

SCIENCES

AGRONOMY AND FOOD SCIENCE

Food Safety

Microbiological Risk Assessment Associated with the Food Processing and Distribution Chain

**Coordinated by
Jeanne-Marie Membré**

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Table of Contents

[Cover](#)

[Title Page](#)

[Copyright](#)

[Preface](#)

[Acknowledgements](#)

[Introduction](#)

[Norovirus](#)

[Campylobacter spp.](#)

[Non-typhoid Salmonella spp.](#)

[Risk analysis](#)

[Microbiological risk assessment](#)

[References](#)

[PART 1: Hazards and Food](#)

[1 Biological Hazard Identification](#)

[1.1. Introduction](#)

[1.2. Who conducts hazard identification?](#)

[1.3. Sources of useful information for hazard identification](#)

[1.4. An example of the use of data in hazard identification, exposure assessment and risk characterization](#)

[1.5. The hazard identification process](#)

[1.6. Scientific work on hazard identification](#)

[1.7. Conclusion and perspective](#)

[1.8. References](#)

2 Detection and Enumeration of Foodborne Pathogens and Bacterial Toxins in Food

2.1. Why should we look for pathogens in food?

2.2. Conventional culture-based methods: how to detect and quantify pathogenic bacteria in food

2.3. Nucleic acid-based methods

2.4. Immunology-based assays

2.5. Other methods

2.6. References

3 Exposure Assessment of Microbial Pathogens

3.1. Introduction/state of the art

3.2. Construction of a food-pathway model

3.3. Conclusion

3.4. References

PART 2: Food and Risk

4 Pathogenic Mechanisms of Bacterial Foodborne Pathogens

4.1. Introduction

4.2. Foodborne pathogens and diseases

4.3. Pathogenic mechanisms of foodborne pathogens

4.4. Prospects for ongoing studies

4.5. References

5 Microbial Dose-Response Models

5.1. Introduction

5.2. Main dose-response models

5.3. Fitting data to a dose-response model

5.4. Discussion and conclusion

5.5. References

6 A Guide for Microbiological Risk Characterization

6.1. Introduction

6.2. Qualitative and semi-quantitative risk characterization

6.3. Quantitative measures of risk

6.4. From results of risk assessment to the application of measures in the food chain

6.5. Concepts of variability and uncertainty in the context of risk characterization

6.6. Risk characterization by taking into account variability and uncertainty

6.7. Software tools and good practices for risk characterization

6.8. References

Conclusion

Scientific work on microbiological risk assessment

Integration of microbiological risks into a more general risk assessment process

Risk ranking of hazards

References

Appendices

Appendix 1. Hazard identification - Example of cooked ham

Appendix 2. Hazard identification - Example of refrigerated vacuum-packed products

Appendix 3. Source attribution

References

Glossary

List of Authors

[Index](#)

[End User License Agreement](#)

List of Tables

Chapter 1

[Table 1.1. The various types of data that can be used in hazard identification \(...\)](#)

[Table 1.2. List of 16 scientific papers dealing with the identification of the m...](#)

Chapter 3

[Table 3.1. Basic processes and their effect on the prevalence \(P; fraction of co...](#)

[Table 3.2. Baseline model parameters](#)

[Table 3.3. Model scenarios](#)

[Table 3.4. Baseline model parameters](#)

Chapter 4

[Table 4.1. Symptoms, delay before the first symptoms occur and causal pathogenic...](#)

[Table 4.2. Some properties and symptoms associated with diarrheagenic E. coli pa...](#)

Chapter 5

[Table 5.1. Dose levels and response to Campylobacter jejuni \(A3249\) \(Black et al...](#)

[Table 5.2. Estimates and standard errors for the parameters from both the expone...](#)

Conclusion

[Table C.1. Recent articles \(titles and DOIs\) on the topic of water and its use f...](#)

[Table C.2. Recent articles \(titles and DOIs\) on the topic of raw milk](#)

[Table C.3. Recent articles \(titles and DOIs\) on the topic of antibiotic resistan...](#)

[Table C.4. Recent articles \(titles and DOIs\) on the topic of the consumer and co...](#)

Appendices

[Table A.1. Frequency of contamination of sliced ham by *L. monocytogenes*, adapted...](#)

[Table A.2. Notifications for *L. monocytogenes* in cooked ham \(or a similar produc...](#)

[Table A.3. Foodborne disease severity scores and estimates of the foodborne morb...](#)

[Table A.4. Short presentation of the hazards listed in Table A.3 \(Augustin et al...](#)

List of Illustrations

Introduction

[Figure I.1. Factors influencing the evolution of food safety. From the FAO and W...](#)

[Figure I.2. The three components of risk analysis: risk assessment, risk managem...](#)

[Figure I.3. Microbiological risk assessment. Adapted from the FAO and WHO \(2020\).](#)

Chapter 1

[Figure.1.1. Structuring of information essential to hazard identification. Creat...](#)

Chapter 2

[Figure 2.1. Schematic representation of the three internationally recommended cu...](#)

[Figure 2.2. Conventional culture-based and nucleic acid-based methods for the de...](#)

[Figure 2.3. Quantitative real-time PCR curves. \(A\) Real-time PCR kinetics, with ...](#)

[Figure 2.4. Real-time PCR detection systems. \(A\) Fluorescent probe-based qPCR. T...](#)

[Figure 2.5. Main steps of digital droplet PCR \(ddPCR\). Step 1: preparation of th...](#)

[Figure 2.6. Main steps of whole genome sequencing \(WGS\). Adapted from Next Gener...](#)

[Figure 2.7. Summary of the potential use of NGS by the food industry according t...](#)

[Figure 2.8. Overview of common enzyme-linked immunosorbent assay \(ELISA\) formats...](#)

[Figure 2.9. Matrix-assisted laser desorption/ionization time-of-flight \(MALDI-TO...](#)

Chapter 3

[Figure 3.1. In the farm-to-fork food pathway, prevalence and concentrations are ...](#)

[Figure 3.2. A schematic representation of the food pathway for a QMRA of E. coli...](#)

[Figure 3.3. Food pathway for Danish meatballs. Meatballs are produced from mince...](#)

[Figure 3.4. The result of the exposure assessment, showing the frequencies of th...](#)

Chapter 4

[Figure 4.1. Simplified schematic representation of bacterial virulence events in...](#)

[Figure 4.2. Mechanisms of action of toxins produced in vivo by *Campylobacter jejuni*...](#)

[Figure 4.3. Schematic attachment and effacement mechanisms of *E. coli* EHEC. Infe...](#)

[Figure 4.4. “Zipper” versus “trigger” mechanisms of bacterial internalization by...](#)

[Figure 4.5. Theoretical *Campylobacter jejuni* mechanisms of intestinal infection....](#)

[Figure 4.6. Evolution of in vitro cell models to study host-foodborne pathogen i...](#)

Chapter 5

[Figure 5.1. Examples of exponential distribution. For a color version of this fi...](#)

[Figure 5.2. Examples of beta distribution. Top: probability density function \(pd...](#)

[Figure 5.3. Examples of beta-Poisson dose-response models. For a color version o...](#)

[Figure 5.4. Examples of beta-Poisson dose-response models. The parameters \$\alpha\$ and ...](#)

[Figure 5.5. Dose-response models \(probability of severe listeriosis cases condit...](#)

[Figure 5.6. Best-fitting curve from the beta-Poisson model and the 95% and 99% c...](#)

[Figure 5.7. Beta-Poisson bootstrap estimates \(10,000 iterations - data in Table ...](#)

[Figure 5.8. Incidence rates of hemolytic uremic syndrome \(HUS\) attributable to e...](#)

[Figure 5.9. Visualization of the Bayesian statistical model for estimating the \$\alpha\$...](#)

[Figure 5.10. Dose-response relationship estimated based on data collected from n...](#)

Chapter 6

[Figure 6.1. Relation between the 11 inputs \(X\) and the outputs \(Y\) of the Risk R...](#)

[Figure 6.2. Different measures of risk](#)

[Figure 6.3. Illustration of DALYs with the case of a person who falls sick and d...](#)

[Figure 6.4. Risk management metrics in the food production chain. ALOP: appropri...](#)

[Figure 6.5. \(A\) Illustration of the two-dimensional Monte-Carlo simulation with ...](#)

Conclusion

[Figure C.1. Breakdown of the 1,037 published articles on microbiological risk as...](#)

[Figure C.2. Microbiological risks repositioned in a more general risk assessment...](#)

[Figure C.3. Example of categorization of microbiological risks based on their pr...](#)

[Figure C.4. Method for simultaneous risk ranking of microbiological and chemical...](#)

Appendices

[Figure A.1. Diagram of cooked ham production, adapted from Zwietering et al. \(20...](#)

[Figure A.2. Combination of thermal processing and pH guaranteeing a 6 log degree...](#)

SCIENCES

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Legrand and Gilles Trystram

Food Safety, Subject Head - Jeanne-Marie Membré and
Thierry Bénézech

Microbiological Risk Assessment Associated with the Food Processing and Distribution Chain

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ISTE

WILEY

First published 2022 in Great Britain and the United States by ISTE Ltd and John Wiley & Sons, Inc.

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John Wiley & Sons, Inc.
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Library of Congress Control Number: 2021952704

British Library Cataloguing-in-Publication Data
A CIP record for this book is available from the British Library
ISBN 978-1-78945-084-2

ERC code:

Applied Life Sciences, Biotechnology, and Molecular and Biosystems
Engineering

LS9_5 Food sciences (including food technology, food safety, nutrition)

LS9_8 Biohazards (including biological containment, biosafety, biosecurity)

Preface

Jeanne-Marie MEMBRÉ

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There are a number of food-associated hazards that can cause harm to human health. Chemicals used in agriculture, environmental pollutants and pathogenic bacteria are all examples of hazards that can ultimately end up on the consumer's plate and in some cases harm their health.

Food safety standards, the development of which began more than 20 years ago, are used to confront these hazards, with their basis in a formal process called "risk analysis". Risk analysis consists of three separate elements: risk assessment, risk management and risk communication.

Three volumes on the subject of Food Safety make it possible to articulate this link between food safety and risk analysis. They have been created by Jeanne-Marie Membré and Thierry Bénézech, with the assistance of Nabila Haddad, and published by ISTE Ltd and Wiley in the SCIENCES series:

- the volume coordinated by Nabila Haddad covers both chemical and microbiological hazards: Haddad, N. (2022), *Hazards in the Food Processing and Distribution Chain*;

- the volume coordinated by Thierry Bénézech and Christine Faille deals with risk management and focuses on microbiological risks: Bénézech, T. and Faille, C. (2022), *Control: Preventing the Biological Risks Associated with Food Contamination During Processing/Distribution and Consumer Usage*;

- this volume, coordinated by Jeanne-Marie Membré, completes the series. It is entitled *Microbiological Risk Assessment Associated with the Food Processing and Distribution Chain*.

Acknowledgements

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I would first of all like to thank Gilles Trystram and Jack Legrand, who entrusted the joint coordination of the topic of Food Safety to me, together with Thierry Bénézech, and also the publishers and their support team.

I would next like to thank Thierry Bénézech and Nabila Haddad, who assisted me in preparing the three volumes on this topic. A big thank you, too, to the authors of the various chapters, without whom this work would not have been possible.

Finally, all my thanks to Marie-France Pilet, director of SECALIM, the INRAE research unit within which I work, who allowed me the time needed to bring this coordination/editorial project to successful fruition.

Introduction

Jeanne-Marie MEMBRÉ

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Food safety is the guarantee that food is harmless, in other words that its consumption will have no adverse consequences for health. As we are reminded by the World Health Organization (WHO), food safety encompasses all the measures taken to provide food that is as safe as possible, and hence the policies and measures applied must relate to the entire food chain, from production to consumption.

Ensuring a safe food supply poses major food safety challenges for public authorities (FAO and WHO 2006). Changing global patterns of food production, international trade, the emergence of new technologies, public expectations in terms of health protection and many other factors have created an increasingly demanding environment in which food safety must operate ([Figure I.1](#)).

There are a number of food-associated risks that can cause harm to human health. Chemicals used in agriculture, environmental pollutants and pathogenic bacteria are all examples of hazards that can ultimately end up on the consumer's plate and in some cases harm their health.

The first estimates of the global and regional burden of foodborne diseases, published by the WHO in December 2015 (WHO 2015), show that this burden is significant all over the world. Every year around the world, 1 in 10 people fall ill from eating contaminated food and 420,000 die from it, nearly a third of whom are children under the age of 5. The hazards responsible for these foodborne illnesses include bacteria, viruses, parasites, toxins and chemicals.

More specifically, diarrheal diseases are responsible for 550 million cases and 230,000 deaths per year. Children are particularly susceptible, with 220 million cases and 96,000 deaths per year. Diarrhea is often caused by eating raw or undercooked meat, eggs, fresh produce and/or dairy produce.

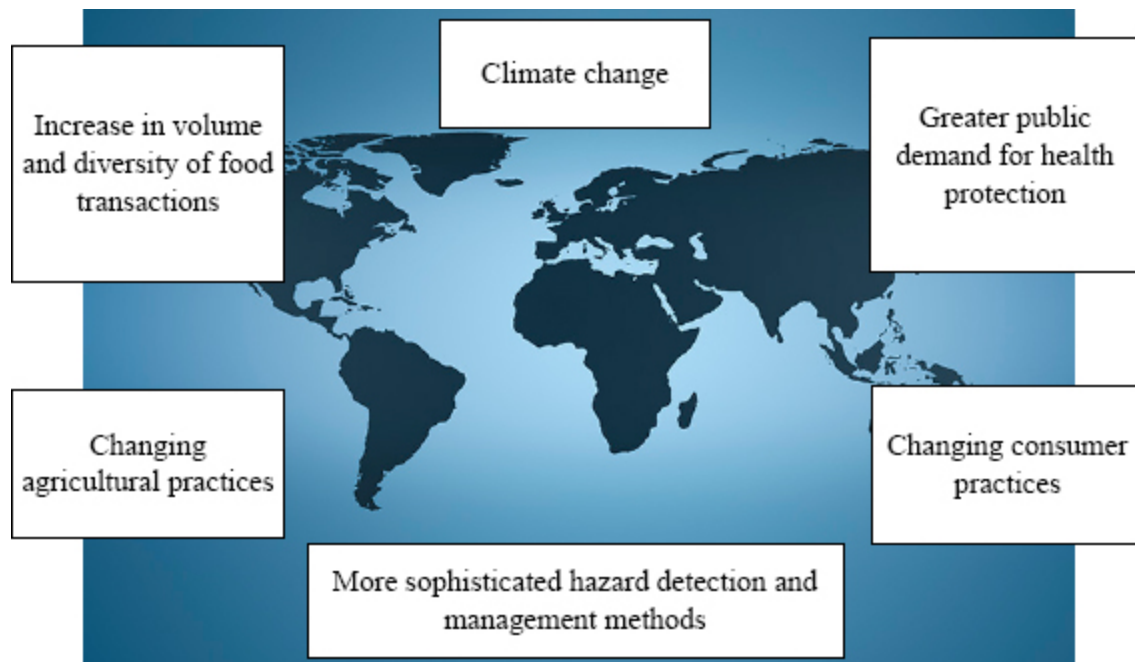


Figure I.1. *Factors influencing the evolution of food safety. From the FAO and WHO (2006)*

In Europe, more than 23 million people fall ill each year after consuming contaminated food, resulting in 5,000 deaths (WHO 2017). Still in Europe, the most common causes of foodborne diseases are noroviruses, followed by *Campylobacter* spp. Non-typhoid *Salmonella* spp. are responsible for the majority of deaths. We will review these three microbiological hazards below.

Norovirus

One of the most common causes of gastroenteritis in humans worldwide is human norovirus, and specifically

genogroup 2 noroviruses. Symptoms include diarrhea, vomiting (including projectile vomiting) and stomach pains. The virus can be transmitted to humans through the ingestion of contaminated food or water and directly from person to person, leading to infection in a relatively large proportion of those exposed.

Estimates by the WHO Foodborne Disease Burden Epidemiology Reference Group (FERG) show that, worldwide, norovirus is linked to about 20% of all foodborne illnesses caused by diarrheal disease hazards (125 million per year). It is the most common cause of diarrheal disease for all ages and in all risk groups, with the most serious outcomes being seen in young children and the elderly. Norovirus infection is the sixth leading cause of diarrheal death in children under 5 and the second leading cause of diarrheal death in children over 5, with similar trends in all regions of the world.

According to a study by ANSES (2018), in France, over the period 2006–2015, the main foods associated with outbreaks of collective food toxi-infections related to norovirus were mollusks (72%) and, in particular, oysters (usually consumed raw in France). Composite dishes were implicated in 10% of norovirus outbreaks. The other food categories (meat, fish, vegetables and egg products) were of equal significance and accounted for a total of 18% of outbreaks.

Campylobacter spp.

Campylobacter spp. are a major cause of foodborne diarrheal disease. Infection with *Campylobacter* is usually acquired by consuming contaminated foods such as undercooked poultry and raw milk; contaminated broiler meat is considered the most significant source of this hazard to humans.

According to a study by ANSES (2018), in France, over the period 2006–2015, the main food categories identified at the time of *Campylobacter* outbreaks were meats (67%) and composite dishes (18%). Poultry was implicated in 71% of the outbreaks caused by meat. The composite dishes were basically sandwiches, mixed salads and ready-cooked meals. Eggs and egg products, milk and milk products and water accounted for a total of 9% of outbreaks.

Death from campylobacteriosis is rare and is usually limited to very young or elderly patients or those suffering from another serious illness such as AIDS. Complications such as bacteremia, hepatitis, pancreatitis and miscarriage have all been reported with varying frequency. Post-infection complications can include reactive arthritis, which can last for several months, and neurological disorders such as Guillain-Barré syndrome, a form of paralysis that can lead to severe respiratory and neurological dysfunction or death in a few cases.

According to the FERG, in 2010, *Campylobacter* spp. foodborne illnesses were responsible for more than 95 million cases of disease and just over 21,000 deaths worldwide. Since 2005, campylobacteriosis has been the most frequently reported foodborne illness in the European Union, with more than 236,000 confirmed cases in 2014. However, it should be noted that the growing trend in the incidence of campylobacteriosis in recent years is partly due to the improvement of surveillance and diagnostic systems in a number of European Union Member States.

Prevention consists of control measures at all stages of the food chain in order to reduce transmission, from the environment to farms, through enhanced biosecurity, appropriate wastewater and fecal disposal systems, hygienic slaughter and the application of good food-handling practices, in particular avoiding cross-

contamination and ensuring proper heat treatment of poultry products.

Non-typhoid Salmonella spp.

Non-typhoid *Salmonella* spp. are generally transmitted to humans through contaminated foods, usually of animal origin, such as eggs, pork and poultry, and dairy products; however, other foods, especially fresh produce, may also be involved in their transmission.

Typhoid *Salmonella* spp. generally cause gastroenteritis characterized by the acute onset of fever, abdominal pain, diarrhea, nausea and sometimes vomiting. Infection with *Salmonella* spp. can, however, cause disease, especially in children, the elderly and the immuno-compromised, and can lead to post-infection complications such as reactive arthritis. In the case of invasive *Salmonella* spp., a number of organs and systems can be affected, resulting in bacteremia, meningitis, osteomyelitis or septic arthritis and sometimes even death.

According to FERG estimates, non-typhoidal *Salmonella* spp. are the foodborne hazards responsible for the highest annual burden and the greatest number of deaths both globally and in the European region. Globally, according to FERG estimates, non-typhoid *Salmonella* spp. are responsible for approximately 78 million cases of disease and 59,000 deaths per year.

In Europe, non-typhoid *Salmonella* spp. hold the number one place in terms of deaths due to food risks. For example, in 2014, there were over 85,000 cases of salmonellosis and 65 deaths. The two most frequently reported *Salmonella* serovars in the European Union are *S. enteritidis* and *S. typhi*. The European Food Safety Authority has estimated

that the overall economic burden of human salmonellosis could reach €3 billion per year.

According to a study by ANSES (2018), in France, over the period 2006–2015, the foods identified at the origin of outbreaks were in 40–45% of cases related to eggs or egg-based preparations. Meats were implicated in around 30% of outbreaks. Milk and dairy products represented only 9% of outbreaks from a suspected or confirmed food, but 19% of outbreaks from a confirmed food. Composite dishes (ready-cooked meals made from multiple ingredients such as couscous, lasagna, pizza, tartiflette) and fishery products were, in total, linked to slightly over 5% of salmonella outbreaks.

Risk analysis

Confronted by these dangers for more than 20 years, the development of food safety standards has been based on a formal process called “risk analysis”. Risk analysis includes risk assessment and risk management as well as risk communication ([Figure I.2](#)). The Food and Agriculture Organization of the United Nations (FAO) and WHO define risk assessment as a decision-making tool: its aim is not necessarily to extend scientific knowledge, but to provide risk managers with a rational and objective picture of what is known, or assumed to be known, about public health risks and their causes at any given time.

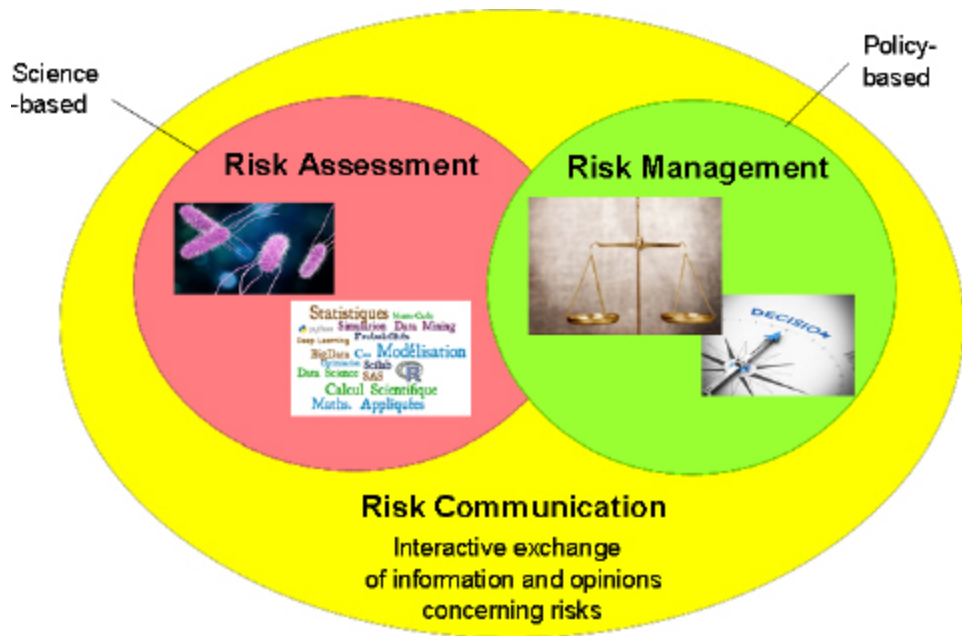


Figure 1.2. *The three components of risk analysis: risk assessment, risk management and risk communication. Adapted from the FAO and WHO (2006)*

No matter what the institutional context, the discipline of risk analysis offers a tool that all public authorities can use to improve food safety (FAO and WHO 2020).

This book focuses on risk assessment and more specifically on microbiological risk assessment. Readers interested in chemical risk assessment can refer to a number of books and in particular to the recent book coordinated by Camel *et al.* (2018).

Microbiological risk assessment

The purpose of microbiological risk assessment is to characterize the nature and probability of harm resulting from human exposure to the biological agents present in foodstuffs. Ever since 1999, the WHO and the FAO, through the Codex Alimentarius Commission (CAC), have set out principles and guidelines for conducting microbiological risk assessment of food (Codex Alimentarius Commission

1999). Since then, they have regularly augmented their work; for example, in 2020 they produced a very comprehensive methodological document (FAO and WHO 2020).

Microbiological risk assessment of food is a scientific process comprising four elements ([Figure I.3](#)): hazard identification, hazard characterization, exposure assessment and finally risk characterization. In the context of production, distribution and consumption of food products, the risks must take into account all stages of the chain: from the production of raw materials (“farm”) to consumption (“fork”), and even through to ingestion (“human”). Microbiological risk assessment thus covers the “farm-to-fork-to-human” continuum. Of course, depending on the food product, its composition, its manufacture and its packaging, the key steps to be taken into account in the risk assessment can be mostly upstream or mostly downstream of this continuum.

In 2000, the WHO and the FAO assembled a group of experts on the subject of microbiological risk assessment: JEMRA. JEMRA aims to develop and optimize the utility of microbiological risk assessment as a tool informing actions and decisions in order to improve food safety and make it available to developed and developing countries (FAO 2020). We strongly recommend the reader follow the work carried out by JEMRA and also consult on a regular basis the WHO and FAO websites dedicated to food safety and microbiological risk assessment.

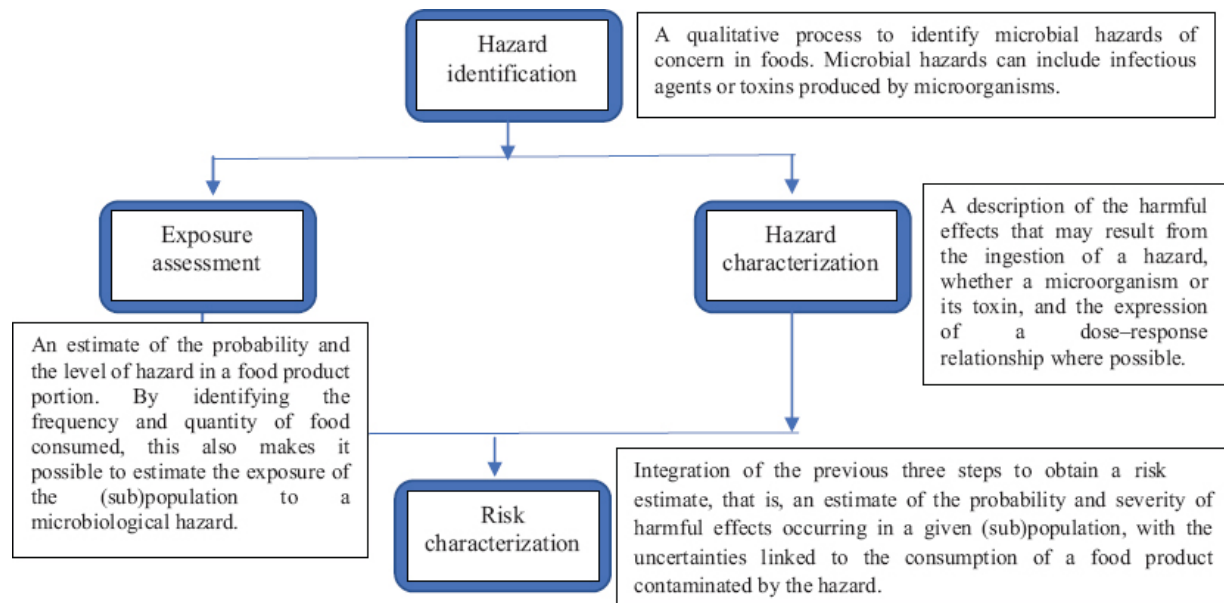


Figure I.3. *Microbiological risk assessment. Adapted from the FAO and WHO (2020)*

The first chapter of this book deals with the first stage of microbiological risk assessment, namely hazard identification. It remains fairly general since the first book in this series is dedicated to hazard analysis (Haddad 2022). The other three stages of microbiological risk assessment, namely hazard characterization, exposure assessment and finally risk characterization, are, however, developed in the various chapters of this book. More specifically, in order to address the biological and mathematical aspects of these steps, hazard characterization and exposure assessment have each been divided into two parts: hazard characterization is subdivided into a pathogenicity mechanism and quantification of the dose-response; exposure assessment is subdivided into methods of detection and enumeration of pathogens and quantification of the level of exposure.

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PART 1

Hazards and Food

1

Biological Hazard Identification

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1.1. Introduction

Contamination of food with microbial agents is a global public health problem. Microbial hazards in food include bacteria such as *Salmonella*, viruses such as norovirus, parasites such as trematodes and also prions. Diarrheal diseases are the most common diseases resulting from the consumption of contaminated food and are the cause of 550 million illnesses and 230,000 deaths each year (WHO 2020). Hazard identification serves to establish whether the hazard is probable or actual in the food product and to document important known information about the relationships and interactions between the hazard, the food and the host, and also their relationship to human disease. Given that a wide range of microbiological hazards can cause foodborne illness, hazard identification should determine whether a potential hazard is realistic for the food product concerned (FAO and WHO 2020).

Epidemiological data from disease surveillance programs or investigations of food-borne outbreaks are often the first clearly documented indications of a food safety issue associated with a pathogen causing adverse effects. Food contamination surveillance data, along with product and process assessments, can help identify combinations of hazards and foods. Evidence from these sources is usually quantitative (i.e. it includes information on the concentration or number of units of the hazard in the food) and may also provide information that feeds into other stages of microbiological risk assessment, such as exposure assessment and/or establishment of a dose-response relationship. Whole genome sequencing (WGS) is increasingly used for the surveillance of foodborne pathogens, the investigation of epidemics and the search for the sources of contamination throughout the food supply chain (Rantsiou *et al.* 2018).

That being said, the epidemiological data must be cross-referenced with product knowledge, in other words its formulation, its process, its distribution channel and the way it is used by the consumer, before conclusions can be drawn on the relevant hazards. Finally, the behavior of the hazard in the food, in other words its ability to multiply, its resistance to stress and its survival, or its inactivation, is the third key element to be

taken into account in hazard identification. ([Figure 1.1](#)). We will return later in the chapter to these different types of data and their cross-use.

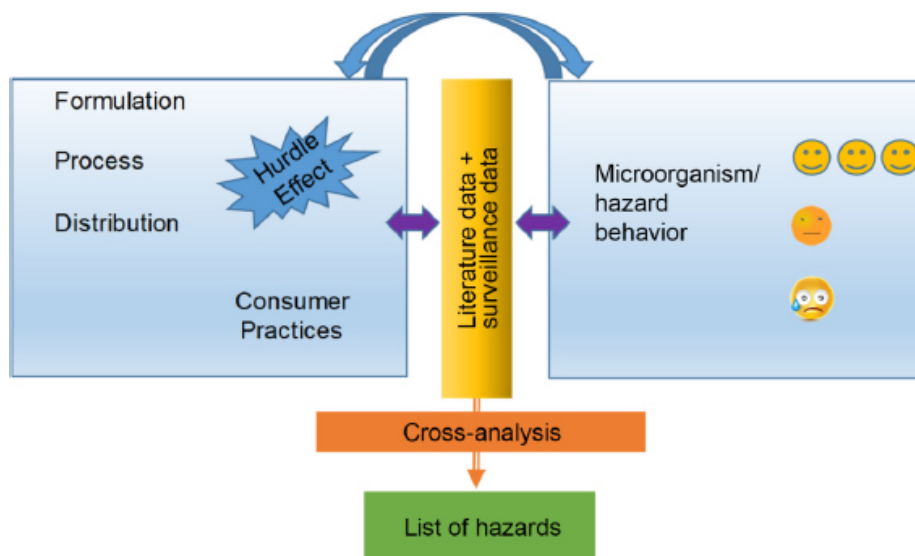


Figure.1.1. Structuring of information essential to hazard identification. Created with [BioRender.com](#)

1.2. Who conducts hazard identification?

Hazard identification is the first stage in risk assessment. It is therefore often carried out by health agencies such as the European Food Safety Authority (EFSA) in Europe or ANSES in France when these agencies are seeking to clarify an action or a decision relating to food safety.

However, hazard identification is also implemented by companies, or more precisely by companies' quality departments, when they are setting up their Hazard Analysis Critical Control Point (HACCP) systems. The HACCP system is a methodology that identifies, assesses and helps control hazards that have significance for food safety (Membré 2014). The HACCP system is a preventive operation, specific to a manufacturing unit, which begins with the purchase of raw materials, ingredients and packaging materials, follows the entire production process and ends at the finished product, ready for consumption. The HACCP system is based on seven principles, the first being "carry out a hazard analysis". This first principle includes hazard identification. Conducting this identification should be assigned to a highly qualified team with proven skills in food microbiology.

1.3. Sources of useful information for hazard identification

The WHO and the FAO have listed the various types of data that can be used in hazard identification (FAO and WHO 2020), along with their benefits and drawbacks. Their main conclusions are summed up in [Table 1.1](#).

The data cited by the WHO and FAO can be categorized according to their origin (whether they have been obtained from the scientific literature or from surveillance) and nature (epidemiological studies, prevalence and concentrations, early warning, toxi-infection, public health).

Food safety agencies provide professionals in the agrifood sector with factsheets describing biological hazards transmissible through food. These factsheets are updated regularly and are available online; they can also provide useful information for hazard identification. By way of example:

- ANSES' factsheets are available in French at <https://www.anses.fr/fr/content/fiches-de-dangers-biologiques-transmissibles-par-les-aliments>;
- Canadian factsheets are available at <https://www.canada.ca/fr/sante-publique/services/biosecurite-biosurete-laboratoire/fiches-techniques-sante-securite-agents-pathogenes-evaluation-risques.html>.

Table 1.1. *The various types of data that can be used in hazard identification (FAO and WHO 2020)*

Type of data	Description	Benefits	Drawbacks
Literature data: epidemiological studies	Epidemiological investigations relate to studies that have been commissioned to specifically study the cause and effect relationship between the appearance of foodborne diseases and exposure to certain microbiological risks through the consumption of food.	Epidemiological studies are very specific and provide a vast amount of detailed information about the hazard and the group of consumers studied.	The data are often generated for a relatively small number of consumers and therefore are not representative of larger consumer groups.
Literature data: prevalence and concentration data	Studies identifying the prevalence and count/concentration of target microorganisms at various stages of production/distribution and studies identifying their evolution, such as the effectiveness of a transformation procedure.	These studies are particularly useful for exposure assessment, but can also be used for hazard identification.	The diversity of detection and/or counting methods makes it difficult to compare final estimates. Internationally validated microbiological methods to facilitate this comparison should be preferred.
Surveillance data: early warning systems	A food-safety early warning system allows national authorities to share information on measures taken in response to serious risks detected in relation to food and can thus provide useful information for	An early warning system enables the sharing of data between geographically linked parties in an efficient manner. The data are	The system is only as good as its least active participant. If one country does not have the resources or the expertise to easily