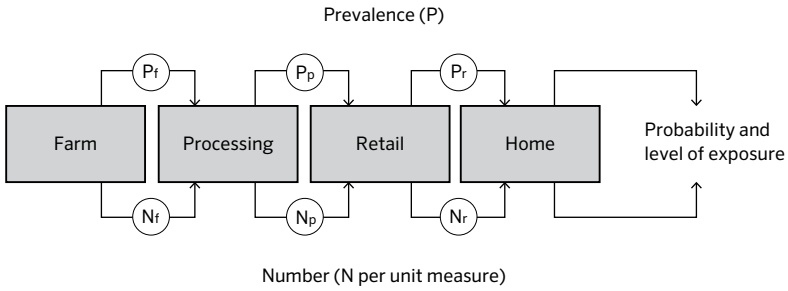

FIGURE 5. An example of an overview of the conceptual model to describe the exposure pathway for a production-to-consumption exposure assessment. To assess exposure, it is necessary to consider both the probability that a unit of food is contaminated with the hazard (denoted P, for 'prevalence'), and the level, or number, of that hazard in the food (denoted N) at the time of consumption. For microbial hazards, in particular, both prevalence and number can change as the commodity is further processed, and as time elapses before the product is finally consumed (Lammerding and Fazil, 2000). (Reproduced with permission from Elsevier)

5.2 MODELLING APPROACHES

5.2.1 Introduction

The goal of exposure assessment is to deduce, from the available information, the probability and magnitude of exposure to the hazard. Detailed exposure data, characterizing the extent of microbiological hazards present in foods at the time of consumption, are usually not available. Thus, exposure assessment will often rely on a model, encompassing knowledge of the factors and their interactions that affect the number and distribution of the hazard in foods, to estimate exposure at consumption. This chapter is primarily concerned with development and application of models used as part of the exposure assessment. General data needs and sources are considered in greater detail in Chapter 10.

A model can be defined as "the description of a system, theory, or phenomenon that accounts for its known or inferred properties and may be used for further study of its characteristics" (McMeekin *et al.*, 2008). The model is a simplified description of some more complex system or phenomenon. Models are also used to communicate an understanding, or hypothesis, concerning some aspect of reality that may, or

may not, be able to be directly observed. Thus, another description is that a model is "a hypothesis or system of beliefs about how a system works or responds to changes in its inputs" (Cullen and Frey, 1999). That hypothesis or description can be expressed in words or as "a system of postulates, data, and inferences presented as a mathematical description of that entity or state of affairs" (Merriam-Webster, 2021).When developing a model – whether it is a full risk assessment or any part thereof – it is important to ensure that the model is fit-for-purpose. As a result, a model should be as simple as possible, but as complex as necessary.[1]

Among the benefits of a model is that it can be used to predict the outcome of events that have not occurred, or have not been observed, e.g. the probability of infection from low doses. However, a fundamental rule of modelling is that no possibility should be modelled that could not actually occur (Vose, 2008). In the context of exposure assessment, the models synthesize data and knowledge from other observations about the pathways of exposure, the behaviour of microbial hazards in foods, patterns of consumption, and so on, to infer what could happen in other circumstances of interest. Models can be used to interpolate among discrete values of observed data and, in some circumstances, to extrapolate beyond the range of observations. In either case, the validity of the interpolation or extrapolation depends on validation of the model (see Sections 16.2).

There is a spectrum of approaches available for exposure assessment, ranging from qualitative to fully quantitative in nature. Quantitative exposure assessments may, in turn, be deterministic or stochastic, with the latter encompassing and representing variability and uncertainty in the data and knowledge as fully as possible and necessary (see Chapter 14).

Although qualitative exposure assessments lack numerical precision, they are still valuable and may, in some circumstances, provide all the decision support needed by the risk manager. Also, as an example, a qualitative assessment may be undertaken as part of a Risk Profile, to determine if the risk is significant enough to warrant a more detailed analysis. This again highlights that risk assessments tend to be, and frequently are, iterative. If a more detailed analysis is needed to answer the risk question and to provide the needed decision support for the risk manager, then a fully quantitative assessment is usually the preferred approach if data, time and resources are available to support it.

[1] A rephrasing of Einstein's principle "A scientific theory should be as simple as possible, but no simpler."

5.2.2 Qualitative and semi-quantitative exposure assessment

A qualitative assessment may be developed by assigning descriptive ratings of probability, such as 'negligible', 'low', 'medium' or 'high', to the factors considered in the assessment (ACMSF, 2012; Fazil, 2005).

As noted in Section 3.5, semi-quantitative exposure assessment provides an intermediary level between qualitative and quantitative exposure assessment. It does not require the same mathematical complexity as quantitative exposure assessment, nor does it require the same amount of data, which means it can be applied to exposure and exposure minimization strategies where precise data are missing. See also Sections 9.1 and 9.2 for more detailed discussion of these qualitative and semi-quantitative risk assessment approaches. Examples of semi-quantitative risk assessment approaches, including exposure assessment, being used to make risk management decisions (Cardoen *et al.*, 2009; Hald *et al.*, 2006; Omurtag *et al.*, 2013; Sumner and Ross, 2002).

5.2.3 Quantitative exposure assessment

As noted above, quantitative exposure assessments provide numerical estimates of exposure. They require models to be developed, in which all relationships between factors affecting exposure are described mathematically. Consequently, quantitative exposure assessments generally require more data than qualitative or semi-quantitative exposures assessments.

Quantitative models can be divided into two categories (Bassett *et al.*, 2012):

1. *Deterministic*, sometimes also referred to as *fixed-value* or *point-estimate* and which in some situations can be solved analytically, and
2. *Stochastic*, sometimes also referred to as *probabilistic*. In some limited circumstance, these models may be able to be evaluated analytically, though most need to be evaluated using *Monte Carlo simulation*.

These are discussed in more detail in Chapter 11. In a mathematical model, *input* variables are those that determine the type and magnitude of the response, or *output*, variables. The output variables in exposure assessment are the frequency and magnitude of exposure of consumers to the microbiological hazard in the food of interest. Depending on how much of the food supply chain is included in the exposure assessment, input variables could include factors such as time, temperature, production volume and dilution during processing (see data sources in Chapter 10). If a modular process framework is utilized for the exposure assessment (e.g. Figure 5), then outputs from one module are the inputs for the next module. *Parameters* quantify the distribution of input variables; they can be

fixed values or described by distributions. For example, while bacterial growth rate is often related to temperature, a mathematical model is needed to quantify that relationship (see Chapter 12). The parameters of that model could be fixed for a specific strain of a hazard but will differ between species and perhaps even for different strains of the same species. In the latter situation the between-strain variability in growth rates, which are a function of temperature, could be described by a distribution.

Stepwise approach to quantitative exposure assessment

As described above, exposure assessments often involve description of very complex systems, where each process step may not contribute equally to exposure and where not all the desired data may be available. In the context of MRA, van Gerwen *et al.* (2000) suggested that, under such conditions, it could be beneficial to conduct an exposure assessment in a series of stages of increasing complexity/sophistication. Similar approaches have been suggested by Cullen and Frey (1999), the USEPA (2006) and WHO (2016) and may be particularly useful when there is an urgent need for an estimate of exposure or risk. A rough estimate is first made of the order of magnitude that individual factors or parameters may contribute to exposure or consequent risk. This could be considered as part of a risk profile. For those factors that contribute most significantly, a more detailed assessment is performed, or more data are gathered and combined in, for instance, a deterministic approach. Where relevant, an even higher level of detail can be achieved using stochastic modelling. Van Gerwen *et al.* (2000) propose that, when using a stepwise approach, both efforts and resources are focused where they add most to reducing uncertainty in the exposure estimate.

5.2.4 Modelling the production-to-consumption pathway

Introduction

The methods by which exposure is estimated depends on the combination of risk management questions being addressed and the amount of data and other resources available, such as expertise and time. An exposure assessment that considers the events from agricultural production through to consumption will demand the most time and resources. Such an exhaustive approach may be appropriate if:

- the risk management questions require consideration of all stages, e.g. the effectiveness or feasibility of mitigation at the farm to estimates of exposure in consumed product, and
- there are sufficient data, knowledge, time and expertise to allow each stage to be considered.

A generic full production-to-consumption pathway is outlined in Figure 5, and various approaches for modelling of this pathway are outlined below. It is important

to emphasize that the final approach utilized depends on the available data and the risk management questions being addressed and is therefore assessment specific. Thus, the following should be viewed as guidance, or examples, rather than as being prescriptive.

Model development

Conceptual model is a term used to describe the understanding of the routes by which the population of interest is exposed to the hazard of concern, including all the factors and their interactions that affect the probability and level of exposure. The conceptual model may be expressed in text, diagrams, as a mathematical model or a combination of these. There is no preferred method to develop and describe the conceptual model. Rather, whatever form the conceptual model takes, it should adhere to the principles and guidelines for the conduct of microbiological risk assessment (CAC, 1999). For the purposes of communication of the conceptual model to nonmathematicians, a diagrammatic representation may be useful and more readily understood than a text-only description, or the mathematical model, alone.

Different approaches can be used to develop the conceptual model. The *Event Tree* approach describes a scenario from a contamination event to a defined endpoint of the assessment, e.g. consumption (Roberts, Ahl and McDowell, 1995). This approach serves to describe or identify the most likely pathways that lead to contamination and subsequent disease and may identify variables in need of further data or modelling. Conversely, the *Fault Tree* approach begins with the occurrence of a hazard and from there describes the events that must have occurred for the hazard to be present (Roberts, Ahl and McDowell, 1995). This approach can provide a framework to analyse the likelihood of an event by determining the complete set of underlying conditions or events that would allow the given event to occur (Jaykus, 1996).

Additional approaches to modelling used in assessments of microbial food hazards include the *Dynamic Flow Tree* model (Marks *et al.*, 1998) and the *Process Risk Model* (PRM) (Cassin, Paoli and Lammerding, 1998). The Dynamic Flow Tree model emphasizes the dynamic nature of bacterial growth and incorporates predictive microbiology using statistical analysis of data. In contrast, the PRM focuses on the integration of predictive microbiology and scenario analysis to provide an assessment of the hygienic characteristics of a manufacturing process.

A general framework is the Modular Process Risk Model (MPRM) (Nauta, 2001, 2008; Nauta *et al.*, 2001), which can be thought of as an extension of the PRM approach. The fundamental assumption of the MPRM approach is that at each of

the steps in the various intermediary stages from production to consumption, at least one of several processes can be assigned. These processes can be divided into microbial and product handling processes. The microbial processes include growth and inactivation, and the food and product handling processes include mixing of units, partitioning of units, removal of parts of units and cross-contamination of organisms among units. The transmission of infection among live animals during primary production could be viewed as an additional biological process, which provides the starting estimates of prevalence in a full production-to-consumption model.

When developing mathematical models, the model structure can facilitate or hinder stochastic modelling and sensitivity analysis (Chapter 15). It is recommended that the models should be formulated such that independent variables affecting exposure are clearly specified. In addition, data for each iteration of the model should be stored for all inputs and outputs for which sensitivity analysis is required. Depending on the modelling approach selected, a one-to-one relationship between the input and output may not be possible when partitioning or combining of units is included (e.g. Kiermeier, Jenson and Sumner, 2015).

The definition of *unit* is crucial when modelling the processes from production to consumption. A unit is defined as a physically separated quantity of product in the process, e.g. an animal, a (part of a) carcase, or a package of ground beef. It may be that one unit from primary production is also the consumer package, such as an egg or whole chicken. However, most examples are more complex, e.g. beef carcase transformed to ground beef burger or milk made into cheeses. In this case, units have to be redefined at each partitioning or mixing stage and thus both the number of organisms (N) in a unit and the prevalence (P) across units (see Figure 5) can be treated as uncertain and variable throughout the model. This makes it possible to assess the uncertainty and variability in the final exposure, and thus the uncertainty in the final risk estimate.

It should also be noted that prevalence and concentration are related. If the (mean) concentration of the pathogen in a batch of food is low (e.g. 1 cell per 5 kg), then the prevalence of contamination will depend on the size of the unit of food. For example, if the unit size is 100 g, then it is expected that one in 50 units contains the pathogen, i.e. the prevalence is 2 percent. But if the unit size is 500 g, then it is expected that one unit in 10, on average, contains the pathogen, i.e. the prevalence equals 10 percent. Similarly, if the unit size is 5 kg, then it is expected that the prevalence is 100 percent. In practice, however, the cells are not expected to be perfectly uniformly distributed, and hence the prevalence will be less than 100

percent, because some units contain more than one cell and, consequently, some others contain none. It is possible to estimate the concentration in a batch from the prevalence and the number of positive samples, provided that not all samples of that size are positive. This approach is based on the same statistical principles as the *Most Probable Number* technique used in microbiology (Cochran, 1950). For a good exploration of the distribution of microbes in food see Bassett *et al.* (2010).

Approaches to mathematical modelling of microbial growth and inactivation and their application are outlined in Sections 12.1 and 12.2. It is difficult to suggest a general model framework for cross-contamination but useful discussion of this topic can be found in Schaffner (2003, 2004), Pérez-Rodríguez *et al.* (2008) and later in this section.

As noted above, different modelling approaches have been proposed and used. The approach used therefore depends on the perspective of the assessor and on the problem being modelled, as indicated by the risk question. Discussion of modelling strategies for the stages from production to consumption is presented below; which stages to include will depend on the scope and purpose of the risk assessment.

Primary production (farm)

The main focus of the primary production or "farm" stage of the exposure assessment is to estimate the prevalence and concentration of the microbiological hazard in the animal population, crop or product of interest; the same approach applies for wild capture/harvest situations. For example, this might be prevalence and contamination levels per live cow, per bird, per homestead, per kg of lettuce leaves, per apple or per vat of raw milk. For animal products, it is important to differentiate infection and colonization from contamination of skin surfaces. These may depend on each other, such as where excretion by infected or colonized animals can result in contamination of that animal's external surface as well as that of other animals in the group.

Recognizing and incorporating dependencies between variables is an important aspect of constructing robust and logical models. This is particularly important when constructing stochastic models in which the variables are described by distributions. Thus, if dependencies are not included in the model structure, then impossible outcomes could occur during the model simulation. For example, consider two variables that are highly positively correlated; ignoring their correlation could result in combinations of values that are not practically feasible. Such model iterations can greatly distort the results of stochastic models, unless

the dependencies between variables are explicitly recognized and included in the modelling. These issues are further exemplified in Section 12.2.

As always, the level of detail required in the farm model depends on the risk questions being addressed and specifically if on-farm control is relevant. This detail will relate to whether or not transmission of infection or contamination is included. For example, the model of Hartnett *et al.* (2001) considers transmission on farm, while the models of Cassin *et al.* (1998) and FSIS (2001) do not. Similarly, FAO/WHO (2009c, 2009d) included on-farm modelling of *Campylobacter* infection in broiler chickens and transmission from fomites, contaminated water, other birds, etc. Conversely, FAO/WHO (2002a) were unable to usefully model pathways of transmission of *Salmonella* on farms.

It must be remembered that animals and plants harvested for food may become infected/ contaminated from many sources including drinking/irrigation water, contaminated feed, vermin and feral animals, bird faeces, etc., or in the case of fish and especially shellfish from the water itself.

Transport to processing plants

Transport from primary production to processing can also be included in the exposure assessment. During transport, cross-contamination of primary production units can occur, or infection can spread between units in close proximity, and thus the overall microbial load can increase. In particular, stress of animals during transport can lead to increased faecal shedding and dissemination of pathogens to uninfected animals. Microbial loads on produce can also increase due to microbial growth during transport (Arthur *et al.*, 2007; FSIS, 2001).

Processing

The stages in processing need to be defined before a model can be constructed to describe the changes in prevalence and in the number of organisms (see also comments above about the interplay between prevalence, unit size at a given contamination level). There can be many stages in food processing, though not all will necessarily have a strong effect on the ultimate risk to human health. Cassin *et al.* (1998), for example, identified 36 distinct processing steps during the slaughter of beef cattle. It is unlikely that all these stages will be followed by all processors, and an added difficulty is elaborating processing scenarios that are both representative of the majority of processors yet take into account differences between processors. Flow diagrams developed for HACCP systems can be useful sources of information on process steps and conditions.

Modelling of processing involves considering how:

- unit size changes from stage to stage and how this affects prevalence and concentration of organisms;
- prevalence and concentration change as a result of cross-contamination, or recontamination after the application of a critical control point, without unit size changing; and
- concentration changes due to microbial growth or inactivation.

Much effort is expended during food processing operations to minimize microbial growth and/or to maximize microbial inactivation, and to prevent cross-contamination from other materials or the processing environment through cleaning and sanitation. For example, Dogan *et al.* (2019) evaluated the effectiveness of various interventions in processing plants to protect the safety of chicken consumers, through the development of quantitative exposure assessment models. Similarly, Smith *et al.* (2013) evaluated the relative effects of preharvest and processing interventions on public health risk for the consumption of ground beef and beef cuts contaminated with *Escherichia coli* O157:H7 in Canada. In contrast, mechanisms of recontamination of products in factory environments were discussed by den Aantrekker *et al.* (2003) and Tenenhaus-Aziza *et al.* (2014). When the process is not relevant to the decision, then detailed modelling is not needed. The reduction (or increase) in numbers is, thus, sometimes modelled using a *black box* approach whereby the changes are modelled without attempting to describe any of the underlying microbial processes.

Important factors controlling the extent of growth and inactivation are the duration of conditions and severity of treatment (particularly temperature) prevailing during the process. Similarly, where changes are due to growth or inactivation, the effects of process duration and conditions on microbial numbers can be estimated using well-established predictive models (e.g. Tenenhaus-Aziza and Ellouze, 2015; Zwietering and Hasting, 1997a, 1997b); predictive microbiological models are discussed in detail in Chapter 12. Finally, the MPRM methodologies for mixing, partitioning and removal can be used to model the effects of changes to unit size (Bassett *et al.*, 2010; Nauta, 2008).

Studies of the effects of processing steps on the levels of microbiological hazards often report on the results of analysis of "before and after" samples, for example, the number of organisms contaminating a broiler carcase before and after defeathering. The results are often reported in terms of $\log_{10}$ concentrations. Caution is needed, however, when modelling contamination events and when the initial contamination levels are reported as $\log_{10}$ populations. For example, if a contamination event *adds* 1 000 organisms per unit (i.e. 3 $\log_{10}$) to a unit containing 100 organisms (i.e. 2

$\log_{10}$) it is incorrect to conclude 2 $\log_{10}$ + 3 $\log_{10}$ = 5 $\log_{10}$ (or 100 000 organisms per unit). The correct calculation involves converting the log counts to their arithmetic value and then adding the numbers, i.e. 100 + 1 000 = 1 100, which means the final contamination is 3.04 $\log_{10}$ organisms per unit, from the original 2 $\log_{10}$. This is because contamination is an additive process. In contrast, microbial growth is a multiplicative process because growth is exponential, i.e. where the increase is based on the initial number of organisms in the product and numbers change exponentially over time. In those cases, the log values can be added, e.g. 2 $\log_{10}$ initial plus 3 $\log_{10}$ growth = 5 $\log_{10}$ at the end of growth, because *every* cell initially present increased in number by 1000-fold. These are examples where errors would result in causal relationships that are incorrect and thus resulting in a flawed assessment; such errors should clearly be avoided.

The variation and uncertainty associated with modelling the change in numbers should also be given careful consideration. When choosing the approach, thought should be given to what the data represent (variation, uncertainty or both) and how representative they are. For example, a problem with modelling the results of carcase samples is ensuring that the sampled portion is representative of the entire carcase. A potential remedy to this challenge is to estimate the magnitude of the bias (due to different carcase parts) in a separate study and include this in the model. A practical corollary of this is that if contamination on the carcases is unevenly distributed, then when the carcase is broken down into smaller pieces, not all will carry the same level of contamination. This is a good example of the consequence of partitioning and where contamination on each smaller unit may vary. Consequently, the prevalence and distribution of contamination levels on subunits would need to be described.

During processing, formulation of products can be altered, and such alterations may change the potential for microbial growth. Examples include adding growth inhibiting compounds, such as salt or organic acids, to processed food; drying/water removal leading to reduction of water activity; acidification during fermentation; addition of water; etc. Similarly, packaging can affect the potential for microbial growth, inactivation, and cross-contamination. Thus, changes in the condition of the product over time must be modelled as part of exposure assessment.

Processing often involves steps designed to reduce or eliminate microbial loads so that not only the expected magnitude of the reductions due to these steps, but also their uncertainty/variability, will need to be modelled. Also, if the initial contamination levels are low, and a typical unit size is small, then not all units will contain the hazard so that increased risk, in the absence of cross-contamination, can only come from growth in the units that *do* contain the hazard.

Postprocessing

The postprocessing environment includes storage and transport/distribution, retail display and handling, food service operations and home kitchens. These steps can allow microbial growth, crosscontamination, but also hazard reduction through cooking, physical removal of contamination, etc. Table 1 lists some of the factors of the postprocessing environment that could affect hazard frequency and level of exposure. While some of these environments may differ in some respects, there are often important similarities and some data collected in one environment may be suitable surrogates for assessing changes in exposure in other environments, e.g. cross-contamination from cutting boards.

TABLE 1. Examples of factors of importance when determining the impact of the postprocessing environment on the level of exposure

Factor	Example
Temperature	
Static (though variable)	Refrigerated storage temperature
Dynamic	Cooling times and temperatures for cooked food
Product formulation	pH and water activity of the food, preservative compounds (sorbate, lactate, nitrite, nisin, etc.)
Biotic factors in food (inter-species competition)	Relative level of spoilage or other microorganisms on the product compared to pathogens, e.g. fermented food, lactic acid bacteria in vacuum-packed foods.
Time	Time on a salad bar, time between cleaning the blade of a processed meat slicer
Cross-contamination	
Foods	Transfer from chicken
Surfaces	
Food contact surface	Transfer from food to cutting board
Hand contact surface	Transfer from refrigerator door or utensils
Cleaning (sponge, cloth)	Survival on a sponge
Hands	Transfer from hands
Bodily orifices	From diarrhoea via hands, fomites
Survival on surfaces	Survival on stainless steel
Cleaning	
Washing	Effect of washing hands with soap and water for 20 seconds
Sanitizing	Effect of 200 ppm chlorine
Discards	Decision to use lunch meat beyond its use-by date

Transport and storage postprocessing can include:

- Transport from the processor to a food service establishment or retail outlet, possibly via a distribution centre, and subsequent storage;
- Warehousing;
- Retail storage and retail display;
- Storage and handing in food service; and
- Transport from retail to the home by the consumer and subsequent home storage. This type of transport and storage is likely to be less well controlled as most consumers do not have a refrigerated vehicle and frequent access to upright, domestic refrigerators means frequent loss of temperature control.

Transport and storage conditions may also be less-well controlled in different regions. For example, in countries where street food vending is common, street vendors often lack the facilities for proper temperature, insect and vermin control. Similarly, farmers markets may pose challenges in terms of temperature control during transport, storage and retail (Young *et al.*, 2017b).

In general, relatively little information is available in the published literature on transport temperature and durations. With respect to transport between processor and retailers (or further processing), information on durations is likely known by the processors, indicating the need for good risk communication and involvement of stakeholders early in the risk assessment process. However, less is known about the temperature profile during transport, although the increasing availability of relatively cheap data loggers, possibly location enabled, are helping to remedy this situation (e.g. Sumner, 2016). Similarly, not many published research articles exist about retail or food service storage. An example of temperature data collection at retail is provided by Ecosure (2008), who collected data on cold temperature storage of products in various areas of retail stores (available in spreadsheet format). The FRISBEE project collected similar cold-chain data in Europe for various food products (FRISBEE project, 2021).

Less is known about the treatment of food during transport to the home, likely related to the logistical difficulties of obtaining such data. Ecosure (2008), however, also collected data from consumer volunteers on transport to the home. The volunteers also reported how product was transported, the temperature in the part of the vehicle where product was located, the outside temperature, and time between purchase and placing each product into the refrigerator/freezer at home. Similarly, Kim et al. (2013) reported on temperature profiles of various food products during transport to the home.

Using information about duration and temperature at each stage during post processing, predictive microbiology models may be used to predict the growth and inactivation of the hazard. Depending on the hazard and the durations involved, the effects of shelf life (limit on total duration between production and consumption) and competing and spoilage bacteria may need to be considered (see also Section 12.2).

Cross-contamination

Cross-contamination has been recognized as an important factor directly related to outbreaks of foodborne diseases and food spoilage and therefore may need to be included in the exposure assessments (Possas *et al.*, 2017).

Postprocessing environments can be more complex than processing environments because of:

- the variety of foods involved – restaurant menus, for example, may have dozens of items, and a cafeteria may have hundreds;
- the complexity of food preparation operations – nonlinear compared with food processing operations;
- differences in preparation setting – home versus food service;
- differences in the physical layout between operations – one kitchen versus another;
- and level of training – new worker or home cook versus a highly experienced worker.

The need to evaluate how microorganisms are transmitted along the food chain has motivated the study of other phenomena besides growth and death.

The potential complexity involved in modelling cross-contamination during food preparation is shown in Figure 6 for the act of preparing a cooked chicken product and a lettuce salad.

Despite its complexity, a number of simplifying assumptions are made in Figure 6.

- The lettuce and the person preparing the food do not contribute any microbiological hazard to the exposure, except for cross-contamination originally arising from the chicken.
- Hands and cutting board are the only cross-contamination vehicles, and other kitchen surfaces and utensils (knives, plates, sponges, towels, aprons, counter-tops, etc.) do not contribute to exposure.
- No changes in microbial numbers occur, due to growth or inactivation, during any step except storage and cooking (e.g. bacterial populations on cutting board do not change).
- The frequency at which each event occurs is not specified, and multiple contamination events may occur in any food preparation procedure.

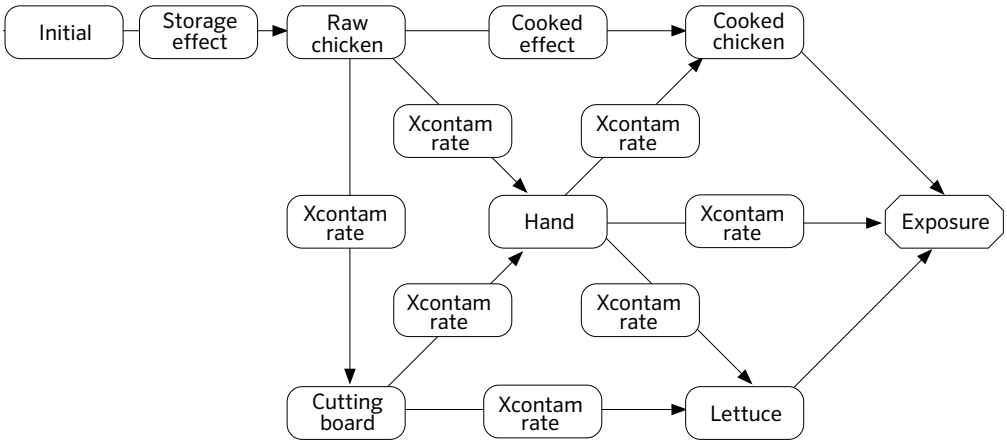

FIGURE 6. An example 'influence diagram' of a model of a cross-contamination pathway for the preparation of cooked chicken and lettuce salad. (Xcontam = cross-contamination)

Some of the simplifying assumptions listed above can be shown to be false in many situations, e.g. that no change in microbial numbers occur during any step except storage and cooking. Growth on contact surfaces does occur and may be important. Surfaces that become contaminated with films of nutrient-rich liquids from raw product may contain bacterial pathogens which could grow in the film. This surface is then replenished with new material from each subsequent unit and can promote cross-contamination to other units. Consider that a work–shift may be 4 to 8 hours in duration and that the working environment is maintained at 10-15 °C (such temperatures are maintained in some food processing operations because at lower temperatures workers became less dextrous and are more likely to have accidents and injuries). Based on estimates from published predictive models, pathogens could increase by 10- to 1000-fold in some products, e.g. *Vibrio parahaemolyticus* on fish and shellfish (100- to 1000-fold), *Listeria monocytogenes* on smoked fish (10-fold) and *E. coli* on raw meat (10-fold). The rate of potential growth on contact surfaces can be used to determine the maximum time interval between successive cleanings of equipment in contact with raw product. However, predicted increases may be quite different under processing settings where food products are moved on and off the preparation surface throughout the shift, each potentially depositing and/or removing some of the contamination.

Another difficulty in populating the diagram in Figure 6 with real numbers and mathematical relationships is a lack of published data on many consumer storage and handling practices and on cross-contamination rates. The large uncertainty and variability associated with preparation and cooking practices has been recognized in national and international reports of exposure assessments. For example, the FAO/WHO exposure assessment models for *Salmonella* spp. and *Campylobacter* spp. in broilers suggest that cross-contamination during preparation and cooking can affect exposure (FAO, 2001; FAO and WHO, 2002a; WHO, 2001). However, despite the large number of studies reviewed by Pérez-Rodríguez *et al.* (2008) the authors concluded:

> *The main objective and challenge when modelling bacterial transfer is to develop reliable mathematical models … However, with today's knowledge, such models are a Utopia, since information is imprecise and scarce, and data show major experimental errors.*

The available cross-contamination modelling approaches in foods as well as the available evaluation methods for model robustness are provided by Possas *et al.* (2017).

Given the limited amount of suitable data available for quantifying the effects of crosscontamination, most exposure assessments have considered this event in a simplistic manner. For example, such simplifications can be achieved by including a limited number of pathways, and by estimating both the probability of transfer and the numbers of organisms transferred (e.g. Hartnett, 2002). Other approaches have also been adopted, such as the Health Canada *Campylobacter* risk assessment, where the transfer of organisms in the drip fluid was also considered (Fazil *et al.*, 1999). Schaffner (2004) modelled the cross-contamination of *Listeria* species using a quantitative mathematical model using Monte Carlo simulation techniques. Chen *et al.* (2001) quantified the probability of bacterial transfer associated with various steps in the food preparation process and provided a scientific basis to include cross-contamination in the exposure assessment with the aim to support risk management strategies to reduce or prevent cross-contamination in the kitchen. Zilelidou *et al.* (2015) evaluated the cross-contamination phenomena that might take place between cutting equipment and leafy vegetables in common households or in food preparation environments and provided quantitative data regarding the transfer rate of *E. coli* O157:H7 and *L. monocytogenes* from contaminated lettuce to kitchen knives and subsequent transmission to fresh lettuce. Other studies have

evaluated the cross-contamination rates of *L. monocytogenes* (Gallagher *et al.*, 2016), *Salmonella* (Smid *et al.*, 2013), *Campylobacter* (Hayama *et al.*, 2011; Moore, Sheldon and Jaykus, 2003; Mylius, Nauta and Havelaar, 2007), and *E. coli* O157:H7 (Jensen *et al.*, 2015; Pérez-Rodríguez *et al.*, 2011).

In summary, postprocess food preparation is a highly complex, and poorly characterized, part of the food chain. Limited data are available, and numerous data gaps have been identified. Given the complexity of this part of the food chain, research to better understand and describe these processes is ongoing. Publication of the results of that research will contribute to improved exposure assessment where cross-contamination may be an important route of exposure. However, cross-contamination is initially a *redistribution* process and, unless that redistribution alters the fate of the hazard, that is, either due to growth or reduction the benefits of cross-contamination modelling should be carefully considered.

5.2.5 Consumption

To characterize the risk from exposure to microbiological hazards in food, it is necessary to know the amount of food consumed per meal, how often it is consumed, the form in which it is consumed (raw or cooked), and by whom because susceptibility is variable and some groups (e.g. very old, very young) are more likely to develop illness from foodborne hazards.

The specific characterization of food consumption patterns used in the MRA depends on the question to be answered, and the food consumption data that are available to the risk assessor (see also Chapter 10). The data collated and published by WHO through the Global Environment Monitoring System (GEMS) cluster diets may be useful when no other data are available (WHO, 2021). However, care needs to be taken, as for any consumption data, to ensure correct interpretation (see below).

Modelling the amount of food consumed

When modelling food consumption, it is important for risk assessors to understand the specifics of how the food consumption data were collected and analysed. It is also necessary to clearly describe how these data are used in the model, including any assumptions used in arriving at the estimates.

The important aspects of calculating the amount of food consumed, particularly when using results from food consumption surveys, include:

- the population divisor, that is, whether the total consumption amount is divided by the total population (amount per capita) or only those who consumed the food (amount per consumer);
- the frequency of consumption (per day/week/month/year); and
- the amount consumed per consumption event.

These are discussed below.

Amount per capita vs per consumer

The per capita amount is calculated by dividing the total amount of a food by the total number of people in the population. The per consumer amount is calculated by dividing the total amount of food only by the number of people who consumed the food.

For foods that are consumed regularly by most of the population (e.g. bread), the per capita and per consumer amounts will be nearly equal. For foods that are consumed by fewer individuals (e.g. raw oysters), the per capita and per consumer amounts will be quite different.

For example, consider that 10 million kg of a food are consumed by 10 percent of the population, which consists of 10 million people. The average consumption per capita equals 1 kg, while the average consumption per consumer equals 10 kg.

Amount per year, per day or per eating occasion

Consumption may be calculated as the amount per time period (e.g. year, month, week or day) or per eating occasion. Definition of the consumption period is particularly important in MRAs because acute, rather than chronic, exposure is of concern. In contrast, chronic exposure may be relevant for some microbial toxins that are released into foods before consumption, e.g. mycotoxins, and in such situations chemical risk assessment approaches are appropriate (e.g. see FAO and WHO, 2009e). For microbial toxins that cause acute illness, such as *Staphylococcus aureus* enterotoxin, the dose of microbial toxins is stoichiometrically related to the level of contamination of the food by the toxigenic organism and microbial risk assessment approaches are generally appropriate.

National food production statistics (e.g. FAOSTAT) (FAO, 2021c) generally report an amount of food produced per year, and care is needed to fully understand the

values. For example, if the amount of fish caught is reported, does the amount relate to whole fish landed, or does it relate to the amount after gilling and gutting? Clearly, amounts ultimately consumed need to be adjusted to remove inedible parts of the food and any losses incurred during processing. Similarly, food wastage in the supply chain due to spoilage or other reasons needs to be accounted for if possible. For highly perishable products (meat, fish, fruits, salad vegetables, etc.), this may be as high as 20 to 25 percent of production (Gustavsson, Cederberg and Sonesson, 2011).

A consumption amount may be estimated by dividing the total annual amount (per capita or per consumer) by the average number of eating occasions. Returning to the example above, if the food product is thought to be consumed daily then the average amount would equal 10 kg divided by 365 days, or about 27.4 g per day. This amount may be too small to be realistic and hence the data and assumptions for the calculations may need be reassessed and adjusted, if necessary. For example, it may be that a typical amount consumed in a meal is closer to 100 g and hence this would imply that the food is consumed about 100 times per year, or approximately once every 3-4 days. Meal size and consumption data may be available from surveys for some countries.

Food consumption surveys of individuals allow much more flexibility in estimating the consumption amount. Survey results are frequently summarized and reported on the basis of daily consumption. If the raw data from the survey are available, then it may also be possible to calculate the amount of food consumed per eating occasion (depends on coding system and questions in the questionnaire) and the frequency of consumption. The basis for consumption is particularly important when considering foods that may be consumed more than once in a single day. For example, if a person drinks a 250-ml glass of milk at each of three meals, the amount per meal would be 250 ml, whereas the amount per day would be 750 ml.

When calculating daily food consumption from food consumption survey data, it is also important to note whether the amount was calculated as an average over all days of the survey or for only the days on which a food was consumed. As an example, consider a study where five days of dietary records were collected for individuals participating in the survey. From those data, consumption could be calculated as consumption on the days the food was actually consumed or as the average, or total, over five days for which each person participated in the survey. Of course, a portion size can vary from meal to meal and different people will consume different amounts per meal (on average), e.g. young children or the elderly might have smaller portion sizes than young adults. In this case, serving size can be modelled as a distribution, if the data are available. In general, all other

things being equal, larger serving sizes would be correlated with slightly higher risk of illness. If there is a correlation between serving size and particular consumer characteristics, these correlations can also be modelled to reflect the differential risk to different consumers.

In addition, when the total exposure from several foods is assessed it may be necessary to consider correlations between the respective serving size. Examples might include consumption of apples in the form of raw apples, apple juice and apple pies, or consumption of cheeses in combination with deli meats. However, accessing data that allows quantification of such correlations will most likely be challenging.

Importance of characterizing the distribution of contamination

The risk to an individual depends on the dose ingested which, in turn, depends on the serving size. The importance of modelling the physical distribution of the number of organisms in a food, i.e. the dose, will depend on the dose–response relationship for that organism. If a high level of growth occurs in a single unit of food prior to consumption, only one person is likely to be affected because that single unit of food will be consumed by one person. Assuming that there are more than enough cells of the hazard present to cause infection in most individuals, if that same dose were spread equally over 100 servings, then the same dose might be enough to infect many of the 100 consumers, assuming a pathogen with a high probability of infection per infectious particle, e.g. norovirus (Teunis *et al.*, 2008). Conversely, for a pathogen with a very low probability of infection per cell, e.g. *L. monocytogenes* (see Table 7), the predicted risk to the entire population from the exposure is largely independent of the distribution of doses among units of food and is effectively estimated from the average dose. This is because there is, effectively, a direct proportionality between the dose and probability of infection for all realistic doses (see Chapter 6) and for those realistic doses the probability of infection is much less than one. In this situation, there is less need to characterize the distribution of the pathogen among different servings. Nauta (2000) provides advice on modelling distribution among individual servings. This is relevant for the physical distribution of doses, but also if we consider the statistical variability of the doses. To realistically determine the population risk, variability in doses should be included since the risk is often determined by the right tail of the distribution. These extremes are affected by the distribution in the initial concentration, the effects of processing and variability of all other factors in the exposure assessment.

Consumption frequency

The frequency of consumption refers to how often an individual consumes a food in a specific period. In MRAs (e.g. FAO and WHO, 2002a; FSIS, 2001; USFDA,

2005; USFDA/FSIS, 2003), frequency of consumption has been expressed in a variety of ways:

- Number of days per year on which the food is consumed.
- Number of eating occasions over a year:
  - annual number of meals,
  - number of times the food is consumed per year, or
  - number of 100-g portions consumed in a year.

For a food consumption survey, the number of days of consumption during the survey period can be determined directly from the survey results; from that, an annual number of days of consumption may be extrapolated. The number of meals, eating occasions or individual food items may also be calculated directly from the survey results, if the survey covers more than one day per individual. Alternatively, data from single 24-hour recall surveys can be combined with information from food frequency surveys on the proportion of the population who usually consume a food in a given period to estimate the annual number of consumption days.

It may be possible to refine or verify the estimated frequency of consumption by combining food consumption data with other industry information, such as annual sales volume or market share information (Chapter 10). For example, if the food consumption data report the frequency of consumption of a broad category such as cheese, market share or loyalty card data may be used to predict the frequency of consuming a particular type of cheese (e.g. Camembert). Note that it might be reasonable to assume that the amount of cheese consumed is similar across types of cheese although the frequency differs by cheese type. As noted above, consideration should be given to the proportion of production that is never consumed due to spoilage, not sold by specified use-by or best-before date, or due to other forms of wastage.

A useful *reality check* is to combine food consumption amounts with frequency of consumption, and number of consumers to calculate approximate production volumes, taking into account wastage, imports and exports, etc. These estimates should be comparable to actual production volumes and big discrepancies may indicate that some of the estimates or assumptions are not valid.

Considerations and challenges in modelling food consumption

There are a number of aspects of food consumption data that should be considered when developing the food consumption model.

Extrapolating data from results of food consumption surveys

Food consumption surveys generally collect information from a subset of the

population (e.g. van Rossum *et al.*, 2011). If the sample is representative of the total population and statistical weights developed for the survey are used in the data analyses, survey results may be used to predict food consumption patterns for the population as a whole.

For MRAs, it may be important to estimate the consumption for sensitive population groups, such as the elderly or the immunocompromised. In the absence of specific data for these groups, it is often assumed, if appropriate, that their consumption patterns are the same as the normal, healthy population of the same age and gender.

Infrequently consumed foods

Estimates of consumption based on a small number of observations, i.e. small number of food consumption records, will be more uncertain than estimates based on larger samples. For this reason, care should be taken when interpreting and extrapolating survey results for infrequently consumed foods, even if the overall survey size was large and survey weights are used in the data analysis.

If the survey data are used to model consumption for an infrequently consumed food, it is important that the consumption amount be calculated from the day or eating occasion on which the food was consumed, rather than as the average over all survey days.

Food consumed as discrete items vs components of mixed dishes

Some foods may be consumed both as discrete items and as components of combination foods or food mixtures. For example, milk may be consumed as a beverage, but also as an ingredient (often in small amounts) in many food items. The normal usage of those foods can also affect hazard levels, e.g. milk consumed in meals may be heated which could reduce pathogen numbers compared to milk consumed as part of a cold milk drink. When modelling food consumption, it is important to know whether the consumption estimate includes all sources of the food or only the amount of food consumed as a discrete item. If the consumption estimate includes consumption of the food from all sources, it may be necessary to consider the *recipes* for foods containing that ingredient. This will not only allow estimation of the total consumption from all sources, but also the form in which the food is eaten, including the effects on the hazard (if any) due to food preparation. Similarly, it may be necessary to estimate the proportion of the total consumption in which the hazard could be present, such as unpasteurized juice or milk, or hot dogs eaten without reheating. As another example of the effect of mixing and partitioning, while consumption data for shell eggs may indicate that a person eats 60 g of shell egg per day, in some situations the serving may have been made from

many eggs combined, such as scrambled eggs in an institutional setting. In such a case, many consumers might be exposed to a single contaminated egg compared to another situation where a single consumer eats the entire contaminated egg.

Aggregation or grouping of foods

If the risk assessment is focused on food groups rather than individual foods, then consider the way in which foods are aggregated for estimating consumption. The average consumption amount for a food category is affected by the number of foods it represents and how similar the foods are in terms of the usual amount and frequency of consumption. If the foods are too dissimilar, the average amount and frequency of consumption may be misrepresented. For example, if fluid milk and cheese are grouped together as 'dairy products', the consumption amounts may be quite different, and the average consumption will likely underestimate consumption of milk and overestimate consumption of cheese. This is because fluid milk is generally consumed more frequently and in greater amounts than cheese. Again, if a food category includes seasonal items as well as foods that are available year-round, the frequency of consumption may be under- or overestimated for the seasonal foods. Some consumption surveys do, however, identify seasonal effects, e.g. by sampling individuals at many times throughout the year.