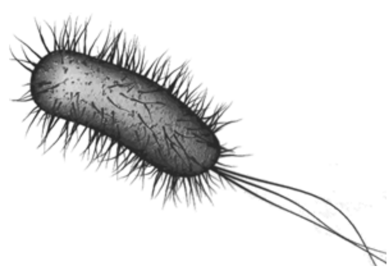
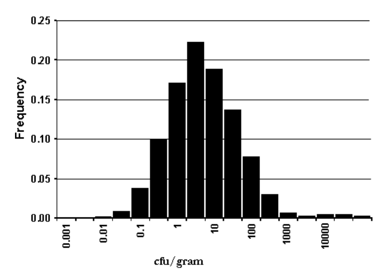
GUIDELINES FOR UNDERTAKING

MICROBIOLOGICAL RISK ASSESSMENTS





Microbiology Discipline Group
Food Standards Australia New Zealand

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Preface

Microbiological risk assessment is a relatively new tool used by food microbiologists to assist in the production of microbiologically safe food. It was first introduced as a food safety measure in the mid 1990's, and provides a structured means of gathering and evaluating scientific information on a microbiological hazard that presents a risk to human health.

As a developing area of food microbiology it will continue to evolve and will increasingly be used by food regulators as a means of informing risk management and risk communication decisions concerning foodborne microbiological hazards.

This ***Guideline*** outlines the framework employed by Food Standards Australia New Zealand (FSANZ) when undertaking microbiological risk assessments. It describes the structured approach to using scientific evidence and data in assessing risks. Over time the methodology used will advance and improvements in data will assist in reducing the uncertainty and variability inherent in many microbiological risk assessments.

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OVERVIEW OF MICROBIOLOGICAL FOOD SAFETY

Introduction

Foodborne illnesses are among the most widespread health problems in the world. Unfortunately, accurate data on the incidence and severity of foodborne illness in the general population is limited.

Where public health data is available, it generally indicates an increase in the burden of illnesses caused by pathogenic bacteria such as *Campylobacter jejuni*, Enterohaemorrhagic *Escherichia coli* (EHEC), *Salmonella* spp., and *Listeria monocytogenes*.

However, other foodborne bacteria, viruses and parasites also pose a constant and increasing hazard to public health, but the aetiology of many of these organisms is not well understood and they are often neglected when assessing food safety hazards.

Factors Contributing to Increased Incidence of Foodborne Disease

A range of social, economic, technical, and environmental factors contribute to the increasing incidence of foodborne illness. Important factors include:

- changing food production and processing technologies (resulting in products with longer shelf-lives and changed microbial ecology);
- consolidation of agricultural and food production and intensification of animal production activities;
- increased time from harvest to consumption (longer food chains);
- changed eating patterns, especially more meals eaten away from home;
- ageing populations and more immuno-compromised citizens;
- population growth and increased urbanization (greater population density facilitates spread of infection;
- expanding international travel; and
- globalization of food trade.

These factors have resulted in the emergence of new foodborne pathogens, the re-emergence of existing microbial pathogens, increased virulence of some pathogens, and development of antibiotic resistance among significant pathogens. It has necessitated a reassessment of foods to determine the likely threats to public health under normal conditions of production, processing, transport, storage, marketing, and consumption.

Determining the Risks of Foodborne Disease

Methods for controlling and managing risks to public health from consuming contaminated food have evolved over time. Microbiological analysis of final products is retrospective, requires extensive sampling plans, is expensive, provides no guarantee of food safety, and does not enable food processors or regulators to manage food safety risks effectively.

Hence the new approach to managing food safety hazards is based on the ability to identify the foods, the pathogens, and the situations which lead to foodborne illness and to determine the impact these factors have on public health. The delineation of this data enables food regulators to determine whether resources should be allocated to manage or regulate a specific hazard, and to determine which interventions would reduce foodborne illness.

Such an approach is encompassed in the risk analysis framework that requires a scientific risk assessment to estimate risks posed by identified microbial pathogen and food combinations. Results from risk assessment permit clarification of public health and food safety priorities and development of risk management and risk communication strategies.

RISK ANALYSIS

Food safety risks are being addressed by the development of harmonized international approaches to the assessment of public health risks and the elaboration of strategies for managing and communicating those risks.

The Codex Alimentarius Commission (Codex) is taking an active role in the development of international approaches to risk analysis.

The Risk Analysis Framework

Risk analysis is a scientifically based, open and transparent process that follows a structured approach comprising three components - risk assessment, risk management and risk communication.

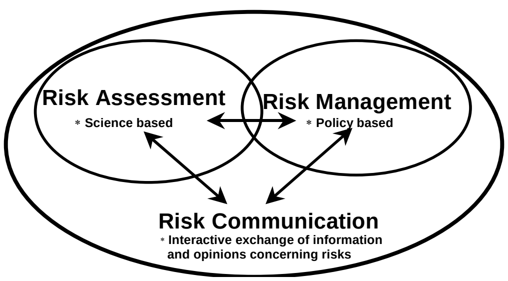


Figure 1: Risk analysis framework

The risk analysis framework is evolving, and the World Health Organization (WHO) and the Food and Agriculture Organization of the United Nations (FAO) continue to develop and publish principles and guidelines to assist risk assessors, risk managers, and risk communicators.

In these **Guidelines for Undertaking *Microbiological* Risk Assessments**, the focus is on completing the risk assessment phase of risk analysis.

The Risk Assessment Model

Risk assessment is the scientific evaluation of known or potential adverse health effects resulting from human exposure to foodborne hazards. The two basic factors associated with risk assessment are the likelihood of the event and the consequences if it occurs.

The Codex risk assessment framework consists of four steps:

- Hazard identification;
- Hazard characterisation;
- Exposure assessment; and
- Risk characterisation.

Each step addresses the following issues:

Hazard identification	What microbiological agents are present in food and description of the adverse health effects they cause?
Hazard characterisation	What is the adverse health effect? Is there a dose-response relationship?
Exposure assessment	What is the likely frequency of intake of the pathogen resulting from consumption of food and what quantity is consumed?
Risk characterisation	Risk characterisation integrates exposure assessment and hazard characterisation leading to a risk estimate:

Risk assessment provides an analytical framework to support decisions related to food safety, hence the purpose and scope of each risk assessment must be clearly identified and stated at the outset.

It is important, therefore, that there is good communication between risk managers and risk assessors to ensure a mutual understanding of the problem and the data needed from the risk assessment. Generally the risk manager compiles background information describing the food safety problem and its context.

There are two approaches to risk assessment: qualitative and quantitative. While both follow consistent systematic approaches, qualitative risk assessments assess the available information in a descriptive manner (and are used where data, time or resources are limited), while quantitative risk assessments involve mathematical analysis of numerical data.

Quantitative risk assessments are further divided into deterministic or probabilistic approaches. Deterministic or point-estimate approaches involve estimates of the average level of contamination of a food and the average quantity of food consumed by an average consumer. This produces a single value for the risk estimate. The probabilistic approach considers probability distributions and then characterizes the range of risk that may be encountered by an individual or a population.

Risk managers are increasingly calling for quantitative assessments, however detailed quantitative data are often not available for foodborne pathogens and foodborne illness.

The framework for microbiological risk assessment is essentially similar to that used for chemical risk assessment. However there are complexities unique to the way risks associated with exposure to microorganisms are assessed. For example, the concentration of microorganisms in a food can change as a result of growth or death, or their distribution in a foodstuff may not be homogenous because of clumping and aggregation. Furthermore, infection through secondary transmission (via person-to-person contact instead of directly through food) may be important for certain pathogens and confound the assessment of food vehicles. Finally, there is the possibility for consumers to be asymptomatic or to develop immunity to some pathogenic microorganisms.

Risk Assessment by Food Standards Australia New Zealand - FSANZ

FSANZ risk assessments are consistent with risk assessment protocols established by Codex and FAO/WHO.

FSANZ only develops food safety measures that can be justified by scientific evidence. Hence risk management options (including food standards) are only developed when risk assessments have identified hazards and characterized the risks to public health and safety. This process facilitates the adoption of outcomes-based standards with the overriding philosophy of risk prevention.

Before commencing a risk assessment, FSANZ often performs a risk profiling exercise.

Risk profiling is defined by the FAO/WHO (1997) as:

a process of describing a food safety problem and its context, in order to identify those elements of the hazard or risk relevant to risk management decisions.

A risk profile provides an initial evaluation of the scope of the public health concerns associated with the safety of a specific food, the availability of scientific data, and existing control measures.

Risk profiling is a tool to direct what further action should be taken, including:

- is a comprehensive microbiological risk assessment required or appropriate;
- the priority given to the issue; and
- requirement for any further action.

Risk Assessment and Risk Management Interactions

Risk assessments provide information upon which risk managers make regulatory decisions. Interaction between risk assessors and managers facilitates definition of the scope of risk assessments and may include revisions of the scope if necessary during the risk assessment.

A FAO/WHO Consultation established that effective management of foodborne hazards requires ongoing interaction and communication between assessors and managers[1]. A second consultation developed principles and guidelines for incorporating risk assessments in food safety standards[2].

[1] FAO/WHO (2000). The interaction between assessors and managers of microbiological hazards in food. Report of a WHO Expert Consultation, Kiel, Germany, 21-23 March 2000.

[2] FAO/WHO (2002). Principles and guidelines for incorporating microbiological risk assessment in the development of food safety standards, guidelines and related texts. Report of the Joint FAO/WHO Consultation, Kiel 18-22 March 2002

HAZARD IDENTIFICATION

Hazard identification is the first step in a microbiological risk assessment, and involves the preliminary assembly and qualitative evaluation of information that will be analysed in greater detail in ensuing risk assessment steps.

Undertaking Hazard Identification

Hazard identification involves gathering information to present an appraisal of the microbial pathogen.

Information in the hazard identification is usually brief, and may overlap with information documented elsewhere in the risk assessment. It includes a:

- review of available scientific data that identifies the microbiological agent and its preferred environment;
- description of the adverse health effects and the mechanism by which the illness is caused; and
- details of the incidence of illness caused by the organism and typical foods the agent may contaminate.

The risk assessor will need to collate and review microbiological, clinical, and surveillance data and epidemiological studies. Includes reviewing previous risk assessments, searches for international outbreak data, gathering epidemiological statistics, *etc,* and considering these in the context of domestic conditions.

Hazard identification is mainly concerned with determining which pathogen(s) may be of concern in a specific food or food commodity group. Since the link between the pathogen and adverse health effect is usually well established, it does not require detailed evaluation.

Reporting Hazard Identification

Presentation of the hazard identification will vary according to the assessor, with no single style prevailing in the literature.

The hazard identification summary needs to be concise and focus on the critical components of the hazard identification, including data on the following:

Description

Characteristics of the organism, where it is found, preferred growth conditions and environmental factors affecting its growth and survival, etc.

Pathology of illness

Brief description of adverse health effects as a result of exposure to the hazard. This ensures the reader has a good understanding of the severity and/or significance of the health consequences.

Susceptible individuals or subpopulations may be identified; however a more detailed description of adverse effects is developed at the hazard characterisation step.

Mode of transmission

Concise description of how the pathogen infects the host.

Epidemiological data

Incidents and outbreaks that are documented must be credible, and thoroughly researched to ensure the suitability of data.

Occurrence in food

Brief overview of foods the organism may occur in and typical contamination levels.

Note

The hazard identification and hazard characterisation are often done concurrently.

For each pathogen:commodity pair, the hazard identification will focus on the pathogen, while hazard characterisation will consider properties of the food commodity and the impact of dose on the consumer.

Hazard Identification - *Listeria monocytogenes*

Description

Listeria are short (1-2 μm), motile, Gram-positive non-sporeforming rods. The genus *Listeria* includes 6 different species (*L. monocytogenes*, *L. ivanovii*, *L. innocua*, *L. welshimeri*, *L. seegligeri*, and *L. grayi*). Only *L. monocytogenes* is consistently associated with human illness. *L. monocytogenes* is classified into subtypes *e.g*. *L. monocytogenes* 1/2a, 1/2b, 1/2c, 3a, 3b, 3c, 4a, 4ab, 4b, 4c, 4d, 4e, or 7 based upon surface antigens.

L. monocytogenes is psychrotrophic and facultatively anaerobic. It is widely distributed in soil, vegetable matter, faecal material, sewage and water, and is commonly found in food processing environments. It may be a transitory resident of the gastrointestinal tract of humans, with 2-10% of people being carriers. The organism:

- Grows between -1°C and 45°C. The optimum temperature for growth is 35-37°C, but it grows rapidly above 7-10°C.
- Survives and grows in a variety of foods under a range of environmental conditions.

Pathology of Illness

- Cases are rare/infrequent in the general population.
- Illness is associated with only a few virulent strains.
- May cause mild febrile gastroenteritis, however after invasion of intestinal tissue, *L. monocytogenes* may spread to blood, the pregnant uterus, or the central nervous system. Invasive listeriosis typically has a 2-3 week incubation time, but can sometimes extend up to three months.
- Serious conditions caused by *L. monocytogenes* in adults can include septicaemia, meningitis, encephalitis, abortion, or stillbirth and the illness may be fatal in 20-30% of susceptible individuals.
- Major risk factors include immunosuppression, pregnancy and age.

Mode of Transmission

- Foodborne exposure is the primary route of transmission.
- Transmitted vertically (mother-to-child), zoonotically, and through hospital-acquired infections.

Incidence and Outbreak Data

- Listeriosis is relatively rare - annual incidence ~3 cases/10^6 people (Australia). May be double that figure due to underreporting.
- Severe nature of the disease ensures that victims seek medical care.
- Cheese responsible for major outbreaks in the U SA, Switzerland and France.

Occurrence in Food

- Found in ready-to-eat foods, seafood, and dairy products (particularly soft cheeses).
- Low levels (<50 *L. monocytogenes*/gram) found in 3 percent of cooked prawns.
- Detectable levels found in 15% of smallgoods during storage and retailing.

HAZARD CHARACTERISATION

Hazard characterisation describes the nature, severity, and duration of adverse health effects resulting from ingestion of the microbial pathogen and also seeks to develop a dose-response relationship.

Assessing the Nature of Adverse Health Effects

The manner in which a population responds to exposure to a foodborne pathogen is highly variable. Many factors influence the likelihood that exposure to a particular number of microorganisms will result in an adverse health effect and the resulting severity of that effect. In a hazard characterisation, the risk assessor will need to describe the following:

The disease process

What is the clinical form of the illness, the duration of illness, and severity (*i.e.* mortality, morbidity and sequelae). Does the disease show any epidemiological pattern? Are alternative modes of transmission possible *e.g*. person-to-person transmission of hepatitis A?

The pathogen

Identify those properties of the microorganism that cause illness. This requires identification of whether the organism is infectious, toxic-infectious or toxigenic; identification of virulence factors; other modes of transmission; etc.

Is there variability between strains or subtypes? Is there host-specificity? Is the organism resistant to antimicrobials and what effect would this have on disease *e.g.* for some pathogens antimicrobial susceptibility is associated with increased virulence.

Adaptive factors affecting growth or survival of a pathogen should also be considered in order to determine when and how the hazard may become a risk to human health, and how specific food production, processing, storage or handling steps affect the pathogen.

These factors may include the general growth characteristics of the microorganism *i.e.* intrinsic and extrinsic parameters affecting growth, death, or survival of the microorganism. Hence it may be necessary to briefly describe aspects of microbial physiology;

Some pathogens are highly infectious *e.g.* intakes of as little as one EHEC cell may result in adverse health effects in susceptible populations.

The host

Adverse health effects will be influenced by the susceptibility of the host, particularly any ***at-risk*** sub-populations. Underlying conditions such as diabetes may predispose the host to infection or illness. Use of antacids may protect a pathogenic bacterium from stomach acids by buffering the pH of the stomach.

Population attributes such as age, pregnancy, nutritional status, and immune status may influence individual host susceptibility to foodborne pathogens.

The food matrix

Food attributes may inhibit competitive microbial flora, enhance pathogen survival, or alter microbial pathogenicity thereby altering host-response *e.g.* fats, oils and carbohydrates may protect the pathogen from stomach acids.

Food properties that affect the growth or survival of a pathogen include pH, temperature, water activity, redox potential, *etc*; and any specific nutrient or growth factor requirements.

Exposure to sub-optimal environmental conditions may also influence the virulence of a pathogen or its capacity to survive. It is also important to consider how specific food production, processing, storage or handling steps affect the pathogen.

This type of data is often obtained during the hazard identification step and will be further evaluated during the exposure assessment step.

Determining a Dose-Response Relationship

Dose-response is defined as the relationship between the number of microorganisms entering the gastrointestinal tract (dose) and the severity and/or frequency of associated adverse health effects (response).

Dose-response is represented as a probability (expressed as either the proportion of a population that become infected or the proportion of a population that become ill after exposure to a specific quantity of the pathogen) and may be represented graphically (Figure 2).

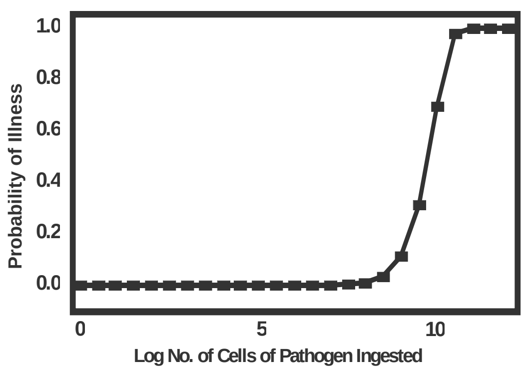


Figure 2: Dose-Response Curve

Microorganisms may produce a variety of effects in the host ranging from no effect (asymptomatic), to acute illness, even death, depending on the virulence of the microorganism and the susceptibility of the host, *etc*. Thus instead of a single dose-response relationship there may be a range of dose responses that describe the relationship between the various biological effects and the magnitude of the dose depending on host susceptibility.

A problem for risk assessors is that usually only very limited data is available for determining dose-response relationships. Dose-response data from volunteers does not exist for many pathogens; hence often there is reliance upon animal feeding studies, and epidemiological information such as data from outbreak investigations.

When undertaking hazard characterisation for a newly emerging pathogen there is invariably little available information. Therefore, hazard characterisation may require additional testing and rapid acquisition of data. Information may be obtained using similar approaches to those employed for chemical hazards *i.e.* clinical, epidemiological and animal studies. However, specific investigations may be needed on the ecology, physiology, growth characteristics, detection methods and identification of species and strains of the microorganism associated with the food in question.

Reporting the Hazard Characterisation

The output from a hazard characterisation is an estimate of the likelihood of an adverse health effect arising in the population from the consumption of the microbial pathogen. This estimate describes the levels at which people become ill, and is influenced by the virulence and infectivity of the microorganism, host susceptibility, and factors related to the food matrix.

Hazard Characterisation – *Listeria monocytogenes*

Epidemiological evidence from investigations where the vehicle of infection has been identified indicates that foods contaminated with <100cfu/g of *L. monocytogenes* are unlikely to cause illness in the general population.

However care must be taken where foods allow the growth of Listeria and there is no listeriocidal step before consumption *e.g*. ready-to-eat (RTE) foods.

Growth conditions for *Listeria monocytogenes*	**Optimum**	**Range**
Temperature ($^{\circ}$C)	37°C	-1 – 45°C
pH	7.0	4.4 - 9.4
Water activity (a_w)	-	>0.9

Dose-response data from human feeding studies with *L. monocytogenes* is not available. Instead, dose-response relationships have been developed and evaluated based on expert opinion, epidemiological data, animal data, or combinations of all of these. The dose-response models in Figure A were derived to estimate the probability of illness resulting from a single serving of contaminated food to the 20% of the population considered to be at high risk *i.e.* pregnant women, elderly persons, or immuno-suppressed individuals.

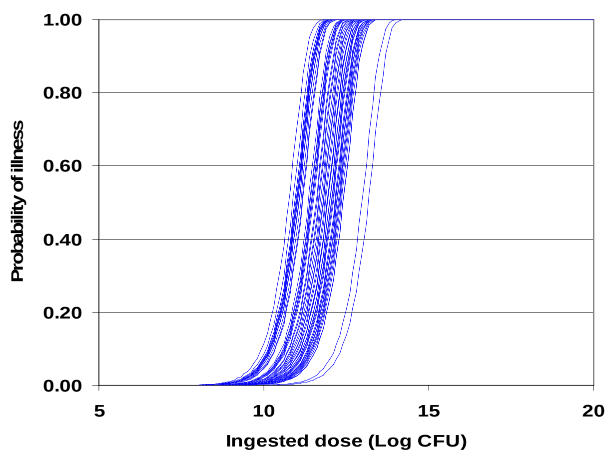


Figure A: Variability in dose-response for at risk individuals

Many factors affect the dose response relationship. These include variability in the pathogenicity of strains, food matrix effects and individual variability. Most models developed stipulate infection or morbidity as the endpoint being modelled. Morbidity is the endpoint of most models that use epidemiological data. The predictions of these models show a wide variation and some appear to be more conservative than others. All these factors contribute to uncertainty in description of the dose-response relationship.

EXPOSURE ASSESSMENT

The exposure assessment step provides the risk assessor with an estimate of the likelihood that an individual (or population) will be exposed to a microbial hazard and the numbers likely to be ingested *i.e*. frequency of food consumption and amount eaten.

To do this, the risk assessor needs to gather data on the amount and frequency of consumption of each food, and combine this with data on the occurrence and quantity of the pathogen present in the food to determine the number of infectious units ingested.

Exposure assessments may be either qualitative or quantitative. Qualitative exposure assessments are used when there is insufficient quantitative data about the microorganism.

Qualitative assessments use descriptive or general terms as categories or ratings *e.g.* terms such as negligible, low, medium or high are used for parameters such as pathogen levels, amount of food consumed, extent of growth, etc. Such descriptive terms are also used for the final risk estimate in risk ranking systems.

Qualitative exposure assessment models usually focus on the point of entry of the pathogen into the food and may attempt to estimate the potential of the microorganism to grow or survive.

In contrast, quantitative exposure assessments involve predictive models that estimate the effect of food processing operations and food storage conditions on microbial growth or survival. Such models are often used to model actions that reduce microbial growth.

Briefings between the risk manager and assessor will determine the detail required in an exposure assessment, and whether the outputs will be quantitative or qualitative.

Undertaking the Exposure Assessment

Assessing exposure is quite complex because microbial pathogens may grow or die. In addition, the risk assessor is often unable to accurately determine pathogen numbers in a food at time of consumption. Risk assessors must therefore use models and make assumptions in order to prepare quantitative estimates of pathogens ingested by an individual.

Various factors need to be considered when estimating exposure to a pathogen, including the:

- frequency and level of food contamination;
- amount and pattern of food consumption *i.e*. grams eaten and temporal nature of exposure;
- route of exposure (typically oral but may include an airborne pathway);
- size, demographics, and behaviour of the exposed population; and
- pathogen characteristics and impact of food processing and handling, and the possibility and extent of recontamination or growth.

Food Consumption Data

The pattern and quantity of food consumed is part of the exposure assessment. The risk assessor will require data on the amount of food consumed in a meal (typical serving sizes); the frequency with which the food is consumed (daily, weekly or monthly); and information on conditions under which food is prepared and consumed.

This may be very region-specific (even country-specific) because of the influence of ethnicity, socio-economic conditions, cultural backgrounds, population demographics, food preferences and behaviours, etc. In Australia there is enormous cultural diversity and varied eating patterns are observed, making the work of the risk assessor more difficult.

Two types of food consumption data are frequently used in microbiological risk assessments: food production statistics and food consumption surveys.

Food production statistics provide an estimate of the amount of food commodities available to the total population *e.g.* national statistics on per-capita food production, disappearance, or utilisation, food import stastics, etc.

Food consumption surveys (such as national nutrition surveys) provide detailed information regarding the types and amounts of foods consumed by individuals or households and sometimes the frequency with which foods are consumed. Using this data it is possible to estimate the level of food intake by dietary modelling of the whole population.

When modelling food consumption, it is important for risk assessors to understand how the food consumption dataset was collected and analysed. Two important considerations when calculating the amount of food consumed, using results from food consumption surveys, are the:

- population divisor (*i.e.* whether the total consumption is divided by the total population (amount per-capita) or only those who consumed the foods (amount per-eater)); and
- timeframe of consumption (per year, per day, or per eating occasion).

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

For foods that are consumed regularly by the majority of the population the per-capita and per-eater amounts will be nearly equal. For foods that are consumed less frequently or by fewer individuals, the per-capita and per-eater amounts will be quite different, and this will impact on the calculated level of exposure.

Food production statistics generally report an amount of food per year. A daily consumption amount may be estimated by dividing the total annual amount by 365, however it is not possible to estimate the consumption amount per eating occasion from these data alone.

Food consumption surveys of individuals allow much more flexibility in estimating the consumption amount, and are frequently summarised and reported on the basis of daily consumption. However such surveys have limitations because they are not undertaken for the purpose of assessing exposure to microbial hazards. For example, data on daily food consumption will not identify how many times the food was eaten during the day, which is a concern for microbiological risk assessment but not necessarily for nutritional analysis or chemical risk assessment.

Identifying At-Risk Populations

The risk assessor may need to consider at-risk sub-populations and derive food consumption data for this group *e.g*. pregnant women, adults over 70 years, infants, immuno-compromised individuals, etc.

Food consumption databases may not be able to identify these groups precisely, so in the absence of this data the risk assessor may need to make assumptions based on national health statistics.

Prevalence Data

The risk assessor needs to gather data on the food commodity being assessed to determine the likely prevalence and concentration of the pathogen.

Accessing relevant and accurate data is problematic, and a lack of data is a major impediment to the development of effective exposure assessment models.

Food monitoring data are often unpublished but may be available from regulatory agencies or Government laboratories. The food industry may also have data, however there is generally a reluctance to provide such data to risk assessors because of concerns about confidentiality.

Animal health data may be available from Departments of Agriculture and veterinarians, and this will be relevant for zoonotic diseases. The published literature may also provide useful data, however it may be necessary to undertake microbiological surveys of food to obtain appropriate data.

Pathogen-Commodity Interactions

To support the risk characterisation step, the exposure assessment will also need to describe interactions between the hazard and the food from production to consumption and their influence on the pathogen. It may be necessary to review current scientific research and to examine consumer and food service practices to understand factors that may affect the growth and survival of pathogens.

As highlighted during the hazard identification and characterisation steps, various factors influence interactions between the pathogen, the food, and the processing environment. They include:

- initial raw material contamination and potential for recontamination and/or growth;
- microbiological ecology of the food *i.e.* pH, water activity, redox potential, nutrient content, presence of antimicrobial substances, etc;
- methods of processing, packaging, distribution and storage of foods, as well as any preparation steps such as cooking and holding; and
- level of sanitation, impact of hygienic practices, and implementation of process controls.

Consumer behaviour influences the growth and survival of a pathogen in food. Hence, risk assessors must consider conditions of transport and handling, length of storage, storage temperatures in the home refrigerator, and cooking practices used by consumers.

Quantitative Modelling

Quantitative assessments utilise mathematical models to predict the growth, death and survival of a pathogenic microorganism in response to environmental conditions along the supply chain. Such models estimate the likely number of pathogens in a food at time of consumption.

Various predictive models are available[3,4,5]. The quantitative models incorporate observed and measured quantities of pathogens at points along the farm-to-plate continuum, and enable the risk assessor to estimate the risk to the consumer at the end of the chain.

Quantitative exposure assessments can be either deterministic point-estimates or probabilistic (stochastic). Point estimate models do not include any consideration of probability *e.g.* knowing that consumers eat a mean of 80 grams of food per serve and that there are a mean of 5 pathogens/gram of food results in an exposure to 400 cells of a pathogen. To estimate the worst-case scenario, point estimates are calculated using 95 percentile values.

However, such approaches ignore variability and uncertainty.

In reality, the numbers of cells in a food will be a distribution as will the amount consumed by an individual. Therefore, when sufficient data is available, risk assessors will undertake probabilistic assessments. Probabilistic assessments consider the range of values that could occur as well as how frequently different values occur.

Probabilistic risk assessments are undertaken using a numerical techniques such as Monte Carlo analysis[4,5]. Using

[3] Ross, T. and McMeekin, T. (1994). Predictive microbiology - a review. *International Journal of Food Microbiology*, **23**, 241-264.

[4] Vose, D. (1996). *Quantitative risk analysis: a guide to Monte Carlo simulation modelling*. John Wiley and Sons, N.Y.

[5] Cassin, M.H. *et al*., (1998). Simulation modelling for microbial risk assessment. *Journal of Food Protection,* **61:** 1560-1566.

this technique, randomly selected point-estimates are selected from each probability distribution for each input parameter. The following graphs demonstrate typical distributions of pathogens in food and the amount consumed per serving.

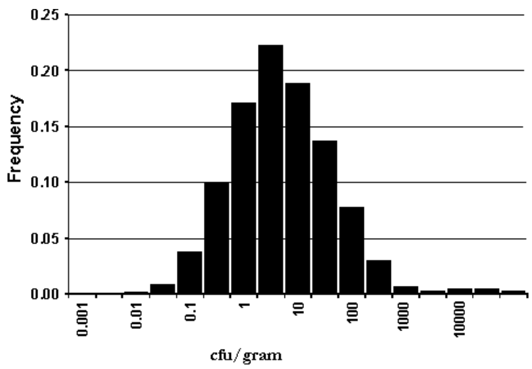


Figure 3: Frequency distribution of pathogen numbers per gram of food

The distribution curve shows that pathogen numbers may range from -2.0 to 5.0 log pathogens per gram. Some values will be more likely than others, as described by the frequency.

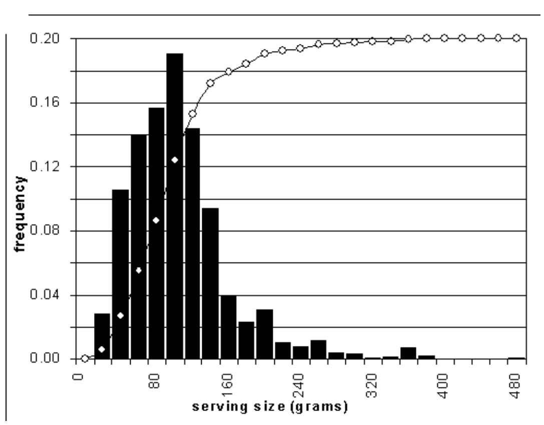


Figure 4: Frequency distribution of grams of food consumed per eating event

A sequence of randomly selected single values is repeated many thousand times, using different sets of values for the inputs. The result of the Monte Carlo simulation is a frequency distribution for the range of values (cfu/gram) possible and how likely it is that they will occur.

Such outputs inform risk managers of the likelihood and magnitude of exposure to the hazard *e.g.* the concentration of the pathogen in the food, the likelihood of producing contaminated foodstuff, and factors that influence contamination.

Comprehensive quantitative exposure models for microbiological risk assessments are more complex than chemical risk assessments, and as a result, only a few have been published (see bibliography).

Reporting the Exposure Assessment

Exposure assessment will generate either a qualitative or quantitative evaluation of the magnitude, frequency and pattern of exposure to the pathogen. Combining consumption data with the frequency with which the hazard is associated with the food will allow an estimate of the exposure to be made. This is usually expressed as the number of contaminated meals consumed annually.

The exposure assessment will provide an estimate of the amount of hazard consumed by the population and the impact of various events in the processing and preparation of the food on this exposure. It will, where appropriate, take into consideration susceptible sub-populations.

Generally, the adverse effects of microbial hazards in foods are not considered to be cumulative, unlike those for many chemical hazards. Thus the level of risk remains the same for each contaminated meal irrespective of the frequency with which the consumer consumes the food.

The foregoing discussion is directed to infectious foodborne pathogens. Toxigenic pathogens present a different set of issues, as there must be microbial growth to produce sufficient toxin to cause illness.

Exposure Assessment – *Listeria monocytogenes in prawns*

Consumption data

Data from the National Nutrition Survey demonstrate the following levels of consumption of prawns and consumption by sub-populations at risk:

Population group	Percentage of consumers (No. surveyed)	Mean consumption (g/meal)
All consumers (15-64 years)	1.6% (9471)	73.9
Aged consumers (65^{+} years)	1.1% (1960)	96.0
Female consumers: (16-44 years)	1.6% (3178)	49.7

Interactions between the hazard and food from production to consumption

- Prawns will permit the growth and/or survival of *L. monocytogenes*.
- Prawns are cooked in boiling water, hence the organism is introduced into cooked prawns as a result of post-processing contamination – poor hygiene, contaminated ice, environmental contamination, *etc*.
- Initial contamination levels: typically <50 cfu/gram.
- Prawns stored at refrigeration temperatures have a short shelf-life. Spoilage would quickly render the food spoiled and hence inedible, before Listeria could multiply to dangerous levels.
- The influence of different scenarios was estimated by mathematical modelling.

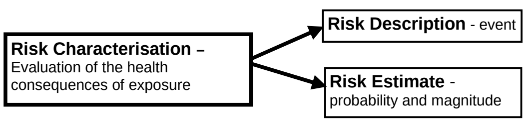
Exposure

- Low levels *(*<50 *L. monocytogenes*/gram) found in 3 percent of cooked prawns.
- Exposure calculated and expressed as the number of contaminated prawn meals consumed annually by an individual in the population of concern

RISK CHARACTERISATION

Risk characterisation is the final phase of the microbiological risk assessment and involves integration of the information collected during the hazard identification, hazard characterisation, and exposure assessment steps to arrive at estimates of adverse events that may arise due to consumption of a food.

Risk characterisation links the probability and magnitude of exposure to the pathogen (through the consumption of food) to an adverse outcome resulting from such exposure. The resulting risk may be expressed as individual risk or the risk per serving of a food.



In expressing risk, a definite level should be stated, even if this is qualitative in nature. Examples of qualitative ratings of risk are: low, medium or high. It may be useful to put the risk estimate in context by comparing it to other known and accepted risks.

The risk estimate will apply generally to the population of a country, but separate estimates may be determined for specific population groups if the data indicates there to be different levels of risk between population groups. This is dependent on the availability of dose-response information for the hazard, but may also be a result of theoretical extrapolations.

For example, high-level exposure to a particular food within an ethnic population may point to a relatively high risk for this group. Similarly, certain sectors of the community, such as immuno-compromised people, could theoretically be at a greater risk of acquiring disease from low-level exposure to a particular microorganism.

Assumptions Underpinning the Risk Characterisation and Risk Estimate

It is important, when establishing a risk estimate, that the assumptions and reasons underlying the particular risk ranking are comprehensively explained and discussed and are therefore transparent. When estimating a level of risk, it is essential to consider the severity of the hazard and any epidemiological link and any occurrence data.

For example, a hazard may be severe but if there is little epidemiological evidence to link it with foodborne illness via a particular food and/or occurrence data suggests it is rarely associated with a particular food, the risk may be considered low.

Conversely, for a moderate hazard with epidemiological and occurrence data that demonstrate a significant association with foodborne illness, the risk may be rated as high. Epidemiological evidence of a national disease association is most relevant and should be given a higher weighting than overseas data that may not be entirely applicable in the domestic context.

Other important factors to consider in arriving at an overall risk estimate are the growth characteristics of a microorganism within a particular food in conjunction with the presence of any terminal steps applied by the consumer. A consideration of how much growth of the agent is required to cause disease is essential *e.g.* can illness result from exposure to low numbers of the pathogen or does the organism need to grow to high population densities *e.g.* $>10^6$ cfu/g in order to cause illness?

While there may be evidence to suggest that a particular food or food group may be frequently contaminated at low levels with a pathogen, this in itself may not be a particular concern.

In addition, subsequent handling and processing of the food may or may not allow for growth. If the food is cooked before consumption, this may theoretically eliminate the hazard and significantly reduce the risk.

Uncertainty and Variability

In characterizing the risk, the level of confidence in the final estimate of risk will depend on the adequacy and quality of the available data. It is important to clearly state whether or not the data was sufficient to allow a comprehensive risk characterisation and to what extent expert judgement has been utilised.

Major gaps and limitations in the dataset that contribute to uncertainty around the risk estimate should be documented, along with any biological variation (variability) inherent in the risk estimate.

Variability is associated with biological systems, food processing technologies, food preservation methods and human behaviour and is therefore inherent.

Uncertainty relates to assumptions, which had to be made due to a lack of information. If the level of uncertainty is significant, it may be necessary to collect and collate more data before completing the risk characterisation.

Where risk is assessed using quantitative methods it may be possible to model the level of uncertainty inherent in the risk estimate. Quantitative modelling may also allow sensitivity analyses to be performed so that the impact of risk reduction measures may be provided to the risk manager for consideration.

Risk Characterisation – *Listeria monocytogenes*

The risk assessment determined the likelihood of contamination of a specific food by *L. monocytogenes* and the probability of such contamination impacting on public health when this food is consumed.

The risk assessment identified:

- Low levels of *L. monocytogenes* (approximately 0.4/100grams) may be present in a small proportion of these food products
- At this level, the probability of being affected by *L. monocytogenes* through the consumption of this food is considered to be very low
- However, the infectious dose of *L. monocytogenes* can be very low for at-risk and susceptible populations. For these populations the impact of listeriosis can be very severe

SUMMARY

The expert assessment of risk is essential in order to make informed risk management decisions.

Microbiological risk assessment is a relatively new tool used to ensure sound science is employed to gather information that will inform food safety risk managers of the risk associated with microbial pathogens in foods.

Microbiological risk assessment comprises the following four key steps:

(1) Hazard identification;

(2) Hazard characterisation;

(3) Exposure assessment; and

(4) Risk characterisation

Microbiological risk assessments assist by identifying which foods, pathogens or situations lead to foodborne illness, and estimates the magnitude of the impact these have on human health.

Microbiological risk assessment is a phase of risk analysis (*i.e.* risk assessment, risk management, and risk communication) and is often used by risk managers to determine appropriate regulatory measures to protect public health and safety. It is important that there is a functional separation of risk assessment from risk management to help ensure the risk assessment process remains unbiased.

Microbiological risk assessments should be fully and systematically documented and communicated to the risk manager. The conclusions should be complete and the narrative detailed and informative.

The risk manager will use this information to identify risk management strategies where there is an identified hazard that needs to be controlled.

Risk assessments should also be made available to other interested independent parties so that other risk assessors can repeat and critique the work. The risk assessment should indicate any constraints, uncertainties, and assumptions and their impact on the risk assessment to ensure transparency.

Microbiological risk assessment estimates should be reassessed over time by comparison with reported human illness data or as new and relevant information becomes available.

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OTHER DATA SOURCES

Internet Data sources for Hazard Identification:

Foodborne Pathogenic Microorganisms and Natural Toxins Handbook (The Bad Bug Book), Centre for Food Safety and Applied Nutrition-http://www.cfsan.fda.gov/~mow/intro.html

Morbidity and Mortality Weekly Report of the Centre of Disease Control and Prevention - http://www.cdc.gov/mmwr/

Food safety authorities: *e.g*.

USDA Food Safety and Inspection Service - http://www.fsis.usda.gov/

Food Safety Authority of Ireland - http://www.fsai.ie/

Food Standards Agency (United Kingdom) - http://www.foodstandards.gov.uk

Scientific Journals and Texts

Risk assessment relies upon a systematic search of data, with a focus on scientific publications in the areas of clinical and epidemiological data, surveillance intelligence, laboratory animal studies, the growth characteristics of microorganisms, and the interaction between microorganisms and their environment along the food chain (from primary production through to consumption). The following journals may be useful sources of information:

Journal of Food Protection - http://www.foodprotection.org/Publications/JFP.htm

International Journal of Food Microbiology - http://www.elsevier.nl/locate/ijfoodmicro

Epidemiology and Infection - www.journals.cambridge.org/journal_epidemiologyandinfection

Journal of Infectious Diseases - http://www.journals.uchicago.edu/JID/home.html

Communicable Disease Intelligence - http://www.health.gov.au/pubhlth/cdi/cdihtml.htm

Journal of Clinical Microbiology - http://jcm.asm.org/

Food Microbiology - http://www.elsevier.com/locate/issn/0740-0020

JEMRA (Joint FAO/WHO expert meetings on microbiological risk assessment)

JEMRA generates expert scientific advice based on microbiological risk assessments. Examples of JEMRA work includes:

FAO/WHO (2002) Risk assessments of *Salmonella* in eggs and broiler chickens. Microbiological Risk Assessment Series 2. FAO/WHO 2002 (ISBN 92-5-104873-8)

ftp://ftp.fao.org/docrep/fao/005/y4392e/y4392e00.pdf

FAO/WHO (2004) *Enterobacter sakazakii* and other microorganisms in powdered infant formula: Meeting report. Microbiological Risk Assessment Series 6. FAO/WHO 2004 (ISBN: 92 5 105164 X)

ftp://ftp.fao.org/docrep/fao/007/y5502e/y5502e00.pdf

Other published reports of JEMRA work may be found on the WHO or FAO websites:

http://www.who.int/foodsafety/micro/jemra/assessment/en/

http://www.fao.org/es/esn/jemra/riskassessment_en.stm

Food Safety Risk Analysis Clearinghouse

The Food Safety Risk Analysis Clearinghouse is operated by the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), and involves collaboration between the University of Maryland and the Food and Drug Administration (FDA). The clearinghouse collects and catalogues available data and methodology on food safety risk analyses prepared by the private sector, trade associations, federal and state agencies, and international sources.

http://www.foodriskclearinghouse.umd.edu/about_us.htm

GLOSSARY OF TERMS

Aetiology	Study of the causes or origins of a disease.
ALOP	Appropriate Level of Protection (ALOP) is the level of protection deemed appropriate by a country establishing a sanitary measure to protect human health within its territory.
Attack rate	Proportion of an exposed population at risk that becomes infected or develops clinical illness during a defined period of time.
Case definition	Standard set of criteria for deciding whether an individual (a case) should be classified as having the health condition of interest.
Dose	Amount of a pathogen that enters or interacts with a person or animal.
Dose-response	Relationship between the magnitude of exposure (dose of a microbiological agent, or toxin, etc) and the severity and/or frequency of adverse health effects it produces (response).
Exposure Assessment	Quantitative and/or qualitative evaluation of the degree of intake of the hazard likely to occur.
Food Safety Objective	Food safety objective (FSO) is the maximum frequency and/or concentration of a microbiological hazard in a food at the time of consumption that provides the appropriate level of protection.
Foodborne pathogen	Microorganism that is capable of causing disease and that is transmissible by ingestion of food.
Hazard	A biological, chemical, or physical agent in, or condition of, food with the potential to cause an adverse health effect.
Hazard Characterisation	The quantitative and/or qualitative evaluation of the nature of an adverse effect associated with a hazard. [Establishing a dose-response relationship is a desirable output from a hazard characterisation].
Hazard Identification	The identification of biological agents capable of causing adverse health effects and which may be present in a particular food or groups of foods.
Illness	A condition marked by pronounced deviation from the normal healthy state.
Incidence	A rate, showing how many new cases of a disease occurred in a population during a specified interval of time (usually expressed as number of new cases per unit time per fixed number of people; *e.g.* number of new cases of cancer per 100,000 persons in one year).
Infection	Entry and development of an infectious agent in the body of man or animals.
Immunocompromised	A state of reduced immune responsiveness as a result of inherited defects, administration of immunosuppressive drugs, infection, irradiation, malnutrition, or certain disease processes.
Microbiological hazards	Microbiological agents in, or conditions of, a food with the potential to cause an adverse health effect.
Outbreak	An incident in which two or e cases of similar illness are linked to ingestion of a common food where epidemiological evidence implicates the food.
Prevalence	The proportion of people in the entire population who are found to be with disease at a certain point in time.

Probability	The frequency with which we obtain samples within a specified range for a specified category *e.g*. the probability that an average individual with a particular mean dose will develop an illness.
Qualitative risk assessment:	A risk assessment based on data, which, while forming an inadequate basis for numerical risk estimations, nonetheless, when conditioned by prior expert knowledge and identification of attendant uncertainties permits risk ranking or separation into descriptive categories of risk.
Quantitative risk assessment:	A risk assessment that provides numerical expressions of risk and an indication of attendant uncertainties.
Risk	A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.
Risk Analysis	A process consisting of three components: risk assessment, risk management, and risk communication.
Risk Assessment	A scientifically based process consisting of the following steps: Hazard identification; hazard characterisation; exposure assessment; and risk characterisation. Risk assessment provides a formal, validated and transparent estimate of the level of risk, which can then be communicated to key policy makers.
Risk Characterisation	The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterisation, and exposure assessment.
Risk Communication	The interactive exchange of information and opinions throughout the risk analysis process concerning the risk, risk related factors and risk perception 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 Estimate	The output of risk characterisation.
Risk Management	The process, distinct from risk assessment, of weighing policy alternatives, in consultation with interested parties, considering risk assessment when available and other factors relevant for the health protection of consumers and for promotion of fair trade practices, and if needed, selecting appropriate prevention and control options.
Risk Profile	A description of a food safety problem and its context so as to guide further risk management action.
Uncertainty	Lack of knowledge or data regarding the true value of a quantity.
Variability	Observed differences attributable to true diversity in a population or exposure parameter. Variability in microbiological risk assessment cannot be reduced but can be characterised more precisely.