



Role of microbial risk assessment in food safety

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Worldwide, food contamination (intentional or unintentional) leading to foodborne diseases is a major public health concern. Over the past 20 - 30 years there has been a major change in the epidemiology of foodborne illness, with global spread of existing and new pathogens. The many factors that have contributed to this change include changes in microbial genetic factors, an increase in global food trade and international travel, antimicrobial resistance, host susceptibility and foodborne zoonotic infections,¹ as well as the emergence of new pathogens, the changing role of food processing operations, and the ageing population.² An Expert Committee on Food Safety in 1983 concluded that 'illness due to contaminated food was perhaps the most widespread health problem in the contemporary world and an important cause of reduced economic productivity'.³ Although efforts to reduce and/or prevent these illnesses, such as cooking, smoking, and sun drying, started eons ago,⁴ novel strategies currently being developed are increasingly relying on science-based approaches. These include the development and increased use of risk assessment as a systematic tool for integrating the many factors that must be considered to develop consistent, science-based standards for decision making and international trade.²

History of microbial risk assessment (MRA)

The history of food regulation in the USA showing the evolution to the current highly preventive approach probably started in 1785 with the Massachusetts statute, which forbade the sale of 'diseased, corrupted, contagious or unwholesome' food or drink.^{5,6} The practice of assessing and managing risk related to foodborne hazards has been going on for several centuries. The US regulatory system has been organised around the evaluation and control of food safety risks.⁶

Quantitative microbial risk assessment (QMRA) techniques are helping to advance the scientific basis of food safety regulation. In 1983 the National Research Council in the USA published a report, known as 'The Red Book'.⁷ It provided information on how federal agencies should evaluate and control risk. The concepts in the report served as a model for several programmes in the 1980s and early 1990s on the risk of

foodborne illness, such as inspection programmes for meat and poultry, beef, and seafood.

In the mid-1990s, increased awareness of the public health impact of microbial foodborne disease, growth of global food trade, establishment of the World Trade Organization, and the signing of the Sanitary and Phytosanitary Agreement and the Technical Barriers to Trade Agreement, which emphasised the role of risk assessment in resolving international trade disputes,^{8,9} prompted regulators worldwide to consider MRA as a new strategy to assist in evaluating foodborne illness and in managing safety of the food supply.

MRA is a process used to evaluate the likelihood of adverse human health effects occurring after exposure to a pathogenic micro-organism.¹⁰ It is a tool used to assist in decision making; it is a systematic way of organising complex or conflicting data/information; it provides information for use in the risk management process of weighing alternatives/options; it predicts the impact of mitigation or intervention strategies; and it identifies/prioritises research needs/data gaps.¹¹

In the past decade, there has been a significant advancement in the application of the principles and practices of risk assessment to microbiological food safety issues. The Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (WHO) Joint Expert Consultation and the International Life Sciences Institute (ILSI) independently published documents on principles and guidelines and developed a framework for conducting risk assessments.^{12,13} Since then, several quantitative microbiological food safety risk assessments have been conducted by industry groups, national governments and international organisations and MRAs are now a standard component in the effort to protect public health and facilitate free trade.¹⁴

MRA framework

MRA is a component of the whole Risk Analysis paradigm, which consists of Risk Management, Risk Assessment, and Risk Communication (Fig. 1).⁹ Risk management is the process of weighing policy alternatives in light of the results of the risk assessment, and, if required, selecting and implementing appropriate control options, including regulatory measures if warranted. Risk assessment is the scientific evaluation of known or potential adverse health effects resulting from human exposure to hazards. Risk communication is the interactive exchange of information and opinions concerning risk and risk management among risk assessors, managers, consumers, industry, and other interested parties.⁹

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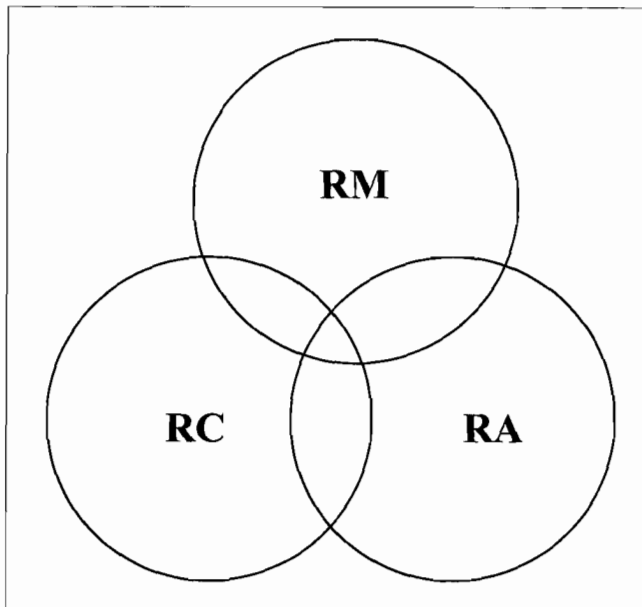


Fig. 1. The three components of Risk Analysis: Risk Management (RM), Risk Assessment (RA), and Risk Communication (RC).

Risk assessments can be qualitative or quantitative. A qualitative risk assessment is a descriptive form of risk assessment that is frequently applied in microbial risk decision-making if no or insufficient quantitative assessments are available.¹⁵ It provides an estimate of risk in words, such as high, medium or low, and utilises all relevant data, including numerical data, in obtaining a conclusion. Quantitative risk assessments describe the risk using mathematical modelling techniques, and the estimate of risk is therefore expressed as a mathematical statement such as 'risk per serving', which is the risk of an individual becoming ill after he/she consumes a single serving of a particular contaminated food, or as 'risk per annum', which is the predicted number of illnesses each year. The benefit of a structured risk assessment process lies in the ability to synthesise data and information, represent complex relationships, and describe the probability and severity of adverse events and inform the decision-making process.¹⁵

The 1999 Joint FAO/WHO Expert Consultation framework for conducting MRAs consists of the following four steps:¹⁶

- Hazard Identification. The identification of known or potential health effects associated with a particular agent in a food(s), and characterisation of the agent.
- Hazard Characterisation/Dose Response. The qualitative or quantitative evaluation of the nature and severity of the adverse effects associated with biological, chemical, and physical agents.
- Exposure Assessment. Characterisation of the source and magnitude of human exposure to the hazard.
- Risk Characterisation. Integration of hazard identification, hazard characterisation and exposure assessment into an

estimation of the adverse effects likely to occur in a given population, including attendant uncertainties.

Types of risk assessment

MRAs can be further delineated into one of at least four specific types: (i) pathogen-commodity product pathway assessments; (ii) relative risk rankings of food commodities; (iii) geographical assessments; and (iv) risk-risk assessments.¹⁷

A. **Risk ranking assessments** compare the relative risk among several hazards or foods. These types of assessment techniques might involve a single pathogen associated with multiple foods, a single food that has multiple pathogens, or multiple pathogens and multiple foods. Risk ranking assessments can help establish regulatory programme priorities and identify the critical research needs. The US Department of Health and Human Services/Food and Drug Administration (USDHHS/FDA) and US Department of Agricultural Food Safety and Inspection Service (USDA/FSIS) *Listeria monocytogenes* risk assessment is an example of a risk ranking assessment.¹⁸

B. **Product pathway analyses** examine the factors that influence the risk associated with specific food/hazard pairs. Ideally this type of analysis starts at the farm and ends with consumption. These types of assessment techniques help to identify the key factors that affect exposure, including the impact of potential mitigation or intervention strategies on the predicted risk. The USDHHS/FDA *Vibrio parahaemolyticus*¹⁹ and the USDA *Escherichia coli* in ground beef risk assessments are examples of product pathway analyses.²⁰

C. **Risk-risk assessments** consider trade-off of one risk for another, i.e. reducing the risk of one hazard increases the risk of another. An example of this would be a determination of the impact on public health of treating drinking water with a chemical (risk of chemical exposure) versus the impact of exposure to pathogenic micro-organisms, such as *Cryptosporidium*, in water not treated.

D. **Geographical risk assessments** examine the factors that either limit or allow the risk to occur. The risk of introduction of disease agents through food, animals or animal products (e.g. intentionally as in bioterrorism or unintentionally) can be examined. For example, the risk of introduction of variant Creutzfeldt-Jakob disease (vCJD) in humans by the transmission of bovine spongiform encephalopathy (BSE) from cattle through meats and animal product pathways might be examined using a geographical approach.²¹

Examples of using RA to make RM decisions

The primary reason for conducting health risk assessments in a regulatory environment is to assist in decision-making.²² In other words, QMRA is intended to answer specific questions



to assist in protecting public health. The scientific evaluations and mathematical models developed for the different microbial hazards can assist the risk managers in evaluating the effectiveness of interventions to reduce or prevent foodborne illness, weigh policy alternatives, and develop appropriate action plans. Below are some examples of risk assessments conducted by regulatory agencies within the USA and their application in decision making.

The USDHHS/FDA-USDA/FSIS quantitative risk ranking risk assessment on *L. monocytogenes* (LMRA) in ready-to-eat foods¹⁸

The LMRA is a good example of using the results of a risk assessment to develop an action plan to reduce foodborne illness due to this microbe.^{18,23} The LMRA was commissioned in response to a presidential request for federal agencies to develop control plans to reduce listeriosis by 50% by the year 2005.²³ The purpose of the assessment was to identify which foods should receive the most regulatory attention in an effort to improve public health. Fig. 2 shows the comparison of the relative risks among the different food categories and population groups considered in the assessment. The very high-risk foods, such as deli meats and unheated frankfurters, would be consistent with the need for immediate attention in relation to the national goal for reducing the incidence of foodborne listeriosis. Likely activities include the development of new control strategies and/or consumer education programmes suitable for these products. Some high-risk foods, such as smoked seafood, pâté and meat spreads, are priority

candidates for new control measures. Other high-risk foods such as unpasteurised milk might call for continued avoidance. High-risk foods such as high-fat and other dairy products, (pasteurised milk, soft unripened cheeses), although they have low rates of contamination and corresponding relatively low predicted relative risks per serving, are foods that are consumed often by a large percentage of the population, resulting in elevated predicted relative risks. These foods would require advanced epidemiological and scientific investigations to either confirm the predictions of the risk assessment or identify the factors not captured by the current models that would reduce the predicted relative risk.

In addition, the 'what-if' scenarios modelled in this risk assessment provide insight to the impact on public health of limiting storage times, avoiding high-temperature refrigeration storage, and reducing contamination levels.

The USDHHS/FDA quantitative risk assessment on the public health impact of *V. parahaemolyticus* in raw oysters (VPRA)¹⁹

The VPRA is another example of the potential application of a risk assessment that can be used by the shellfish industry and state regulators to both better understand the risks of eating raw oysters that might be contaminated with *V. parahaemolyticus*, and develop improved programmes to reduce them. The risk assessment showed that post-harvest measures (e.g. mild heat, high-pressure treatment) aimed at reducing the *V. parahaemolyticus* levels in oysters reduced the model-predicted risk of illness associated with this pathogen. Measures that control or reduce the levels of *V. parahaemolyticus* in oysters reduced the predicted risk of illness associated with this pathogen. For example, treatment such as immediate refrigeration decreased the number of predicted illnesses by approximately 10-fold, whereas treatments such as irradiation (causing a 4.5-log decrease in the number of *V. parahaemolyticus* bacteria) reduce predicted illness to an extent that makes it unlikely that illnesses would be observed. The VPRA also demonstrated that reducing time to refrigeration also reduced predicted illness (Fig. 3).

USDA/FSIS risk assessment on *E. coli* O157:H7 (ECRA) in ground beef²⁰

Another example of a risk assessment that has been used in regulatory decision making is the ECRA. Like the VPRA, this risk assessment is an example of a Product Pathway analysis. The scientific evaluations and mathematical models developed for the ECRA yielded an assessment of the scientific knowledge to assist in reviewing the effectiveness of current policies, programmes and practices, and in identifying strategies to further reduce the public health impact of *E. coli* O157:H7 in ground beef. For instance, the ECRA was used to determine the effect of various mitigations in the slaughter house on the risk

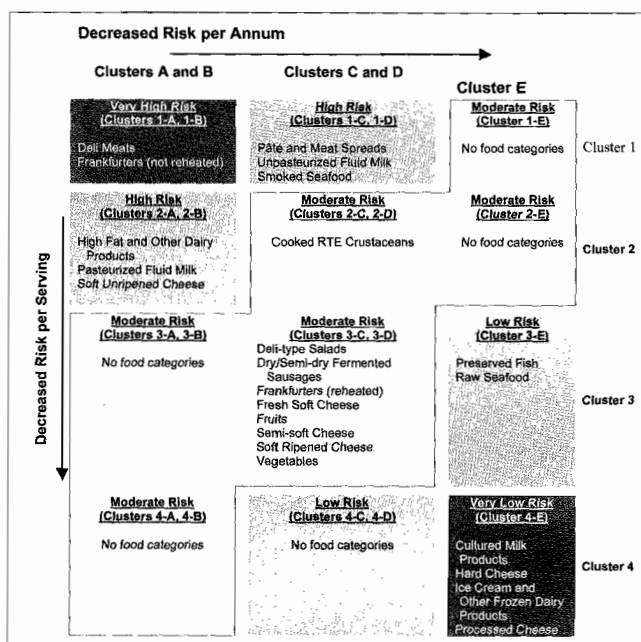


Fig. 2. Two-dimensional matrix of food categories based on cluster analysis of predicted per serving and per annum relative rankings.¹⁷

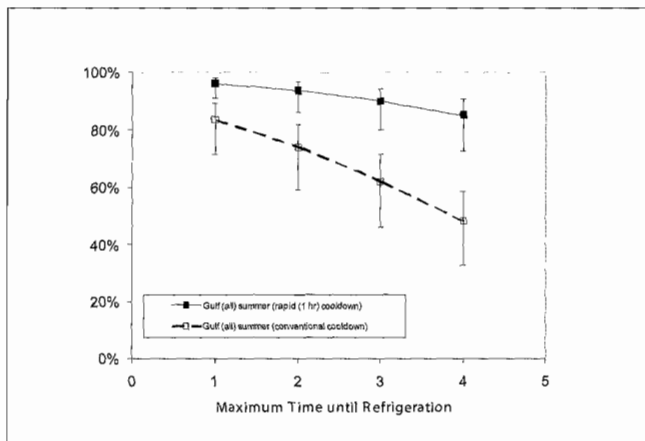


Fig. 3. Predicted effectiveness of rapid versus conventional cooling on *Vibrio parahaemolyticus* risk for Gulf Coast Summer Harvest.18

of illness from *E. coli* O157:H7. Results from the ECRA also provided the basis for the subsequent ruling that *E. coli* O157:H7 is a pathogen reasonably likely to occur in ground beef production and thus subject to Hazard Analysis and Critical Control Point (HACCP) regulations.

Additional information on other MRAs, both national and international, and their impact can be found at <http://www.foodrisk.org> and http://www.fao.org/es/ESN/food/risk_mra_riskassessment_en.stm.

Conclusions

MRA is the process of determining the likelihood that exposure to a foodborne pathogen will result in harm or disease; it helps characterise the nature and magnitude of risks, and is used as a tool for assisting regulators in making decisions on food safety issues.

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