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Microbiological risk assessment: a new approach to food safety control

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Abstract

The food industry is continually looking to be innovative in the development and production of food. New techniques are also being employed to distribute the food, and even the way the consumer treats the food before consumption has changed dramatically over recent years, for example, with the development of microwavable meals. These changes can lead to differences in the pathogens encountered and the general level of immunity in the population. This in turn puts increased emphasis on food producers to know and understand more about the pathogens likely to occur in the products they are making and their origin. To help food manufacturers tackle this consistently, Microbiological Risk Assessment (MRA) is being applied as a systematic tool to allow effective decisions to be made to reduce the impact of pathogens on health.
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1. Introduction

The UK Government's Advisory Committee on Dangerous Pathogens (ACDP) set out the general principles of risk assessment as applied to microbiology in relation to public health issues in June 1996. This came in a document entitled 'Microbiological Risk Assessment: an Interim Report'. Soon after the publication of this ACDP document, the Codex Alimentarius Commission (CODEX) published, in August 1996, a draft document 'Principles and Guidelines for the Application of Microbiological Risk Assessment'. This document is of great importance because, as a result of the GATT (General Agreement on Trade and Tariffs) and SPS (Sanitary and Phytosanitary Measures) Agreements, Guidelines and other documents produced by CODEX become reference standards for international trade. The latest draft of this document was published in July 1998.

In January 1997, a new, two-year European Union Scientific Co-operation Task (SCOOP) was established on MRA for foodborne pathogens. This task is being co-ordinated by France, and sets out to focus on sources of data and expertise on major foodborne hazards relevant to the steps of a formal risk assessment. This information should assist the European Commission in identifying how practical estimates of risks for a population or sub-population can be made. A second phase will involve selected case

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studies to collect information on the methods of MRA for foodborne pathogens in participating countries. A particular aim will be to identify gaps, variability, validity and availability of data. The outcome of the SCOOP task is likely to have an important influence on the direction of food-related MRA at the European level.

It is clear from the above that a number of initiatives throughout the world are being taken to develop the field of MRA. Campden & Chorleywood Food Research Association (CCFRA) is also involved and has set itself the task of putting together a working party to write a guideline document for the food industry on how to carry out an MRA. The document will also contain worked examples to act as guides for industry.

2. What is MRA?

Microbiological Risk Assessment is one of three components of Risk Analysis, the others being Risk Management and Risk Communication. A diagrammatic representation of how these three components interact is given in Fig. 1. Put simply, Risk Assessment is the measurement of risk and the identification of factors that influence it. Risk Management is the development and implementation of strategies to control that risk, and Risk Communication is the exchange of information relevant to the risk among interested parties.

There are a number of important considerations to bear in mind when carrying out a risk assessment, these principles are taken from the Codex Alimentarius Commission (1998) and are given in Fig. 2.

Wherever and whenever possible, Quantitative Risk Assessments should be made. However, the quality of data available will have a bearing on whether this or a Qualitative Risk Assessment can be made. Qualitative Risk Assessment techniques have been used extensively in considering the chemical safety of foods. However, these techniques cannot easily be used in carrying out microbiological evaluations. Some reasons for this include:

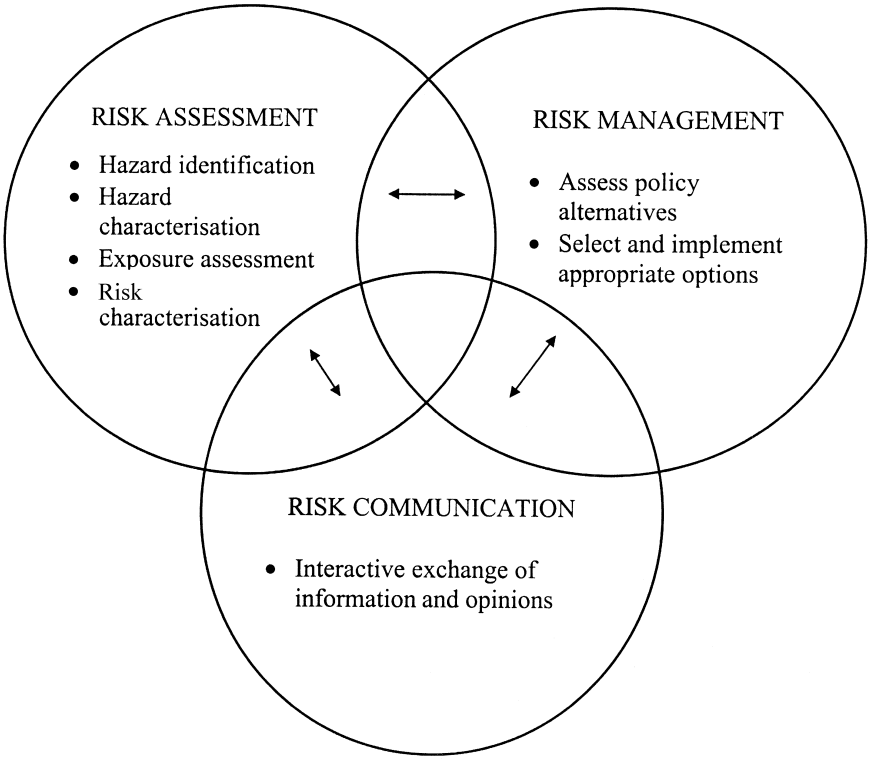

Fig. 1. Risk analysis framework (Lammerding, 1996).

1. Microbiological Risk Assessment must be soundly based upon science.

2. There should be a functional separation between Risk Assessment and Risk Management.

3. Microbiological Risk Assessment should be conducted according to a structured approach that includes Hazard Identification, Hazard Characterisation, Exposure Assessment and Risk Characterisation.

4. A Microbiological Risk Assessment should clearly state the purpose of the exercise, including the form of Risk Estimate that will be the output.

5. A Microbiological Risk Assessment should be transparent. This requires: full and systematic documentation, statement of assumptions and value judgements and rationale, and a formal record.

6. Any constraints that impact on the Risk Assessment, such as cost, resources or time, should be identified and their possible consequences described.

7. The Risk Estimate should contain a description of uncertainty and where the uncertainty arose during the Risk Assessment process.

8. Data should be such that uncertainty in the Risk Estimate can be determined; data and data collection systems should, as far as possible, be of sufficient quality and precision so that uncertainty in the Risk Estimate is minimised.

9. A Microbiological Risk Assessment should explicitly consider the dynamics of microbiological growth, survival and death in foods and the complexity of the interaction (including sequelae) between human and agent following consumption as well as the potential for further spread.

10. Wherever possible, Risk Estimates should be reassessed over time by comparison with independent human illness data.

11. A Microbiological Risk Assessment may need re-evaluation, as new relevant information becomes available.

Fig. 2. General principles of microbiological risk assessment.

(i) Microbial risks are primarily the result of single exposures. Chemical risks on the other hand are often brought about by cumulative effects.

(ii) The population's response to an infectious pathogen is more variable than to acutely toxic chemicals.

(iii) The levels of many toxic components in foods are relatively stable or reduced over time as a result of degradation or dilution. In contrast, levels of pathogenic bacteria capable of growth in foods can change dramatically. They can increase as a result of growth or decrease as a result of processing steps such as cooking.

(iv) Microorganisms are dynamic and adaptable. They can lose or acquire virulence-associated characteristics, and can also adapt to the control measures set to manage microbial risks. For example, two isolates of the same species, *Escherichia coli* and *E. coli* O157:H7, are very different in their disease capabilities.

3. Components of an MRA

A quantitative MRA produces a mathematical statement that links the probability of exposure to an agent and the probability that the exposure will affect the test individual. This is coupled with a consideration of the severity of illness to yield an overall Risk Characterisation. The components of an MRA are given in diagrammatic form in Fig. 3.

The first step is to decide on a *Statement of Purpose*. The specific purpose of the risk assessment needs to be clearly stated. The output and possible alternatives also need to be defined; for example, is the output to be the probability of infection in terms of cases per 100 000?

The second step is one of *Hazard Identification*. This identifies the microorganisms or microbial toxin of concern and evaluates whether the microorganism or the toxin is a hazard when present in food. If the focus of the Risk Assessment is on a pathogen, then, available epidemiological and related data need to be used to determine if foodborne transmission is important to the disease and the foods that are implicated. If a hazard identification is orientated towards the food, then the focus will be to use available epidemiological and microbiological data to determine which pathogens could be associated with the product. To carry out hazard identification successfully, quality public health data and information on the occurrence and levels of pathogenic microorganisms in the foods of concern need to be readily available.

The next step in the Risk Assessment is *Exposure Assessment*. The ultimate goal of exposure assessment is to evaluate the level of microorganisms or microbial toxins in the food at the time of consumption. This may include an assessment of actual or anticipated human exposure. An accurate exposure assessment needs three types of information: (i) the presence of the pathogen in the raw ingredients; (ii) the effect that food processing, distribution, handling and preparation steps have on the pathogen; and (iii) consumption patterns, e.g. portion size. Because the occurrence of a specific pathogen tends to be heterogeneously distributed in food, both the frequency and extent of contamination are needed. Historical data on levels in raw commodities and finished products are useful to provide an estimate of the distribution of a pathogen. The method used to determine levels and statistical sampling, used to accumulate data considering low levels of a specific organism, are very important here. Each step in the manufacture and distribution of a food may have an impact on the levels of the microorganism of concern, hence, they need to be considered. Well validated/mathematical predictions can be useful here, e.g. in assessing the relative safety of thermal processes (Whiting and Buchanan, 1994).

The fourth step is *Hazard Characterisation*, which is the qualitative and/or quantitative evaluation of the nature of the adverse effects associated with biological, chemical and physical agents that may be present in foods. The most important component of a hazard characterisation step is a dose–response assessment. The purpose of hazard characterisation is to provide an estimate of the nature, severity and duration of the adverse effects associated with harmful agents in food. Important factors to consider relate to the microorganisms, the dynamics of infection and the sensitivity of the host.

It is well established that the virulence of closely related species of pathogenic bacteria may vary widely in terms of their capability to cause illness, e.g. *Listeria monocytogenes* is known to be harmful to man, *Listeria ivanovii* on the other hand is not recognised as a human pathogen. A second important

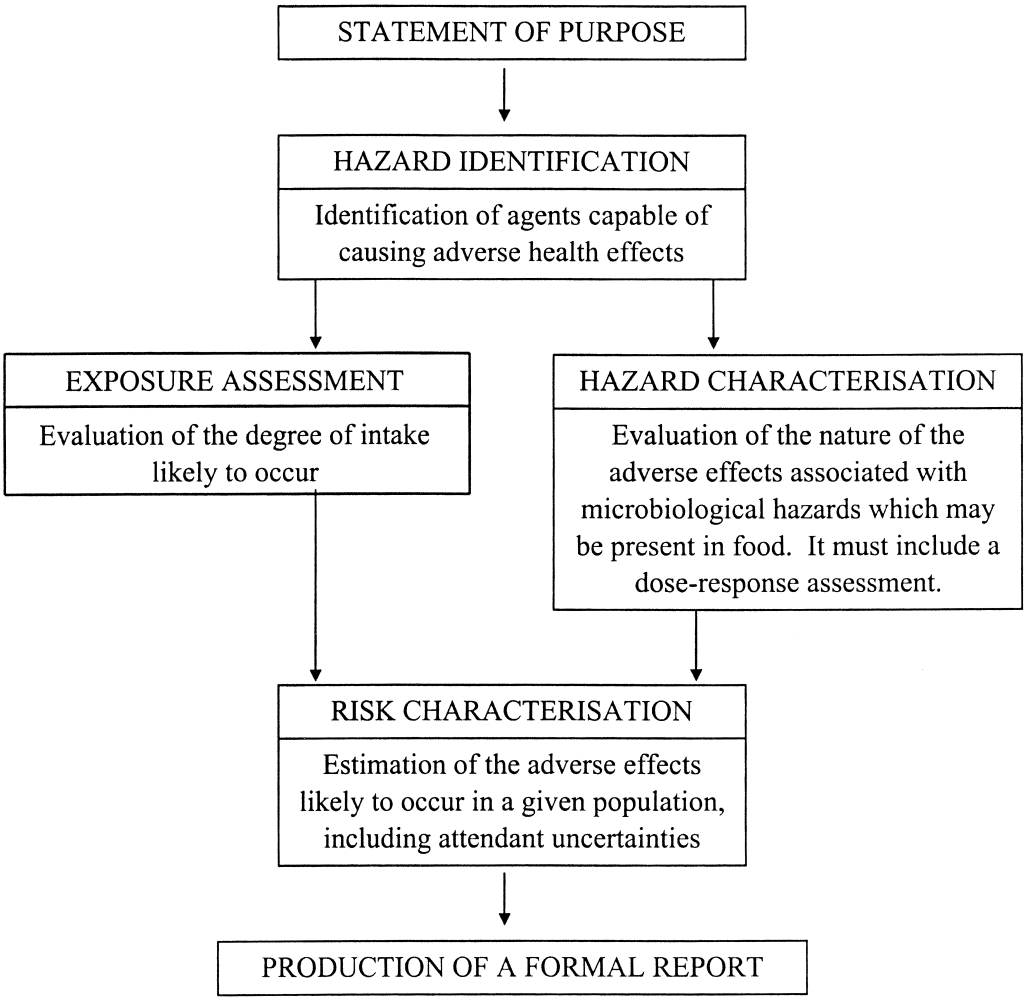

Fig. 3. Risk Assessment scheme for foodborne microbiological hazards (European Commission, 1997).

aspect to the dose–response assessment is the number of bacteria ingested. When the log of the number of bacteria ingested is plotted against the percentage of the population that becomes infected, a sigmoidal relationship is seen. From this, a threshold level below which ingestion of the organism does not produce infection can be determined (see Fig. 4). An example of this is given in Cassin et al. (1998), where probability of illness for consumption of *E. coli* O157:H7 is discussed.

It is easy to see why it is difficult to get hold of this type of information. Even if it does stem from human volunteer studies, which, by its very nature, it has to, the statistics relate only to healthy adults. Every population will contain more susceptible individuals than this, be they elderly, young or immuno-compromised.

The integration of the exposure and dose–response assessment gives the fifth step of the process, the *Risk Characterisation*. This gives an overall probability of occurrence and severity of health effects in a given population. To be meaningful, the risk characterisation should include a description of statistical and biological uncertainties.

The final, sixth, step of the Risk Assessment is to produce a Report. This should contain a full and systematic record of the Risk Assessment. To ensure its transparency, the MRA report should indicate any

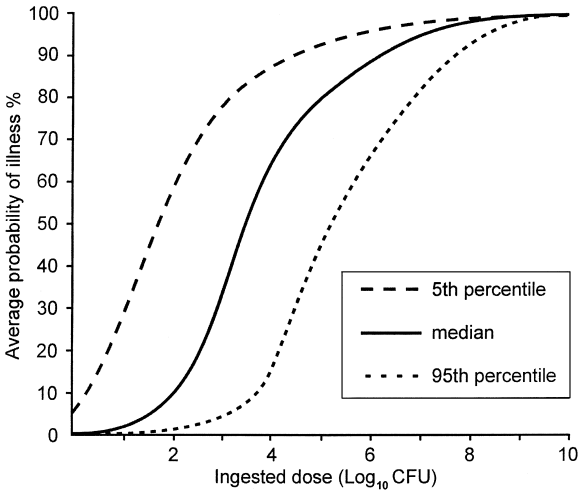

Fig. 4. Model: probability of illness vs. ingested dose (Cassin et al., 1998).

constraints and assumptions relative to the Risk Assessment.

4. MRA and HACCP

The Hazard Analysis and Critical Control Points (HACCP) technique is the foremost system for the control of microbiological hazards in food. The first phase of both MRA and HACCP is the identification of hazards; consequently, there is potential confusion between the two concepts. However, HACCP is really a risk management system, thus the role of MRA is to provide the information that HACCP system developers need to make more informed decisions on. In addition to enhancing the hazard-identification phase of HACCP, Risk Assessment can be used to help identify critical control points (CCPs), establish the critical limits, and determine the extent of hazard associated with a product during periods of CCP deviation (ICMSF, 1998).

5. Examples of quantitative microbial risk assessments

The early MRAs that were carried out focused on establishing drinking water standards on a scientific basis (Macler and Regli, 1993). The hazardous organisms were bacteria, viruses and protozoa, and the target was to evaluate them against risks in using chlorine to control them. As the approach was developed, a quantitative Hazard Assessment for *L. monocytogenes* in milk processing was carried out to evaluate the efficacy of milk production and pasteurisation practices (Peeler and Banning, 1994). Using this Hazard Assessment, the investigations concluded that there was less than a 2% probability that one *L. monocytogenes* would occur in 5.9×10^{10} gallons of pasteurised milk. More recent MRAs have increased in their degree of sophistication and reflect areas where there have been substantial food safety concerns and, in some cases, disagreements, among international trading partners. Three areas that have received a great deal of attention are *S. enteritidis* in eggs and egg products, *L. monocytogenes* in ready-to-eat foods and enterohaemorrhagic *E. coli* in ground beef.

6. Conclusions

Although MRA is a powerful tool for levelling the playing field of food safety, it is apparent that no food can be considered to be risk-free and each step in the processing of food from farm to fork has a role in assuring its safety. An important hurdle is to communicate this to the public in easily understood terms; MRA can assist with this. Currently, there are large gaps in the amount of useful and useable data available; consequently, the number of meaningful MRAs that can be carried out is limited. This area needs attention in terms of resources; however, as a starter, it is important that workers in the area of MRA all have the same understanding of the terms used in MRA. Only in this way can communication of hazards and risks be meaningful to everyone.

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